

COVID-19 Correlates of Risk Analysis Report
MockCOVE Study

USG COVID-19 Response Biostatistics Team

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Contents

1	Disclaimers	29
2	Summary Tables	31
2.1	Demographic and Clinical Characteristics at Baseline in the Baseline SARS-CoV-2 Negative Per-Protocol Cohort	31
2.2	Demographic and Clinical Characteristics at Baseline in the Baseline SARS-CoV-2 Positive Per-Protocol Cohort	33
2.3	Sample Sizes of Random Subcohort Strata for Measuring Antibody Markers	34
2.4	Availability of immunogenicity data by case status	35
2.5	Antibody levels in the baseline SARS-CoV-2 negative per-protocol cohort (vaccine recipients)	36
2.6	Antibody levels in the baseline SARS-CoV-2 positive per-protocol cohort (vaccine recipients)	38
2.7	Antibody levels in the baseline SARS-CoV-2 positive per-protocol cohort (placebo recipients)	40
3	Graphical Descriptions of Antibody Marker Data	43
3.1	Boxplots	44
3.2	Weighted RCDF plots	48
3.3	Weighted RCDF plots of threshold correlate concentration for vaccine efficacy	52
3.4	Spaghetti plots	60
3.5	Violin and line plots	61
4	Day 29 Univariate CoR: Cox Models of Risk	317
4.1	Hazard ratios	317
4.2	Marginalized risk and controlled vaccine efficacy plots	322
4.3	Misc	338
5	Day 57 Univariate CoR: Cox Models of Risk	339
5.1	Hazard ratios	339
5.2	Marginalized risk and controlled vaccine efficacy plots	344
5.3	Misc	360

6 Univariate CoR: Nonparametric Threshold Modeling ($>=s$)	363
6.1 Plots and Tables with estimates and pointwise confidence interval for Day 57	364
6.2 Plots and Tables with estimates and pointwise confidence intervals for Day 29	369
6.3 Plots and Tables with estimates and pointwise confidence interval for Day 57 (monotone-corrected)	374
6.4 Plots and Tables with estimates and pointwise confidence intervals for Day 29 (monotone-corrected)	379
6.5 Plots and Tables with estimates and simultaneous confidence bands for Day 57	384
6.6 Plots and Tables with estimates and simultaneous confidence bands for Day 29	389
6.7 Plots and Tables with estimates and pointwise confidence interval for Day 57 (monotone-corrected)	394
6.8 Plots and Tables with estimates and pointwise confidence intervals for Day 29 (monotone-corrected)	399
7 Univariate CoR: Nonparametric Threshold Modeling ($<=s$)	405
7.1 Plots and Tables with estimates and pointwise confidence interval for Day 57	405
7.2 Plots and Tables with estimates and pointwise confidence intervals for Day 29	410
7.3 Plots and Tables with estimates and pointwise confidence interval for Day 57 (monotone-corrected)	415
7.4 Plots and Tables with estimates and pointwise confidence intervals for Day 29 (monotone-corrected)	420
7.5 Plots and Tables with estimates and simultaneous confidence bands for Day 57	425
7.6 Plots and Tables with estimates and simultaneous confidence bands for Day 29	430
7.7 Plots and Tables with estimates and pointwise confidence interval for Day 57 (monotone-corrected)	435
7.8 Plots and Tables with estimates and pointwise confidence intervals for Day 29 (monotone-corrected)	440
8 Day 57 Univariate CoR: Nonlinear modeling	445
9 Day 29 Univariate CoR: Nonlinear modeling	447
10 Mediators of Vaccine Efficacy	449
11 Appendix	451

List of Tables

2.1	Table 1. Demographic and Clinical Characteristics at Baseline in the Baseline SARS-CoV-2 Negative Per-Protocol Cohort	31
2.2	Table 2. Demographic and Clinical Characteristics at Baseline in the Baseline SARS-CoV-2 Positive Per-Protocol Cohort	33
2.3	Table 3. Sample Sizes of Random Subcohort Strata for Measuring Antibody Markers	34
2.4	Table 4. Availability of immunogenicity data by case status	35
2.5	Table 5. Antibody levels in the baseline SARS-CoV-2 negative per-protocol cohort (vaccine recipients)	36
2.6	Table 6. Antibody levels in the baseline SARS-CoV-2 positive per-protocol cohort (vaccine recipients)	38
2.7	Table 7. Antibody levels in the baseline SARS-CoV-2 positive per-protocol cohort (placebo recipients)	40
4.1	Inference for Day 29 antibody marker covariate-adjusted correlates of risk of COVID in the vaccine group: Hazard ratios per 10-fold increment in the marker*	317
4.2	Inference for Day 29 antibody marker covariate-adjusted correlates of risk of COVID in the vaccine group: Hazard ratios for Middle vs. Upper tertile vs. Lower tertile*	318
4.3	Analysis of Day 29 markers (upper vs. lower tertile) as a CoR and a controlled risk CoP.	322
4.4	Marginalized cumulative risk by Day 192 as functions of Day 29 markers (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence intervals (5 replicates).	329
4.5	Controlled VE as functions of Day 29 markers (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence intervals (5 replicates).Overall cumulative incidence from 7 to 192 days post Day 29 was 0.006 in vaccine recipients compared to 0.102 in placebo recipients, with cumulative vaccine efficacy 94.6% (95% CI 94.3 to 95.3%).	332
4.6	Controlled VE with sensitivity analysis as functions of Day 29 markers (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence intervals (5 replicates).	335
4.7	Summary statistics for the number of days from dose 1 to Day 29 visit. (a) The whole immunogenicity subcohort, (b) non-cases in the immunogenicity subcohort, (c) intercurrent cases, (d) primary cases, i.e. cases from the Day 57 correlates analysis population.	338
5.1	Inference for Day 57 antibody marker covariate-adjusted correlates of risk of COVID in the vaccine group: Hazard ratios per 10-fold increment in the marker*	339
5.2	Inference for Day 57 antibody marker covariate-adjusted correlates of risk of COVID in the vaccine group: Hazard ratios for Middle vs. Upper tertile vs. Lower tertile*	340

5.3	Analysis of Day 57 markers (upper vs. lower tertile) as a CoR and a controlled risk CoP.	344
5.4	Marginalized cumulative risk by Day 164 as functions of Day 57 markers (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence intervals (5 replicates).	351
5.5	Controlled VE as functions of Day 57 markers (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence intervals (5 replicates).Overall cumulative incidence from 7 to 164 days post Day 57 was 0.005 in vaccine recipients compared to 0.090 in placebo recipients, with cumulative vaccine efficacy 94.6% (95% CI 94.1 to 95.6%).	354
5.6	Controlled VE with sensitivity analysis as functions of Day 57 markers (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence intervals (5 replicates).	357
5.7	Summary statistics for the number of days from dose 1 to Day 57 visit. (a) The whole immunogenicity subcohort, (b) non-cases in the immunogenicity subcohort, (c) intercurrent cases, (d) primary cases, i.e. cases from the Day 57 correlates analysis population.	360
6.1	Table of risk estimates for a range of thresholds of Day 57 Spike protein binding antibody levels with pointwise 95% confidence intervals.	365
6.2	Table of risk estimates for a range of thresholds of Day 57 RBD binding antibody levels with pointwise 95% confidence intervals.	366
6.3	Table of risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals.	367
6.4	Table of risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals.	368
6.5	Table of risk estimates for a range of thresholds of Day 29 Spike protein antibody levels with pointwise 95% confidence intervals.	370
6.6	Table of risk estimates for a range of thresholds of Day 29 RBD binding antibody levels with pointwise 95% confidence intervals.	371
6.7	Table of risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals.	372
6.8	Table of risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals.	373
6.9	Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Spike protein binding antibody levels with pointwise 95% confidence intervals.	375
6.10	Table of monotone-corrected risk estimates for a range of thresholds of Day 57 RBD binding antibody levels with pointwise 95% confidence intervals.	376
6.11	Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals.	377
6.12	Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals.	378
6.13	Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Spike protein antibody levels with pointwise 95% confidence intervals.	380
6.14	Table of monotone-corrected risk estimates for a range of thresholds of Day 29 RBD binding antibody levels with pointwise 95% confidence intervals.	381
6.15	Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals.	382
6.16	Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals.	383

6.17	Table of risk estimates for a range of thresholds of Day 57 Spike protein binding antibody levels with simultaneous 95% confidence intervals.	385
6.18	Table of risk estimates for a range of thresholds of Day 57 RBD binding antibody levels with simultaneous 95% confidence intervals.	386
6.19	Table of risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals.	387
6.20	Table of risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals.	388
6.21	Table of risk estimates for a range of thresholds of Day 29 Spike protein antibody levels with simultaneous 95% confidence intervals.	390
6.22	Table of risk estimates for a range of thresholds of Day 29 RBD binding antibody levels with simultaneous 95% confidence intervals.	391
6.23	Table of risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals.	392
6.24	Table of risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals.	393
6.25	Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Spike protein binding antibody levels with simultaneous 95% confidence intervals.	395
6.26	Table of monotone-corrected risk estimates for a range of thresholds of Day 57 RBD binding antibody levels with simultaneous 95% confidence intervals.	396
6.27	Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals.	397
6.28	Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals.	398
6.29	Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Spike protein antibody levels with simultaneous 95% confidence intervals.	400
6.30	Table of monotone-corrected risk estimates for a range of thresholds of Day 29 RBD binding antibody levels with simultaneous 95% confidence intervals.	401
6.31	Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals.	402
6.32	Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals.	403
7.1	Table of risk estimates for a range of thresholds of Day 57 Spike protein binding antibody levels with pointwise 95% confidence intervals.	406
7.2	Table of risk estimates for a range of thresholds of Day 57 RBD binding antibody levels with pointwise 95% confidence intervals.	407
7.3	Table of risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals.	408
7.4	Table of risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals.	409
7.5	Table of risk estimates for a range of thresholds of Day 29 Spike protein antibody levels with pointwise 95% confidence intervals.	411

7.6	Table of risk estimates for a range of thresholds of Day 29 RBD binding antibody levels with pointwise 95% confidence intervals.	412
7.7	Table of risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals.	413
7.8	Table of risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals.	414
7.9	Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Spike protein binding antibody levels with pointwise 95% confidence intervals.	416
7.10	Table of monotone-corrected risk estimates for a range of thresholds of Day 57 RBD binding antibody levels with pointwise 95% confidence intervals.	417
7.11	Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals.	418
7.12	Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals.	419
7.13	Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Spike protein antibody levels with pointwise 95% confidence intervals.	421
7.14	Table of monotone-corrected risk estimates for a range of thresholds of Day 29 RBD binding antibody levels with pointwise 95% confidence intervals.	422
7.15	Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals.	423
7.16	Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals.	424
7.17	Table of risk estimates for a range of thresholds of Day 57 Spike protein binding antibody levels with simultaneous 95% confidence intervals.	426
7.18	Table of risk estimates for a range of thresholds of Day 57 RBD binding antibody levels with simultaneous 95% confidence intervals.	427
7.19	Table of risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals.	428
7.20	Table of risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals.	429
7.21	Table of risk estimates for a range of thresholds of Day 29 Spike protein antibody levels with simultaneous 95% confidence intervals.	431
7.22	Table of risk estimates for a range of thresholds of Day 29 RBD binding antibody levels with simultaneous 95% confidence intervals.	432
7.23	Table of risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals.	433
7.24	Table of risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals.	434
7.25	Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Spike protein binding antibody levels with simultaneous 95% confidence intervals.	436
7.26	Table of monotone-corrected risk estimates for a range of thresholds of Day 57 RBD binding antibody levels with simultaneous 95% confidence intervals.	437
7.27	Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals.	438

7.28	Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals.	439
7.29	Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Spike protein antibody levels with simultaneous 95% confidence intervals.	441
7.30	Table of monotone-corrected risk estimates for a range of thresholds of Day 29 RBD binding antibody levels with simultaneous 95% confidence intervals.	442
7.31	Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals.	443
7.32	Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals.	444
10.1	Table of mediation effect estimates for quantitative markers with 95% confidence intervals. Direct VE = VE comparing vaccine vs. placebo with marker set to distribution in placebo. Indirect VE = VE in vaccinated comparing observed marker vs. hypothetical marker under placebo. Prop. mediated = fraction of total risk reduction from vaccine attributed to antibody response.	449
10.2	Table of mediation effect estimates for tertile markers with 95% confidence intervals. Direct VE = VE comparing vaccine vs. placebo with marker set to distribution in placebo. Indirect VE = VE in vaccinated comparing observed marker vs. hypothetical marker under placebo. Prop. mediated = fraction of total risk reduction from vaccine attributed to antibody response.	449

List of Figures

3.1	Boxplots of D57 Ab markers: vaccine arm. The three dashed lines in each figure are ULOQ, LLOQ, and LLOD, from top to bottom respectively.	44
3.2	Boxplots of D57 fold-rise over D1 Ab markers: vaccine arm.	45
3.3	Boxplots of D29 Ab markers: vaccine arm. The three dashed lines in each figure are ULOQ, LLOQ, and LLOD, from top to bottom respectively.	46
3.4	Boxplots of D29 fold-rise over D1 Ab markers: vaccine arm.	47
3.5	RCDF plots for D57 Ab markers by treatment arm.	48
3.6	RCDF plots for D57 fold-rise over D1 Ab markers by treatment arm.	49
3.7	RCDF plots for D29 Ab markers by treatment arm.	50
3.8	RCDF plots for D29 fold-rise over D1 Ab markers by treatment arm.	51
3.9	Marker RCDF of D57 anti-Spike binding Ab: vaccine arm	52
3.10	Marker RCDF of D57 anti-RBD binding Ab: vaccine arm	53
3.11	Marker RCDF of D57 PsV-nAb ID50: vaccine arm	54
3.12	Marker RCDF of D57 PsV-nAb ID80: vaccine arm	55
3.13	Marker RCDF of D29 anti-Spike binding Ab: vaccine arm	56
3.14	Marker RCDF of D29 anti-RBD binding Ab: vaccine arm	57
3.15	Marker RCDF of D29 PsV-nAb ID50: vaccine arm	58
3.16	Marker RCDF of D29 PsV-nAb ID80: vaccine arm	59
3.17	Spaghetti Plots of Marker Trajectory: vaccine arm	60
3.18	lineplots of Binding Antibody to Spike: baseline negative placebo arm (version 1)	61
3.19	lineplots of Binding Antibody to Spike: baseline negative vaccine arm (version 1)	62
3.20	lineplots of Binding Antibody to RBD: baseline negative placebo arm (version 1)	63
3.21	lineplots of Binding Antibody to RBD: baseline negative vaccine arm (version 1)	64
3.22	lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm (version 1)	65
3.23	lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm (version 1)	66
3.24	lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm (version 1)	67
3.25	lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm (version 1)	68
3.26	violinplots of Binding Antibody to Spike: baseline negative placebo arm (version 1)	69
3.27	violinplots of Binding Antibody to Spike: baseline negative vaccine arm (version 1)	70

3.28 violinplots of Binding Antibody to RBD: baseline negative placebo arm (version 1)	71
3.29 violinplots of Binding Antibody to RBD: baseline negative vaccine arm (version 1)	72
3.30 violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm (version 1) . .	73
3.31 violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm (version 1) . . .	74
3.32 violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm (version 1) . .	75
3.33 violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm (version 1) . . .	76
3.34 lineplots of Binding Antibody to Spike: baseline negative placebo arm (version 2)	77
3.35 lineplots of Binding Antibody to Spike: baseline negative vaccine arm (version 2)	78
3.36 lineplots of Binding Antibody to RBD: baseline negative placebo arm (version 2)	79
3.37 lineplots of Binding Antibody to RBD: baseline negative vaccine arm (version 2)	80
3.38 lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm (version 2) . . .	81
3.39 lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm (version 2) . . .	82
3.40 lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm (version 2) . . .	83
3.41 lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm (version 2) . . .	84
3.42 violinplots of Binding Antibody to Spike: baseline negative placebo arm (version 2)	85
3.43 violinplots of Binding Antibody to Spike: baseline negative vaccine arm (version 2)	86
3.44 violinplots of Binding Antibody to RBD: baseline negative placebo arm (version 2)	87
3.45 violinplots of Binding Antibody to RBD: baseline negative vaccine arm (version 2)	88
3.46 violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm (version 2) . .	89
3.47 violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm (version 2) . . .	90
3.48 violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm (version 2) . .	91
3.49 violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm (version 2) . . .	92
3.50 lineplots of Binding Antibody to Spike: baseline negative placebo arm by age (version 1) . . .	93
3.51 lineplots of Binding Antibody to Spike: baseline negative vaccine arm by age (version 1) . . .	94
3.52 lineplots of Binding Antibody to RBD: baseline negative placebo arm by age (version 1) . . .	95
3.53 lineplots of Binding Antibody to RBD: baseline negative vaccine arm by age (version 1) . . .	96
3.54 lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age (version 1)	97
3.55 lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age (version 1)	98
3.56 lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age (version 1)	99
3.57 lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age (version 1)	100
3.58 violinplots of Binding Antibody to Spike: baseline negative placebo arm by age (version 1) .	101
3.59 violinplots of Binding Antibody to Spike: baseline negative vaccine arm by age (version 1) . .	102
3.60 violinplots of Binding Antibody to RBD: baseline negative placebo arm by age (version 1) . .	103
3.61 violinplots of Binding Antibody to RBD: baseline negative vaccine arm by age (version 1) . .	104
3.62 violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age (version 1)	105

3.63 violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age (version 1)	106
3.64 violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age (version 1)	107
3.65 violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age (version 1)	108
3.66 lineplots of Binding Antibody to Spike: baseline negative placebo arm by age (version 2)	109
3.67 lineplots of Binding Antibody to Spike: baseline negative vaccine arm by age (version 2)	110
3.68 lineplots of Binding Antibody to RBD: baseline negative placebo arm by age (version 2)	111
3.69 lineplots of Binding Antibody to RBD: baseline negative vaccine arm by age (version 2)	112
3.70 lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age (version 2)	113
3.71 lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age (version 2)	114
3.72 lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age (version 2)	115
3.73 lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age (version 2)	116
3.74 violinplots of Binding Antibody to Spike: baseline negative placebo arm by age (version 2)	117
3.75 violinplots of Binding Antibody to Spike: baseline negative vaccine arm by age (version 2)	118
3.76 violinplots of Binding Antibody to RBD: baseline negative placebo arm by age (version 2)	119
3.77 violinplots of Binding Antibody to RBD: baseline negative vaccine arm by age (version 2)	120
3.78 violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age (version 2)	121
3.79 violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age (version 2)	122
3.80 violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age (version 2)	123
3.81 violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age (version 2)	124
3.82 lineplots of Binding Antibody to Spike: baseline negative placebo arm by risk condition (version 1)	125
3.83 lineplots of Binding Antibody to Spike: baseline negative vaccine arm by risk condition (version 1)	126
3.84 lineplots of Binding Antibody to RBD: baseline negative placebo arm by risk condition (version 1)	127
3.85 lineplots of Binding Antibody to RBD: baseline negative vaccine arm by risk condition (version 1)	128
3.86 lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by risk condition (version 1)	129
3.87 lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by risk condition (version 1)	130
3.88 lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by risk condition (version 1)	131
3.89 lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by risk condition (version 1)	132

3.90 violinplots of Binding Antibody to Spike: baseline negative placebo arm by risk condition (version 1)	133
3.91 violinplots of Binding Antibody to Spike: baseline negative vaccine arm by risk condition (version 1)	134
3.92 violinplots of Binding Antibody to RBD: baseline negative placebo arm by risk condition (version 1)	135
3.93 violinplots of Binding Antibody to RBD: baseline negative vaccine arm by risk condition (version 1)	136
3.94 violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by risk condition (version 1)	137
3.95 violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by risk condition (version 1)	138
3.96 violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by risk condition (version 1)	139
3.97 violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by risk condition (version 1)	140
3.98 lineplots of Binding Antibody to Spike: baseline negative placebo arm by risk condition (version 2)	141
3.99 lineplots of Binding Antibody to Spike: baseline negative vaccine arm by risk condition (version 2)	142
3.100lineplots of Binding Antibody to RBD: baseline negative placebo arm by risk condition (version 2)	143
3.101lineplots of Binding Antibody to RBD: baseline negative vaccine arm by risk condition (version 2)	144
3.102lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by risk condition (version 2)	145
3.103lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by risk condition (version 2)	146
3.104lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by risk condition (version 2)	147
3.105lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by risk condition (version 2)	148
3.106violinplots of Binding Antibody to Spike: baseline negative placebo arm by risk condition (version 2)	149
3.107violinplots of Binding Antibody to Spike: baseline negative vaccine arm by risk condition (version 2)	150
3.108violinplots of Binding Antibody to RBD: baseline negative placebo arm by risk condition (version 2)	151
3.109violinplots of Binding Antibody to RBD: baseline negative vaccine arm by risk condition (version 2)	152
3.110violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by risk condition (version 2)	153
3.111violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by risk condition (version 2)	154

3.112violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by risk condition (version 2)	155
3.113violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by risk condition (version 2)	156
3.114lineplots of Binding Antibody to Spike: baseline negative placebo arm by age and risk condition (version 1)	157
3.115lineplots of Binding Antibody to Spike: baseline negative vaccine arm by age and risk condition (version 1)	158
3.116lineplots of Binding Antibody to RBD: baseline negative placebo arm by age and risk condition (version 1)	159
3.117lineplots of Binding Antibody to RBD: baseline negative vaccine arm by age and risk condition (version 1)	160
3.118lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age and risk condition (version 1)	161
3.119lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age and risk condition (version 1)	162
3.120lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age and risk condition (version 1)	163
3.121lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age and risk condition (version 1)	164
3.122violinplots of Binding Antibody to Spike: baseline negative placebo arm by age and risk condition (version 1)	165
3.123violinplots of Binding Antibody to Spike: baseline negative vaccine arm by age and risk condition (version 1)	166
3.124violinplots of Binding Antibody to RBD: baseline negative placebo arm by age and risk condition (version 1)	167
3.125violinplots of Binding Antibody to RBD: baseline negative vaccine arm by age and risk condition (version 1)	168
3.126violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age and risk condition (version 1)	169
3.127violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age and risk condition (version 1)	170
3.128violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age and risk condition (version 1)	171
3.129violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age and risk condition (version 1)	172
3.130lineplots of Binding Antibody to Spike: baseline negative placebo arm by age and risk condition (version 2)	173
3.131lineplots of Binding Antibody to Spike: baseline negative vaccine arm by age and risk condition (version 2)	174
3.132lineplots of Binding Antibody to RBD: baseline negative placebo arm by age and risk condition (version 2)	175
3.133lineplots of Binding Antibody to RBD: baseline negative vaccine arm by age and risk condition (version 2)	176

3.134lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age and risk condition (version 2)	177
3.135lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age and risk condition (version 2)	178
3.136lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age and risk condition (version 2)	179
3.137lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age and risk condition (version 2)	180
3.138violinplots of Binding Antibody to Spike: baseline negative placebo arm by age and risk condition (version 2)	181
3.139violinplots of Binding Antibody to Spike: baseline negative vaccine arm by age and risk condition (version 2)	182
3.140violinplots of Binding Antibody to RBD: baseline negative placebo arm by age and risk condition (version 2)	183
3.141violinplots of Binding Antibody to RBD: baseline negative vaccine arm by age and risk condition (version 2)	184
3.142violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age and risk condition (version 2)	185
3.143violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age and risk condition (version 2)	186
3.144violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age and risk condition (version 2)	187
3.145violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age and risk condition (version 2)	188
3.146lineplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (version 1)	189
3.147lineplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (version 1)	190
3.148lineplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (version 1)	191
3.149lineplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (version 1)	192
3.150lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by sex assigned at birth (version 1)	193
3.151lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by sex assigned at birth (version 1)	194
3.152lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by sex assigned at birth (version 1)	195
3.153lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by sex assigned at birth (version 1)	196
3.154violinplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (version 1)	197
3.155violinplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (version 1)	198

3.156violinplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (version 1)	199
3.157violinplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (version 1)	200
3.158violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by sex assigned at birth (version 1)	201
3.159violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by sex assigned at birth (version 1)	202
3.160violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by sex assigned at birth (version 1)	203
3.161violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by sex assigned at birth (version 1)	204
3.162lineplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (version 2)	205
3.163lineplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (version 2)	206
3.164lineplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (version 2)	207
3.165lineplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (version 2)	208
3.166lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by sex assigned at birth (version 2)	209
3.167lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by sex assigned at birth (version 2)	210
3.168lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by sex assigned at birth (version 2)	211
3.169lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by sex assigned at birth (version 2)	212
3.170violinplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (version 2)	213
3.171violinplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (version 2)	214
3.172violinplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (version 2)	215
3.173violinplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (version 2)	216
3.174violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by sex assigned at birth (version 2)	217
3.175violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by sex assigned at birth (version 2)	218
3.176violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by sex assigned at birth (version 2)	219
3.177violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by sex assigned at birth (version 2)	220

3.178lineplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (version 1)	221
3.179lineplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (version 1)	222
3.180lineplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (version 1)	223
3.181lineplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (version 1)	224
3.182lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by race and ethnic group (version 1)	225
3.183lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by race and ethnic group (version 1)	226
3.184lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by race and ethnic group (version 1)	227
3.185lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by race and ethnic group (version 1)	228
3.186violinplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (version 1)	229
3.187violinplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (version 1)	230
3.188violinplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (version 1)	231
3.189violinplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (version 1)	232
3.190violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by race and ethnic group (version 1)	233
3.191violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by race and ethnic group (version 1)	234
3.192violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by race and ethnic group (version 1)	235
3.193violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by race and ethnic group (version 1)	236
3.194lineplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (version 2)	237
3.195lineplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (version 2)	238
3.196lineplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (version 2)	239
3.197lineplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (version 2)	240
3.198lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by race and ethnic group (version 2)	241
3.199lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by race and ethnic group (version 2)	242

3.200lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by race and ethnic group (version 2)	243
3.201lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by race and ethnic group (version 2)	244
3.202violinplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (version 2)	245
3.203violinplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (version 2)	246
3.204violinplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (version 2)	247
3.205violinplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (version 2)	248
3.206violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by race and ethnic group (version 2)	249
3.207violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by race and ethnic group (version 2)	250
3.208violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by race and ethnic group (version 2)	251
3.209violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by race and ethnic group (version 2)	252
3.210lineplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)	253
3.211lineplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)	254
3.212lineplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)	255
3.213lineplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)	256
3.214lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)	257
3.215lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)	258
3.216lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)	259
3.217lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)	260
3.218violinplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)	261
3.219violinplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)	262
3.220violinplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)	263
3.221violinplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)	264

3.222violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)	265
3.223violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)	266
3.224violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)	267
3.225violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)	268
3.226lineplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)	269
3.227lineplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)	270
3.228lineplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)	271
3.229lineplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)	272
3.230lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)	273
3.231lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)	274
3.232lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)	275
3.233lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)	276
3.234violinplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)	277
3.235violinplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)	278
3.236violinplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)	279
3.237violinplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)	280
3.238violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)	281
3.239violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)	282
3.240violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)	283
3.241violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)	284
3.242scatterplots of Binding Antibody to Spike vs Age: baseline negative vaccine arm at day 1 . .	285
3.243scatterplots of Binding Antibody to Spike vs Age: baseline negative vaccine arm at day 29 .	286
3.244scatterplots of Binding Antibody to Spike vs Age: baseline negative vaccine arm at day 57 .	287

3.245scatterplots of Binding Antibody to RBD vs Age: baseline negative vaccine arm at day 1	288
3.246scatterplots of Binding Antibody to RBD vs Age: baseline negative vaccine arm at day 29	289
3.247scatterplots of Binding Antibody to RBD vs Age: baseline negative vaccine arm at day 57	290
3.248scatterplots of Pseudovirus Neutralization ID50 vs Age: baseline negative vaccine arm at day 1	291
3.249scatterplots of Pseudovirus Neutralization ID50 vs Age: baseline negative vaccine arm at day 29	292
3.250scatterplots of Pseudovirus Neutralization ID50 vs Age: baseline negative vaccine arm at day 57	293
3.251scatterplots of Pseudovirus Neutralization ID80 vs Age: baseline negative vaccine arm at day 1	294
3.252scatterplots of Pseudovirus Neutralization ID80 vs Age: baseline negative vaccine arm at day 29	295
3.253scatterplots of Pseudovirus Neutralization ID80 vs Age: baseline negative vaccine arm at day 57	296
3.254scatterplots of Binding Antibody to Spike vs Age: by arm at day 1	297
3.255scatterplots of Binding Antibody to Spike vs Age: by arm at day 29	298
3.256scatterplots of Binding Antibody to Spike vs Age: by arm at day 57	299
3.257scatterplots of Binding Antibody to RBD vs Age: by arm at day 1	300
3.258scatterplots of Binding Antibody to RBD vs Age: by arm at day 29	301
3.259scatterplots of Binding Antibody to RBD vs Age: by arm at day 57	302
3.260scatterplots of Pseudovirus Neutralization ID50 vs Age vs Age: by arm at day 1	303
3.261scatterplots of Pseudovirus Neutralization ID50 vs Age vs Age: by arm at day 29	304
3.262scatterplots of Pseudovirus Neutralization ID50 vs Age: by arm at day 57	305
3.263scatterplots of Pseudovirus Neutralization ID80 vs Age: by arm at day 1	306
3.264scatterplots of Pseudovirus Neutralization ID80 vs Age: by arm at day 29	307
3.265scatterplots of Pseudovirus Neutralization ID80 vs Age: by arm at day 57	308
3.266scatterplots of Binding Antibody to Spike vs Days Since the Day 29 Visit: baseline negative vaccine arm at day 29 and day 57	309
3.267scatterplots of Binding Antibody to RBD vs Days Since the Day 29 Visit: baseline negative vaccine arm at day 29 and day 57	310
3.268scatterplots of Pseudovirus Neutralization ID50 vs Days Since the Day 29 Visit: baseline negative vaccine arm at day 29 and day 57	311
3.269scatterplots of Pseudovirus Neutralization ID80 vs Days Since the Day 29 Visit: baseline negative vaccine arm at day 29 and day 57	312
3.270scatterplots of Binding Antibody to Spike vs Days Since the Day 29 Visit: by arm at day 29 and day 57	313
3.271scatterplots of Binding Antibody to RBD vs Days Since the Day 29 Visit: by arm at day 29 and day 57	314
3.272scatterplots of Pseudovirus Neutralization ID50 vs Days Since the Day 29 Visit vs Days Since the Day 29 Visit: by arm at day 29 and day 57	315
3.273scatterplots of Pseudovirus Neutralization ID80 vs Days Since the Day 29 Visit: by arm at day 29 and day 57	316

4.1	Forest plots of hazard ratios per 10-fold increase in the marker among baseline negative vaccine recipients and subgroups with 95% point-wise confidence intervals.	319
4.2	Forest plots of hazard ratios per 10-fold increase in the Day 29 binding Ab to spike markers among baseline negative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.	320
4.3	Forest plots of hazard ratios per 10-fold increase in the Day 29 binding Ab to RBD markers among baseline negative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.	320
4.4	Forest plots of hazard ratios per 10-fold increase in the Day 29 pseudo neut ID50 markers among baseline negative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.	321
4.5	Forest plots of hazard ratios per 10-fold increase in the Day 29 pseudo neut ID80 markers among baseline negative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.	321
4.6	Marginalized cumulative incidence rate curves for trichotomized Day 29 markers among baseline negative vaccine recipients. The gray line is the overall cumulative incidence rate curve in the placebo arm.	323
4.7	Marginalized cumulative risk by Day 192 as functions of Day 29 markers (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence bands (5 replicates). The horizontal lines indicate the overall cumulative risk of the placebo and vaccine arms by Day 192 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod = 0.3, 1.6, 2.4, 15 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively.	324
4.8	Controlled VE with sensitivity analysis as functions of Day 29 markers (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence bands (5 replicates). Histograms of the immunological markers in the vaccine arm are overlaid. lod = 0.3, 1.6, 2.4, 15 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively.	325
4.9	Controlled VE with sensitivity analysis as functions of Day 29 markers (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence bands (5 replicates). Histograms of the immunological markers in the vaccine arm are overlaid. lod = 0.3, 1.6, 2.4, 15 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively.	326
4.10	Marginalized cumulative risk by Day 192 as functions of Day 29 markers above a threshold ($\geq s$) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence bands (at least 5 cases are required, 5 replicates). The horizontal lines indicate the overall cumulative risk of the vaccine arm by Day 192 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod = 0.3, 1.6, 2.4, 15 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively.	327
4.11	Controlled VE as functions of Day 29 markers ($>=s$) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence bands (5 replicates). Histograms of the immunological markers in the vaccine arm are overlaid. lod = 0.3, 1.6, 2.4, 15 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively.	328
5.1	Forest plots of hazard ratios per 10-fold increase in the marker among baseline negative vaccine recipients and subgroups with 95% point-wise confidence intervals.	341
5.2	Forest plots of hazard ratios per 10-fold increase in the Day 57 binding Ab to spike markers among baseline negative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.	342

5.3 Forest plots of hazard ratios per 10-fold increase in the Day 57 binding Ab to RBD markers among baseline negative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.	342
5.4 Forest plots of hazard ratios per 10-fold increase in the Day 57 pseudo neut ID50 markers among baseline negative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.	343
5.5 Forest plots of hazard ratios per 10-fold increase in the Day 57 pseudo neut ID80 markers among baseline negative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.	343
5.6 Marginalized cumulative incidence rate curves for trichotomized Day 57 markers among baseline negative vaccine recipients. The gray line is the overall cumulative incidence rate curve in the placebo arm.	345
5.7 Marginalized cumulative risk by Day 164 as functions of Day 57 markers ($=s$) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence bands (5 replicates). The horizontal lines indicate the overall cumulative risk of the placebo and vaccine arms by Day 164 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod = 0.3, 1.6, 2.4, 15 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively.	346
5.8 Controlled VE with sensitivity analysis as functions of Day 57 markers ($=s$) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence bands (5 replicates). Histograms of the immunological markers in the vaccine arm are overlaid. lod = 0.3, 1.6, 2.4, 15 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively.	347
5.9 Controlled VE with sensitivity analysis as functions of Day 57 markers ($=s$) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence bands (5 replicates). Histograms of the immunological markers in the vaccine arm are overlaid. lod = 0.3, 1.6, 2.4, 15 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively.	348
5.10 Marginalized cumulative risk by Day 164 as functions of Day 57 markers above a threshold ($\geq s$) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence bands (at least 5 cases are required, 5 replicates). The horizontal lines indicate the overall cumulative risk of the vaccine arm by Day 164 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod = 0.3, 1.6, 2.4, 15 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively.	349
5.11 Controlled VE as functions of Day 57 markers ($>=s$) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence bands (5 replicates). Histograms of the immunological markers in the vaccine arm are overlaid. lod = 0.3, 1.6, 2.4, 15 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively.	350
5.12 Distribution of the number of days bewteen visits in the immunogenicity subcohort, vaccine arm, baseline negative.	361
5.13 Distribution of the number of days to COVID endpoints, vaccine arm, baseline negative.	361
6.1 Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.	365
6.2 Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.	366
6.3 Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.	367

6.4	Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.	368
6.5	Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.	370
6.6	Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.	371
6.7	Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.	372
6.8	Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.	373
6.9	Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.	375
6.10	Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.	376
6.11	Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.	377
6.12	Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.	378
6.13	Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.	380
6.14	Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.	381
6.15	Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.	382

6.16 Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.	383
6.17 Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.	385
6.18 Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.	386
6.19 Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.	387
6.20 Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.	388
6.21 Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.	390
6.22 Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.	391
6.23 Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.	392
6.24 Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.	393
6.25 Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.	395
6.26 Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.	396
6.27 Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.	397
6.28 Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.	398

6.29 Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.	400
6.30 Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.	401
6.31 Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.	402
6.32 Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.	403
7.1 Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with pointwise 95% confidence intervals.	406
7.2 Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with pointwise 95% confidence intervals.	407
7.3 Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals.	408
7.4 Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals.	409
7.5 Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with pointwise 95% confidence intervals.	411
7.6 Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with pointwise 95% confidence intervals.	412
7.7 Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals.	413
7.8 Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals.	414
7.9 Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with pointwise 95% confidence intervals. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.	416
7.10 Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with pointwise 95% confidence intervals. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.	417
7.11 Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.	418

7.12 Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.	419
7.13 Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with pointwise 95% confidence intervals. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.	421
7.14 Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with pointwise 95% confidence intervals. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.	422
7.15 Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.	423
7.16 Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.	424
7.17 Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with simultaneous 95% confidence intervals.	426
7.18 Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with simultaneous 95% confidence intervals.	427
7.19 Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals.	428
7.20 Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals.	429
7.21 Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with simultaneous 95% confidence intervals.	431
7.22 Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with simultaneous 95% confidence intervals.	432
7.23 Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals.	433
7.24 Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals.	434
7.25 Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with simultaneous 95% confidence intervals. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.	436
7.26 Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with simultaneous 95% confidence intervals. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.	437
7.27 Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.	438

7.28 Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.	439
7.29 Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with simultaneous 95% confidence intervals. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.	441
7.30 Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with simultaneous 95% confidence intervals. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.	442
7.31 Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.	443
7.32 Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.	444
8.1 Marginalized risk as functions of Day 57 markers (= s) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands (5 replicates) as modeled by GAM with automatic smoothness estimation. Baseline covariates adjusted for: baseline risk score, meeting the protocol randomization stratification criterion for being at heightened risk of COVID (yes or no), community of color or not. The horizontal lines indicate the overall cumulative risk of the vaccine and placebo arms by Day 164 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod = 0.3, 1.6, 2.4, 15 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively.	446
9.1 Marginalized risk as functions of Day 29 markers (= s) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands (5 replicates) as modeled by GAM with automatic smoothness estimation. Baseline covariates adjusted for: baseline risk score, meeting the protocol randomization stratification criterion for being at heightened risk of COVID (yes or no), community of color or not. The horizontal lines indicate the overall cumulative risk of the vaccine and placebo arms by Day 192 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod = 0.3, 1.6, 2.4, 15 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively.	448

Chapter 1

Disclaimers

- The data presented in the analysis originated from the Moderna Sponsored mRNA-1273-P301 clinical study and are provided to NIAID in accordance with Clinical Trial Agreement between the parties. The study was funded in part by BARDA under Government Contract No. 75A50120C00034
- The preliminary immunogenicity data presented here do not reflect the Sponsors statistical analysis plan and therefore should not be interpreted as a protocol defined read-out of the clinical study.
- These data are not to be disclosed without written permission of Moderna.

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Chapter 2

Summary Tables

2.1 Demographic and Clinical Characteristics at Baseline in the Baseline SARS-CoV-2 Negative Per-Protocol Cohort

Table 1. Demographic and Clinical Characteristics at Baseline in the Baseline SARS-CoV-2 Negative Per-Protocol Cohort

Characteristics	Vaccine (N = 747)	Placebo (N = 138)	Total (N = 885)
Age			
Age < 65	357 (47.8%)	72 (52.2%)	429 (48.5%)
Age ≥ 65	390 (52.2%)	66 (47.8%)	456 (51.5%)
Mean (Range)	58.5 (18.0, 85.0)	58.3 (18.0, 85.0)	58.5 (18.0, 85.0)
BMI			
Mean ± SD	29.7 ± 6.6	31.4 ± 6.3	30.0 ± 6.6
Risk for Severe Covid-19			
At-risk	381 (51.0%)	71 (51.4%)	452 (51.1%)
Not at-risk	366 (49.0%)	67 (48.6%)	433 (48.9%)
Age, Risk for Severe Covid-19			
Age < 65 At-risk	185 (24.8%)	36 (26.1%)	221 (25.0%)
Age < 65 Not at-risk	172 (23.0%)	36 (26.1%)	208 (23.5%)
Age ≥ 65	390 (52.2%)	66 (47.8%)	456 (51.5%)
Sex			
Female	427 (57.2%)	75 (54.3%)	502 (56.7%)
Male	320 (42.8%)	63 (45.7%)	383 (43.3%)
Hispanic or Latino ethnicity			
Hispanic or Latino	99 (13.3%)	20 (14.5%)	119 (13.4%)
Not Hispanic or Latino	623 (83.4%)	113 (81.9%)	736 (83.2%)
Not reported and unknown	25 (3.3%)	5 (3.6%)	30 (3.4%)
Race			
White	397 (53.1%)	74 (53.6%)	471 (53.2%)
Black or African American	184 (24.6%)	40 (29.0%)	224 (25.3%)
Asian	56 (7.5%)	10 (7.2%)	66 (7.5%)
American Indian or Alaska Native	16 (2.1%)	2 (1.4%)	18 (2.0%)
Native Hawaiian or Other Pacific Islander	17 (2.3%)	2 (1.4%)	19 (2.1%)

(continued)

Characteristics	Vaccine (N = 747)	Placebo (N = 138)	Total (N = 885)
Multiracial	57 (7.6%)	8 (5.8%)	65 (7.3%)
Other	16 (2.1%)	1 (0.7%)	17 (1.9%)
Not reported and unknown	4 (0.5%)	1 (0.7%)	5 (0.6%)
White Non-Hispanic	370 (49.5%)	63 (45.7%)	433 (48.9%)
Communities of Color	377 (50.5%)	75 (54.3%)	452 (51.1%)

This table summarizes the random subcohort, which was randomly sampled from the per-protocol cohort. The sampling was stratified by 24 strata defined by enrollment characteristics: Assigned treatment arm × Baseline SARS-CoV-2 naïve vs. non-naïve status (defined by serostatus and NAAT testing) × Randomization strata (Age < 65 and at-risk, Age < 65 and not at-risk, Age ≥ 65) × Communities of color (Yes/No) defined by White Non-Hispanic vs. all others (following the primary COVE trial paper).

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2.2 Demographic and Clinical Characteristics at Baseline in the Baseline SARS-CoV-2 Positive Per-Protocol Cohort

Table 2. Demographic and Clinical Characteristics at Baseline in the Baseline SARS-CoV-2 Positive Per-Protocol Cohort

Characteristics	Vaccine (N = 234)	Placebo (N = 241)	Total (N = 475)
Age			
Age < 65	114 (48.7%)	120 (49.8%)	234 (49.3%)
Age ≥ 65	120 (51.3%)	121 (50.2%)	241 (50.7%)
Mean (Range)	58.3 (18.0, 85.0)	56.3 (18.0, 85.0)	57.3 (18.0, 85.0)
BMI			
Mean ± SD	29.7 ± 7.5	30.0 ± 6.6	29.9 ± 7.0
Risk for Severe Covid-19			
At-risk	111 (47.4%)	117 (48.5%)	228 (48.0%)
Not at-risk	123 (52.6%)	124 (51.5%)	247 (52.0%)
Age, Risk for Severe Covid-19			
Age < 65 At-risk	56 (23.9%)	59 (24.5%)	115 (24.2%)
Age < 65 Not at-risk	58 (24.8%)	61 (25.3%)	119 (25.1%)
Age ≥ 65	120 (51.3%)	121 (50.2%)	241 (50.7%)
Sex			
Female	139 (59.4%)	133 (55.2%)	272 (57.3%)
Male	95 (40.6%)	108 (44.8%)	203 (42.7%)
Hispanic or Latino ethnicity			
Hispanic or Latino	31 (13.2%)	34 (14.1%)	65 (13.7%)
Not Hispanic or Latino	194 (82.9%)	201 (83.4%)	395 (83.2%)
Not reported and unknown	9 (3.8%)	6 (2.5%)	15 (3.2%)
Race			
White	126 (53.8%)	129 (53.5%)	255 (53.7%)
Black or African American	58 (24.8%)	45 (18.7%)	103 (21.7%)
Asian	19 (8.1%)	27 (11.2%)	46 (9.7%)
American Indian or Alaska Native	10 (4.3%)	7 (2.9%)	17 (3.6%)
Native Hawaiian or Other Pacific Islander	4 (1.7%)	2 (0.8%)	6 (1.3%)
Multiracial	10 (4.3%)	16 (6.6%)	26 (5.5%)
Other	7 (3.0%)	13 (5.4%)	20 (4.2%)
Not reported and unknown		2 (0.8%)	2 (0.4%)
White Non-Hispanic	118 (50.4%)	121 (50.2%)	239 (50.3%)
Communities of Color	116 (49.6%)	120 (49.8%)	236 (49.7%)

This table summarizes the random subcohort, which was randomly sampled from the per-protocol cohort. The sampling was stratified by 24 strata defined by enrollment characteristics: Assigned treatment arm × Baseline SARS-CoV-2 naïve vs. non-naïve status (defined by serostatus and NAAT testing) × Randomization strata (Age < 65 and at-risk, Age < 65 and not at-risk, Age ≥ 65) × Communities of color (Yes/No) defined by White Non-Hispanic vs. all others (following the primary COVE trial paper).

2.3 Sample Sizes of Random Subcohort Strata for Measuring Antibody Markers

Table 3. Sample Sizes of Random Subcohort Strata for Measuring Antibody Markers

Random Subcohort Sample Sizes (N=1360 Participants) (Moderna Trial)																		
	Baseline SARS-CoV-2 Negative									Baseline SARS-CoV-2 Positive								
	1	2	3	4	5	6	7	8	9	1	2	3	4	5	6	7	8	9
Vaccine																		
Day 29 Cases	8	2	3	18	7	12	6	0	3	0	0	2	0	0	0	0	1	0
Day 57 Cases	8	2	1	18	7	9	4	0	3	0	0	2	0	0	0	0	1	0
Non-Cases	153	78	67	235	106	105	69	35	39	48	24	23	72	32	35	26	12	11
Placebo																		
Day 29 Cases	141	48	87	329	109	243	77	31	55	0	0	1	1	1	1	1	0	0
Day 57 Cases	132	37	61	306	93	198	72	27	42	0	0	1	1	1	1	1	0	0
Non-Cases	21	16	16	34	16	18	9	2	3	43	19	22	77	39	38	32	16	9

Demographic covariate strata:

1. Age ≥ 65 , Minority
2. Age < 65 , At risk, Minority
3. Age < 65 , Not at risk, Minority
4. Age ≥ 65 , Non-Minority
5. Age < 65 , At risk, Non-Minority
6. Age < 65 , Not at risk, Non-Minority
7. Age ≥ 65 , Unknown
8. Age < 65 , At risk, Unknown
9. Age < 65 , Not at risk, Unknown

Minority includes Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders.

Non-Minority includes all other races with observed race (Asian, Multiracial, White, Other) and observed ethnicity Not Hispanic or Latino. Participants not classifiable as Minority or Non-Minority because of unknown, unreported or missing were not included.

Observed = Numbers of participants sampled into the subcohort within baseline covariate strata.

Estimated = Estimated numbers of participants in the whole per-protocol cohort within baseline covariate strata, calculated using inverse probability weighting.

2.4 Availability of immunogenicity data by case status

Table 4. Availability of immunogenicity data by case status

Case	---	--+	-+-	-++	+--	+--	++-	+++
Vaccine								
Day 29 Cases	1	0	0	0	0	0	0	59
Day 57 Cases	0	0	0	0	0	0	0	52
Intercurrent Cases	1	0	0	0	0	0	0	7
Placebo								
Day 29 Cases	49	0	0	0	0	0	0	1120
Day 57 Cases	42	0	0	0	0	0	0	968
Intercurrent Cases	6	0	0	0	0	0	0	146

The + (available) and - (unavailable) in the column labels refer to the availability of the baseline, D29 and D57 markers, respectively.

2.5 Antibody levels in the baseline SARS-CoV-2 negative per-protocol cohort (vaccine recipients)

Table 5. Antibody levels in the baseline SARS-CoV-2 negative per-protocol cohort (vaccine recipients)

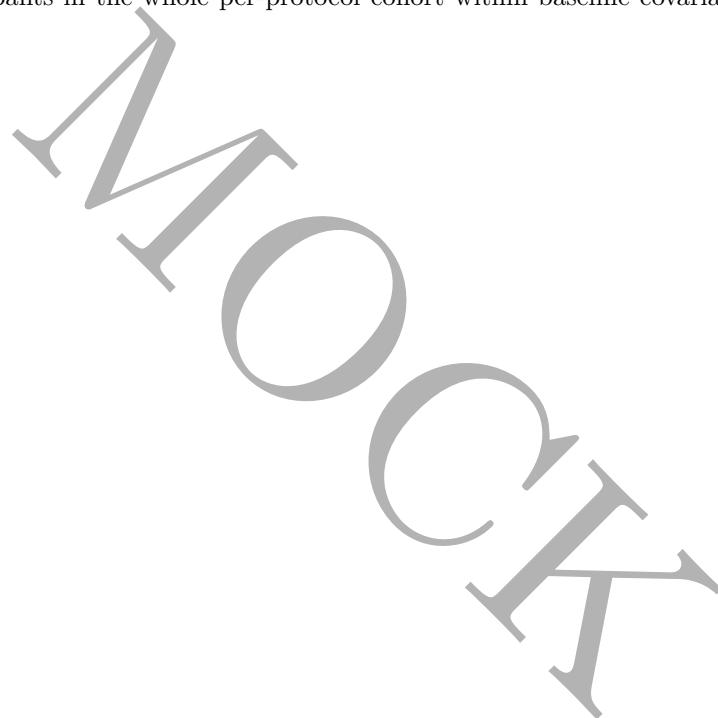
Visit	Marker	Baseline SARS-CoV-2 Negative Vaccine Recipients						Comparison	
		Cases*		Non-Cases/Control		Resp Rate Difference	GMTR/GMCR		
N	Resp rate	N	Resp rate	GMT/GMC					
Day 29	Pseudovirus-nAb cID80	59	35.6/60 = 59.3% (46.2%, 71.3%)	21.18 (17.33, 25.87)	744	6530.6/11070 = 59.0% (54.4%, 63.4%)	25.97 (23.98, 28.13)	0 (-0.14, 0.13)	0.82 (0.66, 1.01)
Day 29	Pseudovirus-nAb cID50	59	53.9/60 = 89.8% (78.9%, 95.4%)	16.19 (12.51, 20.95)	744	9932/11070 = 89.7% (86.2%, 92.4%)	17.35 (15.85, 18.99)	0 (-0.11, 0.07)	0.93 (0.71, 1.23)
Day 29	Anti RBD IgG (IU/ml)	59	60/60 = 100.0% (100.0%, 100.0%)	456.66 (292.67, 712.53)	744	10896.8/11070 = 98.4% (96.6%, 99.3%)	473.53 (412.98, 542.96)	0.02 (0.01, 0.03)	0.96 (0.61, 1.54)
Day 29	Anti Spike IgG (IU/ml)	59	60/60 = 100.0% (100.0%, 100.0%)	236.57 (169.47, 330.25)	744	10981.5/11070 = 99.2% (97.7%, 99.7%)	266.03 (238.38, 296.89)	0.01 (0, 0.02)	0.89 (0.63, 1.26)
Day 29	Anti N IgG (IU/ml)	59	35.6/60 = 59.3% (46.2%, 71.3%)	39.18 (24.94, 61.55)	744	6848.9/11070 = 61.9% (57.3%, 66.2%)	36.77 (31.08, 43.49)	-0.03 (-0.16, 0.1)	1.07 (0.66, 1.73)
Day 57	Pseudovirus-nAb cID80	52	52/52 = 100.0% (100.0%, 100.0%)	408.70 (310.06, 538.71)	744	11065/11065 = 100.0% (100.0%, 100.0%)	564.67 (511.70, 623.12)	0 (0, 0)	0.72 (0.54, 0.97)
Day 57	Pseudovirus-nAb cID50	52	52/52 = 100.0% (100.0%, 100.0%)	320.14 (230.41, 444.83)	744	11065/11065 = 100.0% (100.0%, 100.0%)	427.25 (383.62, 475.84)	0 (0, 0)	0.75 (0.53, 1.06)
Day 57	Anti RBD IgG (IU/ml)	52	52/52 = 100.0% (100.0%, 100.0%)	3325.76 (2232.06, 4955.38)	744	11045.2/11065 = 99.8% (98.7%, 100.0%)	3599.25 (3171.86, 4084.22)	0 (0, 0.01)	0.92 (0.61, 1.40)
Day 57	Anti Spike IgG (IU/ml)	52	52/52 = 100.0% (100.0%, 100.0%)	1847.33 (1337.98, 2550.57)	744	11065/11065 = 100.0% (100.0%, 100.0%)	2668.40 (2364.64, 3011.17)	0 (0, 0)	0.69 (0.49, 0.98)

Day	Anti N IgG (IU/ml)	52	$37/52 = 71.2\%$ (57.2%, 82.0%)	71.78 (43.87, 117.44)	744	$8998.4/11065 = 81.3\%$ (77.3%, 84.8%)	110.30 (94.07, 129.33)	-0.1 (-0.25, 0.01)	0.65 (0.39, 1.09)
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Cases for Day 29 markers are baseline negative per-protocol vaccine recipients with the symptomatic infection COVID-19 primary endpoint diagnosed starting 7 days after the Day 29 study visit. Cases for Day 57 markers are baseline negative per-protocol vaccine recipients with the symptomatic infection COVID-19 primary endpoint diagnosed starting 7 days after the Day 57 study visit. Non-cases/Controls are baseline negative per-protocol vaccine recipients sampled into the random subcohort with no COVID-19 endpoint diagnosis by the time of data-cut.

N is the number of cases sampled into the subcohort within baseline covariate strata.

The denominator in Resp Rate is the number of participants in the whole per-protocol cohort within baseline covariate strata, calculated using inverse probability weighting.



2.6 Antibody levels in the baseline SARS-CoV-2 positive per-protocol cohort (vaccine recipients)

Table 6. Antibody levels in the baseline SARS-CoV-2 positive per-protocol cohort (vaccine recipients)

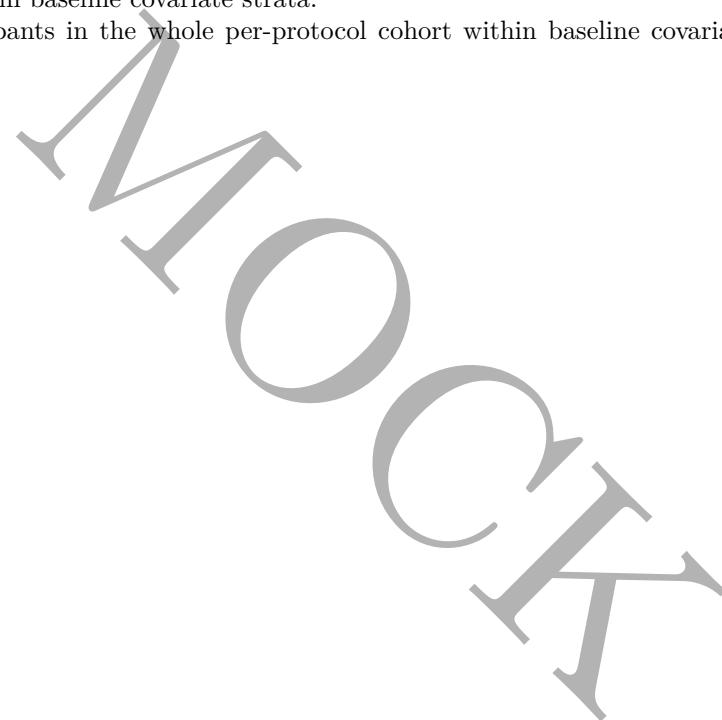
Visit	Marker	Baseline SARS-CoV-2 Positive Vaccine Recipients						Comparison	
		Cases*		Non-Cases/Control				Resp Rate Difference	GMTR/GMCR
	N	Resp rate	GMT/GMC	N	Resp rate	GMT/GMC			
Day 29	Pseudovirus-nAb cID80	3 3.3/5 = 66.7% (0.6%, 99.8%)	28.17 (20.25, 39.20)	234 904.7/1218.1 = 74.3% (66.3%, 80.9%)	51.20 (44.64, 58.73)	-0.08 (-0.74, 0.27)	0.55 (0.38, 0.79)		
Day 29	Pseudovirus-nAb cID50	3 5/5 = 100.0% (100.0%, 100.0%)	37.31 (35.33, 39.40)	234 1159.7/1218.1 = 95.2% (89.2%, 97.9%)	32.70 (28.11, 38.04)	0.05 (0.02, 0.11)	1.14 (0.97, 1.34)		
Day 29	Anti RBD IgG (IU/ml)	3 5/5 = 100.0% (100.0%, 100.0%)	622.59 (124.89, 3103.56)	234 1213.5/1218.1 = 99.6% (97.3%, 99.9%)	823.96 (640.00, 1060.79)	0 (0, 0.03)	0.76 (0.15, 3.84)		
Day 29	Anti Spike IgG (IU/ml)	3 5/5 = 100.0% (100.0%, 100.0%)	180.93 (156.70, 208.91)	234 1209.6/1218.1 = 99.3% (95.1%, 99.9%)	474.27 (397.60, 565.71)	0.01 (0, 0.05)	0.38 (0.30, 0.48)		
Day 29	Anti N IgG (IU/ml)	3 5/5 = 100.0% (100.0%, 100.0%)	220.52 (99.97, 486.42)	234 928.1/1218.1 = 76.2% (68.6%, 82.4%)	70.68 (55.09, 90.70)	0.24 (0.18, 0.31)	3.12 (1.36, 7.15)		
Day 57	Pseudovirus-nAb cID80	3 5/5 = 100.0% (100.0%, 100.0%)	1156.48 (486.62, 2748.44)	233 1229/1229 = 100.0% (100.0%, 100.0%)	1559.92 (1333.89, 1824.26)	0 (0, 0)	0.74 (0.31, 1.79)		
Day 57	Pseudovirus-nAb cID50	3 5/5 = 100.0% (100.0%, 100.0%)	493.08 (319.26, 761.53)	233 1229/1229 = 100.0% (100.0%, 100.0%)	1227.59 (1000.73, 1505.88)	0 (0, 0)	0.40 (0.25, 0.65)		
Day 57	Anti RBD IgG (IU/ml)	3 5/5 = 100.0% (100.0%, 100.0%)	15558.50 (14386.64, 16825.81)	233 1229/1229 = 100.0% (100.0%, 100.0%)	8619.19 (7266.78, 10223.28)	0 (0, 0)	1.81 (1.50, 2.18)		
Day 57	Anti Spike IgG (IU/ml)	3 5/5 = 100.0% (100.0%, 100.0%)	4871.27 (3719.87, 6379.06)	233 1229/1229 = 100.0% (100.0%, 100.0%)	5665.25 (4956.22, 6475.72)	0 (0, 0)	0.86 (0.64, 1.16)		

Day 57	Anti N IgG (IU/ml)	3	$5/5 = 100.0\%$ (100.0%, 100.0%)	293.21 (150.76, 570.25)	233	$1182.5/1229 = 96.2\%$ (90.6%, 98.5%)	248.12 (202.53, 303.97)	0.04 (0.01, 0.09)	1.18 (0.59, 2.37)
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The SAP does not specify correlates analyses in baseline positive vaccine recipients. This table summarizes descriptively the same information for baseline positive vaccine recipients that was summarized for baseline negative vaccine recipients. Cases for Day 29 markers are baseline positive per-protocol vaccine recipients with the symptomatic infection COVID-19 primary endpoint diagnosed starting 7 days after the Day 29 study visit. Cases for Day 57 markers are baseline positive per-protocol vaccine recipients with the symptomatic infection COVID-19 primary endpoint diagnosed starting 7 days after the Day 57 study visit. Non-cases/Controls are baseline positive per-protocol vaccine recipients sampled into the random subcohort with no COVID-19 endpoint diagnosis by the time of data-cut.

N is the number of cases sampled into the subcohort within baseline covariate strata.

The denominator in Resp Rate is the number of participants in the whole per-protocol cohort within baseline covariate strata, calculated using inverse probability weighting.



2.7 Antibody levels in the baseline SARS-CoV-2 positive per-protocol cohort (placebo recipients)

Table 7. Antibody levels in the baseline SARS-CoV-2 positive per-protocol cohort (placebo recipients)

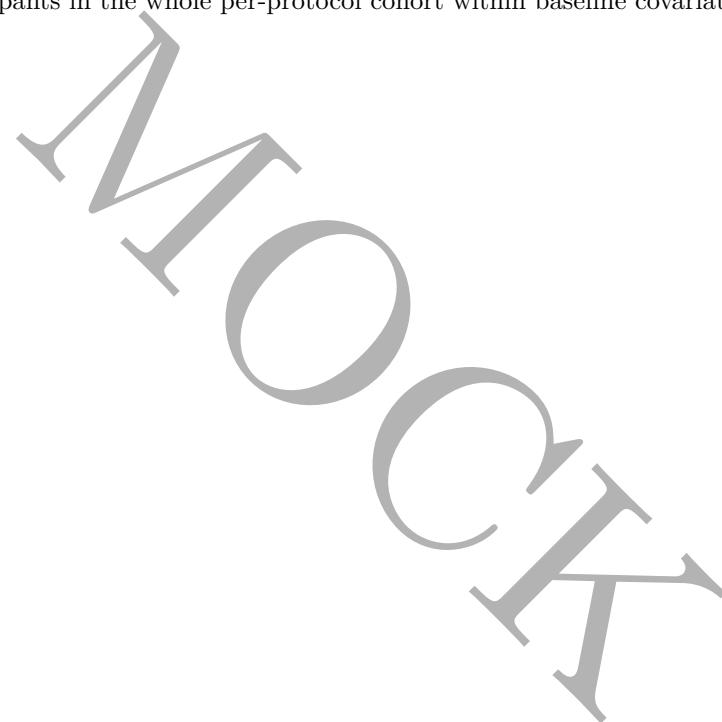
Visit	Marker	Baseline SARS-CoV-2 Positive Placebo Recipients						Comparison	
		N	Resp rate	Cases*	N	Non-Cases/Control	GMT/GMC	Resp Rate Difference	GMTR/GMCR
Day 29	Pseudovirus-nAb cID80	5	3/5 = 60.0% (10.6%, 95.0%)	19.58 (9.63, 39.79)	238	442.9/1121 = 39.5% (32.4%, 47.1%)	20.38 (17.86, 23.27)	0.2 (-0.29, 0.56)	0.96 (0.47, 1.98)
Day 29	Pseudovirus-nAb cID50	5	2/5 = 40.0% (5.0%, 89.4%)	4.46 (1.50, 13.28)	238	896.5/1121 = 80.0% (72.4%, 85.9%)	11.68 (9.90, 13.77)	-0.4 (-0.75, 0.1)	0.38 (0.13, 1.15)
Day 29	Anti RBD IgG (IU/ml)	5	5/5 = 100.0% (100.0%, 100.0%)	498.48 (77.45, 3208.22)	238	1060/1121 = 94.6% (88.4%, 97.5%)	306.92 (232.82, 404.62)	0.05 (0.02, 0.12)	1.62 (0.25, 10.67)
Day 29	Anti Spike IgG (IU/ml)	5	5/5 = 100.0% (100.0%, 100.0%)	266.06 (74.76, 946.84)	238	1085.9/1121 = 96.9% (91.9%, 98.8%)	170.13 (136.41, 212.19)	0.03 (0.01, 0.08)	1.56 (0.43, 5.67)
Day 29	Anti N IgG (IU/ml)	5	3/5 = 60.0% (10.6%, 95.0%)	11.78 (2.03, 68.41)	238	603/1121 = 53.8% (45.9%, 61.5%)	26.96 (20.32, 35.77)	0.06 (-0.44, 0.42)	0.44 (0.07, 2.60)
Day 57	Pseudovirus-nAb cID80	5	5/5 = 100.0% (100.0%, 100.0%)	288.29 (114.87, 723.51)	238	1119/1119 = 100.0% (100.0%, 100.0%)	462.73 (395.43, 541.48)	0 (0, 0)	0.62 (0.24, 1.58)
Day 57	Pseudovirus-nAb cID50	5	5/5 = 100.0% (100.0%, 100.0%)	629.06 (128.64, 3076.16)	238	1119/1119 = 100.0% (100.0%, 100.0%)	313.97 (258.96, 380.65)	0 (0, 0)	2.00 (0.40, 9.91)
Day 57	Anti RBD IgG (IU/ml)	5	5/5 = 100.0% (100.0%, 100.0%)	1704.47 (253.44, 11462.91)	238	1119/1119 = 100.0% (100.0%, 100.0%)	2656.74 (2066.29, 3415.92)	0 (0, 0)	0.64 (0.09, 4.39)
Day 57	Anti Spike IgG (IU/ml)	5	5/5 = 100.0% (100.0%, 100.0%)	1648.06 (332.52, 8168.38)	238	1119/1119 = 100.0% (100.0%, 100.0%)	1953.05 (1538.23, 2479.73)	0 (0, 0)	0.84 (0.17, 4.26)

Day 57	Anti N IgG (IU/ml)	5	$3/5 = 60.0\%$ (10.6%, 95.0%)	49.66 (3.50, 703.93)	238	$865.3/1119 = 77.3\%$ (69.5%, 83.6%)	94.81 (70.11, 128.23)	-0.17 (-0.67, 0.19)	0.52 (0.04, 7.55)
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Cases for Day 29 markers are baseline positive per-protocol placebo recipients with the symptomatic infection COVID-19 primary endpoint diagnosed starting 7 days after the Day 29 study visit. Cases for Day 57 markers are baseline positive per-protocol placebo recipients with the symptomatic infection COVID-19 primary endpoint diagnosed starting 7 days after the Day 57 study visit. Non-cases/Controls are baseline positive per-protocol placebo recipients sampled into the random subcohort with no COVID-19 endpoint diagnosis by the time of data-cut.

N is the number of cases sampled into the subcohort within baseline covariate strata.

The denominator in Resp Rate is the number of participants in the whole per-protocol cohort within baseline covariate strata, calculated using inverse probability weighting.



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Chapter 3

Graphical Descriptions of Antibody Marker Data

3.1 Boxplots

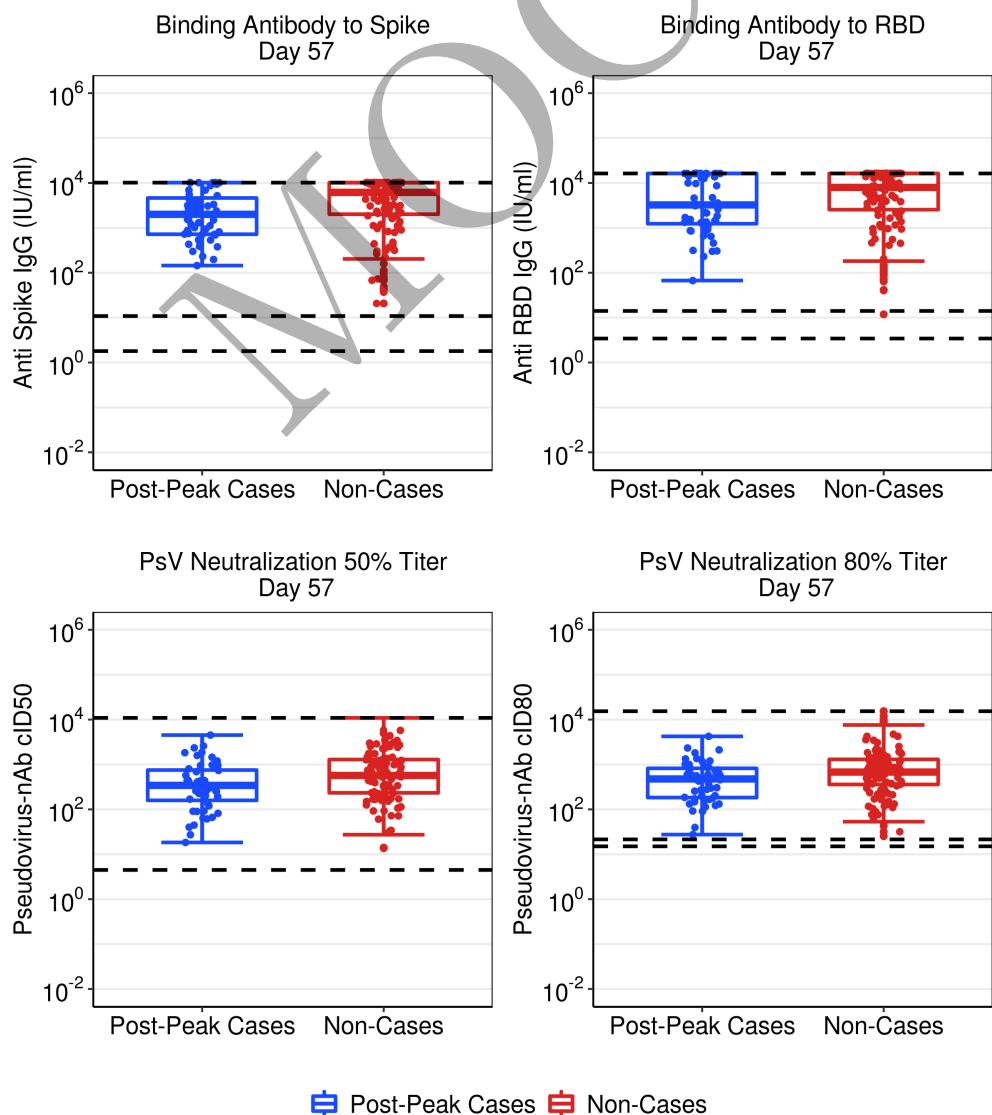


Figure 3.1: Boxplots of D57 Ab markers: vaccine arm. The three dashed lines in each figure are ULOQ, LLOQ, and LLOD, from top to bottom respectively.

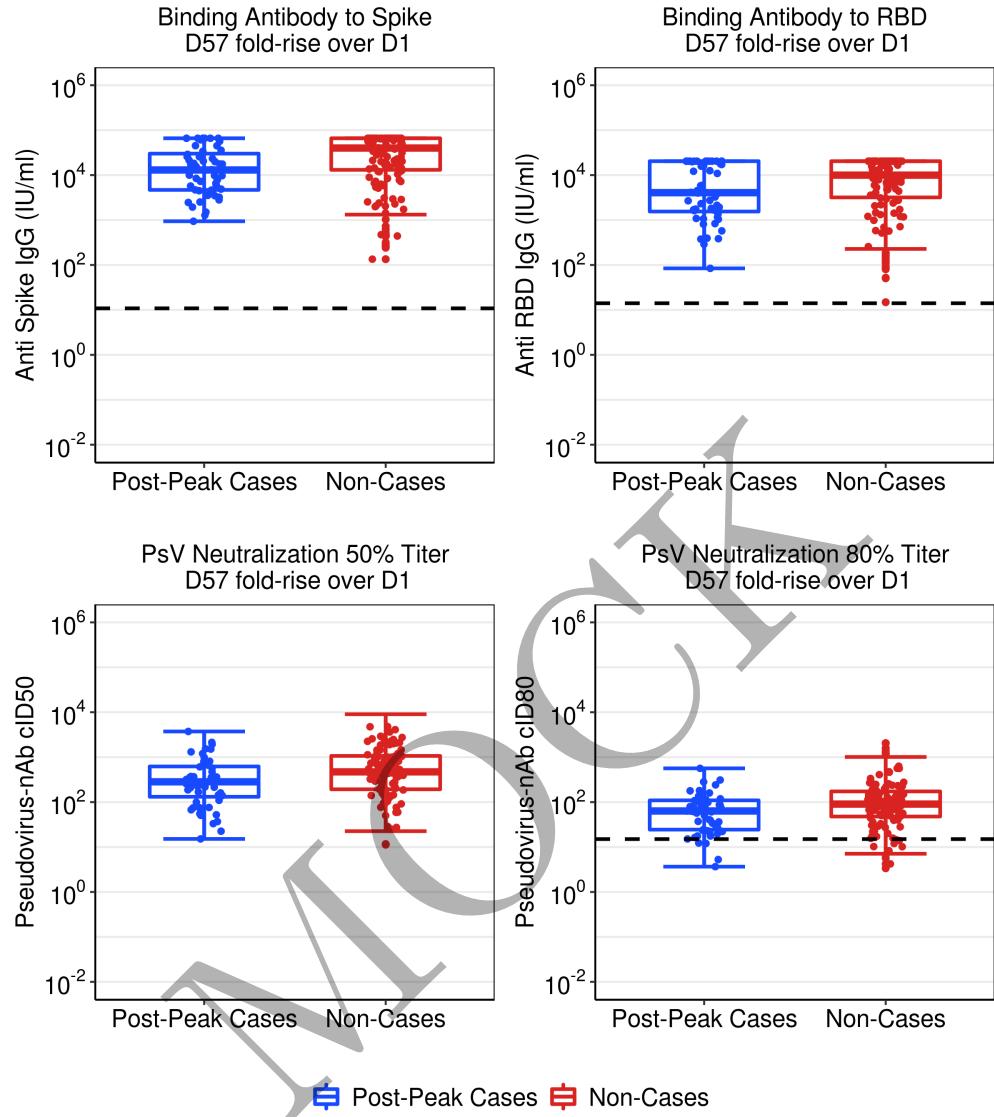


Figure 3.2: Boxplots of D57 fold-rise over D1 Ab markers: vaccine arm.

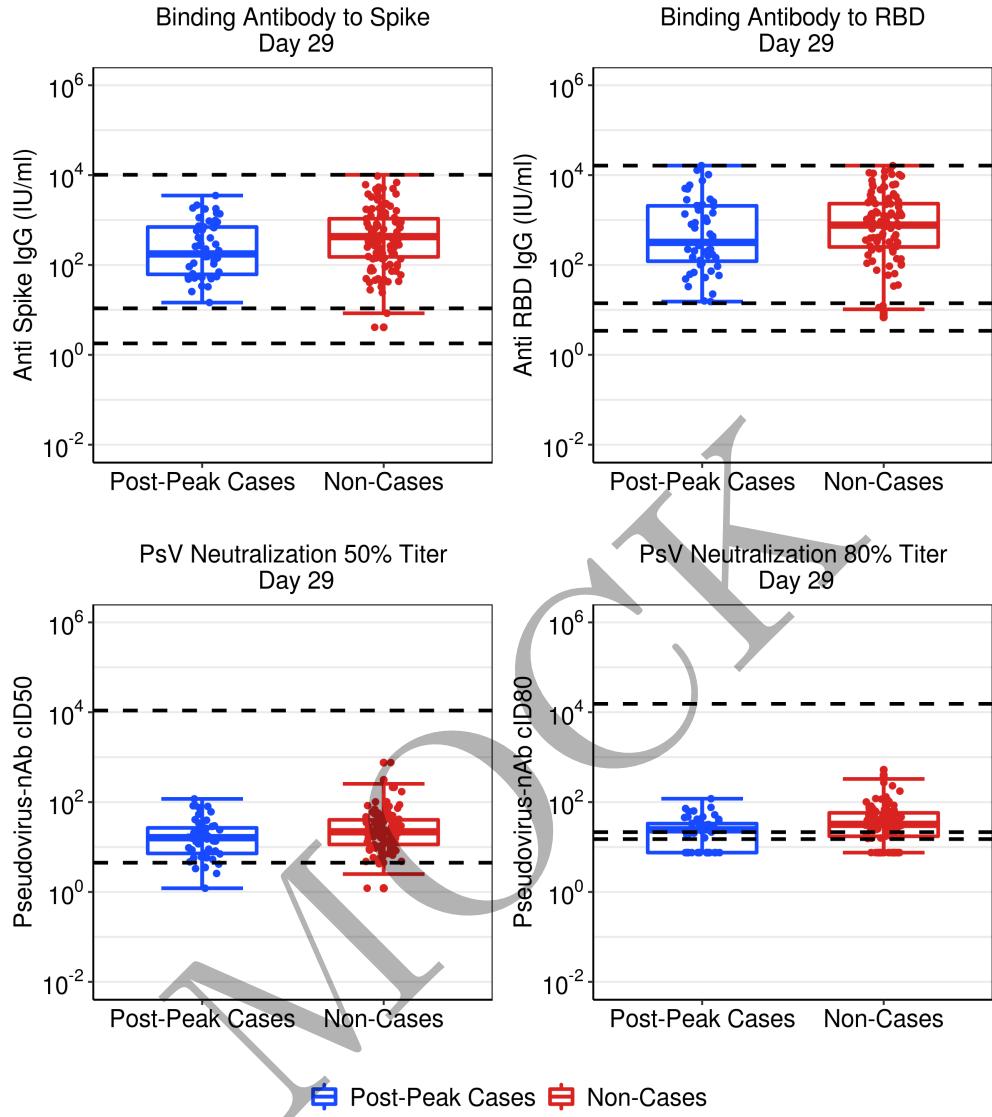


Figure 3.3: Boxplots of D29 Ab markers: vaccine arm. The three dashed lines in each figure are ULOQ, LLOQ, and LLOD, from top to bottom respectively.

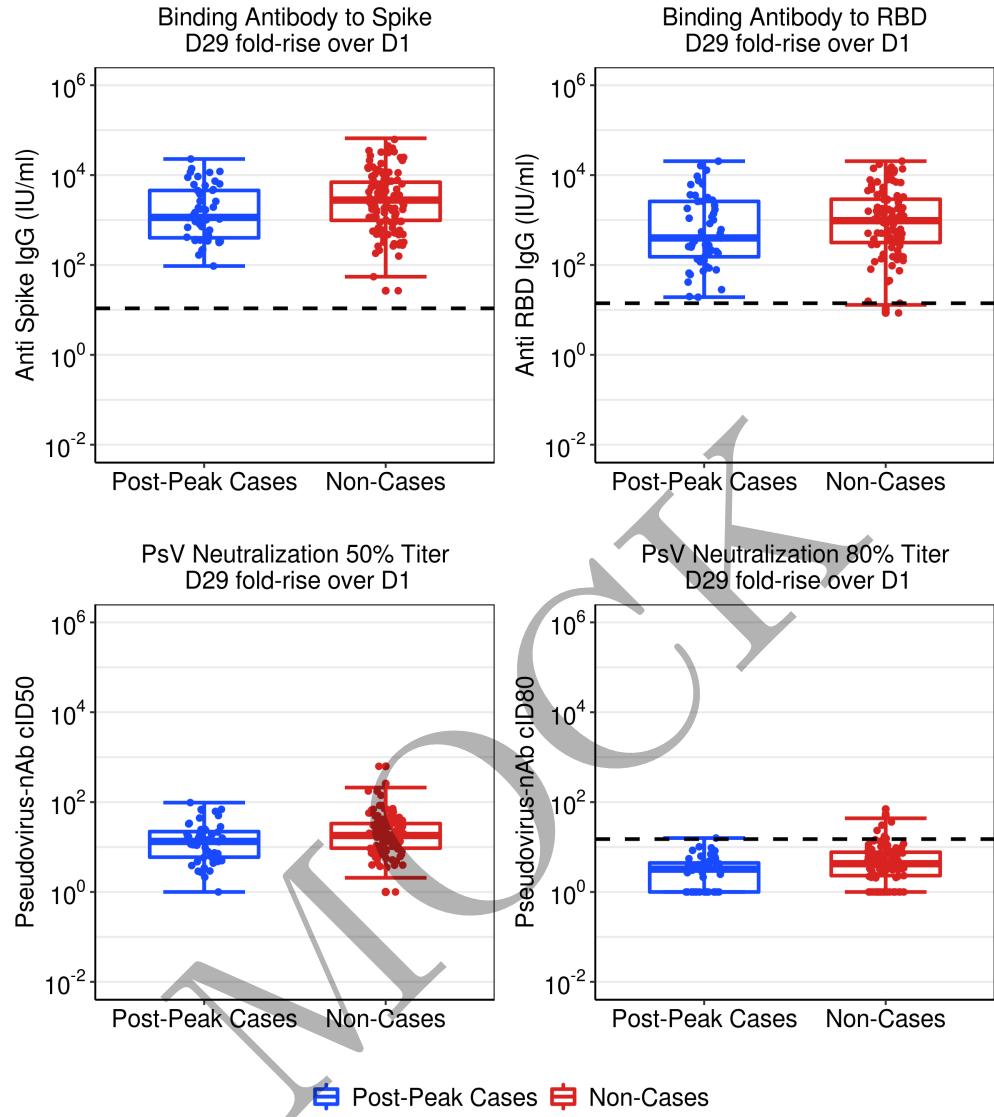


Figure 3.4: Boxplots of D29 fold-rise over D1 Ab markers: vaccine arm.

3.2 Weighted RCDF plots

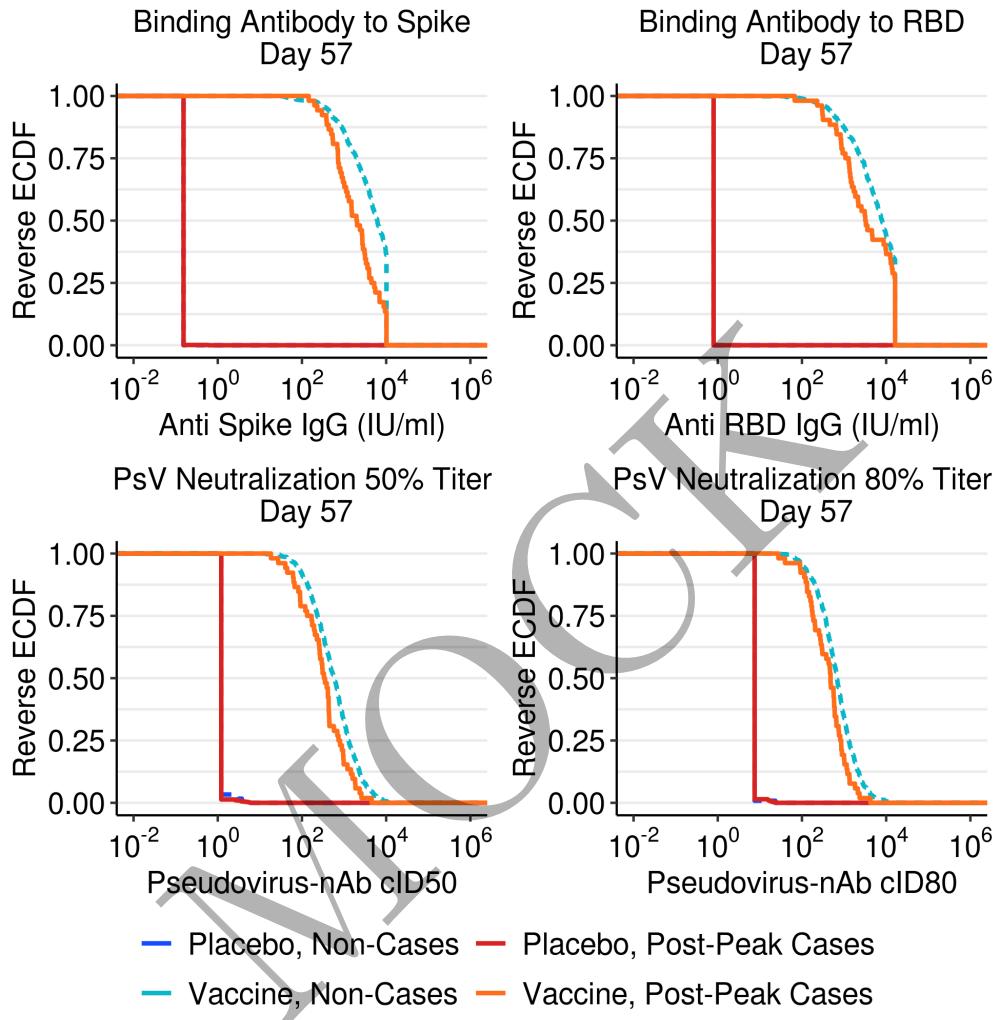


Figure 3.5: RCDF plots for D57 Ab markers by treatment arm.

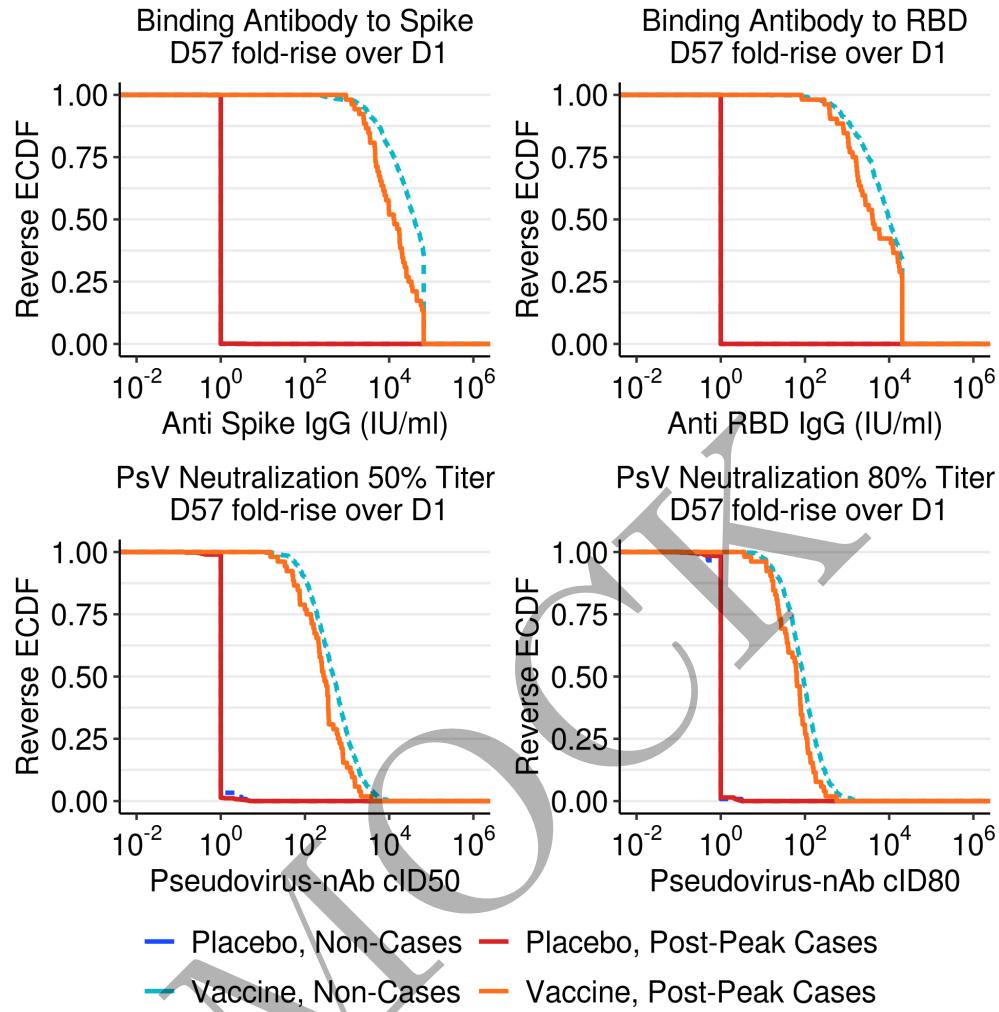


Figure 3.6: RCDF plots for D57 fold-rise over D1 Ab markers by treatment arm.

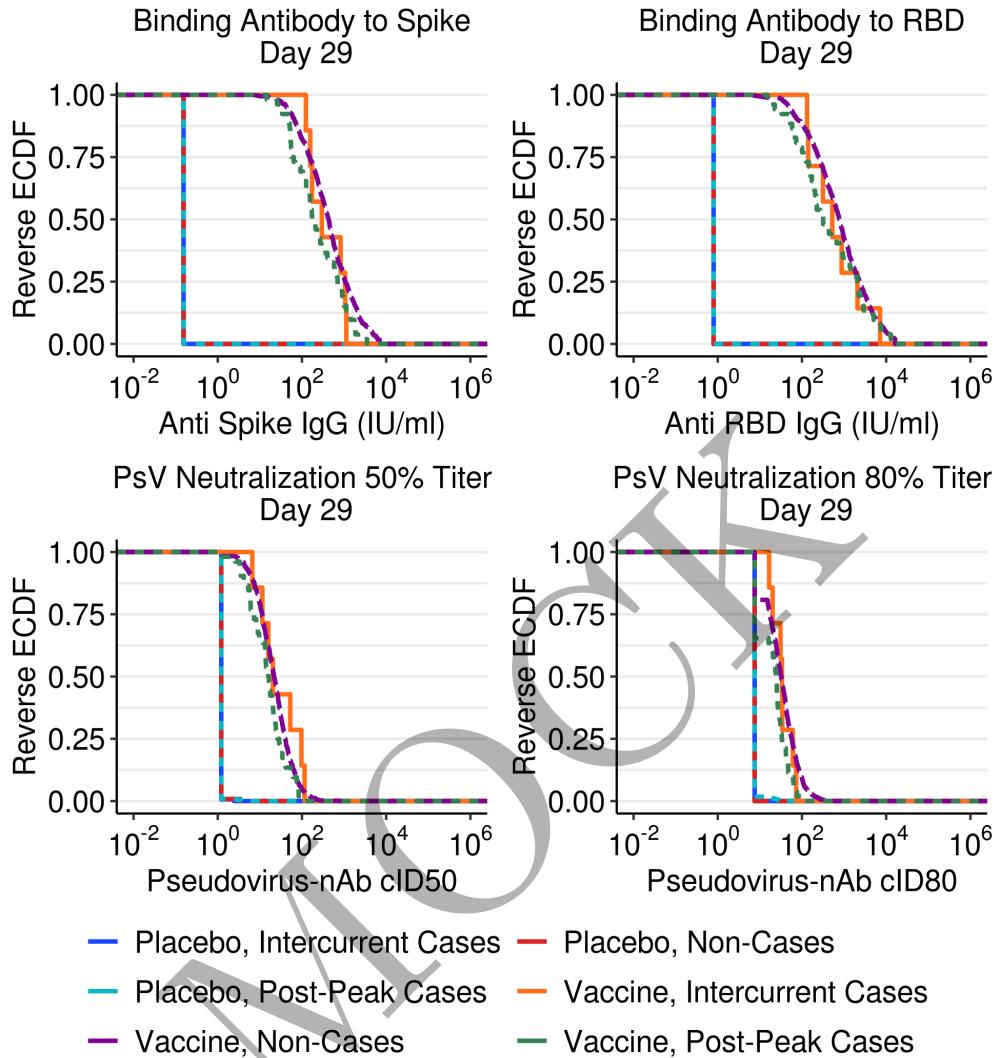


Figure 3.7: RCDF plots for D29 Ab markers by treatment arm.

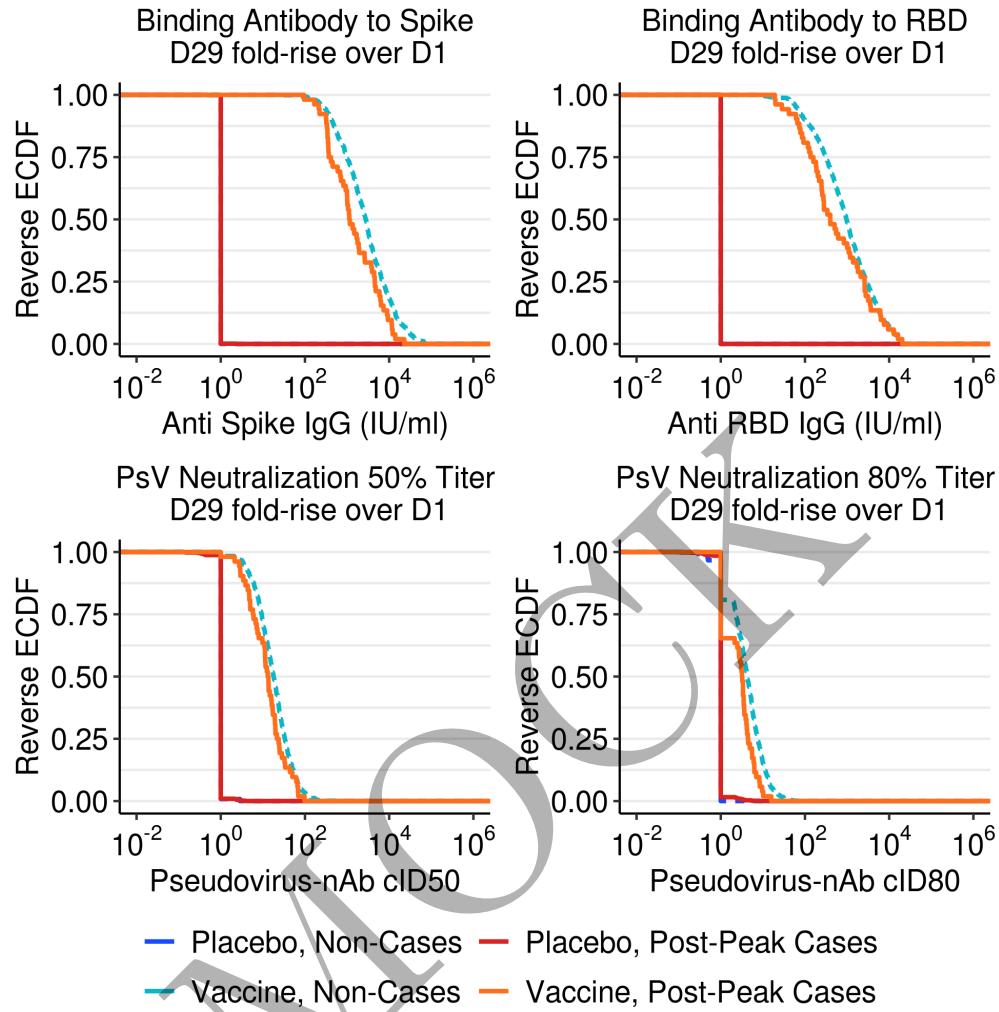


Figure 3.8: RCDF plots for D29 fold-rise over D1 Ab markers by treatment arm.

3.3 Weighted RCDF plots of threshold correlate concentration for vaccine efficacy



Figure 3.9: Marker RCDF of D57 anti-Spike binding Ab: vaccine arm

3.3. WEIGHTED RCDF PLOTS OF THRESHOLD CORRELATE CONCENTRATION FOR VACCINE EFFICACY53



Figure 3.10: Marker RCDF of D57 anti-RBD binding Ab: vaccine arm

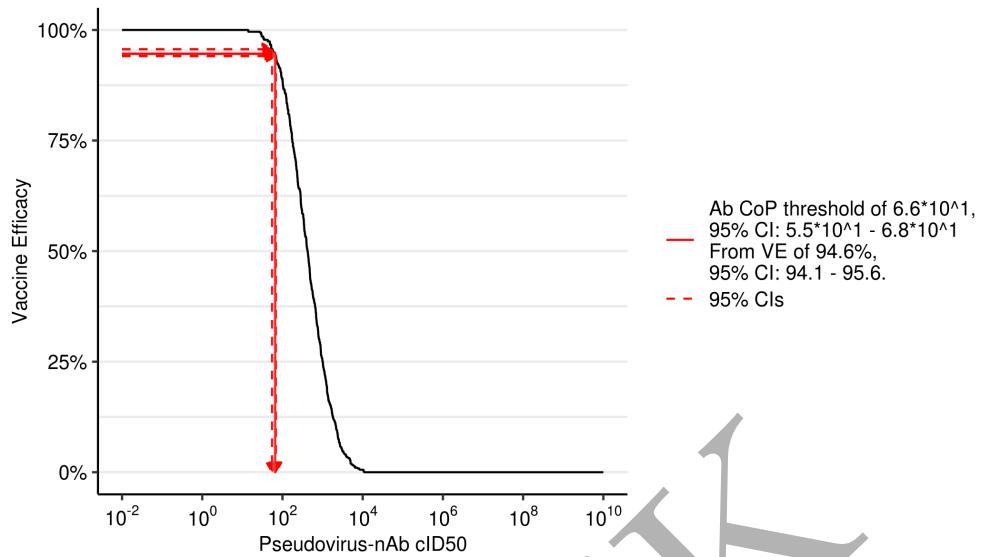


Figure 3.11: Marker RCDF of D57 PsV-nAb ID50: vaccine arm

3.3. WEIGHTED RCDF PLOTS OF THRESHOLD CORRELATE CONCENTRATION FOR VACCINE EFFICACY55

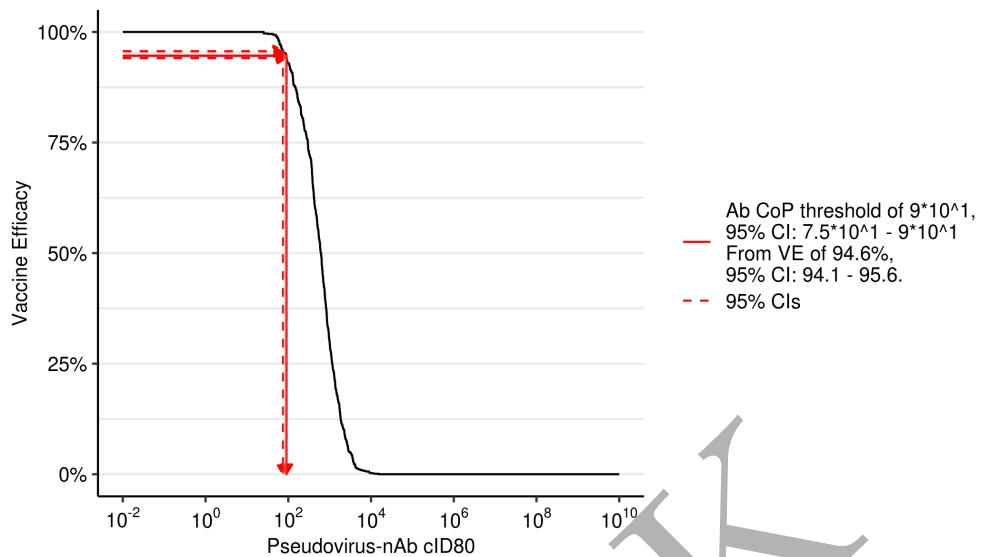


Figure 3.12: Marker RCDF of D57 PsV-nAb ID80: vaccine arm

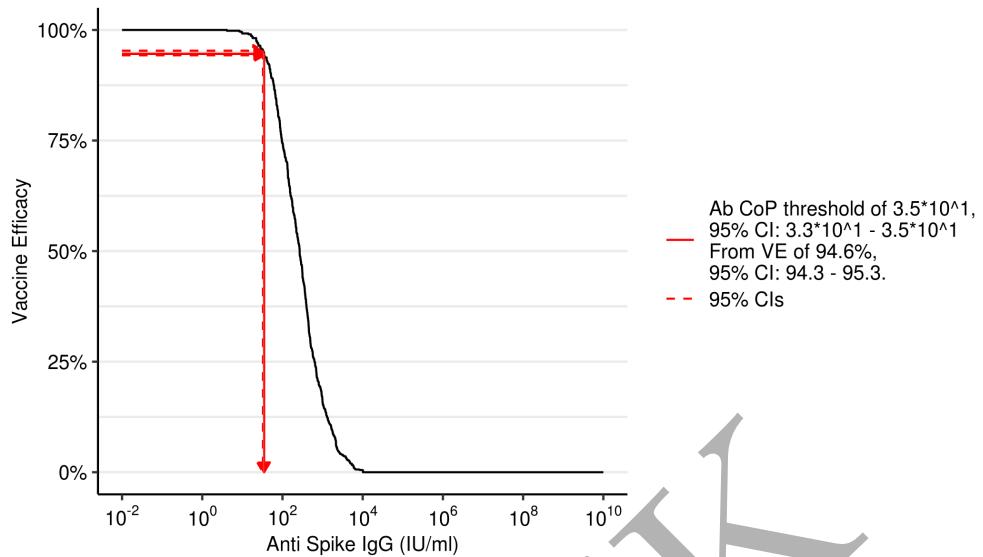


Figure 3.13: Marker RCDF of D29 anti-Spike binding Ab: vaccine arm

3.3. WEIGHTED RCDF PLOTS OF THRESHOLD CORRELATE CONCENTRATION FOR VACCINE EFFICACY57

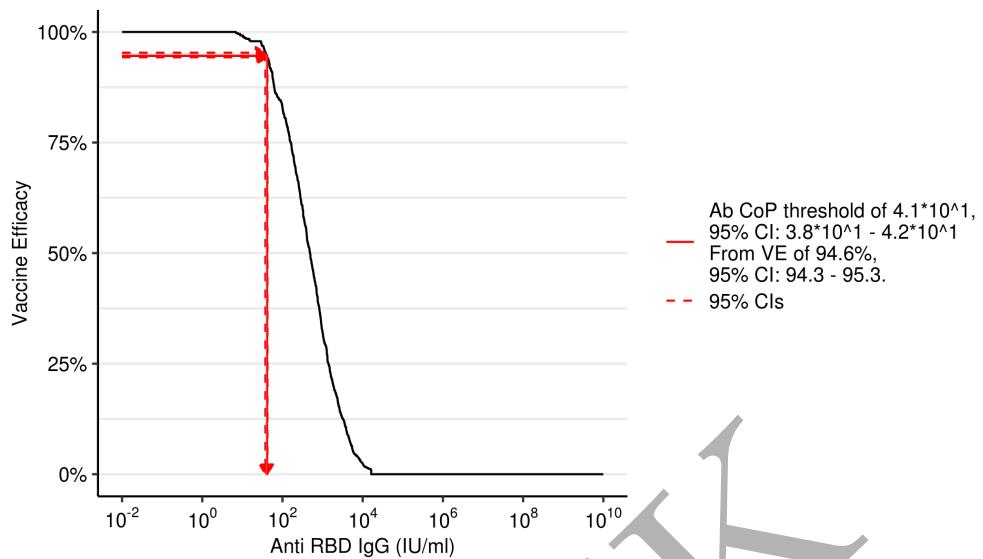


Figure 3.14: Marker RCDF of D29 anti-RBD binding Ab: vaccine arm

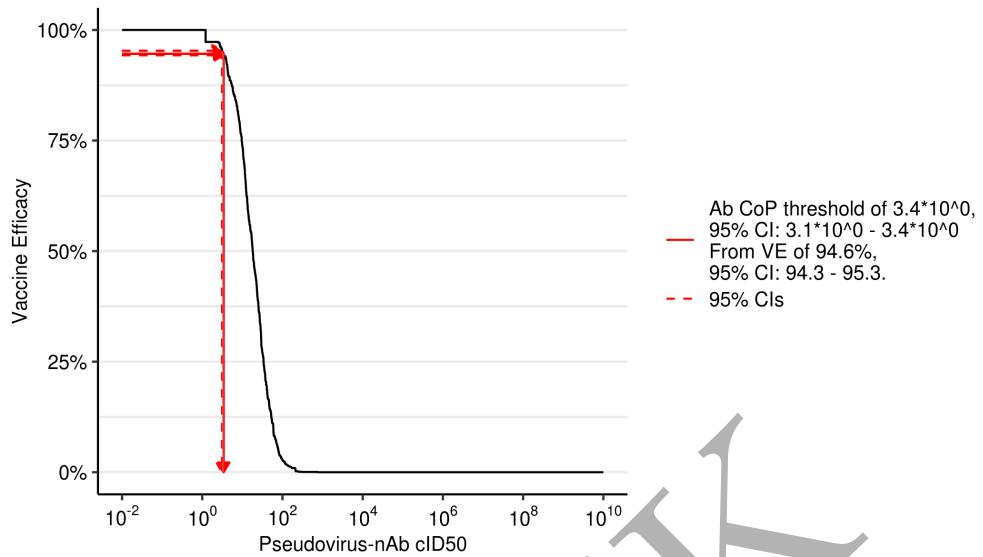


Figure 3.15: Marker RCDF of D29 PsV-nAb ID50: vaccine arm

3.3. WEIGHTED RCDF PLOTS OF THRESHOLD CORRELATE CONCENTRATION FOR VACCINE EFFICACY59

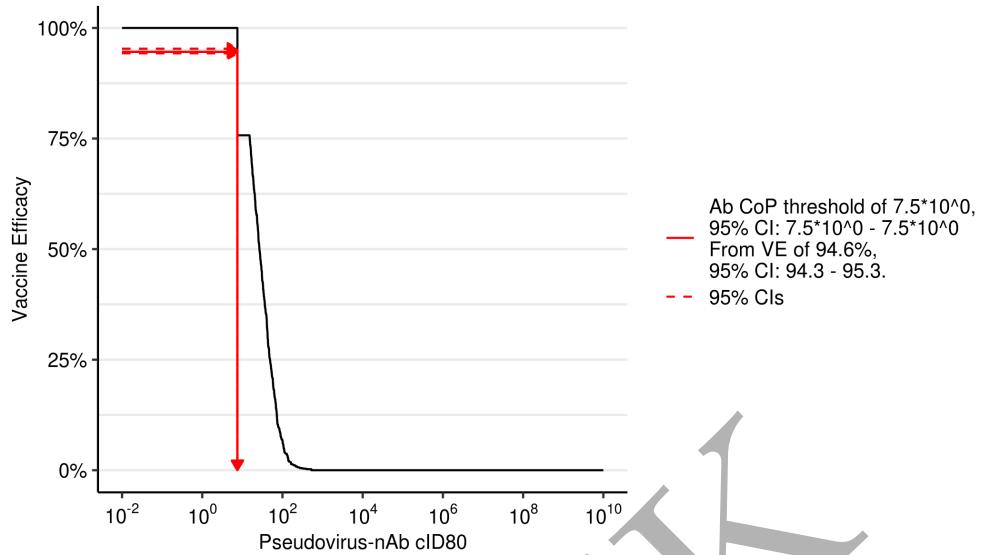


Figure 3.16: Marker RCDF of D29 PsV-nAb ID80: vaccine arm

3.4 Spaghetti plots

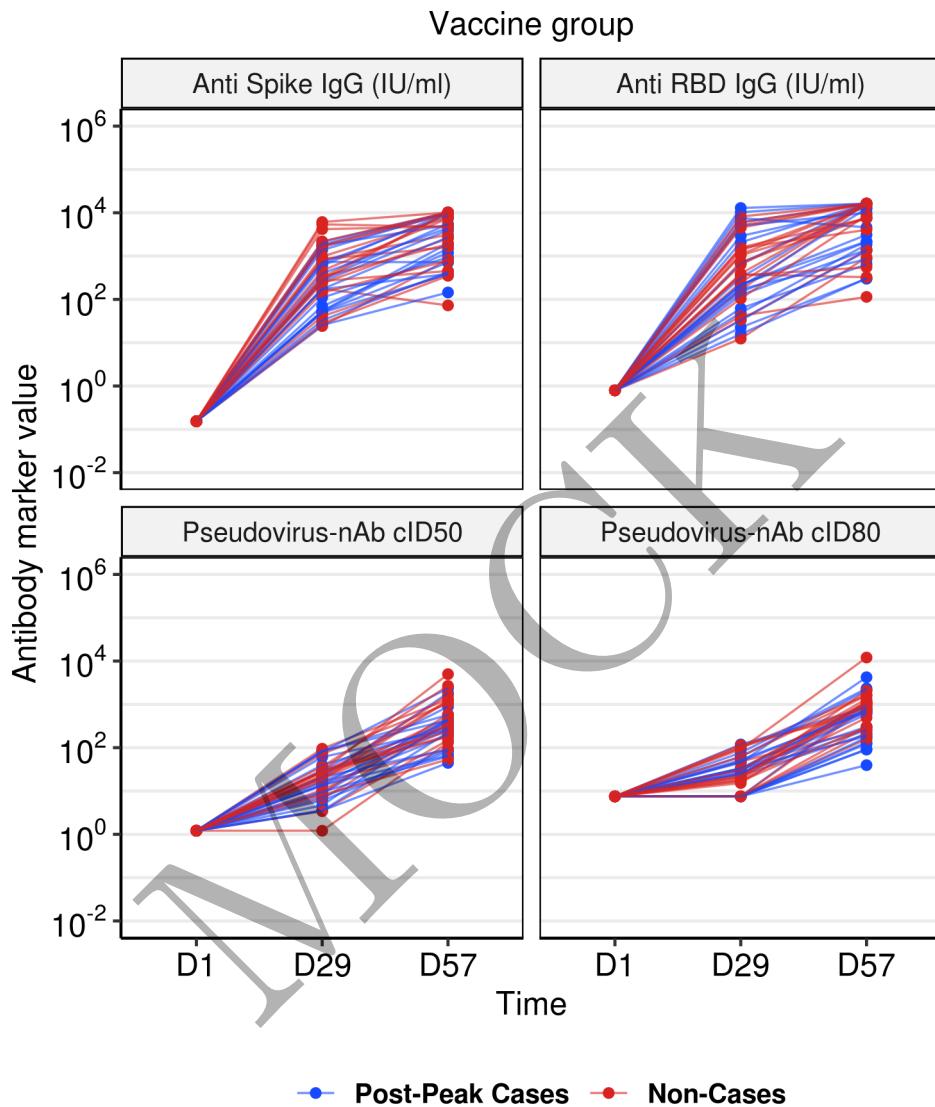


Figure 3.17: Spaghetti Plots of Marker Trajectory: vaccine arm

3.5 Violin and line plots

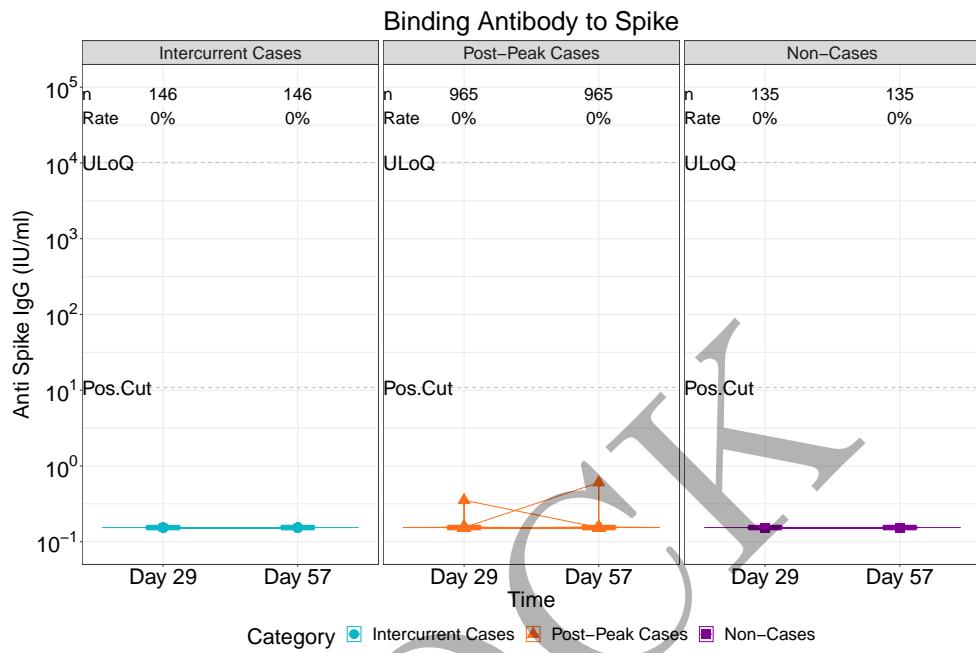
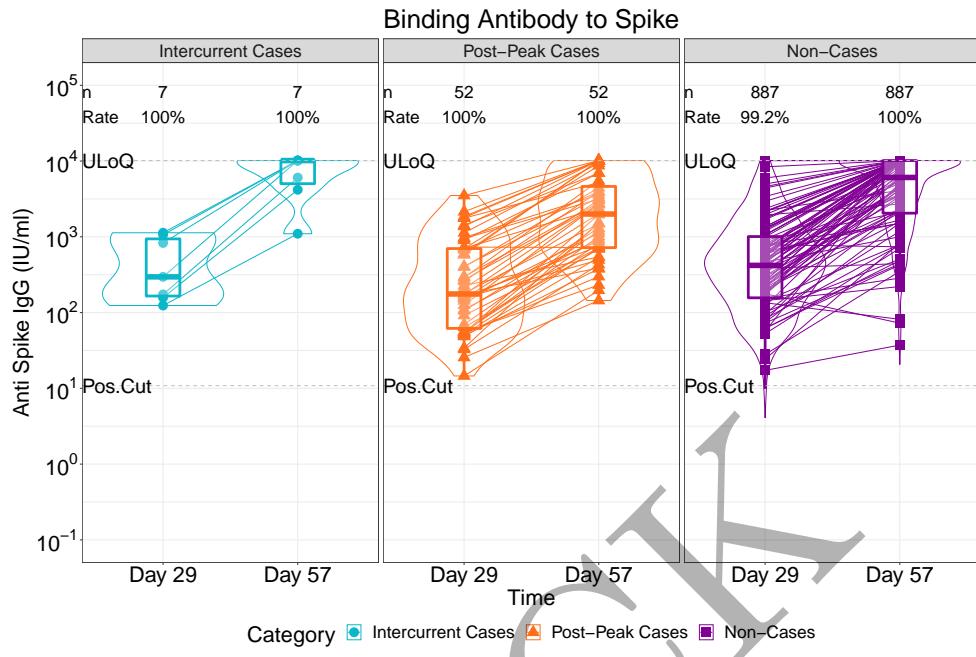


Figure 3.18: lineplots of Binding Antibody to Spike: baseline negative placebo arm (version 1)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.19: lineplots of Binding Antibody to Spike: baseline negative vaccine arm (version 1)

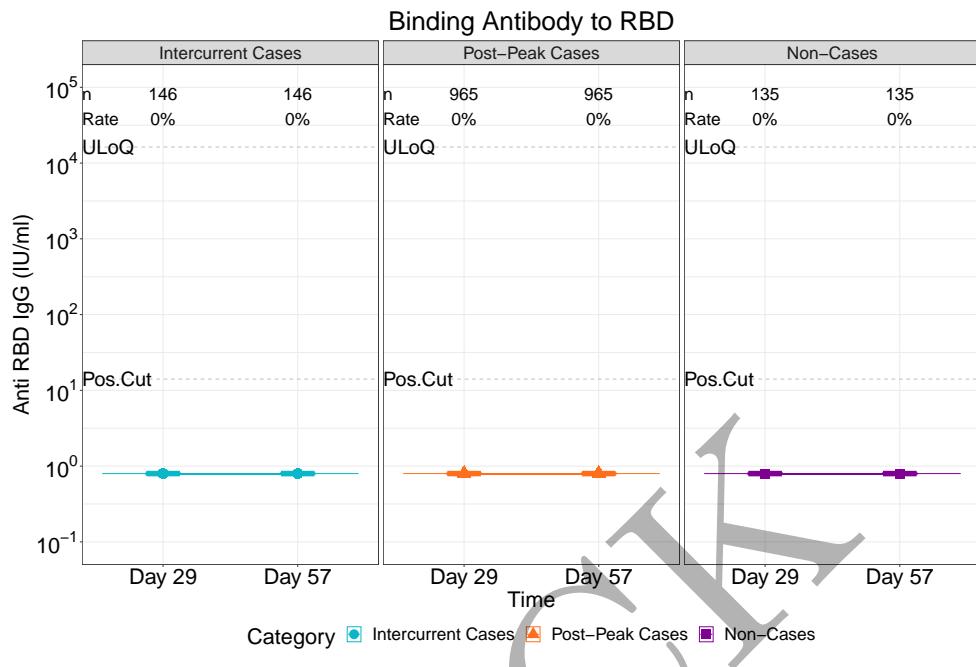


Figure 3.20: lineplots of Binding Antibody to RBD: baseline negative placebo arm (version 1)

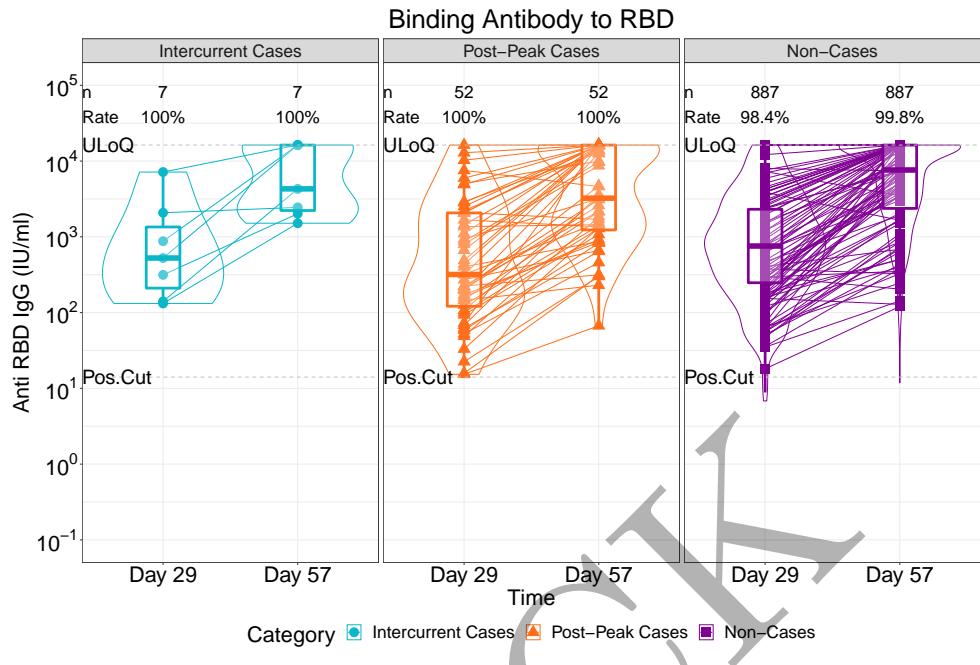


Figure 3.21: lineplots of Binding Antibody to RBD: baseline negative vaccine arm (version 1)

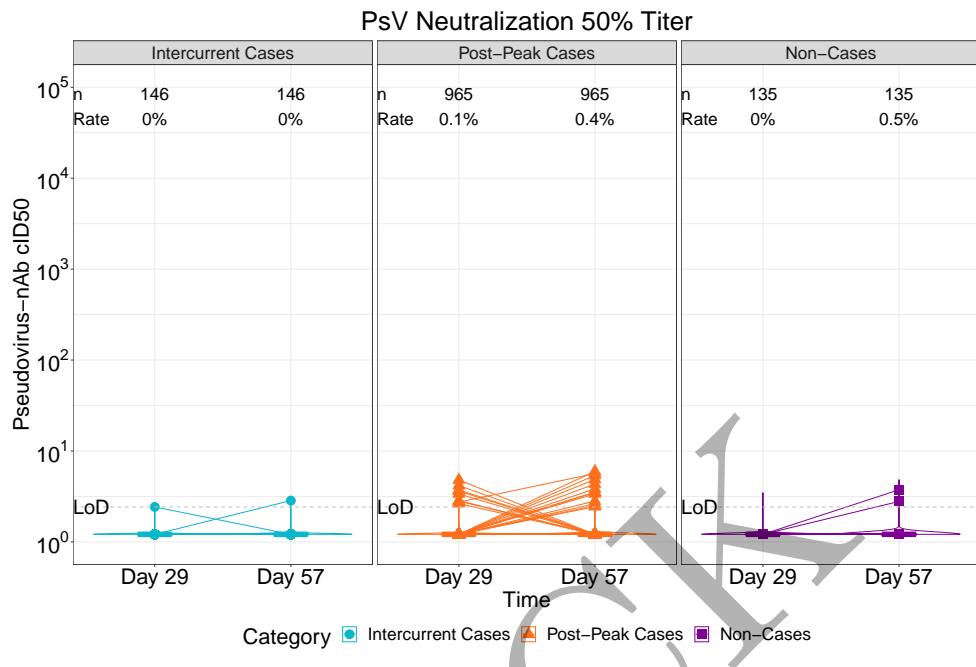


Figure 3.22: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm (version 1)

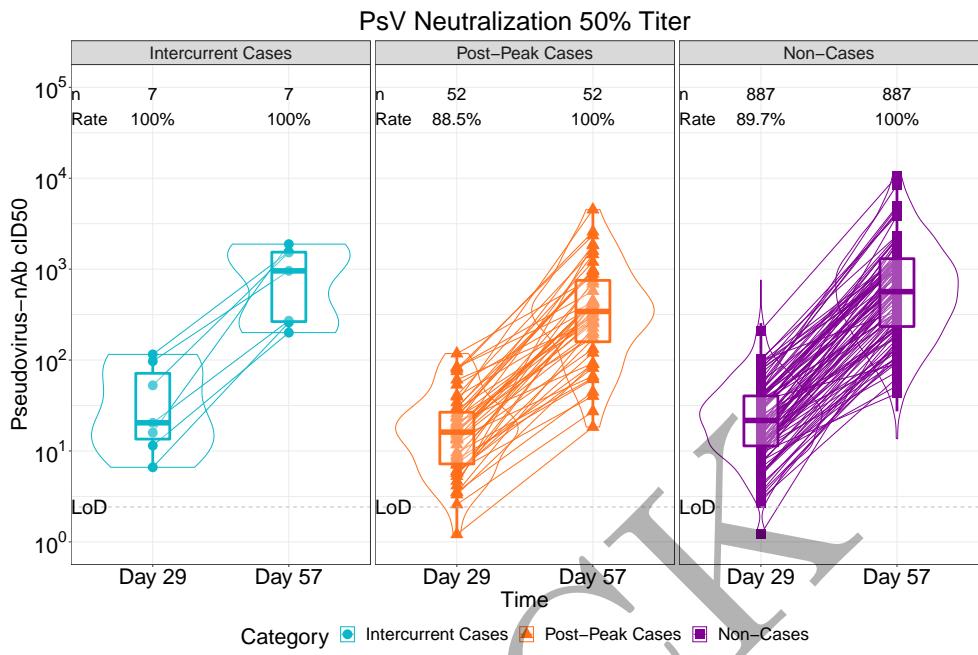
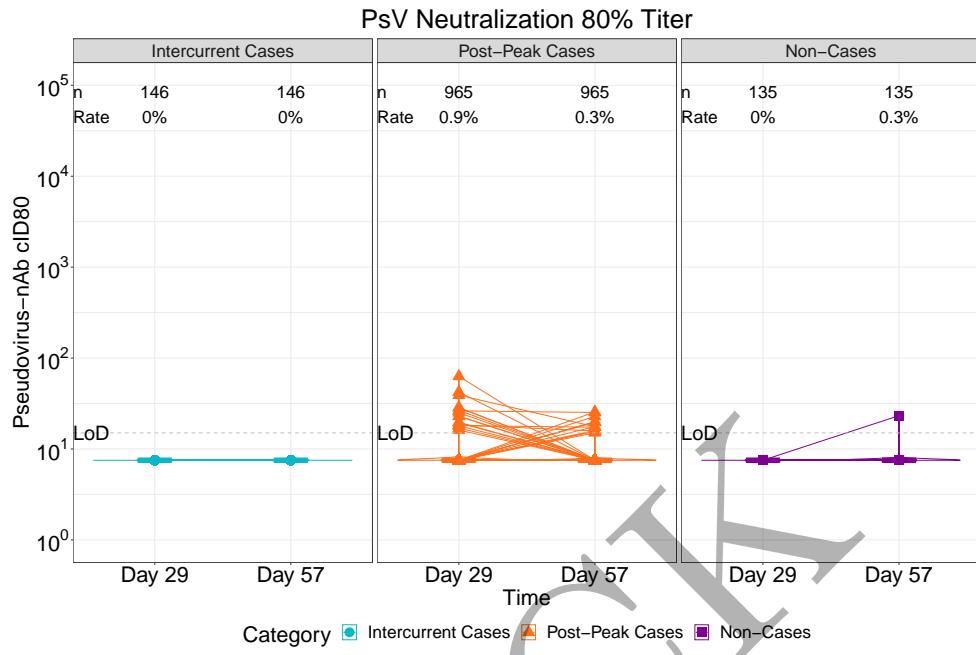


Figure 3.23: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm (version 1)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.24: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm (version 1)

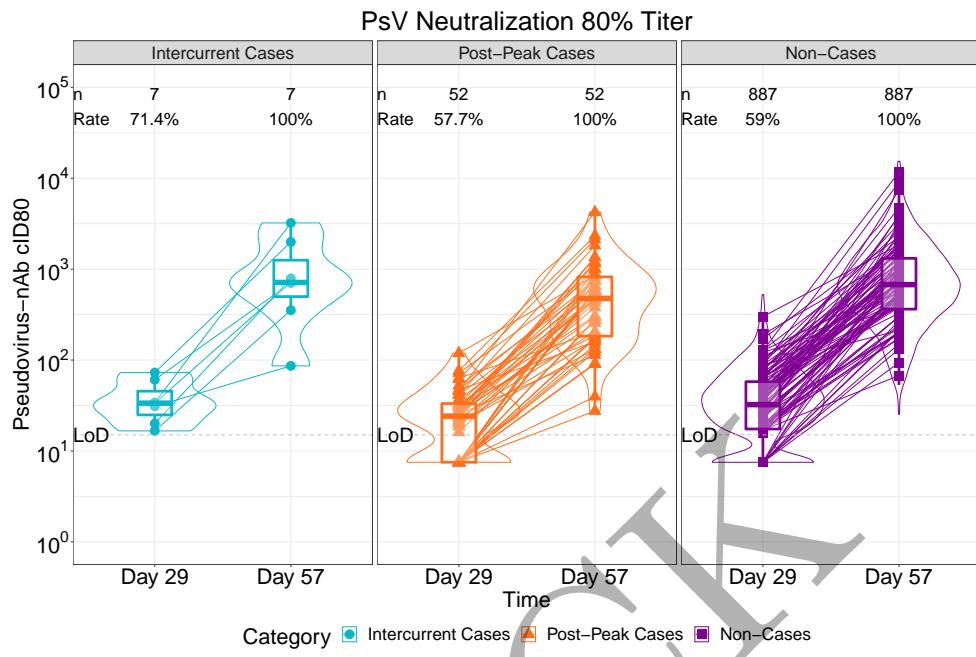


Figure 3.25: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm (version 1)

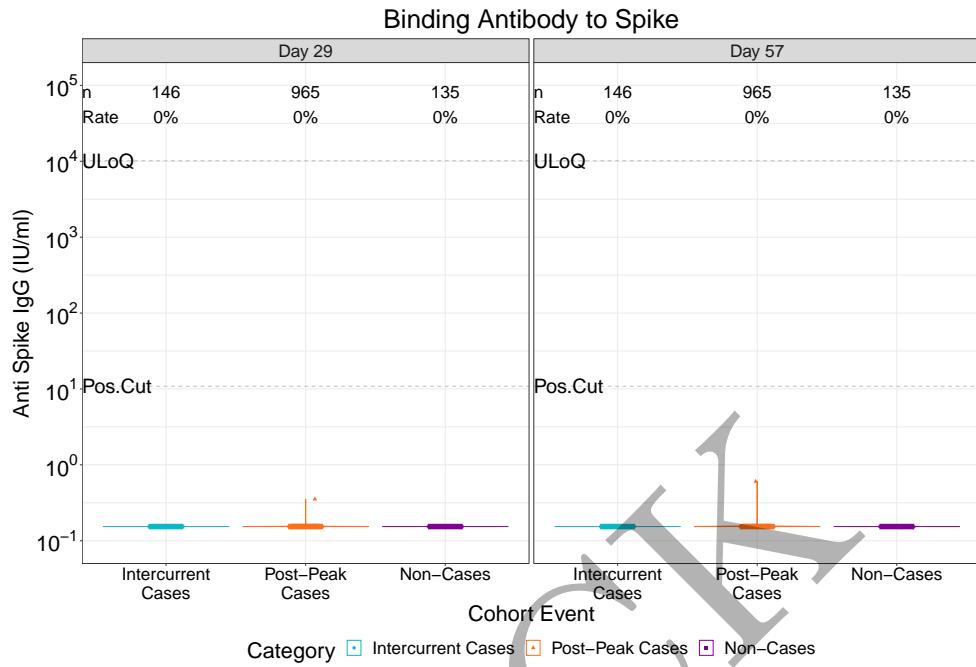


Figure 3.26: violinplots of Binding Antibody to Spike: baseline negative placebo arm (version 1)

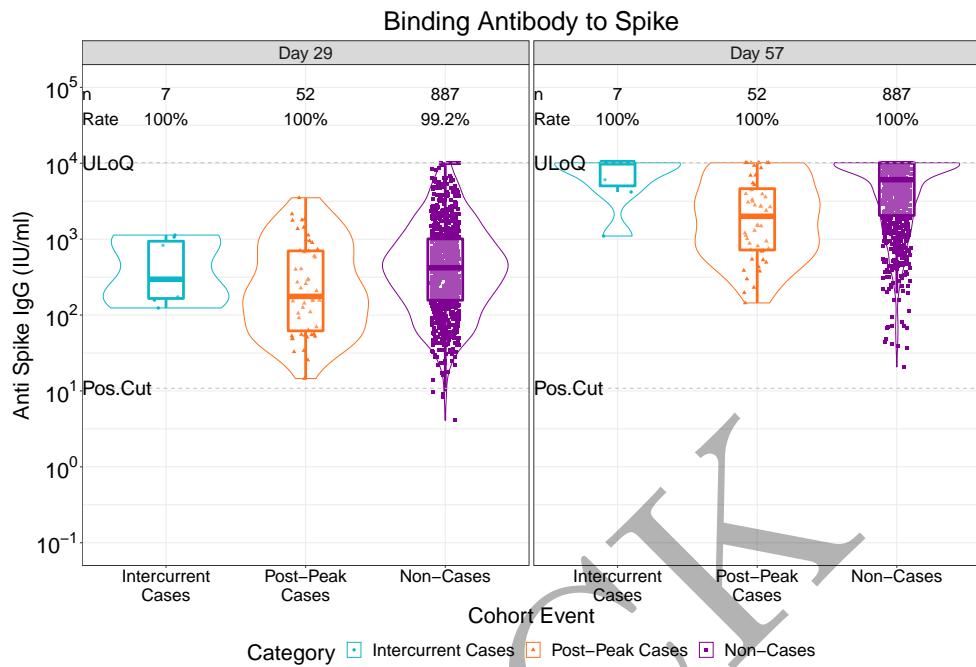


Figure 3.27: violinplots of Binding Antibody to Spike: baseline negative vaccine arm (version 1)

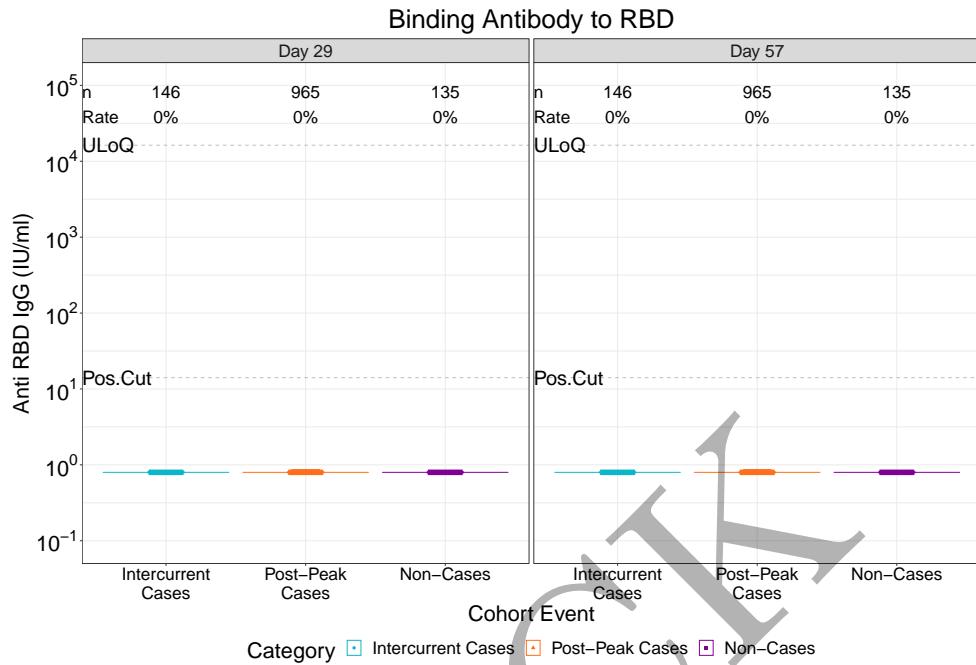


Figure 3.28: violinplots of Binding Antibody to RBD: baseline negative placebo arm (version 1)

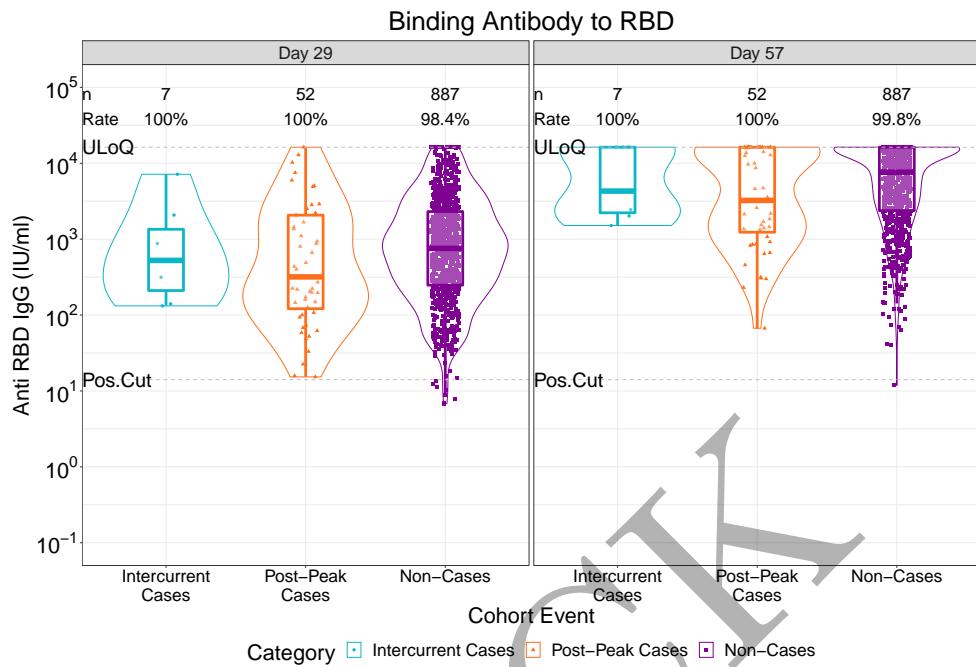


Figure 3.29: violinplots of Binding Antibody to RBD: baseline negative vaccine arm (version 1)

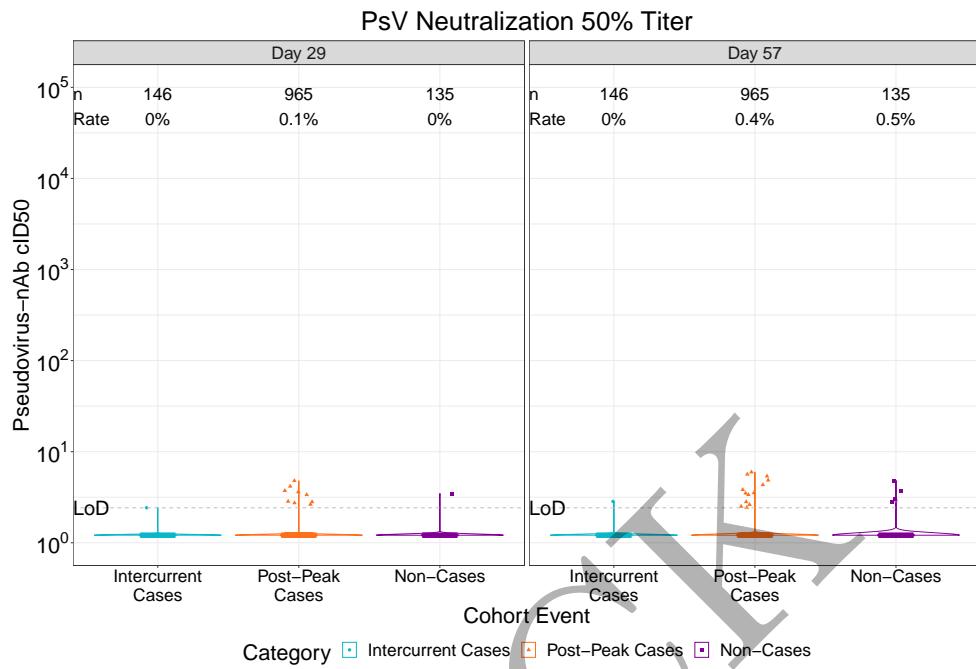


Figure 3.30: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm (version 1)

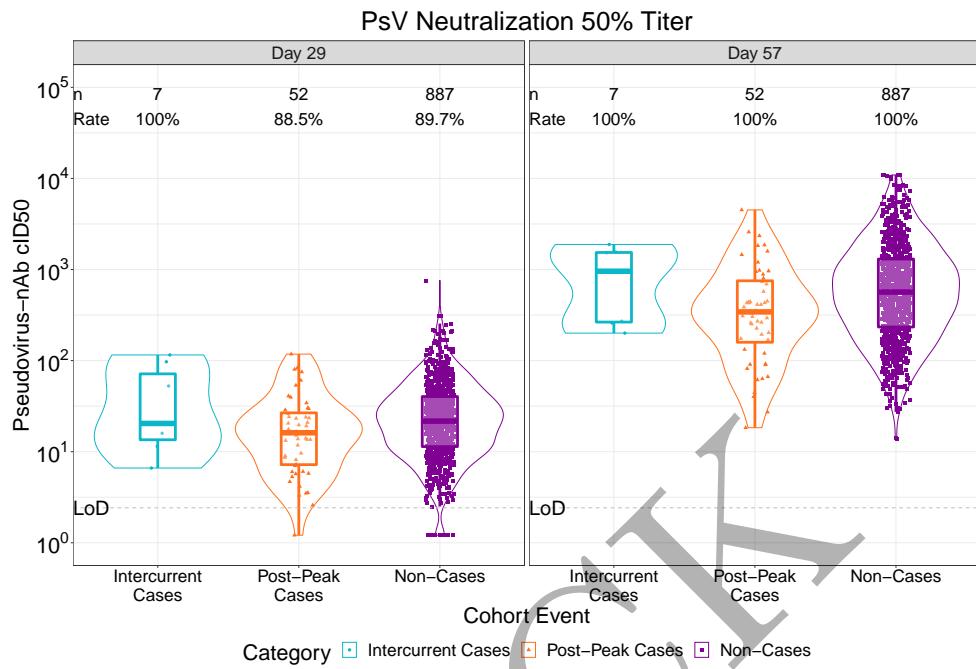


Figure 3.31: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm (version 1)

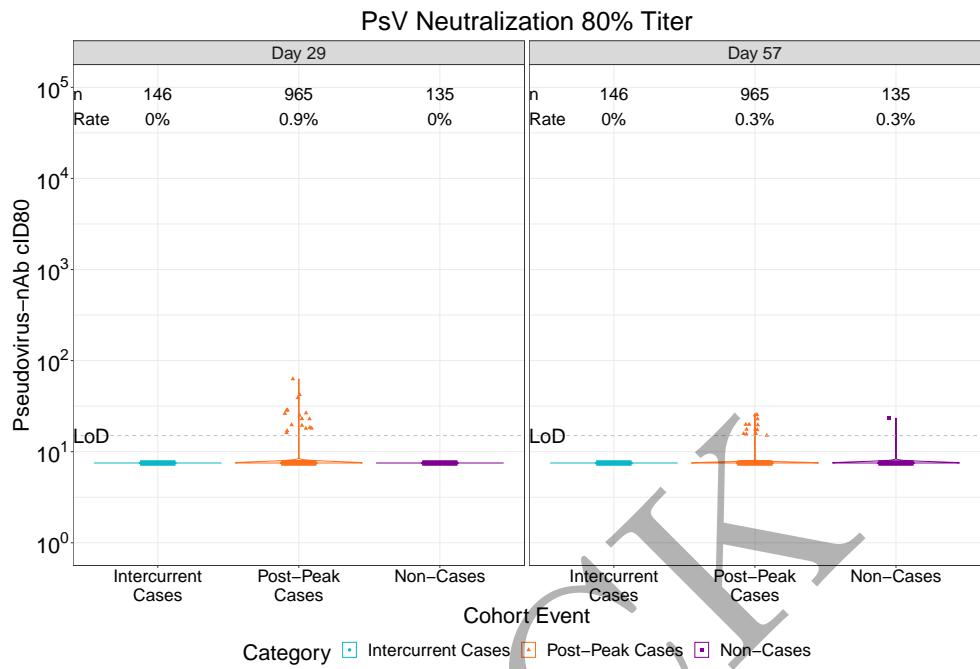


Figure 3.32: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm (version 1)

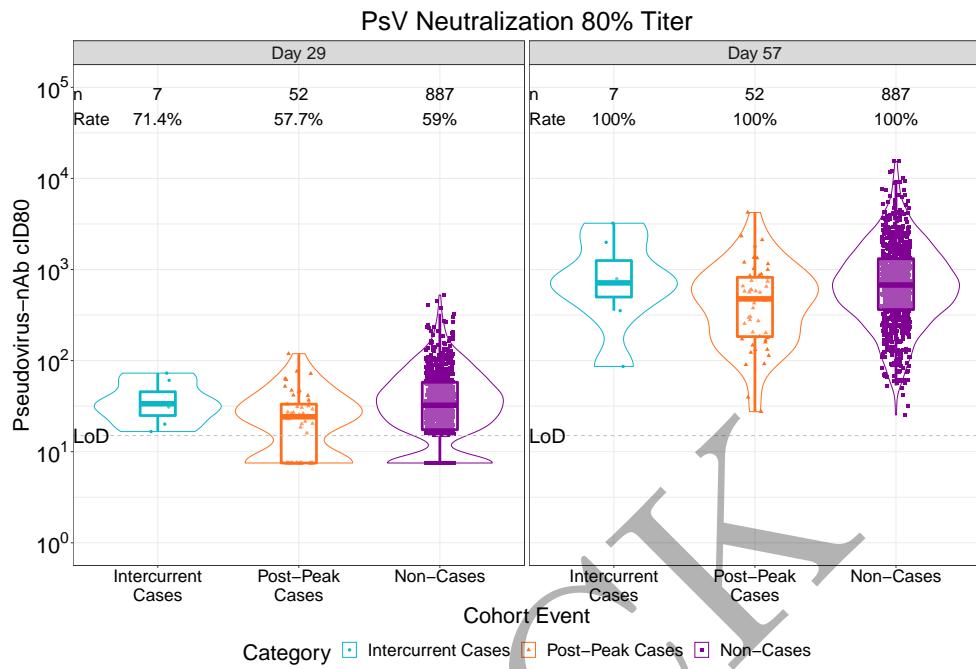
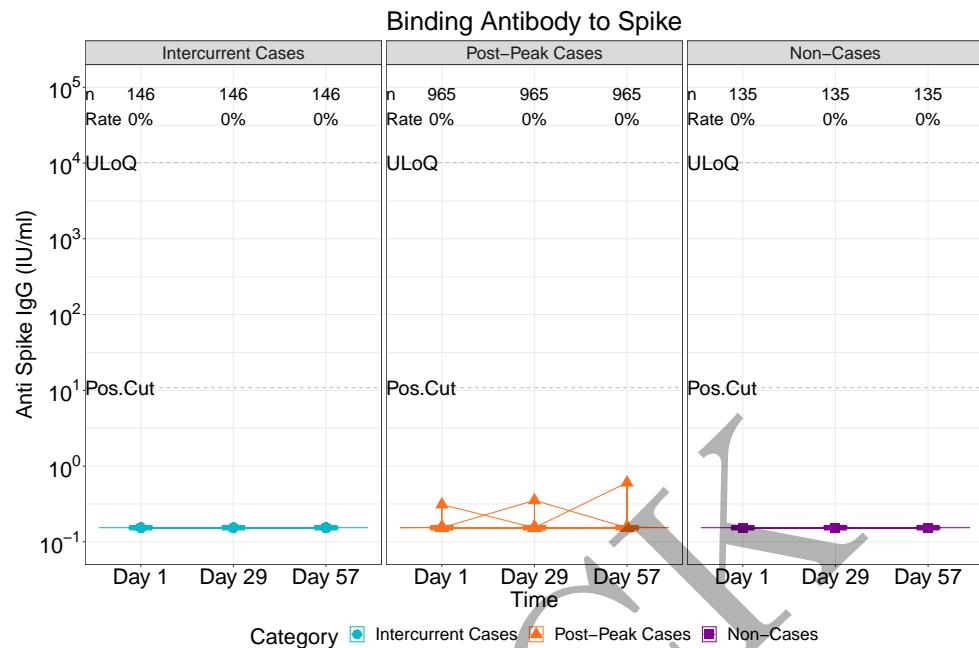
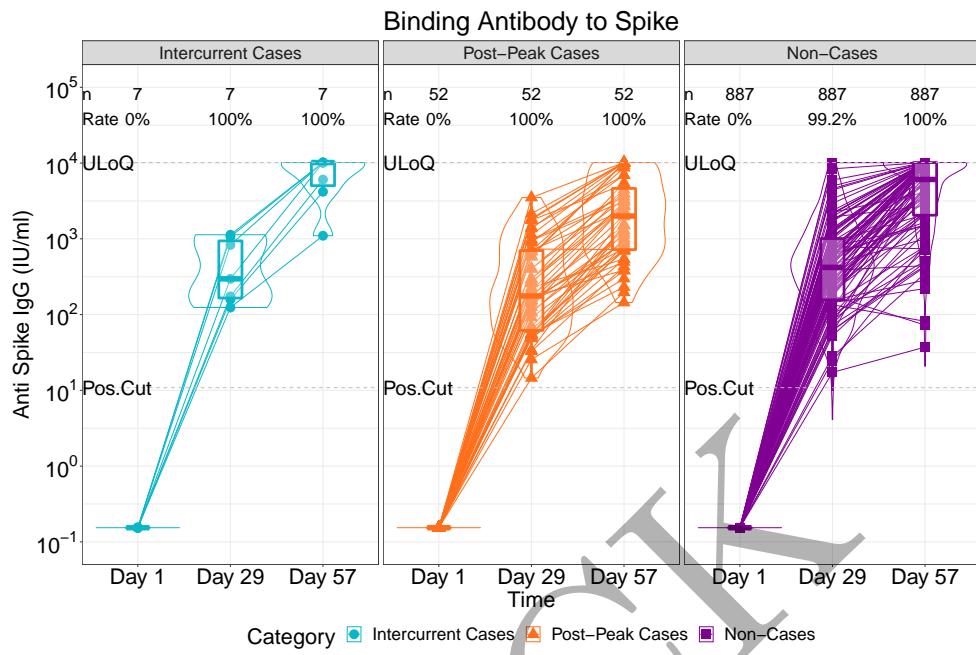


Figure 3.33: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm (version 1)



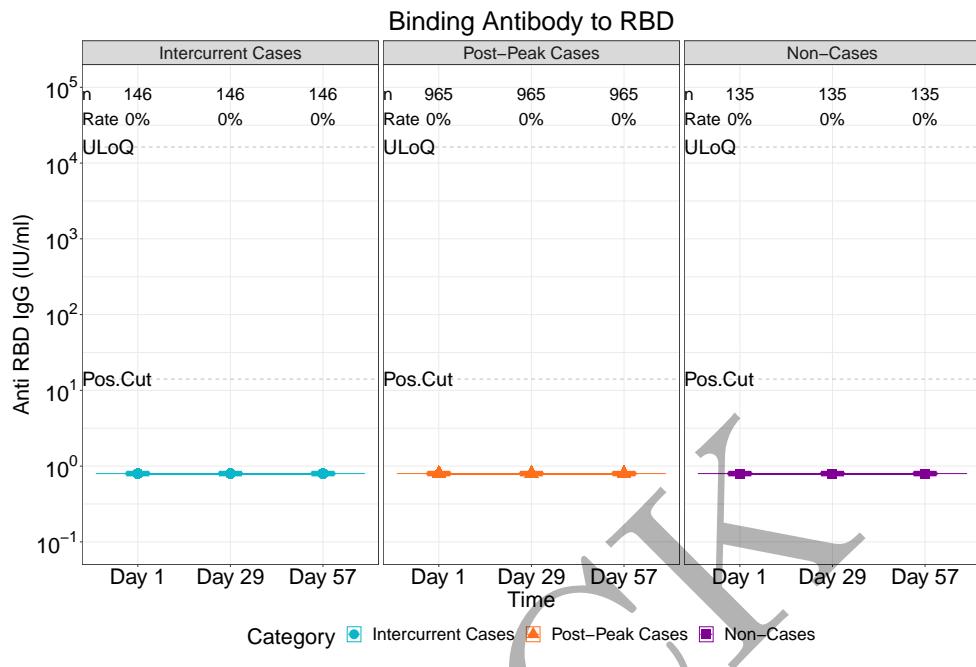
All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.34: lineplots of Binding Antibody to Spike: baseline negative placebo arm (version 2)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.35: lineplots of Binding Antibody to Spike: baseline negative vaccine arm (version 2)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.36: lineplots of Binding Antibody to RBD: baseline negative placebo arm (version 2)

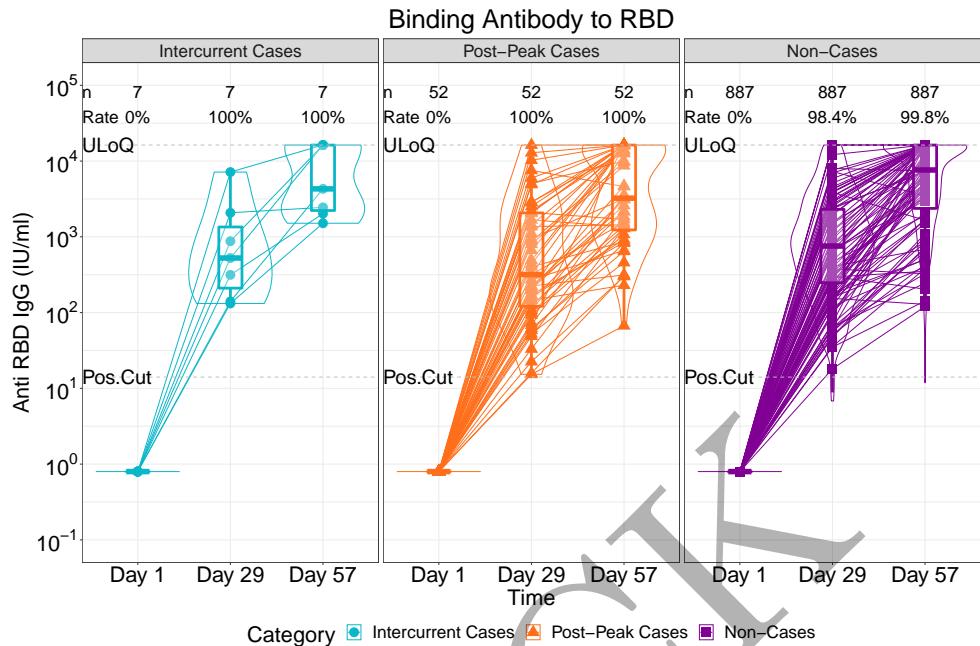
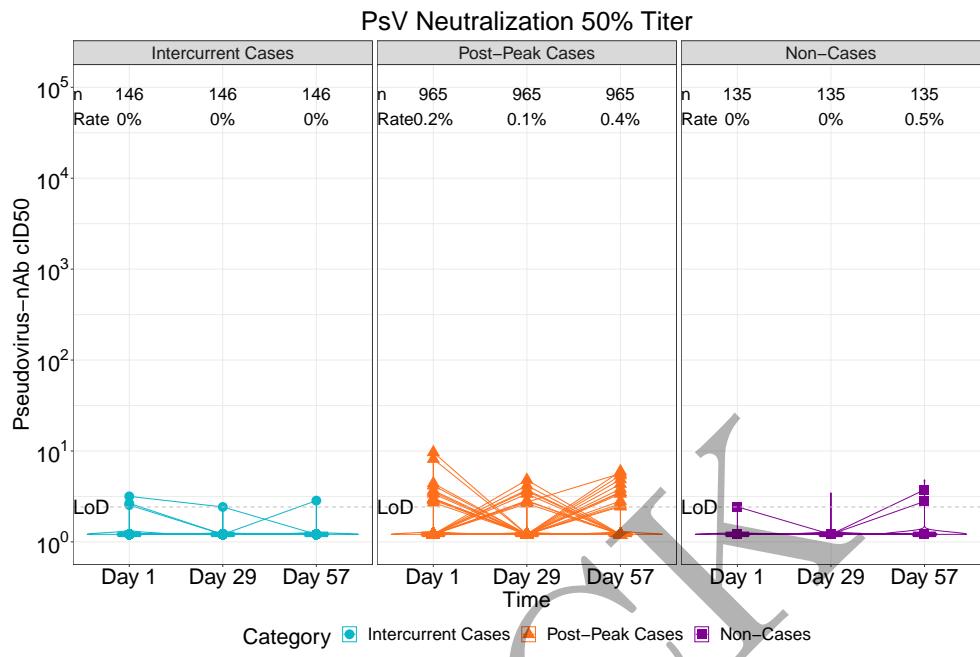


Figure 3.37: lineplots of Binding Antibody to RBD: baseline negative vaccine arm (version 2)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger

Figure 3.38: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm (version 2)

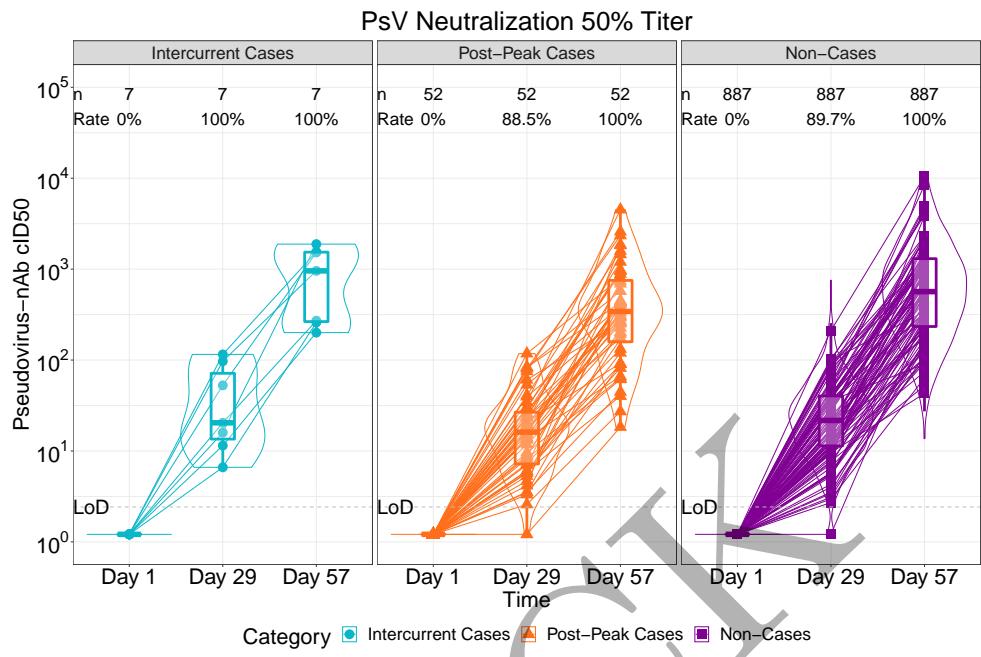


Figure 3.39: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm (version 2)

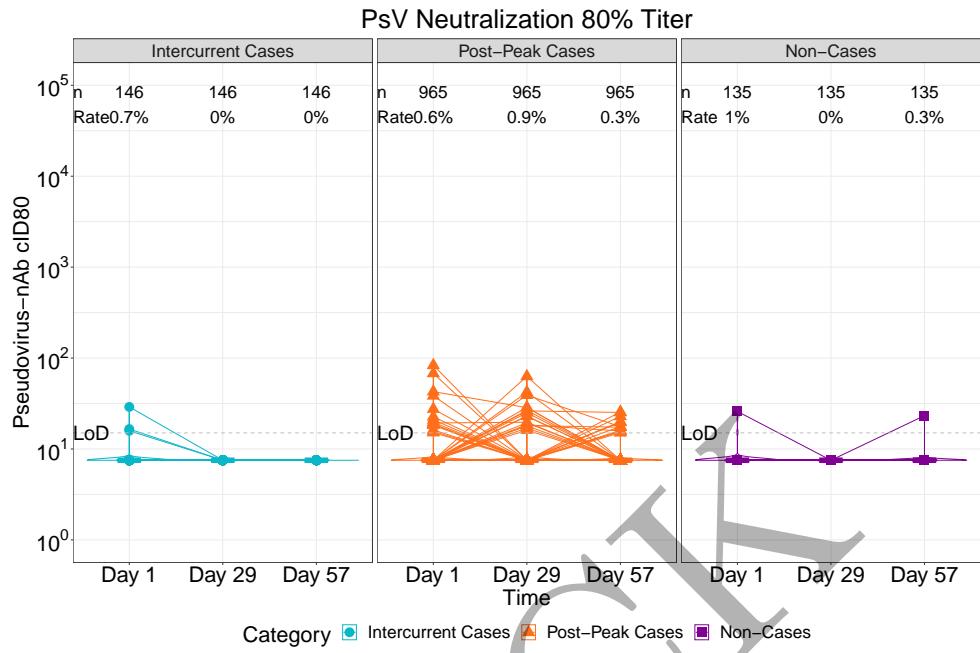
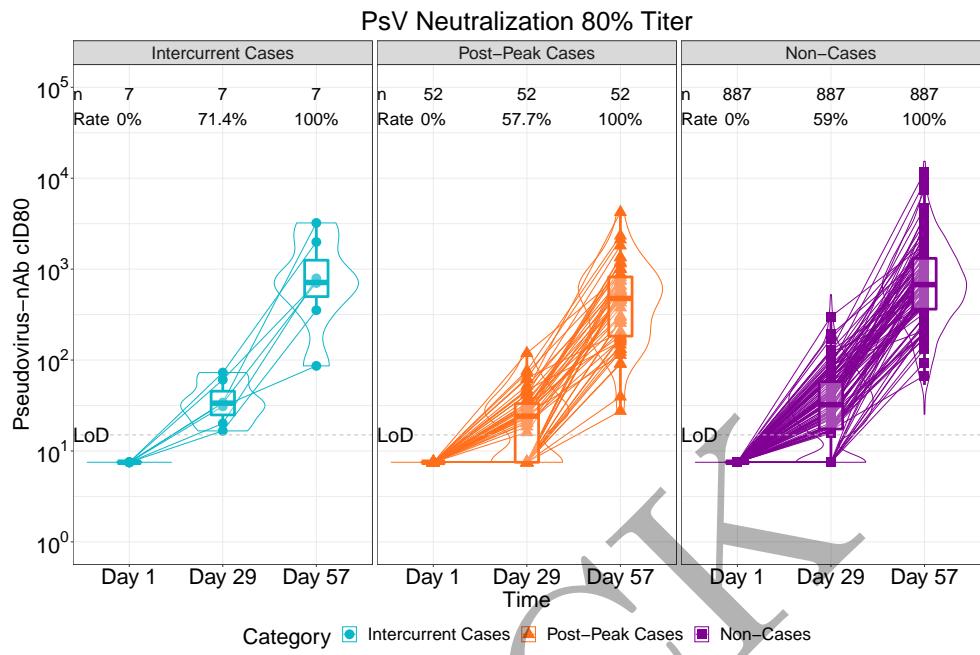


Figure 3.40: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm (version 2)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger

Figure 3.41: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm (version 2)

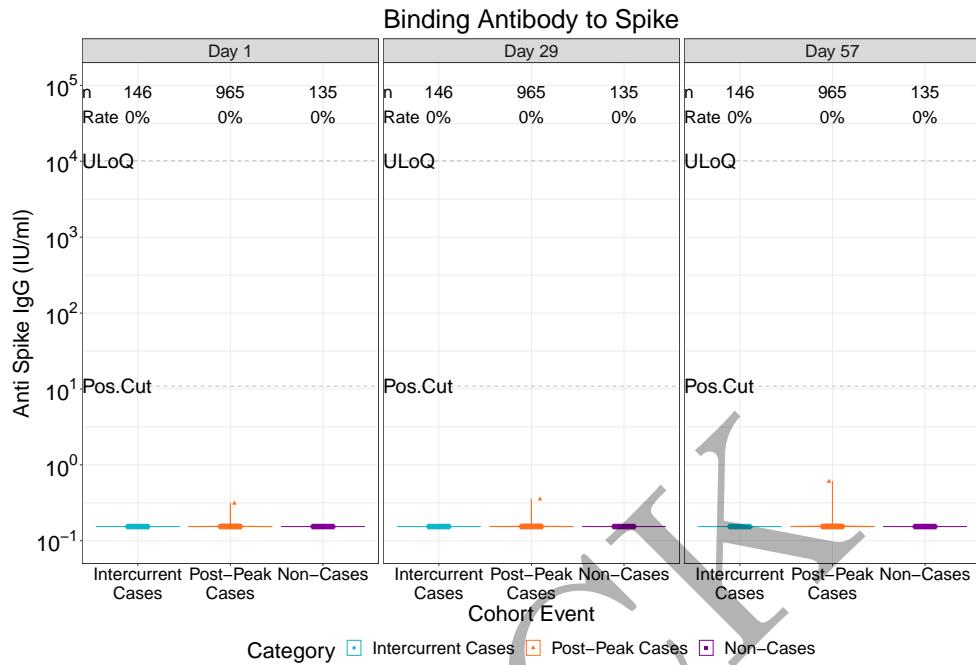


Figure 3.42: violinplots of Binding Antibody to Spike: baseline negative placebo arm (version 2)

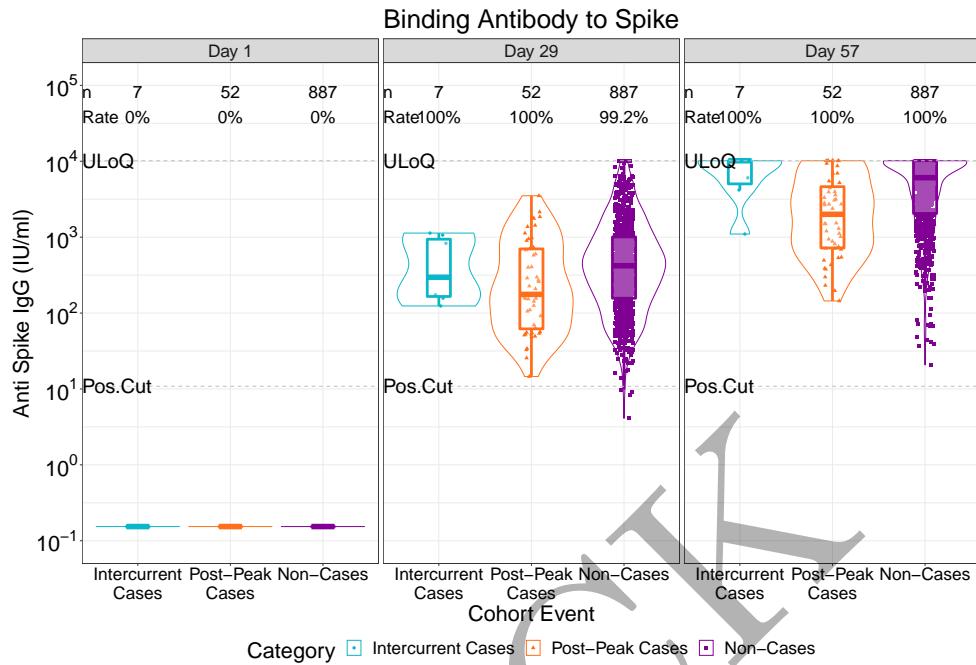


Figure 3.43: violinplots of Binding Antibody to Spike: baseline negative vaccine arm (version 2)

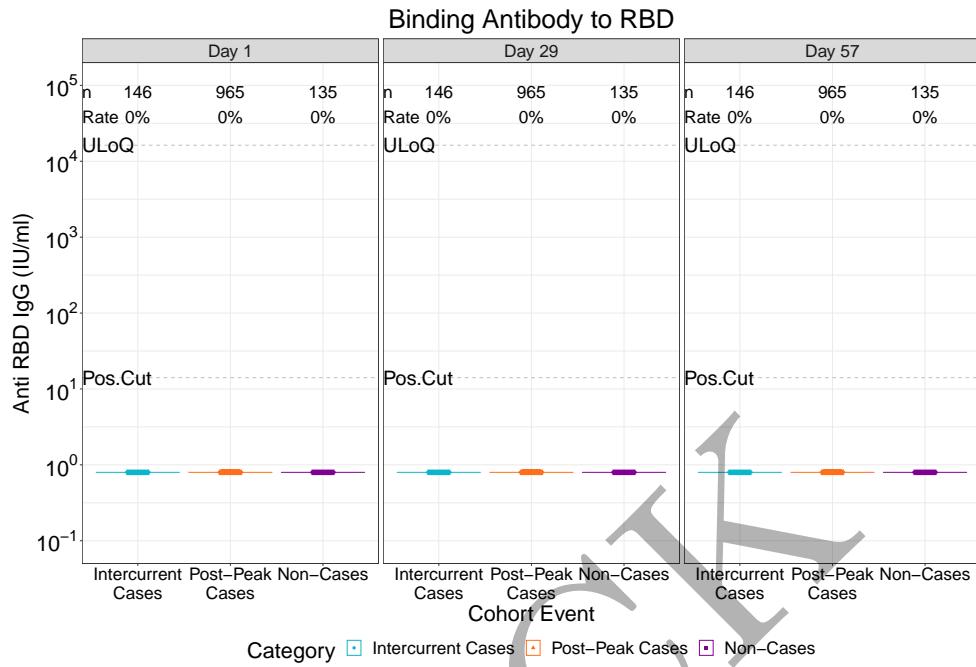


Figure 3.44: violinplots of Binding Antibody to RBD: baseline negative placebo arm (version 2)

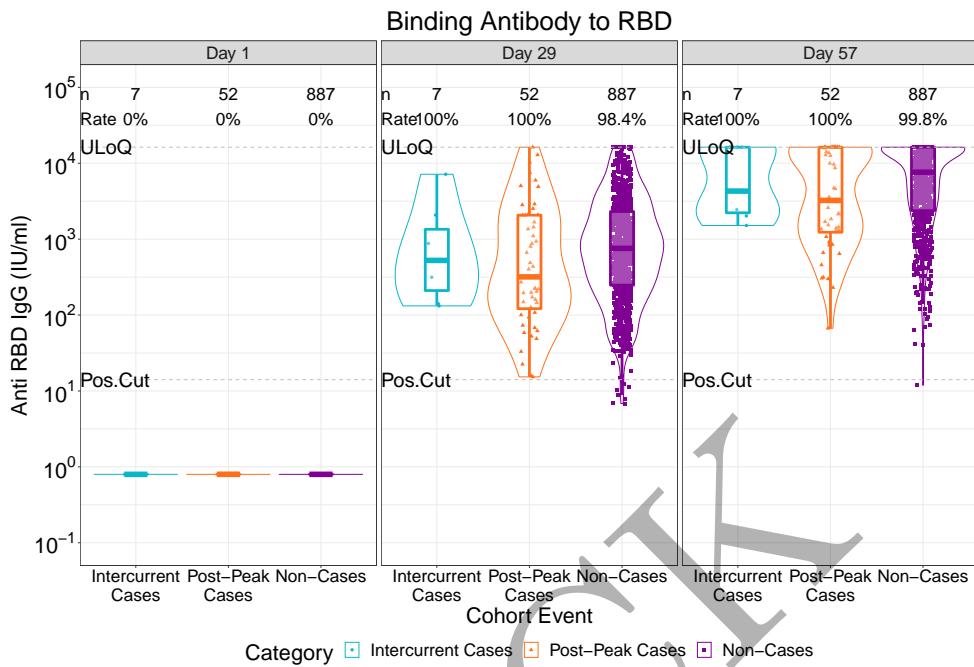


Figure 3.45: violinplots of Binding Antibody to RBD: baseline negative vaccine arm (version 2)

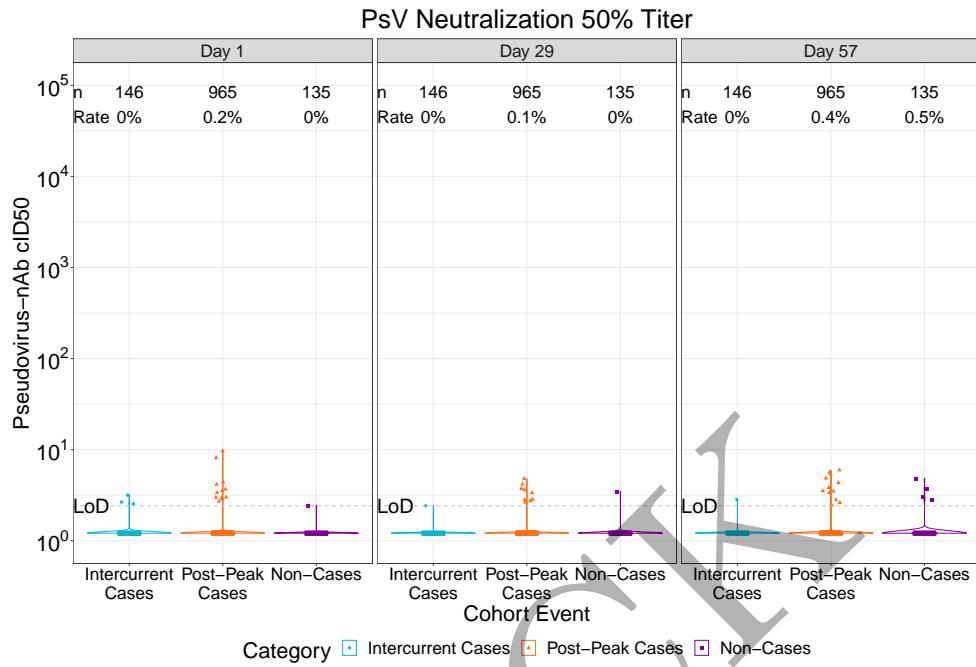


Figure 3.46: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm (version 2)

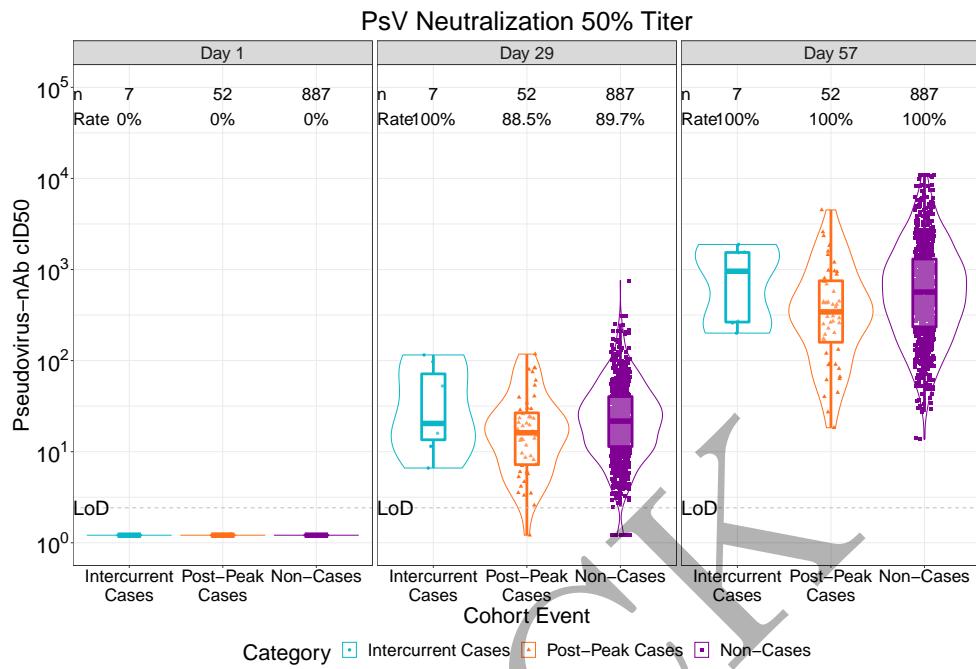


Figure 3.47: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm (version 2)

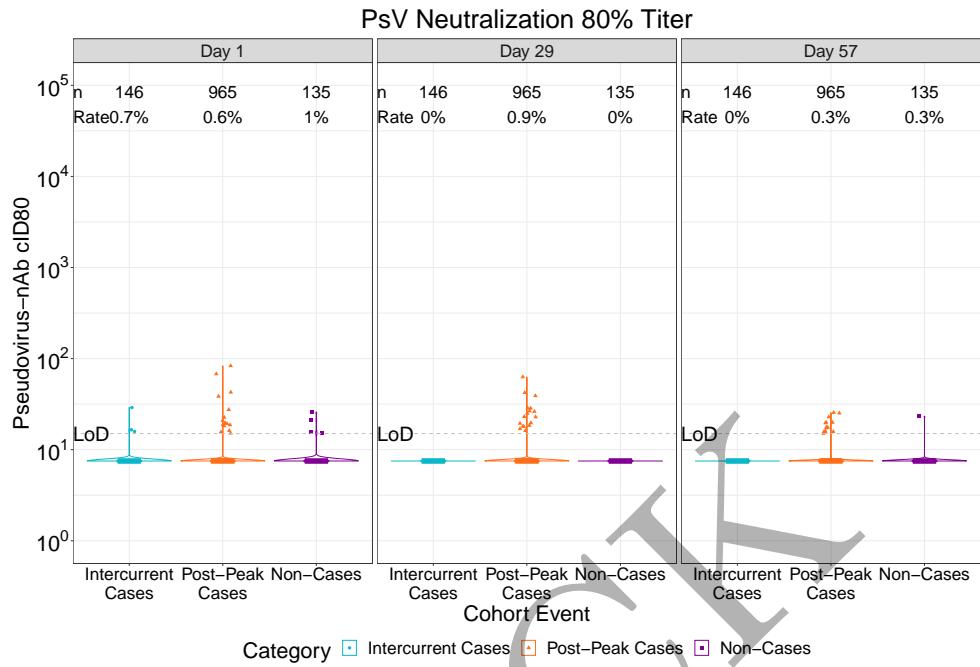


Figure 3.48: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm (version 2)

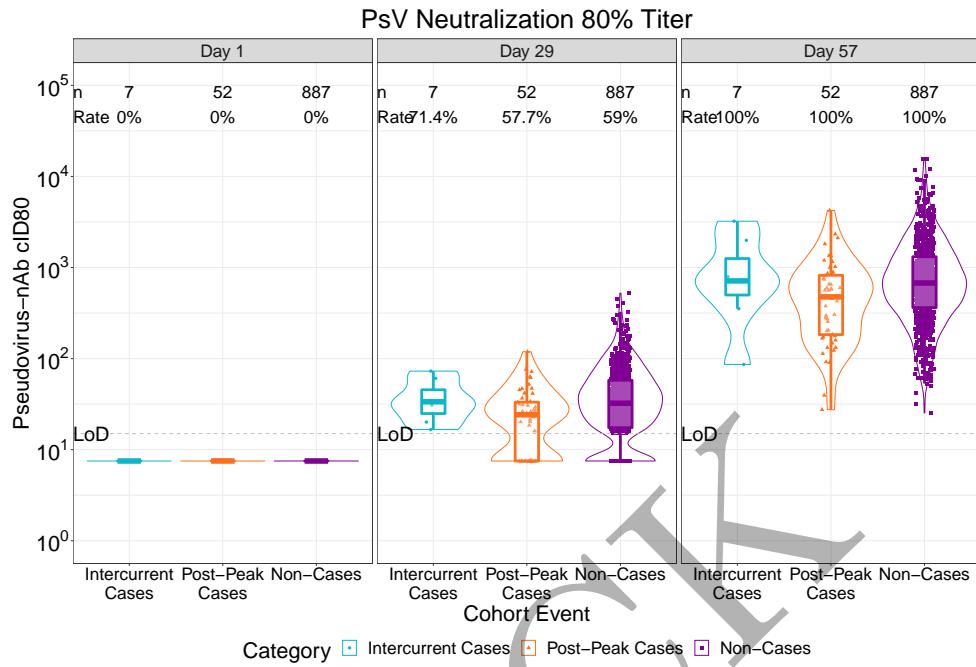
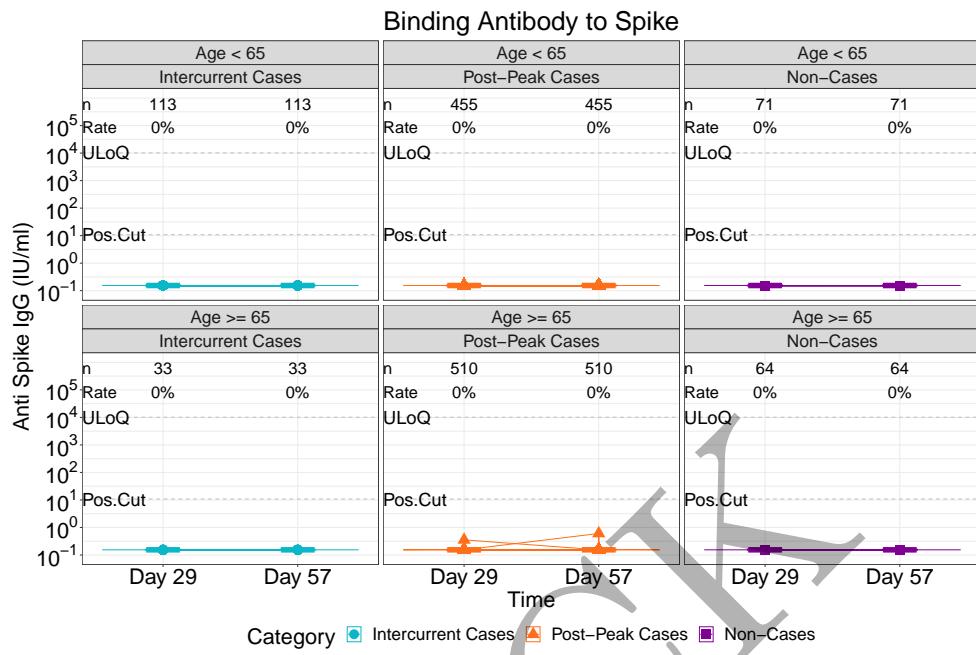


Figure 3.49: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm (version 2)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.50: lineplots of Binding Antibody to Spike: baseline negative placebo arm by age (version 1)

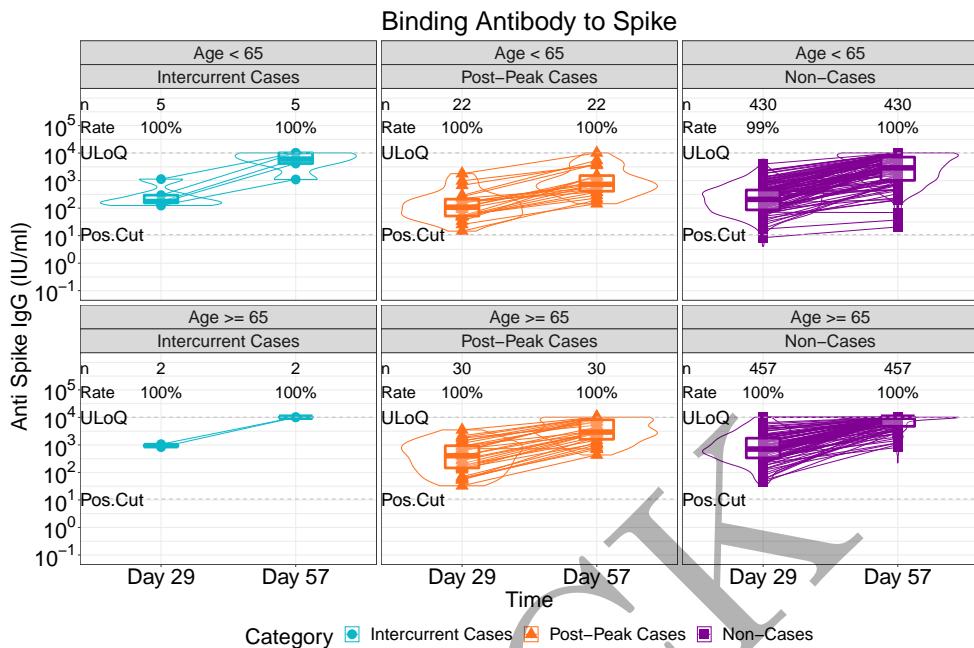
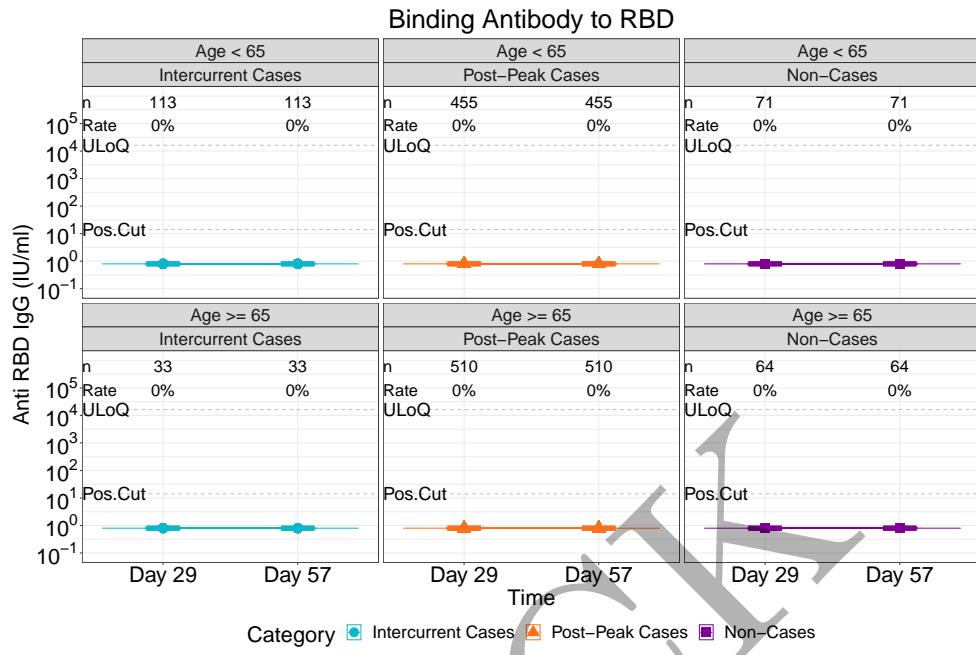


Figure 3.51: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by age (version 1)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.52: lineplots of Binding Antibody to RBD: baseline negative placebo arm by age (version 1)

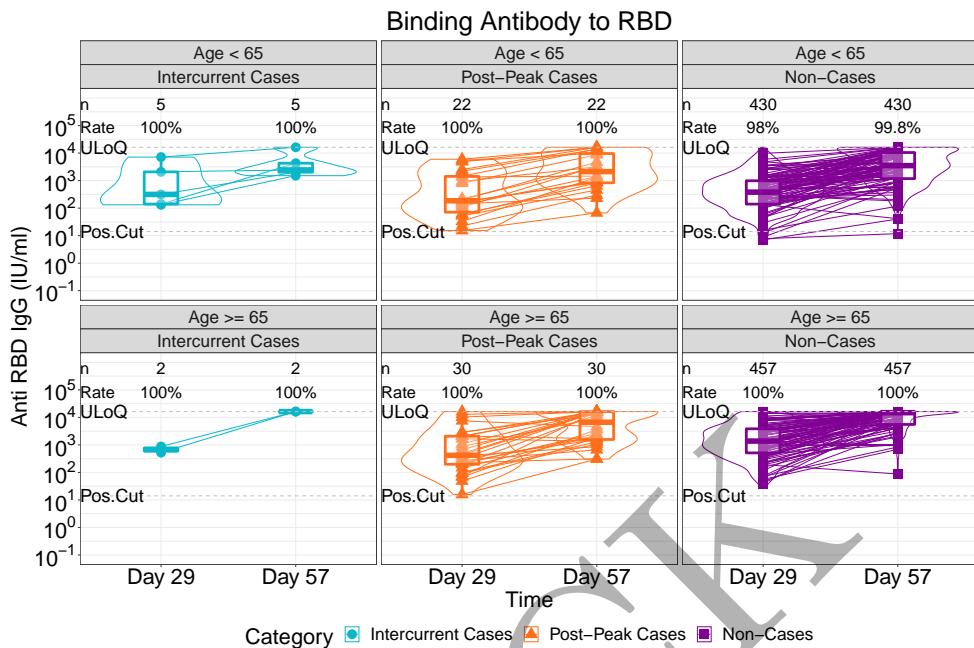


Figure 3.53: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by age (version 1)

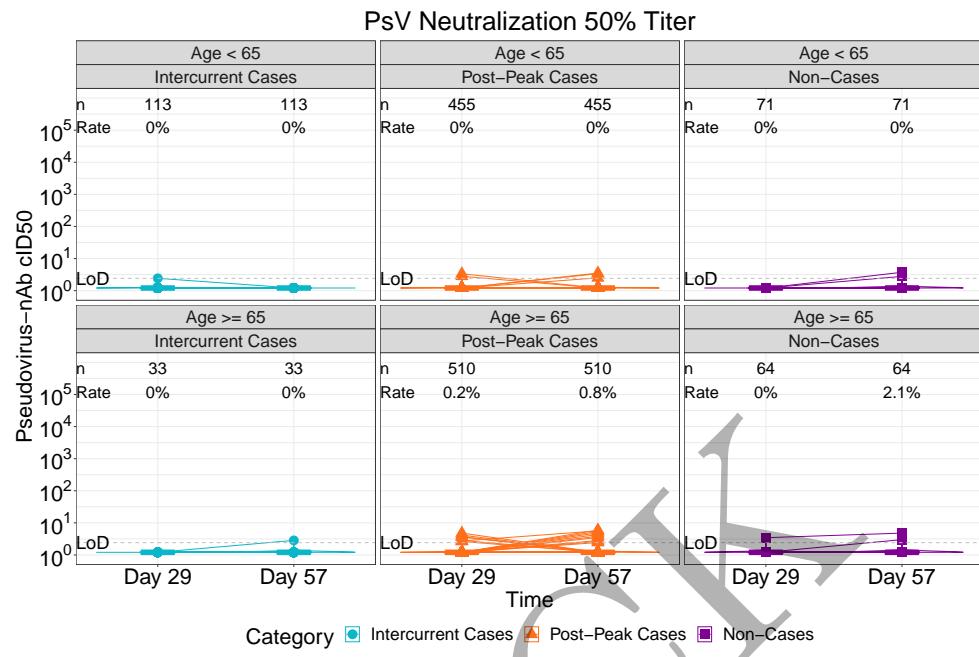


Figure 3.54: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age (version 1)

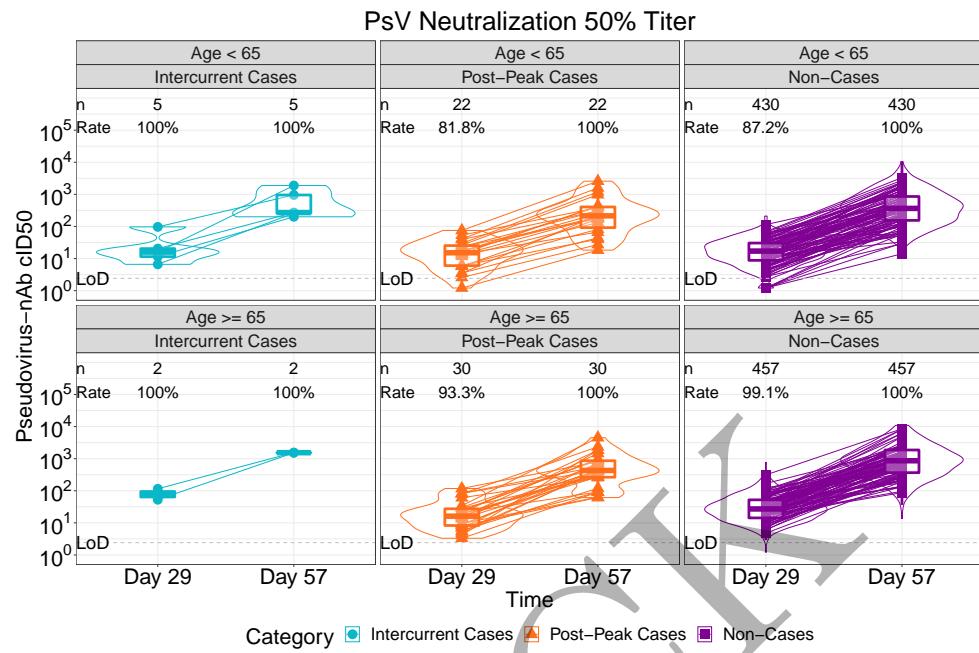


Figure 3.55: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age (version 1)

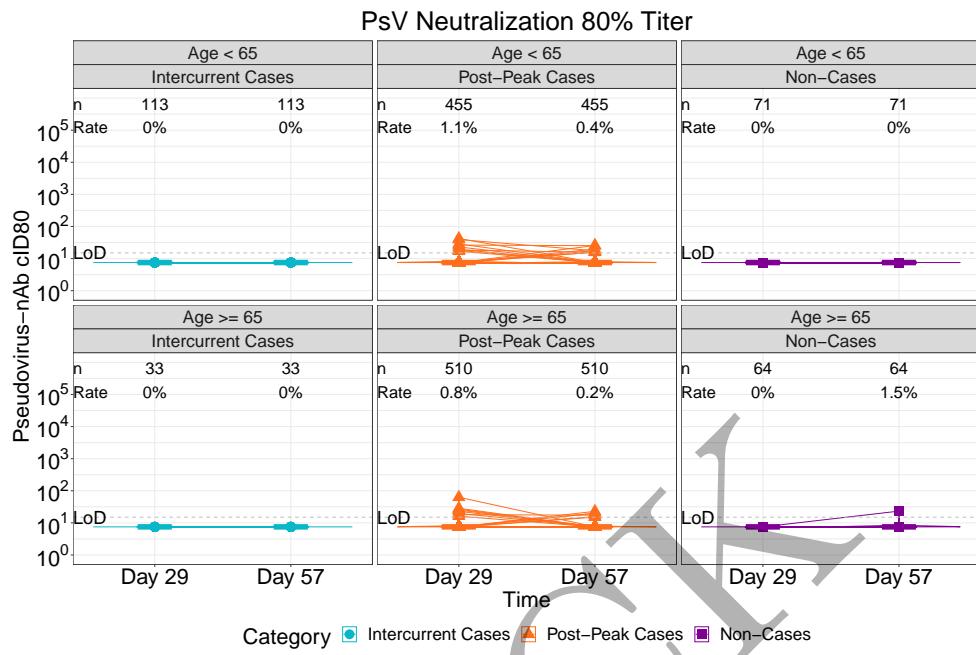
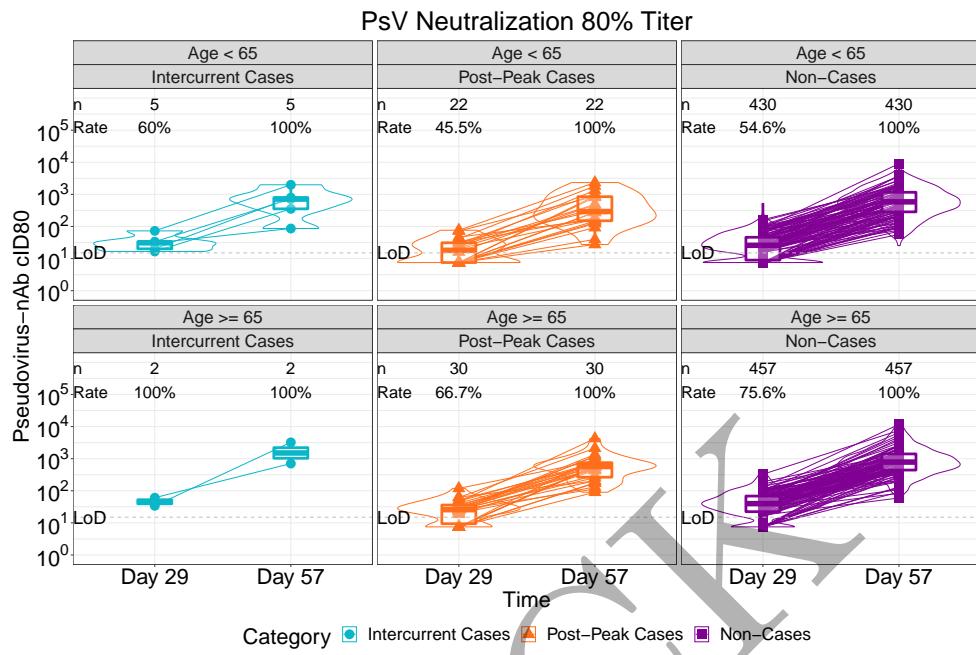


Figure 3.56: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age (version 1)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.57: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age (version 1)

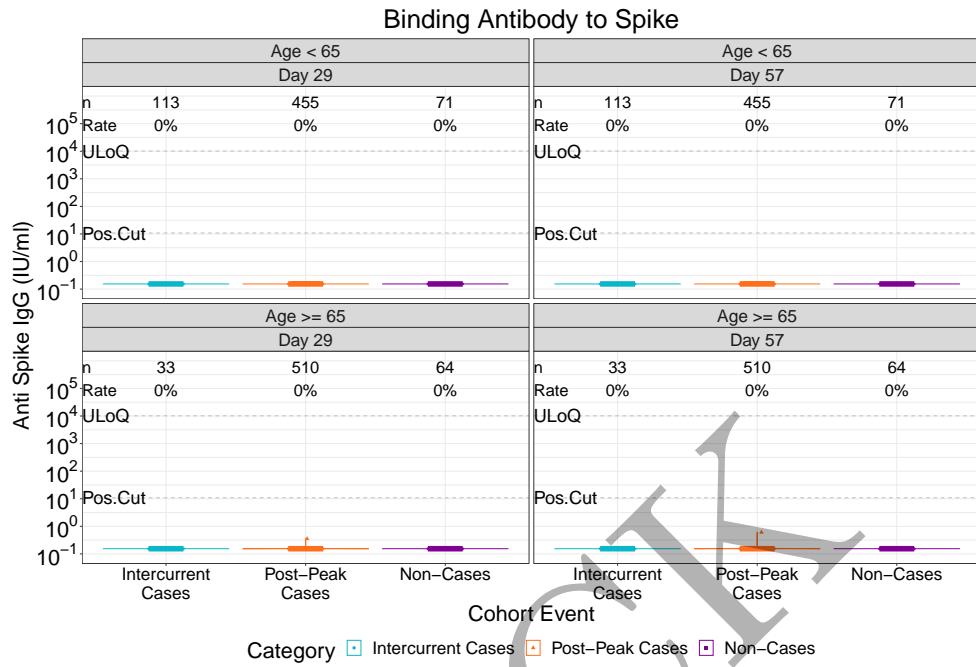


Figure 3.58: violinplots of Binding Antibody to Spike: baseline negative placebo arm by age (version 1)

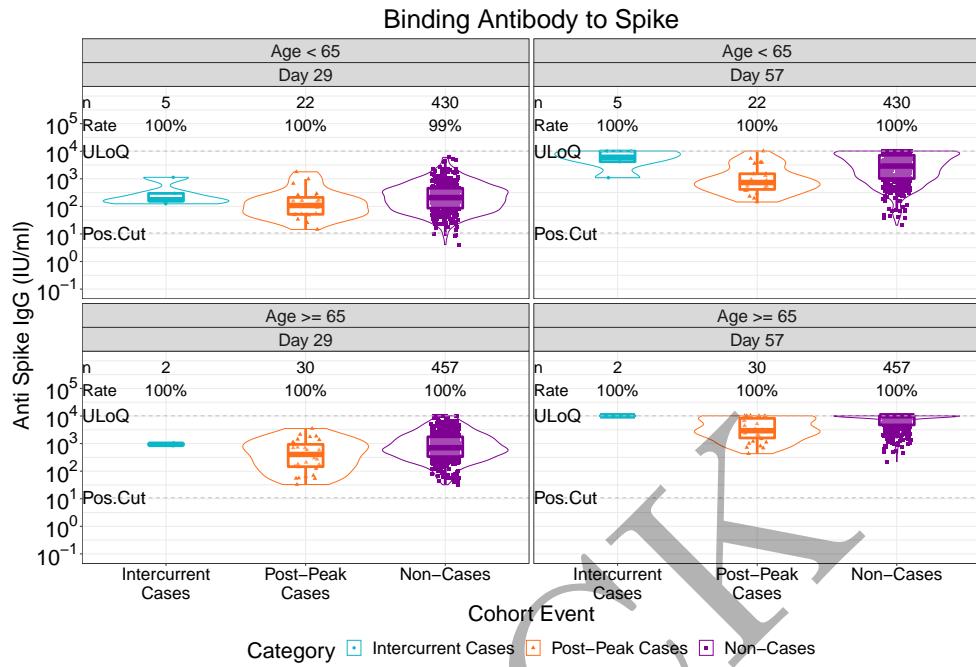


Figure 3.59: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by age (version 1)

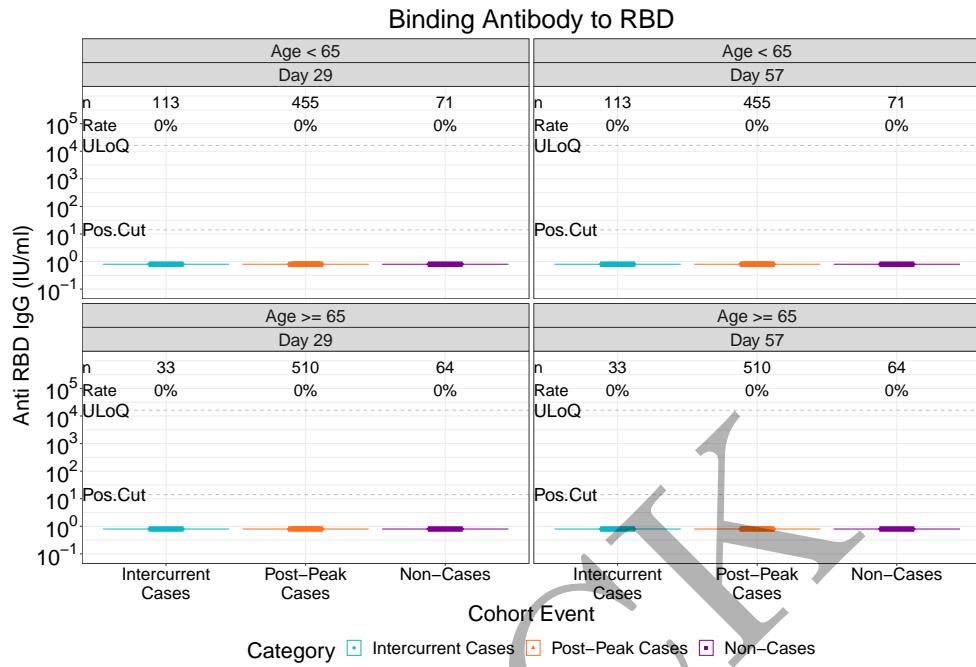


Figure 3.60: violinplots of Binding Antibody to RBD: baseline negative placebo arm by age (version 1)

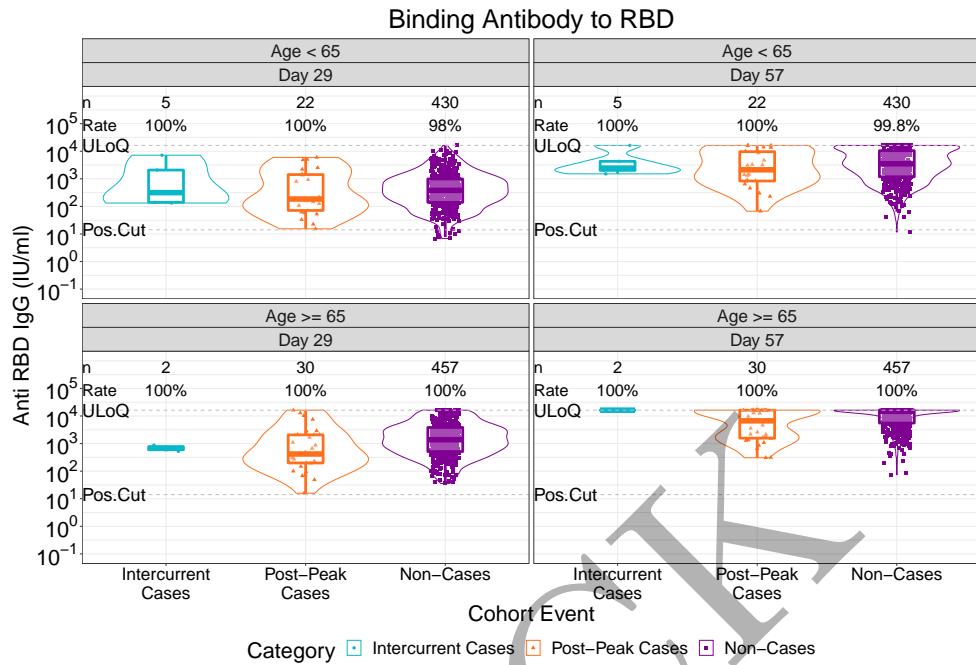


Figure 3.61: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by age (version 1)

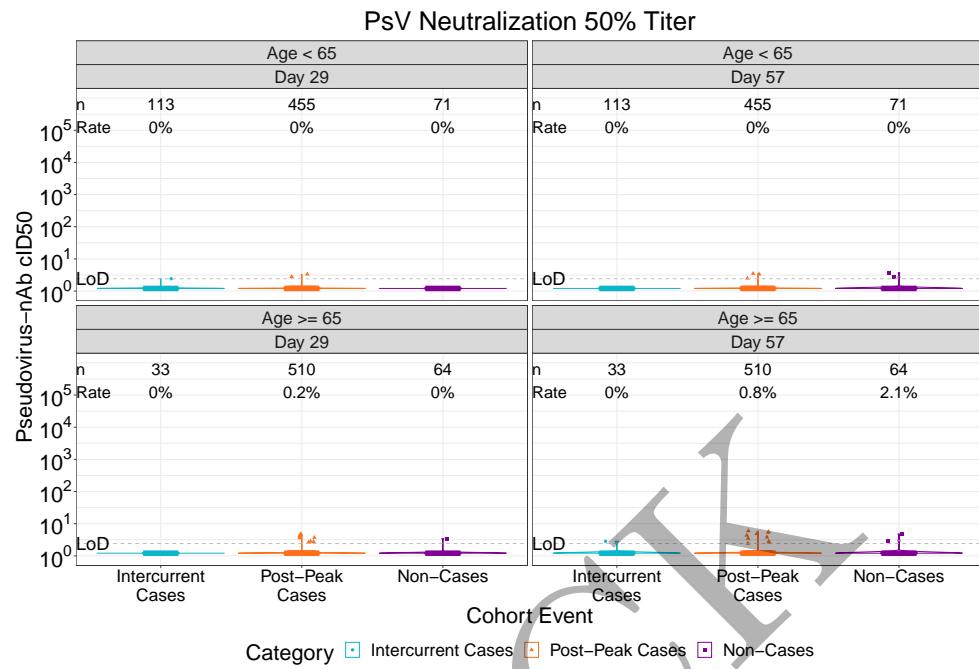


Figure 3.62: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age (version 1)

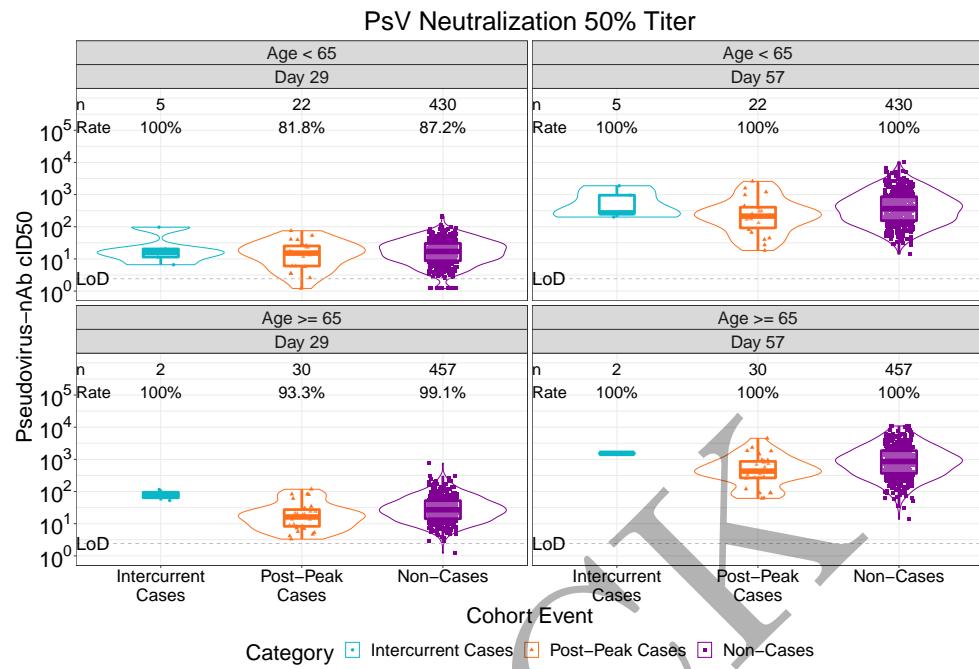


Figure 3.63: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age (version 1)

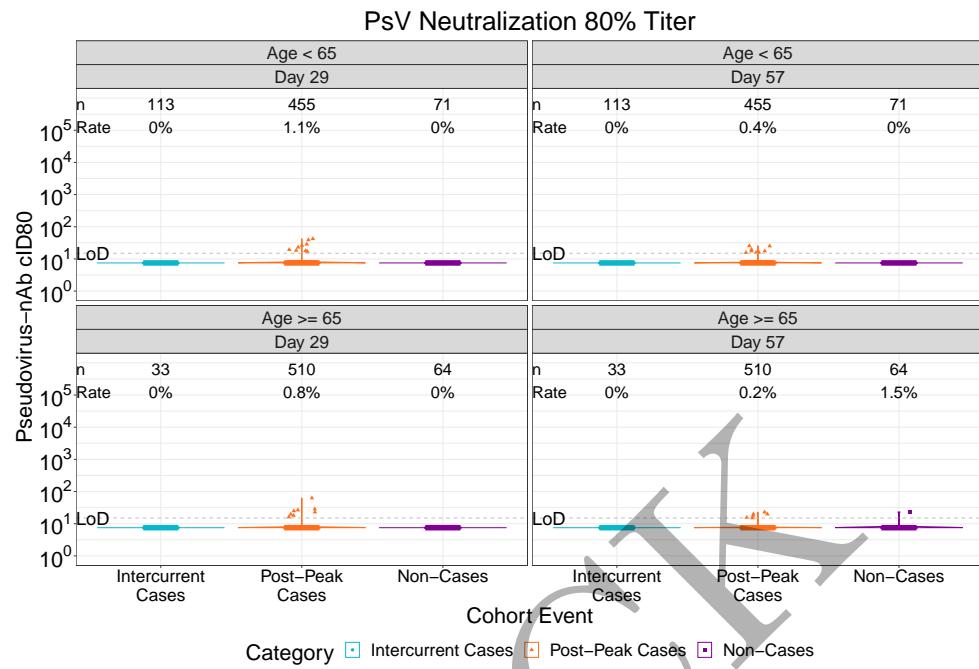


Figure 3.64: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age (version 1)

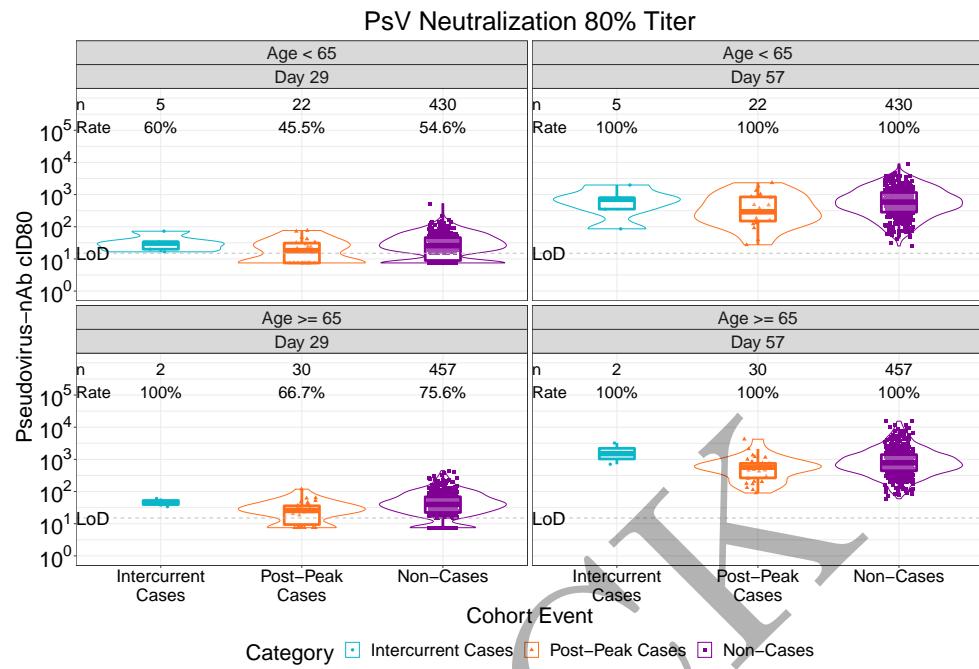
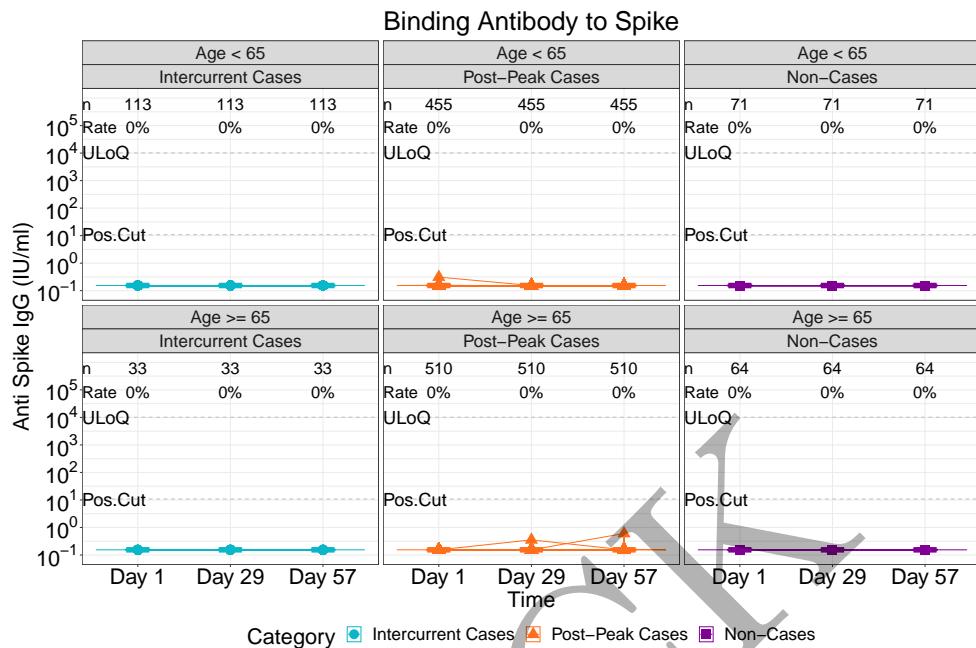
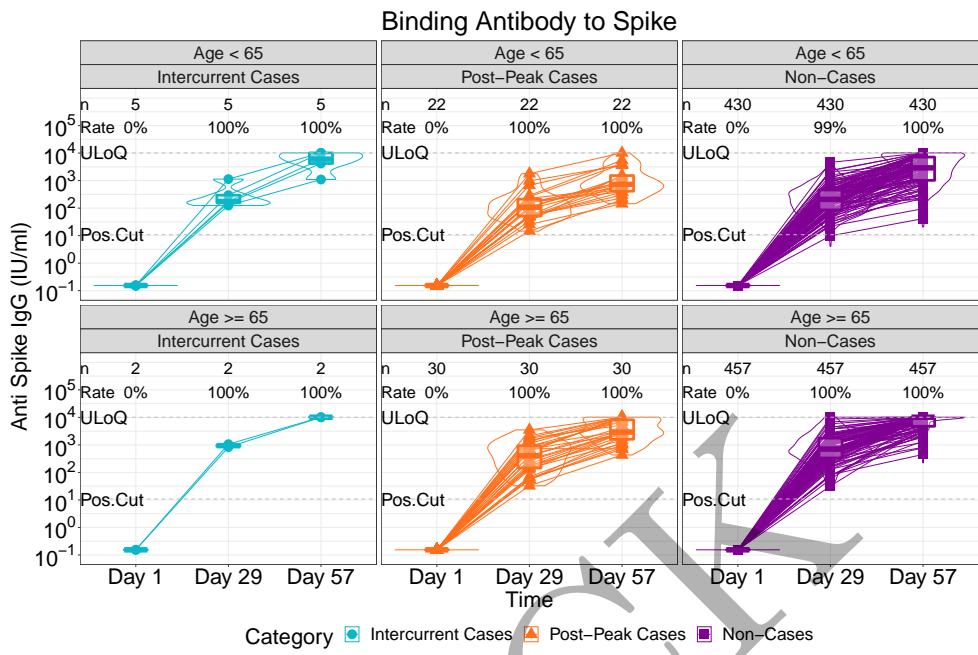


Figure 3.65: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age (version 1)



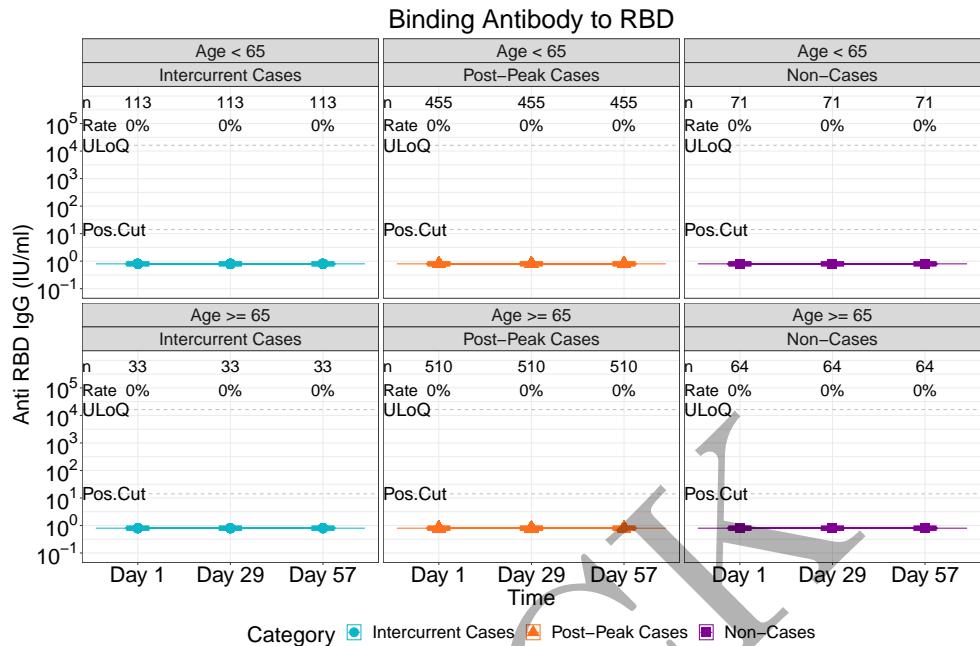
All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.66: lineplots of Binding Antibody to Spike: baseline negative placebo arm by age (version 2)



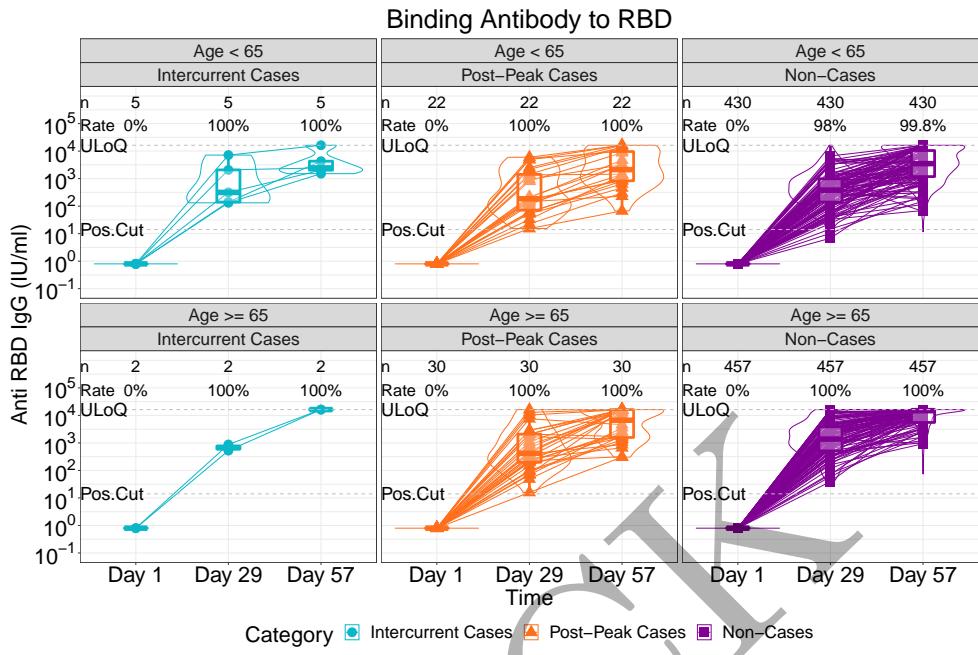
All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.67: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by age (version 2)



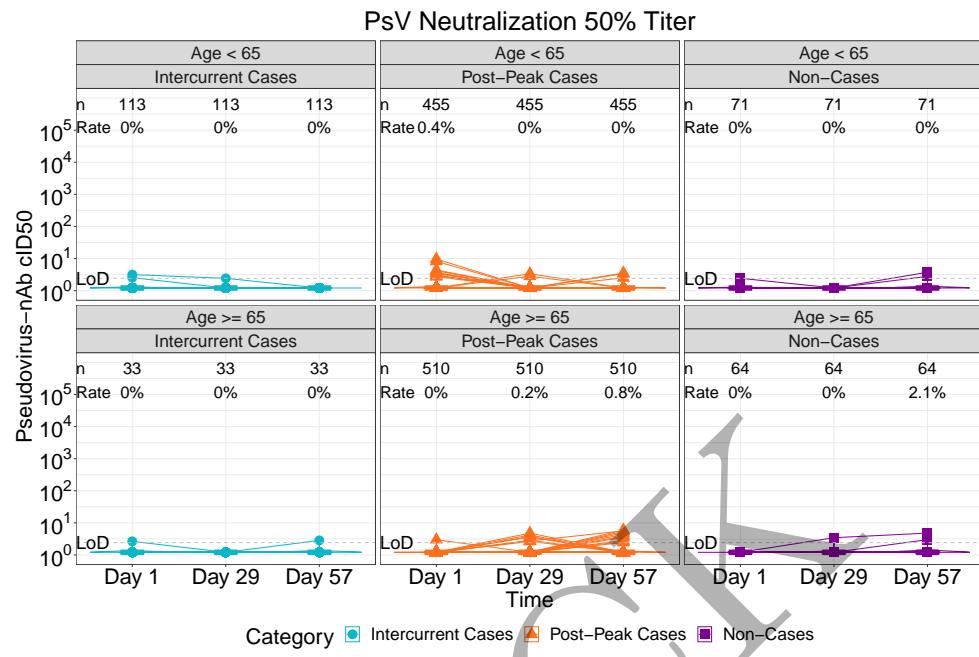
All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.68: lineplots of Binding Antibody to RBD: baseline negative placebo arm by age (version 2)



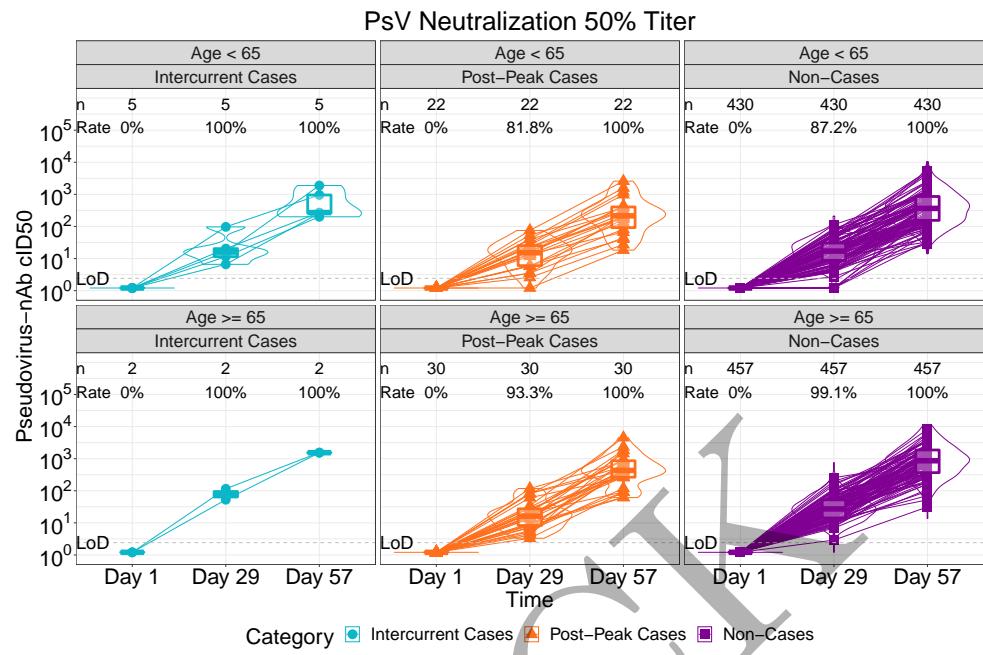
All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.69: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by age (version 2)



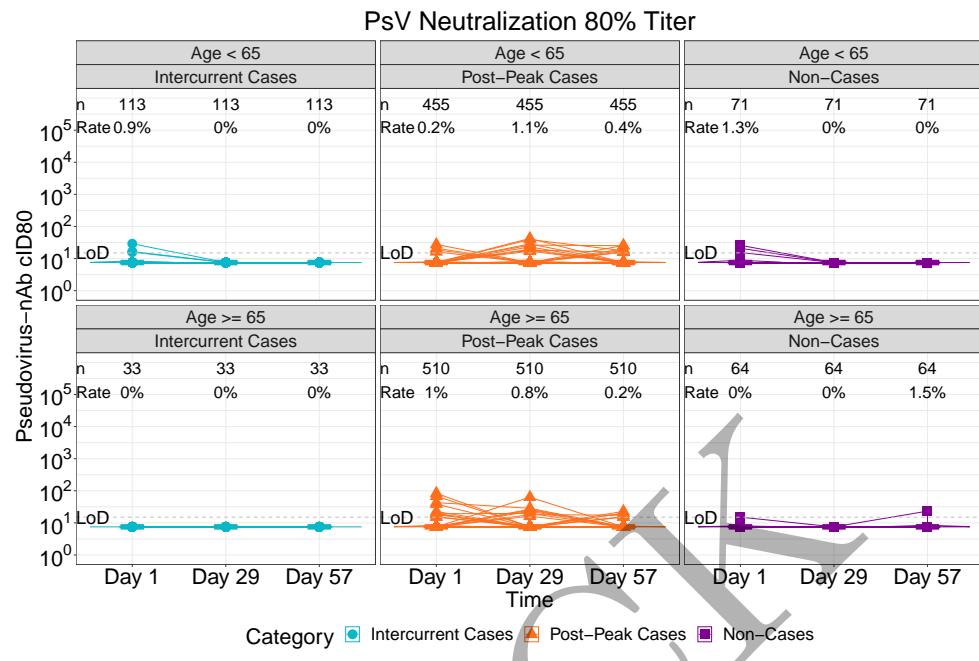
All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.70: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age (version 2)



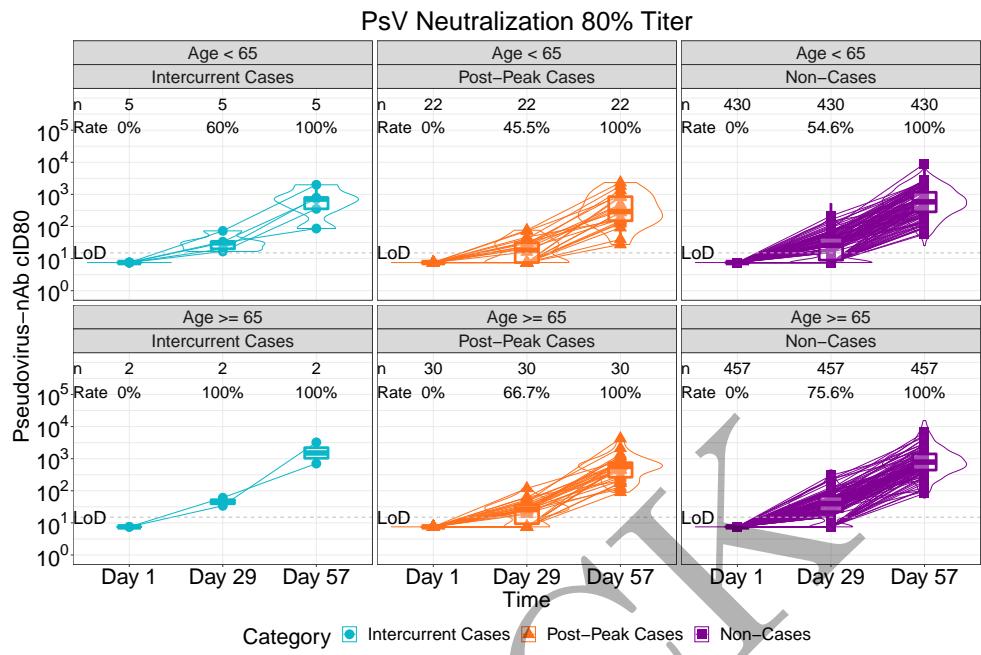
All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.71: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age (version 2)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.72: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age (version 2)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.73: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age (version 2)

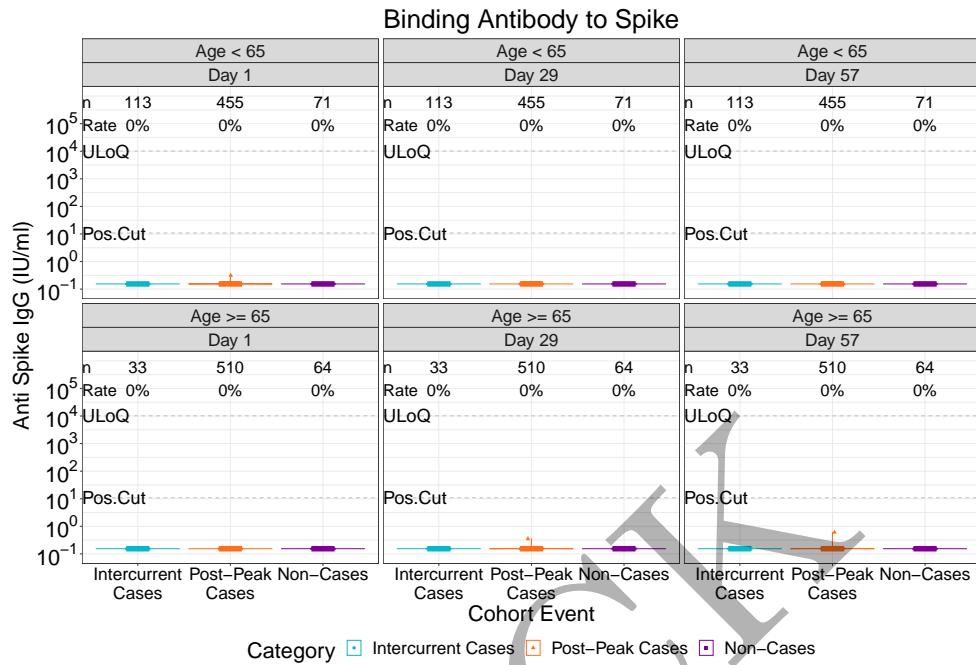


Figure 3.74: violinplots of Binding Antibody to Spike: baseline negative placebo arm by age (version 2)

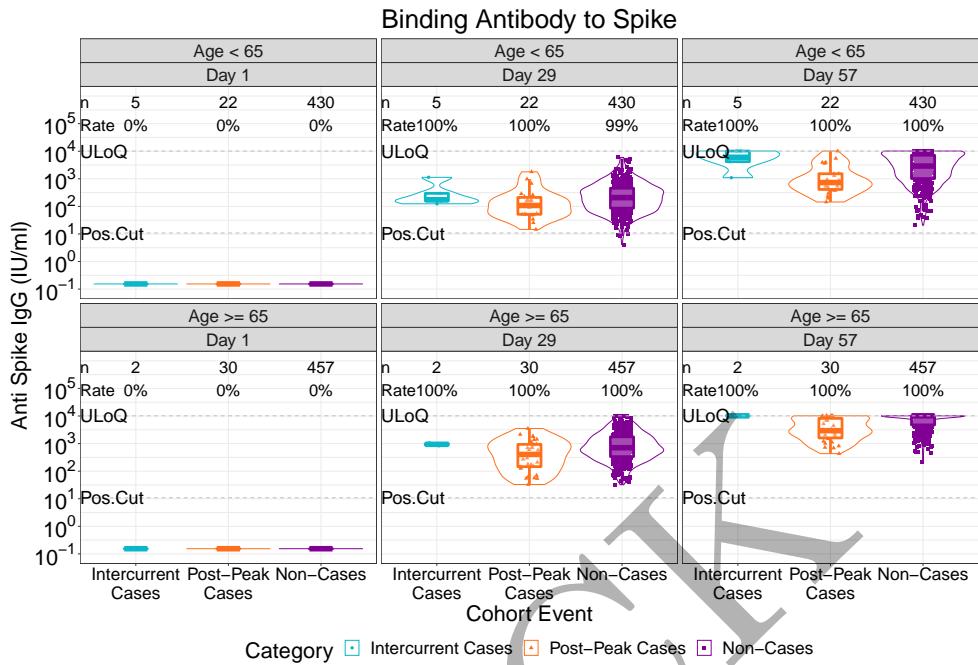


Figure 3.75: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by age (version 2)

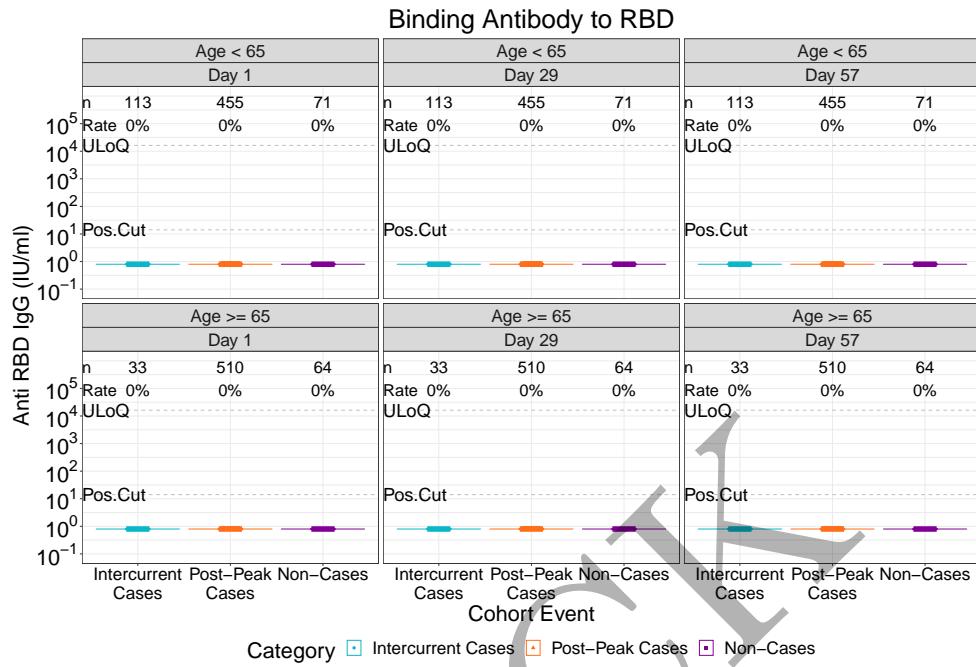


Figure 3.76: violinplots of Binding Antibody to RBD: baseline negative placebo arm by age (version 2)

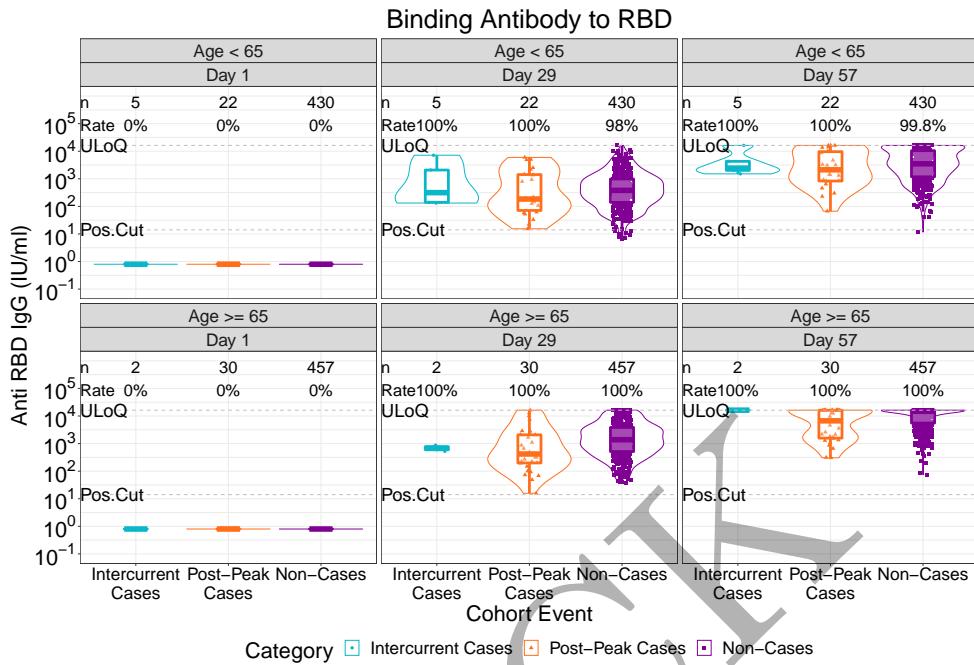


Figure 3.77: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by age (version 2)

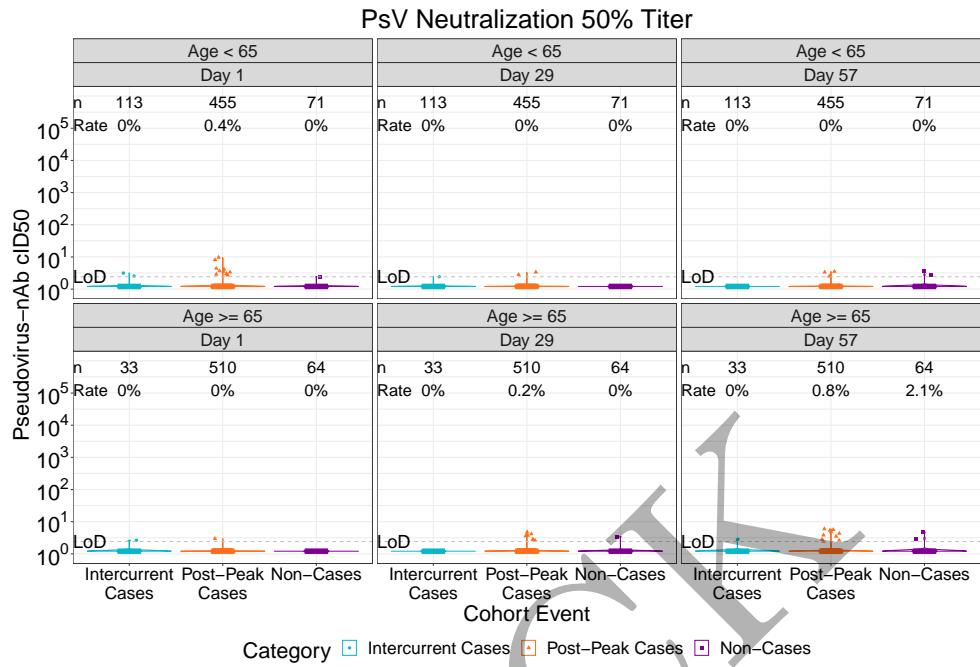


Figure 3.78: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age (version 2)

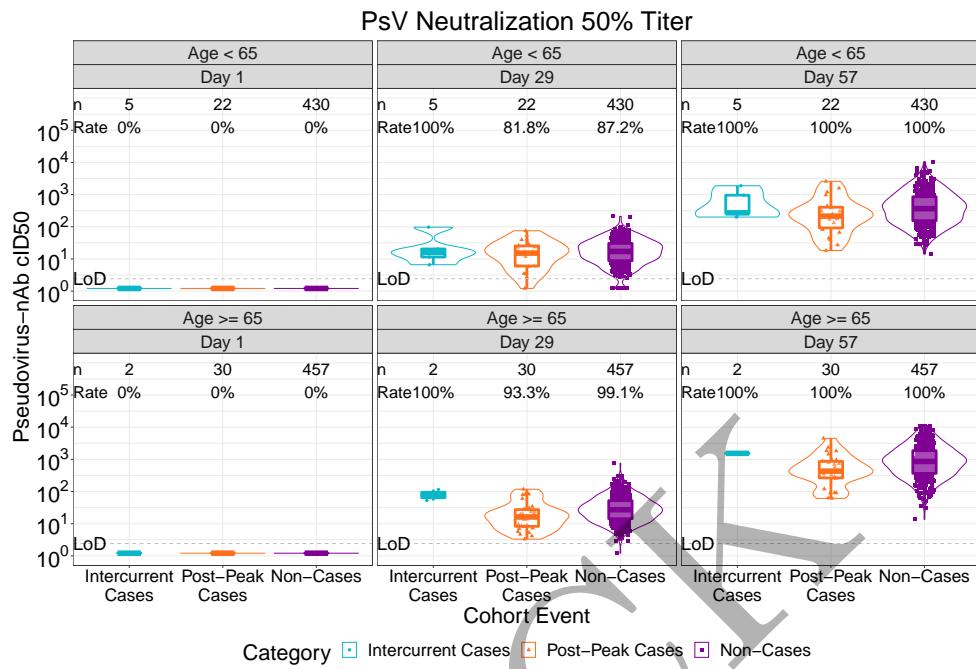


Figure 3.79: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age (version 2)

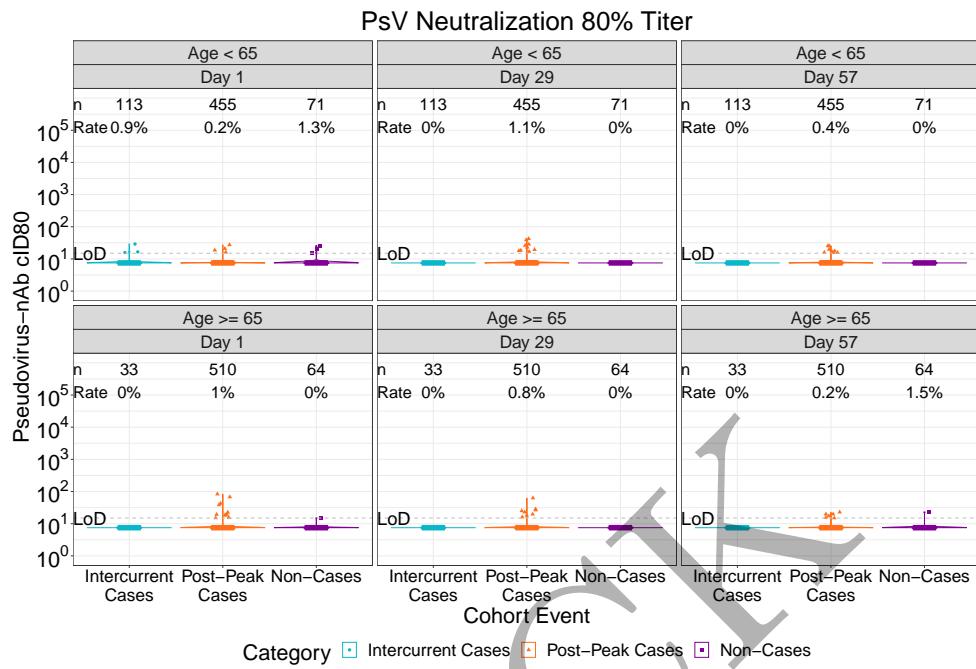


Figure 3.80: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age (version 2)

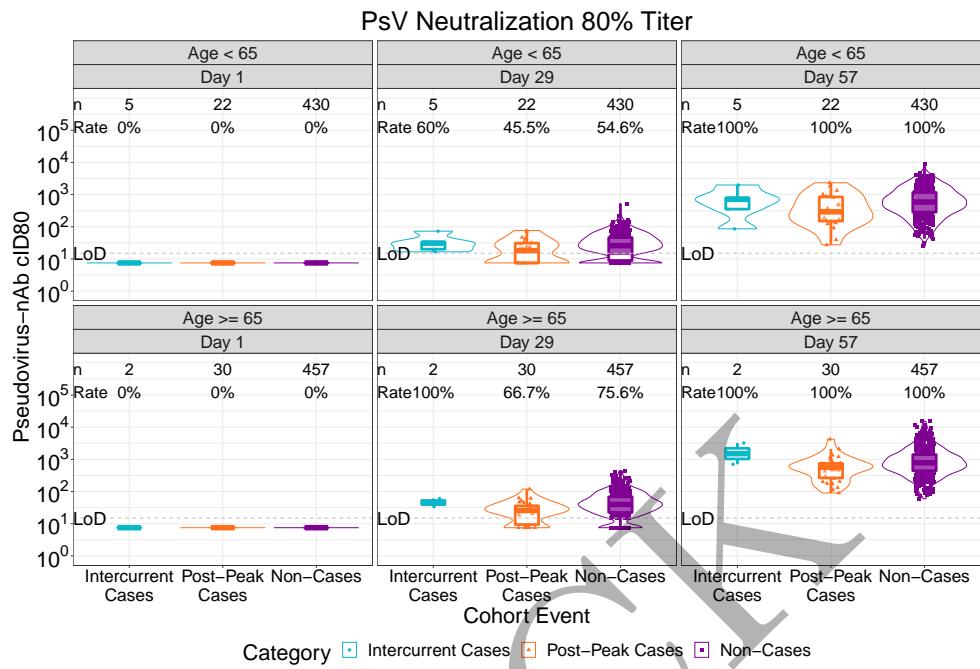
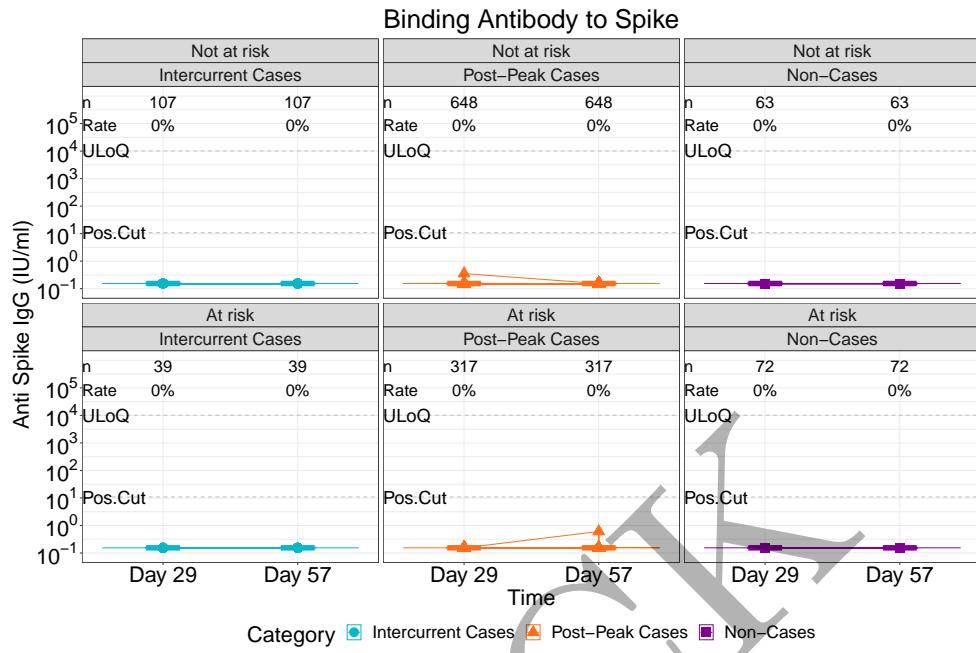
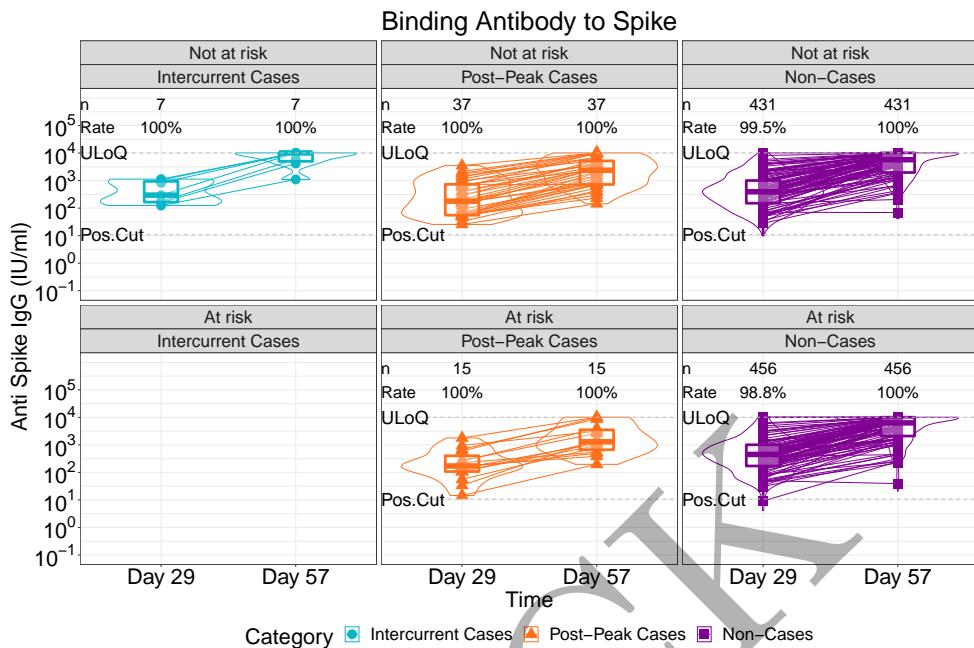


Figure 3.81: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age (version 2)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.82: lineplots of Binding Antibody to Spike: baseline negative placebo arm by risk condition (version 1)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.83: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by risk condition (version 1)

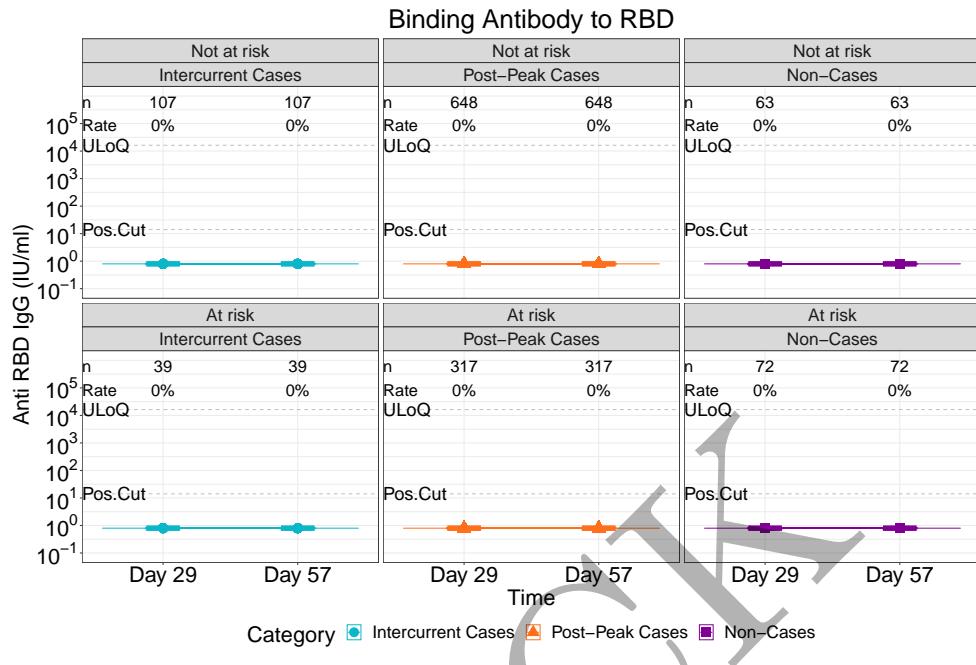
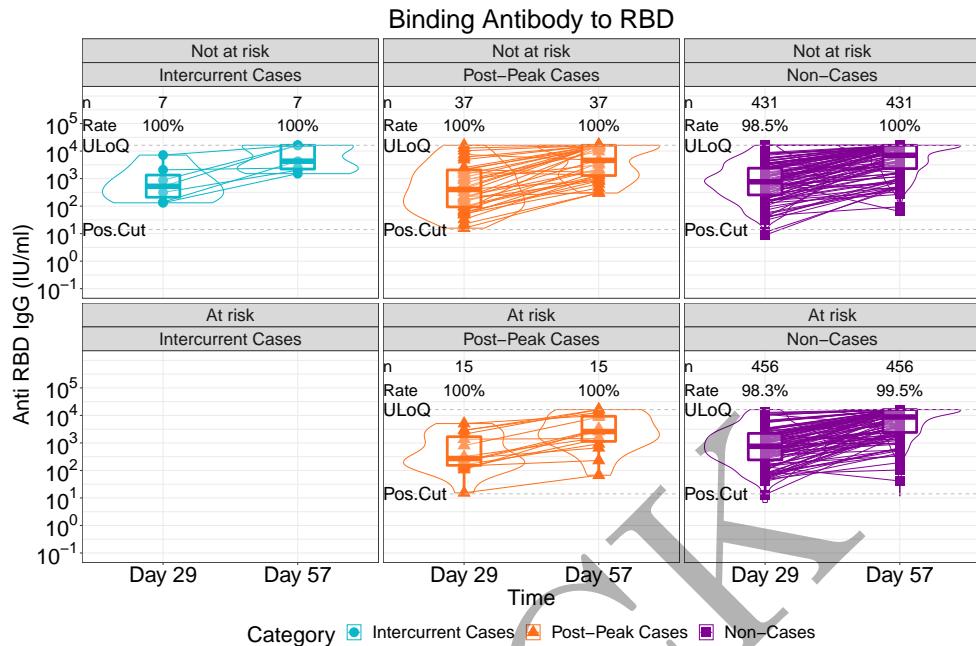


Figure 3.84: lineplots of Binding Antibody to RBD: baseline negative placebo arm by risk condition (version 1)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger

Figure 3.85: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by risk condition (version 1)

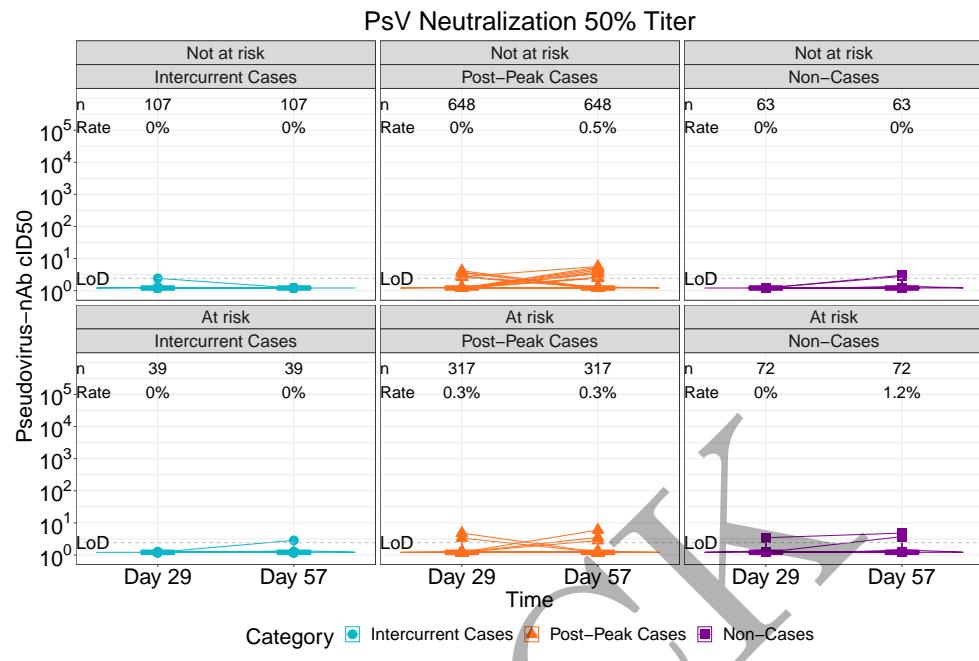
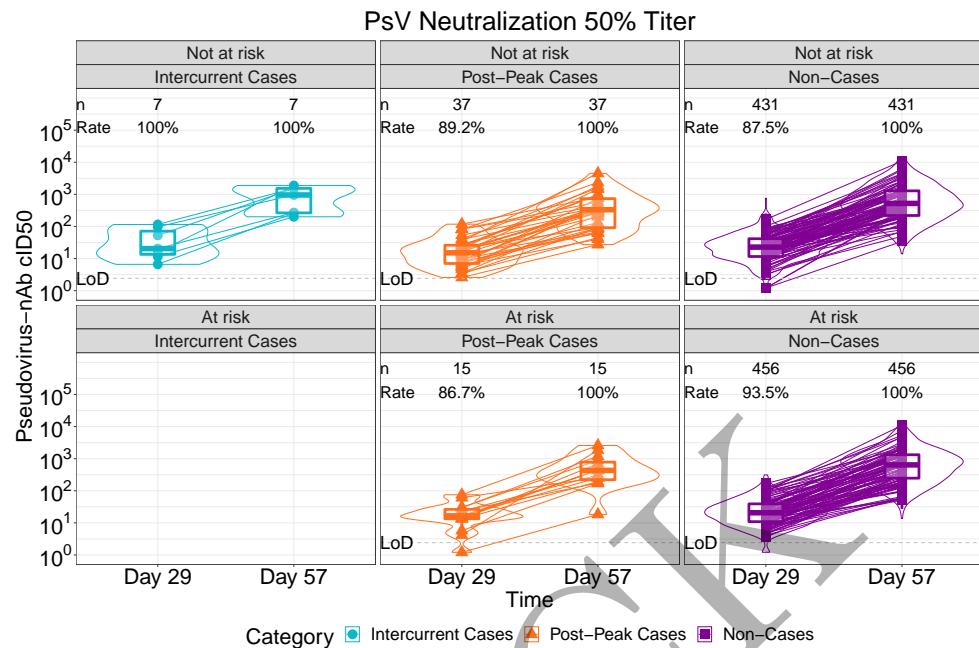


Figure 3.86: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by risk condition (version 1)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.87: lineplots of Pseudovirus Neutralization ID₅₀: baseline negative vaccine arm by risk condition (version 1)

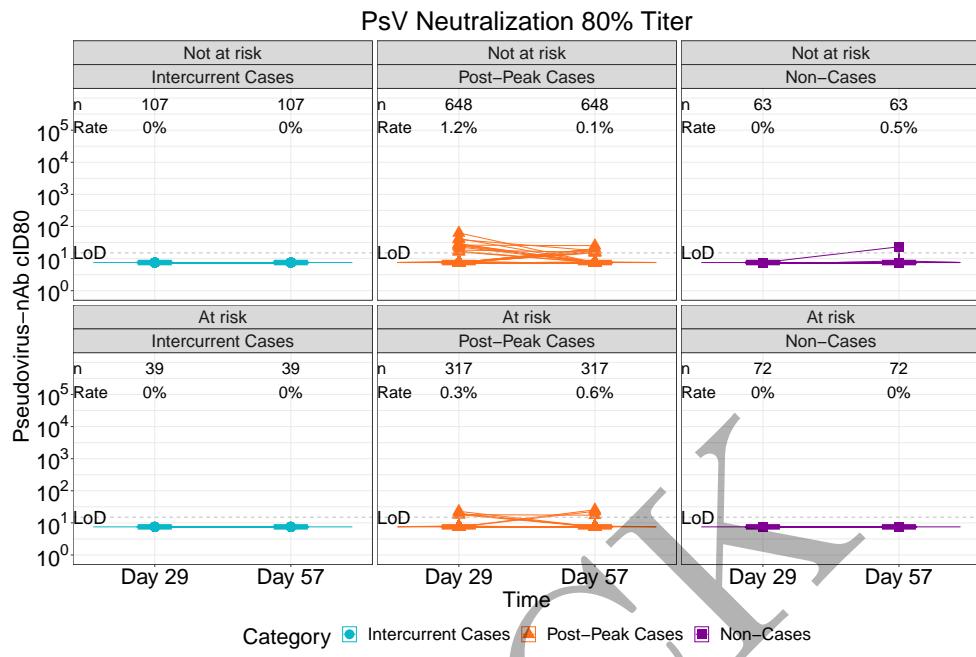


Figure 3.88: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by risk condition (version 1)

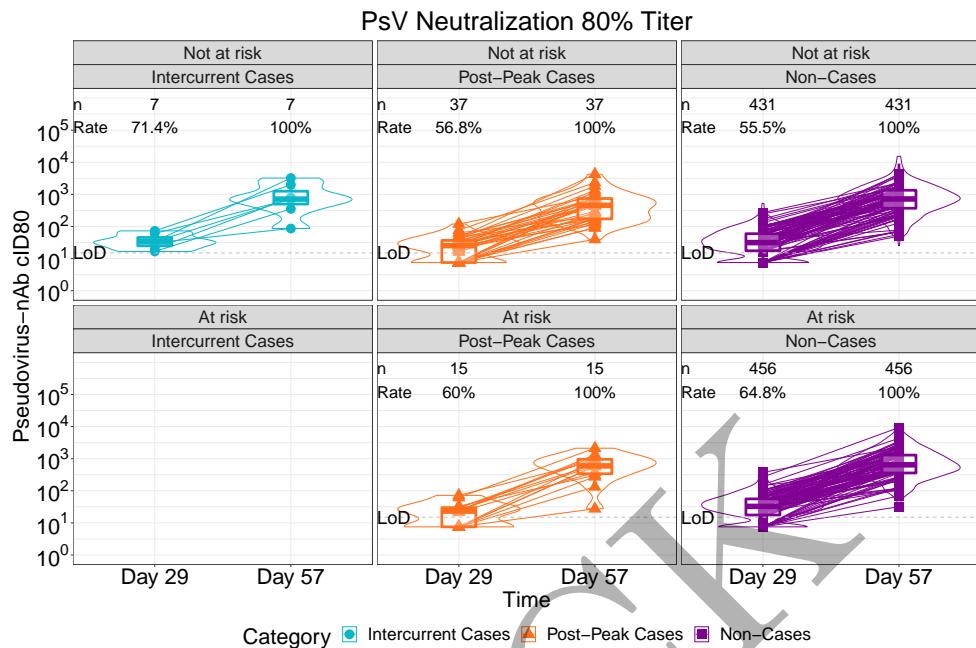


Figure 3.89: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by risk condition (version 1)

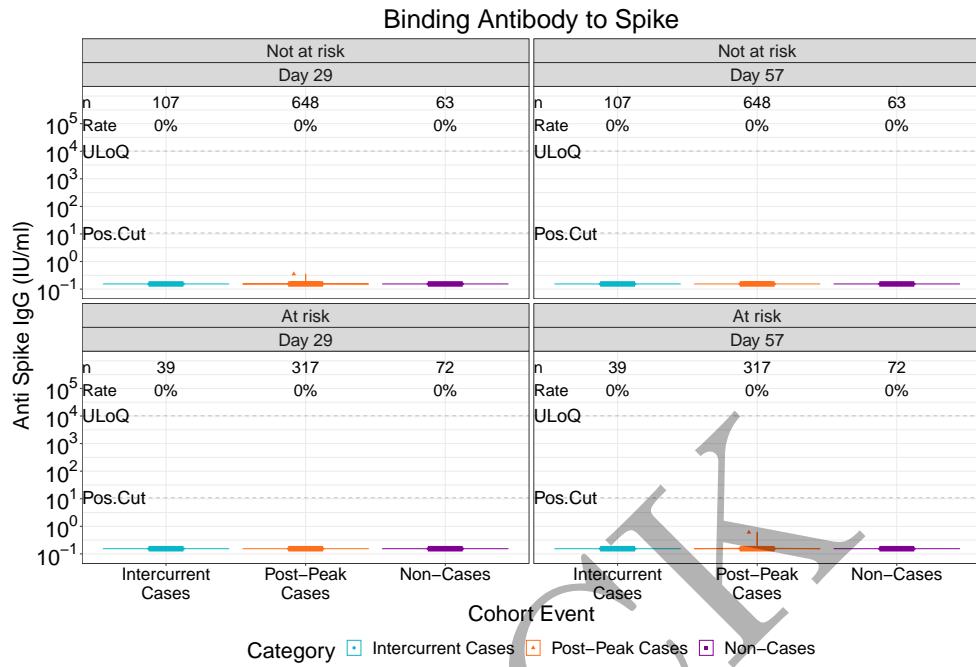


Figure 3.90: violinplots of Binding Antibody to Spike: baseline negative placebo arm by risk condition (version 1)

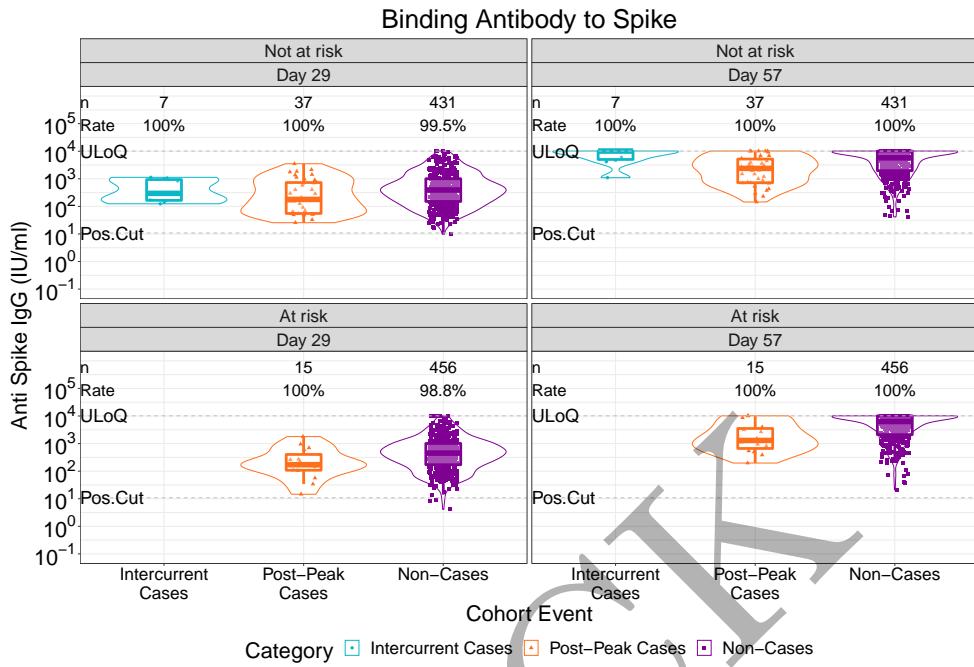


Figure 3.91: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by risk condition (version 1)

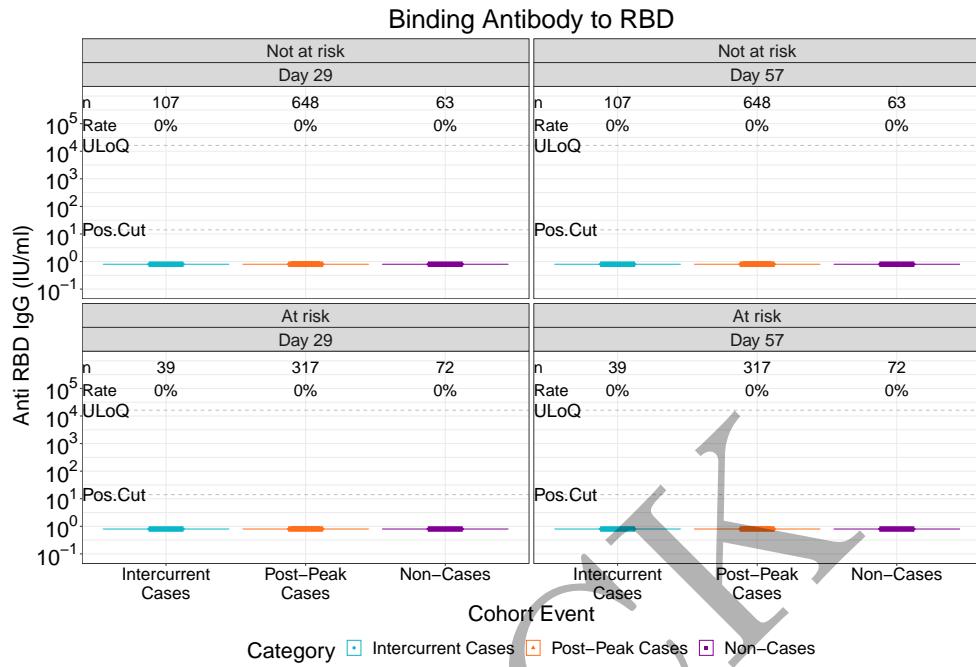


Figure 3.92: violinplots of Binding Antibody to RBD: baseline negative placebo arm by risk condition (version 1)

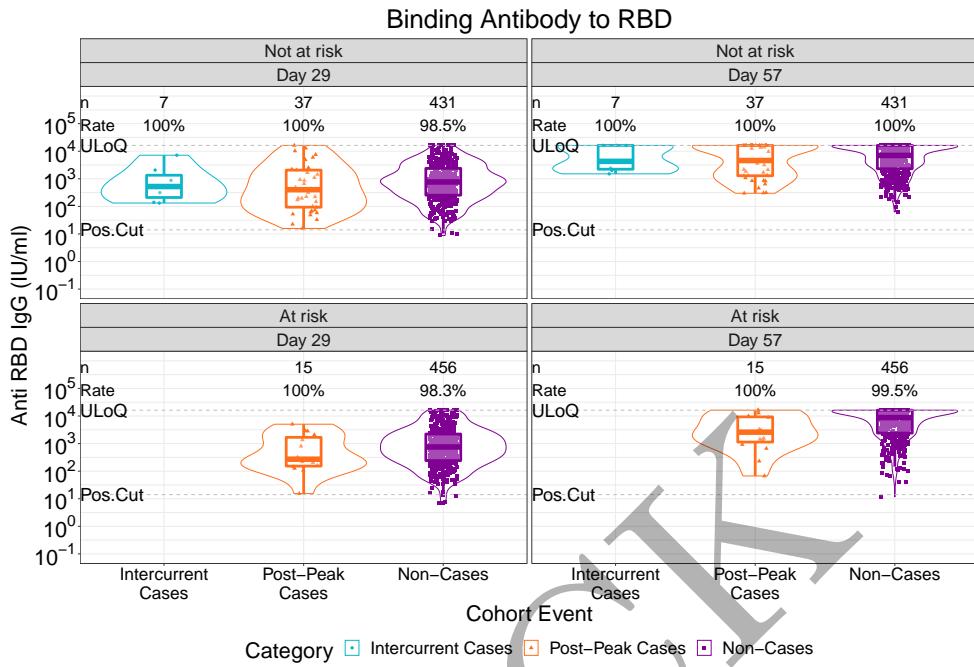


Figure 3.93: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by risk condition (version 1)

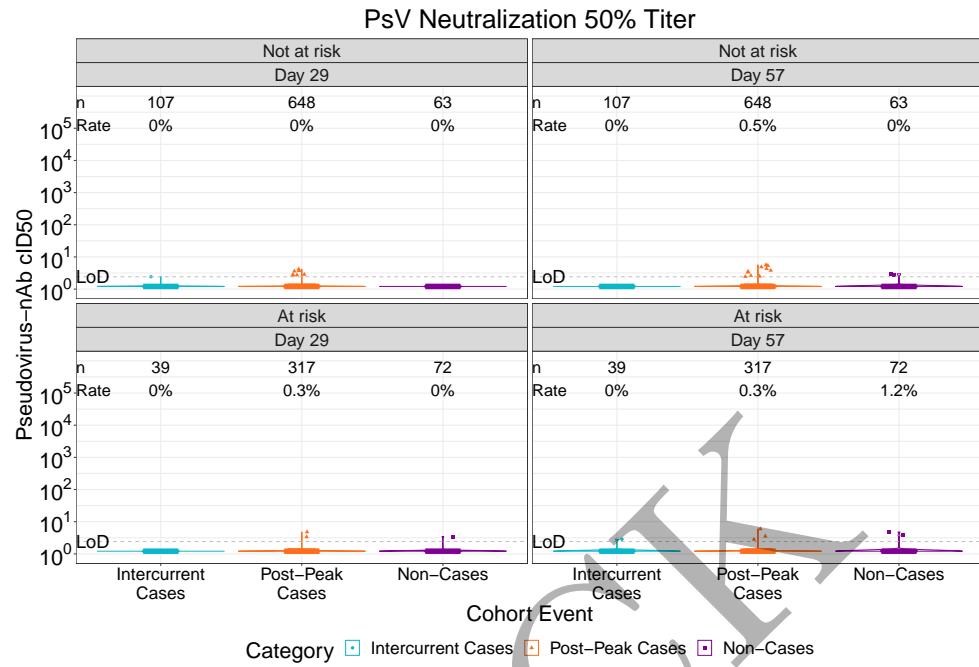


Figure 3.94: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by risk condition (version 1)

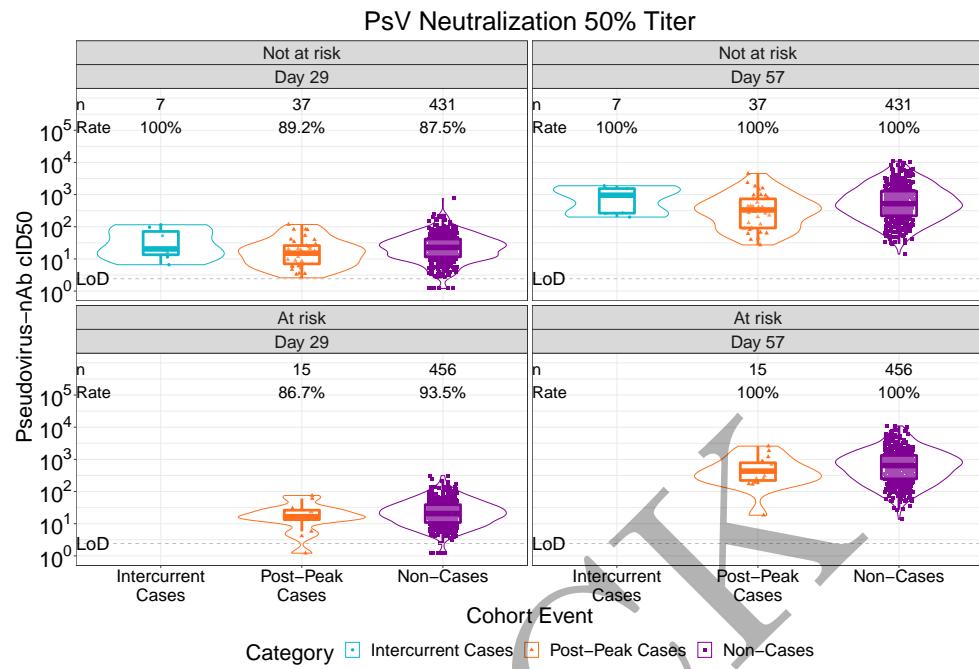


Figure 3.95: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by risk condition (version 1)

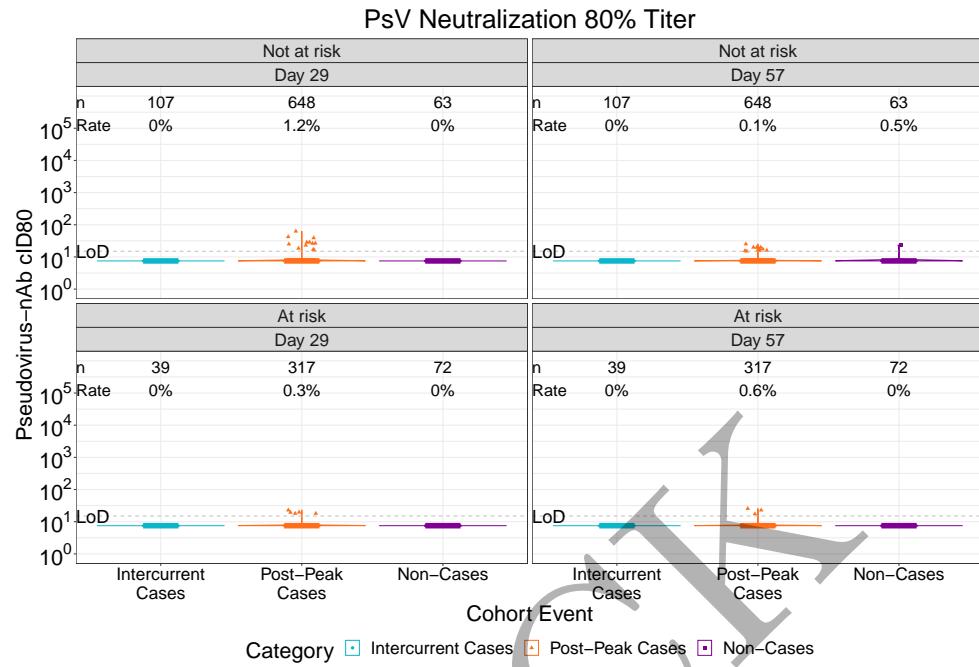


Figure 3.96: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by risk condition (version 1)

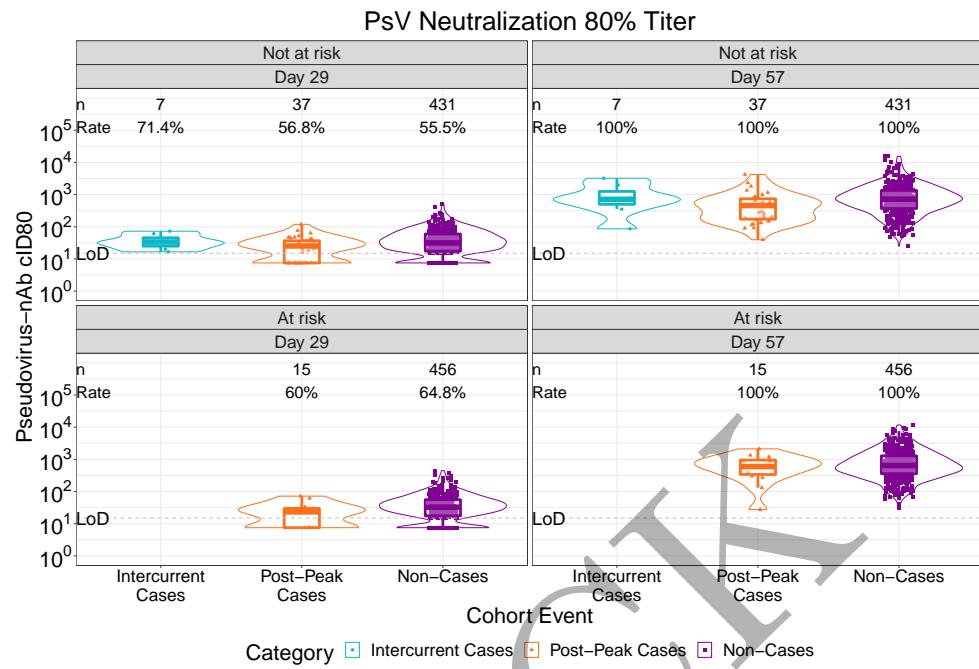
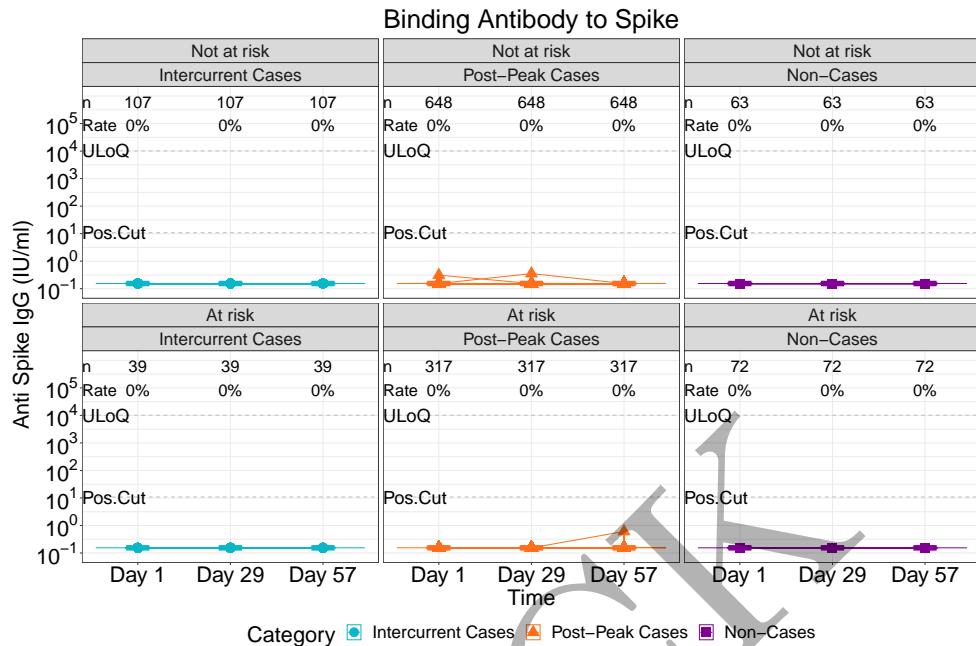


Figure 3.97: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by risk condition (version 1)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.98: lineplots of Binding Antibody to Spike: baseline negative placebo arm by risk condition (version 2)

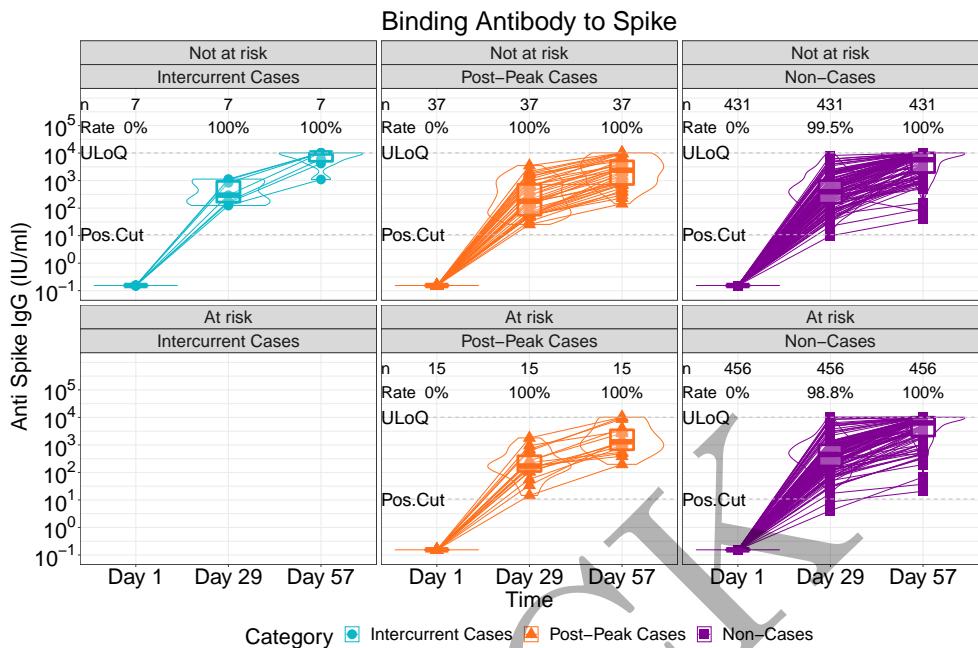
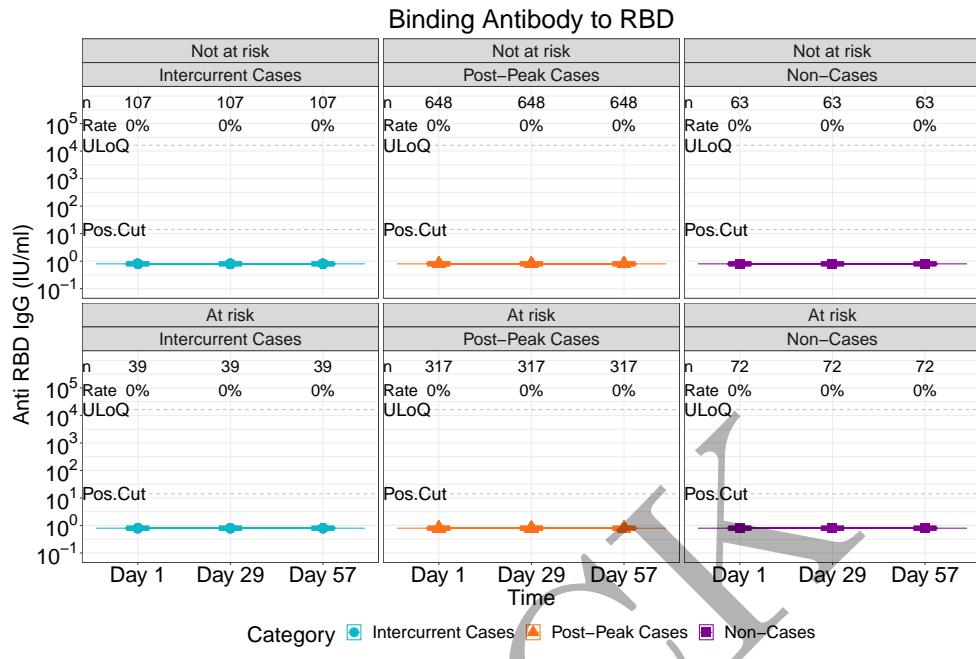
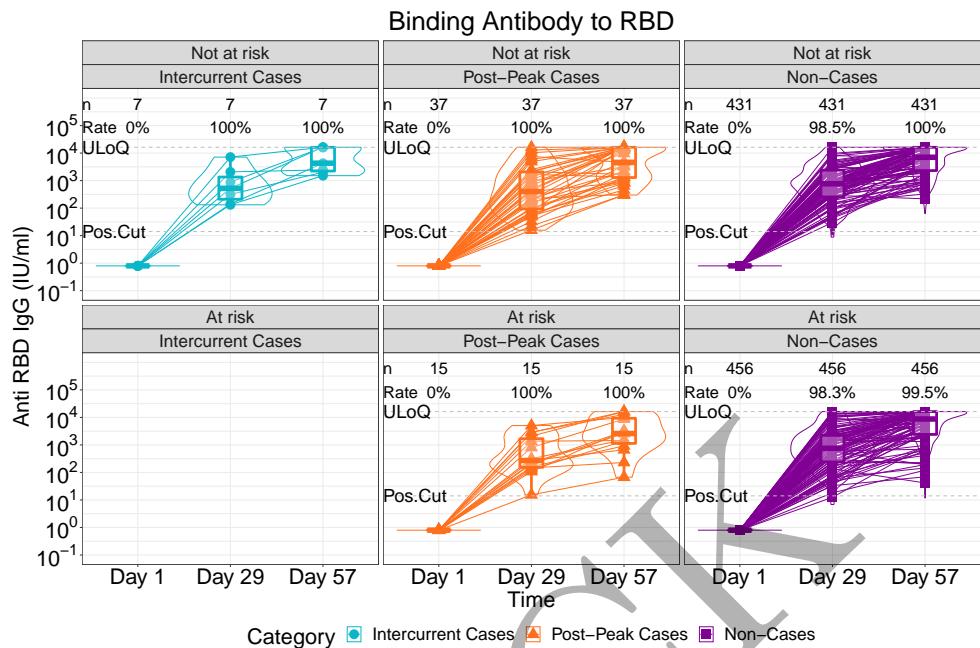


Figure 3.99: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by risk condition (version 2)



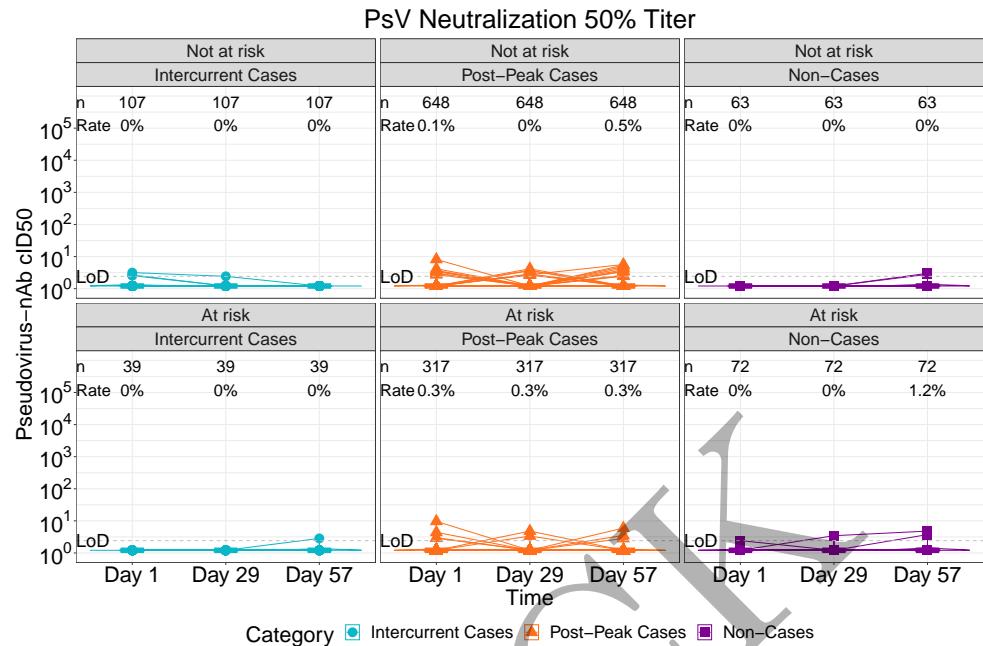
All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.100: lineplots of Binding Antibody to RBD: baseline negative placebo arm by risk condition (version 2)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.101: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by risk condition (version 2)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.102: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by risk condition (version 2)

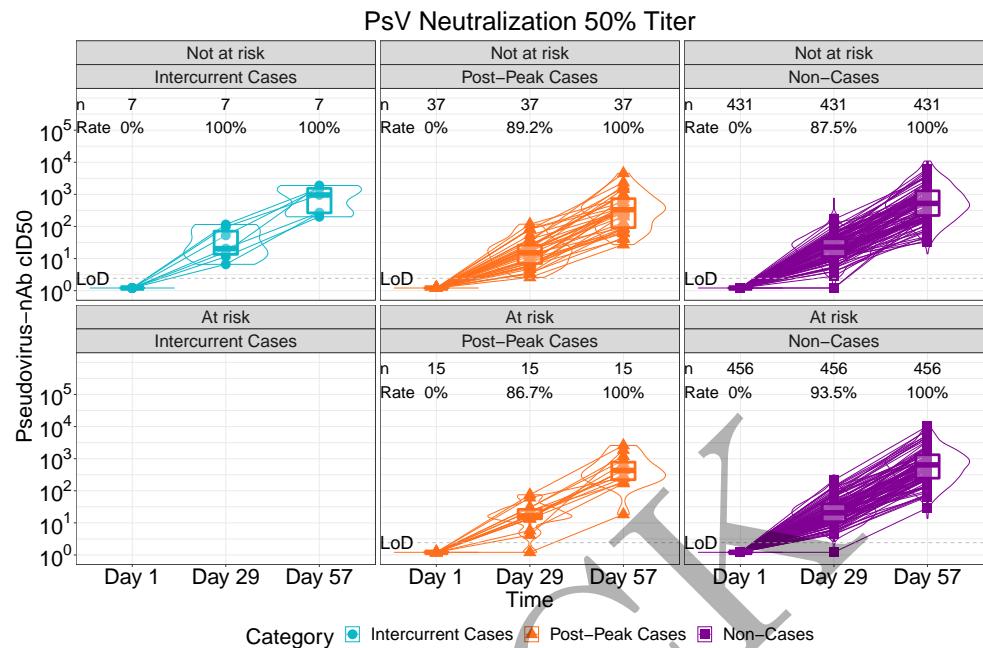
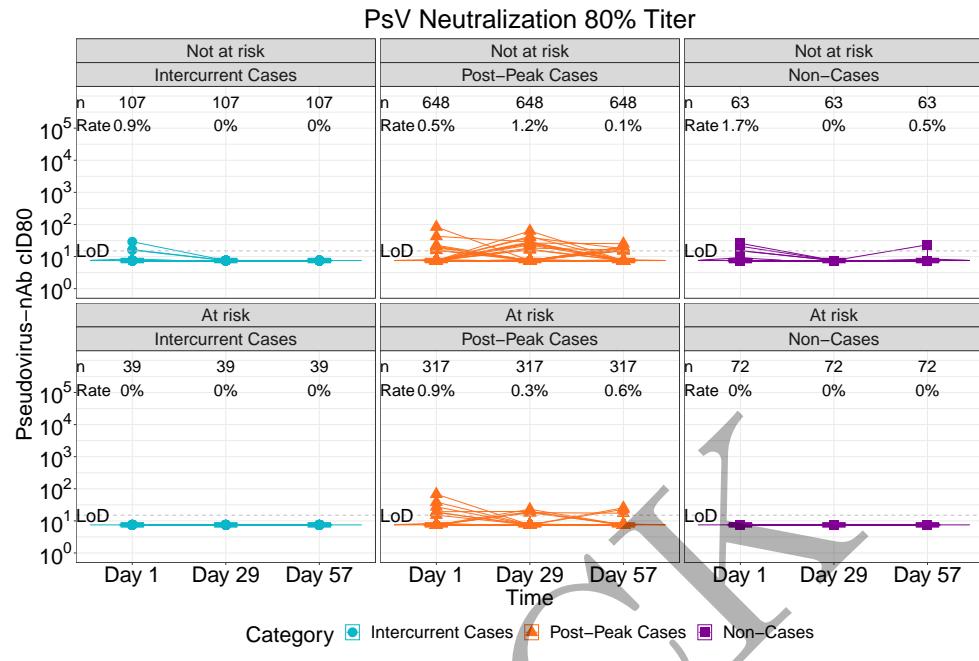


Figure 3.103: lineplots of Pseudovirus Neutralization ID₅₀: baseline negative vaccine arm by risk condition (version 2)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.104: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by risk condition (version 2)

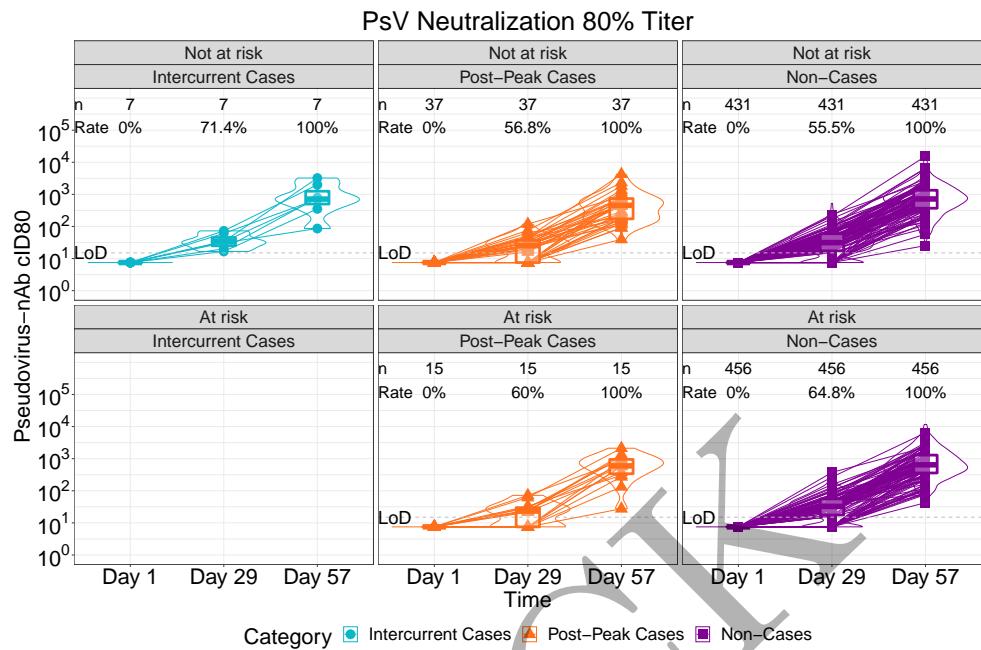


Figure 3.105: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by risk condition (version 2)

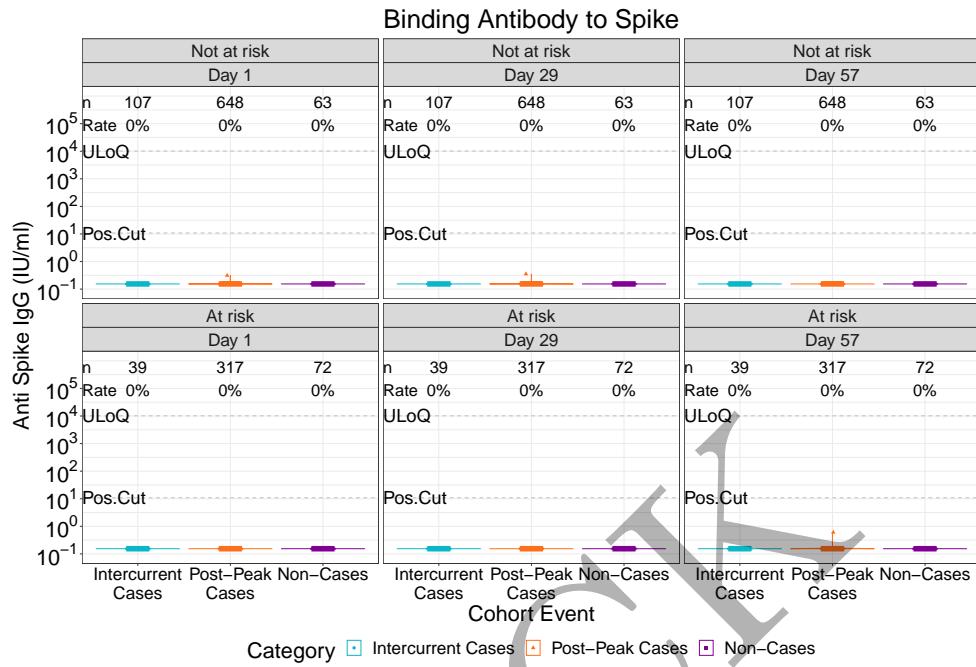


Figure 3.106: violinplots of Binding Antibody to Spike: baseline negative placebo arm by risk condition (version 2)

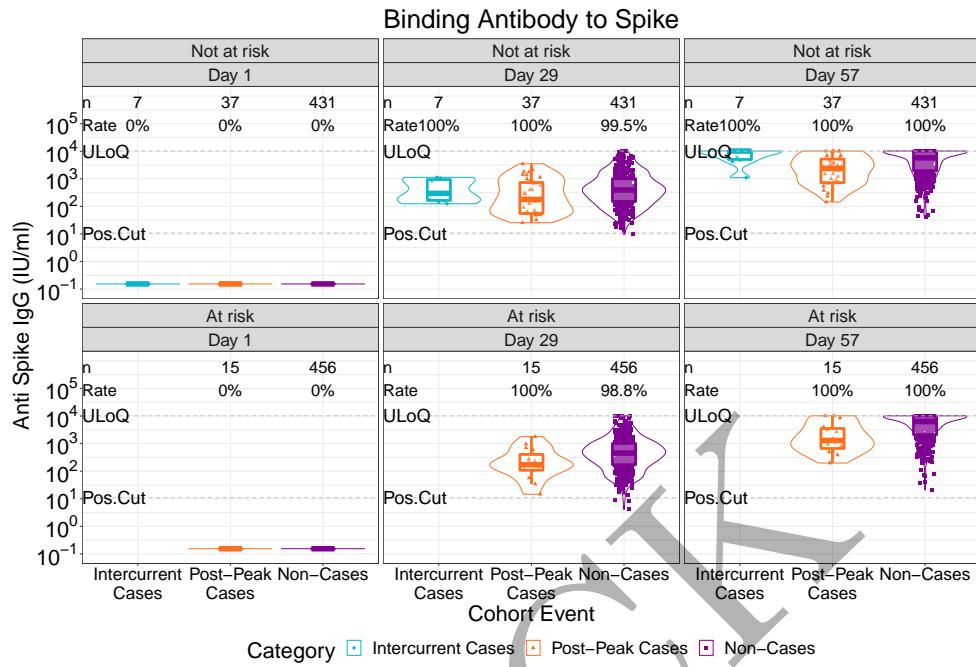


Figure 3.107: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by risk condition (version 2)

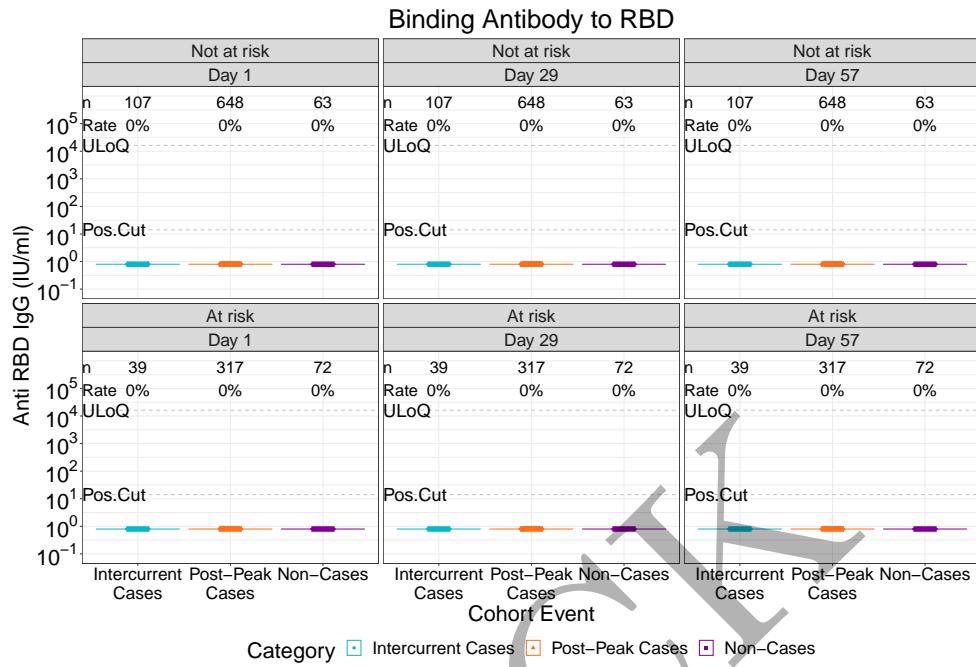


Figure 3.108: violinplots of Binding Antibody to RBD: baseline negative placebo arm by risk condition (version 2)

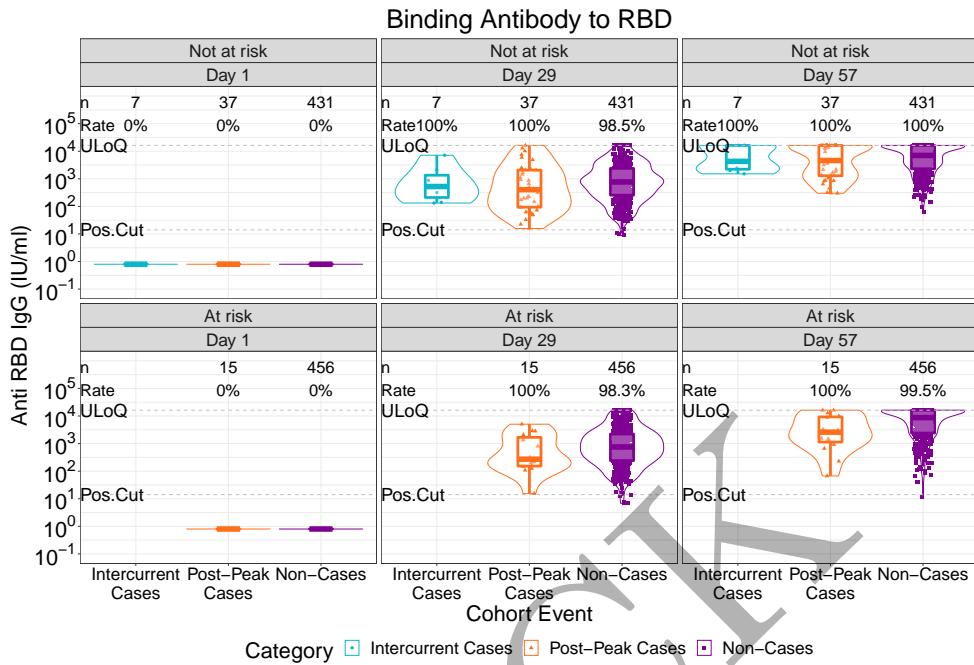


Figure 3.109: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by risk condition (version 2)

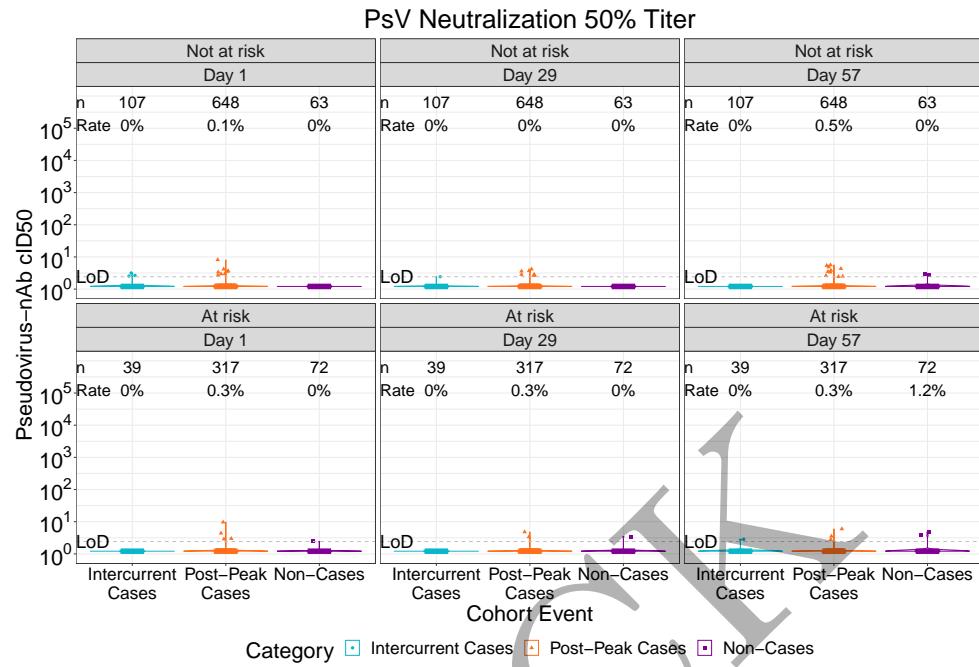


Figure 3.110: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by risk condition (version 2)

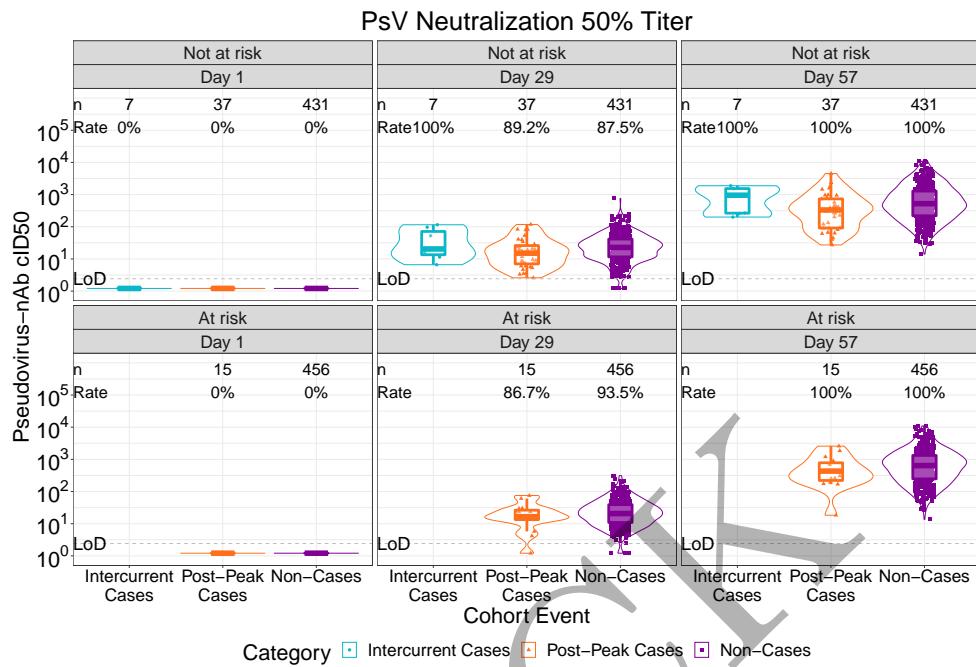


Figure 3.111: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by risk condition (version 2)

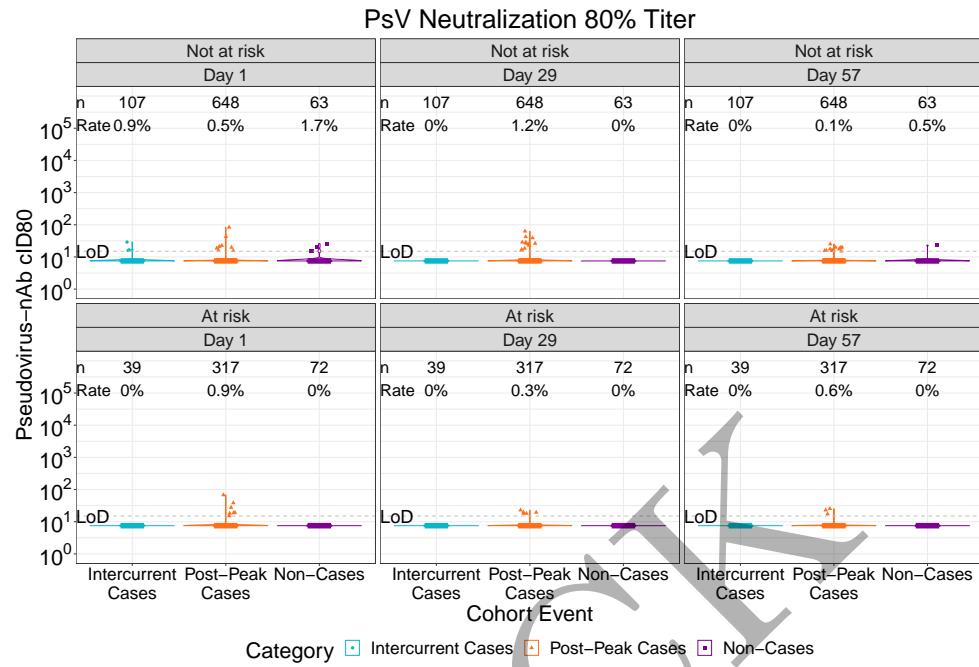


Figure 3.112: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by risk condition (version 2)

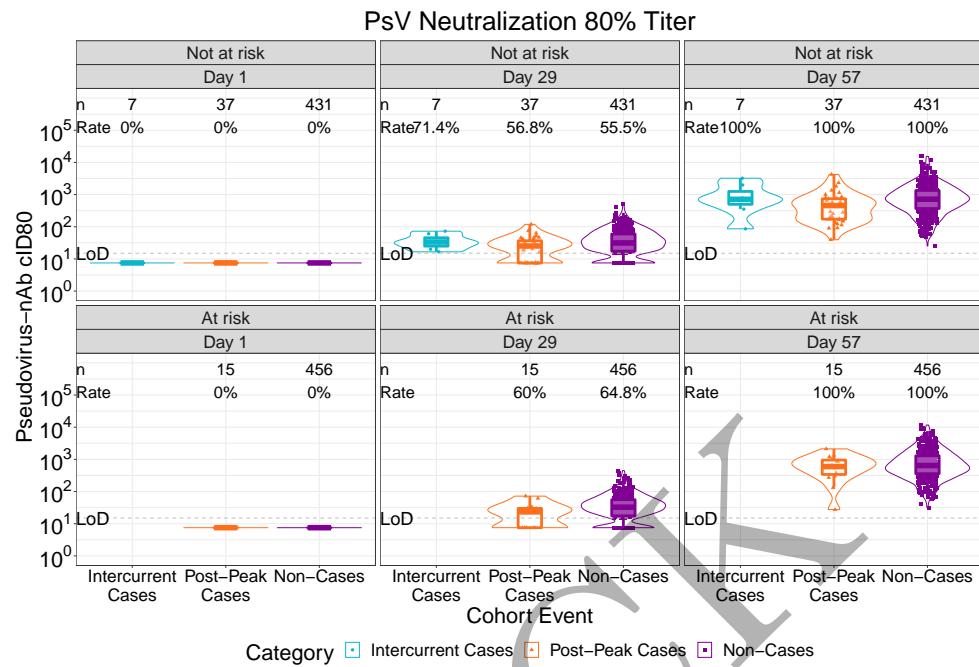


Figure 3.113: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by risk condition (version 2)

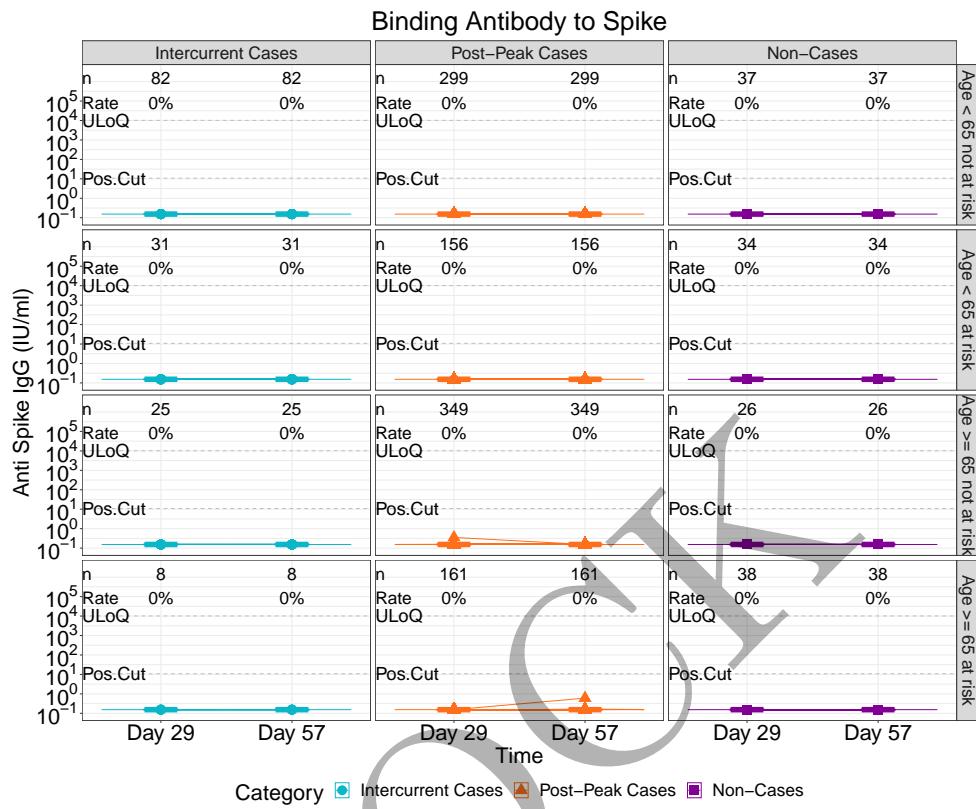
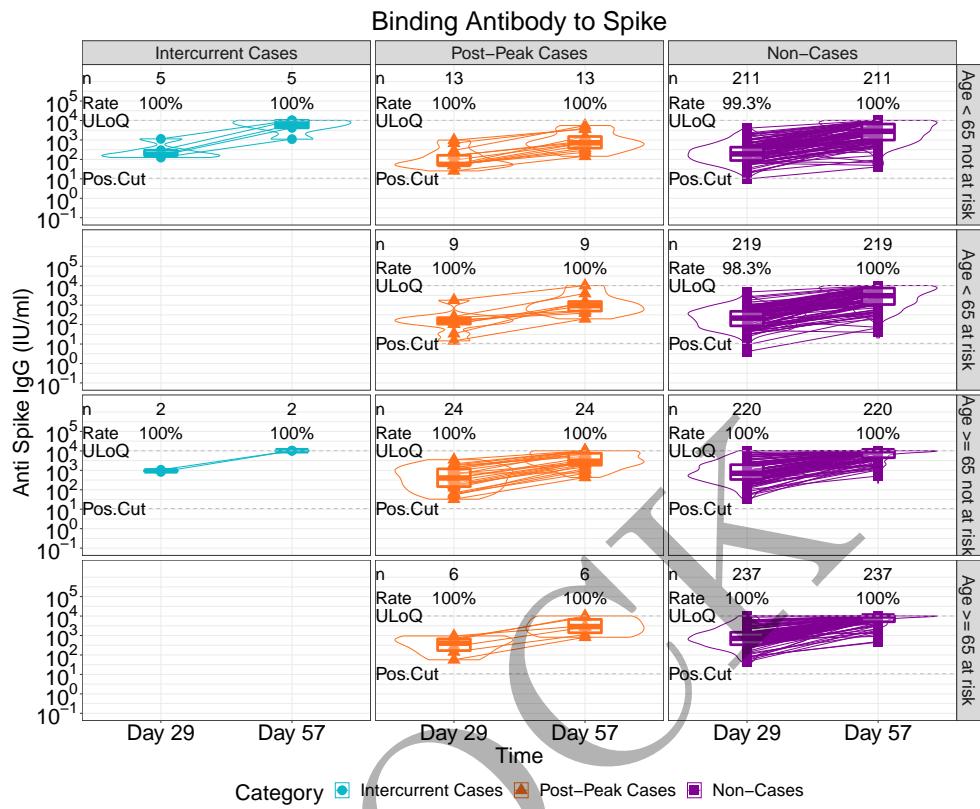


Figure 3.114: lineplots of Binding Antibody to Spike: baseline negative placebo arm by age and risk condition (version 1)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger

Figure 3.115: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by age and risk condition (version 1)

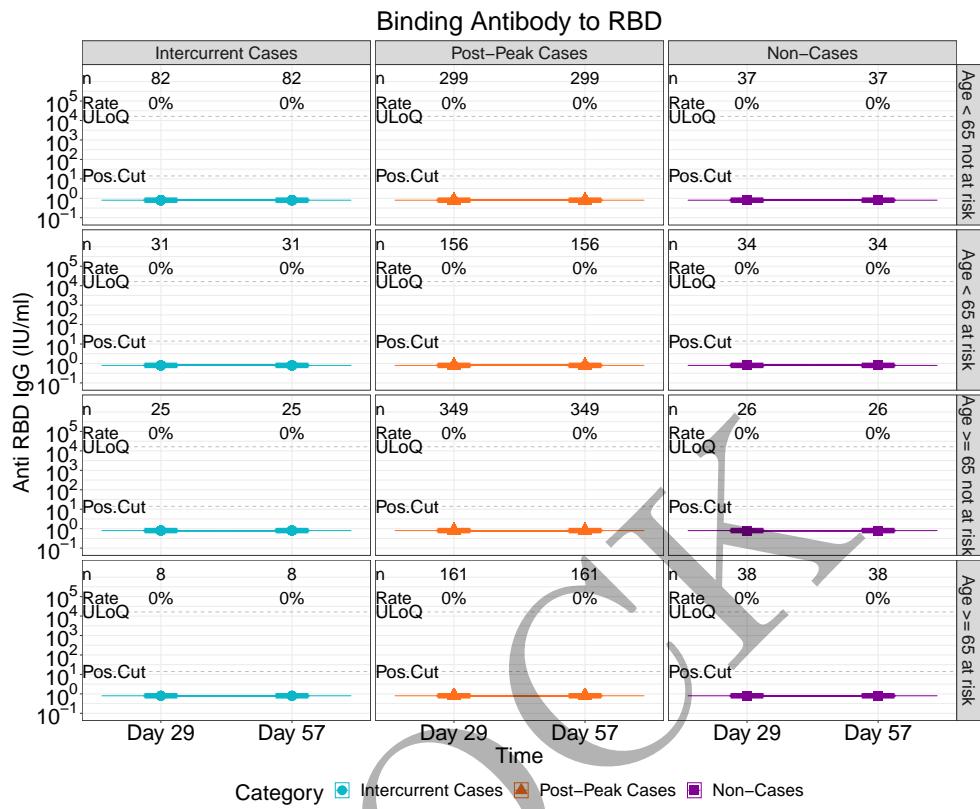


Figure 3.116: lineplots of Binding Antibody to RBD: baseline negative placebo arm by age and risk condition (version 1)

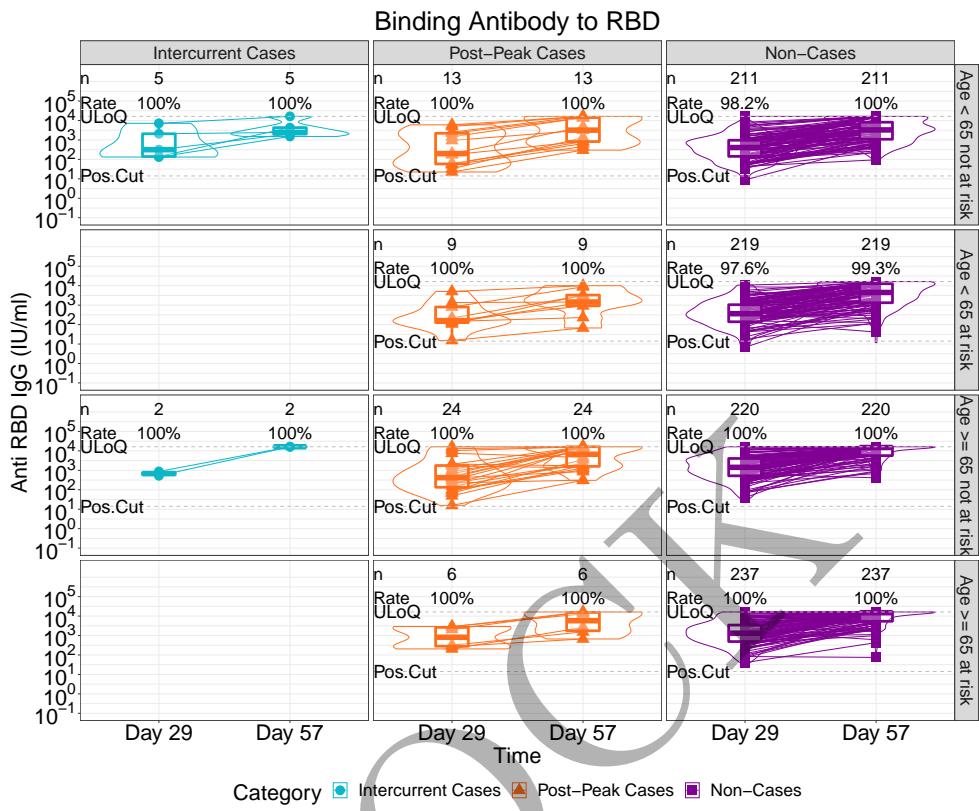
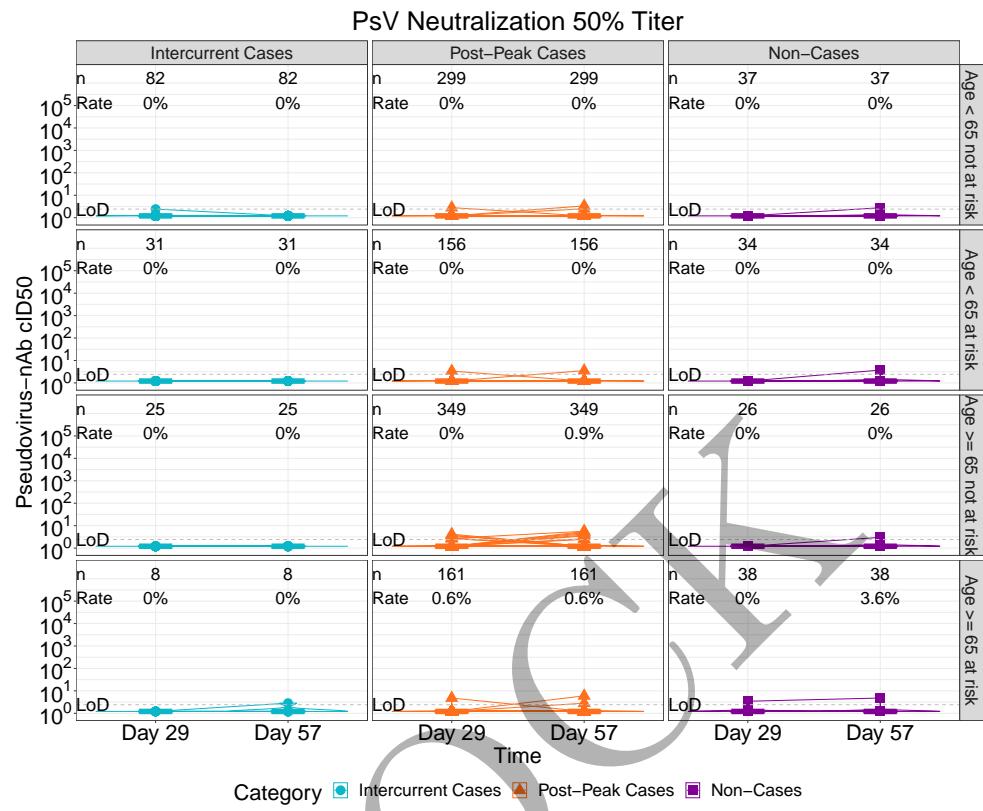
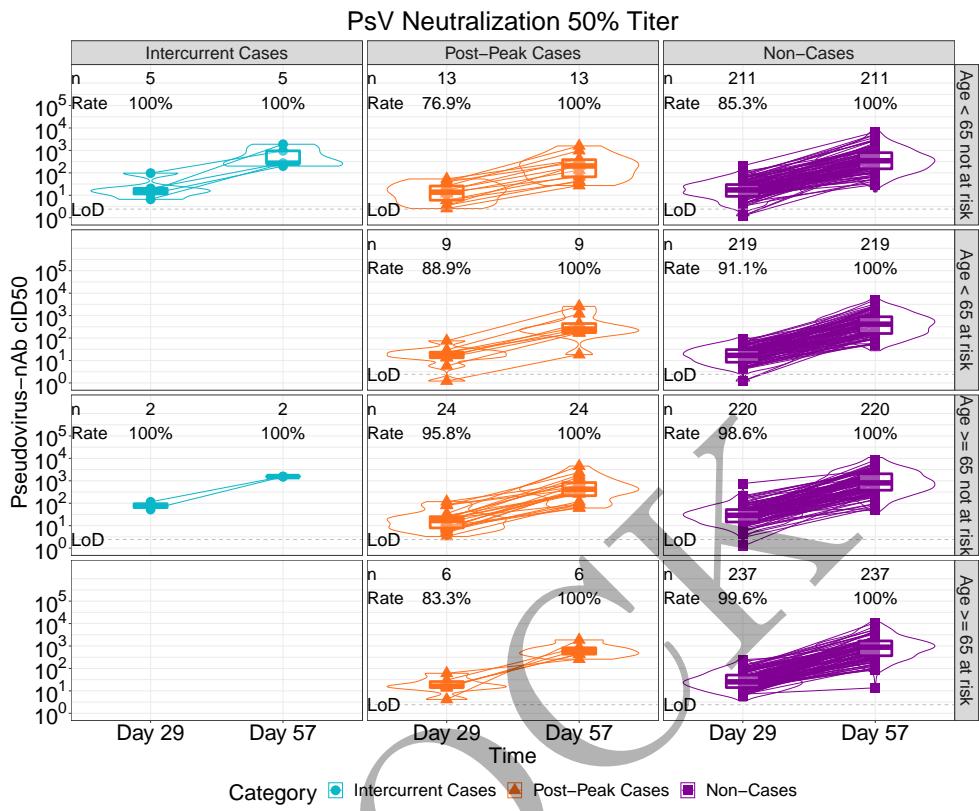


Figure 3.117: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by age and risk condition (version 1)



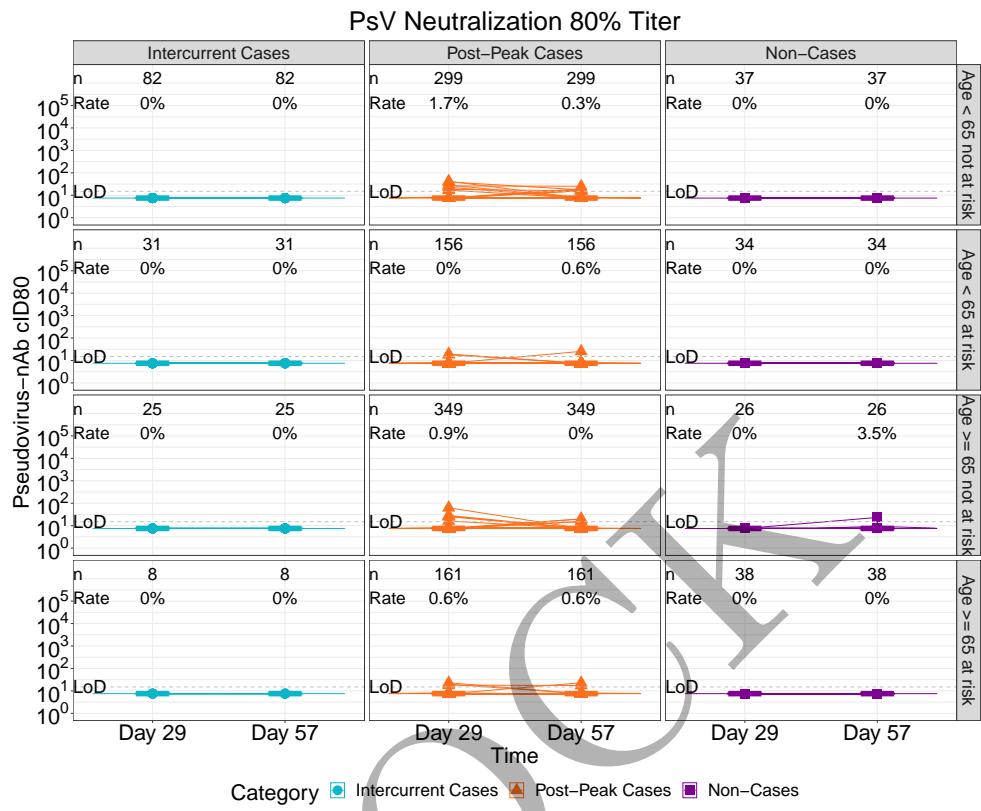
All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.118: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age and risk condition (version 1)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.119: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age and risk condition (version 1)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.120: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age and risk condition (version 1)

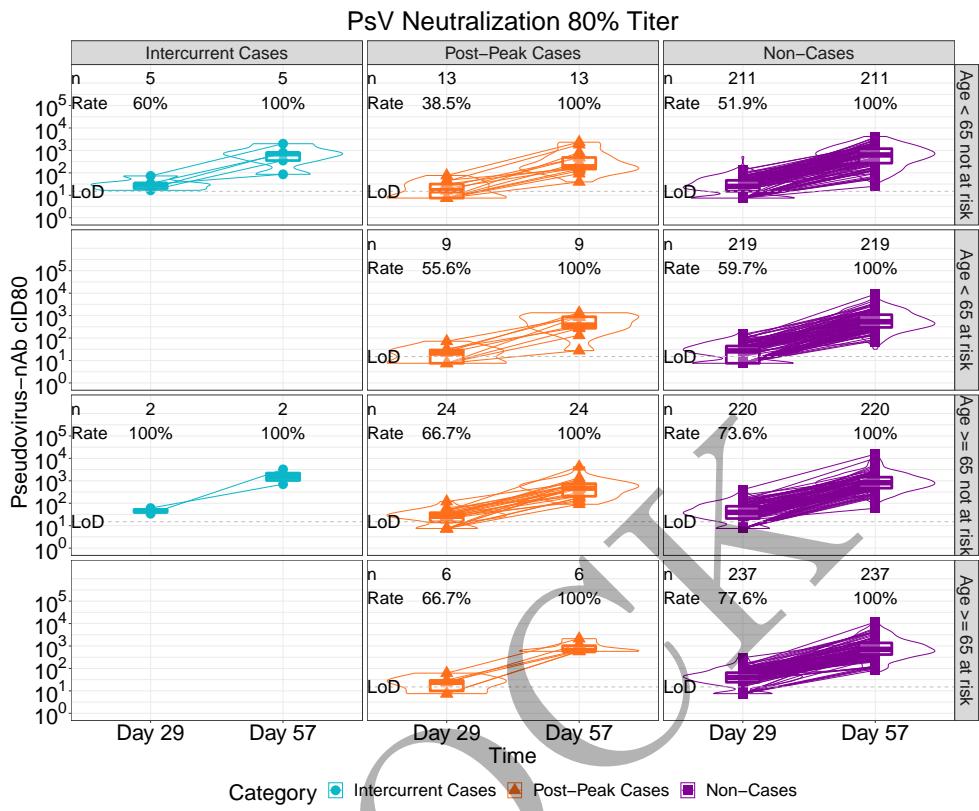


Figure 3.121: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age and risk condition (version 1)

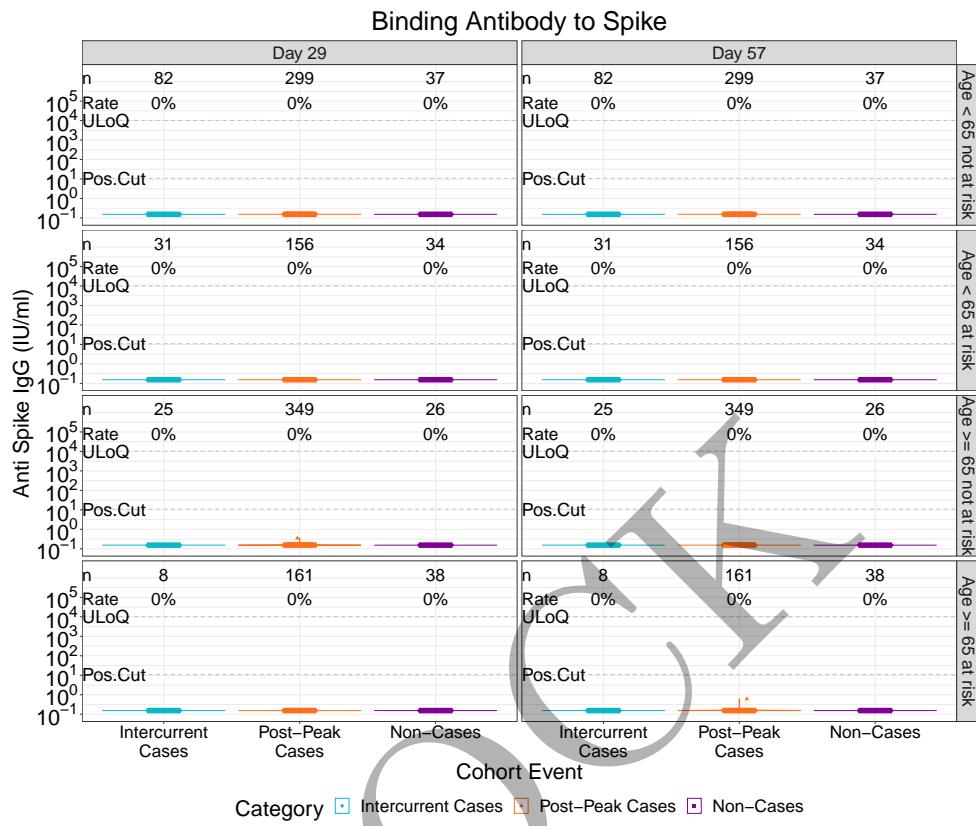


Figure 3.122: violinplots of Binding Antibody to Spike: baseline negative placebo arm by age and risk condition (version 1)

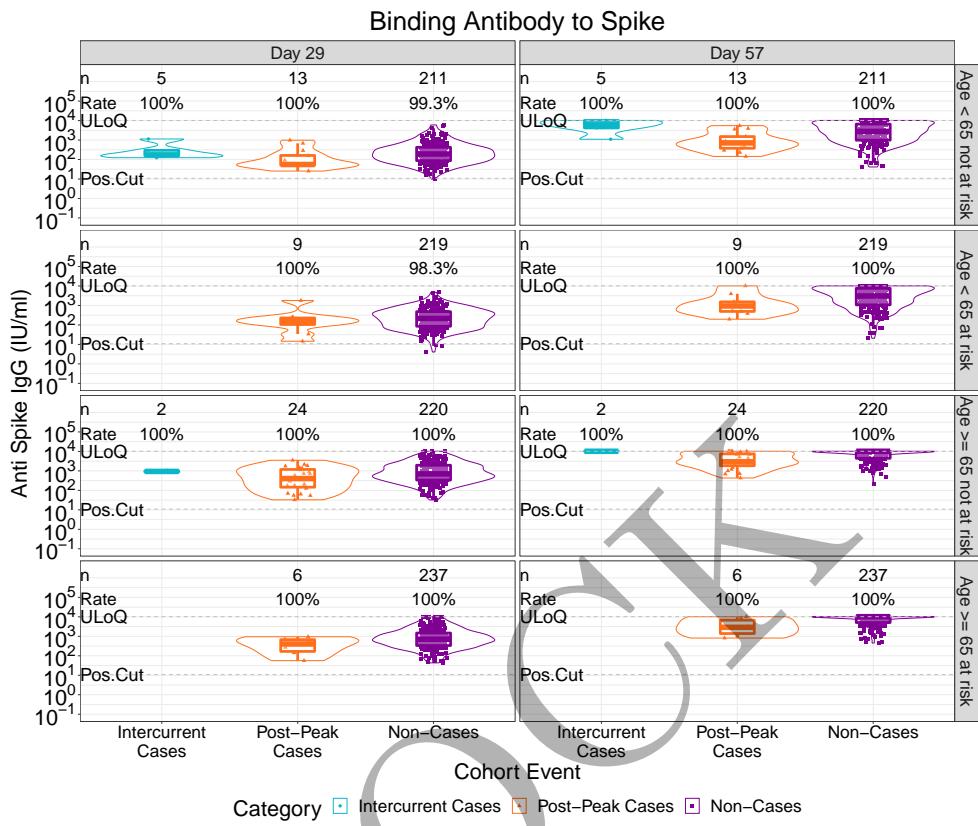


Figure 3.123: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by age and risk condition (version 1)

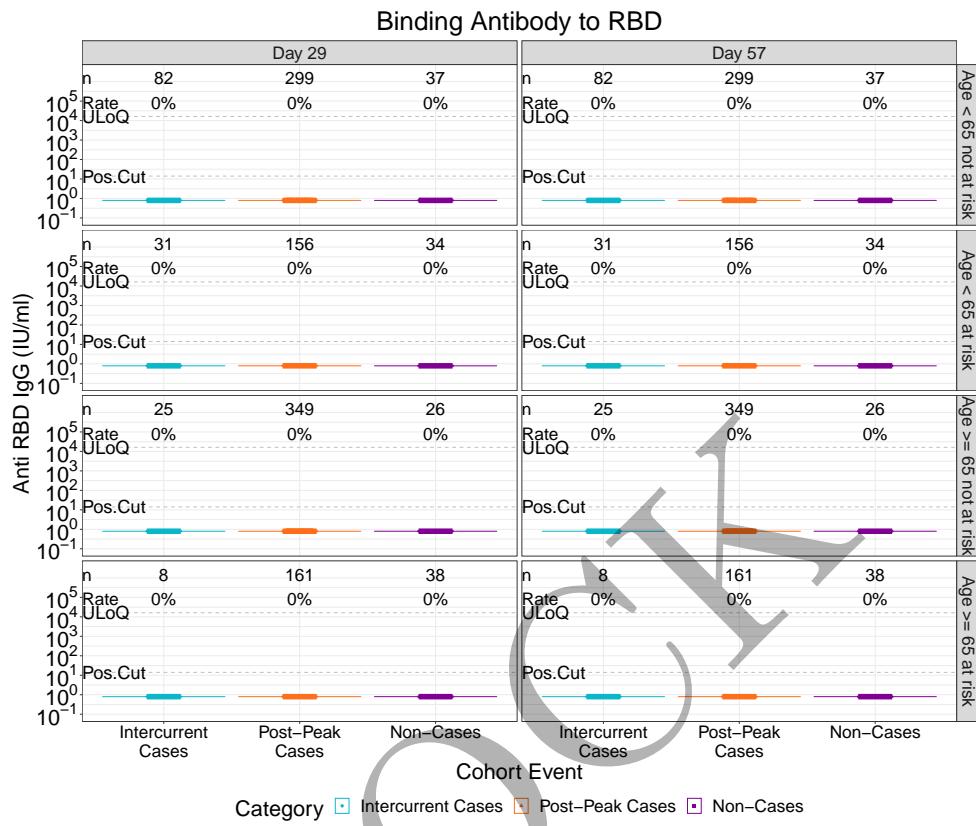


Figure 3.124: violinplots of Binding Antibody to RBD: baseline negative placebo arm by age and risk condition (version 1)

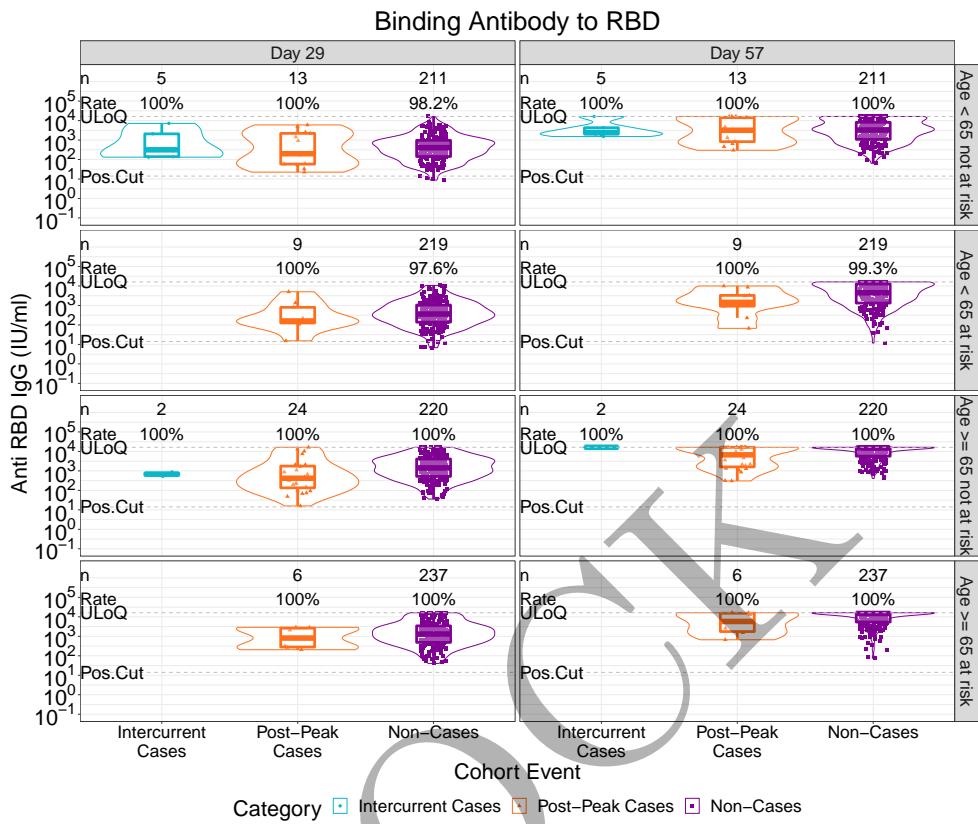


Figure 3.125: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by age and risk condition (version 1)

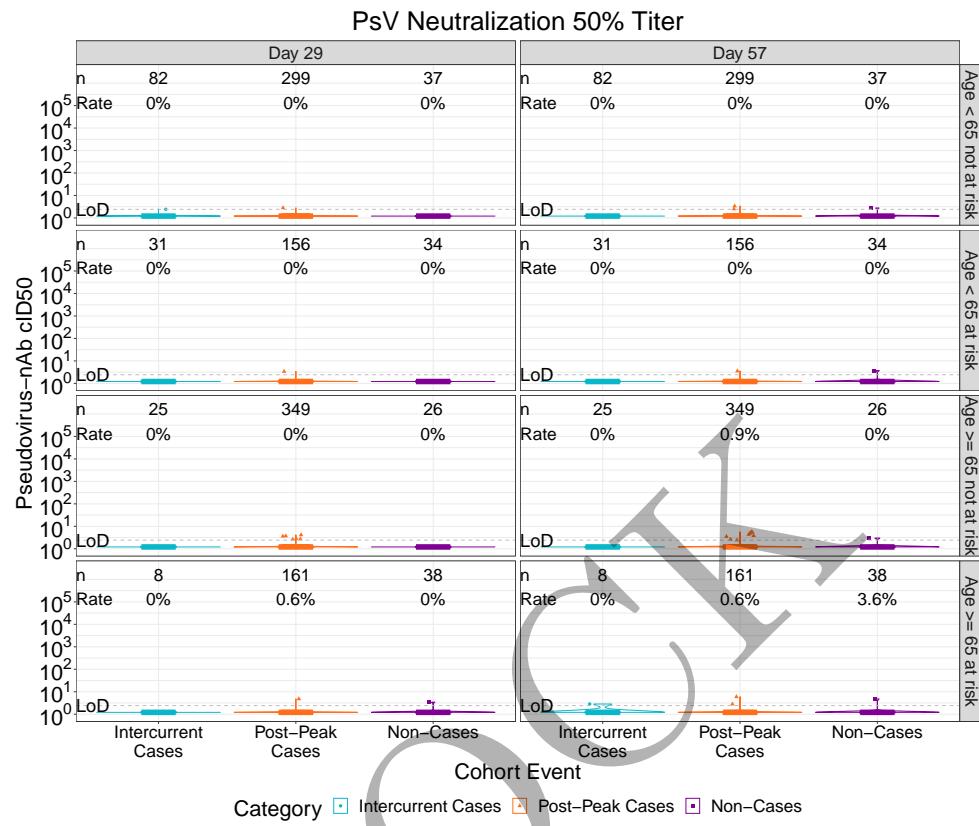


Figure 3.126: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age and risk condition (version 1)

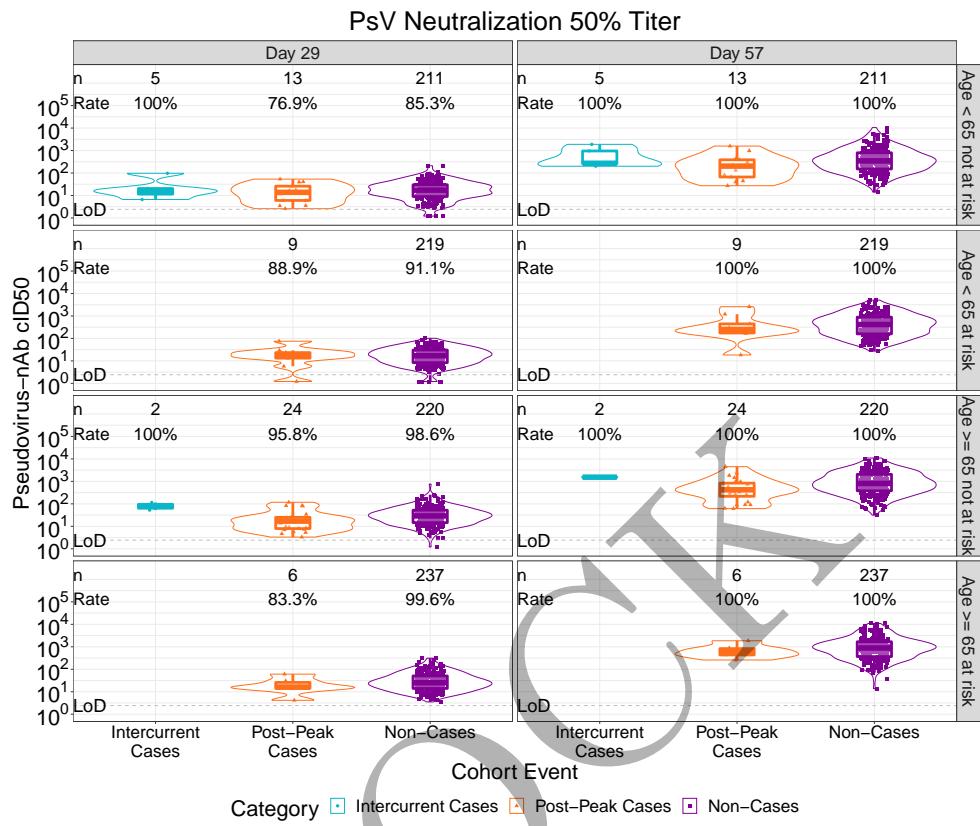


Figure 3.127: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age and risk condition (version 1)

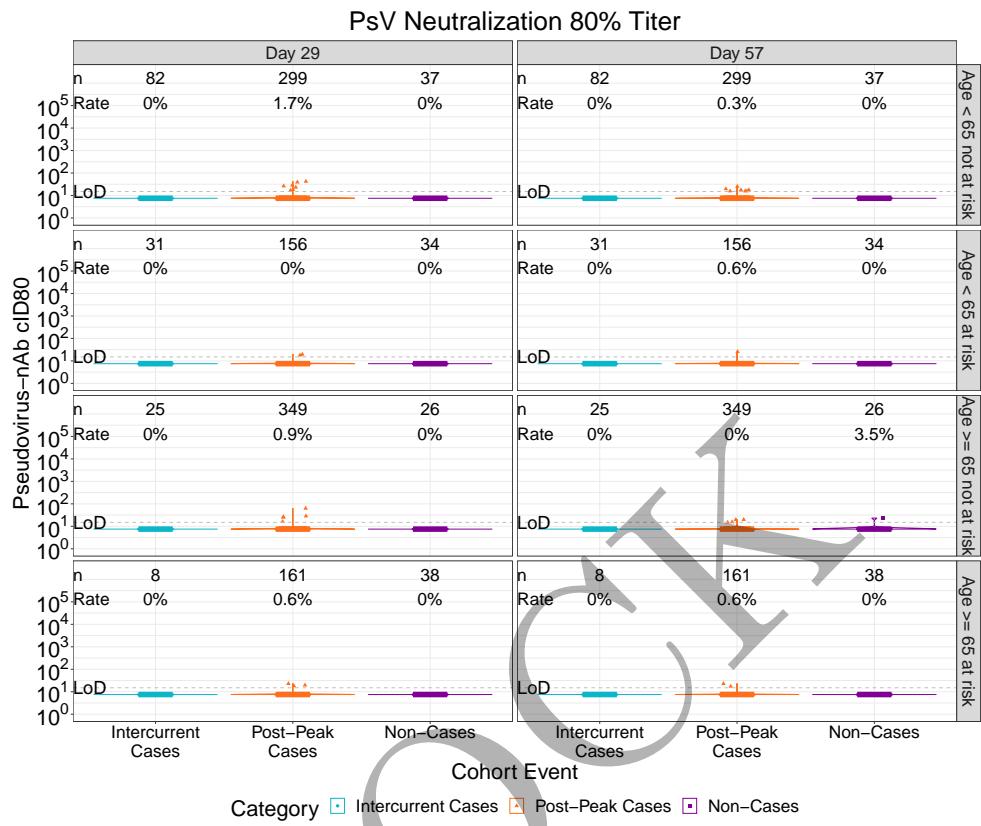


Figure 3.128: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age and risk condition (version 1)

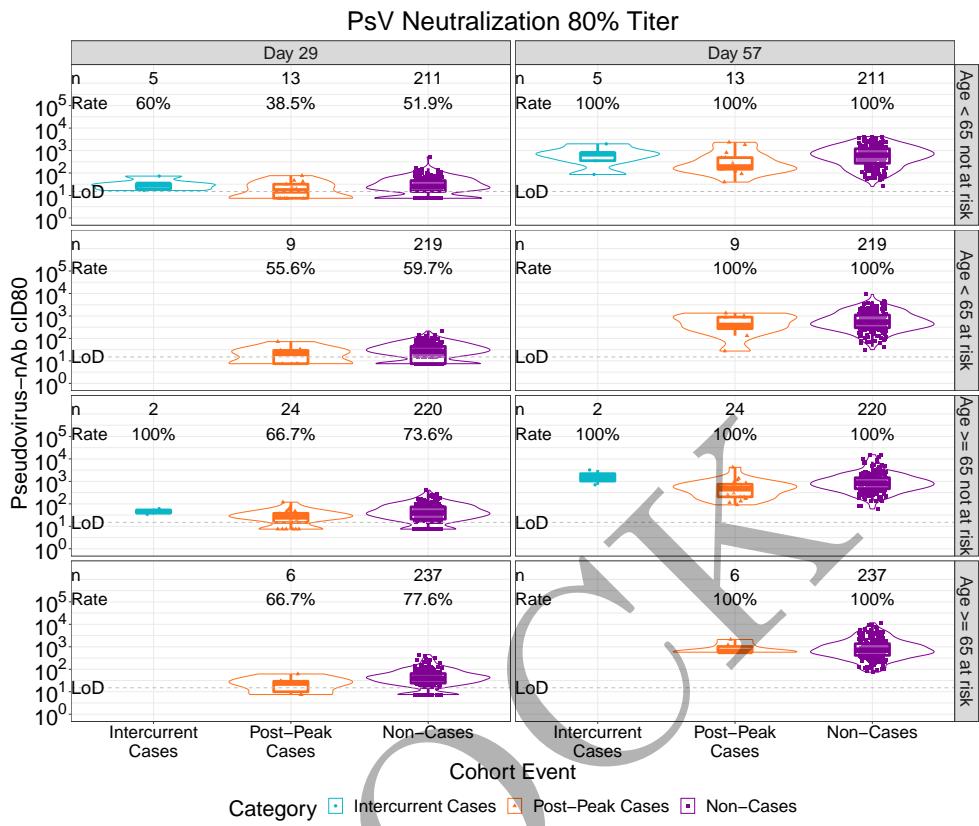
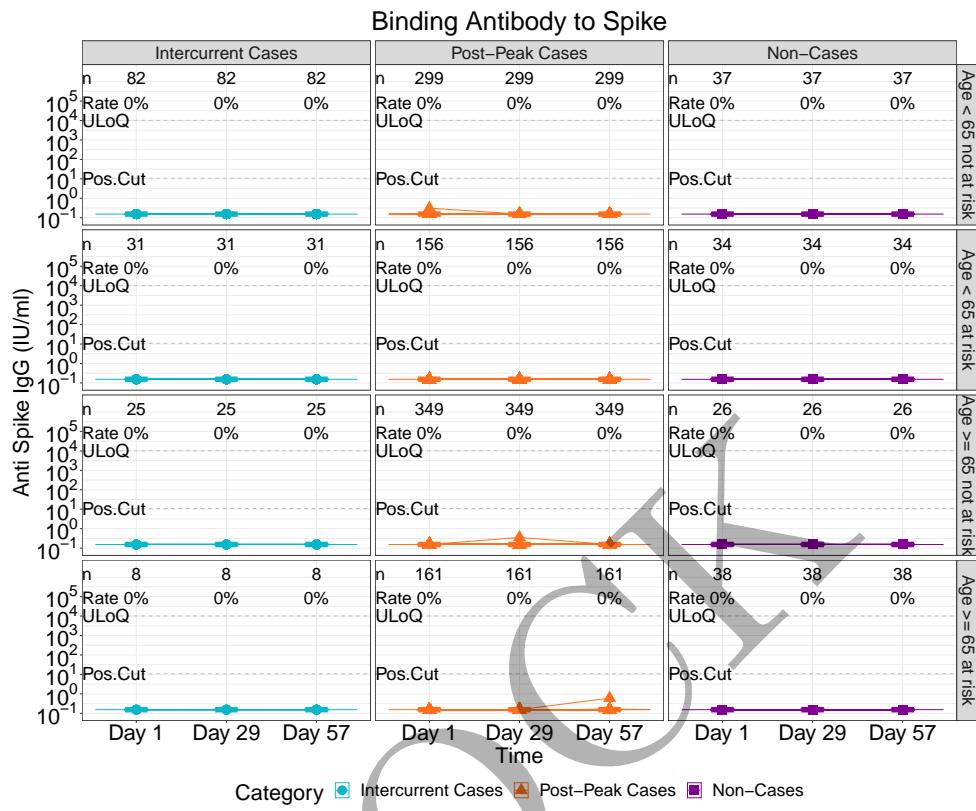
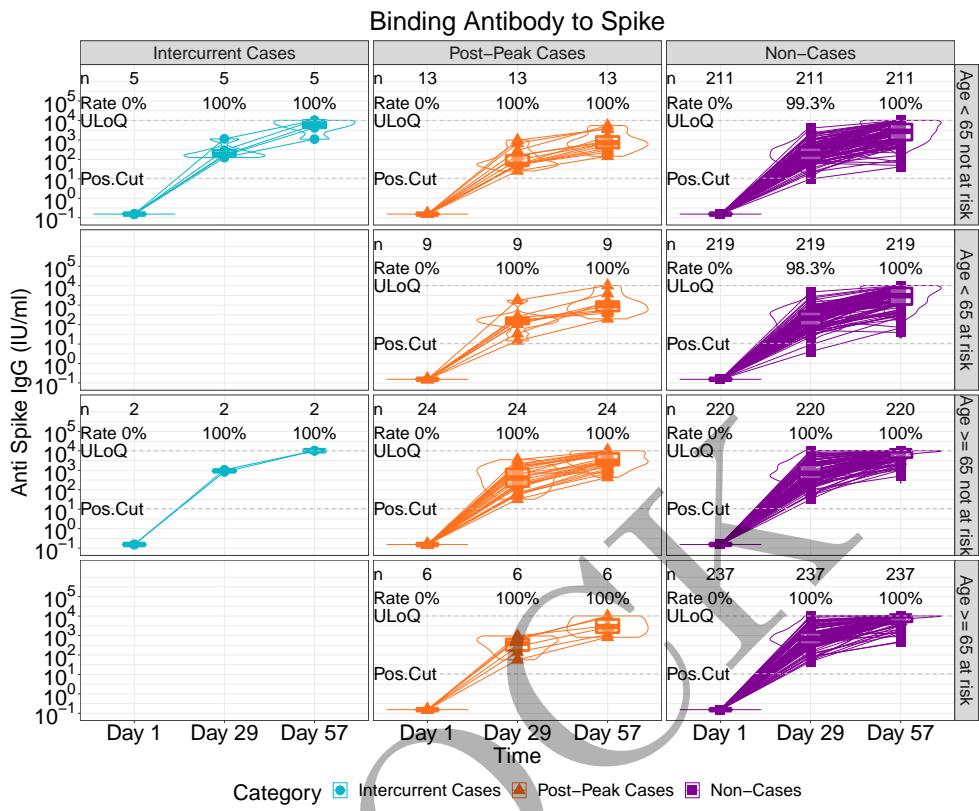


Figure 3.129: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age and risk condition (version 1)



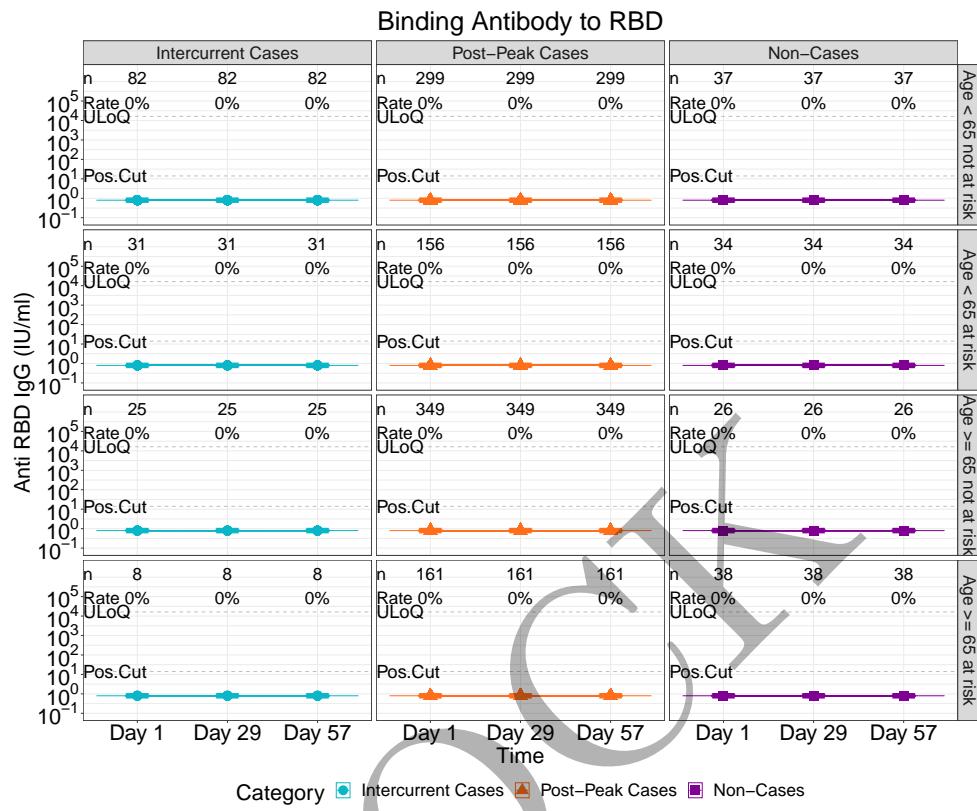
All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.130: lineplots of Binding Antibody to Spike: baseline negative placebo arm by age and risk condition (version 2)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.131: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by age and risk condition (version 2)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger

Figure 3.132: lineplots of Binding Antibody to RBD: baseline negative placebo arm by age and risk condition (version 2)

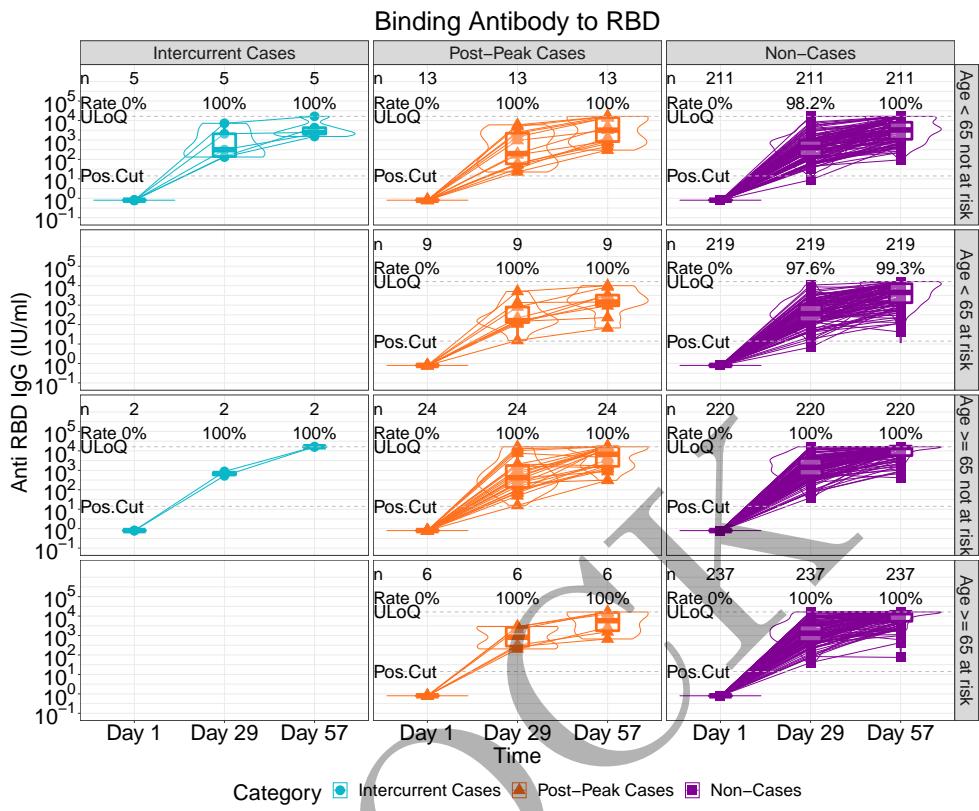


Figure 3.133: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by age and risk condition (version 2)

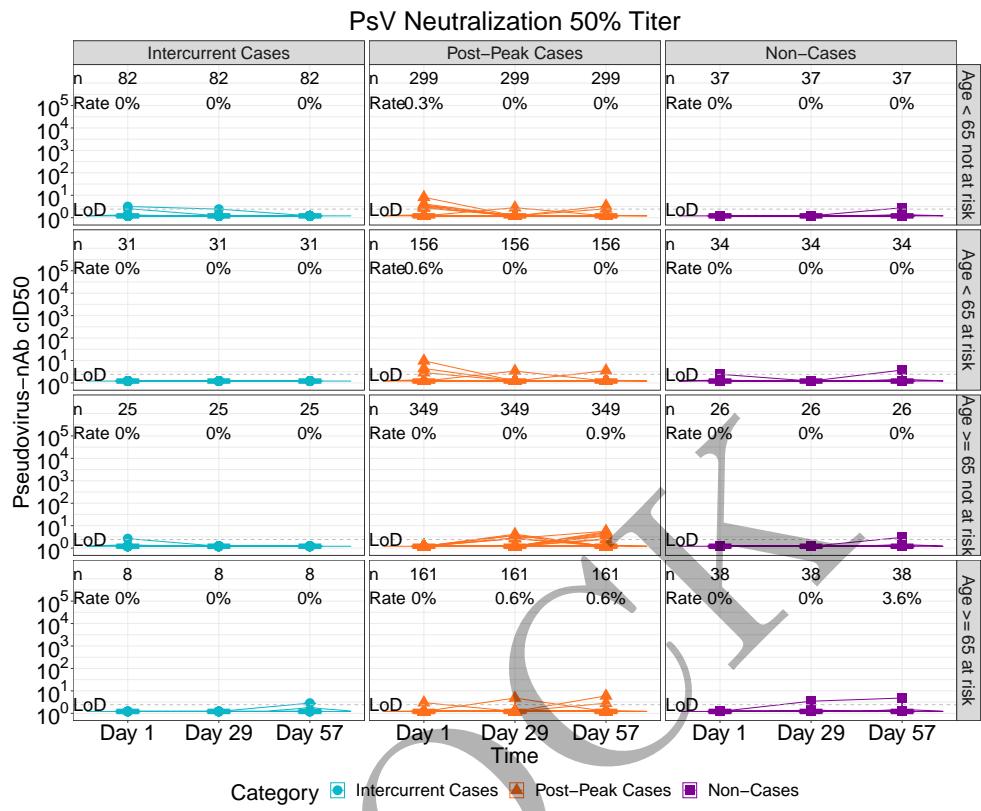
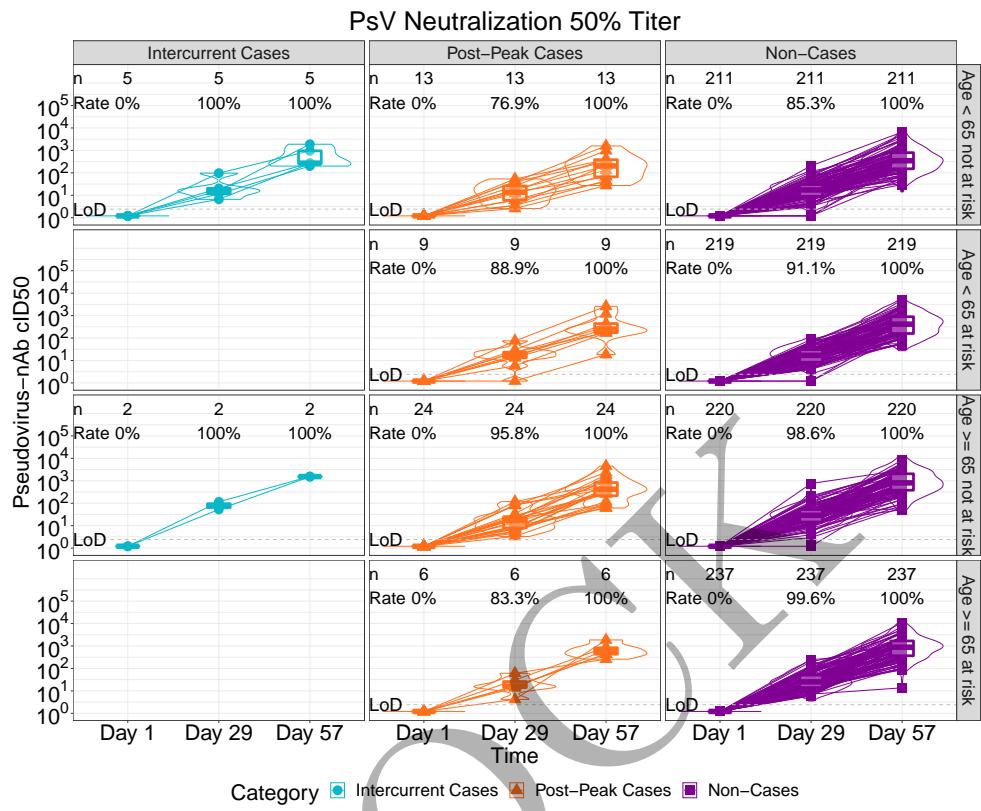
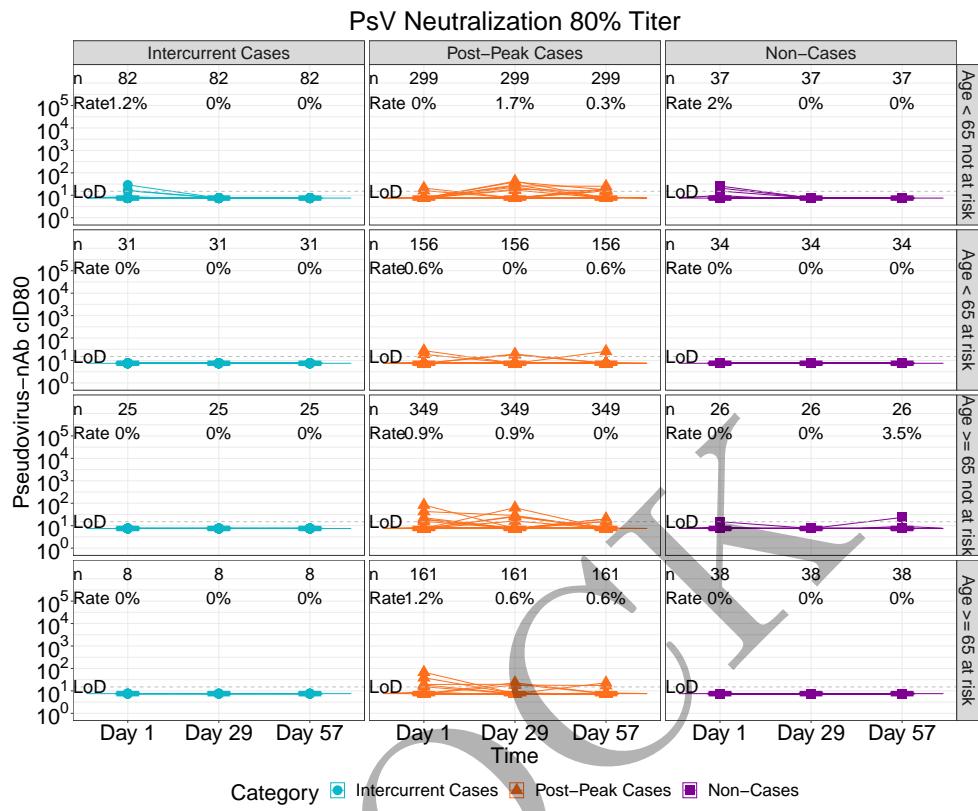


Figure 3.134: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age and risk condition (version 2)



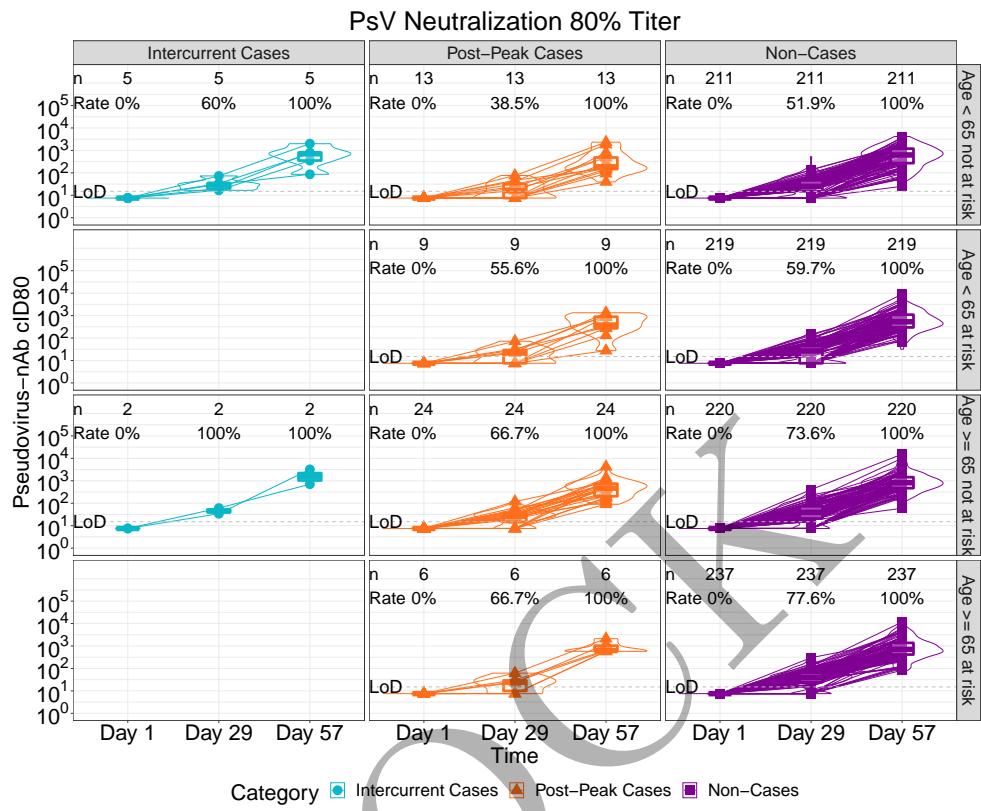
All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.135: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age and risk condition (version 2)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.136: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age and risk condition (version 2)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.137: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age and risk condition (version 2)

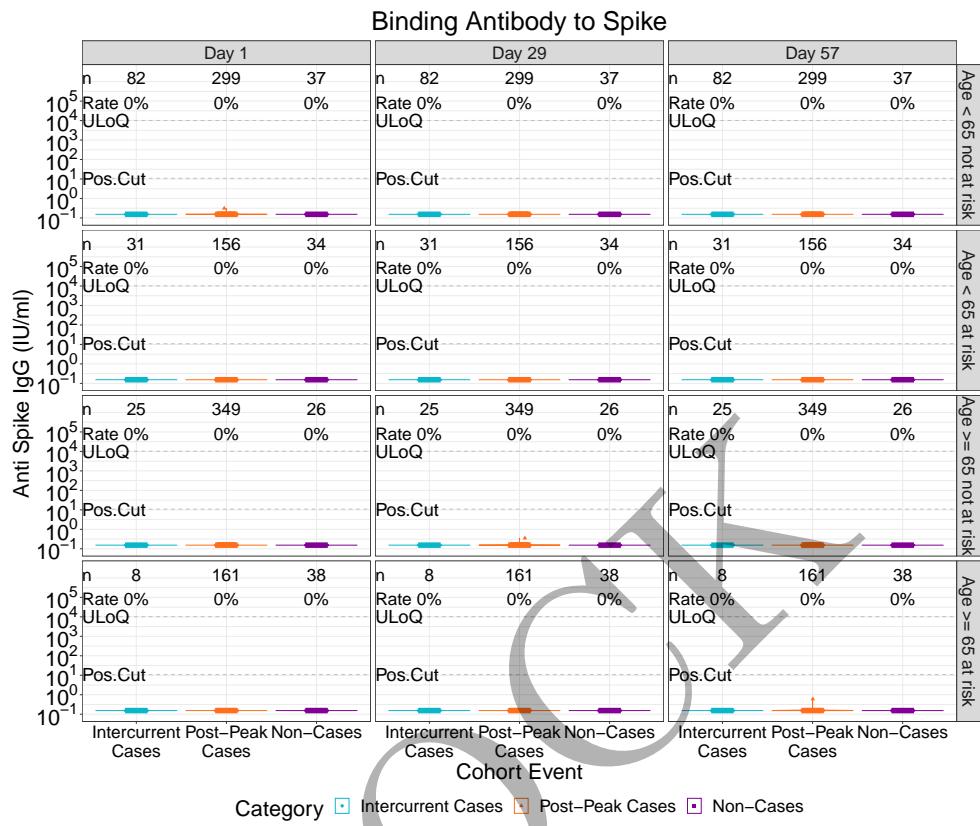


Figure 3.138: violinplots of Binding Antibody to Spike: baseline negative placebo arm by age and risk condition (version 2)

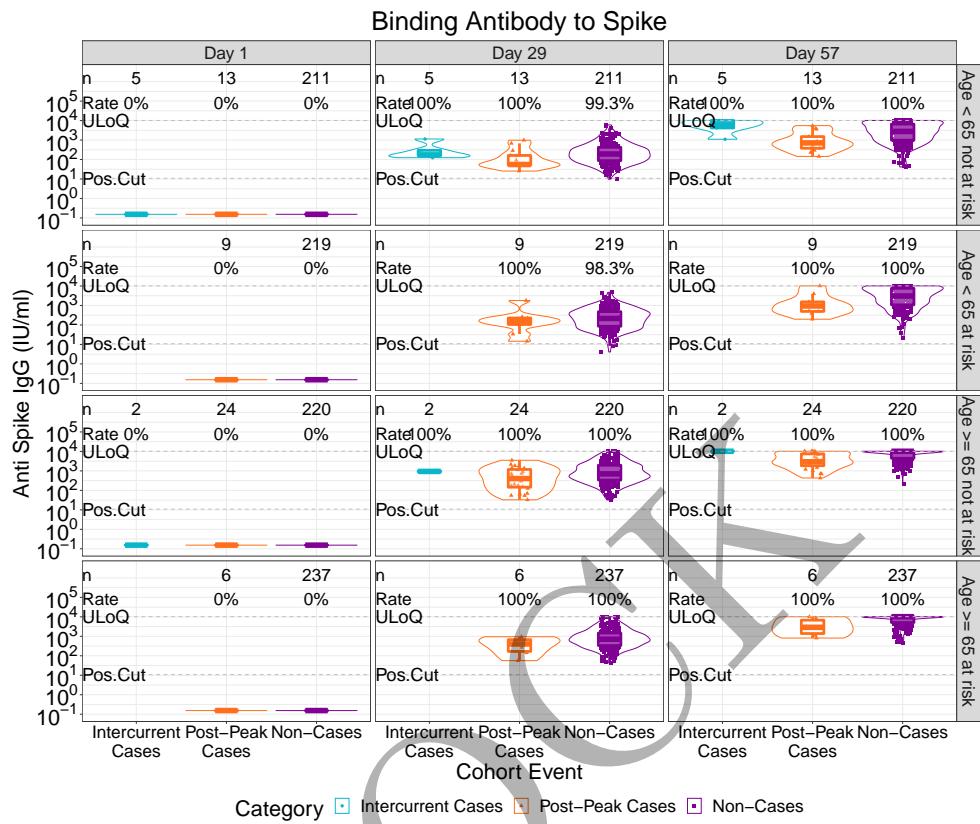


Figure 3.139: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by age and risk condition (version 2)

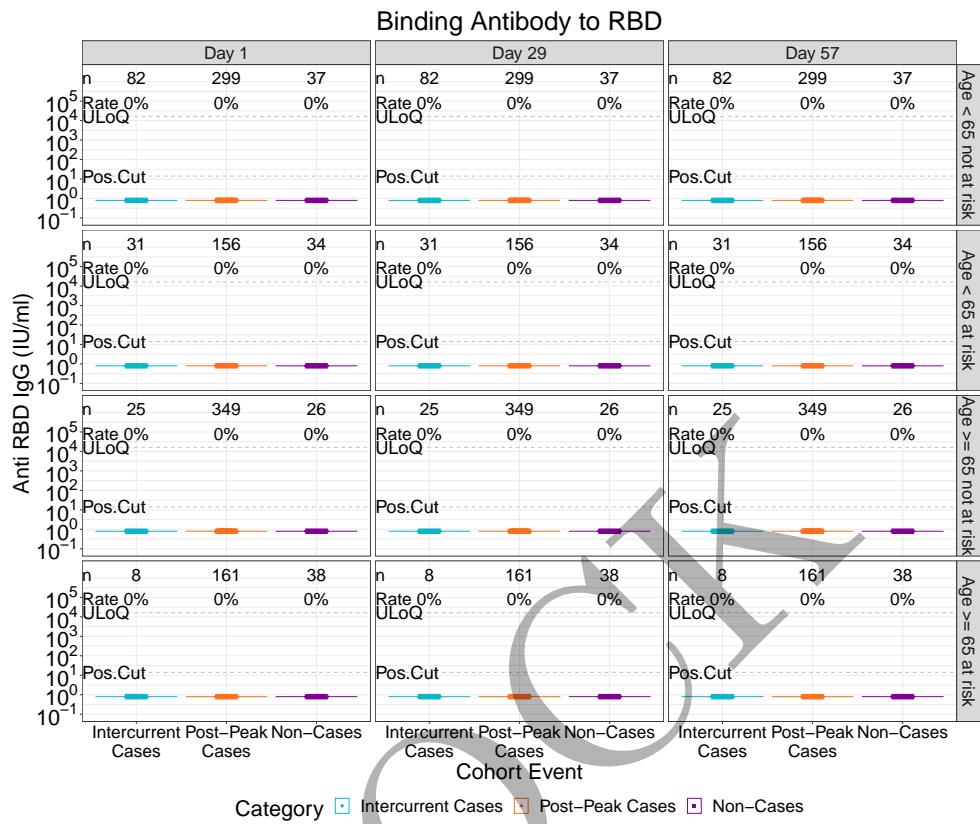


Figure 3.140: violinplots of Binding Antibody to RBD: baseline negative placebo arm by age and risk condition (version 2)

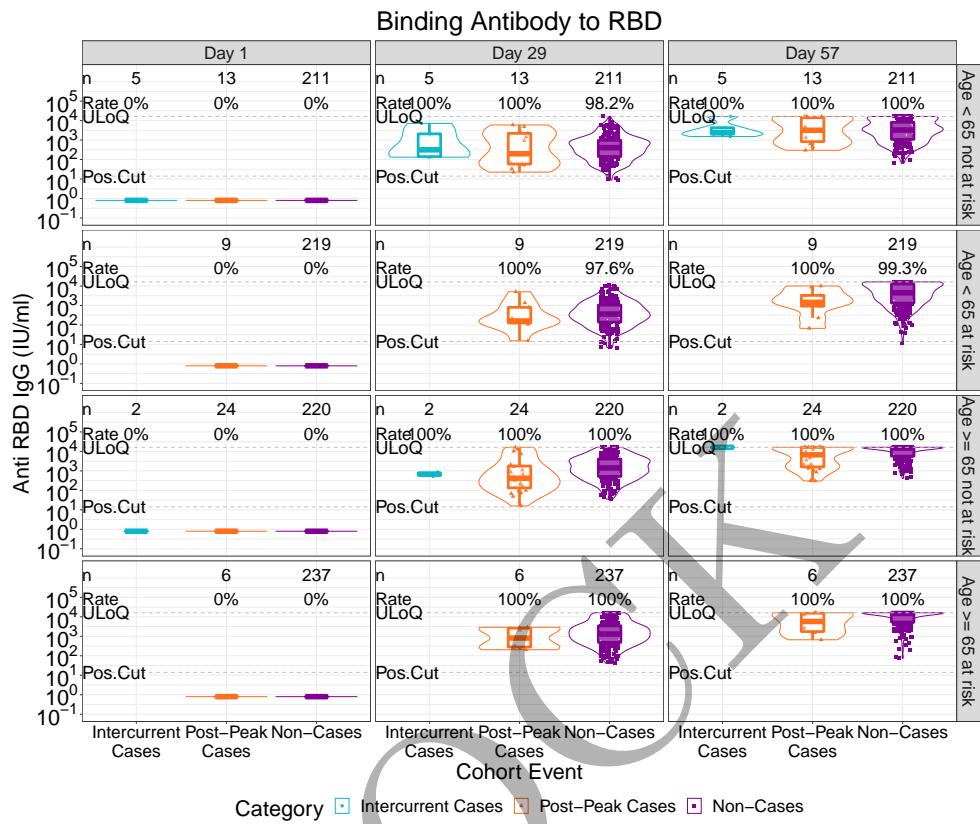


Figure 3.141: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by age and risk condition (version 2)

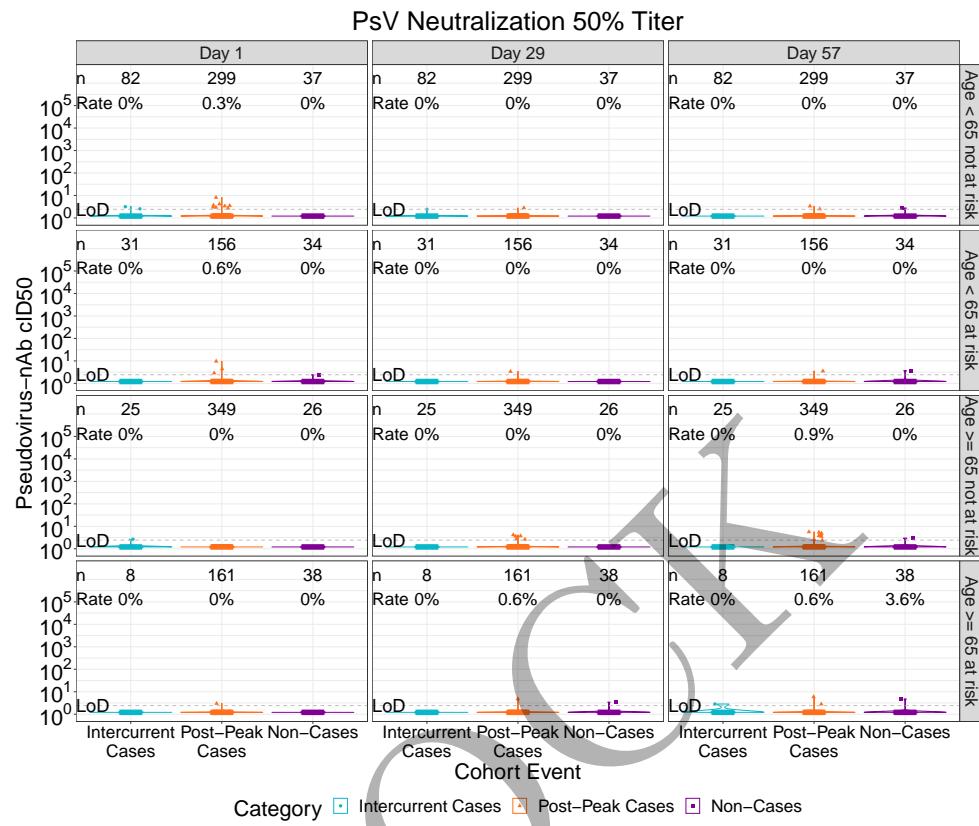


Figure 3.142: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age and risk condition (version 2)

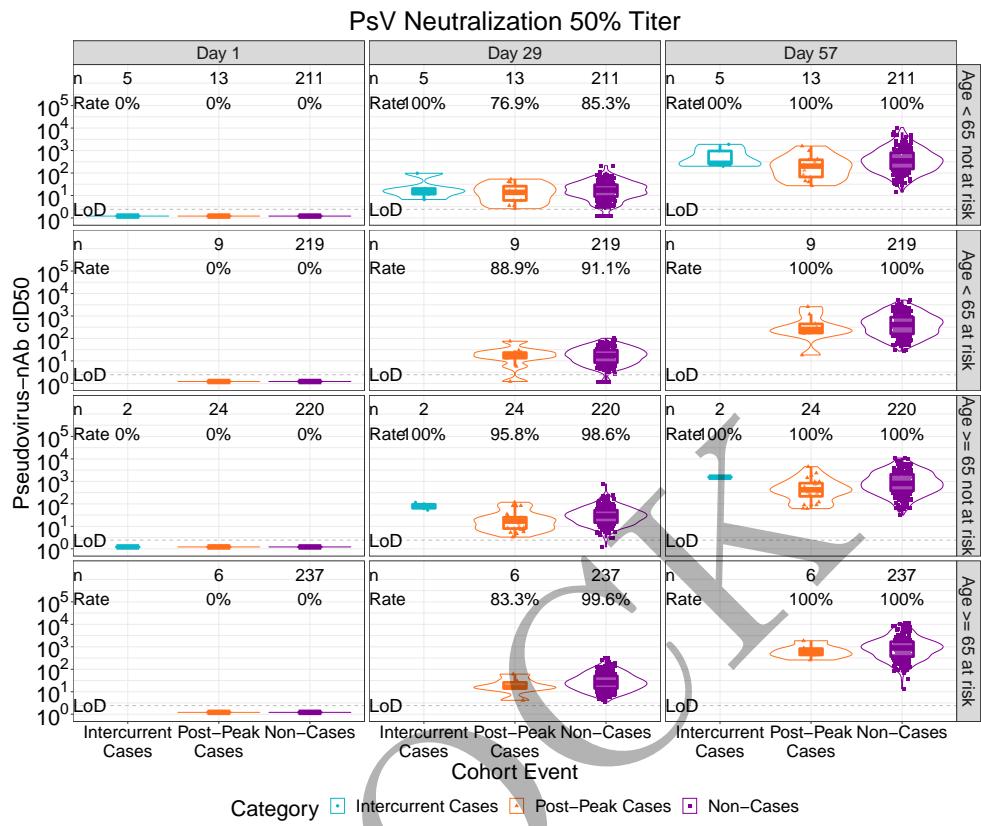


Figure 3.143: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age and risk condition (version 2)

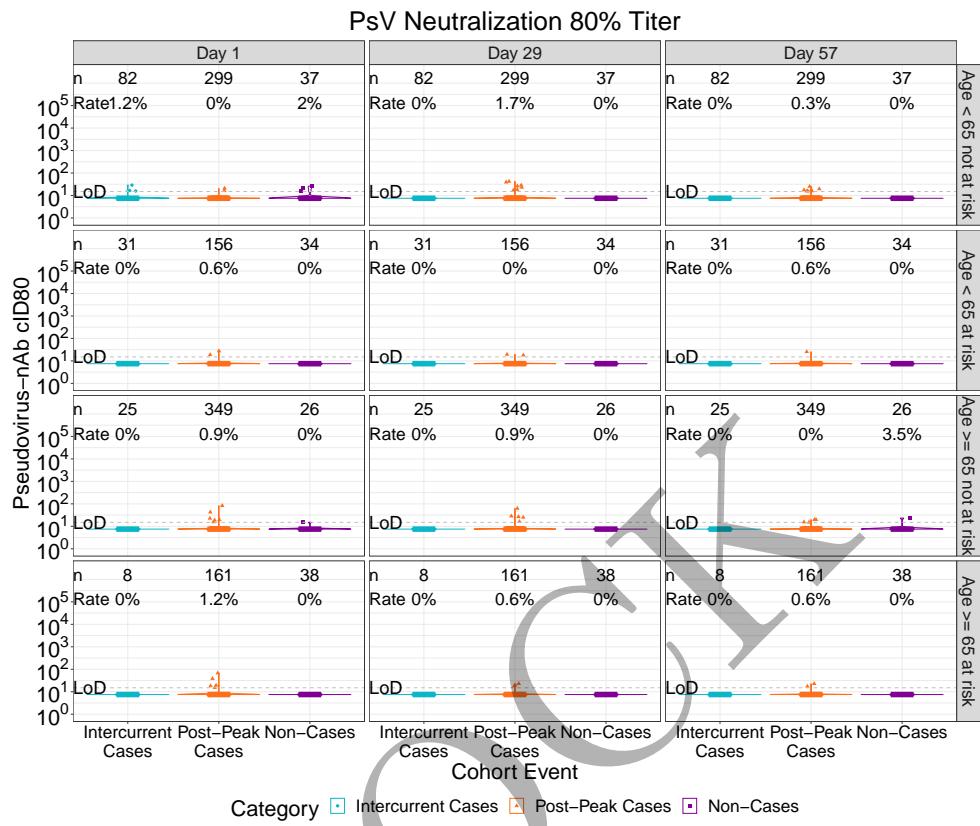


Figure 3.144: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age and risk condition (version 2)

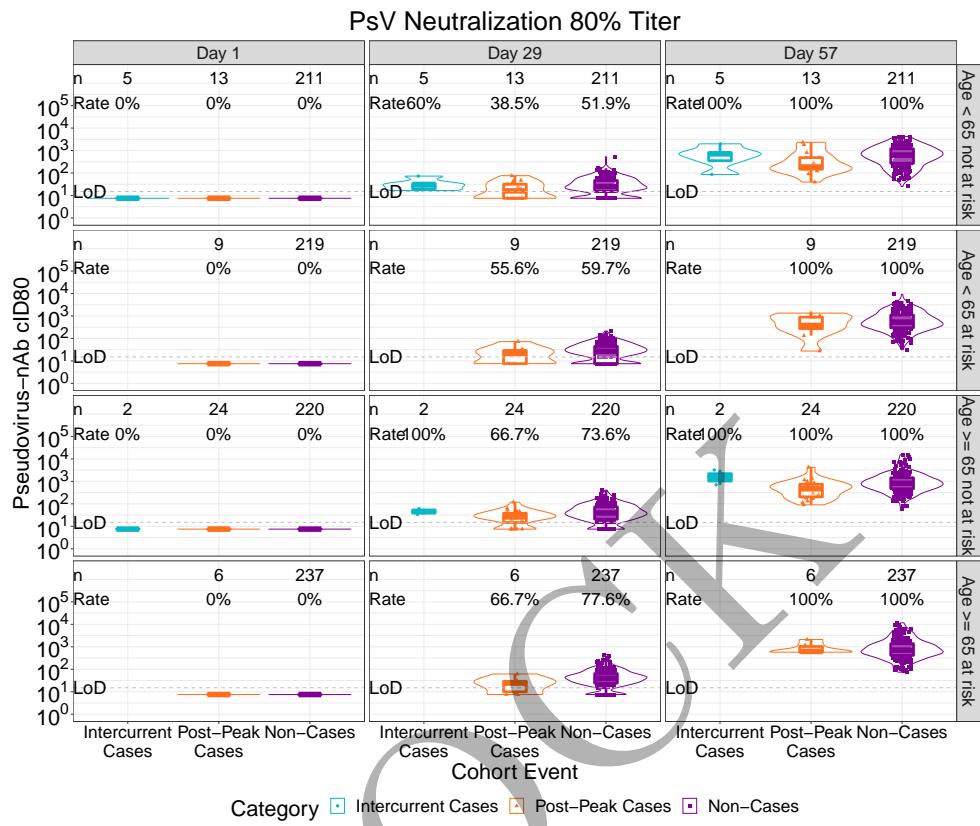
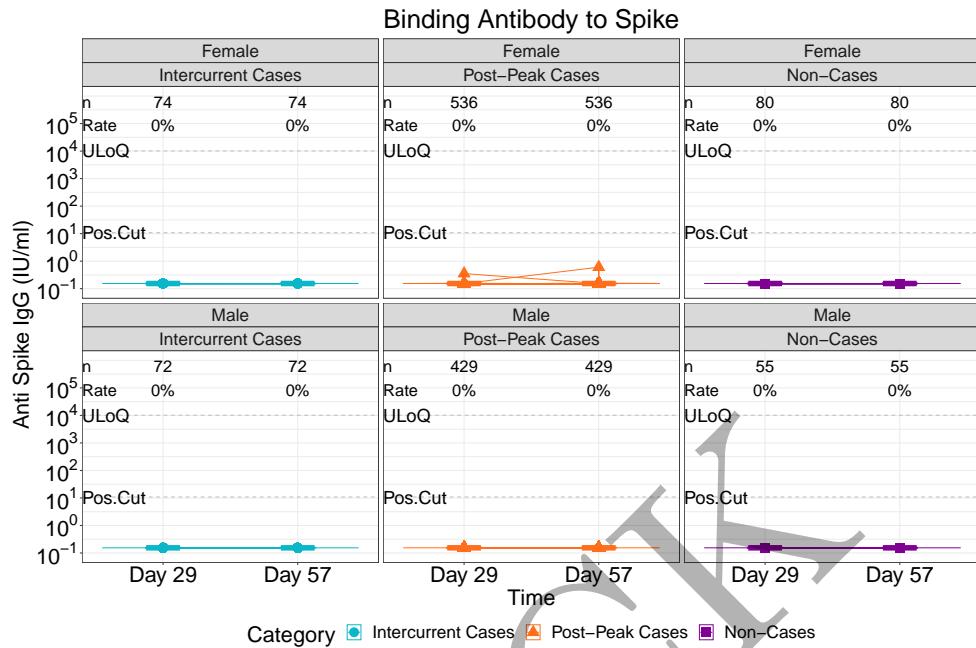
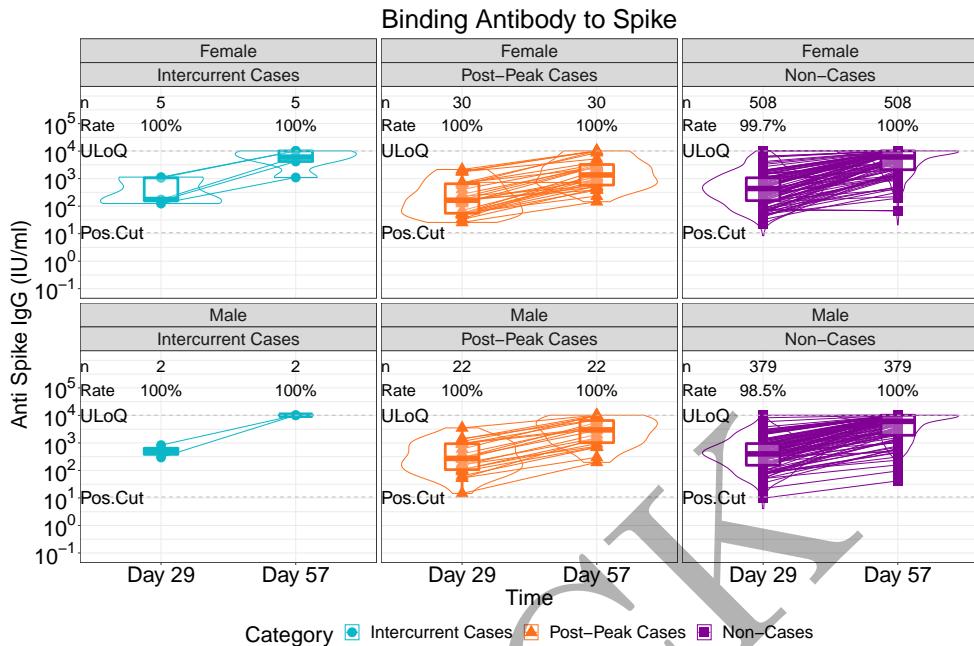


Figure 3.145: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age and risk condition (version 2)



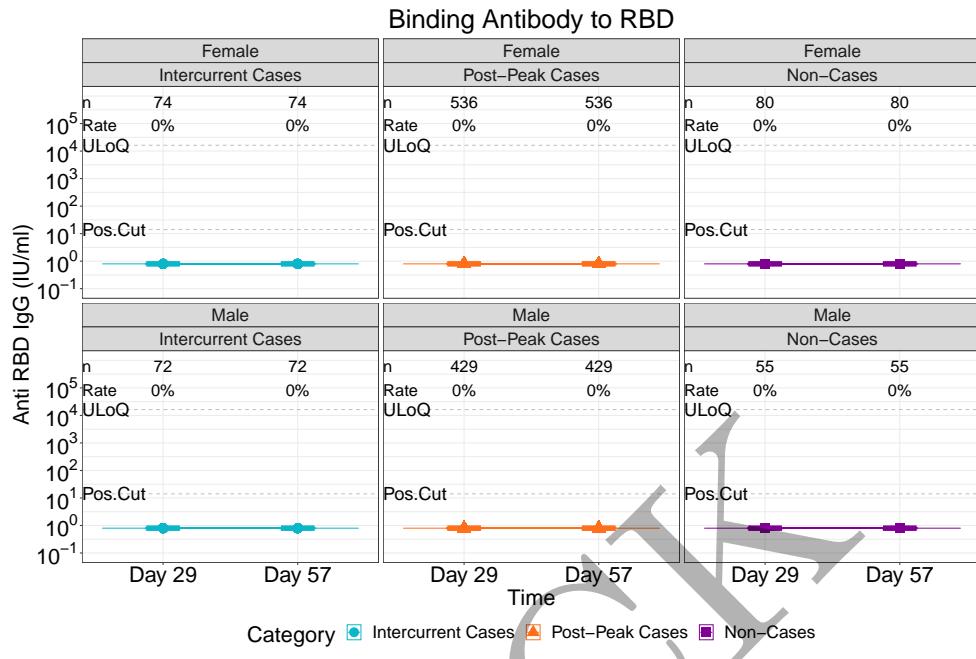
All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.146: lineplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (version 1)



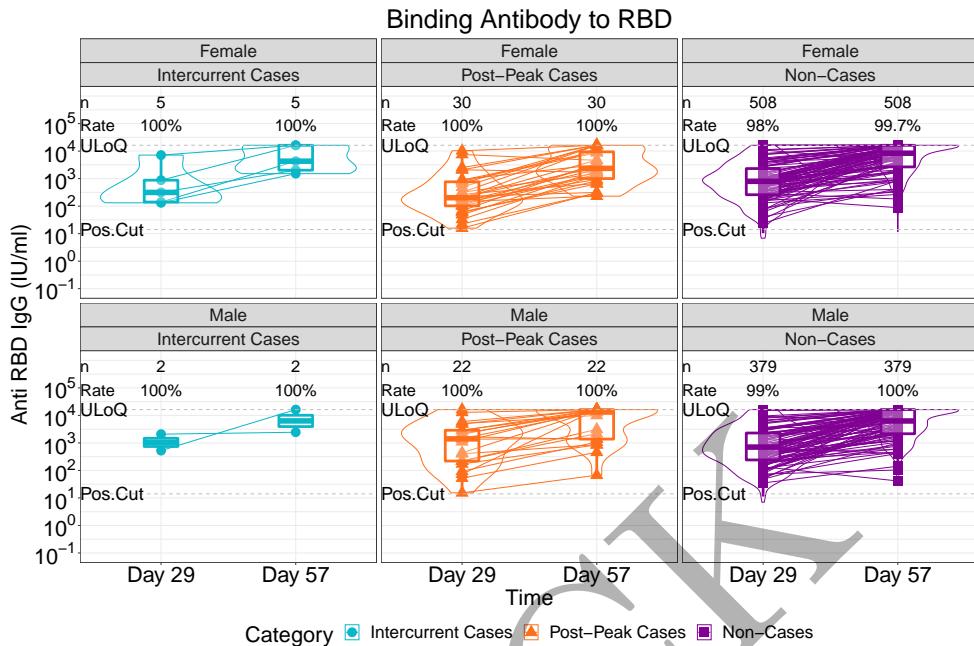
All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger

Figure 3.147: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (version 1)



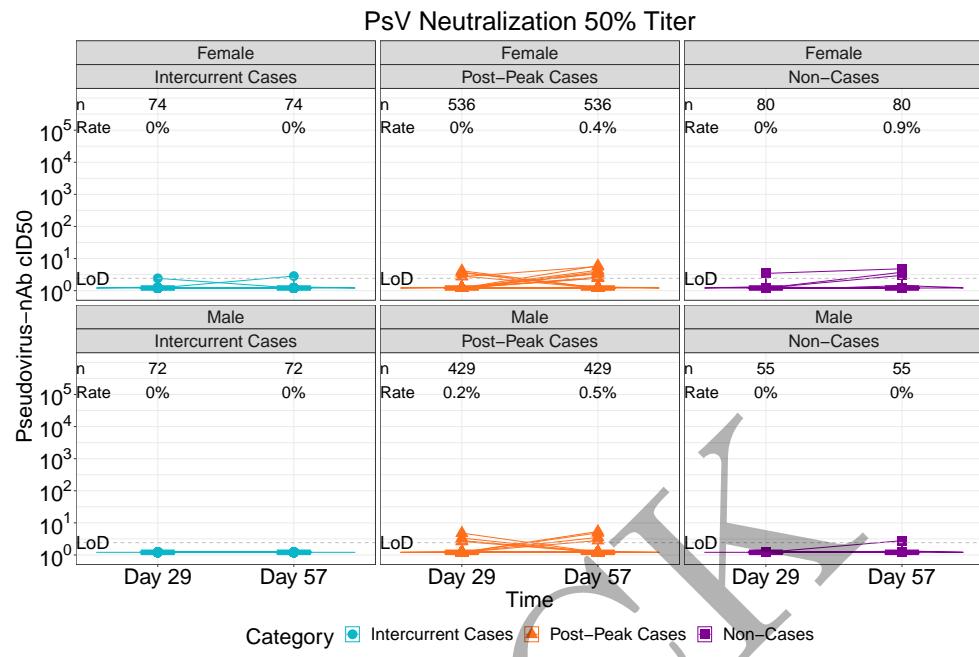
All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger

Figure 3.148: lineplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (version 1)



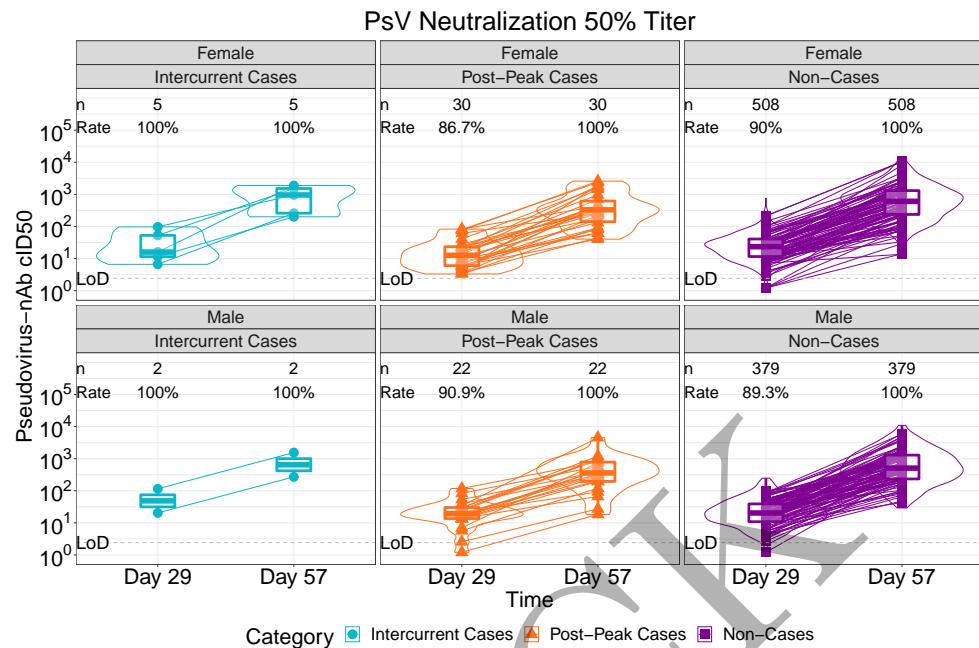
All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.149: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (version 1)



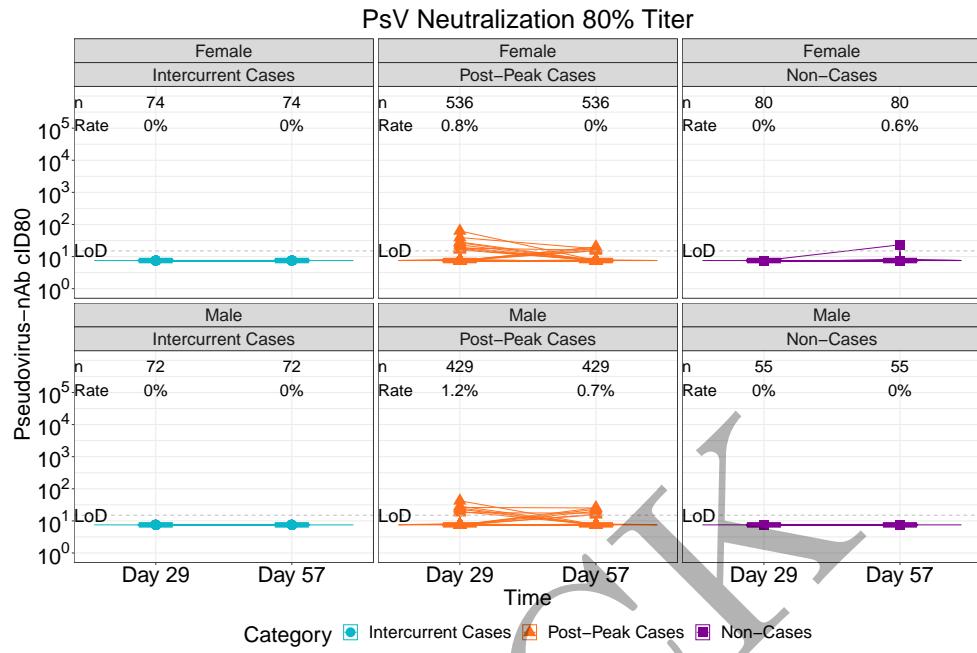
All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.150: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by sex assigned at birth (version 1)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.151: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by sex assigned at birth (version 1)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger

Figure 3.152: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by sex assigned at birth (version 1)

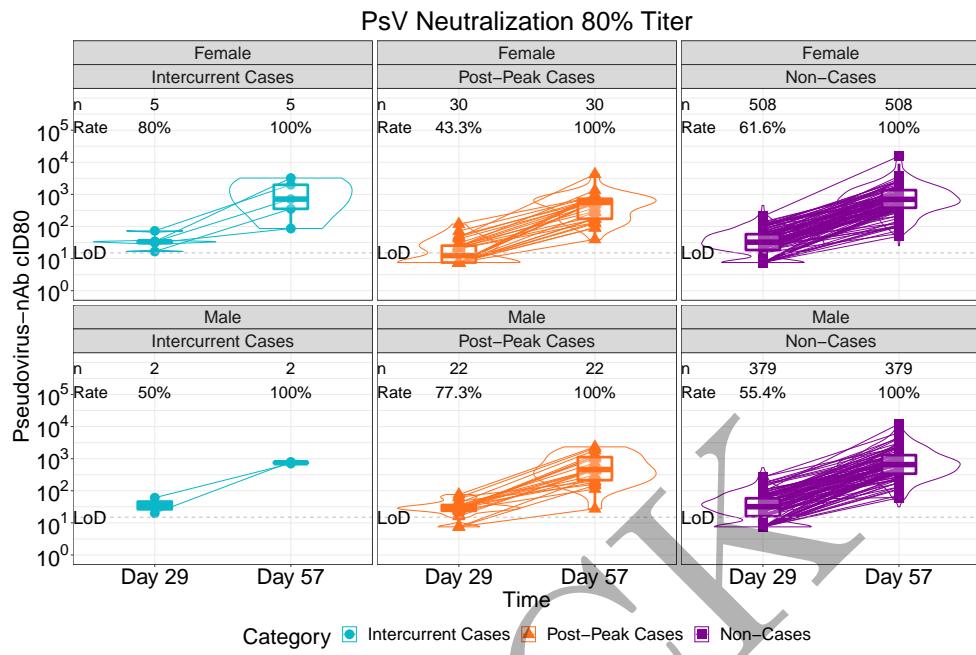


Figure 3.153: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by sex assigned at birth (version 1)

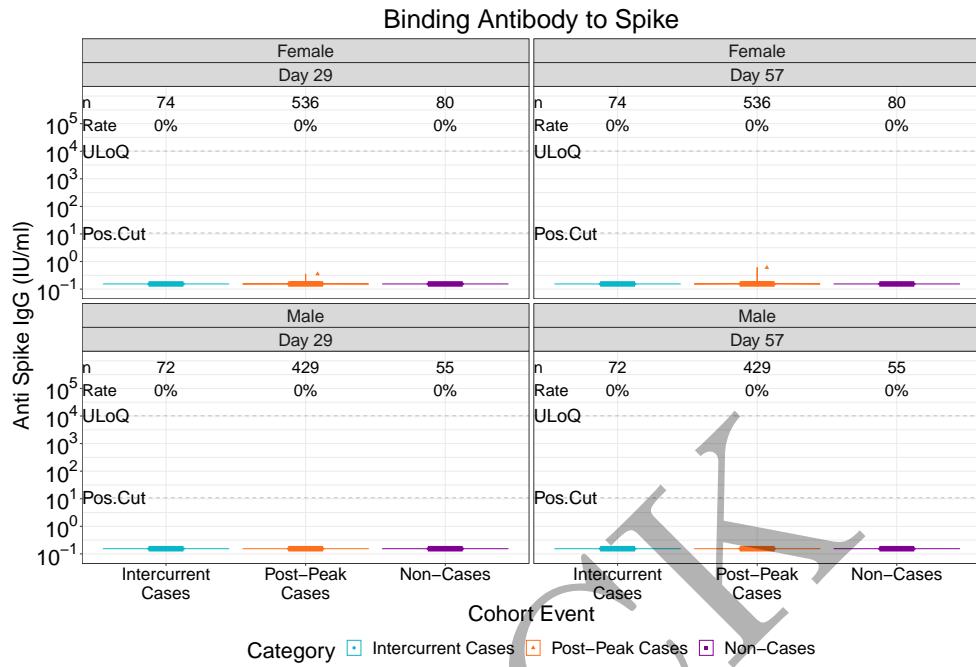


Figure 3.154: violinplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (version 1)

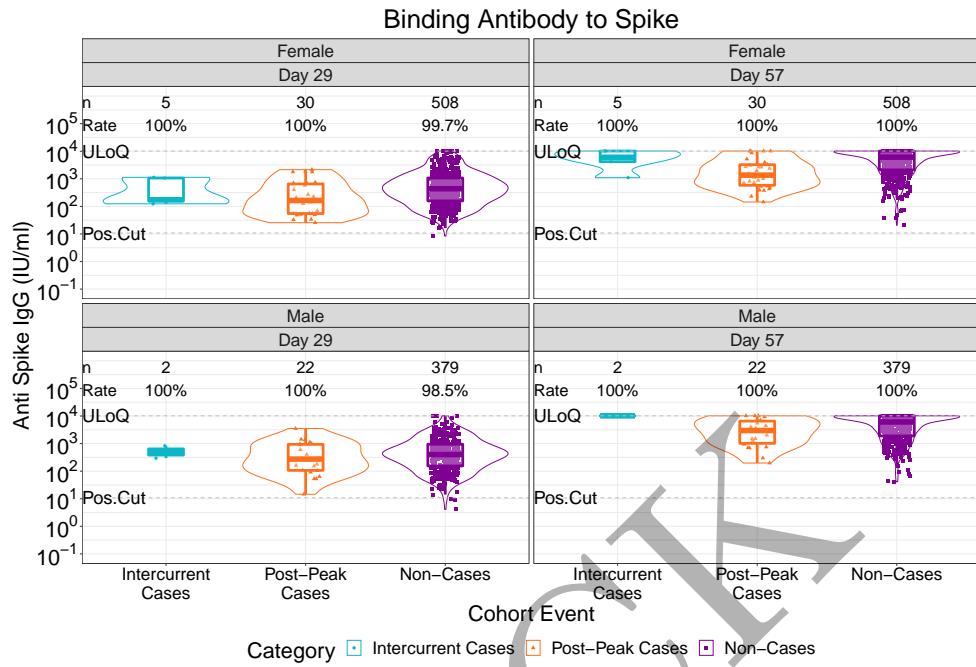


Figure 3.155: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (version 1)

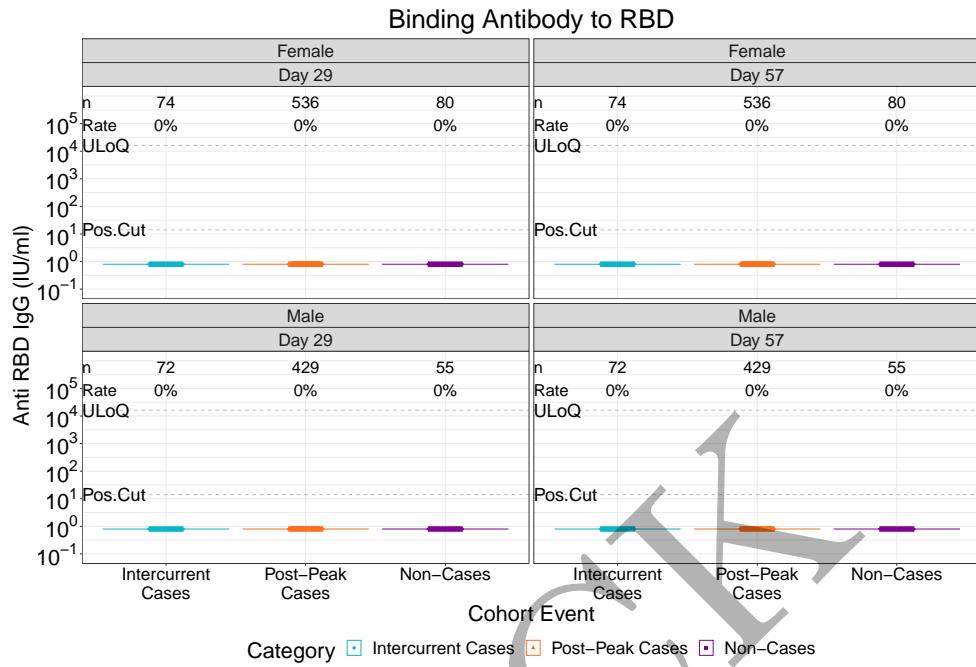


Figure 3.156: violinplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (version 1)

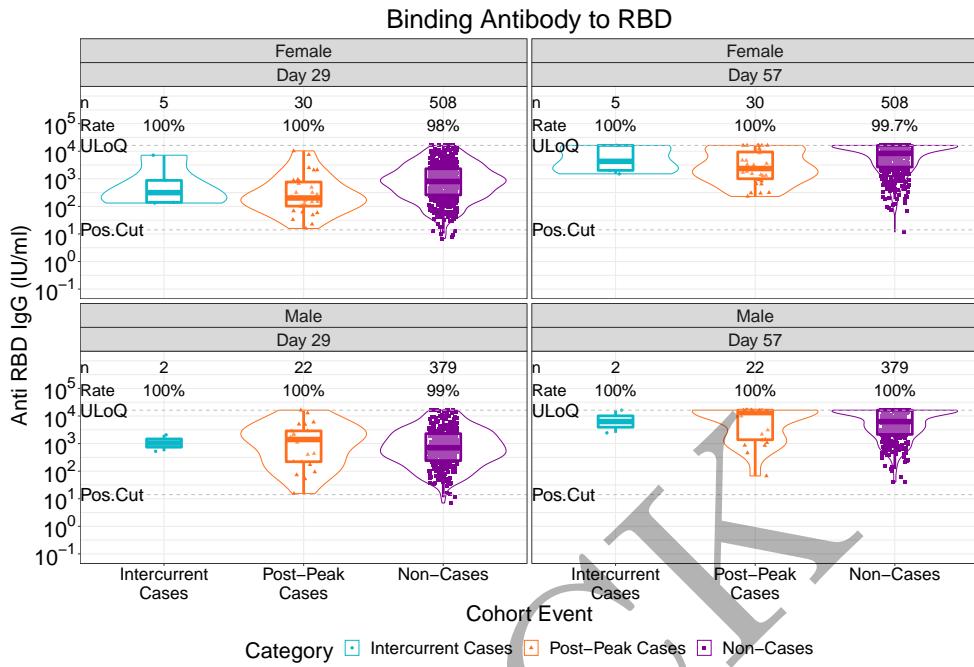


Figure 3.157: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (version 1)

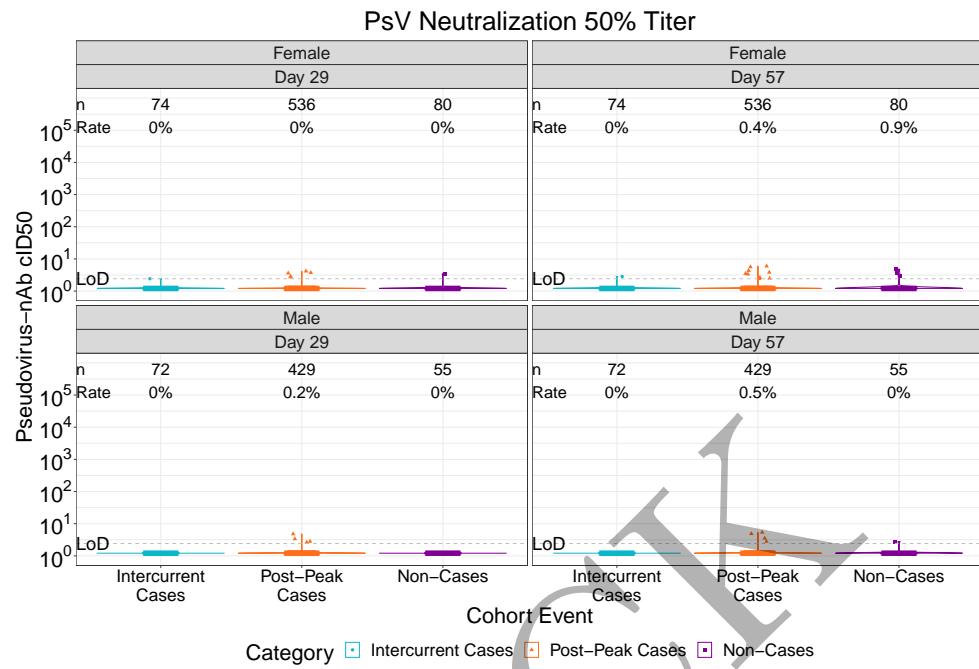


Figure 3.158: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by sex assigned at birth (version 1)

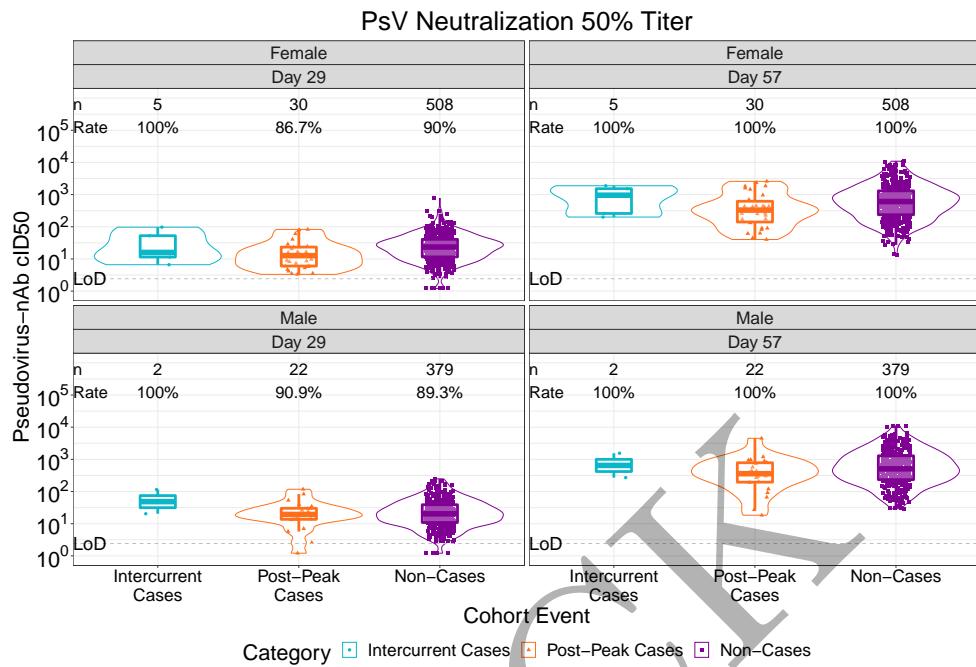


Figure 3.159: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by sex assigned at birth (version 1)

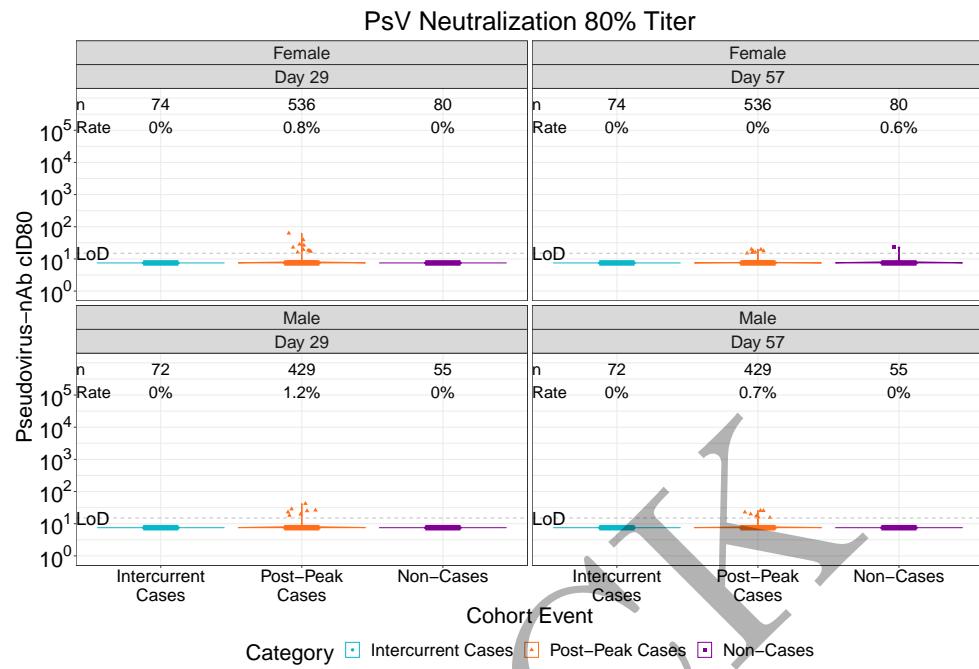


Figure 3.160: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by sex assigned at birth (version 1)

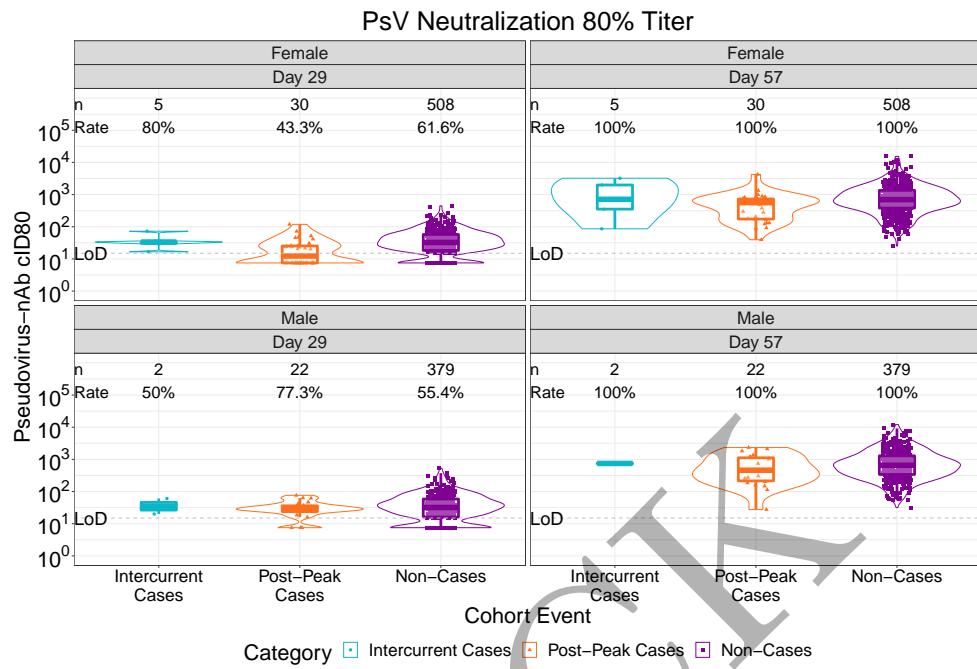
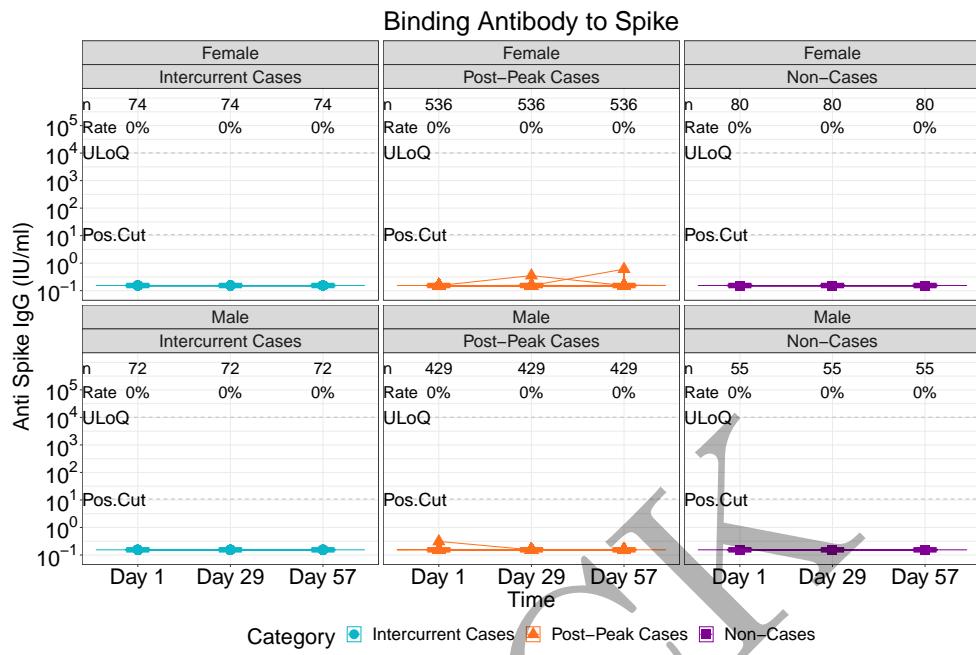
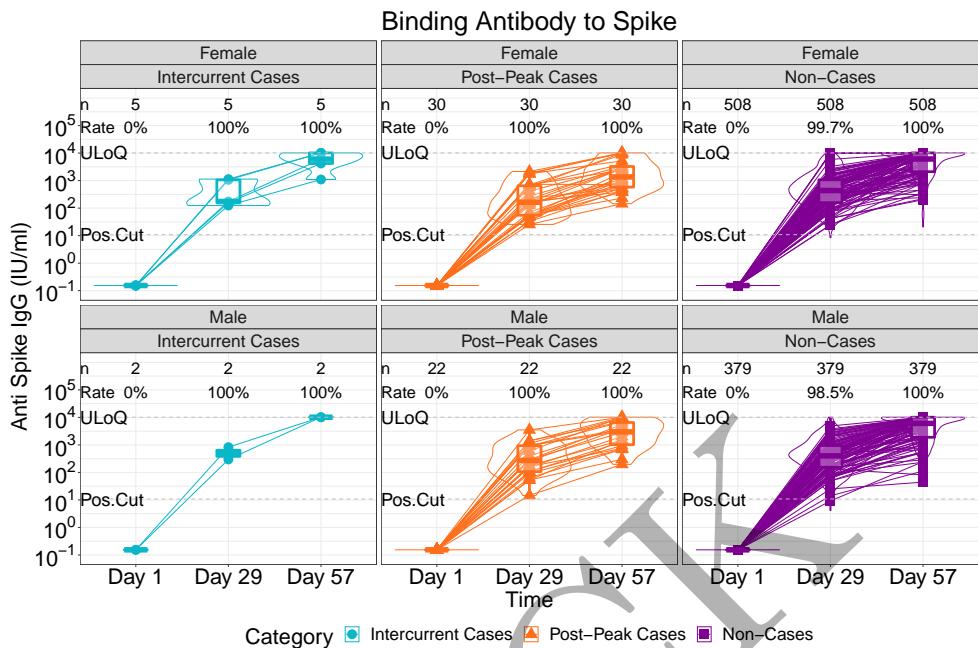


Figure 3.161: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by sex assigned at birth (version 1)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.162: lineplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (version 2)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.163: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (version 2)

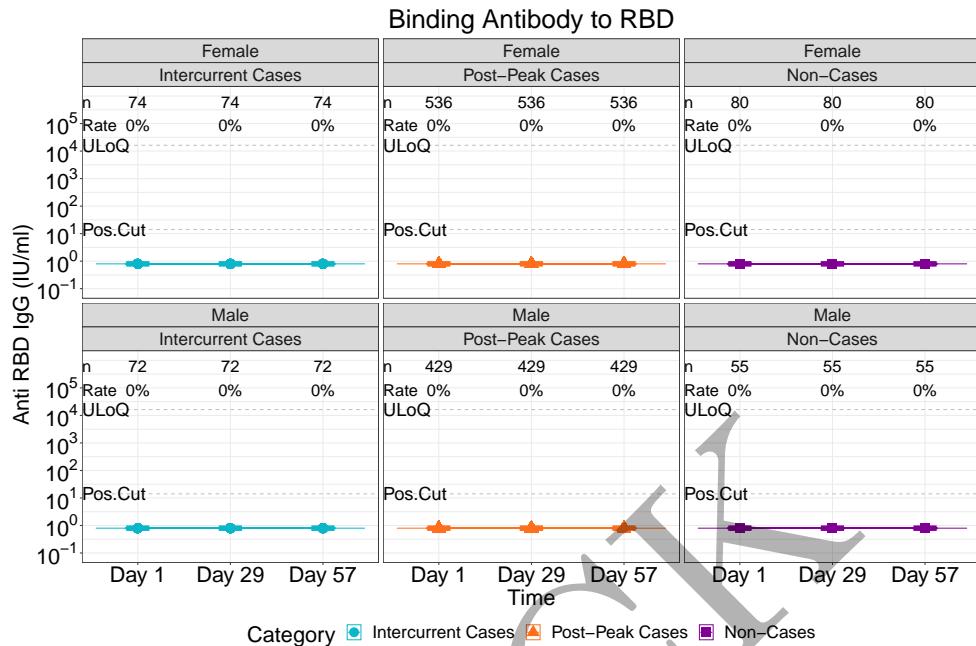
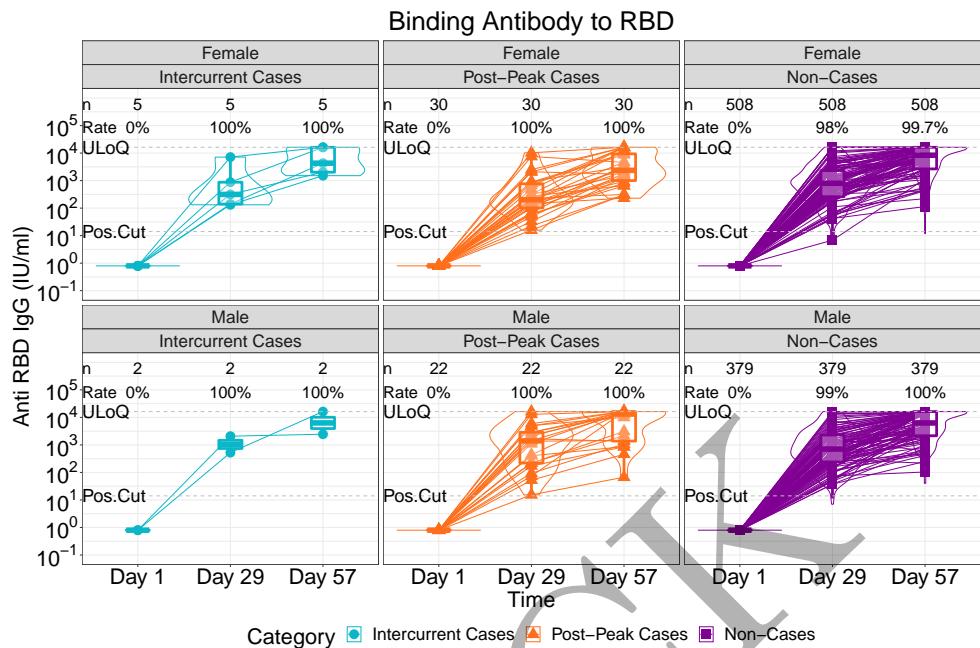
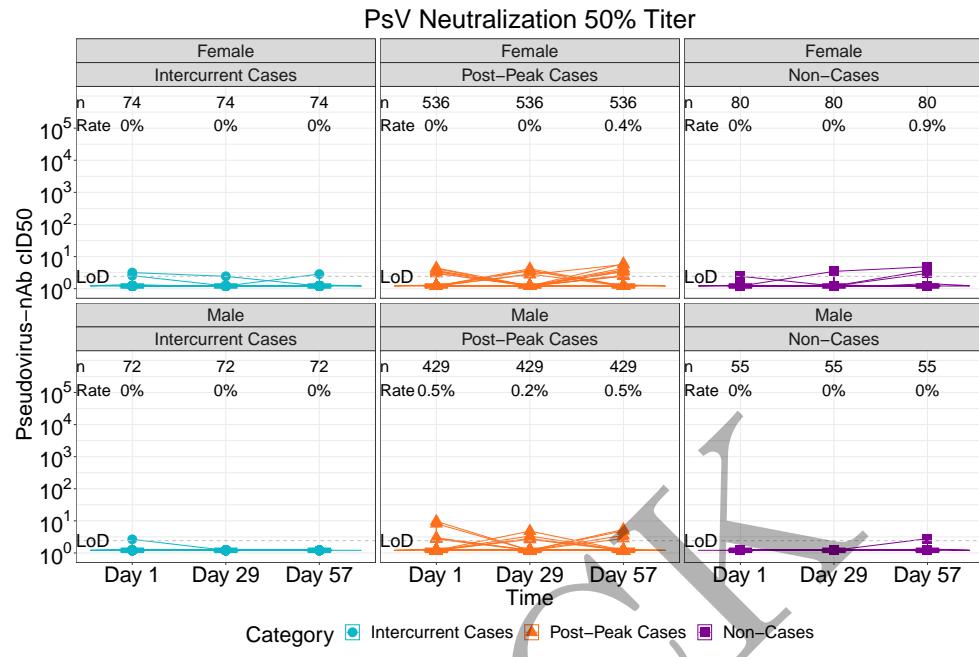


Figure 3.164: lineplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (version 2)



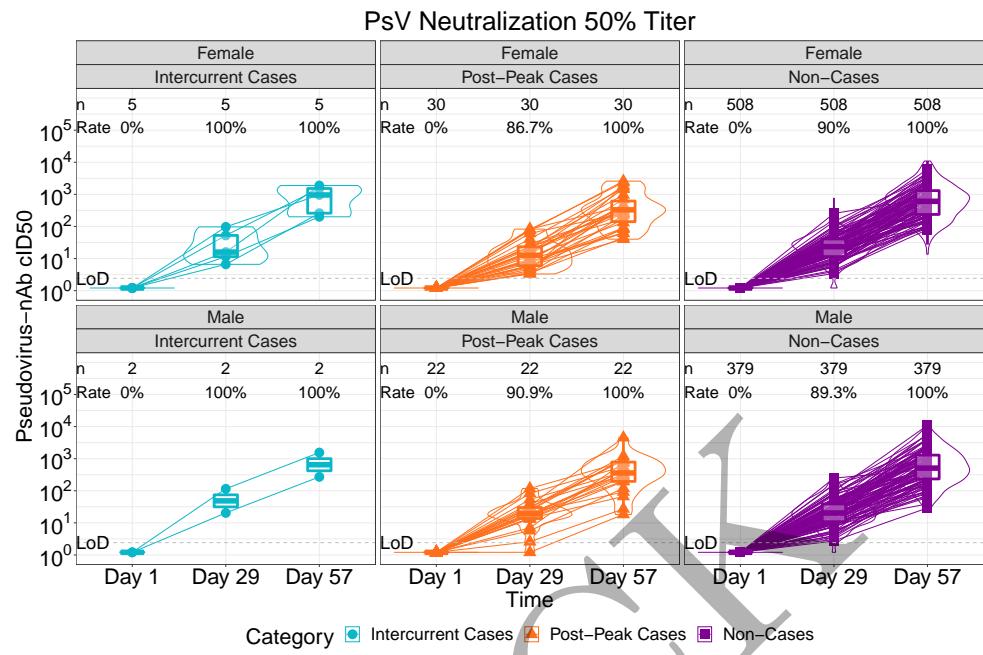
All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.165: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (version 2)



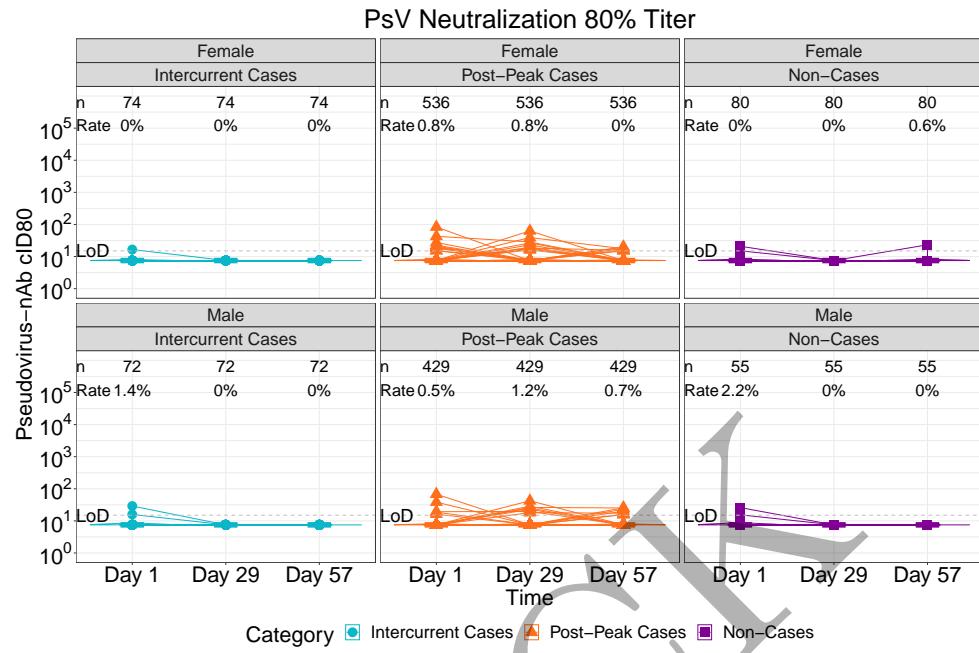
All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger

Figure 3.166: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by sex assigned at birth (version 2)



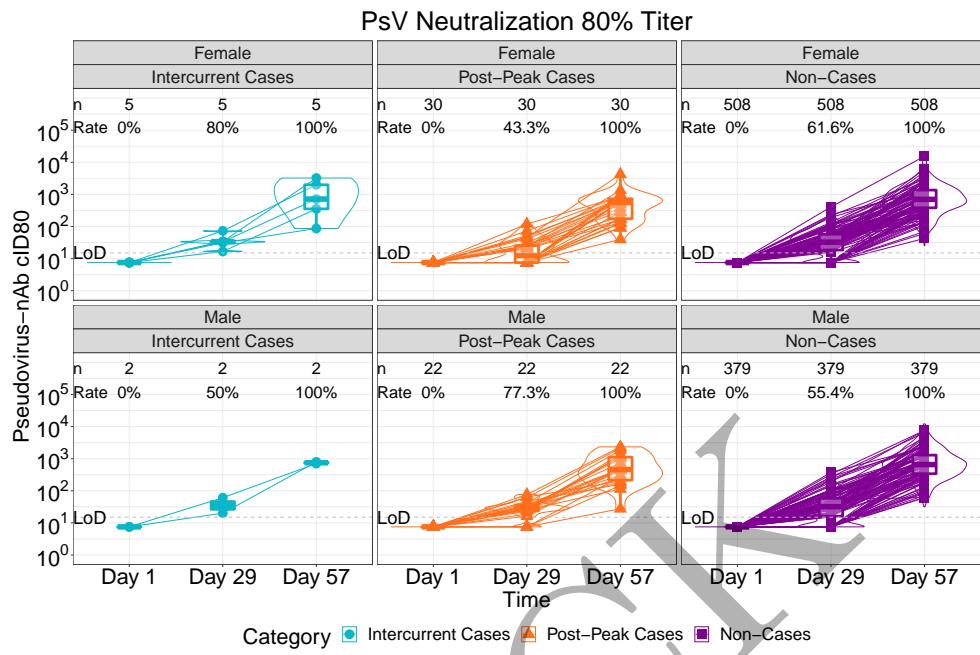
All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.167: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by sex assigned at birth (version 2)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.168: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by sex assigned at birth (version 2)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger

Figure 3.169: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by sex assigned at birth (version 2)

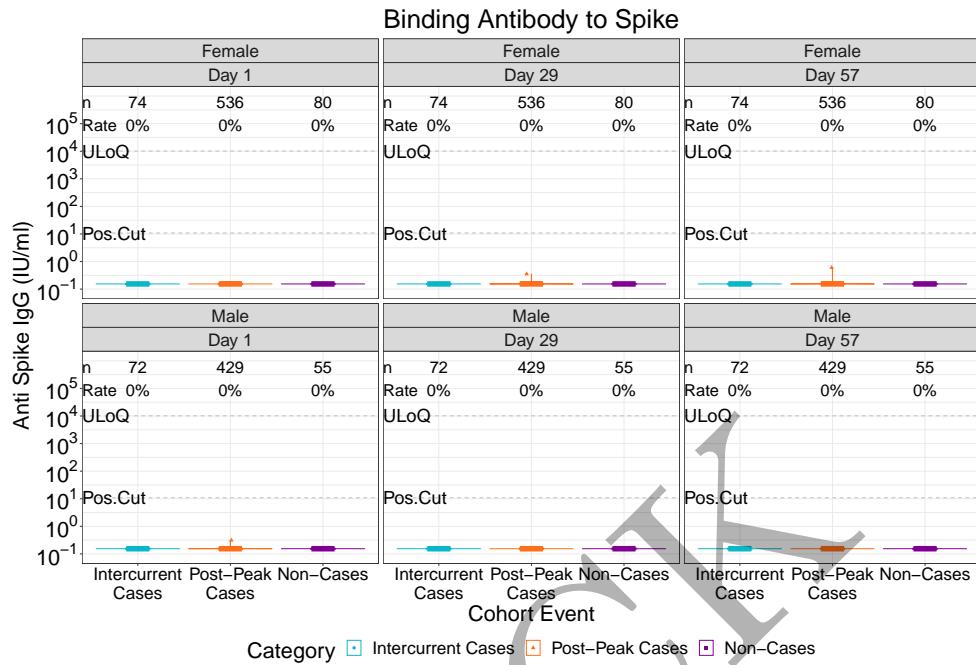


Figure 3.170: violinplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (version 2)

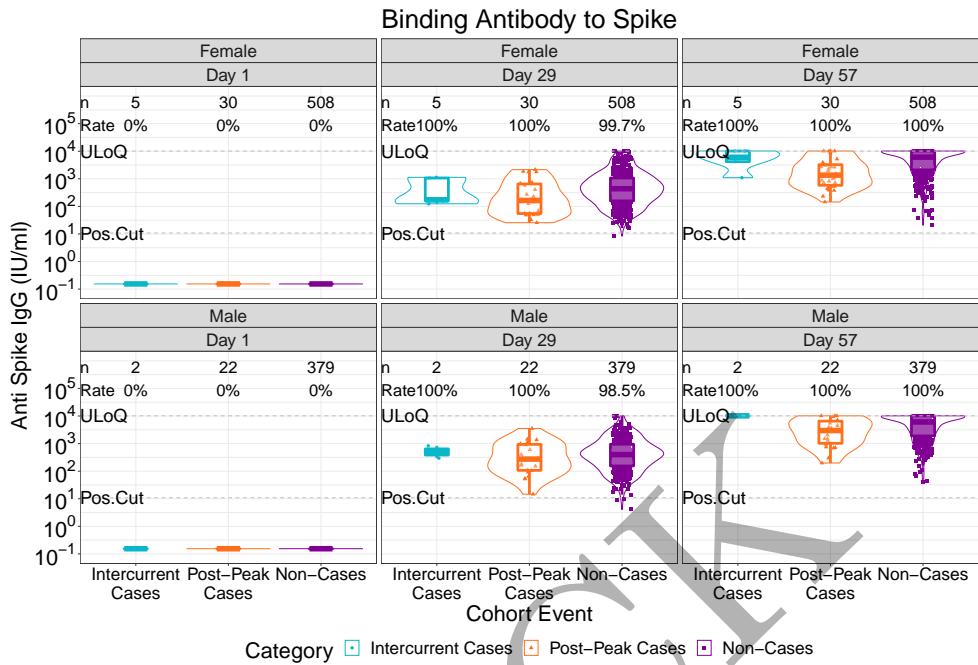


Figure 3.171: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (version 2)

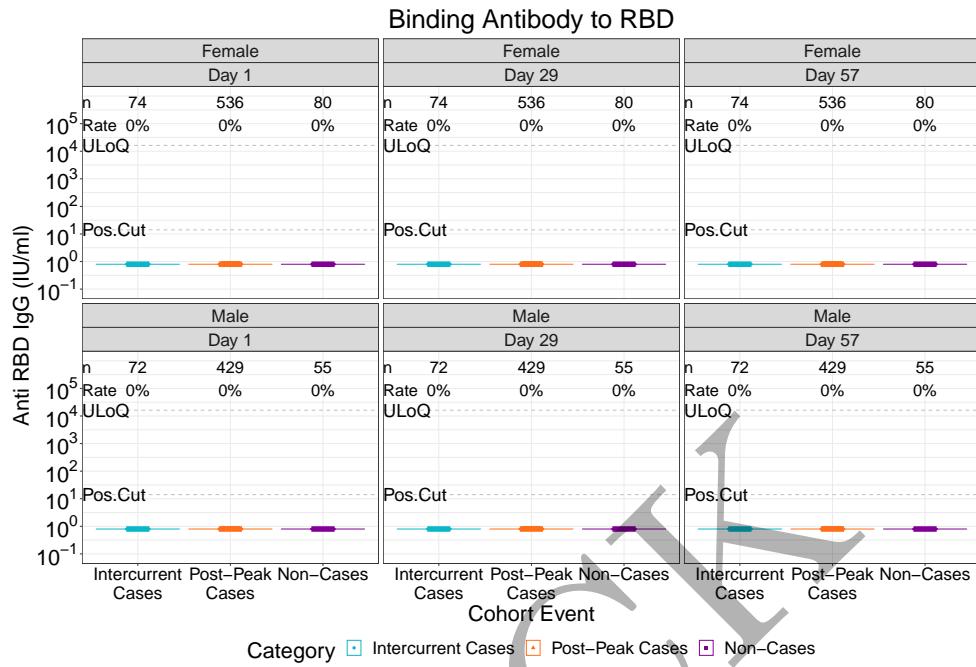


Figure 3.172: violinplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (version 2)

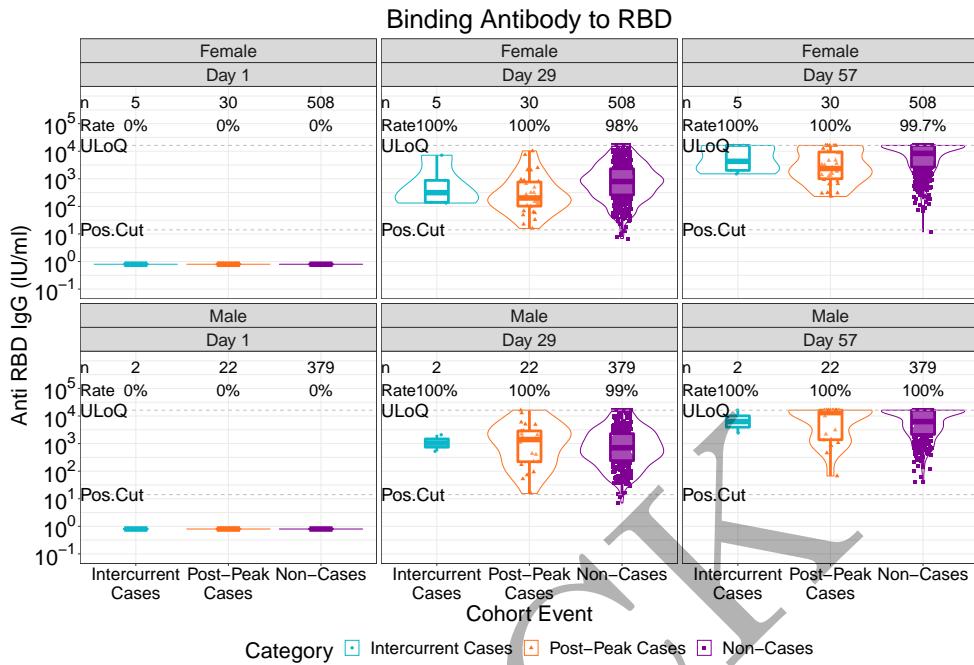


Figure 3.173: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (version 2)

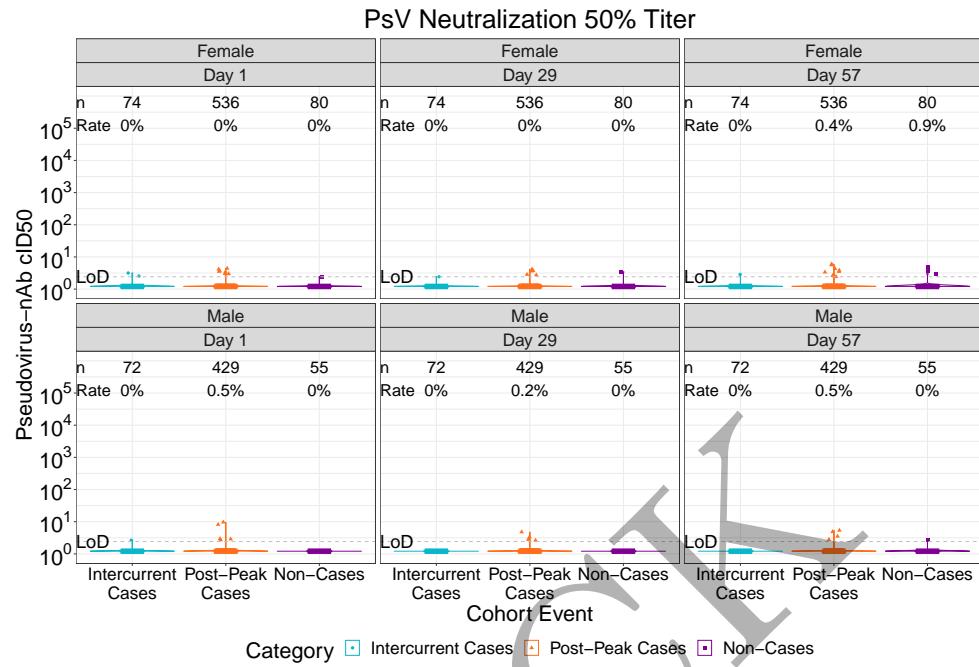


Figure 3.174: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by sex assigned at birth (version 2)

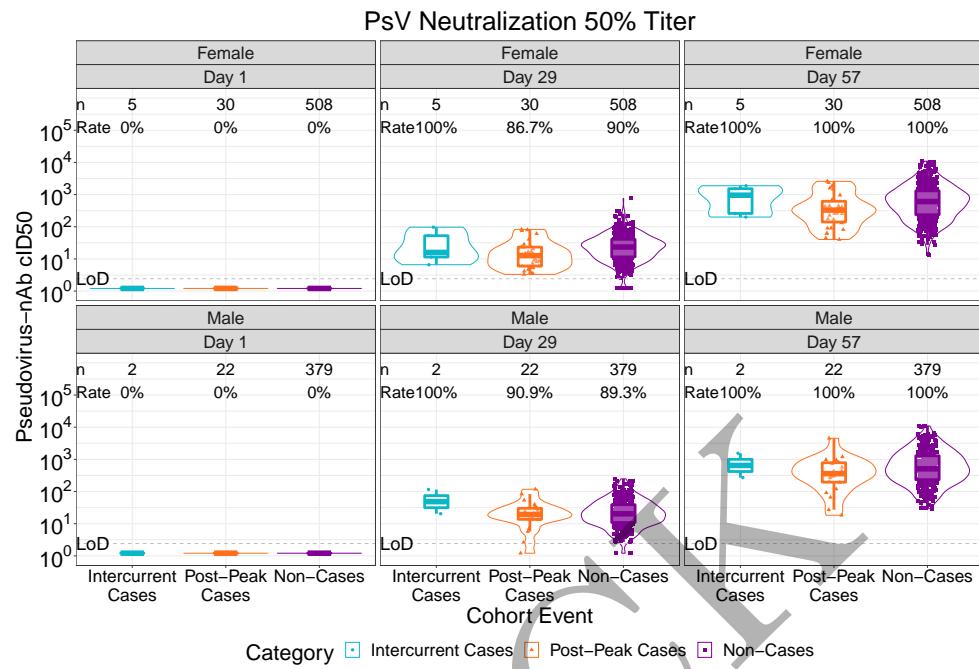


Figure 3.175: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by sex assigned at birth (version 2)

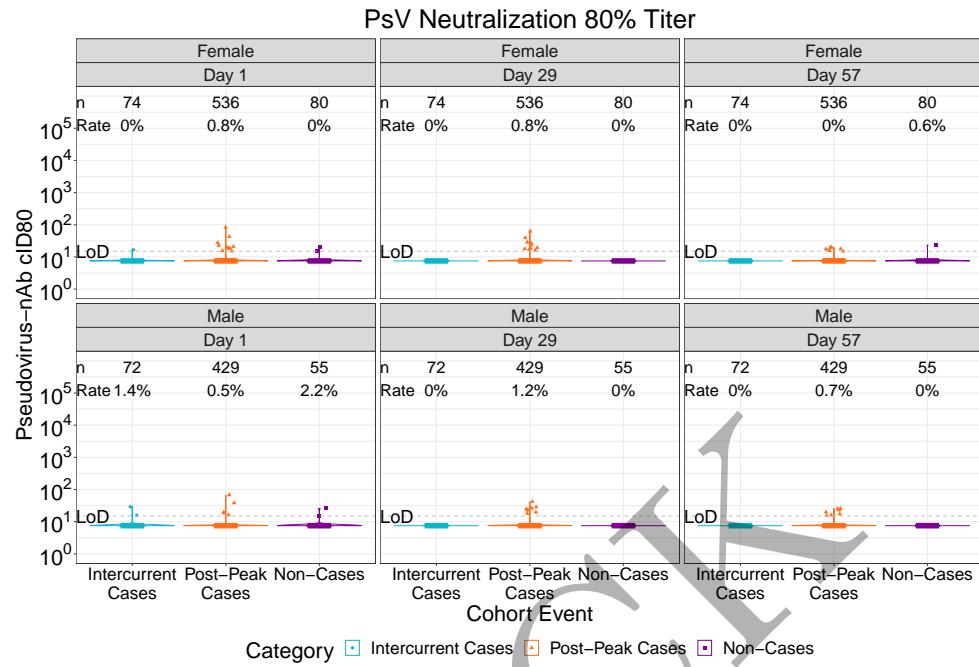


Figure 3.176: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by sex assigned at birth (version 2)

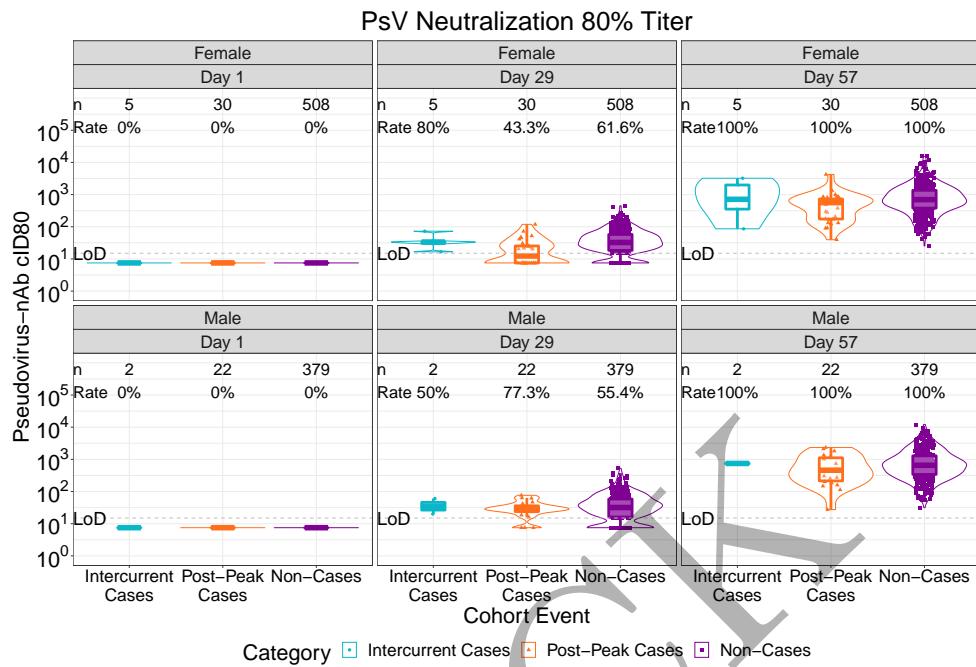
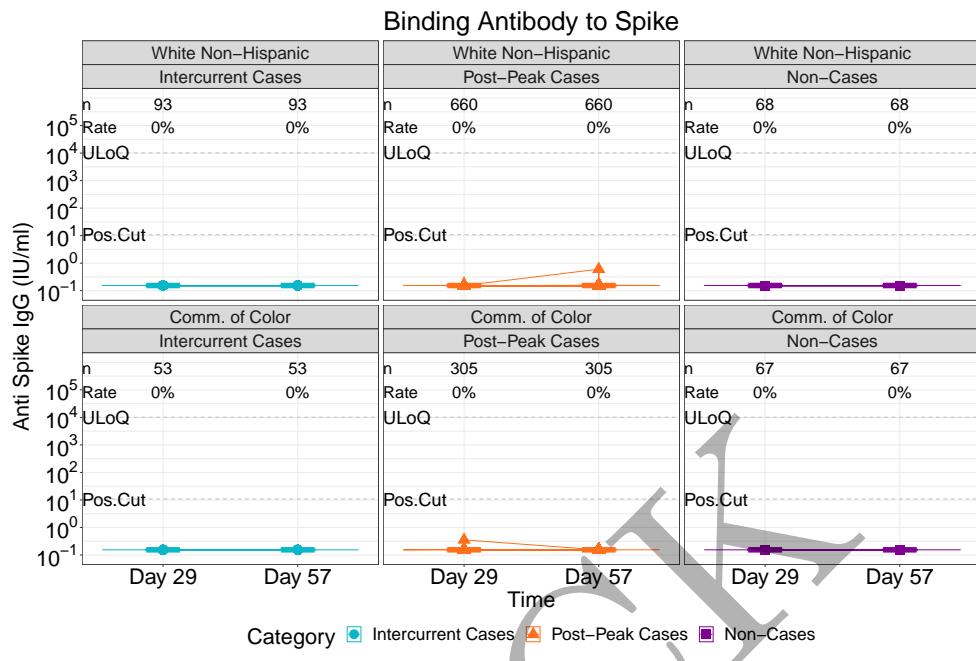
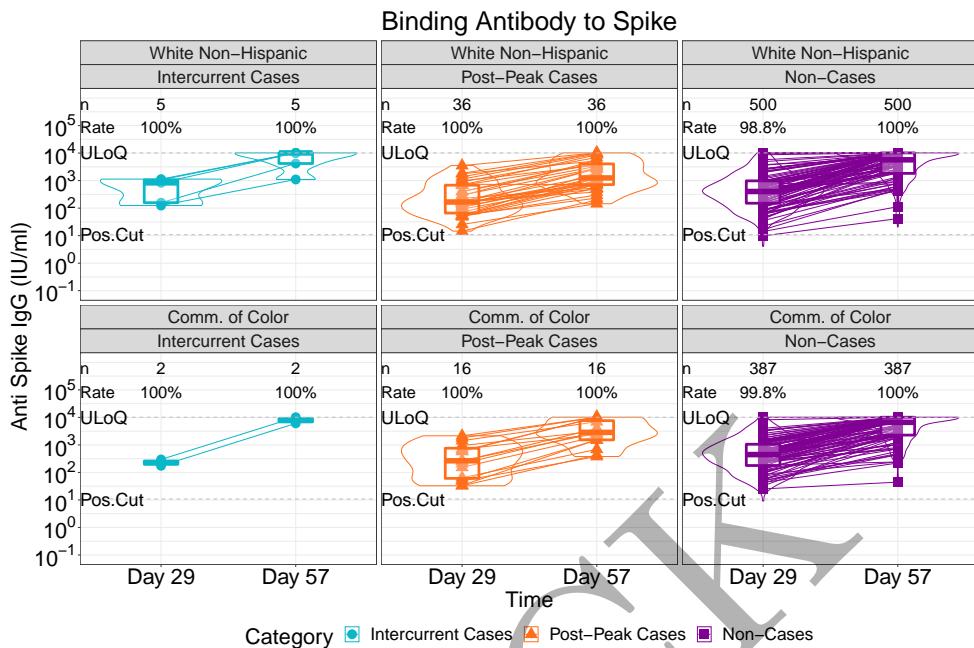


Figure 3.177: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by sex assigned at birth (version 2)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.178: lineplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (version 1)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.179: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (version 1)

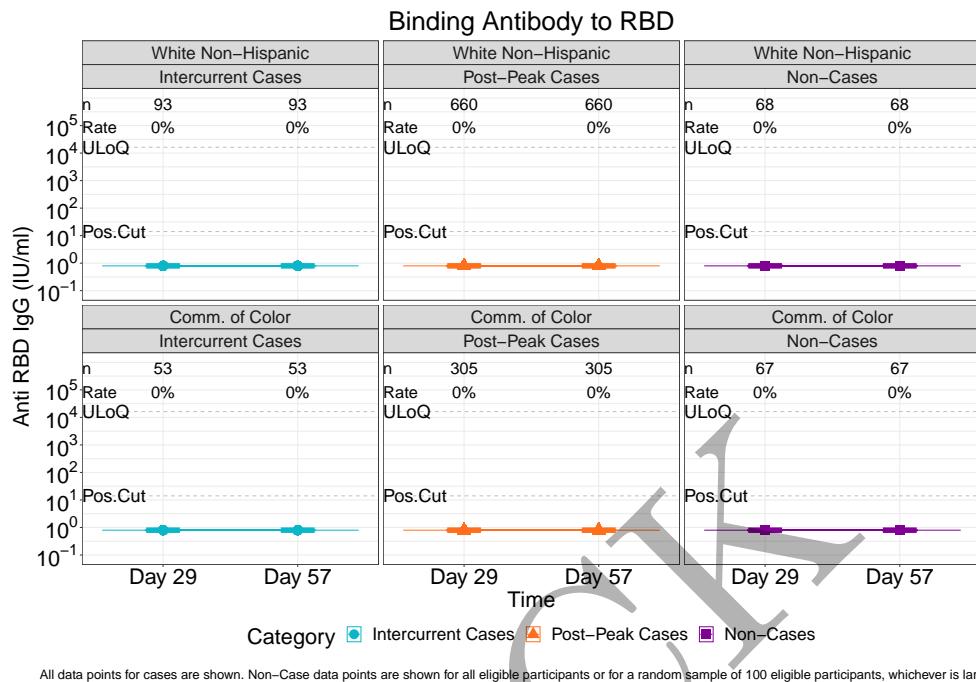
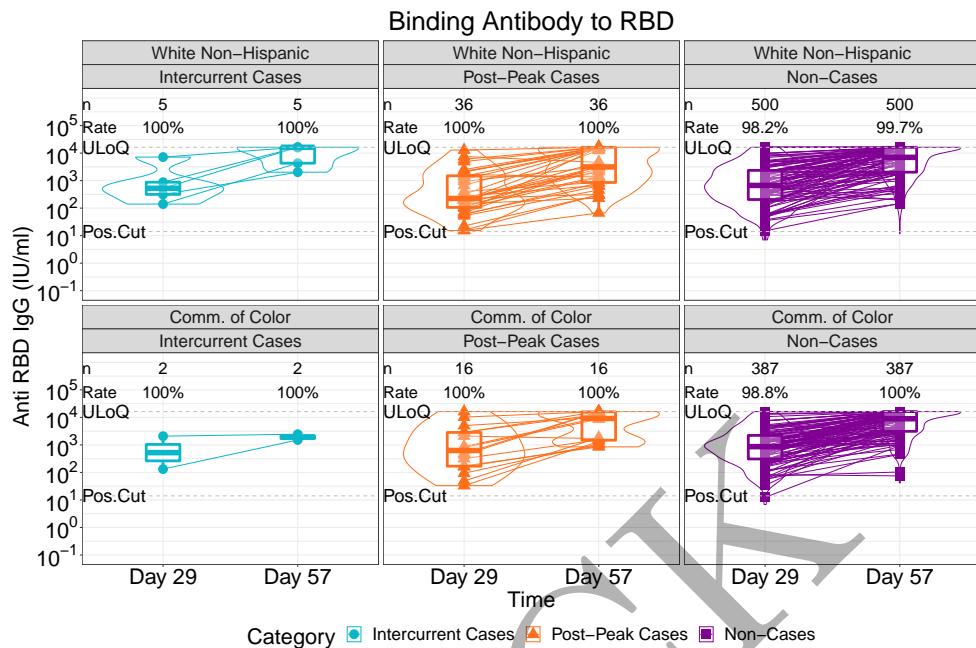
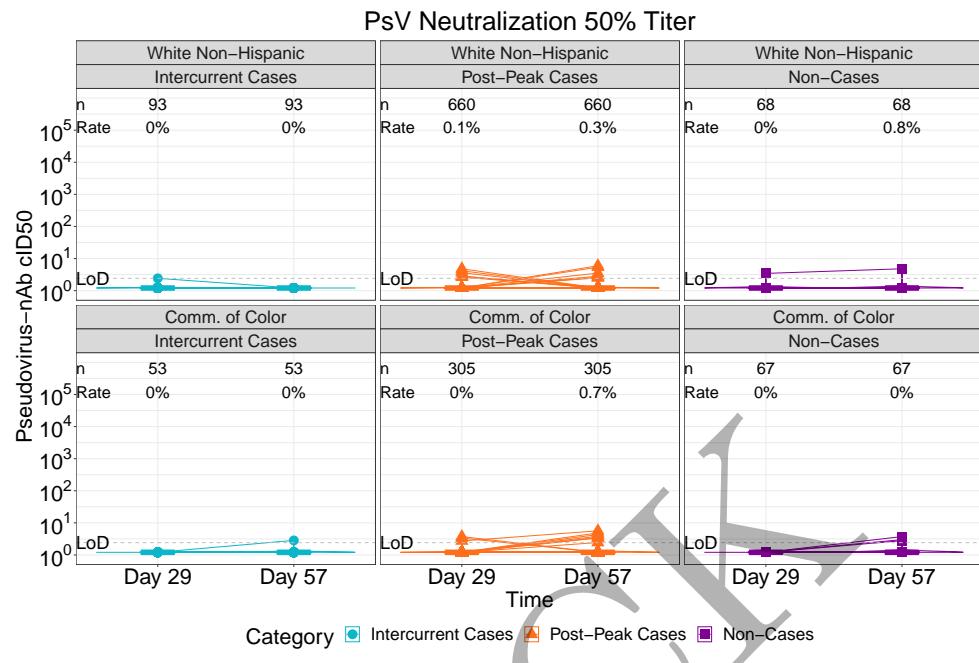


Figure 3.180: lineplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (version 1)



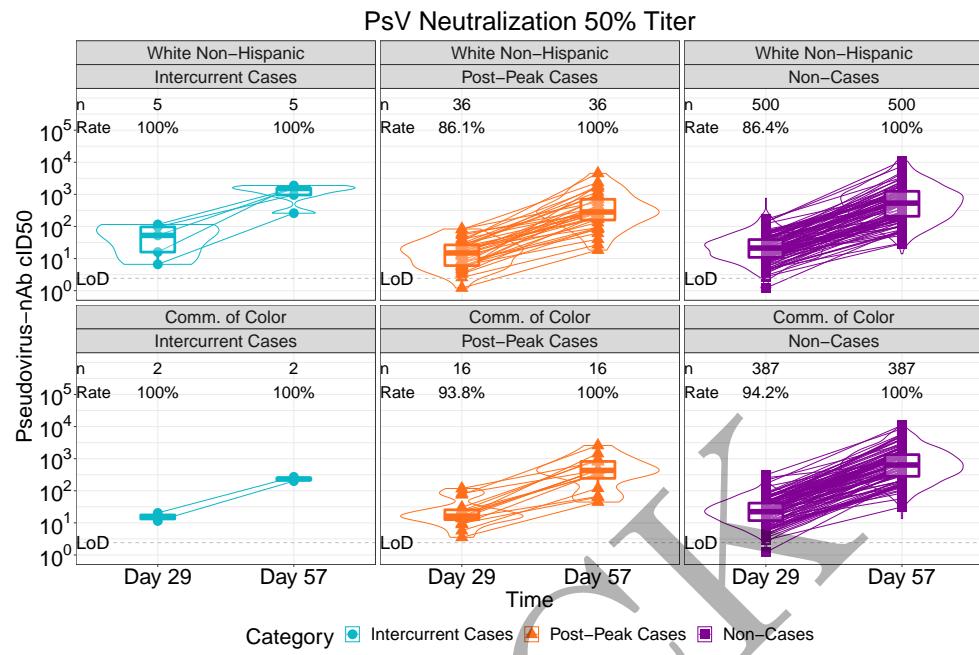
All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.181: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (version 1)



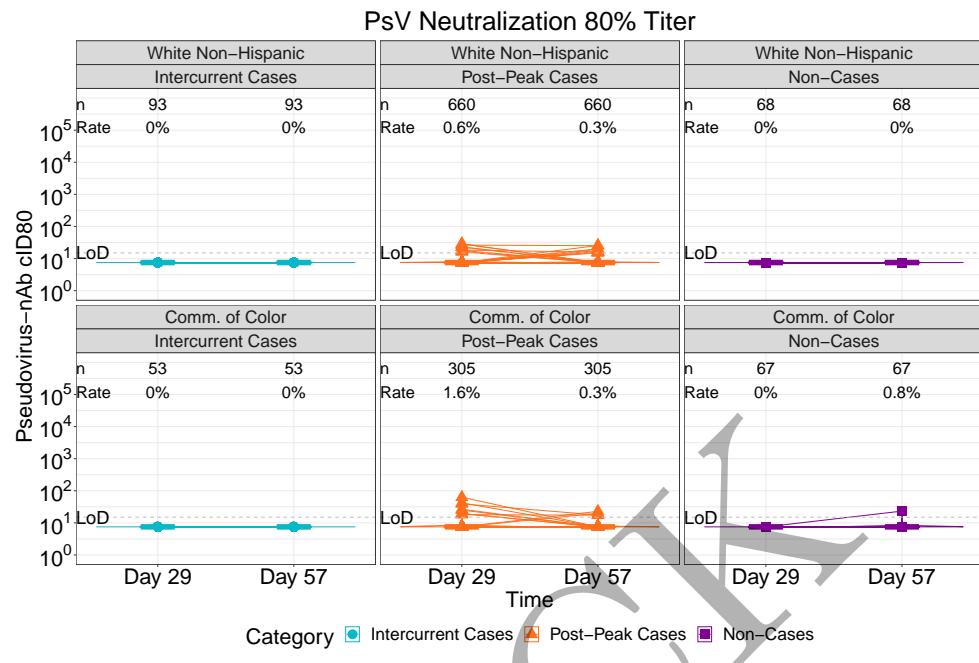
All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.182: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by race and ethnic group (version 1)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.183: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by race and ethnic group (version 1)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.184: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by race and ethnic group (version 1)

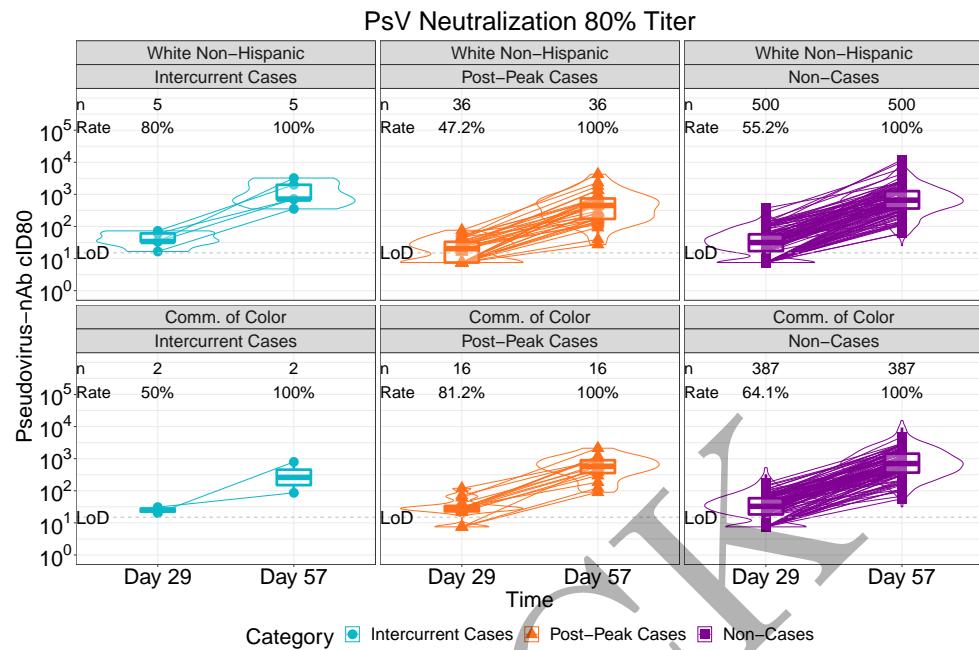


Figure 3.185: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by race and ethnic group (version 1)

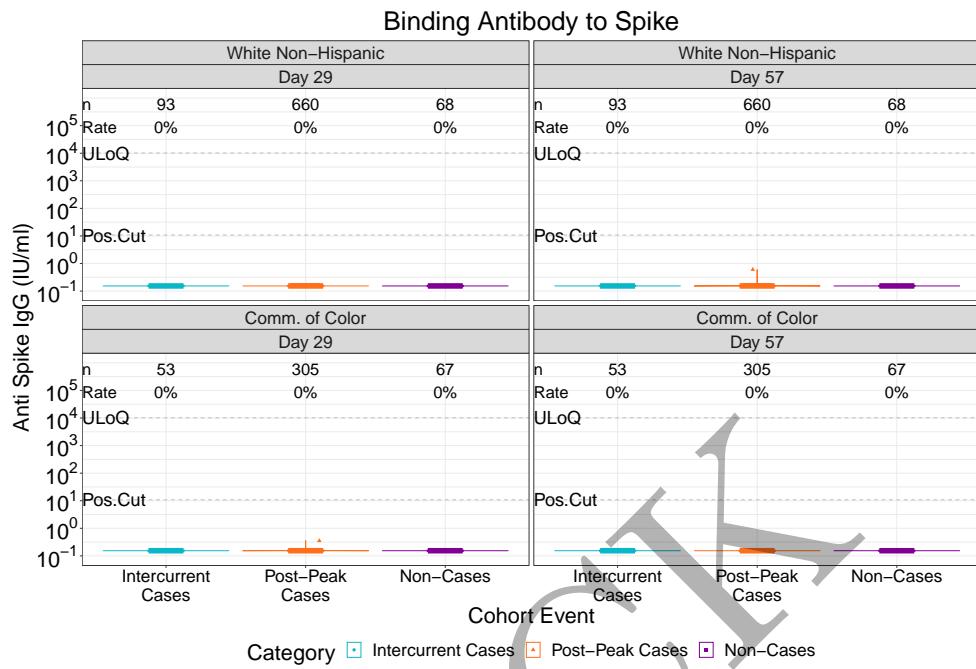


Figure 3.186: violinplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (version 1)

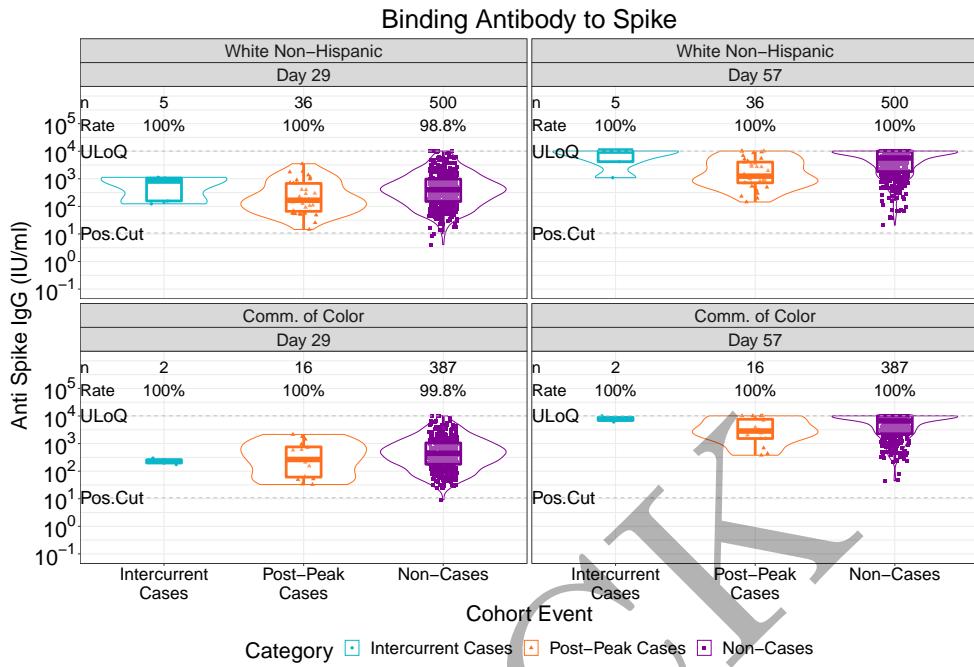


Figure 3.187: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (version 1)

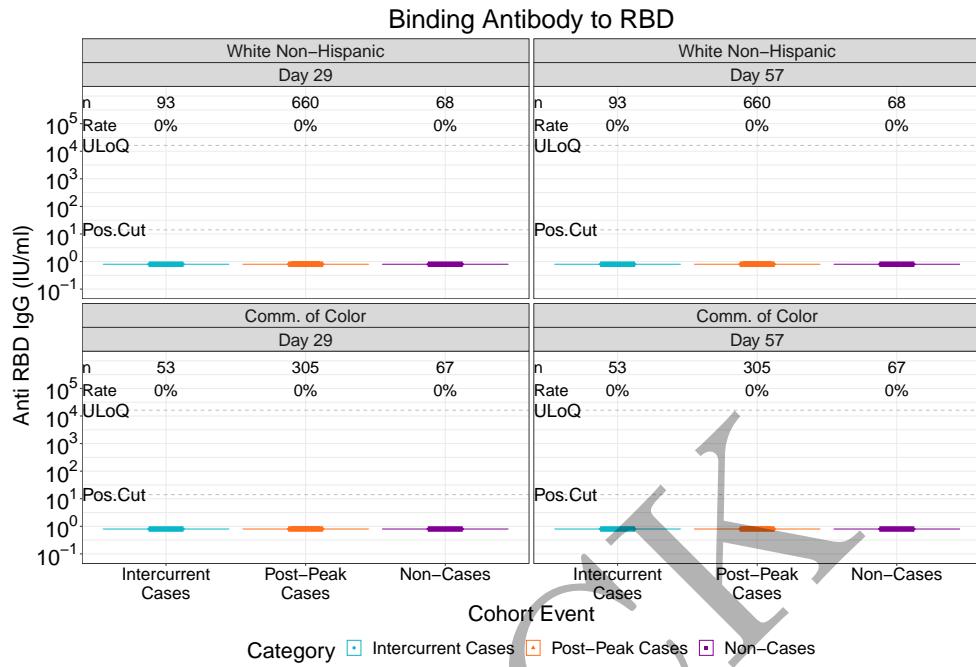


Figure 3.188: violinplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (version 1)

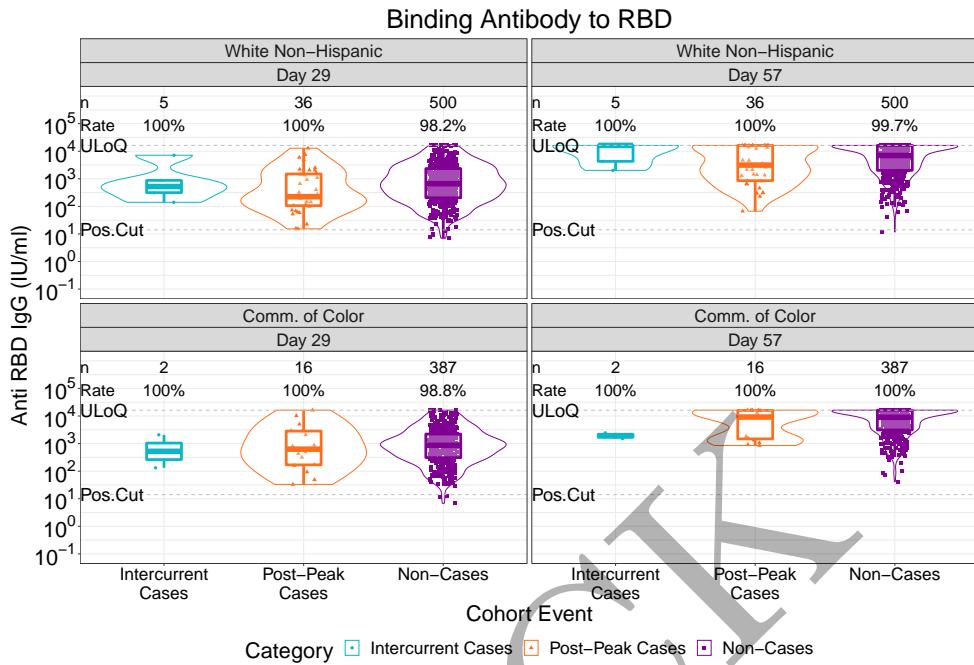


Figure 3.189: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (version 1)

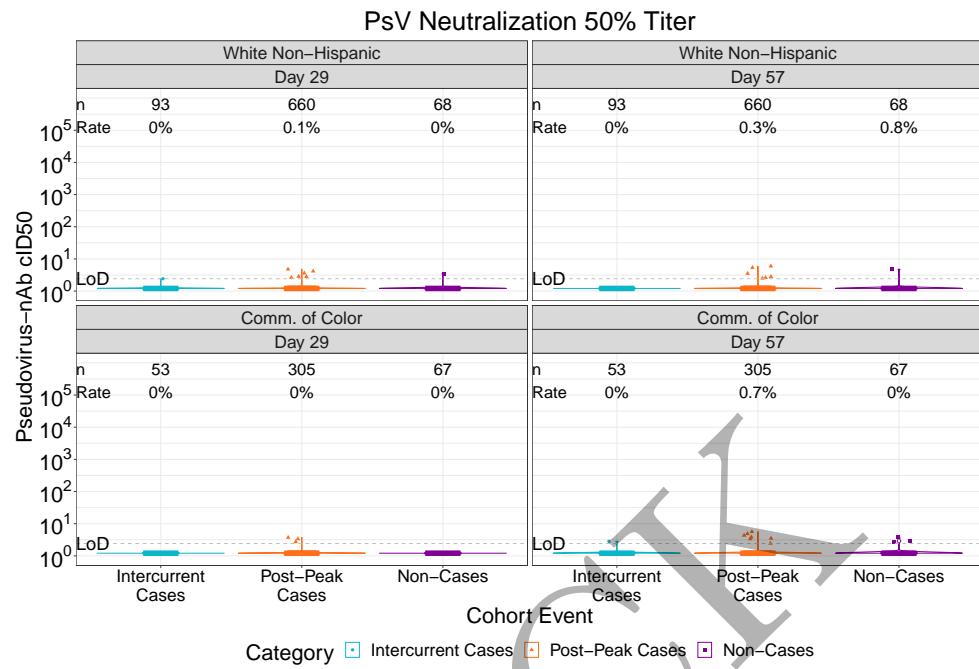


Figure 3.190: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by race and ethnic group (version 1)

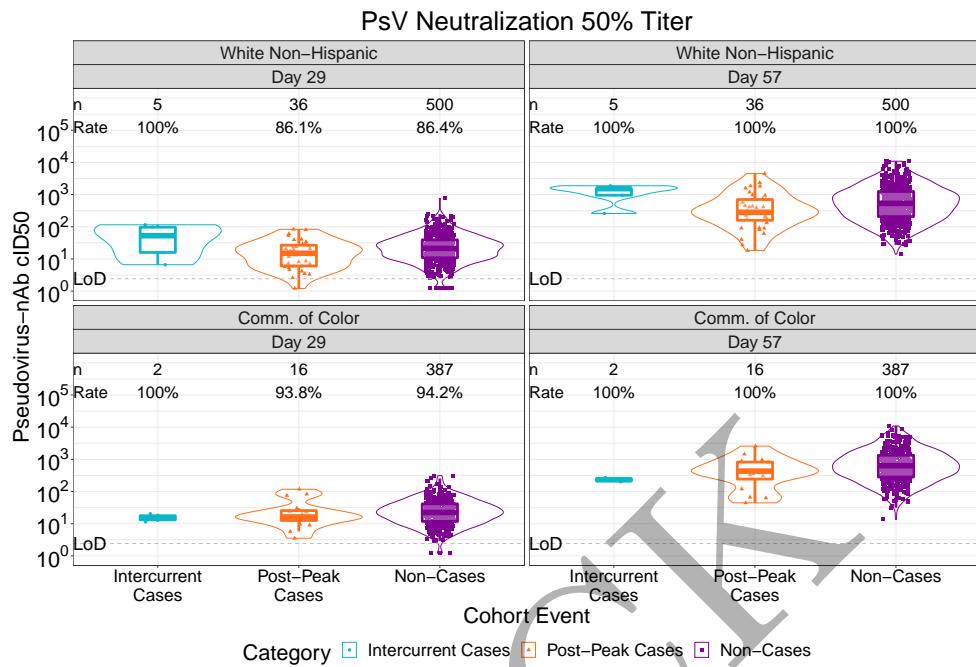


Figure 3.191: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by race and ethnic group (version 1)

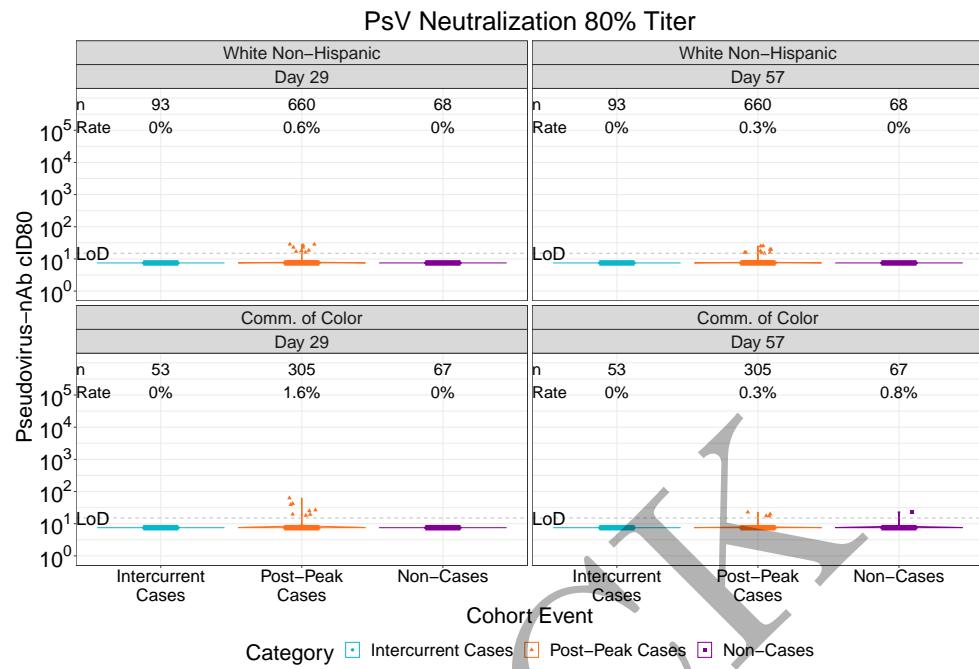


Figure 3.192: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by race and ethnic group (version 1)

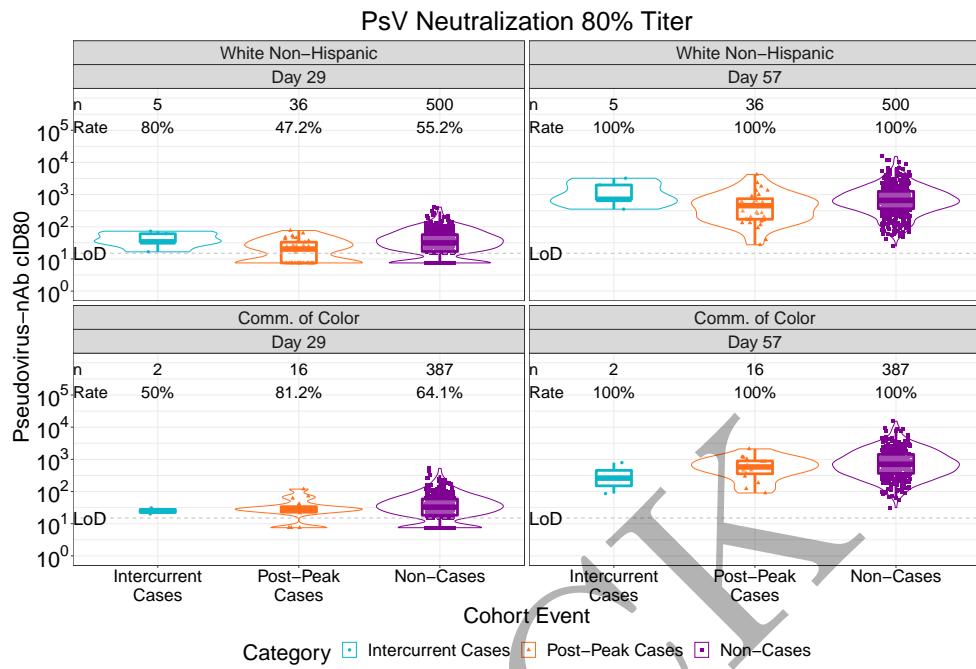
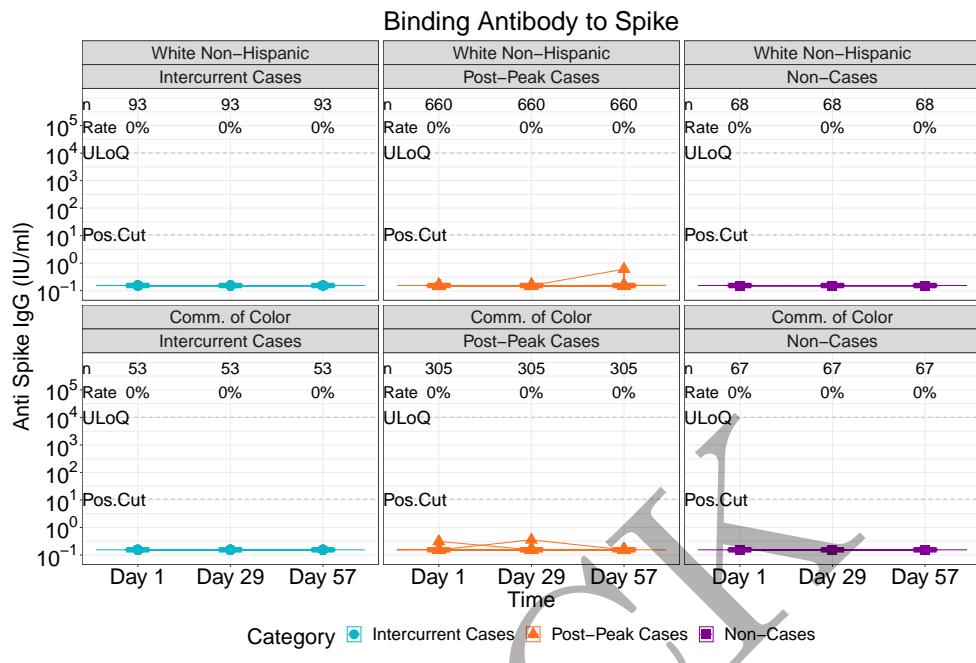
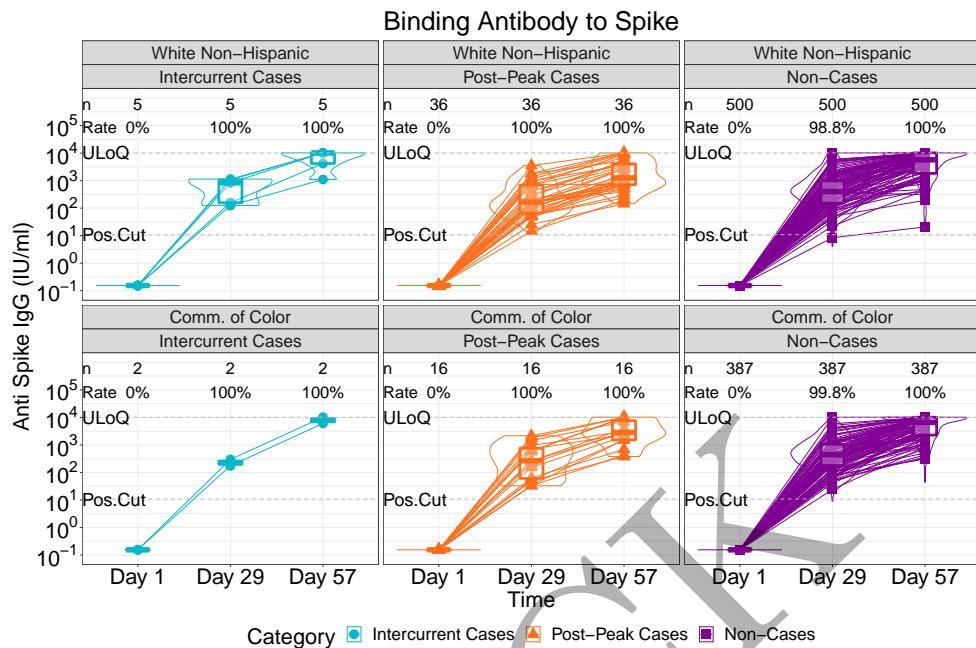


Figure 3.193: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by race and ethnic group (version 1)



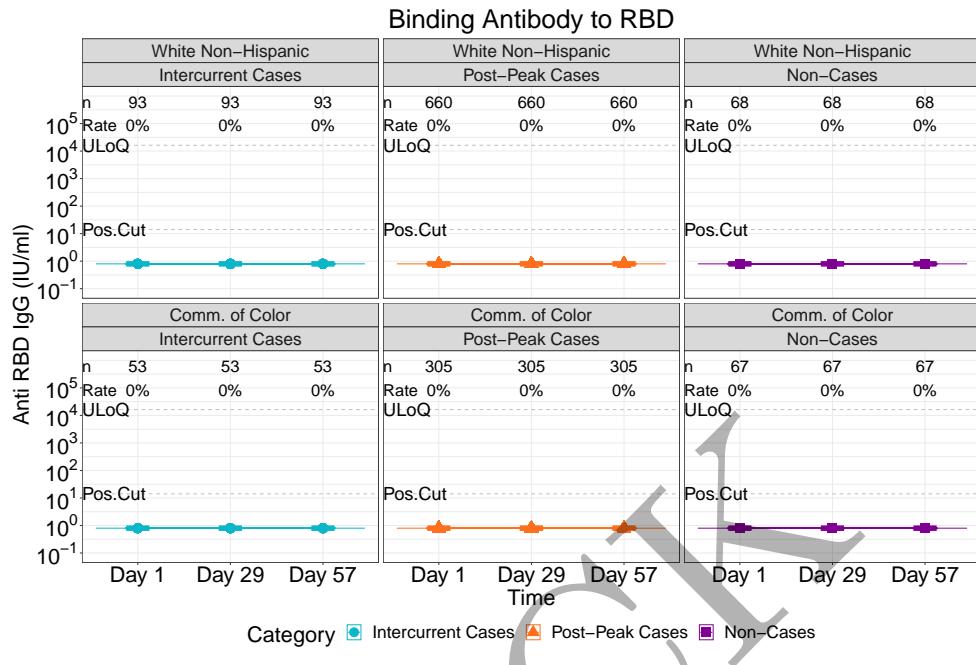
All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.194: lineplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (version 2)



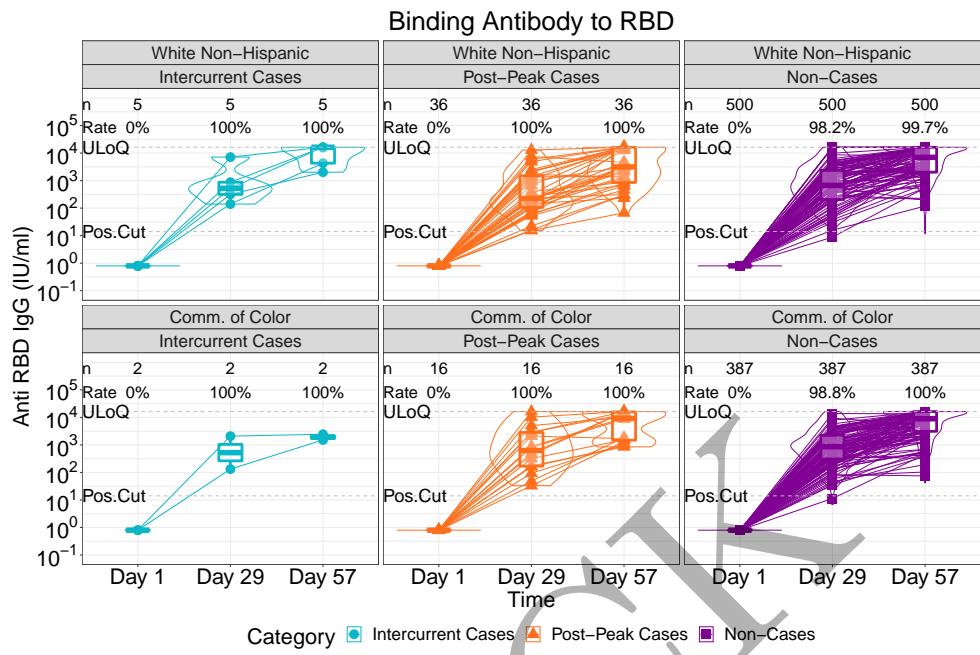
All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.195: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (version 2)



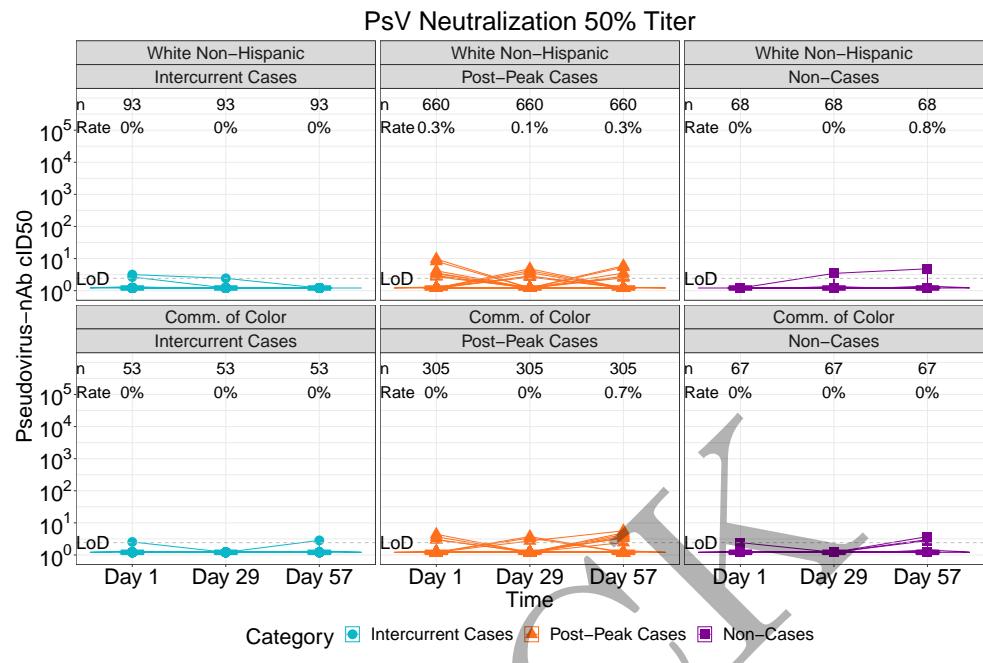
All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger

Figure 3.196: lineplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (version 2)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.197: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (version 2)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.198: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by race and ethnic group (version 2)

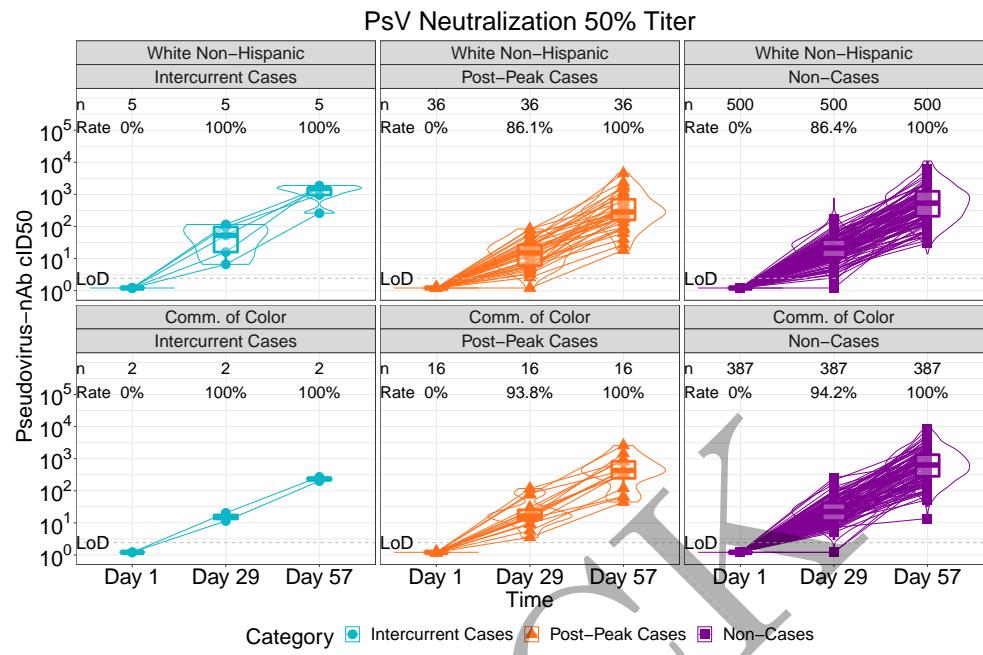
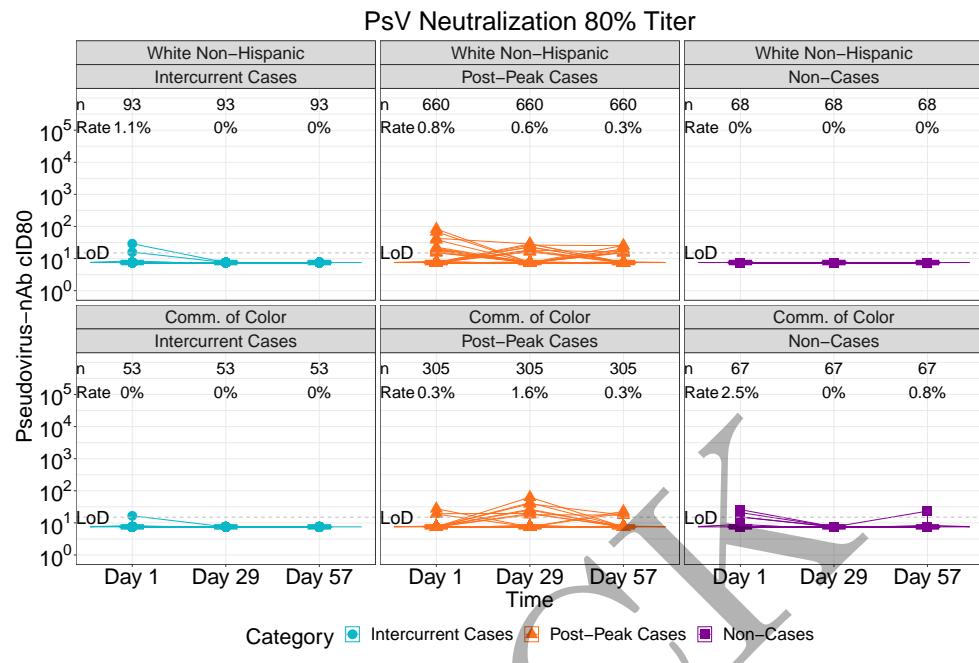
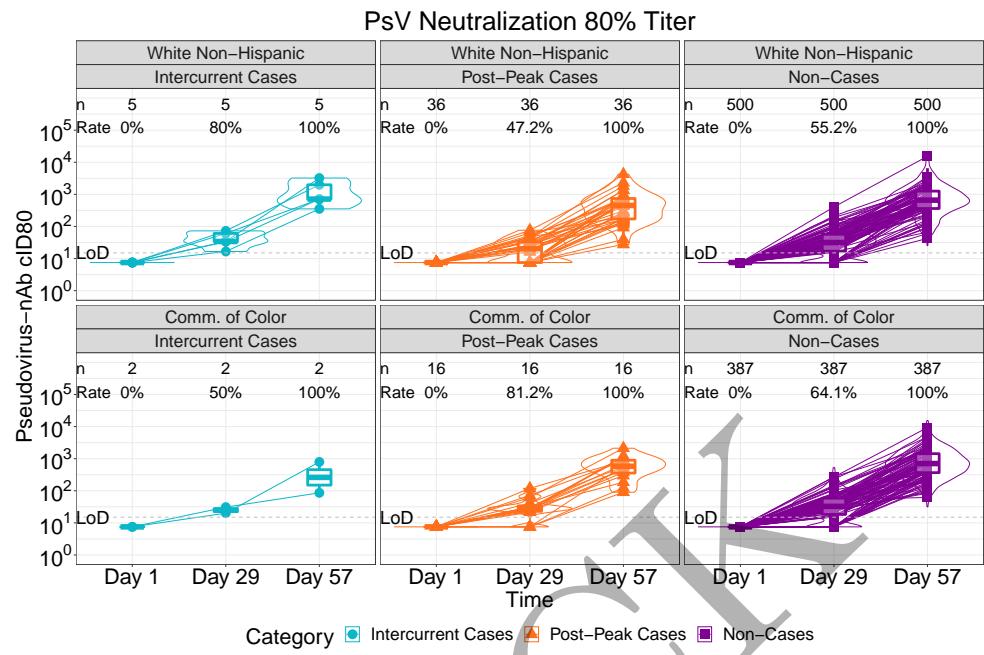


Figure 3.199: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by race and ethnic group (version 2)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.200: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by race and ethnic group (version 2)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.201: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by race and ethnic group (version 2)

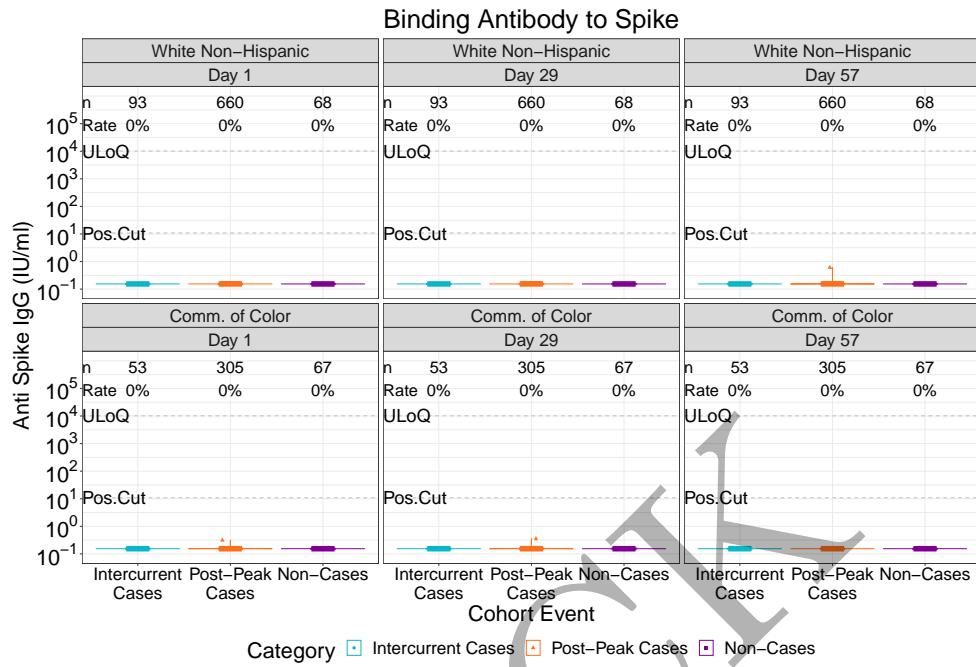


Figure 3.202: violinplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (version 2)

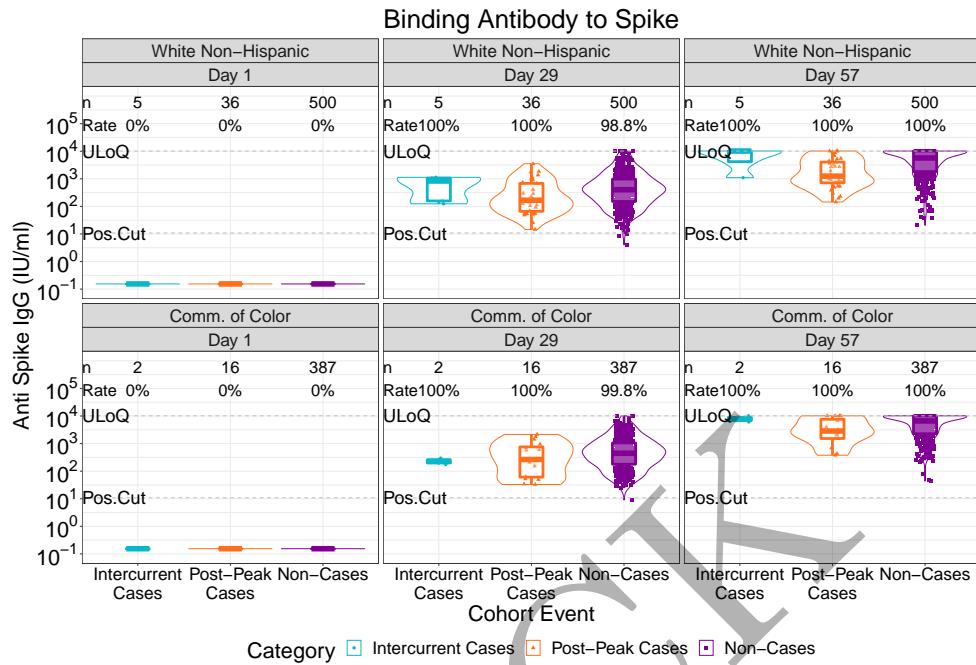


Figure 3.203: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (version 2)

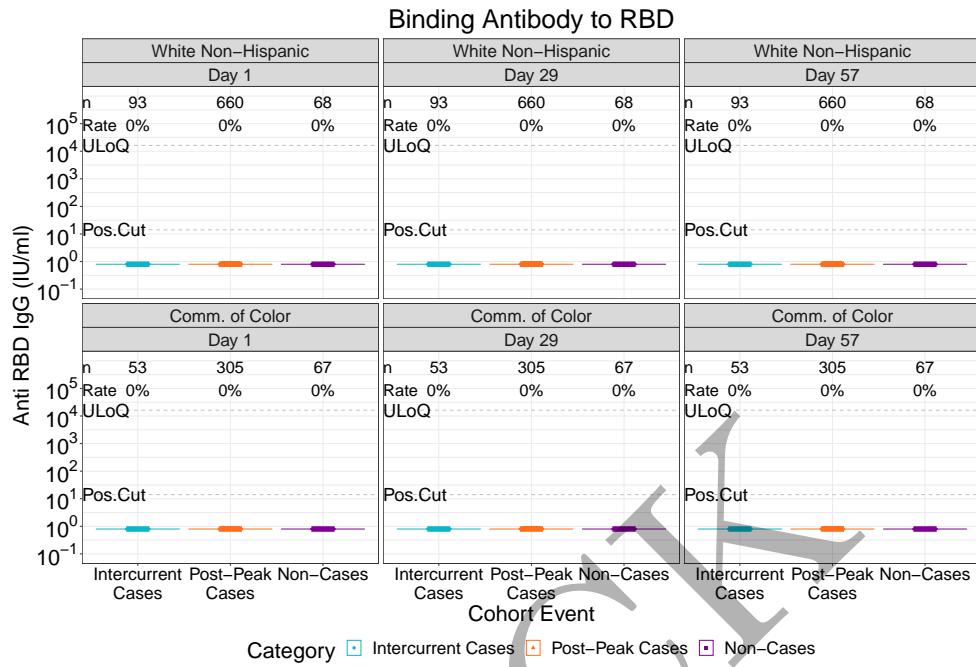


Figure 3.204: violinplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (version 2)

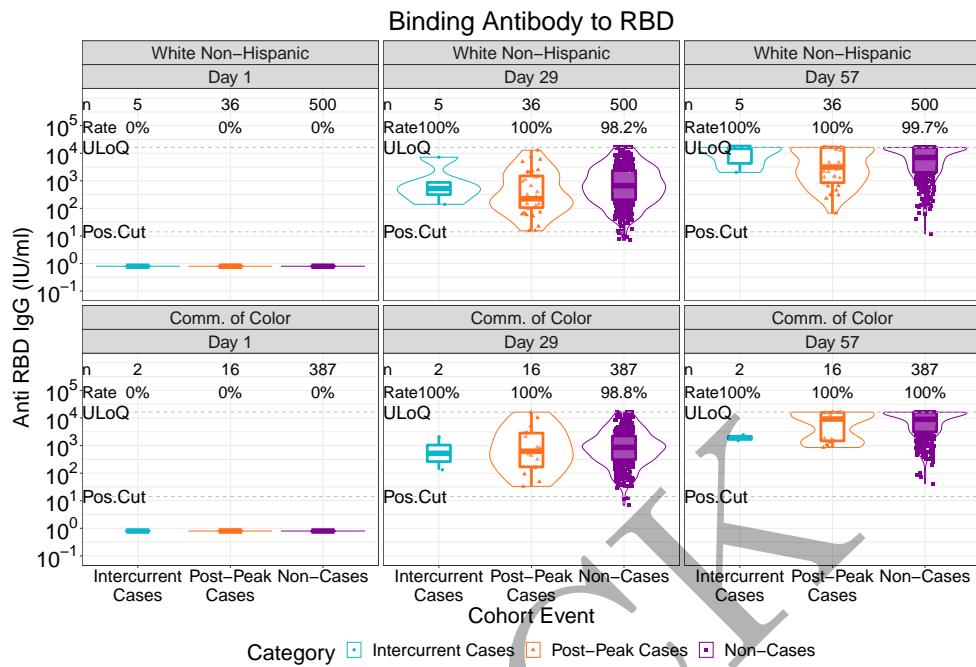


Figure 3.205: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (version 2)

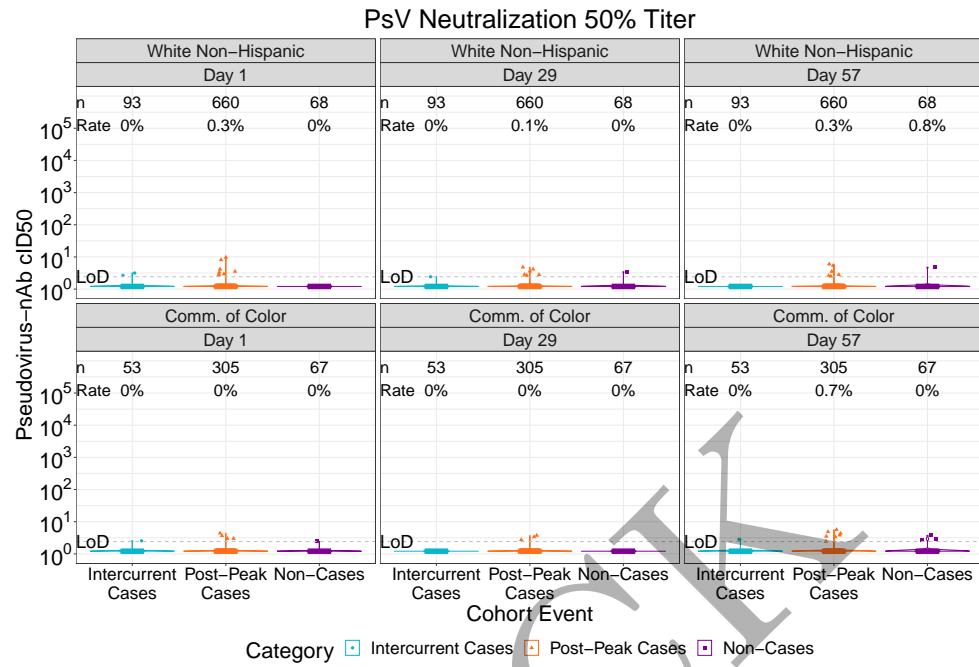


Figure 3.206: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by race and ethnic group (version 2)

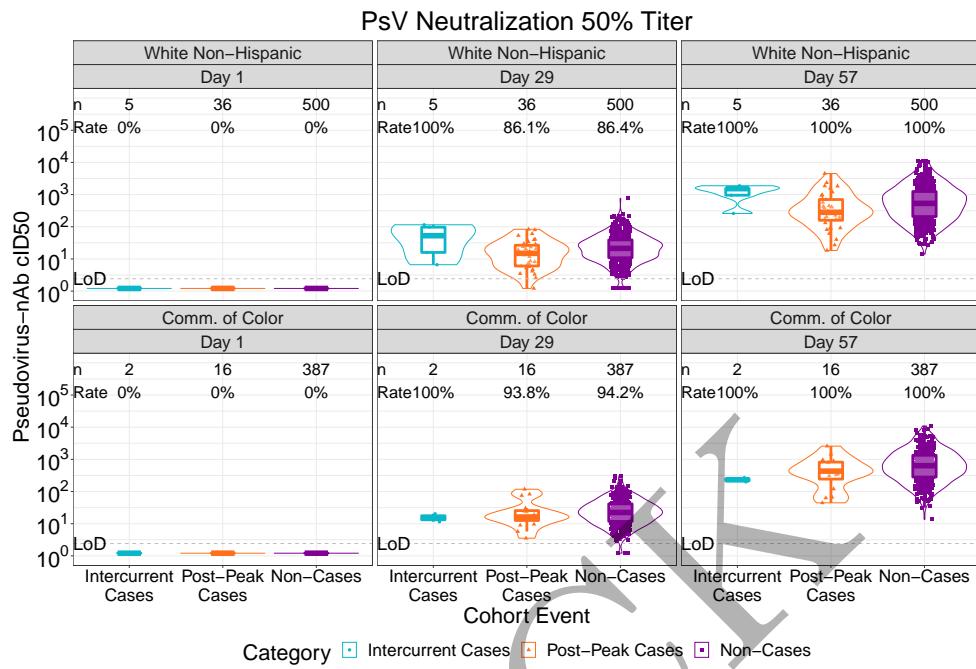


Figure 3.207: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by race and ethnic group (version 2)

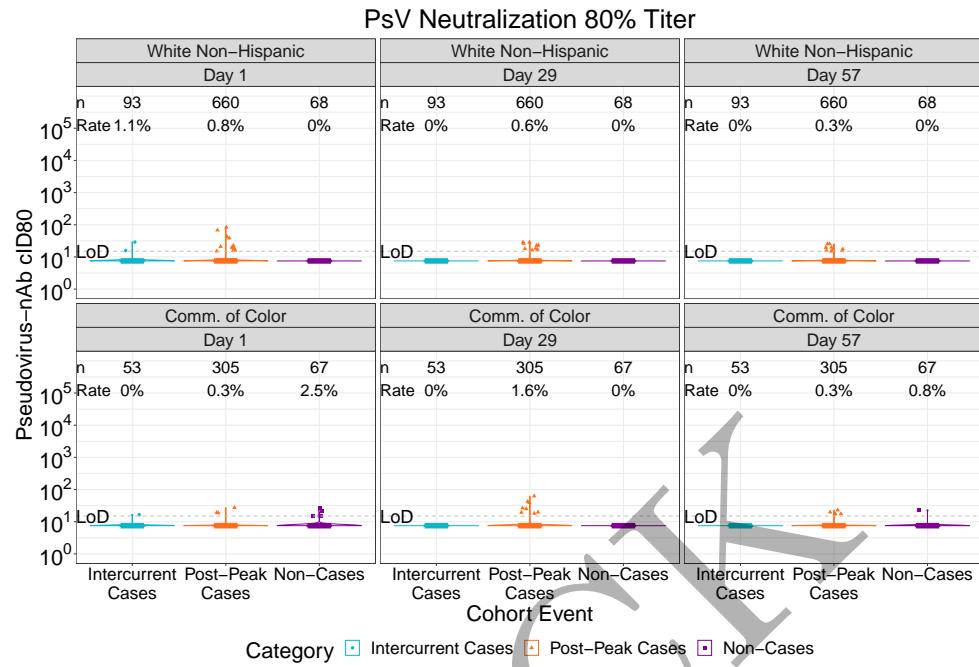


Figure 3.208: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by race and ethnic group (version 2)

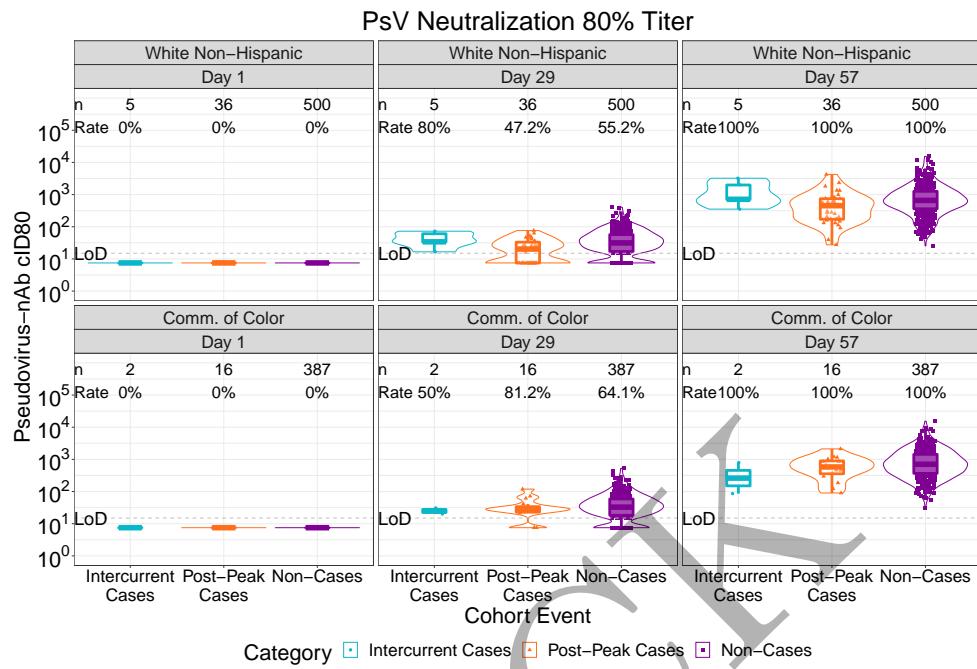
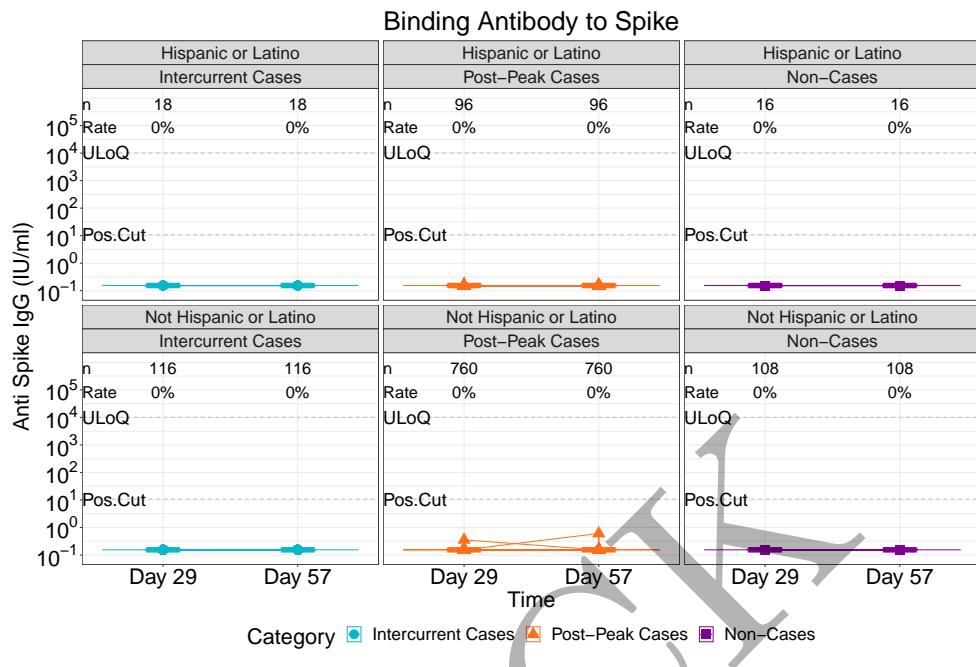
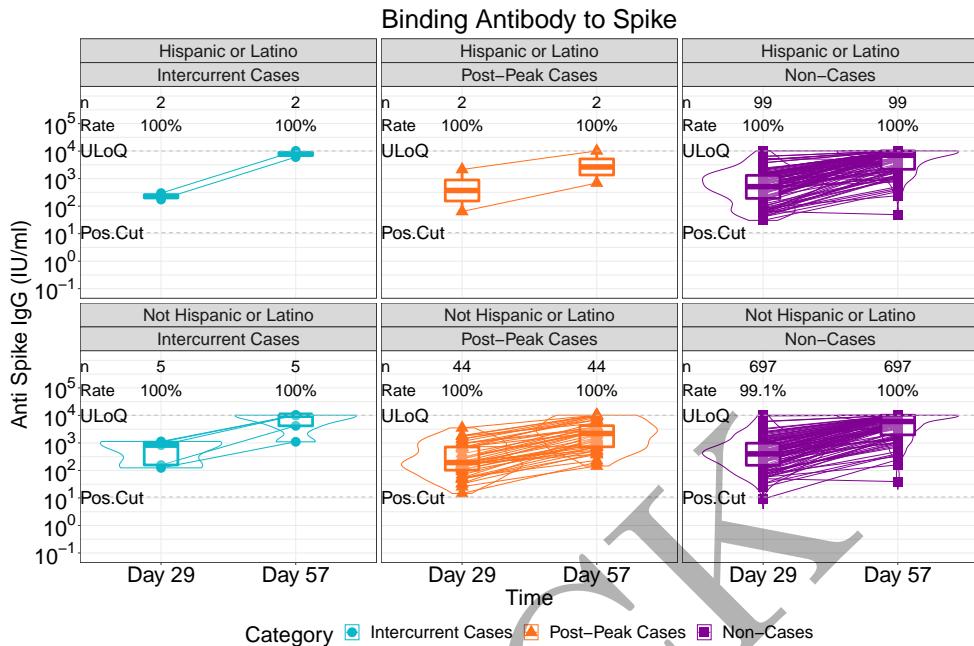


Figure 3.209: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by race and ethnic group (version 2)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.210: lineplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.211: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)

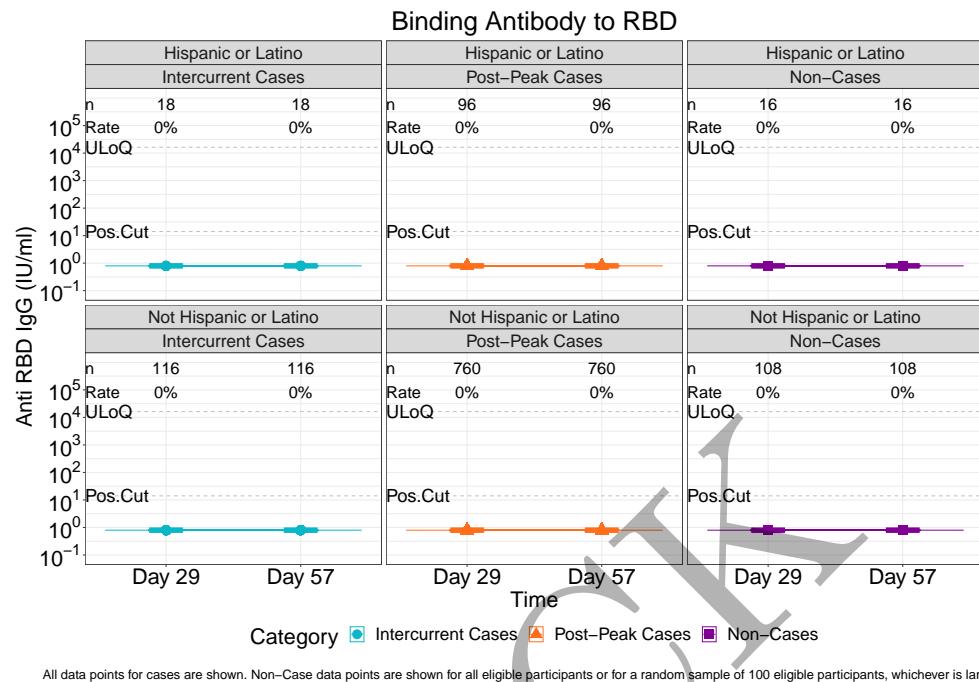


Figure 3.212: lineplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)

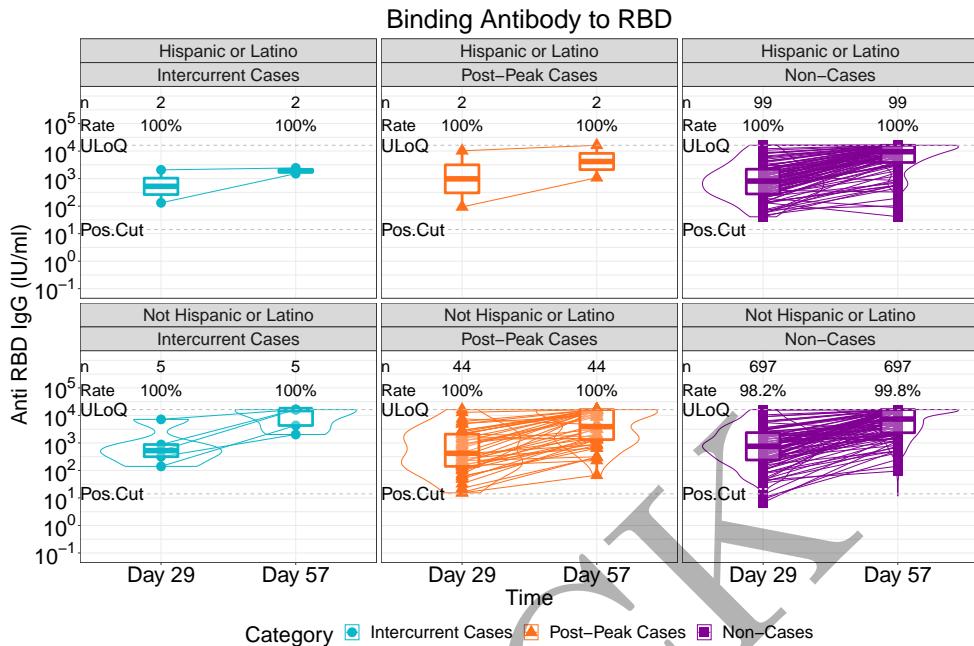


Figure 3.213: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)

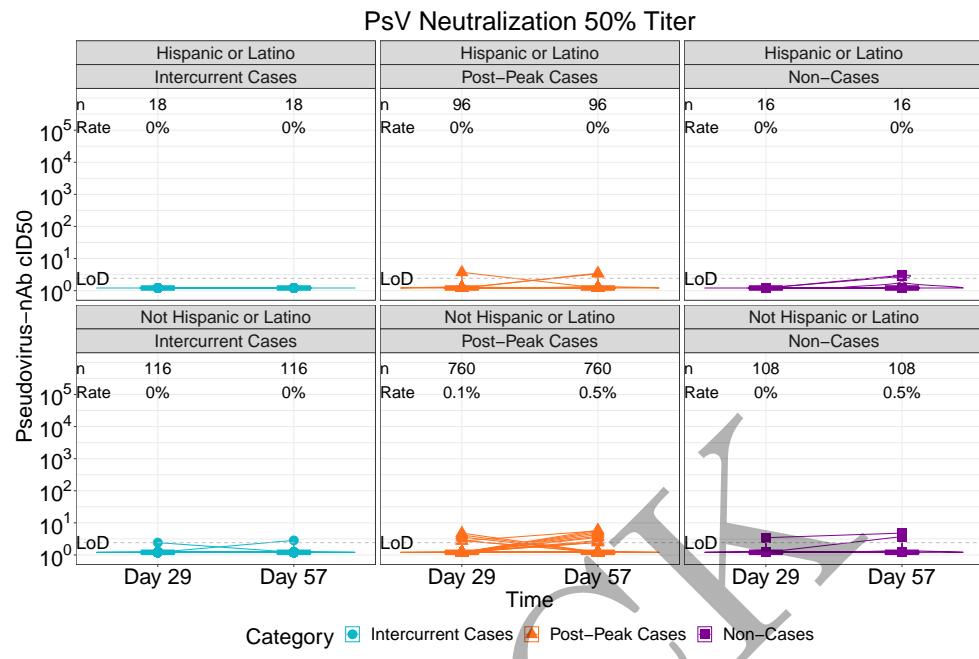


Figure 3.214: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)

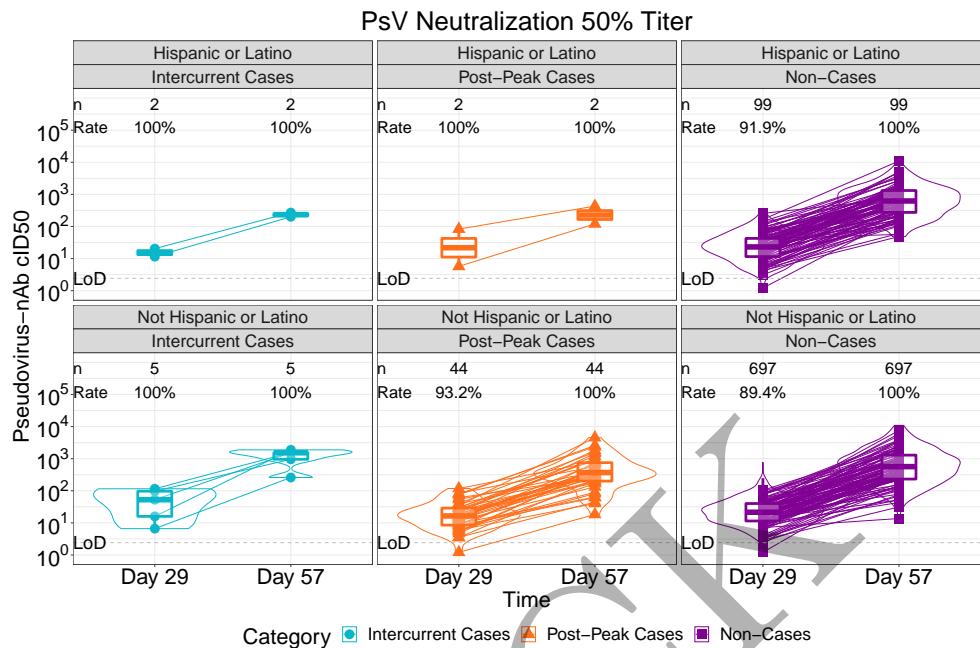
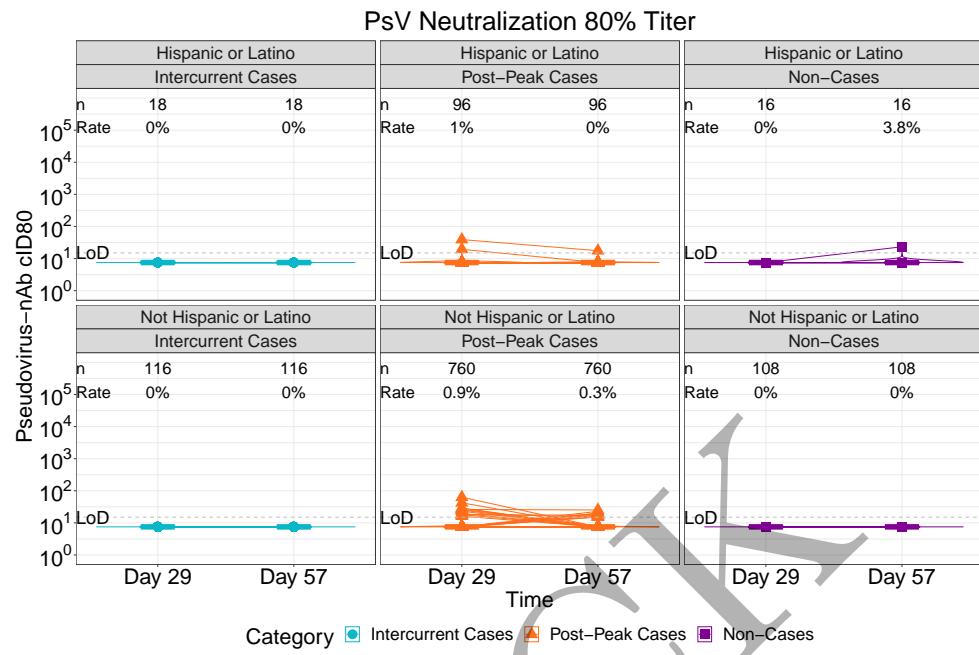


Figure 3.215: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.216: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)

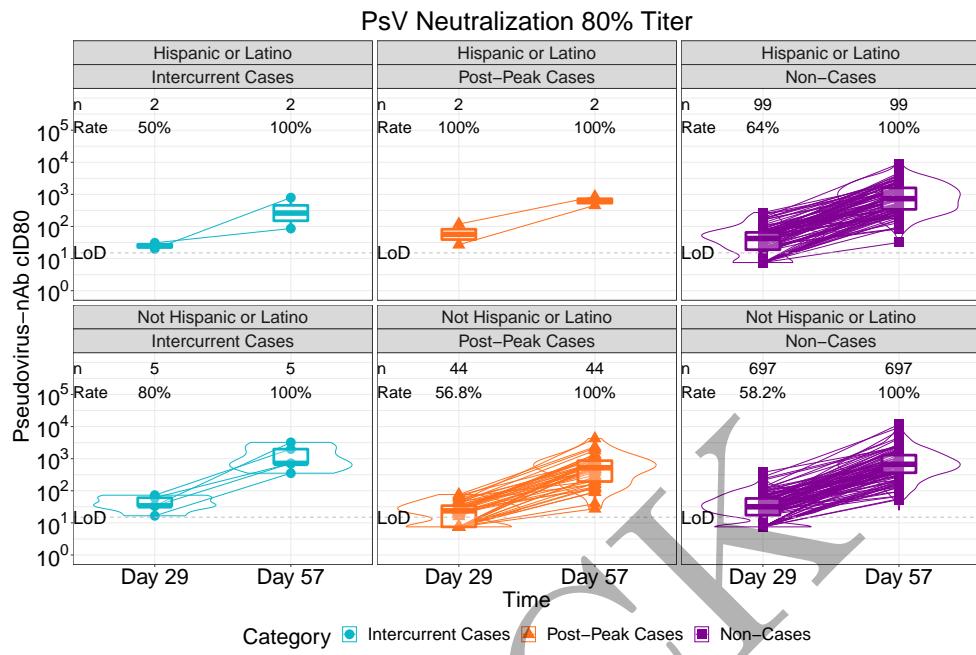


Figure 3.217: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)

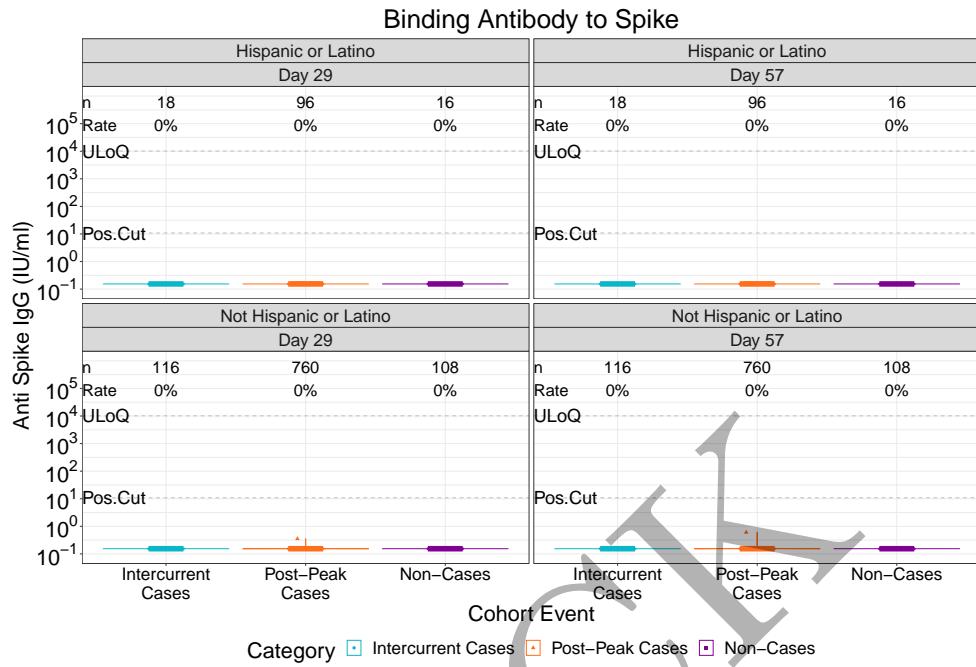


Figure 3.218: violinplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)

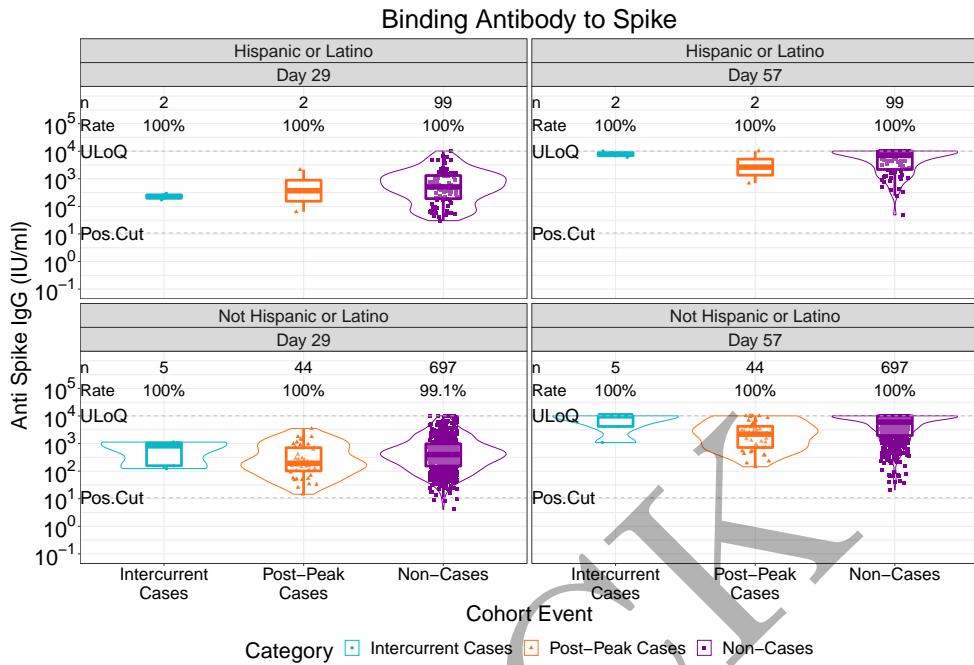


Figure 3.219: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)

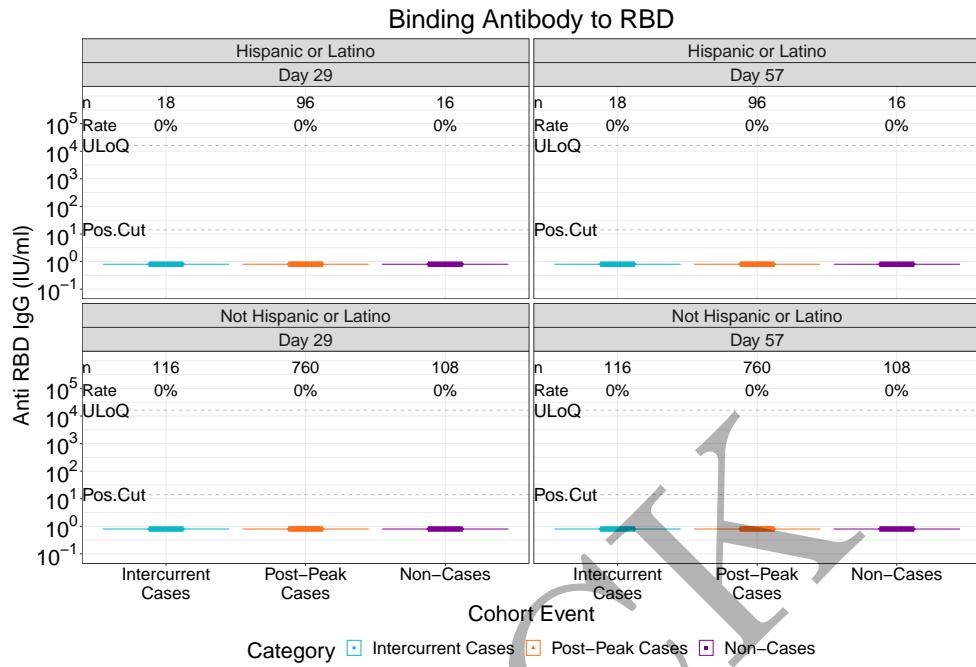


Figure 3.220: violinplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)

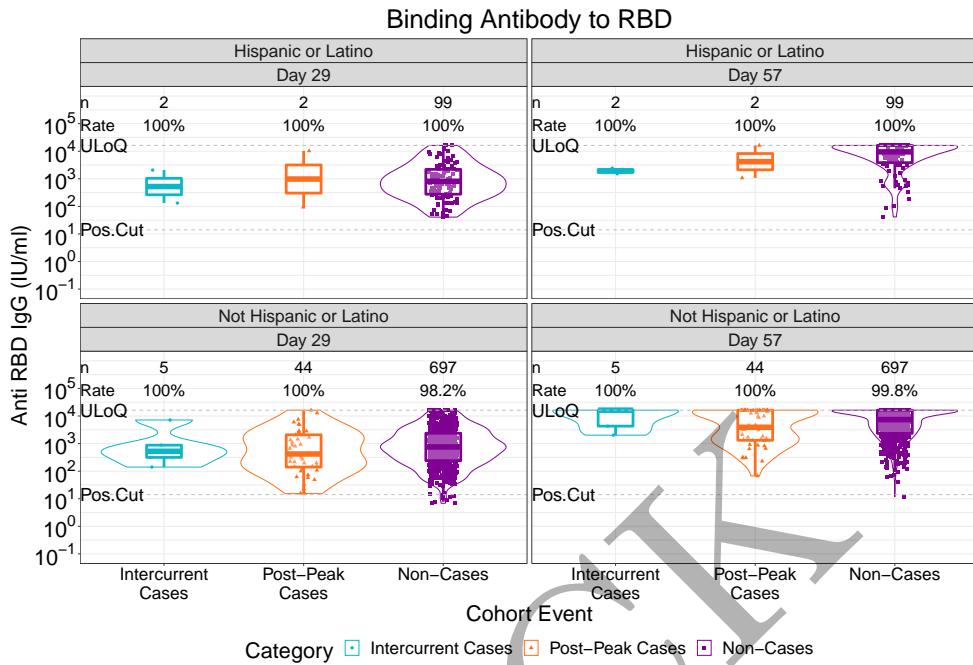


Figure 3.221: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)

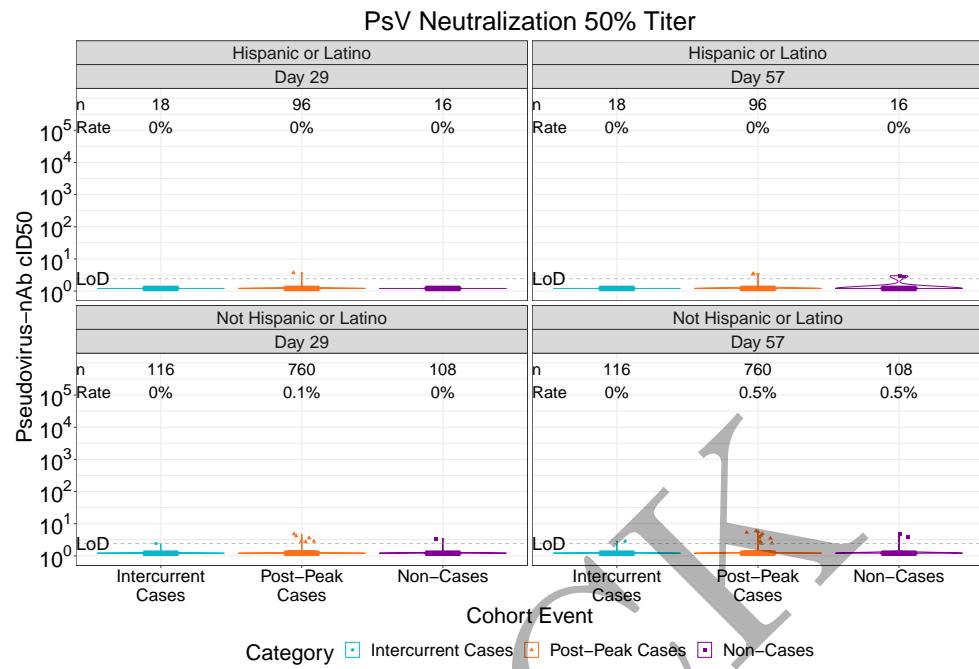


Figure 3.222: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)

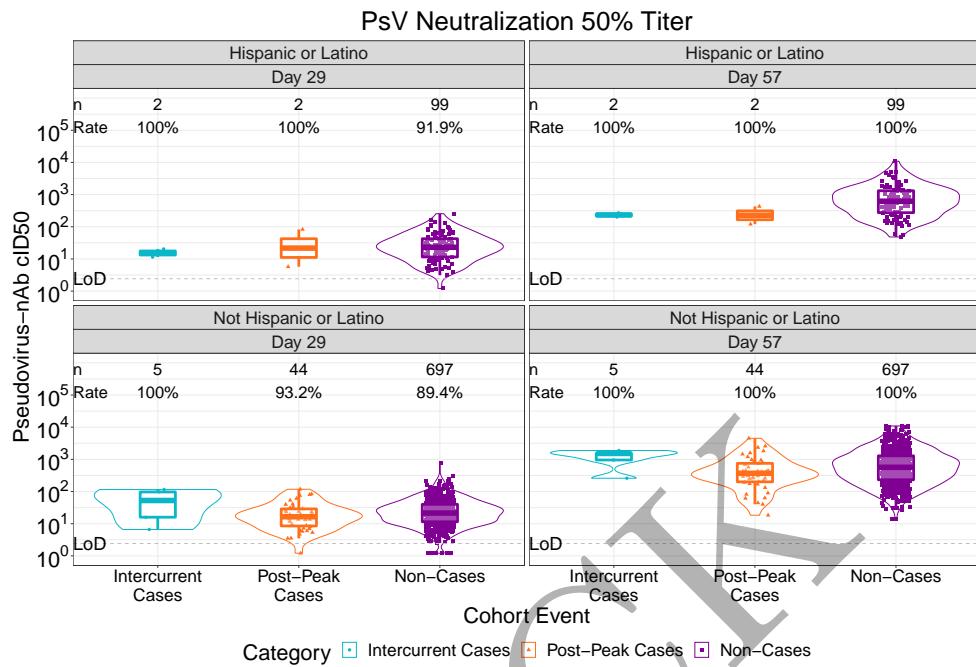


Figure 3.223: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)

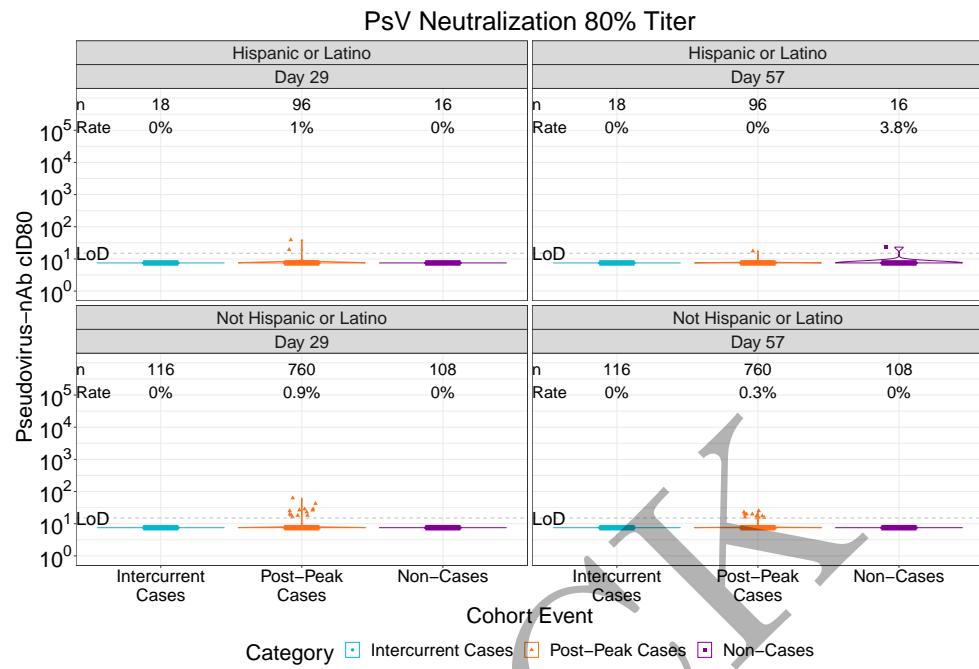


Figure 3.224: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)

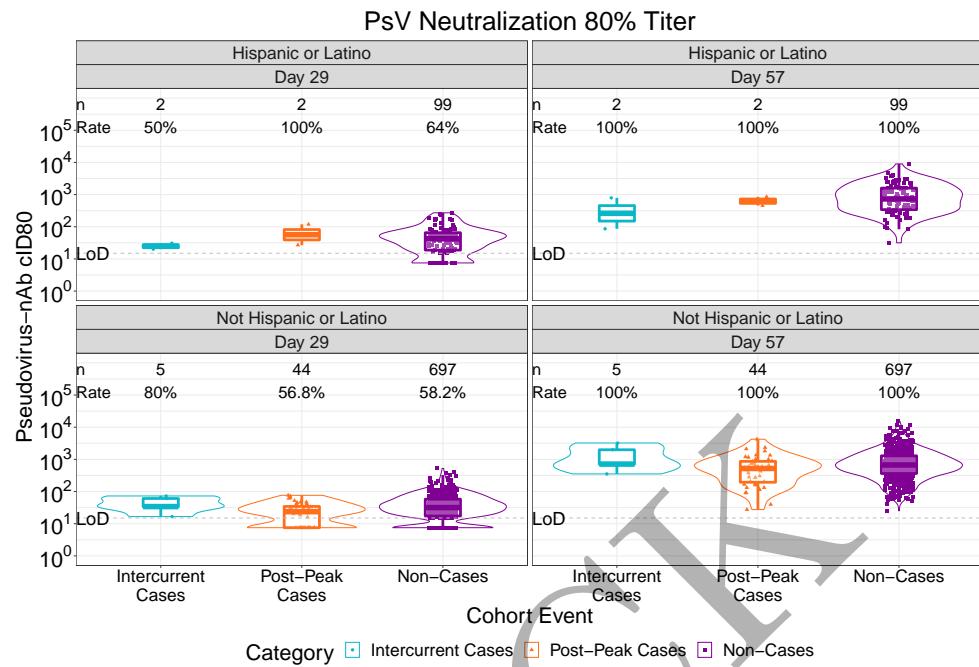
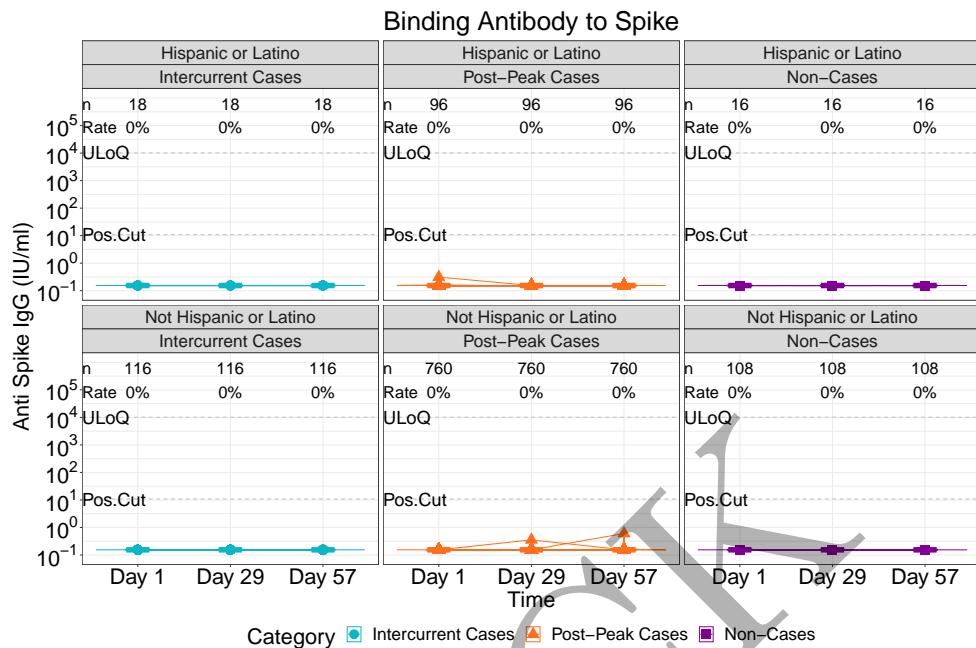
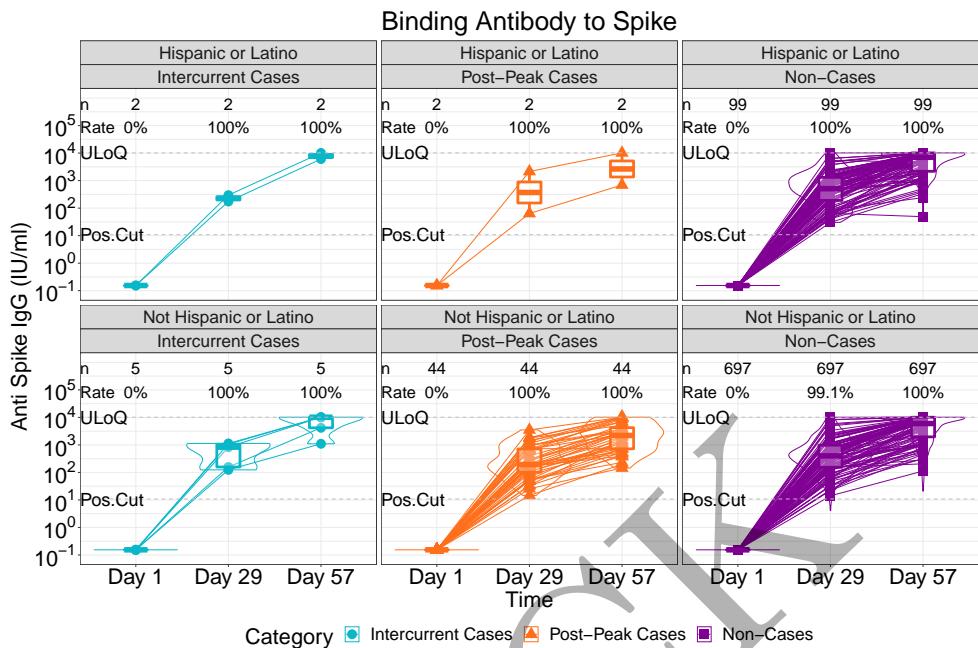


Figure 3.225: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.226: lineplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.227: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)

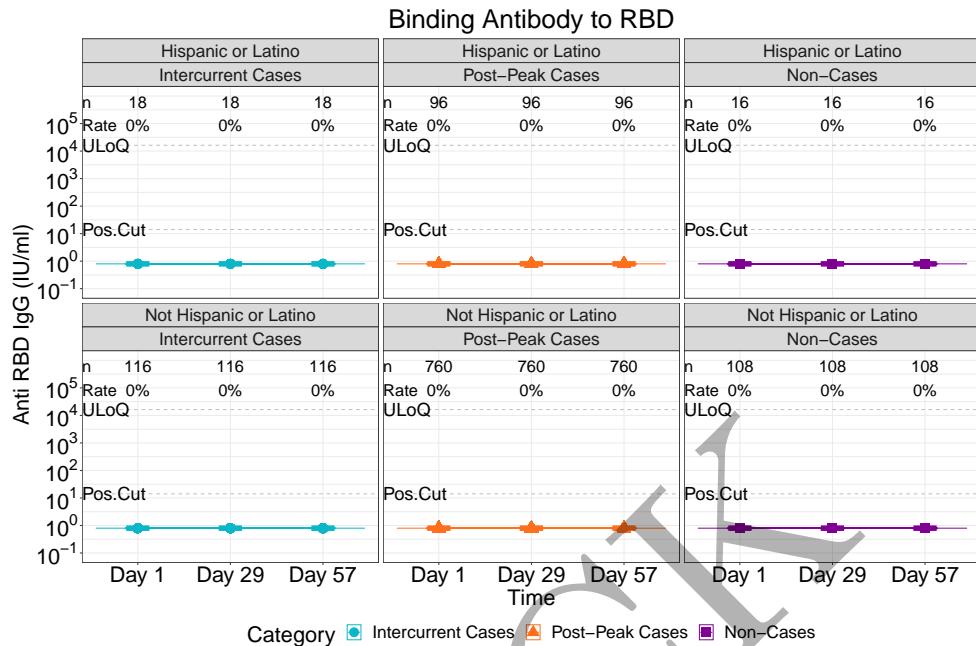
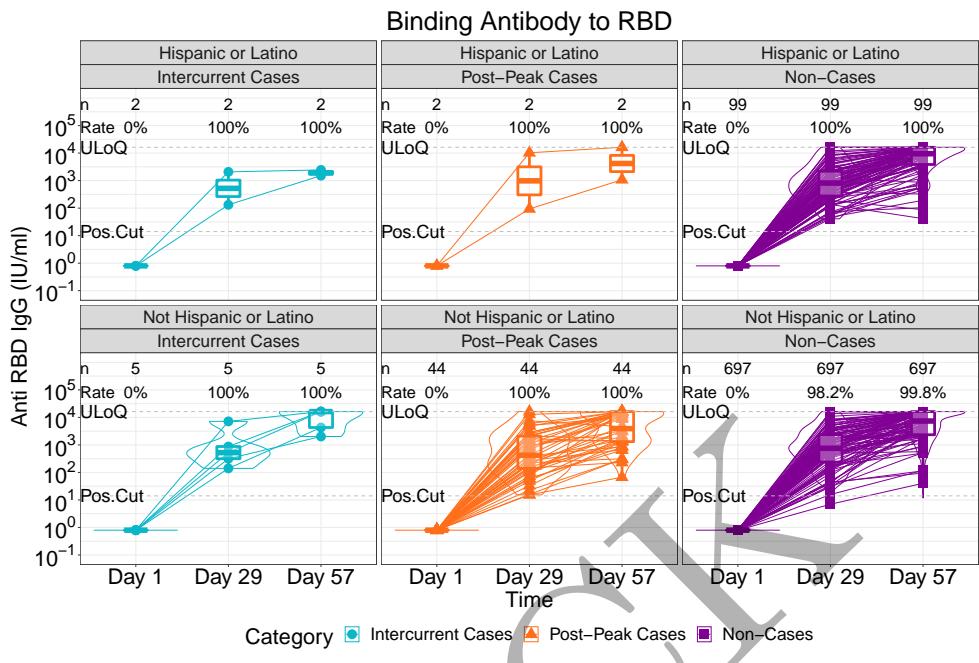
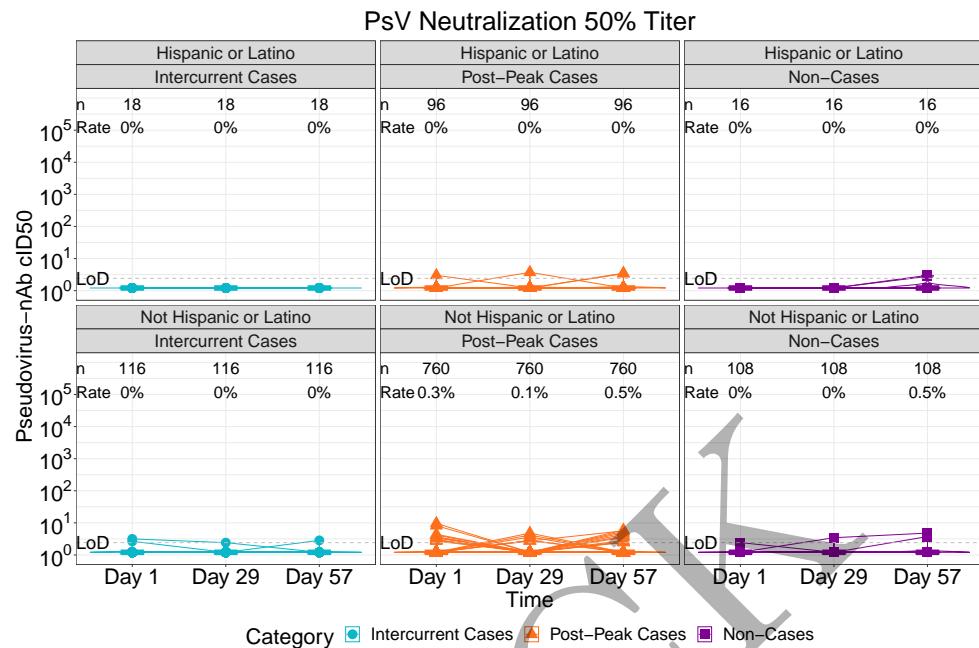


Figure 3.228: lineplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)



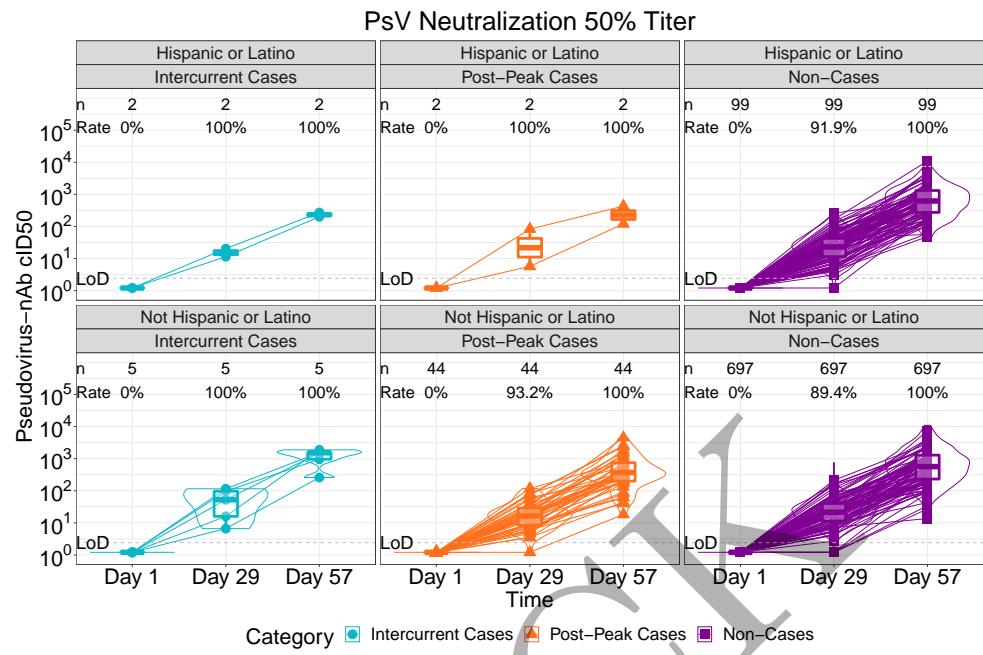
All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.229: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)



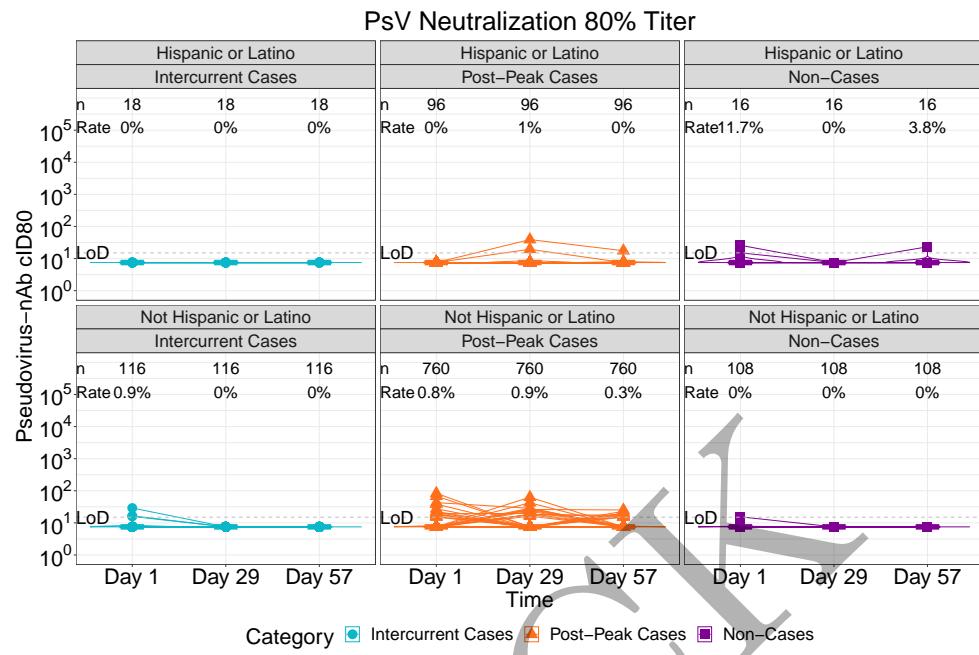
All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.230: lineplots of Pseudovirus Neutralization ID₅₀: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)



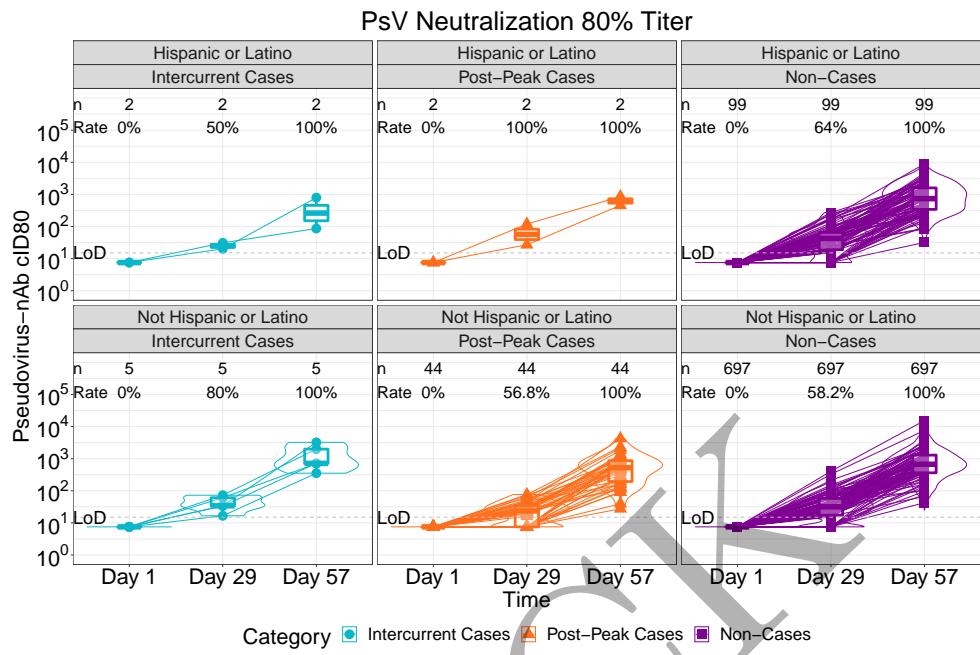
All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.231: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.232: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)



All data points for cases are shown. Non-Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger.

Figure 3.233: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)

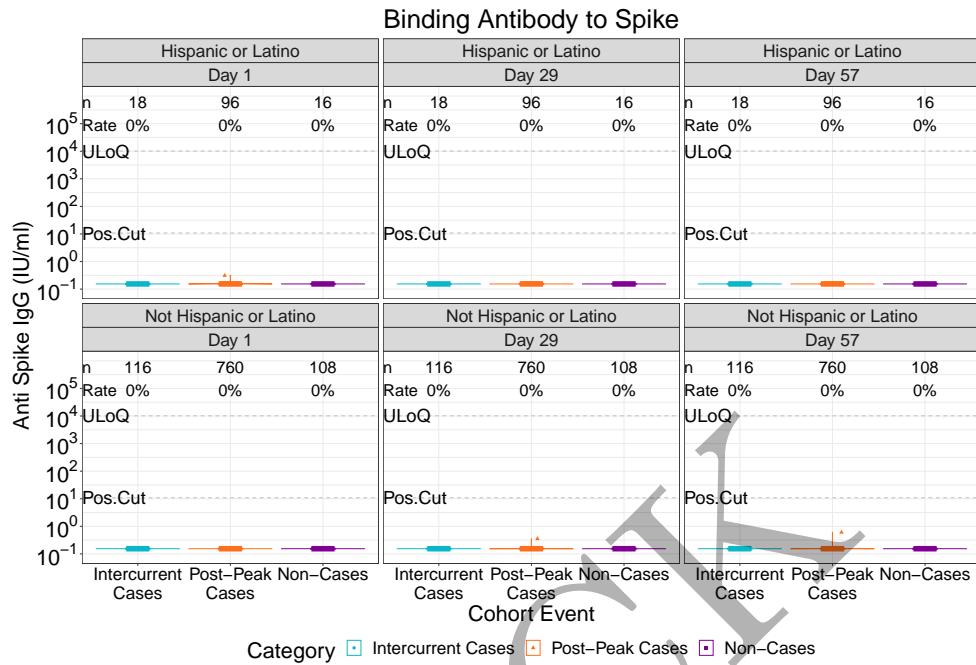


Figure 3.234: violinplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)

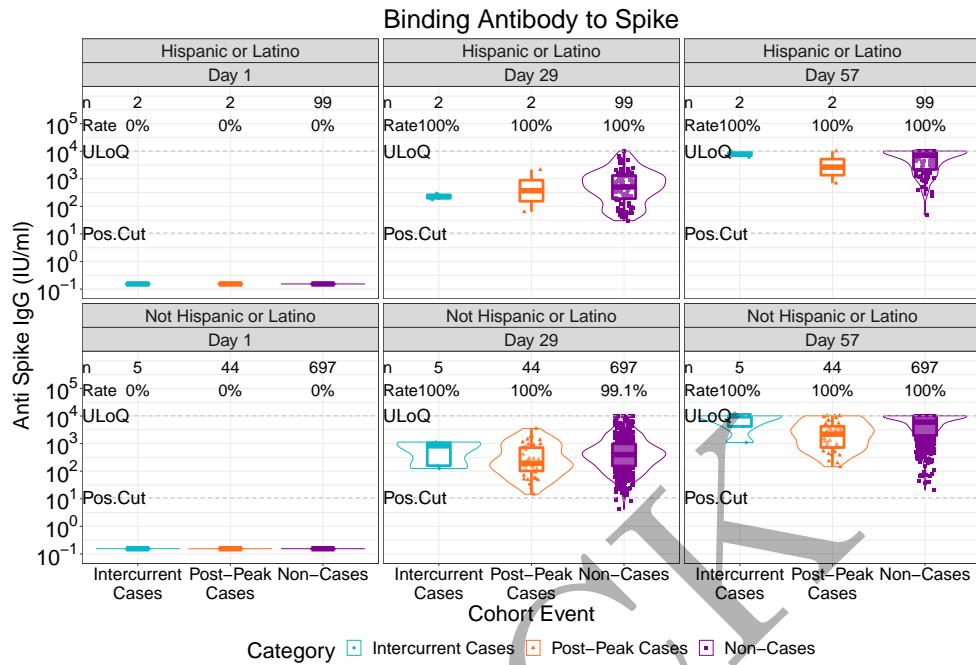


Figure 3.235: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)

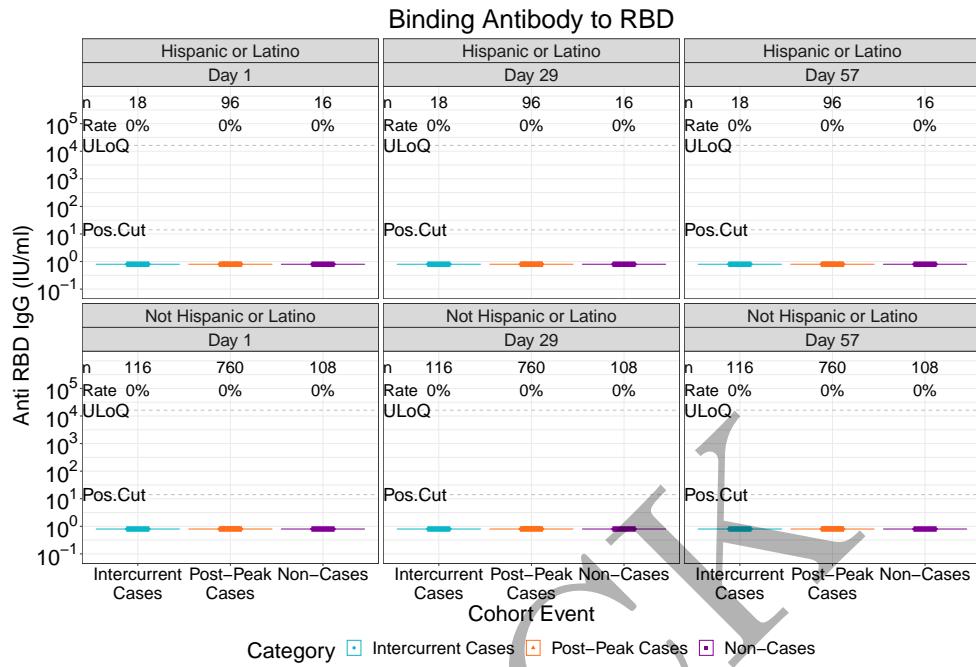


Figure 3.236: violinplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)

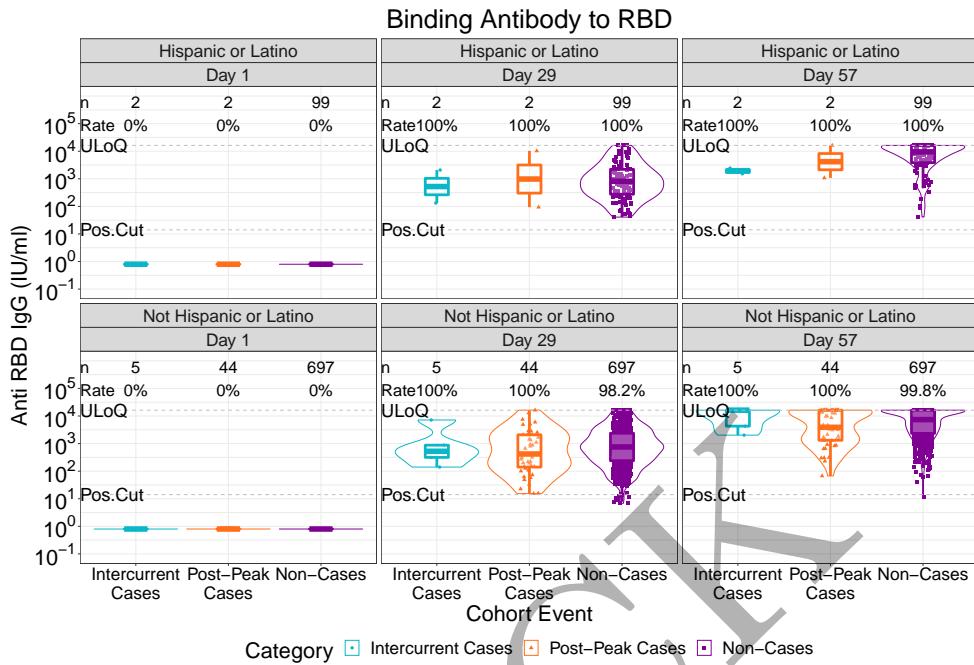


Figure 3.237: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)

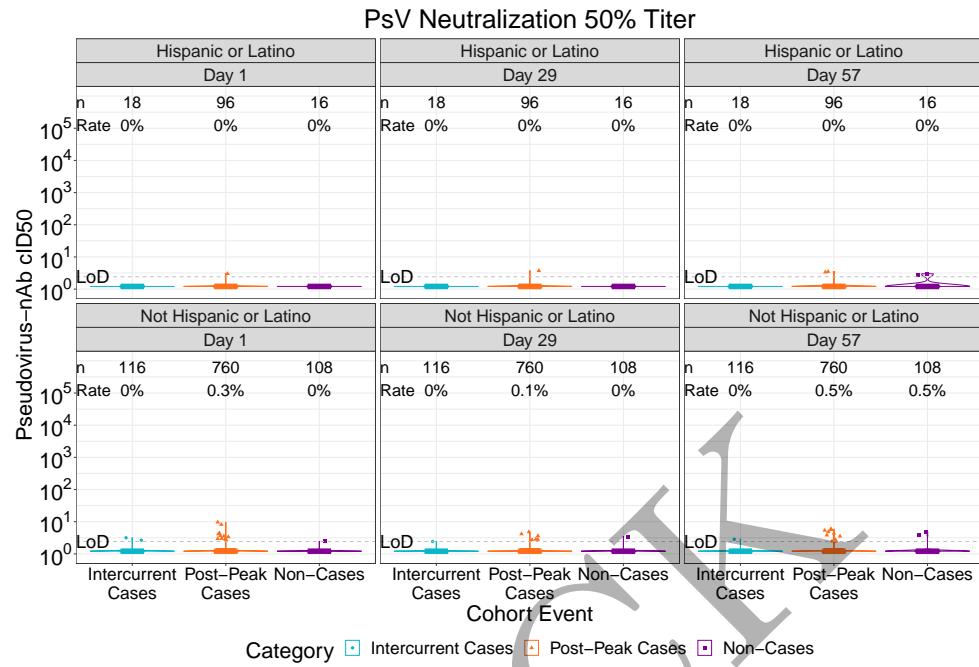


Figure 3.238: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)

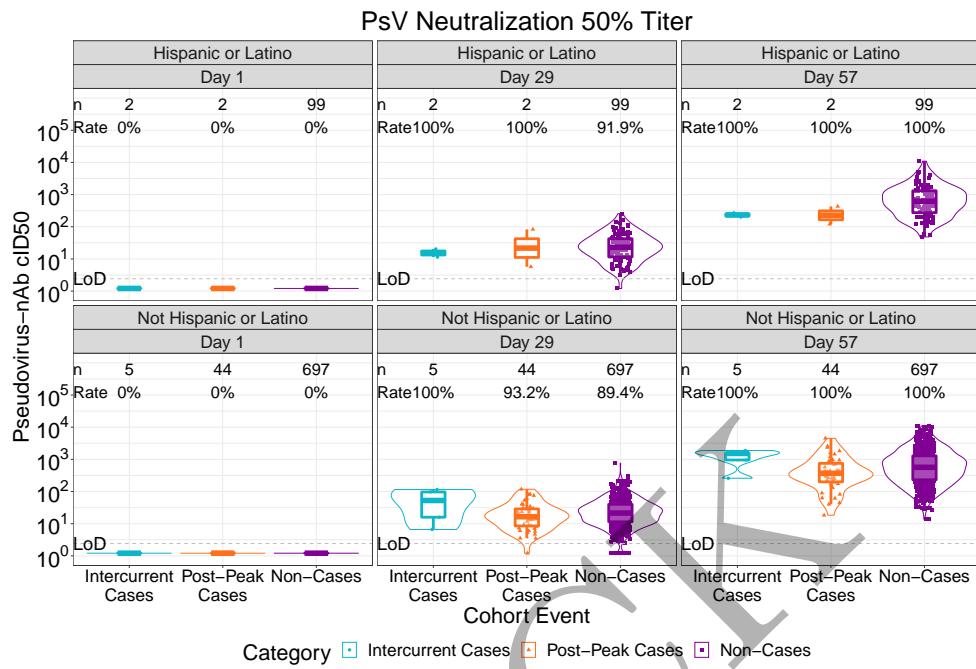


Figure 3.239: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)

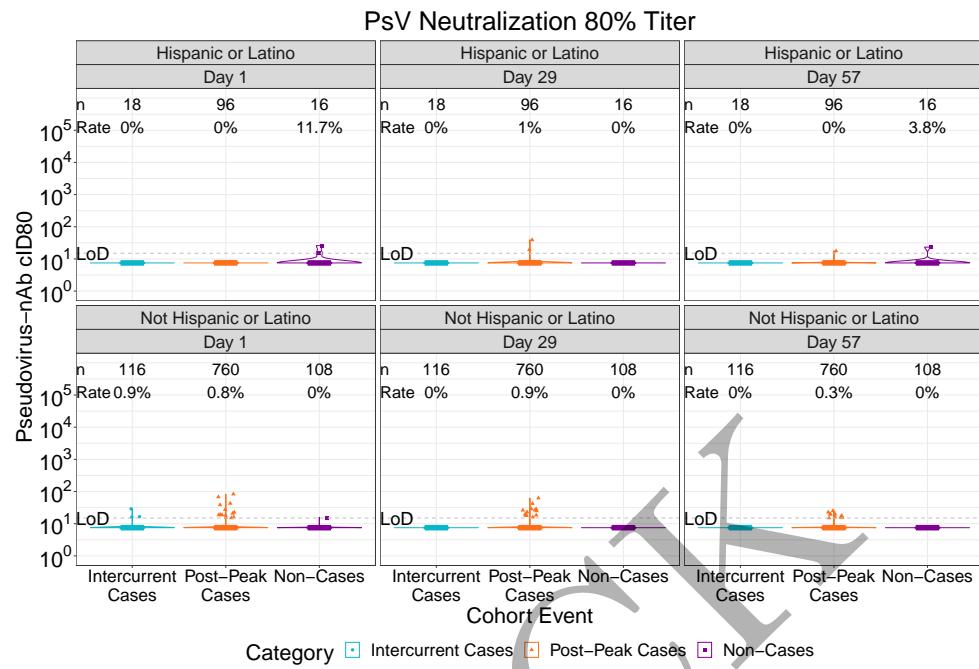


Figure 3.240: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)

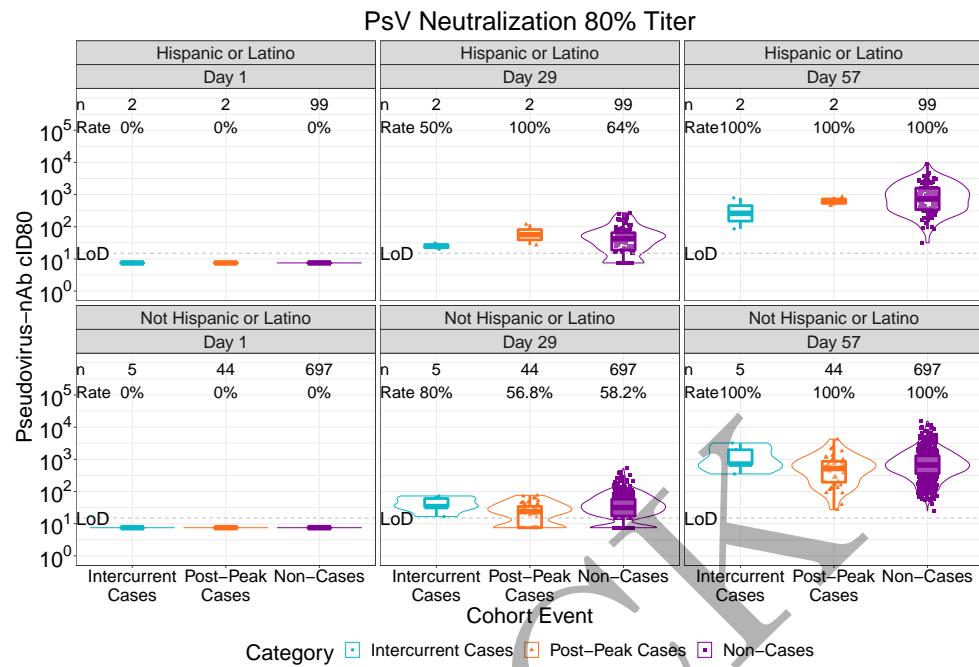


Figure 3.241: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)

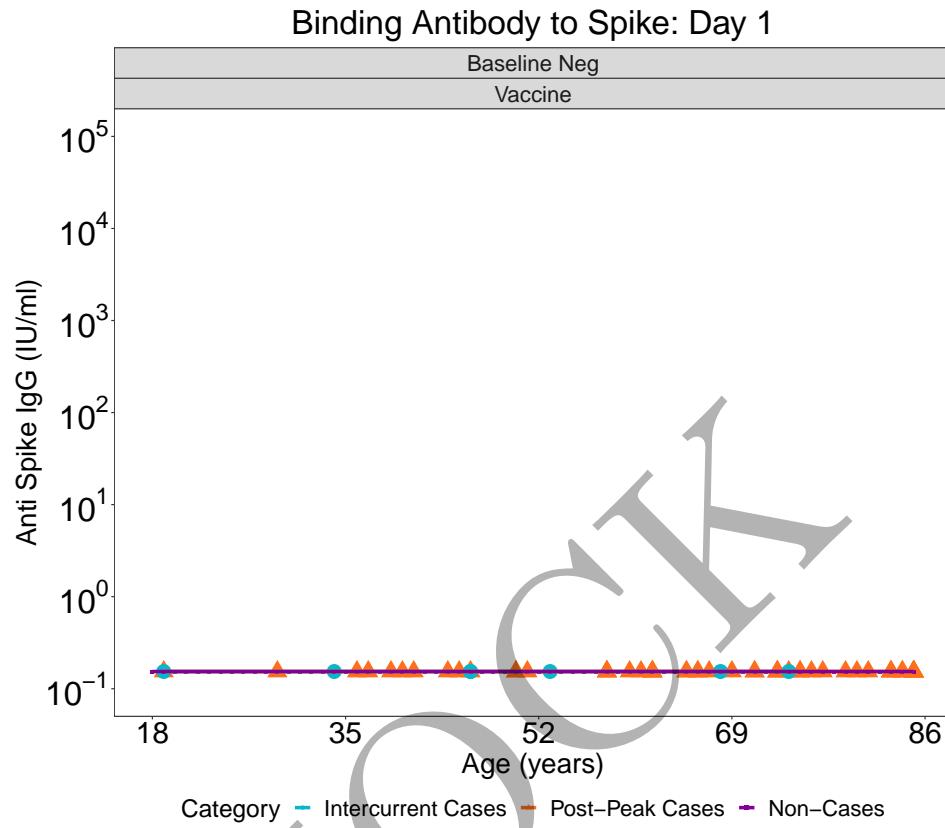


Figure 3.242: scatterplots of Binding Antibody to Spike vs Age: baseline negative vaccine arm at day 1

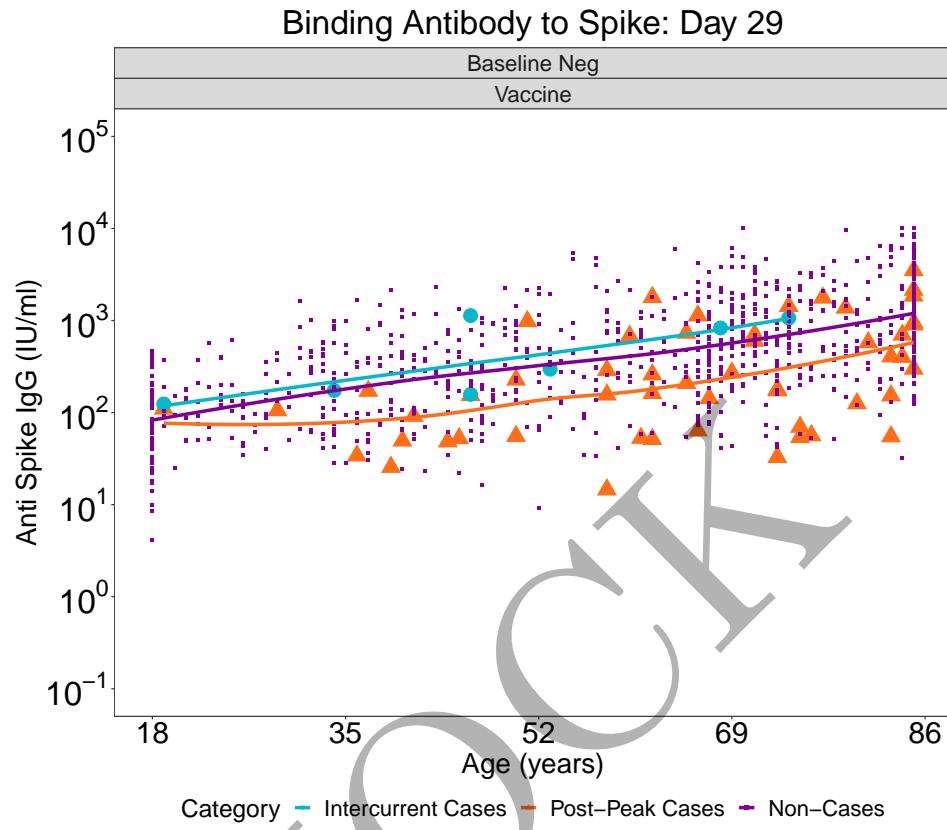


Figure 3.243: scatterplots of Binding Antibody to Spike vs Age: baseline negative vaccine arm at day 29

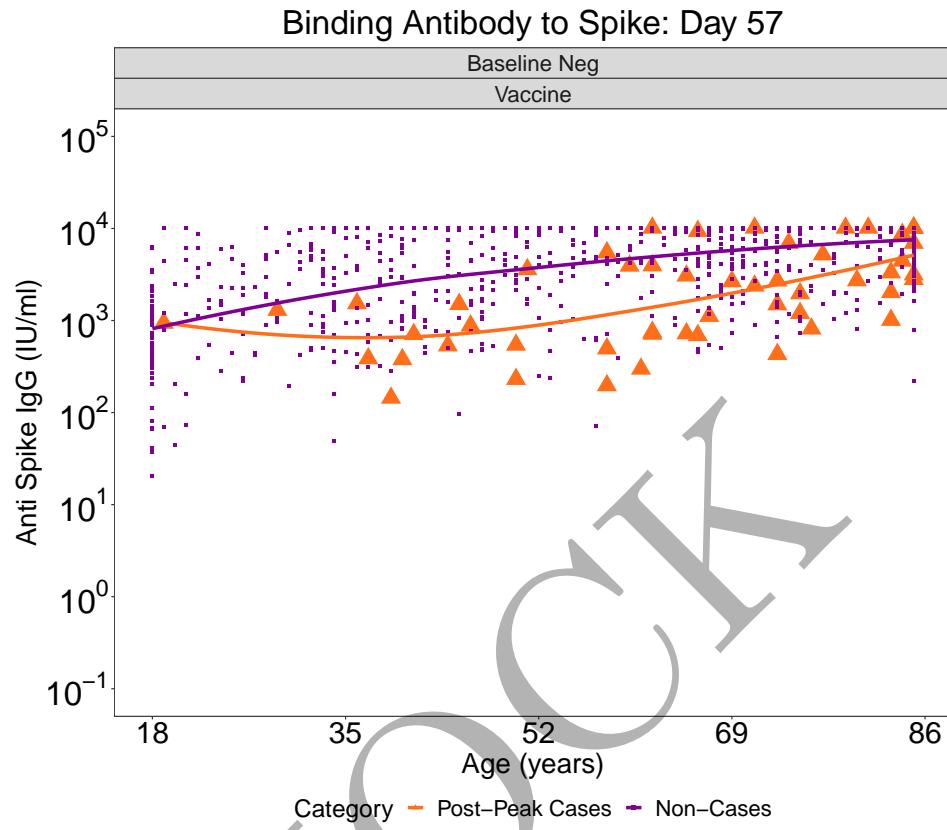


Figure 3.244: scatterplots of Binding Antibody to Spike vs Age: baseline negative vaccine arm at day 57

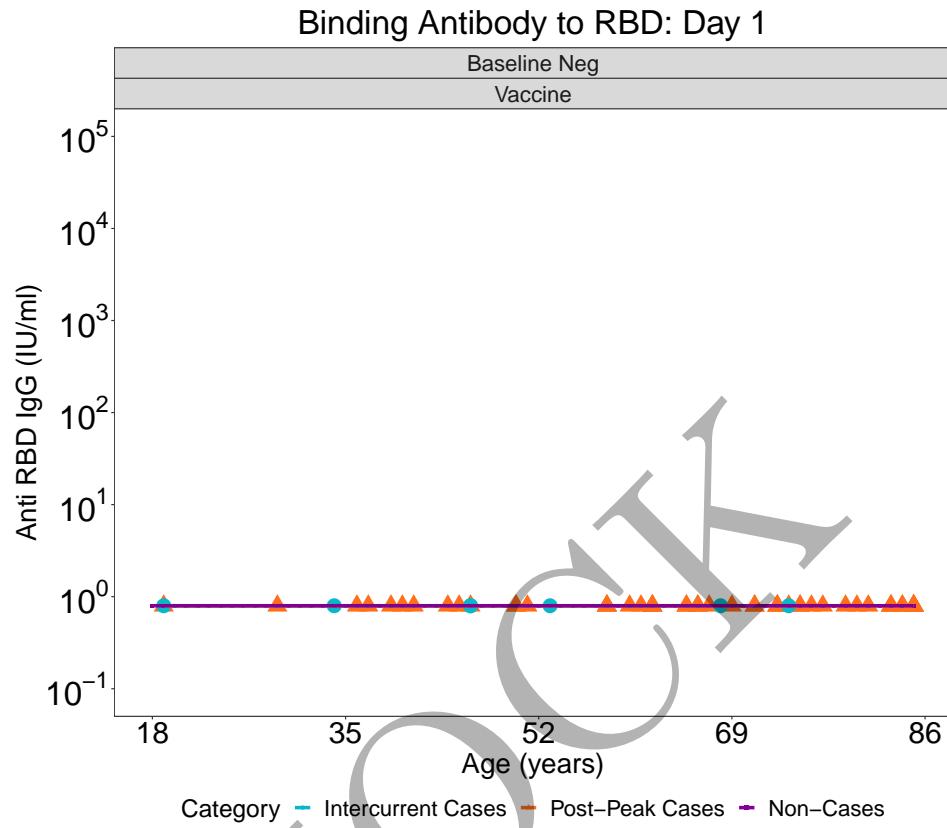


Figure 3.245: scatterplots of Binding Antibody to RBD vs Age: baseline negative vaccine arm at day 1

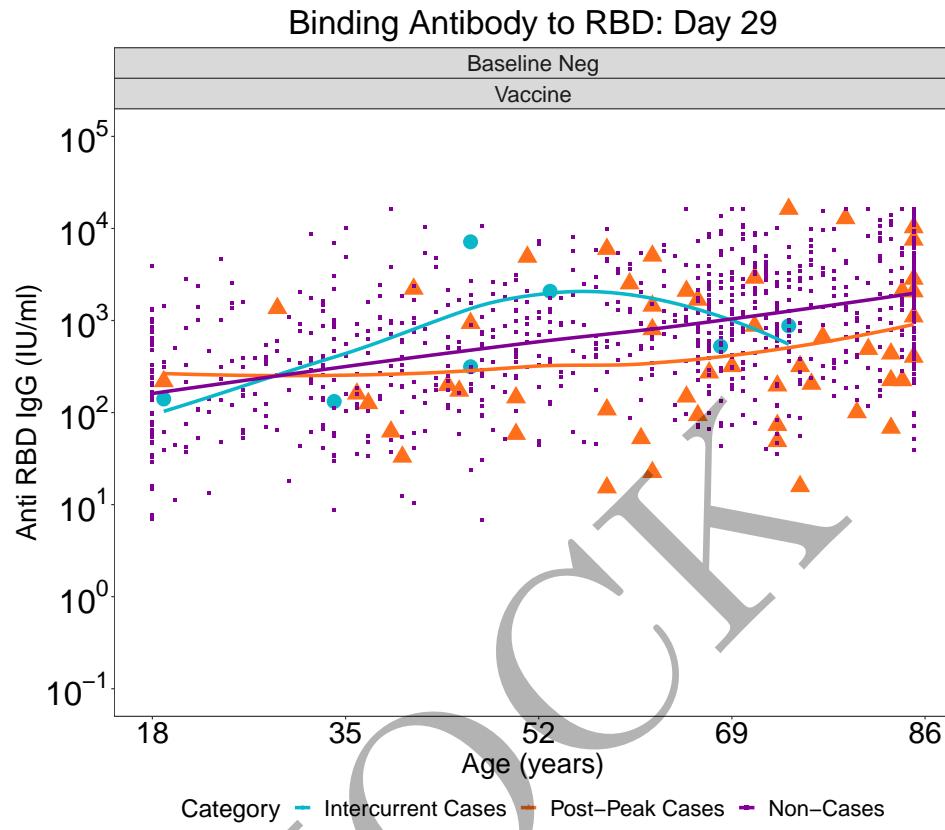


Figure 3.246: scatterplots of Binding Antibody to RBD vs Age: baseline negative vaccine arm at day 29

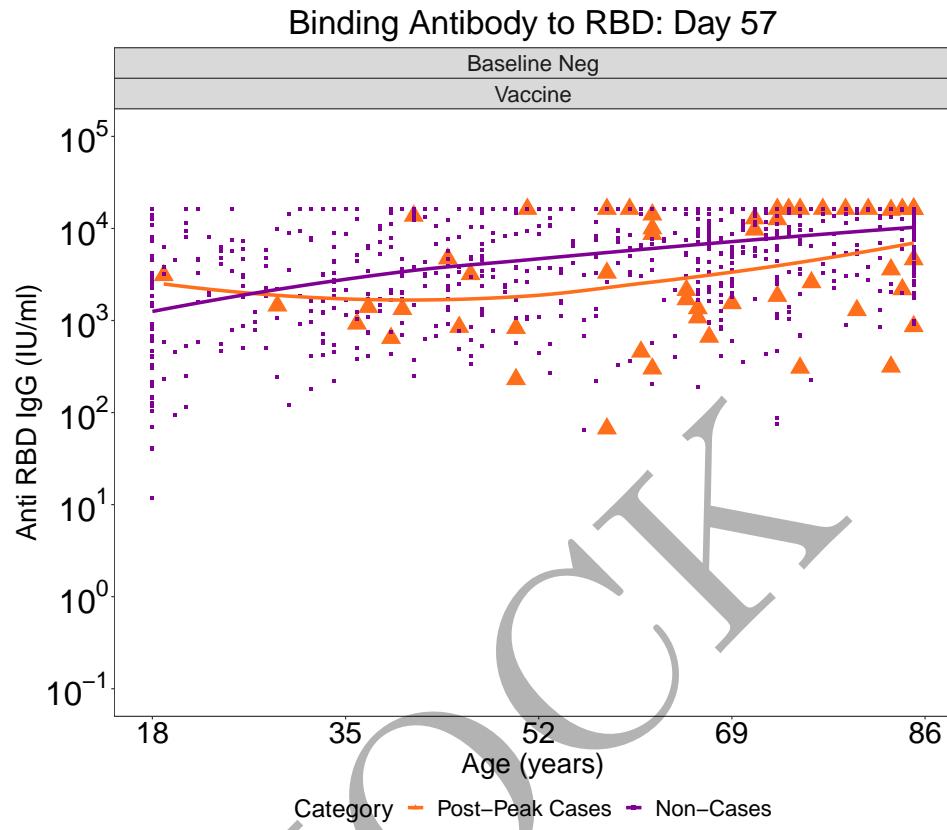


Figure 3.247: scatterplots of Binding Antibody to RBD vs Age: baseline negative vaccine arm at day 57

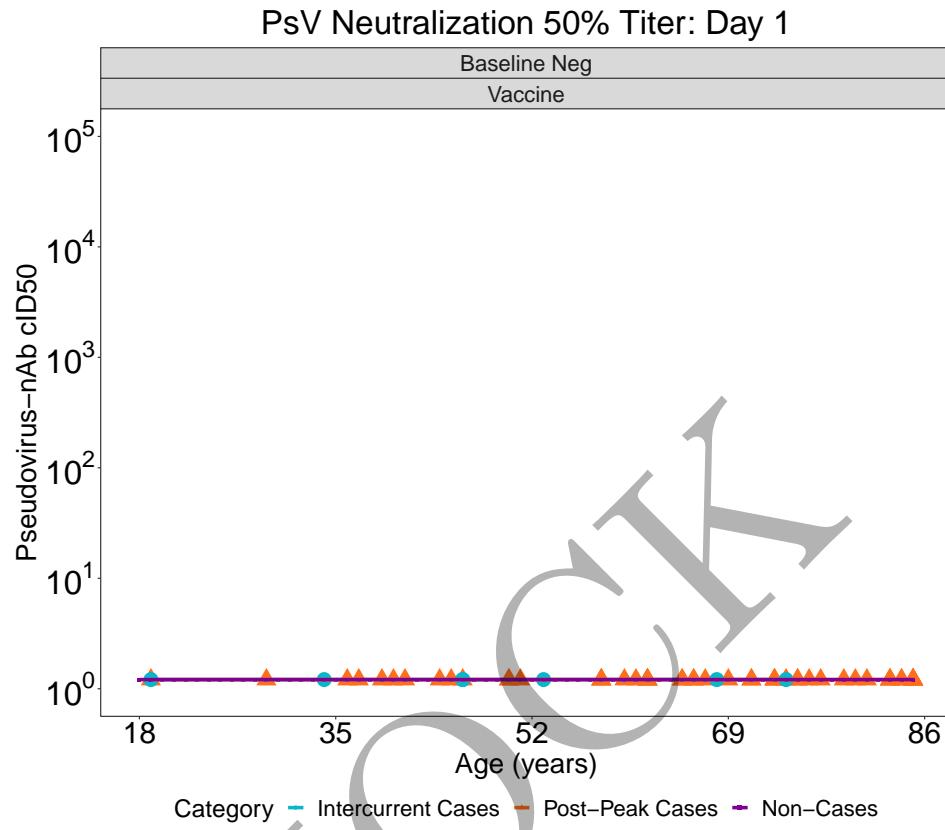


Figure 3.248: scatterplots of Pseudovirus Neutralization ID50 vs Age: baseline negative vaccine arm at day 1

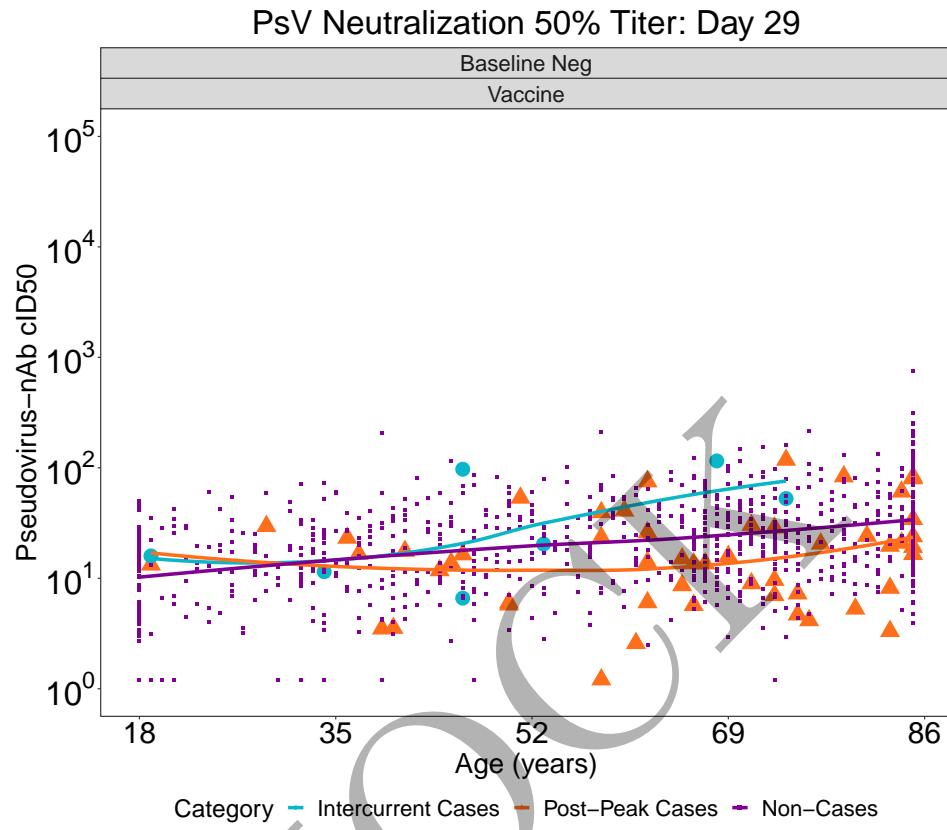


Figure 3.249: scatterplots of Pseudovirus Neutralization ID50 vs Age: baseline negative vaccine arm at day 29

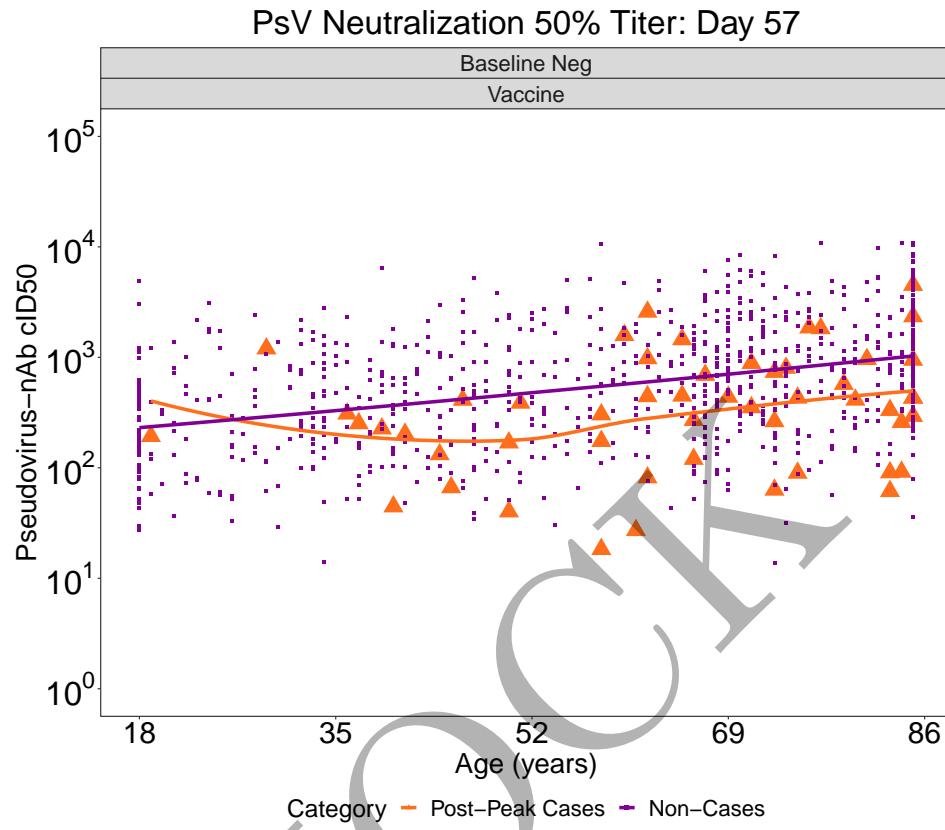


Figure 3.250: scatterplots of Pseudovirus Neutralization ID50 vs Age: baseline negative vaccine arm at day 57

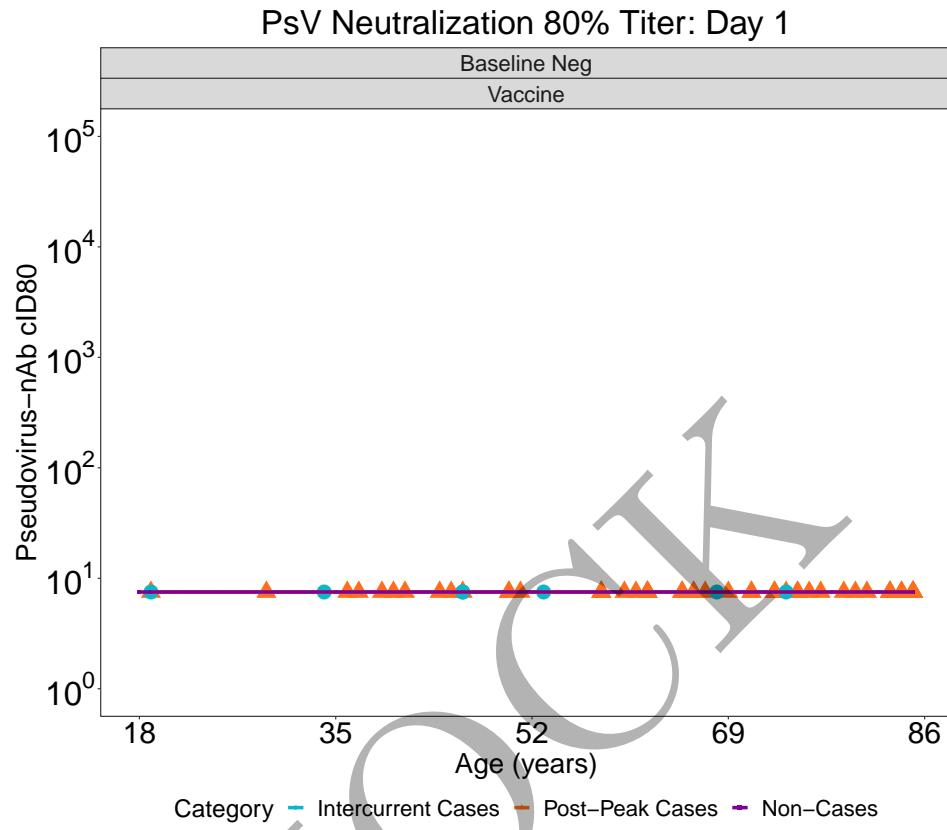


Figure 3.251: scatterplots of Pseudovirus Neutralization ID80 vs Age: baseline negative vaccine arm at day 1

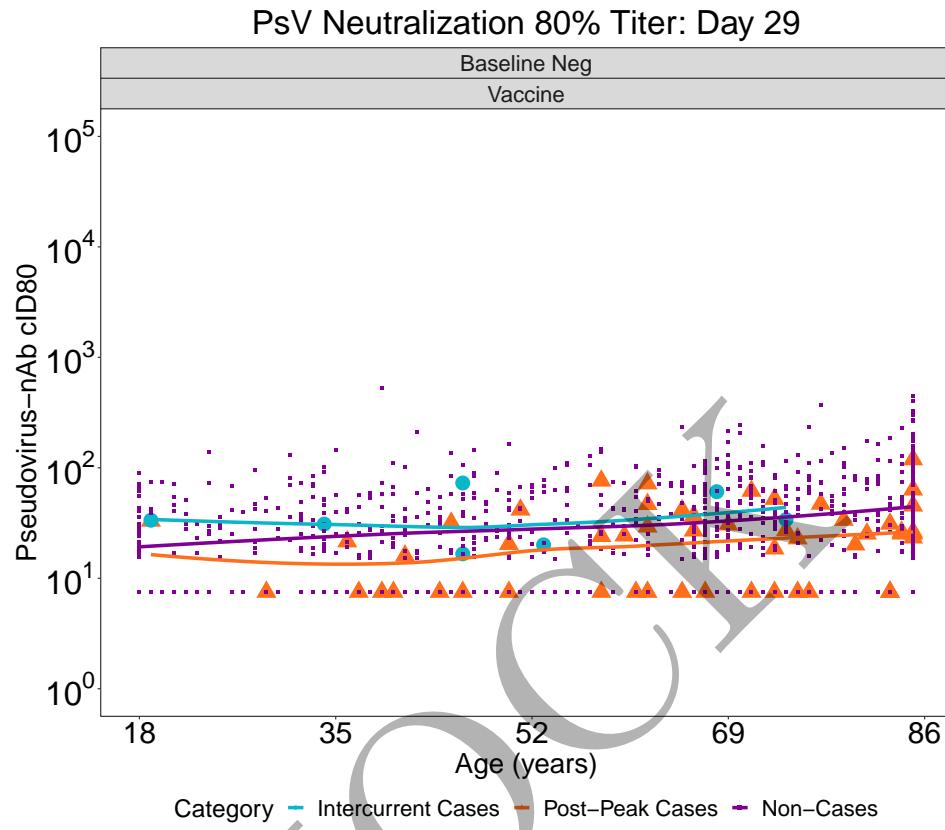


Figure 3.252: scatterplots of Pseudovirus Neutralization ID80 vs Age: baseline negative vaccine arm at day 29

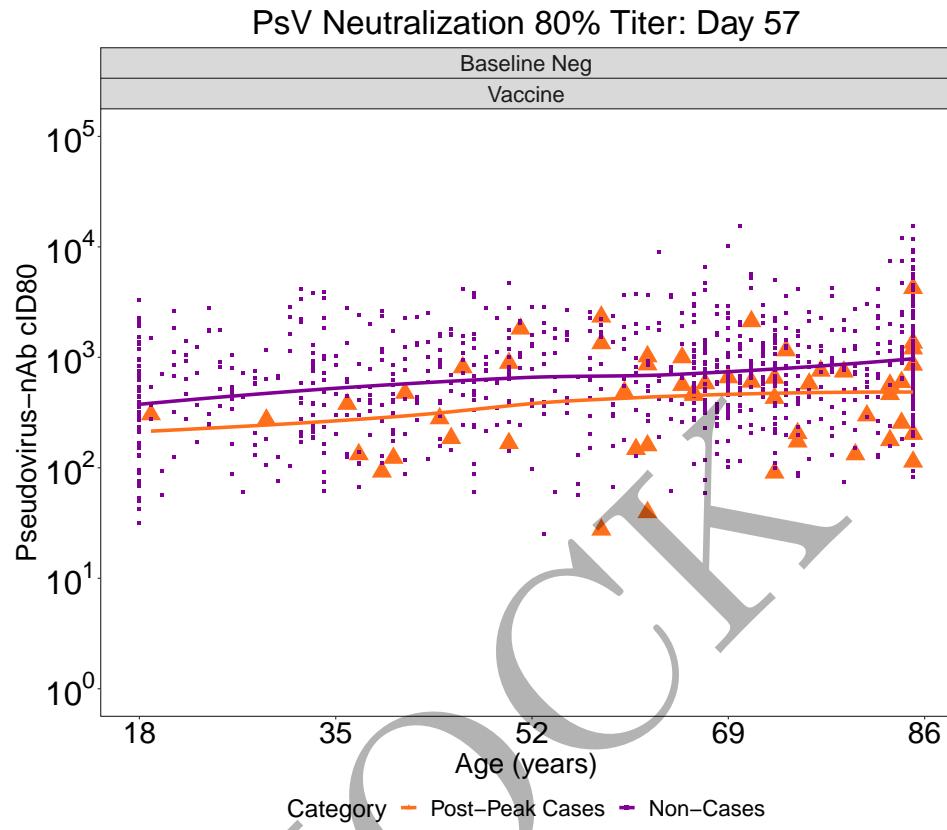


Figure 3.253: scatterplots of Pseudovirus Neutralization ID80 vs Age: baseline negative vaccine arm at day 57

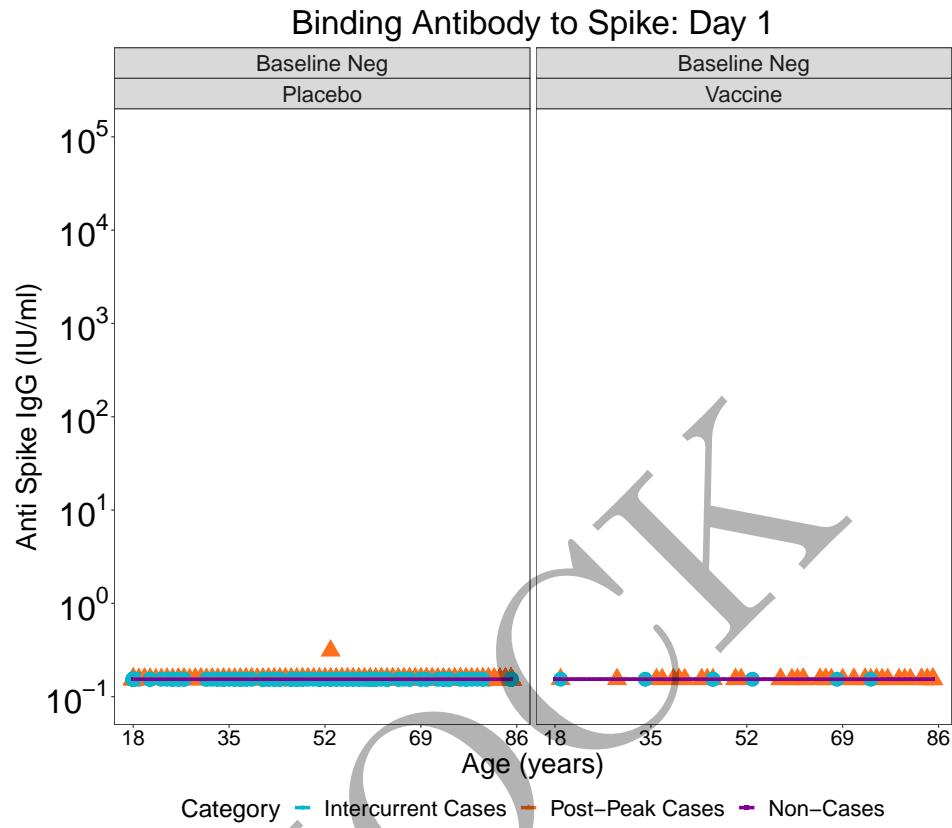


Figure 3.254: scatterplots of Binding Antibody to Spike vs Age: by arm at day 1

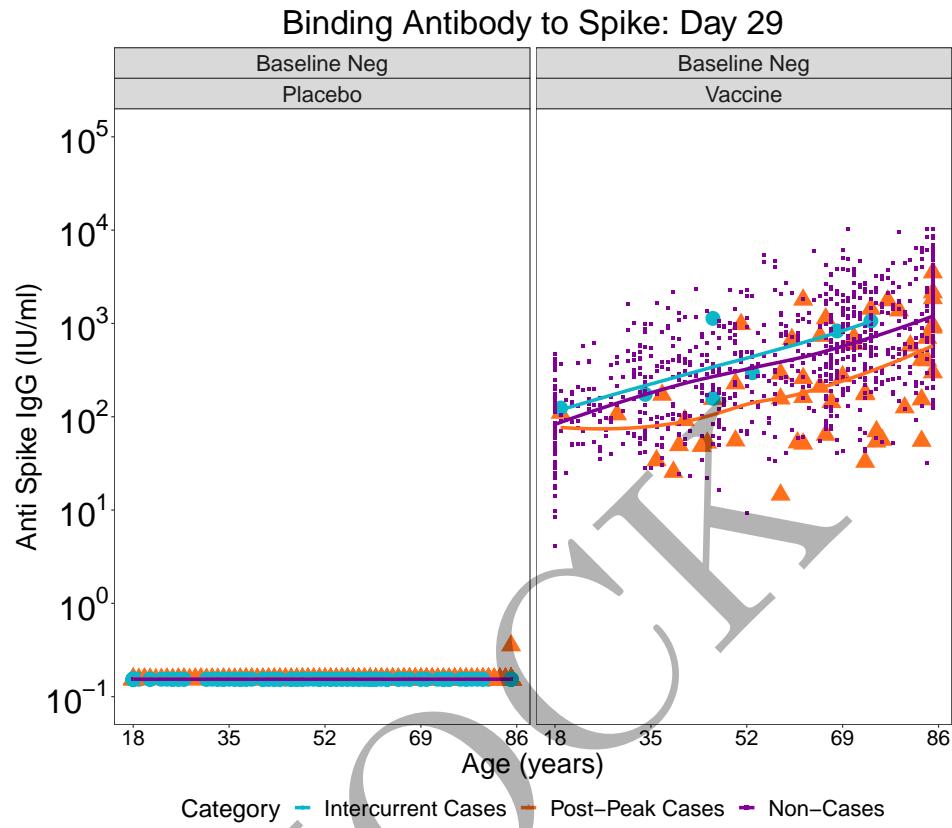


Figure 3.255: scatterplots of Binding Antibody to Spike vs Age: by arm at day 29

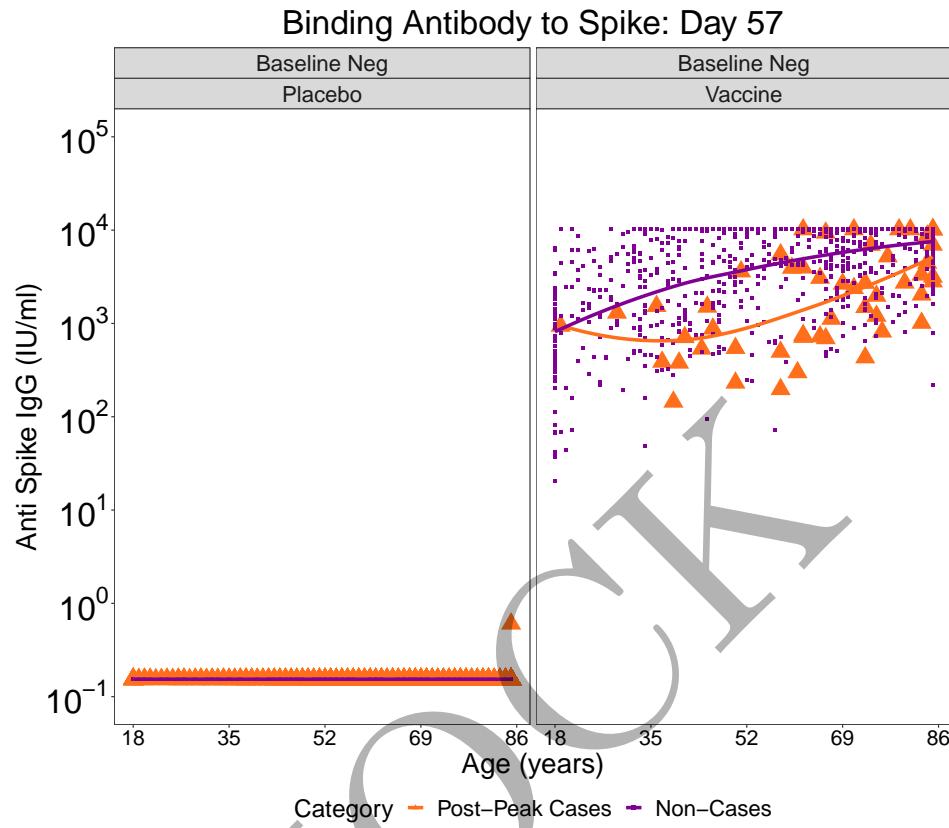


Figure 3.256: scatterplots of Binding Antibody to Spike vs Age: by arm at day 57

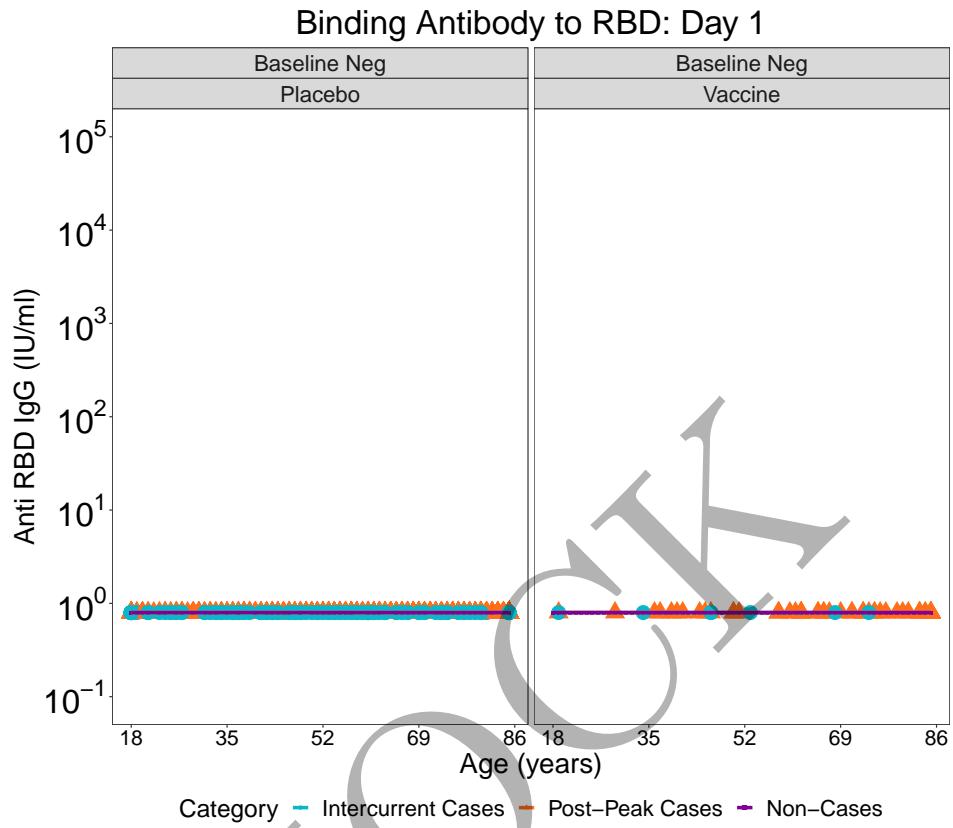


Figure 3.257: scatterplots of Binding Antibody to RBD vs Age: by arm at day 1

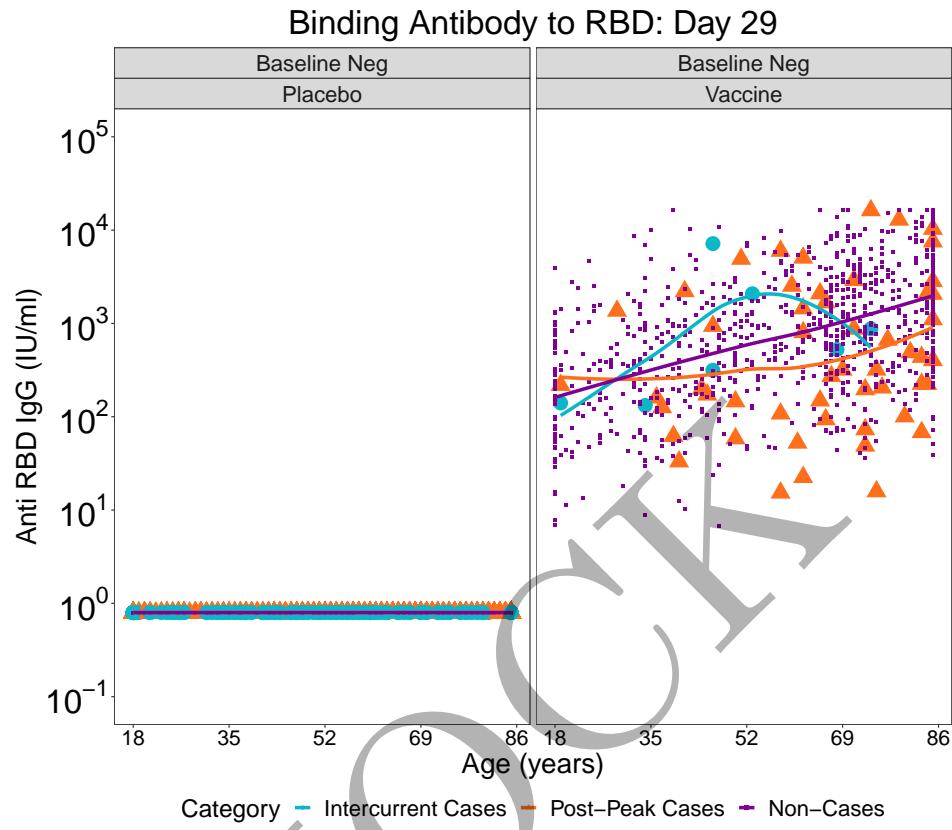


Figure 3.258: scatterplots of Binding Antibody to RBD vs Age: by arm at day 29

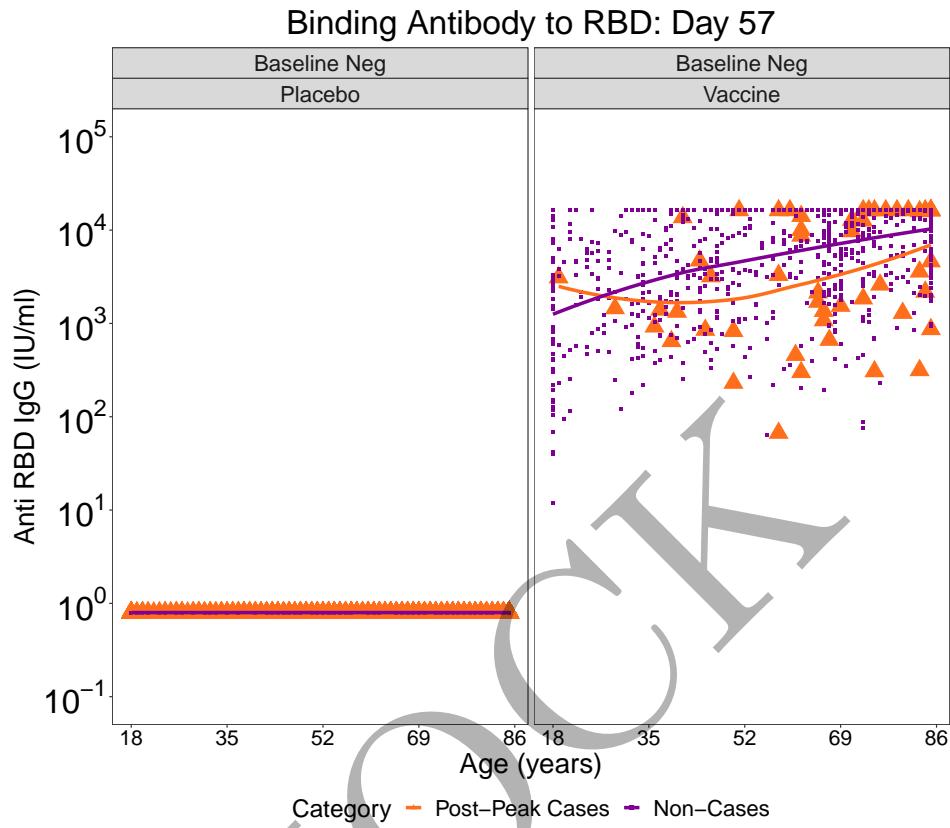


Figure 3.259: scatterplots of Binding Antibody to RBD vs Age: by arm at day 57

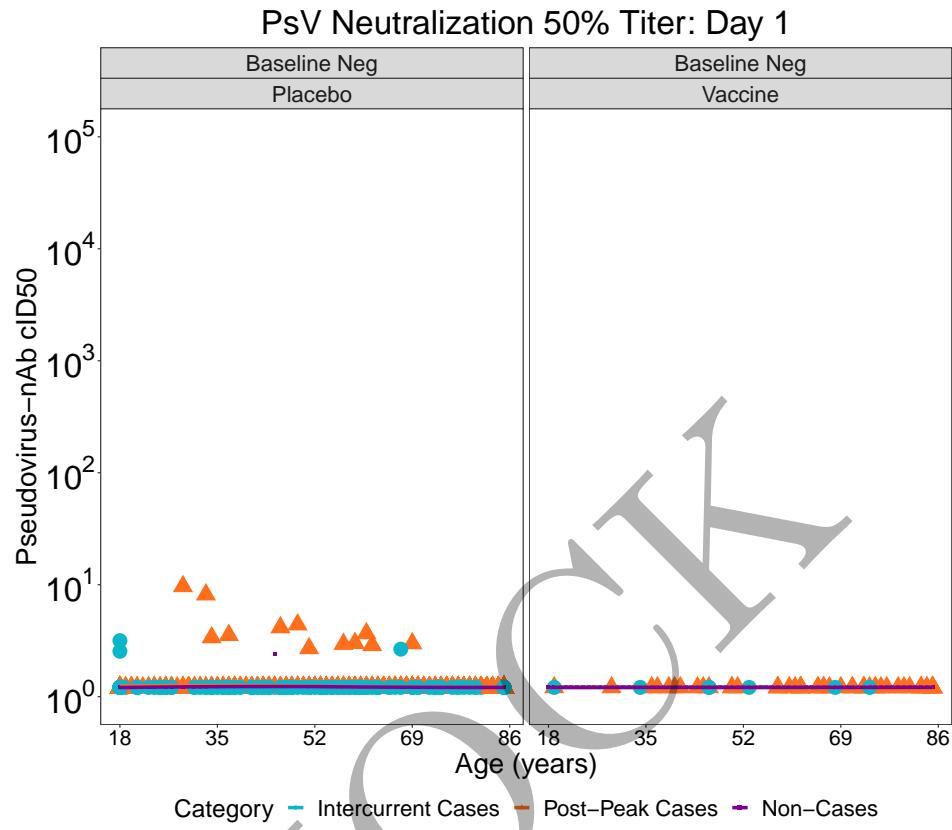


Figure 3.260: scatterplots of Pseudovirus Neutralization ID50 vs Age vs Age: by arm at day 1

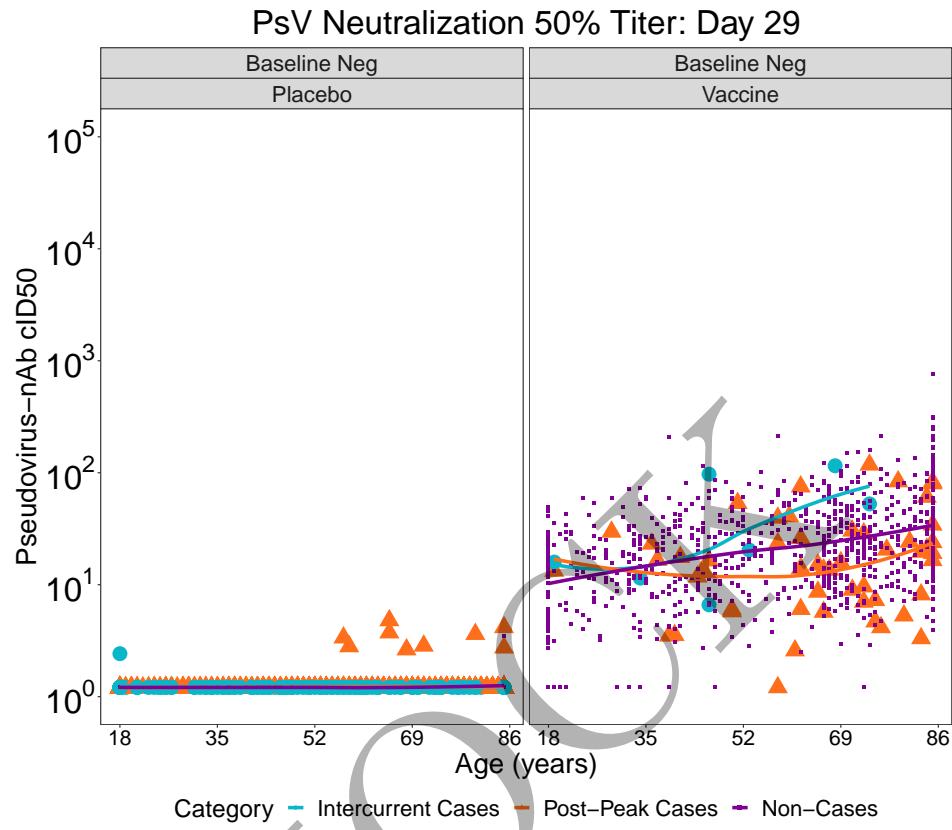


Figure 3.261: scatterplots of Pseudovirus Neutralization ID50 vs Age vs Age: by arm at day 29

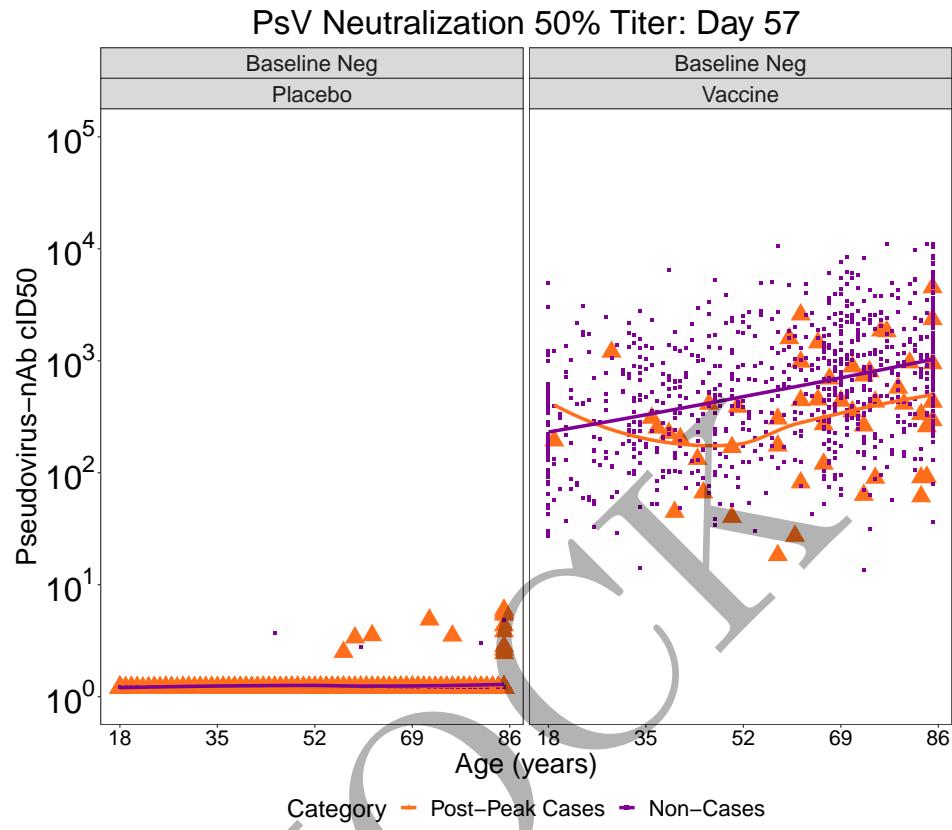


Figure 3.262: scatterplots of Pseudovirus Neutralization ID50 vs Age: by arm at day 57

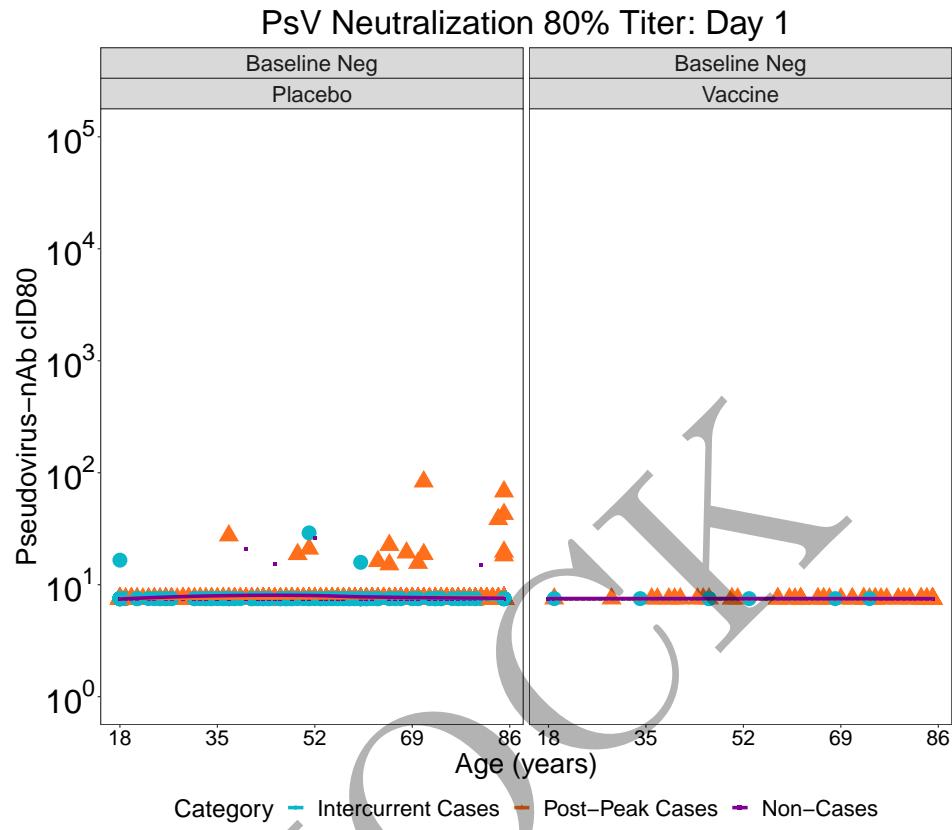


Figure 3.263: scatterplots of Pseudovirus Neutralization ID80 vs Age: by arm at day 1

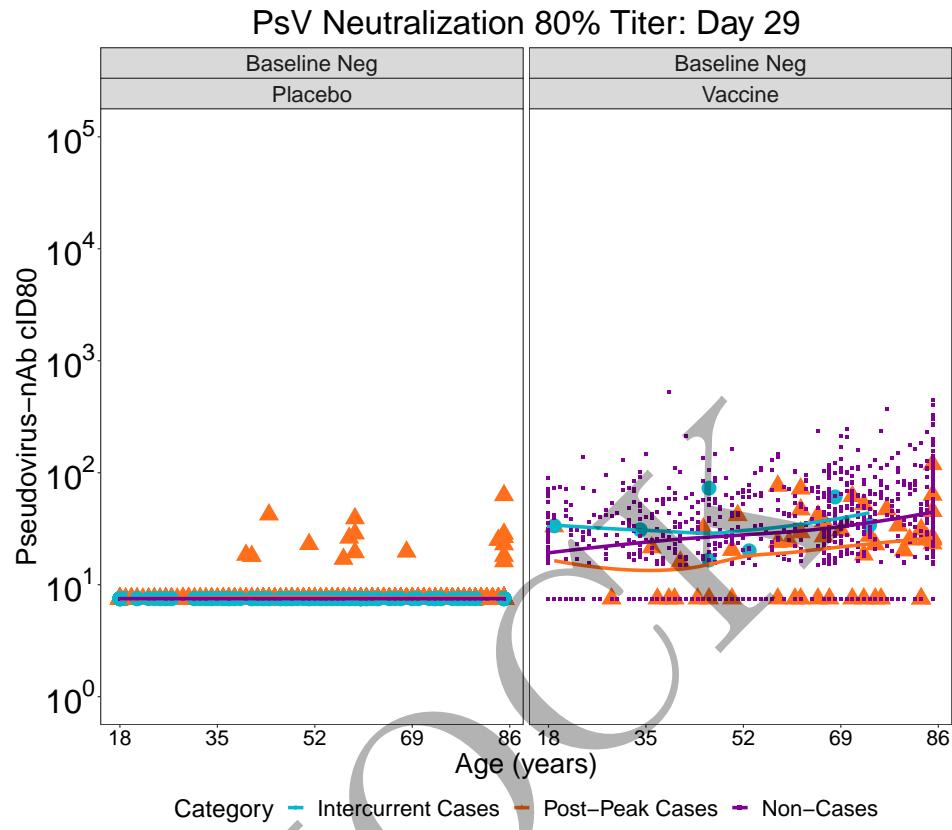


Figure 3.264: scatterplots of Pseudovirus Neutralization ID80 vs Age: by arm at day 29

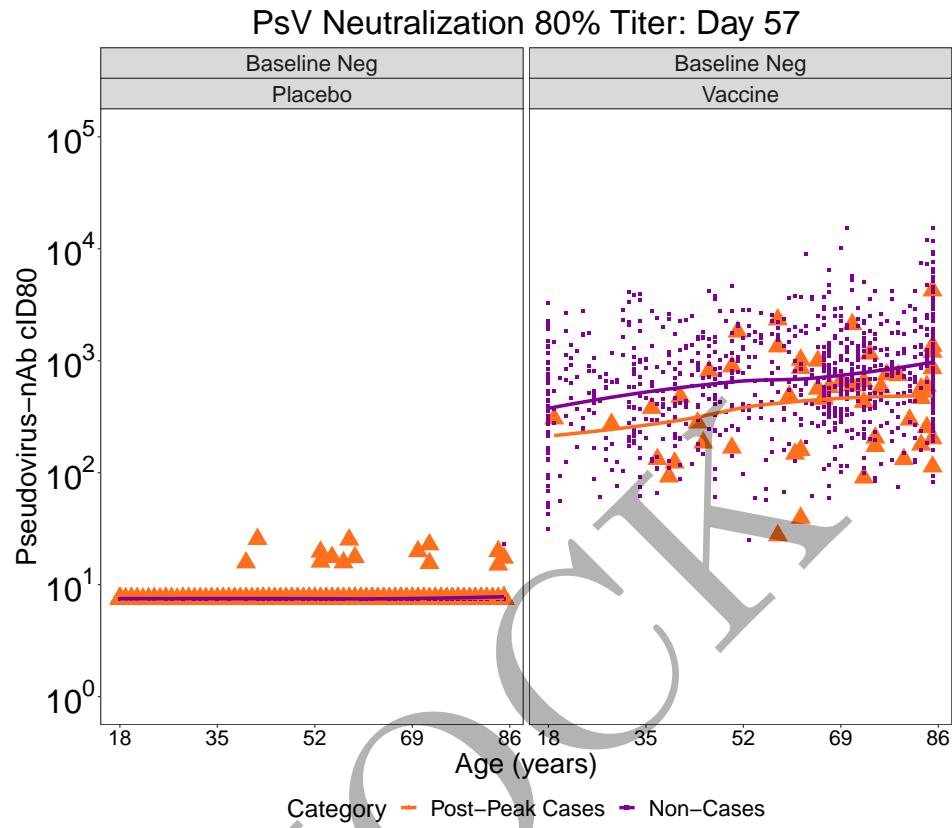


Figure 3.265: scatterplots of Pseudovirus Neutralization ID80 vs Age: by arm at day 57

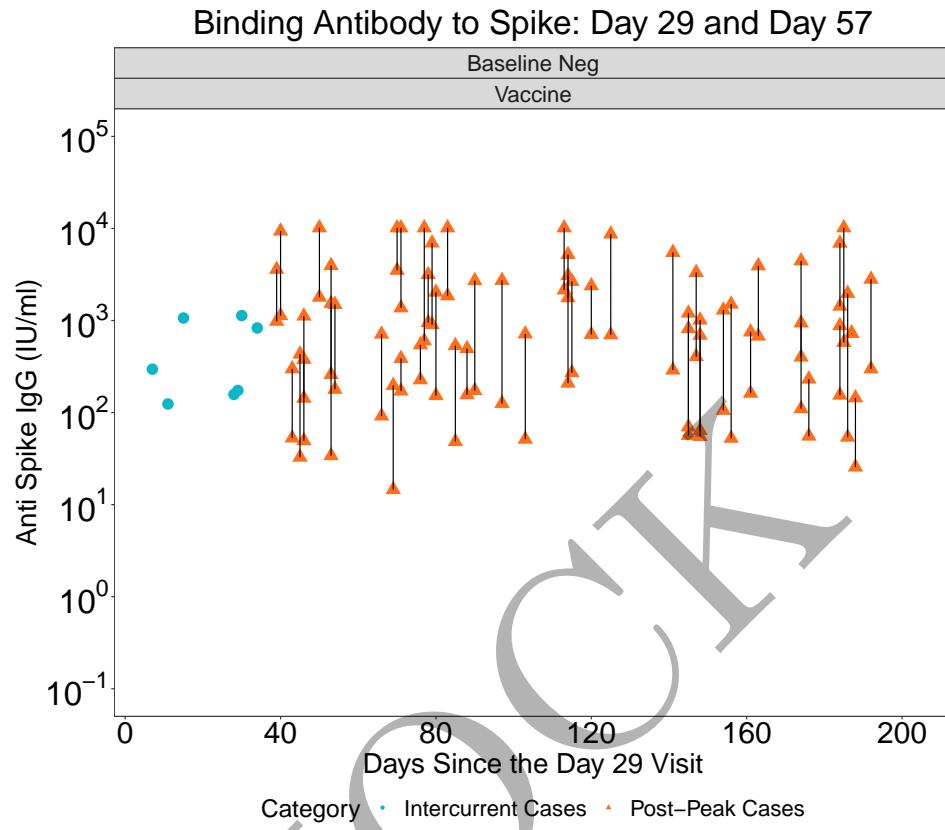


Figure 3.266: scatterplots of Binding Antibody to Spike vs Days Since the Day 29 Visit: baseline negative vaccine arm at day 29 and day 57

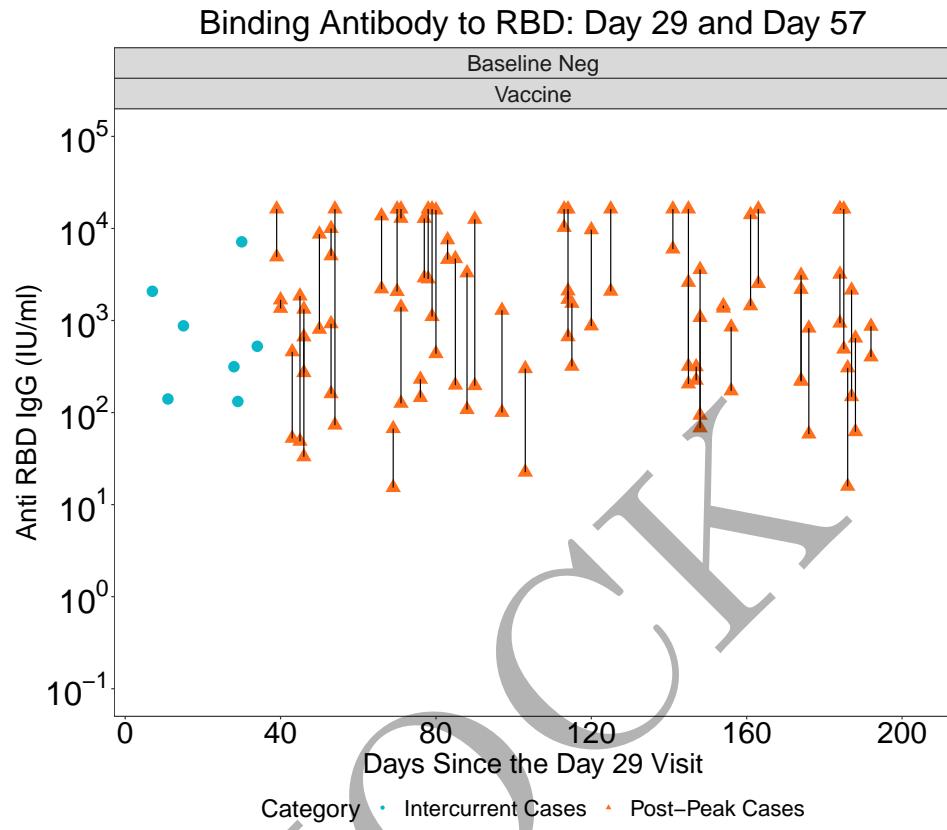


Figure 3.267: scatterplots of Binding Antibody to RBD vs Days Since the Day 29 Visit: baseline negative vaccine arm at day 29 and day 57

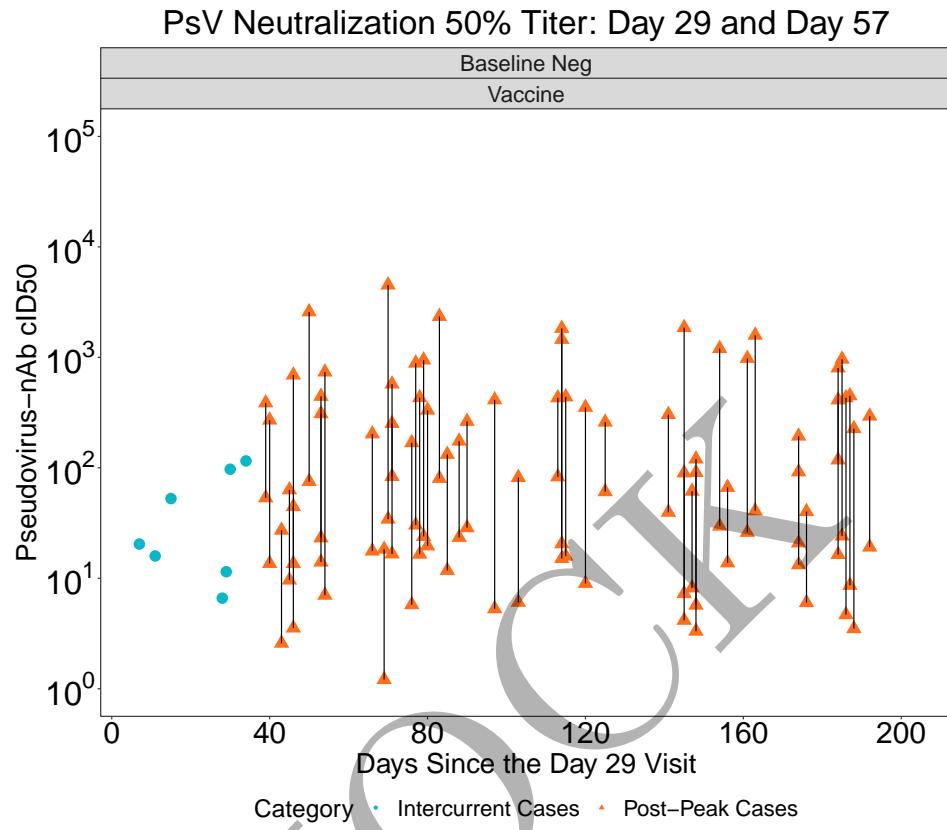


Figure 3.268: scatterplots of Pseudovirus Neutralization ID50 vs Days Since the Day 29 Visit: baseline negative vaccine arm at day 29 and day 57

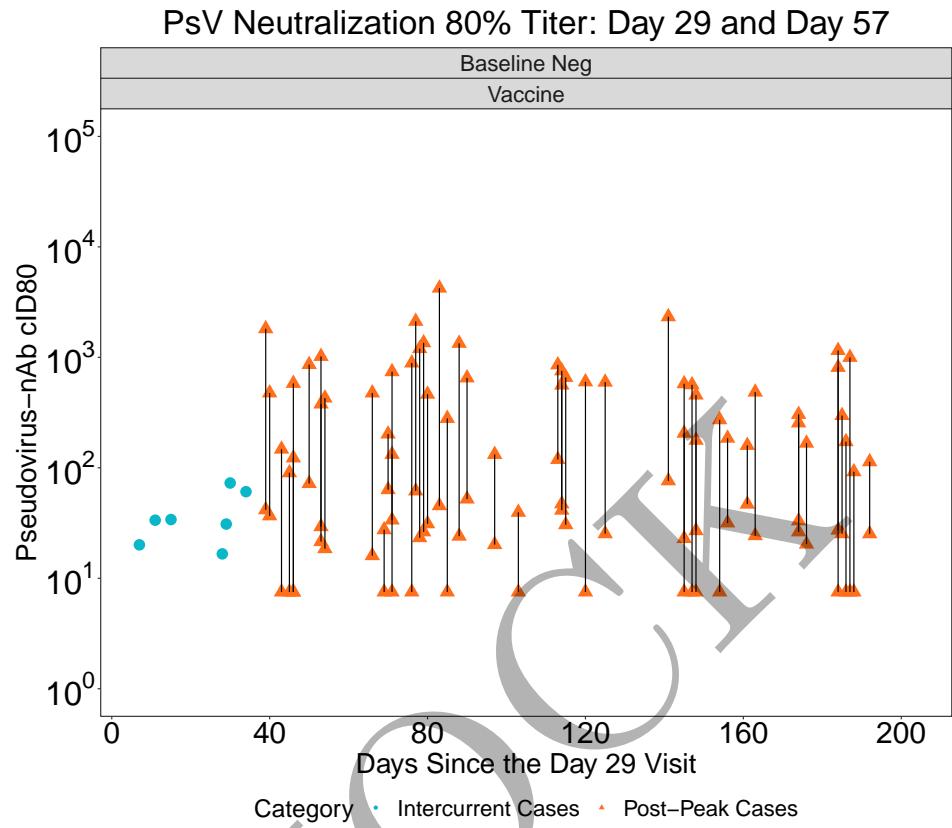


Figure 3.269: scatterplots of Pseudovirus Neutralization ID80 vs Days Since the Day 29 Visit: baseline negative vaccine arm at day 29 and day 57

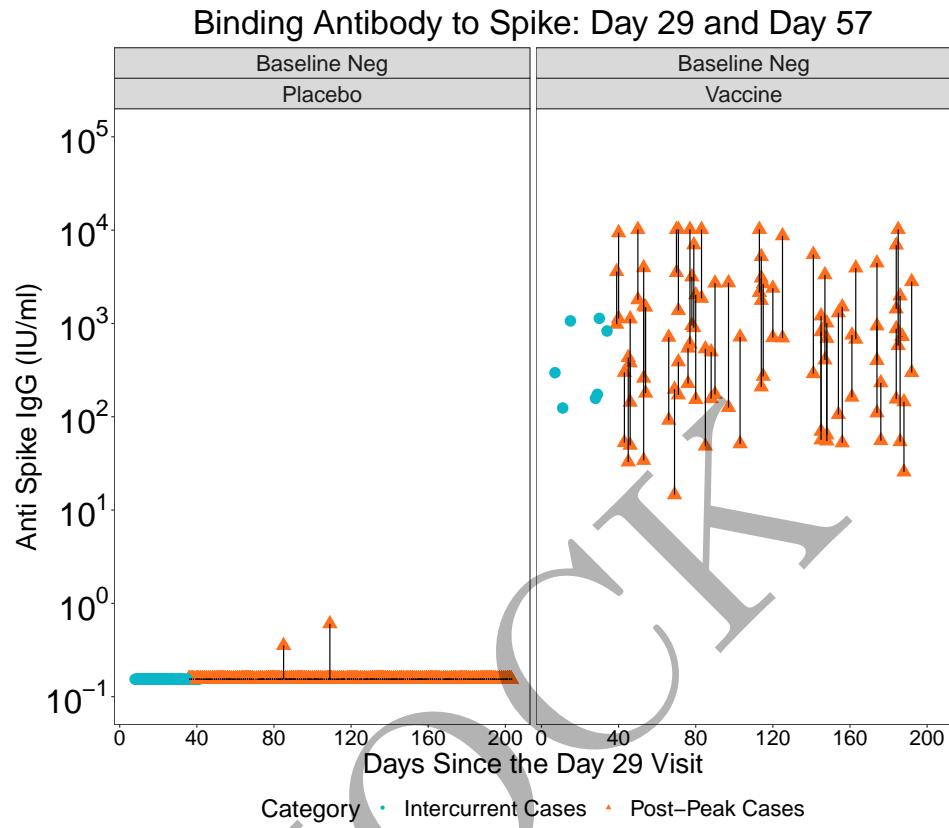


Figure 3.270: scatterplots of Binding Antibody to Spike vs Days Since the Day 29 Visit: by arm at day 29 and day 57

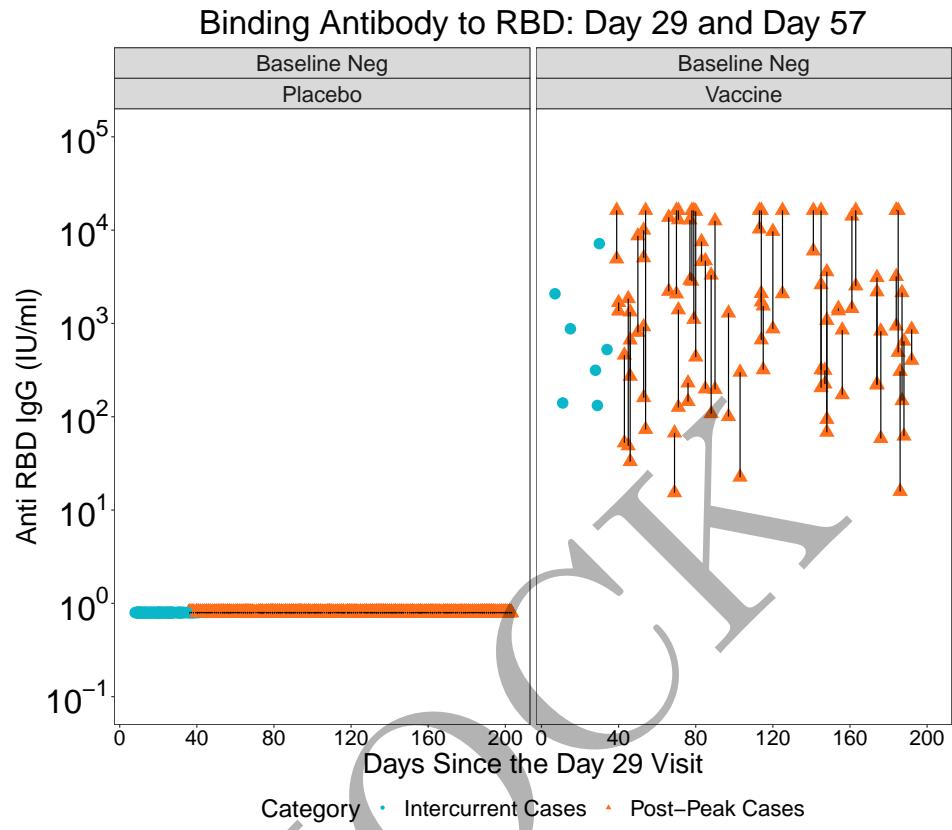


Figure 3.271: scatterplots of Binding Antibody to RBD vs Days Since the Day 29 Visit: by arm at day 29 and day 57

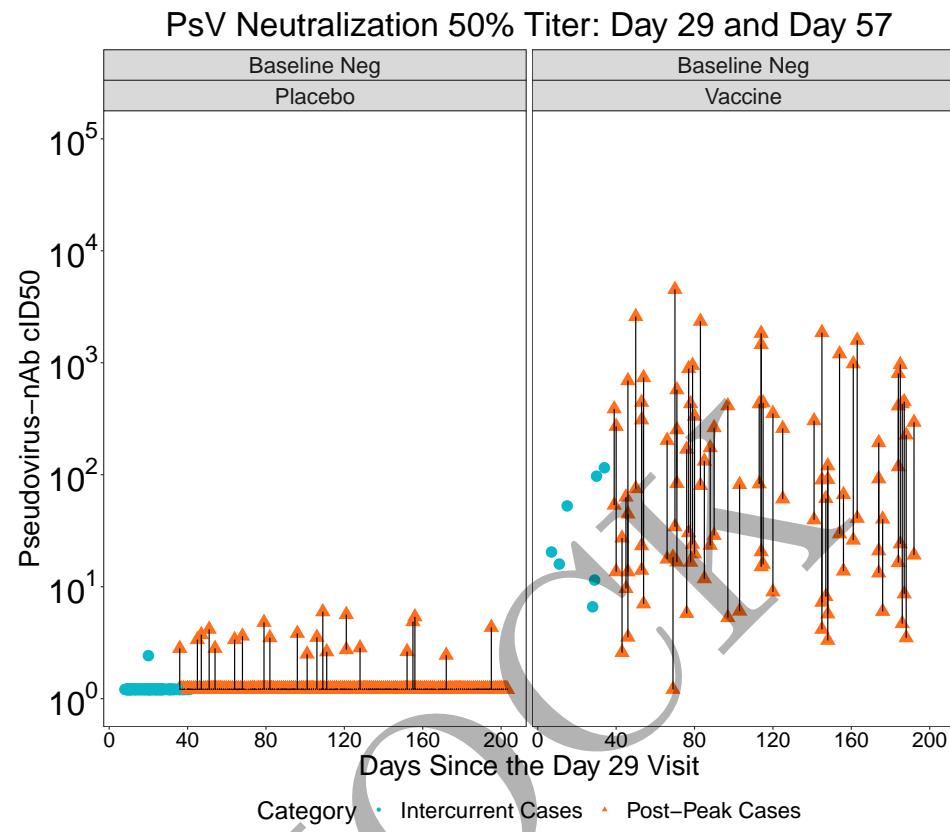


Figure 3.272: scatterplots of Psuedovirus Neutralization ID50 vs Days Since the Day 29 Visit vs Days Since the Day 29 Visit: by arm at day 29 and day 57

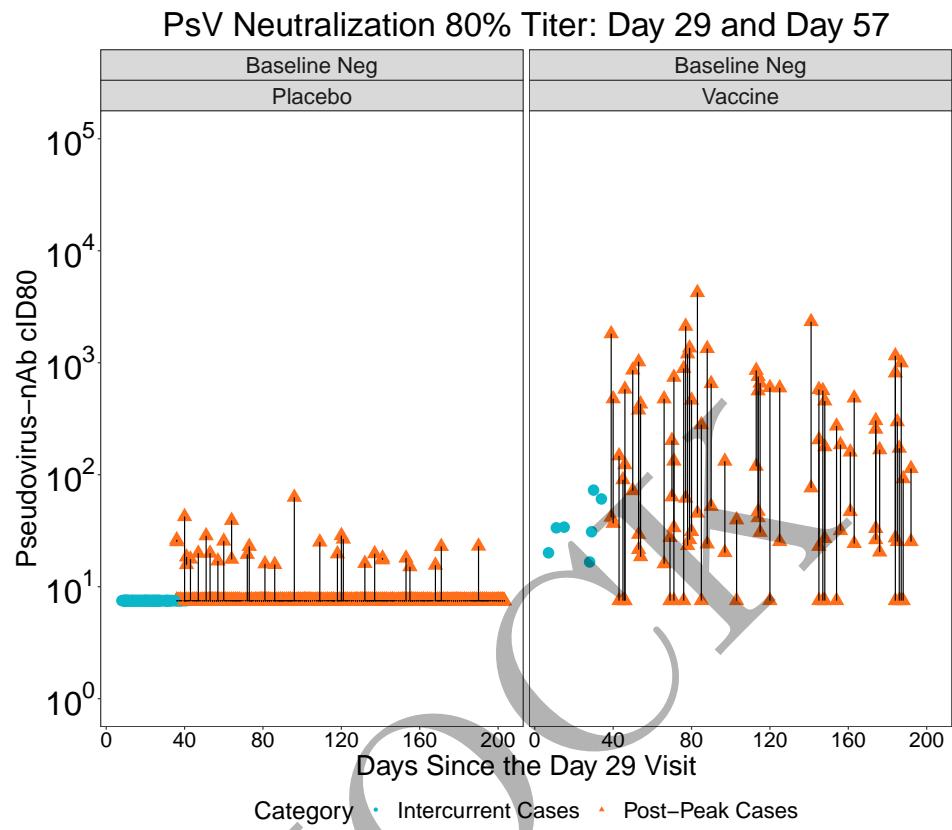


Figure 3.273: scatterplots of Pseudovirus Neutralization ID80 vs Days Since the Day 29 Visit: by arm at day 29 and day 57

Chapter 4

Day 29 Univariate CoR: Cox Models of Risk

The main regression model is the Cox proportional hazards model. All plots are made with Cox models fit unless specified otherwise.

4.1 Hazard ratios

Table 4.1: Inference for Day 29 antibody marker covariate-adjusted correlates of risk of COVID in the vaccine group: Hazard ratios per 10-fold increment in the marker*

MockCOVE Immunologic Marker	No. cases / No. at-risk**	HR per 10-fold incr. Pt. Est.	95% CI	P-value (2-sided)	q-value ***	FWER
Anti Spike IgG (IU/ml)	60/11,157	0.30	(0.17-0.54)	<0.001	<0.001	<0.001
Anti RBD IgG (IU/ml)	60/11,157	0.50	(0.30-0.85)	0.010	<0.001	<0.001
Pseudovirus-nAb cID50	60/11,157	0.43	(0.22-0.86)	0.017	<0.001	<0.001
Pseudovirus-nAb cID80	60/11,157	0.36	(0.19-0.68)	0.002	<0.001	<0.001

*Baseline covariates adjusted for: baseline risk score, meeting the protocol randomization stratification criterion for being at heightened risk of COVID (yes or no), community of color or not. Maximum failure event time 192 days.

**No. at-risk = estimated number in the population for analysis: baseline negative per-protocol vaccine recipients not experiencing the COVID endpoint through 6 days post Day 29 visit; no. cases = number of this cohort with an observed COVID endpoint.

***q-value and FWER (family-wide error rate) are computed over the set of p-values both for quantitative markers and categorical markers using the Westfall and Young permutation method (5 replicates).

Table 4.2: Inference for Day 29 antibody marker covariate-adjusted correlates of risk of COVID in the vaccine group: Hazard ratios for Middle vs. Upper tertile vs. Lower tertile*

MockCOVE Immunologic Marker	Tertile	No. cases / No. at-risk**	Attack rate	Pt. Est.	Haz. Ratio 95% CI	P-value (2-sided)	Overall P- value***	Overall q- value †	Overall FWER
Anti Spike IgG (IU/ml)	Lower	20/3,702	0.0054	1	N/A	N/A	0.004	<0.001	<0.001
	Middle	19/3,705	0.0051	0.56	(0.28-1.15)	0.114			
	Upper	20/3,750	0.0053	0.25	(0.11-0.58)	0.001			
Anti RBD IgG (IU/ml)	Lower	26/3,722	0.0070	1	N/A	N/A	0.001	<0.001	<0.001
	Middle	13/3,740	0.0035	0.32	(0.15-0.66)	0.002			
	Upper	20/3,695	0.0054	0.28	(0.13-0.60)	0.001			
Pseudovirus-nAb cID50	Lower	20/3,690	0.0054	1	N/A	N/A	0.052	<0.001	<0.001
	Middle	23/3,749	0.0061	0.98	(0.50-1.91)	0.953			
	Upper	16/3,718	0.0043	0.45	(0.21-0.96)	0.039			
Pseudovirus-nAb cID80	Lower	20/3,754	0.0053	1	N/A	N/A	0.027	<0.001	<0.001
	Middle	26/3,719	0.0070	1.16	(0.62-2.20)	0.642			
	Upper	13/3,685	0.0035	0.45	(0.21-0.96)	0.039			
Placebo		1112/11,426	0.0973						

*Baseline covariates adjusted for: baseline risk score, meeting the protocol randomization stratification criterion for being at heightened risk of COVID (yes or no), community of color or not. Maximum failure event time 192 days. Cutpoints: Anti Spike IgG (IU/ml) [2.14, 2.65], Anti RBD IgG (IU/ml) [2.37, 2.98], Pseudovirus-nAb cID50 [1.07, 1.45], Pseudovirus-nAb cID80 [1.26, 1.61], all on the log10 scale.

**No. at-risk = estimated number in the population for analysis: baseline negative per-protocol vaccine recipients not experiencing the COVID endpoint through 6 days post Day 29 visit; no. cases = number of this cohort with an observed COVID endpoint.

***Generalized Wald-test p-value of the null hypothesis that the hazard rate is constant across the Lower, Middle, and Upper tertile groups.

† q-value and FWER (family-wide error rate) are computed over the set of p-values both for quantitative markers and categorical markers using the Westfall and Young permutation method (5 replicates).

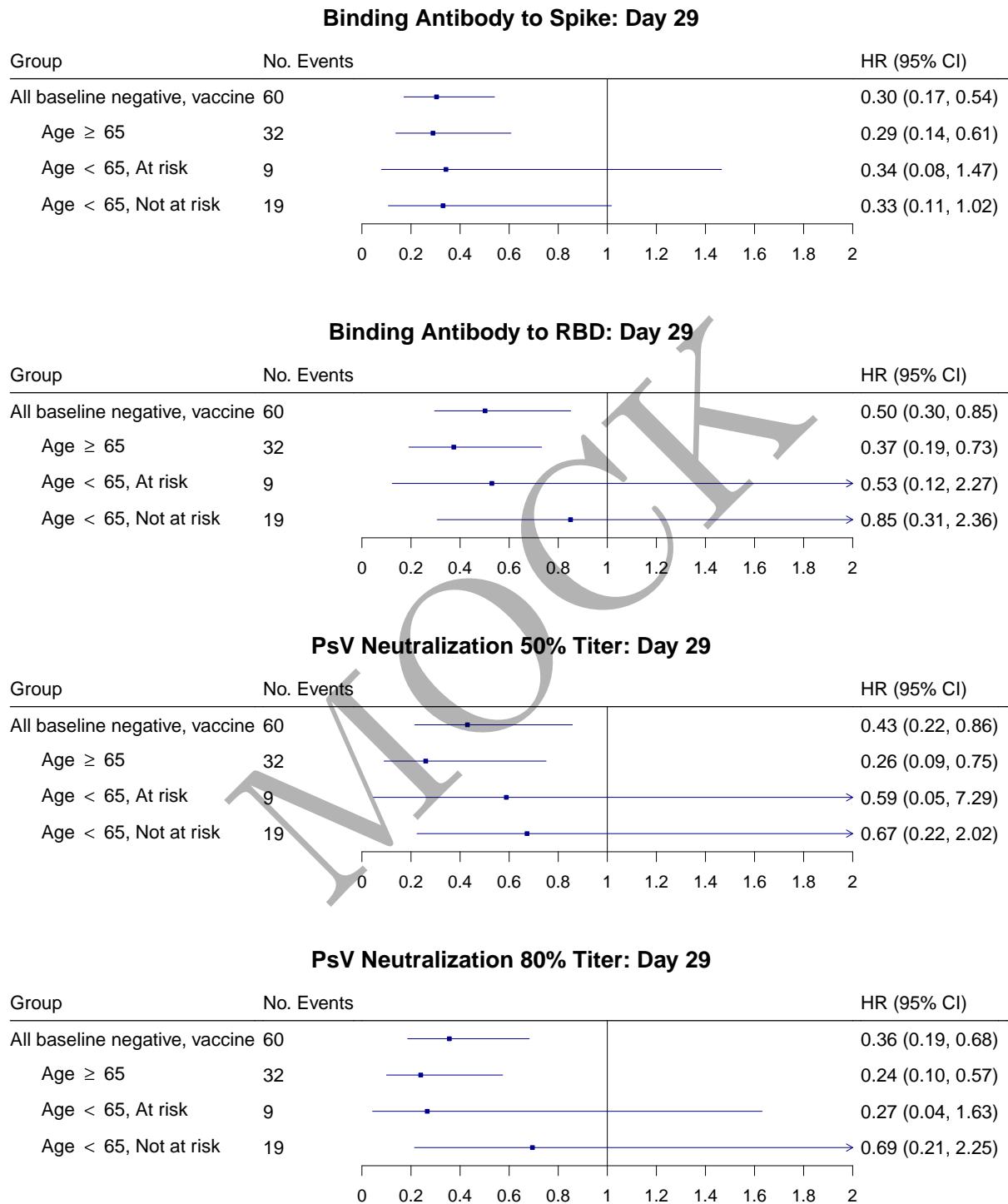


Figure 4.1: Forest plots of hazard ratios per 10-fold increase in the marker among baseline negative vaccine recipients and subgroups with 95% point-wise confidence intervals.

Binding Antibody to Spike: Day 29

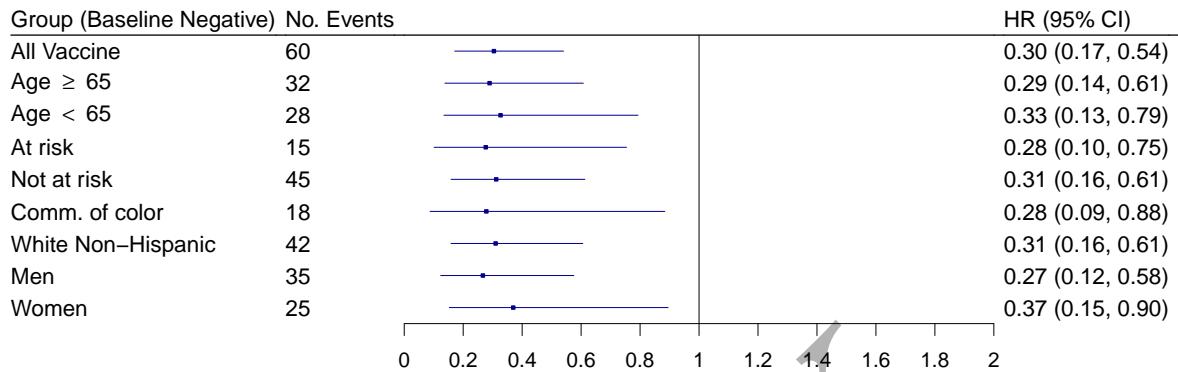


Figure 4.2: Forest plots of hazard ratios per 10-fold increase in the Day 29 binding Ab to spike markers among baseline negative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

Binding Antibody to RBD: Day 29

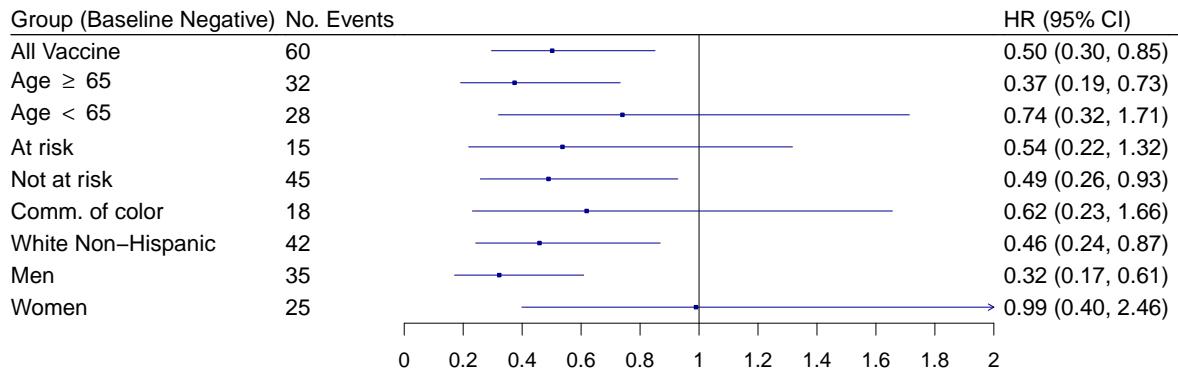


Figure 4.3: Forest plots of hazard ratios per 10-fold increase in the Day 29 binding Ab to RBD markers among baseline negative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

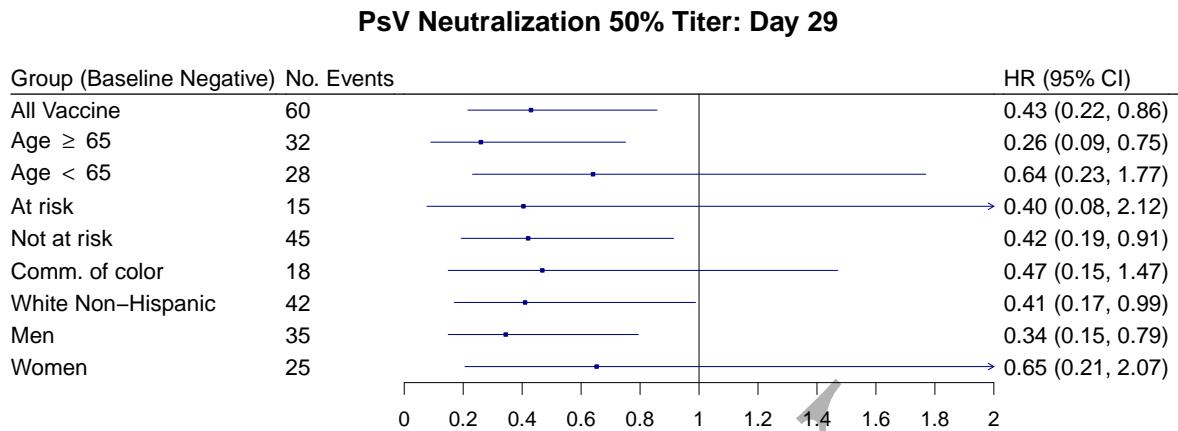


Figure 4.4: Forest plots of hazard ratios per 10-fold increase in the Day 29 pseudo neut ID50 markers among baseline negative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

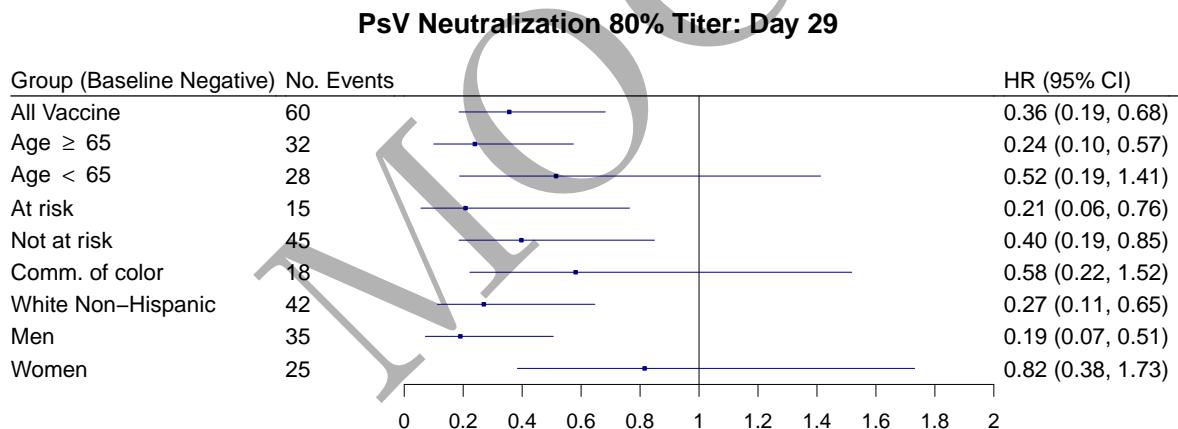


Figure 4.5: Forest plots of hazard ratios per 10-fold increase in the Day 29 pseudo neut ID80 markers among baseline negative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

4.2 Marginalized risk and controlled vaccine efficacy plots

MOCK

Table 4.3: Analysis of Day 29 markers (upper vs. lower tertile) as a CoR and a controlled risk CoP.

	marginalized risk		controlled risk			
	ratio $RR_M(0, 1)$	Point Est. 95% CI	ratio $RR_C(0, 1)^1$	Point Est. 95% CI	e(0,1) ²	Point Est. 95% CI UL
Anti Spike IgG (IU/ml)	0.26	0.13–0.68	0.34	0.17–0.91	7.2	2.3
Anti RBD IgG (IU/ml)	0.29	0.17–0.48	0.38	0.22–0.64	6.4	3.6
Pseudovirus-nAb cID50	0.46	0.28–0.65	0.61	0.37–0.86	3.8	2.5
Pseudovirus-nAb cID80	0.45	0.30–0.83	0.60	0.40–1.10	3.8	1.7

¹Conservative (upper bound) estimate assuming unmeasured confounding at level $RR_{UD}(0, 1) = RR_{EU}(0, 1) = 2$ and thus $B(0, 1) = 4/3$.

²E-values are computed for upper tertile ($s = 1$) vs. lower tertile ($s = 0$) biomarker subgroups after controlling for baseline risk score, meeting the protocol randomization stratification criterion for being at heightened risk of COVID (yes or no), community of color or not; UL = upper limit.

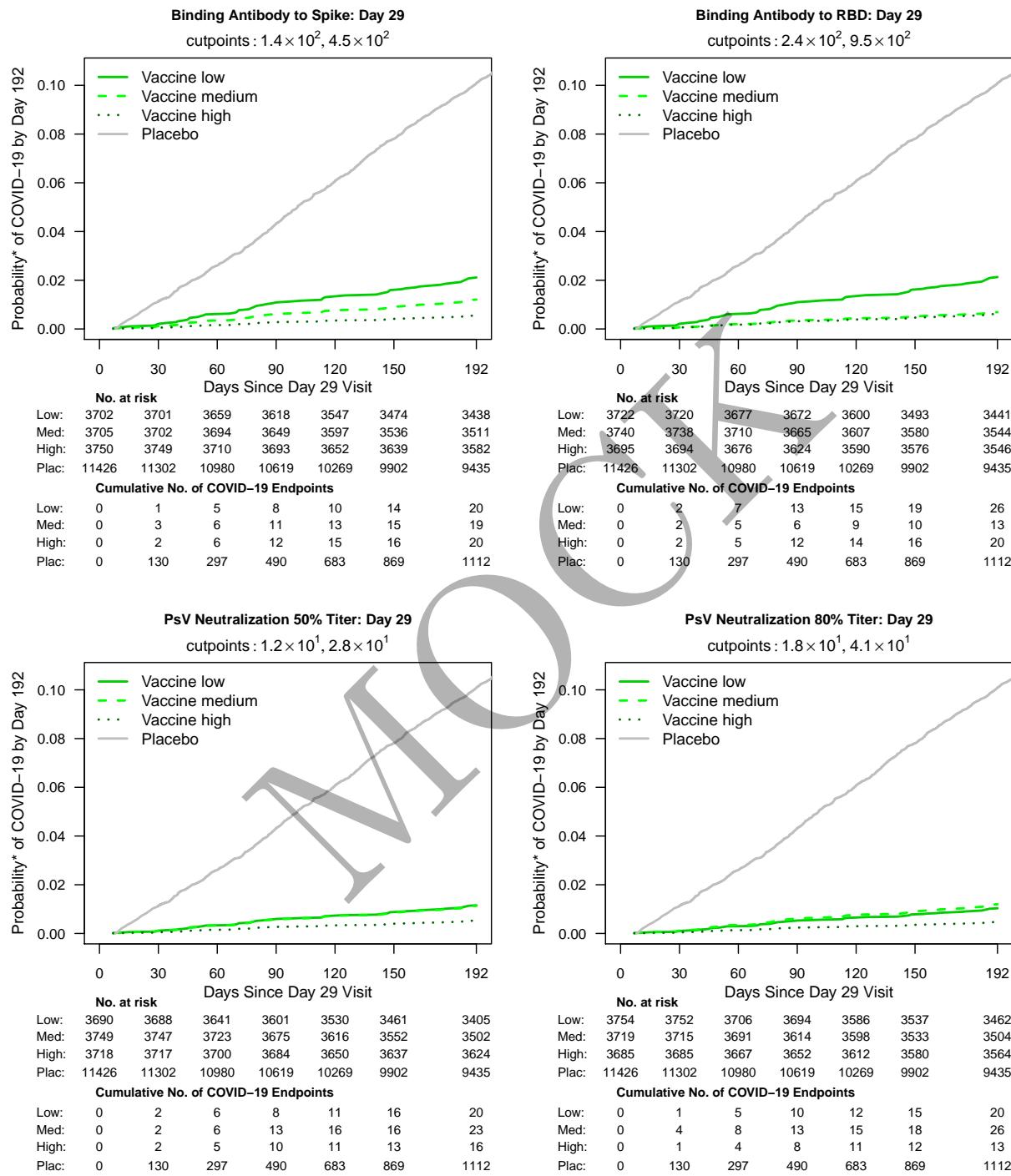


Figure 4.6: Marginalized cumulative incidence rate curves for trichotomized Day 29 markers among baseline negative vaccine recipients. The gray line is the overall cumulative incidence rate curve in the placebo arm.

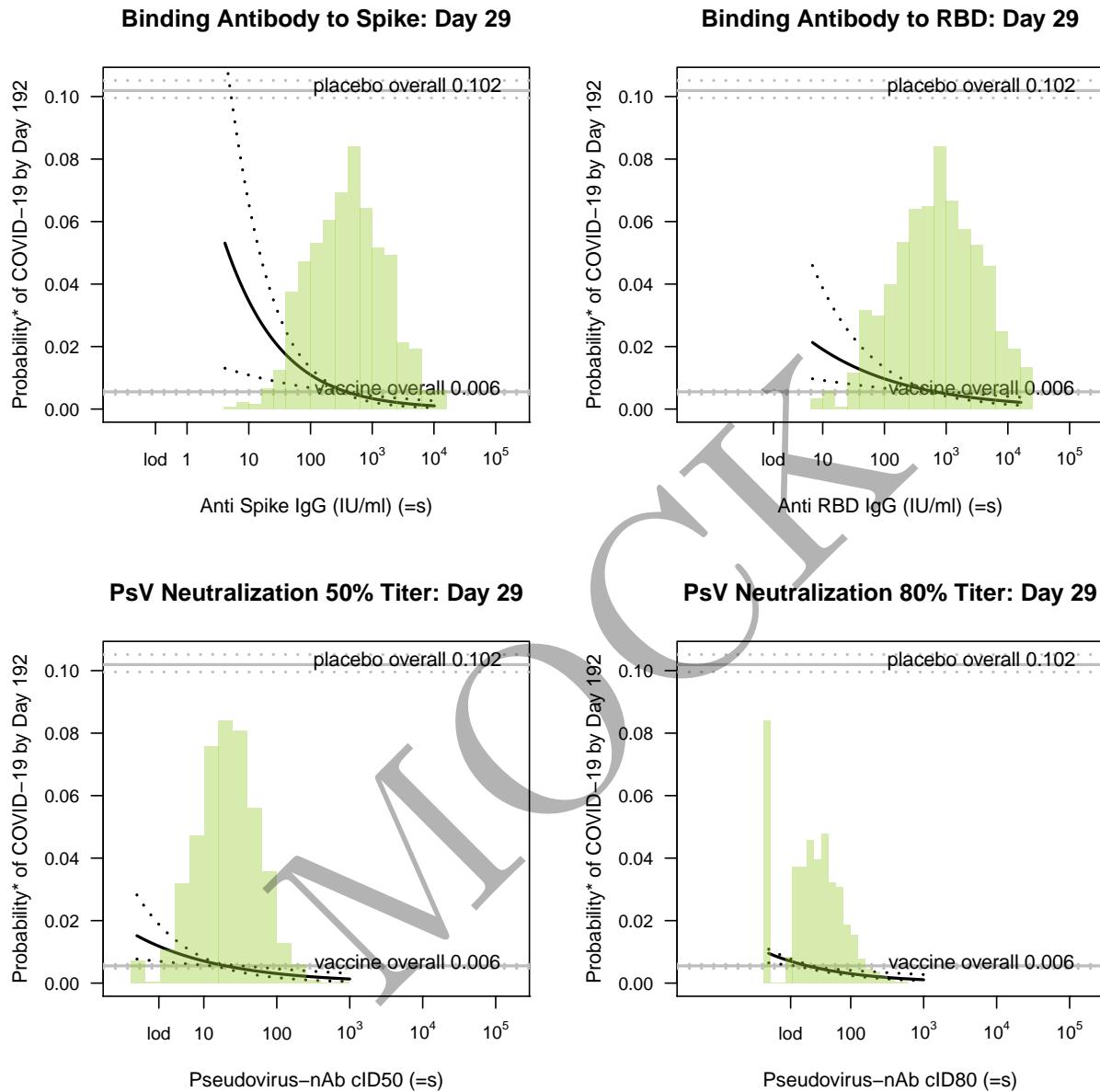


Figure 4.7: Marginalized cumulative risk by Day 192 as functions of Day 29 markers (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence bands (5 replicates). The horizontal lines indicate the overall cumulative risk of the placebo and vaccine arms by Day 192 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod = 0.3, 1.6, 2.4, 15 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively.

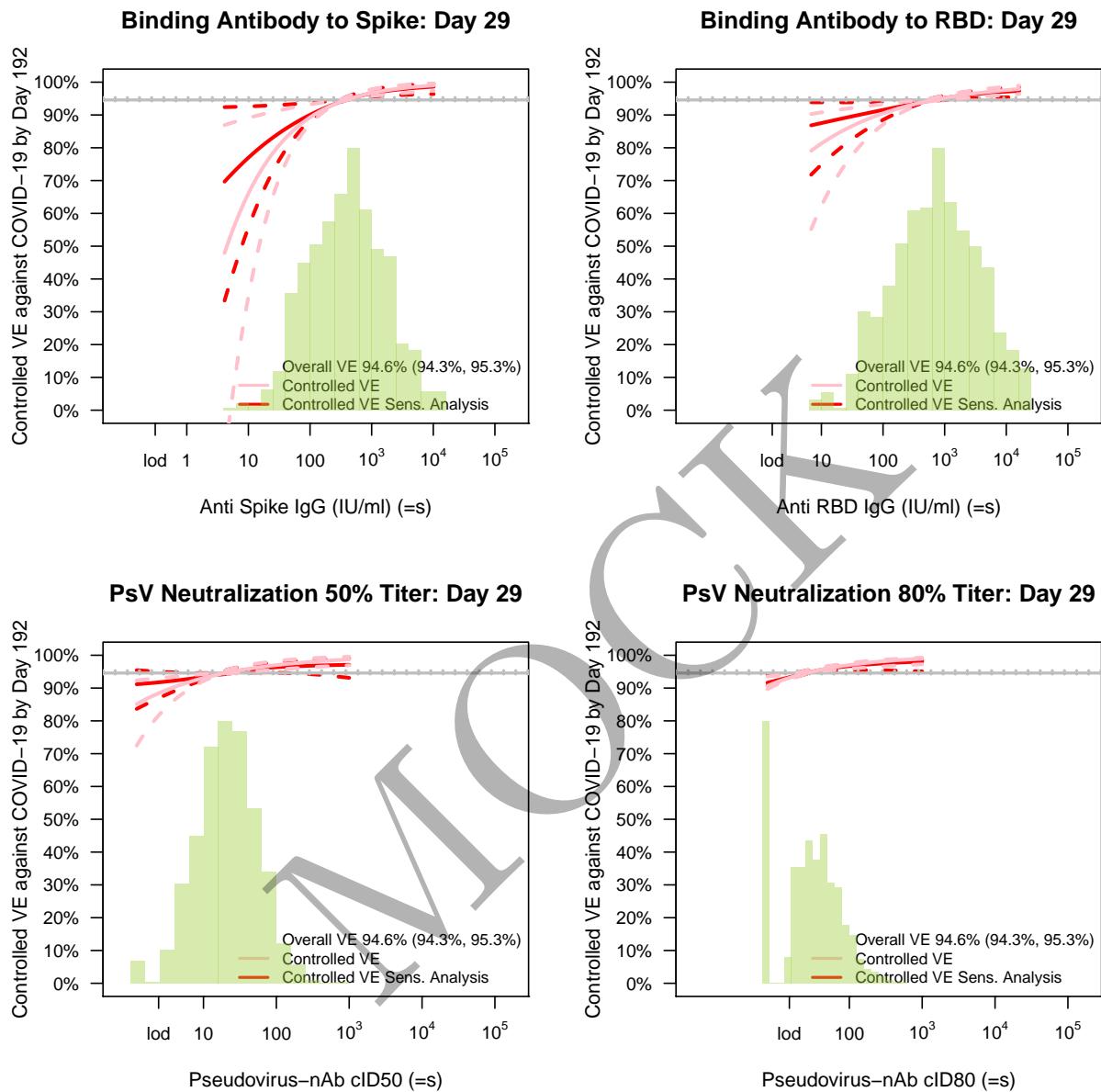


Figure 4.8: Controlled VE with sensitivity analysis as functions of Day 29 markers (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence bands (5 replicates). Histograms of the immunological markers in the vaccine arm are overlaid. $\text{Iod} = 0.3, 1.6, 2.4, 15$ for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively.

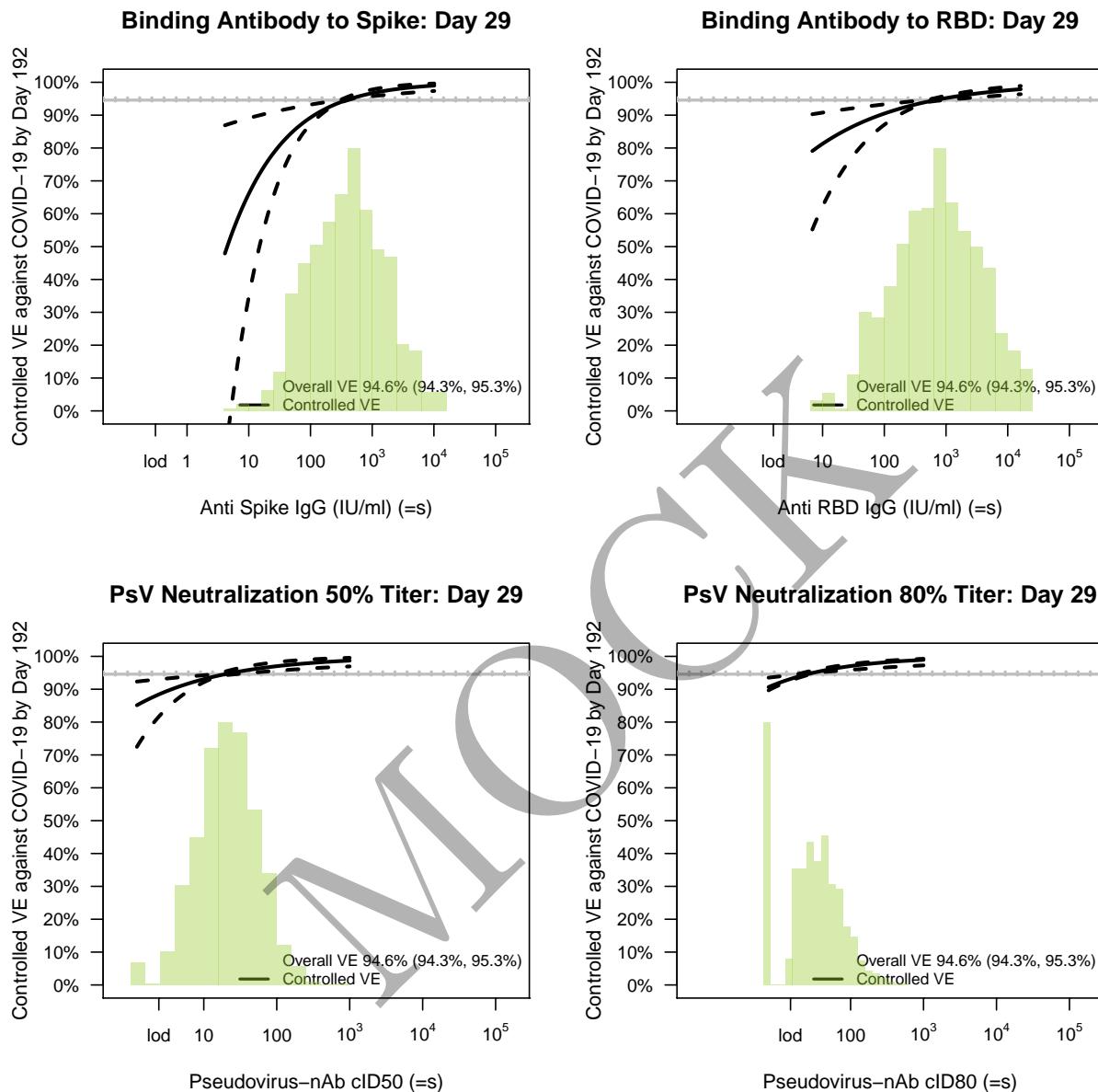


Figure 4.9: Controlled VE with sensitivity analysis as functions of Day 29 markers (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence bands (5 replicates). Histograms of the immunological markers in the vaccine arm are overlaid. lod = 0.3, 1.6, 2.4, 15 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively.

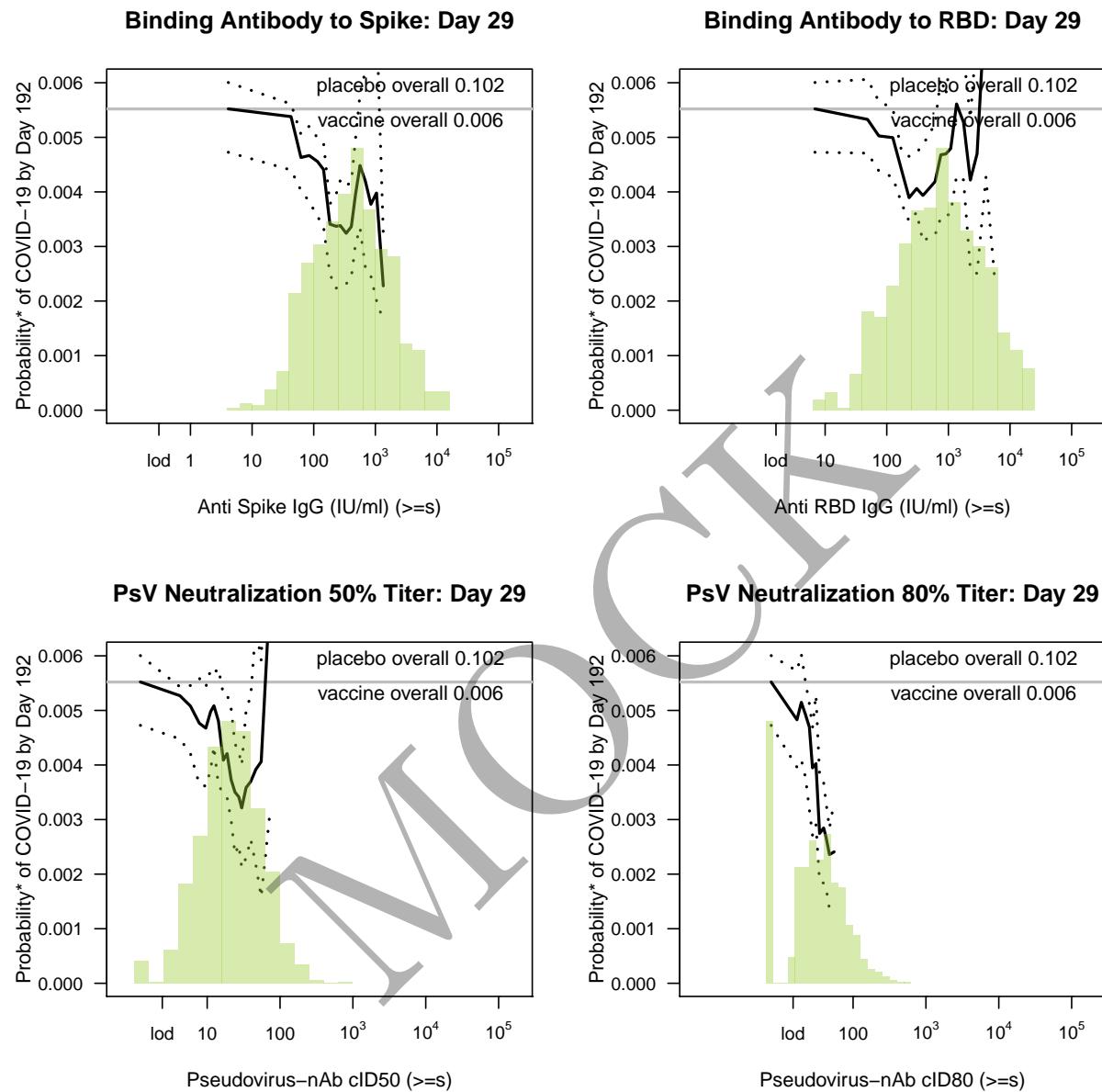


Figure 4.10: Marginalized cumulative risk by Day 192 as functions of Day 29 markers above a threshold ($\geq s$) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence bands (at least 5 cases are required, 5 replicates). The horizontal lines indicate the overall cumulative risk of the vaccine arm by Day 192 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. $l_{od} = 0.3, 1.6, 2.4, 15$ for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively.

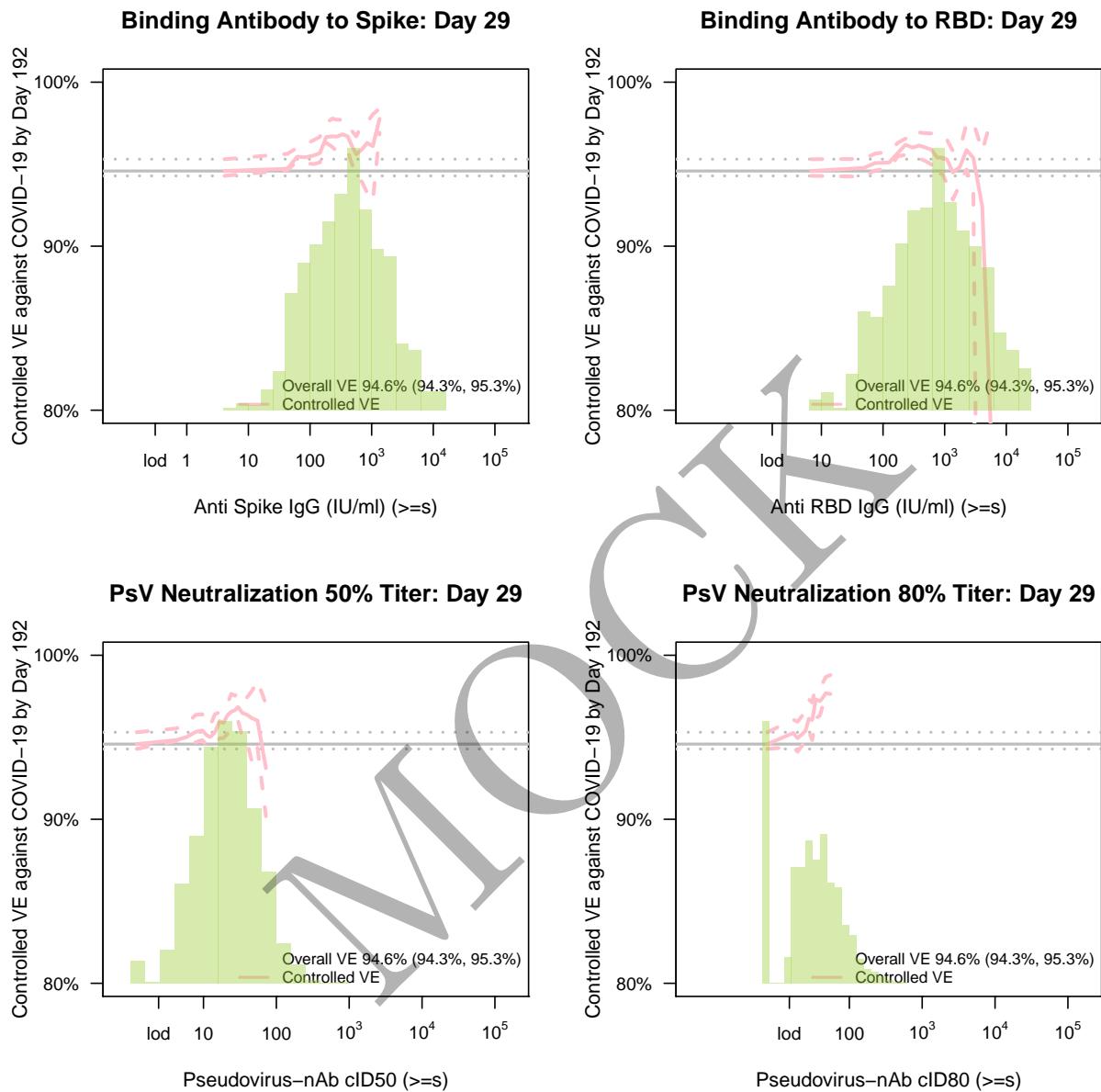


Figure 4.11: Controlled VE as functions of Day 29 markers ($\geq s$) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence bands (5 replicates). Histograms of the immunological markers in the vaccine arm are overlaid. $l_{od} = 0.3, 1.6, 2.4, 15$ for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively.

Table 4.4: Marginalized cumulative risk by Day 192 as functions of Day 29 markers (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence intervals (5 replicates).

	Anti Spike IgG (IU/ml)	s	Estimate	Anti RBD IgG (IU/ml)	s	Estimate	Pseudovirus-nAb cID50	s	Estimate	Pseudovirus-nAb cID80	s	Estimate
4.1	.0531 (.0131,.1151)	6.8	.0213 (.0097,.0460)	1.2	.0152 (.0077,.0282)	7.5	.0095 (.0065,.0109)					
4	.0511 (.0129,.1098)	7	.0208 (.0096,.0444)	1	.0148 (.0076,.0272)	8	.0095 (.0065,.0109)					
5	.0493 (.0127,.1047)	8	.0204 (.0095,.0428)	1	.0145 (.0075,.0262)	8	.0095 (.0065,.0109)					
5	.0474 (.0125,.0998)	9	.0199 (.0094,.0414)	1	.0141 (.0075,.0252)	8	.0094 (.0064,.0106)					
6	.0457 (.0123,.0951)	9	.0195 (.0093,.0399)	2	.0138 (.0074,.0243)	8	.0092 (.0064,.0104)					
6	.0440 (.0121,.0905)	10	.0190 (.0092,.0385)	2	.0135 (.0073,.0234)	9	.0090 (.0063,.0102)					
7	.0424 (.0119,.0861)	11	.0186 (.0091,.0372)	2	.0132 (.0073,.0225)	9	.0088 (.0063,.0100)					
7	.0408 (.0117,.0819)	12	.0182 (.0090,.0359)	2	.0129 (.0072,.0216)	9	.0087 (.0062,.0098)					
8	.0392 (.0115,.0779)	13	.0177 (.0089,.0346)	2	.0126 (.0072,.0208)	10	.0085 (.0062,.0096)					
8	.0378 (.0113,.0740)	14	.0173 (.0088,.0334)	2	.0123 (.0071,.0201)	10	.0083 (.0061,.0094)					
9	.0363 (.0111,.0703)	15	.0170 (.0087,.0322)	2	.0120 (.0070,.0193)	11	.0082 (.0061,.0092)					
10	.0350 (.0109,.0667)	16	.0166 (.0086,.0311)	2	.0117 (.0070,.0186)	11	.0080 (.0060,.0090)					
11	.0337 (.0108,.0633)	18	.0162 (.0085,.0300)	3	.0114 (.0069,.0179)	12	.0079 (.0060,.0088)					
11	.0324 (.0106,.0601)	19	.0158 (.0084,.0289)	3	.0112 (.0068,.0172)	12	.0077 (.0059,.0086)					
12	.0311 (.0104,.0570)	20	.0155 (.0083,.0279)	3	.0109 (.0068,.0165)	13	.0076 (.0059,.0084)					
13	.0300 (.0102,.0540)	22	.0151 (.0082,.0269)	3	.0107 (.0067,.0159)	13	.0074 (.0058,.0083)					
15	.0288 (.0101,.0511)	24	.0148 (.0082,.0259)	3	.0104 (.0067,.0153)	14	.0073 (.0058,.0081)					
16	.0277 (.0099,.0484)	26	.0144 (.0081,.0250)	4	.0102 (.0066,.0147)	14	.0072 (.0057,.0079)					
17	.0267 (.0098,.0459)	28	.0141 (.0080,.0241)	4	.0099 (.0065,.0142)	15	.0070 (.0057,.0078)					
18	.0256 (.0096,.0434)	30	.0138 (.0079,.0232)	4	.0097 (.0065,.0136)	15	.0070 (.0057,.0077)					
20	.0247 (.0094,.0411)	33	.0135 (.0078,.0224)	4	.0095 (.0064,.0131)	16	.0069 (.0056,.0076)					
22	.0237 (.0093,.0389)	36	.0132 (.0077,.0216)	5	.0093 (.0064,.0126)	16	.0068 (.0056,.0075)					
23	.0228 (.0091,.0368)	38	.0129 (.0076,.0208)	5	.0090 (.0063,.0121)	17	.0066 (.0056,.0073)					
25	.0219 (.0090,.0348)	42	.0126 (.0076,.0201)	5	.0088 (.0063,.0117)	18	.0065 (.0055,.0072)					
27	.0211 (.0089,.0329)	45	.0123 (.0075,.0193)	6	.0086 (.0062,.0112)	18	.0064 (.0055,.0070)					
30	.0203 (.0087,.0311)	49	.0120 (.0074,.0186)	6	.0085 (.0062,.0110)	19	.0063 (.0054,.0069)					
32	.0195 (.0086,.0293)	53	.0117 (.0073,.0180)	6	.0084 (.0062,.0108)	20	.0062 (.0053,.0067)					
35	.0187 (.0084,.0277)	57	.0115 (.0072,.0173)	7	.0082 (.0061,.0104)	21	.0060 (.0051,.0066)					
37	.0180 (.0083,.0262)	62	.0112 (.0072,.0167)	7	.0080 (.0060,.0100)	22	.0059 (.0051,.0065)					
40	.0173 (.0082,.0247)	67	.0109 (.0071,.0161)	7	.0079 (.0060,.0096)	22	.0059 (.0050,.0065)					
44	.0166 (.0080,.0233)	72	.0107 (.0070,.0155)	8	.0077 (.0060,.0094)	23	.0058 (.0049,.0063)					
47	.0160 (.0079,.0220)	78	.0104 (.0069,.0149)	8	.0077 (.0059,.0093)	24	.0057 (.0048,.0062)					
51	.0153 (.0078,.0208)	78	.0104 (.0069,.0149)	9	.0075 (.0059,.0089)	25	.0056 (.0047,.0061)					
56	.0148 (.0077,.0196)	84	.0102 (.0069,.0144)	9	.0073 (.0058,.0086)	26	.0055 (.0047,.0060)					
60	.0142 (.0075,.0186)	91	.0100 (.0068,.0138)	10	.0071 (.0058,.0082)	27	.0054 (.0046,.0058)					
64	.0137 (.0074,.0178)	99	.0097 (.0067,.0133)	10	.0071 (.0058,.0082)	28	.0054 (.0045,.0058)					
65	.0136 (.0074,.0176)	107	.0095 (.0066,.0128)	10	.0070 (.0057,.0079)	28	.0053 (.0045,.0057)					
70	.0131 (.0073,.0167)	115	.0093 (.0066,.0124)	11	.0068 (.0056,.0076)	30	.0052 (.0044,.0056)					
76	.0126 (.0072,.0158)	125	.0091 (.0065,.0119)	12	.0067 (.0056,.0074)	31	.0051 (.0043,.0055)					
82	.0121 (.0071,.0150)	125	.0091 (.0065,.0119)	13	.0065 (.0055,.0071)	32	.0050 (.0042,.0054)					
84	.0119 (.0070,.0148)	135	.0089 (.0064,.0115)	13	.0063 (.0054,.0068)	34	.0049 (.0041,.0053)					
89	.0116 (.0069,.0142)	146	.0087 (.0064,.0111)	14	.0062 (.0054,.0067)	35	.0048 (.0041,.0052)					
96	.0112 (.0068,.0135)	158	.0085 (.0063,.0107)	14	.0062 (.0054,.0066)	35	.0048 (.0040,.0052)					
104	.0107 (.0067,.0128)	171	.0083 (.0062,.0103)	15	.0061 (.0053,.0064)	37	.0047 (.0039,.0051)					
113	.0103 (.0066,.0121)	185	.0081 (.0062,.0099)	16	.0059 (.0051,.0063)	38	.0046 (.0039,.0050)					
121	.0100 (.0065,.0116)	188	.0080 (.0061,.0098)	17	.0058 (.0049,.0062)	40	.0045 (.0038,.0049)					
122	.0099 (.0065,.0115)	200	.0079 (.0061,.0095)	19	.0056 (.0048,.0061)	42	.0044 (.0037,.0049)					
132	.0095 (.0064,.0109)	216	.0077 (.0060,.0092)	19	.0056 (.0048,.0061)	43	.0044 (.0037,.0048)					
143	.0091 (.0063,.0103)	234	.0075 (.0060,.0088)	20	.0055 (.0046,.0060)	44	.0044 (.0036,.0048)					

155	.0088 (.0062,.0098)	253	.0074 (.0059,.0085)	21	.0054 (.0045,.0060)	45	.0043 (.0036,.0047)
168	.0084 (.0061,.0093)	274	.0072 (.0058,.0082)	23	.0053 (.0043,.0059)	47	.0042 (.0035,.0047)
181	.0081 (.0060,.0088)	296	.0070 (.0058,.0079)	24	.0051 (.0041,.0058)	50	.0041 (.0034,.0046)
196	.0078 (.0059,.0083)	320	.0069 (.0057,.0076)	24	.0051 (.0041,.0058)	52	.0040 (.0033,.0046)
212	.0075 (.0058,.0079)	347	.0067 (.0056,.0073)	26	.0050 (.0040,.0058)	54	.0040 (.0033,.0046)
224	.0073 (.0057,.0076)	375	.0066 (.0056,.0071)	27	.0049 (.0038,.0057)	56	.0039 (.0032,.0045)
230	.0072 (.0057,.0075)	376	.0066 (.0056,.0071)	29	.0048 (.0037,.0056)	59	.0038 (.0031,.0045)
249	.0069 (.0056,.0072)	406	.0064 (.0055,.0068)	30	.0047 (.0036,.0056)	61	.0037 (.0031,.0045)
269	.0066 (.0055,.0069)	439	.0063 (.0055,.0066)	31	.0047 (.0035,.0056)	63	.0037 (.0030,.0044)
291	.0064 (.0054,.0066)	474	.0061 (.0054,.0064)	33	.0046 (.0034,.0055)	64	.0037 (.0030,.0044)
315	.0061 (.0053,.0064)	500	.0060 (.0054,.0063)	36	.0045 (.0033,.0055)	67	.0036 (.0029,.0044)
333	.0059 (.0051,.0062)	513	.0060 (.0053,.0063)	38	.0043 (.0031,.0054)	70	.0035 (.0029,.0044)
341	.0059 (.0050,.0061)	555	.0058 (.0052,.0062)	41	.0042 (.0030,.0053)	73	.0035 (.0028,.0043)
369	.0056 (.0047,.0059)	601	.0057 (.0050,.0061)	43	.0041 (.0029,.0053)	74	.0034 (.0028,.0043)
399	.0054 (.0045,.0057)	603	.0057 (.0050,.0061)	45	.0041 (.0028,.0052)	76	.0034 (.0028,.0043)
432	.0052 (.0042,.0055)	650	.0056 (.0049,.0060)	46	.0040 (.0028,.0052)	79	.0033 (.0027,.0043)
468	.0050 (.0040,.0053)	703	.0054 (.0047,.0059)	49	.0040 (.0027,.0052)	83	.0033 (.0026,.0042)
475	.0049 (.0039,.0053)	760	.0053 (.0046,.0059)	53	.0039 (.0026,.0051)	87	.0032 (.0026,.0042)
500	.0048 (.0038,.0052)	822	.0052 (.0044,.0058)	55	.0038 (.0025,.0051)	90	.0032 (.0025,.0042)
506	.0048 (.0037,.0051)	889	.0051 (.0043,.0057)	56	.0038 (.0025,.0051)	90	.0032 (.0025,.0042)
548	.0046 (.0035,.0050)	912	.0050 (.0042,.0057)	60	.0037 (.0024,.0050)	94	.0031 (.0025,.0041)
593	.0044 (.0033,.0048)	962	.0050 (.0042,.0057)	64	.0036 (.0023,.0049)	98	.0030 (.0024,.0041)
641	.0042 (.0031,.0046)	1000	.0049 (.0041,.0056)	68	.0035 (.0022,.0049)	103	.0030 (.0024,.0041)
693	.0041 (.0029,.0046)	1041	.0048 (.0040,.0056)	71	.0035 (.0022,.0049)	107	.0029 (.0023,.0040)
694	.0041 (.0029,.0046)	1126	.0047 (.0039,.0056)	73	.0034 (.0021,.0048)	112	.0029 (.0023,.0040)
751	.0039 (.0028,.0045)	1218	.0046 (.0038,.0055)	78	.0033 (.0021,.0048)	117	.0028 (.0022,.0040)
813	.0038 (.0026,.0044)	1317	.0045 (.0036,.0054)	83	.0033 (.0020,.0047)	122	.0028 (.0022,.0040)
879	.0036 (.0024,.0043)	1395	.0044 (.0035,.0054)	89	.0032 (.0019,.0047)	127	.0027 (.0021,.0039)
952	.0035 (.0023,.0043)	1425	.0044 (.0035,.0054)	94	.0031 (.0018,.0046)	133	.0027 (.0021,.0039)
1000	.0034 (.0022,.0042)	1541	.0043 (.0034,.0053)	101	.0030 (.0018,.0046)	139	.0026 (.0020,.0039)
1030	.0033 (.0022,.0042)	1667	.0042 (.0033,.0052)	108	.0030 (.0017,.0045)	145	.0026 (.0020,.0038)
1114	.0032 (.0020,.0041)	1804	.0041 (.0032,.0052)	115	.0029 (.0016,.0045)	151	.0025 (.0019,.0038)
1206	.0031 (.0019,.0041)	1951	.0040 (.0031,.0051)	123	.0028 (.0016,.0044)	158	.0025 (.0019,.0038)
1294	.0030 (.0018,.0040)	2111	.0039 (.0030,.0051)	131	.0028 (.0015,.0044)	165	.0024 (.0019,.0038)
1305	.0029 (.0018,.0040)	2283	.0038 (.0029,.0050)	140	.0027 (.0014,.0043)	172	.0024 (.0018,.0037)
1412	.0028 (.0017,.0039)	2470	.0037 (.0028,.0050)	149	.0026 (.0014,.0043)	179	.0023 (.0018,.0037)
1528	.0027 (.0016,.0039)	2671	.0037 (.0027,.0049)	159	.0026 (.0013,.0042)	187	.0023 (.0017,.0037)
1653	.0026 (.0015,.0038)	2890	.0036 (.0026,.0049)	170	.0025 (.0013,.0042)	195	.0022 (.0017,.0036)
1785	.0025 (.0014,.0038)	2891	.0036 (.0026,.0049)	181	.0025 (.0012,.0042)	204	.0022 (.0017,.0036)
1789	.0025 (.0014,.0038)	3126	.0035 (.0025,.0048)	193	.0024 (.0012,.0041)	213	.0021 (.0016,.0036)
1936	.0024 (.0013,.0037)	3381	.0034 (.0024,.0047)	206	.0023 (.0011,.0041)	222	.0021 (.0016,.0036)
2095	.0023 (.0013,.0036)	3658	.0033 (.0023,.0047)	220	.0023 (.0011,.0040)	232	.0021 (.0016,.0035)
2228	.0022 (.0012,.0036)	3957	.0033 (.0023,.0046)	235	.0022 (.0011,.0040)	242	.0020 (.0015,.0035)
2267	.0022 (.0012,.0036)	4073	.0032 (.0022,.0046)	251	.0022 (.0010,.0039)	253	.0020 (.0015,.0035)
2453	.0021 (.0011,.0035)	4280	.0032 (.0022,.0046)	267	.0021 (.0010,.0039)	264	.0020 (.0015,.0035)
2655	.0020 (.0011,.0035)	4630	.0031 (.0021,.0045)	285	.0021 (.0009,.0038)	275	.0019 (.0014,.0034)
2873	.0020 (.0010,.0034)	5008	.0030 (.0020,.0045)	305	.0020 (.0009,.0038)	288	.0019 (.0014,.0034)
3109	.0019 (.0009,.0034)	5417	.0030 (.0019,.0044)	325	.0020 (.0009,.0038)	300	.0018 (.0014,.0034)
3364	.0018 (.0009,.0033)	5444	.0030 (.0019,.0044)	347	.0019 (.0008,.0037)	313	.0018 (.0013,.0034)
3640	.0017 (.0008,.0032)	5860	.0029 (.0019,.0044)	370	.0019 (.0008,.0037)	327	.0018 (.0013,.0033)
3939	.0017 (.0008,.0032)	6339	.0028 (.0018,.0043)	395	.0018 (.0008,.0036)	341	.0017 (.0013,.0033)
4263	.0016 (.0007,.0031)	6857	.0028 (.0017,.0043)	422	.0018 (.0007,.0036)	356	.0017 (.0013,.0033)
4613	.0015 (.0007,.0031)	7417	.0027 (.0017,.0042)	450	.0018 (.0007,.0036)	372	.0017 (.0012,.0033)
4992	.0015 (.0006,.0030)	8023	.0026 (.0016,.0042)	480	.0017 (.0007,.0035)	388	.0016 (.0012,.0032)

5401	.0014 (.0006,.0030)	8679	.0026 (.0015,.0041)	500	.0017 (.0007,.0035)	405	.0016 (.0012,.0032)
5845	.0014 (.0006,.0029)	9388	.0025 (.0015,.0041)	512	.0017 (.0007,.0035)	423	.0016 (.0011,.0032)
6325	.0013 (.0005,.0029)	10155	.0025 (.0014,.0041)	547	.0016 (.0006,.0035)	441	.0016 (.0011,.0032)
6844	.0013 (.0005,.0029)	10985	.0024 (.0014,.0040)	584	.0016 (.0006,.0034)	461	.0015 (.0011,.0031)
7407	.0012 (.0005,.0028)	11883	.0023 (.0013,.0040)	623	.0016 (.0006,.0034)	481	.0015 (.0011,.0031)
8015	.0012 (.0005,.0028)	12854	.0023 (.0013,.0039)	665	.0015 (.0006,.0033)	500	.0015 (.0011,.0031)
8673	.0011 (.0004,.0027)	13904	.0022 (.0012,.0039)	709	.0015 (.0005,.0033)	502	.0015 (.0011,.0031)
9385	.0011 (.0004,.0027)	15040	.0022 (.0012,.0038)	757	.0015 (.0005,.0033)	524	.0014 (.0010,.0031)
10156	.0010 (.0004,.0026)	16269	.0021 (.0011,.0038)	1000	.0013 (.0004,.0031)	1000	.0011 (.0007,.0027)

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Table 4.5: Controlled VE as functions of Day 29 markers (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence intervals (5 replicates). Overall cumulative incidence from 7 to 192 days post Day 29 was 0.006 in vaccine recipients compared to 0.102 in placebo recipients, with cumulative vaccine efficacy 94.6% (95% CI 94.3 to 95.3%).

	Anti Spike IgG (IU/ml)	Anti RBD IgG (IU/ml)	Pseudovirus-nAb cID50	Pseudovirus-nAb cID80	
s	Estimate	s	Estimate	s	Estimate
4.1	.4790 (-0.1438,.8691)	6.8	.7908 (.5520,.9028)	1.2	.8512 (.7246,.9233)
4	.4982 (-0.0913,.8712)	7	.7956 (.5674,.9038)	1	.8546 (.7348,.9240)
5	.5166 (-0.0407,.8733)	8	.8002 (.5824,.9049)	1	.8580 (.7447,.9247)
5	.5345 (.00082,.8753)	9	.8047 (.5969,.9059)	1	.8613 (.7542,.9253)
6	.5517 (.0552,.8773)	9	.8091 (.6109,.9069)	2	.8645 (.7633,.9260)
6	.5684 (.1005,.8793)	10	.8134 (.6244,.9079)	2	.8676 (.7722,.9266)
7	.5845 (.1440,.8812)	11	.8177 (.6376,.9089)	2	.8707 (.7807,.9273)
7	.6000 (.1859,.8831)	12	.8218 (.6503,.9099)	2	.8737 (.7889,.9279)
8	.6150 (.2261,.8850)	13	.8258 (.6626,.9108)	2	.8766 (.7968,.9286)
8	.6294 (.2646,.8869)	14	.8298 (.6745,.9118)	2	.8795 (.8045,.9292)
9	.6434 (.3015,.8887)	15	.8337 (.6859,.9128)	2	.8823 (.8118,.9298)
10	.6568 (.3369,.8905)	16	.8374 (.6971,.9137)	2	.8850 (.8189,.9304)
11	.6698 (.3707,.8922)	18	.8411 (.7078,.9146)	3	.8877 (.8257,.9311)
11	.6823 (.4031,.8940)	19	.8448 (.7182,.9156)	3	.8903 (.8323,.9317)
12	.6944 (.4340,.8957)	20	.8483 (.7282,.9165)	3	.8928 (.8386,.9323)
13	.7060 (.4635,.8974)	22	.8517 (.7379,.9174)	3	.8953 (.8447,.9329)
15	.7172 (.4917,.8990)	24	.8551 (.7473,.9183)	3	.8978 (.8506,.9335)
16	.7280 (.5185,.9006)	26	.8584 (.7563,.9191)	4	.9001 (.8562,.9341)
17	.7384 (.5441,.9022)	28	.8616 (.7651,.9200)	4	.9025 (.8617,.9346)
18	.7484 (.5685,.9038)	30	.8648 (.7735,.9209)	4	.9047 (.8669,.9352)
20	.7581 (.5916,.9054)	33	.8679 (.7816,.9217)	4	.9070 (.8720,.9358)
22	.7674 (.6137,.9069)	36	.8709 (.7895,.9226)	5	.9091 (.8768,.9364)
23	.7763 (.6346,.9084)	38	.8738 (.7971,.9234)	5	.9112 (.8815,.9369)
25	.7850 (.6545,.9098)	42	.8767 (.8044,.9242)	5	.9133 (.8860,.9375)
27	.7933 (.6734,.9113)	45	.8795 (.8115,.9250)	6	.9153 (.8904,.9380)
30	.8013 (.6914,.9127)	49	.8823 (.8183,.9259)	6	.9166 (.8931,.9384)
32	.8090 (.7084,.9141)	53	.8850 (.8249,.9267)	6	.9173 (.8946,.9386)
35	.8164 (.7245,.9155)	57	.8876 (.8313,.9274)	7	.9192 (.8986,.9391)
37	.8235 (.7398,.9169)	62	.8902 (.8374,.9282)	7	.9211 (.9024,.9397)
40	.8303 (.7543,.9182)	67	.8927 (.8434,.9290)	7	.9229 (.9062,.9402)
44	.8369 (.7681,.9195)	72	.8952 (.8491,.9298)	8	.9241 (.9085,.9405)
47	.8433 (.7811,.9208)	78	.8976 (.8546,.9305)	8	.9247 (.9098,.9407)
51	.8494 (.7934,.9221)	78	.8976 (.8546,.9305)	9	.9265 (.9132,.9412)
56	.8553 (.8050,.9233)	84	.8999 (.8599,.9313)	9	.9282 (.9165,.9418)
60	.8609 (.8160,.9246)	91	.9022 (.8650,.9320)	10	.9299 (.9197,.9423)
64	.8651 (.8241,.9255)	99	.9045 (.8699,.9328)	10	.9300 (.9199,.9423)
65	.8664 (.8265,.9258)	107	.9066 (.8747,.9335)	10	.9315 (.9228,.9428)
70	.8716 (.8363,.9270)	115	.9088 (.8793,.9342)	11	.9331 (.9258,.9434)
76	.8766 (.8455,.9281)	125	.9109 (.8837,.9349)	12	.9347 (.9284,.9440)
82	.8815 (.8536,.9293)	125	.9110 (.8839,.9349)	13	.9362 (.9310,.9446)
84	.8829 (.8560,.9297)	135	.9129 (.8880,.9356)	13	.9377 (.9335,.9453)
89	.8861 (.8612,.9304)	146	.9149 (.8921,.9363)	14	.9387 (.9351,.9457)
96	.8906 (.8684,.9316)	158	.9169 (.8961,.9370)	14	.9392 (.9359,.9459)
104	.8949 (.8753,.9327)	171	.9188 (.8999,.9377)	15	.9406 (.9382,.9470)
113	.8990 (.8818,.9337)	185	.9207 (.9036,.9383)	16	.9420 (.9401,.9489)
121	.9023 (.8869,.9346)	188	.9210 (.9043,.9385)	17	.9433 (.9409,.9507)
122	.9030 (.8880,.9348)	200	.9225 (.9071,.9390)	19	.9447 (.9418,.9524)

132	.9068 (. 0.8939,.9358)	216	.9243 (.9106,.9397)	19	.9447 (.9418,.9525)	43	.9569 (.9524,.9636)
143	.9105 (. 0.8995,.9369)	234	.9260 (.9139,.9404)	20	.9460 (.9426,.9541)	44	.9572 (.9525,.9639)
155	.9140 (. 0.9047,.9379)	253	.9277 (.9171,.9411)	21	.9472 (.9433,.9558)	45	.9580 (.9529,.9647)
168	.9174 (. 0.9097,.9389)	274	.9294 (.9201,.9418)	23	.9485 (.9439,.9574)	47	.9588 (.9532,.9654)
181	.9206 (. 0.9145,.9399)	296	.9310 (.9231,.9425)	24	.9497 (.9445,.9590)	50	.9596 (.9536,.9661)
196	.9238 (. 0.9190,.9408)	320	.9326 (.9259,.9432)	24	.9497 (.9445,.9590)	52	.9604 (.9539,.9669)
212	.9268 (. 0.9231,.9418)	347	.9341 (.9286,.9438)	26	.9508 (.9451,.9605)	54	.9611 (.9543,.9676)
224	.9288 (. 0.9257,.9424)	375	.9357 (.9311,.9445)	27	.9520 (.9457,.9620)	56	.9618 (.9546,.9683)
230	.9297 (. 0.9270,.9427)	376	.9357 (.9312,.9445)	29	.9531 (.9463,.9635)	59	.9626 (.9549,.9690)
249	.9325 (. 0.9307,.9436)	406	.9371 (.9336,.9451)	30	.9537 (.9466,.9642)	61	.9633 (.9553,.9696)
269	.9351 (. 0.9342,.9445)	439	.9386 (.9359,.9458)	31	.9542 (.9469,.9649)	63	.9636 (.9554,.9699)
291	.9377 (. 0.9369,.9454)	474	.9400 (.9381,.9464)	33	.9553 (.9475,.9662)	64	.9640 (.9556,.9703)
315	.9402 (. 0.9393,.9475)	500	.9409 (.9396,.9468)	36	.9563 (.9480,.9675)	67	.9647 (.9560,.9709)
333	.9418 (. 0.9408,.9495)	513	.9414 (.9403,.9470)	38	.9574 (.9486,.9687)	70	.9653 (.9563,.9716)
341	.9425 (. 0.9415,.9504)	555	.9427 (.9411,.9483)	41	.9584 (.9491,.9699)	73	.9660 (.9566,.9722)
369	.9448 (. 0.9437,.9531)	601	.9441 (.9419,.9499)	43	.9593 (.9497,.9711)	74	.9662 (.9567,.9723)
399	.9470 (. 0.9457,.9557)	603	.9441 (.9419,.9500)	45	.9600 (.9501,.9719)	76	.9666 (.9569,.9728)
432	.9491 (. 0.9475,.9583)	650	.9454 (.9427,.9514)	46	.9603 (.9502,.9722)	79	.9673 (.9573,.9734)
468	.9511 (. 0.9493,.9607)	703	.9466 (.9434,.9529)	49	.9612 (.9508,.9732)	83	.9679 (.9576,.9739)
475	.9515 (. 0.9496,.9612)	760	.9478 (.9441,.9544)	53	.9621 (.9513,.9742)	87	.9685 (.9579,.9745)
500	.9528 (. 0.9507,.9627)	822	.9491 (.9447,.9559)	55	.9628 (.9517,.9750)	90	.9691 (.9582,.9750)
506	.9530 (. 0.9510,.9630)	889	.9502 (.9453,.9573)	56	.9630 (.9518,.9752)	90	.9691 (.9582,.9750)
548	.9549 (. 0.9520,.9652)	912	.9506 (.9455,.9578)	60	.9639 (.9524,.9762)	94	.9697 (.9585,.9756)
593	.9567 (. 0.9528,.9672)	962	.9514 (.9459,.9588)	64	.9647 (.9529,.9771)	98	.9702 (.9588,.9761)
641	.9584 (. 0.9536,.9691)	1000	.9519 (.9462,.9594)	68	.9656 (.9534,.9780)	103	.9708 (.9592,.9766)
693	.9601 (. 0.9543,.9709)	1041	.9525 (.9465,.9601)	71	.9661 (.9537,.9785)	107	.9714 (.9595,.9771)
694	.9601 (. 0.9543,.9709)	1126	.9536 (.9471,.9614)	73	.9664 (.9539,.9788)	112	.9719 (.9598,.9776)
751	.9617 (. 0.9550,.9726)	1218	.9547 (.9477,.9627)	78	.9672 (.9544,.9796)	117	.9724 (.9601,.9781)
813	.9632 (. 0.9558,.9742)	1317	.9557 (.9483,.9640)	83	.9679 (.9549,.9804)	122	.9730 (.9604,.9786)
879	.9646 (. 0.9565,.9757)	1395	.9565 (.9487,.9648)	89	.9687 (.9554,.9811)	127	.9735 (.9607,.9790)
952	.9660 (. 0.9572,.9771)	1425	.9567 (.9489,.9651)	94	.9694 (.9558,.9819)	133	.9740 (.9610,.9795)
1000	.9669 (. 0.9576,.9780)	1541	.9577 (.9494,.9663)	101	.9701 (.9563,.9825)	139	.9745 (.9612,.9799)
1030	.9674 (. 0.9579,.9785)	1667	.9587 (.9500,.9674)	108	.9708 (.9568,.9832)	145	.9750 (.9615,.9804)
1114	.9687 (. 0.9585,.9797)	1804	.9597 (.9505,.9685)	115	.9715 (.9573,.9839)	151	.9754 (.9618,.9808)
1206	.9699 (. 0.9592,.9809)	1951	.9606 (.9511,.9695)	123	.9722 (.9577,.9845)	158	.9759 (.9621,.9812)
1294	.9710 (. 0.9598,.9819)	2111	.9615 (.9516,.9705)	131	.9728 (.9582,.9851)	165	.9764 (.9624,.9816)
1305	.9711 (. 0.9598,.9820)	2283	.9624 (.9522,.9715)	140	.9735 (.9586,.9856)	172	.9768 (.9627,.9820)
1412	.9723 (. 0.9605,.9831)	2470	.9633 (.9527,.9725)	149	.9741 (.9591,.9862)	179	.9772 (.9630,.9824)
1528	.9734 (. 0.9611,.9841)	2671	.9641 (.9532,.9734)	159	.9747 (.9595,.9867)	187	.9777 (.9632,.9828)
1653	.9744 (. 0.9617,.9850)	2890	.9650 (.9537,.9743)	170	.9753 (.9600,.9872)	195	.9781 (.9635,.9831)
1785	.9754 (. 0.9623,.9859)	2891	.9650 (.9538,.9744)	181	.9759 (.9604,.9877)	204	.9785 (.9638,.9835)
1789	.9755 (. 0.9624,.9859)	3126	.9658 (.9543,.9753)	193	.9764 (.9608,.9882)	213	.9789 (.9641,.9839)
1936	.9764 (. 0.9630,.9867)	3381	.9666 (.9548,.9762)	206	.9770 (.9613,.9886)	222	.9793 (.9643,.9842)
2095	.9774 (. 0.9635,.9875)	3658	.9673 (.9553,.9771)	220	.9775 (.9617,.9891)	232	.9797 (.9646,.9846)
2228	.9781 (. 0.9640,.9881)	3957	.9681 (.9558,.9780)	235	.9781 (.9621,.9895)	242	.9801 (.9649,.9849)
2267	.9783 (. 0.9641,.9882)	4073	.9684 (.9560,.9783)	251	.9786 (.9625,.9899)	253	.9805 (.9651,.9852)
2453	.9791 (. 0.9647,.9889)	4280	.9688 (.9563,.9788)	267	.9791 (.9629,.9903)	264	.9809 (.9654,.9855)
2655	.9800 (. 0.9653,.9896)	4630	.9695 (.9568,.9796)	285	.9796 (.9633,.9906)	275	.9812 (.9656,.9858)
2873	.9808 (. 0.9658,.9902)	5008	.9702 (.9572,.9803)	305	.9801 (.9637,.9910)	288	.9816 (.9659,.9861)
3109	.9815 (. 0.9664,.9907)	5417	.9709 (.9577,.9811)	325	.9805 (.9641,.9913)	300	.9819 (.9661,.9864)
3364	.9823 (. 0.9669,.9913)	5444	.9710 (.9577,.9811)	347	.9810 (.9645,.9917)	313	.9823 (.9664,.9867)
3640	.9830 (. 0.9674,.9918)	5860	.9716 (.9582,.9818)	370	.9814 (.9649,.9920)	327	.9826 (.9667,.9870)
3939	.9837 (. 0.9680,.9923)	6339	.9723 (.9586,.9825)	395	.9819 (.9652,.9923)	341	.9829 (.9669,.9873)
4263	.9843 (. 0.9685,.9927)	6857	.9729 (.9591,.9831)	422	.9823 (.9655,.9926)	356	.9833 (.9671,.9876)

4613	.9849 (.9690,.9932)	7417	.9735 (.9596,.9837)	450	.9827 (.9658,.9929)	372	.9836 (.9674,.9878)
4992	.9855 (.9695,.9936)	8023	.9742 (.9600,.9843)	480	.9831 (.9661,.9931)	388	.9839 (.9676,.9881)
5401	.9861 (.9700,.9939)	8679	.9747 (.9605,.9849)	500	.9834 (.9663,.9933)	405	.9842 (.9679,.9884)
5845	.9867 (.9704,.9943)	9388	.9753 (.9609,.9855)	512	.9835 (.9664,.9934)	423	.9845 (.9681,.9886)
6325	.9872 (.9709,.9946)	10155	.9759 (.9613,.9860)	547	.9839 (.9667,.9937)	441	.9848 (.9684,.9889)
6844	.9877 (.9714,.9949)	10985	.9765 (.9618,.9866)	584	.9843 (.9670,.9939)	461	.9851 (.9686,.9891)
7407	.9882 (.9718,.9952)	11883	.9770 (.9622,.9871)	623	.9846 (.9673,.9941)	481	.9854 (.9688,.9893)
8015	.9887 (.9723,.9955)	12854	.9775 (.9626,.9875)	665	.9850 (.9676,.9944)	500	.9856 (.9690,.9895)
8673	.9891 (.9727,.9958)	13904	.9781 (.9630,.9880)	709	.9854 (.9679,.9946)	502	.9856 (.9691,.9896)
9385	.9896 (.9732,.9960)	15040	.9786 (.9634,.9885)	757	.9857 (.9681,.9948)	524	.9859 (.9693,.9898)
10156	.9900 (.9736,.9963)	16269	.9791 (.9638,.9889)	1000	.9871 (.9693,.9956)	1000	.9894 (.9726,.9927)
9	.6434 (.3015,8887)		(,)		(,)		(,)
113	.8990 (.8818,.9337)	84	.8999 (.8599,.9313)	4	.9001 (.8562,.9341)	8	.9065 (.8965,.9351)
432	.9491 (.9475,9583)	889	.9502 (.9453,.9573)	24	.9497 (.9445,.9590)	31	.9501 (.9478,.9573)

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Table 4.6: Controlled VE with sensitivity analysis as functions of Day 29 markers (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence intervals (5 replicates).

	Anti Spike IgG (IU/ml)	s	Estimate	Anti RBD IgG (IU/ml)	s	Estimate	Pseudovirus-nAb cID50	s	Estimate	Pseudovirus-nAb cID80	s	Estimate
4.1	.6968 (.3343,.9238)	6.8	.8683 (.7179,.9388)	1.2	.9116 (.8364,.9544)	7.5	.9163 (.9073,.9419)					
4	.7038 (.3558,.9240)	7	.8698 (.7244,.9387)	1	.9121 (.8396,.9540)	8	.9163 (.9073,.9419)					
5	.7107 (.3771,.9241)	8	.8712 (.7308,.9387)	1	.9126 (.8428,.9536)	8	.9163 (.9073,.9419)					
5	.7175 (.3980,.9243)	9	.8726 (.7371,.9386)	1	.9131 (.8460,.9532)	8	.9173 (.9087,.9420)					
6	.7242 (.4186,.9245)	9	.8741 (.7433,.9386)	2	.9136 (.8492,.9528)	8	.9184 (.9101,.9420)					
6	.7308 (.4389,.9247)	10	.8755 (.7494,.9385)	2	.9142 (.8523,.9524)	9	.9194 (.9114,.9421)					
7	.7372 (.4587,.9249)	11	.8769 (.7554,.9385)	2	.9147 (.8553,.9520)	9	.9205 (.9128,.9422)					
7	.7436 (.4782,.9251)	12	.8784 (.7613,.9385)	2	.9153 (.8584,.9516)	9	.9215 (.9141,.9424)					
8	.7499 (.4973,.9253)	13	.8798 (.7671,.9385)	2	.9158 (.8614,.9513)	10	.9226 (.9155,.9425)					
8	.7561 (.5159,.9255)	14	.8812 (.7728,.9384)	2	.9164 (.8644,.9509)	10	.9236 (.9168,.9426)					
9	.7621 (.5341,.9258)	15	.8826 (.7783,.9384)	2	.9170 (.8673,.9505)	11	.9247 (.9181,.9427)					
10	.7681 (.5519,.9260)	16	.8840 (.7838,.9384)	2	.9176 (.8702,.9502)	11	.9257 (.9194,.9429)					
11	.7740 (.5692,.9262)	18	.8854 (.7892,.9384)	3	.9182 (.8731,.9498)	12	.9267 (.9207,.9431)					
11	.7797 (.5861,.9265)	19	.8868 (.7945,.9384)	3	.9189 (.8760,.9495)	12	.9278 (.9220,.9432)					
12	.7854 (.6025,.9267)	20	.8882 (.7997,.9384)	3	.9195 (.8788,.9491)	13	.9288 (.9233,.9434)					
13	.7909 (.6185,.9270)	22	.8896 (.8048,.9385)	3	.9202 (.8816,.9488)	13	.9299 (.9246,.9436)					
15	.7964 (.6340,.9273)	24	.8910 (.8098,.9385)	3	.9209 (.8844,.9485)	14	.9309 (.9258,.9438)					
16	.8017 (.6490,.9276)	26	.8923 (.8147,.9385)	4	.9216 (.8871,.9482)	14	.9319 (.9270,.9441)					
17	.8069 (.6635,.9279)	28	.8937 (.8195,.9385)	4	.9223 (.8898,.9479)	15	.9329 (.9282,.9444)					
18	.8121 (.6776,.9281)	30	.8951 (.8242,.9386)	4	.9230 (.8924,.9476)	15	.9334 (.9288,.9445)					
20	.8171 (.6913,.9285)	33	.8964 (.8288,.9386)	4	.9237 (.8951,.9474)	16	.9340 (.9294,.9447)					
22	.8221 (.7045,.9288)	36	.8978 (.8334,.9387)	5	.9245 (.8977,.9471)	16	.9350 (.9306,.9449)					
23	.8269 (.7173,.9291)	38	.8992 (.8378,.9388)	5	.9253 (.9003,.9469)	17	.9360 (.9318,.9452)					
25	.8317 (.7296,.9294)	42	.9005 (.8422,.9388)	5	.9261 (.9028,.9467)	18	.9370 (.9330,.9455)					
27	.8363 (.7415,.9298)	45	.9019 (.8464,.9389)	6	.9269 (.9053,.9465)	18	.9381 (.9341,.9461)					
30	.8409 (.7529,.9301)	49	.9032 (.8506,.9390)	6	.9274 (.9070,.9464)	19	.9391 (.9353,.9471)					
32	.8454 (.7640,.9305)	53	.9045 (.8547,.9391)	6	.9277 (.9078,.9463)	20	.9401 (.9365,.9480)					
35	.8497 (.7746,.9309)	57	.9059 (.8587,.9392)	7	.9285 (.9103,.9461)	21	.9411 (.9376,.9490)					
37	.8540 (.7849,.9313)	62	.9072 (.8626,.9394)	7	.9294 (.9127,.9460)	22	.9420 (.9387,.9498)					
40	.8582 (.7947,.9316)	67	.9085 (.8665,.9395)	7	.9303 (.9151,.9459)	22	.9421 (.9388,.9499)					
44	.8623 (.8042,.9321)	72	.9099 (.8702,.9396)	8	.9308 (.9166,.9458)	23	.9432 (.9399,.9508)					
47	.8664 (.8133,.9325)	78	.9112 (.8739,.9398)	8	.9312 (.9175,.9458)	24	.9442 (.9411,.9518)					
51	.8703 (.8221,.9329)	78	.9112 (.8739,.9398)	9	.9321 (.9198,.9457)	25	.9452 (.9422,.9527)					
56	.8742 (.8305,.9333)	84	.9125 (.8775,.9399)	9	.9330 (.9221,.9457)	26	.9462 (.9434,.9536)					
60	.8779 (.8385,.9338)	91	.9138 (.8810,.9401)	10	.9340 (.9244,.9456)	27	.9472 (.9445,.9546)					
64	.8808 (.8445,.9341)	99	.9151 (.8845,.9403)	10	.9340 (.9245,.9456)	28	.9475 (.9448,.9549)					
65	.8816 (.8463,.9343)	107	.9164 (.8878,.9404)	10	.9350 (.9267,.9457)	28	.9482 (.9456,.9555)					
70	.8852 (.8537,.9347)	115	.9177 (.8911,.9406)	11	.9360 (.9289,.9458)	30	.9491 (.9467,.9564)					
76	.8888 (.8607,.9352)	125	.9190 (.8943,.9408)	12	.9370 (.9309,.9459)	31	.9501 (.9477,.9573)					
82	.8922 (.8669,.9357)	125	.9191 (.8945,.9409)	13	.9380 (.9330,.9462)	32	.9510 (.9487,.9581)					
84	.8933 (.8687,.9359)	135	.9203 (.8975,.9411)	13	.9391 (.9350,.9465)	34	.9518 (.9496,.9589)					
89	.8956 (.8728,.9362)	146	.9216 (.9006,.9413)	14	.9398 (.9363,.9467)	35	.9524 (.9500,.9595)					
96	.8989 (.8784,.9368)	158	.9229 (.9036,.9415)	14	.9402 (.9369,.9468)	35	.9526 (.9501,.9597)					
104	.9021 (.8839,.9373)	171	.9242 (.9065,.9418)	15	.9413 (.9389,.9477)	37	.9535 (.9506,.9605)					
113	.9053 (.8892,.9379)	185	.9254 (.9094,.9421)	16	.9424 (.9406,.9493)	38	.9542 (.9509,.9612)					
121	.9078 (.8934,.9383)	188	.9257 (.9099,.9421)	17	.9436 (.9412,.9509)	40	.9550 (.9512,.9619)					
122	.9084 (.8942,.9384)	200	.9267 (.9122,.9424)	19	.9448 (.9419,.9525)	42	.9557 (.9514,.9626)					
132	.9114 (.8991,.9390)	216	.9280 (.9150,.9427)	19	.9448 (.9419,.9526)	43	.9562 (.9516,.9630)					
143	.9143 (.9038,.9396)	234	.9292 (.9176,.9430)	20	.9460 (.9426,.9541)	44	.9564 (.9516,.9633)					

155	.9172 (.9083,.9402)	253	.9305 (.9203,.9434)	21	.9472 (.9433,.9558)	45	.9571 (.9518,.9639)
168	.9200 (.9126,.9408)	274	.9318 (.9228,.9438)	23	.9484 (.9439,.9573)	47	.9578 (.9520,.9645)
181	.9228 (.9168,.9415)	296	.9330 (.9253,.9442)	24	.9496 (.9444,.9589)	50	.9584 (.9522,.9652)
196	.9255 (.9208,.9421)	320	.9343 (.9278,.9446)	24	.9496 (.9444,.9589)	52	.9591 (.9524,.9658)
212	.9281 (.9244,.9428)	347	.9355 (.9301,.9450)	26	.9506 (.9449,.9604)	54	.9597 (.9526,.9664)
224	.9298 (.9269,.9433)	375	.9368 (.9323,.9454)	27	.9516 (.9453,.9617)	56	.9603 (.9527,.9670)
230	.9307 (.9280,.9435)	376	.9368 (.9324,.9454)	29	.9526 (.9457,.9630)	59	.9609 (.9529,.9676)
249	.9332 (.9314,.9442)	406	.9380 (.9345,.9459)	30	.9530 (.9458,.9637)	61	.9614 (.9530,.9681)
269	.9356 (.9347,.9449)	439	.9393 (.9366,.9463)	31	.9534 (.9460,.9643)	63	.9617 (.9531,.9683)
291	.9380 (.9372,.9457)	474	.9405 (.9386,.9468)	33	.9543 (.9463,.9654)	64	.9620 (.9532,.9686)
315	.9403 (.9394,.9477)	500	.9413 (.9400,.9471)	36	.9551 (.9465,.9665)	67	.9625 (.9533,.9692)
333	.9419 (.9409,.9496)	513	.9417 (.9406,.9473)	38	.9558 (.9467,.9676)	70	.9630 (.9534,.9697)
341	.9426 (.9416,.9504)	555	.9430 (.9413,.9485)	41	.9565 (.9469,.9686)	73	.9635 (.9535,.9702)
369	.9448 (.9437,.9531)	601	.9442 (.9420,.9500)	43	.9572 (.9470,.9695)	74	.9637 (.9535,.9703)
399	.9470 (.9457,.9557)	603	.9442 (.9420,.9501)	45	.9576 (.9471,.9702)	76	.9640 (.9536,.9707)
432	.9491 (.9475,.9583)	650	.9454 (.9427,.9515)	46	.9578 (.9472,.9704)	79	.9645 (.9537,.9711)
468	.9511 (.9492,.9607)	703	.9466 (.9435,.9529)	49	.9584 (.9472,.9713)	83	.9650 (.9538,.9716)
475	.9514 (.9495,.9611)	760	.9478 (.9441,.9544)	53	.9590 (.9473,.9721)	87	.9655 (.9539,.9720)
500	.9526 (.9506,.9626)	822	.9490 (.9447,.9559)	55	.9594 (.9473,.9727)	90	.9659 (.9539,.9725)
506	.9529 (.9508,.9629)	889	.9502 (.9453,.9573)	56	.9596 (.9473,.9729)	90	.9659 (.9539,.9725)
548	.9547 (.9517,.9650)	912	.9505 (.9454,.9577)	60	.9601 (.9473,.9737)	94	.9663 (.9540,.9729)
593	.9564 (.9524,.9669)	962	.9513 (.9458,.9587)	64	.9606 (.9473,.9744)	98	.9668 (.9540,.9733)
641	.9580 (.9531,.9688)	1000	.9518 (.9461,.9593)	68	.9611 (.9473,.9751)	103	.9672 (.9541,.9737)
693	.9595 (.9537,.9705)	1041	.9523 (.9463,.9600)	71	.9614 (.9473,.9755)	107	.9676 (.9541,.9741)
694	.9595 (.9537,.9705)	1126	.9533 (.9468,.9612)	73	.9615 (.9473,.9758)	112	.9680 (.9542,.9745)
751	.9610 (.9542,.9721)	1218	.9543 (.9473,.9624)	78	.9620 (.9472,.9764)	117	.9684 (.9542,.9749)
813	.9623 (.9548,.9736)	1317	.9552 (.9477,.9636)	83	.9624 (.9471,.9770)	122	.9688 (.9542,.9753)
879	.9637 (.9553,.9750)	1395	.9559 (.9480,.9644)	89	.9628 (.9470,.9776)	127	.9692 (.9543,.9756)
952	.9649 (.9557,.9764)	1425	.9561 (.9481,.9647)	94	.9632 (.9469,.9782)	133	.9695 (.9543,.9760)
1000	.9657 (.9560,.9772)	1541	.9570 (.9485,.9657)	101	.9636 (.9467,.9787)	139	.9699 (.9543,.9763)
1030	.9661 (.9562,.9776)	1667	.9578 (.9489,.9667)	108	.9639 (.9465,.9792)	145	.9702 (.9543,.9767)
1114	.9673 (.9567,.9788)	1804	.9586 (.9493,.9677)	115	.9643 (.9464,.9797)	151	.9706 (.9543,.9770)
1206	.9684 (.9571,.9799)	1951	.9594 (.9496,.9686)	123	.9646 (.9462,.9802)	158	.9709 (.9543,.9773)
1294	.9693 (.9574,.9809)	2111	.9602 (.9499,.9695)	131	.9649 (.9460,.9807)	165	.9713 (.9543,.9776)
1305	.9694 (.9575,.9810)	2283	.9609 (.9503,.9704)	140	.9652 (.9458,.9812)	172	.9716 (.9543,.9780)
1412	.9704 (.9579,.9820)	2470	.9616 (.9505,.9712)	149	.9655 (.9455,.9816)	179	.9719 (.9543,.9783)
1528	.9714 (.9582,.9829)	2671	.9623 (.9508,.9720)	159	.9658 (.9453,.9820)	187	.9722 (.9543,.9786)
1653	.9723 (.9586,.9838)	2890	.9629 (.9511,.9729)	170	.9661 (.9450,.9824)	195	.9725 (.9542,.9789)
1785	.9732 (.9589,.9846)	2891	.9629 (.9511,.9729)	181	.9663 (.9447,.9828)	204	.9728 (.9542,.9791)
1789	.9732 (.9589,.9846)	3126	.9636 (.9513,.9737)	193	.9666 (.9444,.9832)	213	.9731 (.9542,.9794)
1936	.9741 (.9593,.9854)	3381	.9642 (.9516,.9745)	206	.9668 (.9441,.9836)	222	.9734 (.9541,.9797)
2095	.9749 (.9596,.9861)	3658	.9648 (.9518,.9753)	220	.9671 (.9438,.9840)	232	.9737 (.9541,.9800)
2228	.9755 (.9598,.9867)	3957	.9654 (.9520,.9761)	235	.9673 (.9435,.9843)	242	.9740 (.9540,.9802)
2267	.9757 (.9599,.9868)	4073	.9656 (.9521,.9764)	251	.9675 (.9431,.9847)	253	.9743 (.9540,.9805)
2453	.9765 (.9602,.9875)	4280	.9659 (.9522,.9768)	267	.9677 (.9428,.9850)	264	.9745 (.9539,.9808)
2655	.9772 (.9604,.9881)	4630	.9665 (.9524,.9775)	285	.9680 (.9424,.9853)	275	.9748 (.9539,.9810)
2873	.9779 (.9607,.9887)	5008	.9670 (.9526,.9782)	305	.9682 (.9421,.9856)	288	.9751 (.9538,.9813)
3109	.9786 (.9609,.9893)	5417	.9675 (.9528,.9789)	325	.9684 (.9417,.9859)	300	.9753 (.9538,.9815)
3364	.9792 (.9612,.9898)	5444	.9676 (.9528,.9789)	347	.9686 (.9413,.9862)	313	.9756 (.9537,.9817)
3640	.9798 (.9614,.9903)	5860	.9680 (.9529,.9795)	370	.9687 (.9409,.9865)	327	.9758 (.9536,.9820)
3939	.9804 (.9616,.9908)	6339	.9685 (.9531,.9801)	395	.9689 (.9403,.9868)	341	.9761 (.9536,.9822)
4263	.9810 (.9619,.9912)	6857	.9690 (.9532,.9807)	422	.9691 (.9398,.9871)	356	.9763 (.9535,.9824)
4613	.9816 (.9621,.9916)	7417	.9695 (.9534,.9812)	450	.9693 (.9392,.9873)	372	.9765 (.9534,.9826)
4992	.9821 (.9623,.9920)	8023	.9699 (.9535,.9818)	480	.9694 (.9386,.9876)	388	.9768 (.9533,.9829)

5401	.9827 (.9625,.9924)	8679	.9704 (.9536,.9823)	500	.9695 (.9383,.9877)	405	.9770 (.9532,.9831)
5845	.9832 (.9626,.9928)	9388	.9708 (.9537,.9828)	512	.9696 (.9380,.9878)	423	.9772 (.9532,.9833)
6325	.9836 (.9628,.9931)	10155	.9712 (.9538,.9833)	547	.9697 (.9374,.9881)	441	.9774 (.9531,.9835)
6844	.9841 (.9630,.9935)	10985	.9716 (.9539,.9838)	584	.9699 (.9368,.9883)	461	.9777 (.9530,.9837)
7407	.9846 (.9632,.9938)	11883	.9720 (.9540,.9843)	623	.9700 (.9362,.9886)	481	.9779 (.9529,.9839)
8015	.9850 (.9633,.9941)	12854	.9724 (.9541,.9847)	665	.9702 (.9355,.9888)	500	.9781 (.9528,.9841)
8673	.9854 (.9635,.9943)	13904	.9728 (.9542,.9851)	709	.9703 (.9349,.9890)	502	.9781 (.9528,.9841)
9385	.9859 (.9636,.9946)	15040	.9732 (.9542,.9856)	757	.9705 (.9342,.9892)	524	.9783 (.9527,.9843)
10156	.9862 (.9638,.9949)	16269	.9736 (.9543,.9860)	1000	.9710 (.9311,.9901)	1000	.9811 (.9508,.9868)
9	.6434 (.3015,.8887)		(,)		(,)		(,)
113	.8990 (.8818,.9337)	84	.8999 (.8599,.9313)	4	.9001 (.8562,.9341)	8	.9065 (.8965,.9351)
432	.9491 (.9475,.9583)	889	.9502 (.9453,.9573)	24	.9497 (.9445,.9590)	31	.9501 (.9478,.9573)

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4.3 Misc

Average follow-up of vaccine recipients (in the Day 29 correlates analyses population) starting at 7 days post Day 29 visit is 193 days.

Table 4.7: Summary statistics for the number of days from dose 1 to Day 29 visit. (a) The whole immunogenicity subcohort, (b) non-cases in the immunogenicity subcohort, (c) intercurrent cases, (d) primary cases, i.e. cases from the Day 57 correlates analysis population.

	min	1st quartile	median	3d quartile	max
(a)	26	27	29	31	32
(b)	26	28	29	31	32
(c)	26	28	30	30	32
(d)	26	28	29	31	32

Chapter 5

Day 57 Univariate CoR: Cox Models of Risk

The main regression model is the Cox proportional hazards model. All plots are made with Cox models fit unless specified otherwise.

5.1 Hazard ratios

Table 5.1: Inference for Day 57 antibody marker covariate-adjusted correlates of risk of COVID in the vaccine group: Hazard ratios per 10-fold increment in the marker*

MockCOVE Immunologic Marker	No. cases / No. at-risk**	HR per 10-fold incr. Pt. Est.	P-value 95% CI (2-sided)	q-value ***	FWER
Anti Spike IgG (IU/ml)	52/11,117	0.20	(0.11-0.35)	<0.001	<0.001 <0.001
Anti RBD IgG (IU/ml)	52/11,117	0.43	(0.25-0.75)	0.003	<0.001 <0.001
Pseudovirus-nAb cID50	52/11,117	0.32	(0.17-0.60)	<0.001	<0.001 <0.001
Pseudovirus-nAb cID80	52/11,117	0.35	(0.19-0.64)	<0.001	<0.001 <0.001

*Baseline covariates adjusted for: baseline risk score, meeting the protocol randomization stratification criterion for being at heightened risk of COVID (yes or no), community of color or not. Maximum failure event time 164 days.

**No. at-risk = estimated number in the population for analysis: baseline negative per-protocol vaccine recipients not experiencing the COVID endpoint through 6 days post Day 57 visit; no. cases = number of this cohort with an observed COVID endpoint.

***q-value and FWER (family-wide error rate) are computed over the set of p-values both for quantitative markers and categorical markers using the Westfall and Young permutation method (5 replicates).

Table 5.2: Inference for Day 57 antibody marker covariate-adjusted correlates of risk of COVID in the vaccine group: Hazard ratios for Middle vs. Upper tertile vs. Lower tertile*

MockCOVE Immunologic Marker	Tertile	No. cases / No. at-risk**	Attack rate	Pt. Est.	Haz. Ratio 95% CI	P-value (2-sided)	Overall P- value***	Overall q- value †	Overall FWER
Anti Spike IgG (IU/ml)	Lower	27/4,235	0.0064	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	18/4,243	0.0042	0.30	(0.15-0.58)	<0.001			
	Upper	7/2,638	0.0027	0.08	(0.03-0.21)	<0.001			
Anti RBD IgG (IU/ml)	Lower	24/4,242	0.0057	1	N/A	N/A	0.003	<0.001	<0.001
	Middle	14/4,209	0.0033	0.33	(0.15-0.71)	0.005			
	Upper	14/2,666	0.0053	0.29	(0.13-0.64)	0.002			
Pseudovirus-nAb cID50	Lower	18/3,697	0.0049	1	N/A	N/A	0.036	<0.001	<0.001
	Middle	20/3,701	0.0054	0.80	(0.39-1.64)	0.539			
	Upper	14/3,719	0.0038	0.37	(0.16-0.82)	0.015			
Pseudovirus-nAb cID80	Lower	22/3,724	0.0059	1	N/A	N/A	0.010	<0.001	<0.001
	Middle	20/3,707	0.0054	0.66	(0.34-1.27)	0.213			
	Upper	10/3,687	0.0027	0.29	(0.13-0.65)	0.002			
Placebo		953/11,217	0.0850						

*Baseline covariates adjusted for: baseline risk score, meeting the protocol randomization stratification criterion for being at heightened risk of COVID (yes or no), community of color or not. Maximum failure event time 164 days. Cutpoints: Anti Spike IgG (IU/ml) [3.34, 4.01], Anti RBD IgG (IU/ml) [3.48, 4.21], Pseudovirus-nAb cID50 [2.37, 2.86], Pseudovirus-nAb cID80 [2.58, 2.96], all on the log10 scale.

**No. at-risk = estimated number in the population for analysis: baseline negative per-protocol vaccine recipients not experiencing the COVID endpoint through 6 days post Day 57 visit; no. cases = number of this cohort with an observed COVID endpoint.

***Generalized Wald-test p-value of the null hypothesis that the hazard rate is constant across the Lower, Middle, and Upper tertile groups.

† q-value and FWER (family-wide error rate) are computed over the set of p-values both for quantitative markers and categorical markers using the Westfall and Young permutation method (5 replicates).

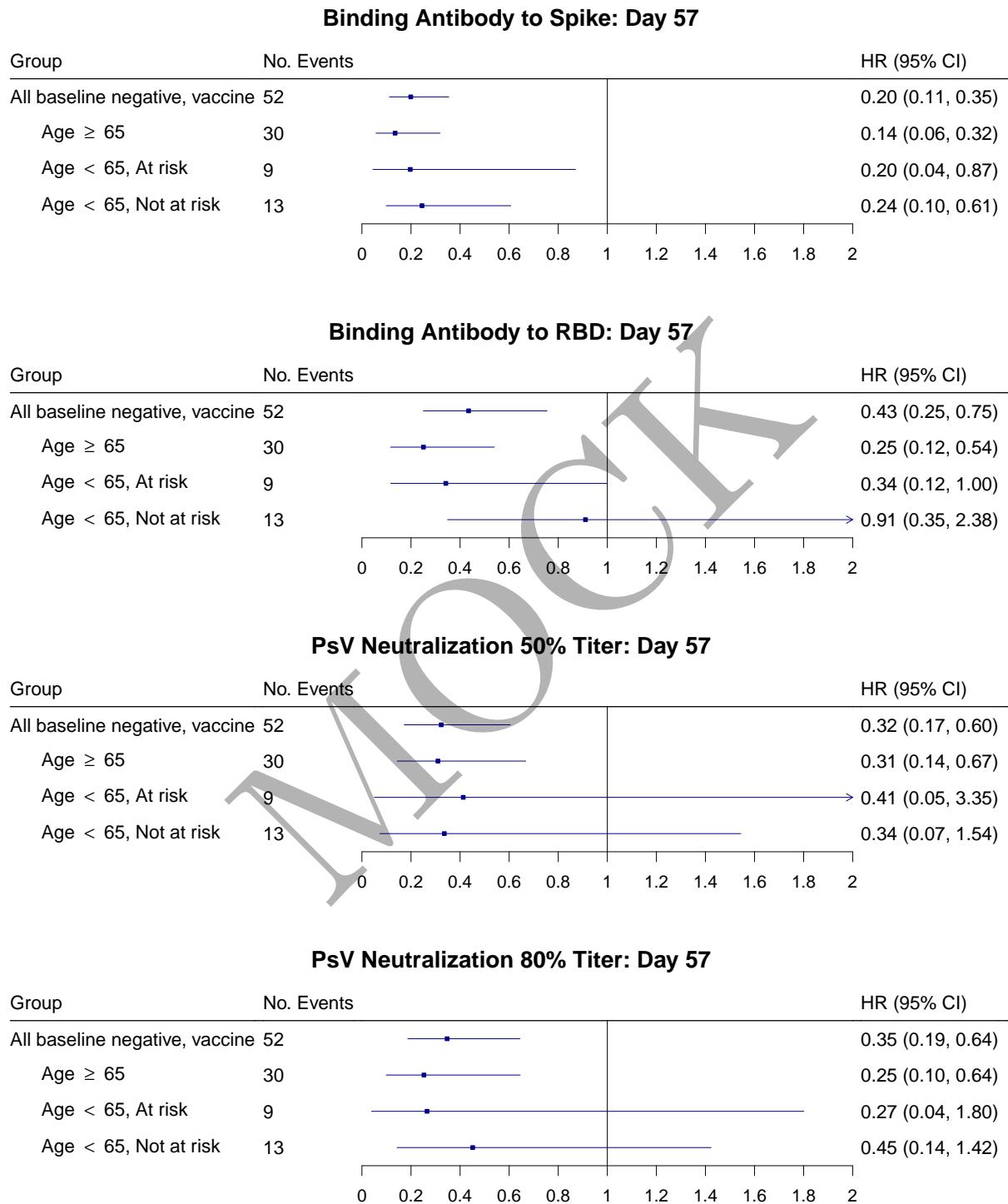


Figure 5.1: Forest plots of hazard ratios per 10-fold increase in the marker among baseline negative vaccine recipients and subgroups with 95% point-wise confidence intervals.

Binding Antibody to Spike: Day 57

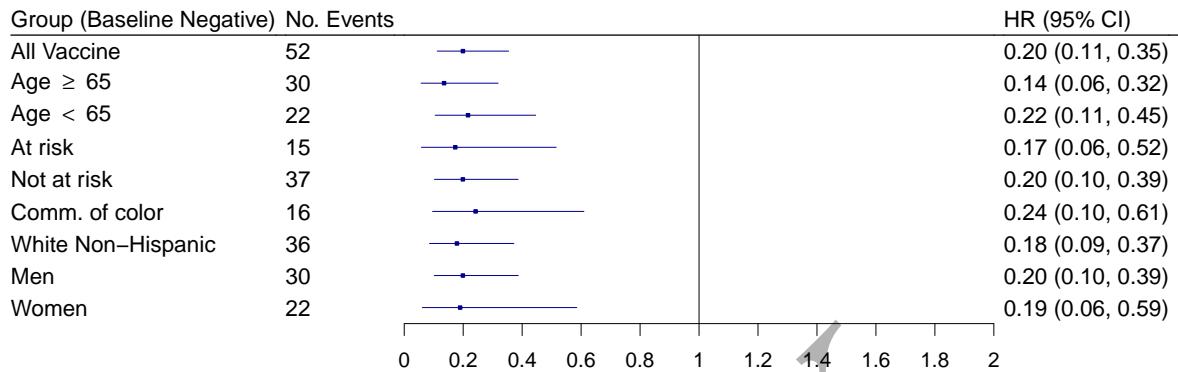


Figure 5.2: Forest plots of hazard ratios per 10-fold increase in the Day 57 binding Ab to spike markers among baseline negative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

Binding Antibody to RBD: Day 57

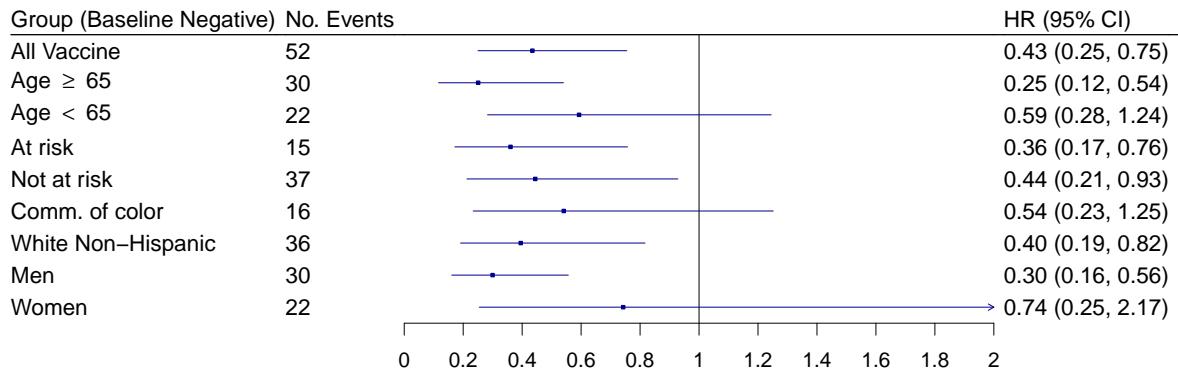


Figure 5.3: Forest plots of hazard ratios per 10-fold increase in the Day 57 binding Ab to RBD markers among baseline negative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

PsV Neutralization 50% Titer: Day 57

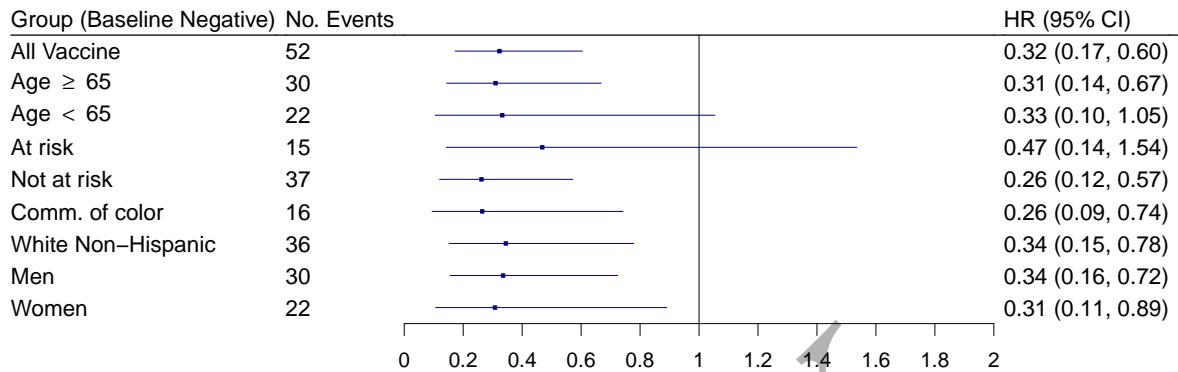


Figure 5.4: Forest plots of hazard ratios per 10-fold increase in the Day 57 pseudo neut ID50 markers among baseline negative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

PsV Neutralization 80% Titer: Day 57

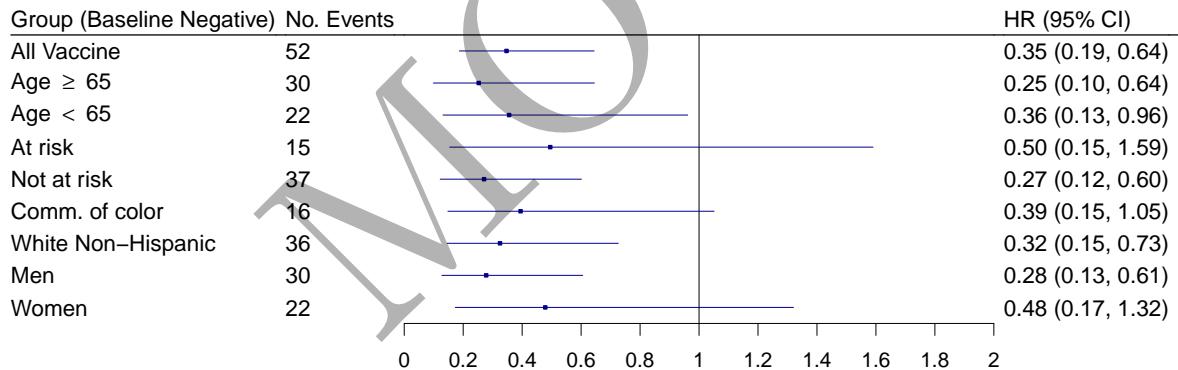


Figure 5.5: Forest plots of hazard ratios per 10-fold increase in the Day 57 pseudo neut ID80 markers among baseline negative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

5.2 Marginalized risk and controlled vaccine efficacy plots

MOCK

Table 5.3: Analysis of Day 57 markers (upper vs. lower tertile) as a CoR and a controlled risk CoP.

	marginalized risk			controlled risk		
	ratio $RR_M(0, 1)$	Point Est.	95% CI	ratio $RR_C(0, 1)^1$	Point Est.	95% CI
Anti Spike IgG (IU/ml)	0.08	0.05–0.14	0.11	0.07–0.18	23.2	14.2
Anti RBD IgG (IU/ml)	0.29	0.27–0.37	0.39	0.36–0.49	6.3	4.8
Pseudovirus-nAb cID50	0.37	0.25–0.48	0.49	0.34–0.64	4.9	3.6
Pseudovirus-nAb cID80	0.30	0.13–0.65	0.39	0.18–0.87	6.2	2.4

¹Conservative (upper bound) estimate assuming unmeasured confounding at level $RR_{UD}(0, 1) = RR_{EU}(0, 1) = 2$ and thus $B(0, 1) = 4/3$.

²E-values are computed for upper tertile ($s = 1$) vs. lower tertile ($s = 0$) biomarker subgroups after controlling for baseline risk score, meeting the protocol randomization stratification criterion for being at heightened risk of COVID (yes or no), community of color or not; UL = upper limit.

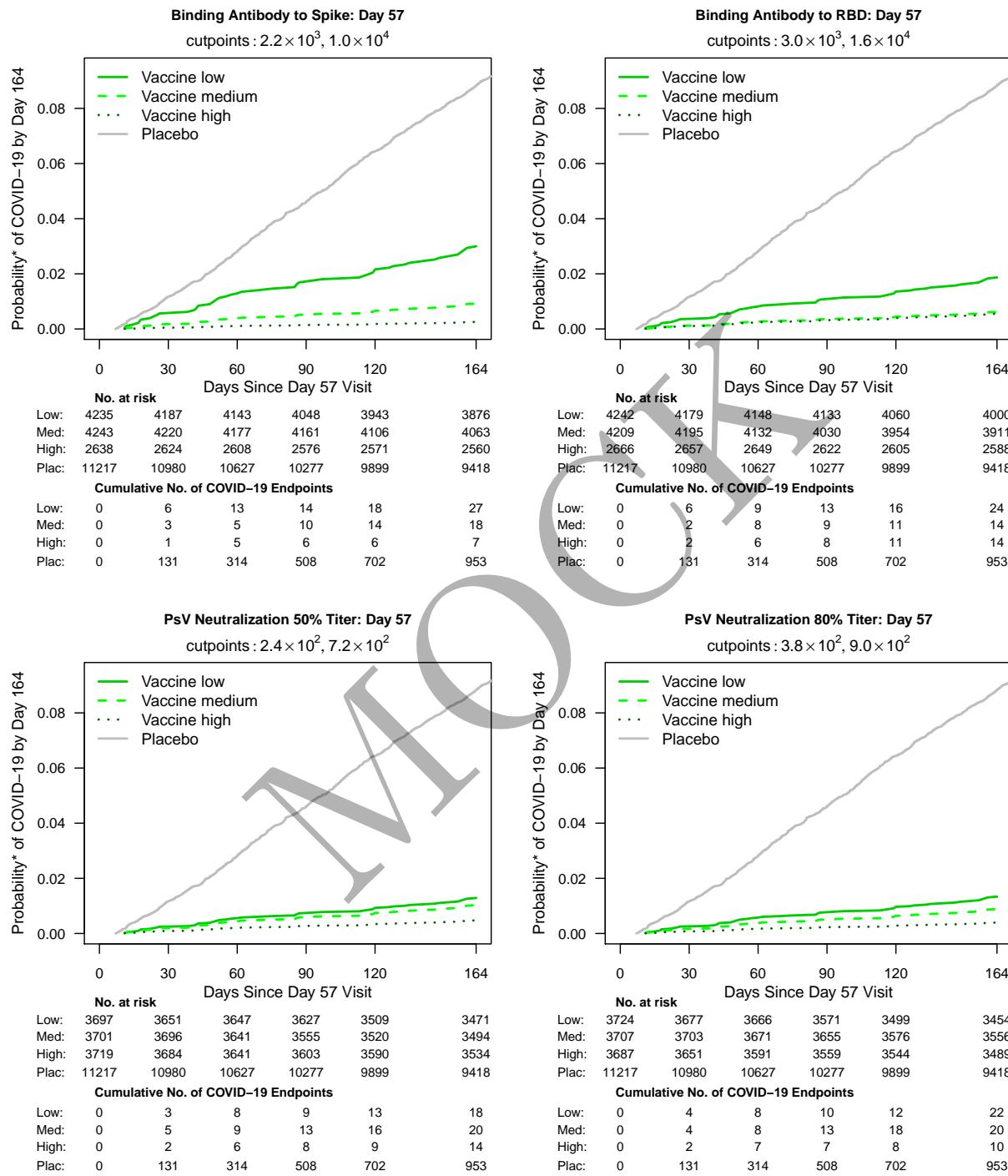


Figure 5.6: Marginalized cumulative incidence rate curves for trichotomized Day 57 markers among baseline negative vaccine recipients. The gray line is the overall cumulative incidence rate curve in the placebo arm.

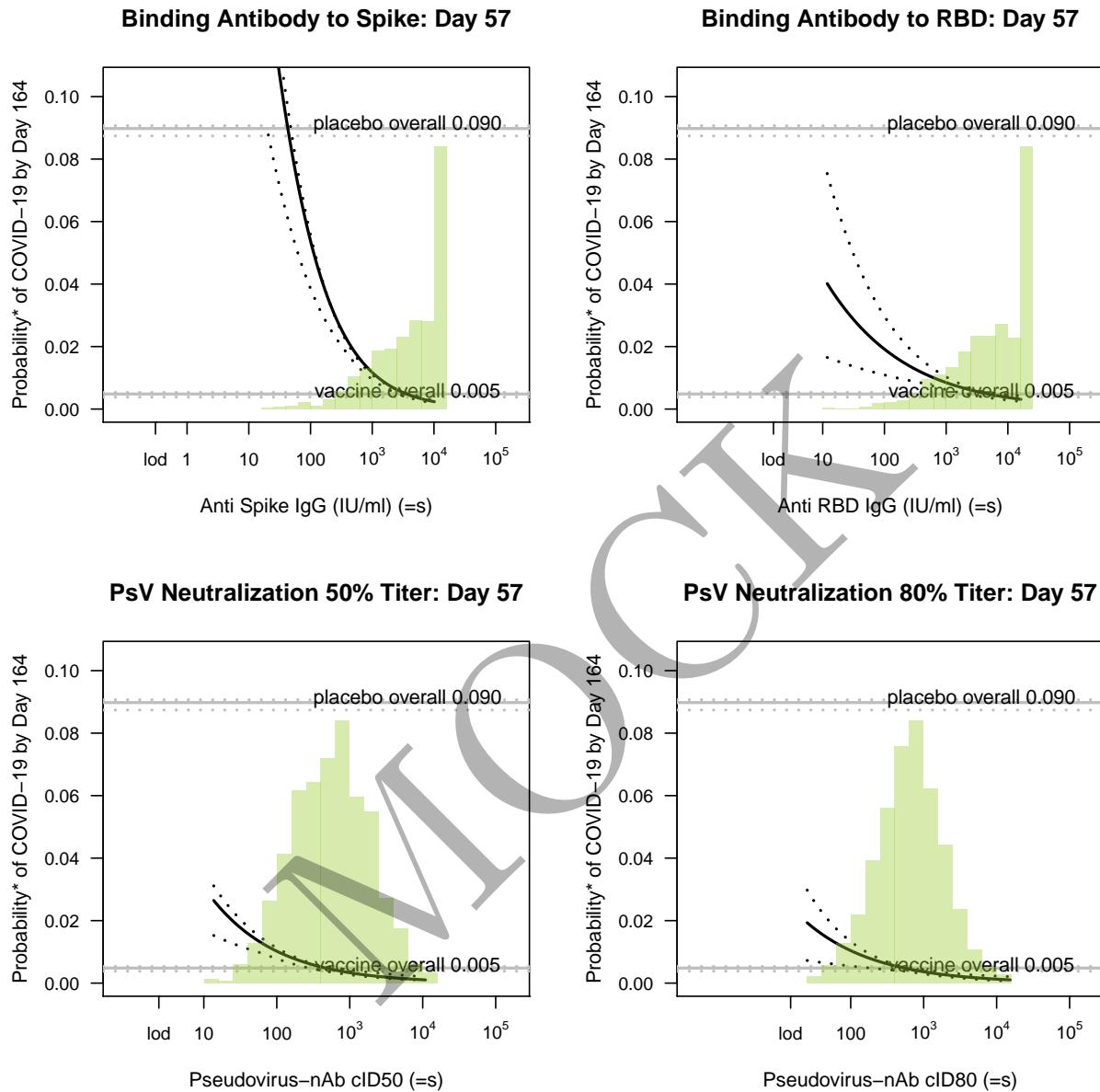


Figure 5.7: Marginalized cumulative risk by Day 164 as functions of Day 57 markers (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence bands (5 replicates). The horizontal lines indicate the overall cumulative risk of the placebo and vaccine arms by Day 164 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod = 0.3, 1.6, 2.4, 15 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively.

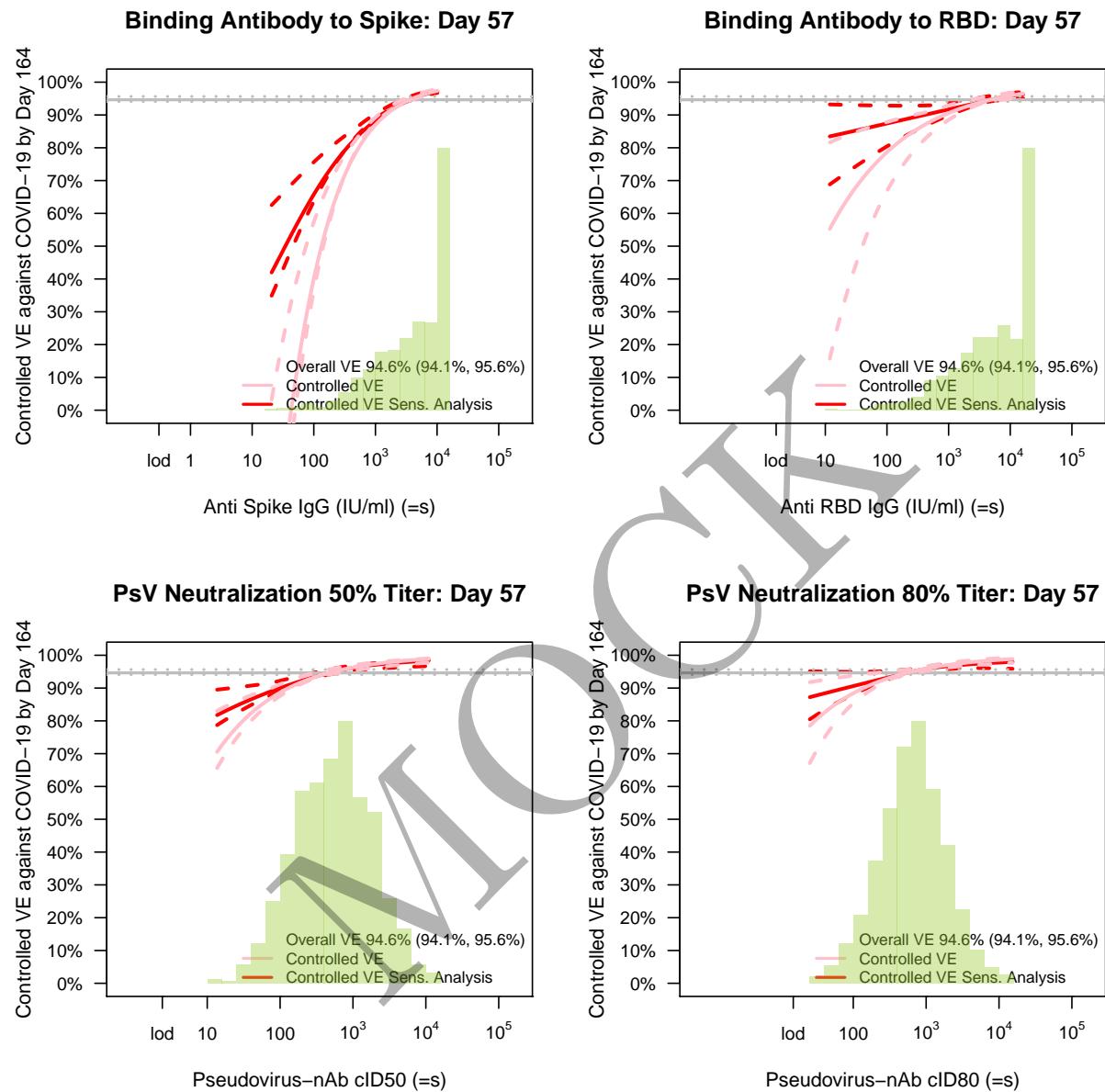


Figure 5.8: Controlled VE with sensitivity analysis as functions of Day 57 markers (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence bands (5 replicates). Histograms of the immunological markers in the vaccine arm are overlaid. lod = 0.3, 1.6, 2.4, 15 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively.

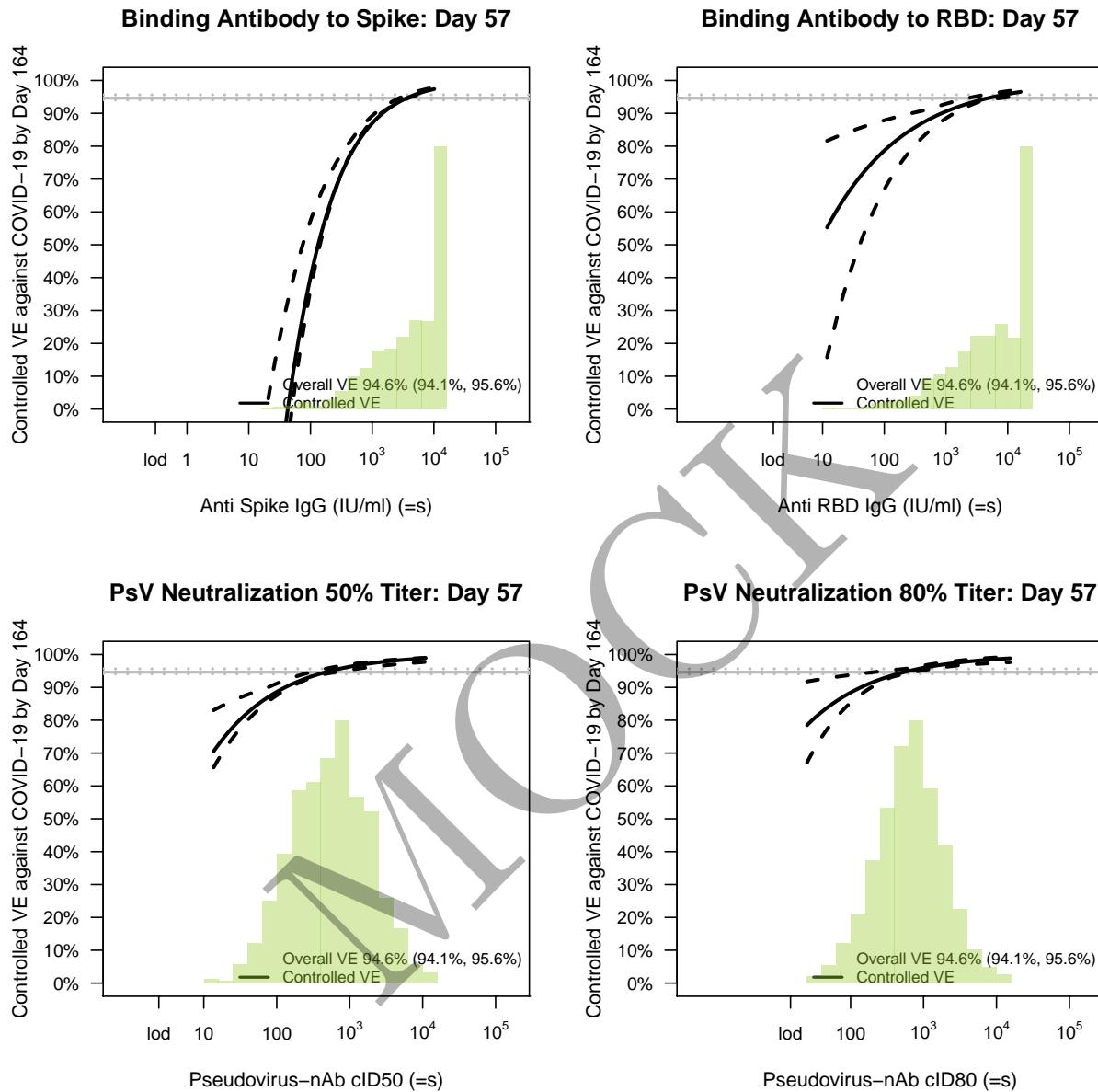


Figure 5.9: Controlled VE with sensitivity analysis as functions of Day 57 markers (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence bands (5 replicates). Histograms of the immunological markers in the vaccine arm are overlaid. lod = 0.3, 1.6, 2.4, 15 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively.

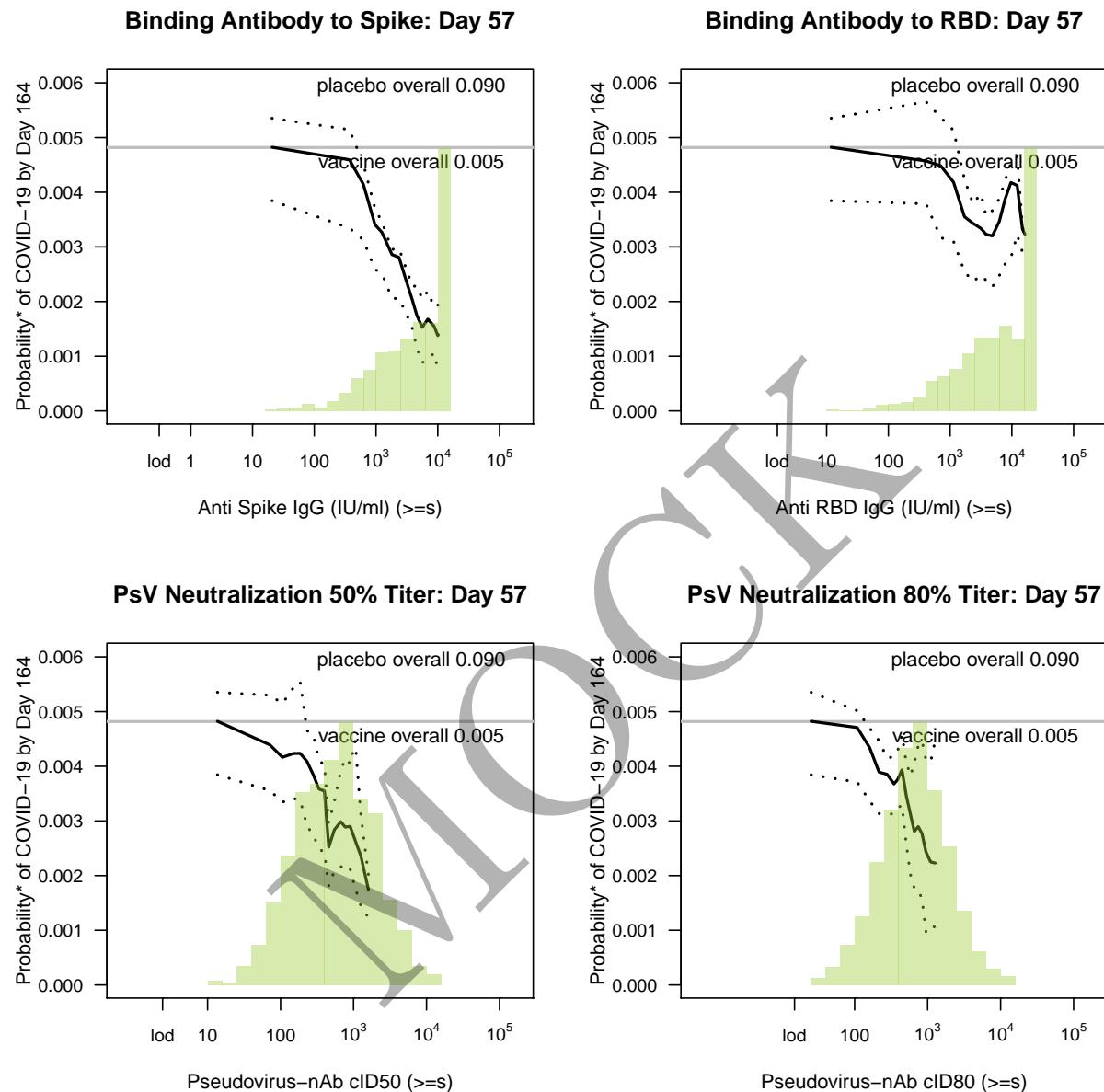


Figure 5.10: Marginalized cumulative risk by Day 164 as functions of Day 57 markers above a threshold ($\geq s$) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence bands (at least 5 cases are required, 5 replicates). The horizontal lines indicate the overall cumulative risk of the vaccine arm by Day 164 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. $l_{od} = 0.3, 1.6, 2.4, 15$ for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively.

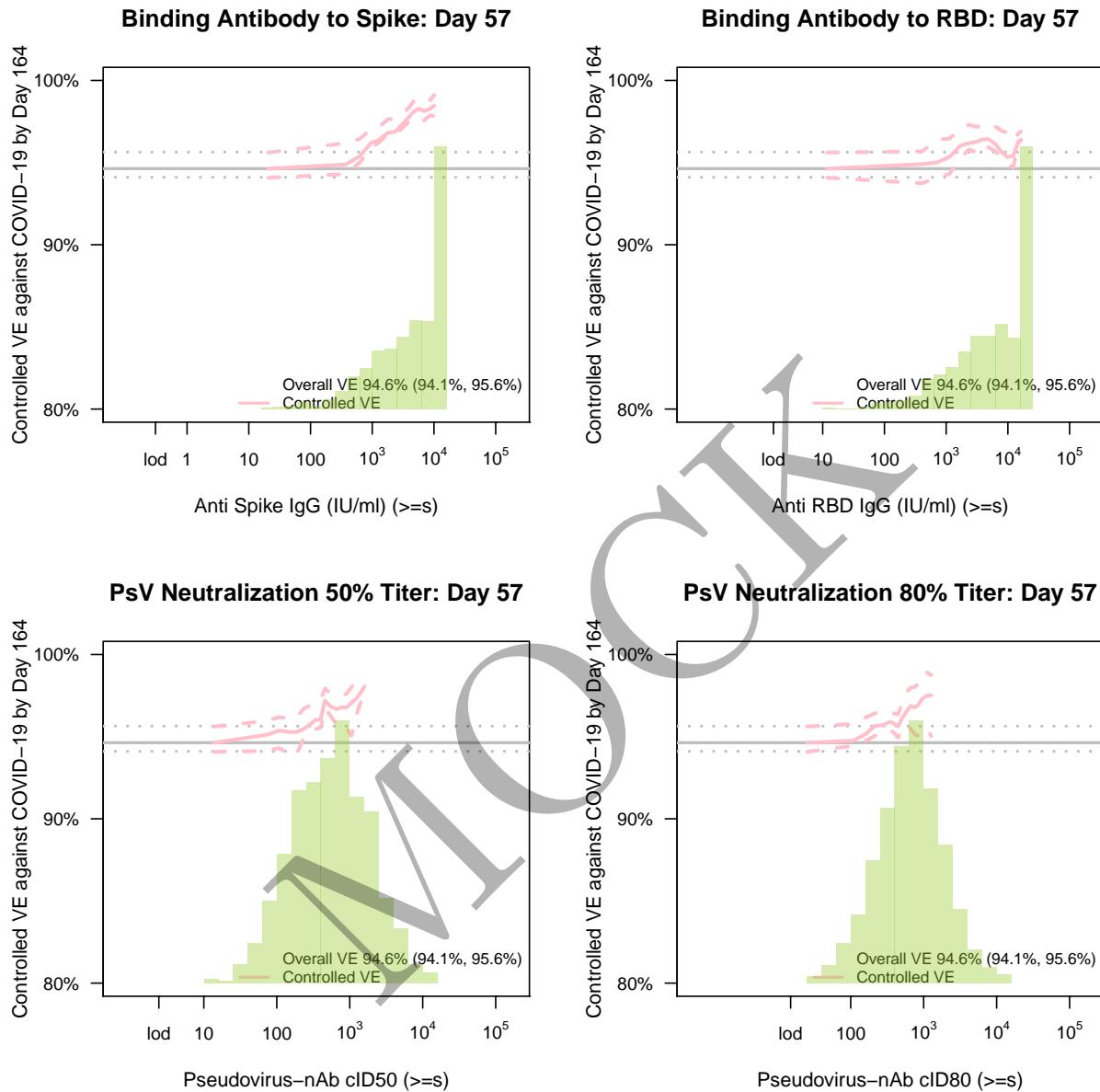


Figure 5.11: Controlled VE as functions of Day 57 markers ($\geq s$) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence bands (5 replicates). Histograms of the immunological markers in the vaccine arm are overlaid. lod = 0.3, 1.6, 2.4, 15 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively.

Table 5.4: Marginalized cumulative risk by Day 164 as functions of Day 57 markers (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence intervals (5 replicates).

	Anti Spike IgG (IU/ml)	Anti RBD IgG (IU/ml)	Pseudovirus-nAb cID50	Pseudovirus-nAb cID80	
s	Estimate	s	Estimate	s	Estimate
20.7	.1345 (.0877,.1469)	11.8	.0402 (.0165,.0754)	13.7	.0264 (.0152,.0311)
22	.1301 (.0851,.1419)	13	.0392 (.0163,.0731)	15	.0256 (.0149,.0301)
23	.1258 (.0826,.1371)	14	.0382 (.0160,.0709)	16	.0248 (.0146,.0291)
25	.1217 (.0801,.1324)	15	.0373 (.0158,.0688)	17	.0240 (.0143,.0281)
27	.1176 (.0776,.1278)	16	.0363 (.0156,.0667)	18	.0233 (.0140,.0272)
28	.1136 (.0752,.1233)	17	.0354 (.0154,.0646)	19	.0225 (.0137,.0263)
30	.1098 (.0729,.1189)	18	.0346 (.0152,.0627)	20	.0218 (.0135,.0254)
32	.1060 (.0706,.1146)	20	.0337 (.0149,.0607)	22	.0211 (.0132,.0246)
34	.1023 (.0684,.1104)	21	.0329 (.0147,.0589)	23	.0205 (.0129,.0237)
36	.0988 (.0663,.1064)	23	.0321 (.0145,.0571)	25	.0198 (.0127,.0229)
39	.0953 (.0642,.1024)	25	.0313 (.0143,.0553)	27	.0192 (.0124,.0222)
41	.0919 (.0622,.0986)	26	.0305 (.0141,.0536)	29	.0186 (.0121,.0214)
44	.0887 (.0602,.0949)	28	.0297 (.0139,.0519)	31	.0180 (.0119,.0207)
47	.0855 (.0583,.0913)	31	.0290 (.0137,.0503)	33	.0174 (.0117,.0200)
50	.0824 (.0564,.0878)	33	.0283 (.0135,.0487)	35	.0169 (.0114,.0193)
53	.0794 (.0545,.0844)	35	.0276 (.0133,.0472)	38	.0163 (.0112,.0187)
56	.0765 (.0527,.0812)	38	.0269 (.0132,.0457)	40	.0158 (.0110,.0180)
60	.0737 (.0510,.0780)	41	.0262 (.0130,.0442)	43	.0153 (.0107,.0174)
64	.0710 (.0493,.0749)	44	.0255 (.0128,.0428)	46	.0148 (.0105,.0168)
68	.0683 (.0476,.0719)	47	.0249 (.0126,.0415)	49	.0144 (.0103,.0162)
72	.0658 (.0460,.0691)	51	.0243 (.0124,.0402)	53	.0139 (.0101,.0157)
77	.0633 (.0445,.0663)	55	.0237 (.0123,.0389)	56	.0135 (.0099,.0152)
82	.0609 (.0430,.0636)	59	.0231 (.0121,.0376)	60	.0130 (.0097,.0146)
87	.0586 (.0416,.0610)	63	.0225 (.0119,.0364)	65	.0126 (.0095,.0141)
93	.0563 (.0402,.0585)	68	.0219 (.0118,.0353)	69	.0122 (.0092,.0136)
99	.0542 (.0388,.0561)	73	.0214 (.0116,.0341)	74	.0118 (.0089,.0132)
105	.0521 (.0375,.0538)	79	.0208 (.0114,.0330)	79	.0114 (.0086,.0127)
112	.0501 (.0362,.0516)	85	.0203 (.0113,.0320)	85	.0111 (.0084,.0123)
119	.0481 (.0350,.0494)	91	.0198 (.0111,.0309)	90	.0107 (.0081,.0119)
127	.0462 (.0338,.0473)	98	.0193 (.0110,.0299)	97	.0104 (.0079,.0115)
135	.0444 (.0326,.0454)	106	.0188 (.0108,.0290)	104	.0100 (.0077,.0111)
144	.0427 (.0315,.0434)	114	.0183 (.0107,.0280)	111	.0097 (.0074,.0107)
153	.0410 (.0305,.0416)	122	.0179 (.0105,.0271)	113	.0096 (.0074,.0105)
163	.0394 (.0294,.0398)	131	.0174 (.0104,.0262)	118	.0094 (.0072,.0103)
174	.0378 (.0284,.0381)	141	.0170 (.0102,.0254)	127	.0091 (.0070,.0099)
185	.0363 (.0274,.0365)	152	.0165 (.0101,.0245)	136	.0088 (.0068,.0096)
197	.0349 (.0265,.0349)	164	.0161 (.0099,.0237)	145	.0085 (.0066,.0093)
210	.0335 (.0256,.0334)	176	.0157 (.0098,.0230)	150	.0084 (.0064,.0091)
223	.0321 (.0247,.0319)	189	.0153 (.0097,.0222)	155	.0082 (.0063,.0089)
238	.0308 (.0238,.0305)	204	.0149 (.0095,.0215)	166	.0080 (.0062,.0086)
253	.0296 (.0230,.0292)	219	.0145 (.0094,.0208)	178	.0077 (.0060,.0083)
269	.0284 (.0222,.0279)	236	.0142 (.0093,.0201)	190	.0075 (.0058,.0080)
287	.0272 (.0214,.0267)	254	.0138 (.0091,.0194)	191	.0075 (.0058,.0080)
305	.0261 (.0207,.0255)	273	.0134 (.0090,.0188)	203	.0072 (.0056,.0078)
325	.0250 (.0200,.0244)	294	.0131 (.0089,.0182)	218	.0070 (.0054,.0075)
346	.0240 (.0193,.0233)	316	.0128 (.0088,.0176)	233	.0068 (.0053,.0072)
368	.0230 (.0185,.0223)	340	.0124 (.0086,.0170)	249	.0066 (.0051,.0070)
392	.0221 (.0178,.0213)	365	.0121 (.0085,.0164)	266	.0063 (.0049,.0067)
417	.0212 (.0170,.0204)	393	.0118 (.0084,.0159)	285	.0061 (.0048,.0065)

444	.0203 (.0163,.0194)	423	.0115 (.0083,.0153)	305	.0059 (.0046,.0063)	466	.0052 (.0040,.0057)
473	.0195 (.0157,.0186)	455	.0112 (.0081,.0148)	326	.0058 (.0045,.0061)	497	.0050 (.0039,.0055)
500	.0188 (.0151,.0178)	489	.0109 (.0079,.0143)	330	.0057 (.0045,.0060)	500	.0050 (.0039,.0055)
504	.0187 (.0150,.0177)	500	.0108 (.0079,.0142)	349	.0056 (.0043,.0059)	531	.0049 (.0039,.0054)
536	.0179 (.0144,.0170)	526	.0106 (.0077,.0139)	373	.0054 (.0042,.0057)	566	.0047 (.0038,.0053)
571	.0172 (.0138,.0162)	566	.0104 (.0075,.0134)	399	.0052 (.0041,.0056)	581	.0047 (.0038,.0052)
608	.0164 (.0133,.0155)	609	.0101 (.0074,.0130)	427	.0050 (.0040,.0055)	604	.0046 (.0037,.0051)
647	.0158 (.0127,.0148)	655	.0098 (.0072,.0125)	454	.0049 (.0038,.0054)	644	.0045 (.0036,.0050)
653	.0157 (.0126,.0147)	705	.0096 (.0070,.0121)	457	.0049 (.0038,.0054)	687	.0043 (.0035,.0049)
689	.0151 (.0122,.0141)	758	.0093 (.0068,.0117)	489	.0047 (.0037,.0053)	733	.0042 (.0034,.0048)
733	.0145 (.0117,.0135)	763	.0093 (.0068,.0117)	500	.0047 (.0037,.0052)	749	.0042 (.0034,.0048)
780	.0139 (.0112,.0129)	816	.0091 (.0067,.0113)	523	.0046 (.0036,.0052)	782	.0041 (.0033,.0047)
831	.0133 (.0107,.0123)	877	.0089 (.0065,.0109)	560	.0044 (.0035,.0050)	835	.0040 (.0032,.0046)
884	.0127 (.0103,.0118)	944	.0086 (.0063,.0106)	599	.0043 (.0034,.0049)	891	.0038 (.0031,.0045)
942	.0122 (.0099,.0114)	1000	.0085 (.0062,.0103)	641	.0041 (.0033,.0048)	950	.0037 (.0030,.0044)
960	.0120 (.0097,.0112)	1015	.0084 (.0062,.0102)	673	.0040 (.0032,.0048)	958	.0037 (.0030,.0044)
1000	.0117 (.0095,.0109)	1092	.0082 (.0060,.0099)	686	.0040 (.0032,.0047)	1000	.0036 (.0029,.0043)
1002	.0117 (.0095,.0109)	1139	.0081 (.0060,.0097)	733	.0039 (.0031,.0046)	1014	.0036 (.0029,.0043)
1067	.0112 (.0091,.0105)	1175	.0080 (.0059,.0095)	785	.0037 (.0030,.0045)	1081	.0035 (.0028,.0042)
1136	.0107 (.0087,.0101)	1264	.0078 (.0058,.0092)	839	.0036 (.0029,.0044)	1154	.0034 (.0027,.0041)
1209	.0103 (.0083,.0097)	1360	.0076 (.0056,.0089)	898	.0035 (.0028,.0044)	1231	.0033 (.0026,.0040)
1288	.0098 (.0080,.0093)	1463	.0074 (.0055,.0086)	909	.0035 (.0028,.0043)	1313	.0032 (.0026,.0039)
1297	.0098 (.0079,.0093)	1573	.0072 (.0053,.0083)	961	.0034 (.0027,.0043)	1401	.0031 (.0025,.0038)
1371	.0094 (.0076,.0090)	1693	.0070 (.0052,.0081)	1000	.0033 (.0027,.0042)	1452	.0031 (.0024,.0038)
1459	.0090 (.0073,.0086)	1817	.0068 (.0051,.0078)	1028	.0033 (.0026,.0042)	1495	.0030 (.0024,.0038)
1553	.0087 (.0070,.0083)	1821	.0068 (.0051,.0078)	1100	.0032 (.0025,.0041)	1595	.0029 (.0023,.0037)
1654	.0083 (.0067,.0080)	1959	.0067 (.0050,.0075)	1177	.0031 (.0025,.0040)	1701	.0029 (.0022,.0036)
1761	.0079 (.0064,.0077)	2107	.0065 (.0048,.0073)	1259	.0030 (.0024,.0039)	1815	.0028 (.0022,.0035)
1874	.0076 (.0061,.0074)	2267	.0063 (.0047,.0070)	1347	.0029 (.0023,.0038)	1840	.0028 (.0022,.0035)
1995	.0073 (.0059,.0071)	2438	.0062 (.0046,.0068)	1441	.0028 (.0022,.0038)	1936	.0027 (.0021,.0034)
2124	.0070 (.0056,.0068)	2623	.0060 (.0045,.0066)	1491	.0027 (.0022,.0037)	2066	.0026 (.0020,.0034)
2261	.0067 (.0054,.0066)	2821	.0058 (.0044,.0063)	1541	.0027 (.0022,.0037)	2204	.0025 (.0020,.0033)
2408	.0064 (.0051,.0064)	3035	.0057 (.0043,.0061)	1649	.0026 (.0021,.0036)	2349	.0025 (.0019,.0032)
2563	.0061 (.0049,.0061)	3265	.0055 (.0042,.0059)	1764	.0025 (.0020,.0035)	2352	.0025 (.0019,.0032)
2729	.0059 (.0047,.0059)	3512	.0054 (.0041,.0057)	1887	.0024 (.0020,.0035)	2509	.0024 (.0018,.0032)
2905	.0056 (.0045,.0057)	3607	.0054 (.0040,.0057)	2019	.0024 (.0019,.0034)	2677	.0023 (.0018,.0031)
2957	.0055 (.0045,.0056)	3778	.0053 (.0040,.0056)	2027	.0024 (.0019,.0034)	2856	.0023 (.0017,.0030)
3092	.0054 (.0043,.0055)	4064	.0051 (.0039,.0055)	2160	.0023 (.0018,.0033)	3047	.0022 (.0017,.0030)
3292	.0051 (.0041,.0053)	4372	.0050 (.0038,.0054)	2311	.0022 (.0018,.0033)	3250	.0021 (.0016,.0029)
3505	.0049 (.0040,.0051)	4703	.0049 (.0037,.0053)	2440	.0022 (.0017,.0032)	3468	.0021 (.0016,.0028)
3731	.0047 (.0038,.0049)	5059	.0047 (.0036,.0053)	2472	.0021 (.0017,.0032)	3699	.0020 (.0015,.0028)
3972	.0045 (.0036,.0048)	5443	.0046 (.0035,.0052)	2645	.0021 (.0017,.0031)	3947	.0019 (.0014,.0027)
4229	.0043 (.0035,.0046)	5855	.0045 (.0034,.0051)	2830	.0020 (.0016,.0031)	4211	.0019 (.0014,.0027)
4502	.0041 (.0033,.0044)	6262	.0044 (.0033,.0050)	3028	.0019 (.0016,.0030)	4492	.0018 (.0013,.0026)
4553	.0041 (.0033,.0044)	6298	.0044 (.0033,.0050)	3239	.0019 (.0015,.0029)	4793	.0018 (.0013,.0026)
4792	.0040 (.0032,.0043)	6775	.0043 (.0033,.0050)	3465	.0018 (.0015,.0029)	5113	.0017 (.0012,.0026)
5102	.0038 (.0030,.0041)	7288	.0042 (.0032,.0049)	3707	.0018 (.0014,.0028)	5455	.0017 (.0012,.0025)
5431	.0036 (.0029,.0040)	7840	.0040 (.0031,.0048)	3966	.0017 (.0014,.0028)	5820	.0016 (.0011,.0025)
5782	.0035 (.0028,.0038)	8434	.0039 (.0030,.0048)	4243	.0016 (.0013,.0027)	6209	.0016 (.0011,.0025)
6156	.0033 (.0027,.0037)	9073	.0038 (.0029,.0047)	4540	.0016 (.0013,.0027)	6625	.0015 (.0010,.0024)
6553	.0032 (.0025,.0036)	9688	.0038 (.0029,.0046)	4857	.0015 (.0013,.0026)	7068	.0015 (.0010,.0024)
6937	.0031 (.0024,.0034)	9760	.0037 (.0029,.0046)	5196	.0015 (.0012,.0026)	7540	.0014 (.0010,.0024)
6976	.0031 (.0024,.0034)	10499	.0036 (.0028,.0046)	5559	.0014 (.0012,.0025)	8044	.0014 (.0009,.0023)
7427	.0029 (.0023,.0033)	11294	.0035 (.0027,.0045)	5947	.0014 (.0011,.0024)	8582	.0014 (.0009,.0023)

7907	.0028 (.0022,.0032)	12149	.0035 (.0027,.0044)	6362	.0013 (.0011,.0024)	9156	.0013 (.0009,.0023)
8417	.0027 (.0021,.0031)	13069	.0034 (.0026,.0044)	6807	.0013 (.0011,.0024)	9769	.0013 (.0008,.0023)
8961	.0026 (.0020,.0030)	14059	.0033 (.0025,.0043)	7282	.0013 (.0010,.0023)	10422	.0012 (.0008,.0022)
9540	.0025 (.0019,.0029)	15124	.0032 (.0025,.0042)	7791	.0012 (.0010,.0023)	11119	.0012 (.0008,.0022)
10145	.0024 (.0018,.0028)	15353	.0032 (.0025,.0042)	8335	.0012 (.0010,.0022)	11862	.0012 (.0007,.0022)
10156	.0023 (.0018,.0028)	16269	.0031 (.0024,.0042)	8917	.0011 (.0009,.0022)	12656	.0011 (.0007,.0022)
10156	.0023 (.0018,.0028)	16269	.0031 (.0024,.0042)	9540	.0011 (.0009,.0021)	13502	.0011 (.0007,.0021)
10156	.0023 (.0018,.0028)	16269	.0031 (.0024,.0042)	10206	.0011 (.0009,.0021)	14405	.0011 (.0007,.0021)
10156	.0023 (.0018,.0028)	16269	.0031 (.0024,.0042)	10919	.0010 (.0009,.0020)	15368	.0010 (.0006,.0021)

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Table 5.5: Controlled VE as functions of Day 57 markers (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence intervals (5 replicates). Overall cumulative incidence from 7 to 164 days post Day 57 was 0.005 in vaccine recipients compared to 0.090 in placebo recipients, with cumulative vaccine efficacy 94.6% (95% CI 94.1 to 95.6%).

Anti Spike IgG (IU/ml)		Anti RBD IgG (IU/ml)		Pseudovirus-nAb cID50		Pseudovirus-nAb cID80	
s	Estimate	s	Estimate	s	Estimate	s	Estimate
20.7	-0.4978 (-0.6806,.0323)	11.8	.5528 (.1570,.8164)	13.7	.7054 (.6562,.8306)	25.3	.7848 (.6711,.9178)
22	-0.4491 (-0.6240,.0613)	13	.5637 (.1823,.8190)	15	.7146 (.6676,.8341)	27	.7910 (.6832,.9189)
23	-0.4016 (-0.5686,.0895)	14	.5745 (.2069,.8216)	16	.7236 (.6786,.8375)	29	.7969 (.6948,.9200)
25	-0.3552 (-0.5146,.1171)	15	.5849 (.2309,.8241)	17	.7323 (.6893,.8408)	31	.8027 (.7061,.9210)
27	-0.3099 (-0.4618,.1440)	16	.5952 (.2543,.8266)	18	.7407 (.6997,.8441)	33	.8084 (.7170,.9221)
28	-0.2657 (-0.4103,.1703)	17	.6051 (.2770,.8290)	19	.7489 (.7097,.8473)	35	.8139 (.7274,.9231)
30	-0.2227 (-0.3601,.1959)	18	.6149 (.2991,.8314)	20	.7568 (.7194,.8504)	37	.8192 (.7375,.9241)
32	-0.1808 (-0.3112,.2208)	20	.6244 (.3206,.8338)	22	.7645 (.7288,.8535)	40	.8244 (.7473,.9251)
34	-0.1400 (-0.2636,.2451)	21	.6337 (.3415,.8361)	23	.7719 (.7379,.8565)	42	.8295 (.7567,.9261)
36	-0.1003 (-0.2173,.2688)	23	.6428 (.3618,.8384)	25	.7791 (.7468,.8594)	45	.8344 (.7658,.9270)
39	-0.0616 (-0.1722,.2919)	25	.6517 (.3816,.8407)	27	.7861 (.7553,.8623)	48	.8391 (.7745,.9280)
41	-0.0241 (-0.1284,.3143)	26	.6604 (.4008,.8430)	29	.7929 (.7635,.8651)	52	.8437 (.7829,.9289)
44	0.0124 (-0.0859,.3361)	28	.6688 (.4195,.8452)	31	.7995 (.7715,.8679)	55	.8482 (.7911,.9299)
47	0.0478 (-0.0446,.3574)	31	.6771 (.4377,.8473)	33	.8058 (.7793,.8706)	59	.8526 (.7989,.9308)
50	0.0822 (-0.0046,.3780)	33	.6851 (.4553,.8495)	35	.8120 (.7868,.8732)	63	.8569 (.8065,.9317)
53	0.1155 (.0343,.3981)	35	.6930 (.4724,.8516)	38	.8180 (.7940,.8758)	67	.8610 (.8137,.9326)
56	0.1479 (.0719,.4176)	38	.7007 (.4891,.8537)	40	.8238 (.8010,.8784)	71	.8650 (.8208,.9334)
60	0.1792 (.1083,.4366)	41	.7082 (.5052,.8557)	43	.8294 (.8078,.8809)	76	.8689 (.8275,.9343)
64	0.2096 (.1436,.4551)	44	.7155 (.5209,.8578)	46	.8348 (.8143,.8833)	81	.8727 (.8340,.9352)
68	0.2390 (.1777,.4730)	47	.7226 (.5361,.8598)	49	.8401 (.8207,.8857)	87	.8764 (.8403,.9360)
72	0.2675 (.2107,.4906)	51	.7296 (.5509,.8617)	53	.8452 (.8268,.8880)	92	.8799 (.8462,.9368)
77	0.2951 (.2425,.5077)	55	.7364 (.5652,.8637)	56	.8501 (.8327,.8903)	99	.8834 (.8519,.9376)
82	0.3218 (.2731,.5242)	59	.7430 (.5791,.8656)	60	.8549 (.8385,.8925)	105	.8868 (.8574,.9384)
87	0.3475 (.3027,.5402)	63	.7495 (.5926,.8675)	65	.8596 (.8440,.8947)	112	.8900 (.8628,.9392)
93	0.3725 (.3312,.5557)	68	.7558 (.6057,.8693)	69	.8641 (.8494,.8969)	120	.8932 (.8679,.9400)
99	0.3965 (.3587,.5707)	73	.7620 (.6184,.8712)	74	.8684 (.8545,.8990)	128	.8963 (.8728,.9408)
105	0.4198 (.3852,.5852)	79	.7680 (.6307,.8730)	79	.8726 (.8595,.9017)	136	.8993 (.8775,.9415)
112	0.4423 (.4108,.5993)	85	.7738 (.6426,.8747)	85	.8767 (.8644,.9046)	145	.9022 (.8821,.9423)
119	0.4639 (.4354,.6129)	91	.7796 (.6542,.8765)	90	.8807 (.8691,.9075)	155	.9051 (.8865,.9430)
127	0.4849 (.4591,.6261)	98	.7851 (.6654,.8782)	97	.8845 (.8736,.9102)	165	.9078 (.8907,.9438)
135	0.5051 (.4819,.6388)	106	.7906 (.6762,.8799)	104	.8882 (.8779,.9129)	166	.9079 (.8909,.9438)
144	0.5245 (.5038,.6512)	114	.7959 (.6867,.8816)	111	.8918 (.8822,.9154)	177	.9105 (.8948,.9445)
153	0.5433 (.5249,.6631)	122	.8011 (.6969,.8833)	113	.8930 (.8836,.9163)	188	.9131 (.8987,.9452)
163	0.5614 (.5452,.6746)	131	.8061 (.7068,.8849)	118	.8953 (.8862,.9179)	201	.9156 (.9025,.9459)
174	0.5788 (.5646,.6858)	141	.8110 (.7164,.8865)	127	.8986 (.8902,.9204)	214	.9181 (.9061,.9467)
185	0.5956 (.5834,.6966)	152	.8158 (.7257,.8881)	136	.9019 (.8940,.9229)	216	.9184 (.9067,.9468)
197	0.6117 (.6013,.7071)	164	.8205 (.7347,.8896)	145	.9051 (.8977,.9253)	229	.9204 (.9096,.9474)
210	0.6273 (.6186,.7172)	176	.8251 (.7434,.8912)	150	.9067 (.8996,.9265)	244	.9228 (.9130,.9481)
223	0.6423 (.6351,.7269)	189	.8295 (.7518,.8927)	155	.9081 (.9012,.9276)	260	.9250 (.9163,.9489)
238	0.6567 (.6510,.7364)	204	.8339 (.7599,.8942)	166	.9111 (.9046,.9298)	278	.9272 (.9194,.9496)
253	0.6706 (.6663,.7456)	219	.8381 (.7678,.8957)	178	.9139 (.9079,.9320)	285	.9280 (.9206,.9499)
269	0.6839 (.6809,.7545)	236	.8423 (.7755,.8971)	190	.9167 (.9111,.9341)	296	.9293 (.9224,.9503)
287	0.6968 (.6949,.7632)	254	.8463 (.7829,.8986)	191	.9169 (.9114,.9343)	316	.9313 (.9253,.9510)
305	0.7091 (.7083,.7715)	273	.8502 (.7900,.9000)	203	.9194 (.9142,.9362)	337	.9333 (.9281,.9517)
325	0.7210 (.7212,.7796)	294	.8540 (.7970,.9014)	218	.9220 (.9172,.9382)	360	.9353 (.9308,.9523)
346	0.7324 (.7335,.7874)	316	.8578 (.8037,.9027)	233	.9245 (.9201,.9401)	384	.9372 (.9327,.9530)
368	0.7434 (.7453,.7949)	340	.8614 (.8102,.9041)	249	.9269 (.9229,.9419)	410	.9390 (.9343,.9536)

392	0.7539 (0.7567,.8022)	365	.8649 (.8165,.9055)	266	.9293 (.9256,.9438)	437	.9408 (.9359,.9543)
417	0.7640 (0.7675,.8092)	393	.8684 (.8225,.9068)	285	.9316 (.9281,.9455)	440	.9410 (.9361,.9543)
444	0.7737 (0.7778,.8160)	423	.8718 (.8284,.9081)	305	.9338 (.9305,.9472)	466	.9425 (.9374,.9549)
473	0.7831 (0.7878,.8226)	455	.8751 (.8341,.9094)	326	.9359 (.9329,.9488)	497	.9442 (.9389,.9555)
500	0.7910 (0.7962,.8285)	489	.8783 (.8396,.9107)	330	.9363 (.9333,.9491)	500	.9443 (.9390,.9555)
504	0.7920 (0.7973,.8293)	500	.8792 (.8412,.9111)	349	.9380 (.9351,.9504)	531	.9458 (.9403,.9561)
536	0.8006 (0.8064,.8363)	526	.8814 (.8450,.9120)	373	.9400 (.9367,.9520)	566	.9474 (.9417,.9567)
571	0.8089 (0.8150,.8430)	566	.8844 (.8501,.9140)	399	.9419 (.9380,.9535)	581	.9480 (.9423,.9569)
608	0.8168 (0.8234,.8494)	609	.8874 (.8551,.9161)	427	.9438 (.9393,.9549)	604	.9489 (.9430,.9573)
647	0.8245 (0.8313,.8556)	655	.8903 (.8599,.9181)	454	.9454 (.9404,.9562)	644	.9504 (.9443,.9586)
653	0.8256 (0.8325,.8565)	705	.8931 (.8646,.9201)	457	.9456 (.9406,.9563)	687	.9518 (.9455,.9598)
689	0.8318 (0.8389,.8616)	758	.8959 (.8691,.9220)	489	.9474 (.9418,.9577)	733	.9532 (.9467,.9610)
733	0.8388 (0.8462,.8673)	763	.8961 (.8695,.9222)	500	.9480 (.9422,.9581)	749	.9537 (.9471,.9614)
780	0.8455 (0.8531,.8728)	816	.8985 (.8735,.9239)	523	.9491 (.9430,.9590)	782	.9546 (.9479,.9622)
831	0.8520 (0.8598,.8780)	877	.9011 (.8777,.9258)	560	.9508 (.9442,.9603)	835	.9559 (.9491,.9633)
884	0.8582 (0.8661,.8831)	944	.9037 (.8818,.9276)	599	.9523 (.9454,.9615)	891	.9572 (.9502,.9644)
942	0.8641 (0.8722,.8879)	1000	.9057 (.8849,.9290)	641	.9539 (.9465,.9627)	950	.9585 (.9513,.9656)
960	0.8659 (0.8740,.8894)	1015	.9062 (.8857,.9294)	673	.9550 (.9473,.9636)	958	.9586 (.9514,.9657)
1000	0.8696 (0.8772,.8924)	1092	.9086 (.8896,.9311)	686	.9554 (.9476,.9639)	1000	.9594 (.9521,.9665)
1002	0.8698 (0.8774,.8926)	1139	.9099 (.8917,.9321)	733	.9568 (.9487,.9650)	1014	.9597 (.9524,.9667)
1067	0.8753 (0.8822,.8970)	1175	.9109 (.8933,.9328)	785	.9582 (.9497,.9661)	1081	.9609 (.9534,.9678)
1136	0.8805 (0.8868,.9013)	1264	.9132 (.8968,.9344)	839	.9596 (.9508,.9672)	1154	.9620 (.9544,.9688)
1209	0.8855 (0.8913,.9054)	1360	.9155 (.9003,.9360)	898	.9609 (.9518,.9682)	1231	.9631 (.9554,.9699)
1288	0.8903 (0.8955,.9093)	1463	.9176 (.9036,.9376)	909	.9611 (.9520,.9684)	1313	.9642 (.9564,.9708)
1297	0.8909 (0.8960,.9098)	1573	.9198 (.9068,.9391)	961	.9622 (.9528,.9692)	1401	.9652 (.9574,.9718)
1371	0.8950 (0.8995,.9131)	1693	.9218 (.9100,.9406)	1000	.9629 (.9534,.9698)	1452	.9658 (.9579,.9723)
1459	0.8994 (0.9033,.9167)	1817	.9238 (.9129,.9420)	1028	.9634 (.9538,.9701)	1495	.9662 (.9583,.9727)
1553	0.9036 (0.9070,.9203)	1821	.9239 (.9130,.9420)	1100	.9646 (.9547,.9711)	1595	.9672 (.9592,.9736)
1654	0.9077 (0.9106,.9237)	1959	.9258 (.9159,.9435)	1177	.9657 (.9556,.9720)	1701	.9682 (.9601,.9745)
1761	0.9116 (0.9140,.9269)	2107	.9277 (.9187,.9448)	1259	.9668 (.9565,.9729)	1815	.9691 (.9610,.9753)
1874	0.9153 (0.9173,.9301)	2267	.9296 (.9214,.9462)	1347	.9679 (.9574,.9737)	1840	.9693 (.9612,.9755)
1995	0.9189 (0.9205,.9331)	2438	.9314 (.9241,.9475)	1441	.9690 (.9583,.9745)	1936	.9700 (.9618,.9761)
2124	0.9224 (0.9235,.9360)	2623	.9332 (.9266,.9488)	1491	.9695 (.9587,.9749)	2066	.9709 (.9626,.9769)
2261	0.9256 (0.9264,.9387)	2821	.9349 (.9291,.9500)	1541	.9700 (.9592,.9753)	2204	.9717 (.9634,.9776)
2408	0.9288 (0.9293,.9413)	3035	.9366 (.9314,.9513)	1649	.9709 (.9600,.9761)	2349	.9726 (.9642,.9784)
2563	0.9318 (0.9320,.9439)	3265	.9382 (.9336,.9525)	1764	.9719 (.9608,.9768)	2352	.9726 (.9642,.9784)
2729	0.9347 (0.9345,.9463)	3512	.9398 (.9358,.9536)	1887	.9728 (.9616,.9776)	2509	.9734 (.9650,.9791)
2905	0.9375 (0.9368,.9486)	3607	.9404 (.9366,.9540)	2019	.9737 (.9624,.9783)	2677	.9741 (.9657,.9799)
2957	0.9382 (0.9375,.9492)	3778	.9414 (.9379,.9548)	2027	.9737 (.9624,.9783)	2856	.9749 (.9664,.9807)
3092	0.9401 (0.9391,.9508)	4064	.9429 (.9391,.9559)	2160	.9745 (.9632,.9789)	3047	.9756 (.9671,.9814)
3292	0.9427 (0.9413,.9529)	4372	.9444 (.9400,.9569)	2311	.9754 (.9639,.9796)	3250	.9764 (.9678,.9821)
3505	0.9451 (0.9434,.9550)	4703	.9458 (.9409,.9580)	2440	.9760 (.9645,.9801)	3468	.9770 (.9685,.9828)
3731	0.9474 (0.9454,.9569)	5059	.9472 (.9418,.9590)	2472	.9762 (.9646,.9802)	3699	.9777 (.9690,.9835)
3972	0.9497 (0.9473,.9588)	5443	.9486 (.9427,.9600)	2645	.9769 (.9654,.9809)	3947	.9784 (.9694,.9841)
4229	0.9518 (0.9492,.9605)	5855	.9499 (.9435,.9610)	2830	.9777 (.9661,.9815)	4211	.9790 (.9698,.9847)
4502	0.9539 (0.9510,.9622)	6262	.9511 (.9443,.9619)	3028	.9784 (.9668,.9820)	4492	.9796 (.9702,.9853)
4553	0.9542 (0.9514,.9625)	6298	.9512 (.9443,.9620)	3239	.9791 (.9674,.9826)	4793	.9802 (.9705,.9859)
4792	0.9558 (0.9528,.9639)	6775	.9525 (.9451,.9629)	3465	.9798 (.9681,.9831)	5113	.9808 (.9709,.9864)
5102	0.9577 (0.9545,.9654)	7288	.9537 (.9459,.9638)	3707	.9804 (.9687,.9837)	5455	.9813 (.9712,.9870)
5431	0.9595 (0.9561,.9669)	7840	.9549 (.9467,.9647)	3966	.9811 (.9694,.9842)	5820	.9819 (.9716,.9875)
5782	0.9612 (0.9577,.9684)	8434	.9561 (.9474,.9656)	4243	.9817 (.9700,.9847)	6209	.9824 (.9720,.9880)
6156	0.9629 (0.9592,.9697)	9073	.9572 (.9482,.9664)	4540	.9823 (.9706,.9852)	6625	.9829 (.9723,.9884)
6553	0.9645 (0.9607,.9710)	9688	.9582 (.9488,.9671)	4857	.9829 (.9712,.9856)	7068	.9834 (.9726,.9889)
6937	0.9659 (0.9620,.9722)	9760	.9583 (.9489,.9672)	5196	.9834 (.9718,.9861)	7540	.9839 (.9730,.9893)

6976	0.9660	(0.9621,.9723)	10499	.9594	(.9496,.9680)	5559	.9840	(.9723,.9865)	8044	.9844	(.9733,.9897)
7427	0.9674	(0.9634,.9736)	11294	.9605	(.9503,.9688)	5947	.9845	(.9729,.9869)	8582	.9848	(.9736,.9901)
7907	0.9688	(0.9648,.9748)	12149	.9615	(.9510,.9696)	6362	.9850	(.9734,.9873)	9156	.9853	(.9740,.9905)
8417	0.9702	(0.9660,.9760)	13069	.9625	(.9517,.9703)	6807	.9855	(.9740,.9877)	9769	.9857	(.9743,.9909)
8961	0.9714	(0.9672,.9771)	14059	.9635	(.9524,.9711)	7282	.9860	(.9745,.9881)	10422	.9861	(.9746,.9912)
9540	0.9727	(0.9684,.9782)	15124	.9644	(.9531,.9719)	7791	.9864	(.9750,.9885)	11119	.9865	(.9749,.9915)
10145	0.9738	(0.9695,.9792)	15353	.9646	(.9532,.9720)	8335	.9869	(.9755,.9888)	11862	.9869	(.9752,.9919)
10156	0.9738	(0.9695,.9792)	16269	.9653	(.9537,.9726)	8917	.9873	(.9760,.9892)	12656	.9873	(.9755,.9922)
10156	0.9738	(0.9695,.9792)	16269	.9653	(.9537,.9726)	9540	.9877	(.9765,.9895)	13502	.9877	(.9758,.9925)
10156	0.9738	(0.9695,.9792)	16269	.9653	(.9537,.9726)	10206	.9881	(.9769,.9899)	14405	.9881	(.9761,.9928)
10156	0.9738	(0.9695,.9792)	16269	.9653	(.9537,.9726)	10919	.9885	(.9774,.9902)	15368	.9884	(.9764,.9931)
237.6	.6567	(.6510,.7364)	24.5	.6517	(.3816,.8407)		(,)			(,)	
1459	.8994	(.9033,.9167)	877	.9011	(.8777,.9258)	127	.8986	(.8902,.9204)	136	.8993	(.8775,.9415)
3972	.9497	(.9473,.9588)	5855	.9499	(.9435,.9610)	560	.9508	(.9442,.9603)	644	.9504	(.9443,.9586)

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Table 5.6: Controlled VE with sensitivity analysis as functions of Day 57 markers (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence intervals (5 replicates).

	Anti Spike IgG (IU/ml)	Anti RBD IgG (IU/ml)	Pseudovirus-nAb cID50	Pseudovirus-nAb cID80	
s	Estimate	s	Estimate	s	Estimate
20.7	.4199 (.3491,.6252)	11.8	.8346 (.6883,.9321)	13.7	.8175 (.7870,.8951)
22	.4296 (.3608,.6305)	13	.8360 (.6925,.9319)	15	.8208 (.7913,.8958)
23	.4394 (.3726,.6358)	14	.8373 (.6967,.9318)	16	.8240 (.7954,.8966)
25	.4492 (.3844,.6411)	15	.8386 (.7010,.9316)	17	.8273 (.7995,.8973)
27	.4590 (.3963,.6465)	16	.8399 (.7052,.9314)	18	.8304 (.8036,.8981)
28	.4688 (.4082,.6518)	17	.8413 (.7093,.9313)	19	.8336 (.8076,.8988)
30	.4787 (.4201,.6572)	18	.8426 (.7135,.9311)	20	.8367 (.8116,.8996)
32	.4885 (.4320,.6625)	20	.8439 (.7177,.9309)	22	.8398 (.8155,.9003)
34	.4984 (.4440,.6678)	21	.8453 (.7218,.9308)	23	.8428 (.8194,.9011)
36	.5082 (.4559,.6731)	23	.8466 (.7260,.9306)	25	.8458 (.8232,.9019)
39	.5179 (.4677,.6784)	25	.8480 (.7301,.9305)	27	.8488 (.8270,.9027)
41	.5277 (.4796,.6837)	26	.8493 (.7342,.9303)	29	.8517 (.8307,.9035)
44	.5374 (.4913,.6890)	28	.8507 (.7383,.9302)	31	.8546 (.8344,.9042)
47	.5470 (.5030,.6943)	31	.8520 (.7423,.9300)	33	.8575 (.8380,.9050)
50	.5566 (.5147,.6995)	33	.8534 (.7463,.9299)	35	.8603 (.8416,.9058)
53	.5661 (.5262,.7047)	35	.8547 (.7503,.9298)	38	.8631 (.8451,.9067)
56	.5755 (.5376,.7099)	38	.8561 (.7543,.9296)	40	.8659 (.8486,.9075)
60	.5848 (.5490,.7150)	41	.8574 (.7583,.9295)	43	.8687 (.8520,.9083)
64	.5941 (.5602,.7202)	44	.8588 (.7622,.9294)	46	.8714 (.8554,.9091)
68	.6033 (.5713,.7253)	47	.8601 (.7661,.9293)	49	.8740 (.8587,.9099)
72	.6124 (.5823,.7304)	51	.8615 (.7700,.9292)	53	.8767 (.8620,.9108)
77	.6213 (.5931,.7355)	55	.8629 (.7738,.9291)	56	.8793 (.8653,.9116)
82	.6302 (.6037,.7406)	59	.8642 (.7776,.9290)	60	.8819 (.8684,.9125)
87	.6390 (.6141,.7456)	63	.8656 (.7814,.9289)	65	.8844 (.8716,.9133)
93	.6476 (.6245,.7505)	68	.8669 (.7851,.9288)	69	.8869 (.8747,.9142)
99	.6562 (.6346,.7554)	73	.8683 (.7888,.9287)	74	.8894 (.8777,.9151)
105	.6646 (.6446,.7602)	79	.8696 (.7925,.9286)	79	.8918 (.8807,.9165)
112	.6729 (.6544,.7650)	85	.8710 (.7961,.9286)	85	.8943 (.8837,.9182)
119	.6810 (.6640,.7697)	91	.8724 (.7998,.9285)	90	.8966 (.8866,.9199)
127	.6891 (.6735,.7743)	98	.8737 (.8033,.9284)	97	.8990 (.8895,.9215)
135	.6970 (.6828,.7789)	106	.8751 (.8069,.9284)	104	.9013 (.8923,.9231)
144	.7048 (.6919,.7834)	114	.8764 (.8104,.9283)	111	.9036 (.8951,.9247)
153	.7125 (.7009,.7879)	122	.8778 (.8138,.9283)	113	.9044 (.8960,.9252)
163	.7200 (.7096,.7923)	131	.8792 (.8173,.9283)	118	.9059 (.8978,.9263)
174	.7274 (.7182,.7967)	141	.8805 (.8207,.9282)	127	.9081 (.9005,.9279)
185	.7347 (.7266,.8009)	152	.8819 (.8240,.9282)	136	.9104 (.9031,.9295)
197	.7418 (.7349,.8052)	164	.8832 (.8274,.9282)	145	.9125 (.9057,.9312)
210	.7488 (.7429,.8093)	176	.8846 (.8307,.9282)	150	.9137 (.9071,.9320)
223	.7557 (.7508,.8135)	189	.8860 (.8339,.9282)	155	.9147 (.9083,.9328)
238	.7624 (.7585,.8175)	204	.8873 (.8371,.9282)	166	.9168 (.9108,.9344)
253	.7690 (.7660,.8216)	219	.8887 (.8403,.9282)	178	.9189 (.9133,.9360)
269	.7755 (.7733,.8256)	236	.8900 (.8435,.9283)	190	.9210 (.9157,.9375)
287	.7818 (.7805,.8296)	254	.8914 (.8466,.9283)	191	.9212 (.9159,.9376)
305	.7880 (.7875,.8335)	273	.8927 (.8497,.9284)	203	.9231 (.9181,.9391)
325	.7941 (.7943,.8373)	294	.8941 (.8527,.9284)	218	.9251 (.9205,.9406)
346	.8001 (.8009,.8411)	316	.8954 (.8557,.9285)	233	.9271 (.9228,.9421)
368	.8059 (.8074,.8449)	340	.8968 (.8587,.9286)	249	.9290 (.9251,.9436)
392	.8116 (.8137,.8486)	365	.8982 (.8616,.9287)	266	.9310 (.9273,.9451)
417	.8172 (.8199,.8522)	393	.8995 (.8645,.9288)	285	.9329 (.9295,.9466)

444	.8226 (.8259,.8558)	423	.9009 (.8674,.9290)	305	.9348 (.9316,.9480)	466	.9428 (.9377,.9551)
473	.8280 (.8317,.8593)	455	.9022 (.8702,.9291)	326	.9367 (.9336,.9494)	497	.9443 (.9390,.9556)
500	.8326 (.8368,.8626)	489	.9036 (.8730,.9293)	330	.9370 (.9340,.9497)	500	.9444 (.9391,.9556)
504	.8332 (.8374,.8631)	500	.9040 (.8738,.9293)	349	.9385 (.9357,.9508)	531	.9458 (.9404,.9561)
536	.8383 (.8429,.8672)	526	.9049 (.8758,.9295)	373	.9403 (.9371,.9522)	566	.9474 (.9417,.9567)
571	.8433 (.8483,.8712)	566	.9063 (.8785,.9303)	399	.9421 (.9382,.9536)	581	.9480 (.9423,.9569)
608	.8481 (.8535,.8752)	609	.9076 (.8812,.9312)	427	.9439 (.9394,.9550)	604	.9489 (.9430,.9573)
647	.8529 (.8586,.8790)	655	.9090 (.8838,.9321)	454	.9455 (.9405,.9562)	644	.9503 (.9442,.9585)
653	.8536 (.8594,.8796)	705	.9104 (.8865,.9330)	457	.9457 (.9406,.9564)	687	.9517 (.9454,.9597)
689	.8575 (.8636,.8828)	758	.9117 (.8891,.9339)	489	.9474 (.9418,.9577)	733	.9530 (.9465,.9608)
733	.8621 (.8684,.8865)	763	.9118 (.8893,.9340)	500	.9480 (.9422,.9581)	749	.9534 (.9468,.9611)
780	.8665 (.8731,.8900)	816	.9131 (.8916,.9348)	523	.9491 (.9430,.9590)	782	.9542 (.9475,.9618)
831	.8708 (.8776,.8936)	877	.9144 (.8941,.9358)	560	.9507 (.9442,.9602)	835	.9554 (.9484,.9628)
884	.8750 (.8821,.8970)	944	.9158 (.8966,.9367)	599	.9522 (.9452,.9614)	891	.9565 (.9493,.9638)
942	.8792 (.8863,.9003)	1000	.9169 (.8986,.9374)	641	.9537 (.9463,.9626)	950	.9575 (.9502,.9648)
960	.8804 (.8877,.9014)	1015	.9171 (.8991,.9376)	673	.9547 (.9470,.9634)	958	.9577 (.9503,.9649)
1000	.8830 (.8899,.9035)	1092	.9185 (.9015,.9386)	686	.9551 (.9473,.9636)	1000	.9583 (.9509,.9656)
1002	.8832 (.8900,.9036)	1139	.9193 (.9029,.9391)	733	.9564 (.9482,.9647)	1014	.9586 (.9510,.9658)
1067	.8871 (.8934,.9068)	1175	.9199 (.9039,.9395)	785	.9577 (.9491,.9657)	1081	.9595 (.9518,.9667)
1136	.8909 (.8967,.9099)	1264	.9212 (.9063,.9405)	839	.9589 (.9499,.9666)	1154	.9604 (.9526,.9675)
1209	.8946 (.8999,.9129)	1360	.9226 (.9087,.9414)	898	.9601 (.9508,.9675)	1231	.9613 (.9533,.9684)
1288	.8983 (.9031,.9159)	1463	.9239 (.9110,.9423)	909	.9603 (.9509,.9677)	1313	.9621 (.9539,.9692)
1297	.8987 (.9034,.9162)	1573	.9253 (.9133,.9433)	961	.9612 (.9515,.9684)	1401	.9630 (.9546,.9699)
1371	.9018 (.9060,.9188)	1693	.9267 (.9155,.9443)	1000	.9618 (.9520,.9689)	1452	.9634 (.9549,.9704)
1459	.9052 (.9090,.9216)	1817	.9280 (.9177,.9452)	1028	.9622 (.9523,.9692)	1495	.9637 (.9552,.9707)
1553	.9086 (.9118,.9244)	1821	.9280 (.9177,.9452)	1100	.9633 (.9530,.9700)	1595	.9645 (.9558,.9714)
1654	.9119 (.9146,.9271)	1959	.9294 (.9199,.9462)	1177	.9642 (.9537,.9708)	1701	.9652 (.9564,.9721)
1761	.9151 (.9174,.9298)	2107	.9307 (.9221,.9471)	1259	.9652 (.9544,.9715)	1815	.9659 (.9569,.9727)
1874	.9182 (.9201,.9324)	2267	.9321 (.9242,.9481)	1347	.9661 (.9550,.9722)	1840	.9660 (.9570,.9728)
1995	.9212 (.9227,.9350)	2438	.9335 (.9264,.9491)	1441	.9670 (.9556,.9729)	1936	.9665 (.9574,.9733)
2124	.9242 (.9253,.9374)	2623	.9348 (.9284,.9501)	1491	.9674 (.9559,.9732)	2066	.9672 (.9579,.9739)
2261	.9270 (.9278,.9399)	2821	.9362 (.9305,.9510)	1541	.9678 (.9562,.9735)	2204	.9678 (.9583,.9745)
2408	.9298 (.9303,.9422)	3035	.9376 (.9325,.9520)	1649	.9686 (.9568,.9742)	2349	.9684 (.9587,.9751)
2563	.9326 (.9327,.9445)	3265	.9390 (.9344,.9530)	1764	.9694 (.9573,.9748)	2352	.9684 (.9587,.9751)
2729	.9352 (.9350,.9467)	3512	.9403 (.9363,.9540)	1887	.9701 (.9579,.9754)	2509	.9690 (.9591,.9756)
2905	.9378 (.9371,.9488)	3607	.9408 (.9370,.9544)	2019	.9709 (.9584,.9759)	2677	.9695 (.9595,.9763)
2957	.9385 (.9378,.9494)	3778	.9417 (.9382,.9550)	2027	.9709 (.9584,.9760)	2856	.9700 (.9599,.9769)
3092	.9403 (.9393,.9509)	4064	.9431 (.9393,.9560)	2160	.9716 (.9589,.9765)	3047	.9706 (.9603,.9776)
3292	.9428 (.9413,.9530)	4372	.9445 (.9401,.9570)	2311	.9722 (.9594,.9770)	3250	.9711 (.9606,.9782)
3505	.9451 (.9434,.9550)	4703	.9458 (.9409,.9580)	2440	.9728 (.9597,.9774)	3468	.9716 (.9610,.9787)
3731	.9474 (.9454,.9569)	5059	.9472 (.9418,.9590)	2472	.9729 (.9598,.9775)	3699	.9720 (.9611,.9793)
3972	.9497 (.9473,.9587)	5443	.9486 (.9427,.9600)	2645	.9735 (.9603,.9780)	3947	.9725 (.9611,.9798)
4229	.9518 (.9492,.9605)	5855	.9498 (.9435,.9610)	2830	.9741 (.9607,.9785)	4211	.9729 (.9610,.9803)
4502	.9537 (.9509,.9621)	6262	.9510 (.9441,.9618)	3028	.9747 (.9611,.9790)	4492	.9734 (.9610,.9808)
4553	.9541 (.9512,.9624)	6298	.9511 (.9442,.9619)	3239	.9753 (.9615,.9794)	4793	.9738 (.9610,.9813)
4792	.9556 (.9526,.9637)	6775	.9522 (.9448,.9627)	3465	.9759 (.9619,.9799)	5113	.9742 (.9609,.9818)
5102	.9574 (.9541,.9652)	7288	.9533 (.9454,.9635)	3707	.9764 (.9623,.9803)	5455	.9746 (.9608,.9822)
5431	.9591 (.9556,.9666)	7840	.9544 (.9460,.9643)	3966	.9769 (.9626,.9807)	5820	.9750 (.9608,.9827)
5782	.9607 (.9571,.9679)	8434	.9554 (.9466,.9650)	4243	.9774 (.9630,.9811)	6209	.9754 (.9607,.9831)
6156	.9622 (.9584,.9691)	9073	.9563 (.9471,.9657)	4540	.9779 (.9633,.9815)	6625	.9757 (.9606,.9835)
6553	.9636 (.9597,.9703)	9688	.9572 (.9475,.9663)	4857	.9784 (.9637,.9819)	7068	.9761 (.9605,.9839)
6937	.9649 (.9609,.9714)	9760	.9573 (.9476,.9664)	5196	.9789 (.9640,.9822)	7540	.9764 (.9604,.9843)
6976	.9650 (.9610,.9715)	10499	.9581 (.9480,.9670)	5559	.9793 (.9643,.9826)	8044	.9768 (.9603,.9847)
7427	.9663 (.9622,.9727)	11294	.9590 (.9485,.9677)	5947	.9798 (.9646,.9829)	8582	.9771 (.9602,.9850)

7907	.9676	(.9633,.9738)	12149	.9598	(.9489,.9683)	6362	.9802	(.9649,.9833)	9156	.9774	(.9600,.9854)
8417	.9688	(.9644,.9748)	13069	.9606	(.9493,.9688)	6807	.9806	(.9652,.9836)	9769	.9777	(.9599,.9857)
8961	.9699	(.9655,.9759)	14059	.9613	(.9496,.9694)	7282	.9810	(.9655,.9839)	10422	.9780	(.9598,.9861)
9540	.9710	(.9665,.9768)	15124	.9621	(.9500,.9700)	7791	.9814	(.9658,.9842)	11119	.9783	(.9596,.9864)
10145	.9720	(.9674,.9777)	15353	.9622	(.9500,.9701)	8335	.9818	(.9660,.9845)	11862	.9786	(.9595,.9867)
10156	.9720	(.9674,.9777)	16269	.9628	(.9503,.9706)	8917	.9822	(.9663,.9848)	12656	.9789	(.9593,.9870)
10156	.9720	(.9674,.9777)	16269	.9628	(.9503,.9706)	9540	.9825	(.9666,.9851)	13502	.9792	(.9592,.9873)
10156	.9720	(.9674,.9777)	16269	.9628	(.9503,.9706)	10206	.9829	(.9668,.9854)	14405	.9795	(.9590,.9876)
10156	.9720	(.9674,.9777)	16269	.9628	(.9503,.9706)	10919	.9832	(.9671,.9857)	15368	.9797	(.9588,.9879)
237.6	.6567	(.6510,.7364)	24.5	.6517	(.3816,.8407)		(,)		(,)		
1459	.8994	(.9033,.9167)	877	.9011	(.8777,.9258)	127	.8986	(.8902,.9204)	136	.8993	(.8775,.9415)
3972	.9497	(.9473,.9588)	5855	.9499	(.9435,.9610)	560	.9508	(.9442,.9603)	644	.9504	(.9443,.9586)

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5.3 Misc

Average follow-up of vaccine recipients (in the Day 57 correlates analyses population) starting at 7 days post Day 57 visit is 166 days.

Number of breakthrough vaccine cases (in the Day 57 correlates analyses population) with Day 57 ID80 > 660 IU: 16 .

Table 5.7: Summary statistics for the number of days from dose 1 to Day 57 visit. (a) The whole immunogenicity subcohort, (b) non-cases in the immunogenicity subcohort, (c) intercurrent cases, (d) primary cases, i.e. cases from the Day 57 correlates analysis population.

	min	1st quartile	median	3d quartile	max
(a)	51	54	57	60	63
(b)	51	55	58	61	63
(c)	54	56	58	61	62
(d)	51	55	58	60	63

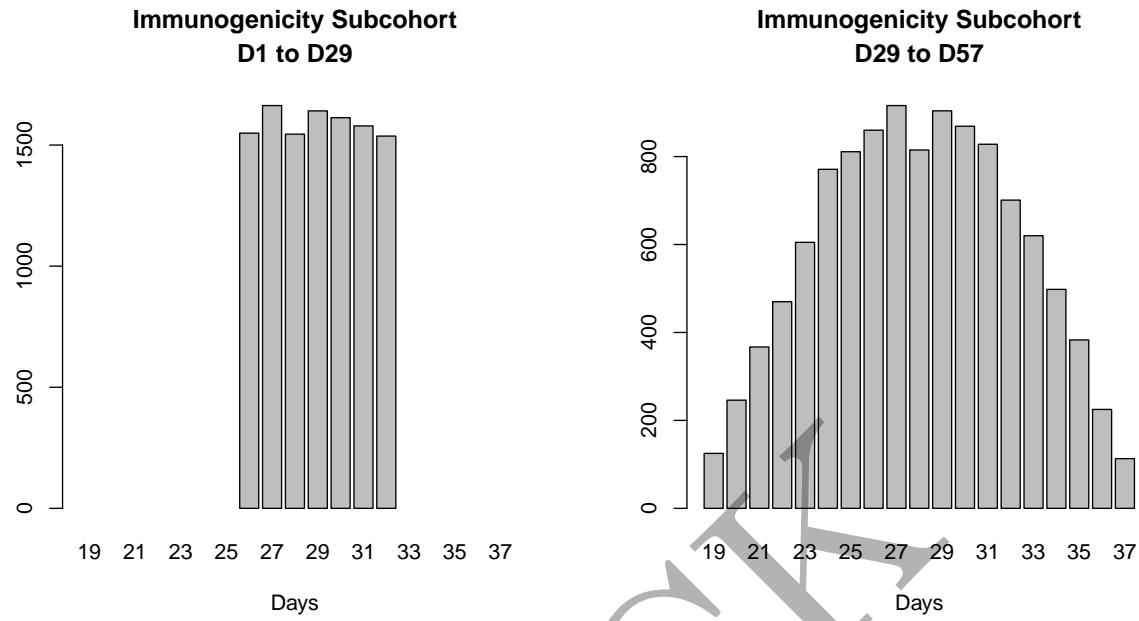


Figure 5.12: Distribution of the number of days bewteen visits in the immunogenicity subcohort, vaccine arm, baseline negative.

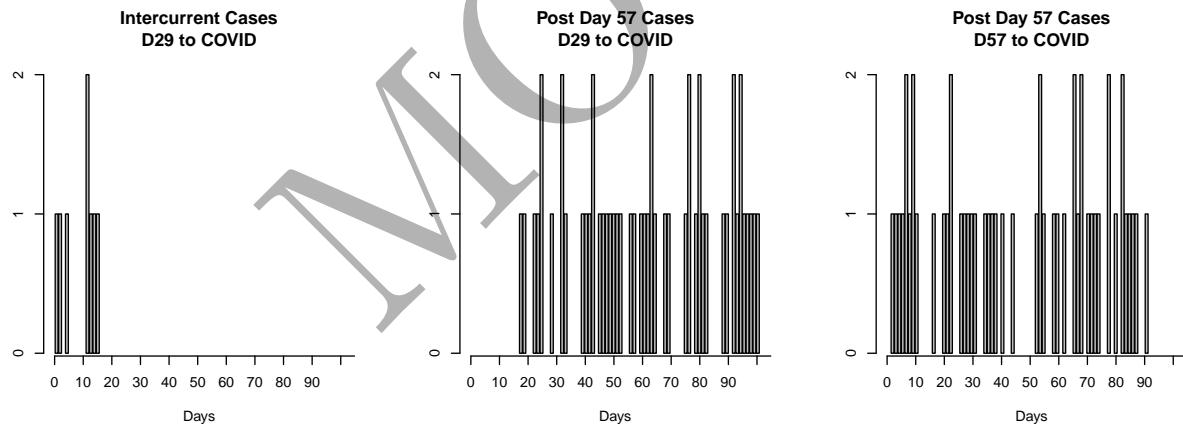


Figure 5.13: Distribution of the number of days to COVID endpoints, vaccine arm, baseline negative.

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Chapter 6

Univariate CoR: Nonparametric Threshold Modeling ($>= s$)

An extension of the unadjusted nonparametric threshold-searching approach developed in Donovan, Hudgens, and Gilbert (2019), the covariate-adjusted TMLE-based approach developed by van der Laan, Zhang, Gilbert (submitted) is used to estimate the so-called threshold-response function $E_X[E[Y | S \geq s, X, A = 1] | A = 1]$ for a range of thresholds s . Here, X is a set of baseline characteristics, $A = 1$ represents the vaccine group, S is the biomarker/immune-response/correlate of interest, and Y is the indicator of COVID disease before some time point t_f . This parameter can be viewed as a causal/covariate-adjusted version of the parameter $P(Y = 1 | S \geq s, A = 1)$. Intuitively, the threshold-response at a given threshold is the expected probability of obtaining COVID disease if one experiences a marker/immune-response value above that threshold. The threshold-response function is estimated for each of the four Day 57 antibody markers, in each case adjusting for the baseline covariates: baseline risk score, high risk indicator, and underrepresented minority status. A parametric learner, selected via cross-validation, is used for the covariate adjustment. A number of plots and tables are reported:

1. A plot and table with risk estimates and point-wise 95% confidence intervals
2. A plot and table with risk estimates and simultaneous 95% confidence bands
3. Monotone-corrected versions of 1 and 2.

A reverse cumulative distribution function curve estimated by the IPW NPMLE of the marker values is superimposed on the threshold-response plots and a dashed red line is added to mark the threshold value after which no more events are observed.

6.1 Plots and Tables with estimates and pointwise confidence interval for Day 57

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6.1.1 Day 57 Spike protein binding antibody

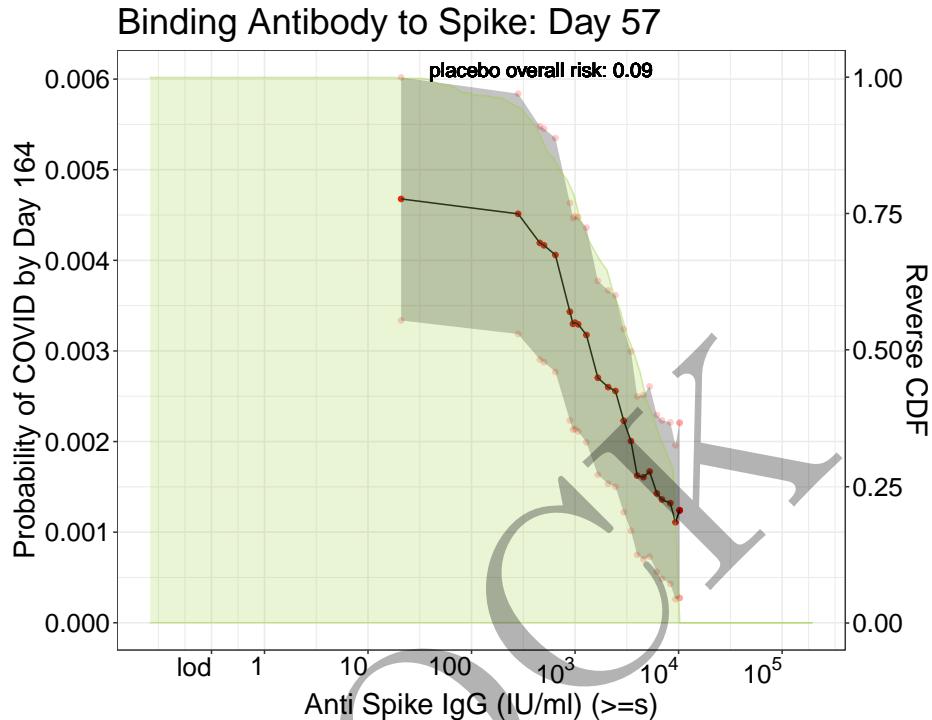


Figure 6.1: Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table 6.1: Table of risk estimates for a range of thresholds of Day 57 Spike protein binding antibody levels with pointwise 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
1.316	$2.07 * 10^1$	0.00468	0.00334	0.00602
2.699	$5.00 * 10^2$	0.00417	0.00288	0.00545
2.815	$6.53 * 10^2$	0.00406	0.00277	0.00535
2.982	$9.59 * 10^2$	0.00330	0.00213	0.00447
3.000	$1.00 * 10^3$	0.00331	0.00214	0.00449
3.113	$1.30 * 10^3$	0.00318	0.00199	0.00436
3.471	$2.96 * 10^3$	0.00223	0.00122	0.00324
3.658	$4.55 * 10^3$	0.00161	0.00070	0.00251
3.841	$6.93 * 10^3$	0.00136	0.00049	0.00223
4.006	$1.01 * 10^4$	0.00124	0.00027	0.00221
4.007	$1.02 * 10^4$	0.00124	0.00027	0.00220
4.007	$1.02 * 10^4$	0.00124	0.00027	0.00220
4.007	$1.02 * 10^4$	0.00124	0.00027	0.00220

6.1.2 Day 57 RBD binding antibody

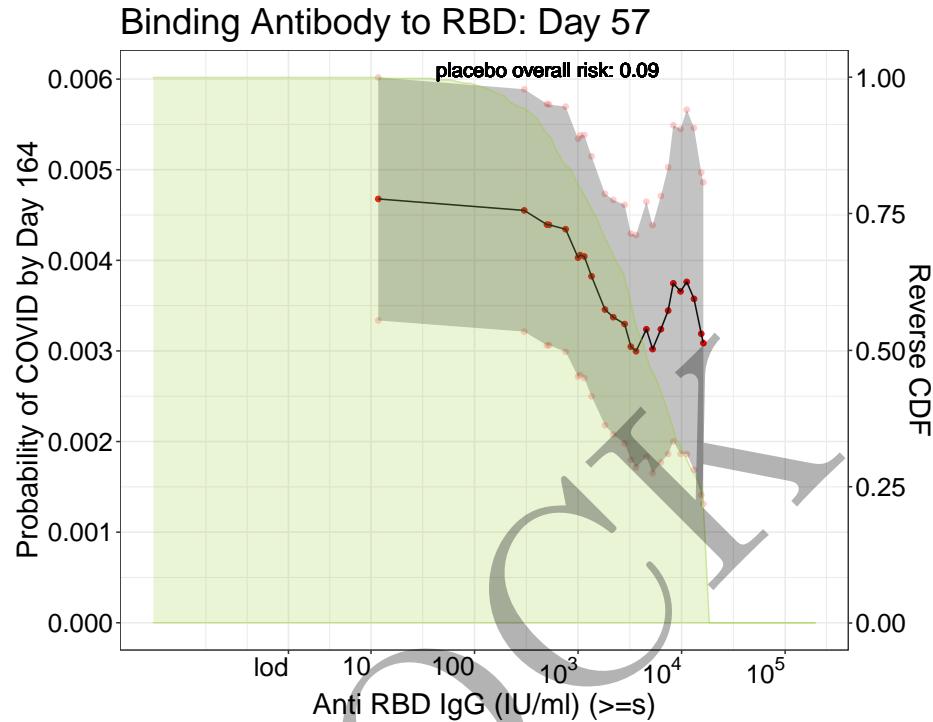


Figure 6.2: Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table 6.2: Table of risk estimates for a range of thresholds of Day 57 RBD binding antibody levels with pointwise 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
1.073	$1.18 * 10^1$	0.00468	0.00334	0.00602
2.699	$5.00 * 10^2$	0.00439	0.00306	0.00573
2.882	$7.62 * 10^2$	0.00434	0.00299	0.00570
3.000	$1.00 * 10^3$	0.00403	0.00272	0.00534
3.056	$1.14 * 10^3$	0.00404	0.00270	0.00538
3.259	$1.82 * 10^3$	0.00346	0.00218	0.00473
3.557	$3.61 * 10^3$	0.00300	0.00171	0.00428
3.797	$6.27 * 10^3$	0.00324	0.00177	0.00471
3.986	$9.68 * 10^3$	0.00366	0.00186	0.00545
4.186	$1.53 * 10^4$	0.00319	0.00141	0.00497
4.211	$1.63 * 10^4$	0.00309	0.00131	0.00486
4.211	$1.63 * 10^4$	0.00309	0.00131	0.00486
4.211	$1.63 * 10^4$	0.00309	0.00131	0.00486

6.1.3 Day 57 Pseudo virus-neutralizing antibody (50% titer)

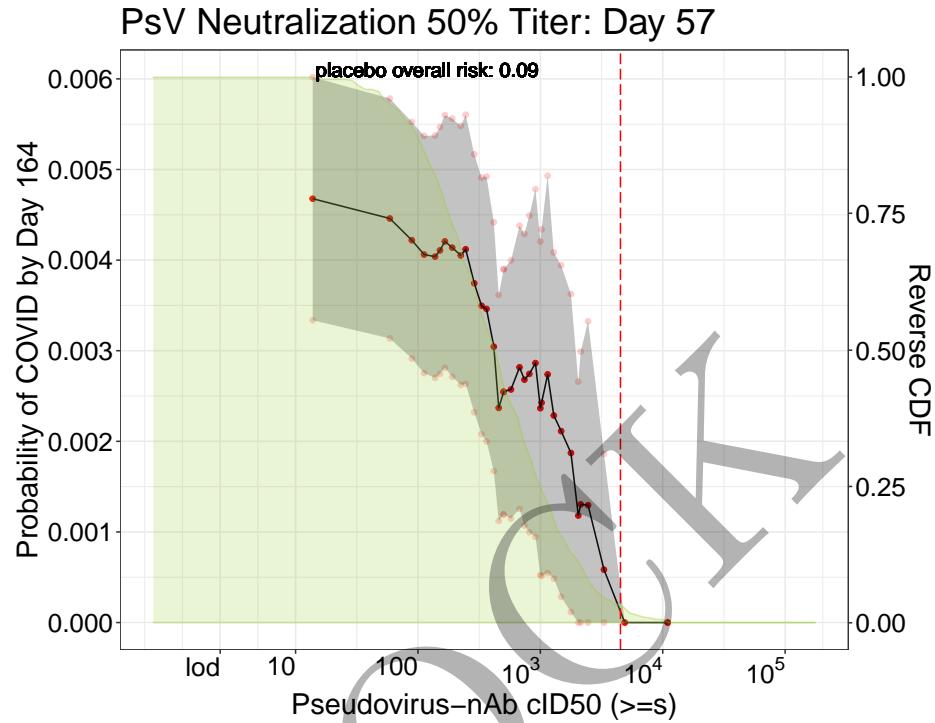


Figure 6.3: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table 6.3: Table of risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals.

log ₁₀ -Threshold	Threshold	Risk estimate	CI left	CI right
1.135	1.36 * 10 ¹	0.00468	0.00334	0.00602
2.055	1.14 * 10 ²	0.00406	0.00275	0.00537
2.177	1.50 * 10 ²	0.00411	0.00275	0.00547
2.281	1.91 * 10 ²	0.00414	0.00271	0.00556
2.519	3.30 * 10 ²	0.00350	0.00208	0.00491
2.657	4.54 * 10 ²	0.00237	0.00112	0.00362
2.699	5.00 * 10 ²	0.00255	0.00120	0.00390
2.828	6.73 * 10 ²	0.00282	0.00125	0.00438
2.959	9.10 * 10 ²	0.00286	0.00094	0.00478
3.000	1.00 * 10 ³	0.00236	0.00053	0.00420
3.174	1.49 * 10 ³	0.00211	0.00028	0.00394
3.307	2.03 * 10 ³	0.00118	0.00000	0.00266
3.387	2.44 * 10 ³	0.00130	0.00000	0.00333
4.038	1.09 * 10 ⁴	0.00000	0.00000	NA

6.1.4 Day 57 Pseudo virus-neutralizing antibody (80% titer)

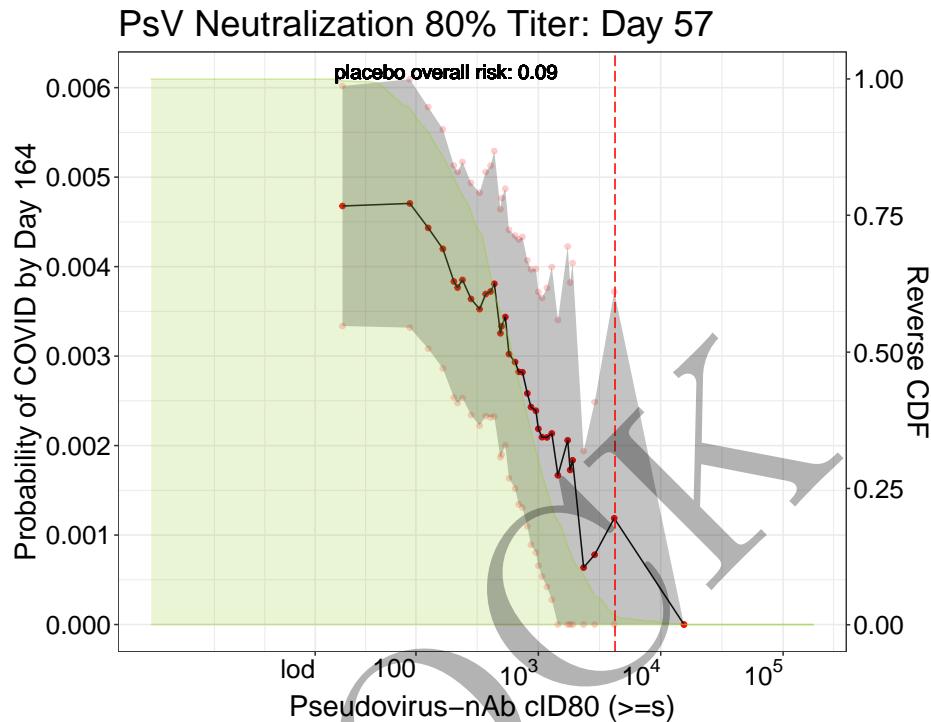


Figure 6.4: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table 6.4: Table of risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals.

log ₁₀ -Threshold	Threshold	Risk estimate	CI left	CI right
1.403	2.53×10^1	0.00468	0.00334	0.00602
2.220	1.66×10^2	0.00420	0.00286	0.00553
2.335	2.16×10^2	0.00377	0.00247	0.00506
2.455	2.85×10^2	0.00364	0.00234	0.00494
2.644	4.41×10^2	0.00381	0.00232	0.00529
2.699	5.00×10^2	0.00333	0.00190	0.00477
2.764	5.81×10^2	0.00302	0.00163	0.00441
2.874	7.48×10^2	0.00282	0.00131	0.00433
2.981	9.57×10^2	0.00239	0.00080	0.00397
3.000	1.00×10^3	0.00219	0.00066	0.00372
3.162	1.45×10^3	0.00167	0.00000	0.00340
3.265	1.84×10^3	0.00173	0.00000	0.00382
3.371	2.35×10^3	0.00064	0.00000	0.00194
4.187	1.54×10^4	0.00000	0.00000	NA

6.2 Plots and Tables with estimates and pointwise confidence intervals for Day 29

MOCK

6.2.1 Day 29 Spike protein antibody

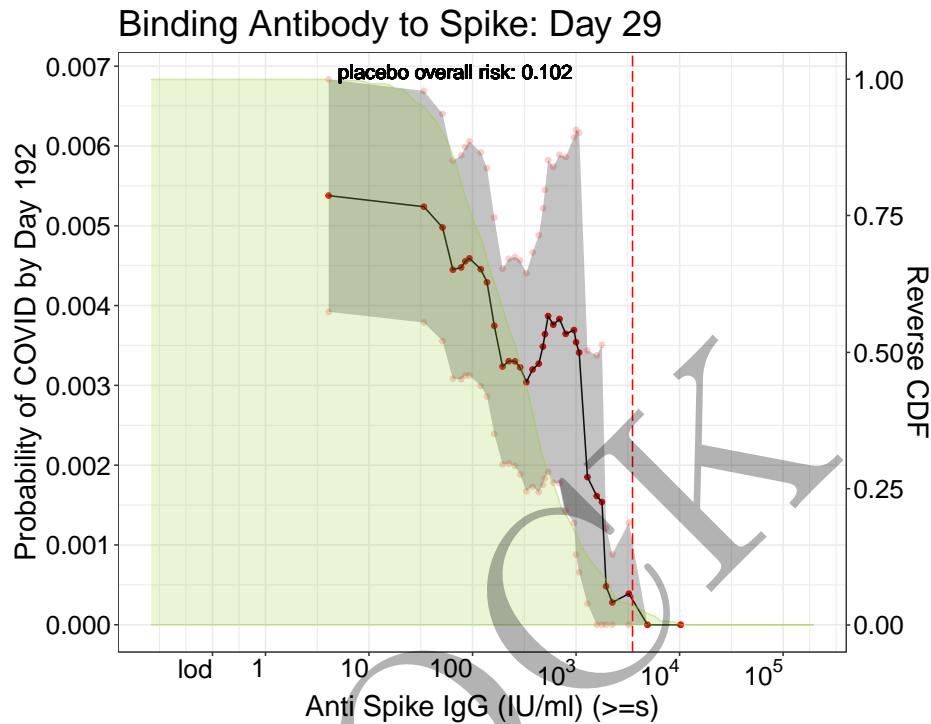


Figure 6.5: Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table 6.5: Table of risk estimates for a range of thresholds of Day 29 Spike protein antibody levels with pointwise 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
0.613	4.10×10^0	0.00538	0.00392	0.00683
1.805	6.38×10^1	0.00445	0.00308	0.00581
1.927	8.45×10^1	0.00455	0.00312	0.00599
2.081	1.21×10^2	0.00446	0.00299	0.00592
2.351	2.24×10^2	0.00330	0.00202	0.00459
2.522	3.33×10^2	0.00304	0.00167	0.00441
2.677	4.75×10^2	0.00349	0.00175	0.00522
2.699	5.00×10^2	0.00364	0.00183	0.00545
2.841	6.93×10^2	0.00383	0.00177	0.00589
3.000	1.00×10^3	0.00354	0.00088	0.00620
3.112	1.29×10^3	0.00185	0.00026	0.00344
3.252	1.79×10^3	0.00154	0.00000	0.00351
3.348	2.23×10^3	0.00028	0.00000	0.00088
4.007	1.02×10^4	0.00000	0.00000	NA

6.2.2 Day 29 RBD binding antibody

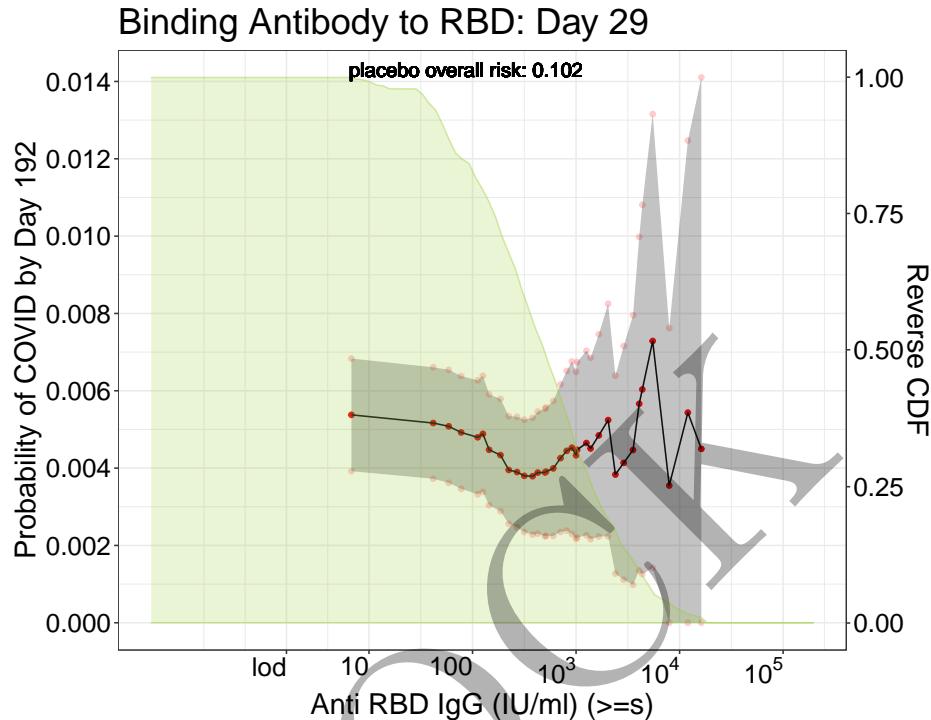


Figure 6.6: Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table 6.6: Table of risk estimates for a range of thresholds of Day 29 RBD binding antibody levels with pointwise 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
0.834	$6.82 * 10^0$	0.00538	0.00392	0.00683
1.892	$7.80 * 10^1$	0.00492	0.00346	0.00638
2.098	$1.25 * 10^2$	0.00489	0.00338	0.00639
2.273	$1.87 * 10^2$	0.00434	0.00288	0.00579
2.575	$3.76 * 10^2$	0.00379	0.00228	0.00530
2.699	$5.00 * 10^2$	0.00389	0.00224	0.00554
2.780	$6.03 * 10^2$	0.00399	0.00225	0.00574
2.960	$9.12 * 10^2$	0.00453	0.00230	0.00676
3.000	$1.00 * 10^3$	0.00433	0.00217	0.00650
3.144	$1.39 * 10^3$	0.00451	0.00216	0.00685
3.461	$2.89 * 10^3$	0.00413	0.00111	0.00716
3.610	$4.07 * 10^3$	0.00566	0.00135	0.00998
3.736	$5.45 * 10^3$	0.00729	0.00142	0.01316
4.211	$1.63 * 10^4$	0.00450	0.00000	0.01410

6.2.3 Day 29 Pseudo virus-neutralizing antibody (50% titer)

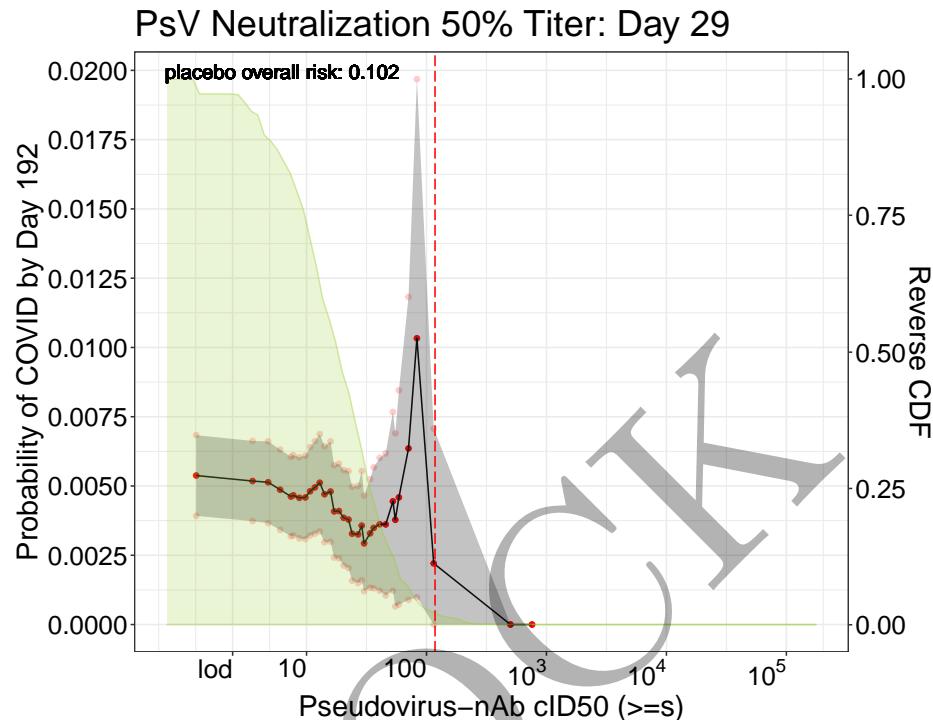


Figure 6.7: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table 6.7: Table of risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
0.083	$1.21 * 10^0$	0.00538	0.00392	0.00683
0.779	$6.01 * 10^0$	0.00487	0.00342	0.00631
0.892	$7.80 * 10^0$	0.00466	0.00321	0.00611
0.988	$9.73 * 10^0$	0.00459	0.00308	0.00609
1.147	$1.40 * 10^1$	0.00470	0.00297	0.00643
1.271	$1.87 * 10^1$	0.00410	0.00239	0.00581
1.382	$2.41 * 10^1$	0.00328	0.00158	0.00497
1.481	$3.03 * 10^1$	0.00293	0.00121	0.00465
1.656	$4.53 * 10^1$	0.00361	0.00105	0.00618
1.741	$5.51 * 10^1$	0.00378	0.00066	0.00690
1.852	$7.11 * 10^1$	0.00636	0.00089	0.01182
2.699	$5.00 * 10^2$	0.00000	0.00000	NA
2.879	$7.57 * 10^2$	0.00000	0.00000	NA
2.879	$7.57 * 10^2$	0.00000	0.00000	NA

6.2.4 Day 29 Pseudo virus-neutralizing antibody (80% titer)

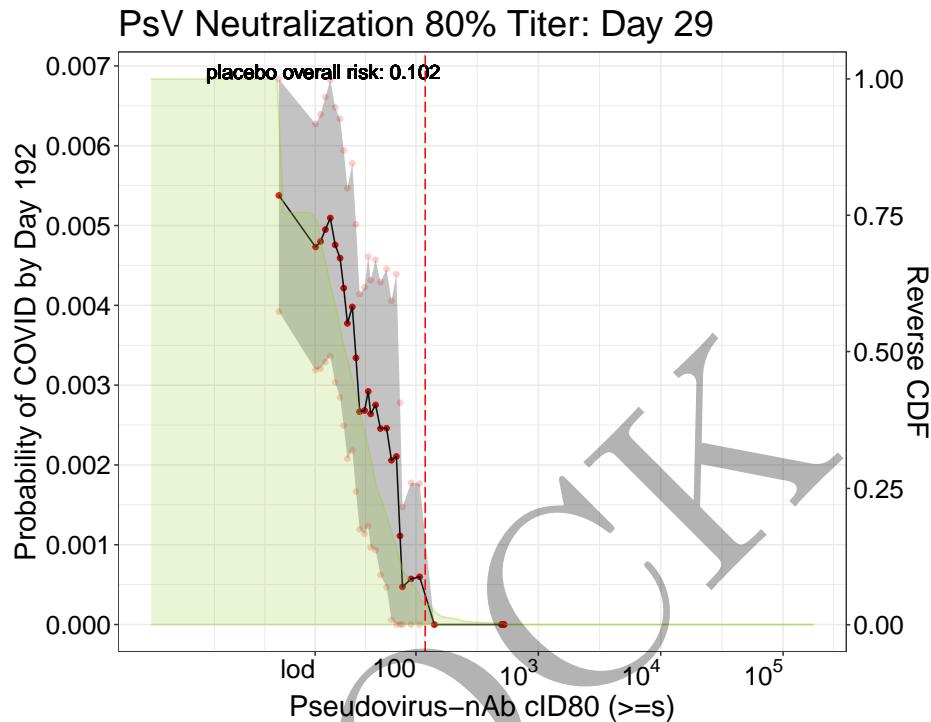


Figure 6.8: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table 6.8: Table of risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals.

log ₁₀ -Threshold	Threshold	Risk estimate	CI left	CI right
0.876	7.52 * 10 ⁰	0.00538	0.00392	0.00683
0.876	7.52 * 10 ⁰	0.00538	0.00392	0.00683
0.876	7.52 * 10 ⁰	0.00538	0.00392	0.00683
1.183	1.52 * 10 ¹	0.00473	0.00319	0.00627
1.339	2.18 * 10 ¹	0.00476	0.00304	0.00648
1.440	2.75 * 10 ¹	0.00377	0.00208	0.00547
1.541	3.48 * 10 ¹	0.00267	0.00119	0.00414
1.632	4.29 * 10 ¹	0.00264	0.00097	0.00431
1.796	6.25 * 10 ¹	0.00206	0.00006	0.00406
1.868	7.38 * 10 ¹	0.00111	0.00000	0.00278
1.956	9.04 * 10 ¹	0.00057	0.00000	0.00178
2.699	5.00 * 10 ²	0.00000	0.00000	NA
2.719	5.24 * 10 ²	0.00000	0.00000	NA
2.719	5.24 * 10 ²	0.00000	0.00000	NA

6.3 Plots and Tables with estimates and pointwise confidence interval for Day 57 (monotone-corrected)

MOCK

6.3.1 Day 57 Spike protein binding antibody

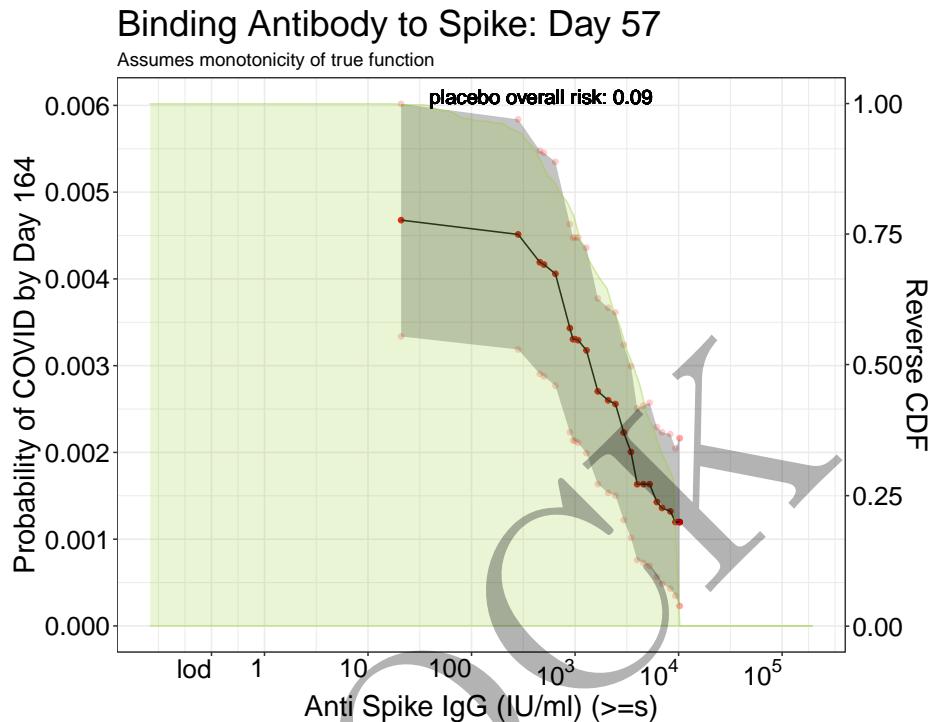


Figure 6.9: Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.9: Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Spike protein binding antibody levels with pointwise 95% confidence intervals.

log ₁₀ -Threshold	Threshold	Risk estimate	CI left	CI right
1.316	2.07 * 10 ¹	0.00468	0.00334	0.00602
2.699	5.00 * 10 ²	0.00417	0.00288	0.00545
2.815	6.53 * 10 ²	0.00406	0.00277	0.00535
2.982	9.59 * 10 ²	0.00331	0.00214	0.00447
3.000	1.00 * 10 ³	0.00331	0.00213	0.00448
3.113	1.30 * 10 ³	0.00318	0.00199	0.00436
3.471	2.96 * 10 ³	0.00223	0.00122	0.00324
3.658	4.55 * 10 ³	0.00163	0.00073	0.00254
3.841	6.93 * 10 ³	0.00136	0.00049	0.00223
4.006	1.01 * 10 ⁴	0.00120	0.00023	0.00217
4.007	1.02 * 10 ⁴	0.00120	0.00023	0.00216
4.007	1.02 * 10 ⁴	0.00120	0.00023	0.00216
4.007	1.02 * 10 ⁴	0.00120	0.00023	0.00216

6.3.2 Day 57 RBD binding antibody

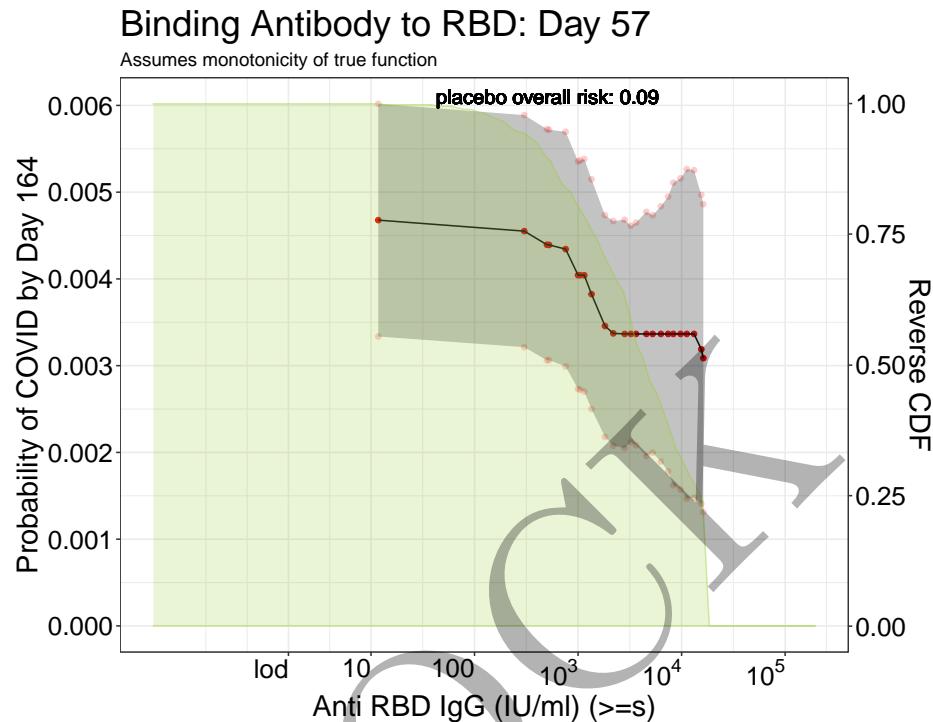


Figure 6.10: Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.10: Table of monotone-corrected risk estimates for a range of thresholds of Day 57 RBD binding antibody levels with pointwise 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
1.073	$1.18 * 10^1$	0.00468	0.00334	0.00602
2.699	$5.00 * 10^2$	0.00439	0.00306	0.00573
2.882	$7.62 * 10^2$	0.00434	0.00299	0.00570
3.000	$1.00 * 10^3$	0.00404	0.00273	0.00536
3.056	$1.14 * 10^3$	0.00404	0.00270	0.00538
3.259	$1.82 * 10^3$	0.00346	0.00218	0.00473
3.557	$3.61 * 10^3$	0.00337	0.00208	0.00465
3.797	$6.27 * 10^3$	0.00337	0.00190	0.00484
3.986	$9.68 * 10^3$	0.00337	0.00157	0.00516
4.186	$1.53 * 10^4$	0.00319	0.00141	0.00497
4.211	$1.63 * 10^4$	0.00309	0.00131	0.00486
4.211	$1.63 * 10^4$	0.00309	0.00131	0.00486
4.211	$1.63 * 10^4$	0.00309	0.00131	0.00486

6.3.3 Day 57 Pseudo virus-neutralizing antibody (50% titer)

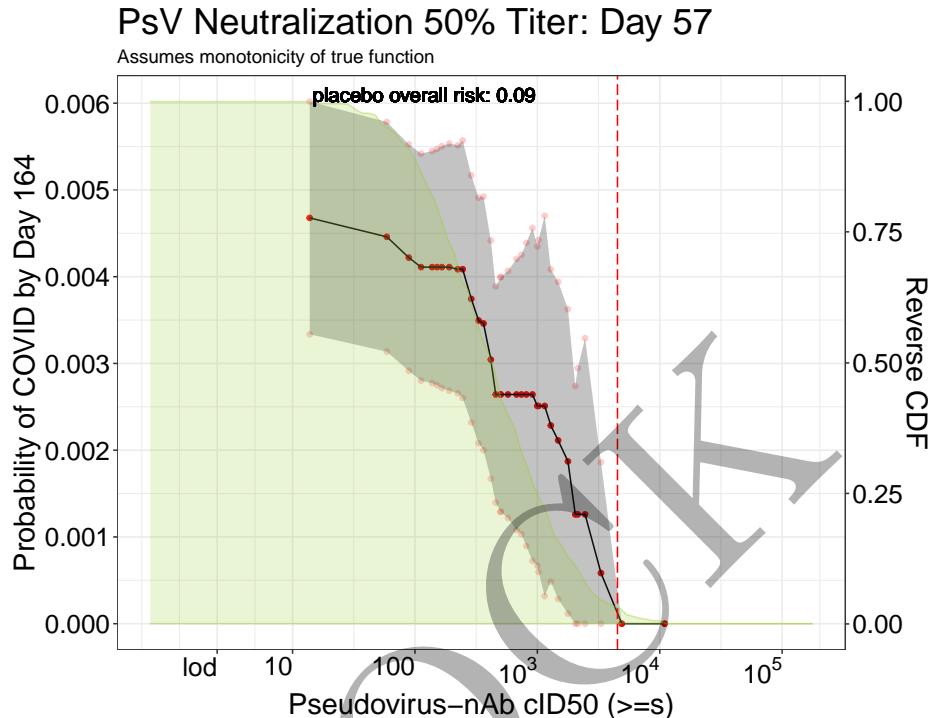


Figure 6.11: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.11: Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
1.135	1.36×10^1	0.00468	0.00334	0.00602
2.055	1.14×10^2	0.00411	0.00280	0.00542
2.177	1.50×10^2	0.00411	0.00275	0.00547
2.281	1.91×10^2	0.00411	0.00269	0.00553
2.519	3.30×10^2	0.00350	0.00208	0.00491
2.657	4.54×10^2	0.00264	0.00140	0.00389
2.699	5.00×10^2	0.00264	0.00129	0.00400
2.828	6.73×10^2	0.00264	0.00108	0.00420
2.959	9.10×10^2	0.00264	0.00072	0.00456
3.000	1.00×10^3	0.00251	0.00067	0.00435
3.174	1.49×10^3	0.00211	0.00028	0.00394
3.307	2.03×10^3	0.00126	0.00000	0.00274
3.387	2.44×10^3	0.00126	0.00000	0.00329
4.038	1.09×10^4	0.00000	0.00000	NA

6.3.4 Day 57 Pseudo virus-neutralizing antibody (80% titer)

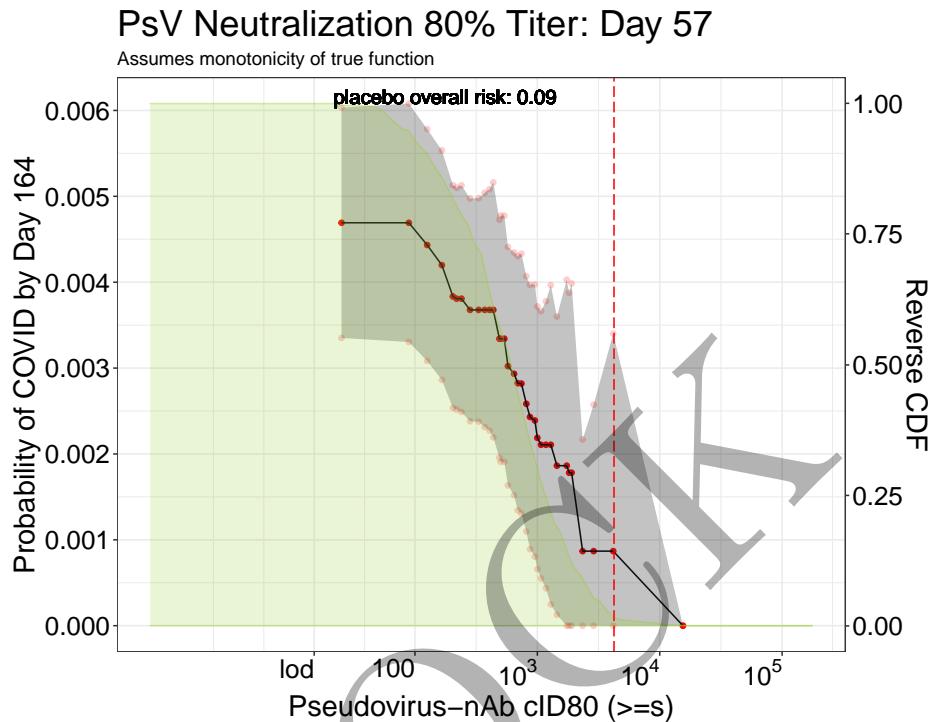


Figure 6.12: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.12: Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
1.403	$2.53 * 10^1$	0.00469	0.00335	0.00603
2.220	$1.66 * 10^2$	0.00420	0.00286	0.00553
2.335	$2.16 * 10^2$	0.00381	0.00252	0.00510
2.455	$2.85 * 10^2$	0.00368	0.00238	0.00497
2.644	$4.41 * 10^2$	0.00368	0.00219	0.00516
2.699	$5.00 * 10^2$	0.00334	0.00191	0.00477
2.764	$5.81 * 10^2$	0.00302	0.00163	0.00441
2.874	$7.48 * 10^2$	0.00282	0.00131	0.00433
2.981	$9.57 * 10^2$	0.00239	0.00080	0.00397
3.000	$1.00 * 10^3$	0.00219	0.00066	0.00372
3.162	$1.45 * 10^3$	0.00186	0.00013	0.00360
3.265	$1.84 * 10^3$	0.00178	0.00000	0.00388
3.371	$2.35 * 10^3$	0.00087	0.00000	0.00217
4.187	$1.54 * 10^4$	0.00000	0.00000	NA

6.4 Plots and Tables with estimates and pointwise confidence intervals for Day 29 (monotone-corrected)

MOCK

6.4.1 Day 29 Spike protein antibody

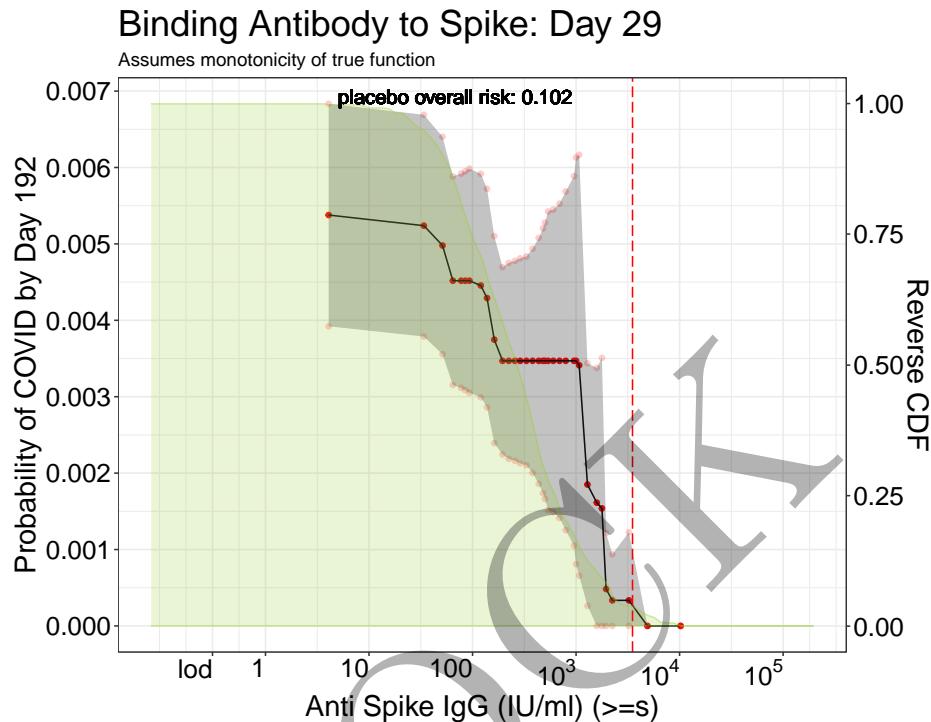


Figure 6.13: Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.13: Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Spike protein antibody levels with pointwise 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
0.613	4.10×10^0	0.00538	0.00392	0.00683
1.805	6.38×10^1	0.00452	0.00315	0.00588
1.927	8.45×10^1	0.00452	0.00309	0.00595
2.081	1.21×10^2	0.00446	0.00299	0.00592
2.351	2.24×10^2	0.00347	0.00219	0.00475
2.522	3.33×10^2	0.00347	0.00210	0.00484
2.677	4.75×10^2	0.00347	0.00174	0.00520
2.699	5.00×10^2	0.00347	0.00166	0.00528
2.841	6.93×10^2	0.00347	0.00141	0.00553
3.000	1.00×10^3	0.00347	0.00081	0.00613
3.112	1.29×10^3	0.00185	0.00026	0.00344
3.252	1.79×10^3	0.00154	0.00000	0.00351
3.348	2.23×10^3	0.00033	0.00000	0.00094
4.007	1.02×10^4	0.00000	0.00000	NA

6.4.2 Day 29 RBD binding antibody

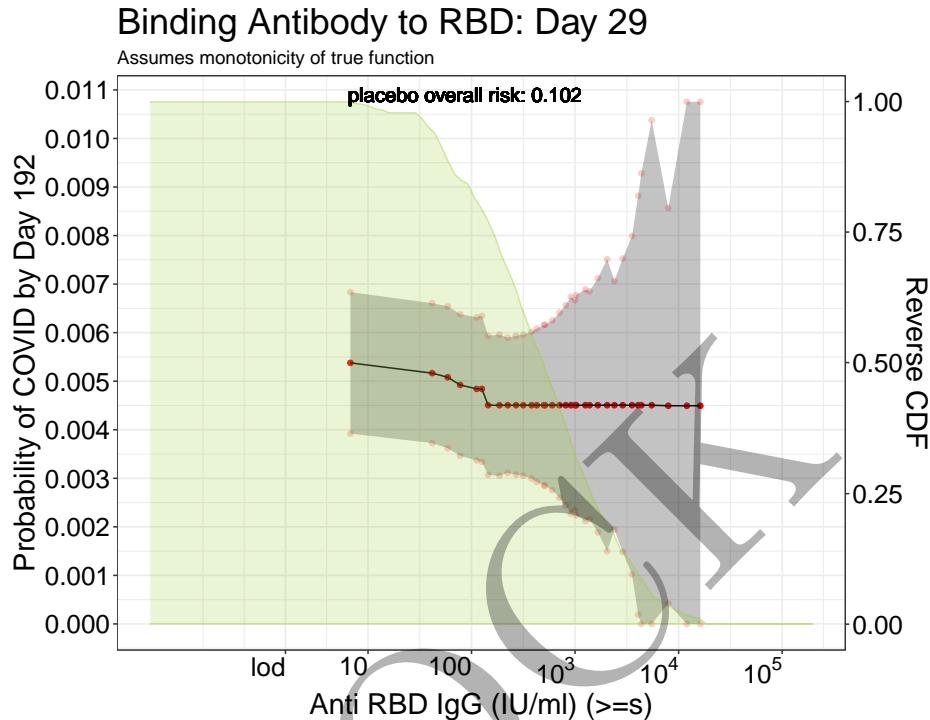


Figure 6.14: Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.14: Table of monotone-corrected risk estimates for a range of thresholds of Day 29 RBD binding antibody levels with pointwise 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
0.834	6.82×10^0	0.00538	0.00392	0.00683
1.892	7.80×10^1	0.00492	0.00346	0.00638
2.098	1.25×10^2	0.00484	0.00334	0.00634
2.273	1.87×10^2	0.00451	0.00305	0.00596
2.575	3.76×10^2	0.00451	0.00299	0.00602
2.699	5.00×10^2	0.00451	0.00285	0.00616
2.780	6.03×10^2	0.00451	0.00276	0.00625
2.960	9.12×10^2	0.00451	0.00227	0.00674
3.000	1.00×10^3	0.00451	0.00234	0.00667
3.144	1.39×10^3	0.00451	0.00216	0.00685
3.461	2.89×10^3	0.00451	0.00148	0.00753
3.610	4.07×10^3	0.00451	0.00019	0.00882
3.736	5.45×10^3	0.00451	0.00000	0.01037
4.211	1.63×10^4	0.00449	0.00000	0.01410

6.4.3 Day 29 Pseudo virus-neutralizing antibody (50% titer)

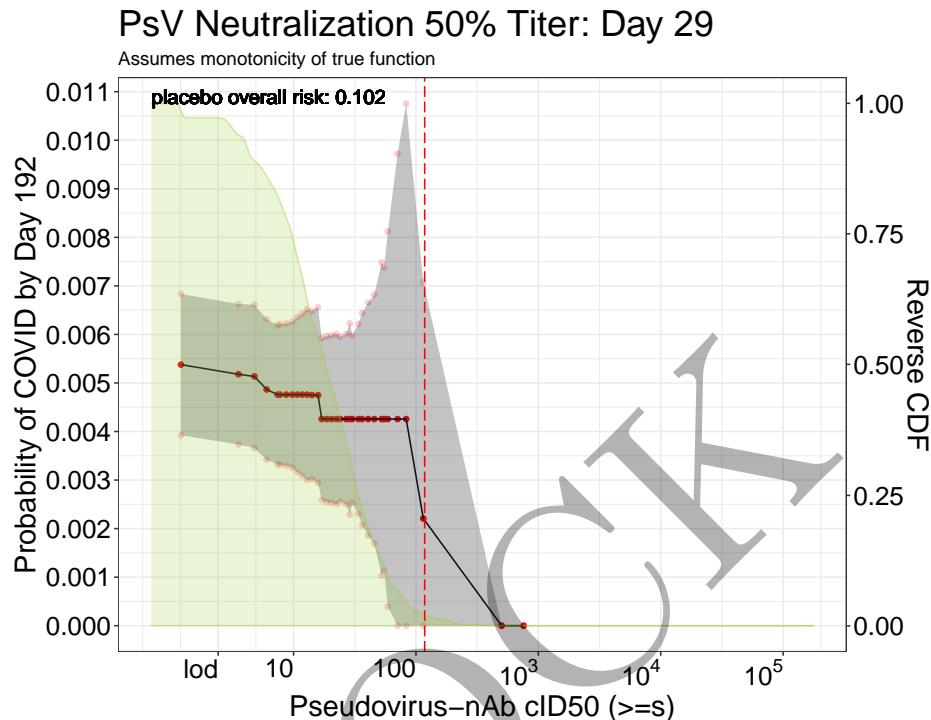


Figure 6.15: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.15: Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
0.083	$1.21 * 10^0$	0.00538	0.00392	0.00683
0.779	$6.01 * 10^0$	0.00487	0.00342	0.00631
0.892	$7.80 * 10^0$	0.00476	0.00331	0.00621
0.988	$9.73 * 10^0$	0.00476	0.00326	0.00626
1.147	$1.40 * 10^1$	0.00475	0.00302	0.00648
1.271	$1.87 * 10^1$	0.00426	0.00255	0.00597
1.382	$2.41 * 10^1$	0.00426	0.00256	0.00595
1.481	$3.03 * 10^1$	0.00426	0.00253	0.00598
1.656	$4.53 * 10^1$	0.00426	0.00169	0.00682
1.741	$5.51 * 10^1$	0.00426	0.00113	0.00738
1.852	$7.11 * 10^1$	0.00426	0.00000	0.00972
2.699	$5.00 * 10^2$	0.00000	0.00000	NA
2.879	$7.57 * 10^2$	0.00000	0.00000	NA
2.879	$7.57 * 10^2$	0.00000	0.00000	NA

6.4.4 Day 29 Pseudo virus-neutralizing antibody (80% titer)

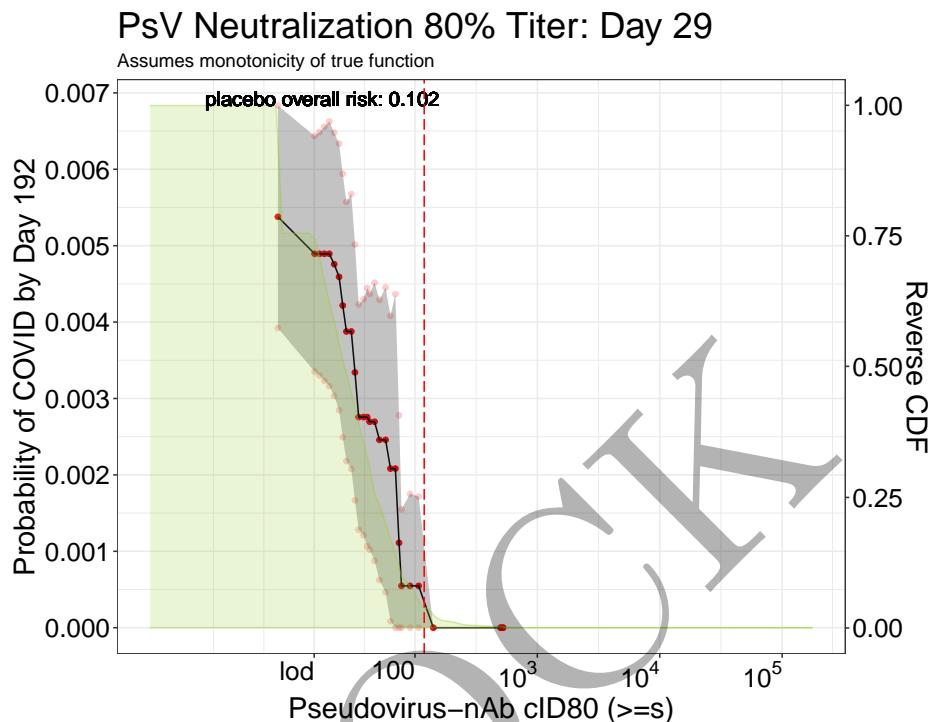


Figure 6.16: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.16: Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
	$0.876 \cdot 7.52 \cdot 10^0$	0.00538	0.00392	0.00683
	$0.876 \cdot 7.52 \cdot 10^0$	0.00538	0.00392	0.00683
	$0.876 \cdot 7.52 \cdot 10^0$	0.00538	0.00392	0.00683
	$1.183 \cdot 1.52 \cdot 10^1$	0.00489	0.00335	0.00644
	$1.339 \cdot 2.18 \cdot 10^1$	0.00476	0.00304	0.00648
	$1.440 \cdot 2.75 \cdot 10^1$	0.00388	0.00218	0.00557
	$1.541 \cdot 3.48 \cdot 10^1$	0.00276	0.00128	0.00423
	$1.632 \cdot 4.29 \cdot 10^1$	0.00270	0.00102	0.00437
	$1.796 \cdot 6.25 \cdot 10^1$	0.00208	0.00008	0.00408
	$1.868 \cdot 7.38 \cdot 10^1$	0.00111	0.00000	0.00278
	$1.956 \cdot 9.04 \cdot 10^1$	0.00055	0.00000	0.00175
	$2.699 \cdot 5.00 \cdot 10^2$	0.00000	0.00000	NA
	$2.719 \cdot 5.24 \cdot 10^2$	0.00000	0.00000	NA
	$2.719 \cdot 5.24 \cdot 10^2$	0.00000	0.00000	NA

6.5 Plots and Tables with estimates and simultaneous confidence bands for Day 57

MOCK

6.5.1 Day 57 Spike protein binding antibody

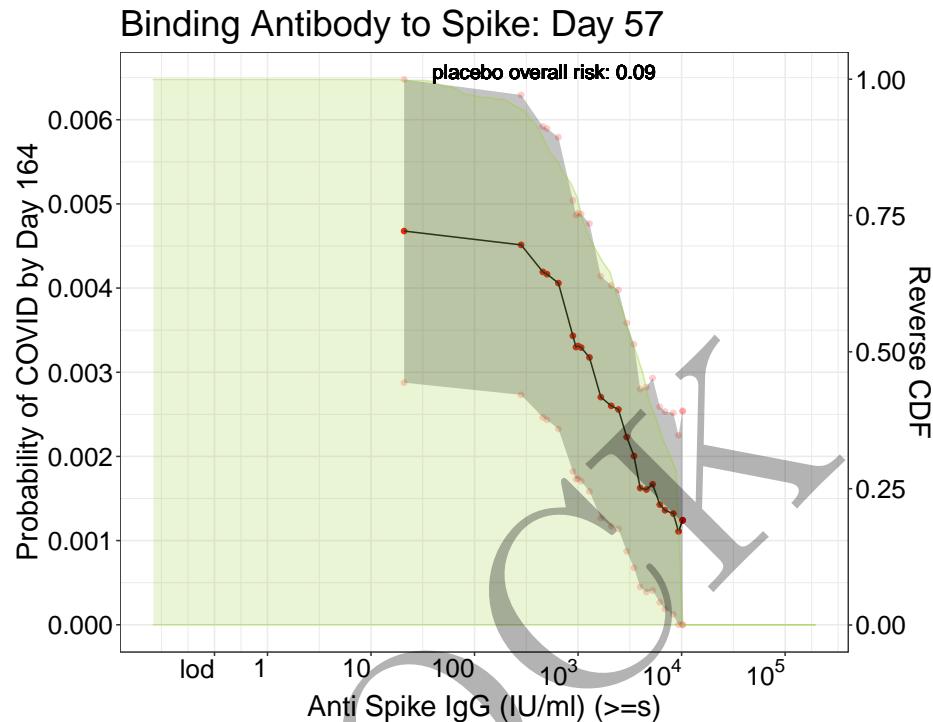


Figure 6.17: Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table 6.17: Table of risk estimates for a range of thresholds of Day 57 Spike protein binding antibody levels with simultaneous 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
1.316	$2.07 * 10^1$	0.00468	0.00288	0.00648
2.699	$5.00 * 10^2$	0.00417	0.00243	0.00590
2.815	$6.53 * 10^2$	0.00406	0.00233	0.00579
2.982	$9.59 * 10^2$	0.00330	0.00173	0.00487
3.000	$1.00 * 10^3$	0.00331	0.00173	0.00489
3.113	$1.30 * 10^3$	0.00318	0.00159	0.00477
3.471	$2.96 * 10^3$	0.00223	0.00087	0.00359
3.658	$4.55 * 10^3$	0.00161	0.00039	0.00282
3.841	$6.93 * 10^3$	0.00136	0.00019	0.00253
4.006	$1.01 * 10^4$	0.00124	0.00000	0.00254
4.007	$1.02 * 10^4$	0.00124	0.00000	0.00253
4.007	$1.02 * 10^4$	0.00124	0.00000	0.00253
4.007	$1.02 * 10^4$	0.00124	0.00000	0.00253

6.5.2 Day 57 RBD binding antibody

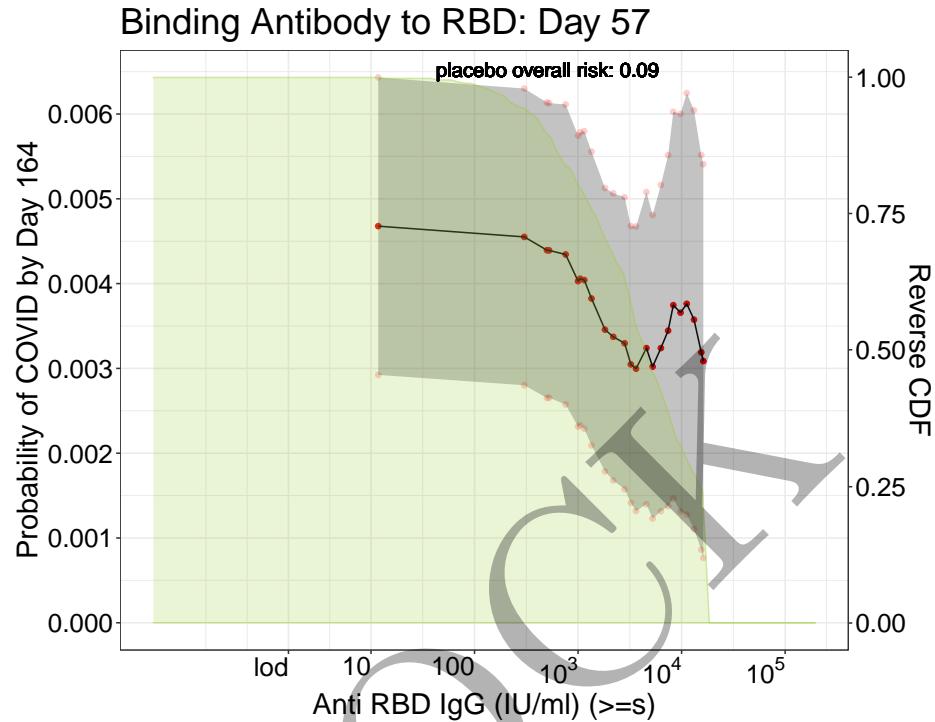


Figure 6.18: Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table 6.18: Table of risk estimates for a range of thresholds of Day 57 RBD binding antibody levels with simultaneous 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
1.073	$1.18 * 10^1$	0.00468	0.00292	0.00643
2.699	$5.00 * 10^2$	0.00439	0.00265	0.00614
2.882	$7.62 * 10^2$	0.00434	0.00257	0.00611
3.000	$1.00 * 10^3$	0.00403	0.00231	0.00575
3.056	$1.14 * 10^3$	0.00404	0.00229	0.00580
3.259	$1.82 * 10^3$	0.00346	0.00179	0.00513
3.557	$3.61 * 10^3$	0.00300	0.00132	0.00467
3.797	$6.27 * 10^3$	0.00324	0.00132	0.00516
3.986	$9.68 * 10^3$	0.00366	0.00131	0.00600
4.186	$1.53 * 10^4$	0.00319	0.00086	0.00552
4.211	$1.63 * 10^4$	0.00309	0.00077	0.00541
4.211	$1.63 * 10^4$	0.00309	0.00077	0.00541
4.211	$1.63 * 10^4$	0.00309	0.00077	0.00541

6.5.3 Day 57 Pseudo virus-neutralizing antibody (50% titer)

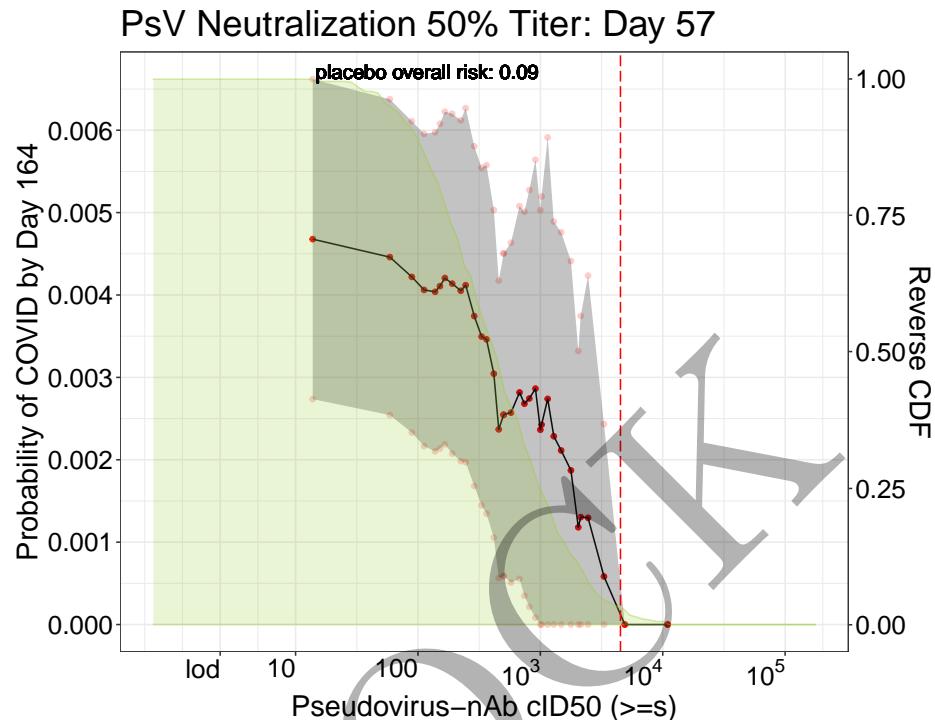


Figure 6.19: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table 6.19: Table of risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals.

log ₁₀ -Threshold	Threshold	Risk estimate	CI left	CI right
1.135	1.36 * 10 ¹	0.00468	0.00274	0.00662
2.055	1.14 * 10 ²	0.00406	0.00217	0.00596
2.177	1.50 * 10 ²	0.00411	0.00214	0.00608
2.281	1.91 * 10 ²	0.00414	0.00208	0.00620
2.519	3.30 * 10 ²	0.00350	0.00145	0.00554
2.657	4.54 * 10 ²	0.00237	0.00056	0.00417
2.699	5.00 * 10 ²	0.00255	0.00059	0.00451
2.828	6.73 * 10 ²	0.00282	0.00055	0.00508
2.959	9.10 * 10 ²	0.00286	0.00009	0.00564
3.000	1.00 * 10 ³	0.00236	0.00000	0.00503
3.174	1.49 * 10 ³	0.00211	0.00000	0.00476
3.307	2.03 * 10 ³	0.00118	0.00000	0.00332
3.387	2.44 * 10 ³	0.00130	0.00000	0.00424
4.038	1.09 * 10 ⁴	0.00000	0.00000	NA

6.5.4 Day 57 Pseudo virus-neutralizing antibody (80% titer)

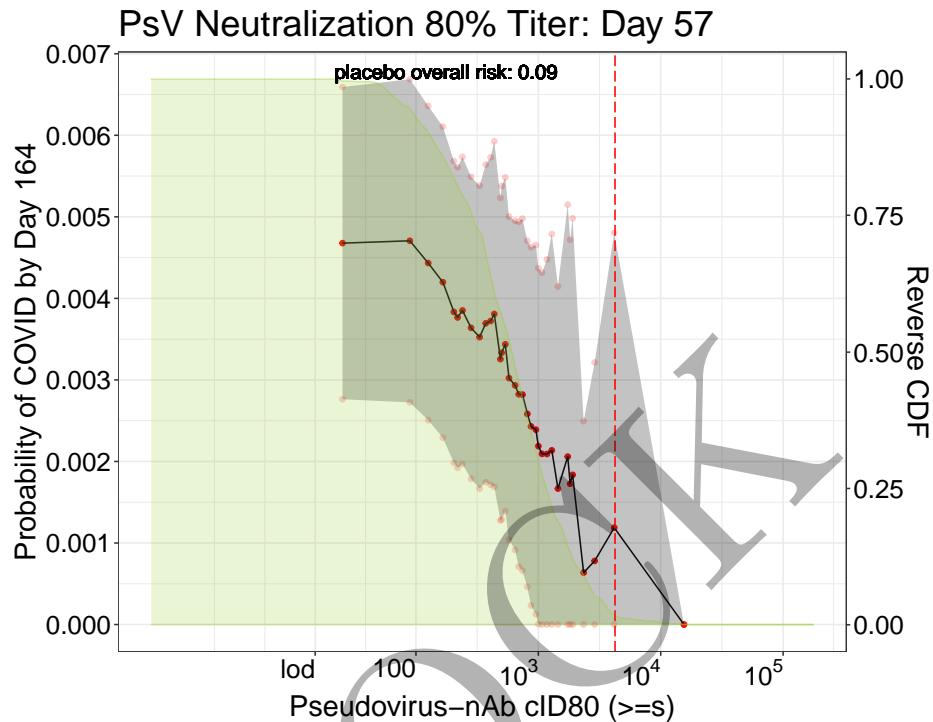


Figure 6.20: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table 6.20: Table of risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals.

log ₁₀ -Threshold	Threshold	Risk estimate	CI left	CI right
1.403	2.53 * 10 ¹	0.00468	0.00276	0.00659
2.220	1.66 * 10 ²	0.00420	0.00229	0.00611
2.335	2.16 * 10 ²	0.00377	0.00192	0.00561
2.455	2.85 * 10 ²	0.00364	0.00179	0.00549
2.644	4.41 * 10 ²	0.00381	0.00169	0.00593
2.699	5.00 * 10 ²	0.00333	0.00129	0.00538
2.764	5.81 * 10 ²	0.00302	0.00104	0.00500
2.874	7.48 * 10 ²	0.00282	0.00066	0.00498
2.981	9.57 * 10 ²	0.00239	0.00013	0.00465
3.000	1.00 * 10 ³	0.00219	0.00000	0.00437
3.162	1.45 * 10 ³	0.00167	0.00000	0.00415
3.265	1.84 * 10 ³	0.00173	0.00000	0.00472
3.371	2.35 * 10 ³	0.00064	0.00000	0.00249
4.187	1.54 * 10 ⁴	0.00000	0.00000	NA

6.6 Plots and Tables with estimates and simultaneous confidence bands for Day 29

MOCK

6.6.1 Day 29 Spike protein antibody

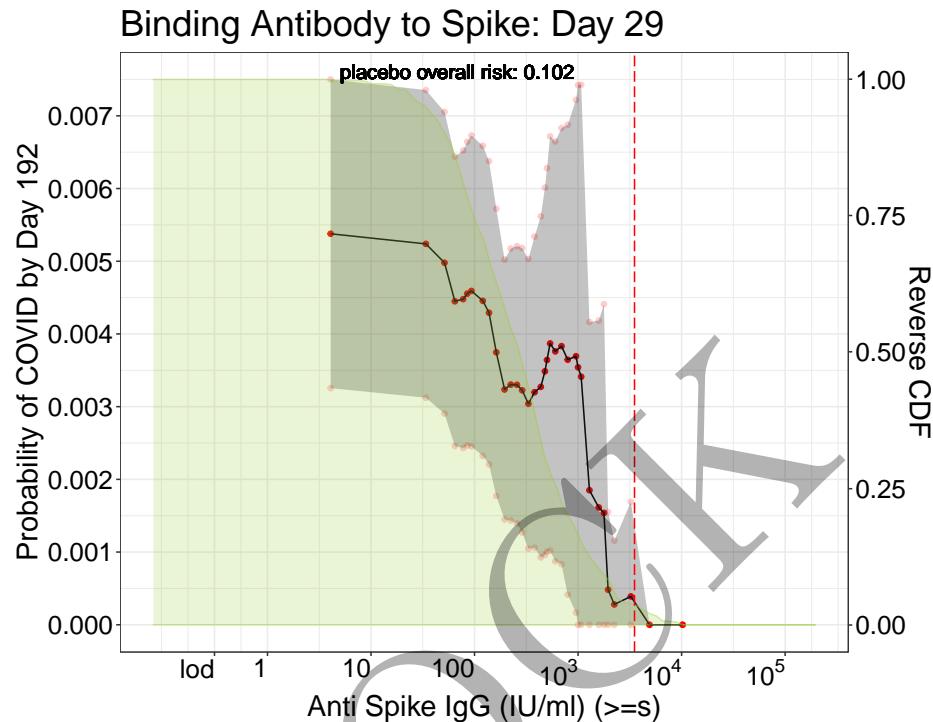


Figure 6.21: Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table 6.21: Table of risk estimates for a range of thresholds of Day 29 Spike protein antibody levels with simultaneous 95% confidence intervals.

log ₁₀ -Threshold	Threshold	Risk estimate	CI left	CI right
0.613	4.10×10^0	0.00538	0.00325	0.00750
1.805	6.38×10^1	0.00445	0.00246	0.00644
1.927	8.45×10^1	0.00455	0.00247	0.00664
2.081	1.21×10^2	0.00446	0.00232	0.00659
2.351	2.24×10^2	0.00330	0.00143	0.00517
2.522	3.33×10^2	0.00304	0.00105	0.00503
2.677	4.75×10^2	0.00349	0.00096	0.00601
2.699	5.00×10^2	0.00364	0.00101	0.00628
2.841	6.93×10^2	0.00383	0.00083	0.00683
3.000	1.00×10^3	0.00354	0.00000	0.00742
3.112	1.29×10^3	0.00185	0.00000	0.00416
3.252	1.79×10^3	0.00154	0.00000	0.00441
3.348	2.23×10^3	0.00028	0.00000	0.00116
4.007	1.02×10^4	0.00000	0.00000	NA

6.6.2 Day 29 RBD binding antibody

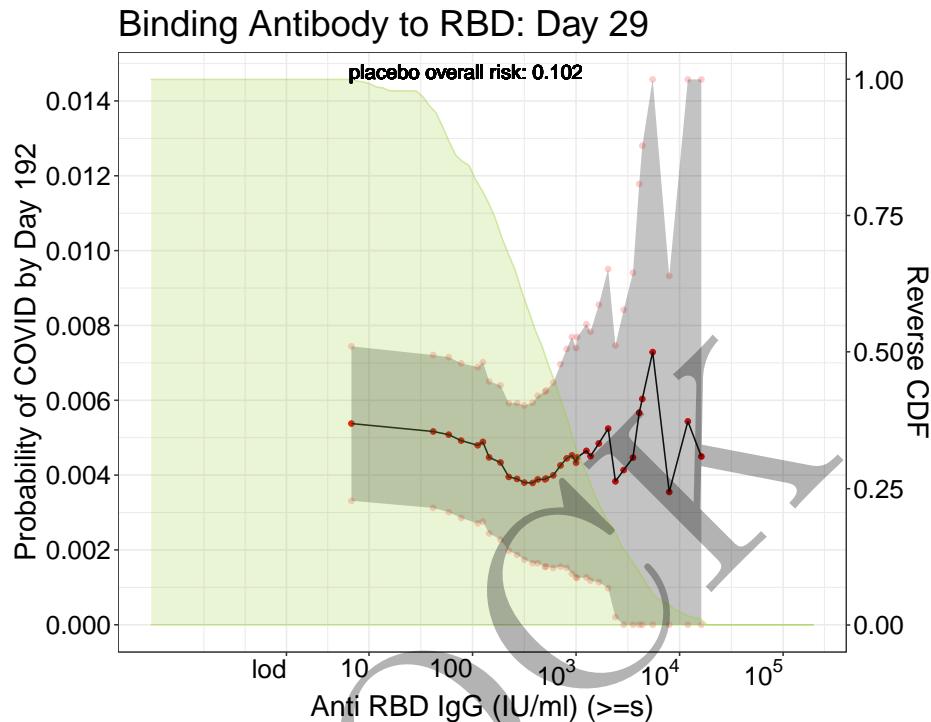


Figure 6.22: Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table 6.22: Table of risk estimates for a range of thresholds of Day 29 RBD binding antibody levels with simultaneous 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
0.834	$6.82 * 10^0$	0.00538	0.00331	0.00744
1.892	$7.80 * 10^1$	0.00492	0.00285	0.00699
2.098	$1.25 * 10^2$	0.00489	0.00276	0.00702
2.273	$1.87 * 10^2$	0.00434	0.00228	0.00640
2.575	$3.76 * 10^2$	0.00379	0.00165	0.00593
2.699	$5.00 * 10^2$	0.00389	0.00155	0.00623
2.780	$6.03 * 10^2$	0.00399	0.00152	0.00647
2.960	$9.12 * 10^2$	0.00453	0.00136	0.00769
3.000	$1.00 * 10^3$	0.00433	0.00127	0.00740
3.144	$1.39 * 10^3$	0.00451	0.00118	0.00783
3.461	$2.89 * 10^3$	0.00413	0.00000	0.00842
3.610	$4.07 * 10^3$	0.00566	0.00000	0.01178
3.736	$5.45 * 10^3$	0.00729	0.00000	0.01561
4.211	$1.63 * 10^4$	0.00450	0.00000	0.01812

6.6.3 Day 29 Pseudo virus-neutralizing antibody (50% titer)

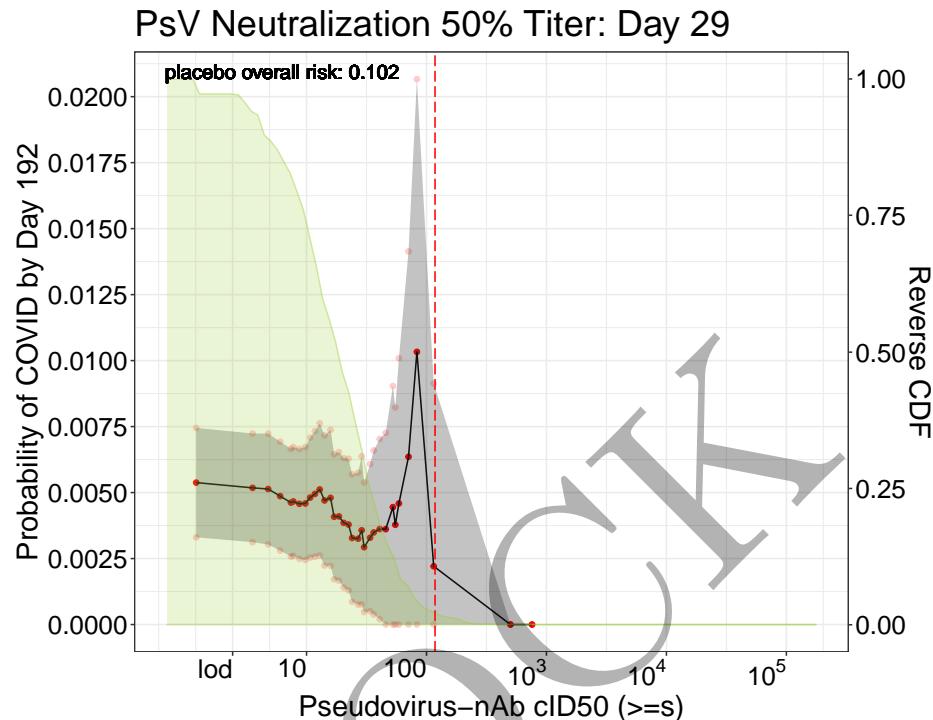


Figure 6.23: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table 6.23: Table of risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals.

log ₁₀ -Threshold	Threshold	Risk estimate	CI left	CI right
0.083	1.21 * 10 ⁰	0.00538	0.00331	0.00745
0.779	6.01 * 10 ⁰	0.00487	0.00280	0.00693
0.892	7.80 * 10 ⁰	0.00466	0.00260	0.00673
0.988	9.73 * 10 ⁰	0.00459	0.00245	0.00673
1.147	1.40 * 10 ¹	0.00470	0.00224	0.00717
1.271	1.87 * 10 ¹	0.00410	0.00166	0.00653
1.382	2.41 * 10 ¹	0.00328	0.00086	0.00569
1.481	3.03 * 10 ¹	0.00293	0.00048	0.00538
1.656	4.53 * 10 ¹	0.00361	0.00000	0.00726
1.741	5.51 * 10 ¹	0.00378	0.00000	0.00823
1.852	7.11 * 10 ¹	0.00636	0.00000	0.01414
2.699	5.00 * 10 ²	0.00000	0.00000	NA
2.879	7.57 * 10 ²	0.00000	0.00000	NA
2.879	7.57 * 10 ²	0.00000	0.00000	NA

6.6.4 Day 29 Pseudo virus-neutralizing antibody (80% titer)

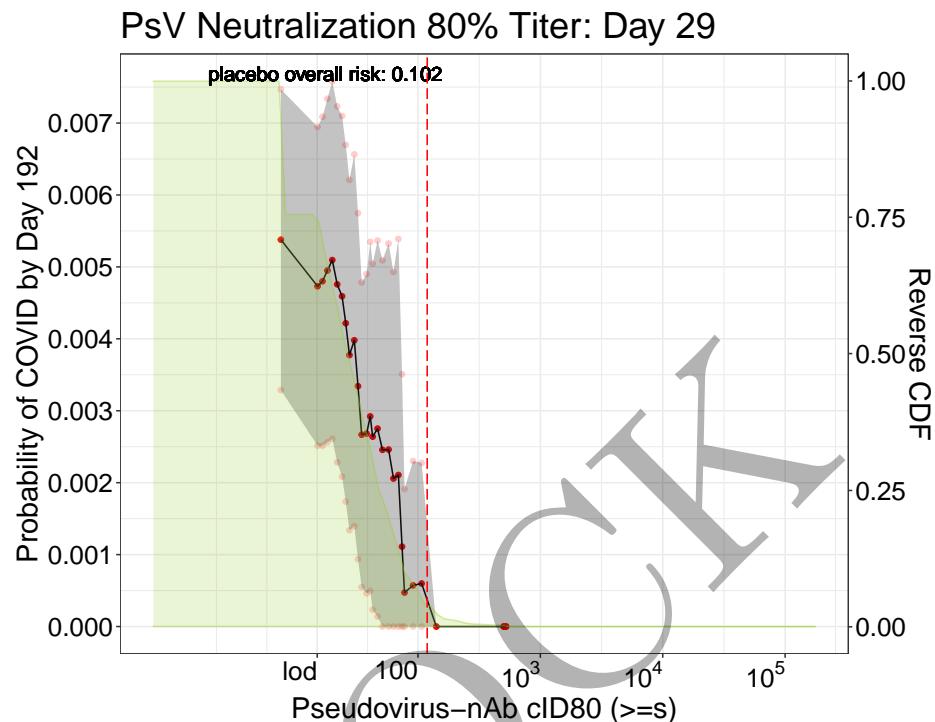


Figure 6.24: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table 6.24: Table of risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals.

log ₁₀ -Threshold	Threshold	Risk estimate	CI left	CI right
0.876	7.52 * 10 ⁰	0.00538	0.00329	0.00747
0.876	7.52 * 10 ⁰	0.00538	0.00329	0.00747
0.876	7.52 * 10 ⁰	0.00538	0.00329	0.00747
1.183	1.52 * 10 ¹	0.00473	0.00252	0.00695
1.339	2.18 * 10 ¹	0.00476	0.00228	0.00723
1.440	2.75 * 10 ¹	0.00377	0.00134	0.00621
1.541	3.48 * 10 ¹	0.00267	0.00055	0.00478
1.632	4.29 * 10 ¹	0.00264	0.00023	0.00504
1.796	6.25 * 10 ¹	0.00206	0.00000	0.00493
1.868	7.38 * 10 ¹	0.00111	0.00000	0.00351
1.956	9.04 * 10 ¹	0.00057	0.00000	0.00230
2.699	5.00 * 10 ²	0.00000	0.00000	NA
2.719	5.24 * 10 ²	0.00000	0.00000	NA
2.719	5.24 * 10 ²	0.00000	0.00000	NA

6.7 Plots and Tables with estimates and pointwise confidence interval for Day 57 (monotone-corrected)

MOCK

6.7.1 Day 57 Spike protein binding antibody

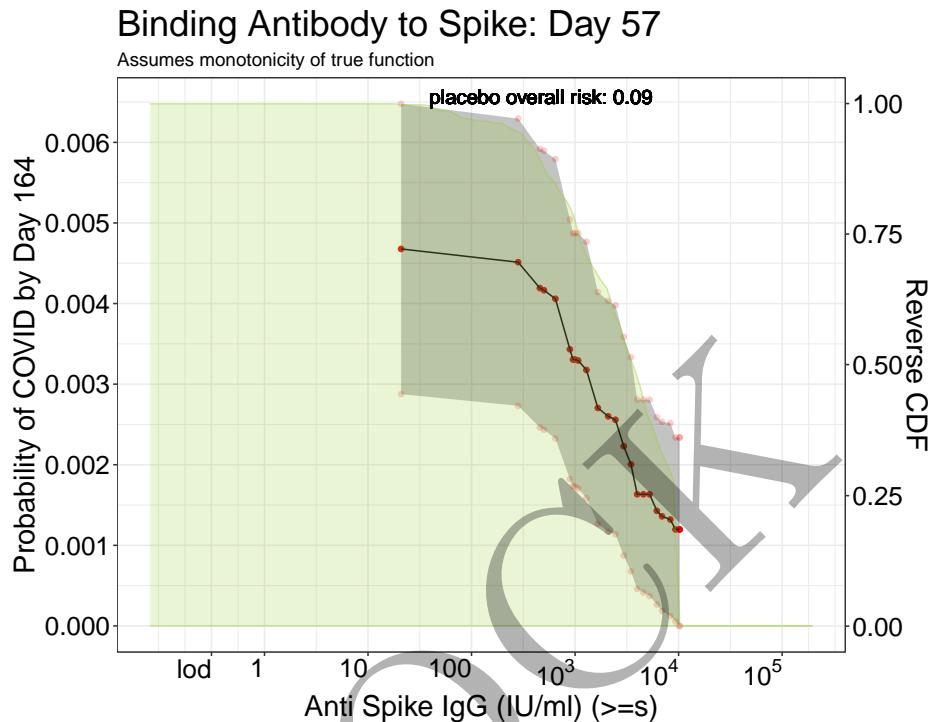


Figure 6.25: Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.25: Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Spike protein binding antibody levels with simultaneous 95% confidence intervals.

log ₁₀ -Threshold	Threshold	Risk estimate	CI left	CI right
1.316	2.07×10^1	0.00468	0.00288	0.00648
2.699	5.00×10^2	0.00417	0.00243	0.00590
2.815	6.53×10^2	0.00406	0.00233	0.00579
2.982	9.59×10^2	0.00331	0.00174	0.00487
3.000	1.00×10^3	0.00331	0.00173	0.00488
3.113	1.30×10^3	0.00318	0.00159	0.00477
3.471	2.96×10^3	0.00223	0.00087	0.00359
3.658	4.55×10^3	0.00163	0.00042	0.00285
3.841	6.93×10^3	0.00136	0.00019	0.00253
4.006	1.01×10^4	0.00120	0.00000	0.00250
4.007	1.02×10^4	0.00120	0.00000	0.00249
4.007	1.02×10^4	0.00120	0.00000	0.00249
4.007	1.02×10^4	0.00120	0.00000	0.00249

6.7.2 Day 57 RBD binding antibody

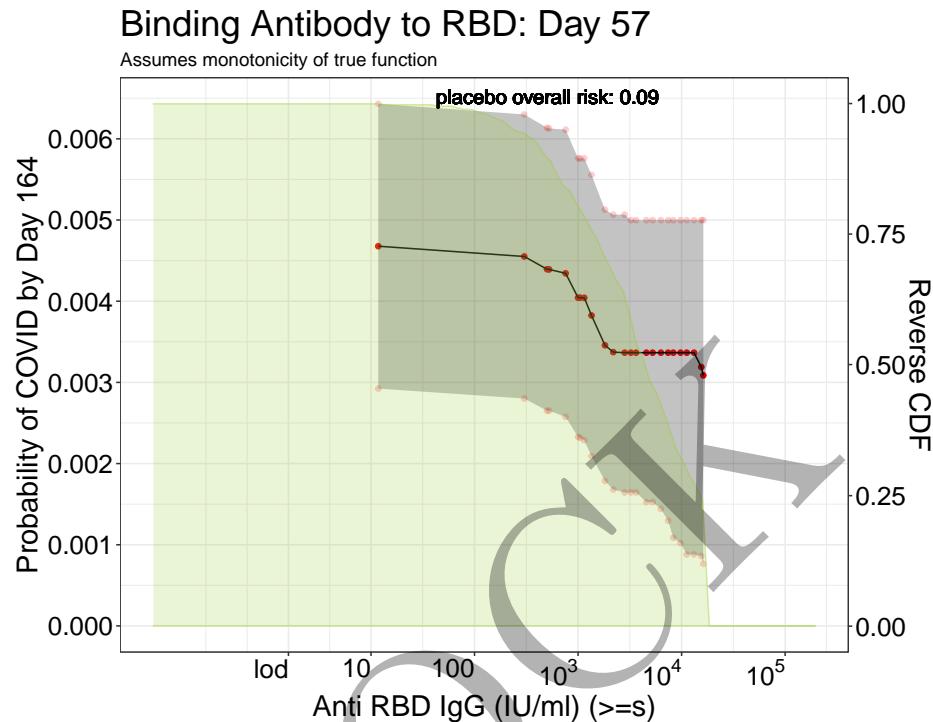


Figure 6.26: Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.26: Table of monotone-corrected risk estimates for a range of thresholds of Day 57 RBD binding antibody levels with simultaneous 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
1.073	$1.18 * 10^1$	0.00468	0.00292	0.00643
2.699	$5.00 * 10^2$	0.00439	0.00265	0.00614
2.882	$7.62 * 10^2$	0.00434	0.00257	0.00611
3.000	$1.00 * 10^3$	0.00404	0.00233	0.00576
3.056	$1.14 * 10^3$	0.00404	0.00229	0.00580
3.259	$1.82 * 10^3$	0.00346	0.00179	0.00513
3.557	$3.61 * 10^3$	0.00337	0.00169	0.00504
3.797	$6.27 * 10^3$	0.00337	0.00144	0.00529
3.986	$9.68 * 10^3$	0.00337	0.00102	0.00571
4.186	$1.53 * 10^4$	0.00319	0.00086	0.00552
4.211	$1.63 * 10^4$	0.00309	0.00077	0.00541
4.211	$1.63 * 10^4$	0.00309	0.00077	0.00541
4.211	$1.63 * 10^4$	0.00309	0.00077	0.00541

6.7.3 Day 57 Pseudo virus-neutralizing antibody (50% titer)

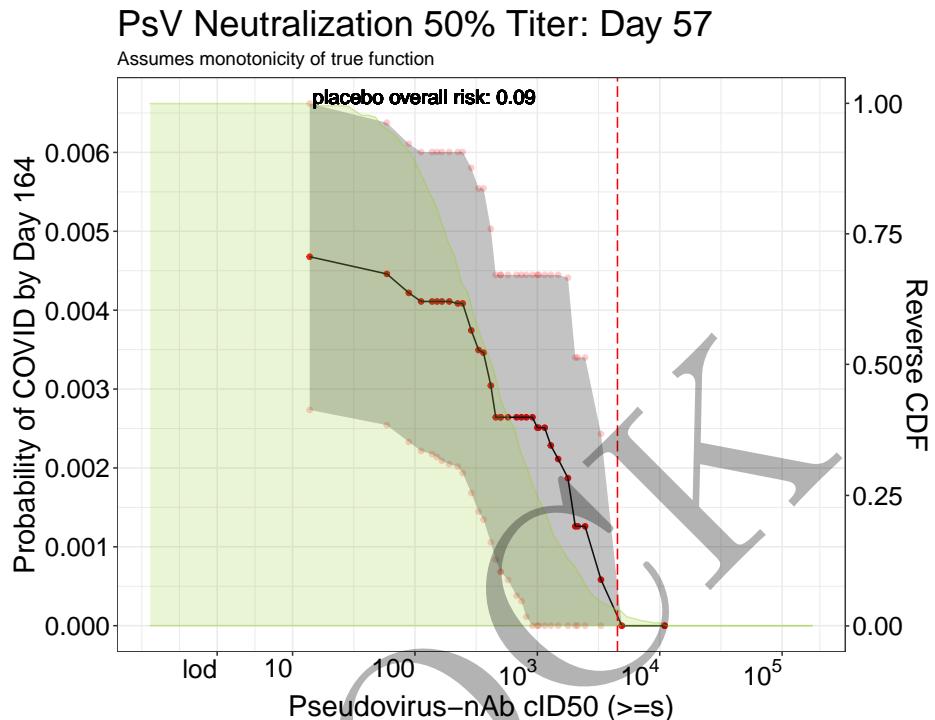


Figure 6.27: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.27: Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
1.135	1.36×10^1	0.00468	0.00274	0.00662
2.055	1.14×10^2	0.00411	0.00222	0.00601
2.177	1.50×10^2	0.00411	0.00214	0.00608
2.281	1.91×10^2	0.00411	0.00205	0.00617
2.519	3.30×10^2	0.00350	0.00145	0.00554
2.657	4.54×10^2	0.00264	0.00084	0.00445
2.699	5.00×10^2	0.00264	0.00068	0.00460
2.828	6.73×10^2	0.00264	0.00038	0.00490
2.959	9.10×10^2	0.00264	0.00000	0.00542
3.000	1.00×10^3	0.00251	0.00000	0.00517
3.174	1.49×10^3	0.00211	0.00000	0.00476
3.307	2.03×10^3	0.00126	0.00000	0.00340
3.387	2.44×10^3	0.00126	0.00000	0.00420
4.038	1.09×10^4	0.00000	0.00000	NA

6.7.4 Day 57 Pseudo virus-neutralizing antibody (80% titer)

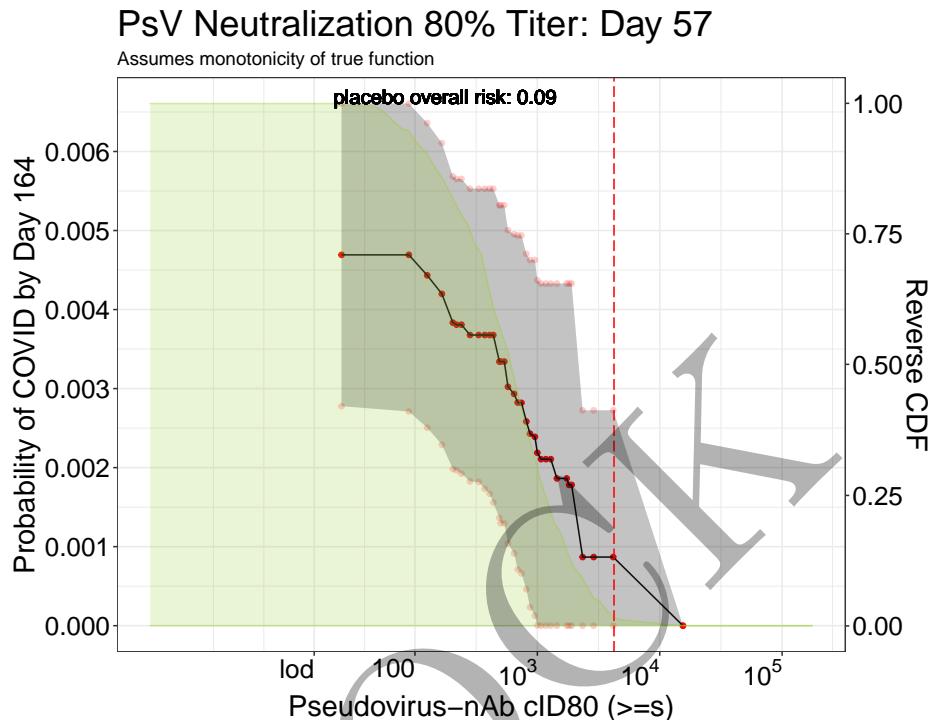


Figure 6.28: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.28: Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
1.403	2.53×10^1	0.00469	0.00278	0.00661
2.220	1.66×10^2	0.00420	0.00229	0.00611
2.335	2.16×10^2	0.00381	0.00196	0.00565
2.455	2.85×10^2	0.00368	0.00183	0.00553
2.644	4.41×10^2	0.00368	0.00156	0.00580
2.699	5.00×10^2	0.00334	0.00130	0.00539
2.764	5.81×10^2	0.00302	0.00104	0.00500
2.874	7.48×10^2	0.00282	0.00066	0.00498
2.981	9.57×10^2	0.00239	0.00013	0.00465
3.000	1.00×10^3	0.00219	0.00000	0.00437
3.162	1.45×10^3	0.00186	0.00000	0.00434
3.265	1.84×10^3	0.00178	0.00000	0.00477
3.371	2.35×10^3	0.00087	0.00000	0.00273
4.187	1.54×10^4	0.00000	0.00000	NA

6.8 Plots and Tables with estimates and pointwise confidence intervals for Day 29 (monotone-corrected)

MOCK

6.8.1 Day 29 Spike protein antibody

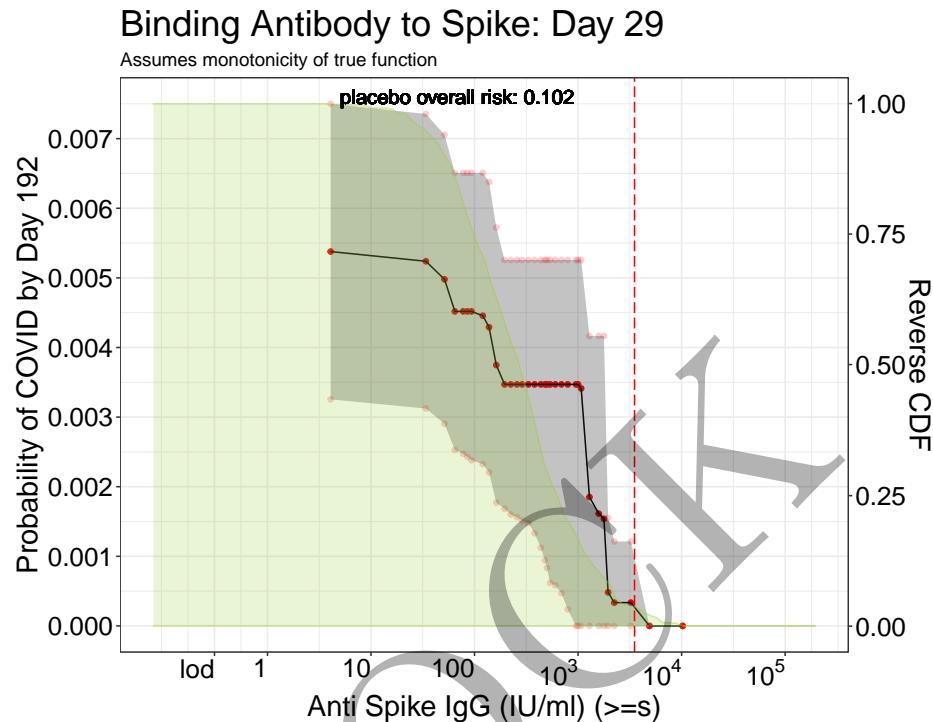


Figure 6.29: Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.29: Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Spike protein antibody levels with simultaneous 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
0.613	4.10×10^0	0.00538	0.00325	0.00750
1.805	6.38×10^1	0.00452	0.00253	0.00651
1.927	8.45×10^1	0.00452	0.00243	0.00661
2.081	1.21×10^2	0.00446	0.00232	0.00659
2.351	2.24×10^2	0.00347	0.00160	0.00534
2.522	3.33×10^2	0.00347	0.00148	0.00546
2.677	4.75×10^2	0.00347	0.00094	0.00600
2.699	5.00×10^2	0.00347	0.00083	0.00611
2.841	6.93×10^2	0.00347	0.00047	0.00647
3.000	1.00×10^3	0.00347	0.00000	0.00735
3.112	1.29×10^3	0.00185	0.00000	0.00416
3.252	1.79×10^3	0.00154	0.00000	0.00441
3.348	2.23×10^3	0.00033	0.00000	0.00121
4.007	1.02×10^4	0.00000	0.00000	NA

6.8.2 Day 29 RBD binding antibody

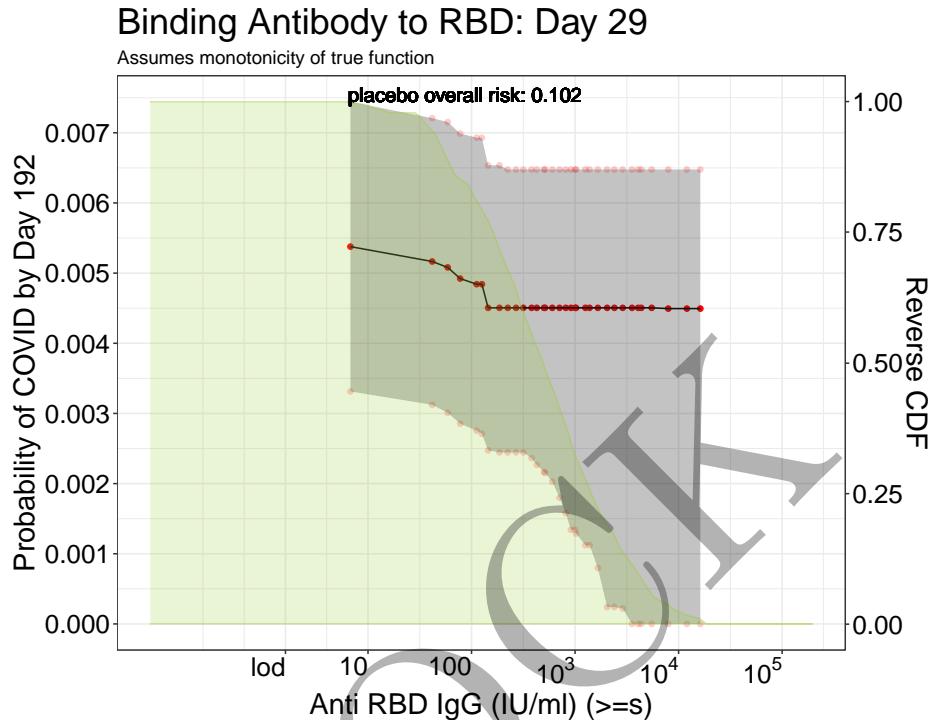


Figure 6.30: Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.30: Table of monotone-corrected risk estimates for a range of thresholds of Day 29 RBD binding antibody levels with simultaneous 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
0.834	$6.82 * 10^0$	0.00538	0.00331	0.00744
1.892	$7.80 * 10^1$	0.00492	0.00285	0.00699
2.098	$1.25 * 10^2$	0.00484	0.00271	0.00697
2.273	$1.87 * 10^2$	0.00451	0.00244	0.00657
2.575	$3.76 * 10^2$	0.00451	0.00236	0.00665
2.699	$5.00 * 10^2$	0.00451	0.00216	0.00685
2.780	$6.03 * 10^2$	0.00451	0.00203	0.00698
2.960	$9.12 * 10^2$	0.00451	0.00134	0.00767
3.000	$1.00 * 10^3$	0.00451	0.00144	0.00757
3.144	$1.39 * 10^3$	0.00451	0.00118	0.00783
3.461	$2.89 * 10^3$	0.00451	0.00022	0.00879
3.610	$4.07 * 10^3$	0.00451	0.00000	0.01062
3.736	$5.45 * 10^3$	0.00451	0.00000	0.01283
4.211	$1.63 * 10^4$	0.00449	0.00000	0.01811

6.8.3 Day 29 Pseudo virus-neutralizing antibody (50% titer)

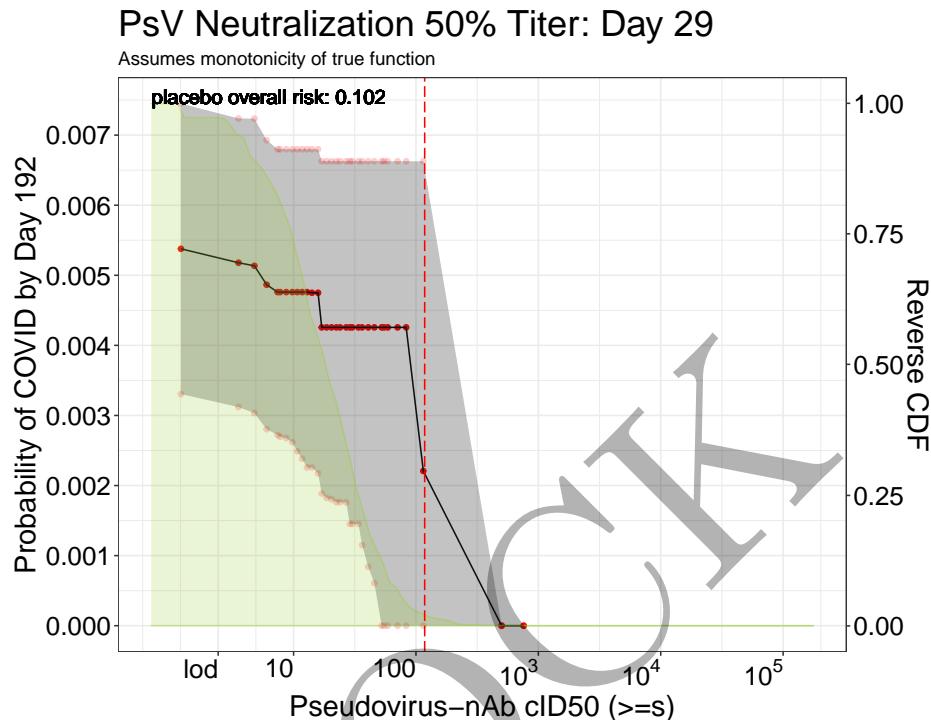


Figure 6.31: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.31: Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right	
	0.083	1.21 * 10^0	0.00538	0.00331	0.00745
	0.779	6.01 * 10^0	0.00487	0.00280	0.00693
	0.892	7.80 * 10^0	0.00476	0.00270	0.00682
	0.988	9.73 * 10^0	0.00476	0.00262	0.00690
	1.147	1.40 * 10^1	0.00475	0.00229	0.00722
	1.271	1.87 * 10^1	0.00426	0.00182	0.00669
	1.382	2.41 * 10^1	0.00426	0.00184	0.00667
	1.481	3.03 * 10^1	0.00426	0.00180	0.00671
	1.656	4.53 * 10^1	0.00426	0.00061	0.00791
	1.741	5.51 * 10^1	0.00426	0.00000	0.00870
	1.852	7.11 * 10^1	0.00426	0.00000	0.01204
	2.699	5.00 * 10^2	0.00000	0.00000	NA
	2.879	7.57 * 10^2	0.00000	0.00000	NA
	2.879	7.57 * 10^2	0.00000	0.00000	NA

6.8.4 Day 29 Pseudo virus-neutralizing antibody (80% titer)

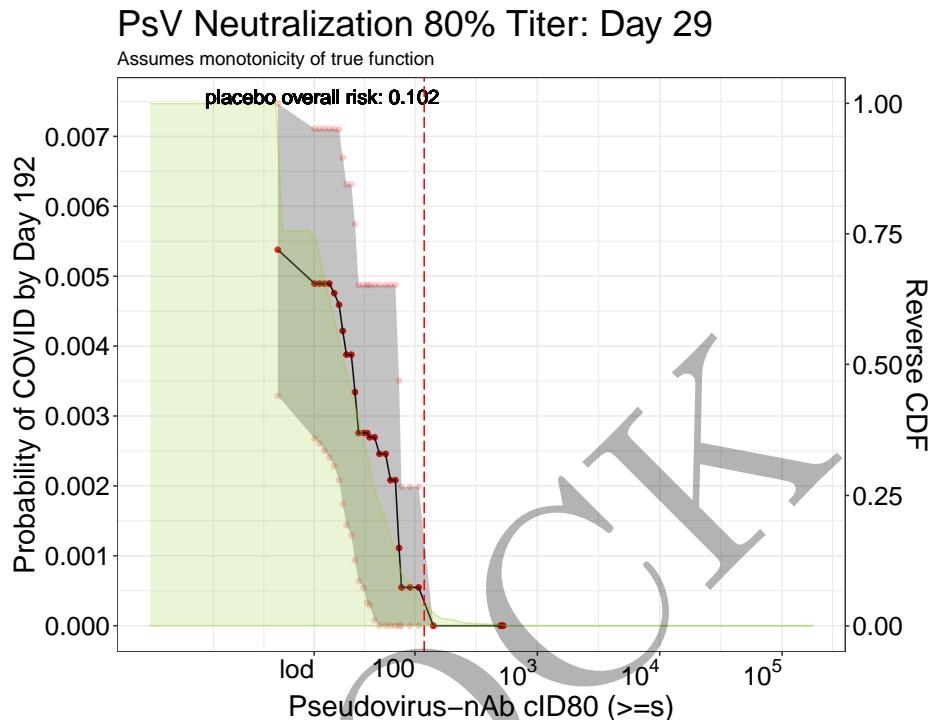


Figure 6.32: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.32: Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
0.876	$7.52 * 10^0$	0.00538	0.00329	0.00747
0.876	$7.52 * 10^0$	0.00538	0.00329	0.00747
0.876	$7.52 * 10^0$	0.00538	0.00329	0.00747
1.183	$1.52 * 10^1$	0.00489	0.00268	0.00711
1.339	$2.18 * 10^1$	0.00476	0.00228	0.00723
1.440	$2.75 * 10^1$	0.00388	0.00144	0.00631
1.541	$3.48 * 10^1$	0.00276	0.00064	0.00487
1.632	$4.29 * 10^1$	0.00270	0.00029	0.00510
1.796	$6.25 * 10^1$	0.00208	0.00000	0.00495
1.868	$7.38 * 10^1$	0.00111	0.00000	0.00351
1.956	$9.04 * 10^1$	0.00055	0.00000	0.00228
2.699	$5.00 * 10^2$	0.00000	0.00000	NA
2.719	$5.24 * 10^2$	0.00000	0.00000	NA
2.719	$5.24 * 10^2$	0.00000	0.00000	NA

MOCK

Chapter 7

Univariate CoR: Nonparametric Threshold Modeling ($\leq s$)

The same methodology as the previous section is apply to estimate the “below” threshold-response function $E_{W|A=1}[Y = 1 | A = 1, X, S \leq s]$.

7.1 Plots and Tables with estimates and pointwise confidence interval for Day 57

7.1.1 Day 57 Spike protein binding antibody

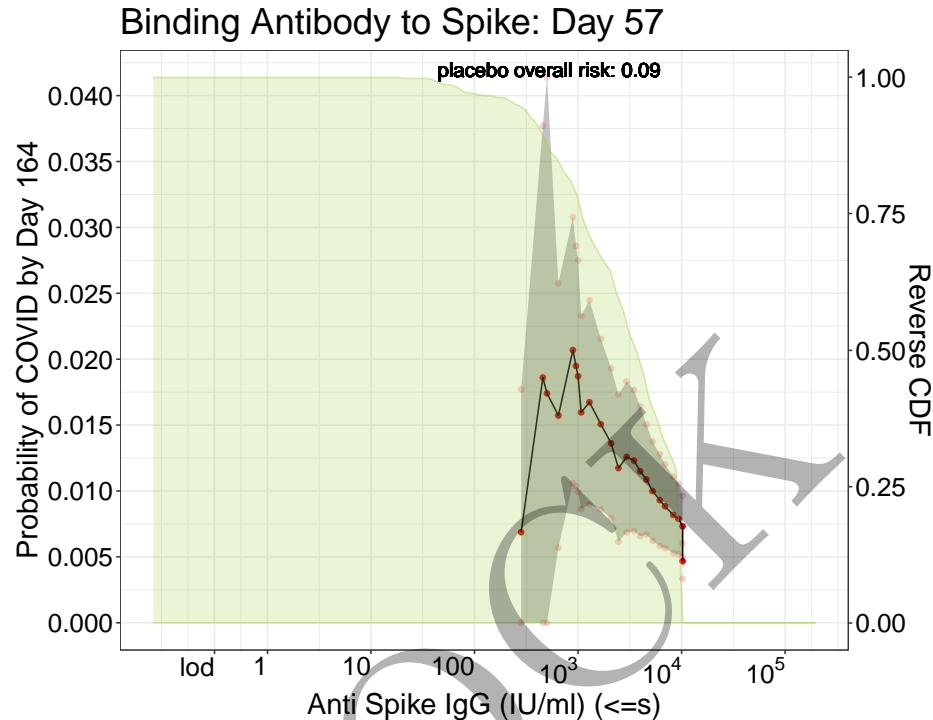


Figure 7.1: Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with pointwise 95% confidence intervals.

Table 7.1: Table of risk estimates for a range of thresholds of Day 57 Spike protein binding antibody levels with pointwise 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
2.450	$2.82 * 10^2$	0.00687	0.00000	0.01771
2.699	$5.00 * 10^2$	0.01741	0.00000	0.04344
2.815	$6.53 * 10^2$	0.01572	0.00569	0.02576
2.982	$9.59 * 10^2$	0.01948	0.01036	0.02860
3.000	$1.00 * 10^3$	0.01870	0.00992	0.02749
3.113	$1.30 * 10^3$	0.01674	0.00901	0.02447
3.471	$2.96 * 10^3$	0.01259	0.00687	0.01831
3.658	$4.55 * 10^3$	0.01087	0.00669	0.01505
3.841	$6.93 * 10^3$	0.00884	0.00566	0.01201
4.006	$1.01 * 10^4$	0.00732	0.00501	0.00964
4.007	$1.02 * 10^4$	0.00468	0.00334	0.00602
4.007	$1.02 * 10^4$	0.00468	0.00334	0.00602
4.007	$1.02 * 10^4$	0.00468	0.00334	0.00602

7.1.2 Day 57 RBD binding antibody

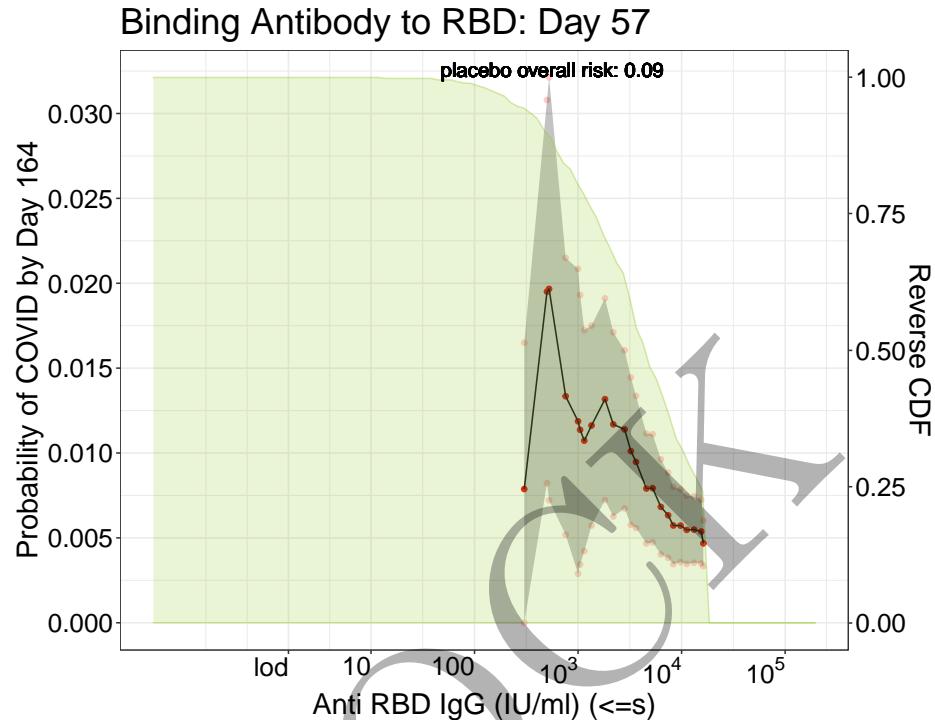


Figure 7.2: Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with pointwise 95% confidence intervals.

Table 7.2: Table of risk estimates for a range of thresholds of Day 57 RBD binding antibody levels with pointwise 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
2.478	$3.01 * 10^2$	0.00787	0.00000	0.01650
2.699	$5.00 * 10^2$	0.01950	0.00822	0.03079
2.882	$7.62 * 10^2$	0.01334	0.00519	0.02150
3.000	$1.00 * 10^3$	0.01187	0.00289	0.02085
3.056	$1.14 * 10^3$	0.01073	0.00422	0.01724
3.259	$1.82 * 10^3$	0.01317	0.00723	0.01911
3.557	$3.61 * 10^3$	0.00948	0.00559	0.01337
3.797	$6.27 * 10^3$	0.00683	0.00403	0.00963
3.986	$9.68 * 10^3$	0.00572	0.00358	0.00787
4.186	$1.53 * 10^4$	0.00537	0.00350	0.00725
4.211	$1.63 * 10^4$	0.00468	0.00334	0.00602
4.211	$1.63 * 10^4$	0.00468	0.00334	0.00602
4.211	$1.63 * 10^4$	0.00468	0.00334	0.00602

7.1.3 Day 57 Pseudo virus-neutralizing antibody (50% titer)

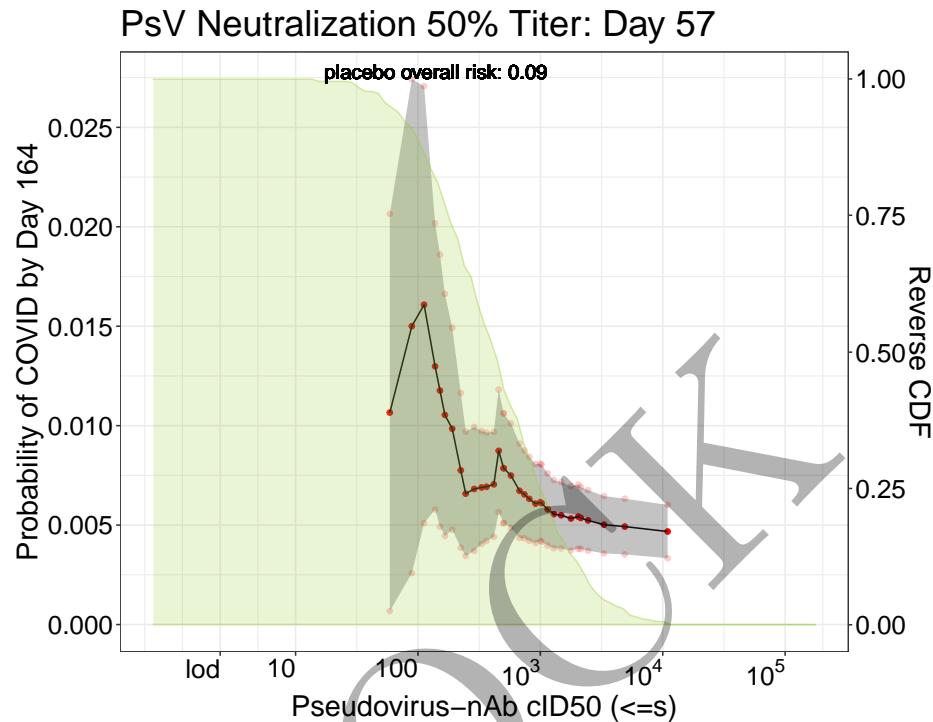


Figure 7.3: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals.

Table 7.3: Table of risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
1.765	$5.82 * 10^1$	0.01066	0.00067	0.02064
2.055	$1.14 * 10^2$	0.01608	0.00510	0.02706
2.177	$1.50 * 10^2$	0.01177	0.00493	0.01860
2.281	$1.91 * 10^2$	0.00985	0.00477	0.01492
2.519	$3.30 * 10^2$	0.00689	0.00405	0.00973
2.657	$4.54 * 10^2$	0.00874	0.00566	0.01181
2.699	$5.00 * 10^2$	0.00786	0.00510	0.01062
2.828	$6.73 * 10^2$	0.00672	0.00435	0.00909
2.959	$9.10 * 10^2$	0.00608	0.00410	0.00807
3.000	$1.00 * 10^3$	0.00615	0.00421	0.00808
3.174	$1.49 * 10^3$	0.00549	0.00382	0.00717
3.307	$2.03 * 10^3$	0.00543	0.00381	0.00704
3.387	$2.44 * 10^3$	0.00524	0.00371	0.00676
4.038	$1.09 * 10^4$	0.00468	0.00334	0.00602

7.1.4 Day 57 Pseudo virus-neutralizing antibody (80% titer)

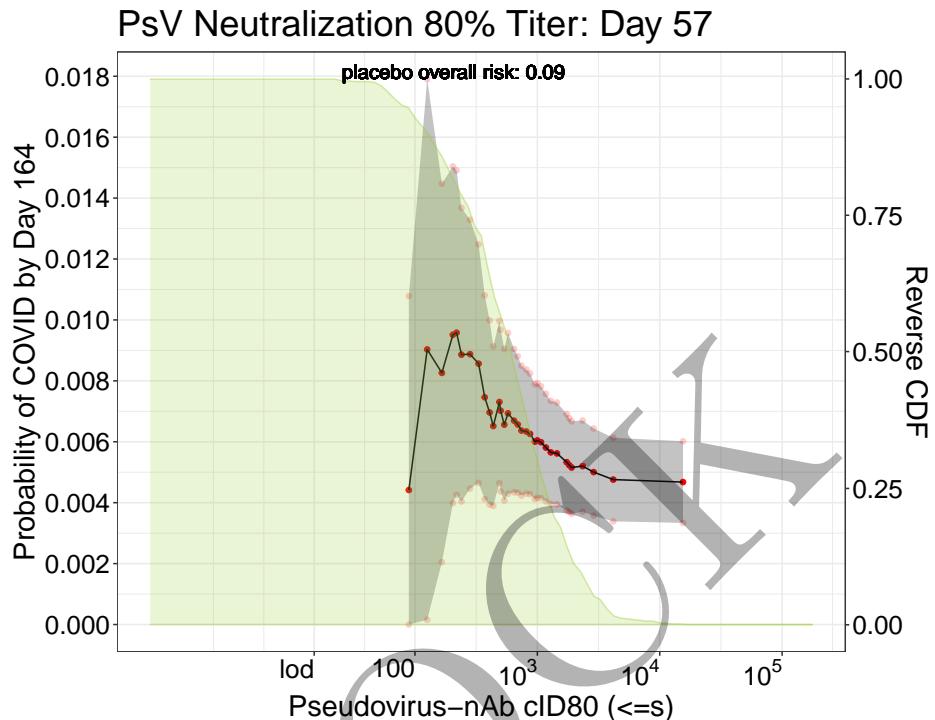


Figure 7.4: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals.

Table 7.4: Table of risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
1.954	$8.99 * 10^1$	0.00441	0.00000	0.01079
2.220	$1.66 * 10^2$	0.00826	0.00205	0.01447
2.335	$2.16 * 10^2$	0.00958	0.00426	0.01491
2.455	$2.85 * 10^2$	0.00888	0.00446	0.01329
2.644	$4.41 * 10^2$	0.00652	0.00390	0.00913
2.699	$5.00 * 10^2$	0.00702	0.00437	0.00967
2.764	$5.81 * 10^2$	0.00693	0.00429	0.00957
2.874	$7.48 * 10^2$	0.00637	0.00424	0.00850
2.981	$9.57 * 10^2$	0.00600	0.00412	0.00789
3.000	$1.00 * 10^3$	0.00604	0.00416	0.00793
3.162	$1.45 * 10^3$	0.00562	0.00395	0.00729
3.265	$1.84 * 10^3$	0.00524	0.00370	0.00677
3.371	$2.35 * 10^3$	0.00520	0.00370	0.00670
4.187	$1.54 * 10^4$	0.00468	0.00334	0.00602

7.2 Plots and Tables with estimates and pointwise confidence intervals for Day 29

MOCK

7.2.1 Day 29 Spike protein antibody

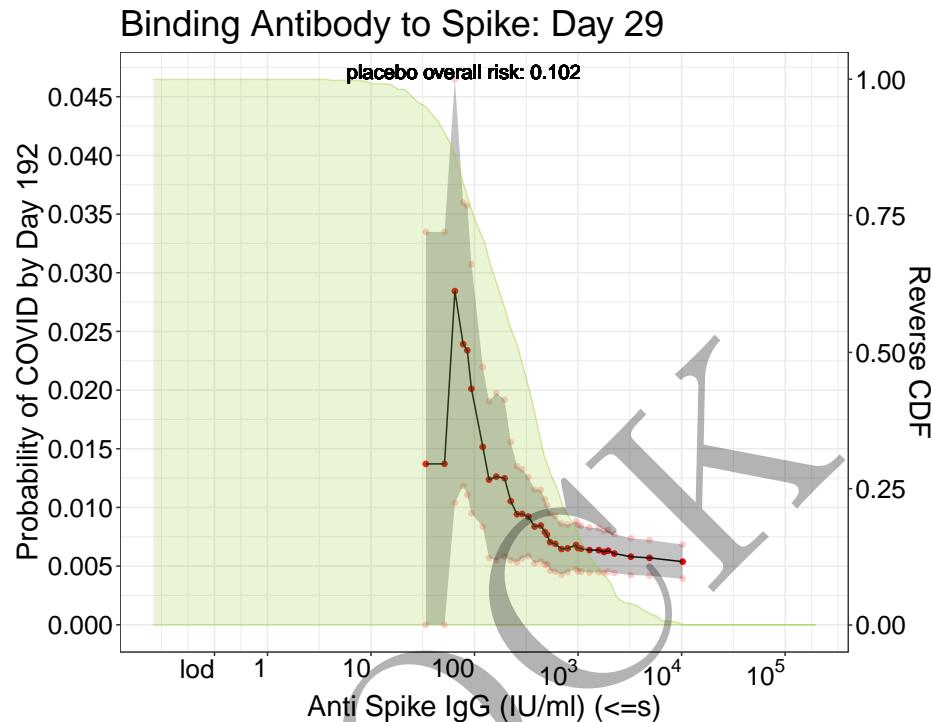


Figure 7.5: Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with pointwise 95% confidence intervals.

Table 7.5: Table of risk estimates for a range of thresholds of Day 29 Spike protein antibody levels with pointwise 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
1.532	$3.40 * 10^1$	0.01371	0.00000	0.03348
1.805	$6.38 * 10^1$	0.02843	0.01039	0.04647
1.927	$8.45 * 10^1$	0.02339	0.01106	0.03571
2.081	$1.21 * 10^2$	0.01516	0.00836	0.02196
2.351	$2.24 * 10^2$	0.01053	0.00549	0.01557
2.522	$3.33 * 10^2$	0.00921	0.00586	0.01257
2.677	$4.75 * 10^2$	0.00790	0.00510	0.01071
2.699	$5.00 * 10^2$	0.00767	0.00515	0.01019
2.841	$6.93 * 10^2$	0.00646	0.00428	0.00863
3.000	$1.00 * 10^3$	0.00653	0.00455	0.00852
3.112	$1.29 * 10^3$	0.00637	0.00445	0.00828
3.252	$1.79 * 10^3$	0.00621	0.00441	0.00800
3.348	$2.23 * 10^3$	0.00607	0.00441	0.00773
4.007	$1.02 * 10^4$	0.00538	0.00392	0.00683

7.2.2 Day 29 RBD binding antibody

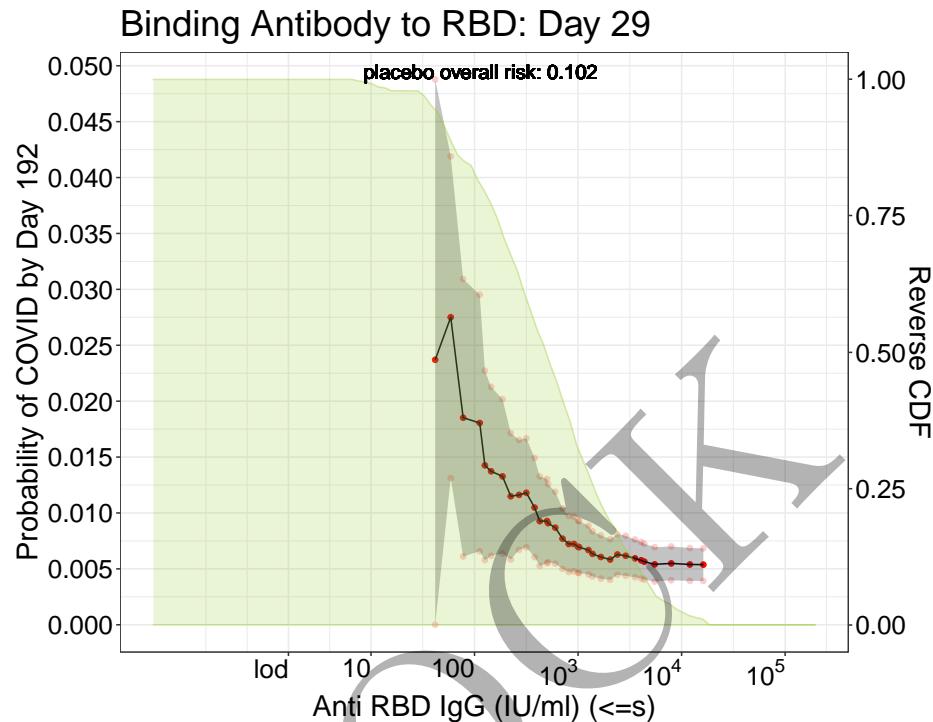


Figure 7.6: Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with pointwise 95% confidence intervals.

Table 7.6: Table of risk estimates for a range of thresholds of Day 29 RBD binding antibody levels with pointwise 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
1.620	$4.17 * 10^1$	0.02370	0.00000	0.04878
1.892	$7.80 * 10^1$	0.01852	0.00611	0.03093
2.098	$1.25 * 10^2$	0.01426	0.00579	0.02273
2.273	$1.87 * 10^2$	0.01327	0.00637	0.02018
2.575	$3.76 * 10^2$	0.01048	0.00605	0.01492
2.699	$5.00 * 10^2$	0.00928	0.00551	0.01305
2.780	$6.03 * 10^2$	0.00868	0.00547	0.01189
2.960	$9.12 * 10^2$	0.00723	0.00478	0.00968
3.000	$1.00 * 10^3$	0.00697	0.00466	0.00929
3.144	$1.39 * 10^3$	0.00634	0.00432	0.00835
3.461	$2.89 * 10^3$	0.00617	0.00438	0.00796
3.610	$4.07 * 10^3$	0.00576	0.00413	0.00740
3.736	$5.45 * 10^3$	0.00540	0.00386	0.00694
4.211	$1.63 * 10^4$	0.00538	0.00392	0.00683

7.2.3 Day 29 Pseudo virus-neutralizing antibody (50% titer)

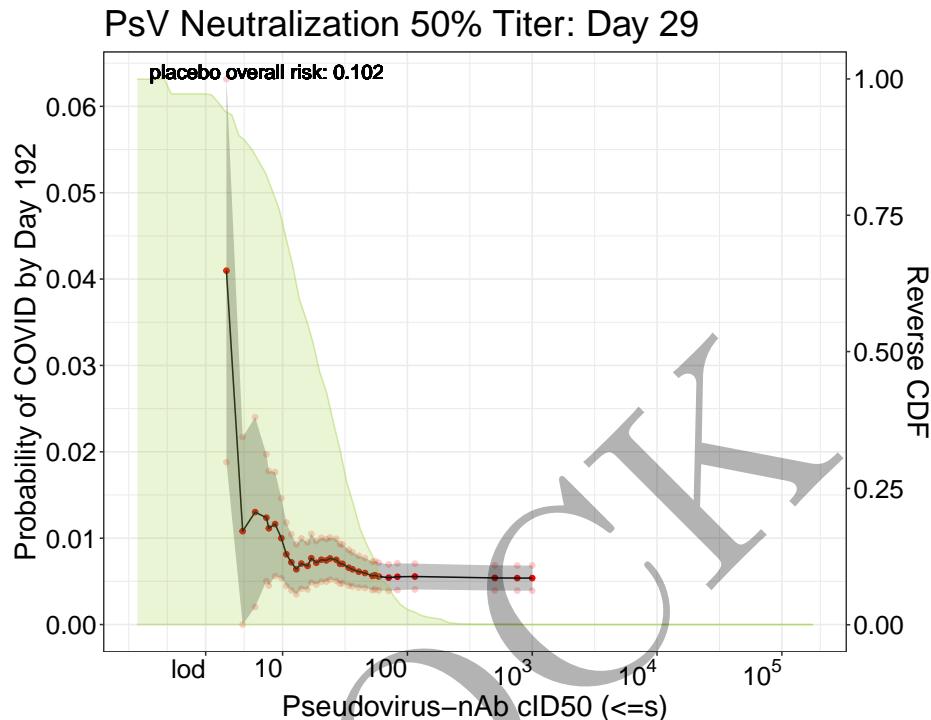


Figure 7.7: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals.

Table 7.7: Table of risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
0.548	$3.53 * 10^0$	0.04097	0.01880	0.06314
0.779	$6.01 * 10^0$	0.01302	0.00203	0.02401
0.892	$7.80 * 10^0$	0.01114	0.00451	0.01777
0.988	$9.73 * 10^0$	0.01000	0.00536	0.01463
1.147	$1.40 * 10^1$	0.00705	0.00413	0.00997
1.271	$1.87 * 10^1$	0.00715	0.00465	0.00966
1.382	$2.41 * 10^1$	0.00765	0.00522	0.01008
1.481	$3.03 * 10^1$	0.00703	0.00479	0.00926
1.656	$4.53 * 10^1$	0.00597	0.00423	0.00770
1.741	$5.51 * 10^1$	0.00571	0.00406	0.00736
1.852	$7.11 * 10^1$	0.00543	0.00389	0.00697
2.699	$5.00 * 10^2$	0.00540	0.00394	0.00685
2.879	$7.57 * 10^2$	0.00538	0.00392	0.00683
3.000	$1.00 * 10^3$	0.00538	0.00392	0.00683

7.2.4 Day 29 Pseudo virus-neutralizing antibody (80% titer)

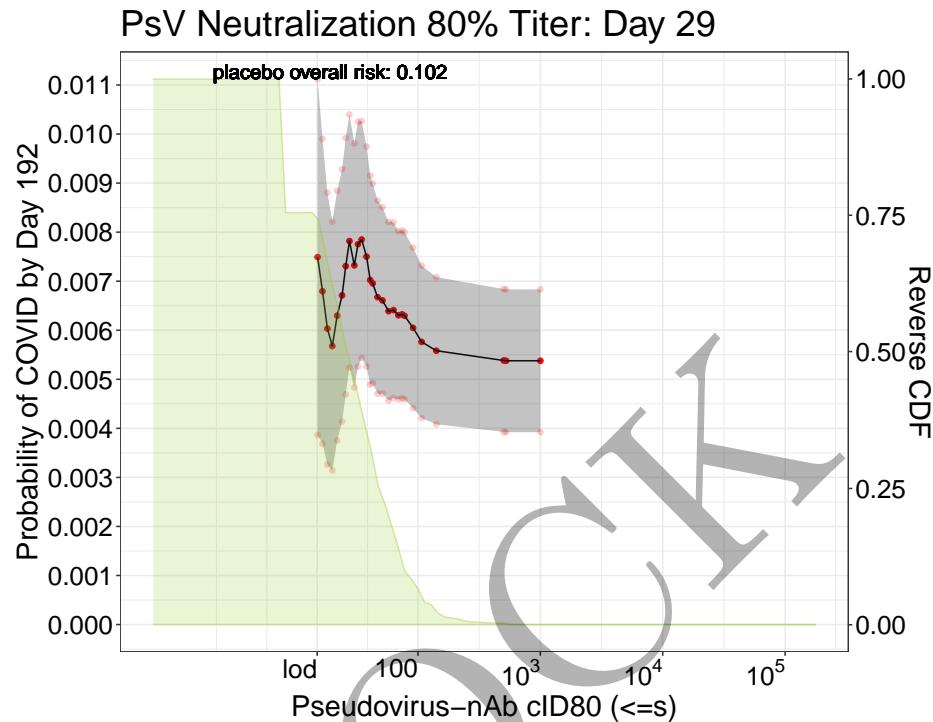


Figure 7.8: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals.

Table 7.8: Table of risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
1.183	$1.52 * 10^1$	0.00749	0.00386	0.01112
1.183	$1.52 * 10^1$	0.00749	0.00386	0.01112
1.183	$1.52 * 10^1$	0.00749	0.00386	0.01112
1.183	$1.52 * 10^1$	0.00749	0.00386	0.01112
1.339	$2.18 * 10^1$	0.00630	0.00375	0.00884
1.440	$2.75 * 10^1$	0.00782	0.00524	0.01040
1.541	$3.48 * 10^1$	0.00785	0.00543	0.01026
1.632	$4.29 * 10^1$	0.00696	0.00492	0.00899
1.796	$6.25 * 10^1$	0.00641	0.00462	0.00820
1.868	$7.38 * 10^1$	0.00632	0.00461	0.00803
1.956	$9.04 * 10^1$	0.00605	0.00441	0.00768
2.699	$5.00 * 10^2$	0.00538	0.00393	0.00684
2.719	$5.24 * 10^2$	0.00538	0.00392	0.00683
3.000	$1.00 * 10^3$	0.00538	0.00392	0.00683

7.3 Plots and Tables with estimates and pointwise confidence interval for Day 57 (monotone-corrected)

MOCK

7.3.1 Day 57 Spike protein binding antibody

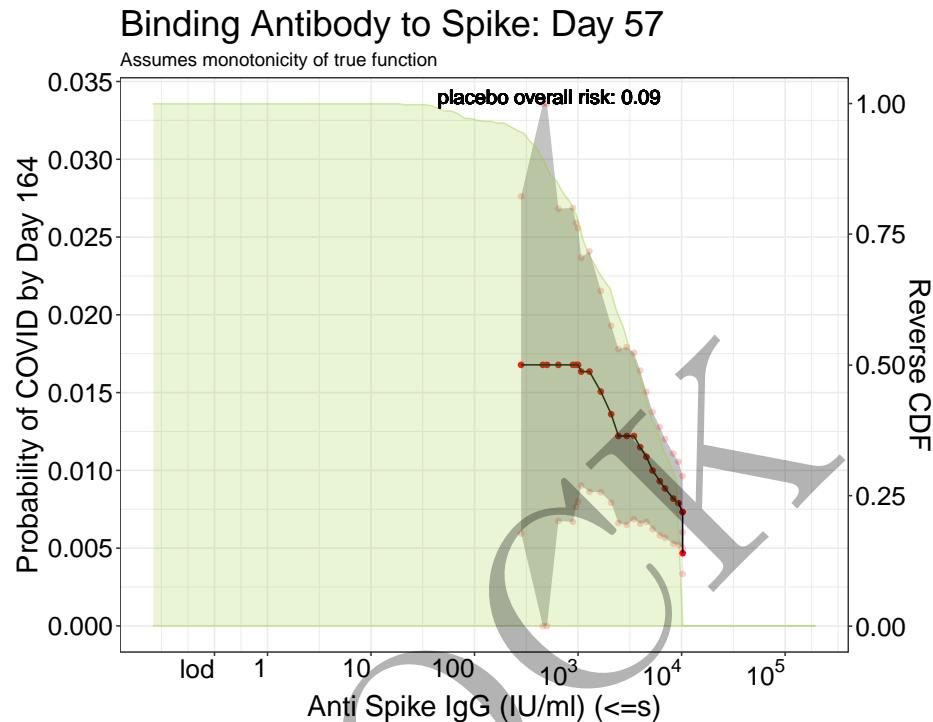


Figure 7.9: Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with pointwise 95% confidence intervals. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 7.9: Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Spike protein binding antibody levels with pointwise 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
2.450	$2.82 * 10^2$	0.01678	0.00594	0.02762
2.699	$5.00 * 10^2$	0.01678	0.00000	0.04282
2.815	$6.53 * 10^2$	0.01678	0.00675	0.02682
2.982	$9.59 * 10^2$	0.01678	0.00766	0.02590
3.000	$1.00 * 10^3$	0.01678	0.00800	0.02557
3.113	$1.30 * 10^3$	0.01635	0.00862	0.02408
3.471	$2.96 * 10^3$	0.01221	0.00649	0.01793
3.658	$4.55 * 10^3$	0.01087	0.00669	0.01505
3.841	$6.93 * 10^3$	0.00884	0.00566	0.01201
4.006	$1.01 * 10^4$	0.00732	0.00501	0.00964
4.007	$1.02 * 10^4$	0.00468	0.00334	0.00602
4.007	$1.02 * 10^4$	0.00468	0.00334	0.00602
4.007	$1.02 * 10^4$	0.00468	0.00334	0.00602

7.3.2 Day 57 RBD binding antibody

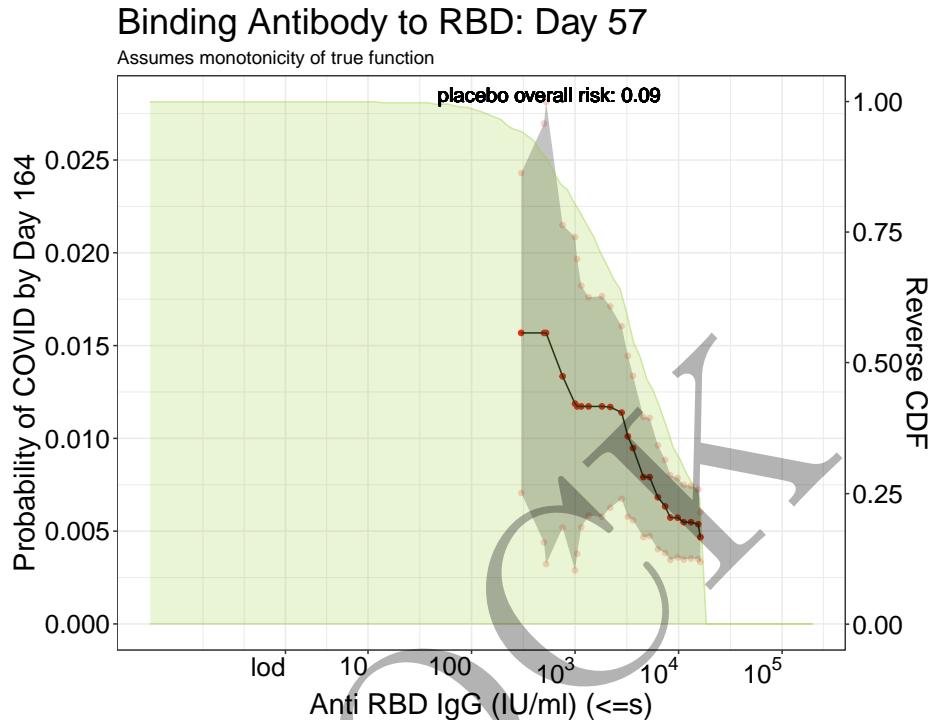


Figure 7.10: Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with pointwise 95% confidence intervals. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 7.10: Table of monotone-corrected risk estimates for a range of thresholds of Day 57 RBD binding antibody levels with pointwise 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
2.478	$3.01 * 10^2$	0.01568	0.00706	0.02431
2.699	$5.00 * 10^2$	0.01568	0.00439	0.02697
2.882	$7.62 * 10^2$	0.01334	0.00519	0.02150
3.000	$1.00 * 10^3$	0.01187	0.00289	0.02085
3.056	$1.14 * 10^3$	0.01172	0.00521	0.01823
3.259	$1.82 * 10^3$	0.01172	0.00578	0.01766
3.557	$3.61 * 10^3$	0.00948	0.00559	0.01337
3.797	$6.27 * 10^3$	0.00683	0.00403	0.00963
3.986	$9.68 * 10^3$	0.00572	0.00358	0.00787
4.186	$1.53 * 10^4$	0.00537	0.00350	0.00725
4.211	$1.63 * 10^4$	0.00468	0.00334	0.00602
4.211	$1.63 * 10^4$	0.00468	0.00334	0.00602
4.211	$1.63 * 10^4$	0.00468	0.00334	0.00602

7.3.3 Day 57 Pseudo virus-neutralizing antibody (50% titer)

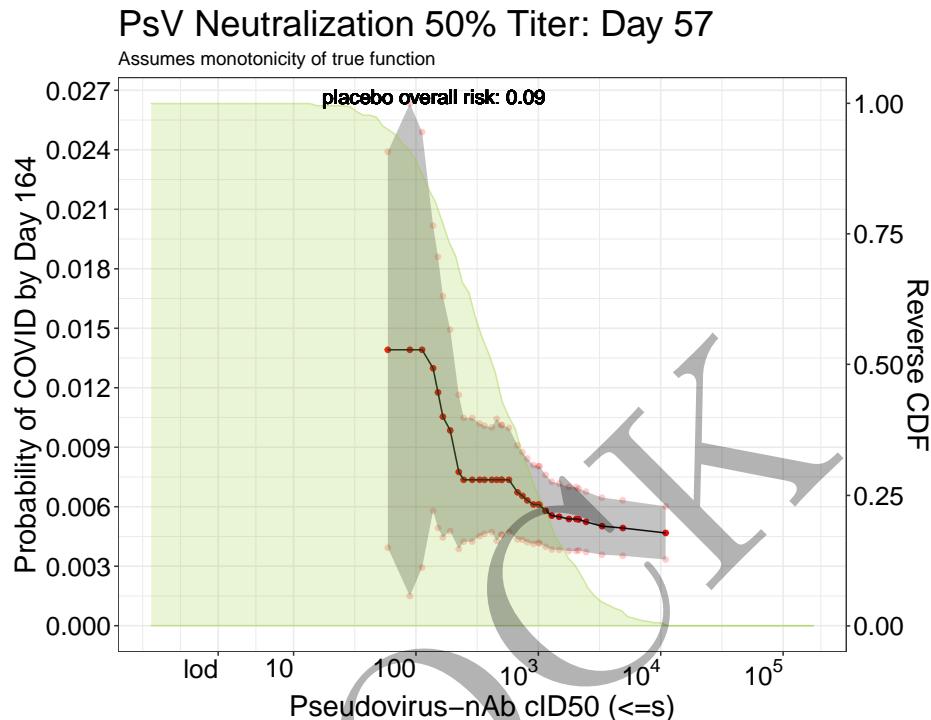


Figure 7.11: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 7.11: Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
1.765	$5.82 * 10^1$	0.01391	0.00393	0.02390
2.055	$1.14 * 10^2$	0.01391	0.00293	0.02490
2.177	$1.50 * 10^2$	0.01177	0.00493	0.01860
2.281	$1.91 * 10^2$	0.00985	0.00477	0.01492
2.519	$3.30 * 10^2$	0.00736	0.00452	0.01020
2.657	$4.54 * 10^2$	0.00736	0.00428	0.01044
2.699	$5.00 * 10^2$	0.00736	0.00460	0.01012
2.828	$6.73 * 10^2$	0.00672	0.00435	0.00909
2.959	$9.10 * 10^2$	0.00611	0.00413	0.00810
3.000	$1.00 * 10^3$	0.00611	0.00418	0.00804
3.174	$1.49 * 10^3$	0.00549	0.00382	0.00717
3.307	$2.03 * 10^3$	0.00538	0.00377	0.00699
3.387	$2.44 * 10^3$	0.00524	0.00371	0.00676
4.038	$1.09 * 10^4$	0.00468	0.00334	0.00602

7.3.4 Day 57 Pseudo virus-neutralizing antibody (80% titer)

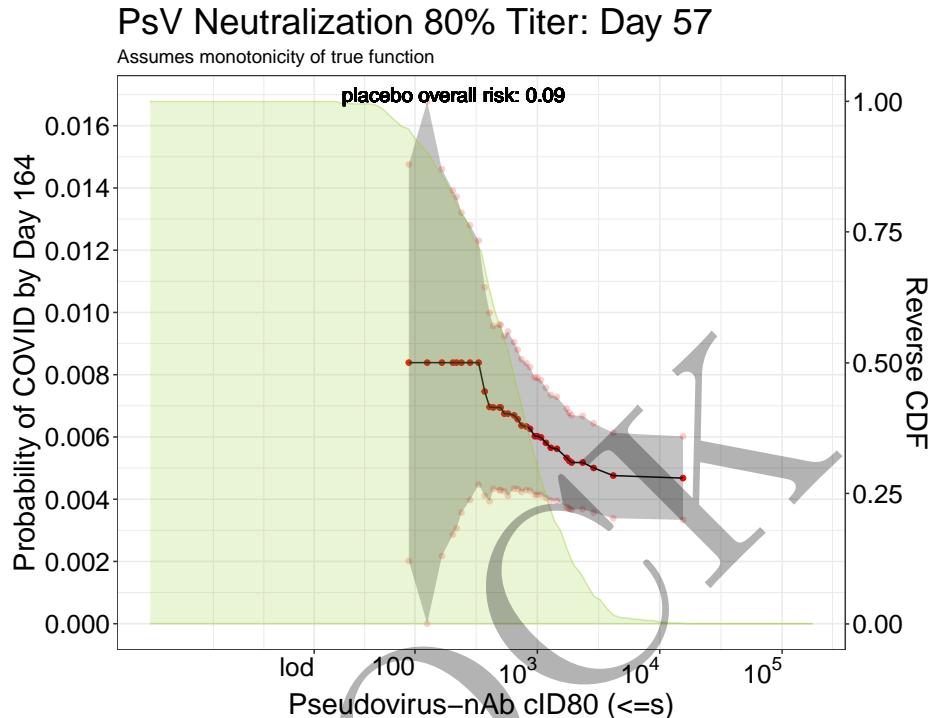


Figure 7.12: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 7.12: Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals.

log ₁₀ -Threshold	Threshold	Risk estimate	CI left	CI right
1.954	8.99 * 10 ¹	0.00839	0.00202	0.01476
2.220	1.66 * 10 ²	0.00839	0.00217	0.01460
2.335	2.16 * 10 ²	0.00839	0.00306	0.01371
2.455	2.85 * 10 ²	0.00839	0.00398	0.01280
2.644	4.41 * 10 ²	0.00695	0.00433	0.00956
2.699	5.00 * 10 ²	0.00695	0.00430	0.00960
2.764	5.81 * 10 ²	0.00675	0.00411	0.00939
2.874	7.48 * 10 ²	0.00637	0.00424	0.00850
2.981	9.57 * 10 ²	0.00602	0.00414	0.00791
3.000	1.00 * 10 ³	0.00602	0.00414	0.00791
3.162	1.45 * 10 ³	0.00562	0.00395	0.00729
3.265	1.84 * 10 ³	0.00524	0.00370	0.00677
3.371	2.35 * 10 ³	0.00518	0.00368	0.00668
4.187	1.54 * 10 ⁴	0.00468	0.00334	0.00602

7.4 Plots and Tables with estimates and pointwise confidence intervals for Day 29 (monotone-corrected)

MOCK

7.4.1 Day 29 Spike protein antibody

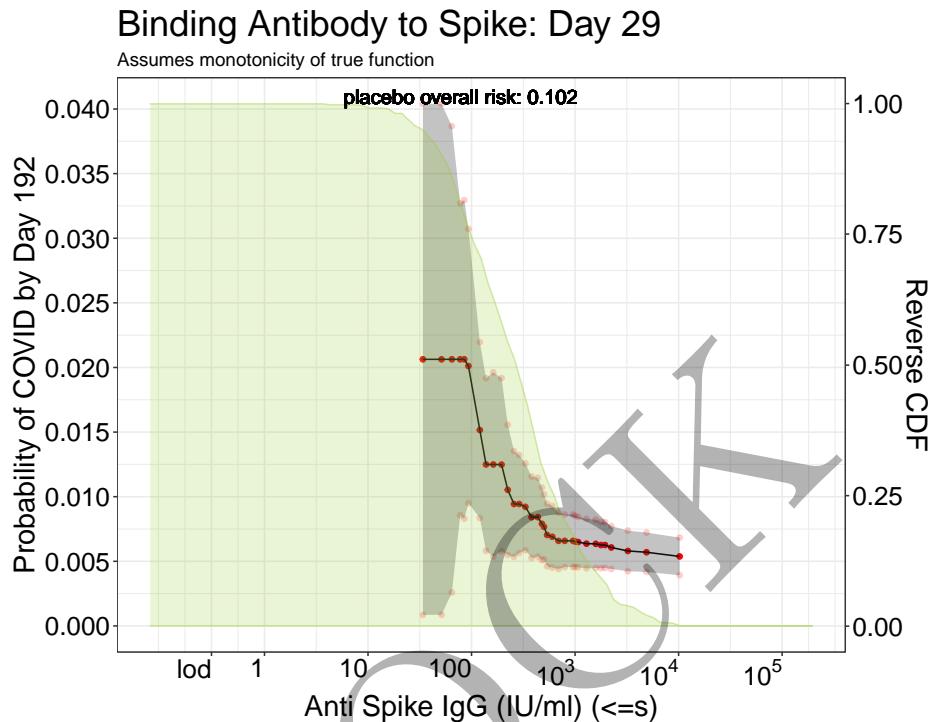


Figure 7.13: Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with pointwise 95% confidence intervals. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 7.13: Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Spike protein antibody levels with pointwise 95% confidence intervals.

log ₁₀ -Threshold	Threshold	Risk estimate	CI left	CI right
1.532	$3.40 * 10^1$	0.02063	0.00086	0.04040
1.805	$6.38 * 10^1$	0.02063	0.00259	0.03867
1.927	$8.45 * 10^1$	0.02063	0.00831	0.03295
2.081	$1.21 * 10^2$	0.01516	0.00836	0.02196
2.351	$2.24 * 10^2$	0.01053	0.00549	0.01557
2.522	$3.33 * 10^2$	0.00921	0.00586	0.01257
2.677	$4.75 * 10^2$	0.00790	0.00510	0.01071
2.699	$5.00 * 10^2$	0.00767	0.00515	0.01019
2.841	$6.93 * 10^2$	0.00659	0.00441	0.00876
3.000	$1.00 * 10^3$	0.00653	0.00455	0.00852
3.112	$1.29 * 10^3$	0.00637	0.00445	0.00828
3.252	$1.79 * 10^3$	0.00626	0.00447	0.00805
3.348	$2.23 * 10^3$	0.00607	0.00441	0.00773
4.007	$1.02 * 10^4$	0.00538	0.00392	0.00683

7.4.2 Day 29 RBD binding antibody

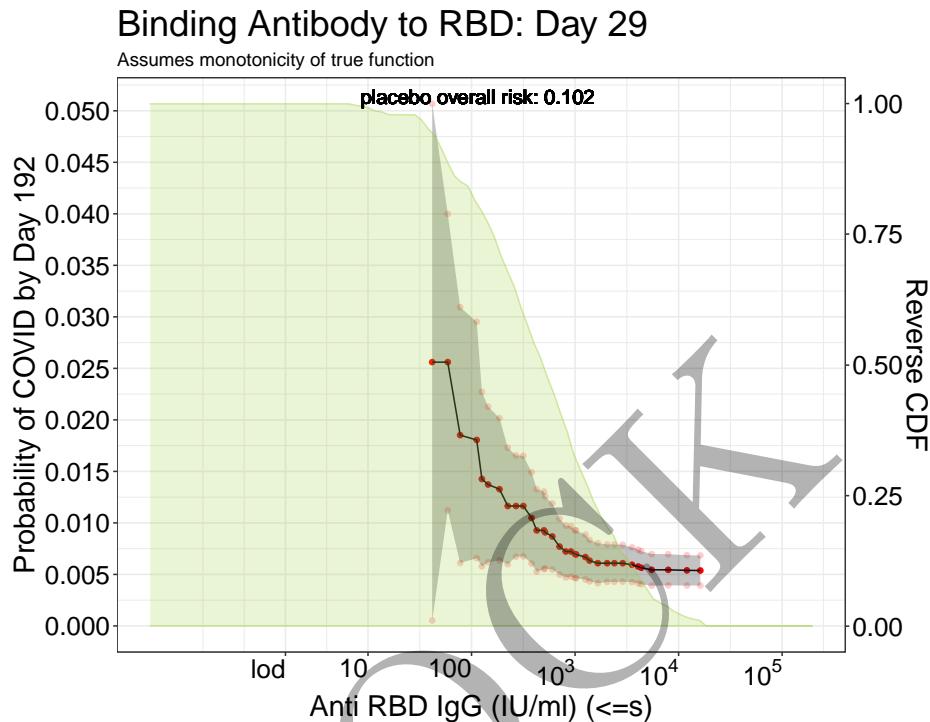


Figure 7.14: Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with pointwise 95% confidence intervals. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 7.14: Table of monotone-corrected risk estimates for a range of thresholds of Day 29 RBD binding antibody levels with pointwise 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
1.620	$4.17 * 10^1$	0.02560	0.00053	0.05068
1.892	$7.80 * 10^1$	0.01852	0.00611	0.03093
2.098	$1.25 * 10^2$	0.01426	0.00579	0.02273
2.273	$1.87 * 10^2$	0.01327	0.00637	0.02018
2.575	$3.76 * 10^2$	0.01048	0.00605	0.01492
2.699	$5.00 * 10^2$	0.00927	0.00550	0.01304
2.780	$6.03 * 10^2$	0.00868	0.00547	0.01189
2.960	$9.12 * 10^2$	0.00723	0.00478	0.00968
3.000	$1.00 * 10^3$	0.00697	0.00466	0.00929
3.144	$1.39 * 10^3$	0.00634	0.00432	0.00835
3.461	$2.89 * 10^3$	0.00609	0.00429	0.00788
3.610	$4.07 * 10^3$	0.00576	0.00413	0.00740
3.736	$5.45 * 10^3$	0.00545	0.00391	0.00698
4.211	$1.63 * 10^4$	0.00538	0.00392	0.00683

7.4.3 Day 29 Pseudo virus-neutralizing antibody (50% titer)

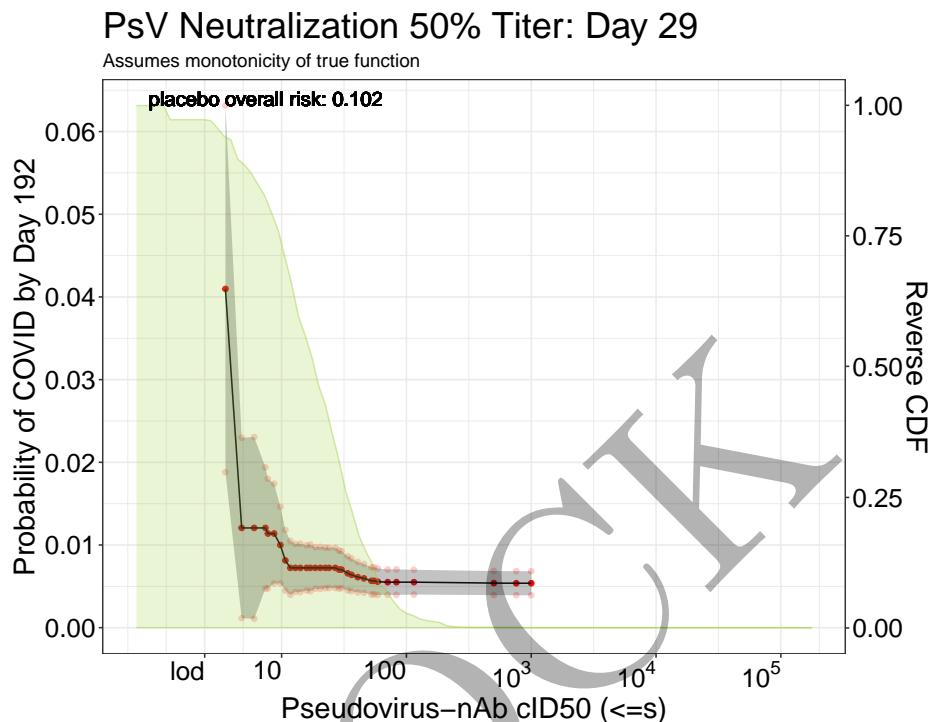


Figure 7.15: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 7.15: Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
0.548	$3.53 * 10^0$	0.04097	0.01880	0.06314
0.779	$6.01 * 10^0$	0.01207	0.00108	0.02305
0.892	$7.80 * 10^0$	0.01139	0.00475	0.01802
0.988	$9.73 * 10^0$	0.01000	0.00536	0.01463
1.147	$1.40 * 10^1$	0.00724	0.00432	0.01016
1.271	$1.87 * 10^1$	0.00724	0.00473	0.00974
1.382	$2.41 * 10^1$	0.00724	0.00480	0.00967
1.481	$3.03 * 10^1$	0.00703	0.00479	0.00926
1.656	$4.53 * 10^1$	0.00597	0.00423	0.00770
1.741	$5.51 * 10^1$	0.00567	0.00402	0.00732
1.852	$7.11 * 10^1$	0.00551	0.00397	0.00704
2.699	$5.00 * 10^2$	0.00540	0.00394	0.00685
2.879	$7.57 * 10^2$	0.00538	0.00392	0.00683
3.000	$1.00 * 10^3$	0.00538	0.00392	0.00683

7.4.4 Day 29 Pseudo virus-neutralizing antibody (80% titer)

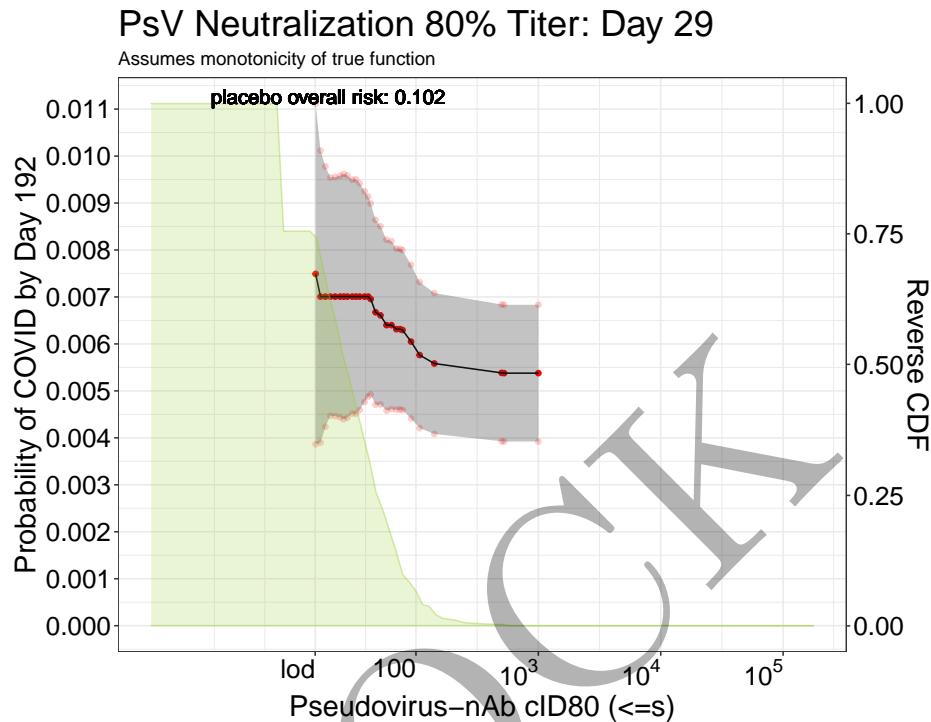


Figure 7.16: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 7.16: Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
1.183	$1.52 * 10^1$	0.00749	0.00386	0.01112
1.183	$1.52 * 10^1$	0.00749	0.00386	0.01112
1.183	$1.52 * 10^1$	0.00749	0.00386	0.01112
1.183	$1.52 * 10^1$	0.00749	0.00386	0.01112
1.339	$2.18 * 10^1$	0.00701	0.00446	0.00955
1.440	$2.75 * 10^1$	0.00701	0.00443	0.00959
1.541	$3.48 * 10^1$	0.00701	0.00459	0.00942
1.632	$4.29 * 10^1$	0.00696	0.00492	0.00899
1.796	$6.25 * 10^1$	0.00640	0.00461	0.00819
1.868	$7.38 * 10^1$	0.00631	0.00460	0.00803
1.956	$9.04 * 10^1$	0.00605	0.00441	0.00768
2.699	$5.00 * 10^2$	0.00538	0.00393	0.00684
2.719	$5.24 * 10^2$	0.00538	0.00392	0.00683
3.000	$1.00 * 10^3$	0.00538	0.00392	0.00683

7.5 Plots and Tables with estimates and simultaneous confidence bands for Day 57

MOCK

7.5.1 Day 57 Spike protein binding antibody

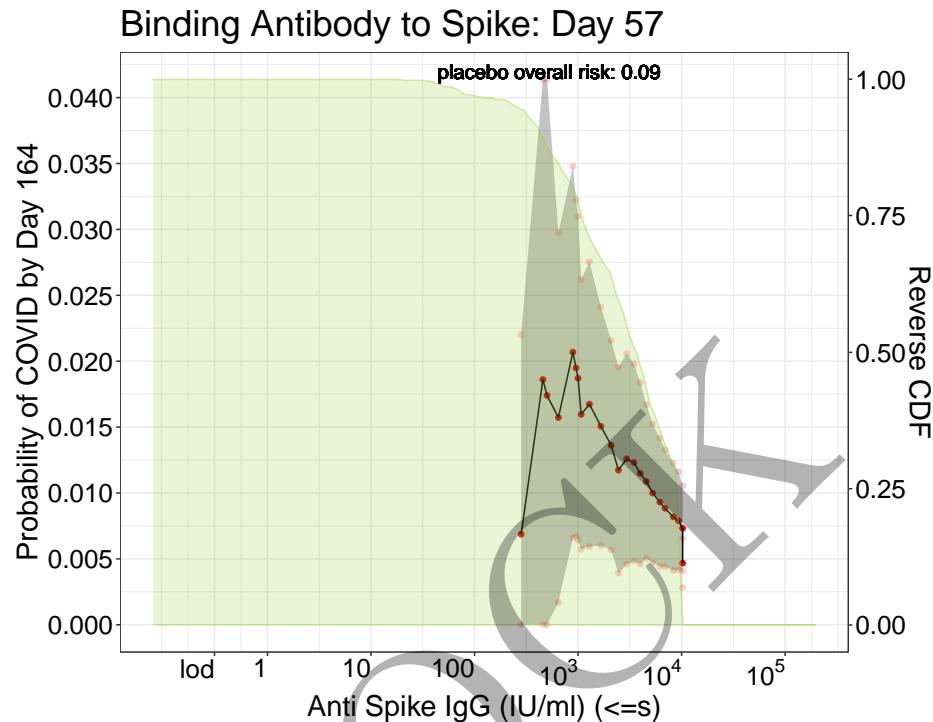


Figure 7.17: Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with simultaneous 95% confidence intervals.

Table 7.17: Table of risk estimates for a range of thresholds of Day 57 Spike protein binding antibody levels with simultaneous 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
2.450	$2.82 * 10^2$	0.00687	0.00000	0.02202
2.699	$5.00 * 10^2$	0.01741	0.00000	0.05379
2.815	$6.53 * 10^2$	0.01572	0.00170	0.02975
2.982	$9.59 * 10^2$	0.01948	0.00674	0.03223
3.000	$1.00 * 10^3$	0.01870	0.00643	0.03098
3.113	$1.30 * 10^3$	0.01674	0.00594	0.02754
3.471	$2.96 * 10^3$	0.01259	0.00460	0.02058
3.658	$4.55 * 10^3$	0.01087	0.00503	0.01671
3.841	$6.93 * 10^3$	0.00884	0.00440	0.01327
4.006	$1.01 * 10^4$	0.00732	0.00409	0.01056
4.007	$1.02 * 10^4$	0.00468	0.00280	0.00655
4.007	$1.02 * 10^4$	0.00468	0.00280	0.00655
4.007	$1.02 * 10^4$	0.00468	0.00280	0.00655

7.5.2 Day 57 RBD binding antibody

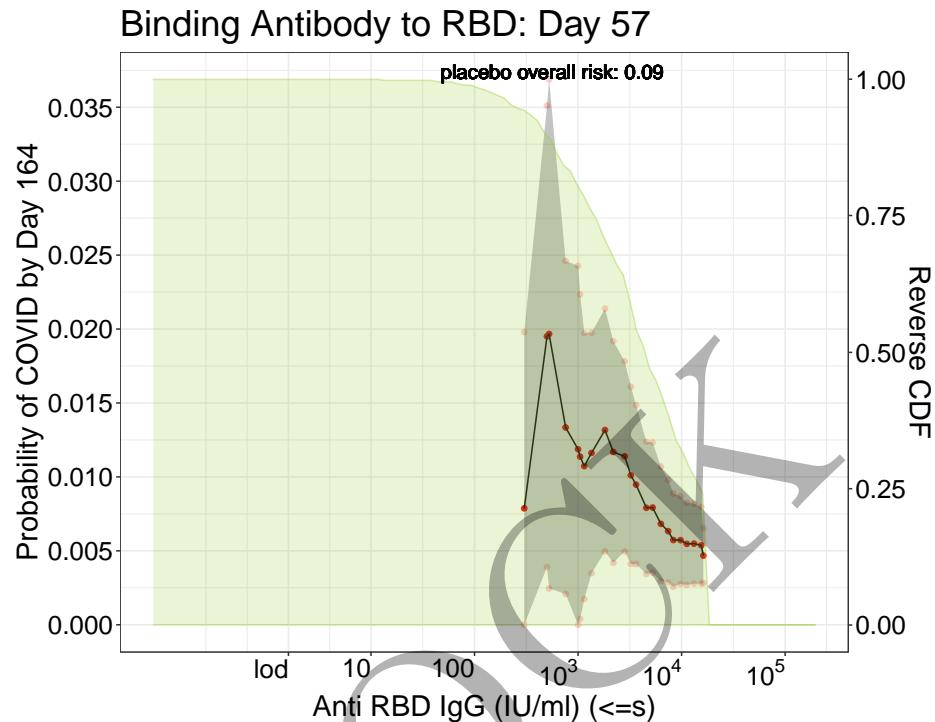


Figure 7.18: Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with simultaneous 95% confidence intervals.

Table 7.18: Table of risk estimates for a range of thresholds of Day 57 RBD binding antibody levels with simultaneous 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
2.478	$3.01 * 10^2$	0.00787	0.00000	0.01979
2.699	$5.00 * 10^2$	0.01950	0.00390	0.03511
2.882	$7.62 * 10^2$	0.01334	0.00208	0.02461
3.000	$1.00 * 10^3$	0.01187	0.00000	0.02428
3.056	$1.14 * 10^3$	0.01073	0.00173	0.01973
3.259	$1.82 * 10^3$	0.01317	0.00496	0.02138
3.557	$3.61 * 10^3$	0.00948	0.00410	0.01485
3.797	$6.27 * 10^3$	0.00683	0.00296	0.01070
3.986	$9.68 * 10^3$	0.00572	0.00276	0.00868
4.186	$1.53 * 10^4$	0.00537	0.00278	0.00797
4.211	$1.63 * 10^4$	0.00468	0.00282	0.00653
4.211	$1.63 * 10^4$	0.00468	0.00282	0.00653
4.211	$1.63 * 10^4$	0.00468	0.00282	0.00653

7.5.3 Day 57 Pseudo virus-neutralizing antibody (50% titer)

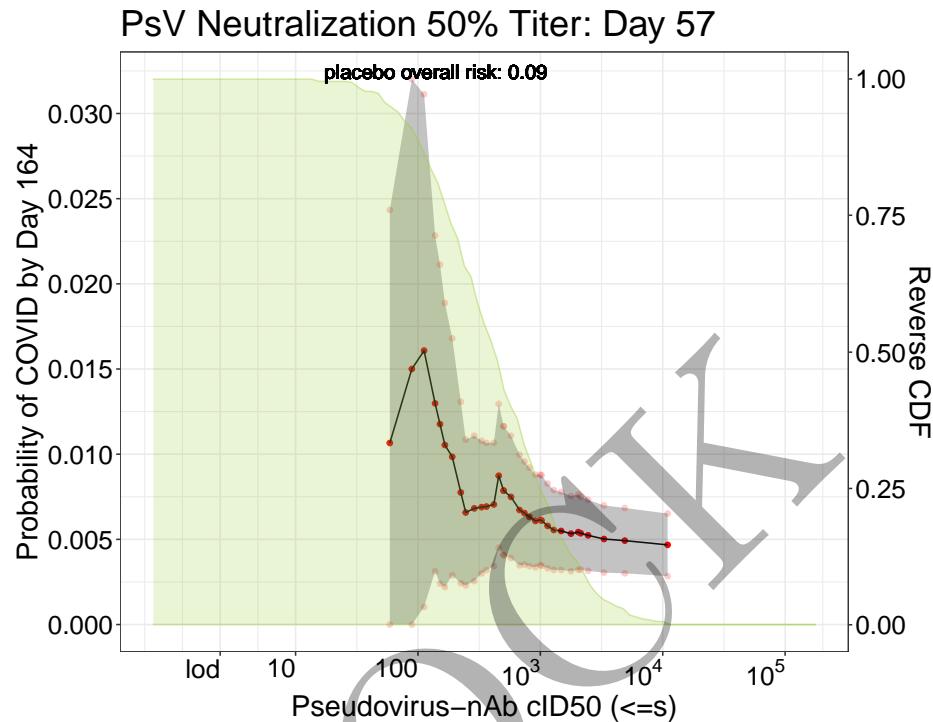


Figure 7.19: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals.

Table 7.19: Table of risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
1.765	$5.82 * 10^1$	0.01066	0.00000	0.02434
2.055	$1.14 * 10^2$	0.01608	0.00103	0.03113
2.177	$1.50 * 10^2$	0.01177	0.00240	0.02113
2.281	$1.91 * 10^2$	0.00985	0.00289	0.01680
2.519	$3.30 * 10^2$	0.00689	0.00300	0.01078
2.657	$4.54 * 10^2$	0.00874	0.00452	0.01295
2.699	$5.00 * 10^2$	0.00786	0.00408	0.01164
2.828	$6.73 * 10^2$	0.00672	0.00348	0.00997
2.959	$9.10 * 10^2$	0.00608	0.00336	0.00880
3.000	$1.00 * 10^3$	0.00615	0.00350	0.00879
3.174	$1.49 * 10^3$	0.00549	0.00320	0.00778
3.307	$2.03 * 10^3$	0.00543	0.00322	0.00763
3.387	$2.44 * 10^3$	0.00524	0.00315	0.00732
4.038	$1.09 * 10^4$	0.00468	0.00284	0.00651

7.5.4 Day 57 Pseudo virus-neutralizing antibody (80% titer)

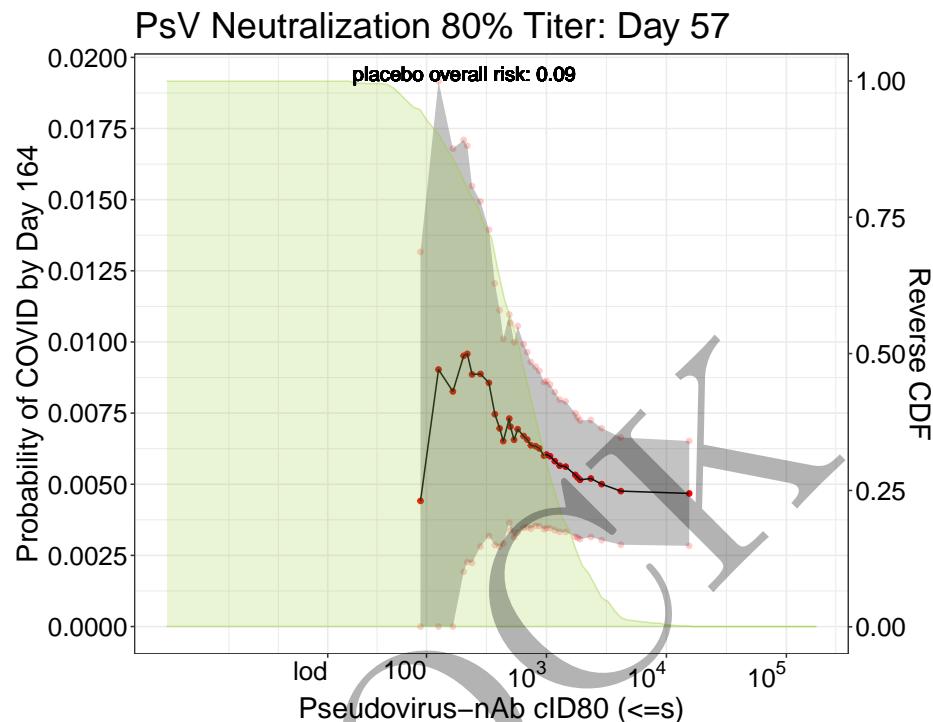


Figure 7.20: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals.

Table 7.20: Table of risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
1.954	$8.99 * 10^1$	0.00441	0.00000	0.01317
2.220	$1.66 * 10^2$	0.00826	0.00000	0.01679
2.335	$2.16 * 10^2$	0.00958	0.00227	0.01689
2.455	$2.85 * 10^2$	0.00888	0.00281	0.01494
2.644	$4.41 * 10^2$	0.00652	0.00292	0.01011
2.699	$5.00 * 10^2$	0.00702	0.00338	0.01066
2.764	$5.81 * 10^2$	0.00693	0.00331	0.01056
2.874	$7.48 * 10^2$	0.00637	0.00344	0.00930
2.981	$9.57 * 10^2$	0.00600	0.00342	0.00859
3.000	$1.00 * 10^3$	0.00604	0.00346	0.00863
3.162	$1.45 * 10^3$	0.00562	0.00332	0.00791
3.265	$1.84 * 10^3$	0.00524	0.00312	0.00735
3.371	$2.35 * 10^3$	0.00520	0.00315	0.00726
4.187	$1.54 * 10^4$	0.00468	0.00284	0.00652

7.6 Plots and Tables with estimates and simultaneous confidence bands for Day 29

MOCK

7.6.1 Day 29 Spike protein antibody

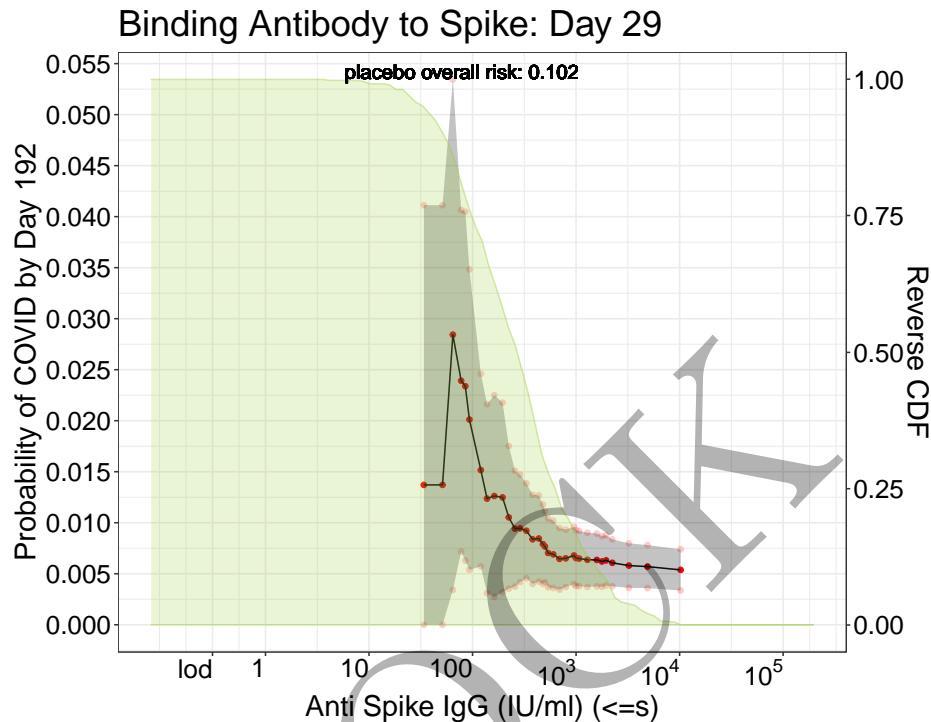


Figure 7.21: Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with simultaneous 95% confidence intervals.

Table 7.21: Table of risk estimates for a range of thresholds of Day 29 Spike protein antibody levels with simultaneous 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
1.532	$3.40 * 10^1$	0.01371	0.00000	0.04113
1.805	$6.38 * 10^1$	0.02843	0.00342	0.05345
1.927	$8.45 * 10^1$	0.02339	0.00630	0.04047
2.081	$1.21 * 10^2$	0.01516	0.00572	0.02460
2.351	$2.24 * 10^2$	0.01053	0.00354	0.01752
2.522	$3.33 * 10^2$	0.00921	0.00456	0.01387
2.677	$4.75 * 10^2$	0.00790	0.00402	0.01179
2.699	$5.00 * 10^2$	0.00767	0.00417	0.01116
2.841	$6.93 * 10^2$	0.00646	0.00343	0.00948
3.000	$1.00 * 10^3$	0.00653	0.00379	0.00928
3.112	$1.29 * 10^3$	0.00637	0.00371	0.00902
3.252	$1.79 * 10^3$	0.00621	0.00372	0.00869
3.348	$2.23 * 10^3$	0.00607	0.00377	0.00838
4.007	$1.02 * 10^4$	0.00538	0.00336	0.00740

7.6.2 Day 29 RBD binding antibody

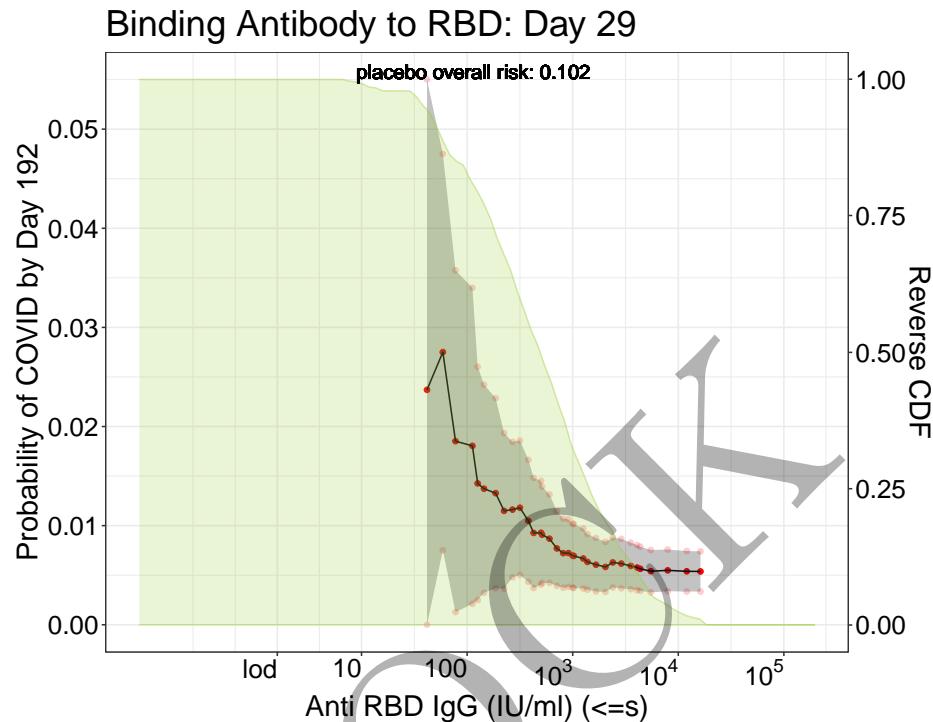


Figure 7.22: Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with simultaneous 95% confidence intervals.

Table 7.22: Table of risk estimates for a range of thresholds of Day 29 RBD binding antibody levels with simultaneous 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
1.620	$4.17 * 10^1$	0.02370	0.00000	0.05854
1.892	$7.80 * 10^1$	0.01852	0.00128	0.03576
2.098	$1.25 * 10^2$	0.01426	0.00249	0.02603
2.273	$1.87 * 10^2$	0.01327	0.00368	0.02287
2.575	$3.76 * 10^2$	0.01048	0.00432	0.01664
2.699	$5.00 * 10^2$	0.00928	0.00405	0.01452
2.780	$6.03 * 10^2$	0.00868	0.00422	0.01314
2.960	$9.12 * 10^2$	0.00723	0.00383	0.01063
3.000	$1.00 * 10^3$	0.00697	0.00375	0.01020
3.144	$1.39 * 10^3$	0.00634	0.00354	0.00914
3.461	$2.89 * 10^3$	0.00617	0.00368	0.00866
3.610	$4.07 * 10^3$	0.00576	0.00349	0.00804
3.736	$5.45 * 10^3$	0.00540	0.00327	0.00754
4.211	$1.63 * 10^4$	0.00538	0.00335	0.00740

7.6.3 Day 29 Pseudo virus-neutralizing antibody (50% titer)

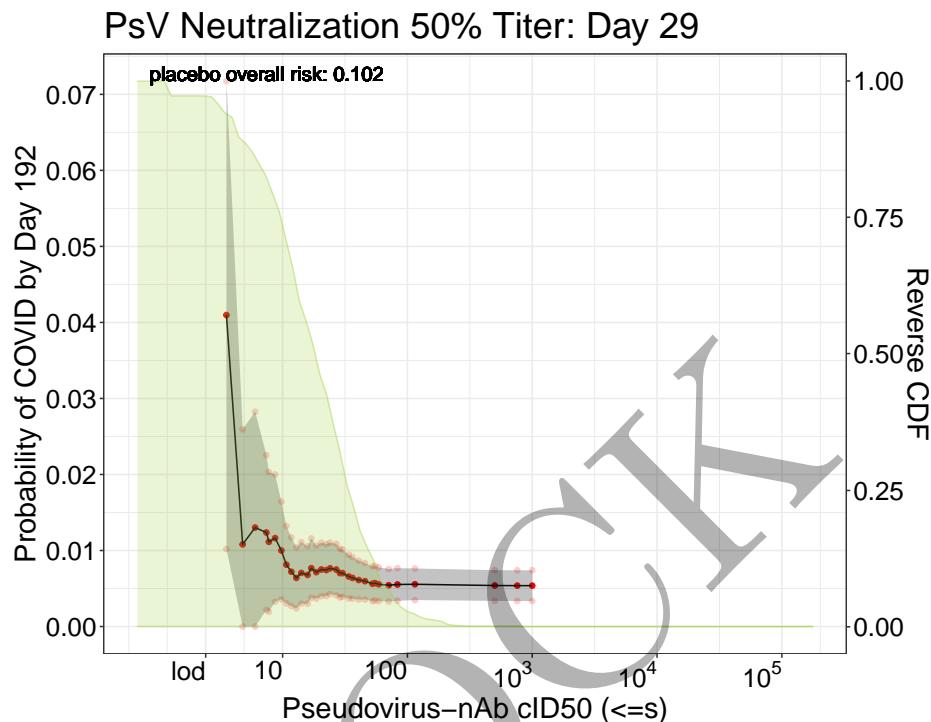


Figure 7.23: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals.

Table 7.23: Table of risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
0.548	$3.53 * 10^0$	0.04097	0.01021	0.07173
0.779	$6.01 * 10^0$	0.01302	0.00000	0.02826
0.892	$7.80 * 10^0$	0.01114	0.00194	0.02034
0.988	$9.73 * 10^0$	0.01000	0.00356	0.01643
1.147	$1.40 * 10^1$	0.00705	0.00300	0.01111
1.271	$1.87 * 10^1$	0.00715	0.00367	0.01063
1.382	$2.41 * 10^1$	0.00765	0.00427	0.01103
1.481	$3.03 * 10^1$	0.00703	0.00392	0.01013
1.656	$4.53 * 10^1$	0.00597	0.00356	0.00837
1.741	$5.51 * 10^1$	0.00571	0.00342	0.00799
1.852	$7.11 * 10^1$	0.00543	0.00330	0.00756
2.699	$5.00 * 10^2$	0.00540	0.00337	0.00742
2.879	$7.57 * 10^2$	0.00538	0.00336	0.00740
3.000	$1.00 * 10^3$	0.00538	0.00336	0.00740

7.6.4 Day 29 Pseudo virus-neutralizing antibody (80% titer)

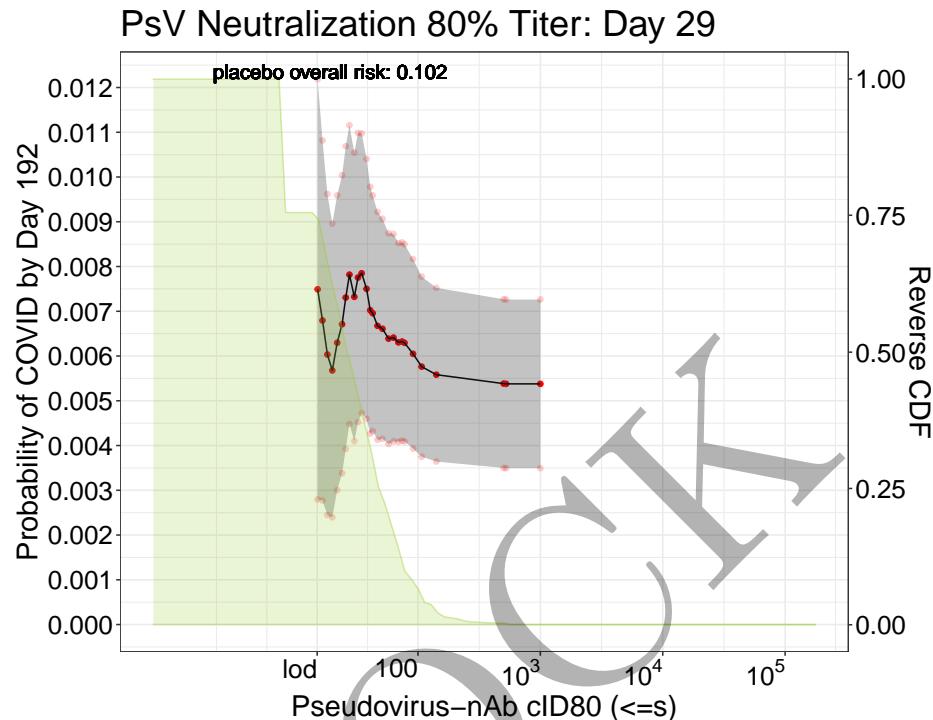


Figure 7.24: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals.

Table 7.24: Table of risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
1.183	$1.52 * 10^1$	0.00749	0.00280	0.01219
1.183	$1.52 * 10^1$	0.00749	0.00280	0.01219
1.183	$1.52 * 10^1$	0.00749	0.00280	0.01219
1.183	$1.52 * 10^1$	0.00749	0.00280	0.01219
1.339	$2.18 * 10^1$	0.00630	0.00300	0.00959
1.440	$2.75 * 10^1$	0.00782	0.00448	0.01116
1.541	$3.48 * 10^1$	0.00785	0.00472	0.01097
1.632	$4.29 * 10^1$	0.00696	0.00432	0.00959
1.796	$6.25 * 10^1$	0.00641	0.00409	0.00873
1.868	$7.38 * 10^1$	0.00632	0.00411	0.00854
1.956	$9.04 * 10^1$	0.00605	0.00393	0.00817
2.699	$5.00 * 10^2$	0.00538	0.00350	0.00727
2.719	$5.24 * 10^2$	0.00538	0.00349	0.00726
3.000	$1.00 * 10^3$	0.00538	0.00349	0.00726

7.7 Plots and Tables with estimates and pointwise confidence interval for Day 57 (monotone-corrected)

MOCK

7.7.1 Day 57 Spike protein binding antibody

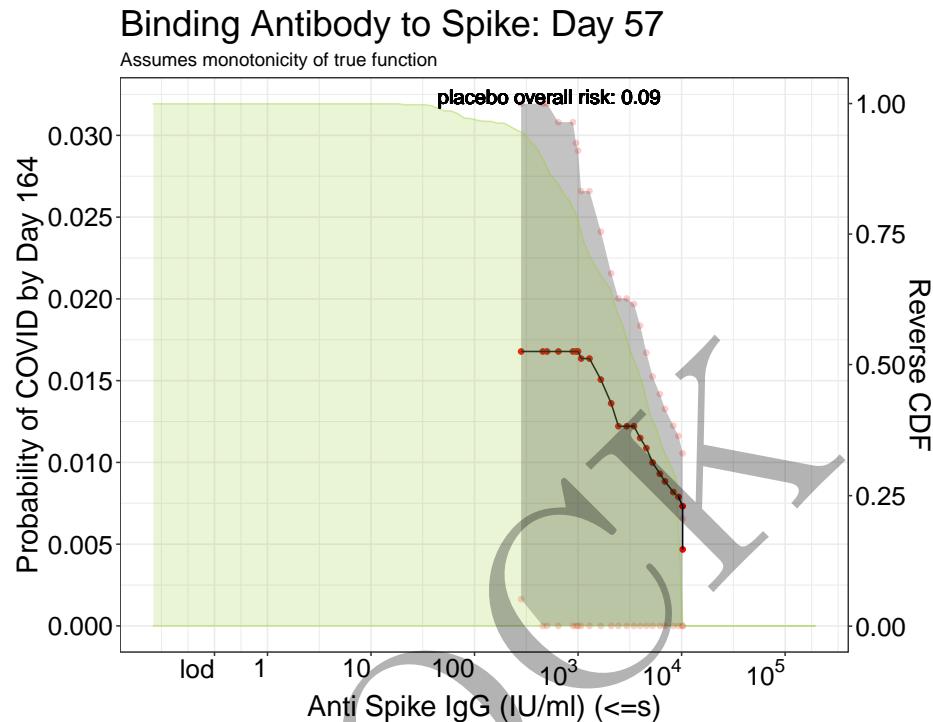


Figure 7.25: Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with simultaneous 95% confidence intervals. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 7.25: Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Spike protein binding antibody levels with simultaneous 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
2.450	$2.82 * 10^2$	0.01678	0.00164	0.03193
2.699	$5.00 * 10^2$	0.01678	0.00000	0.05316
2.815	$6.53 * 10^2$	0.01678	0.00276	0.03081
2.982	$9.59 * 10^2$	0.01678	0.00404	0.02953
3.000	$1.00 * 10^3$	0.01678	0.00451	0.02906
3.113	$1.30 * 10^3$	0.01635	0.00555	0.02715
3.471	$2.96 * 10^3$	0.01221	0.00422	0.02020
3.658	$4.55 * 10^3$	0.01087	0.00503	0.01671
3.841	$6.93 * 10^3$	0.00884	0.00440	0.01327
4.006	$1.01 * 10^4$	0.00732	0.00409	0.01056
4.007	$1.02 * 10^4$	0.00468	0.00280	0.00655
4.007	$1.02 * 10^4$	0.00468	0.00280	0.00655
4.007	$1.02 * 10^4$	0.00468	0.00280	0.00655

7.7.2 Day 57 RBD binding antibody

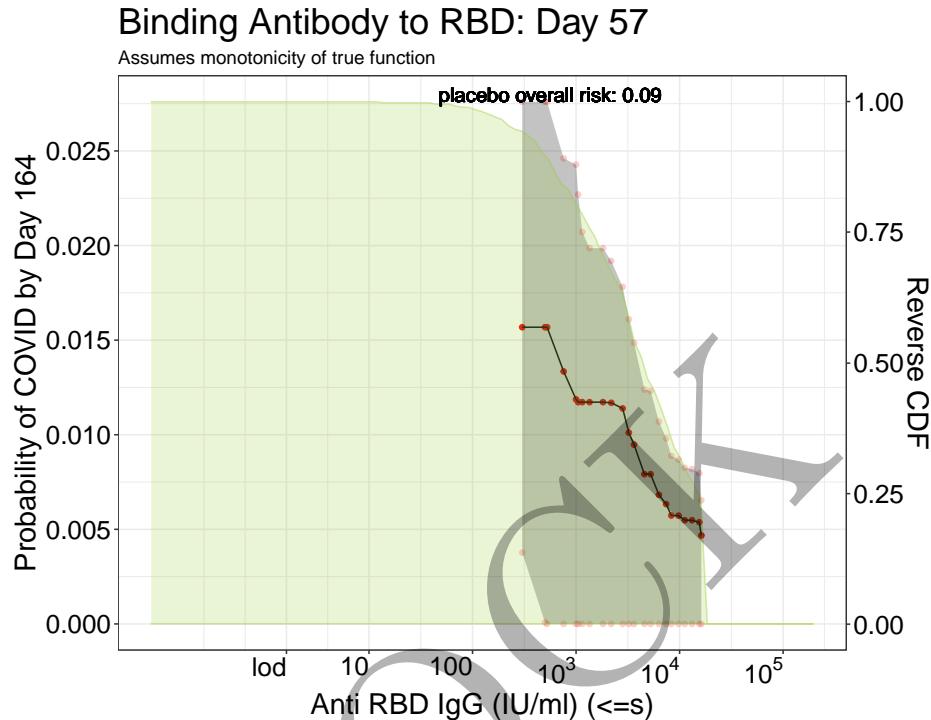


Figure 7.26: Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with simultaneous 95% confidence intervals. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 7.26: Table of monotone-corrected risk estimates for a range of thresholds of Day 57 RBD binding antibody levels with simultaneous 95% confidence intervals.

log ₁₀ -Threshold	Threshold	Risk estimate	CI left	CI right
2.478	3.01 * 10 ²	0.01568	0.00377	0.02760
2.699	5.00 * 10 ²	0.01568	0.00008	0.03128
2.882	7.62 * 10 ²	0.01334	0.00208	0.02461
3.000	1.00 * 10 ³	0.01187	0.00000	0.02428
3.056	1.14 * 10 ³	0.01172	0.00273	0.02072
3.259	1.82 * 10 ³	0.01172	0.00351	0.01993
3.557	3.61 * 10 ³	0.00948	0.00410	0.01485
3.797	6.27 * 10 ³	0.00683	0.00296	0.01070
3.986	9.68 * 10 ³	0.00572	0.00276	0.00868
4.186	1.53 * 10 ⁴	0.00537	0.00278	0.00797
4.211	1.63 * 10 ⁴	0.00468	0.00282	0.00653
4.211	1.63 * 10 ⁴	0.00468	0.00282	0.00653
4.211	1.63 * 10 ⁴	0.00468	0.00282	0.00653

7.7.3 Day 57 Pseudo virus-neutralizing antibody (50% titer)

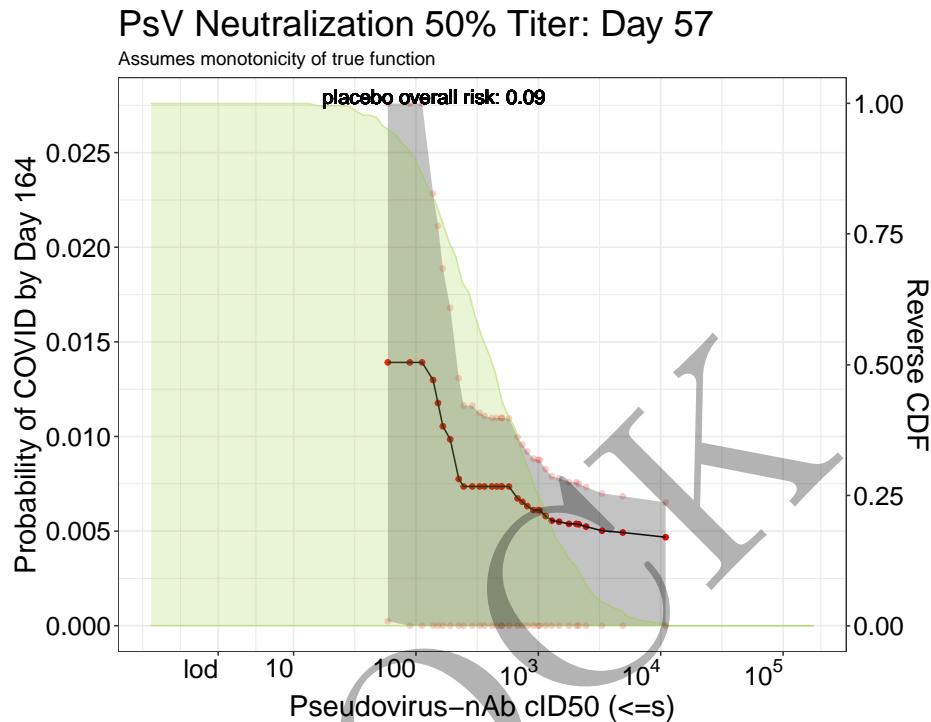


Figure 7.27: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 7.27: Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
1.765	$5.82 * 10^1$	0.01391	0.00023	0.02759
2.055	$1.14 * 10^2$	0.01391	0.00000	0.02896
2.177	$1.50 * 10^2$	0.01177	0.00240	0.02113
2.281	$1.91 * 10^2$	0.00985	0.00289	0.01680
2.519	$3.30 * 10^2$	0.00736	0.00347	0.01125
2.657	$4.54 * 10^2$	0.00736	0.00314	0.01157
2.699	$5.00 * 10^2$	0.00736	0.00357	0.01114
2.828	$6.73 * 10^2$	0.00672	0.00348	0.00997
2.959	$9.10 * 10^2$	0.00611	0.00339	0.00883
3.000	$1.00 * 10^3$	0.00611	0.00347	0.00876
3.174	$1.49 * 10^3$	0.00549	0.00320	0.00778
3.307	$2.03 * 10^3$	0.00538	0.00317	0.00759
3.387	$2.44 * 10^3$	0.00524	0.00315	0.00732
4.038	$1.09 * 10^4$	0.00468	0.00284	0.00651

7.7.4 Day 57 Pseudo virus-neutralizing antibody (80% titer)

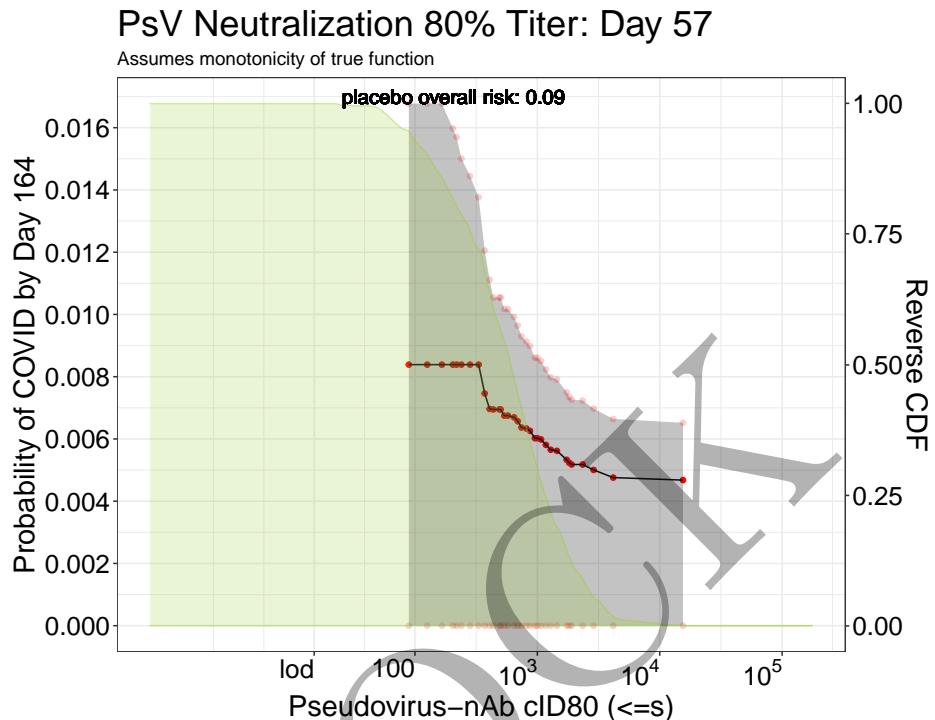


Figure 7.28: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 7.28: Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
1.954	$8.99 * 10^1$	0.00839	0.00000	0.01714
2.220	$1.66 * 10^2$	0.00839	0.00000	0.01692
2.335	$2.16 * 10^2$	0.00839	0.00107	0.01570
2.455	$2.85 * 10^2$	0.00839	0.00233	0.01445
2.644	$4.41 * 10^2$	0.00695	0.00335	0.01054
2.699	$5.00 * 10^2$	0.00695	0.00330	0.01059
2.764	$5.81 * 10^2$	0.00675	0.00312	0.01037
2.874	$7.48 * 10^2$	0.00637	0.00344	0.00930
2.981	$9.57 * 10^2$	0.00602	0.00344	0.00861
3.000	$1.00 * 10^3$	0.00602	0.00344	0.00861
3.162	$1.45 * 10^3$	0.00562	0.00332	0.00791
3.265	$1.84 * 10^3$	0.00524	0.00312	0.00735
3.371	$2.35 * 10^3$	0.00518	0.00312	0.00723
4.187	$1.54 * 10^4$	0.00468	0.00284	0.00652

7.8 Plots and Tables with estimates and pointwise confidence intervals for Day 29 (monotone-corrected)

MOCK

7.8.1 Day 29 Spike protein antibody

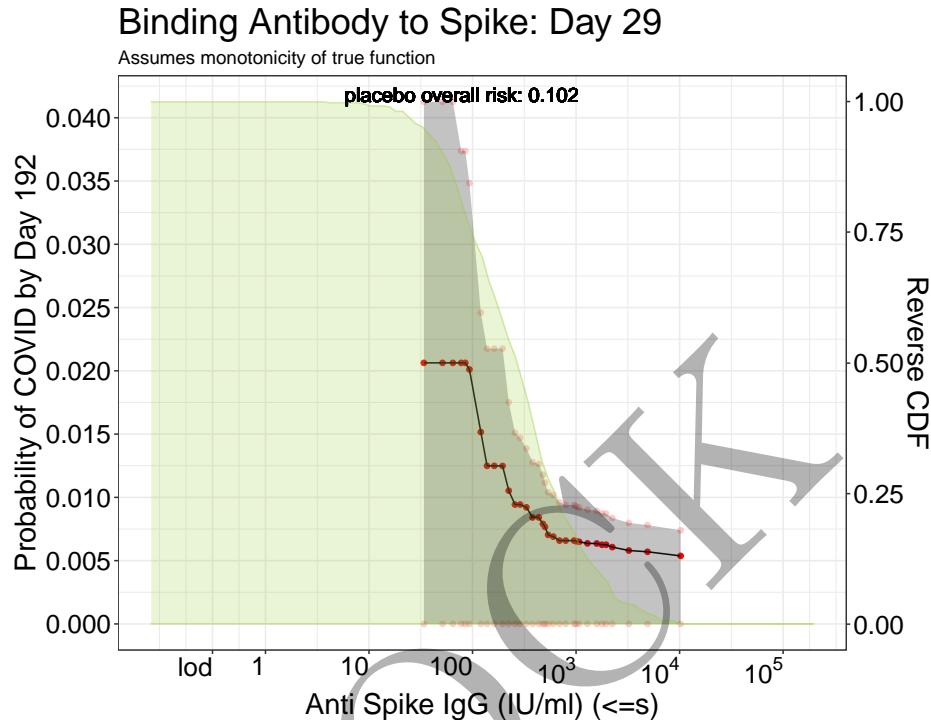


Figure 7.29: Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with simultaneous 95% confidence intervals. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 7.29: Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Spike protein antibody levels with simultaneous 95% confidence intervals.

log ₁₀ -Threshold	Threshold	Risk estimate	CI left	CI right
1.532	3.40 * 10 ¹	0.02063	0.00000	0.04805
1.805	6.38 * 10 ¹	0.02063	0.00000	0.04565
1.927	8.45 * 10 ¹	0.02063	0.00354	0.03772
2.081	1.21 * 10 ²	0.01516	0.00572	0.02460
2.351	2.24 * 10 ²	0.01053	0.00354	0.01752
2.522	3.33 * 10 ²	0.00921	0.00456	0.01387
2.677	4.75 * 10 ²	0.00790	0.00402	0.01179
2.699	5.00 * 10 ²	0.00767	0.00417	0.01116
2.841	6.93 * 10 ²	0.00659	0.00357	0.00961
3.000	1.00 * 10 ³	0.00653	0.00379	0.00928
3.112	1.29 * 10 ³	0.00637	0.00371	0.00902
3.252	1.79 * 10 ³	0.00626	0.00377	0.00874
3.348	2.23 * 10 ³	0.00607	0.00377	0.00838
4.007	1.02 * 10 ⁴	0.00538	0.00336	0.00740

7.8.2 Day 29 RBD binding antibody

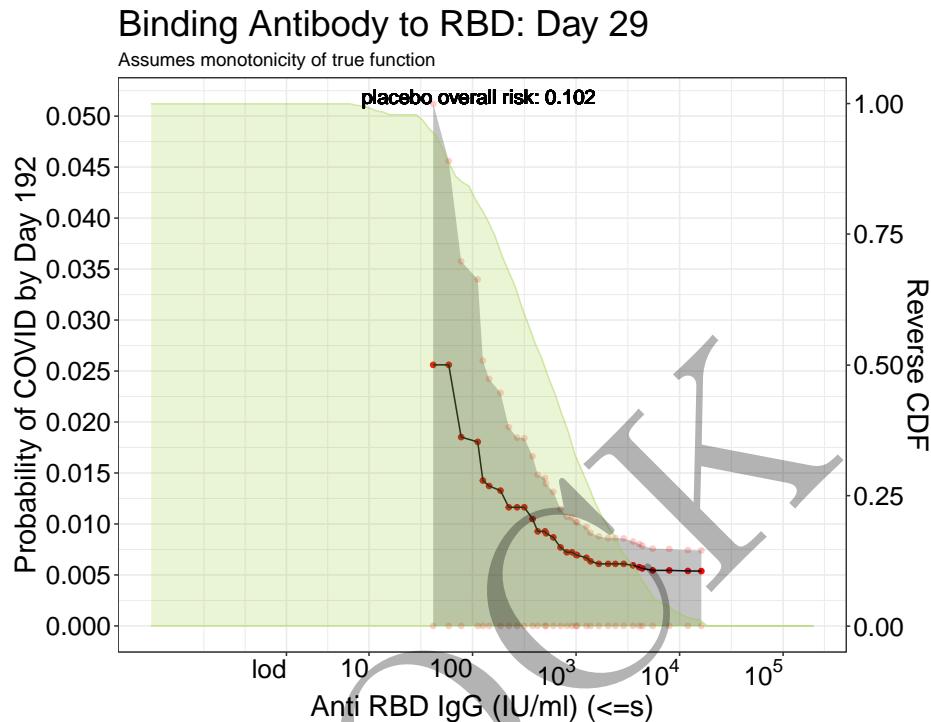


Figure 7.30: Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with simultaneous 95% confidence intervals. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 7.30: Table of monotone-corrected risk estimates for a range of thresholds of Day 29 RBD binding antibody levels with simultaneous 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
1.620	$4.17 * 10^1$	0.02560	0.00000	0.06044
1.892	$7.80 * 10^1$	0.01852	0.00128	0.03576
2.098	$1.25 * 10^2$	0.01426	0.00249	0.02603
2.273	$1.87 * 10^2$	0.01327	0.00368	0.02287
2.575	$3.76 * 10^2$	0.01048	0.00432	0.01664
2.699	$5.00 * 10^2$	0.00927	0.00404	0.01451
2.780	$6.03 * 10^2$	0.00868	0.00422	0.01314
2.960	$9.12 * 10^2$	0.00723	0.00382	0.01063
3.000	$1.00 * 10^3$	0.00697	0.00375	0.01020
3.144	$1.39 * 10^3$	0.00634	0.00354	0.00914
3.461	$2.89 * 10^3$	0.00609	0.00360	0.00858
3.610	$4.07 * 10^3$	0.00576	0.00349	0.00804
3.736	$5.45 * 10^3$	0.00545	0.00331	0.00758
4.211	$1.63 * 10^4$	0.00538	0.00335	0.00740

7.8.3 Day 29 Pseudo virus-neutralizing antibody (50% titer)

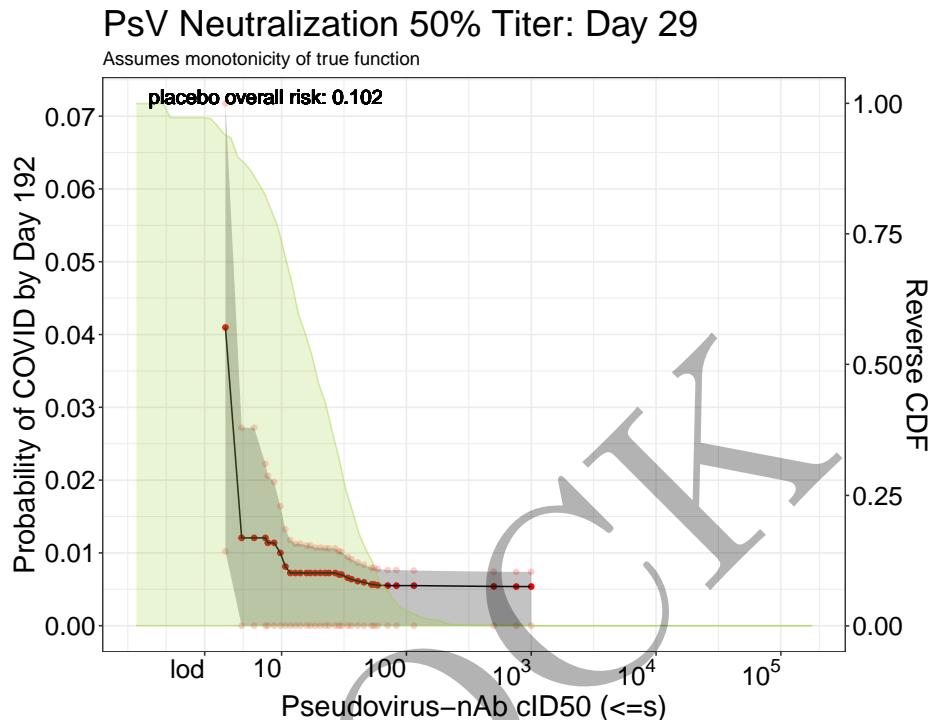


Figure 7.31: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 7.31: Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right	
	0.548	3.53 * 10 ⁰	0.04097	0.01021	0.07173
	0.779	6.01 * 10 ⁰	0.01207	0.00000	0.02731
	0.892	7.80 * 10 ⁰	0.01139	0.00219	0.02059
	0.988	9.73 * 10 ⁰	0.01000	0.00356	0.01643
	1.147	1.40 * 10 ¹	0.00724	0.00318	0.01129
	1.271	1.87 * 10 ¹	0.00724	0.00376	0.01072
	1.382	2.41 * 10 ¹	0.00724	0.00386	0.01061
	1.481	3.03 * 10 ¹	0.00703	0.00392	0.01013
	1.656	4.53 * 10 ¹	0.00597	0.00356	0.00837
	1.741	5.51 * 10 ¹	0.00567	0.00338	0.00795
	1.852	7.11 * 10 ¹	0.00551	0.00337	0.00764
	2.699	5.00 * 10 ²	0.00540	0.00337	0.00742
	2.879	7.57 * 10 ²	0.00538	0.00336	0.00740
	3.000	1.00 * 10 ³	0.00538	0.00336	0.00740

7.8.4 Day 29 Pseudo virus-neutralizing antibody (80% titer)

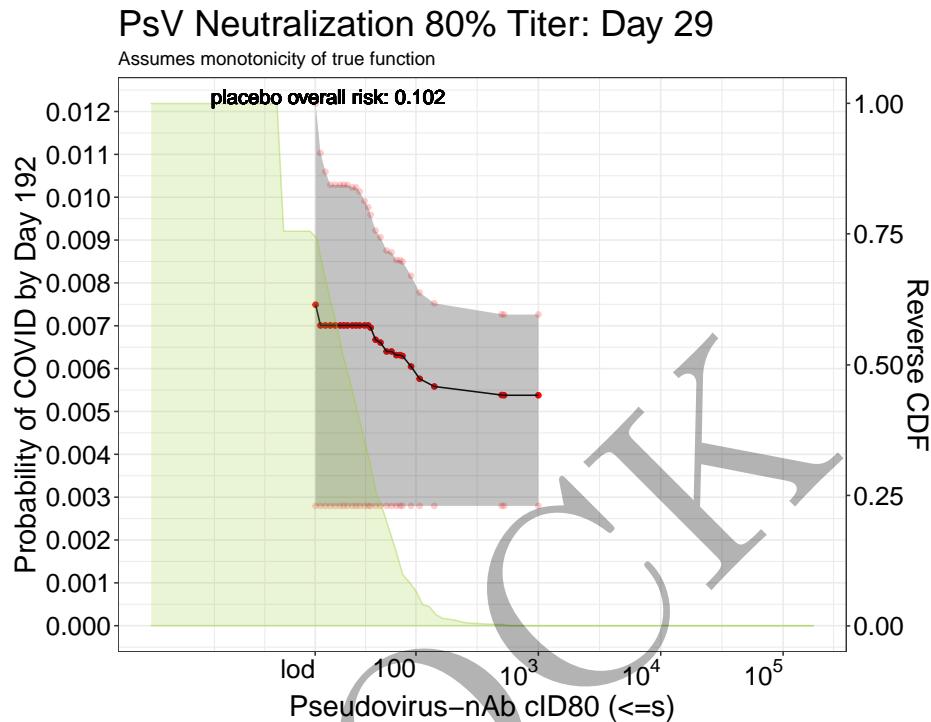


Figure 7.32: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 7.32: Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals.

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
1.183	$1.52 * 10^1$	0.00749	0.00280	0.01219
1.183	$1.52 * 10^1$	0.00749	0.00280	0.01219
1.183	$1.52 * 10^1$	0.00749	0.00280	0.01219
1.183	$1.52 * 10^1$	0.00749	0.00280	0.01219
1.339	$2.18 * 10^1$	0.00701	0.00371	0.01030
1.440	$2.75 * 10^1$	0.00701	0.00367	0.01034
1.541	$3.48 * 10^1$	0.00701	0.00388	0.01013
1.632	$4.29 * 10^1$	0.00696	0.00432	0.00959
1.796	$6.25 * 10^1$	0.00640	0.00408	0.00872
1.868	$7.38 * 10^1$	0.00631	0.00410	0.00853
1.956	$9.04 * 10^1$	0.00605	0.00393	0.00817
2.699	$5.00 * 10^2$	0.00538	0.00350	0.00727
2.719	$5.24 * 10^2$	0.00538	0.00349	0.00726
3.000	$1.00 * 10^3$	0.00538	0.00349	0.00726

Chapter 8

Day 57 Univariate CoR: Nonlinear modeling

To explore nonlinear association and threshold modeling, we fit smoothing spline models with degrees of freedom selected by cross-validation using the mgcv R package.

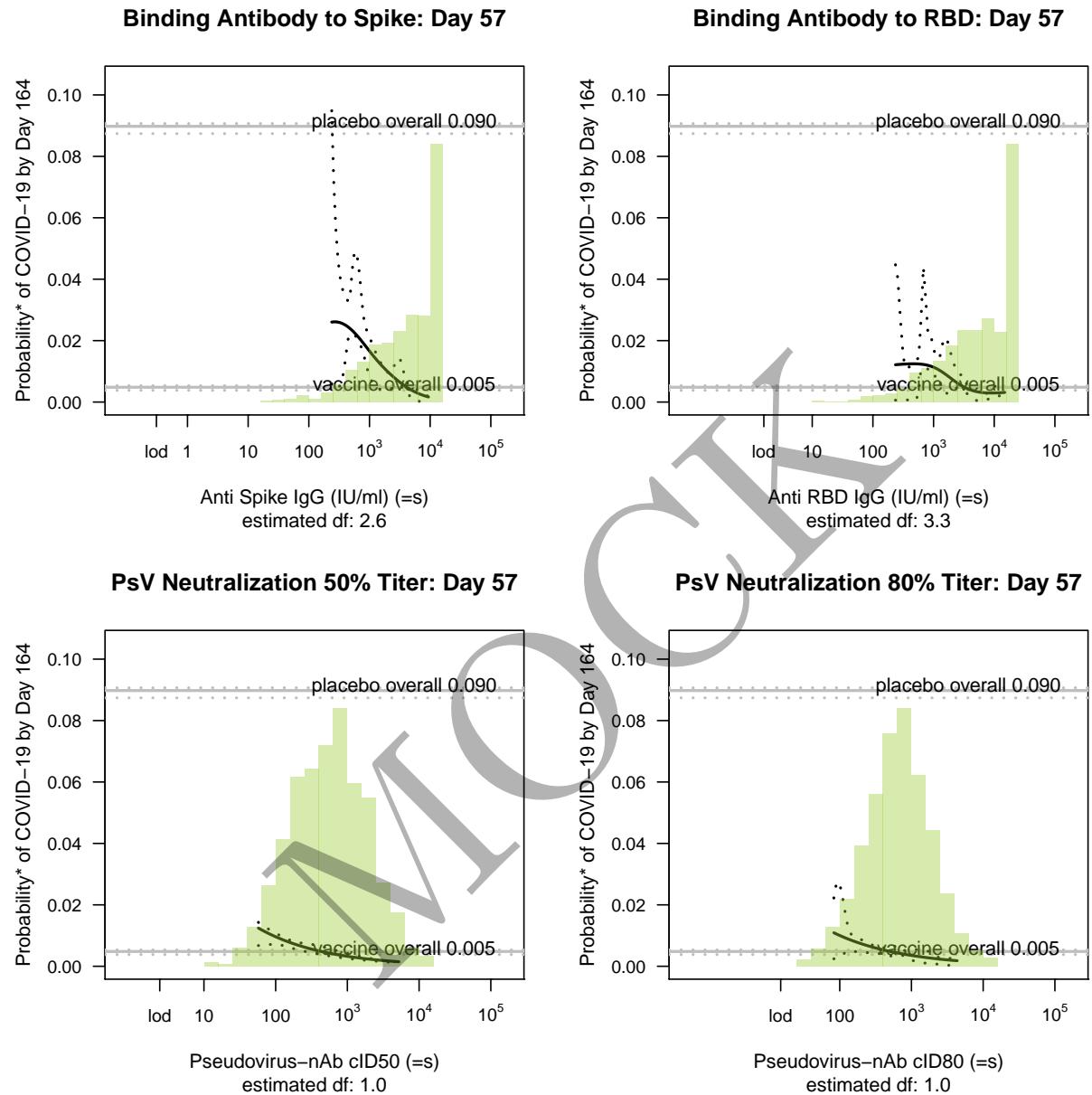


Figure 8.1: Marginalized risk as functions of Day 57 markers ($=s$) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands (5 replicates) as modeled by GAM with automatic smoothness estimation. Baseline covariates adjusted for: baseline risk score, meeting the protocol randomization criterion for being at heightened risk of COVID (yes or no), community of color or not. The horizontal lines indicate the overall cumulative risk of the vaccine and placebo arms by Day 164 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod = 0.3, 1.6, 2.4, 15 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively.

Chapter 9

Day 29 Univariate CoR: Nonlinear modeling

To explore nonlinear association and threshold modeling, we fit smoothing spline models with degrees of freedom selected by cross-validation using the mgcv R package.

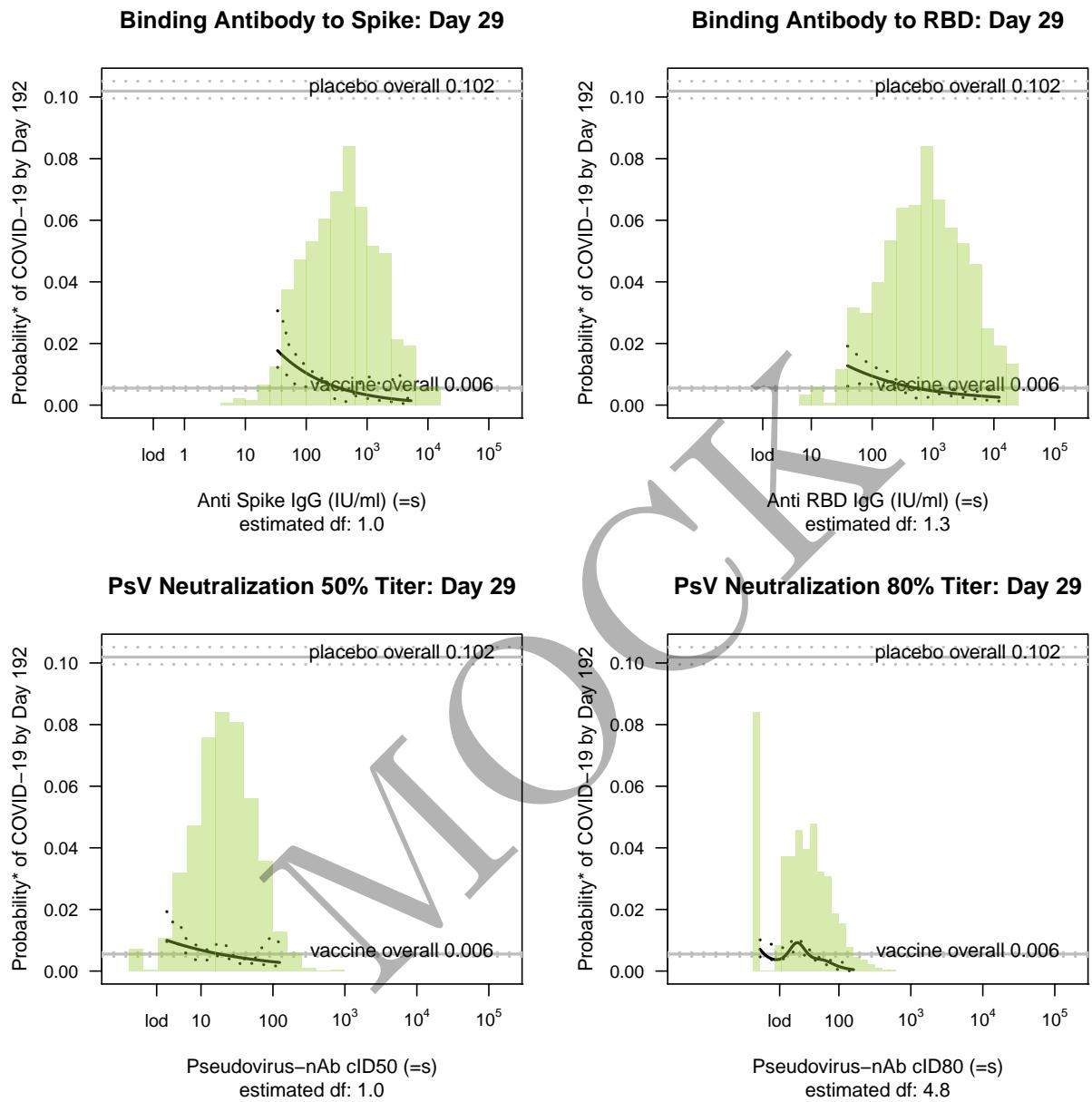


Figure 9.1: Marginalized risk as functions of Day 29 markers ($=s$) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands (5 replicates) as modeled by GAM with automatic smoothness estimation. Baseline covariates adjusted for: baseline risk score, meeting the protocol randomization criterion for being at heightened risk of COVID (yes or no), community of color or not. The horizontal lines indicate the overall cumulative risk of the vaccine and placebo arms by Day 192 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod = 0.3, 1.6, 2.4, 15 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively.

Chapter 10

Mediators of Vaccine Efficacy

Table 10.1: Table of mediation effect estimates for quantitative markers with 95% confidence intervals.
Direct VE = VE comparing vaccine vs. placebo with marker set to distribution in placebo.

Indirect VE = VE in vaccinated comparing observed marker vs. hypothetical marker under placebo.

Prop. mediated = fraction of total risk reduction from vaccine attributed to antibody response.

Time	Assay	Direct VE	Indirect VE	Prop. mediated
Day 29	PsV Neutralization 50% Titer	0.885 (0.716, 0.954)	0.512 (-0.215, 0.804)	0.249 (-0.065, 0.563)
Day 29	PsV Neutralization 80% Titer	0.906 (0.846, 0.943)	0.402 (0.066, 0.617)	0.179 (0.024, 0.333)

Table 10.2: Table of mediation effect estimates for tertile markers with 95% confidence intervals.

Direct VE = VE comparing vaccine vs. placebo with marker set to distribution in placebo.

Indirect VE = VE in vaccinated comparing observed marker vs. hypothetical marker under placebo.

Prop. mediated = fraction of total risk reduction from vaccine attributed to antibody response.

Time	Assay	Direct VE	Indirect VE	Prop. mediated
Day 29	PsV Neutralization 50% Titer	0.909 (0.870, 0.936)	0.387 (0.169, 0.548)	0.170 (0.066, 0.273)
Day 29	PsV Neutralization 80% Titer	0.914 (0.869, 0.943)	0.349 (0.051, 0.553)	0.149 (0.020, 0.278)

MOCK

Chapter 11

Appendix

- This report was built from the [CoVPN/correlates_reporting](#) repository with commit hash edd366aa9c66ac885e66bd62b355d43f86d15ead. A diff of the changes introduced by that commit may be viewed at https://github.com/CoVPN/correlates_reporting/commit/edd366aa9c66ac885e66bd62b355d43f86d15ead
- The sha256 hash sum of the raw input file, “COVID_VEtiral_practicedata_primarystage1.csv”: 83d0f55d1745ffd42be124d8f9ec9a9903abcc13cd22f95e537542a08b41300a
- The sha256 hash sum of the processed file, “moderna_mock_data_processed.csv”: b693743f019df4aab6f3e36a230927f15