

COVID-19 Correlates of Risk Analysis Report
mock Study

USG COVID-19 Response Biostatistics Team

May 15, 2021

Contents

1	Summary Tables	25
2	Graphical Descriptions of Antibody Marker Data	31
2.1	Boxplots	31
2.2	Weighted RCDF plots	40
2.3	Weighted RCDF plots of threshold correlate concentration for vaccine efficacy	48
2.4	Spaghetti plots	52
2.5	Violin and line plots	54
3	Day 57 Univariate CoR: Cox Models of Risk	303
3.1	Hazard ratios	303
3.2	Marginalized risk and controlled vaccine efficacy plots	308
4	Day 29 Univariate CoR: Cox Models of Risk	313
4.1	Hazard ratios	313
4.2	Marginalized risk and controlled vaccine efficacy plots	318
5	Univariate CoR: Nonparametric Threshold Modeling	323
5.1	Plots and Tables with estimates and pointwise confidence interval for Day 57	324
5.2	Plots and Tables with estimates and pointwise confidence intervals for Day 29	329
5.3	Plots and Tables with estimates and pointwise confidence interval for Day 57 (monotone-corrected)	334
5.4	Plots and Tables with estimates and pointwise confidence intervals for Day 29 (monotone-corrected)	339
5.5	Plots and Tables with estimates and simultaneous confidence bands for Day 57	344
5.6	Plots and Tables with estimates and simultaneous confidence bands for Day 29	349
5.7	Plots and Tables with estimates and pointwise confidence interval for Day 57 (monotone-corrected)	354
5.8	Plots and Tables with estimates and pointwise confidence intervals for Day 29 (monotone-corrected)	359
6	Appendix	365

List of Tables

1.1	Table 1. Demographic and Clinical Characteristics at Baseline in the Baseline SARS-CoV-2 Negative Per-Protocol Cohort	25
1.2	Table 2. Demographic and Clinical Characteristics at Baseline in the Baseline SARS-CoV-2 Positive Per-Protocol Cohort	27
1.3	Table 3. Antibody levels in the baseline SARS-CoV-2 negative per-protocol cohort (vaccine recipients)	28
1.4	Table 4. Antibody levels in the baseline SARS-CoV-2 positive per-protocol cohort (vaccine recipients)	29
1.5	Table 5. Antibody levels in the baseline SARS-CoV-2 positive per-protocol cohort (placebo recipients)	30
3.1	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*	303
3.2	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*	304
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*	313
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*	314
5.1	Table of risk estimates for a range of thresholds of Day 57 Spike protein binding antibody levels with pointwise 95% confidence intervals.	325
5.2	Table of risk estimates for a range of thresholds of Day 57 RBD binding antibody levels with pointwise 95% confidence intervals.	326
5.3	Table of risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals.	327
5.4	Table of risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals.	328
5.5	Table of risk estimates for a range of thresholds of Day 29 Spike protein antibody levels with pointwise 95% confidence intervals.	330
5.6	Table of risk estimates for a range of thresholds of Day 29 RBD binding antibody levels with pointwise 95% confidence intervals.	331
5.7	Table of risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals.	332

5.8	Table of risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals.	333
5.9	Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Spike protein binding antibody levels with pointwise 95% confidence intervals.	335
5.10	Table of monotone-corrected risk estimates for a range of thresholds of Day 57 RBD binding antibody levels with pointwise 95% confidence intervals.	336
5.11	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.	337
5.12	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.	338
5.13	Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Spike protein antibody levels with pointwise 95% confidence intervals.	340
5.14	Table of monotone-corrected risk estimates for a range of thresholds of Day 29 RBD binding antibody levels with pointwise 95% confidence intervals.	341
5.15	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.	342
5.16	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.	343
5.17	Table of risk estimates for a range of thresholds of Day 57 Spike protein binding antibody levels with simultaneous 95% confidence intervals.	345
5.18	Table of risk estimates for a range of thresholds of Day 57 RBD binding antibody levels with simultaneous 95% confidence intervals.	346
5.19	Table of risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals.	347
5.20	Table of risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals.	348
5.21	Table of risk estimates for a range of thresholds of Day 29 Spike protein antibody levels with simultaneous 95% confidence intervals.	350
5.22	Table of risk estimates for a range of thresholds of Day 29 RBD binding antibody levels with simultaneous 95% confidence intervals.	351
5.23	Table of risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals.	352
5.24	Table of risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals.	353
5.25	Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Spike protein binding antibody levels with simultaneous 95% confidence intervals.	355
5.26	Table of monotone-corrected risk estimates for a range of thresholds of Day 57 RBD binding antibody levels with simultaneous 95% confidence intervals.	356
5.27	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.	357
5.28	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.	358
5.29	Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Spike protein antibody levels with simultaneous 95% confidence intervals.	360

5.30 Table of monotone-corrected risk estimates for a range of thresholds of Day 29 RBD binding antibody levels with simultaneous 95% confidence intervals.	361
5.31 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.	362
5.32 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.	363

List of Figures

2.1	Boxplots of D57 Ab markers: baseline negative vaccine arm	32
2.2	Boxplots of D57 fold-rise over D1 Ab markers: baseline negative vaccine arm	33
2.3	Boxplots of D29 Ab markers: baseline negative vaccine arm	34
2.4	Boxplots of D29 fold-rise over D1 Ab markers: baseline negative vaccine arm	35
2.5	Boxplots of D57 Ab markers: baseline positive vaccine arm	36
2.6	Boxplots of D57 fold-rise over D1 Ab markers: baseline positive vaccine arm	37
2.7	Boxplots of D29 Ab markers: baseline positive vaccine arm	38
2.8	Boxplots of D29 fold-rise over D1 Ab markers: baseline positive vaccine arm	39
2.9	RCDF plots for D57 Ab markers: baseline negative by treatment arm	40
2.10	RCDF plots for D57 fold-rise over D1 Ab markers: baseline negative by treatment arm	41
2.11	RCDF plots for D29 Ab markers: baseline negative by treatment arm	42
2.12	RCDF plots for D29 fold-rise over D1 Ab markers: baseline negative by treatment arm	43
2.13	RCDF plots for D57 Ab markers: baseline positive by treatment arm	44
2.14	RCDF plots for D57 fold-rise over D1 Ab markers: baseline positive by treatment arm	45
2.15	RCDF plots for D29 Ab markers: baseline positive by treatment arm	46
2.16	RCDF plots for D29 fold-rise over D1 Ab markers: baseline positive by treatment arm	47
2.17	Marker RCDF of D57 anti-Spike binding Ab: baseline negative vaccine arm	48
2.18	Marker RCDF of D57 anti-RBD binding Ab: baseline negative vaccine arm	49
2.19	Marker RCDF of D57 PsV-nAb ID50: baseline negative vaccine arm	50
2.20	Marker RCDF of D57 PsV-nAb ID80: baseline negative vaccine arm	51
2.21	Spaghetti Plots of Marker Trajectory: baseline negative vaccine arm	52
2.22	Spaghetti Plots of Marker Trajectory: baseline positive vaccine arm	53
2.23	lineplots of Binding Antibody to Spike: baseline negative placebo arm (version 1)	54
2.24	lineplots of Binding Antibody to Spike: baseline negative vaccine arm (version 1)	55
2.25	lineplots of Binding Antibody to RBD: baseline negative placebo arm (version 1)	56
2.26	lineplots of Binding Antibody to RBD: baseline negative vaccine arm (version 1)	57
2.27	lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm (version 1)	58
2.28	lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm (version 1)	59

2.29 lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm (version 1)	60
2.30 lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm (version 1)	61
2.31 violinplots of Binding Antibody to Spike: baseline negative placebo arm (version 1)	62
2.32 violinplots of Binding Antibody to Spike: baseline negative vaccine arm (version 1)	63
2.33 violinplots of Binding Antibody to RBD: baseline negative placebo arm (version 1)	64
2.34 violinplots of Binding Antibody to RBD: baseline negative vaccine arm (version 1)	65
2.35 violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm (version 1) . . .	66
2.36 violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm (version 1) . . .	67
2.37 violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm (version 1) . .	68
2.38 violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm (version 1) . .	69
2.39 lineplots of Binding Antibody to Spike: baseline negative placebo arm (version 2)	70
2.40 lineplots of Binding Antibody to Spike: baseline negative vaccine arm (version 2)	71
2.41 lineplots of Binding Antibody to RBD: baseline negative placebo arm (version 2)	72
2.42 lineplots of Binding Antibody to RBD: baseline negative vaccine arm (version 2)	73
2.43 lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm (version 2) . . .	74
2.44 lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm (version 2) . . .	75
2.45 lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm (version 2) . . .	76
2.46 lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm (version 2) . . .	77
2.47 violinplots of Binding Antibody to Spike: baseline negative placebo arm (version 2)	78
2.48 violinplots of Binding Antibody to Spike: baseline negative vaccine arm (version 2)	79
2.49 violinplots of Binding Antibody to RBD: baseline negative placebo arm (version 2)	80
2.50 violinplots of Binding Antibody to RBD: baseline negative vaccine arm (version 2)	81
2.51 violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm (version 2) . .	82
2.52 violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm (version 2) . .	83
2.53 violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm (version 2) . .	84
2.54 violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm (version 2) . .	85
2.55 lineplots of Binding Antibody to Spike: baseline negative placebo arm by age (version 1) . . .	86
2.56 lineplots of Binding Antibody to Spike: baseline negative vaccine arm by age (version 1) . . .	87
2.57 lineplots of Binding Antibody to RBD: baseline negative placebo arm by age (version 1) . . .	88
2.58 lineplots of Binding Antibody to RBD: baseline negative vaccine arm by age (version 1) . . .	89
2.59 lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age (version 1)	90
2.60 lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age (version 1)	91
2.61 lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age (version 1)	92
2.62 lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age (version 1)	93
2.63 violinplots of Binding Antibody to Spike: baseline negative placebo arm by age (version 1) . .	94
2.64 violinplots of Binding Antibody to Spike: baseline negative vaccine arm by age (version 1) . .	95

2.65 violinplots of Binding Antibody to RBD: baseline negative placebo arm by age (version 1)	96
2.66 violinplots of Binding Antibody to RBD: baseline negative vaccine arm by age (version 1)	97
2.67 violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age (version 1)	98
2.68 violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age (version 1)	99
2.69 violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age (version 1)	100
2.70 violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age (version 1)	101
2.71 lineplots of Binding Antibody to Spike: baseline negative placebo arm by age (version 2)	102
2.72 lineplots of Binding Antibody to Spike: baseline negative vaccine arm by age (version 2)	103
2.73 lineplots of Binding Antibody to RBD: baseline negative placebo arm by age (version 2)	104
2.74 lineplots of Binding Antibody to RBD: baseline negative vaccine arm by age (version 2)	105
2.75 lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age (version 2)	106
2.76 lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age (version 2)	107
2.77 lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age (version 2)	108
2.78 lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age (version 2)	109
2.79 violinplots of Binding Antibody to Spike: baseline negative placebo arm by age (version 2)	110
2.80 violinplots of Binding Antibody to Spike: baseline negative vaccine arm by age (version 2)	111
2.81 violinplots of Binding Antibody to RBD: baseline negative placebo arm by age (version 2)	112
2.82 violinplots of Binding Antibody to RBD: baseline negative vaccine arm by age (version 2)	113
2.83 violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age (version 2)	114
2.84 violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age (version 2)	115
2.85 violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age (version 2)	116
2.86 violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age (version 2)	117
2.87 lineplots of Binding Antibody to Spike: baseline negative placebo arm by risk condition (version 1)	118
2.88 lineplots of Binding Antibody to Spike: baseline negative vaccine arm by risk condition (version 1)	119
2.89 lineplots of Binding Antibody to RBD: baseline negative placebo arm by risk condition (version 1)	120
2.90 lineplots of Binding Antibody to RBD: baseline negative vaccine arm by risk condition (version 1)	121
2.91 lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by risk condition (version 1)	122

2.92 lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by risk condition (version 1)	123
2.93 lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by risk condition (version 1)	124
2.94 lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by risk condition (version 1)	125
2.95 violinplots of Binding Antibody to Spike: baseline negative placebo arm by risk condition (version 1)	126
2.96 violinplots of Binding Antibody to Spike: baseline negative vaccine arm by risk condition (version 1)	127
2.97 violinplots of Binding Antibody to RBD: baseline negative placebo arm by risk condition (version 1)	128
2.98 violinplots of Binding Antibody to RBD: baseline negative vaccine arm by risk condition (version 1)	129
2.99 violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by risk condition (version 1)	130
2.100 violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by risk condition (version 1)	131
2.101 violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by risk condition (version 1)	132
2.102 violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by risk condition (version 1)	133
2.103 lineplots of Binding Antibody to Spike: baseline negative placebo arm by risk condition (version 2)	134
2.104 lineplots of Binding Antibody to Spike: baseline negative vaccine arm by risk condition (ver- sion 2)	135
2.105 lineplots of Binding Antibody to RBD: baseline negative placebo arm by risk condition (ver- sion 2)	136
2.106 lineplots of Binding Antibody to RBD: baseline negative vaccine arm by risk condition (ver- sion 2)	137
2.107 lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by risk condition (version 2)	138
2.108 lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by risk condition (version 2)	139
2.109 lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by risk condition (version 2)	140
2.110 lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by risk condition (version 2)	141
2.111 violinplots of Binding Antibody to Spike: baseline negative placebo arm by risk condition (version 2)	142
2.112 violinplots of Binding Antibody to Spike: baseline negative vaccine arm by risk condition (version 2)	143
2.113 violinplots of Binding Antibody to RBD: baseline negative placebo arm by risk condition (version 2)	144

2.114violinplots of Binding Antibody to RBD: baseline negative vaccine arm by risk condition (version 2)	145
2.115violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by risk condition (version 2)	146
2.116violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by risk condition (version 2)	147
2.117violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by risk condition (version 2)	148
2.118violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by risk condition (version 2)	149
2.119lineplots of Binding Antibody to Spike: baseline negative placebo arm by age and risk condition (version 1)	150
2.120lineplots of Binding Antibody to Spike: baseline negative vaccine arm by age and risk condition (version 1)	151
2.121lineplots of Binding Antibody to RBD: baseline negative placebo arm by age and risk condition (version 1)	152
2.122lineplots of Binding Antibody to RBD: baseline negative vaccine arm by age and risk condition (version 1)	153
2.123lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age and risk condition (version 1)	154
2.124lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age and risk condition (version 1)	155
2.125lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age and risk condition (version 1)	156
2.126lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age and risk condition (version 1)	157
2.127violinplots of Binding Antibody to Spike: baseline negative placebo arm by age and risk condition (version 1)	158
2.128violinplots of Binding Antibody to Spike: baseline negative vaccine arm by age and risk condition (version 1)	159
2.129violinplots of Binding Antibody to RBD: baseline negative placebo arm by age and risk condition (version 1)	160
2.130violinplots of Binding Antibody to RBD: baseline negative vaccine arm by age and risk condition (version 1)	161
2.131violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age and risk condition (version 1)	162
2.132violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age and risk condition (version 1)	163
2.133violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age and risk condition (version 1)	164
2.134violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age and risk condition (version 1)	165
2.135lineplots of Binding Antibody to Spike: baseline negative placebo arm by age and risk condition (version 2)	166

2.136lineplots of Binding Antibody to Spike: baseline negative vaccine arm by age and risk condition (version 2)	167
2.137lineplots of Binding Antibody to RBD: baseline negative placebo arm by age and risk condition (version 2)	168
2.138lineplots of Binding Antibody to RBD: baseline negative vaccine arm by age and risk condition (version 2)	169
2.139lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age and risk condition (version 2)	170
2.140lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age and risk condition (version 2)	171
2.141lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age and risk condition (version 2)	172
2.142lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age and risk condition (version 2)	173
2.143violinplots of Binding Antibody to Spike: baseline negative placebo arm by age and risk condition (version 2)	174
2.144violinplots of Binding Antibody to Spike: baseline negative vaccine arm by age and risk condition (version 2)	175
2.145violinplots of Binding Antibody to RBD: baseline negative placebo arm by age and risk con- dition (version 2)	176
2.146violinplots of Binding Antibody to RBD: baseline negative vaccine arm by age and risk con- dition (version 2)	177
2.147violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age and risk condition (version 2)	178
2.148violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age and risk condition (version 2)	179
2.149violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age and risk condition (version 2)	180
2.150violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age and risk condition (version 2)	181
2.151lineplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (version 1)	182
2.152lineplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (version 1)	183
2.153lineplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (version 1)	184
2.154lineplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (version 1)	185
2.155lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by sex assigned at birth (version 1)	186
2.156lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by sex assigned at birth (version 1)	187
2.157lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by sex assigned at birth (version 1)	188

2.158lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by sex assigned at birth (version 1)	189
2.159violinplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (version 1)	190
2.160violinplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (version 1)	191
2.161violinplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (version 1)	192
2.162violinplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (version 1)	193
2.163violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by sex assigned at birth (version 1)	194
2.164violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by sex assigned at birth (version 1)	195
2.165violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by sex assigned at birth (version 1)	196
2.166violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by sex assigned at birth (version 1)	197
2.167lineplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (version 2)	198
2.168lineplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (version 2)	199
2.169lineplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (version 2)	200
2.170lineplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (version 2)	201
2.171lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by sex assigned at birth (version 2)	202
2.172lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by sex assigned at birth (version 2)	203
2.173lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by sex assigned at birth (version 2)	204
2.174lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by sex assigned at birth (version 2)	205
2.175violinplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (version 2)	206
2.176violinplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (version 2)	207
2.177violinplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (version 2)	208
2.178violinplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (version 2)	209
2.179violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by sex assigned at birth (version 2)	210

2.180violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by sex assigned at birth (version 2)	211
2.181violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by sex assigned at birth (version 2)	212
2.182violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by sex assigned at birth (version 2)	213
2.183lineplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (version 1)	214
2.184lineplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (version 1)	215
2.185lineplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (version 1)	216
2.186lineplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (version 1)	217
2.187lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by race and ethnic group (version 1)	218
2.188lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by race and ethnic group (version 1)	219
2.189lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by race and ethnic group (version 1)	220
2.190lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by race and ethnic group (version 1)	221
2.191violinplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (version 1)	222
2.192violinplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (version 1)	223
2.193violinplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (version 1)	224
2.194violinplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (version 1)	225
2.195violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by race and ethnic group (version 1)	226
2.196violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by race and ethnic group (version 1)	227
2.197violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by race and ethnic group (version 1)	228
2.198violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by race and ethnic group (version 1)	229
2.199lineplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (version 2)	230
2.200lineplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (version 2)	231
2.201lineplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (version 2)	232

2.202lineplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (version 2)	233
2.203lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by race and ethnic group (version 2)	234
2.204lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by race and ethnic group (version 2)	235
2.205lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by race and ethnic group (version 2)	236
2.206lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by race and ethnic group (version 2)	237
2.207violinplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (version 2)	238
2.208violinplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (version 2)	239
2.209violinplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (version 2)	240
2.210violinplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (version 2)	241
2.211violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by race and ethnic group (version 2)	242
2.212violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by race and ethnic group (version 2)	243
2.213violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by race and ethnic group (version 2)	244
2.214violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by race and ethnic group (version 2)	245
2.215lineplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)	246
2.216lineplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)	247
2.217lineplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)	248
2.218lineplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)	249
2.219lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)	250
2.220lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)	251
2.221lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)	252
2.222lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)	253
2.223violinplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)	254

2.224violinplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)	255
2.225violinplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)	256
2.226violinplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)	257
2.227violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)	258
2.228violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)	259
2.229violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)	260
2.230violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)	261
2.231lineplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)	262
2.232lineplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)	263
2.233lineplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)	264
2.234lineplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)	265
2.235lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)	266
2.236lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)	267
2.237lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)	268
2.238lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)	269
2.239violinplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)	270
2.240violinplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)	271
2.241violinplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)	272
2.242violinplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)	273
2.243violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)	274
2.244violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)	275
2.245violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)	276

2.246violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)	277
2.247scatterplots of Binding Antibody to Spike: baseline negative vaccine arm at day 1	278
2.248scatterplots of Binding Antibody to Spike: baseline negative vaccine arm at day 29	279
2.249scatterplots of Binding Antibody to Spike: baseline negative vaccine arm at day 57	280
2.250scatterplots of Binding Antibody to RBD: baseline negative vaccine arm at day 1	281
2.251scatterplots of Binding Antibody to RBD: baseline negative vaccine arm at day 29	282
2.252scatterplots of Binding Antibody to RBD: baseline negative vaccine arm at day 57	283
2.253scatterplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm at day 1	284
2.254scatterplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm at day 29	285
2.255scatterplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm at day 57	286
2.256scatterplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm at day 1	287
2.257scatterplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm at day 29	288
2.258scatterplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm at day 57	289
2.259scatterplots of Binding Antibody to Spike: by arm at day 1	290
2.260scatterplots of Binding Antibody to Spike: by arm at day 29	291
2.261scatterplots of Binding Antibody to Spike: by arm at day 57	292
2.262scatterplots of Binding Antibody to RBD: by arm at day 1	293
2.263scatterplots of Binding Antibody to RBD: by arm at day 29	294
2.264scatterplots of Binding Antibody to RBD: by arm at day 57	295
2.265scatterplots of Pseudovirus Neutralization ID50: by arm at day 1	296
2.266scatterplots of Pseudovirus Neutralization ID50: by arm at day 29	297
2.267scatterplots of Pseudovirus Neutralization ID50: by arm at day 57	298
2.268scatterplots of Pseudovirus Neutralization ID80: by arm at day 1	299
2.269scatterplots of Pseudovirus Neutralization ID80: by arm at day 29	300
2.270scatterplots of Pseudovirus Neutralization ID80: by arm at day 57	301
3.1 Forest plots of hazard ratios per 10-fold increase in the marker among baseline seronegative vaccine recipients and subgroups with 95% point-wise confidence intervals.	305
3.2 Forest plots of hazard ratios per 10-fold increase in the Day 57 binding Ab to spike markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.	306
3.3 Forest plots of hazard ratios per 10-fold increase in the Day 57 binding Ab to RBD markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.	306
3.4 Forest plots of hazard ratios per 10-fold increase in the Day 57 pseudo neut ID50 markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.	307
3.5 Forest plots of hazard ratios per 10-fold increase in the Day 57 pseudo neut ID80 markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.	307

3.6 Marginalized cumulative risk by Day 174 as functions of Day 57 markers ($=s$) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. The horizontal lines indicate the overall cumulative risk of the placebo and vaccine arms by Day 174 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.	308
3.7 Controlled VE with sensitivity analysis as functions of Day 57 markers ($=s$) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.	309
3.8 Marginalized cumulative risk by Day 174 as functions of Day 57 markers above a threshold ($\geq s$) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands (at least 5 cases are required). The horizontal lines indicate the overall cumulative risk of the vaccine arm by Day 174 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.	310
3.9 Controlled VE as functions of Day 57 markers ($>=s$) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.	311
3.10 Marginalized cumulative incidence rate curves for trichotomized Day 57 markers among baseline seronegative vaccine recipients. The gray line is the overall cumulative incidence rate curve in the placebo arm.	312
4.1 Forest plots of hazard ratios per 10-fold increase in the marker among baseline seronegative vaccine recipients and subgroups with 95% point-wise confidence intervals.	315
4.2 Forest plots of hazard ratios per 10-fold increase in the Day 29 binding Ab to spike markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.	316
4.3 Forest plots of hazard ratios per 10-fold increase in the Day 29 binding Ab to RBD markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.	316
4.4 Forest plots of hazard ratios per 10-fold increase in the Day 29 pseudo neut ID50 markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.	317
4.5 Forest plots of hazard ratios per 10-fold increase in the Day 29 pseudo neut ID80 markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.	317
4.6 Marginalized cumulative risk by Day 202 as functions of Day 29 markers ($=s$) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. The horizontal lines indicate the overall cumulative risk of the placebo and vaccine arms by Day 202 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.	318
4.7 Controlled VE with sensitivity analysis as functions of Day 29 markers ($=s$) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.	319
4.8 Marginalized cumulative risk by Day 202 as functions of Day 29 markers above a threshold ($\geq s$) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands (at least 5 cases are required). The horizontal lines indicate the overall cumulative risk of the vaccine arm by Day 202 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.	320

4.9	Controlled VE as functions of Day 29 markers ($\geq s$) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.	321
4.10	Marginalized cumulative incidence rate curves for trichotomized Day 29 markers among baseline seronegative vaccine recipients. The gray line is the overall cumulative incidence rate curve in the placebo arm.	322
5.1	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.	325
5.2	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.	326
5.3	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.	327
5.4	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.	328
5.5	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.	330
5.6	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.	331
5.7	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.	332
5.8	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.	333
5.9	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.	335
5.10	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.	336
5.11	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.	337
5.12	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.	338

5.13 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.	340
5.14 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.	341
5.15 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.	342
5.16 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.	343
5.17 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.	345
5.18 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.	346
5.19 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.	347
5.20 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.	348
5.21 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.	350
5.22 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.	351
5.23 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.	352
5.24 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.	353
5.25 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.	355

5.26 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.	356
5.27 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.	357
5.28 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.	358
5.29 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.	360
5.30 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.	361
5.31 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.	362
5.32 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.	363

MOCK

Chapter 1

Summary Tables

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

Characteristics	Vaccine (N = 749)	Placebo (N = 132)	Total (N = 881)
Age			
Age < 65	353 (47.1%)	66 (50.0%)	419 (47.6%)
Age ≥ 65	396 (52.9%)	66 (50.0%)	462 (52.4%)
Mean (Range)	58.7 (18.0, 85.0)	58.5 (18.0, 85.0)	58.7 (18.0, 85.0)
BMI			
Mean ± SD	29.7 ± 6.9	30.8 ± 7.3	29.9 ± 6.9
Risk for Severe Covid-19			
At-risk	379 (50.6%)	66 (50.0%)	445 (50.5%)
Not at-risk	370 (49.4%)	66 (50.0%)	436 (49.5%)
Age, Risk for Severe Covid-19			
Age < 65 At-risk	169 (22.6%)	31 (23.5%)	200 (22.7%)
Age < 65 Not at-risk	184 (24.6%)	35 (26.5%)	219 (24.9%)
Age ≥ 65	396 (52.9%)	66 (50.0%)	462 (52.4%)
Sex			
Female	443 (59.1%)	81 (61.4%)	524 (59.5%)
Male	306 (40.9%)	51 (38.6%)	357 (40.5%)
Hispanic or Latino ethnicity			
Hispanic or Latino	122 (16.3%)	15 (11.4%)	137 (15.6%)
Not Hispanic or Latino	604 (80.6%)	112 (84.8%)	716 (81.3%)
Not reported and unknown	23 (3.1%)	5 (3.8%)	28 (3.2%)
Race			
White Non-Hispanic	359 (47.9%)	66 (50.0%)	425 (48.2%)
Black or African American	172 (23.0%)	32 (24.2%)	204 (23.2%)
Asian	68 (9.1%)	11 (8.3%)	79 (9.0%)
American Indian or Alaska Native	17 (2.3%)	4 (3.0%)	21 (2.4%)
Native Hawaiian or Other Pacific Islander	13 (1.7%)	3 (2.3%)	16 (1.8%)
Multiracial	59 (7.9%)	8 (6.1%)	67 (7.6%)
Other	28 (3.7%)	4 (3.0%)	32 (3.6%)
Not reported and unknown	5 (0.7%)	1 (0.8%)	6 (0.7%)
Communities of Color	390 (52.1%)	66 (50.0%)	456 (51.8%)

(continued)

Characteristics	Vaccine (N = 749)	Placebo (N = 132)	Total (N = 881)
-----------------	----------------------	----------------------	--------------------

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).

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

Characteristics	Vaccine (N = 224)	Placebo (N = 226)	Total (N = 450)
Age			
Age < 65	123 (54.9%)	119 (52.7%)	242 (53.8%)
Age ≥ 65	101 (45.1%)	107 (47.3%)	208 (46.2%)
Mean (Range)	56.5 (18.0, 85.0)	55.4 (18.0, 85.0)	56.0 (18.0, 85.0)
BMI			
Mean ± SD	29.5 ± 7.0	30.2 ± 7.1	29.9 ± 7.1
Risk for Severe Covid-19			
At-risk	99 (44.2%)	103 (45.6%)	202 (44.9%)
Not at-risk	125 (55.8%)	123 (54.4%)	248 (55.1%)
Age, Risk for Severe Covid-19			
Age < 65 At-risk	60 (26.8%)	60 (26.5%)	120 (26.7%)
Age < 65 Not at-risk	63 (28.1%)	59 (26.1%)	122 (27.1%)
Age ≥ 65	101 (45.1%)	107 (47.3%)	208 (46.2%)
Sex			
Female	134 (59.8%)	125 (55.3%)	259 (57.6%)
Male	90 (40.2%)	101 (44.7%)	191 (42.4%)
Hispanic or Latino ethnicity			
Hispanic or Latino	42 (18.8%)	32 (14.2%)	74 (16.4%)
Not Hispanic or Latino	177 (79.0%)	184 (81.4%)	361 (80.2%)
Not reported and unknown	5 (2.2%)	10 (4.4%)	15 (3.3%)
Race			
White Non-Hispanic	106 (47.3%)	114 (50.4%)	220 (48.9%)
Black or African American	41 (18.3%)	56 (24.8%)	97 (21.6%)
Asian	24 (10.7%)	14 (6.2%)	38 (8.4%)
American Indian or Alaska Native	7 (3.1%)	8 (3.5%)	15 (3.3%)
Native Hawaiian or Other Pacific Islander	2 (0.9%)	3 (1.3%)	5 (1.1%)
Multiracial	18 (8.0%)	19 (8.4%)	37 (8.2%)
Other	5 (2.2%)	6 (2.7%)	11 (2.4%)
Not reported and unknown	2 (0.9%)		2 (0.4%)
Communities of Color	118 (52.7%)	112 (49.6%)	230 (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).

Table 3. Antibody levels in the baseline SARS-CoV-2 negative per-protocol cohort (vaccine recipients)

Baseline SARS-CoV-2 Negative Vaccine Recipients										
Visit	Marker	Cases*				Non-Cases/Control			Comparison	
		N	Resp rate	GMT/GMC	N	Resp rate	GMT/GMC	Resp Rate Difference	GMTR/GMCR	
Day 29	Pseudovirus-nAb ID80	69	69.5/71.6 = 97.1% (88.9%, 99.3%)	49.07 (42.20, 57.05)	753	10840.4/11038.4 = 98.2% (96.3%, 99.1%)	62.15 (57.88, 66.73)	-0.01 (-0.09, 0.02)	0.79 (0.67, 0.93)	
Day 29	Pseudovirus-nAb ID50	69	71.6/71.6 = 100.0% (100.0%, 100.0%)	156.32 (131.48, 185.85)	753	10944.7/11038.4 = 99.2% (96.7%, 99.8%)	253.26 (232.18, 276.25)	0.01 (0, 0.03)	0.62 (0.51, 0.75)	
Day 29	Anti RBD IgG (IU/ml)	69	71.6/71.6 = 100.0% (100.0%, 100.0%)	328.45 (229.42, 470.24)	753	11030.5/11038.4 = 99.9% (99.5%, 100.0%)	514.47 (442.33, 598.39)	0 (0, 0.01)	0.64 (0.43, 0.94)	
Day 29	Anti Spike IgG (IU/ml)	69	71.6/71.6 = 100.0% (100.0%, 100.0%)	158.37 (121.64, 206.20)	753	11038.4/11038.4 = 100.0% (100.0%, 100.0%)	304.29 (266.30, 347.70)	0 (0, 0)	0.52 (0.39, 0.70)	
Day 29	Anti N IgG (IU/ml)	69	71.6/71.6 = 100.0% (100.0%, 100.0%)	32.52 (21.95, 48.16)	753	10957.7/11038.4 = 99.3% (97.3%, 99.8%)	43.24 (35.94, 52.03)	0.01 (0, 0.03)	0.75 (0.49, 1.16)	
Day 57	Pseudovirus-nAb ID80	68	71/71 = 100.0% (100.0%, 100.0%)	659.65 (561.68, 774.72)	741	11000/11000 = 100.0% (100.0%, 100.0%)	1611.12 (1504.50, 1725.30)	0 (0, 0)	0.41 (0.34, 0.49)	
Day 57	Pseudovirus-nAb ID50	68	71/71 = 100.0% (100.0%, 100.0%)	2822.52 (2336.75, 3409.27)	741	11000/11000 = 100.0% (100.0%, 100.0%)	8298.74 (7641.77, 9012.18)	0 (0, 0)	0.34 (0.28, 0.42)	
Day 57	Anti RBD IgG (IU/ml)	68	71/71 = 100.0% (100.0%, 100.0%)	7893.43 (5319.91, 11711.92)	741	11000/11000 = 100.0% (100.0%, 100.0%)	21439.57 (18195.15, 25262.51)	0 (0, 0)	0.37 (0.24, 0.56)	
Day 57	Anti Spike IgG (IU/ml)	68	71/71 = 100.0% (100.0%, 100.0%)	3769.14 (2709.47, 5243.25)	741	11000/11000 = 100.0% (100.0%, 100.0%)	13843.73 (11869.97, 16145.70)	0 (0, 0)	0.27 (0.19, 0.39)	
Day 57	Anti N IgG (IU/ml)	68	71/71 = 100.0% (100.0%, 100.0%)	320.79 (199.13, 516.79)	741	10953.4/11000 = 99.6% (97.1%, 99.9%)	570.38 (459.45, 708.10)	0 (0, 0.03)	0.56 (0.33, 0.95)	

*Cases 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 evidence of SARS-CoV-2 infection up to the time of data cut.

Table 4. 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 ID80	5 5/5 = 100.0% (100.0%, 100.0%)	113.78 (68.85, 188.05)	222 1180/1180 = 100.0% (100.0%, 100.0%)	109.07 (97.84, 121.60)	0 (0, 0)	1.04 (0.62, 1.74)		
Day 29	Pseudovirus-nAb ID50	5 5/5 = 100.0% (100.0%, 100.0%)	609.85 (311.96, 1192.17)	222 1180/1180 = 100.0% (100.0%, 100.0%)	494.75 (433.95, 564.07)	0 (0, 0)	1.23 (0.62, 2.44)		
Day 29	Anti RBD IgG (IU/ml)	5 5/5 = 100.0% (100.0%, 100.0%)	1216.77 (478.82, 3092.02)	222 1180/1180 = 100.0% (100.0%, 100.0%)	1306.70 (1037.63, 1645.55)	0 (0, 0)	0.93 (0.36, 2.43)		
Day 29	Anti Spike IgG (IU/ml)	5 5/5 = 100.0% (100.0%, 100.0%)	1128.71 (737.73, 1726.90)	222 1180/1180 = 100.0% (100.0%, 100.0%)	560.78 (450.91, 697.40)	0 (0, 0)	2.01 (1.25, 3.25)		
Day 29	Anti N IgG (IU/ml)	5 5/5 = 100.0% (100.0%, 100.0%)	111.67 (30.06, 414.84)	222 1180/1180 = 100.0% (100.0%, 100.0%)	105.51 (78.09, 142.55)	0 (0, 0)	1.06 (0.28, 4.07)		
Day 57	Pseudovirus-nAb ID80	5 5/5 = 100.0% (100.0%, 100.0%)	3750.08 (2067.12, 6803.21)	222 1179/1179 = 100.0% (100.0%, 100.0%)	4715.05 (4186.08, 5310.85)	0 (0, 0)	0.80 (0.43, 1.46)		
Day 57	Pseudovirus-nAb ID50	5 5/5 = 100.0% (100.0%, 100.0%)	13785.42 (8717.88, 21798.64)	222 1179/1179 = 100.0% (100.0%, 100.0%)	24076.54 (20954.91, 27663.21)	0 (0, 0)	0.57 (0.35, 0.92)		
Day 57	Anti RBD IgG (IU/ml)	5 5/5 = 100.0% (100.0%, 100.0%)	37186.81 (18268.26, 75697.36)	222 1179/1179 = 100.0% (100.0%, 100.0%)	57282.36 (44664.88, 73464.17)	0 (0, 0)	0.65 (0.31, 1.38)		
Day 57	Anti Spike IgG (IU/ml)	5 5/5 = 100.0% (100.0%, 100.0%)	43928.11 (24250.80, 79571.75)	222 1179/1179 = 100.0% (100.0%, 100.0%)	43229.74 (33771.33, 55337.18)	0 (0, 0)	1.02 (0.53, 1.93)		
Day 57	Anti N IgG (IU/ml)	5 5/5 = 100.0% (100.0%, 100.0%)	1730.10 (540.84, 5534.43)	222 1179/1179 = 100.0% (100.0%, 100.0%)	1802.94 (1249.00, 2602.56)	0 (0, 0)	0.96 (0.28, 3.25)		

*Cases 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 negative per-protocol vaccine recipients sampled into the random subcohort with no evidence of SARS-CoV-2 infection up to the time of data cut.

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

Visit	Marker	Baseline SARS-CoV-2 Positive Placebo Recipients							
		Cases*			Non-Cases/Control			Comparison	
N	Resp rate	GMT/GMC	N	Resp rate	GMT/GMC	Resp Rate Difference	GMTR/GMCR		
Day 29	Pseudovirus-nAb ID80	4 (10.8%, 98.7%)	3.8/5 = 75.0% (14.26, 39.04)	23.60 (14.26, 39.04)	225 (81.9%, 94.2%)	977.5/1091 = 89.6% (36.65, 47.61)	41.77 (-0.79, 0.1)	-0.15 (0.34, 0.95)	0.56
Day 29	Pseudovirus-nAb ID50	4 (100.0%, 100.0%)	5/5 = 100.0% (25.73, 331.80)	92.40 (25.73, 331.80)	225 (91.2%, 99.8%)	1076.6/1091 = 98.7% (121.67, 165.48)	141.90 (0, 0.09)	0.01 (0.18, 2.36)	0.65
Day 29	Anti RBD IgG (IU/ml)	4 (100.0%, 100.0%)	5/5 = 100.0% (9.86, 408.91)	63.50 (9.86, 408.91)	225 (92.1%, 99.7%)	1073.6/1091 = 98.4% (199.49, 371.06)	272.07 (0, 0.08)	0.02 (0.04, 1.54)	0.23
Day 29	Anti Spike IgG (IU/ml)	4 (100.0%, 100.0%)	5/5 = 100.0% (11.76, 209.97)	49.68 (11.76, 209.97)	225 (91.2%, 99.8%)	1076.6/1091 = 98.7% (120.92, 206.13)	157.88 (0, 0.09)	0.01 (0.07, 1.36)	0.31
Day 29	Anti N IgG (IU/ml)	4 (100.0%, 100.0%)	5/5 = 100.0% (1.17, 53.10)	7.89 (1.17, 53.10)	225 (90.2%, 98.8%)	1053.2/1091 = 96.5% (16.51, 32.89)	23.31 (0.01, 0.1)	0.03 (0.05, 2.35)	0.34
Day 57	Pseudovirus-nAb ID80	4 (100.0%, 100.0%)	5/5 = 100.0% (299.98, 818.39)	495.48 (299.98, 818.39)	225 (100.0%, 100.0%)	1089/1089 = 100.0% (806.70, 1115.74)	948.72 (0, 0)	0 (0.31, 0.88)	0.52
Day 57	Pseudovirus-nAb ID50	4 (100.0%, 100.0%)	5/5 = 100.0% (1110.54, 4733.86)	2292.85 (1110.54, 4733.86)	225 (100.0%, 100.0%)	1089/1089 = 100.0% (3548.60, 4969.22)	4199.26 (0, 0)	0 (0.26, 1.15)	0.55
Day 57	Anti RBD IgG (IU/ml)	4 (100.0%, 100.0%)	5/5 = 100.0% (319.47, 9725.55)	1762.66 (319.47, 9725.55)	225 (100.0%, 100.0%)	1089/1089 = 100.0% (7875.80, 17096.96)	11603.97 (0, 0)	0 (0.03, 0.88)	0.15
Day 57	Anti Spike IgG (IU/ml)	4 (100.0%, 100.0%)	5/5 = 100.0% (633.20, 12792.17)	2846.05 (633.20, 12792.17)	225 (100.0%, 100.0%)	1089/1089 = 100.0% (4693.07, 8810.10)	6430.12 (0, 0)	0 (0.10, 2.06)	0.44
Day 57	Anti N IgG (IU/ml)	4 (100.0%, 100.0%)	5/5 = 100.0% (9.01, 1035.45)	96.61 (9.01, 1035.45)	225 (91.3%, 99.8%)	1074.6/1089 = 98.7% (188.31, 491.10)	304.10 (0, 0.09)	0.01 (0.03, 3.57)	0.32

*Cases 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 evidence of SARS-CoV-2 infection up to the time of data cut.

Chapter 2

Graphical Descriptions of Antibody Marker Data

2.1 Boxplots

2.1.1 Baseline seronegative

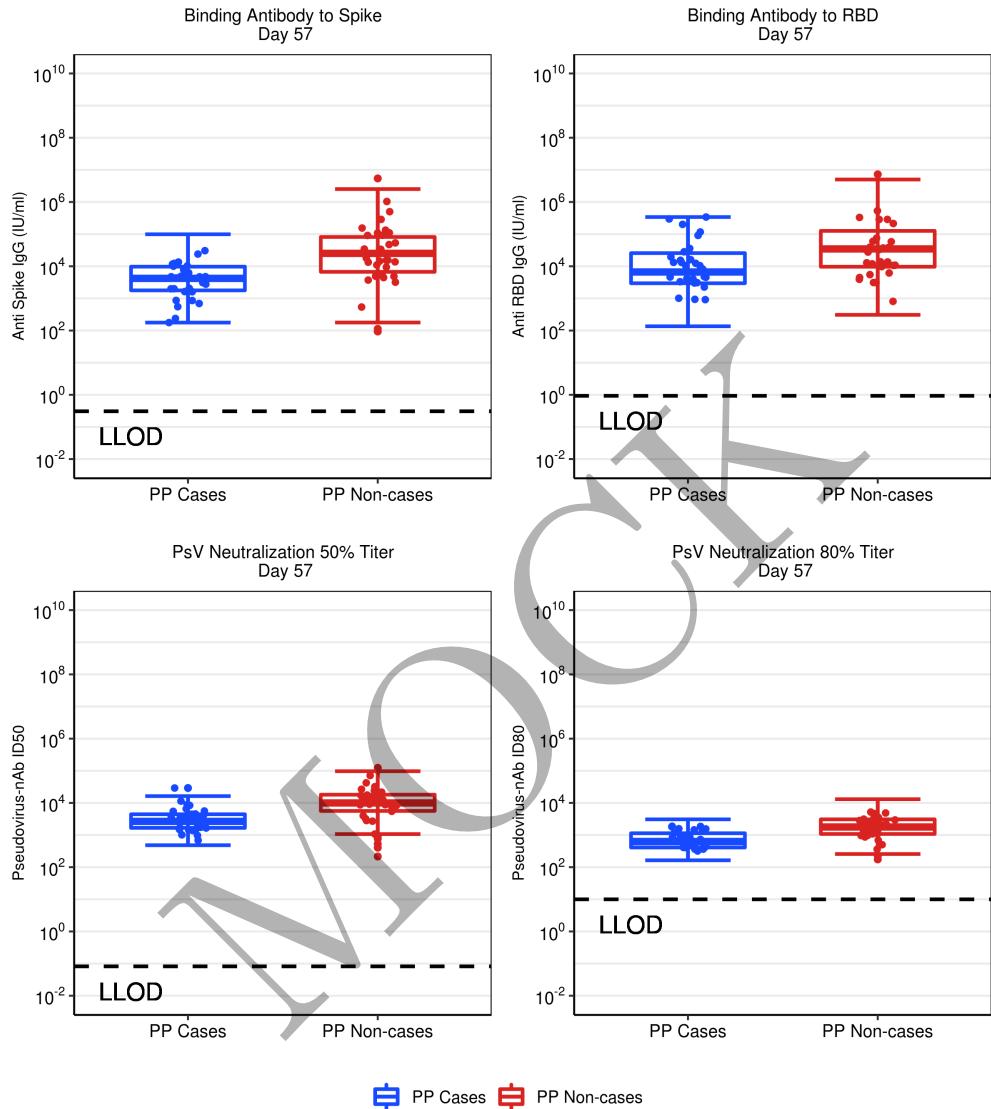


Figure 2.1: Boxplots of D57 Ab markers: baseline negative vaccine arm.

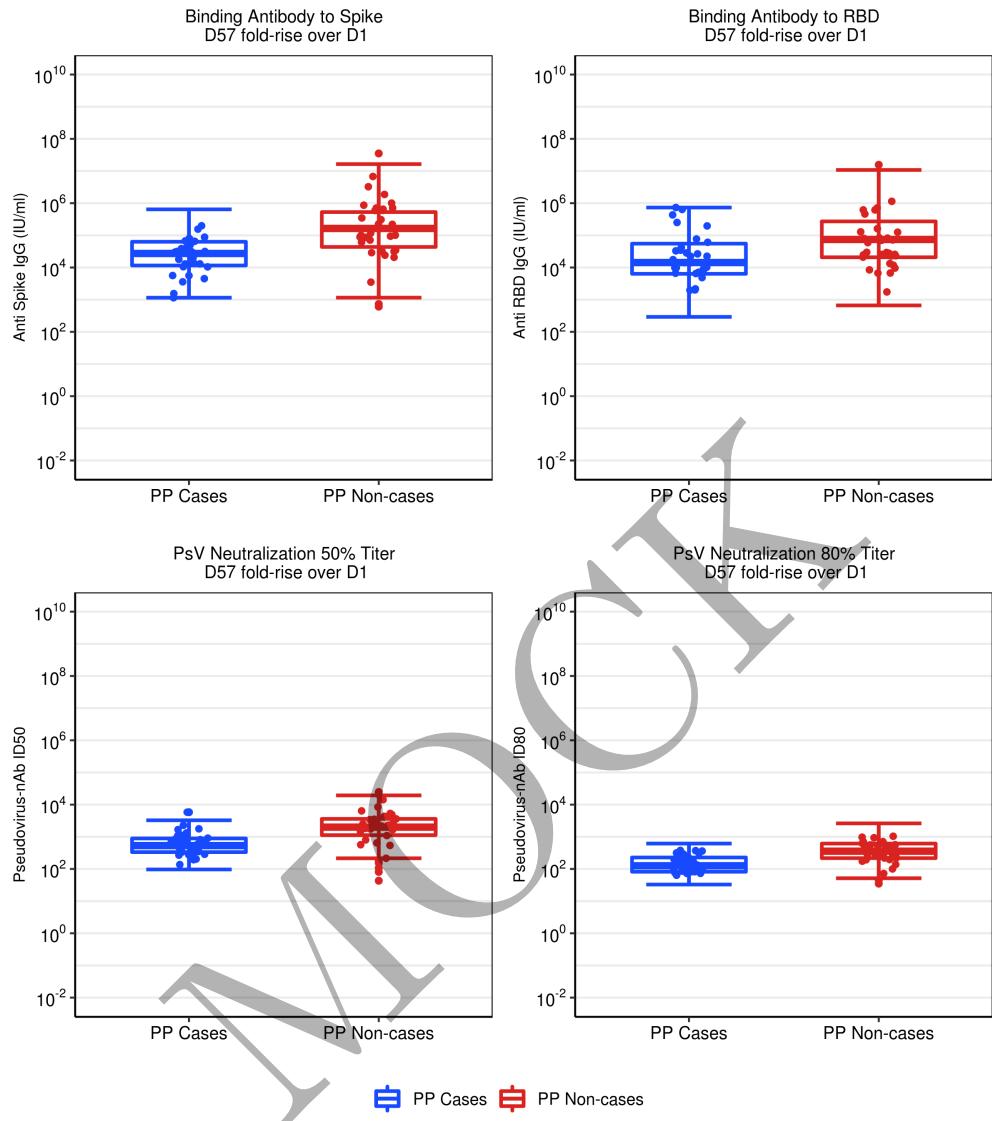


Figure 2.2: Boxplots of D57 fold-rise over D1 Ab markers: baseline negative vaccine arm.

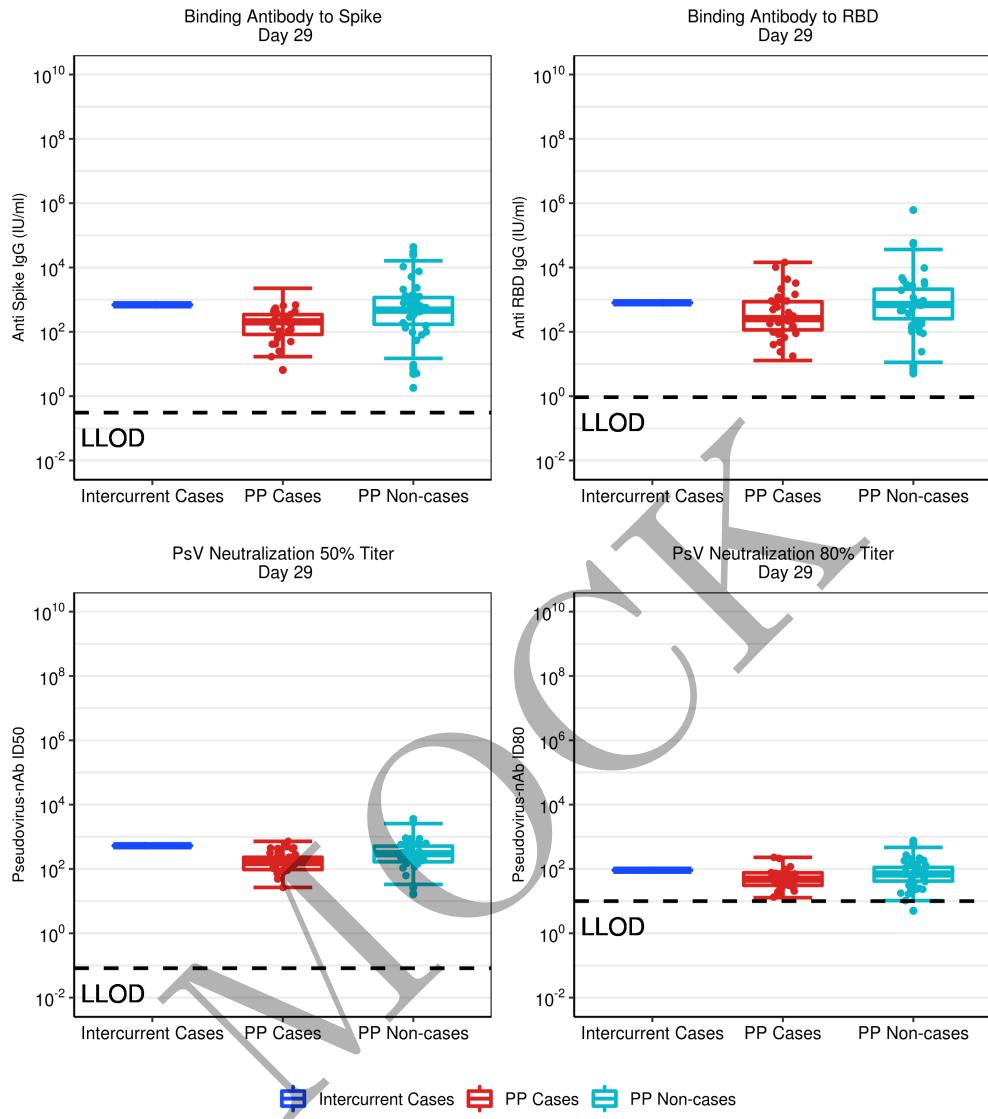


Figure 2.3: Boxplots of D29 Ab markers: baseline negative vaccine arm.

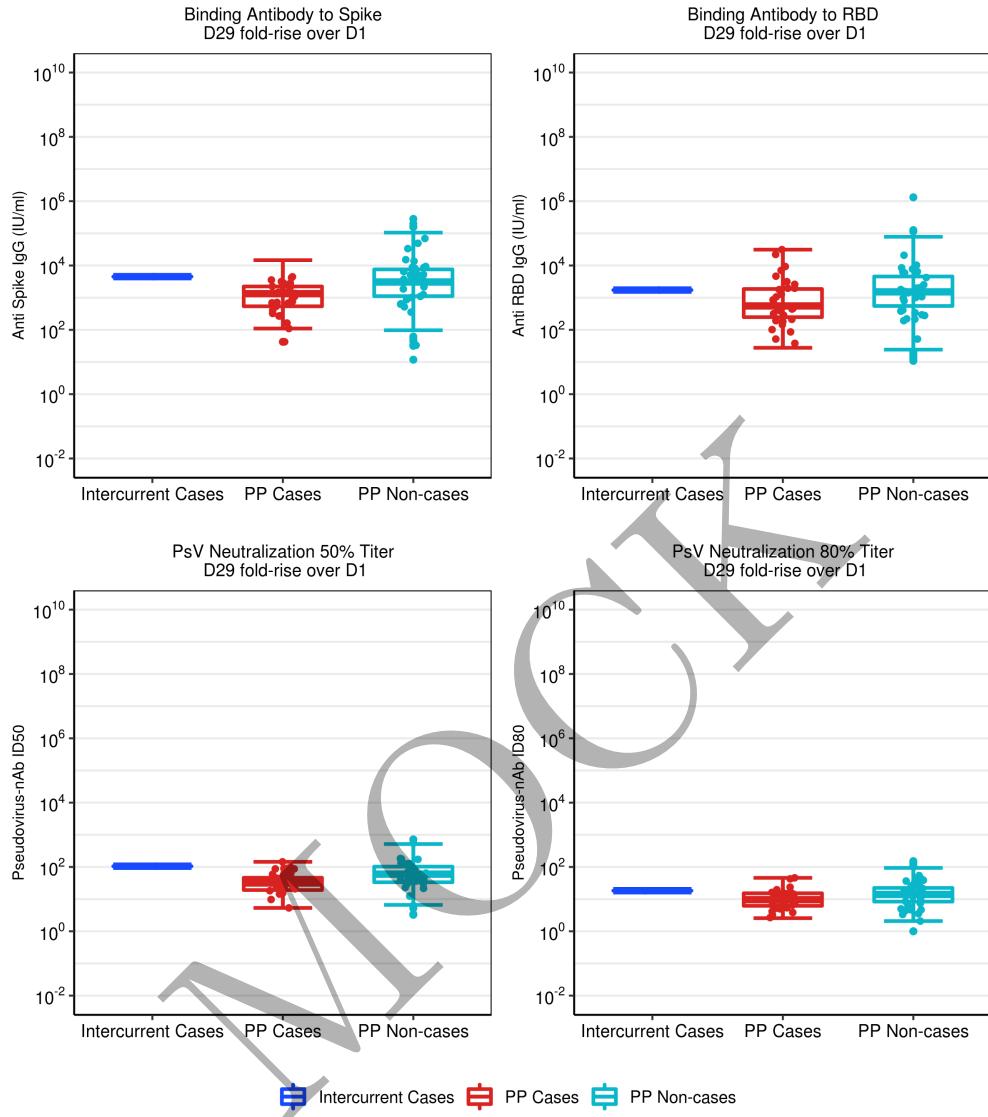


Figure 2.4: Boxplots of D29 fold-rise over D1 Ab markers: baseline negative vaccine arm.

2.1.2 Baseline seropositive

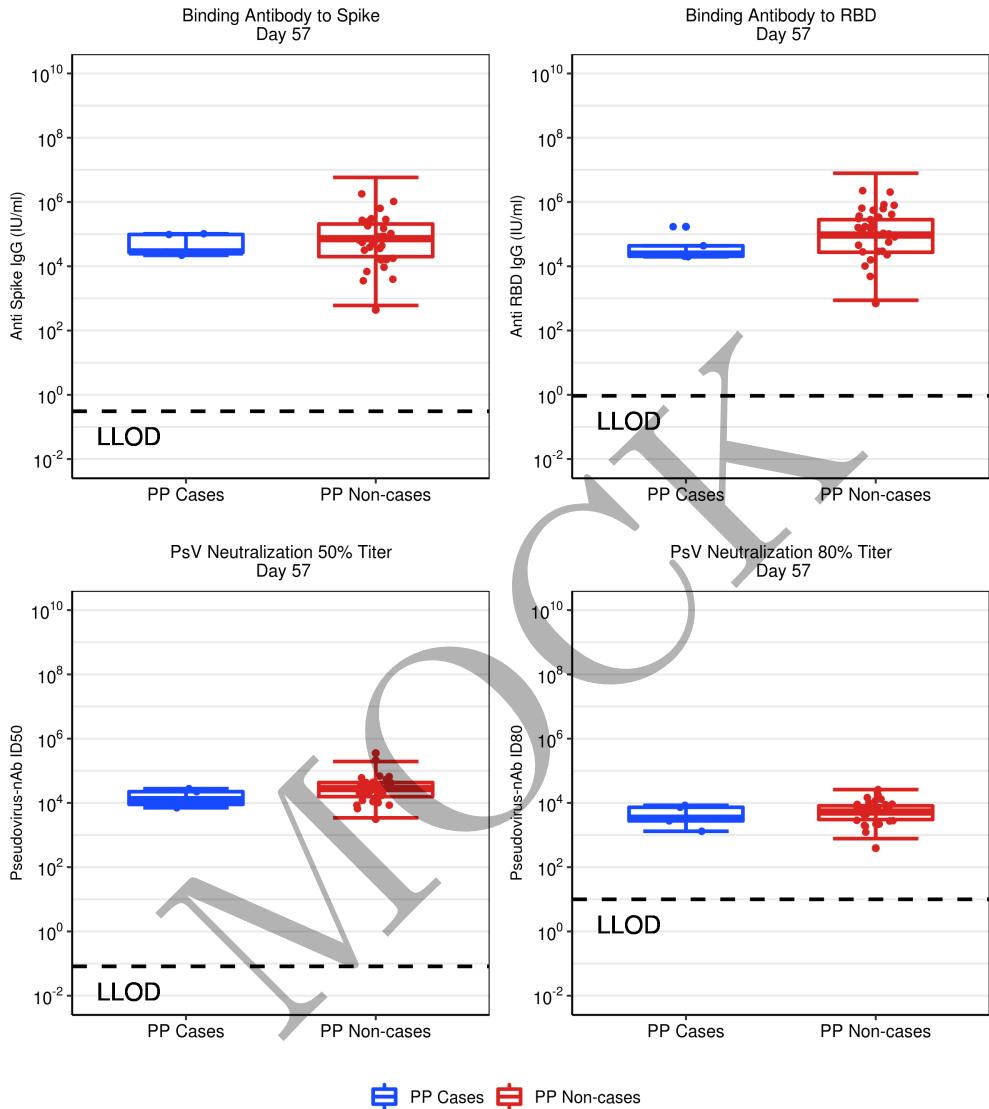


Figure 2.5: Boxplots of D57 Ab markers: baseline positive vaccine arm.



Figure 2.6: Boxplots of D57 fold-rise over D1 Ab markers: baseline positive vaccine arm.

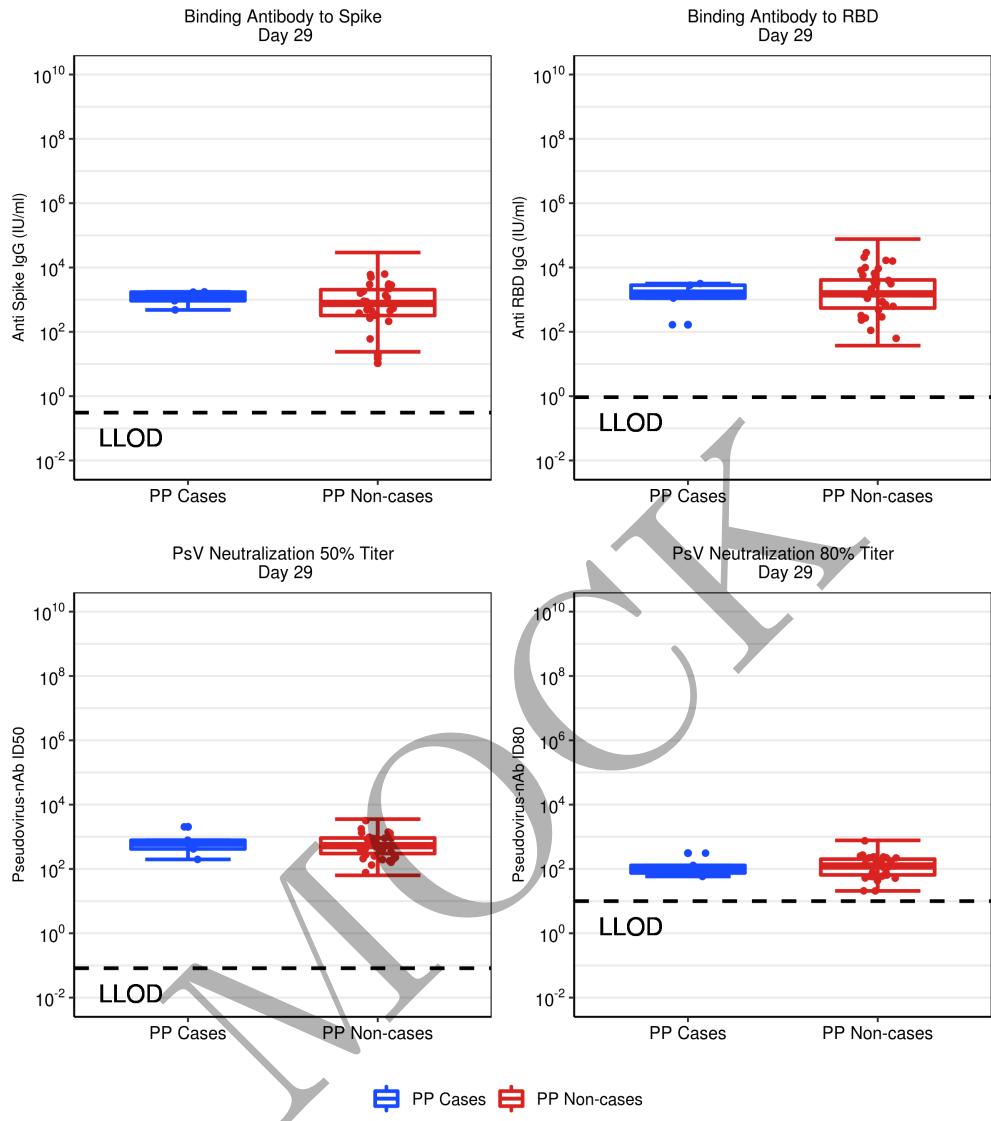


Figure 2.7: Boxplots of D29 Ab markers: baseline positive vaccine arm.

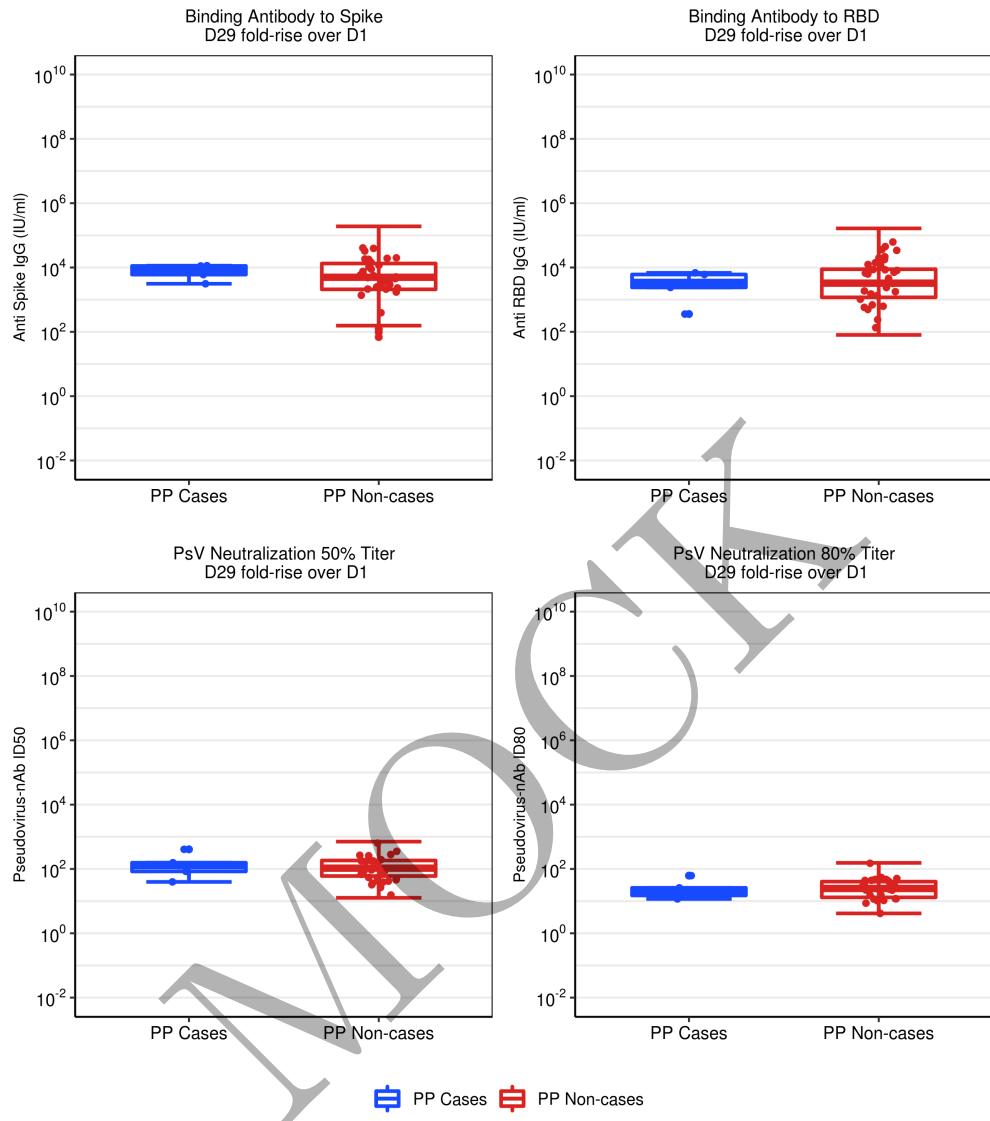


Figure 2.8: Boxplots of D29 fold-rise over D1 Ab markers: baseline positive vaccine arm.

2.2 Weighted RCDF plots

2.2.1 Baseline seronegative

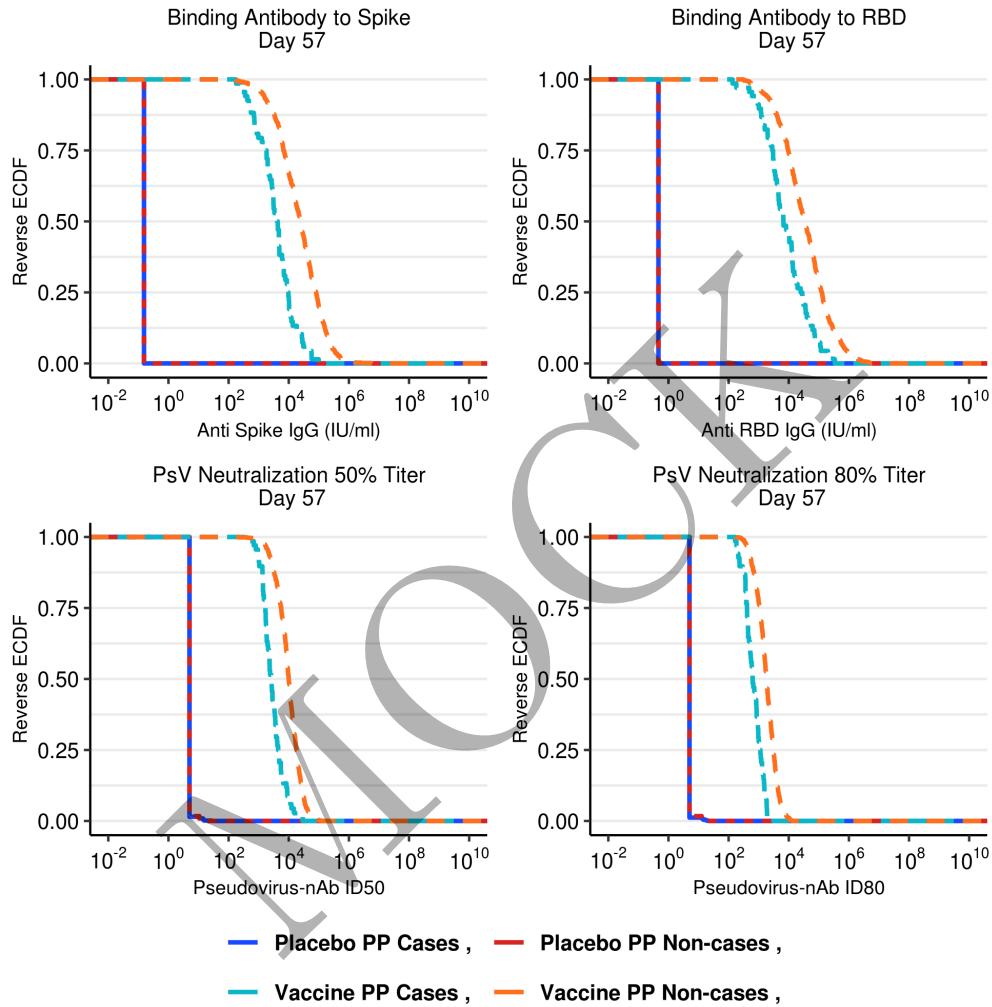


Figure 2.9: RCDF plots for D57 Ab markers: baseline negative by treatment arm.

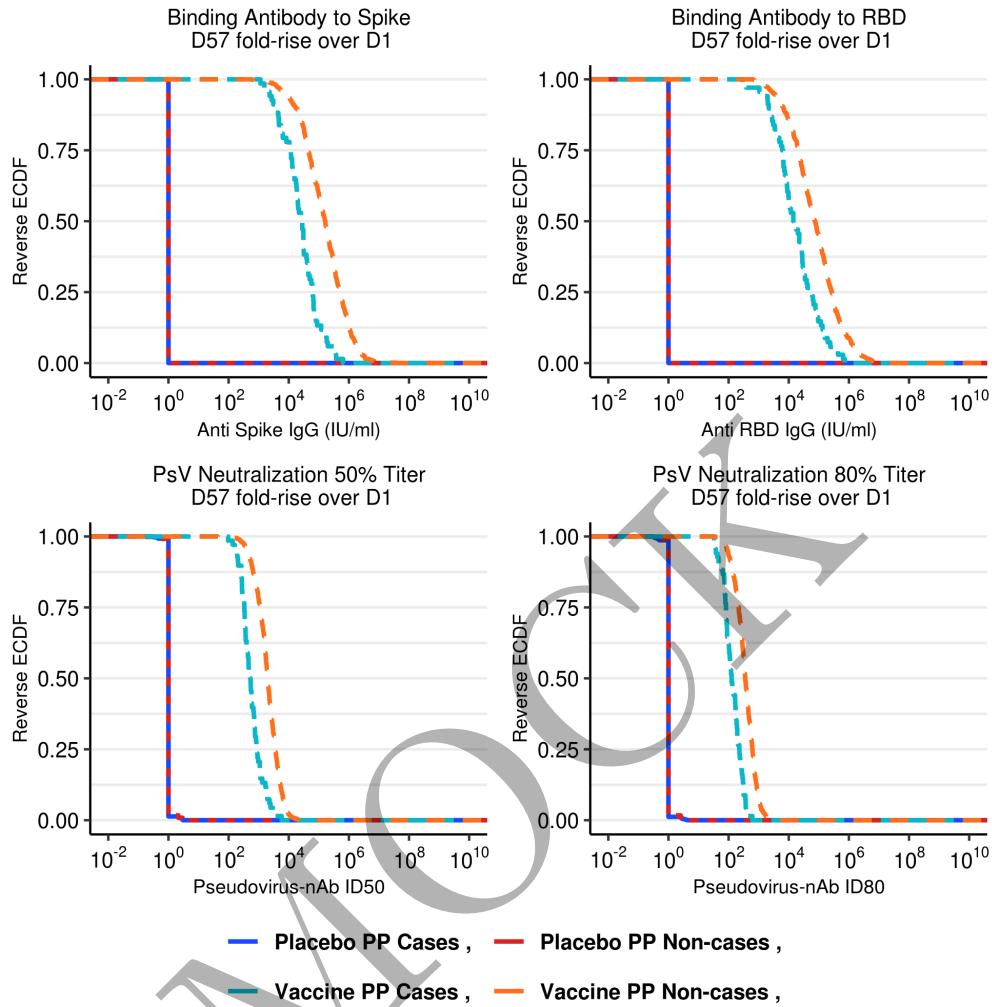


Figure 2.10: RCDF plots for D57 fold-rise over D1 Ab markers: baseline negative by treatment arm.

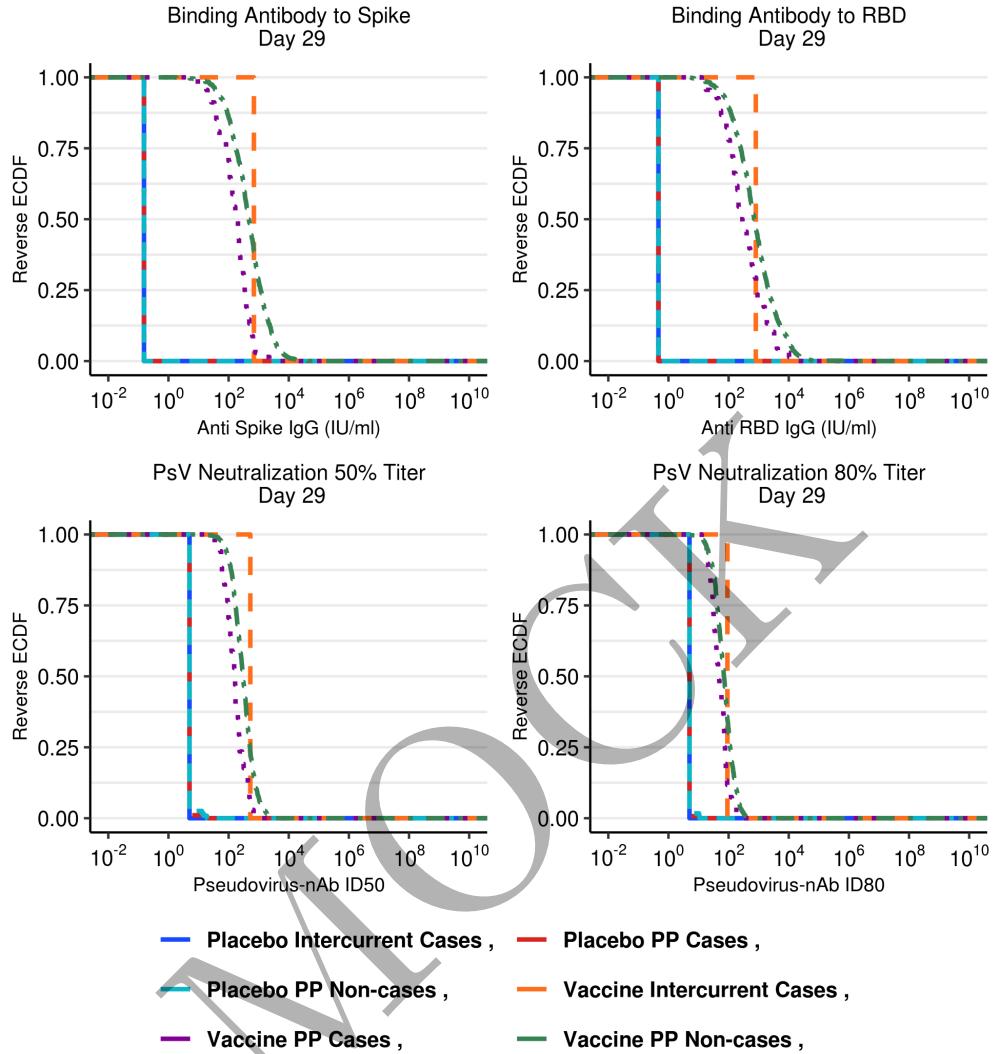


Figure 2.11: RCDF plots for D29 Ab markers: baseline negative by treatment arm.

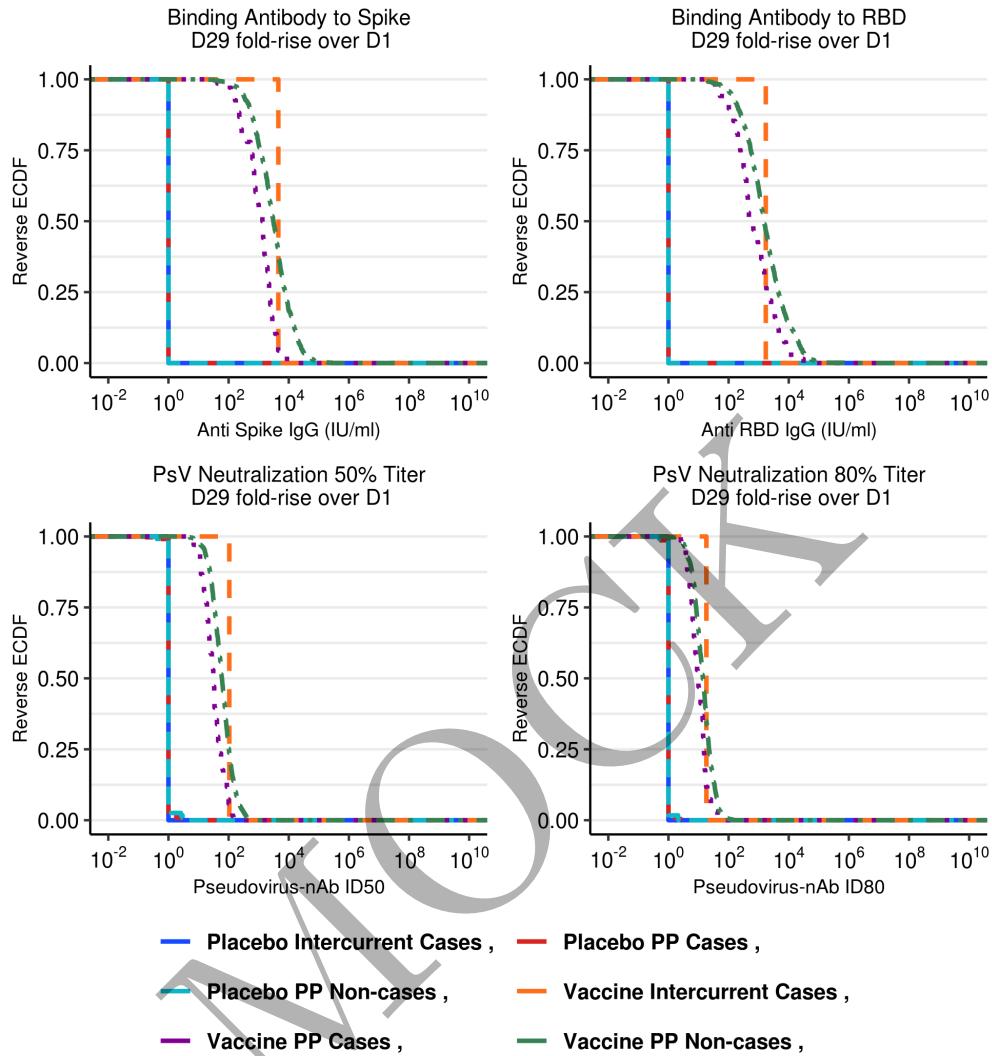


Figure 2.12: RCDF plots for D29 fold-rise over D1 Ab markers: baseline negative by treatment arm.

2.2.2 Baseline seropositive



Figure 2.13: RCDF plots for D57 Ab markers: baseline positive by treatment arm.

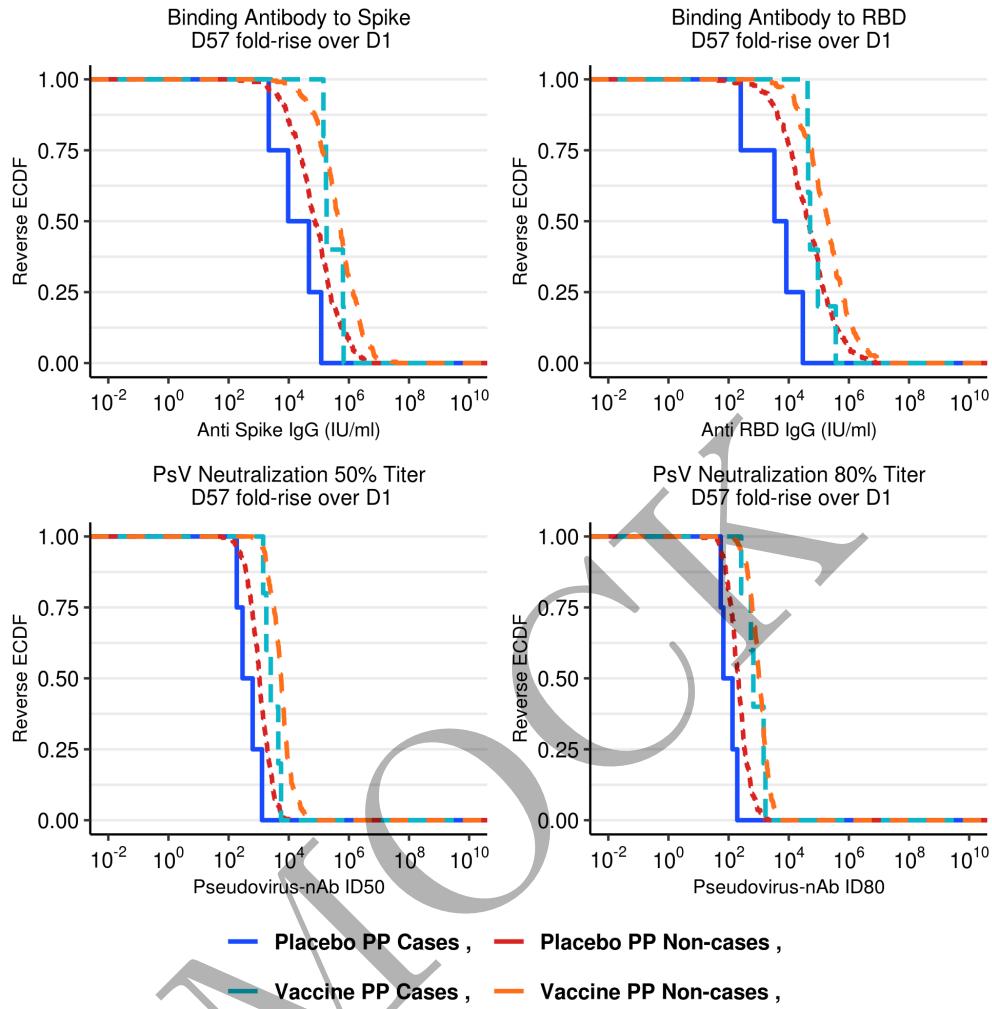


Figure 2.14: RCDF plots for D57 fold-rise over D1 Ab markers: baseline positive by treatment arm.

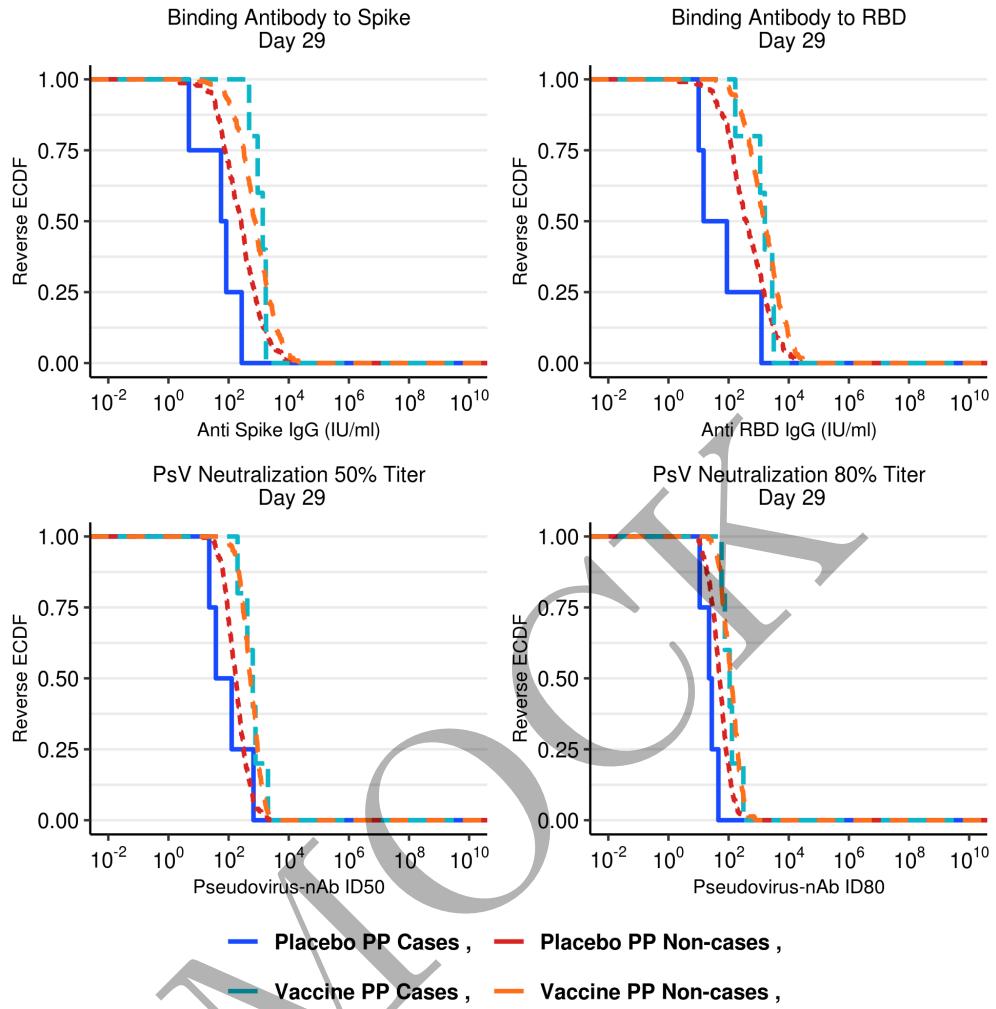


Figure 2.15: RCDF plots for D29 Ab markers: baseline positive by treatment arm.

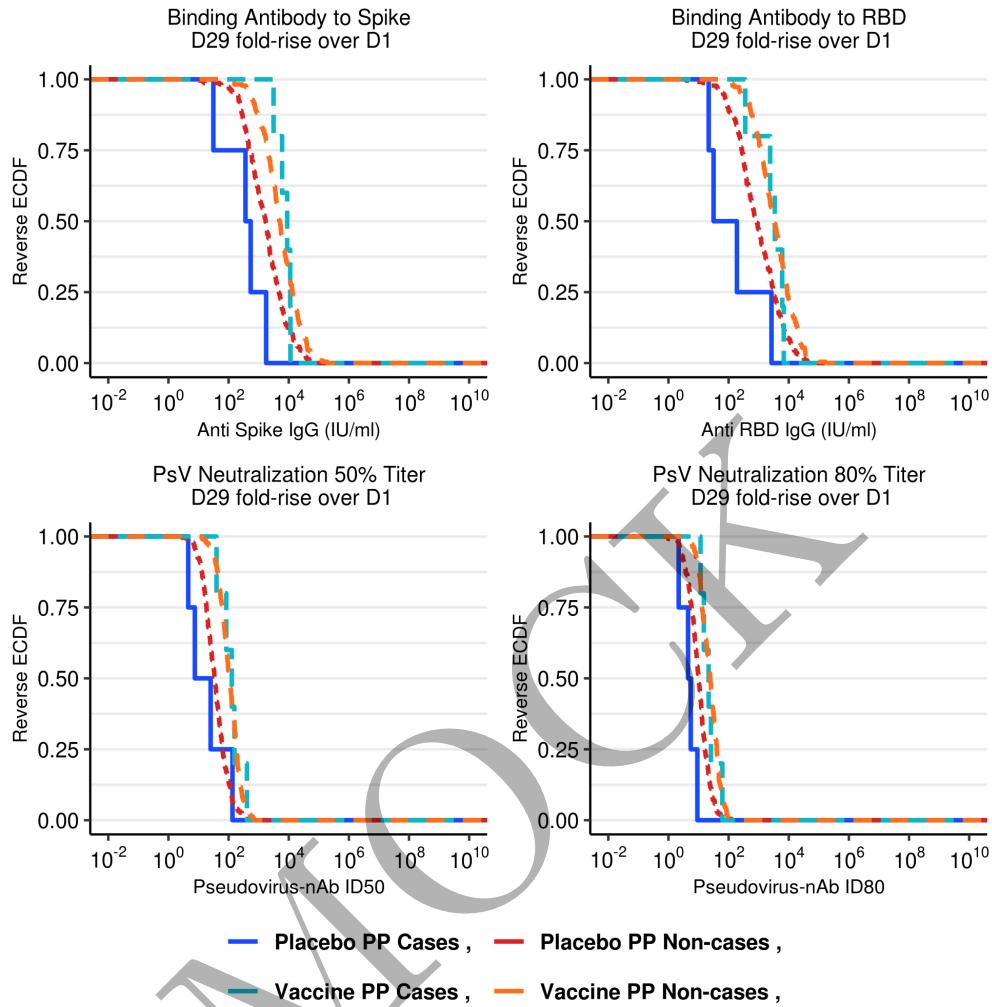


Figure 2.16: RCDF plots for D29 fold-rise over D1 Ab markers: baseline positive by treatment arm.

2.3 Weighted RCDF plots of threshold correlate concentration for vaccine efficacy

2.3.1 Baseline seronegative

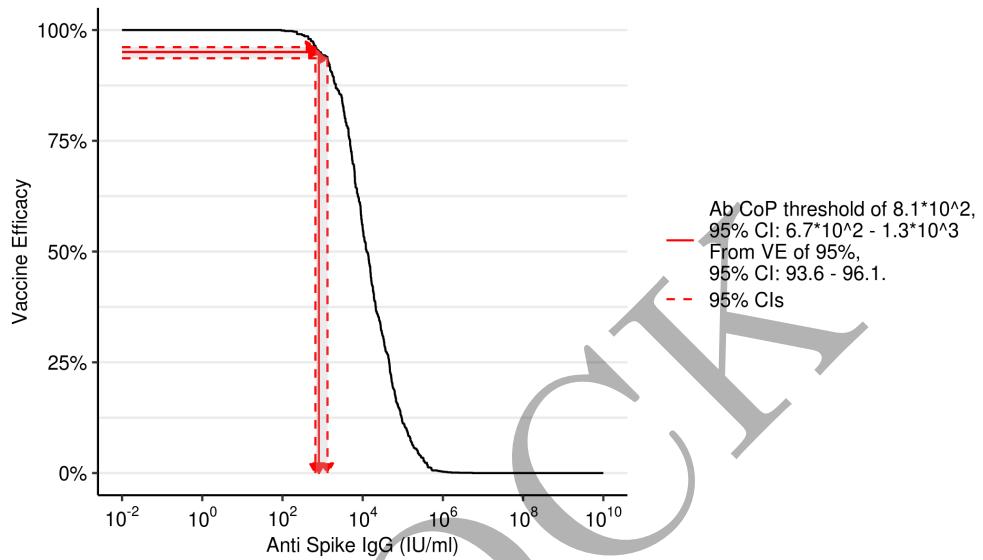


Figure 2.17: Marker RCDF of D57 anti-Spike binding Ab: baseline negative vaccine arm

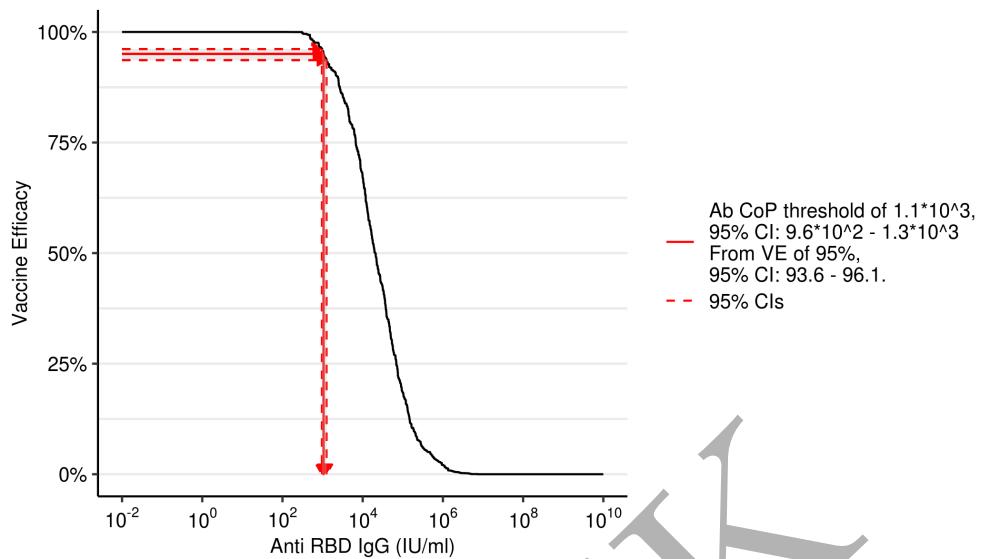


Figure 2.18: Marker RCDF of D57 anti-RBD binding Ab: baseline negative vaccine arm

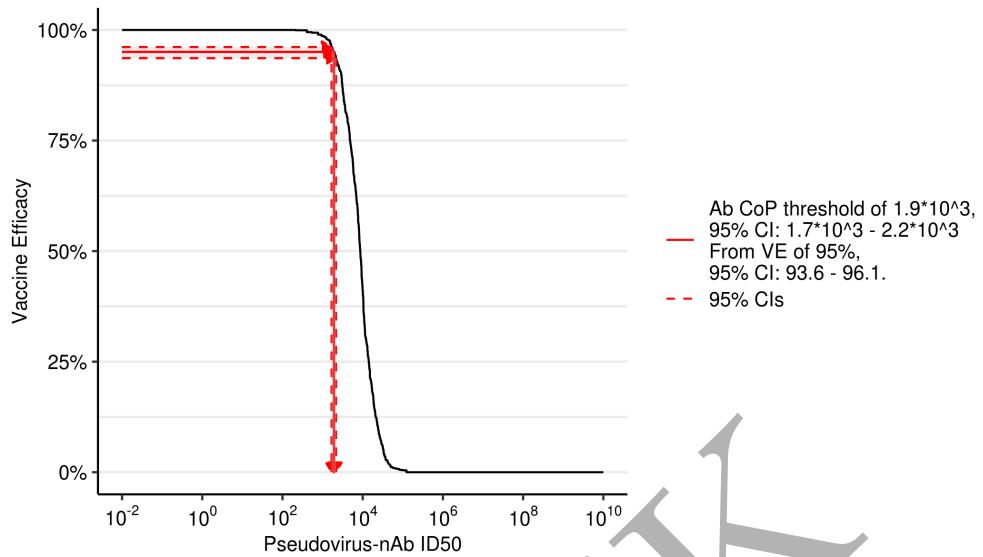


Figure 2.19: Marker RCDF of D57 PsV-nAb ID50: baseline negative vaccine arm

2.3. WEIGHTED RCDF PLOTS OF THRESHOLD CORRELATE CONCENTRATION FOR VACCINE EFFICACY51

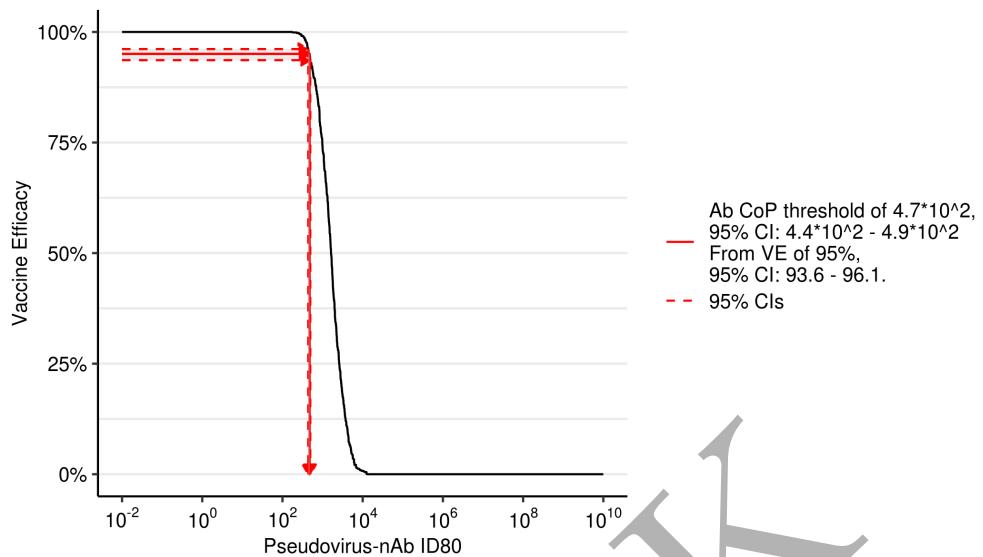


Figure 2.20: Marker RCDF of D57 PsV-nAb ID80: baseline negative vaccine arm

2.4 Spaghetti plots

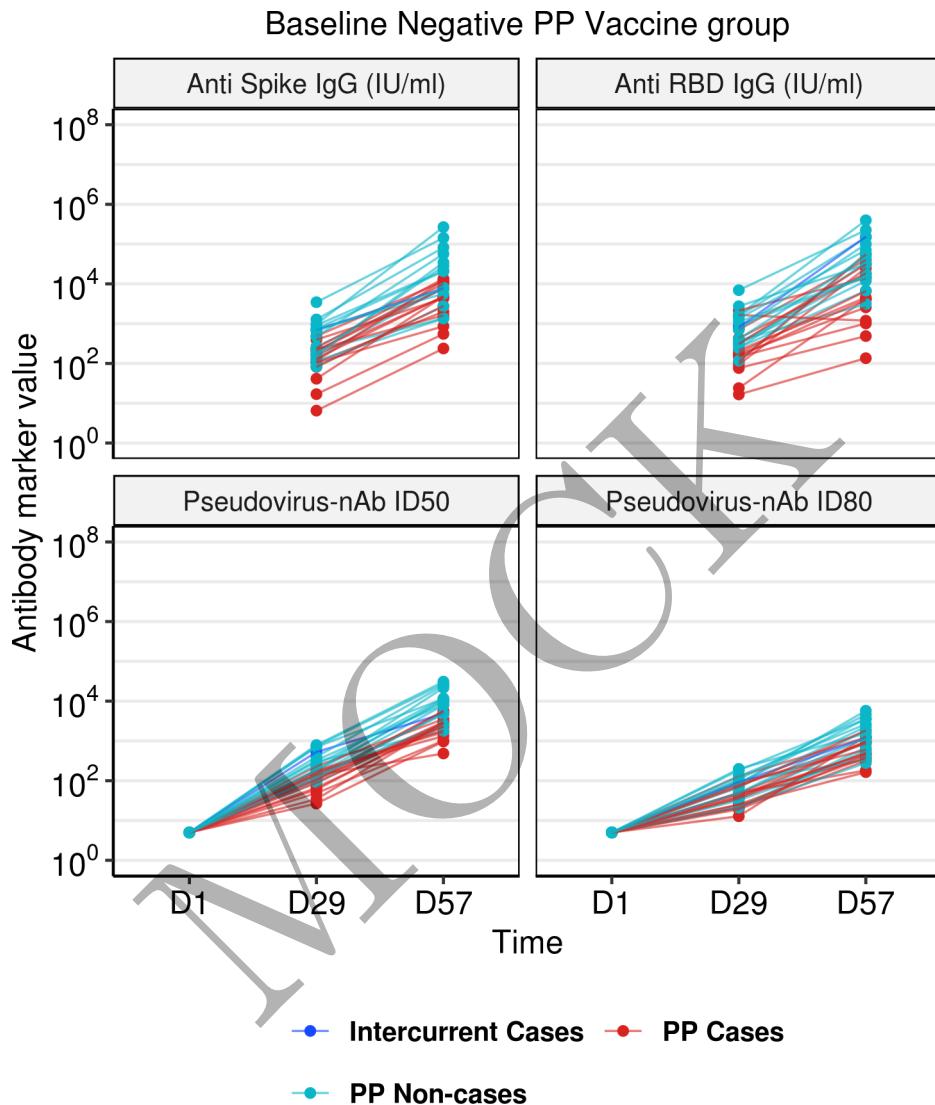


Figure 2.21: Spaghetti Plots of Marker Trajectory: baseline negative vaccine arm



Figure 2.22: Spaghetti Plots of Marker Trajectory: baseline positive vaccine arm

2.5 Violin and line plots

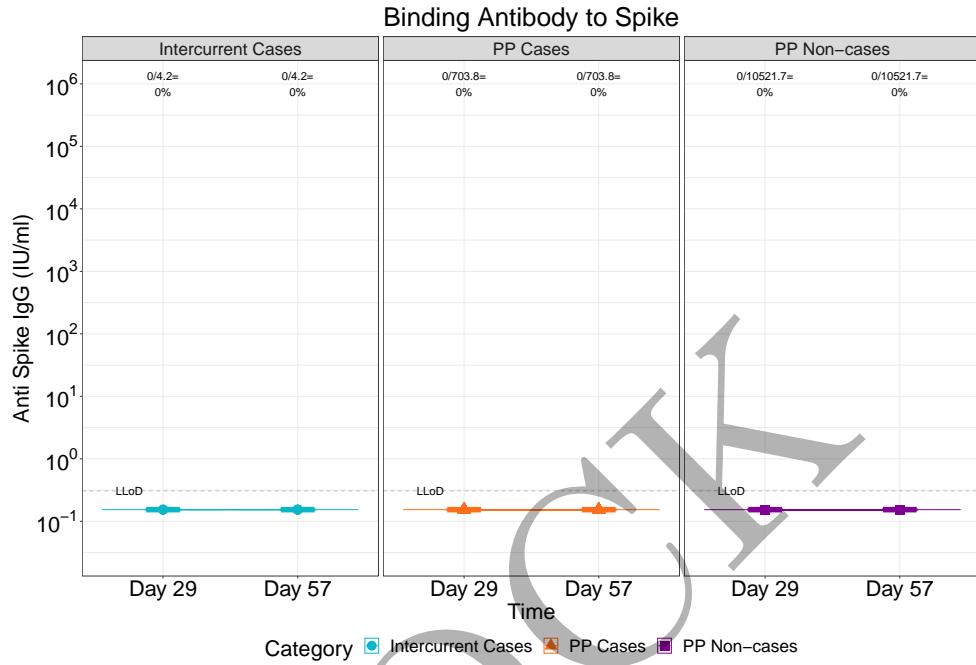


Figure 2.23: lineplots of Binding Antibody to Spike: baseline negative placebo arm (version 1)

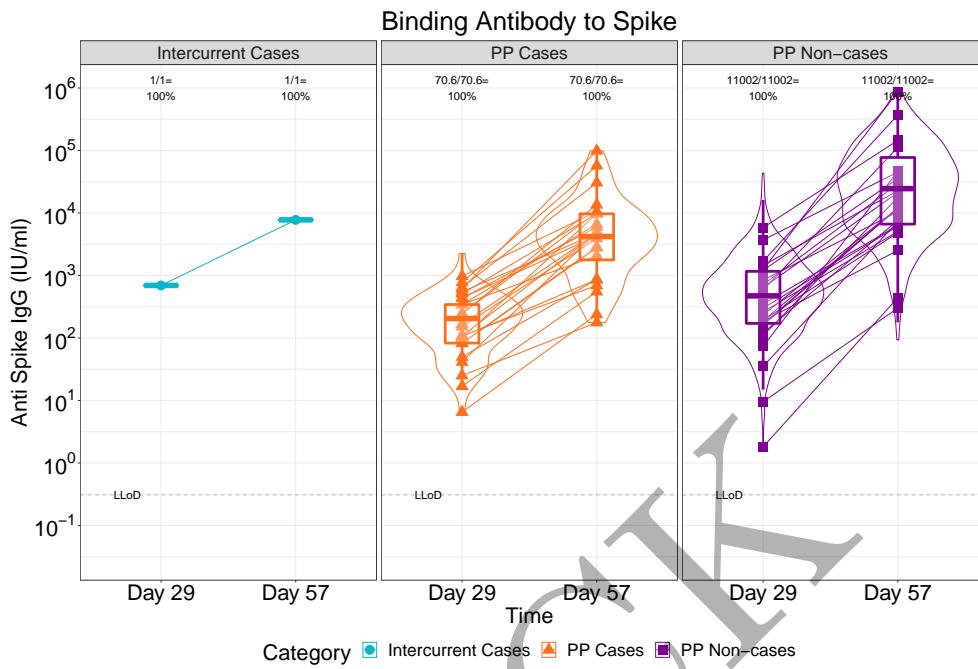


Figure 2.24: lineplots of Binding Antibody to Spike: baseline negative vaccine arm (version 1)

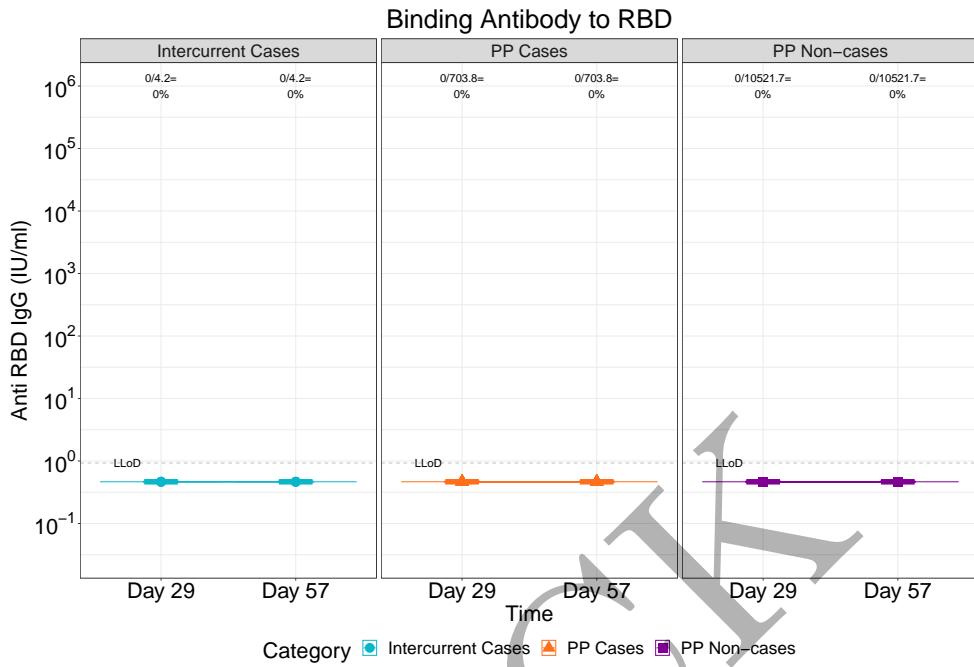


Figure 2.25: lineplots of Binding Antibody to RBD: baseline negative placebo arm (version 1)

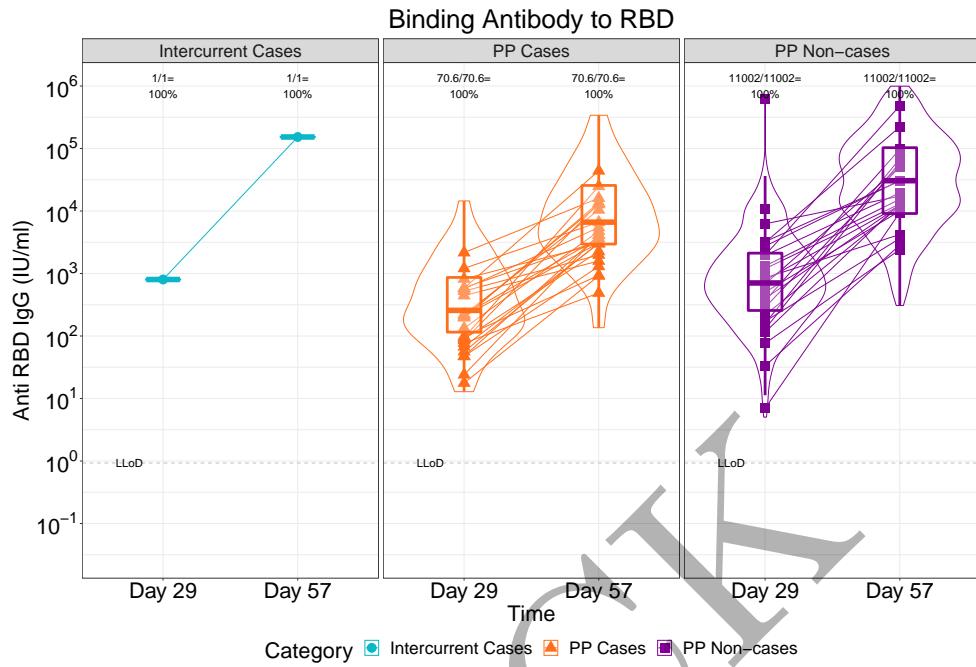


Figure 2.26: lineplots of Binding Antibody to RBD: baseline negative vaccine arm (version 1)

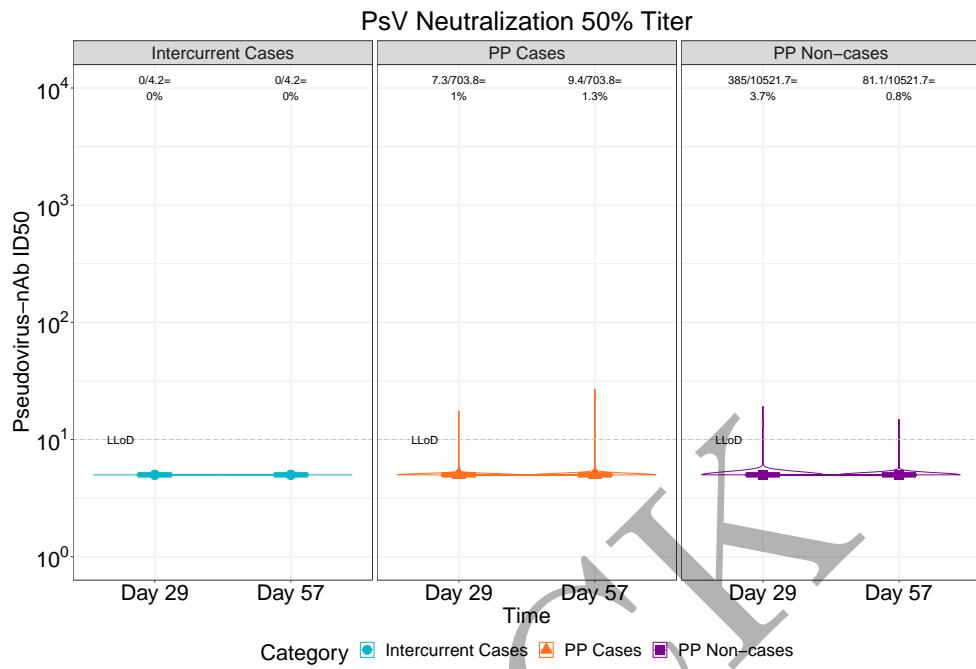


Figure 2.27: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm (version 1)

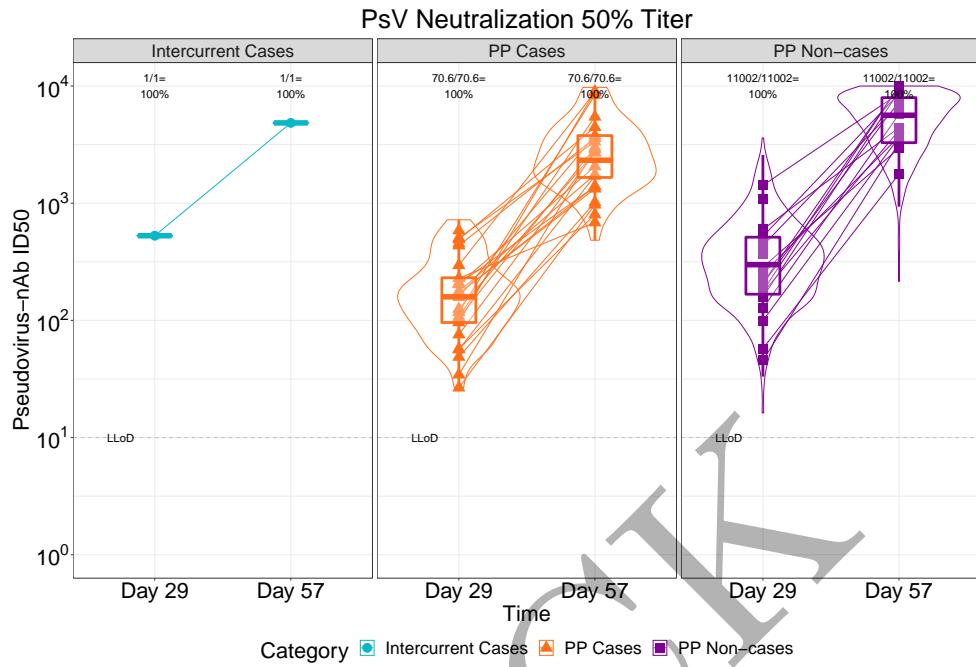


Figure 2.28: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm (version 1)

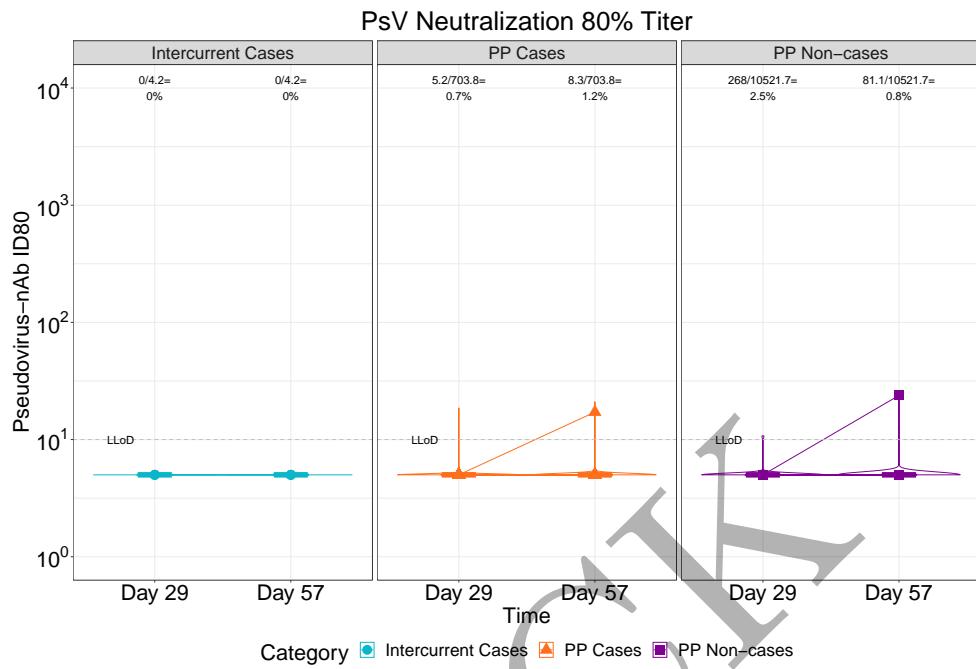


Figure 2.29: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm (version 1)

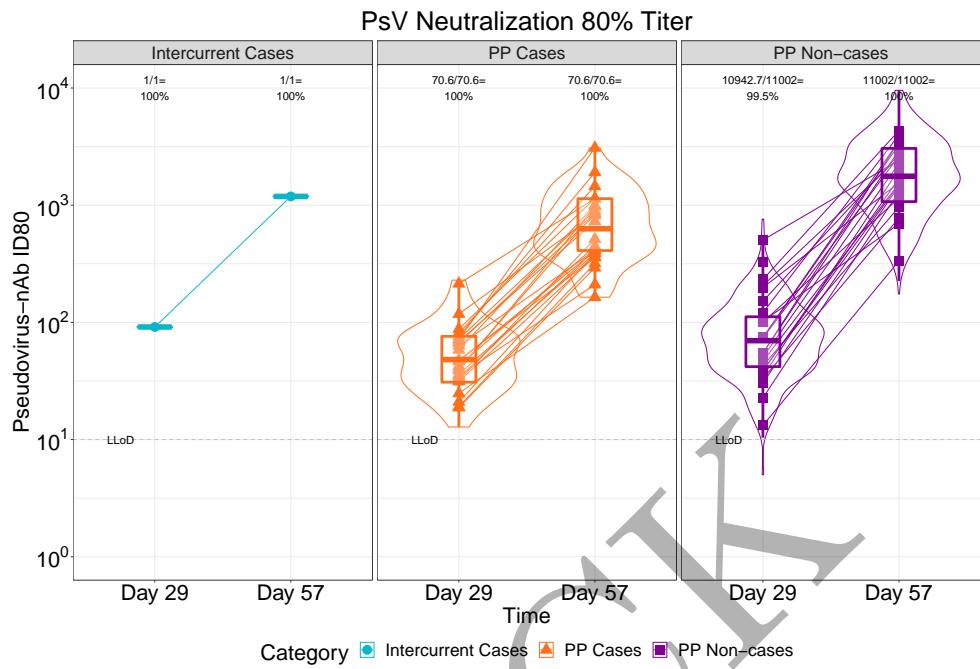


Figure 2.30: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm (version 1)

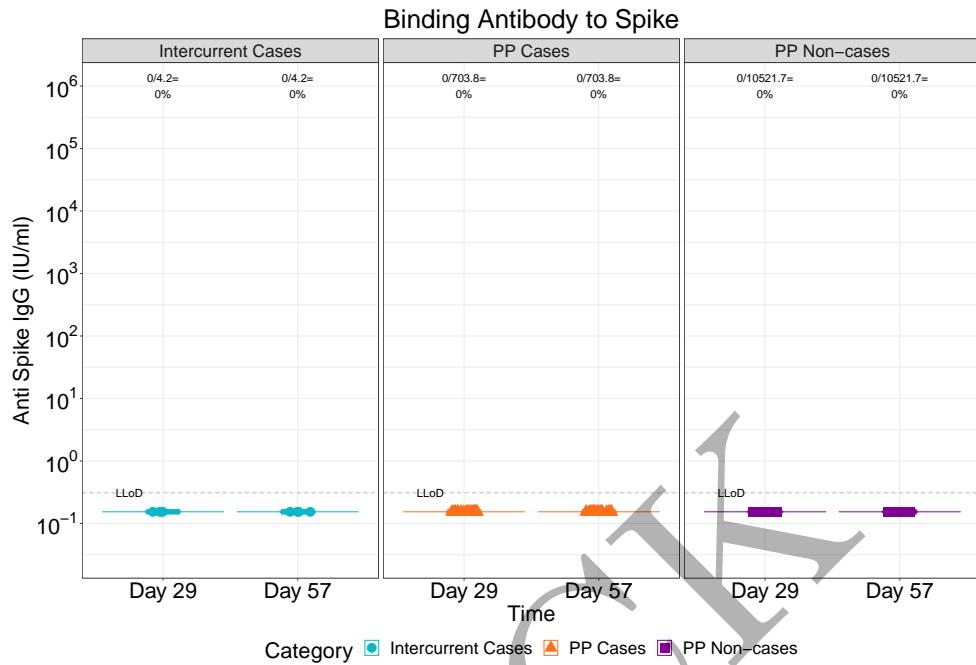


Figure 2.31: violinplots of Binding Antibody to Spike: baseline negative placebo arm (version 1)

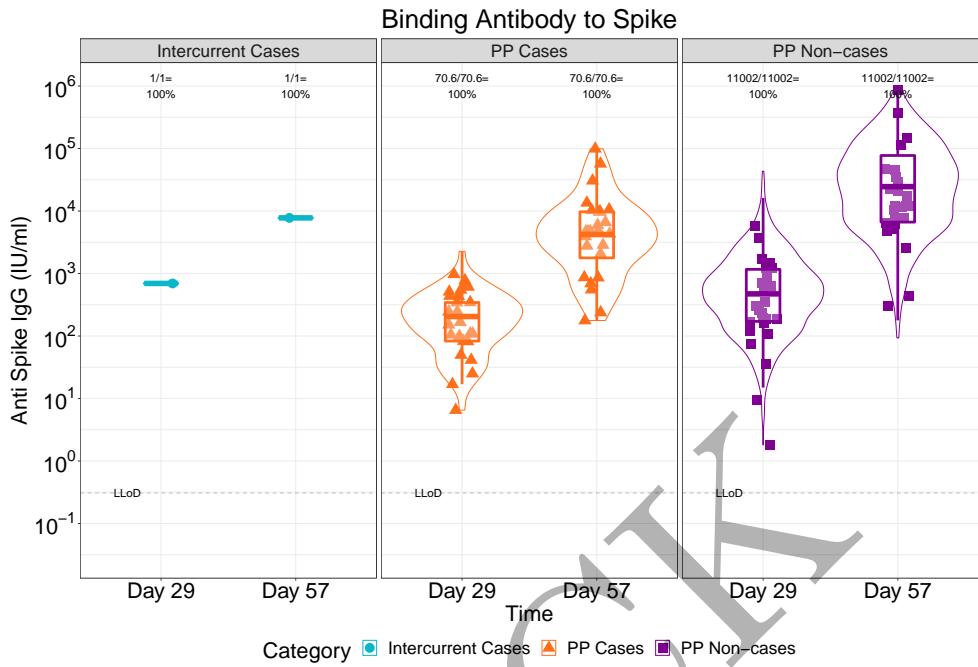


Figure 2.32: violinplots of Binding Antibody to Spike: baseline negative vaccine arm (version 1)

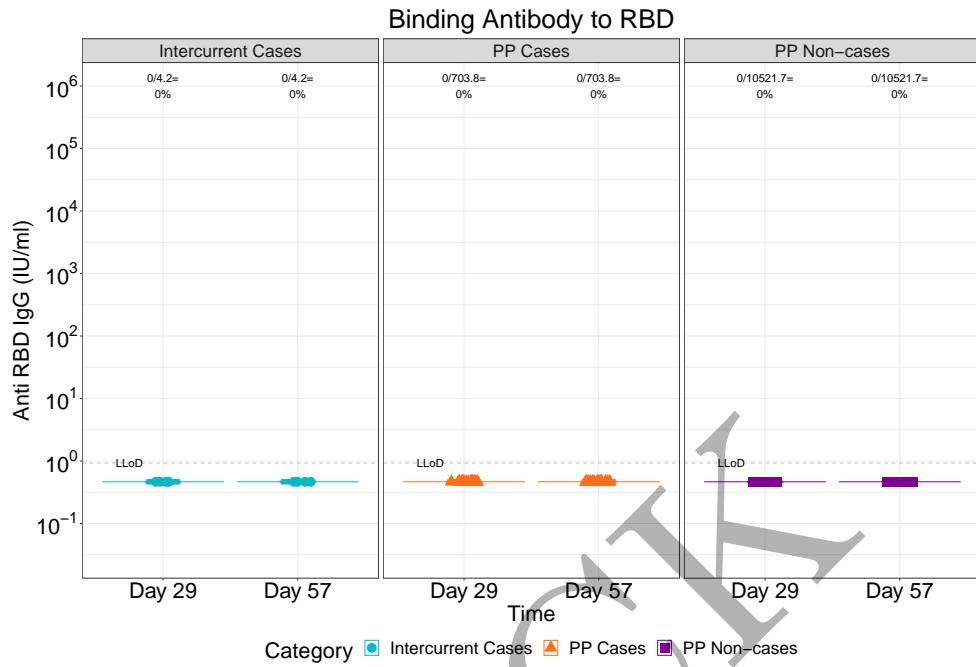


Figure 2.33: violinplots of Binding Antibody to RBD: baseline negative placebo arm (version 1)

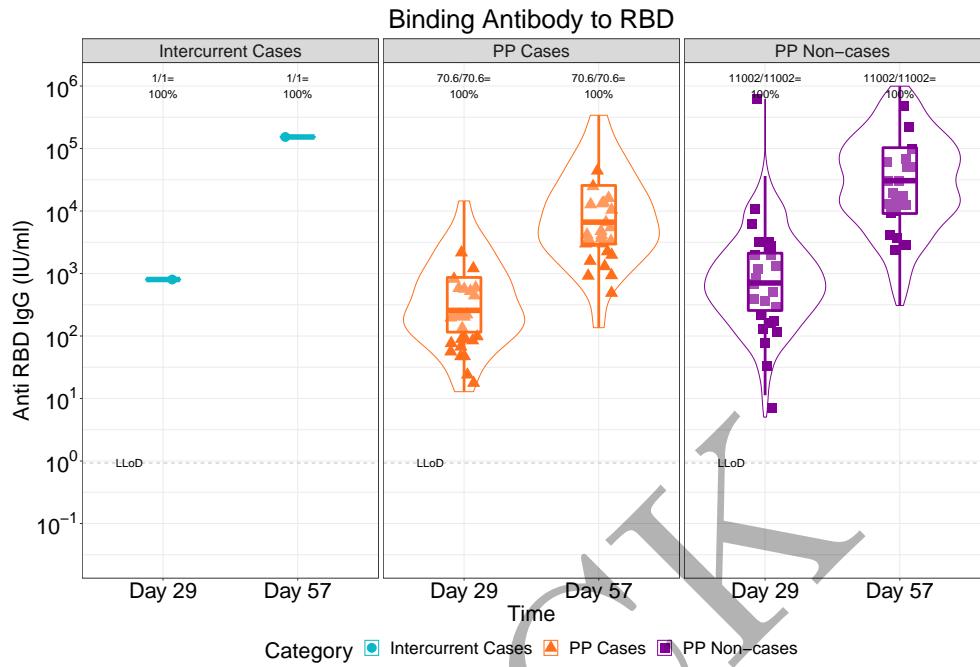


Figure 2.34: violinplots of Binding Antibody to RBD: baseline negative vaccine arm (version 1)

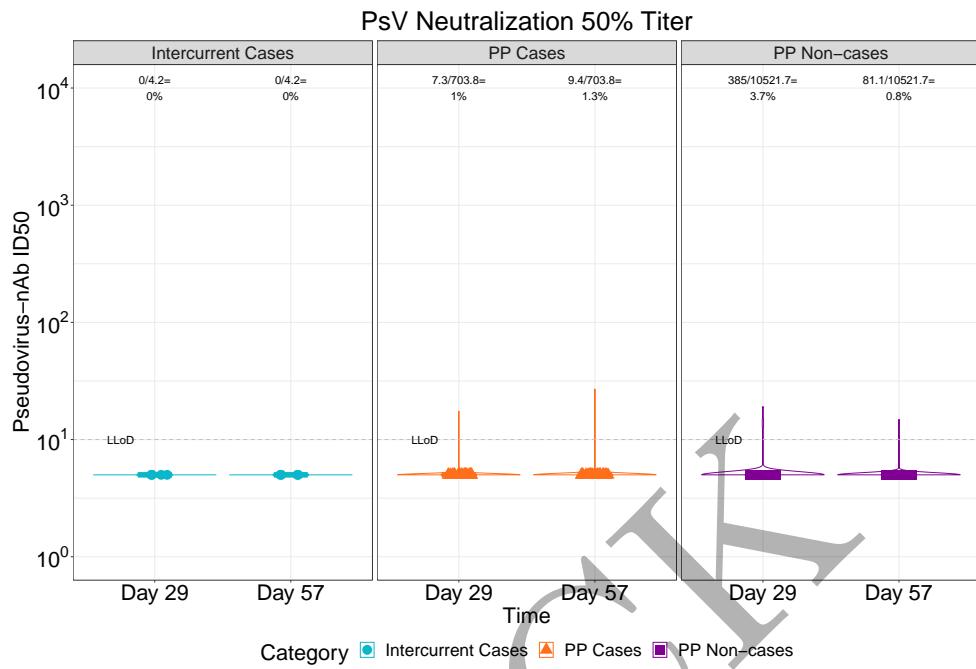


Figure 2.35: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm (version 1)

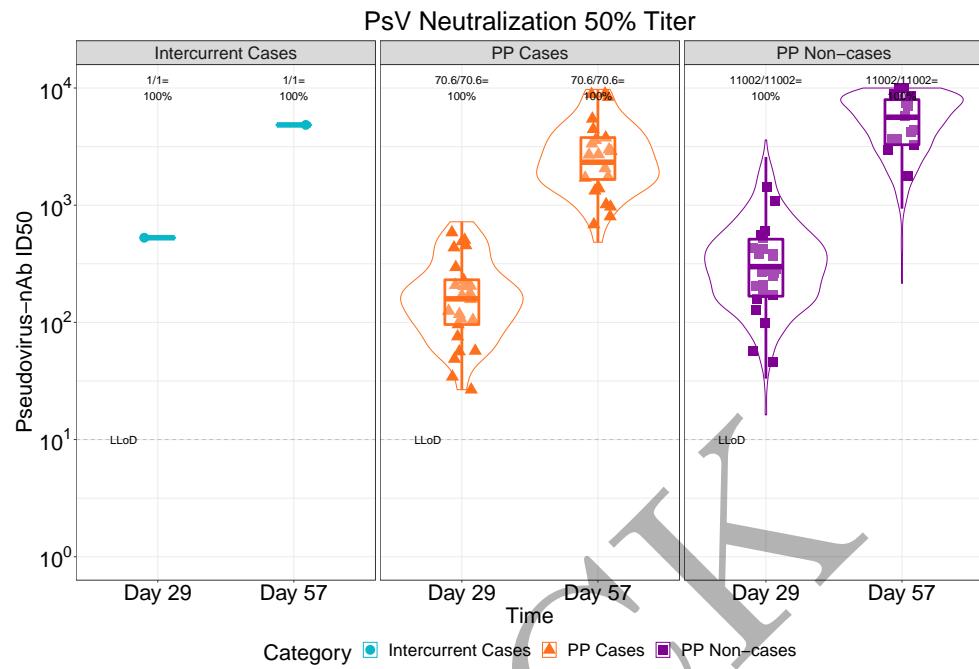


Figure 2.36: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm (version 1)

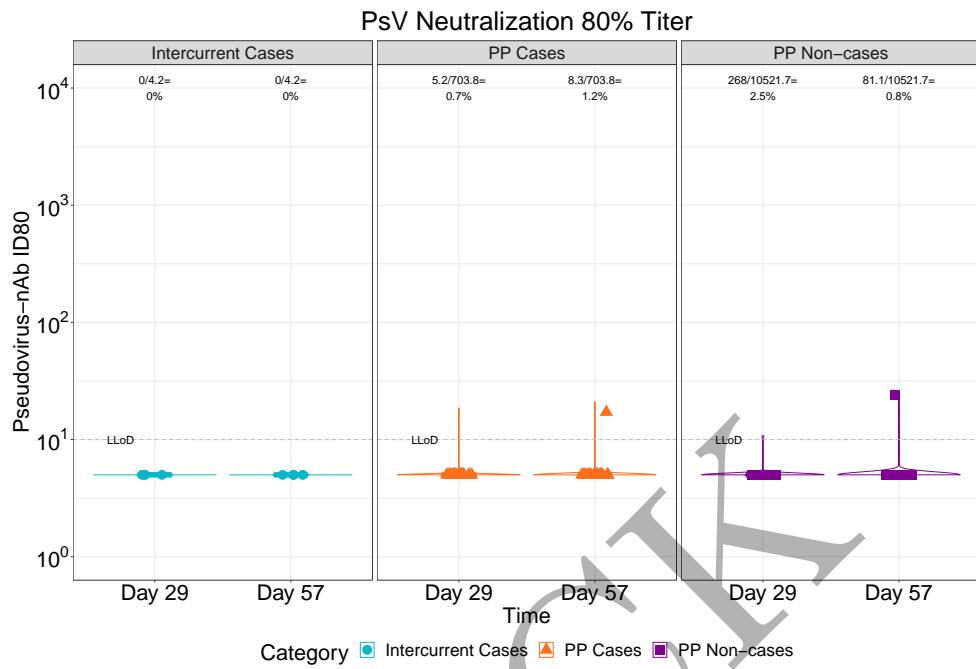


Figure 2.37: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm (version 1)

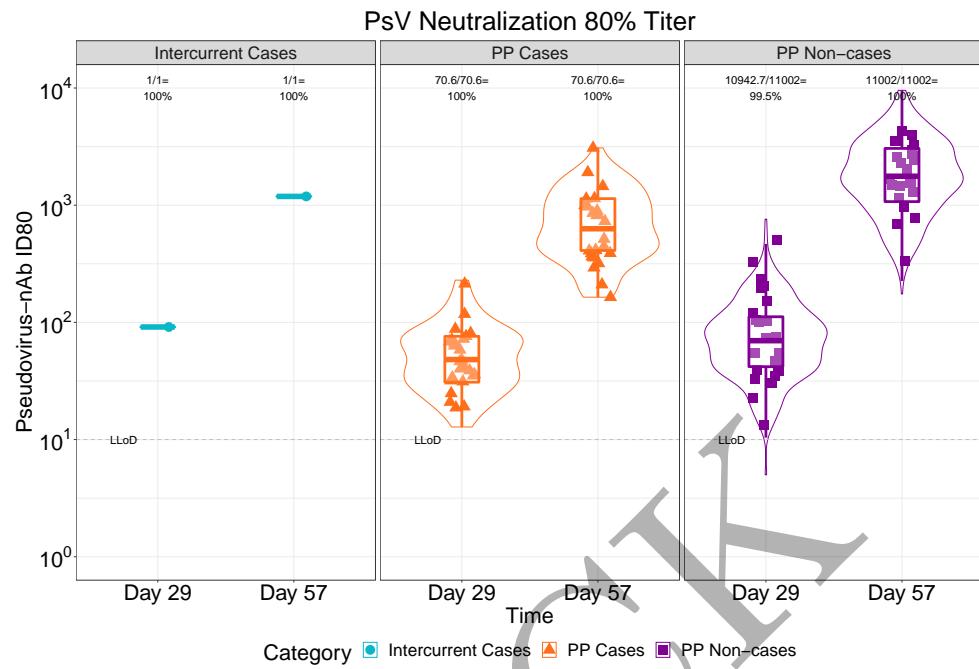


Figure 2.38: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm (version 1)

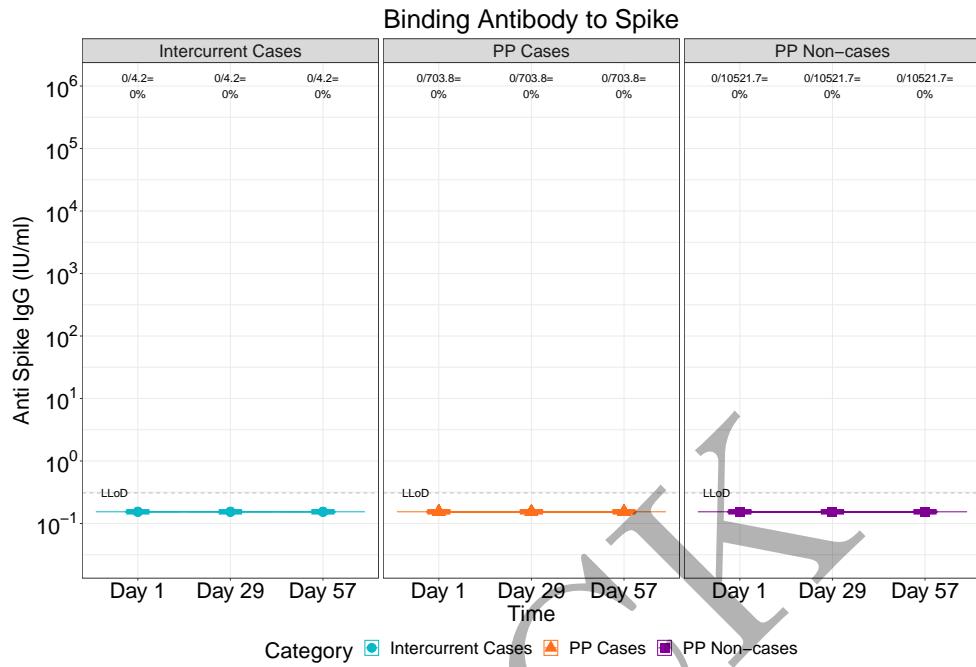


Figure 2.39: lineplots of Binding Antibody to Spike: baseline negative placebo arm (version 2)

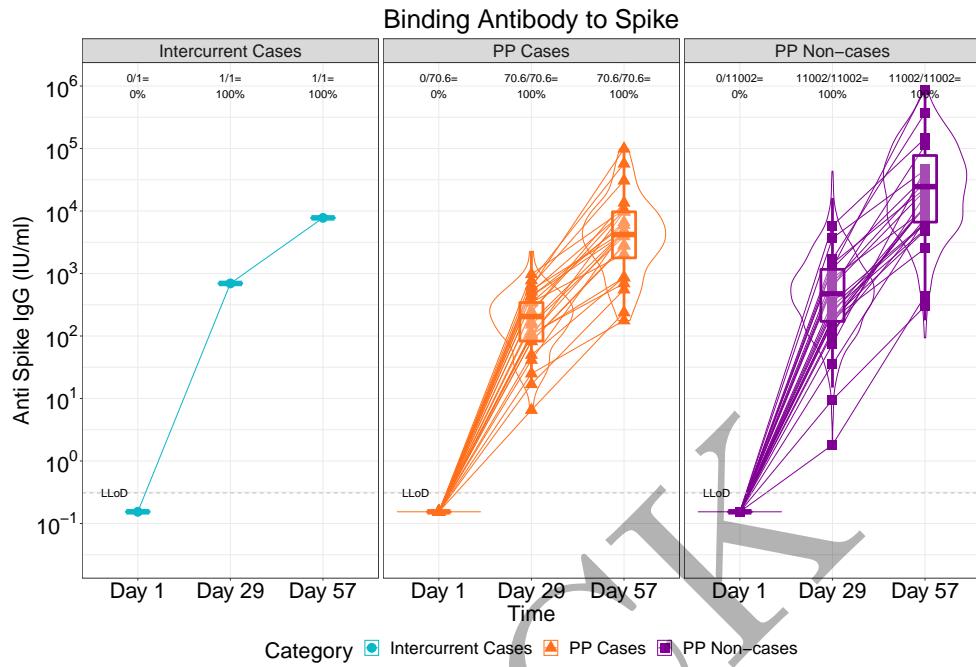


Figure 2.40: lineplots of Binding Antibody to Spike: baseline negative vaccine arm (version 2)

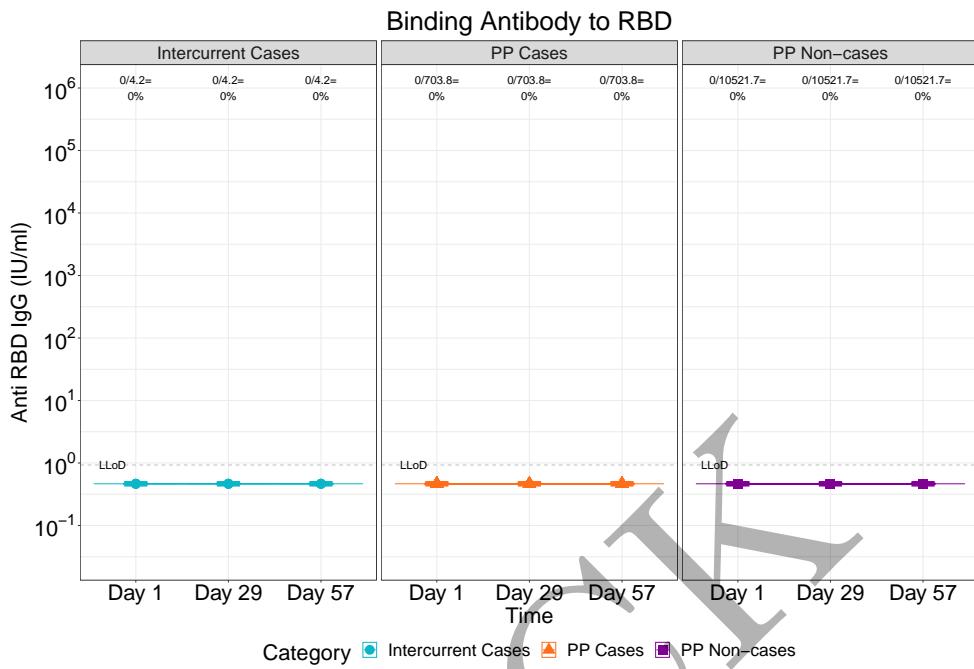


Figure 2.41: lineplots of Binding Antibody to RBD: baseline negative placebo arm (version 2)

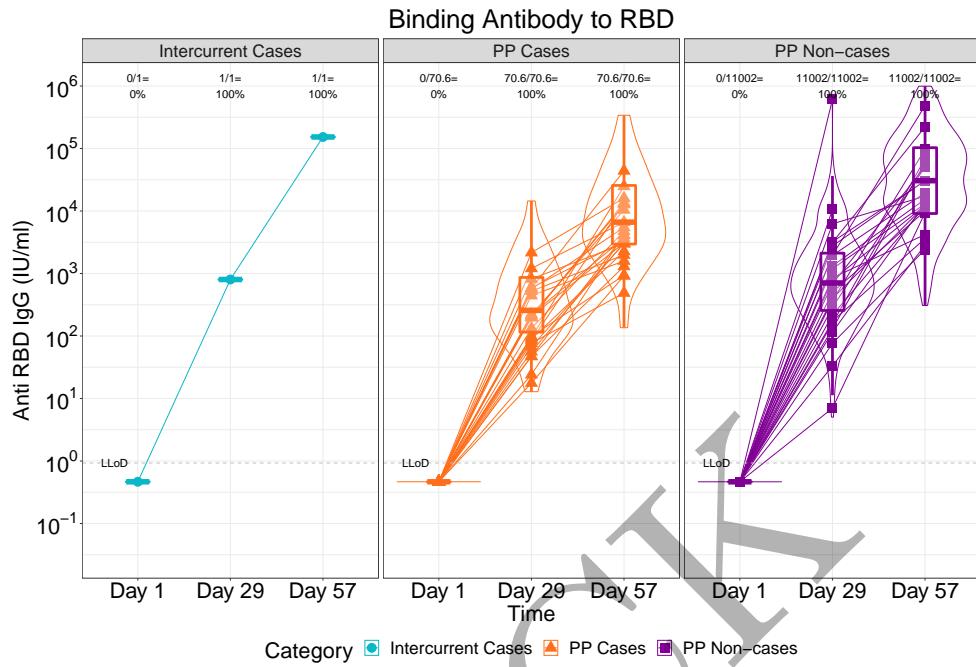


Figure 2.42: lineplots of Binding Antibody to RBD: baseline negative vaccine arm (version 2)

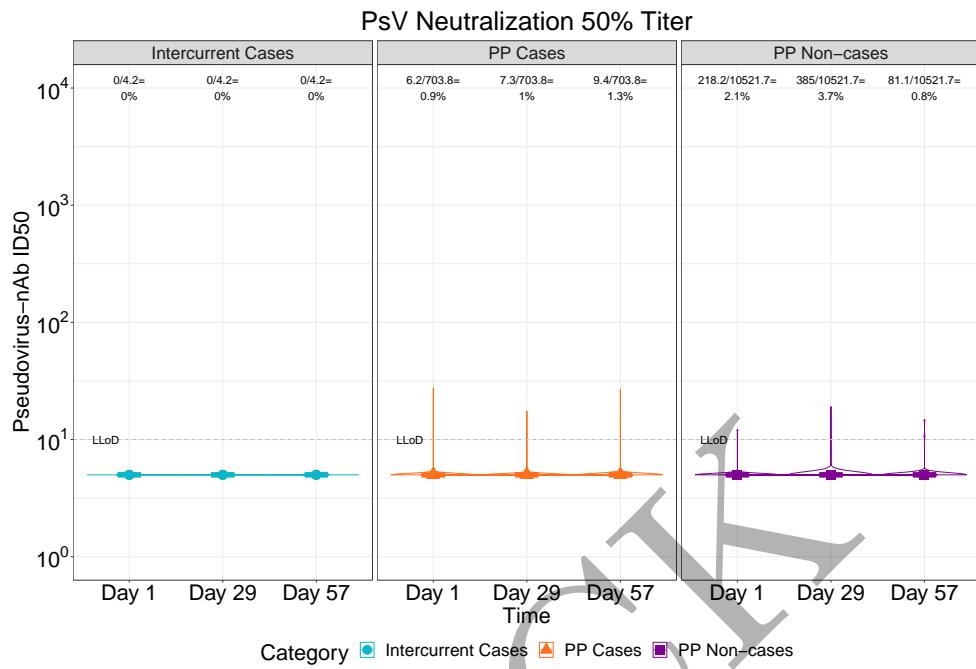


Figure 2.43: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm (version 2)

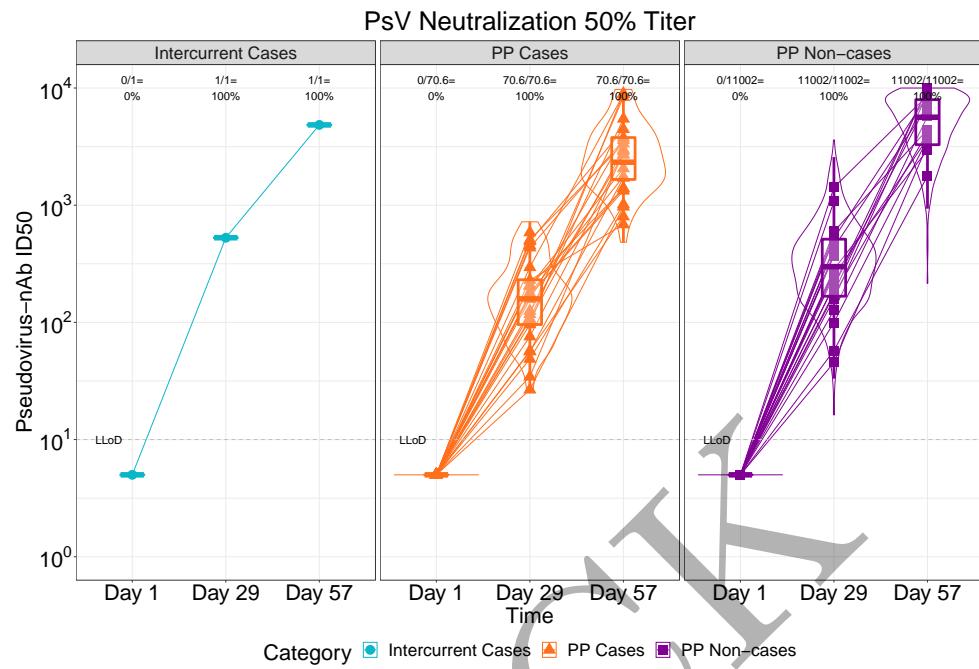


Figure 2.44: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm (version 2)

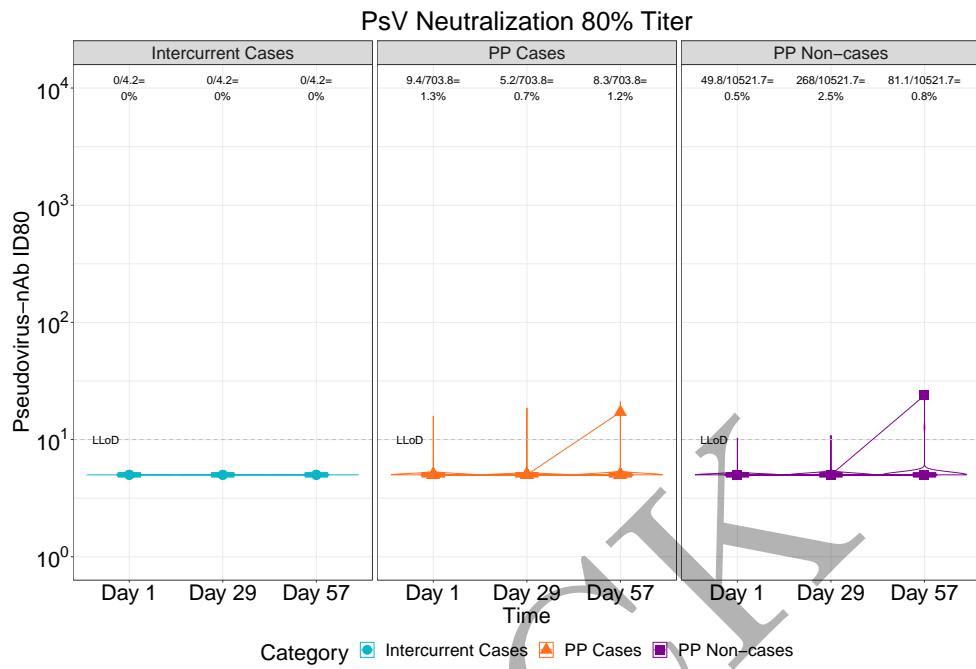


Figure 2.45: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm (version 2)

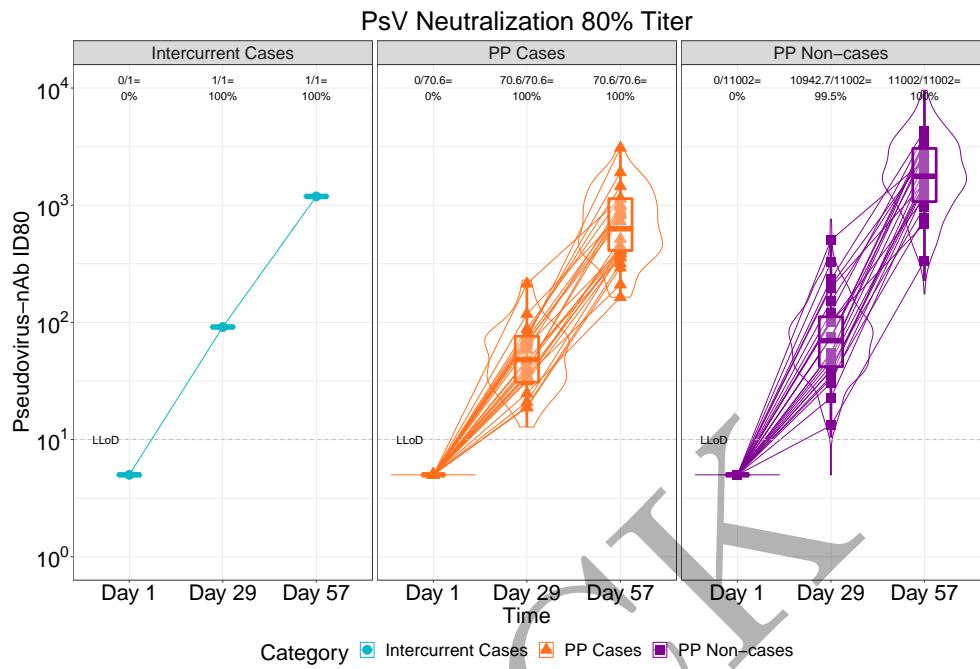


Figure 2.46: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm (version 2)

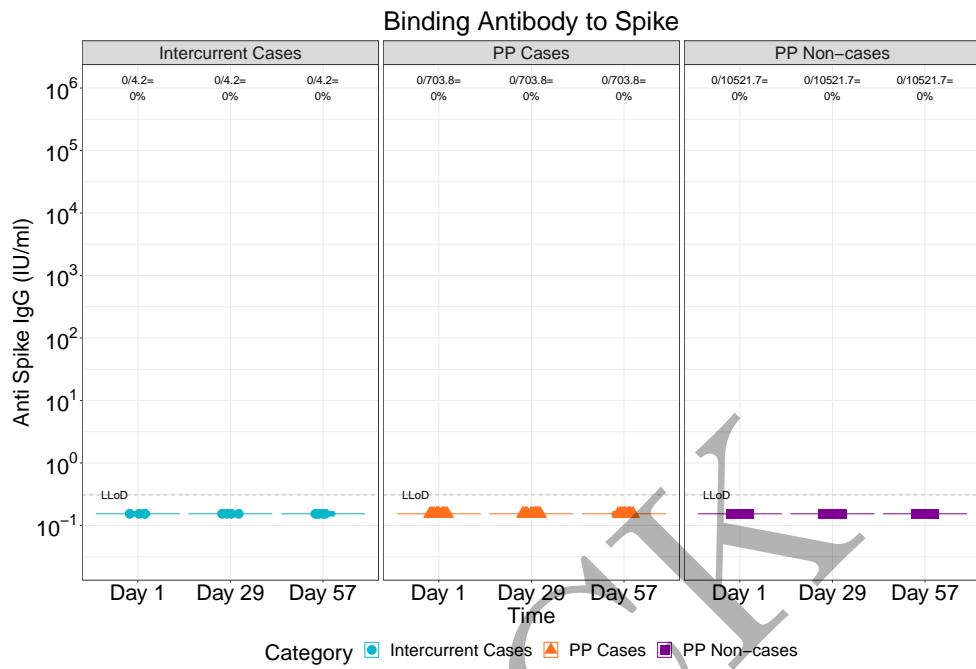


Figure 2.47: violinplots of Binding Antibody to Spike: baseline negative placebo arm (version 2)

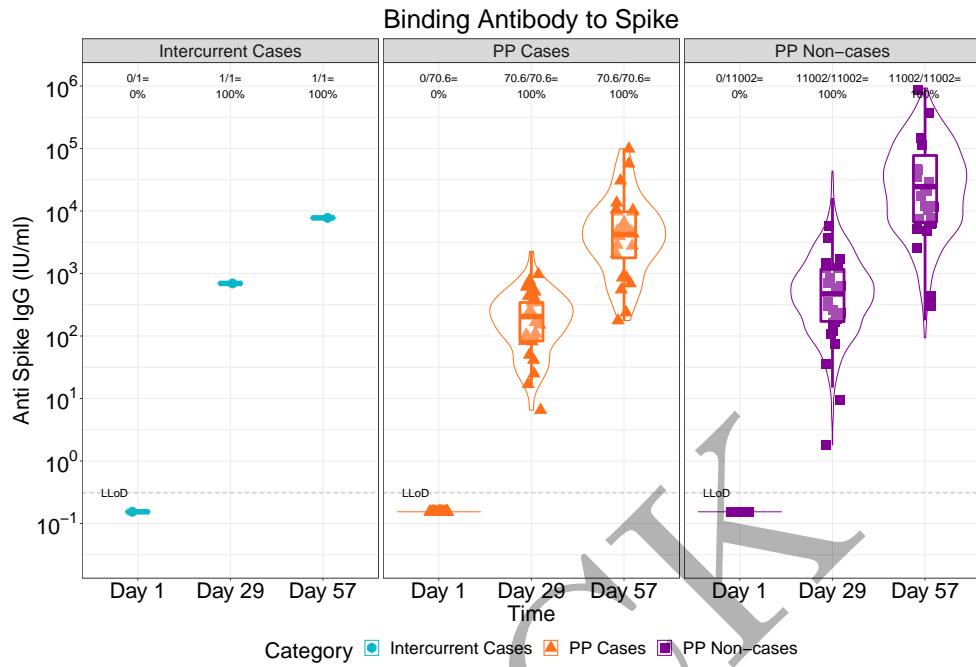


Figure 2.48: violinplots of Binding Antibody to Spike: baseline negative vaccine arm (version 2)

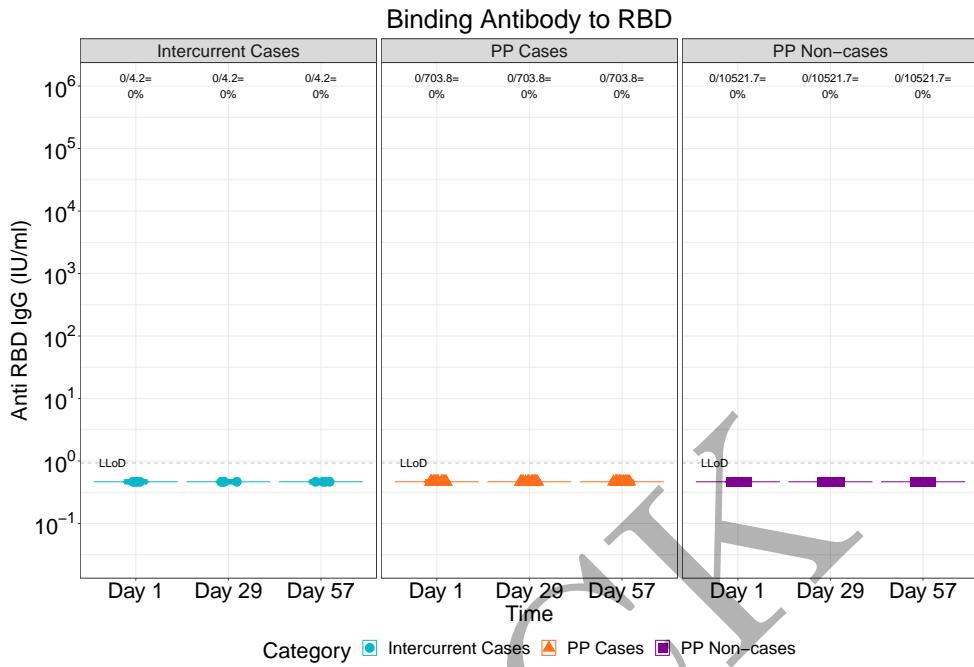


Figure 2.49: violinplots of Binding Antibody to RBD: baseline negative placebo arm (version 2)

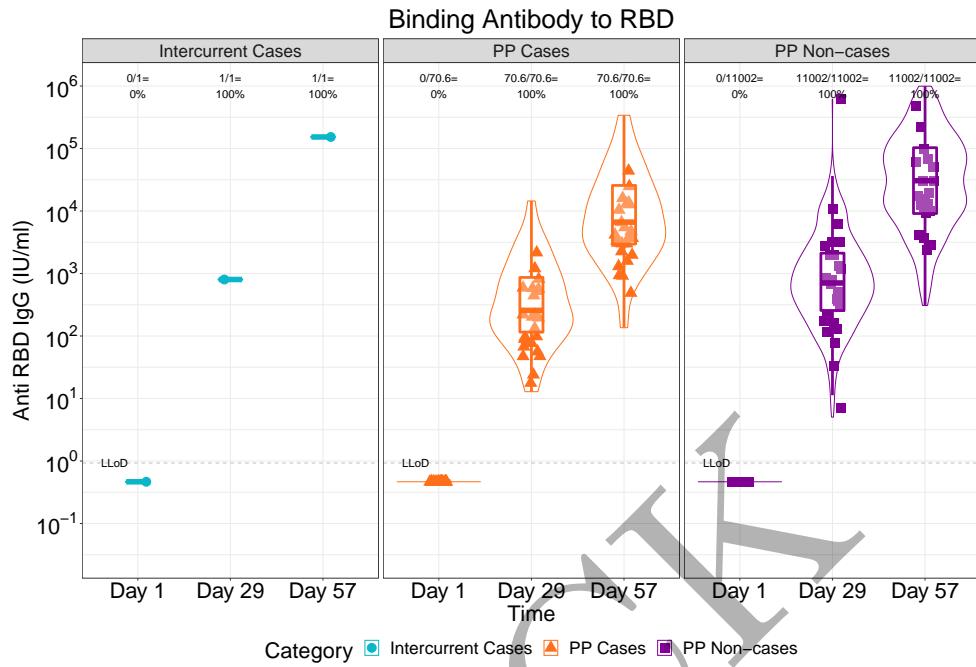


Figure 2.50: violinplots of Binding Antibody to RBD: baseline negative vaccine arm (version 2)

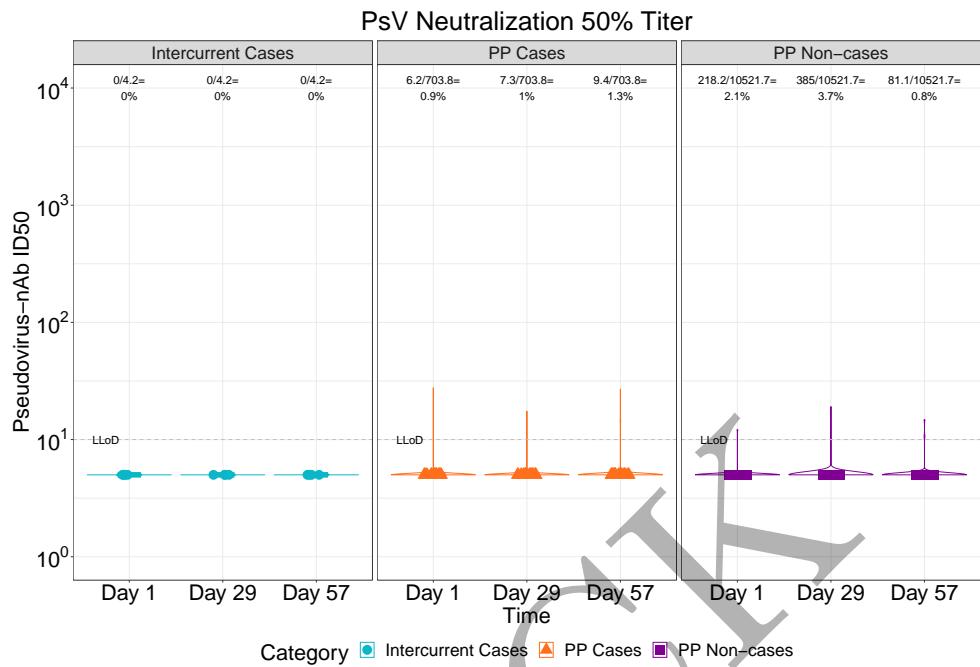


Figure 2.51: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm (version 2)

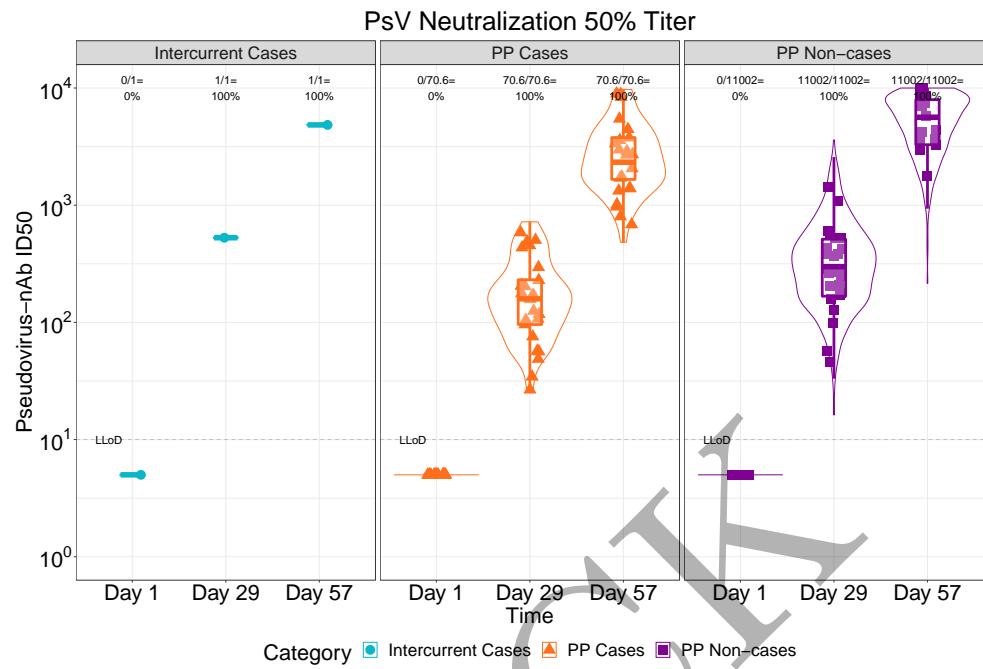


Figure 2.52: violinplots of Pseudovirus Neutralization ID₅₀: baseline negative vaccine arm (version 2)

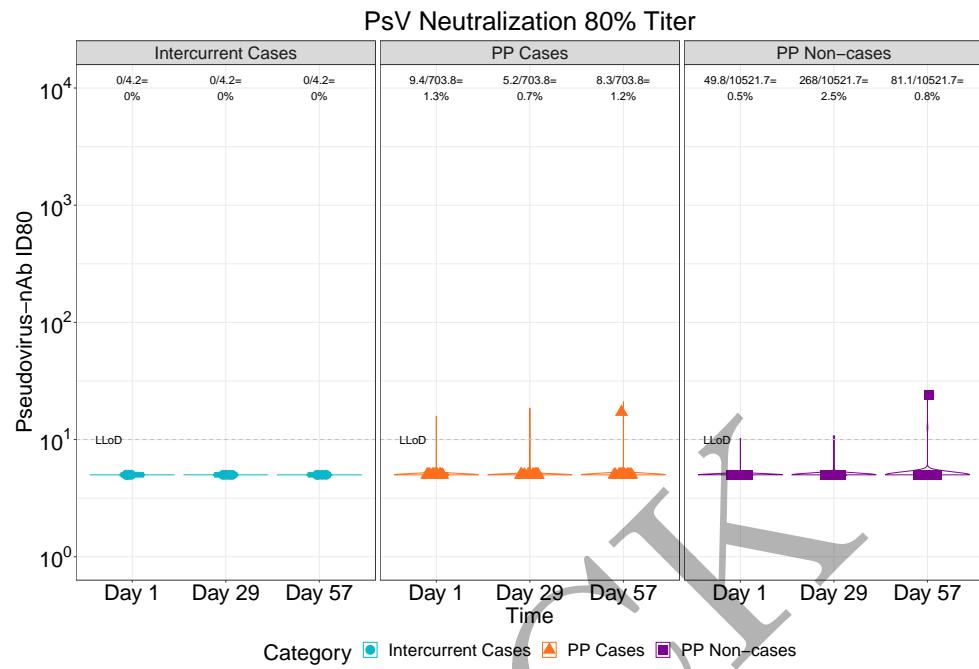


Figure 2.53: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm (version 2)

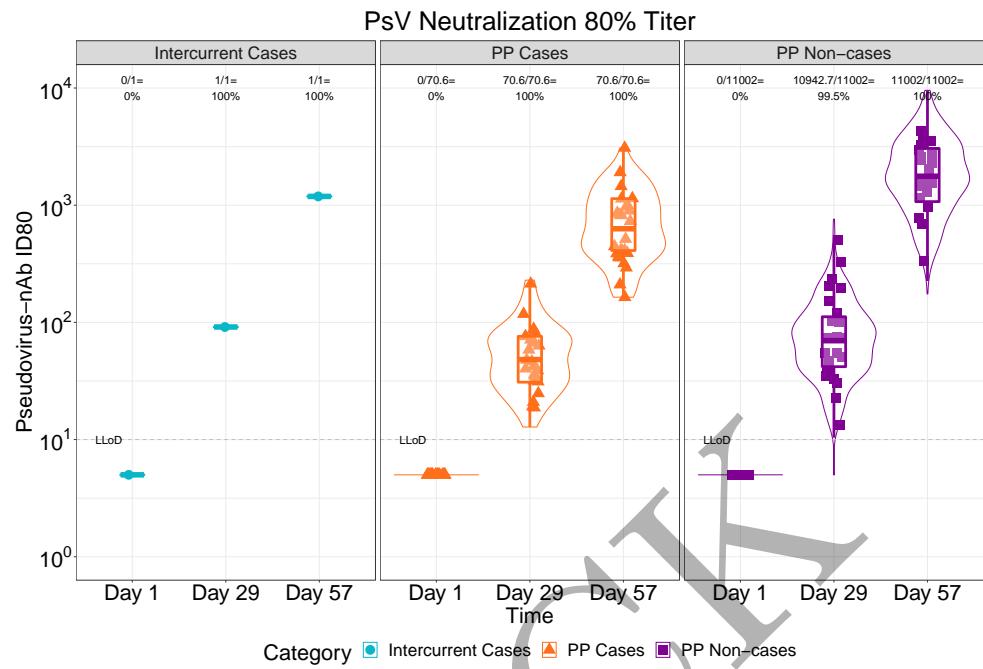


Figure 2.54: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm (version 2)

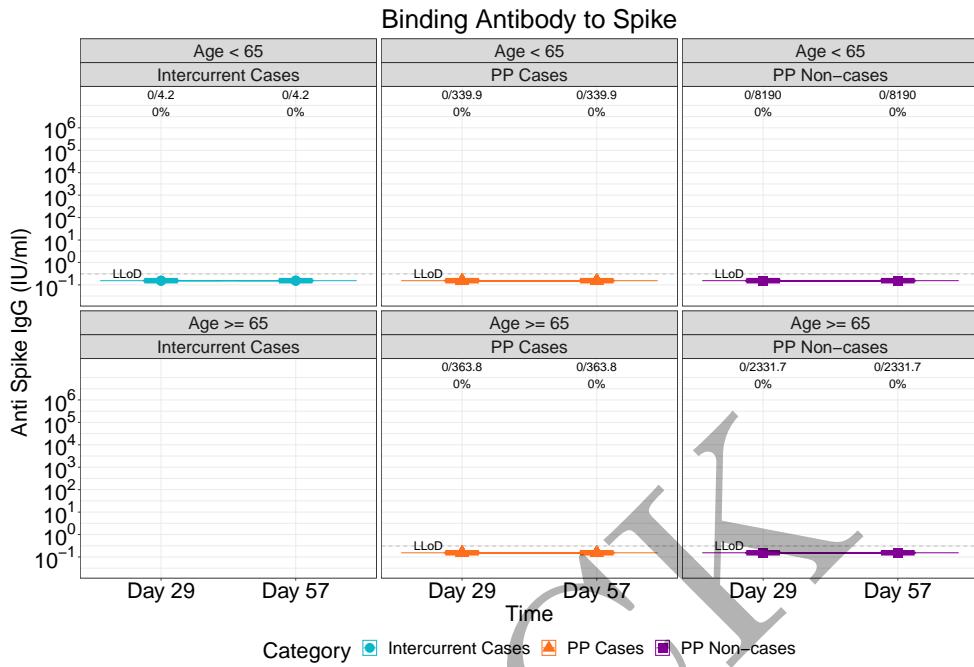


Figure 2.55: lineplots of Binding Antibody to Spike: baseline negative placebo arm by age (version 1)

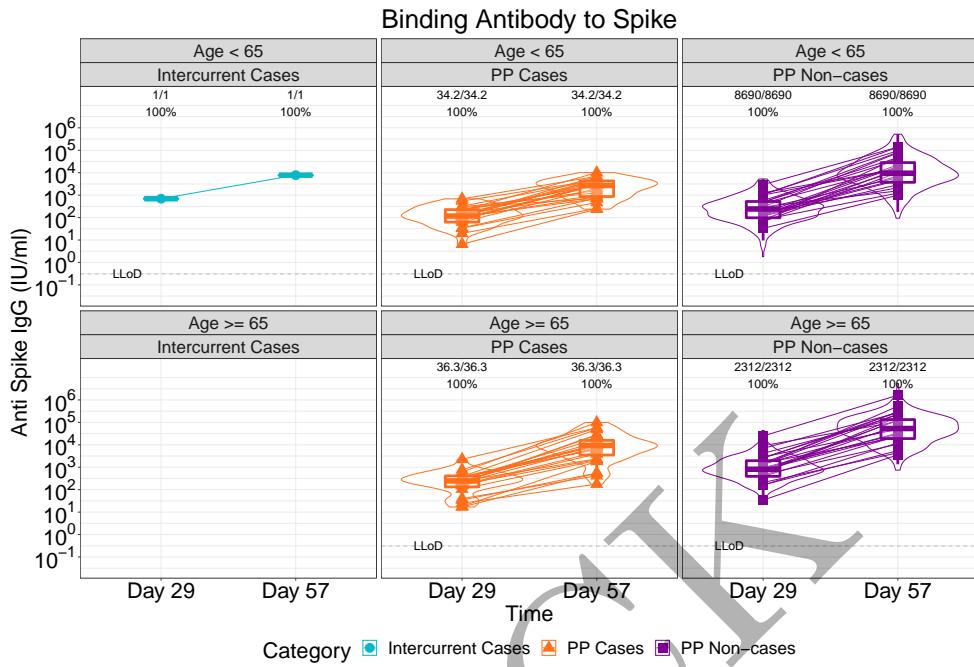


Figure 2.56: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by age (version 1)

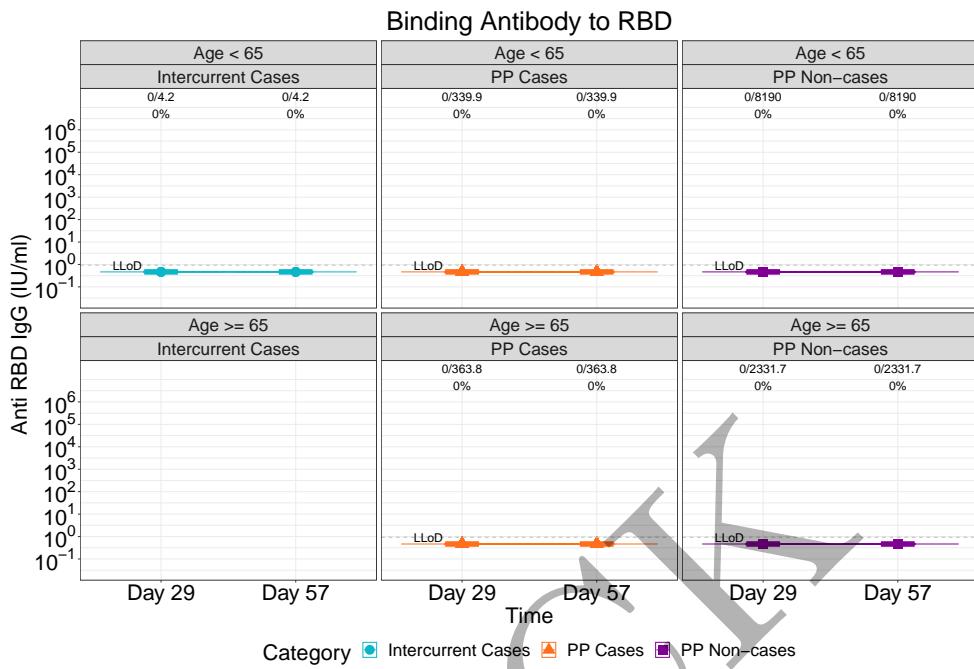


Figure 2.57: lineplots of Binding Antibody to RBD: baseline negative placebo arm by age (version 1)

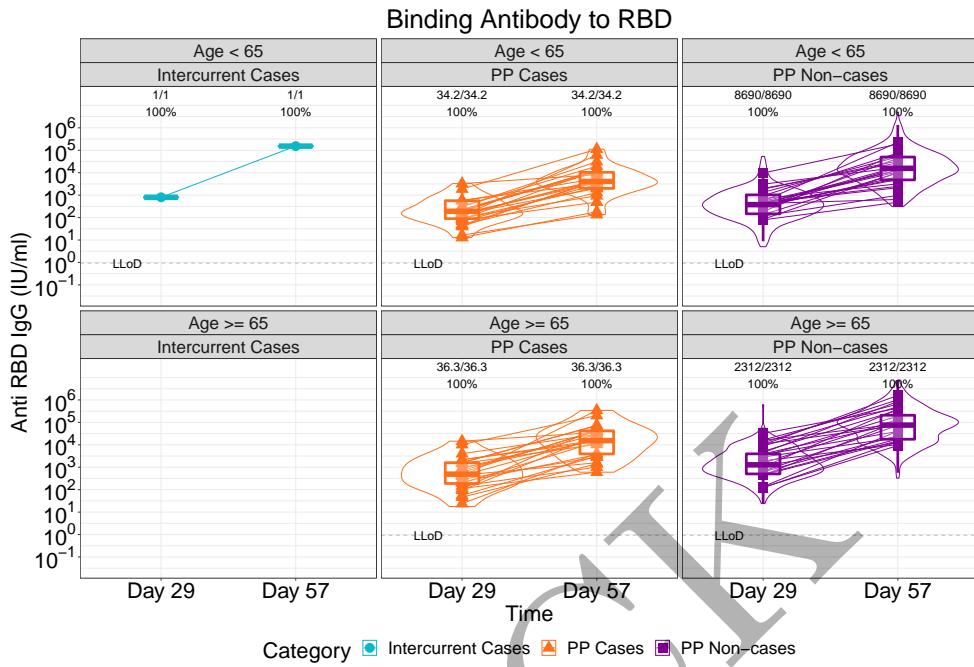


Figure 2.58: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by age (version 1)

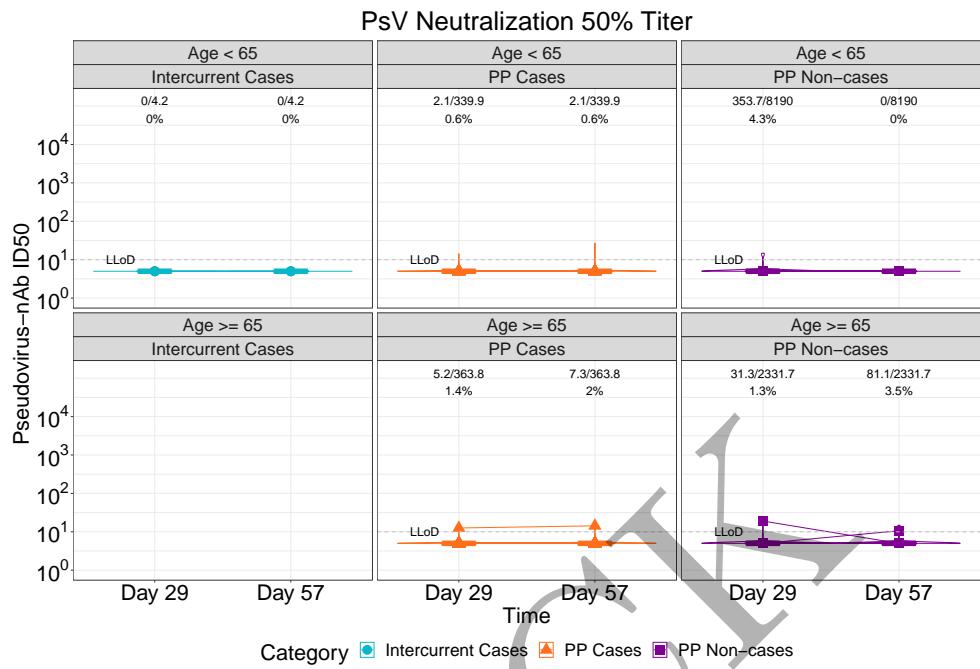


Figure 2.59: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age (version 1)

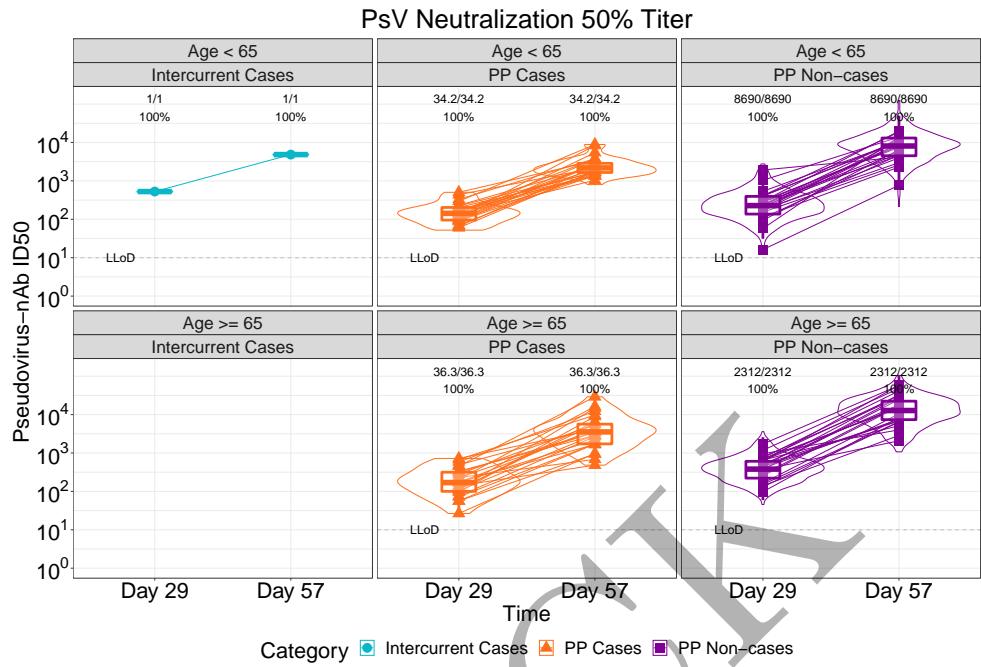


Figure 2.60: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age (version 1)

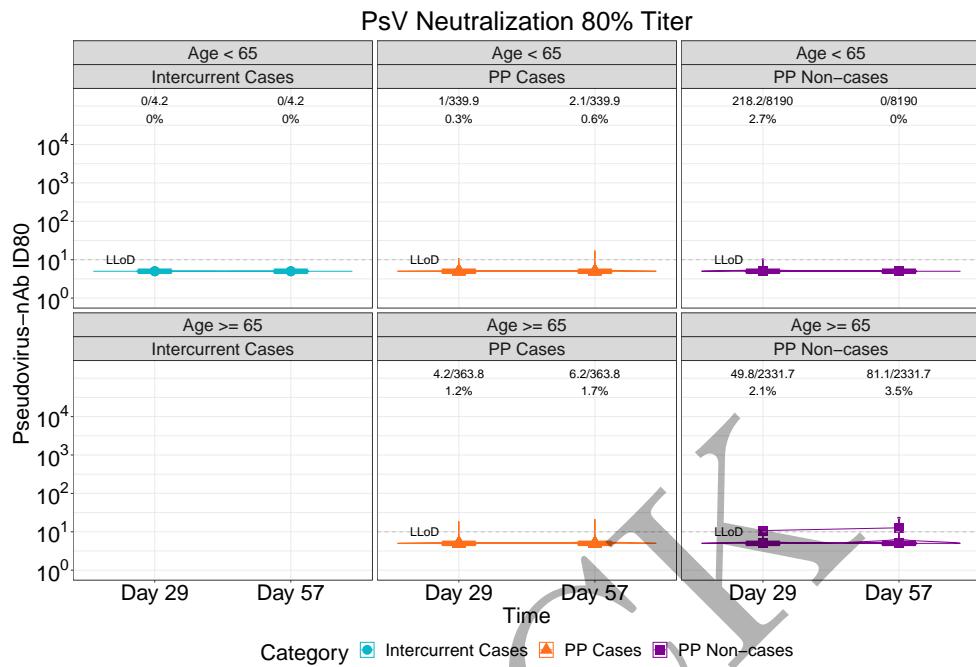


Figure 2.61: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age (version 1)

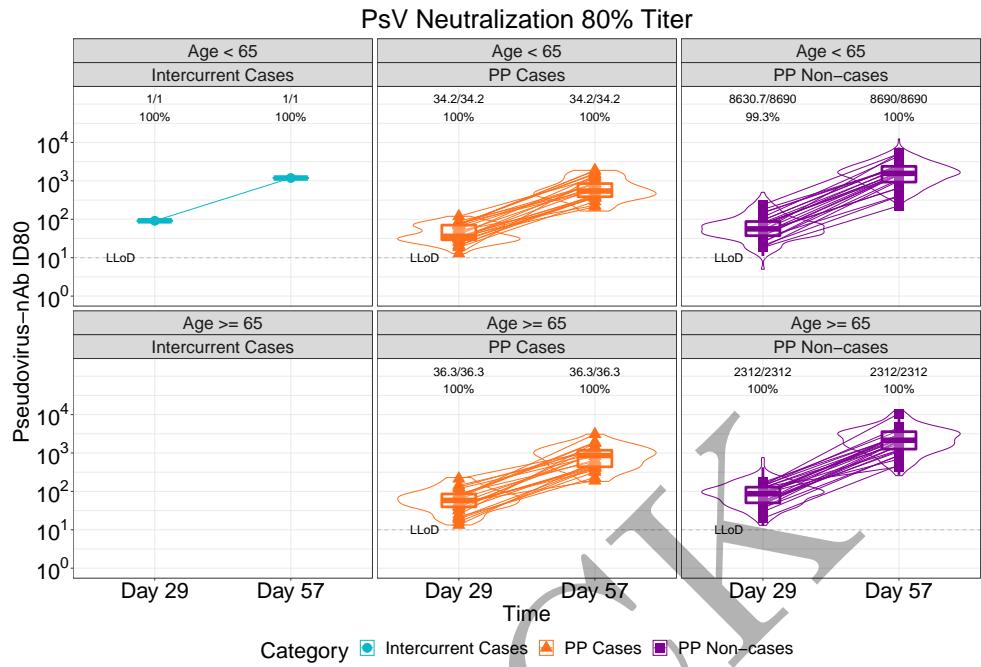


Figure 2.62: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age (version 1)

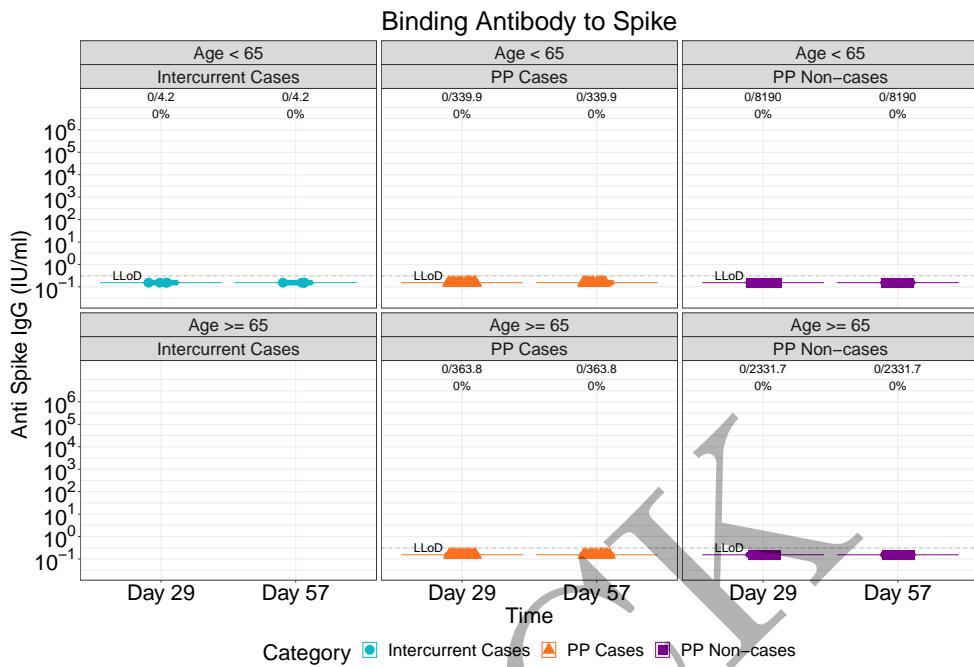


Figure 2.63: violinplots of Binding Antibody to Spike: baseline negative placebo arm by age (version 1)

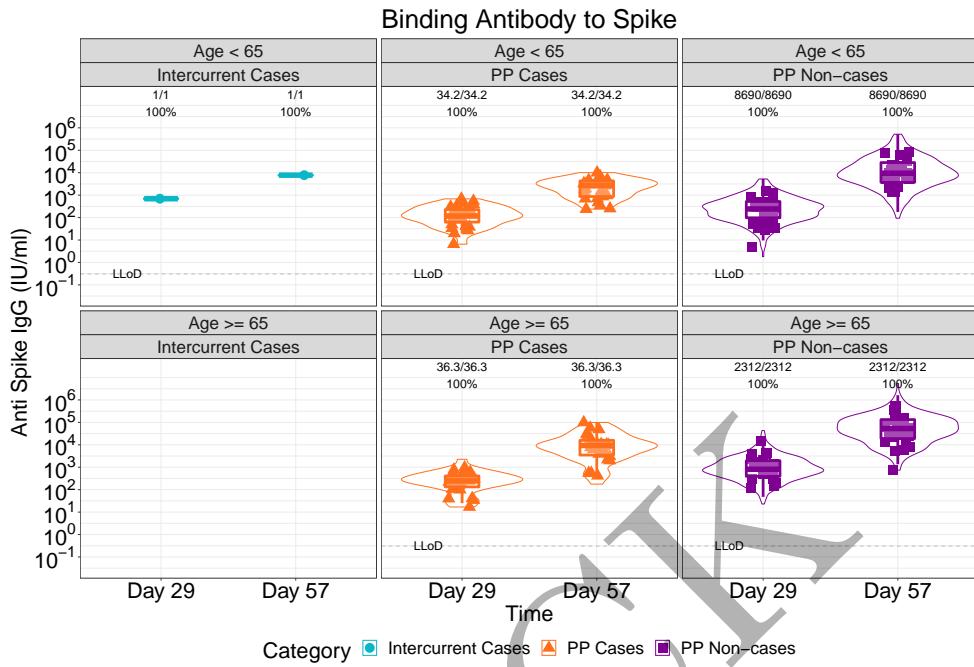


Figure 2.64: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by age (version 1)

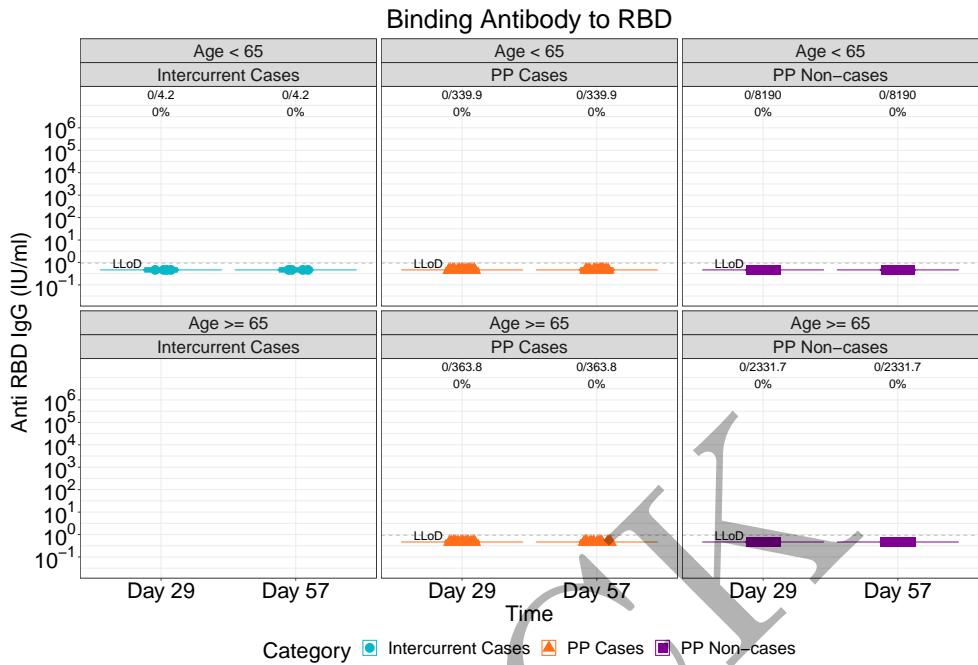


Figure 2.65: violinplots of Binding Antibody to RBD: baseline negative placebo arm by age (version 1)

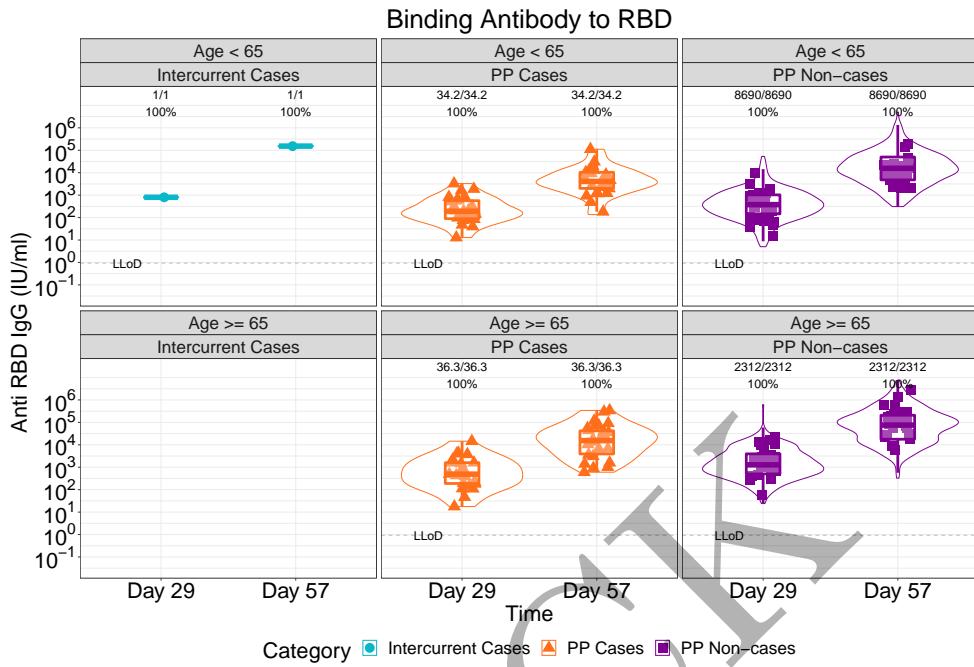


Figure 2.66: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by age (version 1)

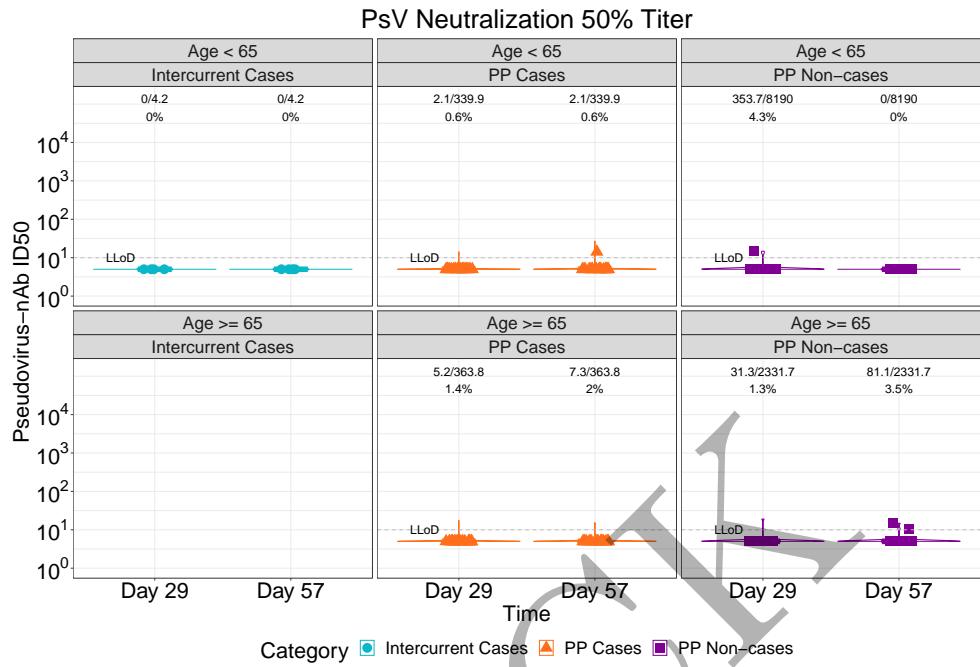


Figure 2.67: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age (version 1)

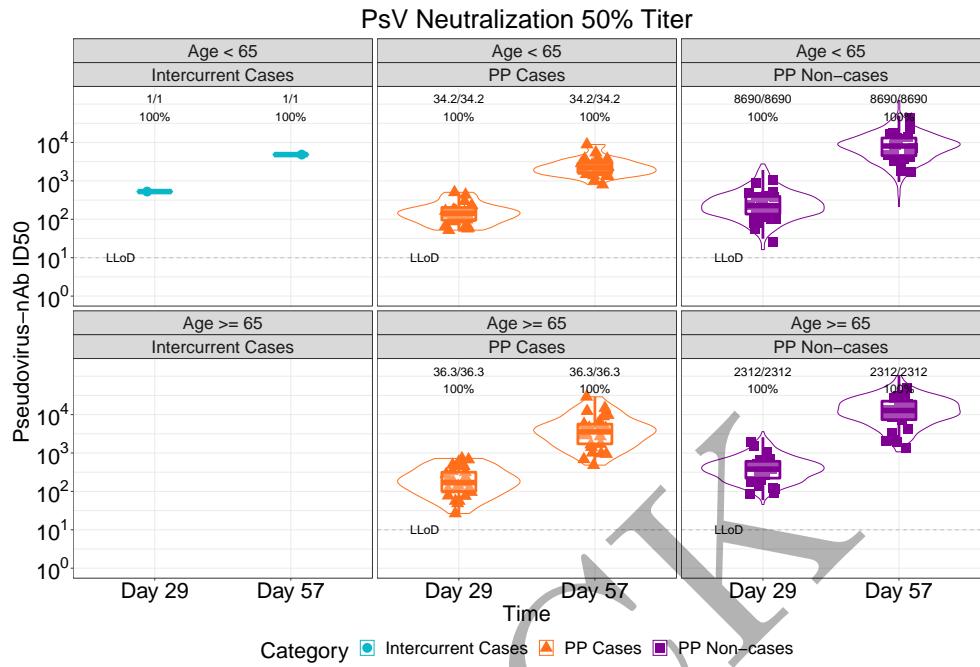


Figure 2.68: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age (version 1)

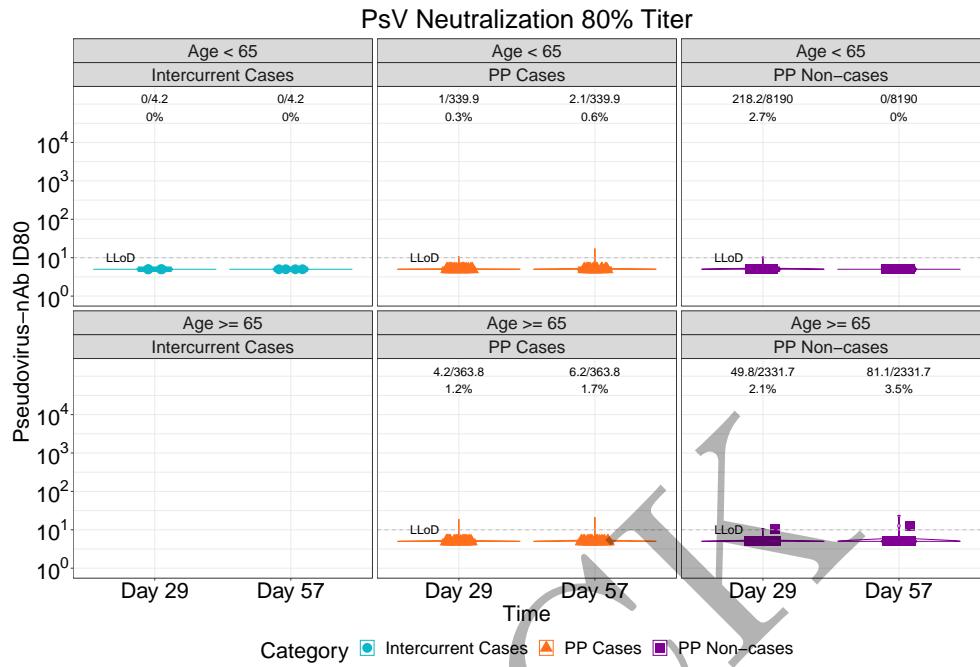


Figure 2.69: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age (version 1)

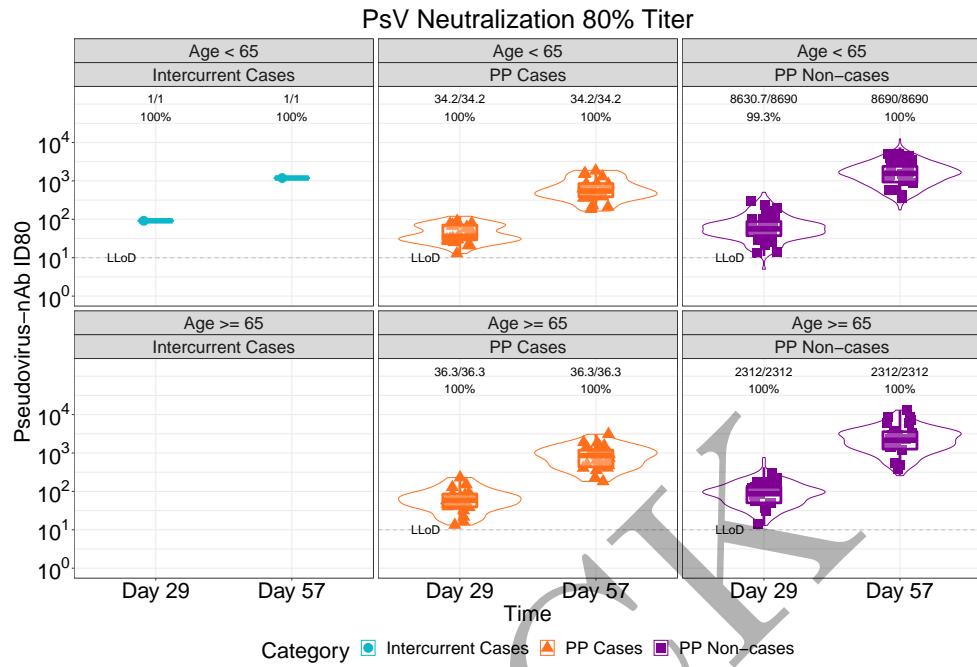


Figure 2.70: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age (version 1)

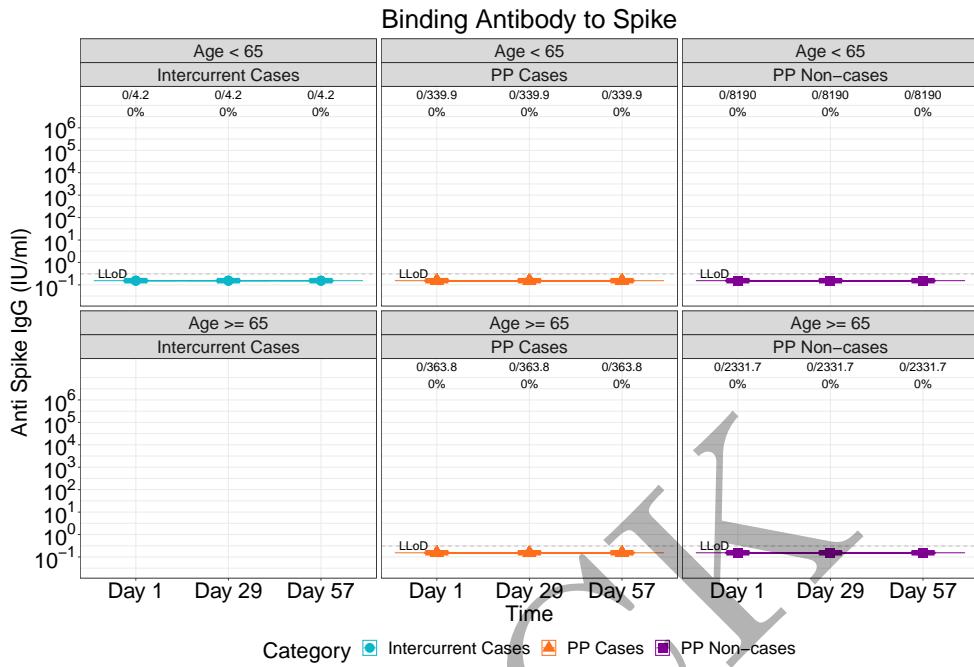


Figure 2.71: lineplots of Binding Antibody to Spike: baseline negative placebo arm by age (version 2)

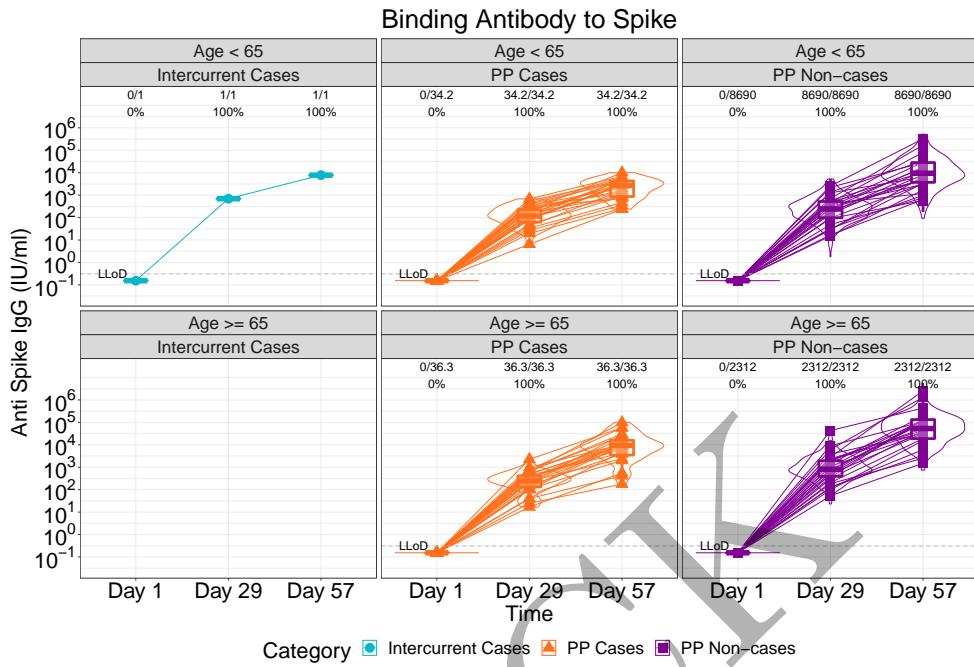


Figure 2.72: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by age (version 2)

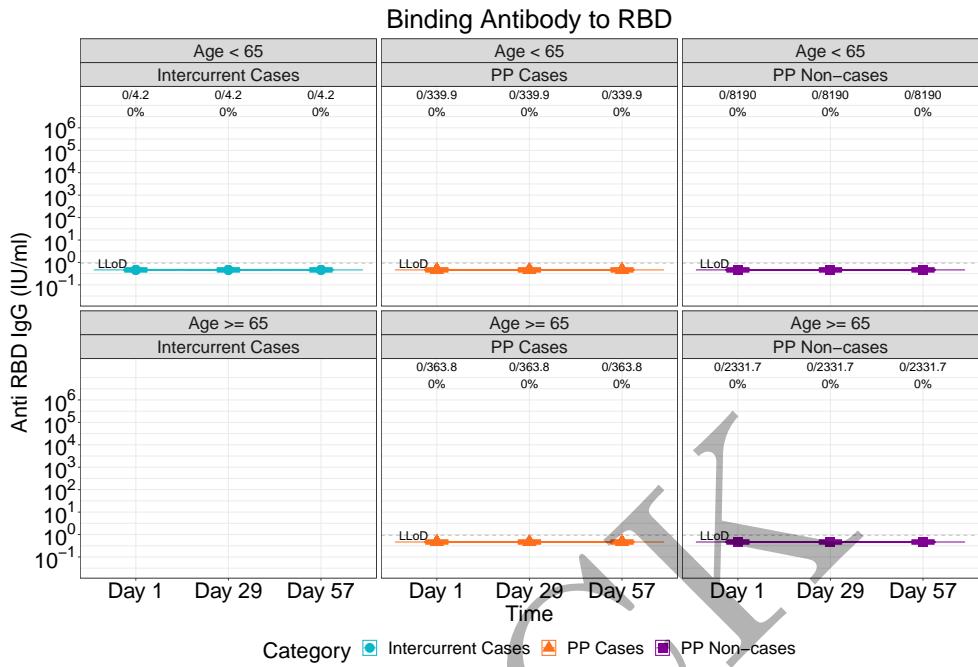


Figure 2.73: lineplots of Binding Antibody to RBD: baseline negative placebo arm by age (version 2)

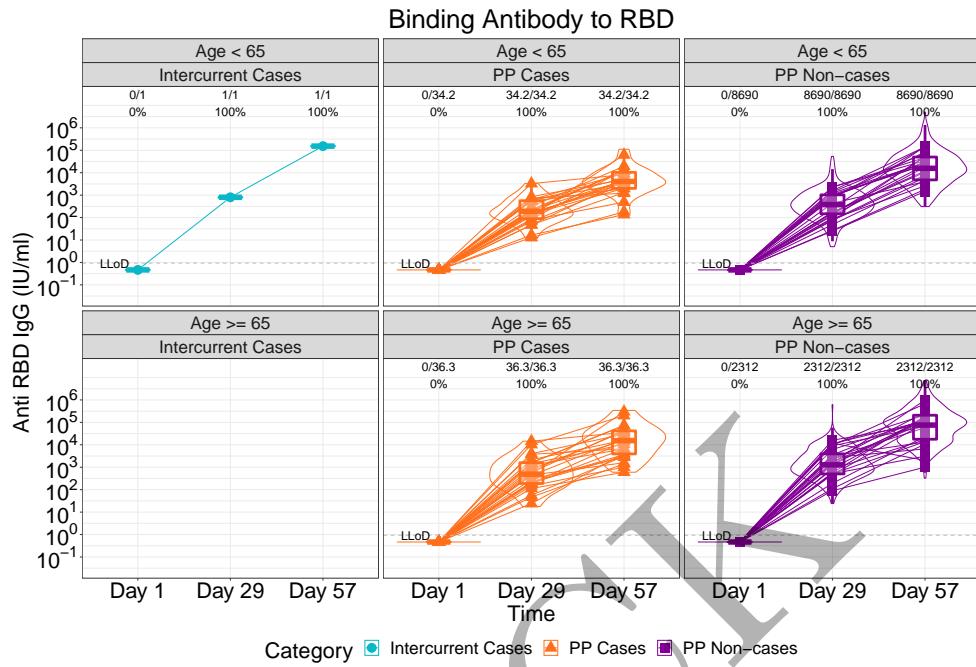


Figure 2.74: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by age (version 2)

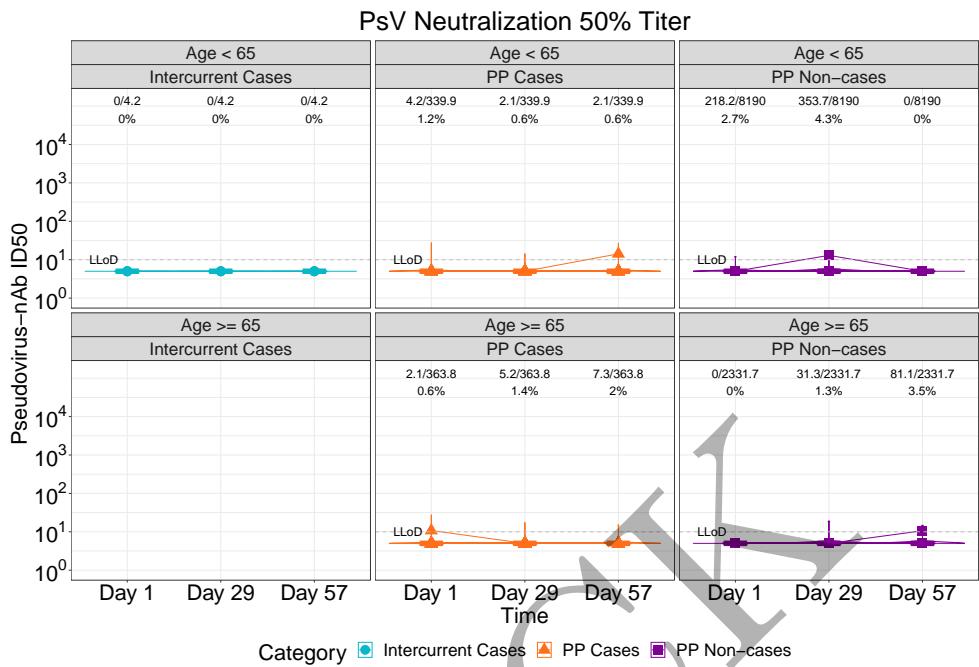


Figure 2.75: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age (version 2)

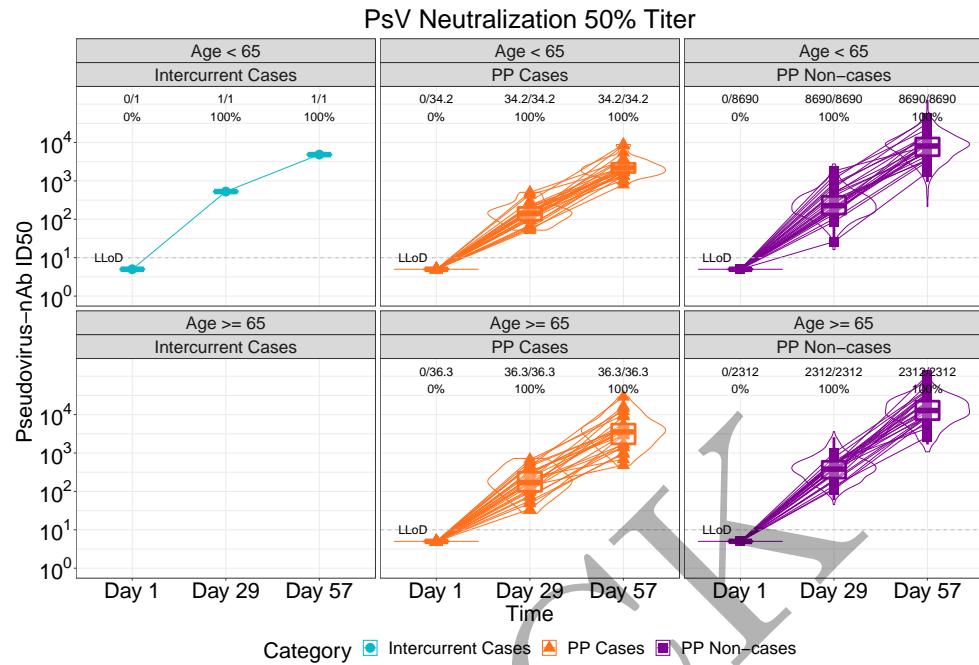


Figure 2.76: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age (version 2)

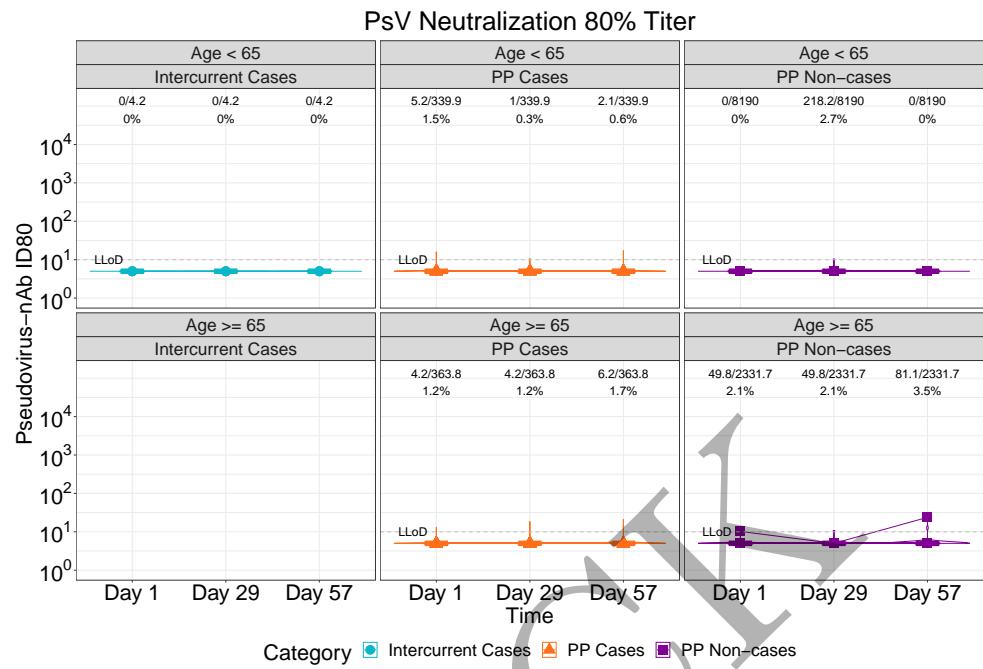


Figure 2.77: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age (version 2)

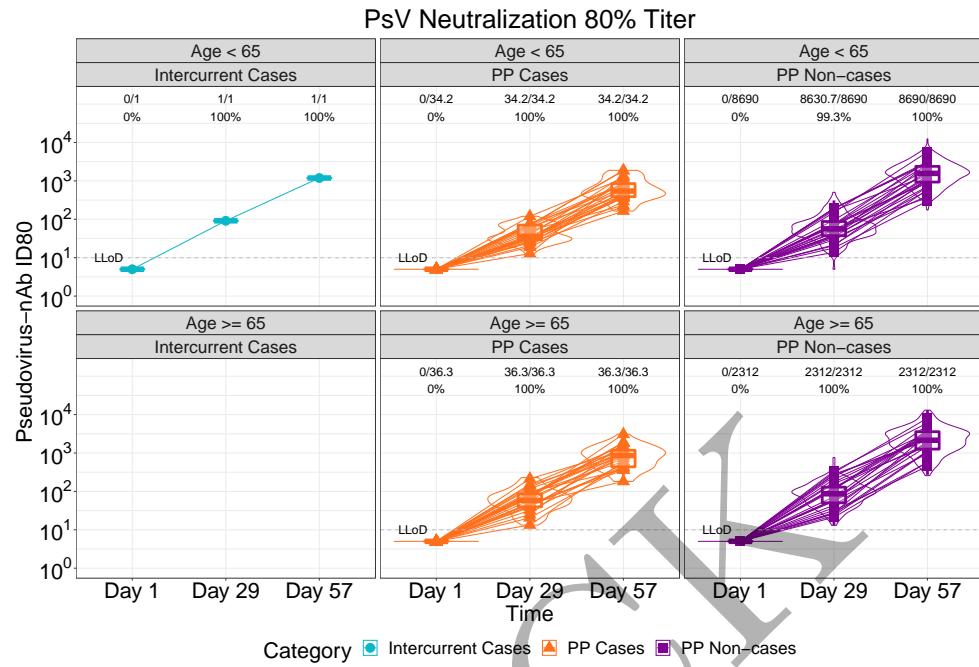


Figure 2.78: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age (version 2)

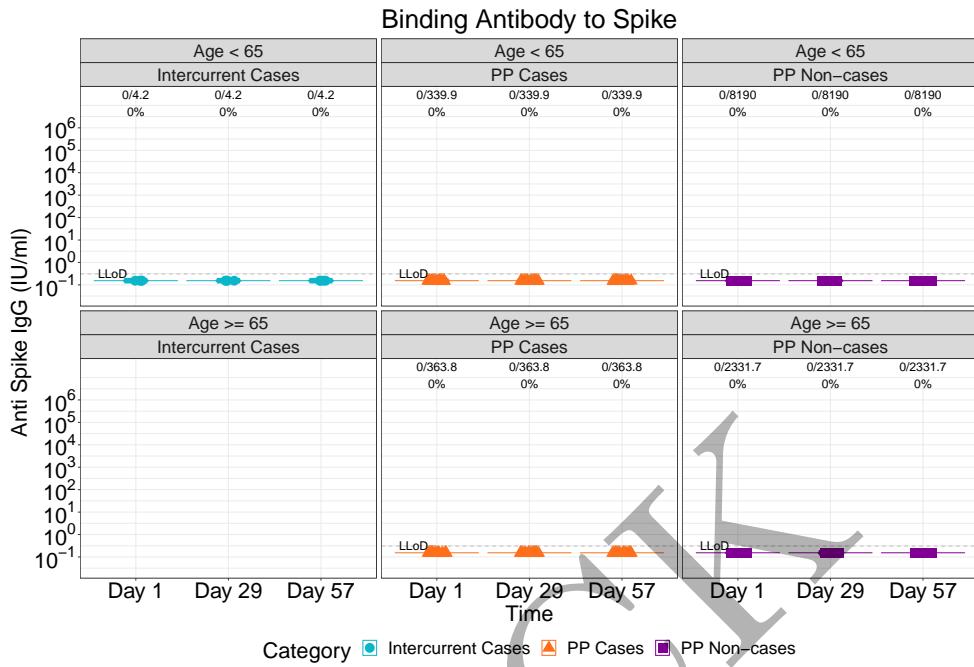


Figure 2.79: violinplots of Binding Antibody to Spike: baseline negative placebo arm by age (version 2)

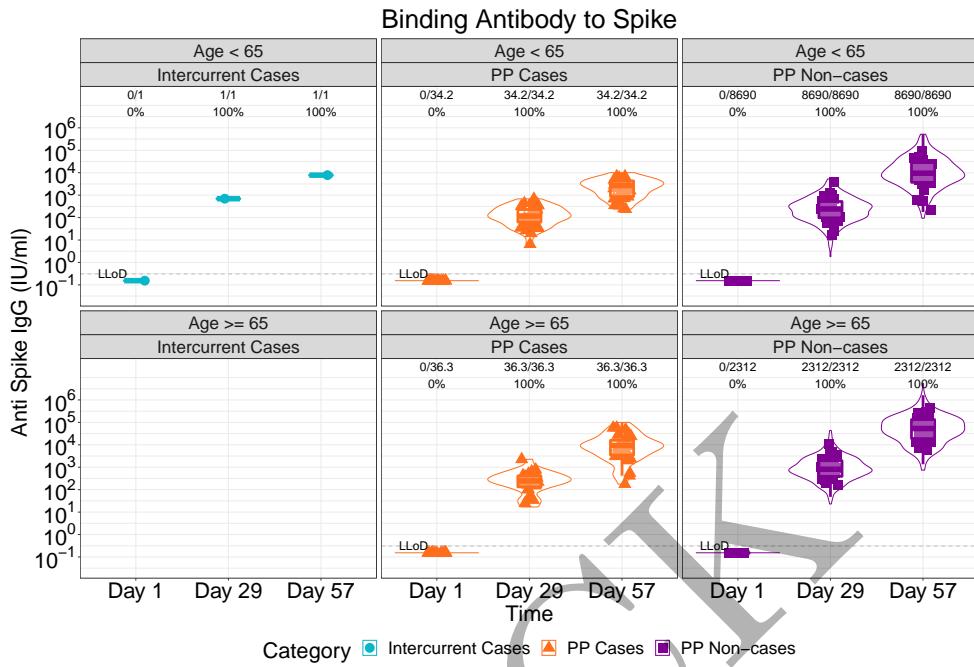


Figure 2.80: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by age (version 2)

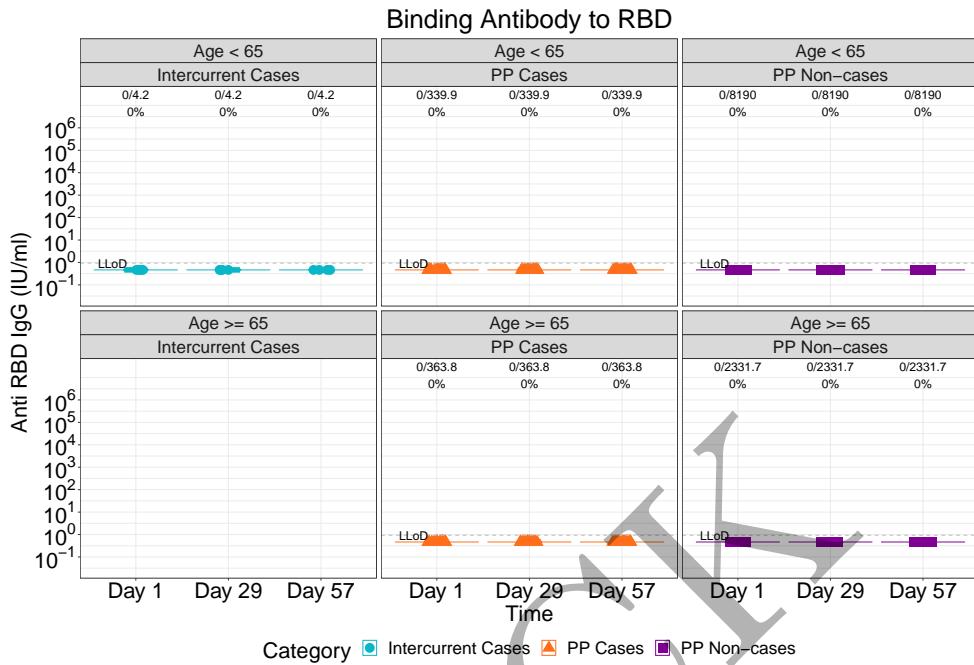


Figure 2.81: violinplots of Binding Antibody to RBD: baseline negative placebo arm by age (version 2)

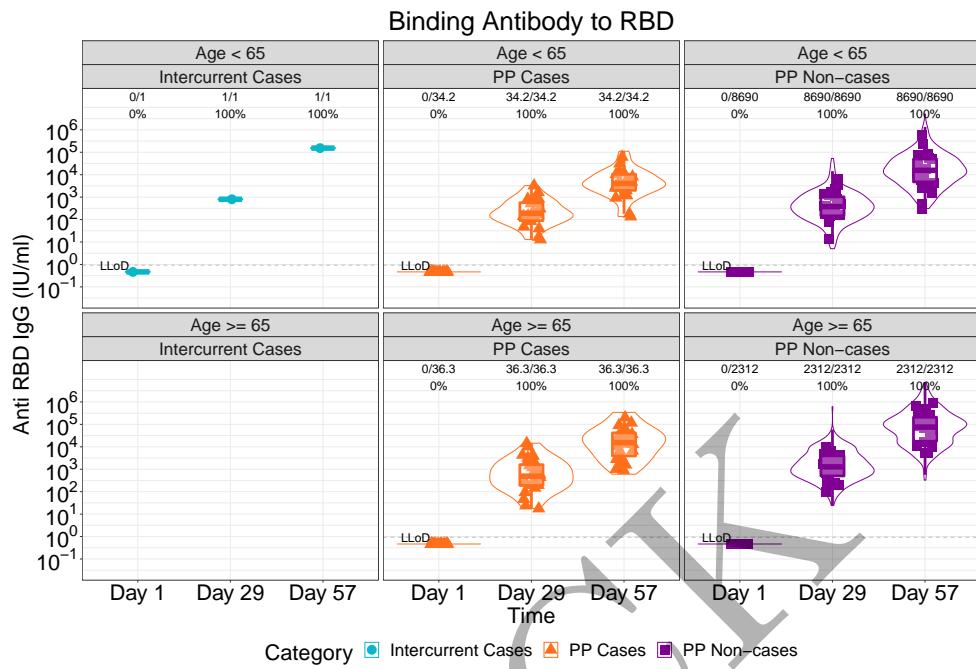


Figure 2.82: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by age (version 2)

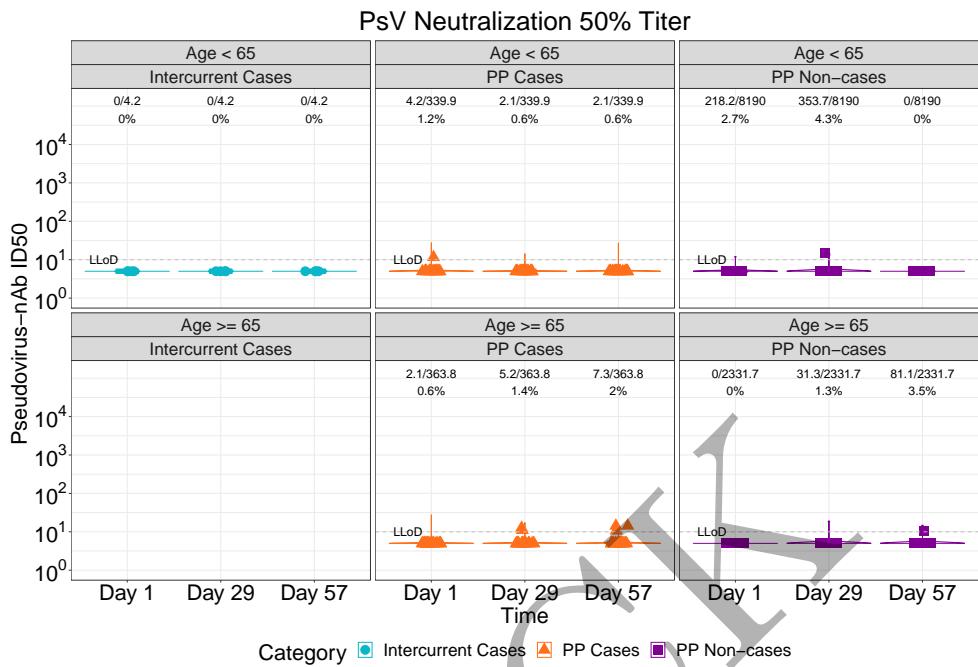


Figure 2.83: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age (version 2)

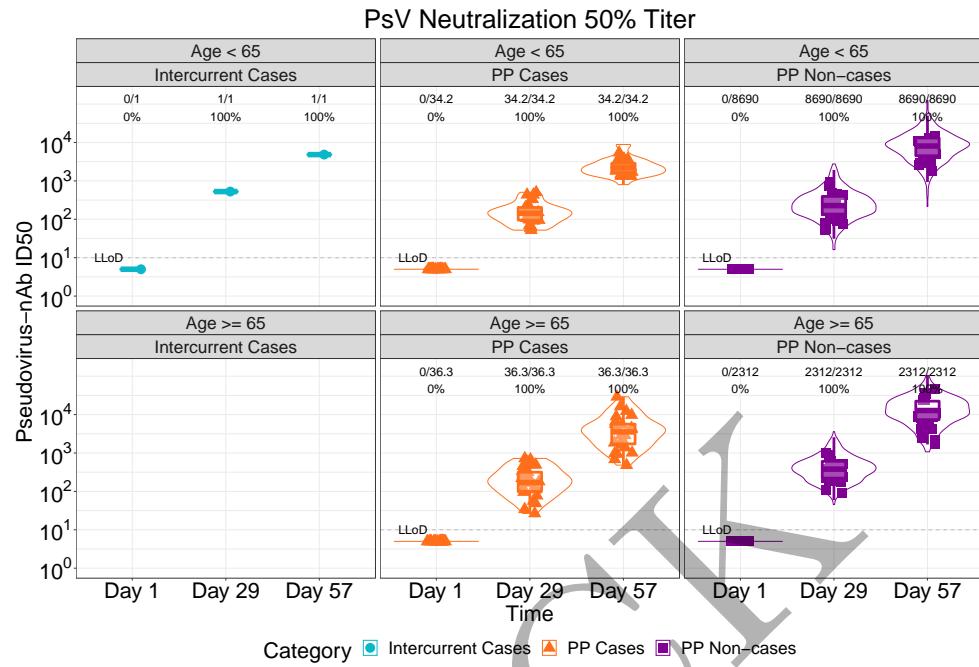


Figure 2.84: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age (version 2)

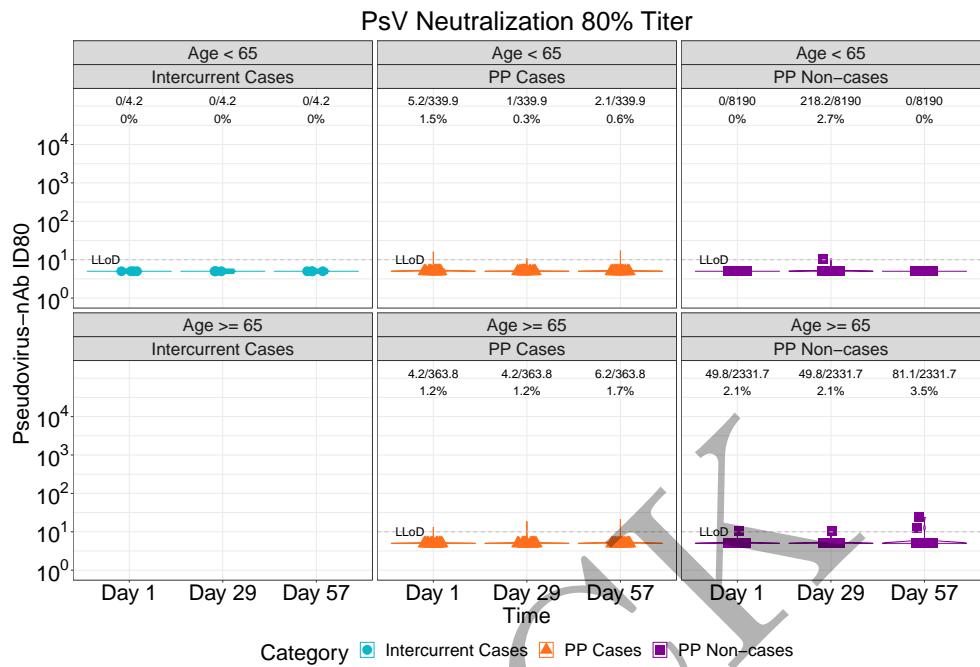


Figure 2.85: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age (version 2)

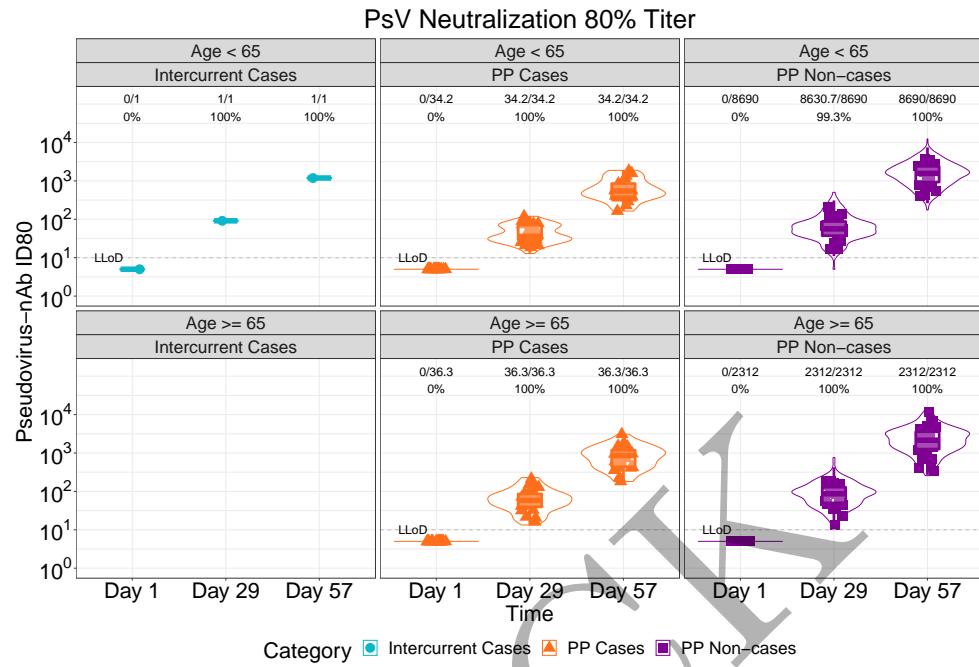


Figure 2.86: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age (version 2)

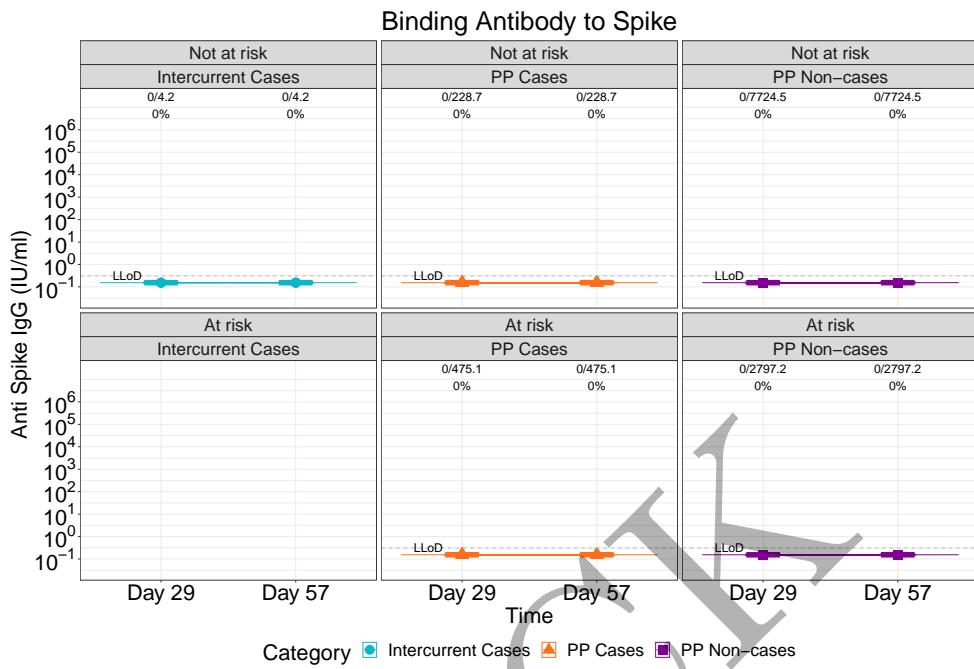


Figure 2.87: lineplots of Binding Antibody to Spike: baseline negative placebo arm by risk condition (version 1)

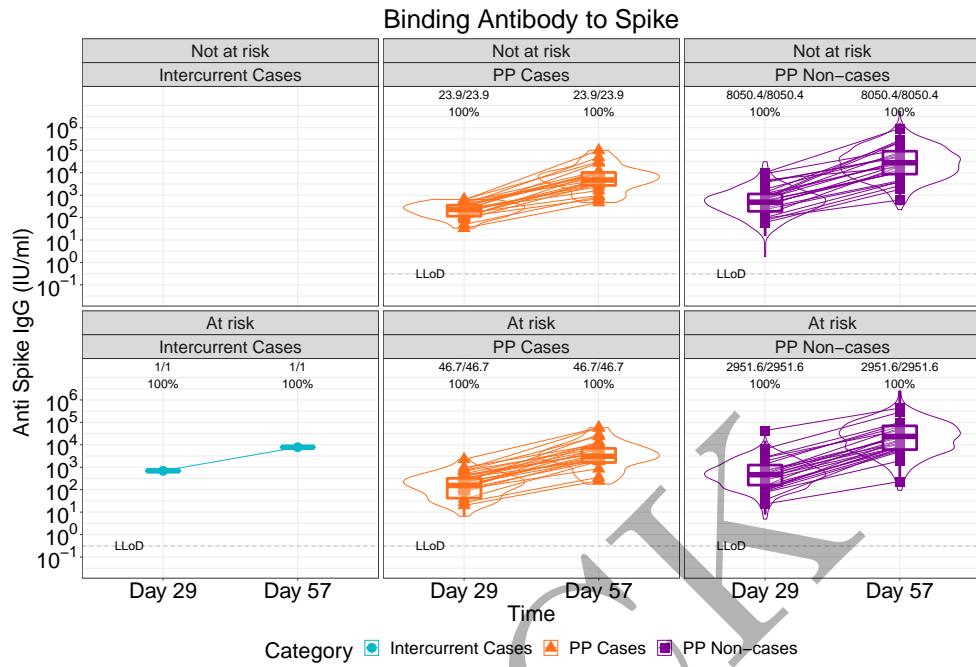


Figure 2.88: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by risk condition (version 1)

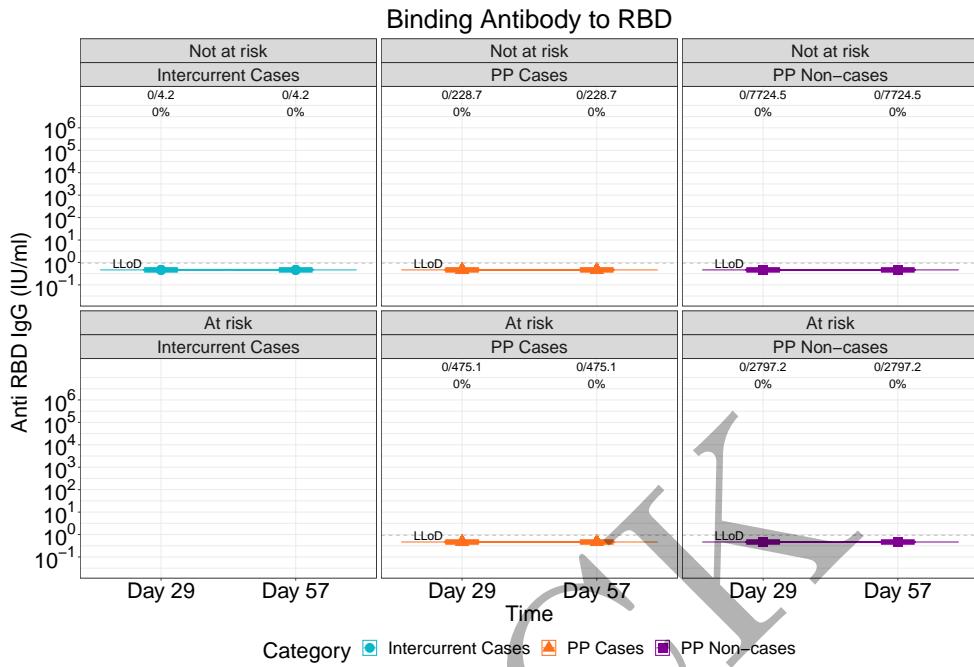


Figure 2.89: lineplots of Binding Antibody to RBD: baseline negative placebo arm by risk condition (version 1)

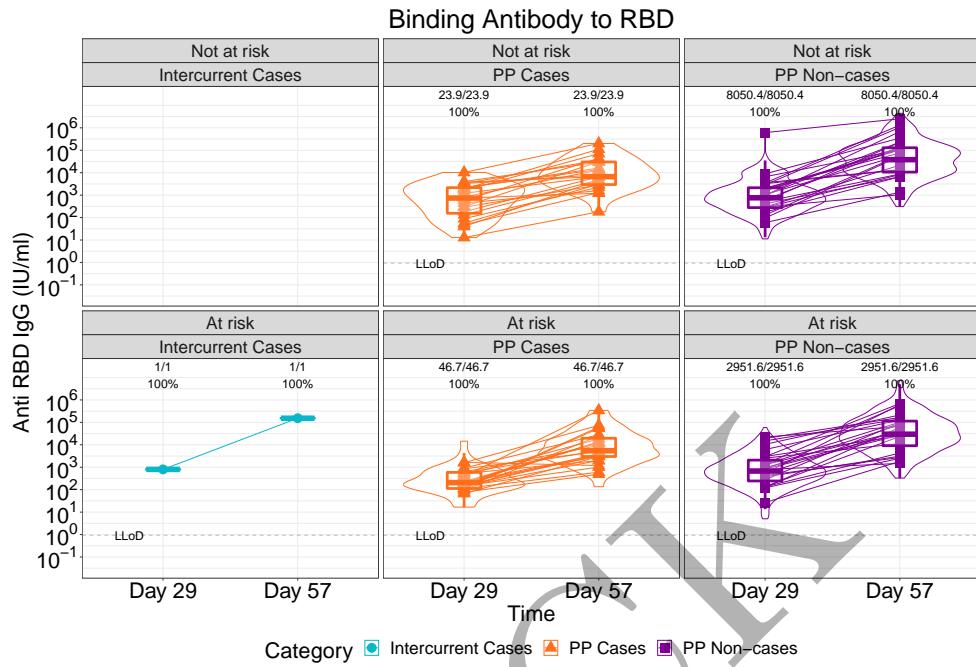


Figure 2.90: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by risk condition (version 1)

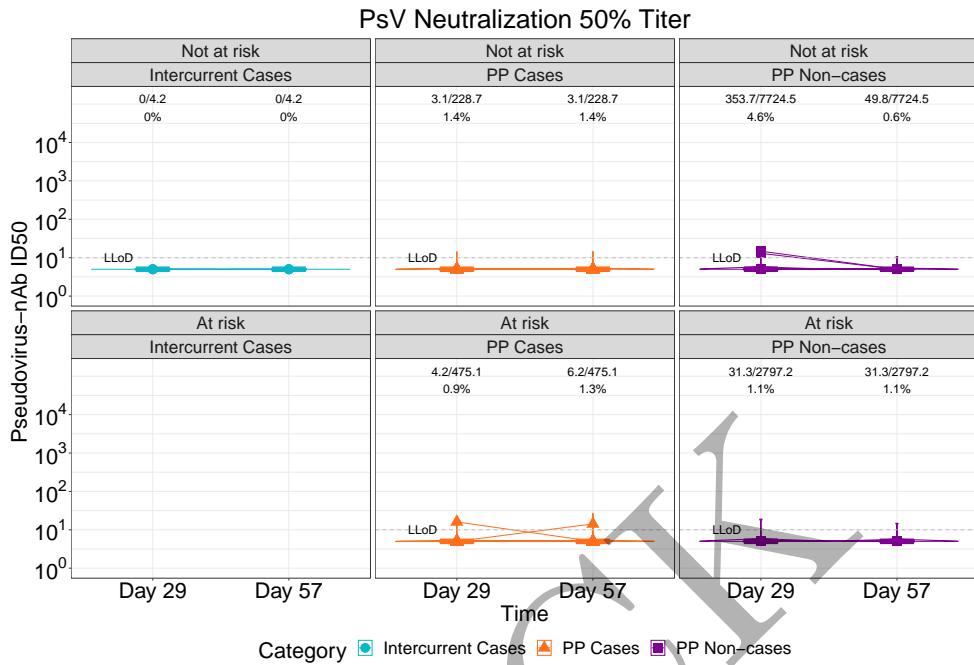


Figure 2.91: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by risk condition (version 1)

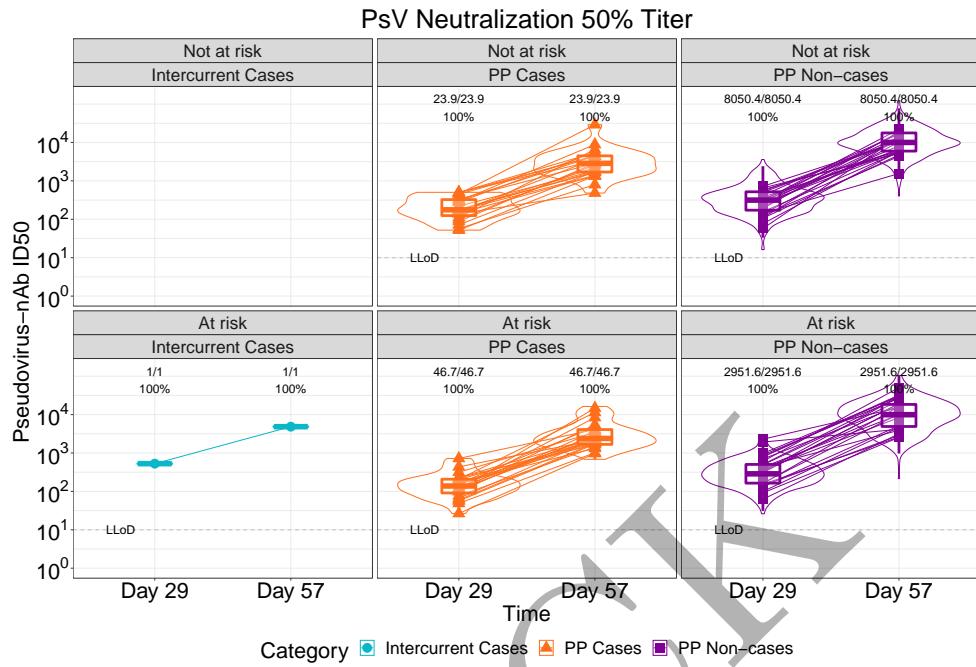


Figure 2.92: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by risk condition (version 1)

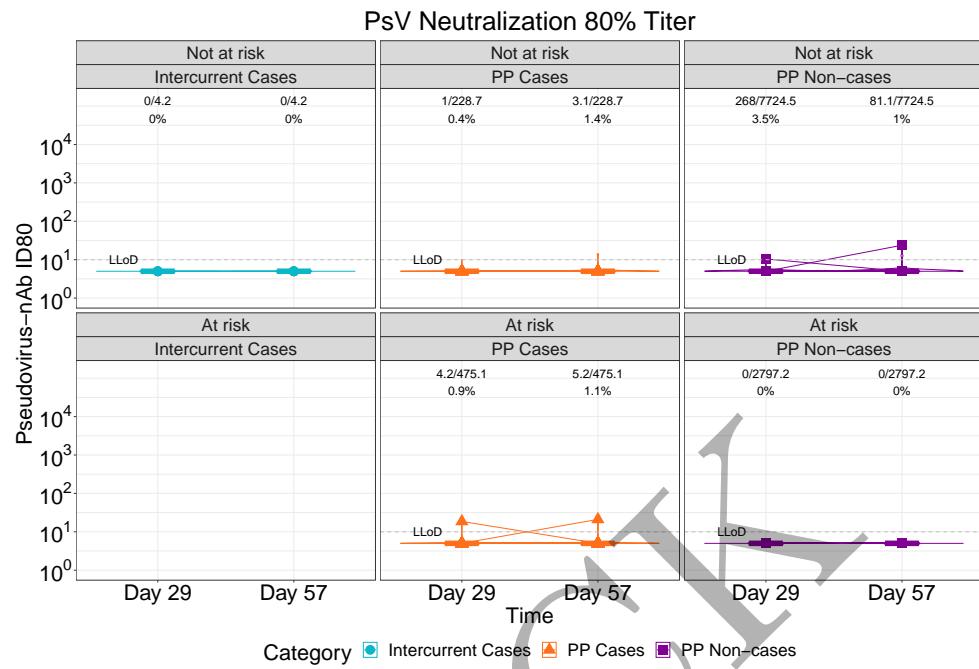


Figure 2.93: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by risk condition (version 1)

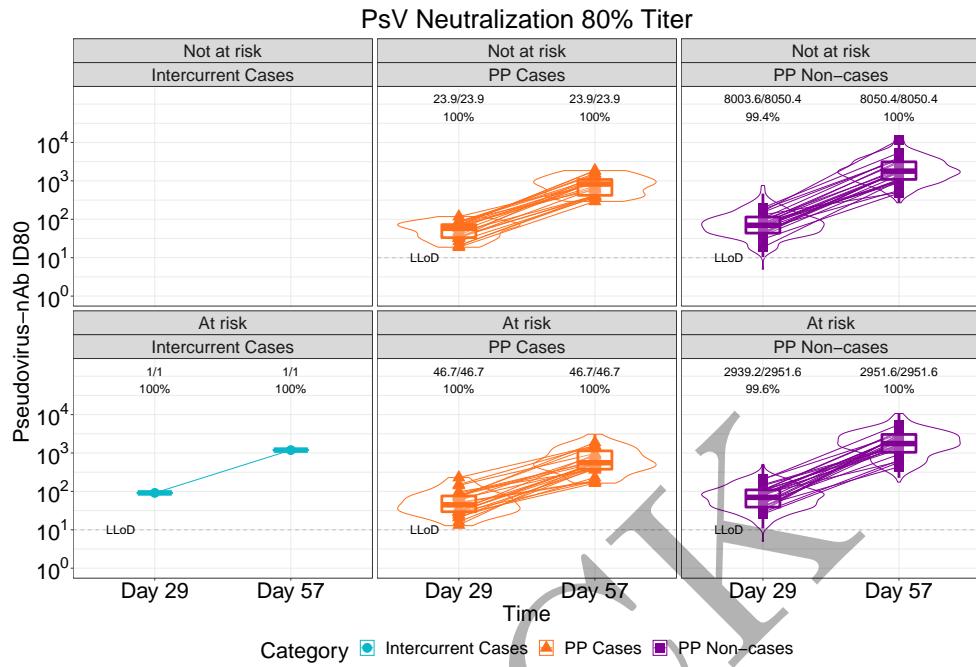


Figure 2.94: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by risk condition (version 1)

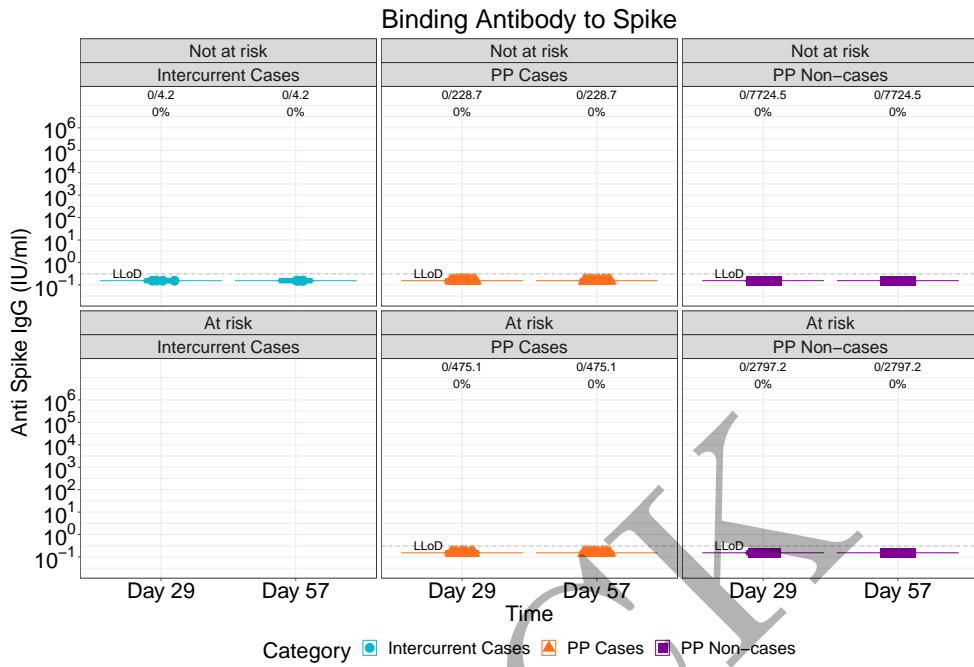


Figure 2.95: violinplots of Binding Antibody to Spike: baseline negative placebo arm by risk condition (version 1)

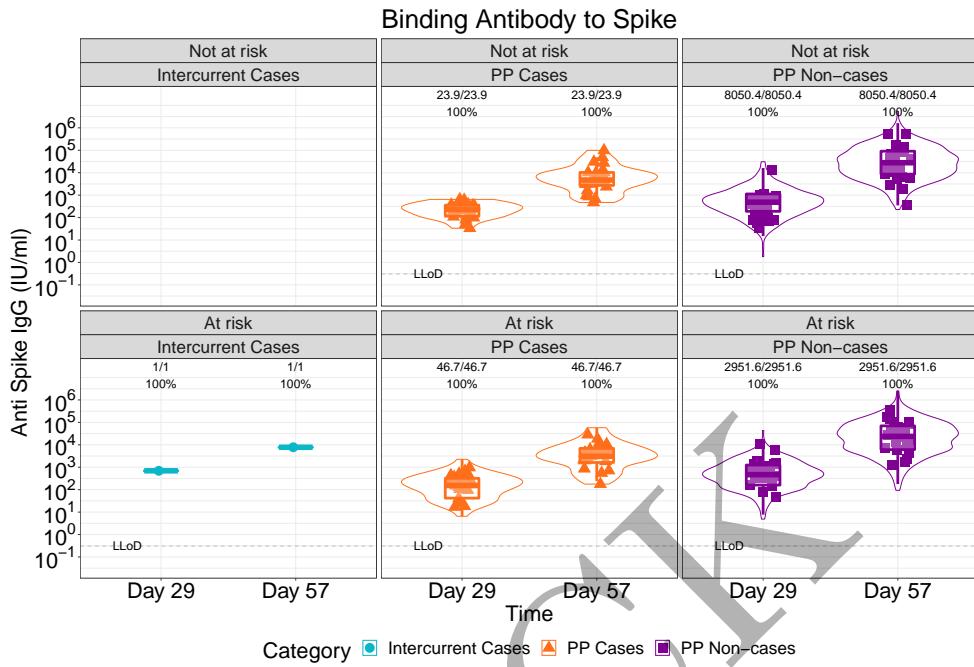


Figure 2.96: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by risk condition (version 1)

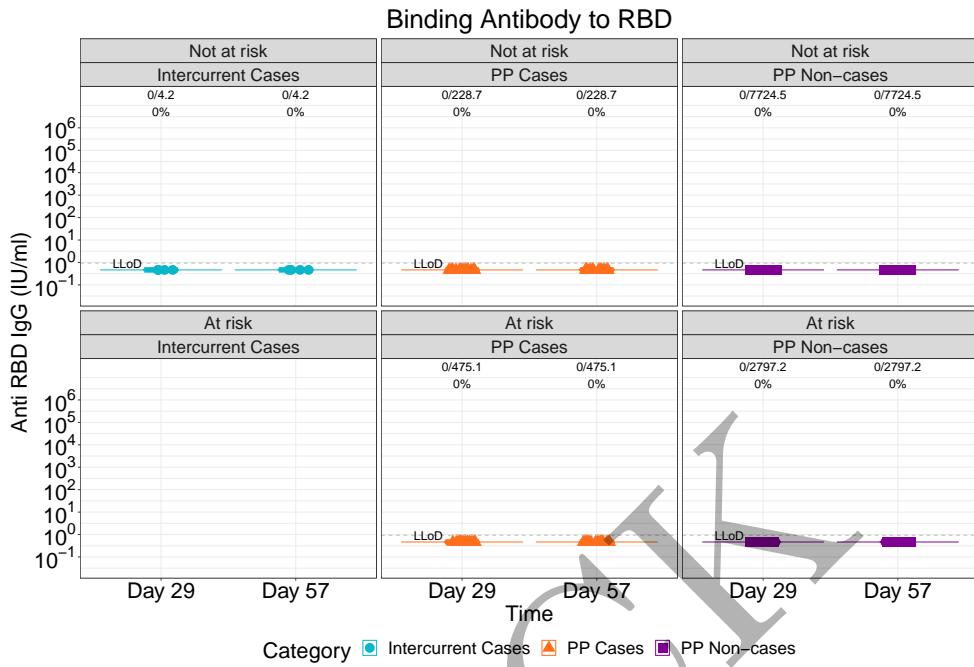


Figure 2.97: violinplots of Binding Antibody to RBD: baseline negative placebo arm by risk condition (version 1)

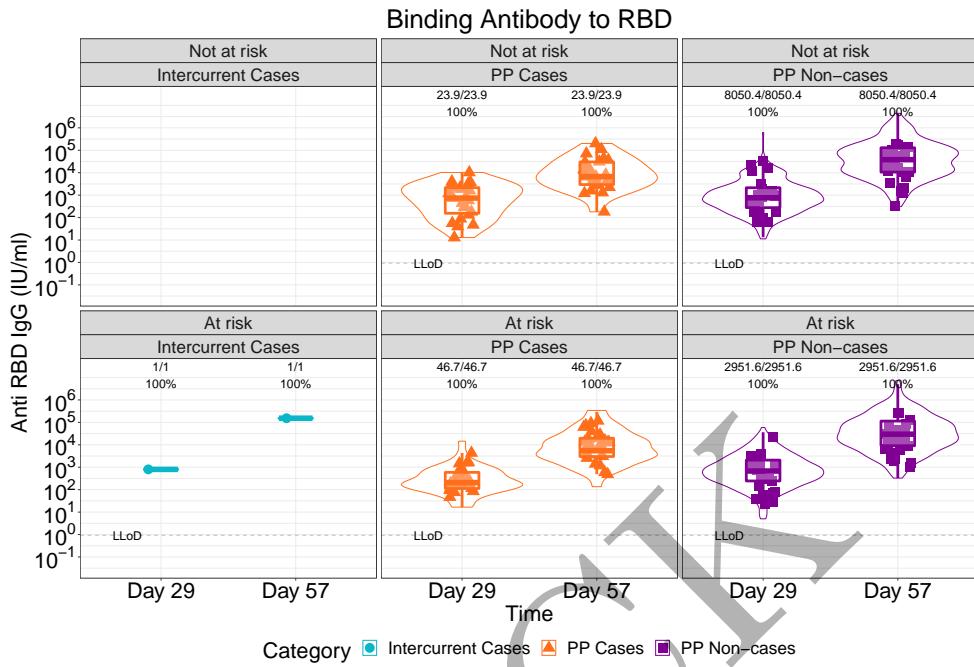


Figure 2.98: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by risk condition (version 1)

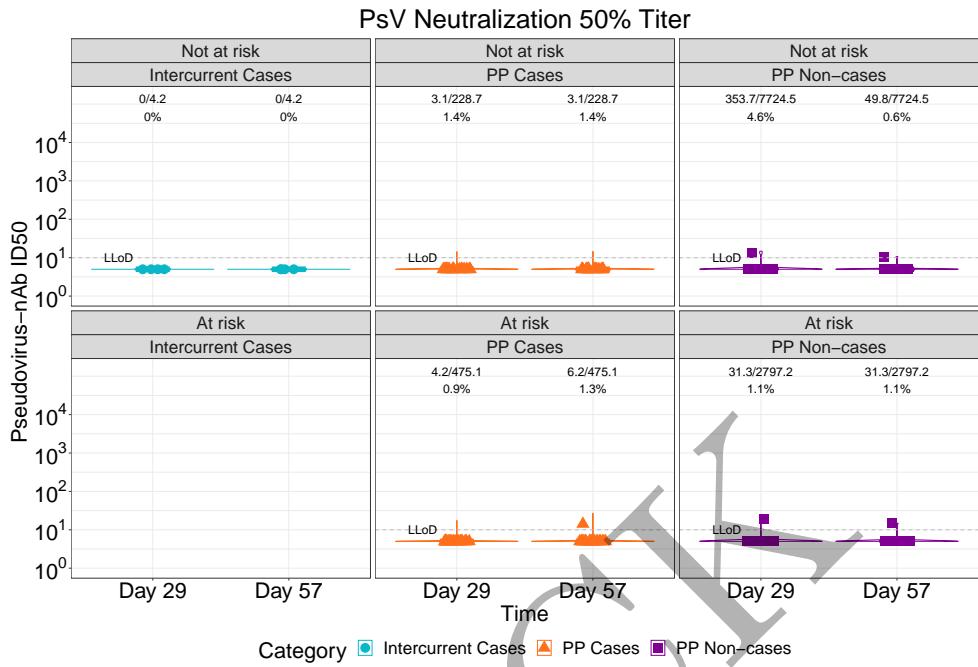


Figure 2.99: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by risk condition (version 1)

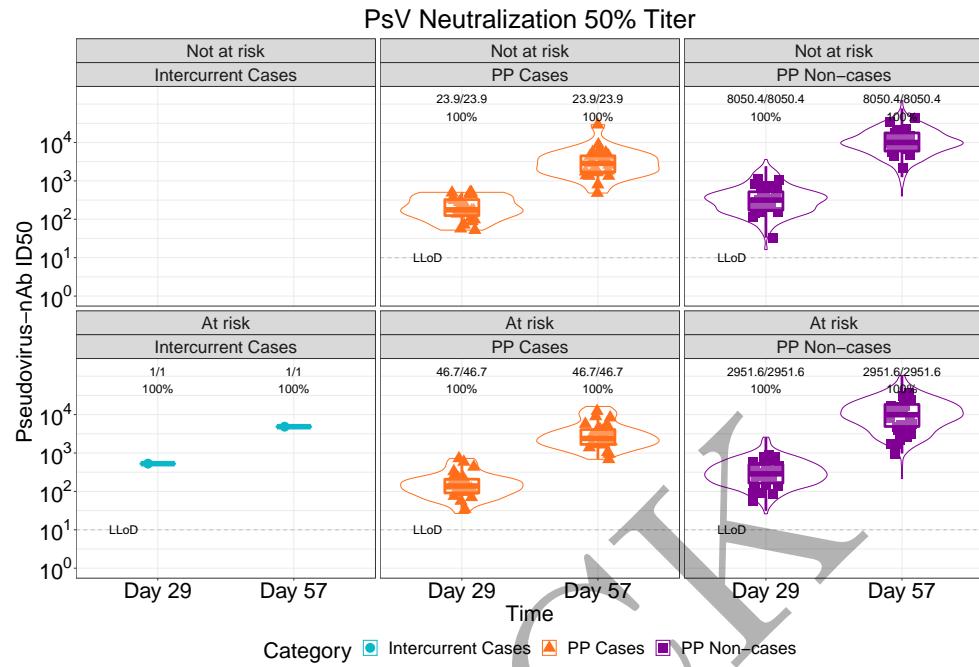


Figure 2.100: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by risk condition (version 1)

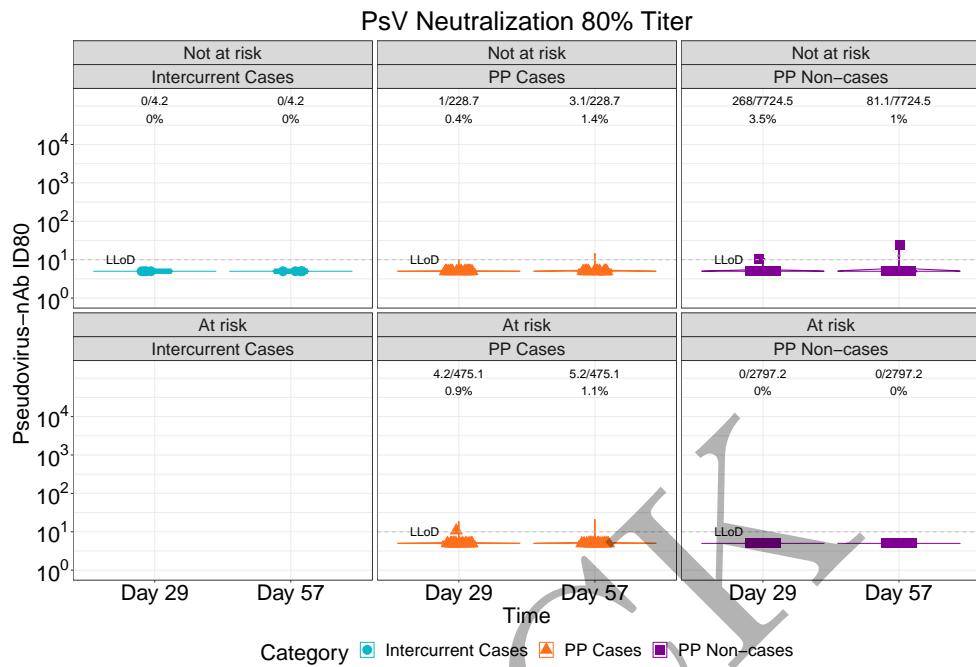


Figure 2.101: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by risk condition (version 1)

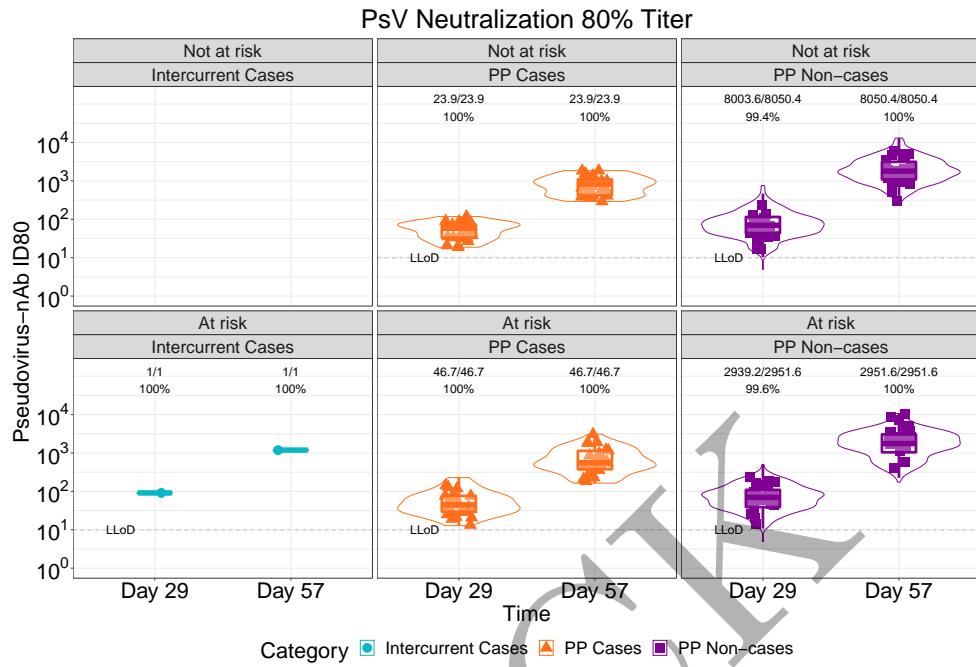


Figure 2.102: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by risk condition (version 1)

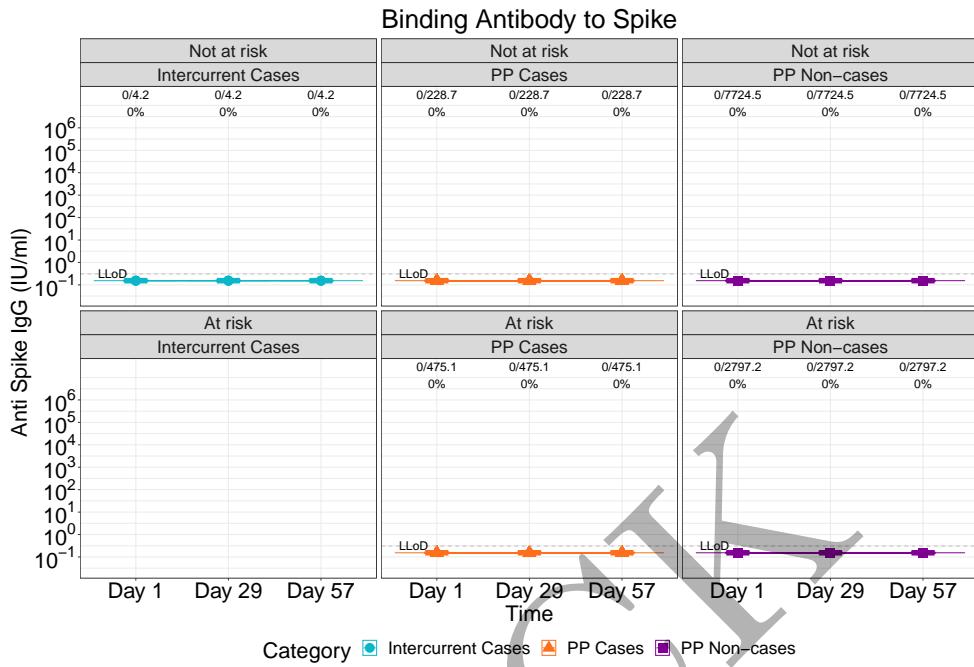


Figure 2.103: lineplots of Binding Antibody to Spike: baseline negative placebo arm by risk condition (version 2)

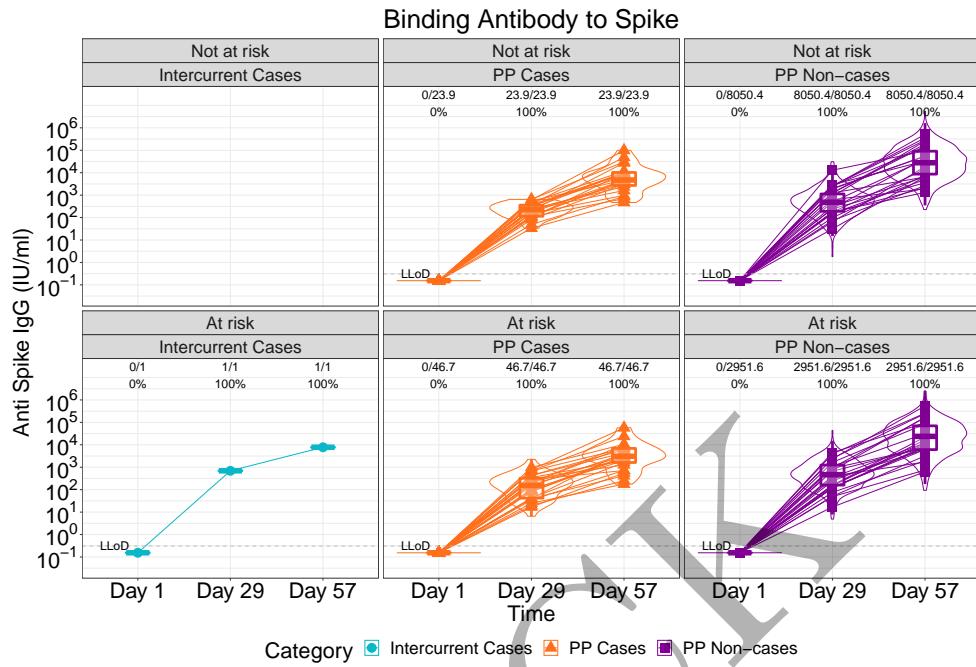


Figure 2.104: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by risk condition (version 2)

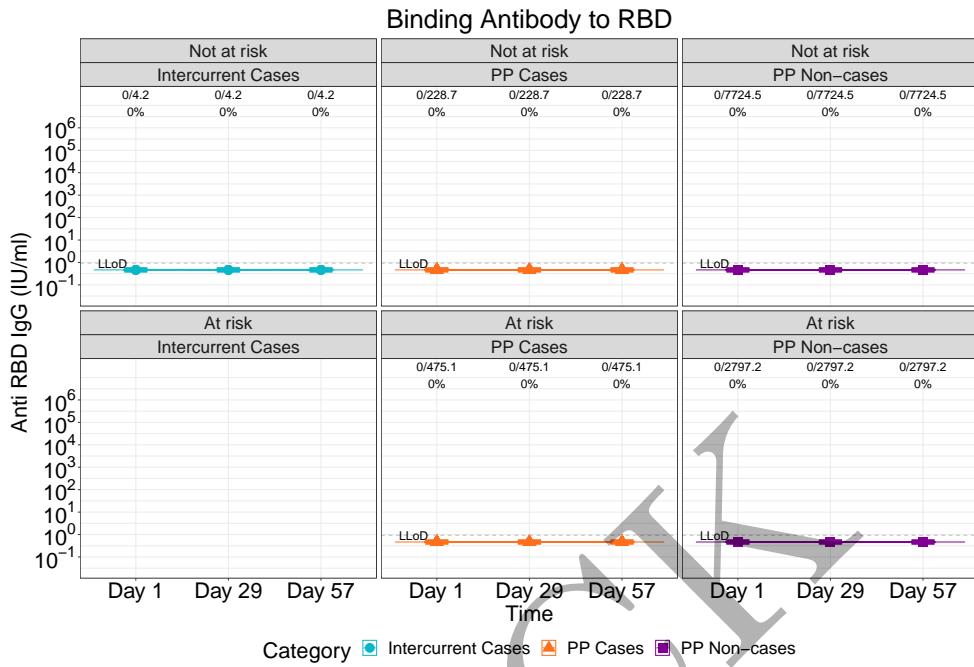


Figure 2.105: lineplots of Binding Antibody to RBD: baseline negative placebo arm by risk condition (version 2)

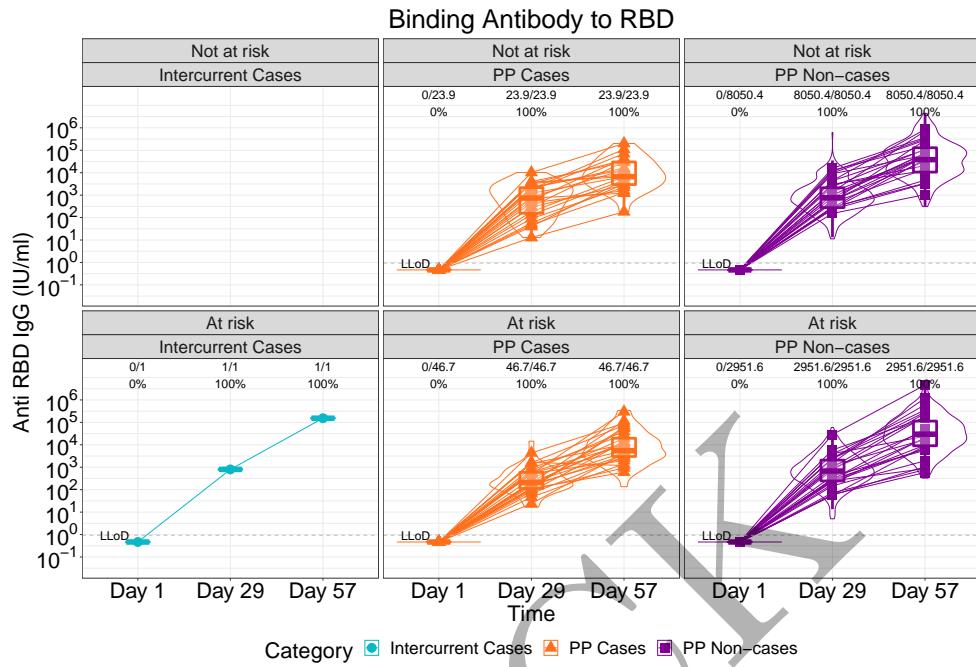


Figure 2.106: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by risk condition (version 2)

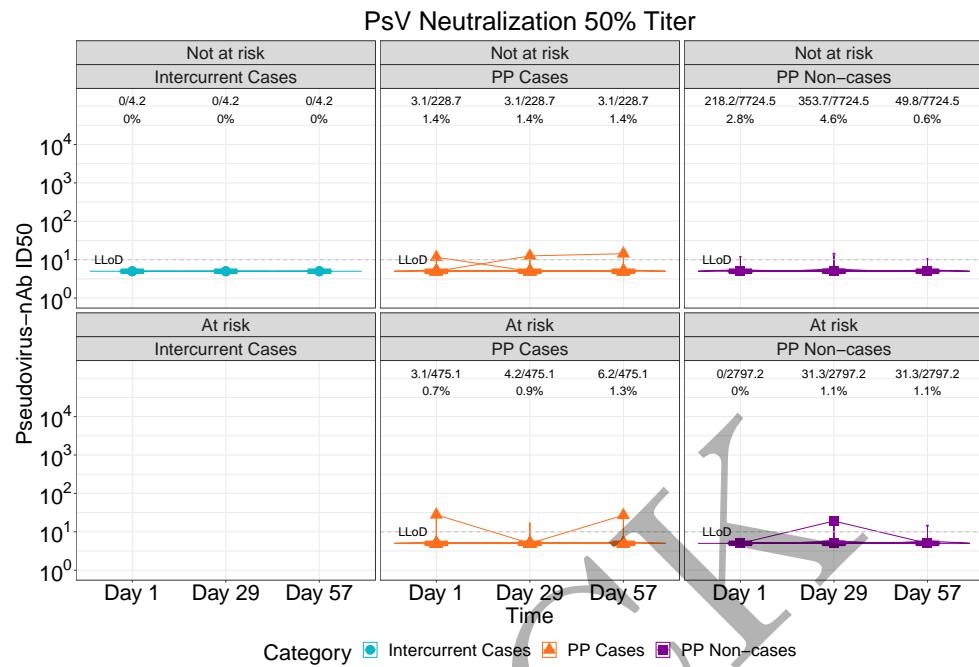


Figure 2.107: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by risk condition (version 2)

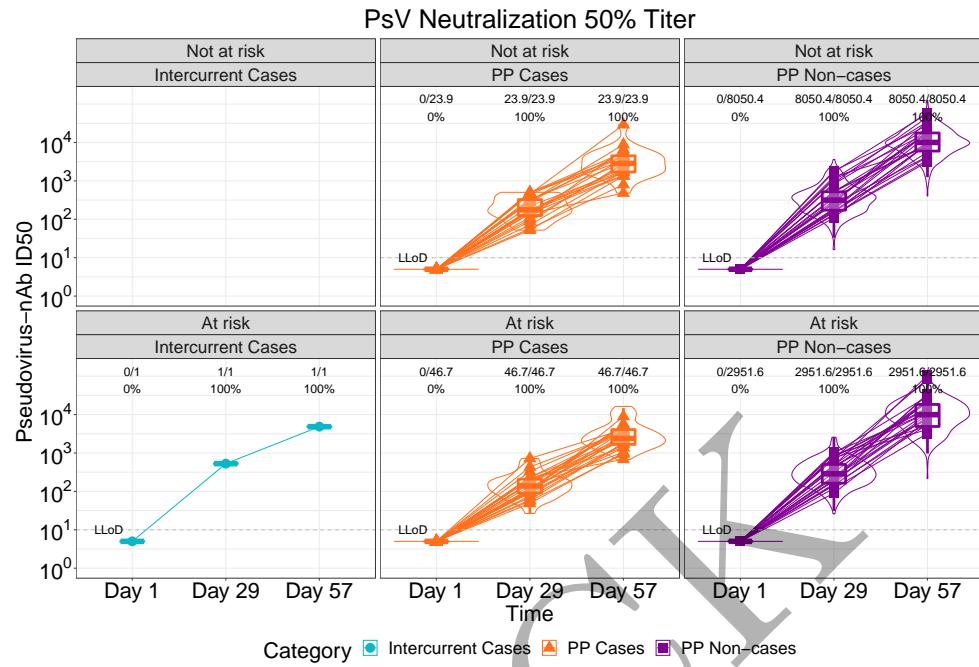


Figure 2.108: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by risk condition (version 2)

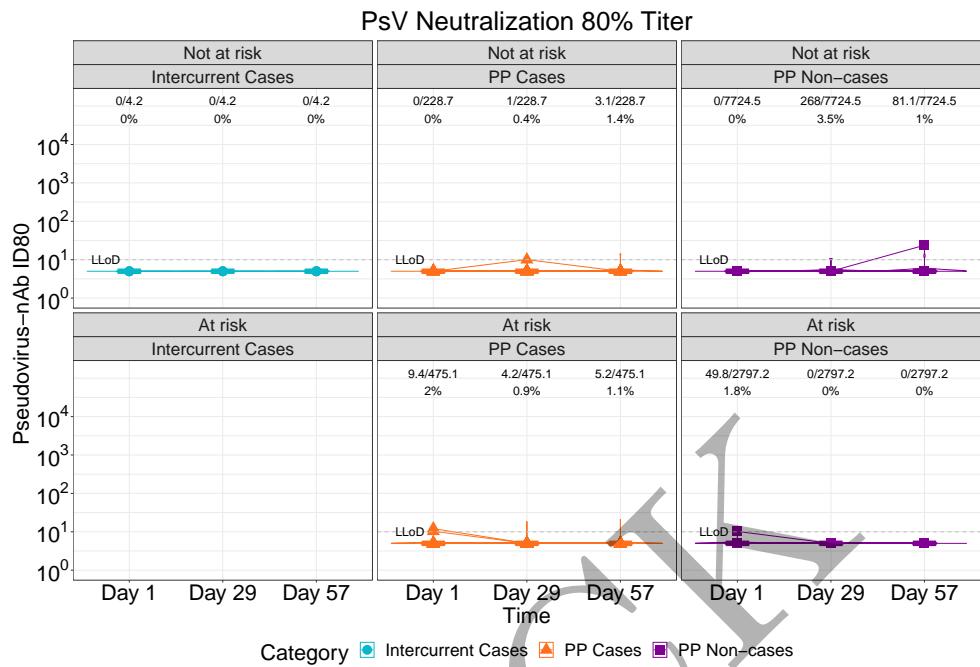


Figure 2.109: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by risk condition (version 2)

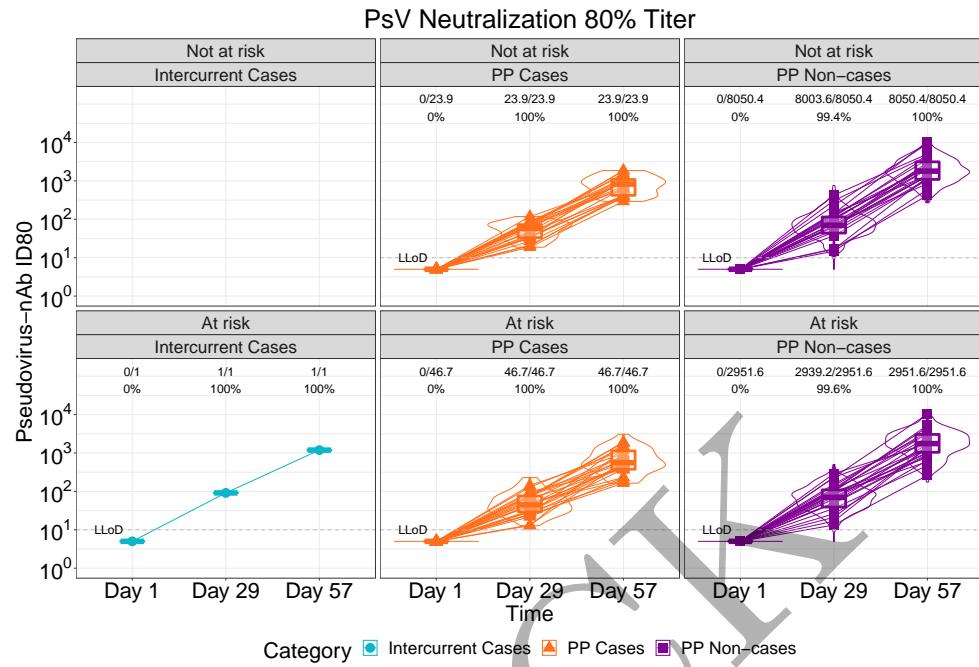


Figure 2.110: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by risk condition (version 2)

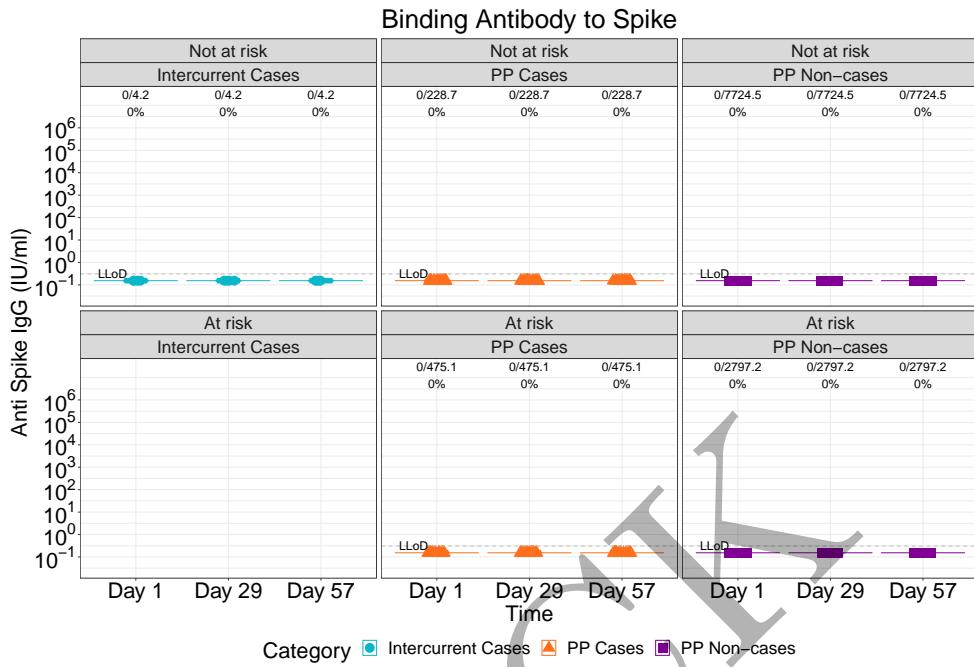


Figure 2.111: violinplots of Binding Antibody to Spike: baseline negative placebo arm by risk condition (version 2)

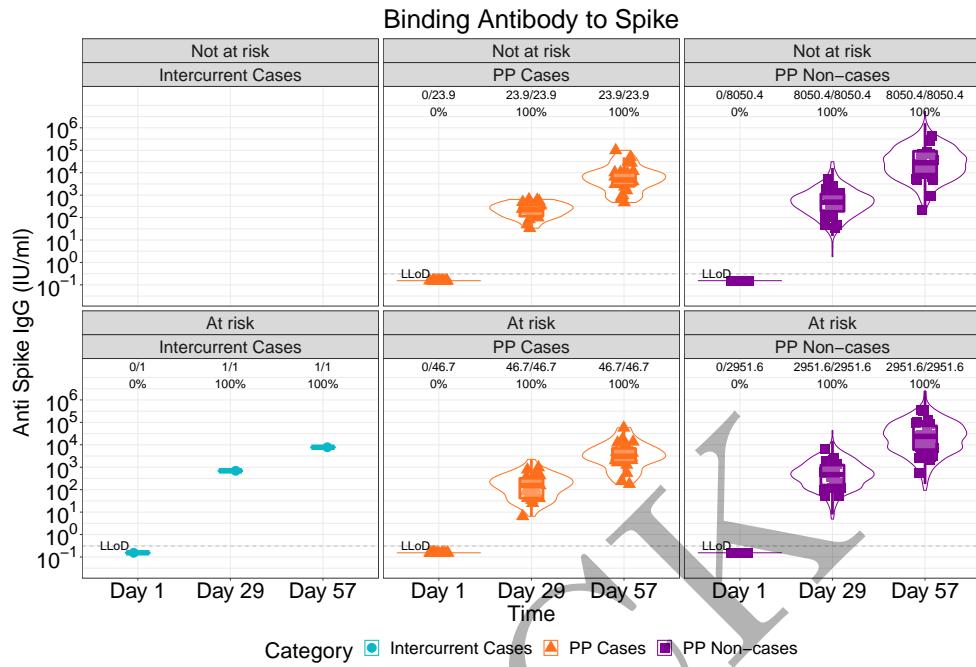


Figure 2.112: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by risk condition (version 2)

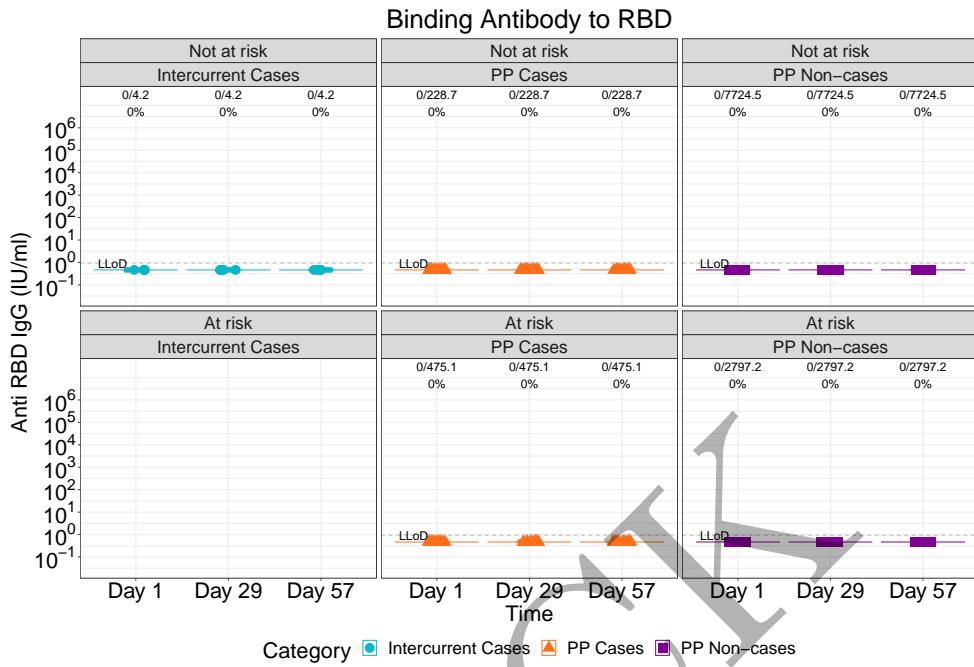


Figure 2.113: violinplots of Binding Antibody to RBD: baseline negative placebo arm by risk condition (version 2)

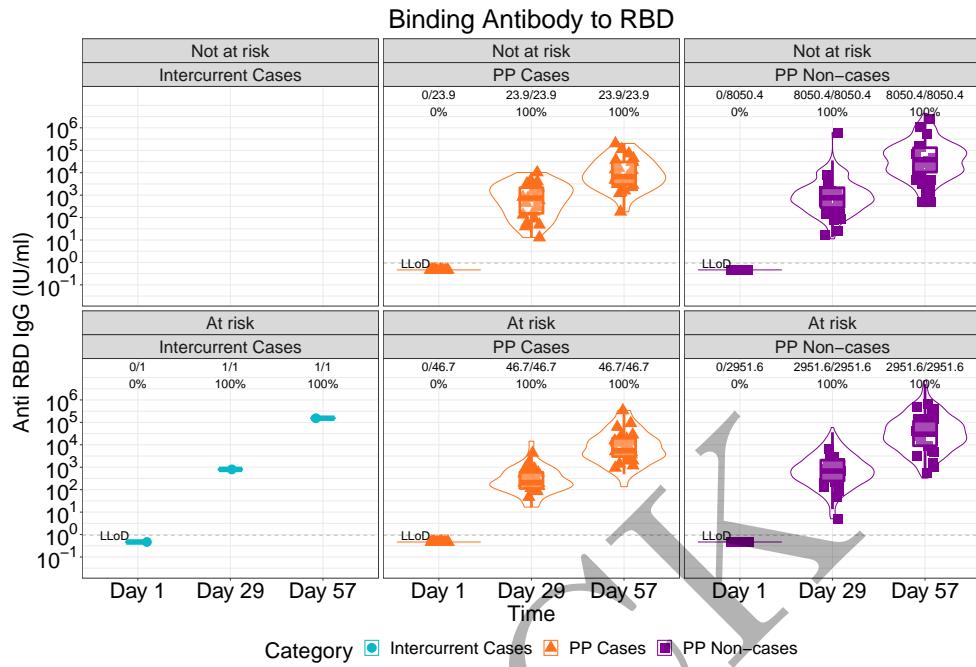


Figure 2.114: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by risk condition (version 2)

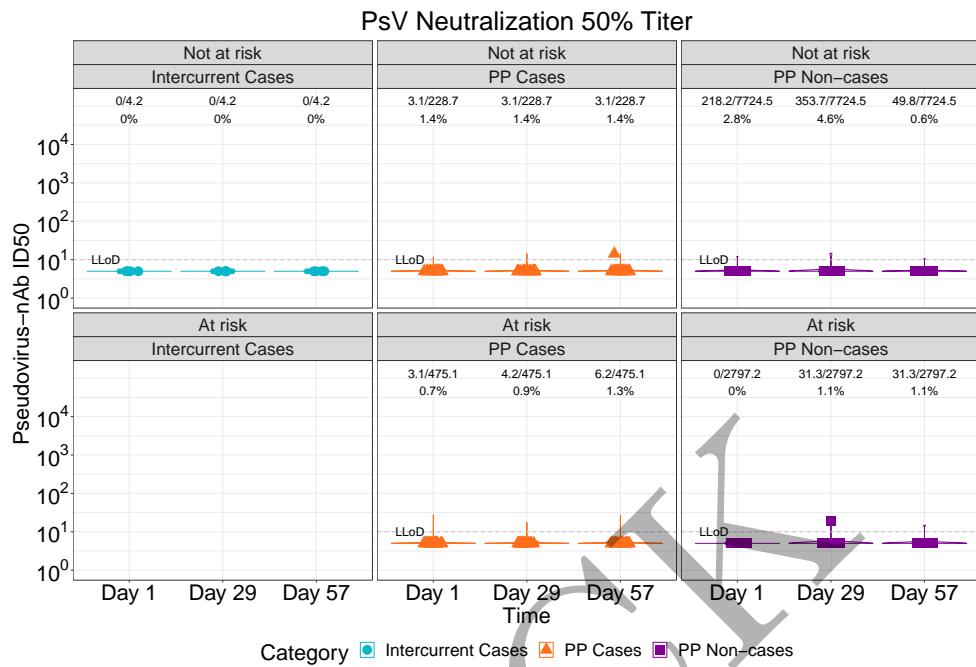


Figure 2.115: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by risk condition (version 2)

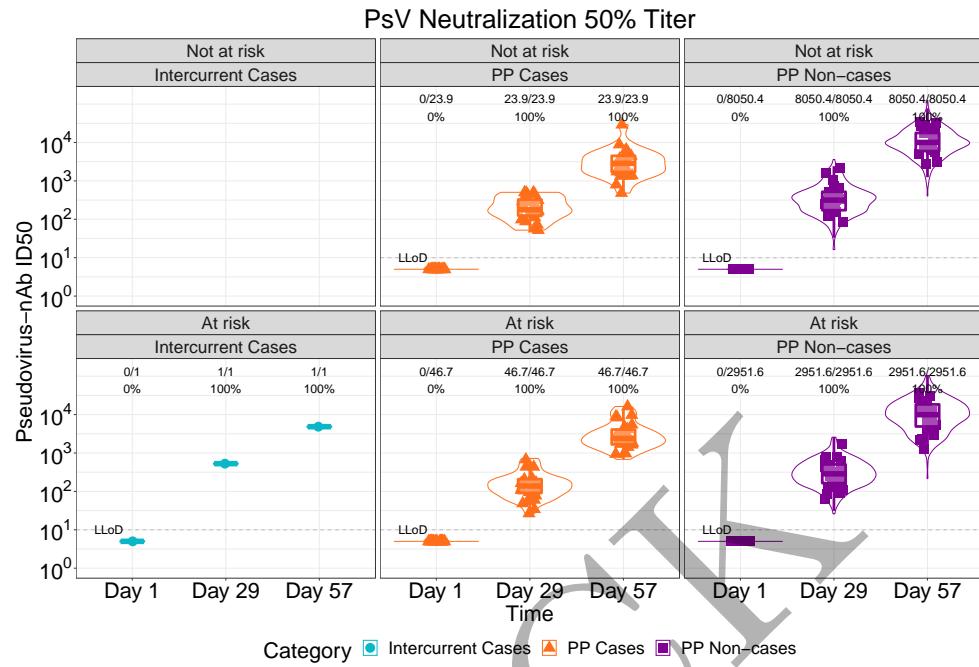


Figure 2.116: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by risk condition (version 2)

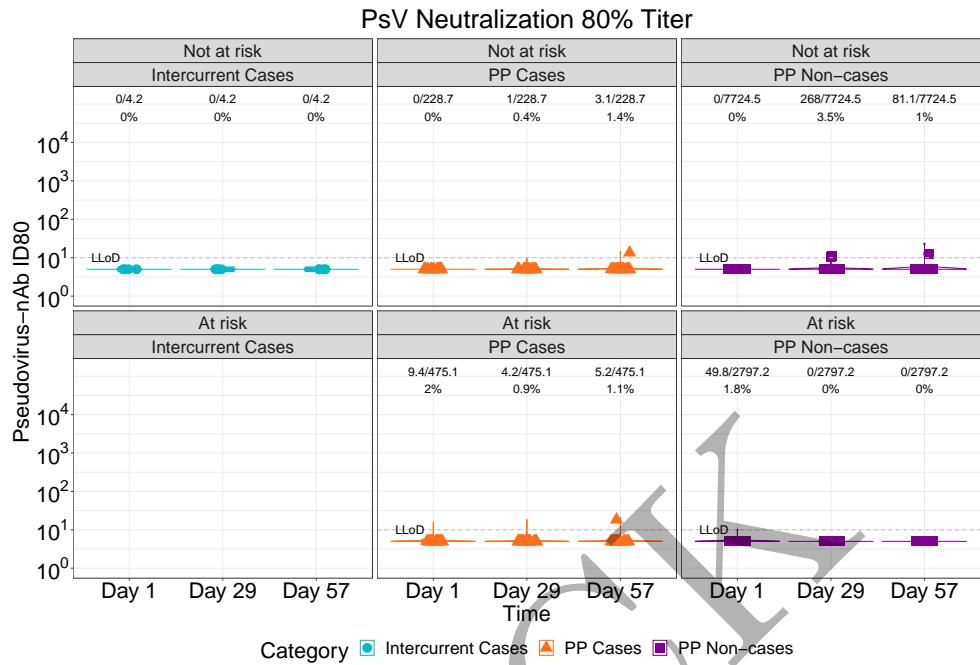


Figure 2.117: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by risk condition (version 2)

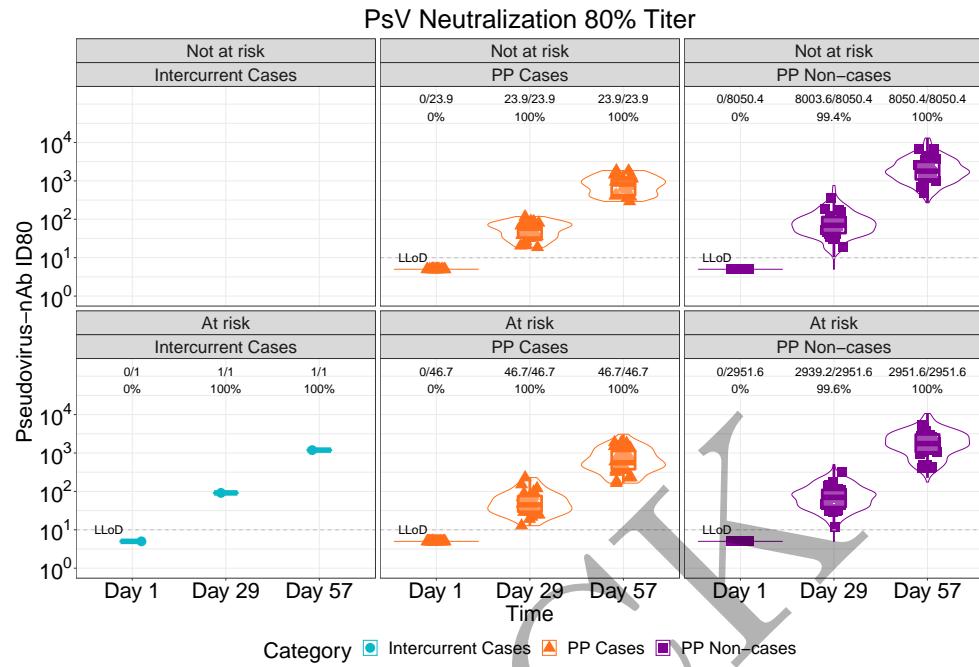


Figure 2.118: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by risk condition (version 2)

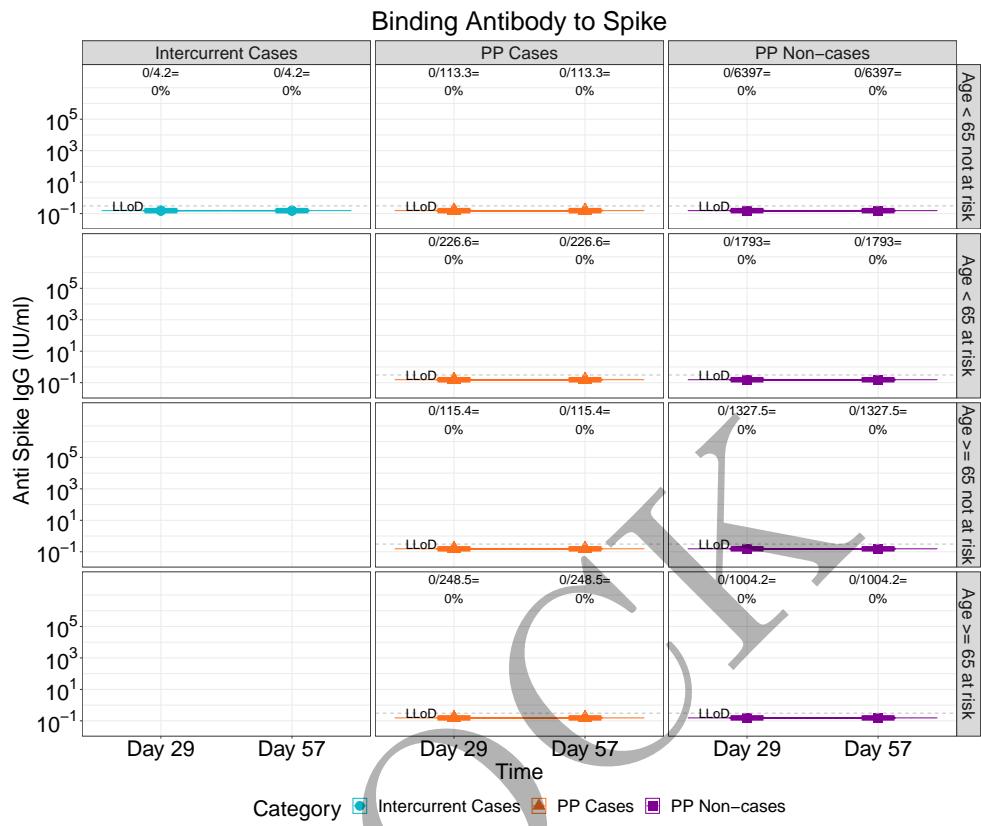


Figure 2.119: lineplots of Binding Antibody to Spike: baseline negative placebo arm by age and risk condition (version 1)

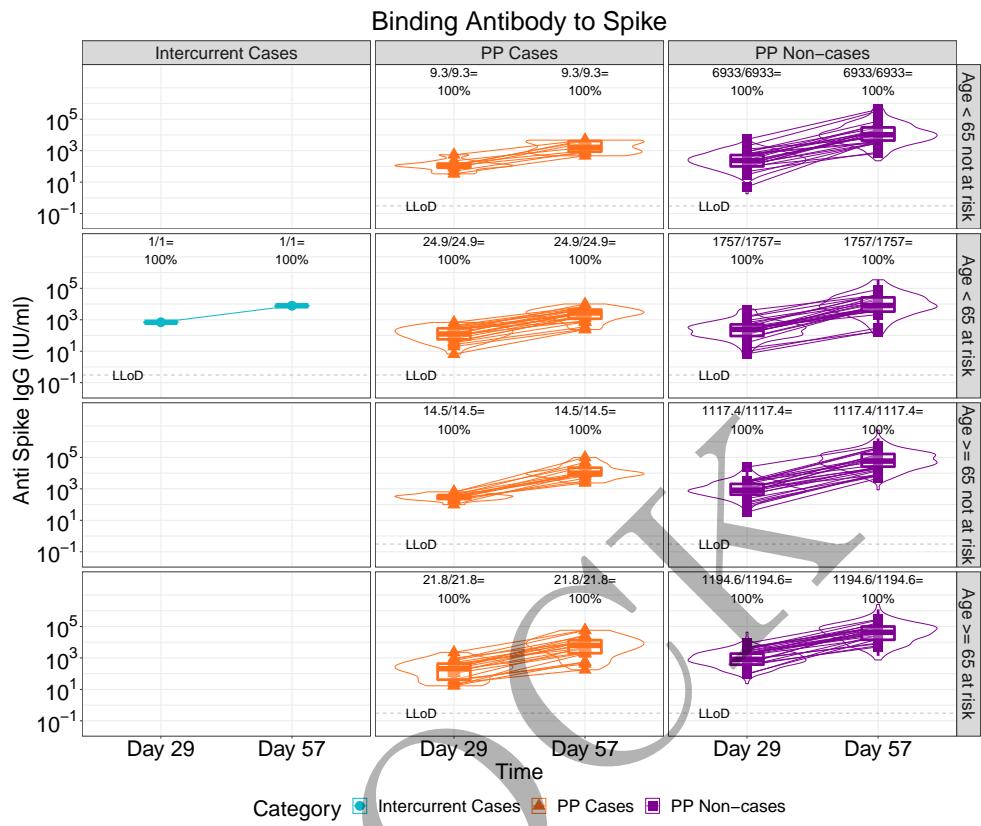


Figure 2.120: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by age and risk condition (version 1)

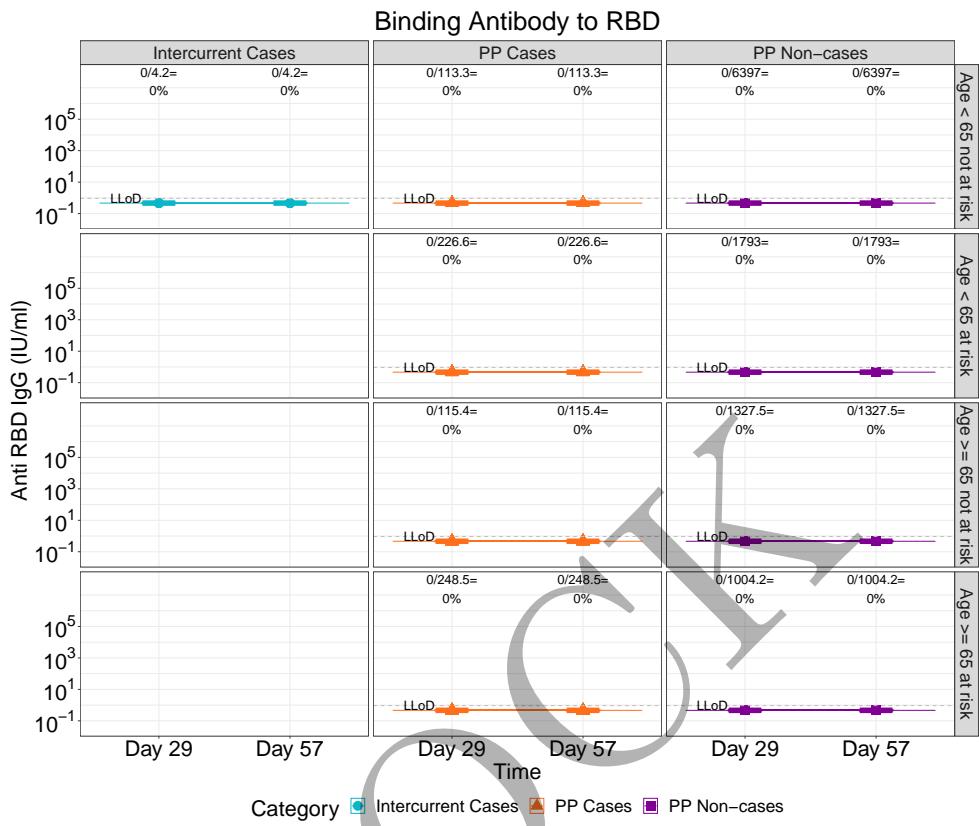


Figure 2.121: lineplots of Binding Antibody to RBD: baseline negative placebo arm by age and risk condition (version 1)

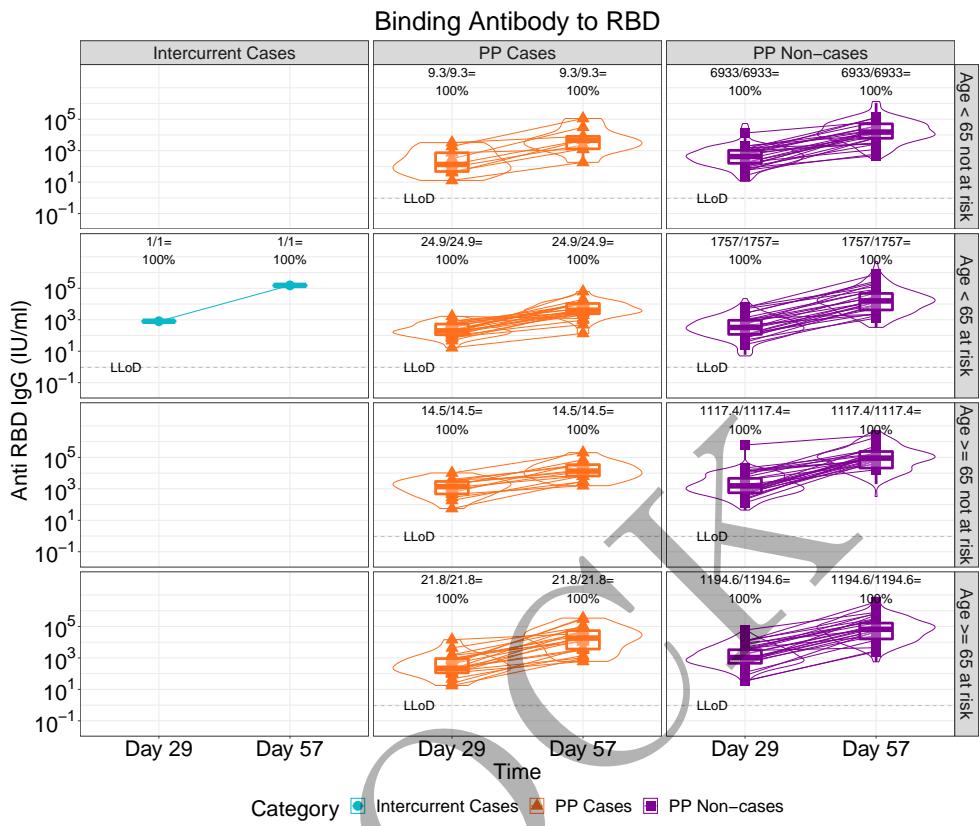


Figure 2.122: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by age and risk condition (version 1)

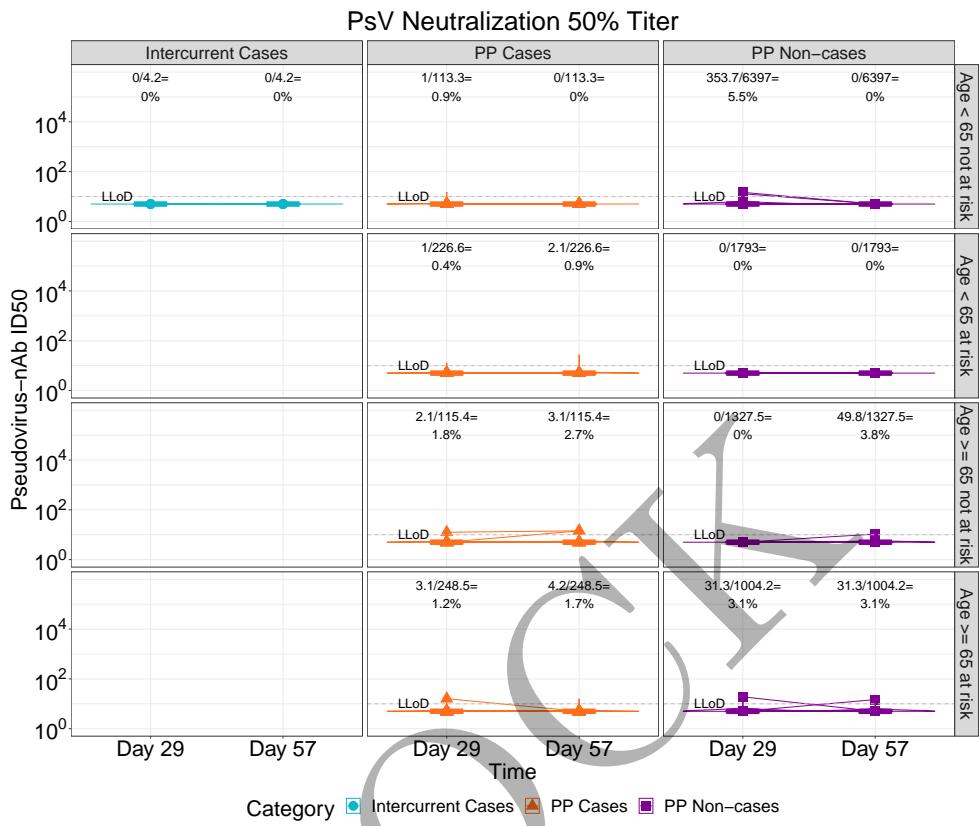


Figure 2.123: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age and risk condition (version 1)

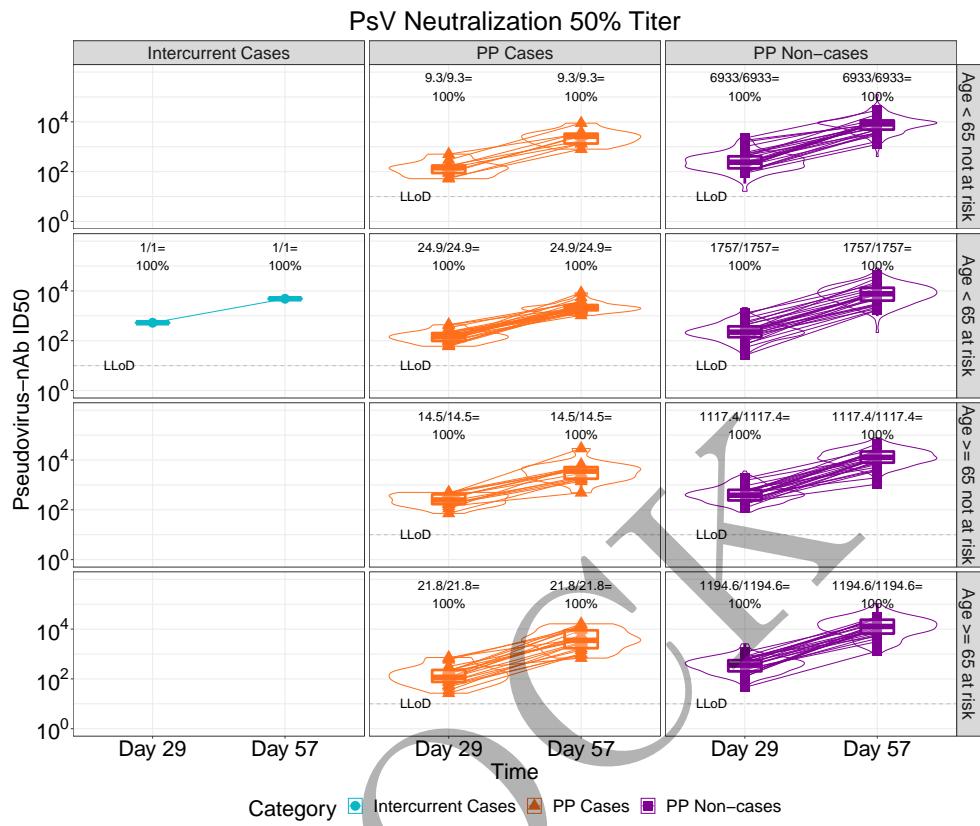


Figure 2.124: lineplots of Pseudovirus Neutralization ID₅₀: baseline negative vaccine arm by age and risk condition (version 1)

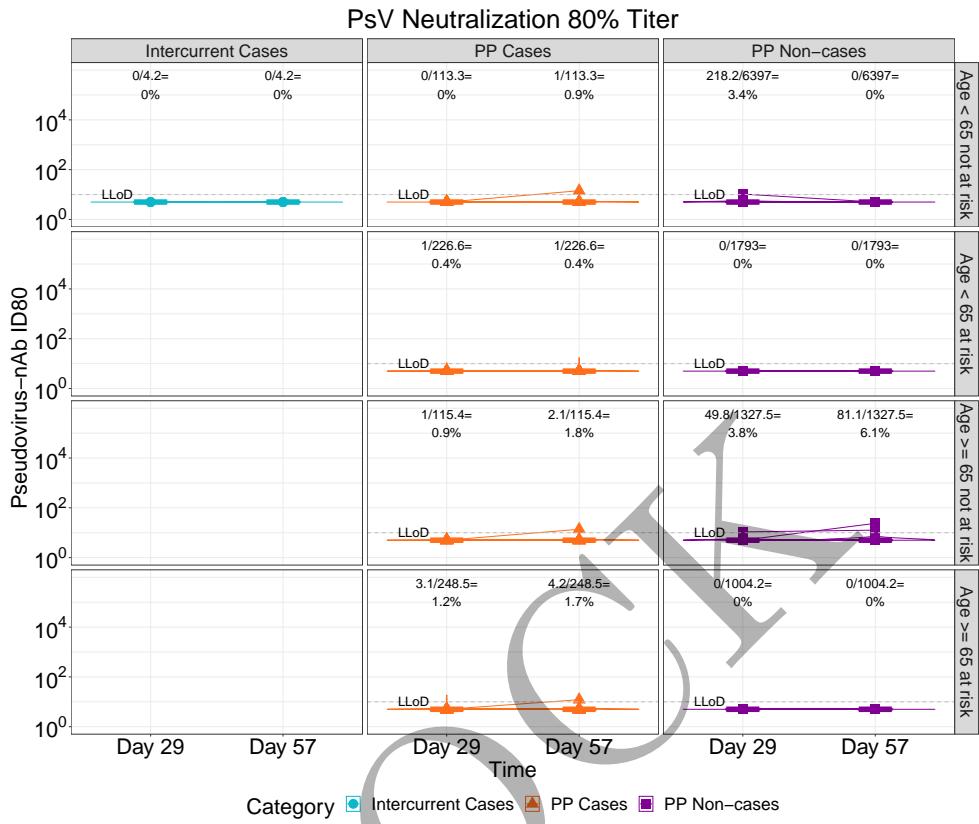


Figure 2.125: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age and risk condition (version 1)

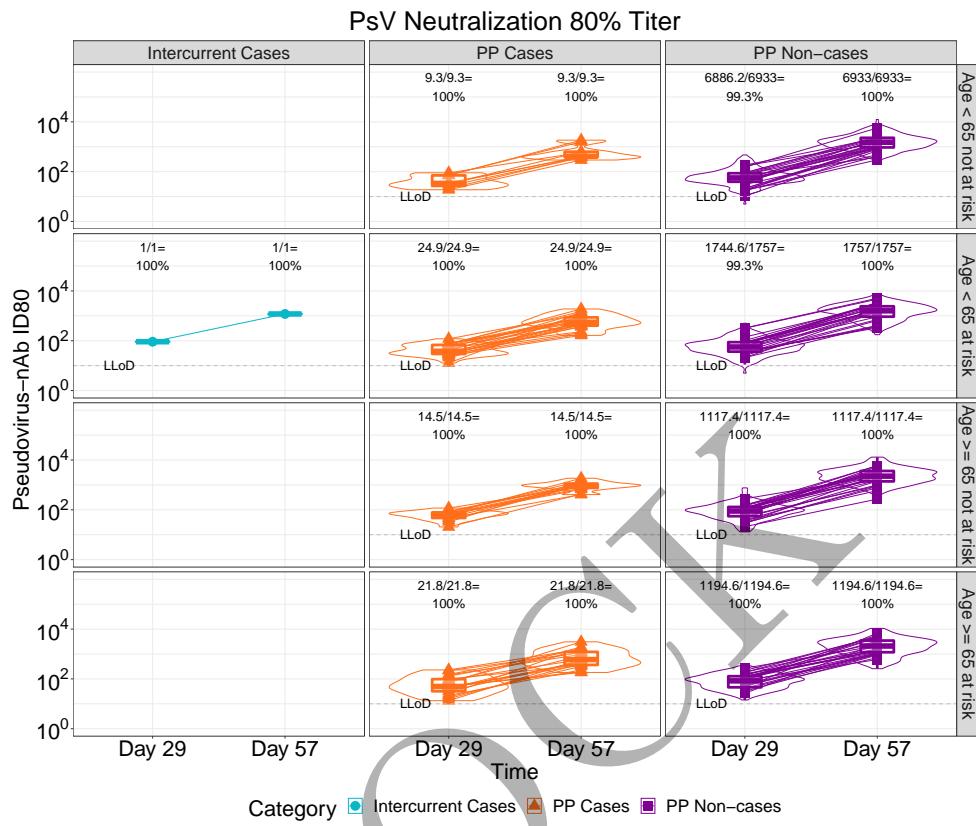


Figure 2.126: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age and risk condition (version 1)

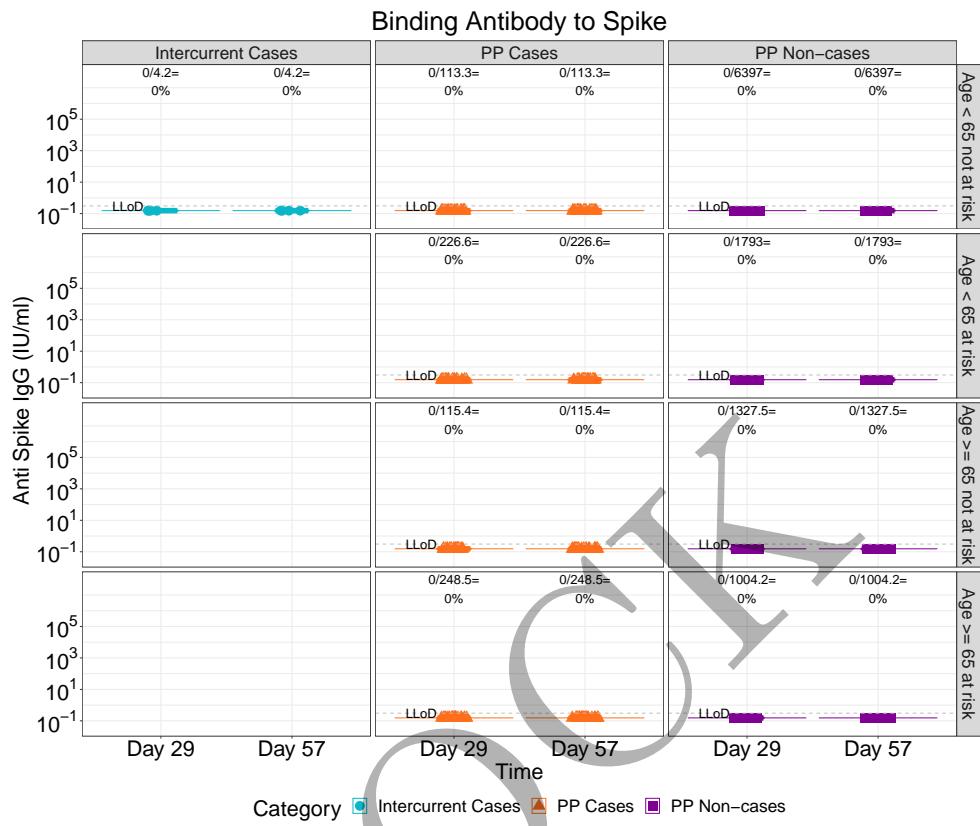


Figure 2.127: violinplots of Binding Antibody to Spike: baseline negative placebo arm by age and risk condition (version 1)

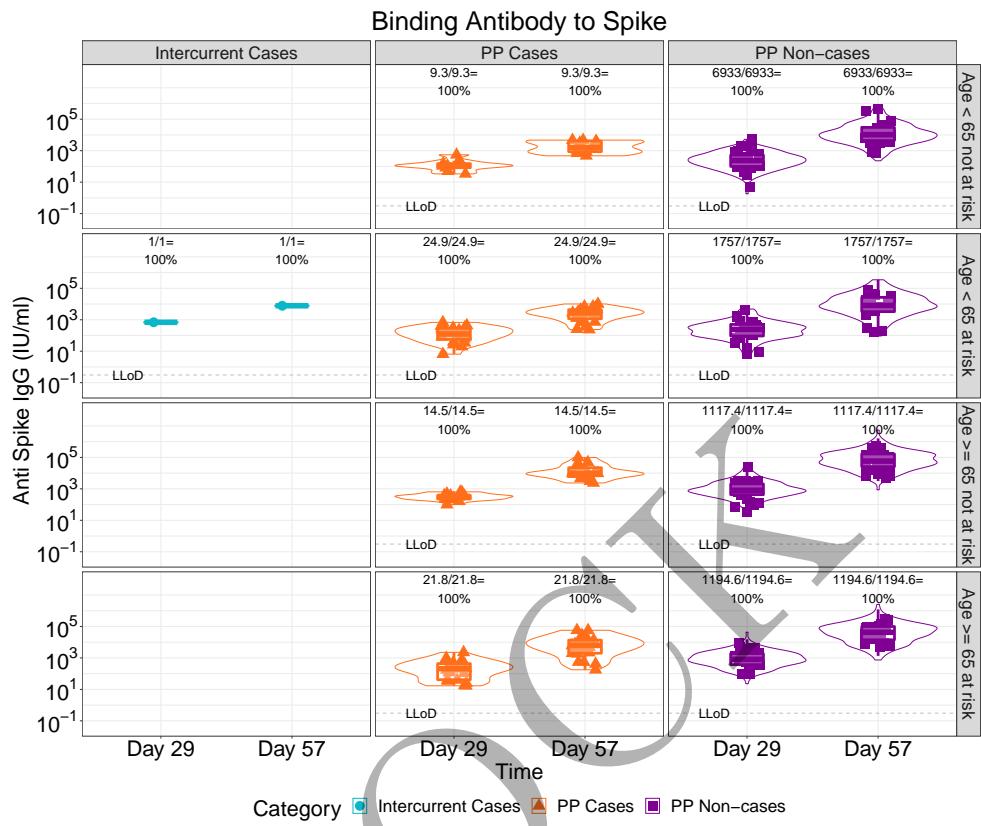


Figure 2.128: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by age and risk condition (version 1)

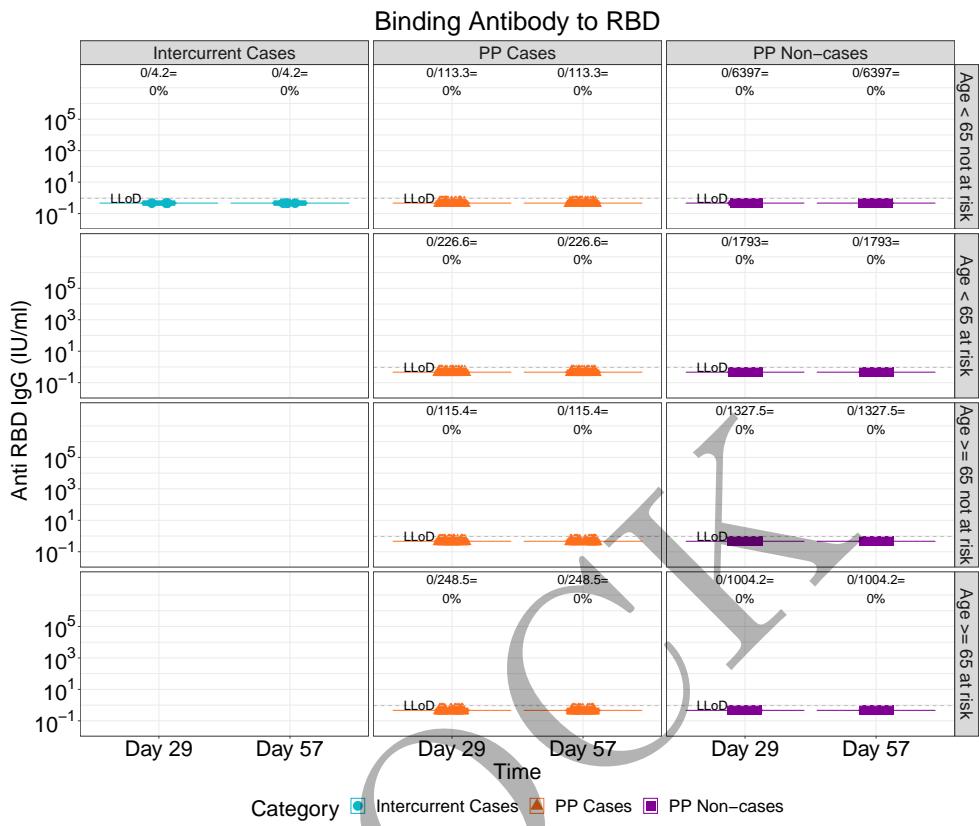


Figure 2.129: violinplots of Binding Antibody to RBD: baseline negative placebo arm by age and risk condition (version 1)

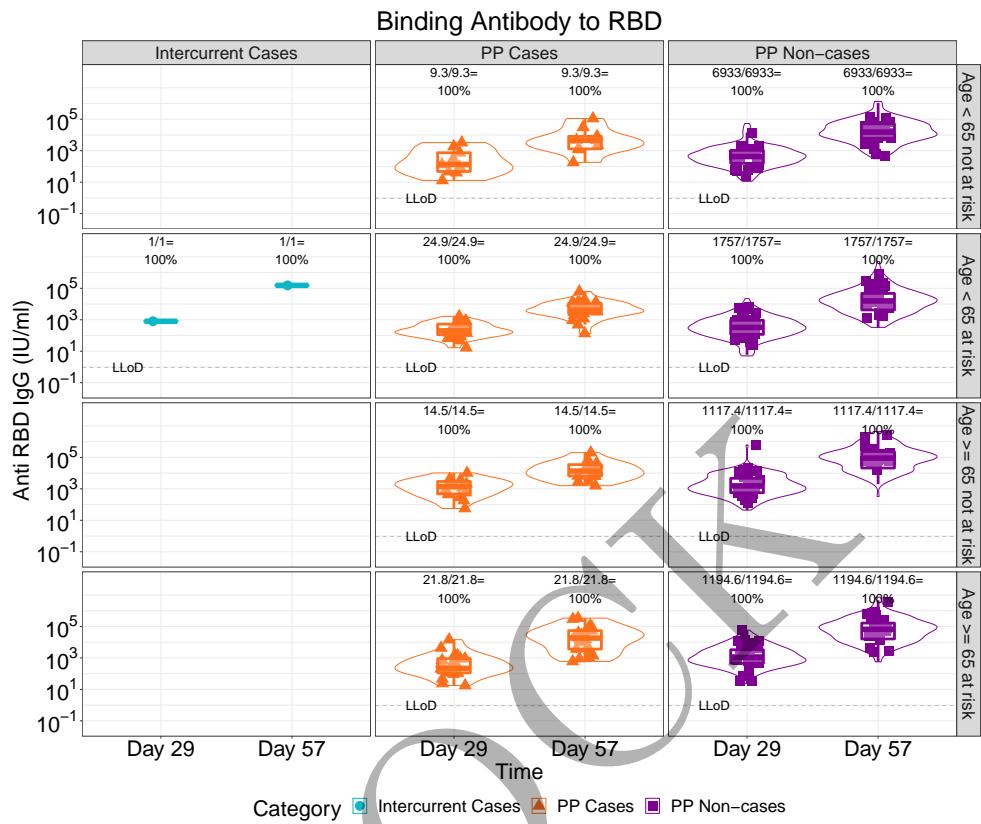


Figure 2.130: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by age and risk condition (version 1)

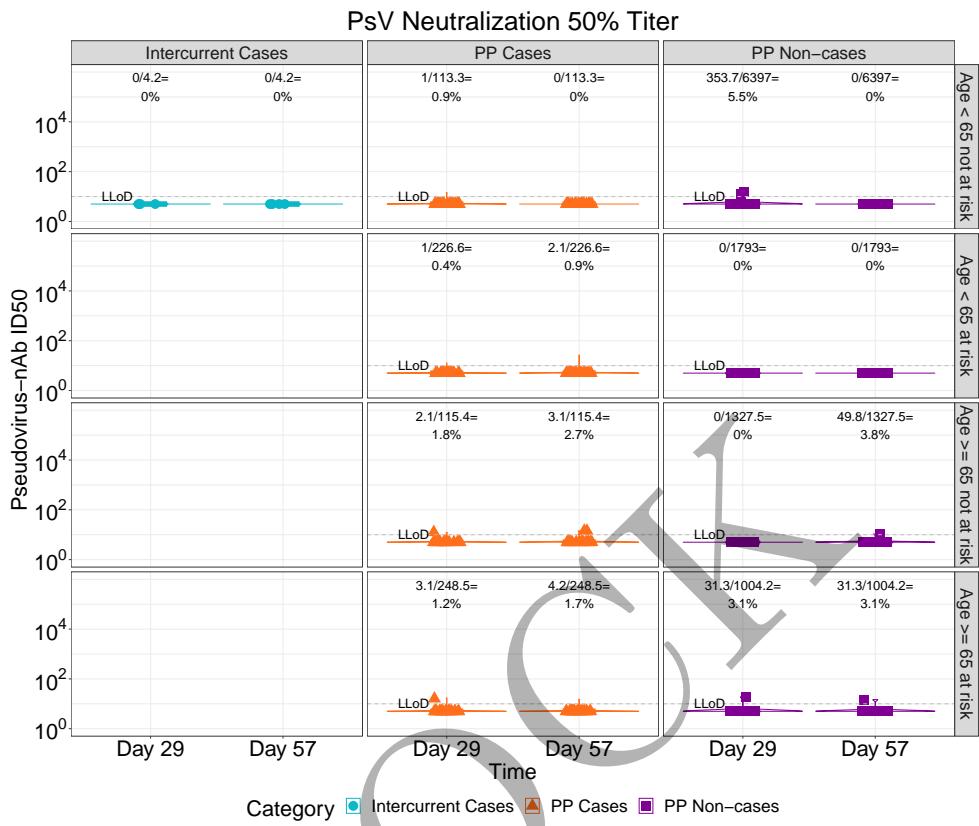


Figure 2.131: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age and risk condition (version 1)

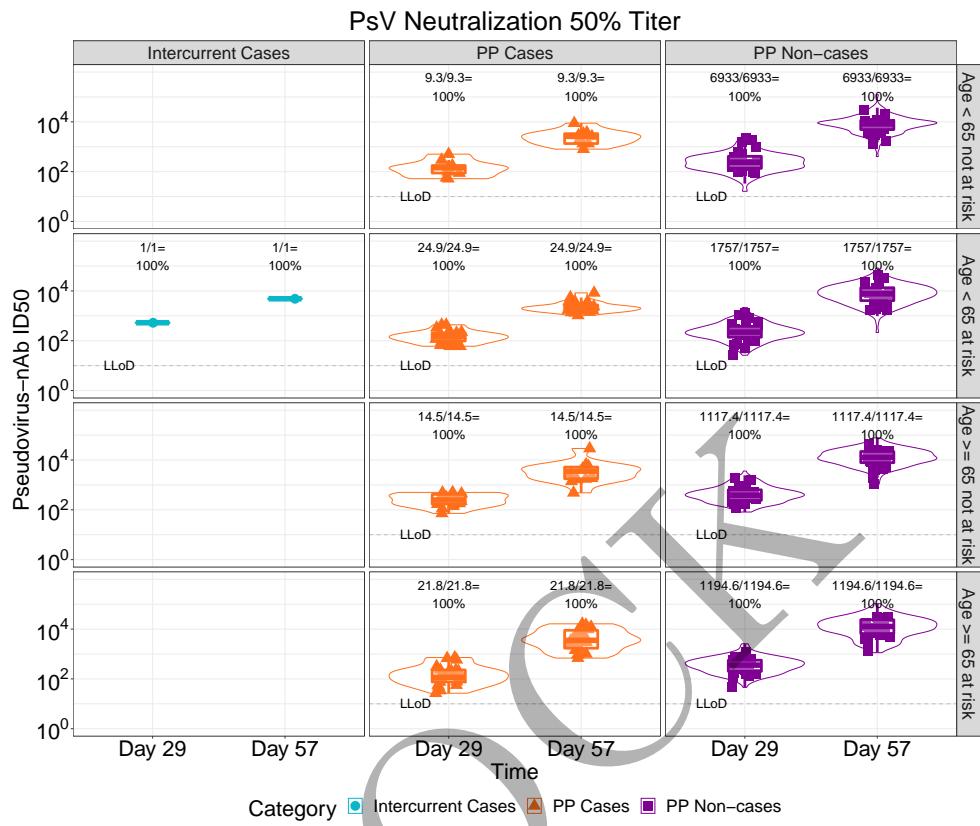


Figure 2.132: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age and risk condition (version 1)

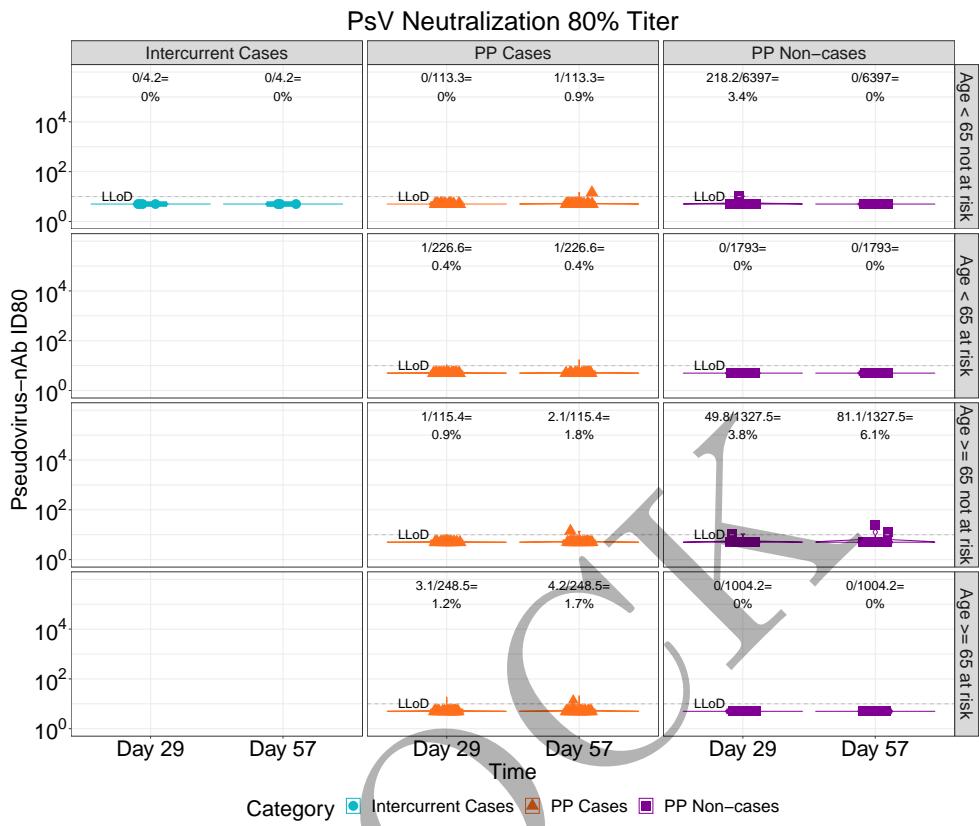


Figure 2.133: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age and risk condition (version 1)

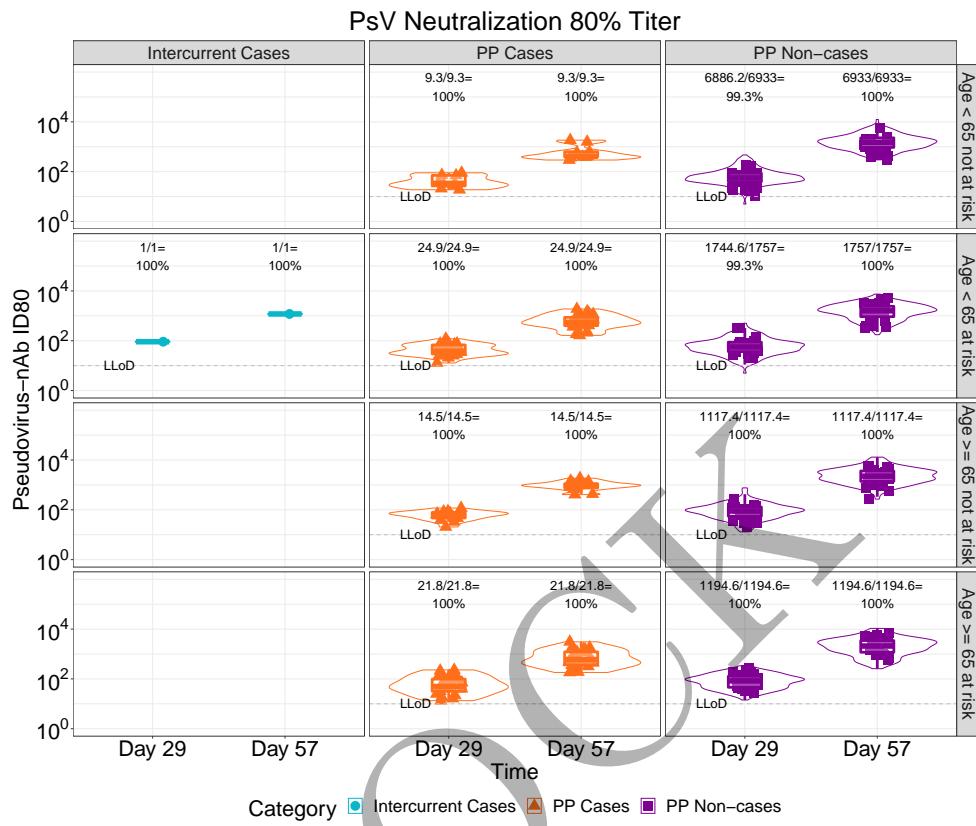


Figure 2.134: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age and risk condition (version 1)

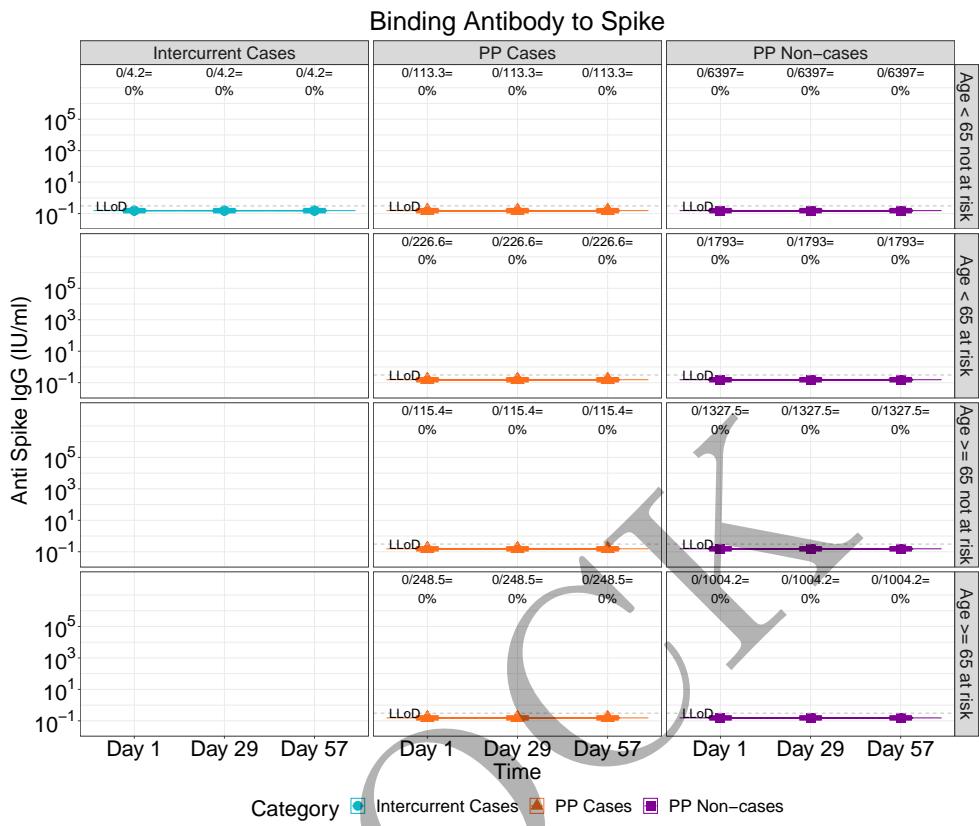


Figure 2.135: lineplots of Binding Antibody to Spike: baseline negative placebo arm by age and risk condition (version 2)

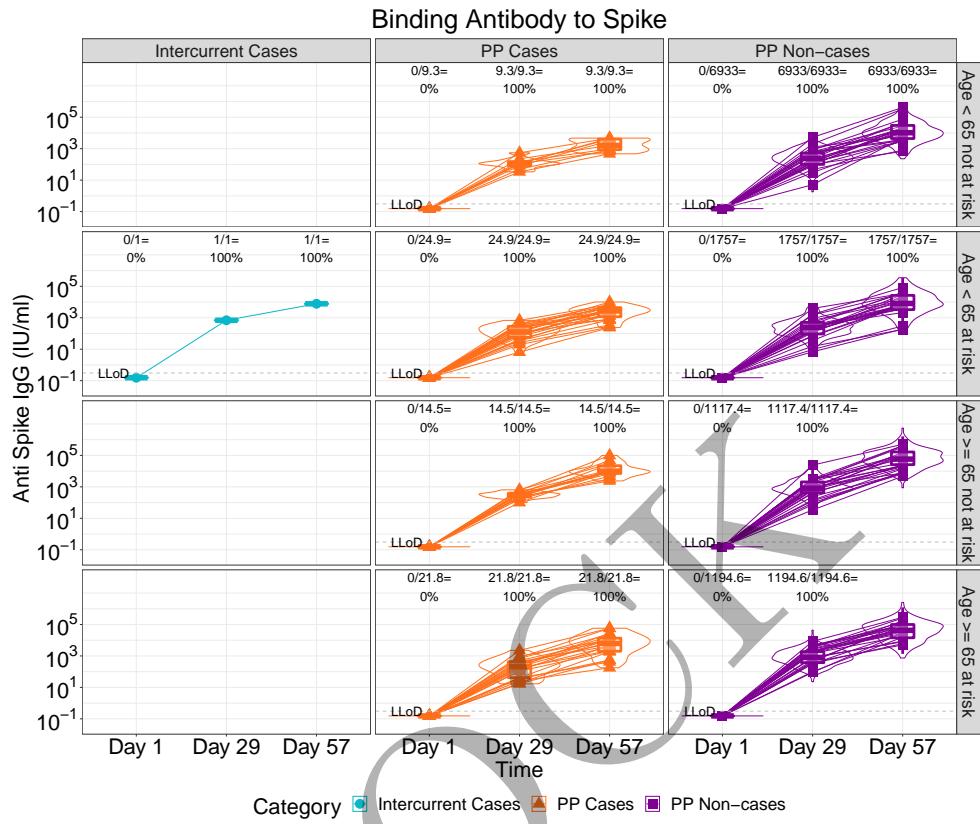


Figure 2.136: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by age and risk condition (version 2)

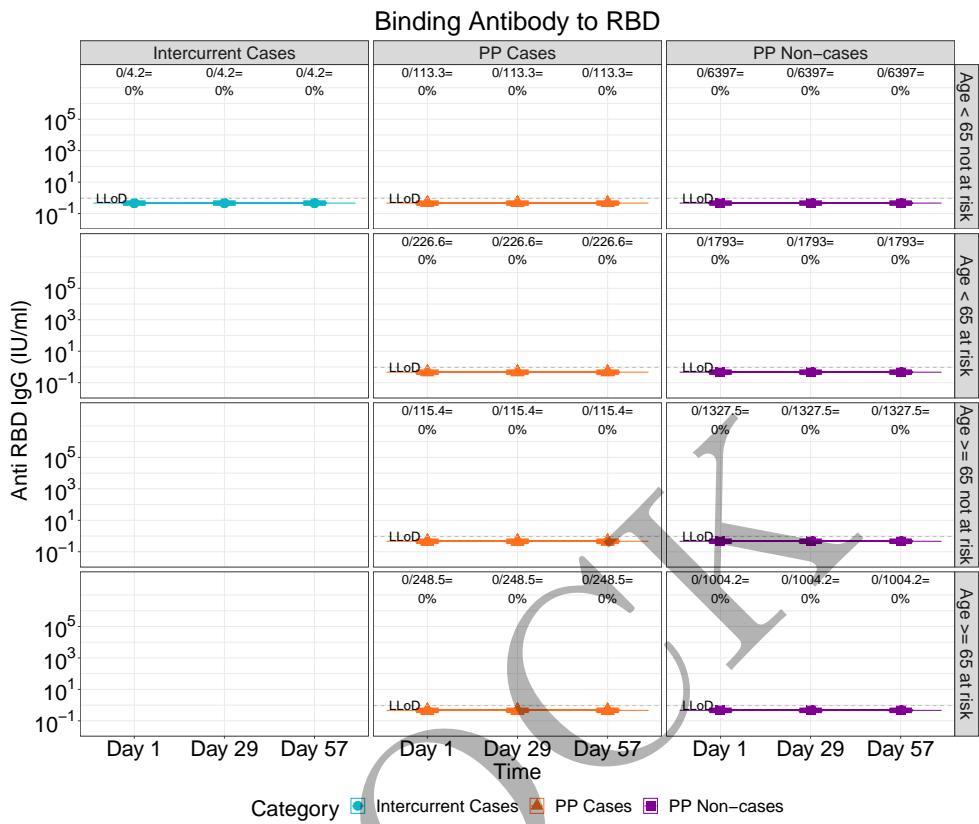


Figure 2.137: lineplots of Binding Antibody to RBD: baseline negative placebo arm by age and risk condition (version 2)

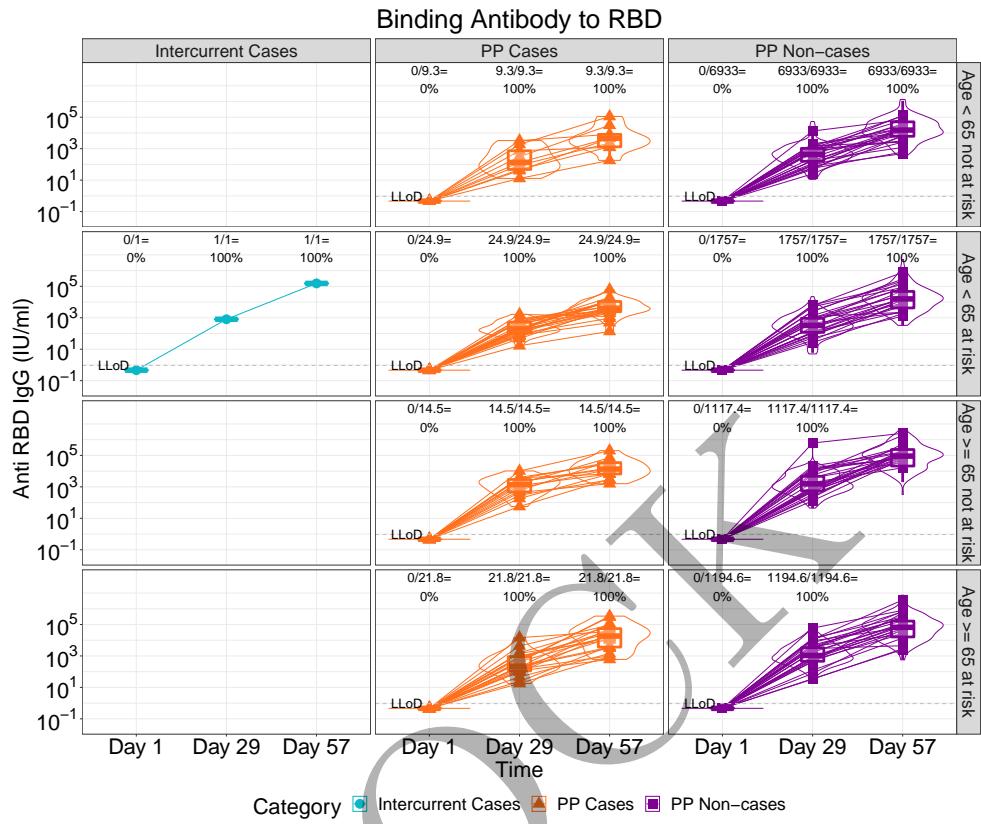


Figure 2.138: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by age and risk condition (version 2)

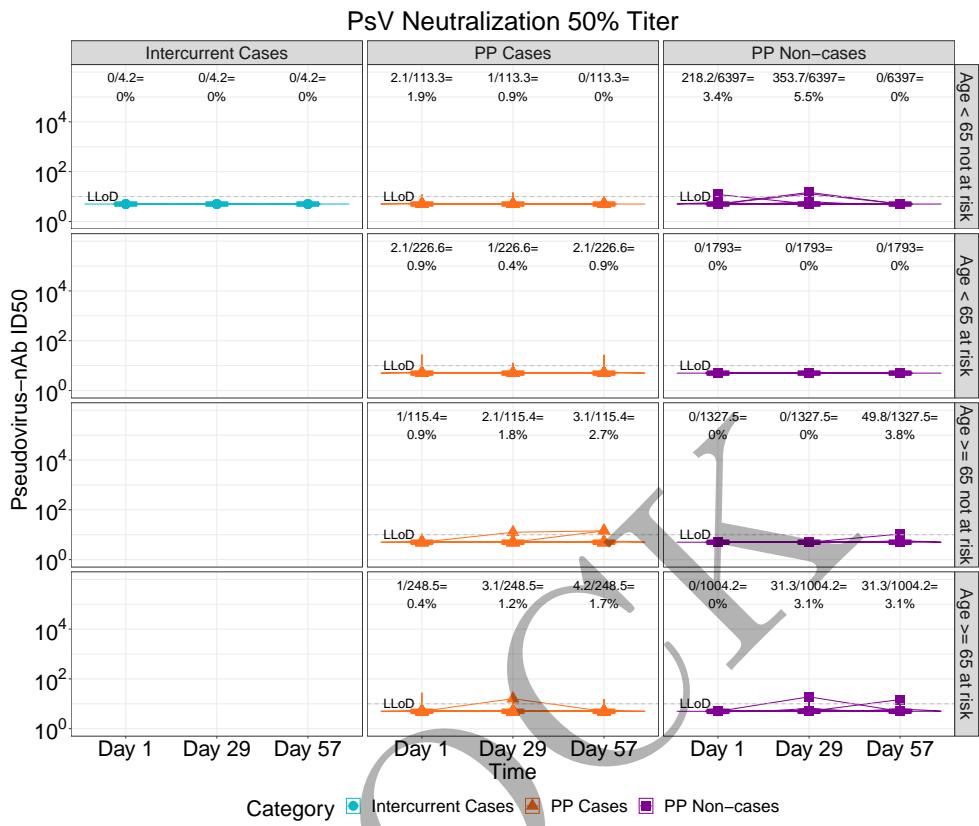


Figure 2.139: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age and risk condition (version 2)

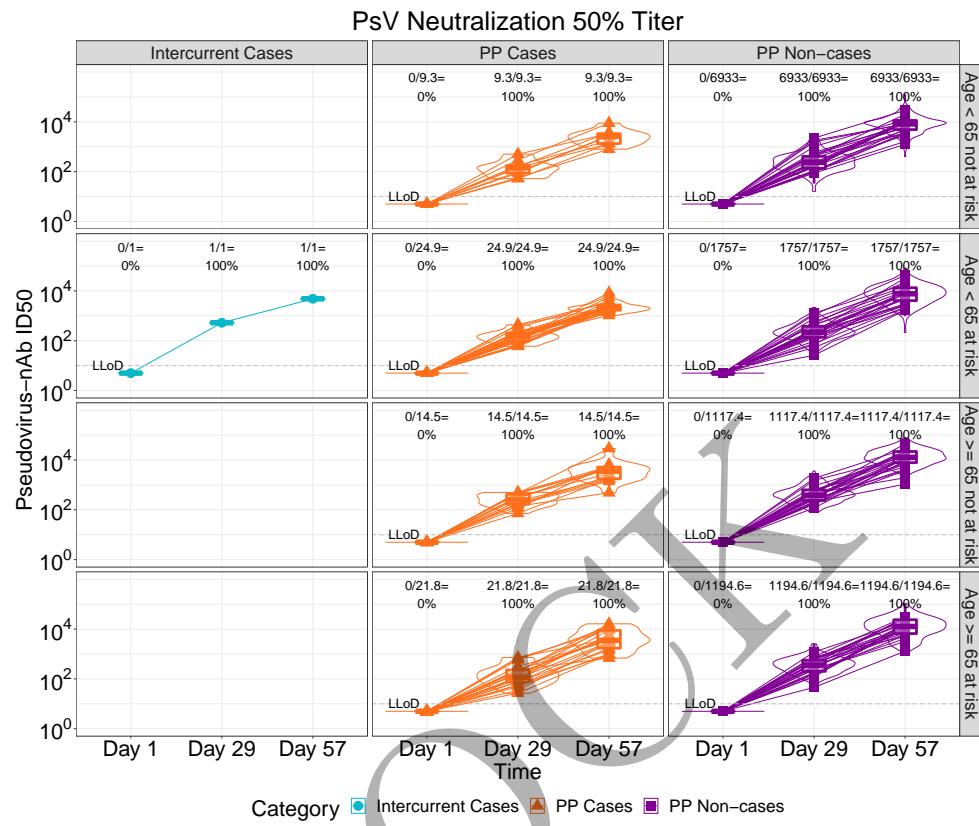


Figure 2.140: lineplots of Pseudovirus Neutralization ID₅₀: baseline negative vaccine arm by age and risk condition (version 2)

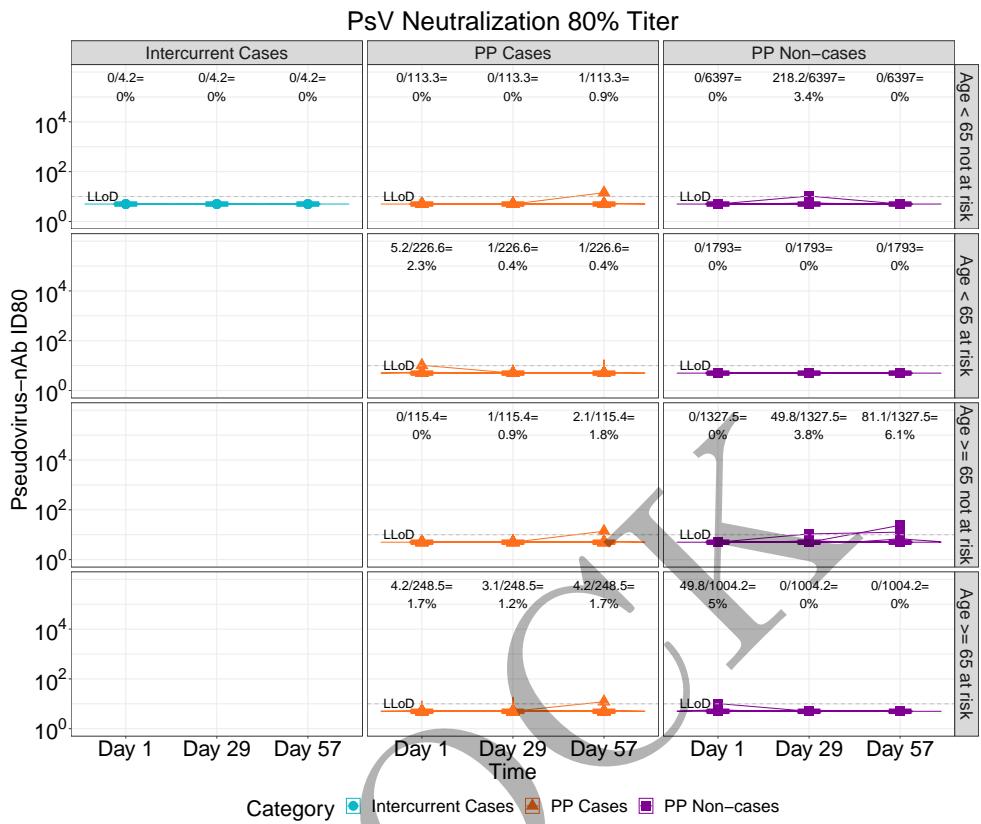


Figure 2.141: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age and risk condition (version 2)

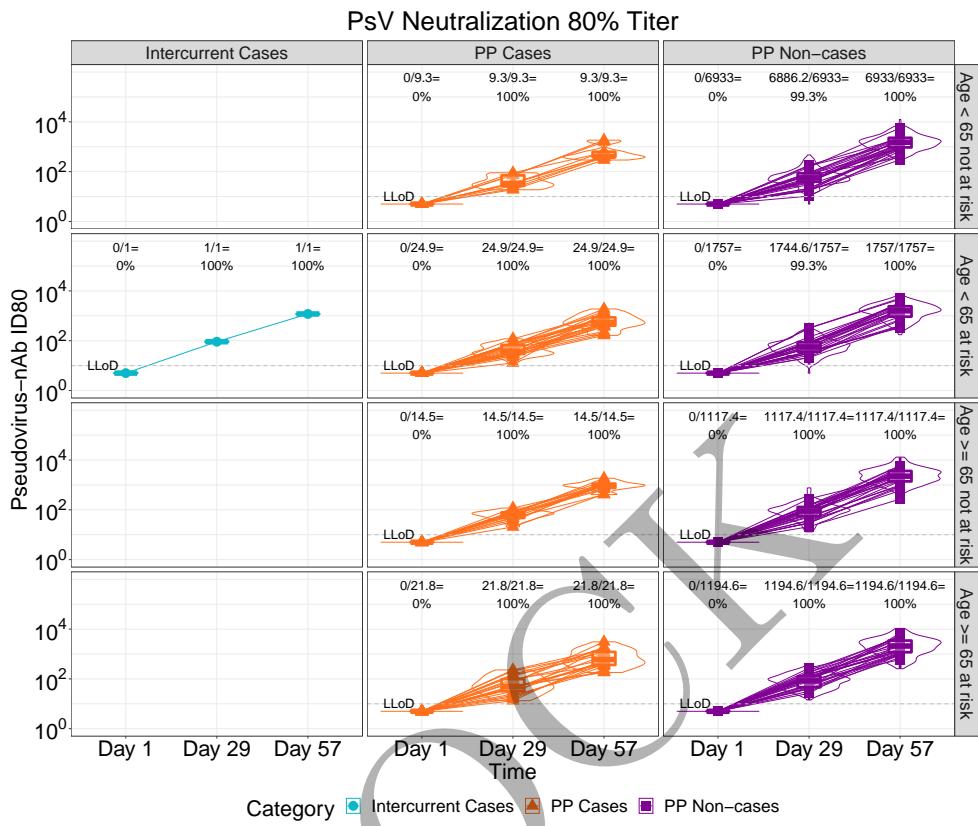


Figure 2.142: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age and risk condition (version 2)

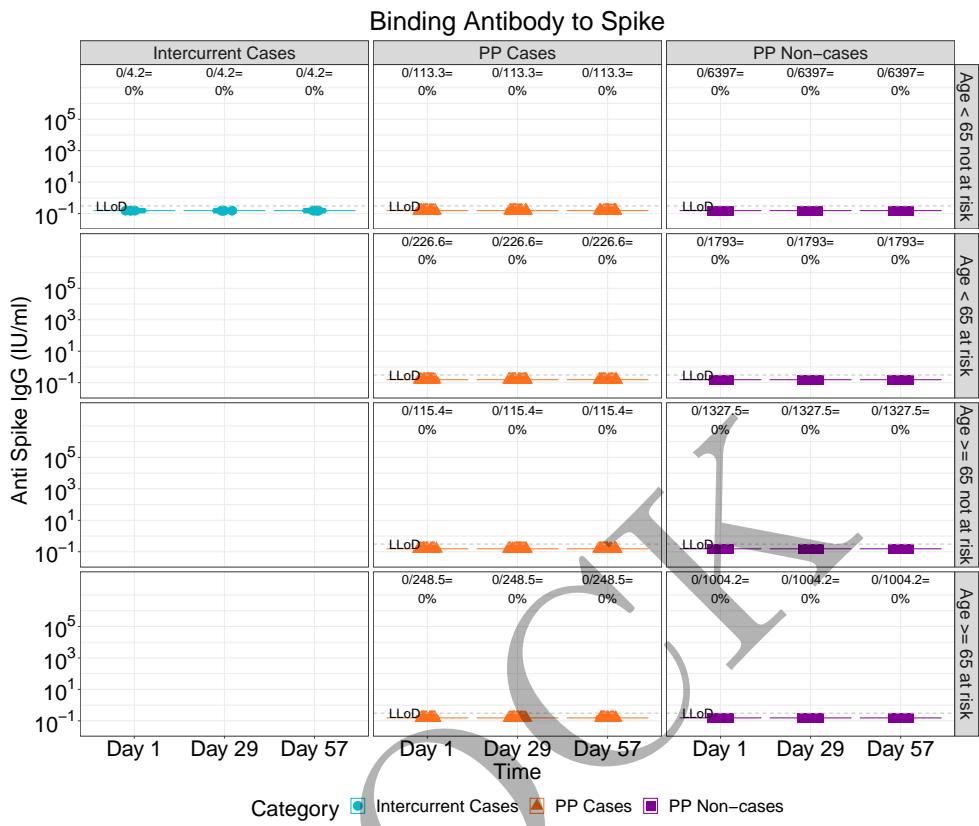


Figure 2.143: violinplots of Binding Antibody to Spike: baseline negative placebo arm by age and risk condition (version 2)

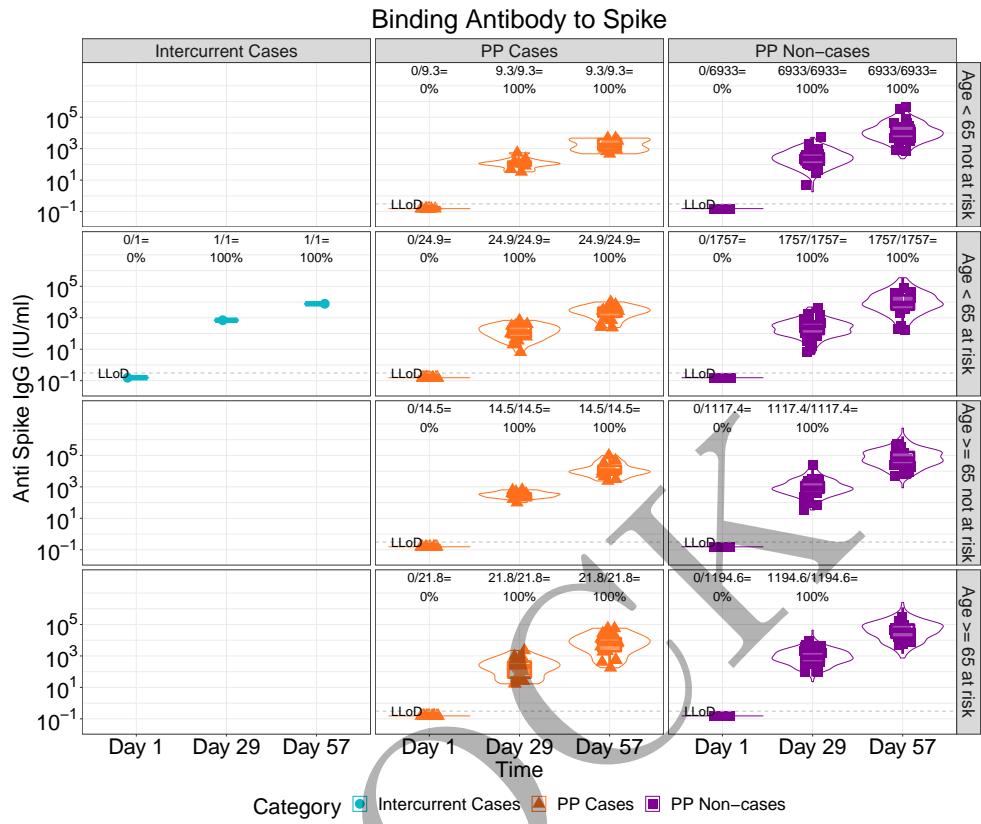


Figure 2.144: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by age and risk condition (version 2)

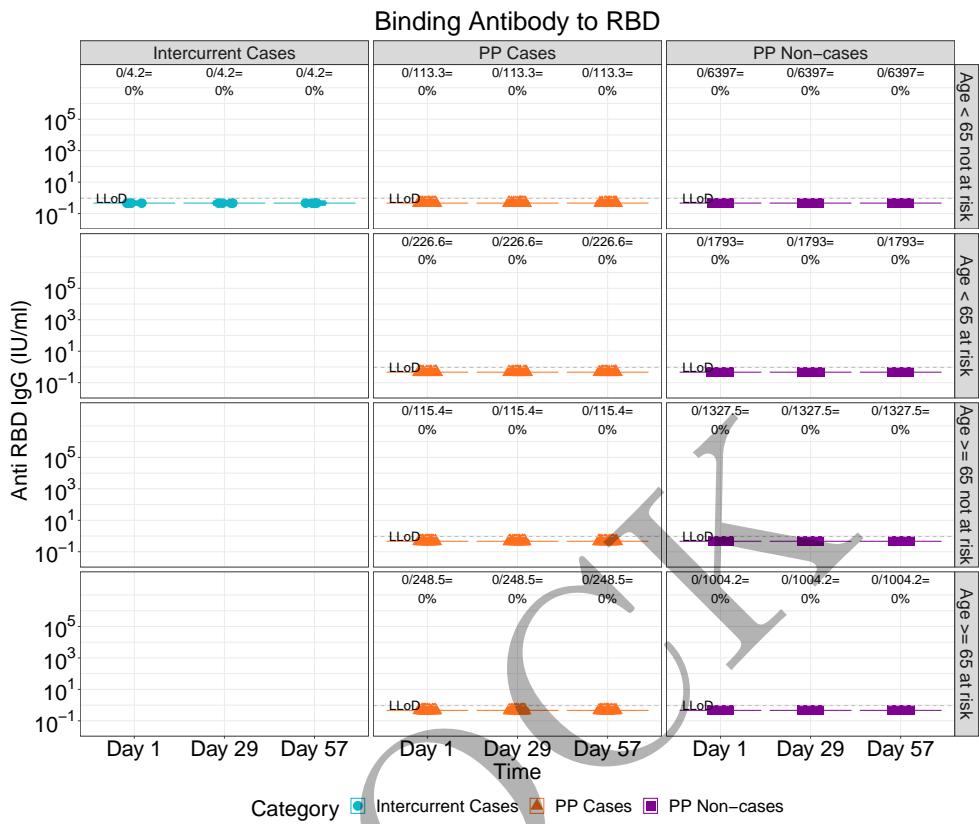


Figure 2.145: violinplots of Binding Antibody to RBD: baseline negative placebo arm by age and risk condition (version 2)

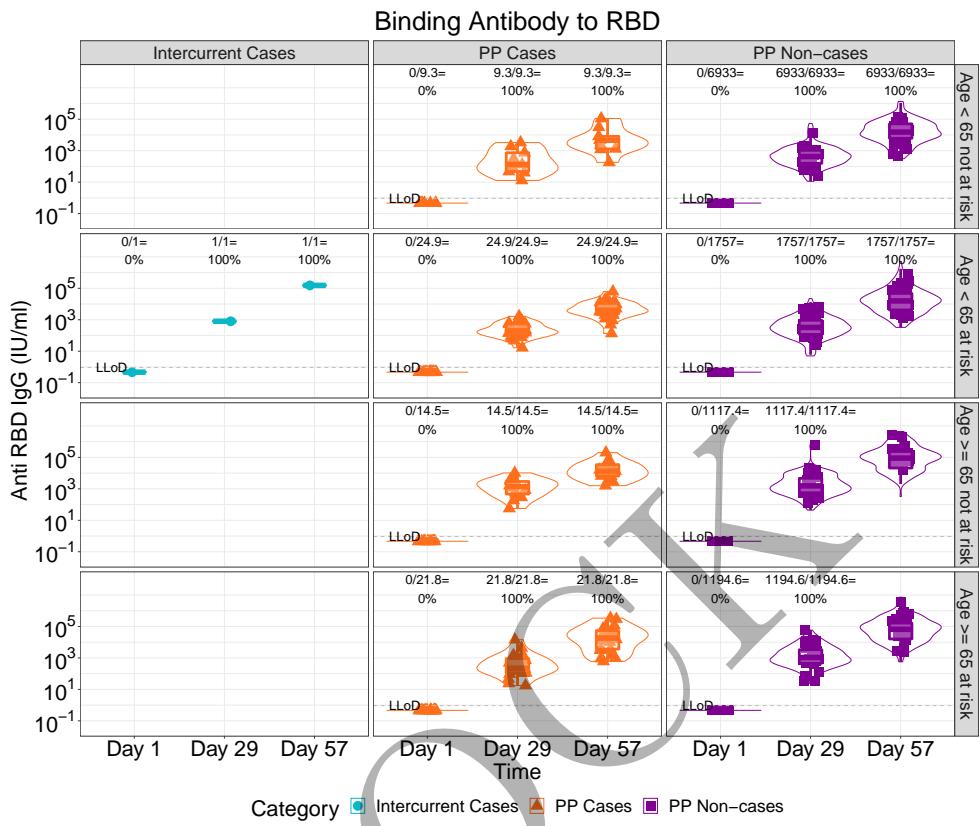


Figure 2.146: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by age and risk condition (version 2)

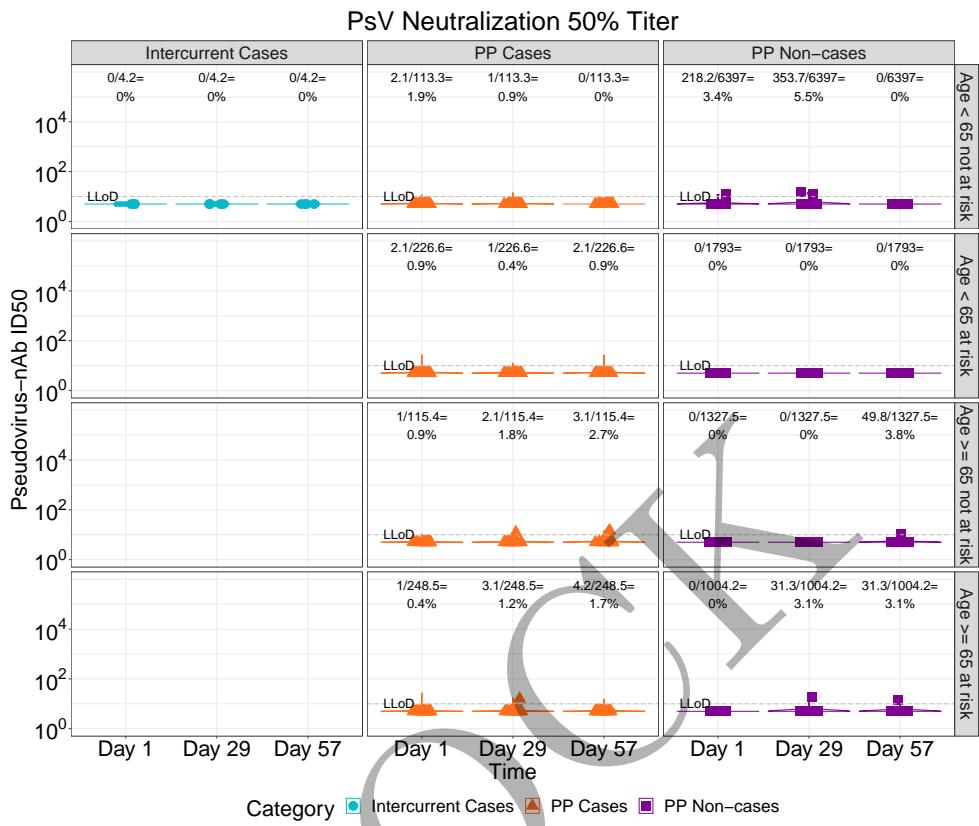


Figure 2.147: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age and risk condition (version 2)

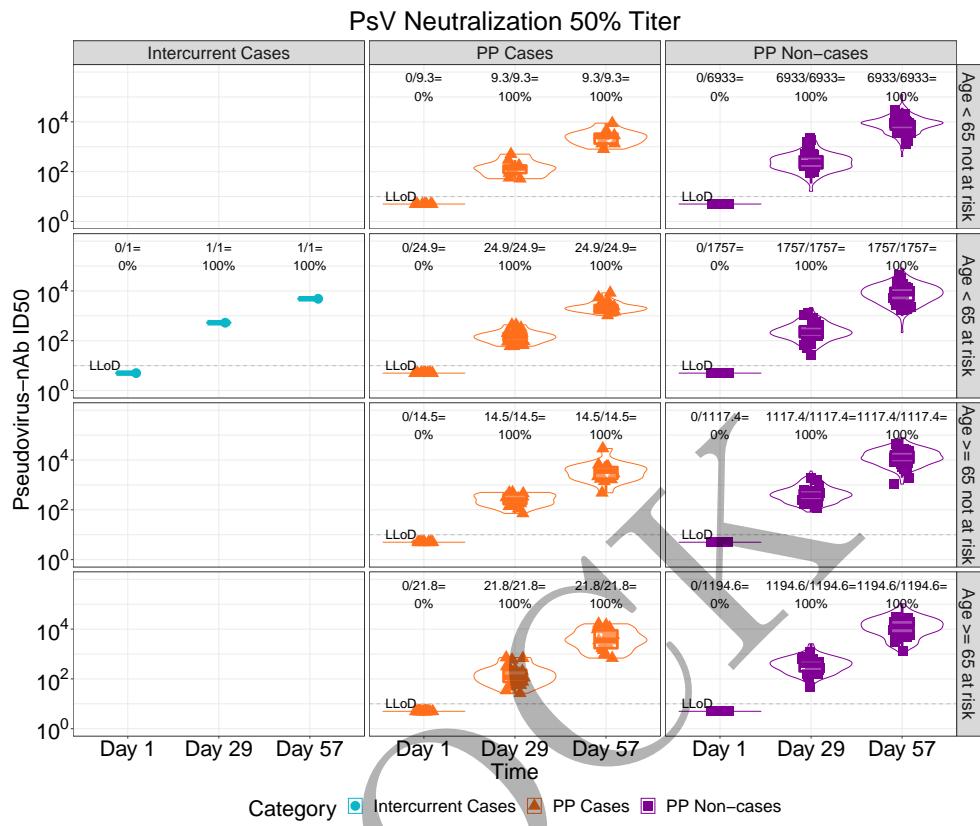


Figure 2.148: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age and risk condition (version 2)

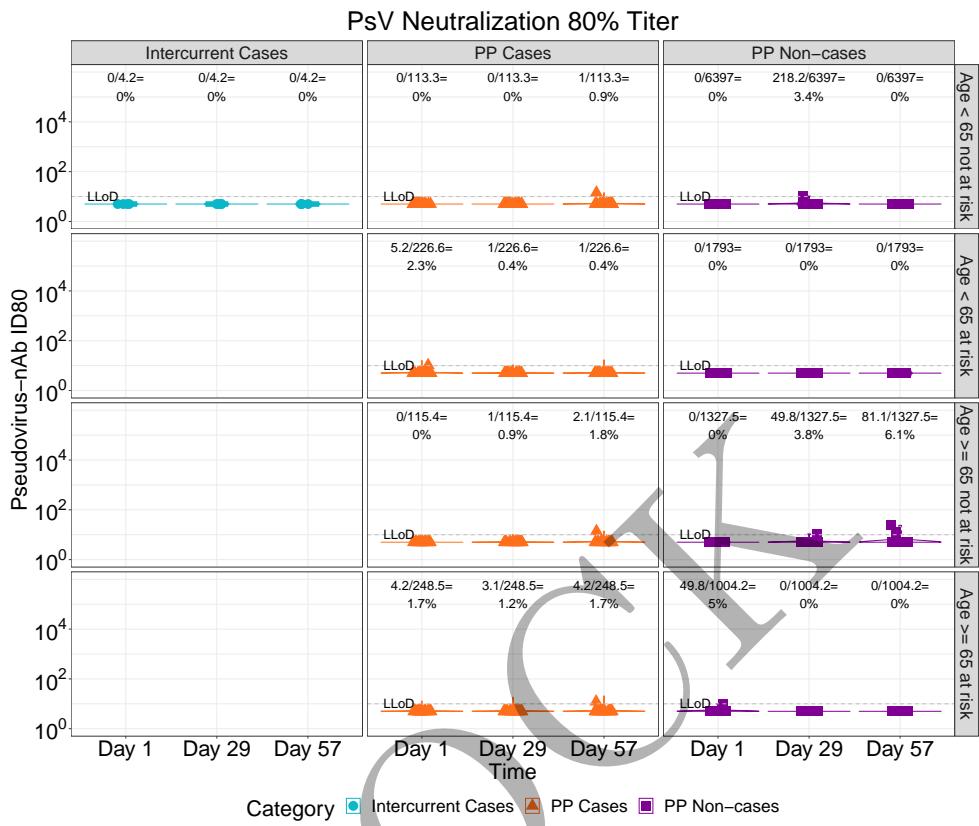


Figure 2.149: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age and risk condition (version 2)

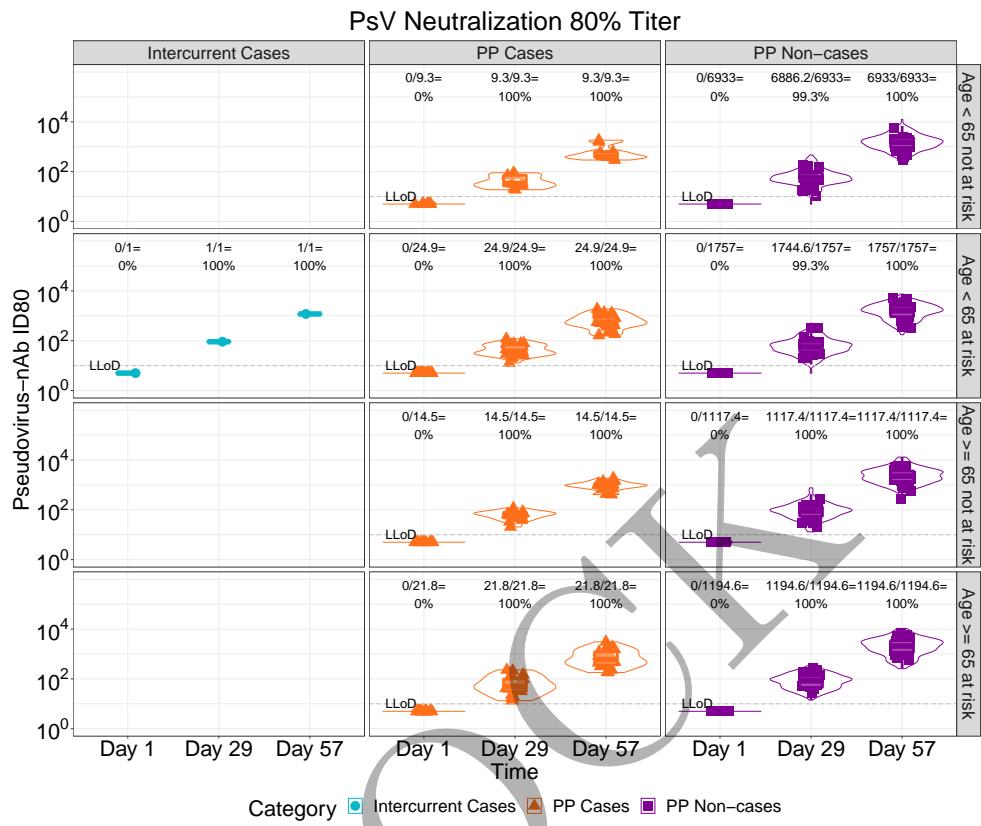


Figure 2.150: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age and risk condition (version 2)

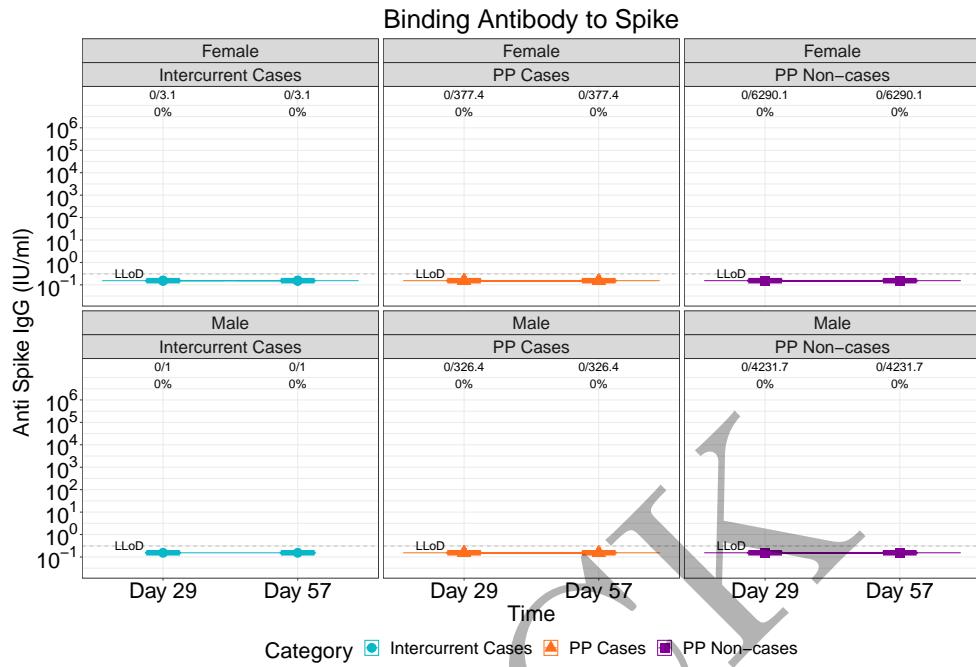


Figure 2.151: lineplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (version 1)

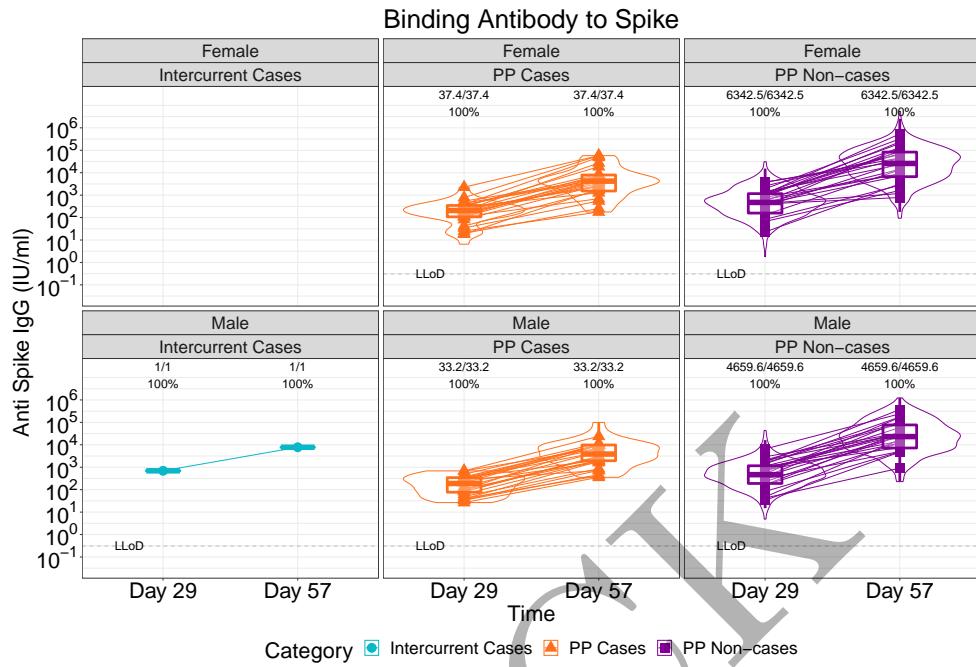


Figure 2.152: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (version 1)

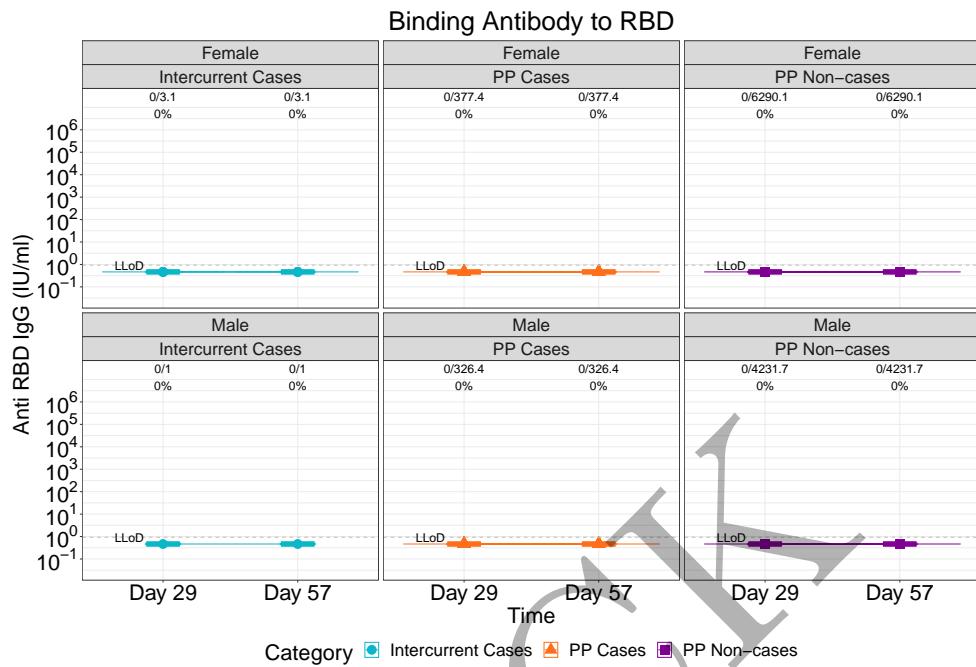


Figure 2.153: lineplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (version 1)

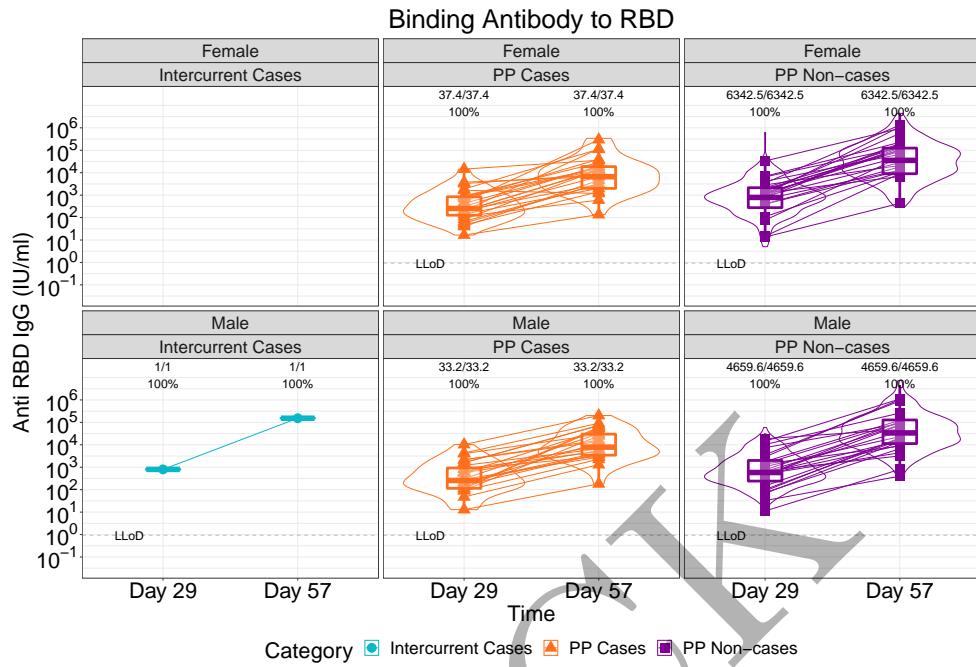


Figure 2.154: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (version 1)

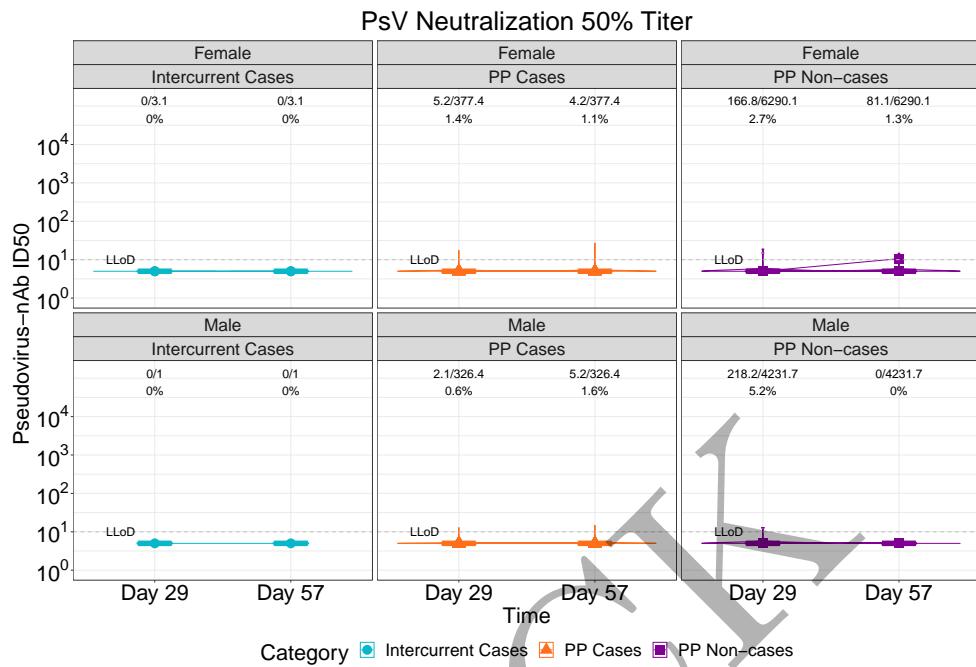


Figure 2.155: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by sex assigned at birth (version 1)

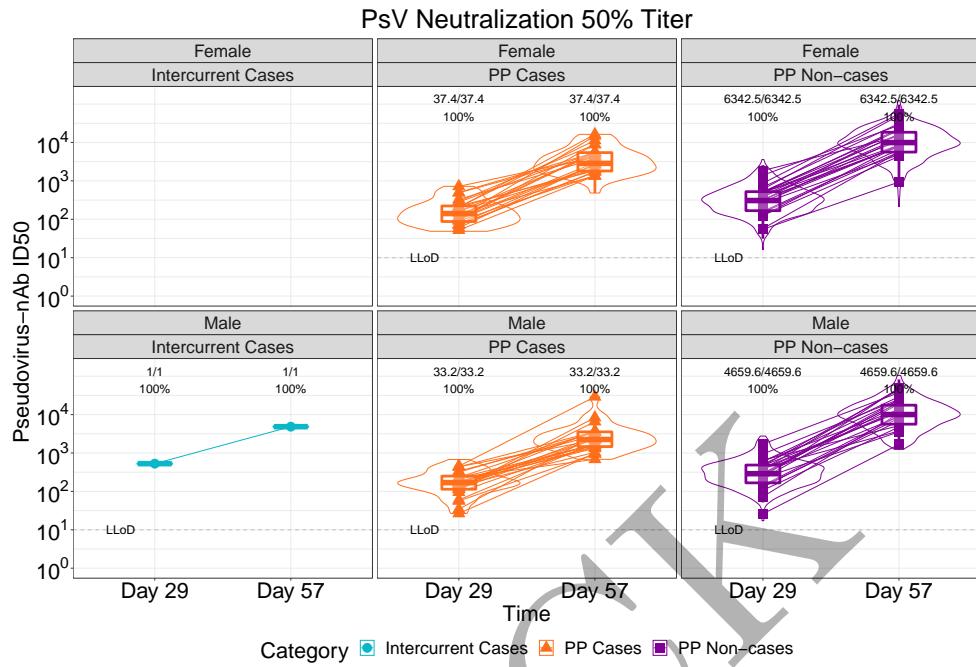


Figure 2.156: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by sex assigned at birth (version 1)

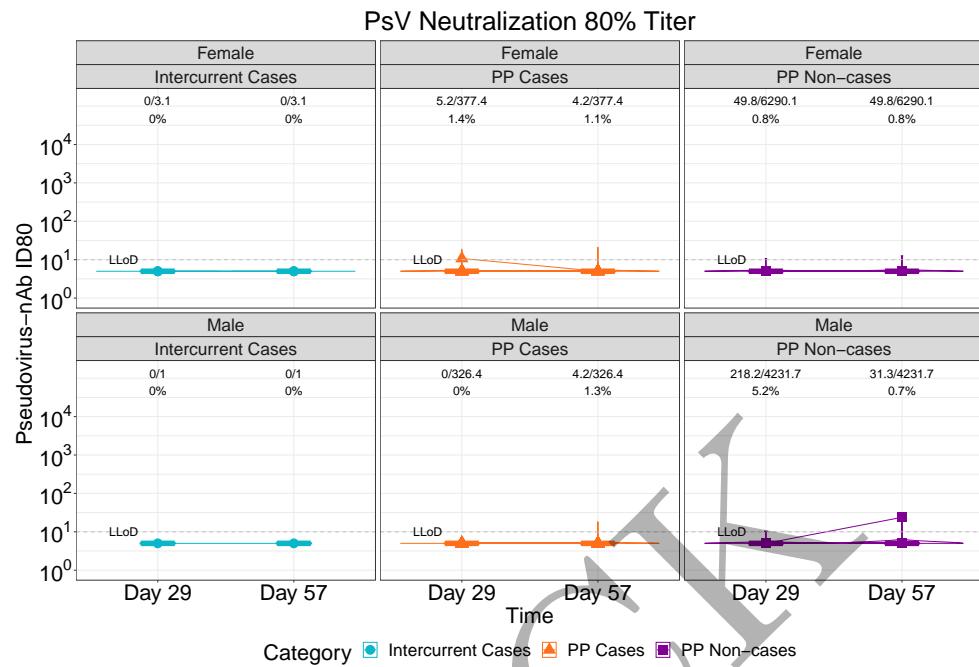


Figure 2.157: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by sex assigned at birth (version 1)

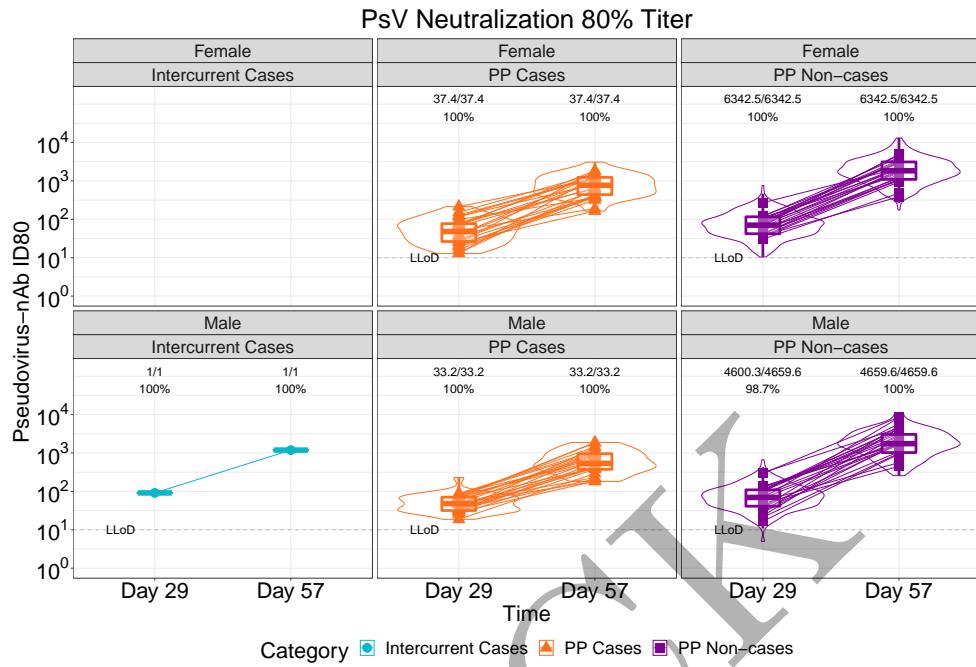


Figure 2.158: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by sex assigned at birth (version 1)

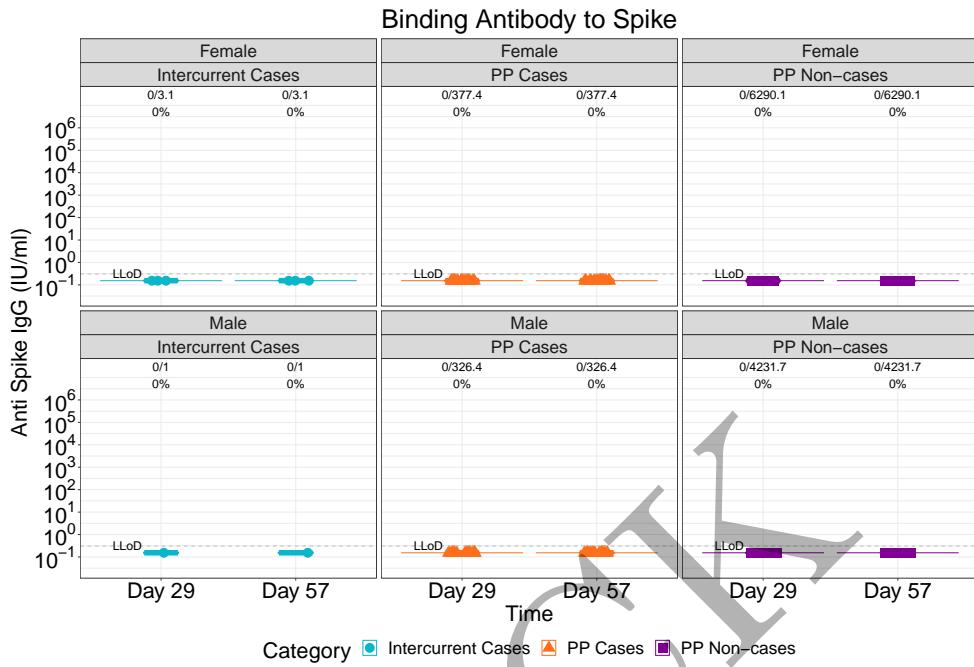


Figure 2.159: violinplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (version 1)

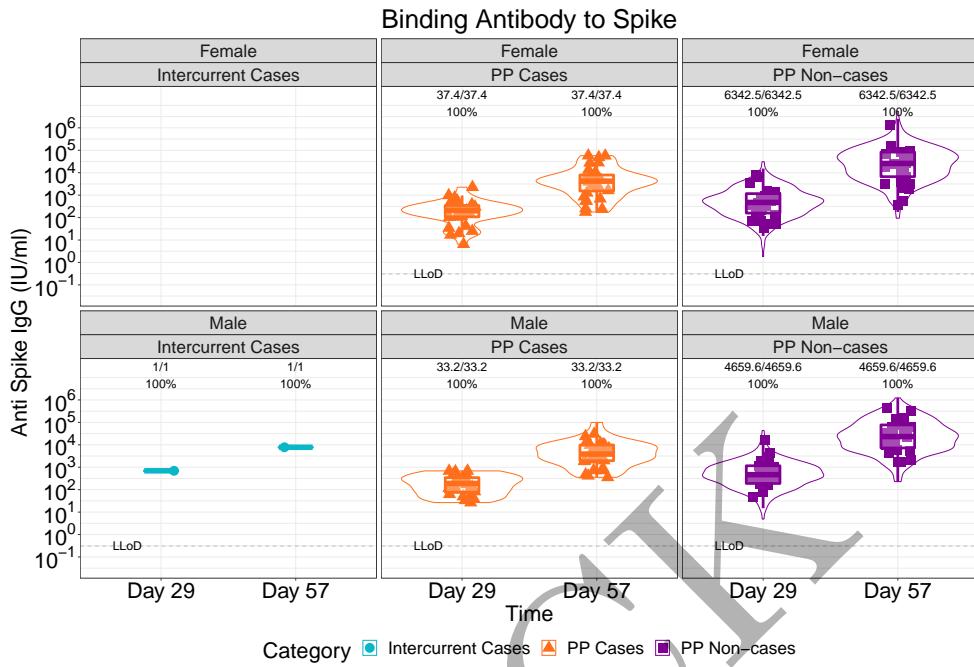


Figure 2.160: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (version 1)

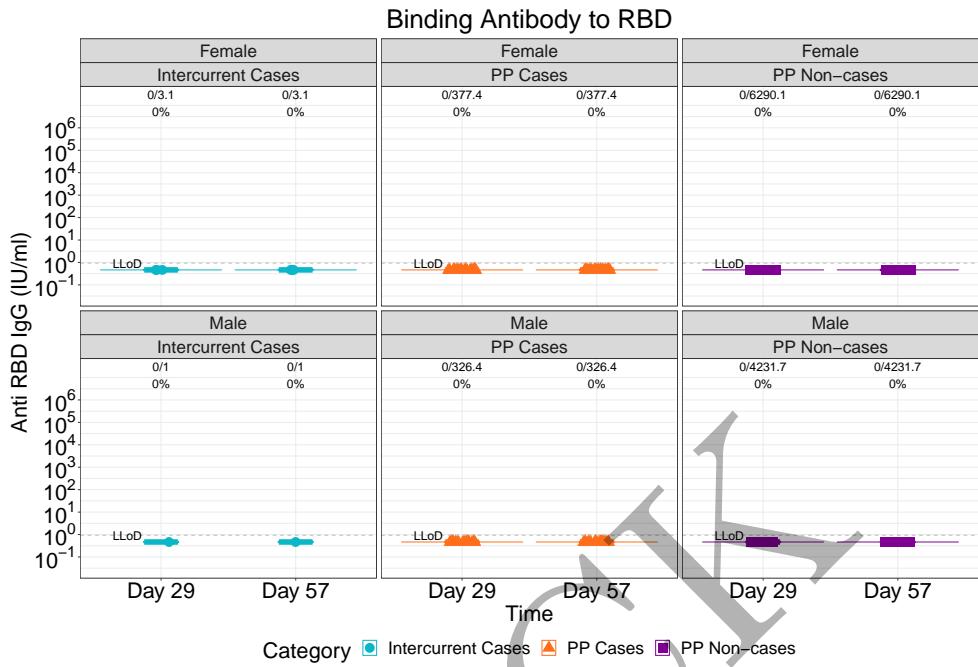


Figure 2.161: violinplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (version 1)

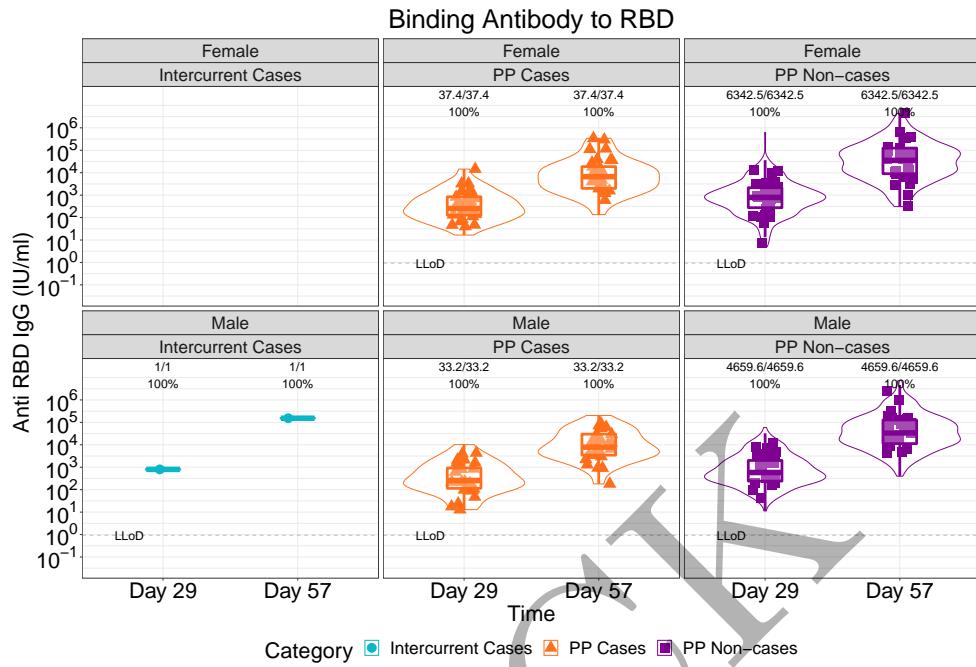


Figure 2.162: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (version 1)

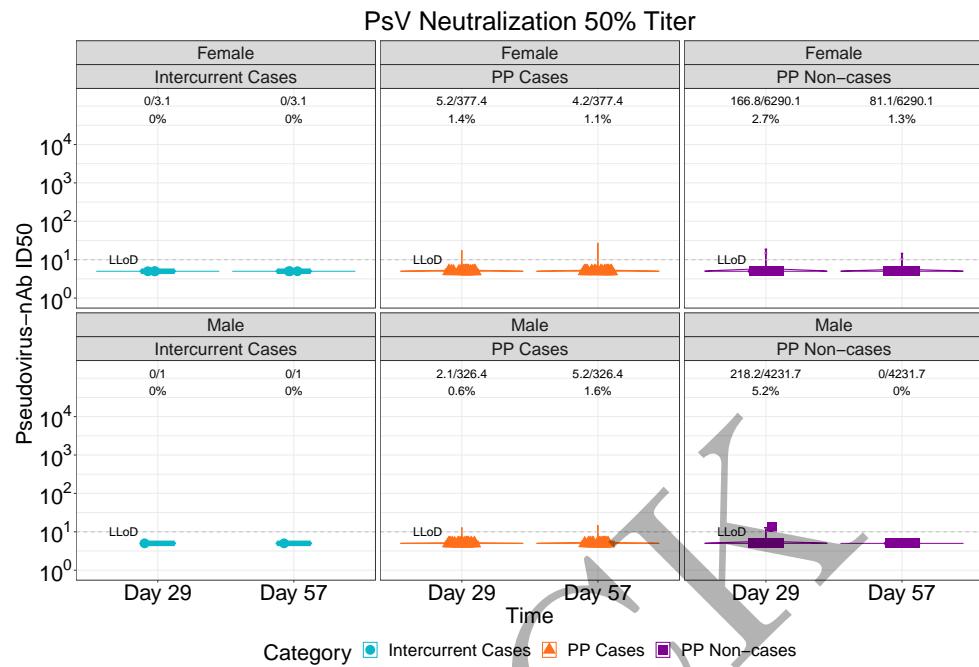


Figure 2.163: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by sex assigned at birth (version 1)

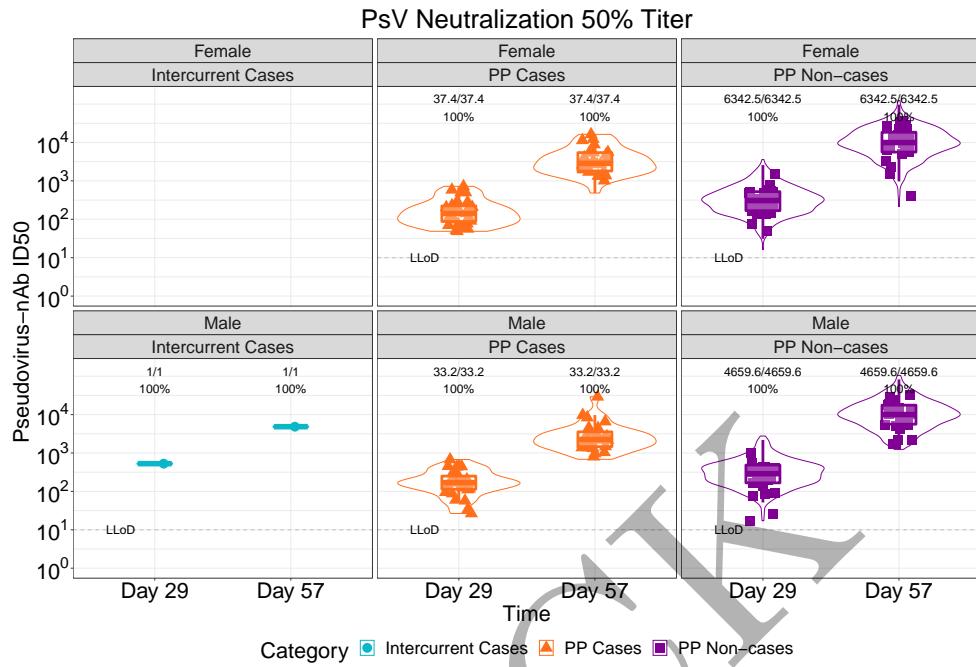


Figure 2.164: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by sex assigned at birth (version 1)

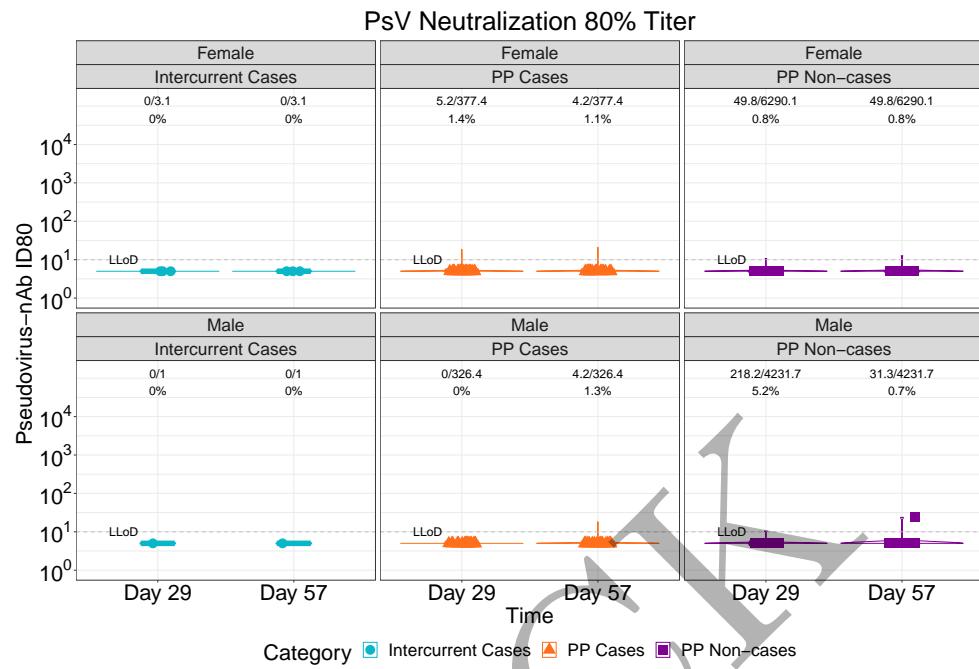


Figure 2.165: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by sex assigned at birth (version 1)

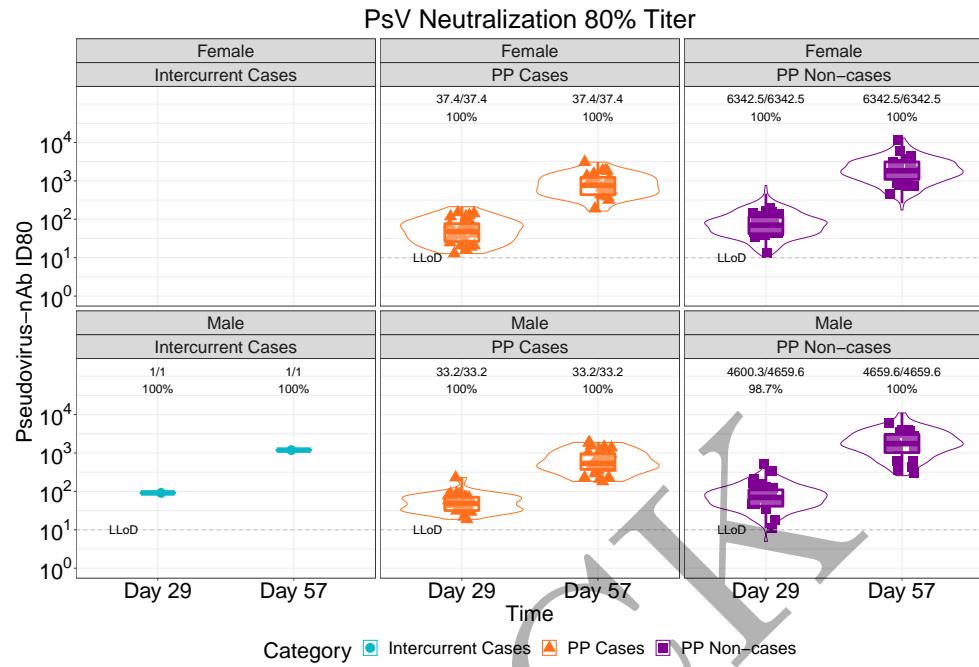


Figure 2.166: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by sex assigned at birth (version 1)

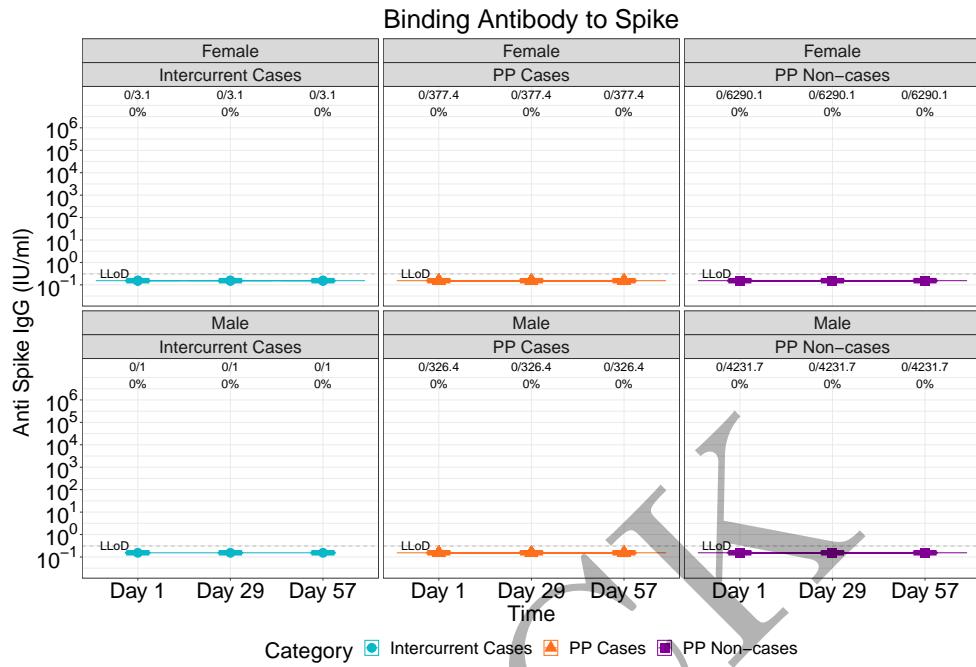


Figure 2.167: lineplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (version 2)

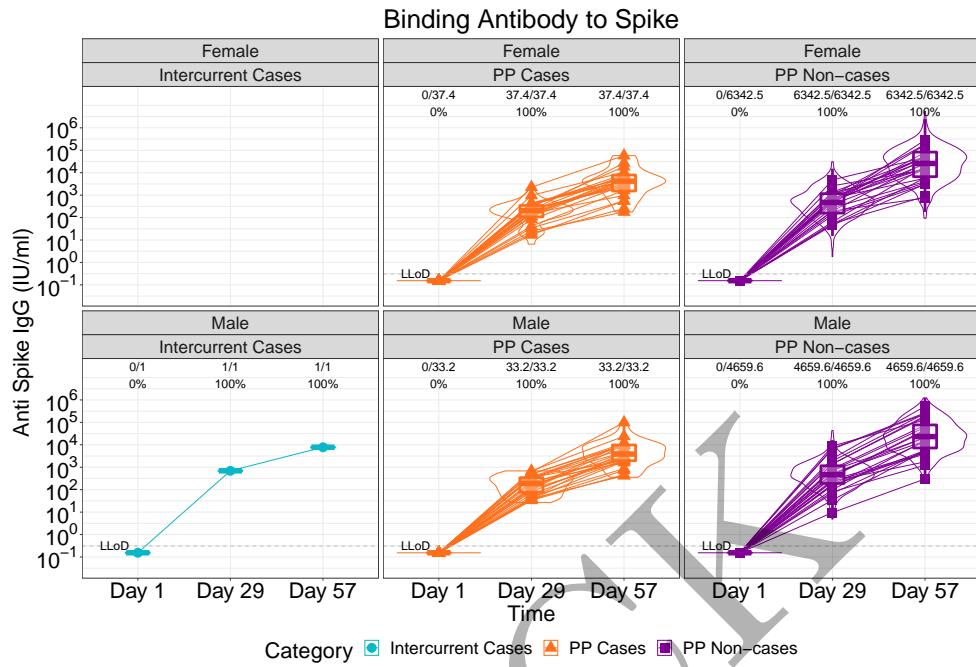


Figure 2.168: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (version 2)

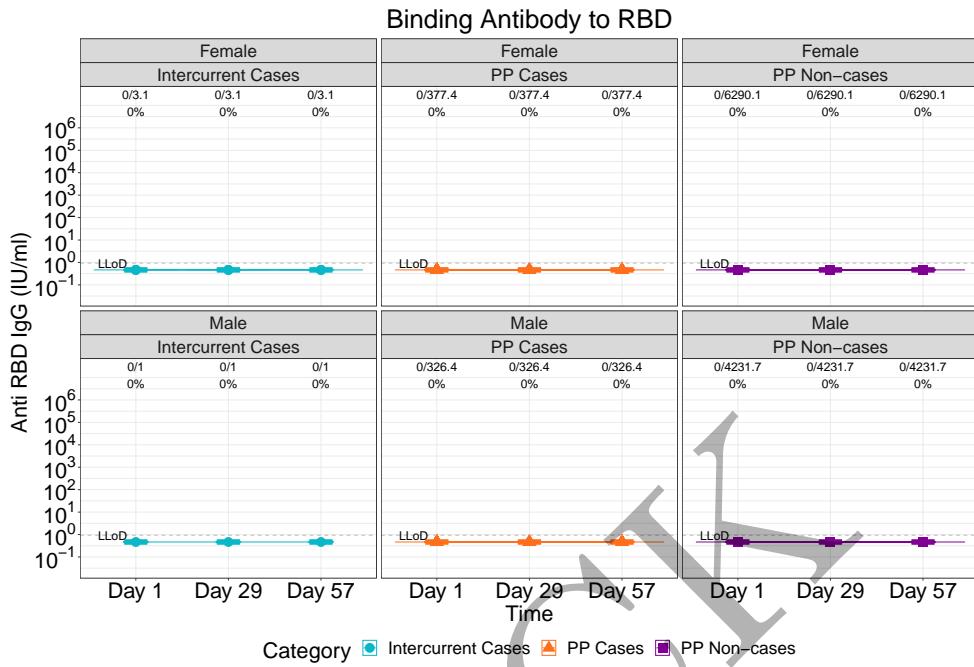


Figure 2.169: lineplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (version 2)

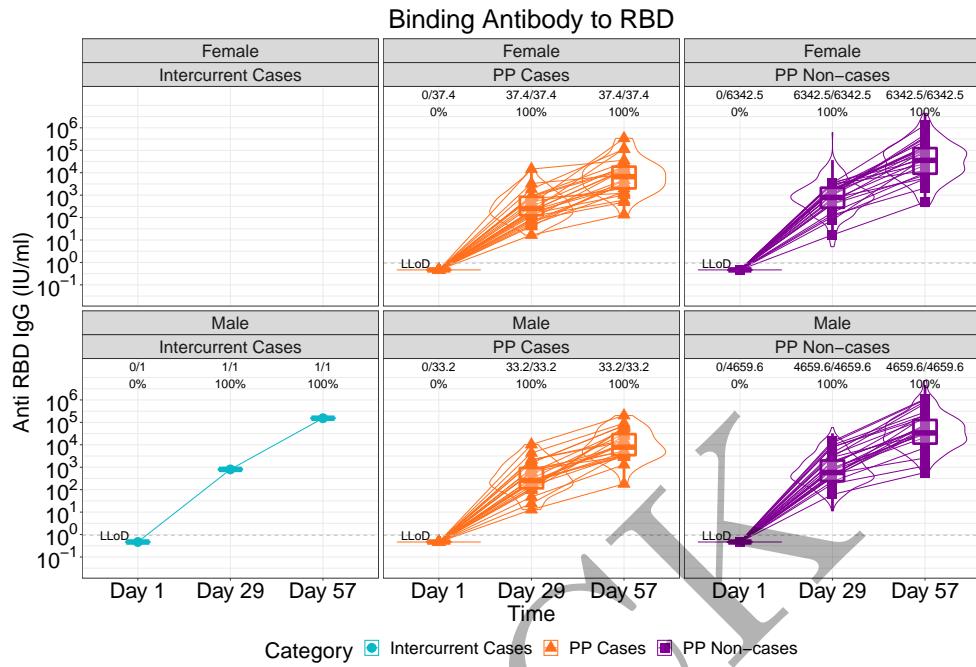


Figure 2.170: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (version 2)

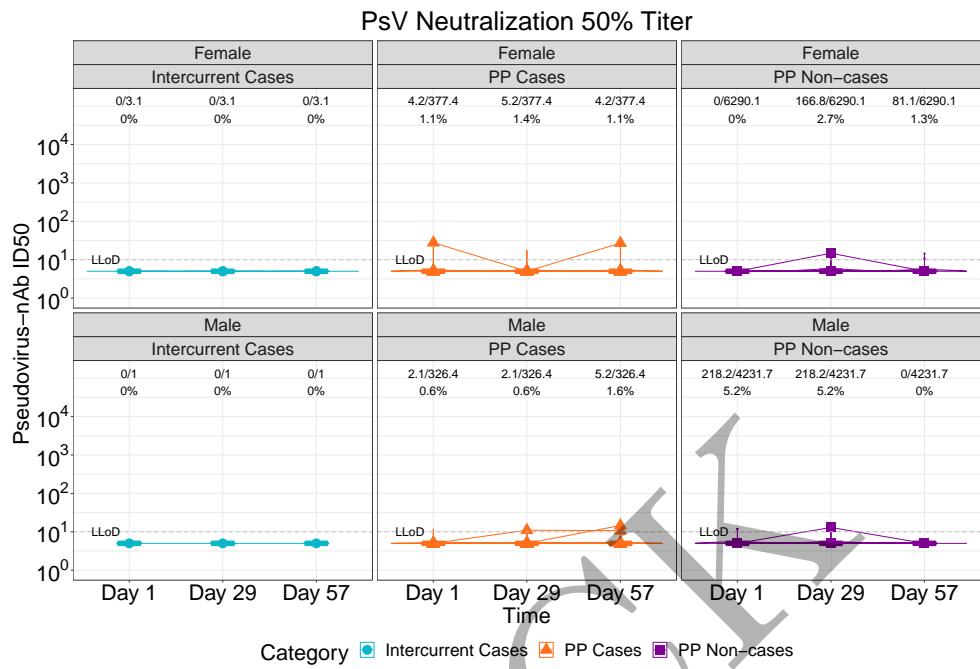


Figure 2.171: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by sex assigned at birth (version 2)

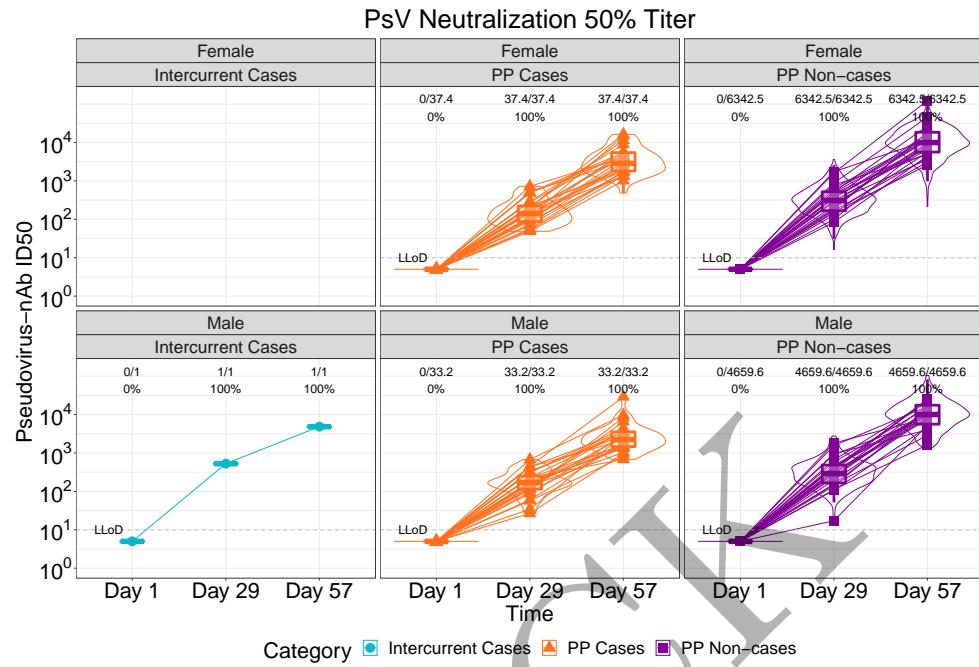


Figure 2.172: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by sex assigned at birth (version 2)

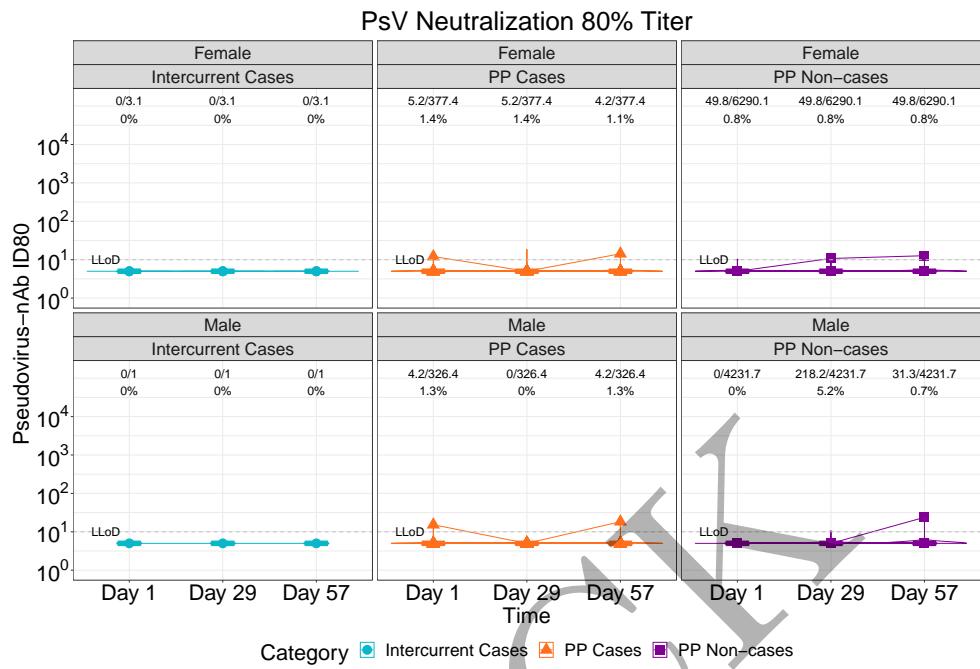


Figure 2.173: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by sex assigned at birth (version 2)

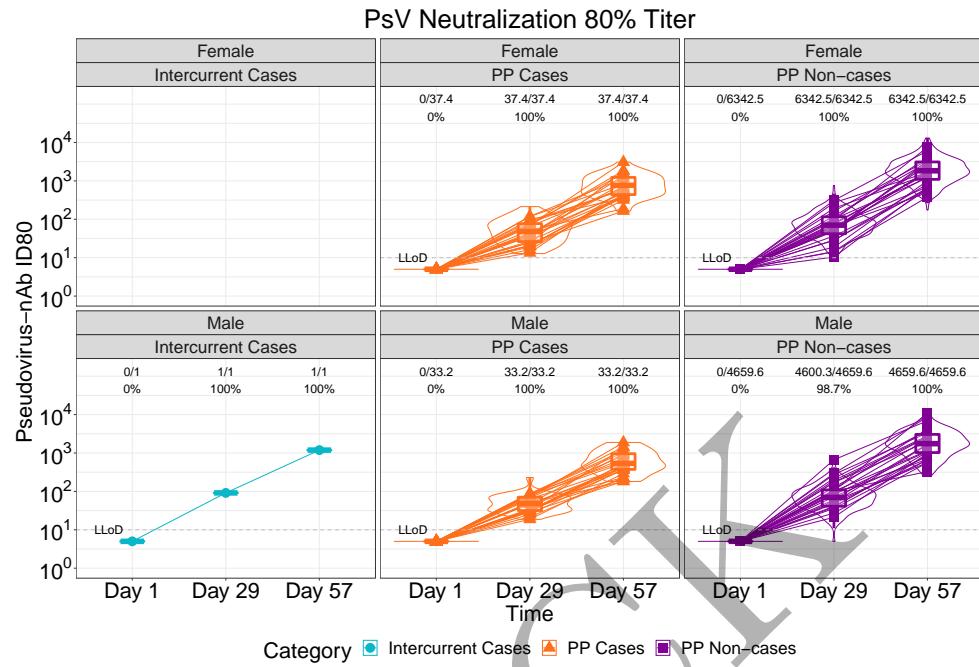


Figure 2.174: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by sex assigned at birth (version 2)

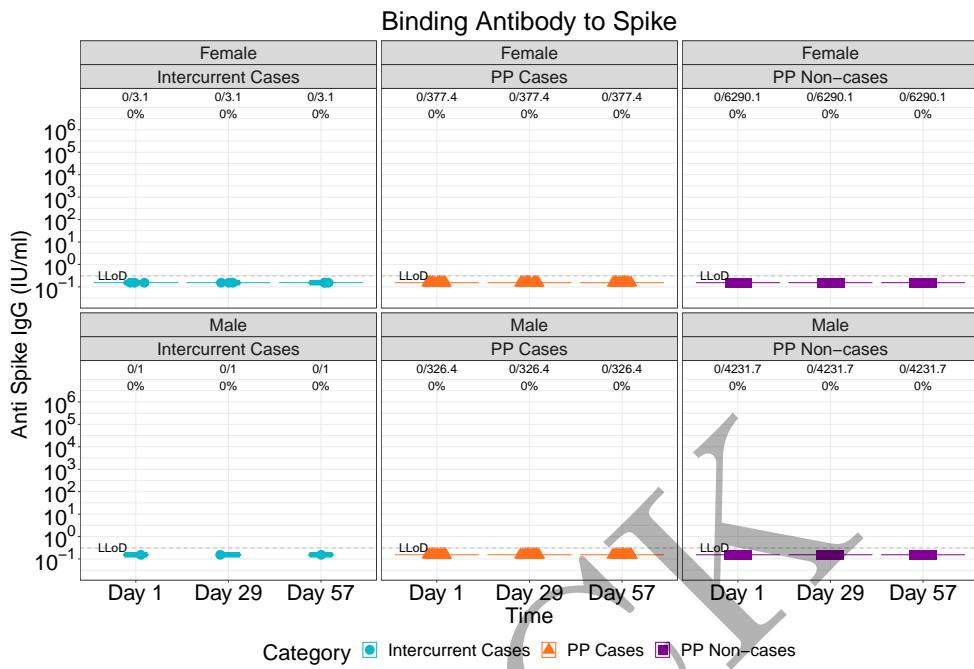


Figure 2.175: violinplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (version 2)

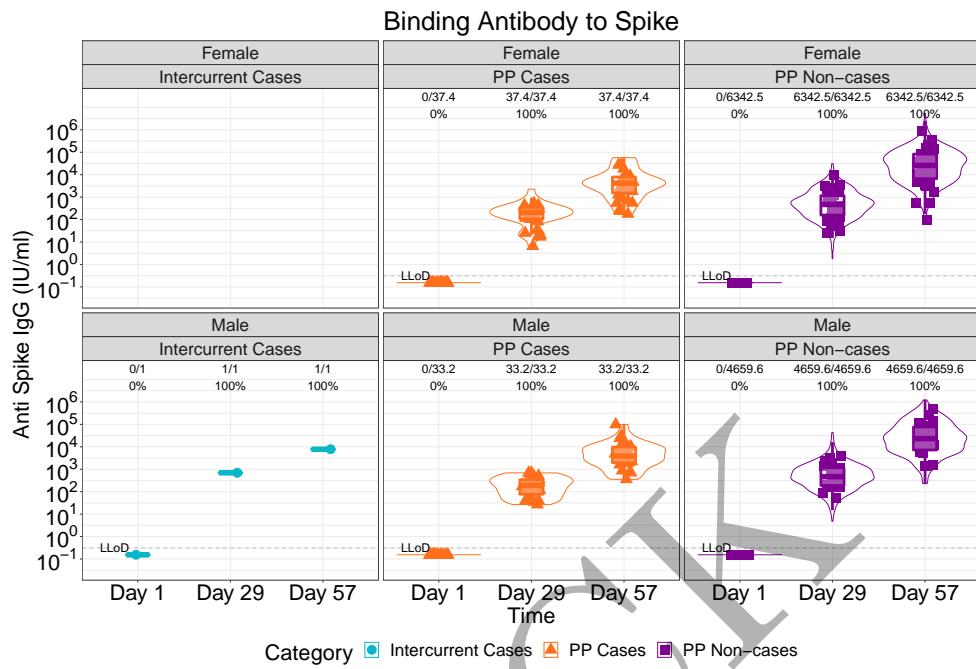


Figure 2.176: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (version 2)

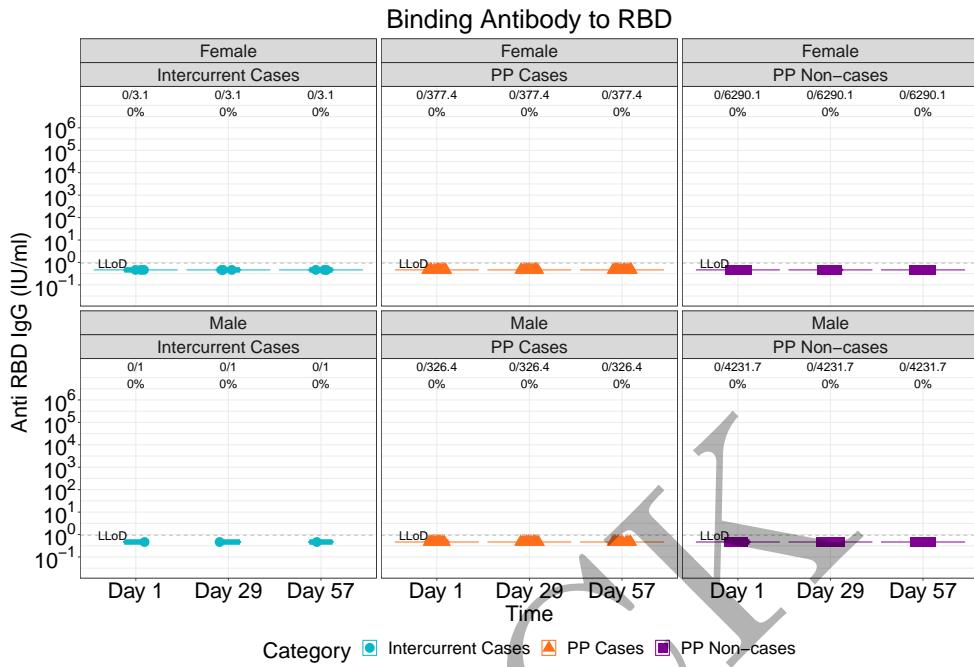


Figure 2.177: violinplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (version 2)

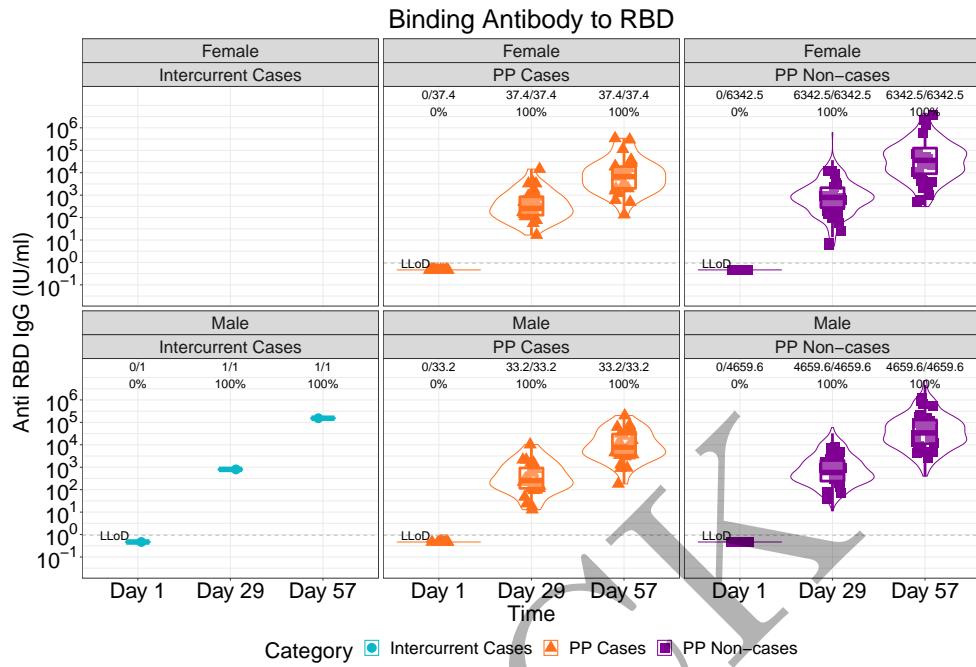


Figure 2.178: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (version 2)

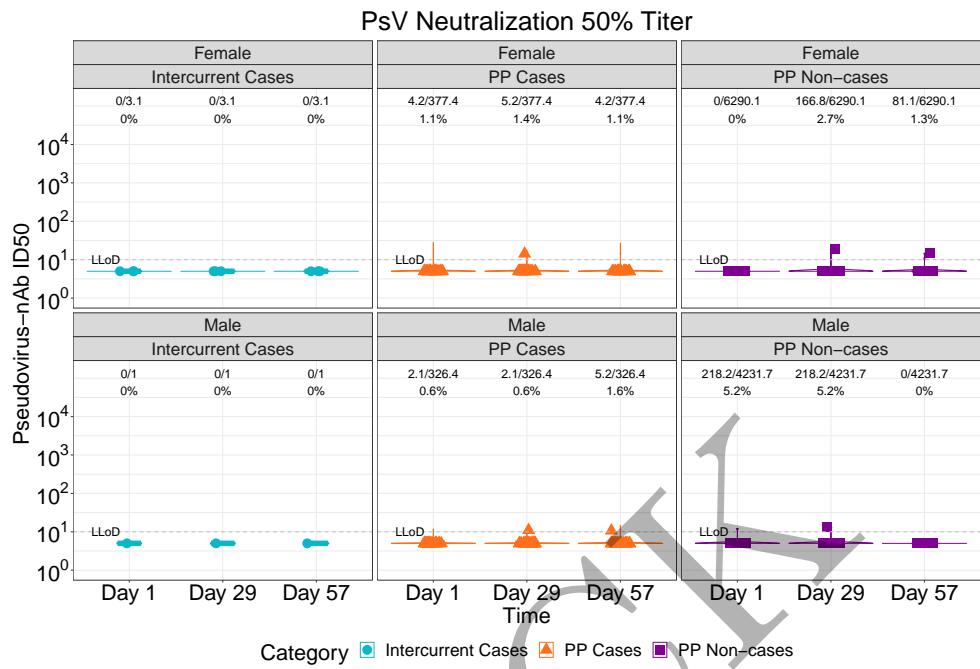


Figure 2.179: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by sex assigned at birth (version 2)

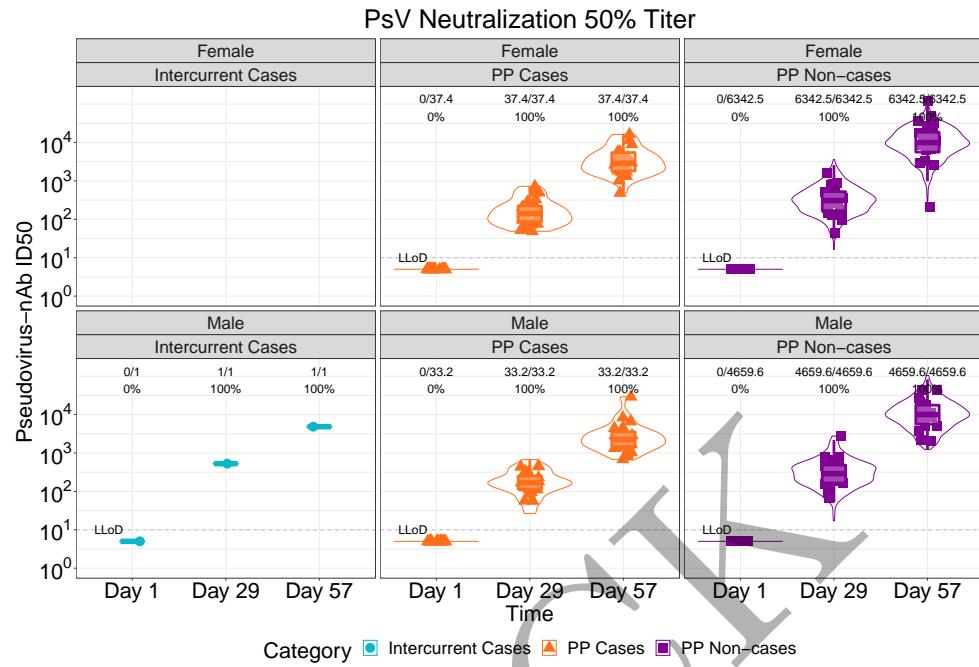


Figure 2.180: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by sex assigned at birth (version 2)

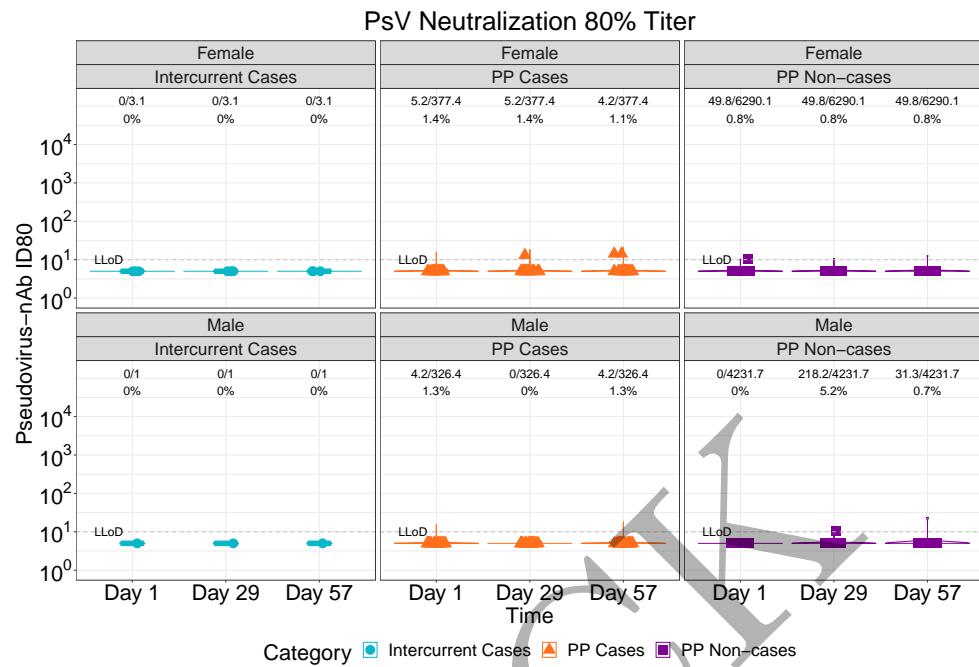


Figure 2.181: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by sex assigned at birth (version 2)

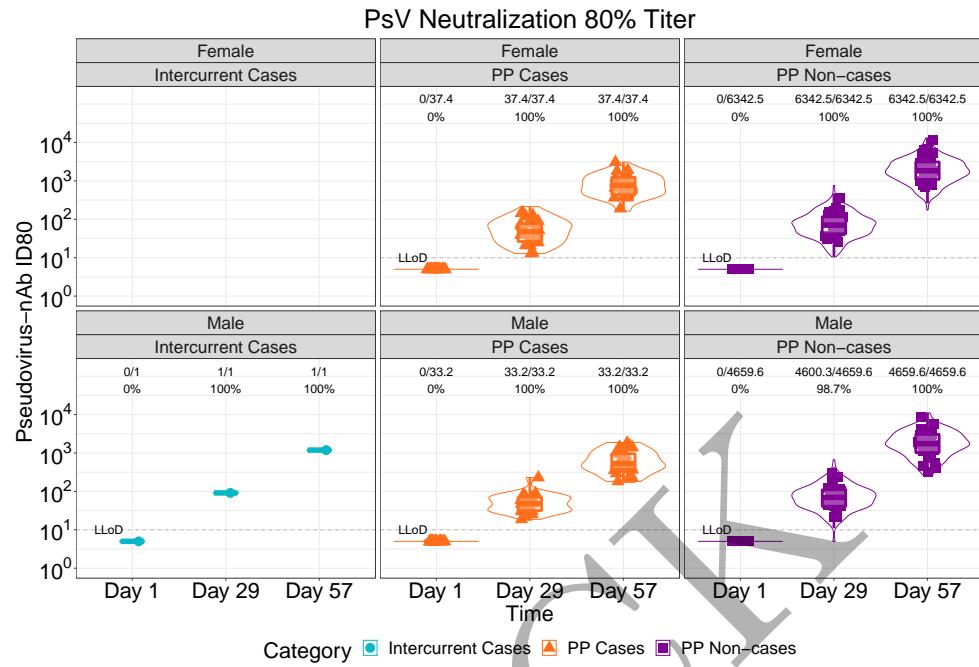


Figure 2.182: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by sex assigned at birth (version 2)

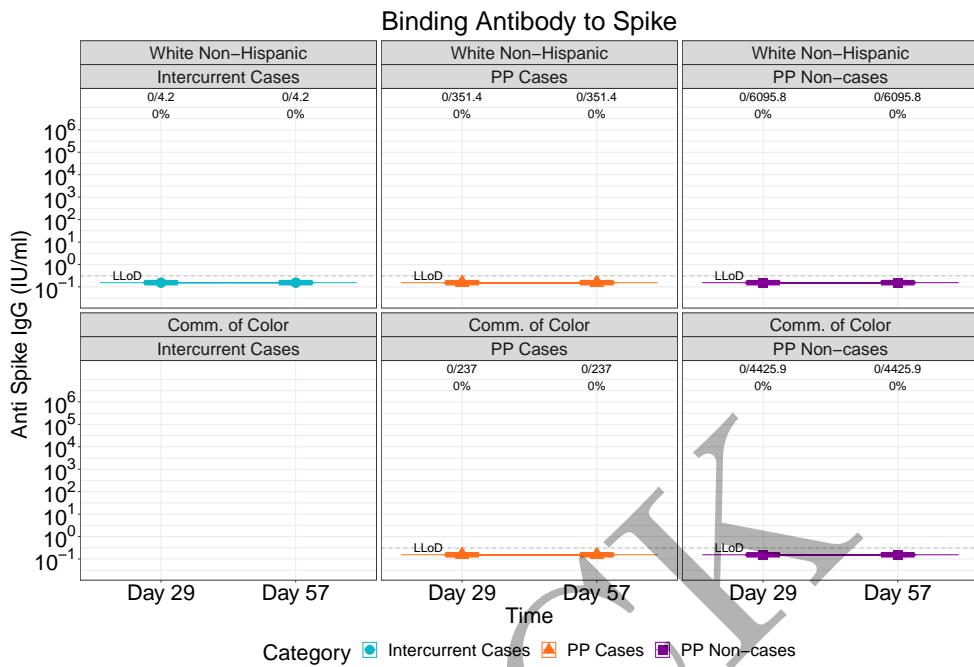


Figure 2.183: lineplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (version 1)

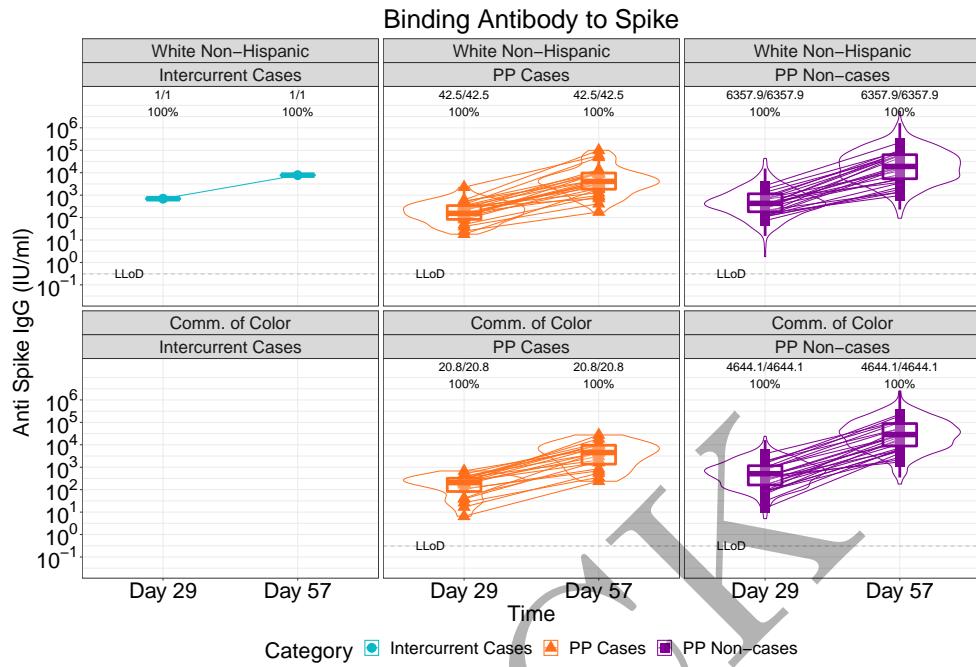


Figure 2.184: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (version 1)

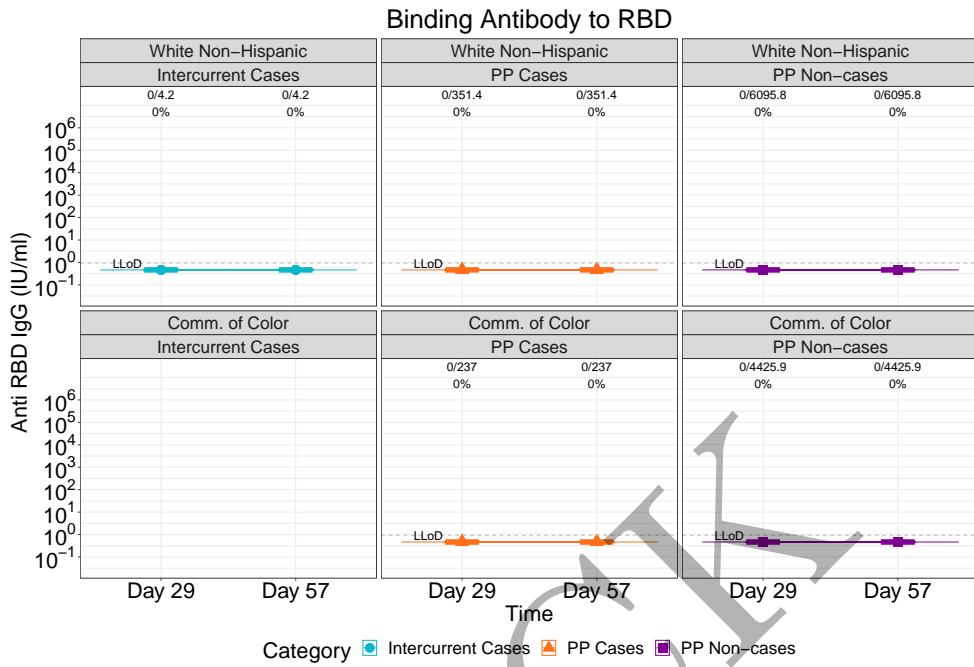


Figure 2.185: lineplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (version 1)

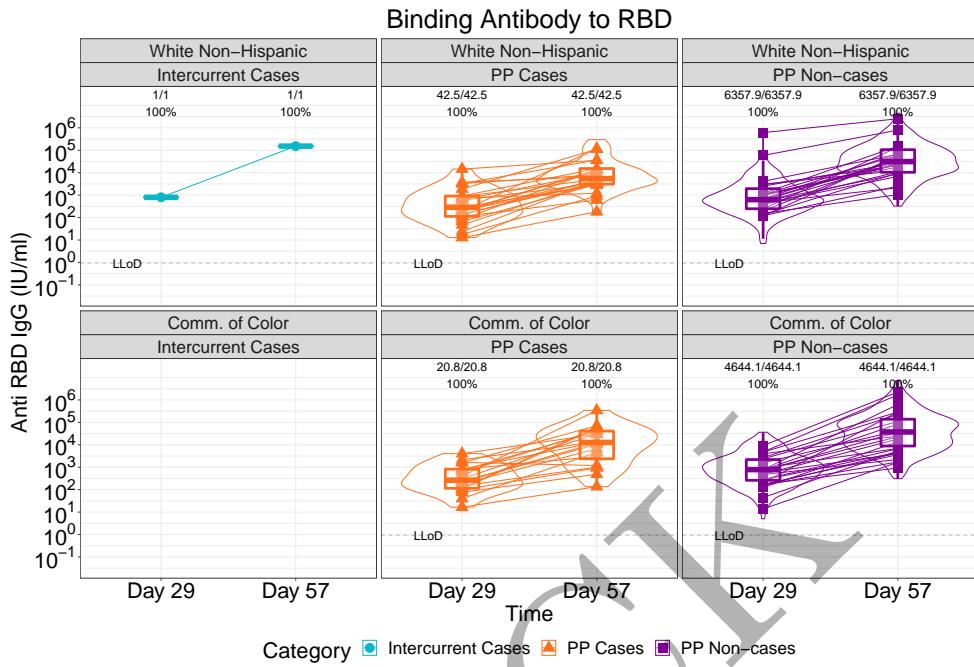


Figure 2.186: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (version 1)

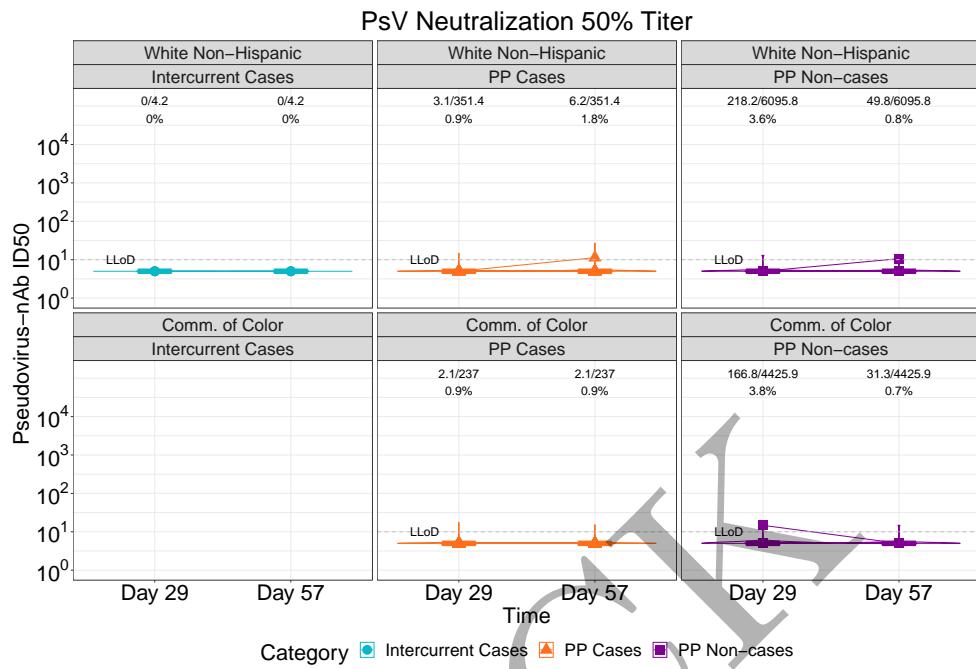


Figure 2.187: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by race and ethnic group (version 1)

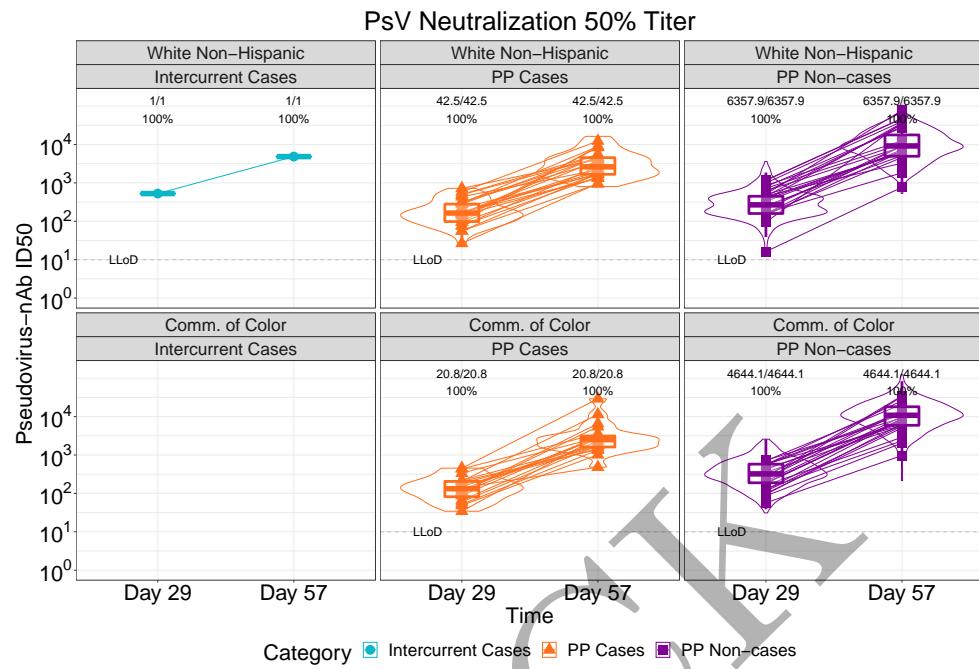


Figure 2.188: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by race and ethnic group (version 1)

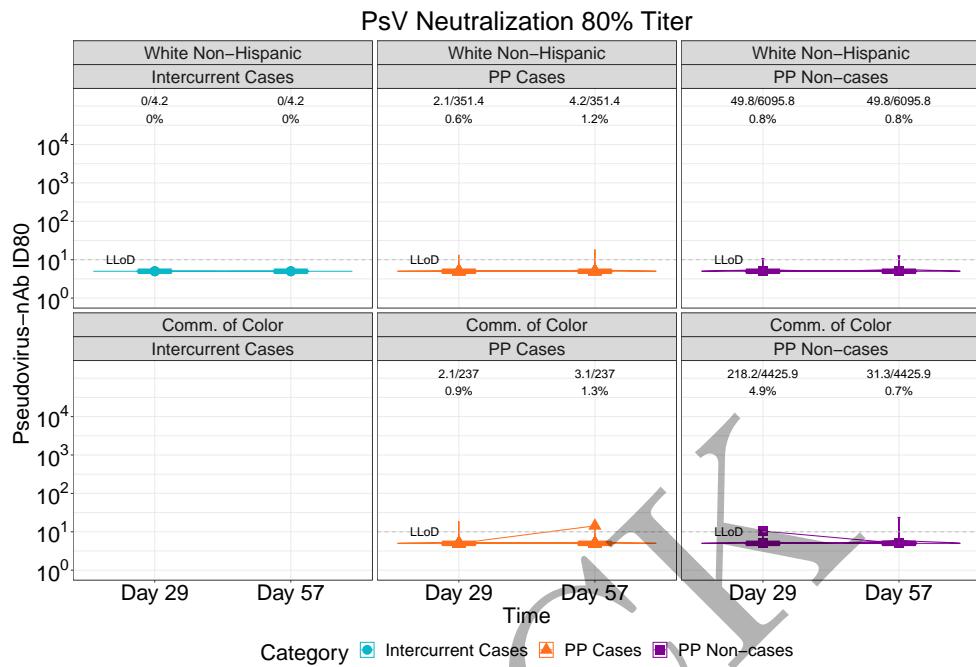


Figure 2.189: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by race and ethnic group (version 1)

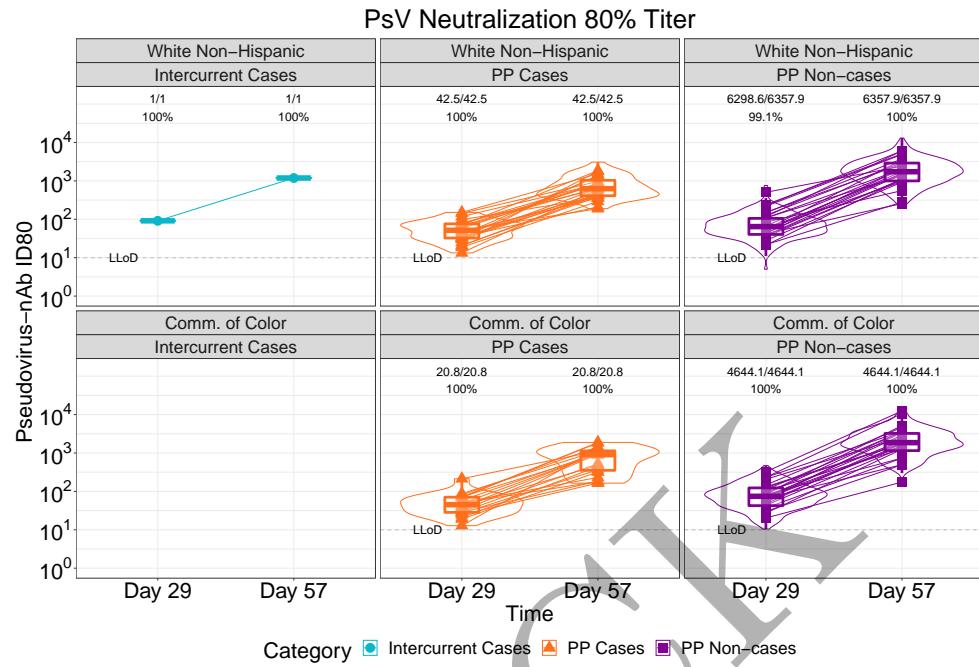


Figure 2.190: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by race and ethnic group (version 1)

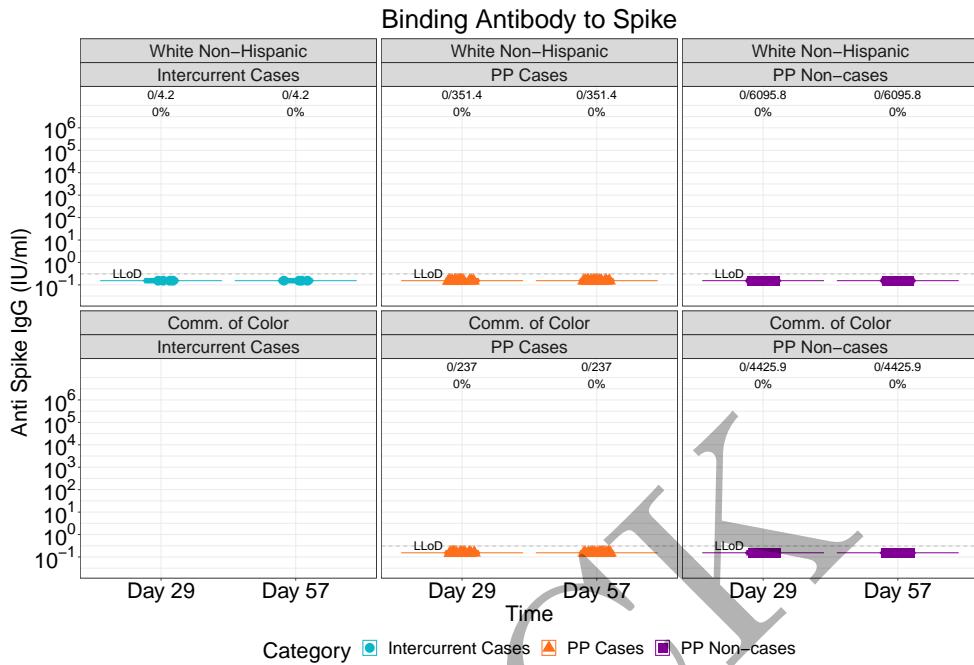


Figure 2.191: violinplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (version 1)

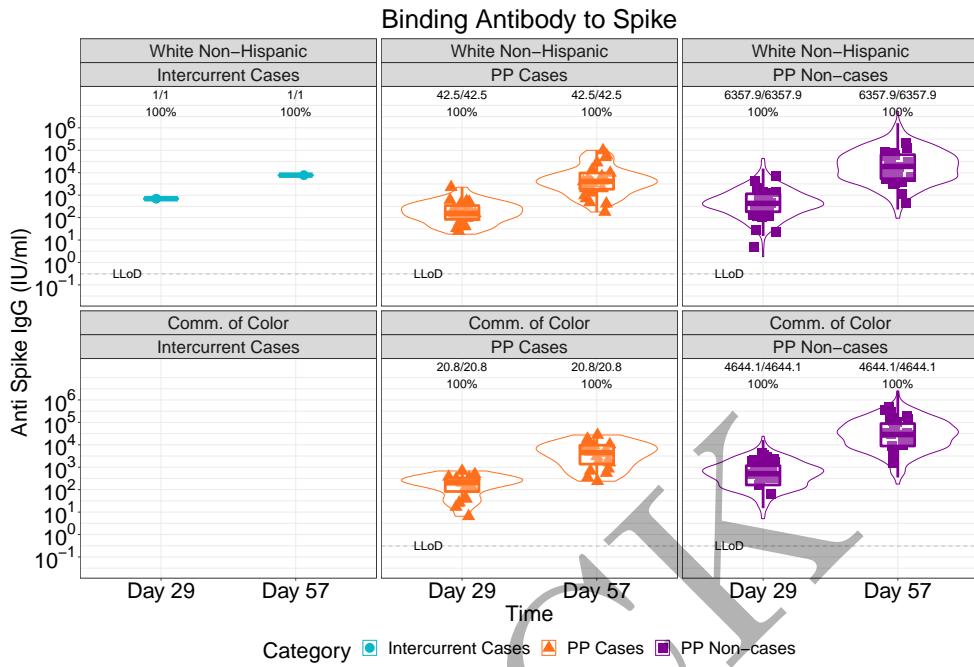


Figure 2.192: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (version 1)

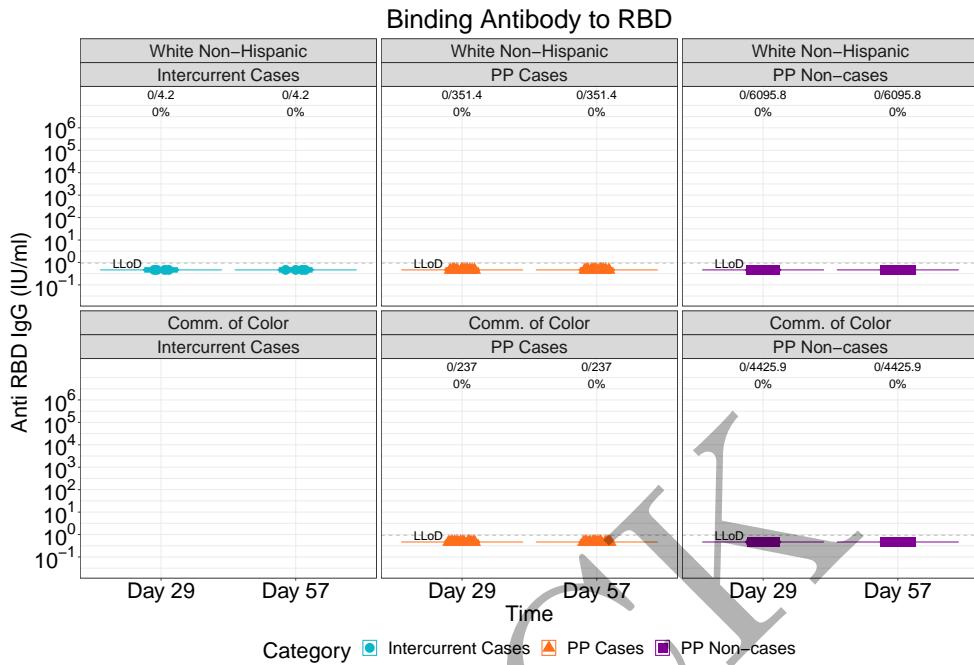


Figure 2.193: violinplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (version 1)

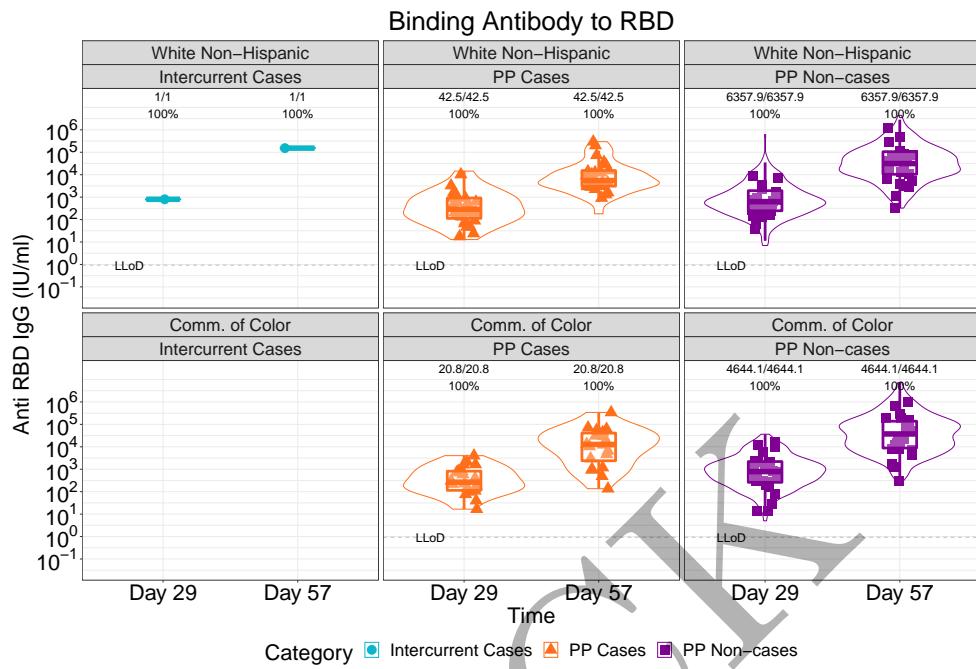


Figure 2.194: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (version 1)

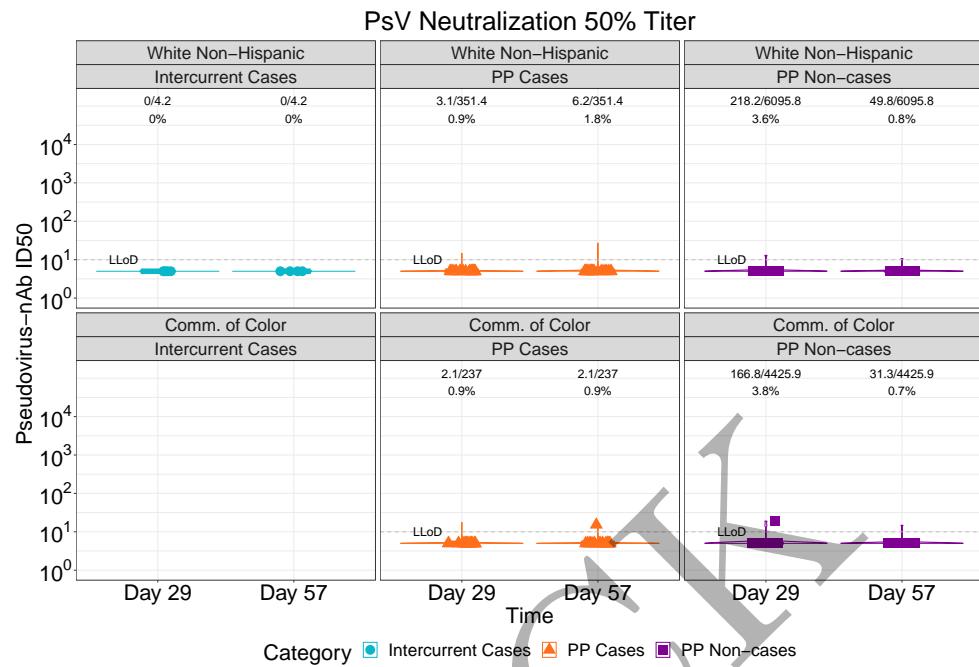


Figure 2.195: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by race and ethnic group (version 1)

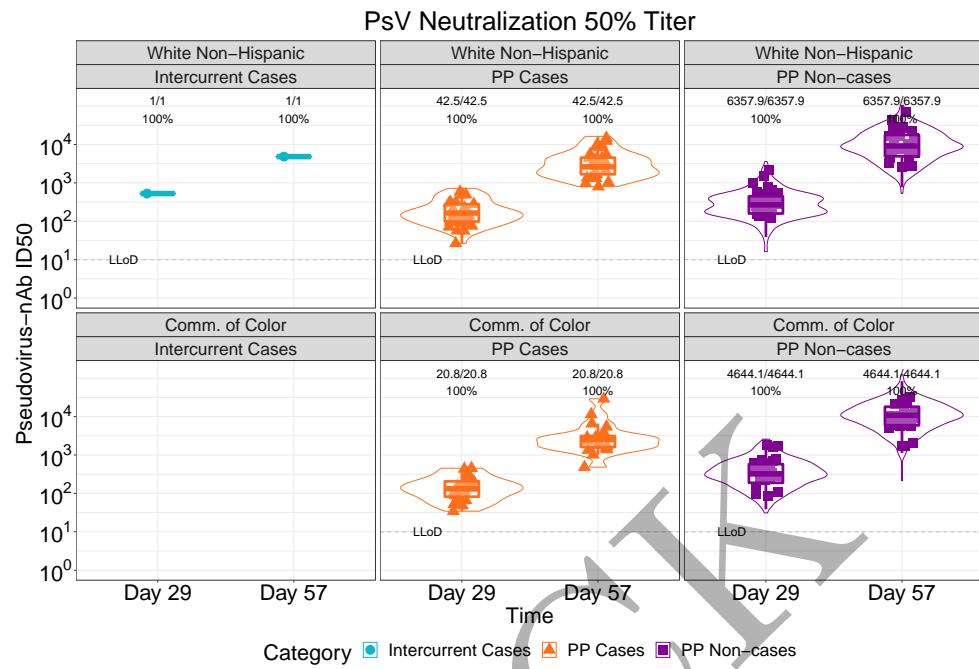


Figure 2.196: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by race and ethnic group (version 1)

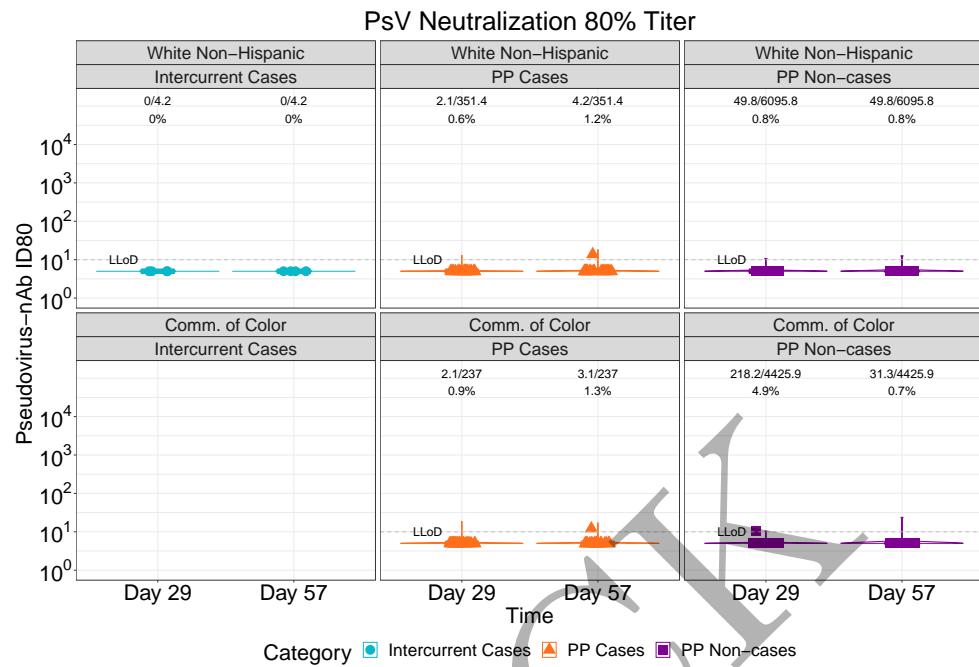


Figure 2.197: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by race and ethnic group (version 1)

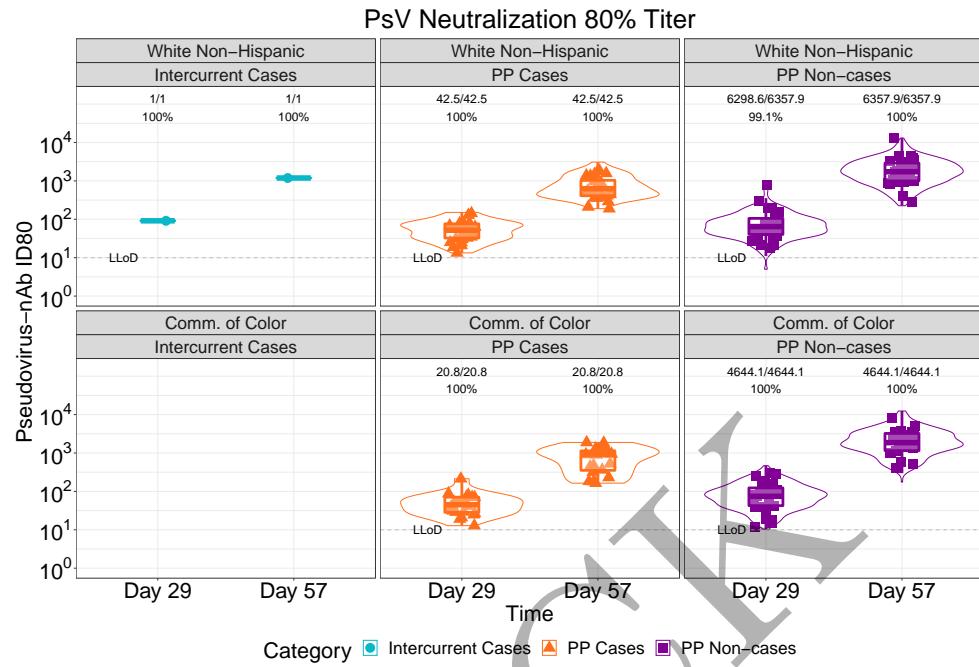


Figure 2.198: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by race and ethnic group (version 1)

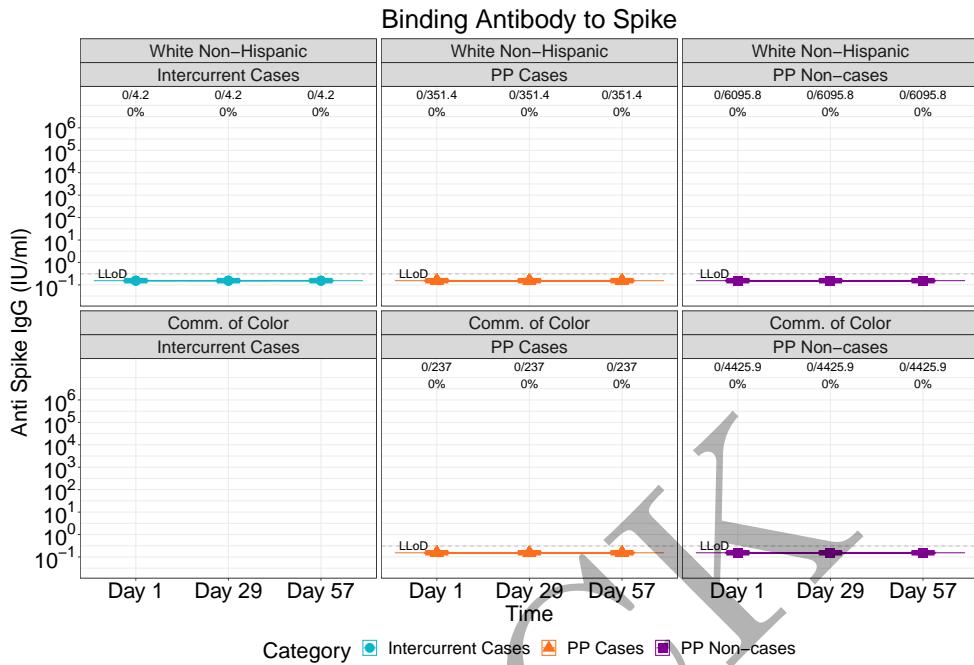


Figure 2.199: lineplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (version 2)

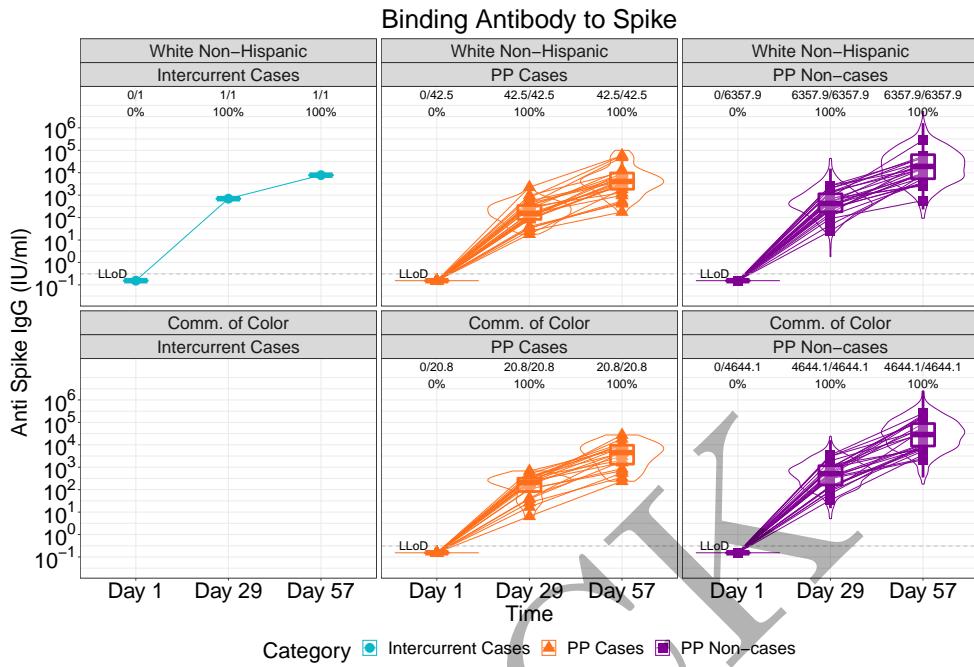


Figure 2.200: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (version 2)

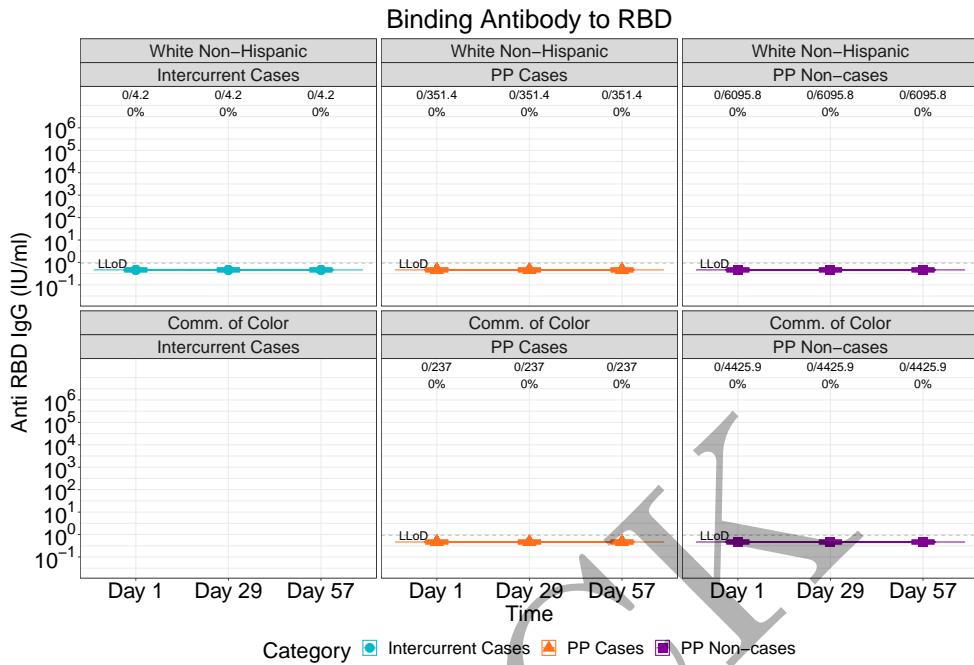


Figure 2.201: lineplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (version 2)

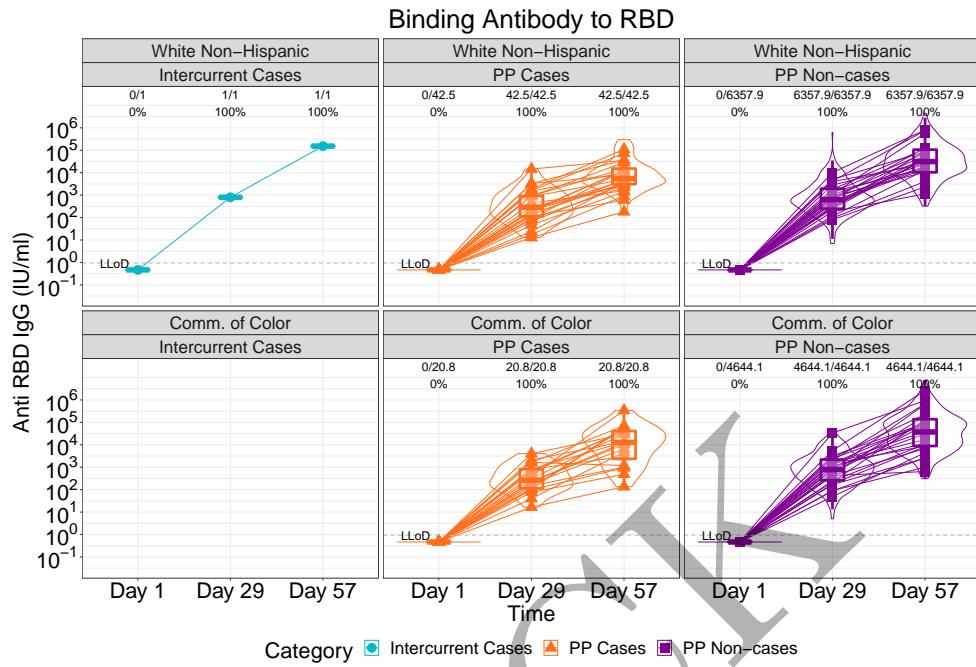


Figure 2.202: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (version 2)

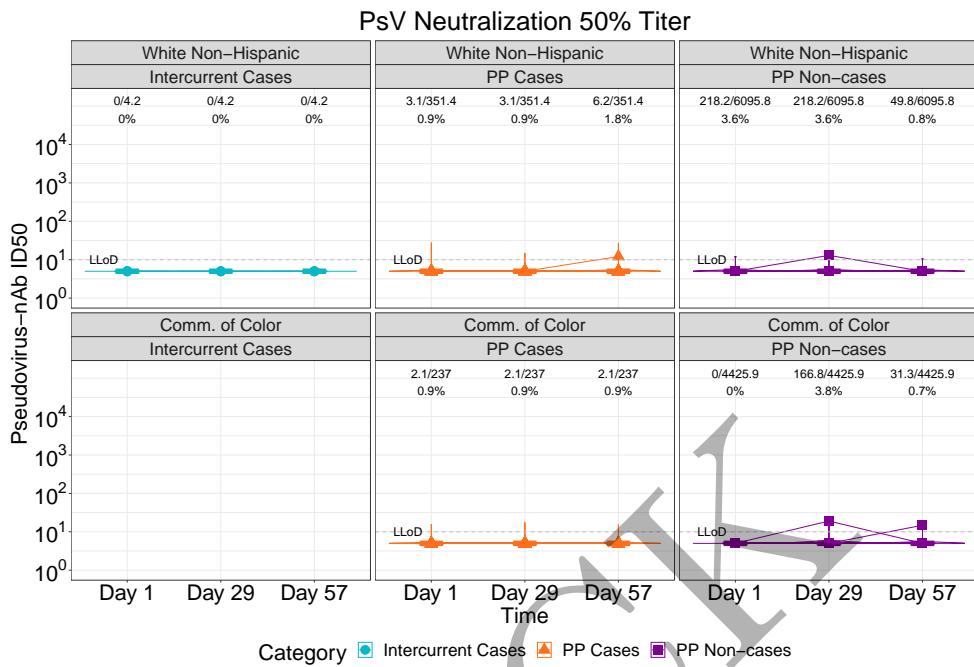


Figure 2.203: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by race and ethnic group (version 2)

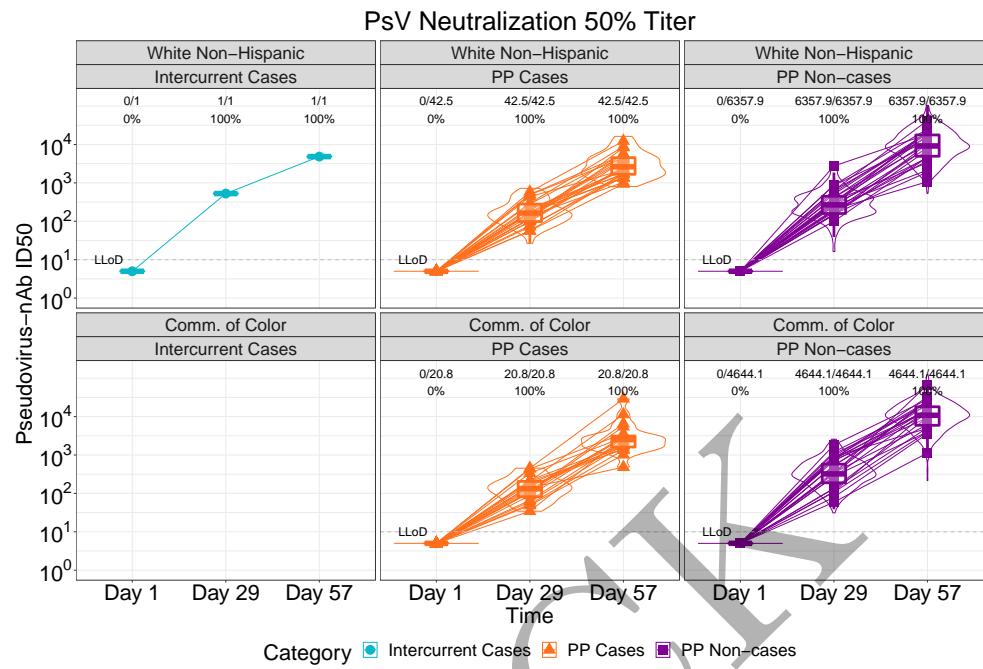


Figure 2.204: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by race and ethnic group (version 2)

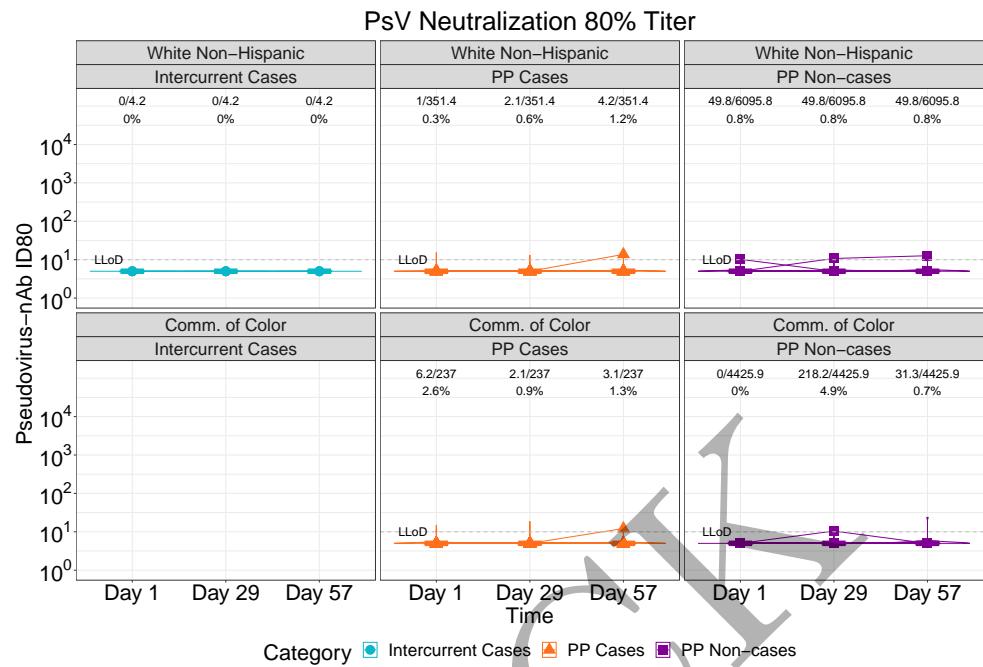


Figure 2.205: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by race and ethnic group (version 2)

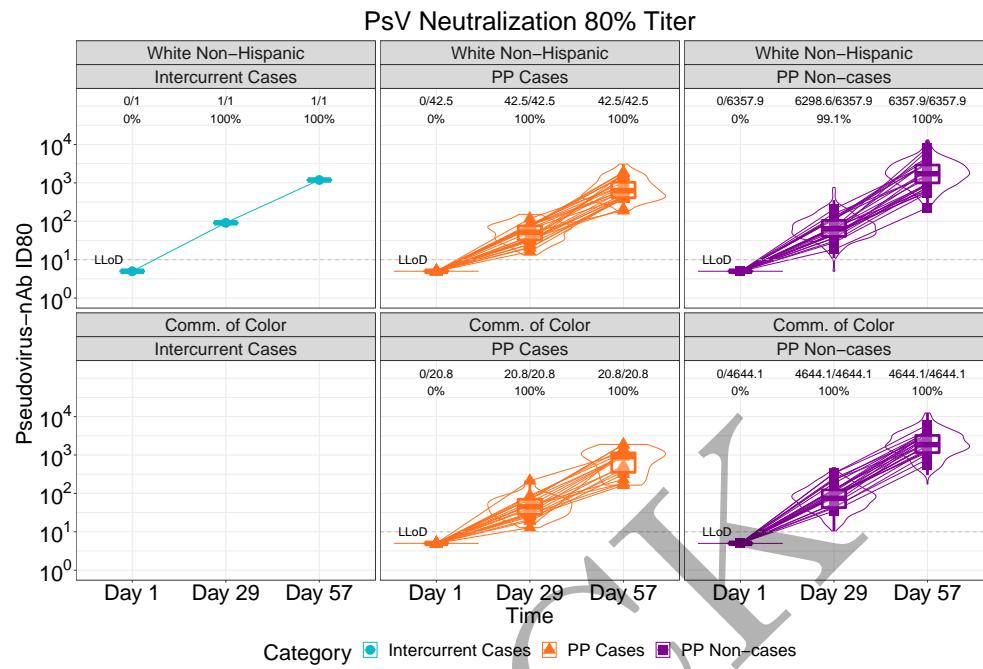


Figure 2.206: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by race and ethnic group (version 2)

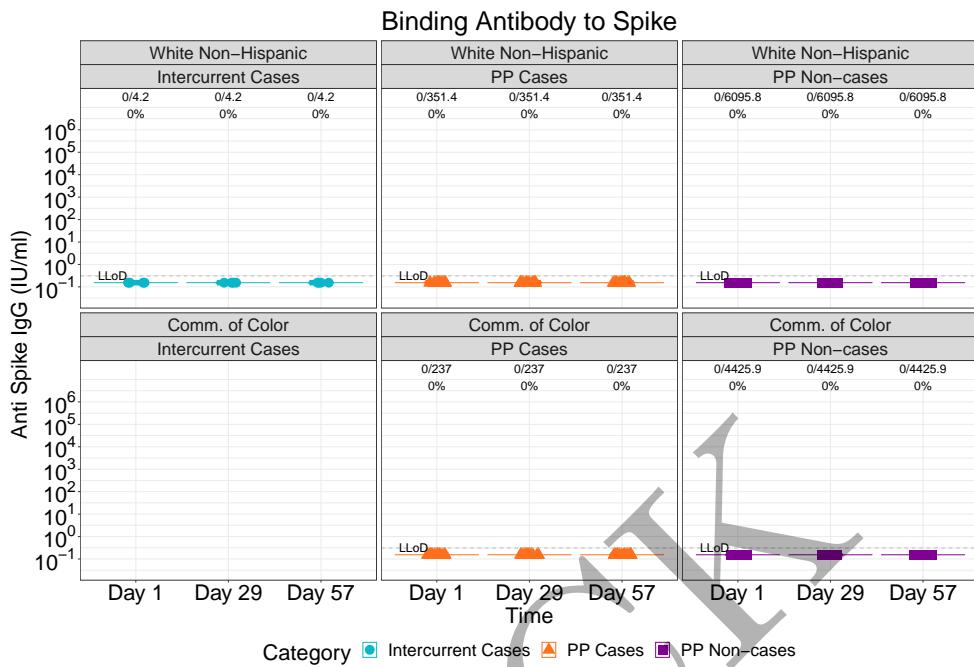


Figure 2.207: violinplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (version 2)

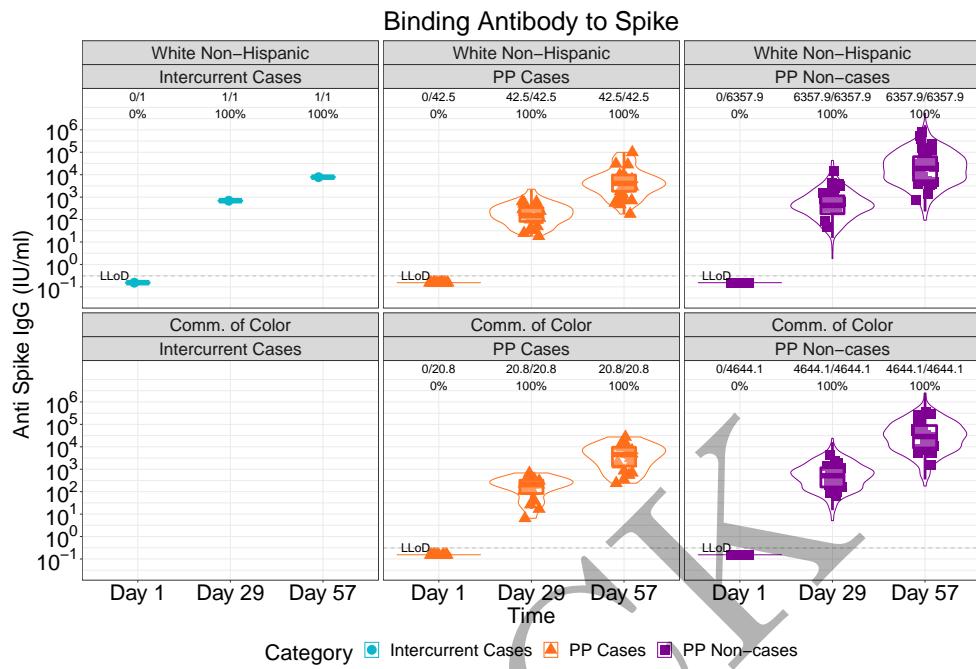


Figure 2.208: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (version 2)

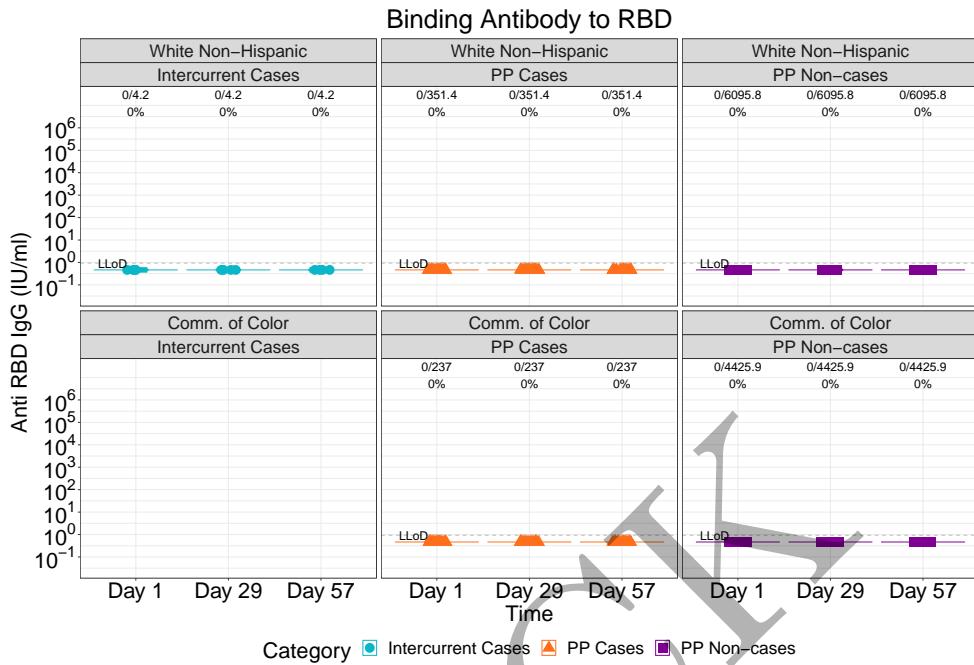


Figure 2.209: violinplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (version 2)

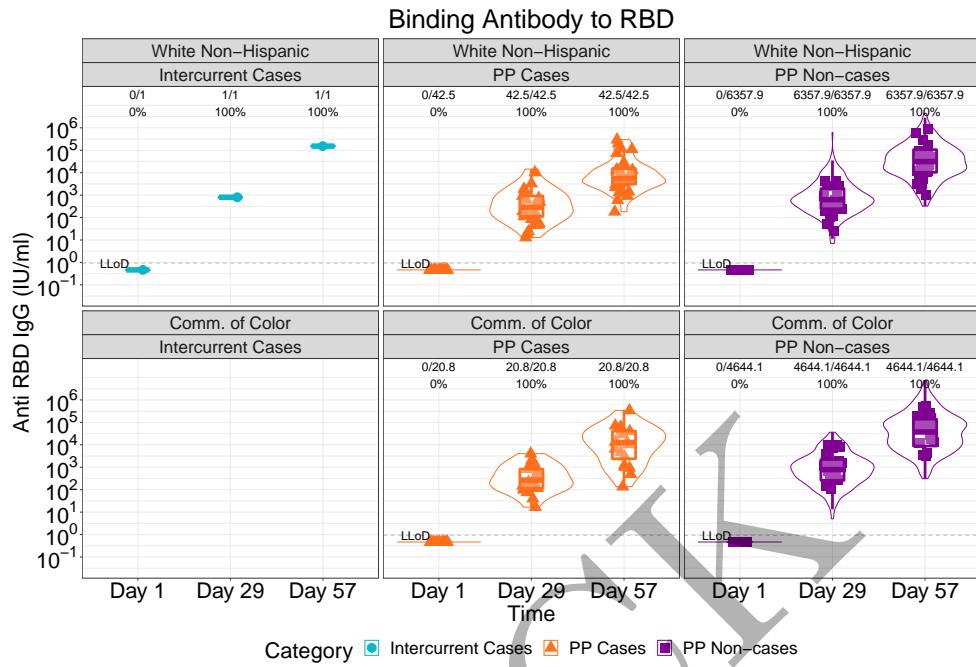


Figure 2.210: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (version 2)

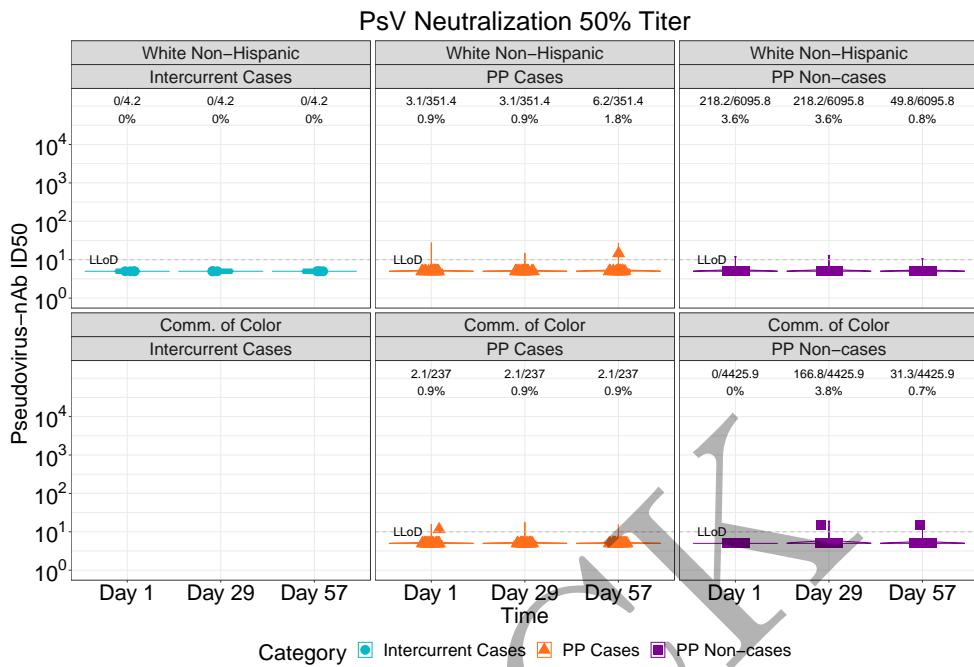


Figure 2.211: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by race and ethnic group (version 2)

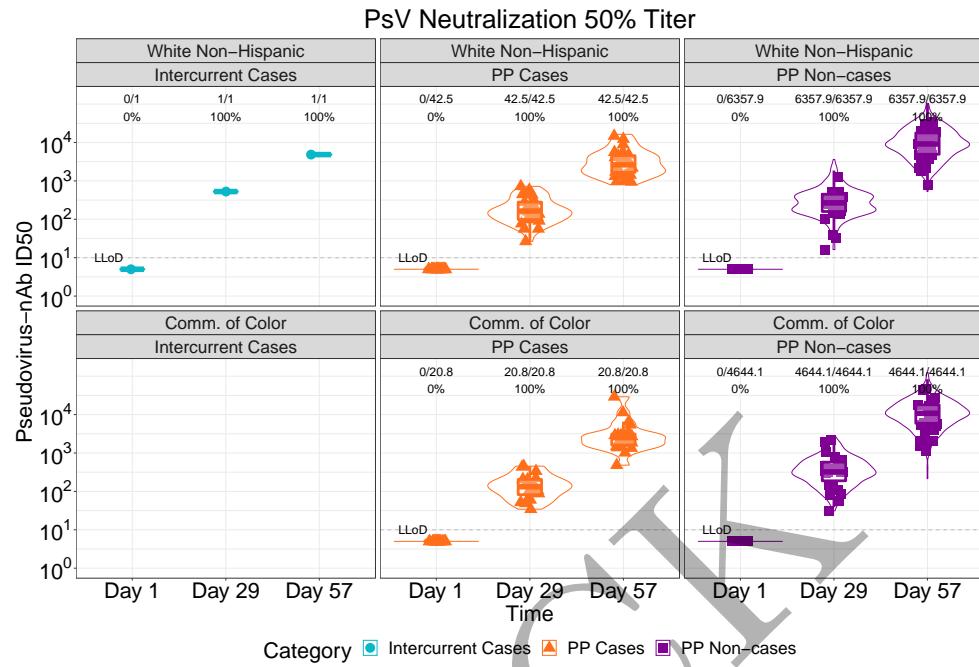


Figure 2.212: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by race and ethnic group (version 2)

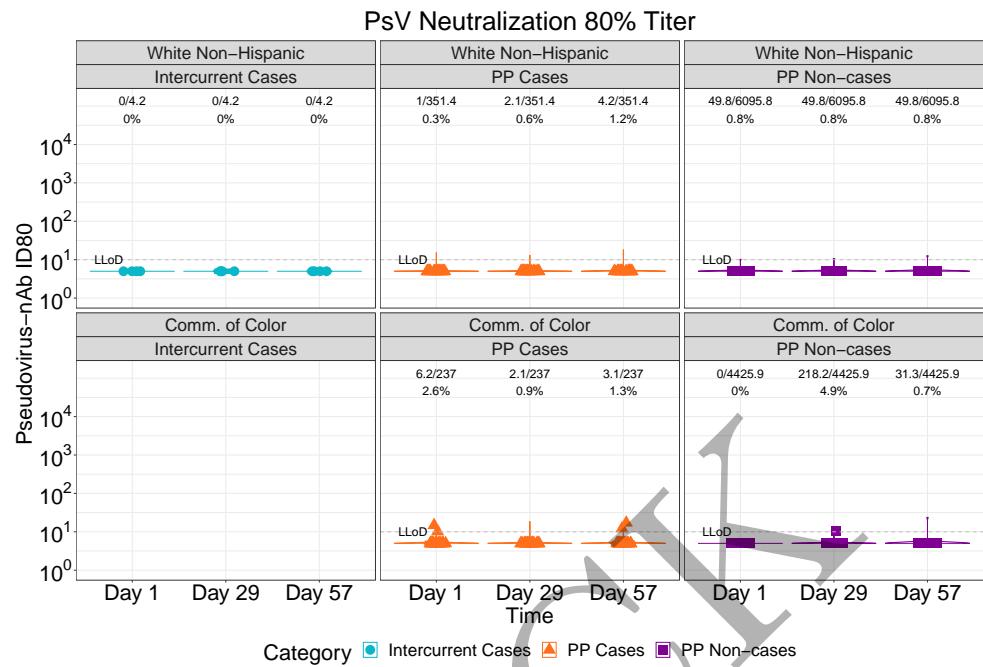


Figure 2.213: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by race and ethnic group (version 2)

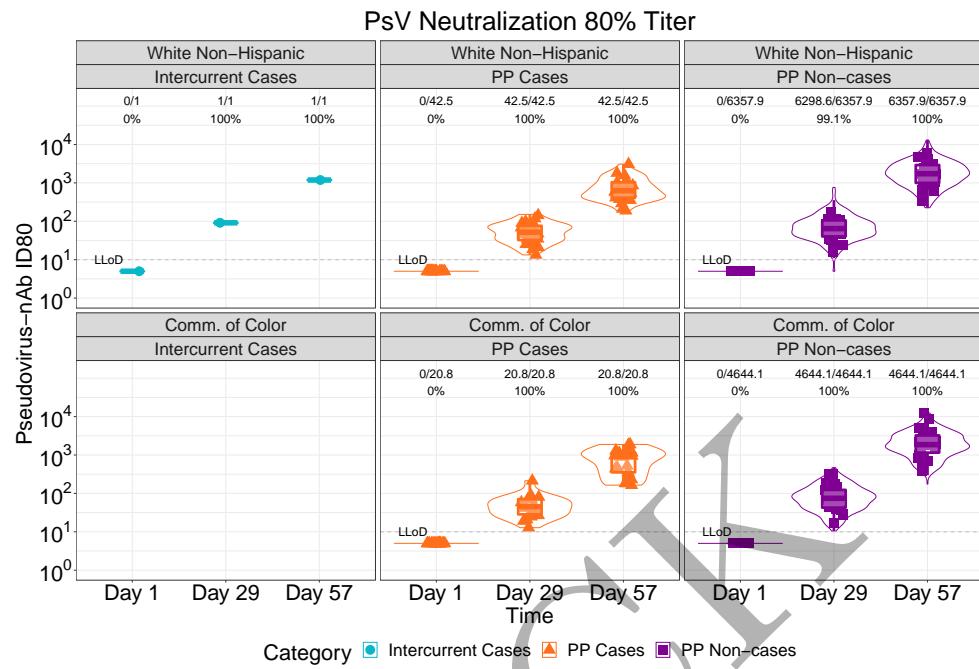


Figure 2.214: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by race and ethnic group (version 2)

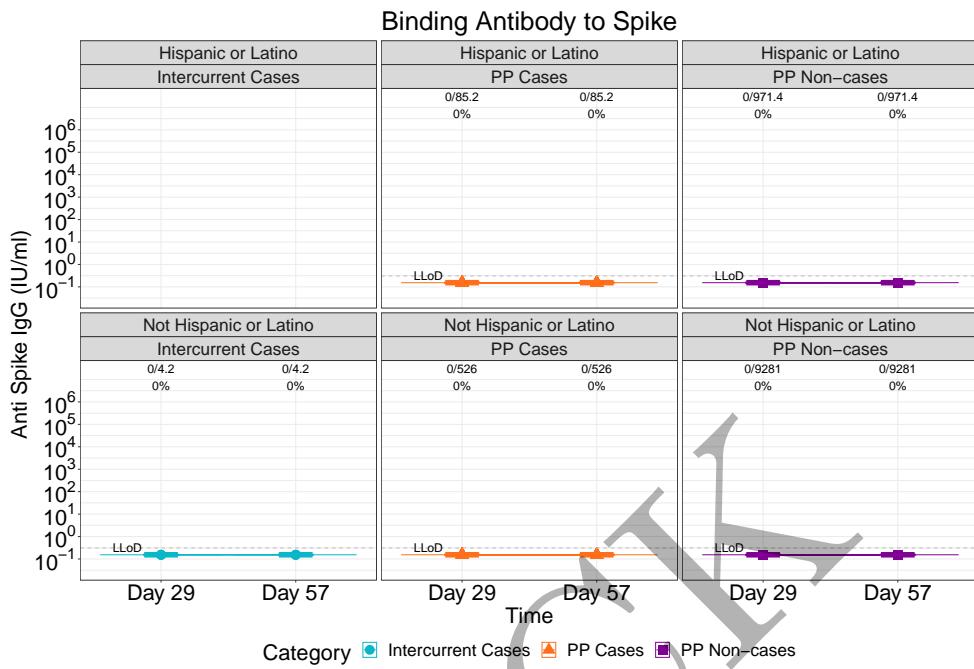


Figure 2.215: lineplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)

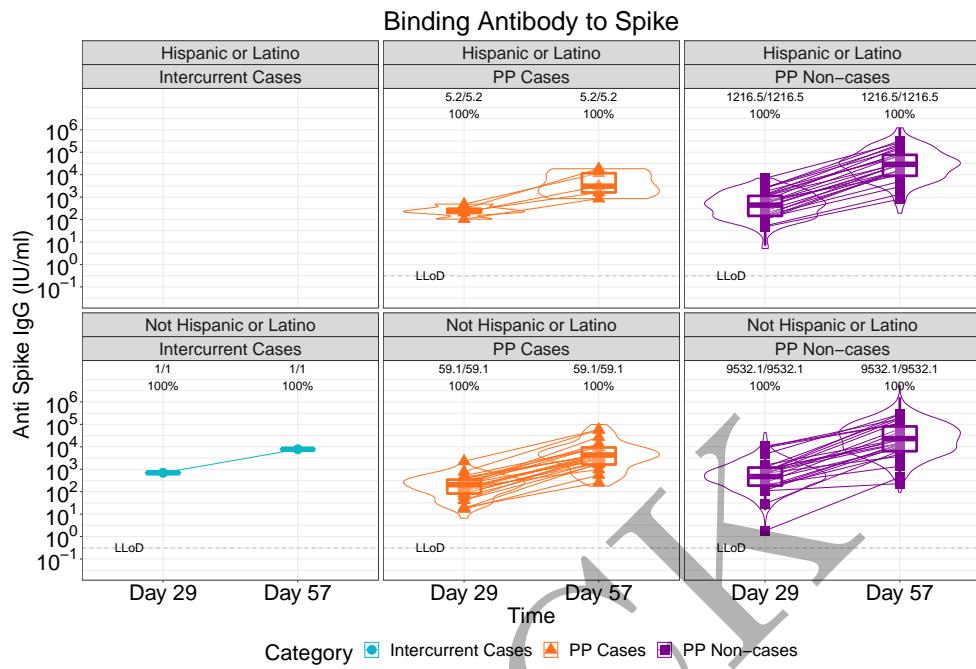


Figure 2.216: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)

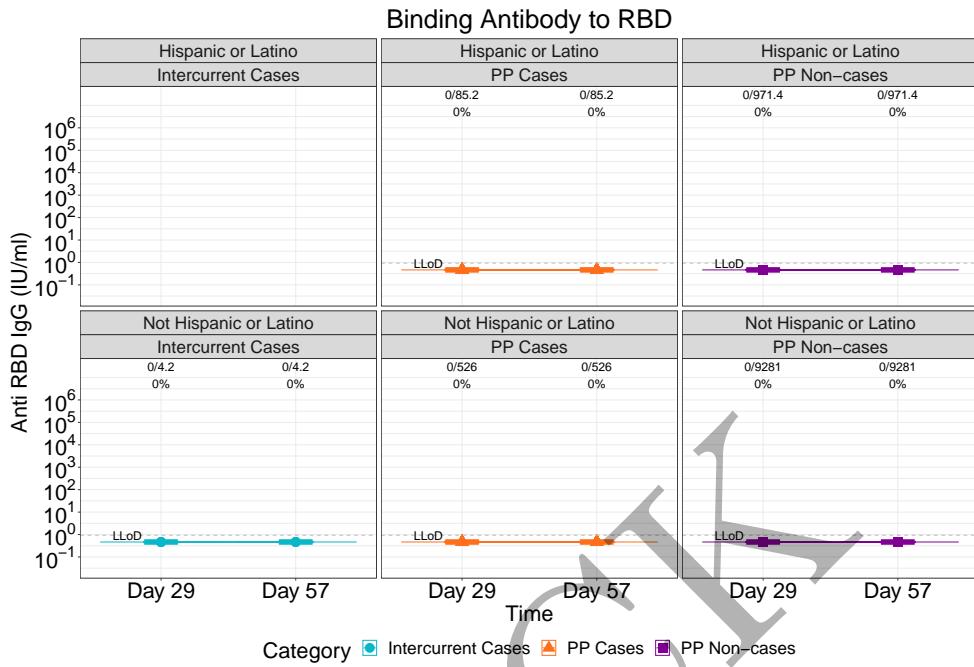


Figure 2.217: lineplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)

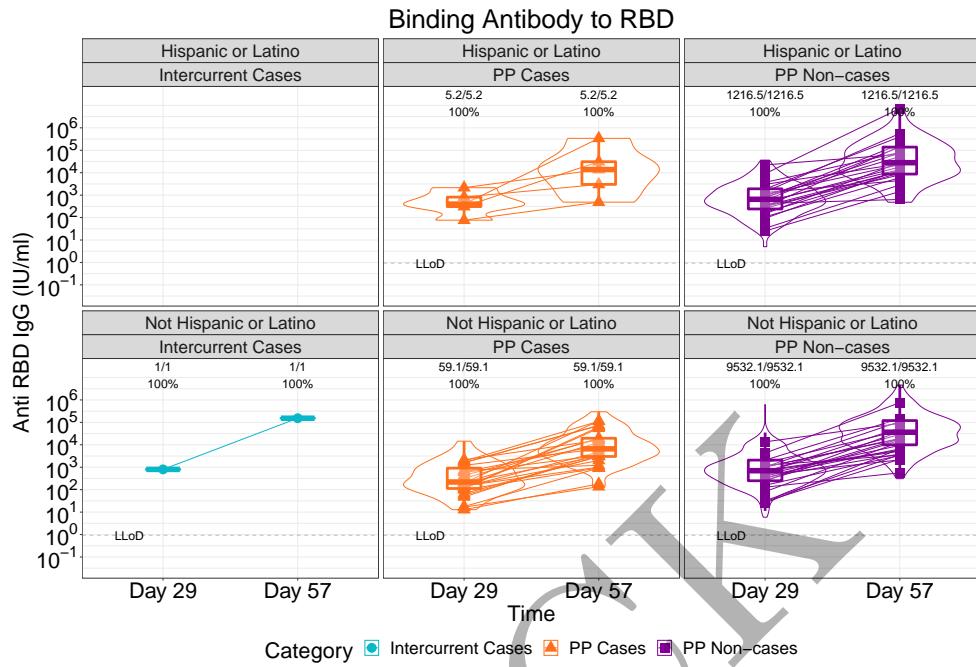


Figure 2.218: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)

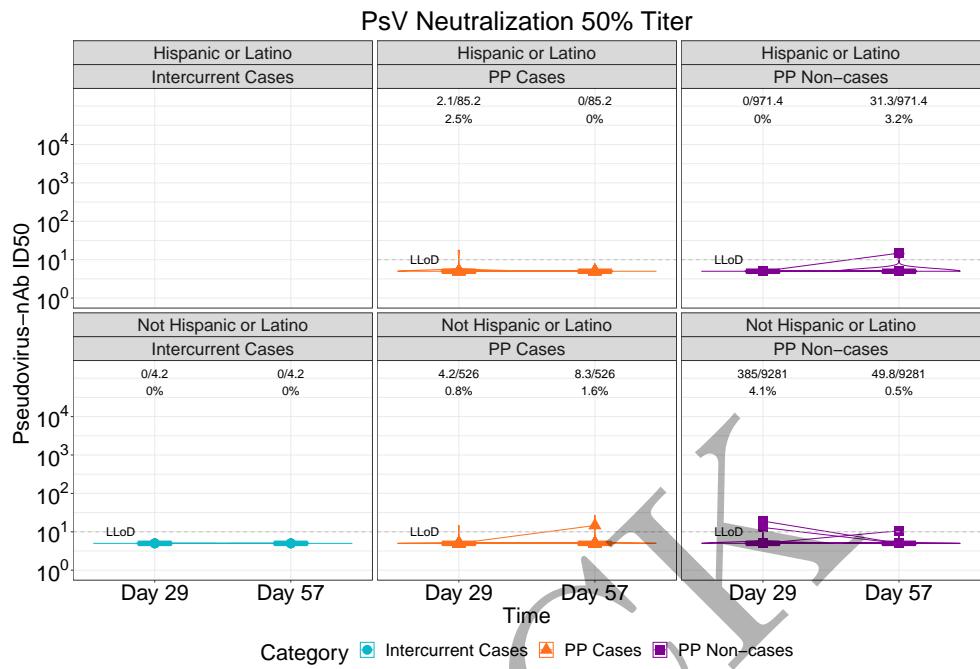


Figure 2.219: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)

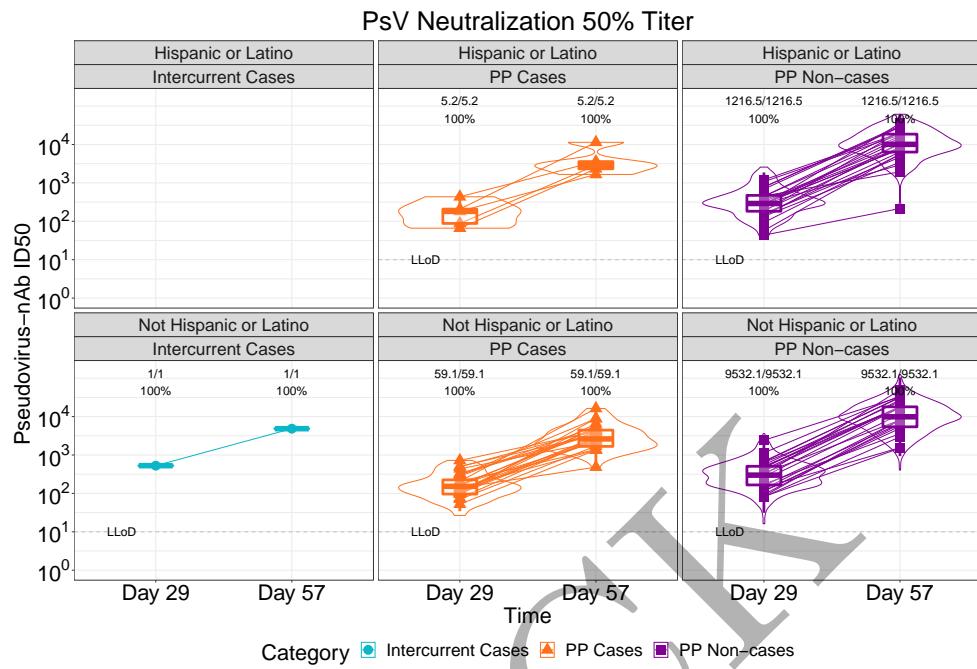


Figure 2.220: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)

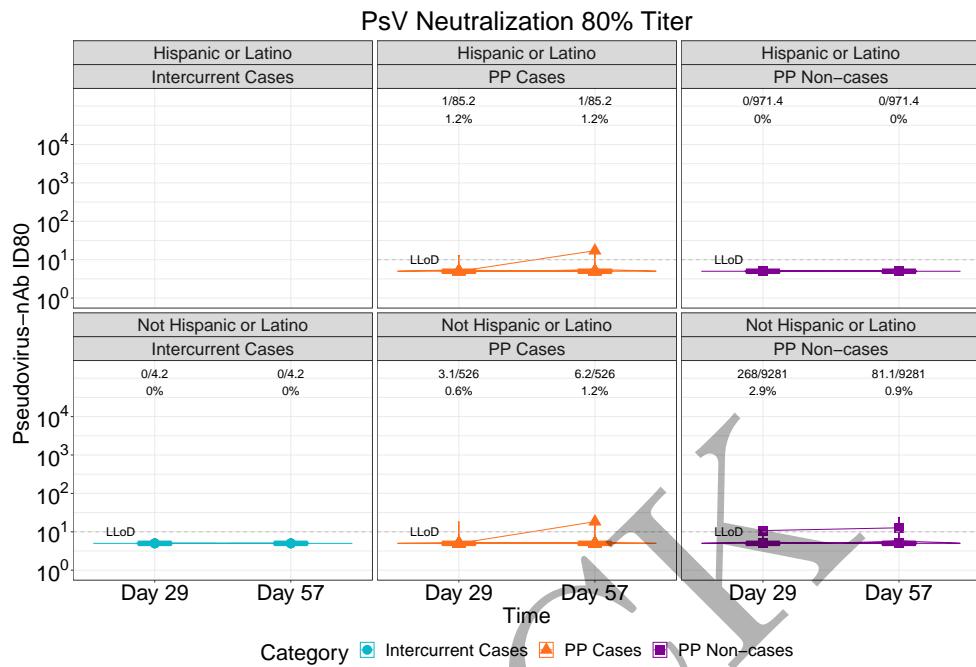


Figure 2.221: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)

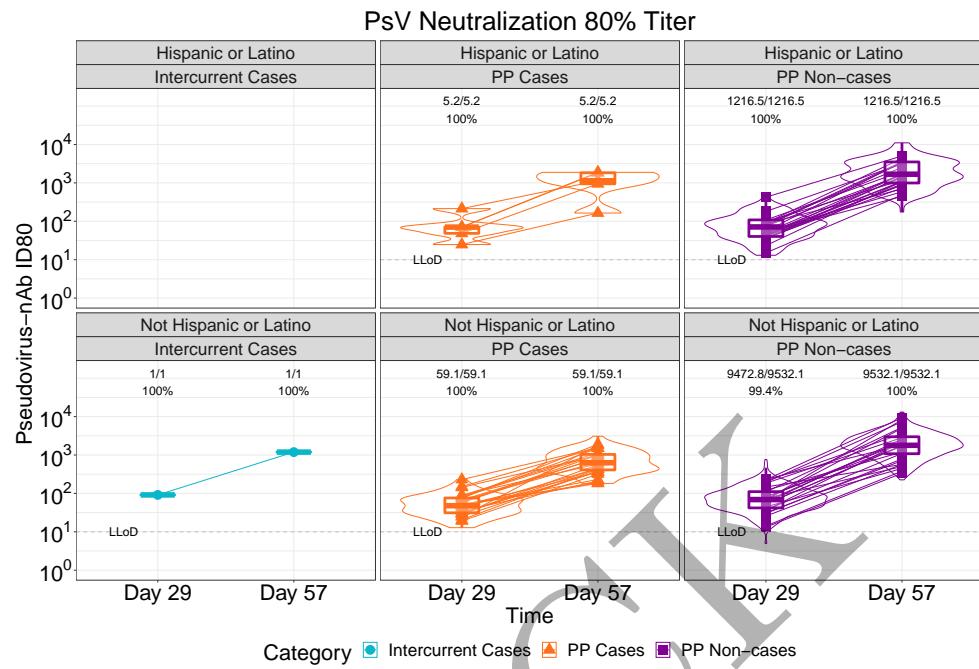


Figure 2.222: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)

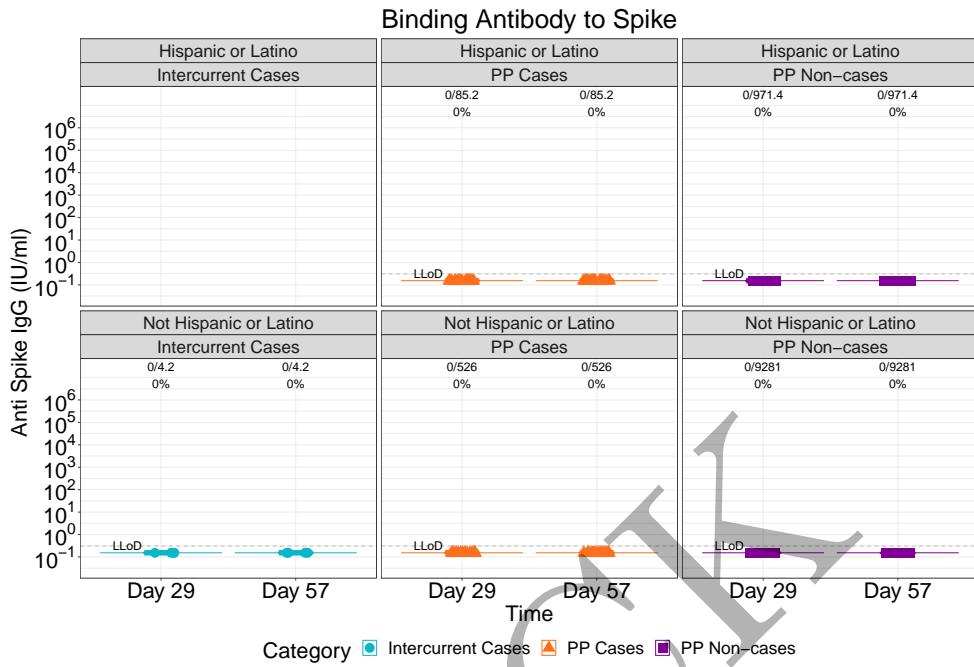


Figure 2.223: violinplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)

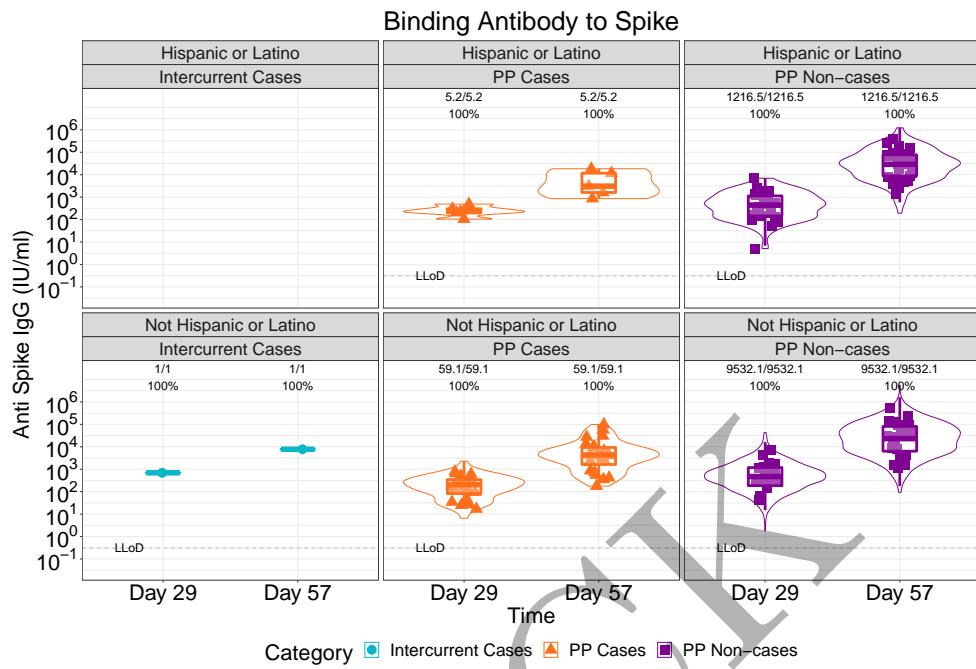


Figure 2.224: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)

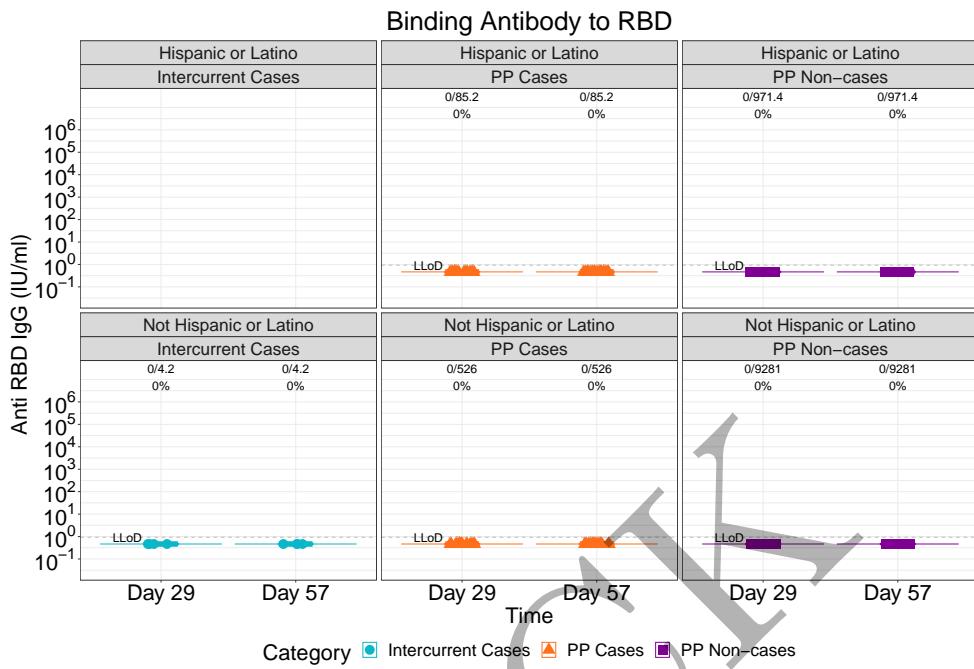


Figure 2.225: violinplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)

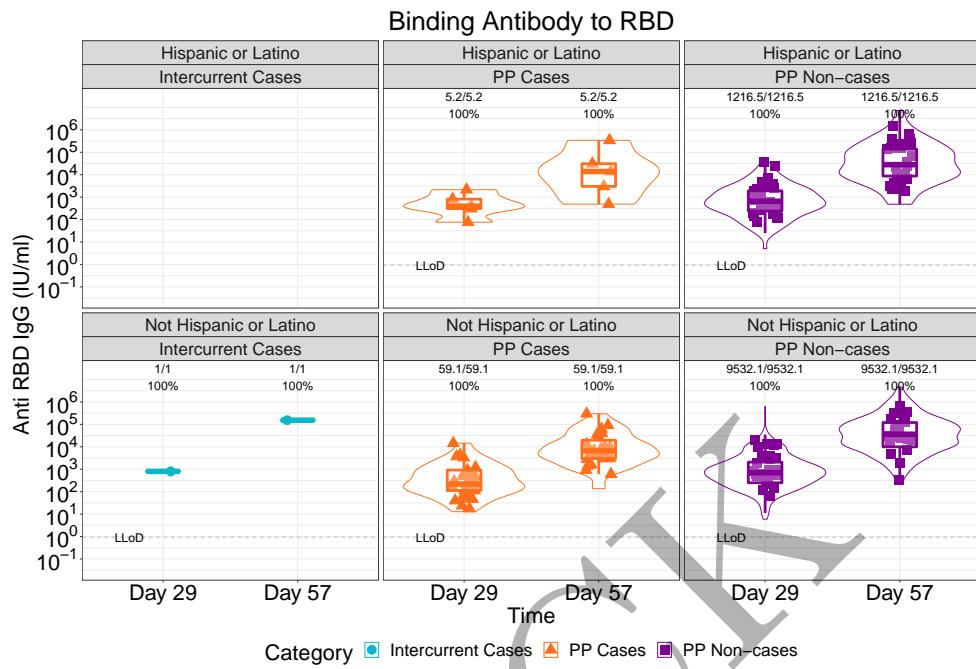


Figure 2.226: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)

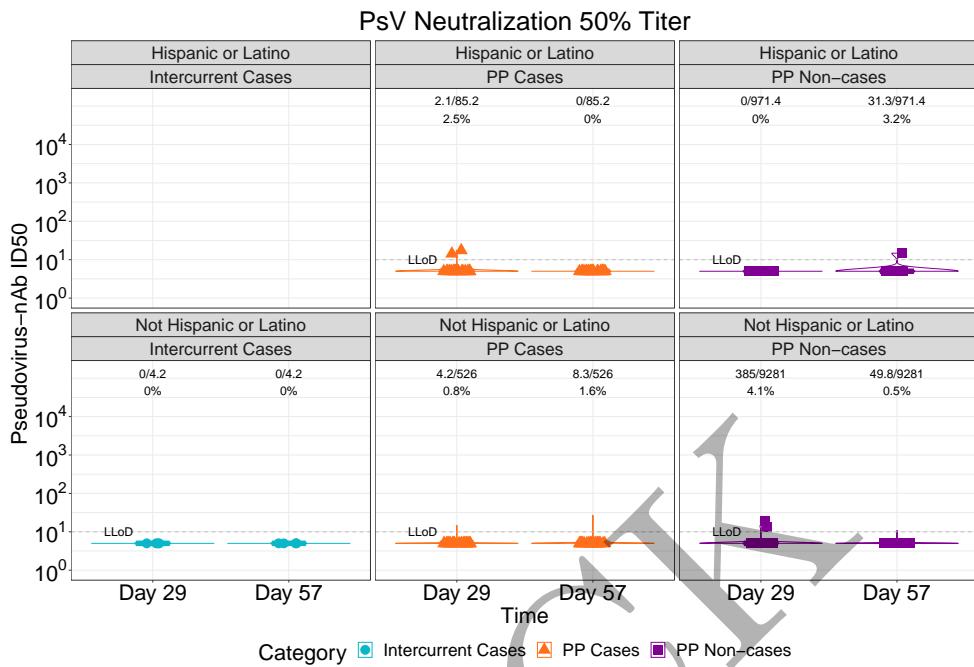


Figure 2.227: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)

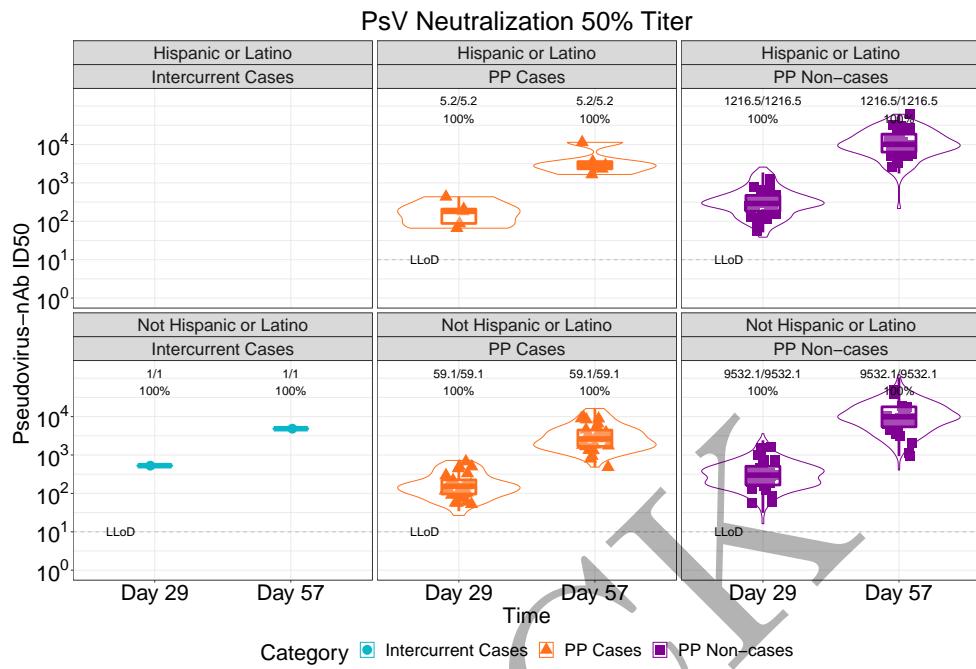


Figure 2.228: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)

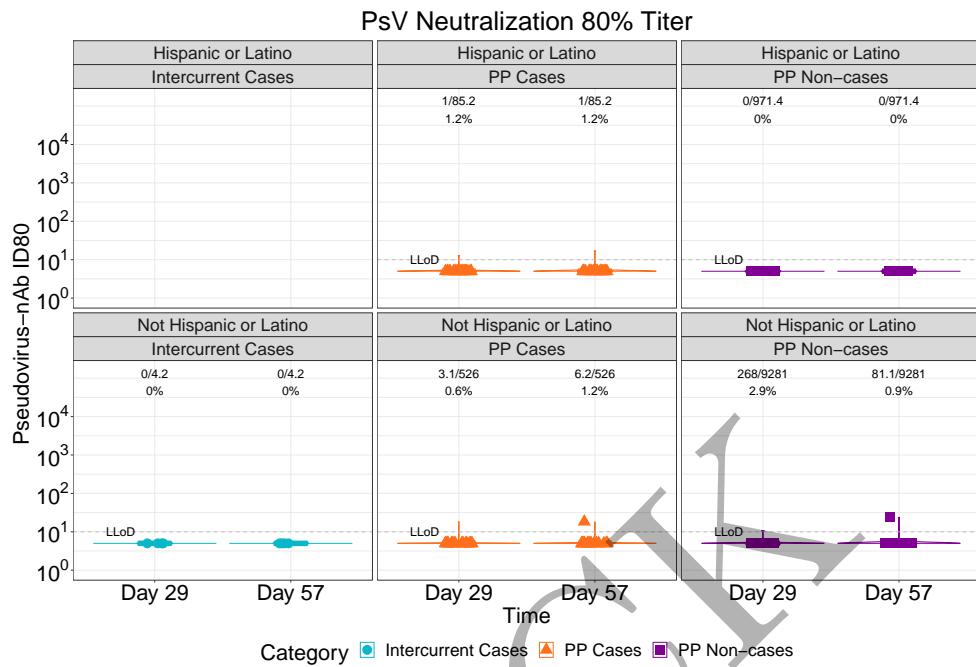


Figure 2.229: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)

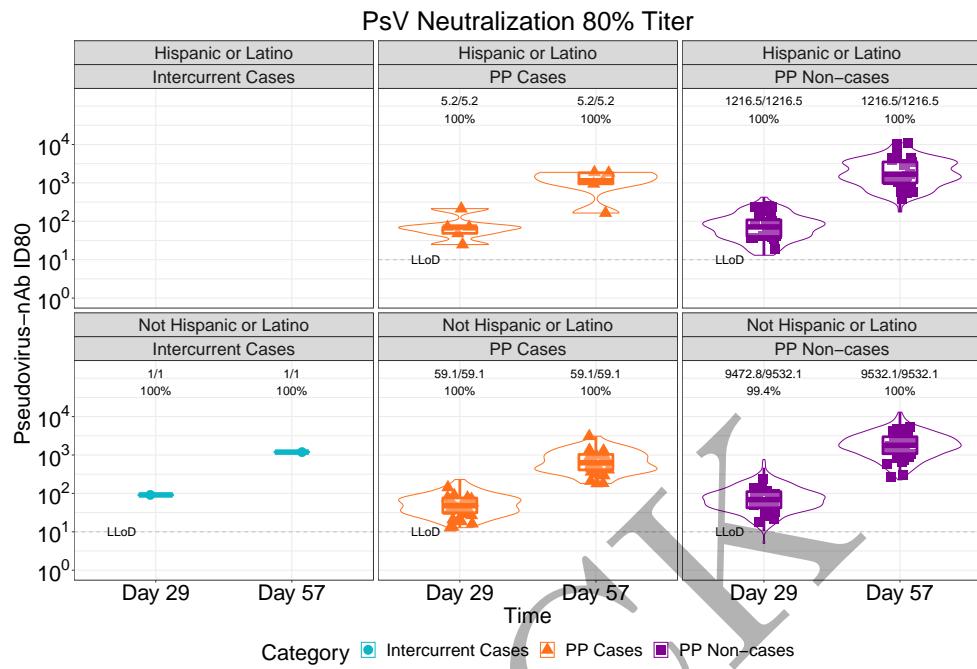


Figure 2.230: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)

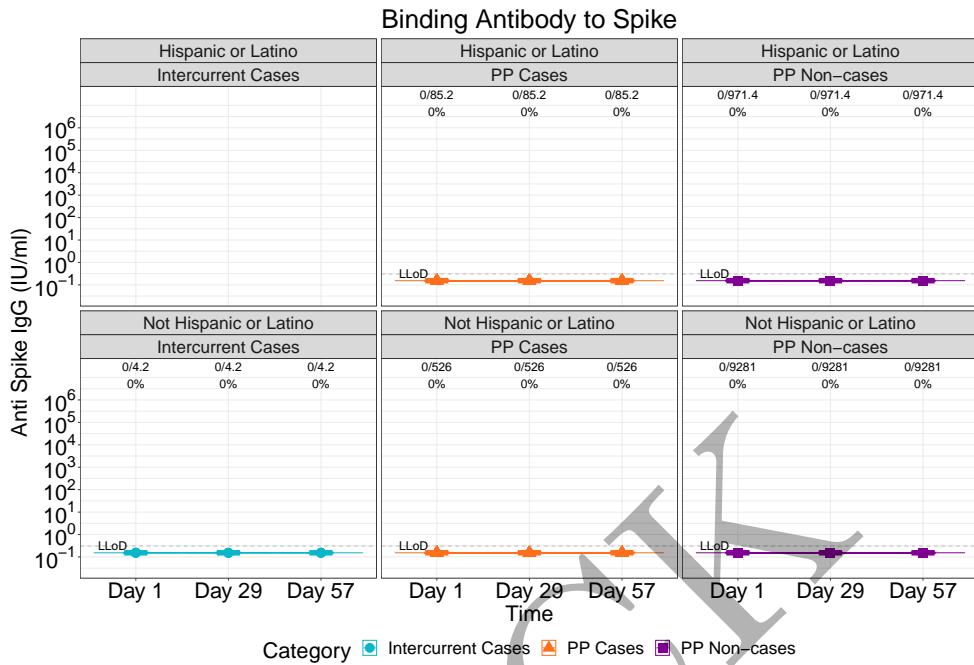


Figure 2.231: lineplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)

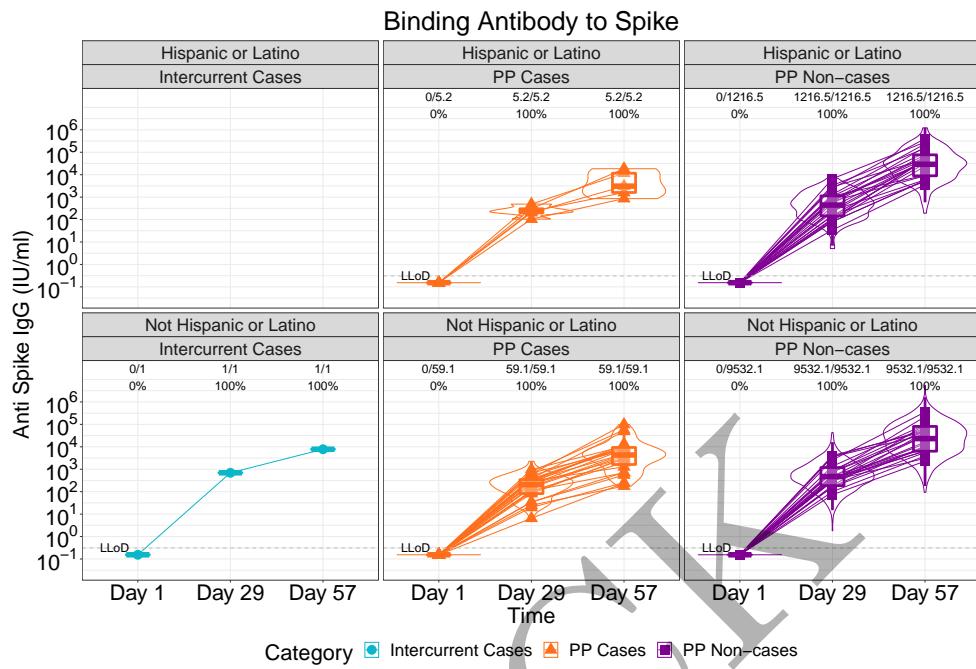


Figure 2.232: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)

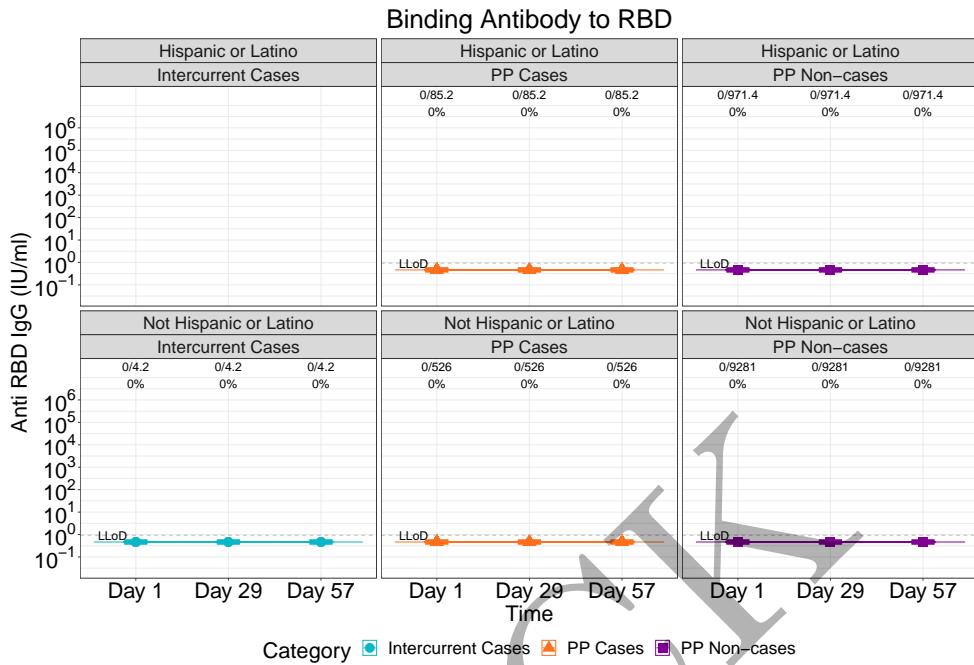


Figure 2.233: lineplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)

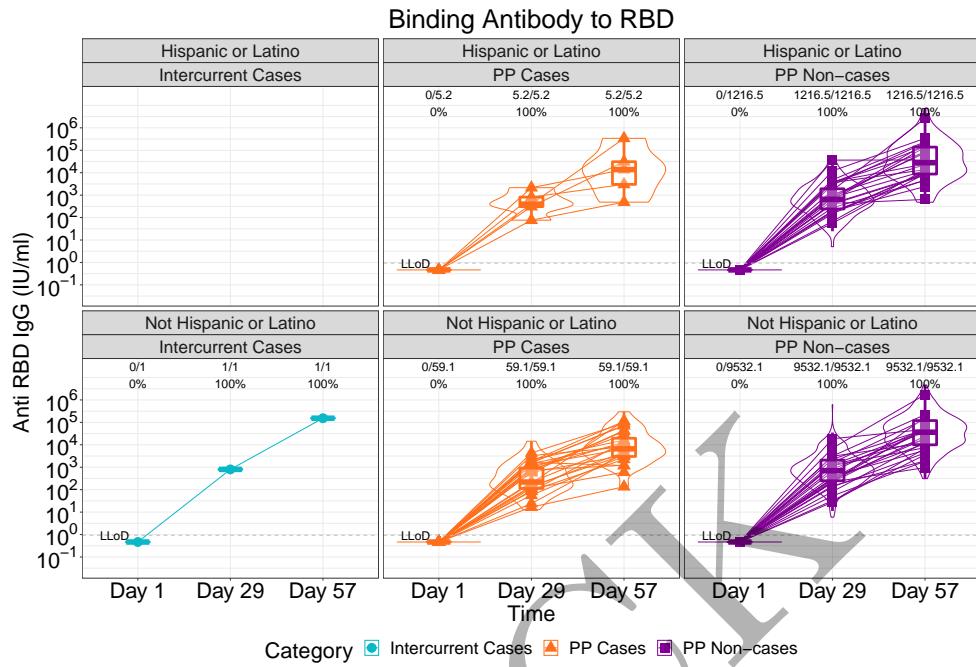


Figure 2.234: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)

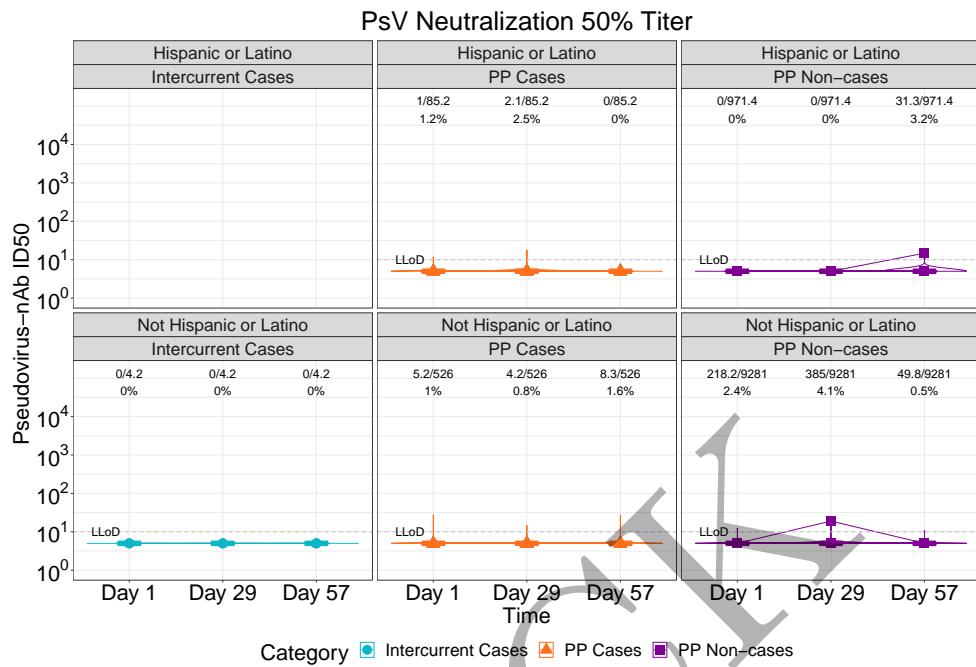


Figure 2.235: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)

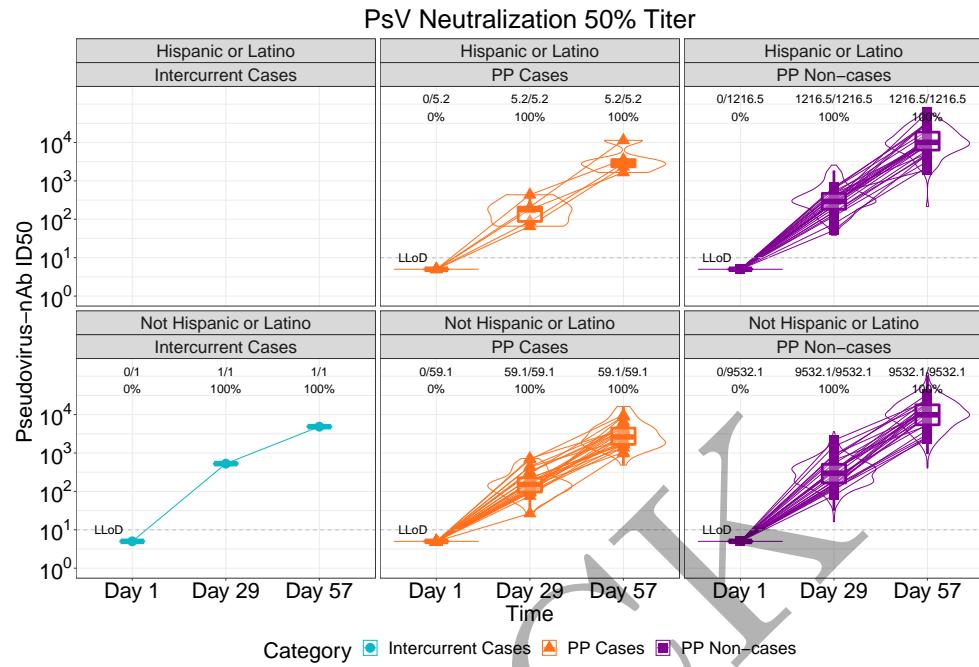


Figure 2.236: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)

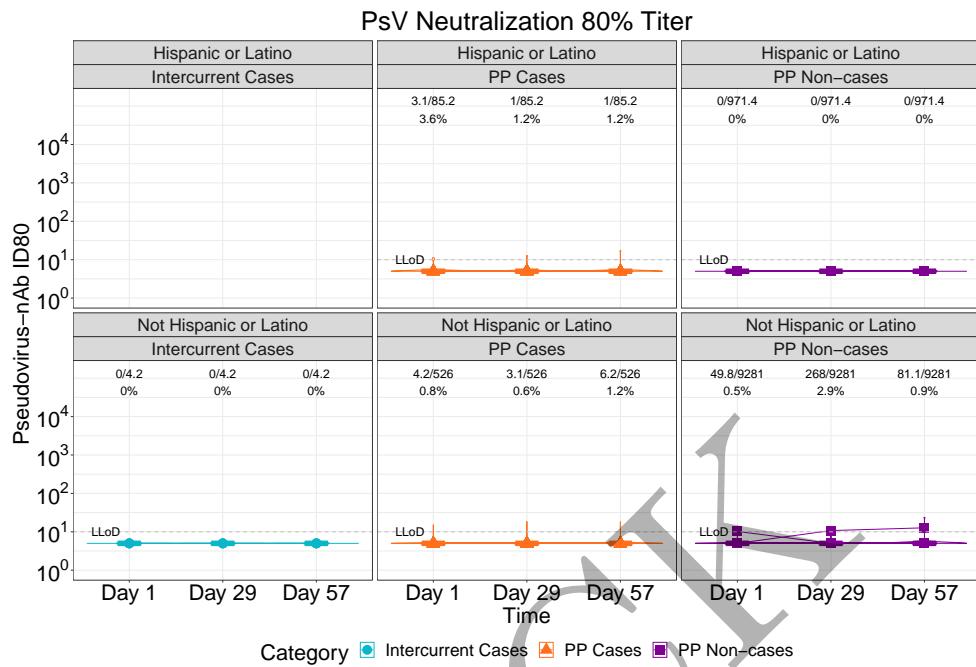


Figure 2.237: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)

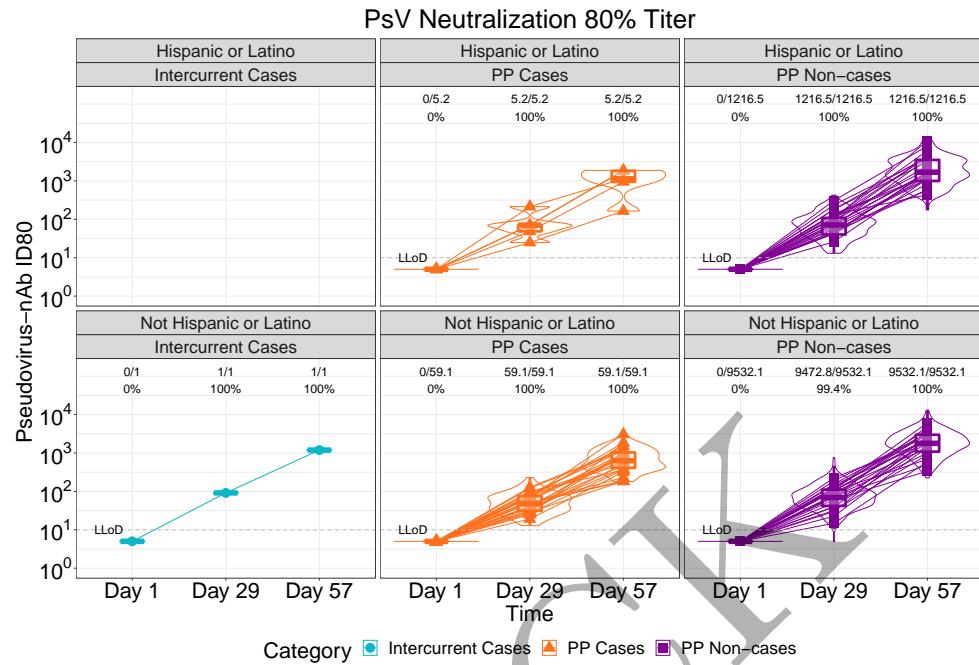


Figure 2.238: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)

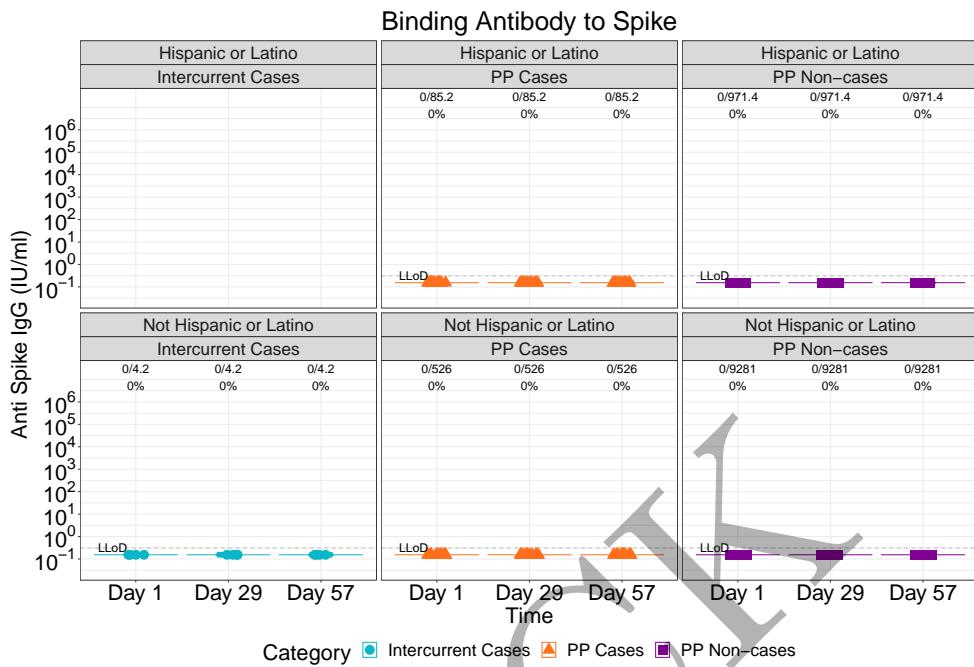


Figure 2.239: violinplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)

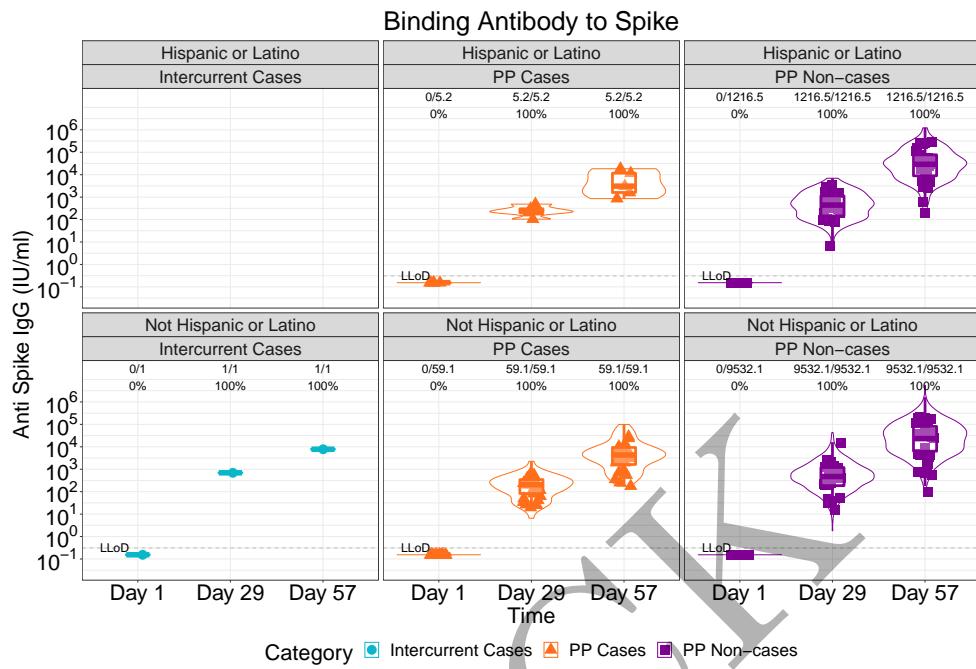


Figure 2.240: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)

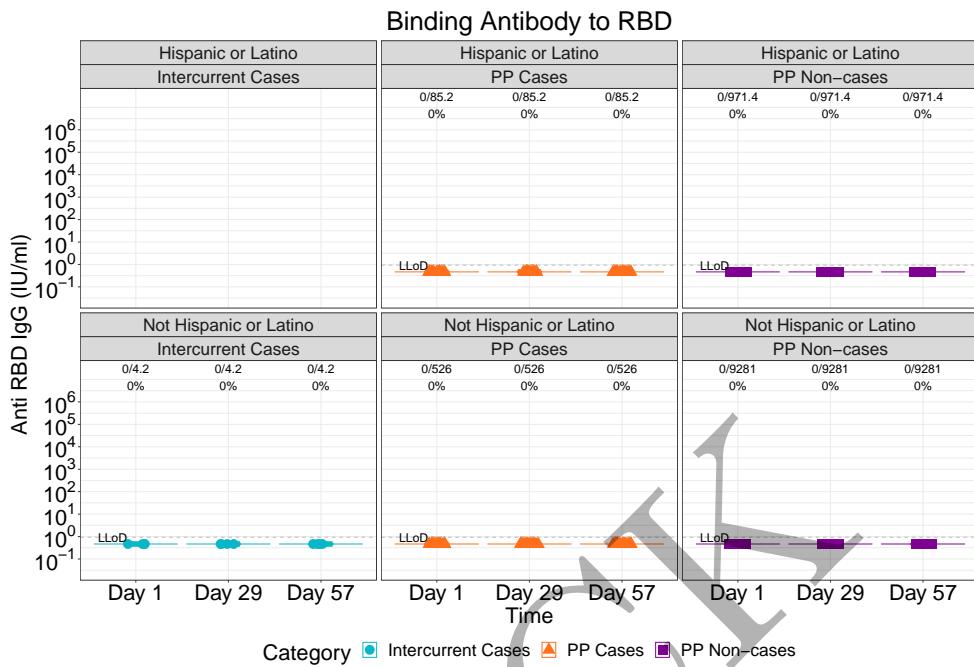


Figure 2.241: violinplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)

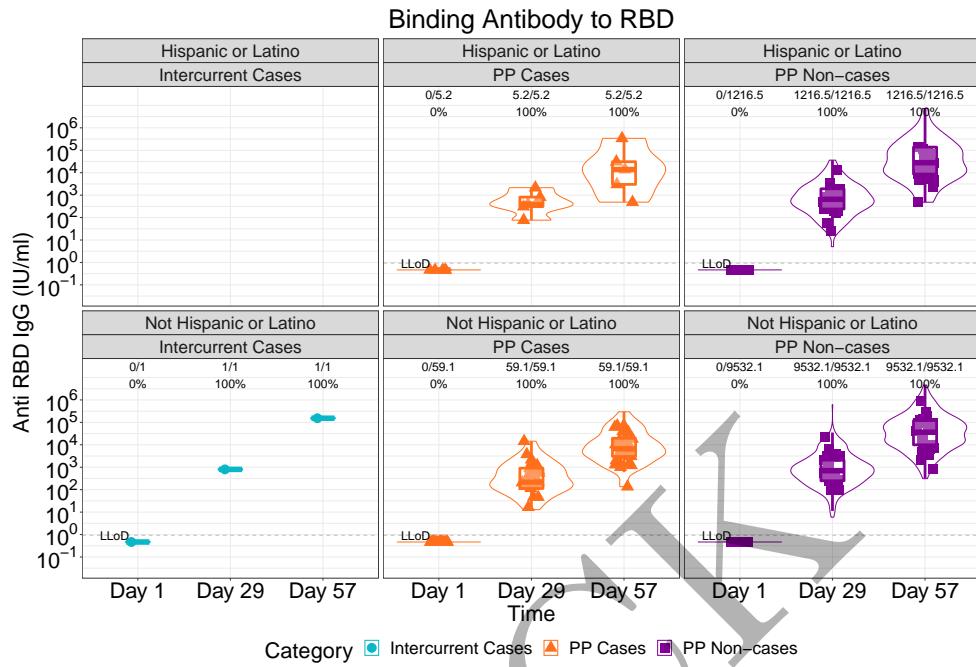


Figure 2.242: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)

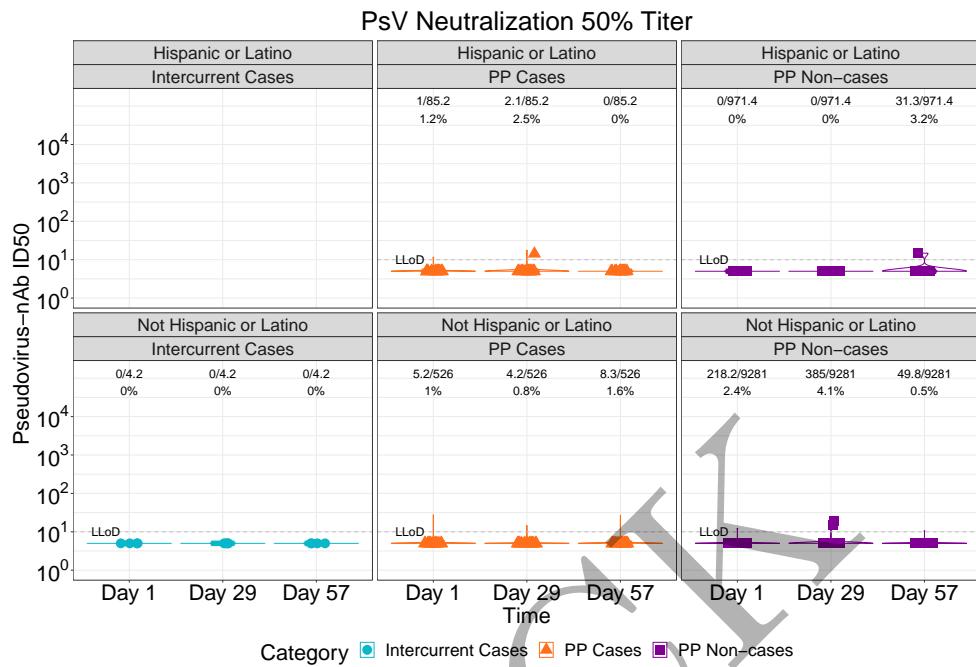


Figure 2.243: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)

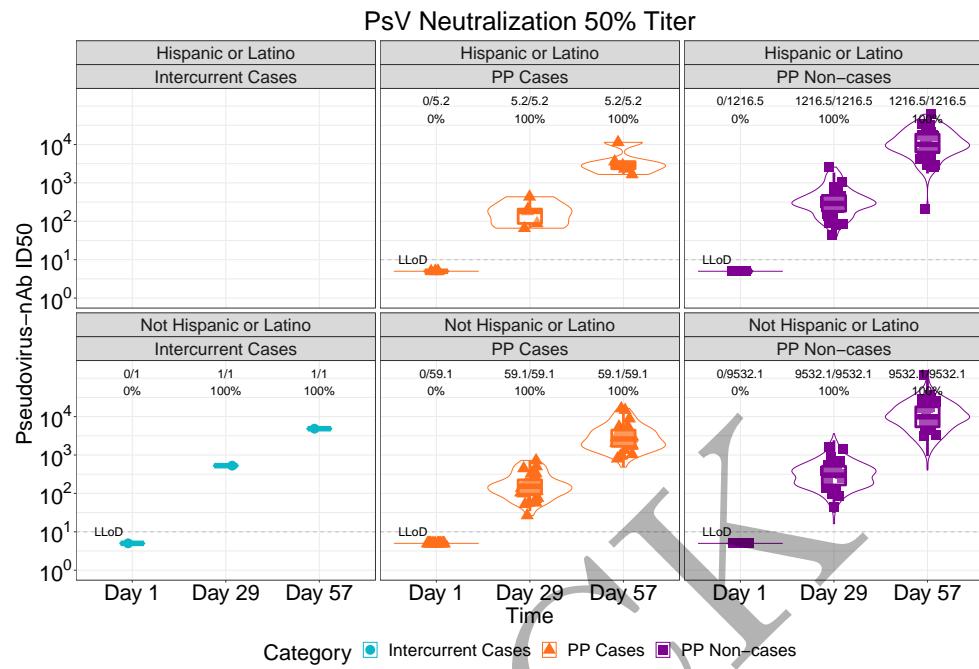


Figure 2.244: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)

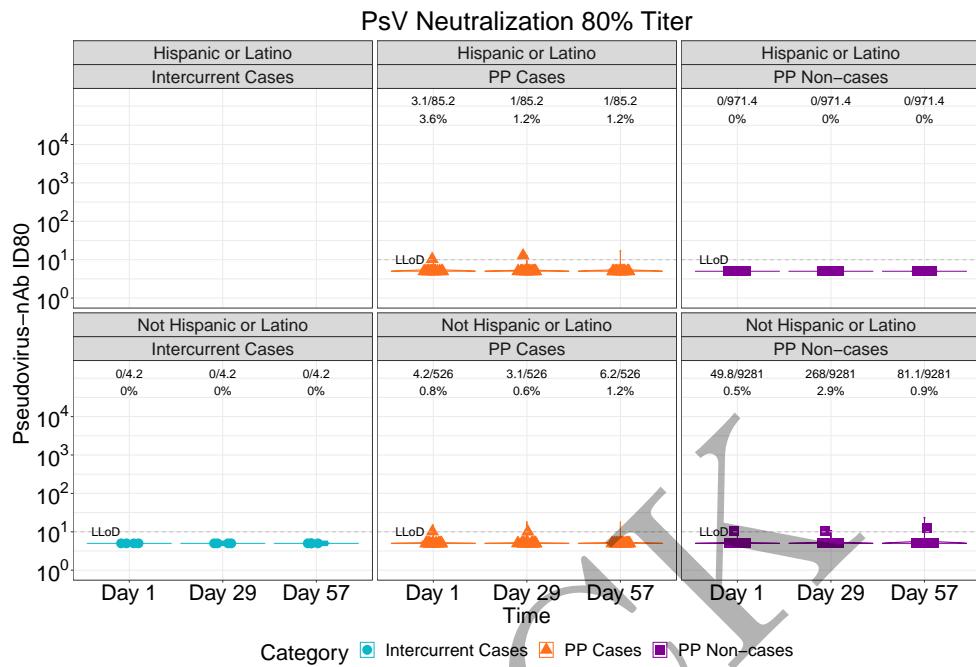


Figure 2.245: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)

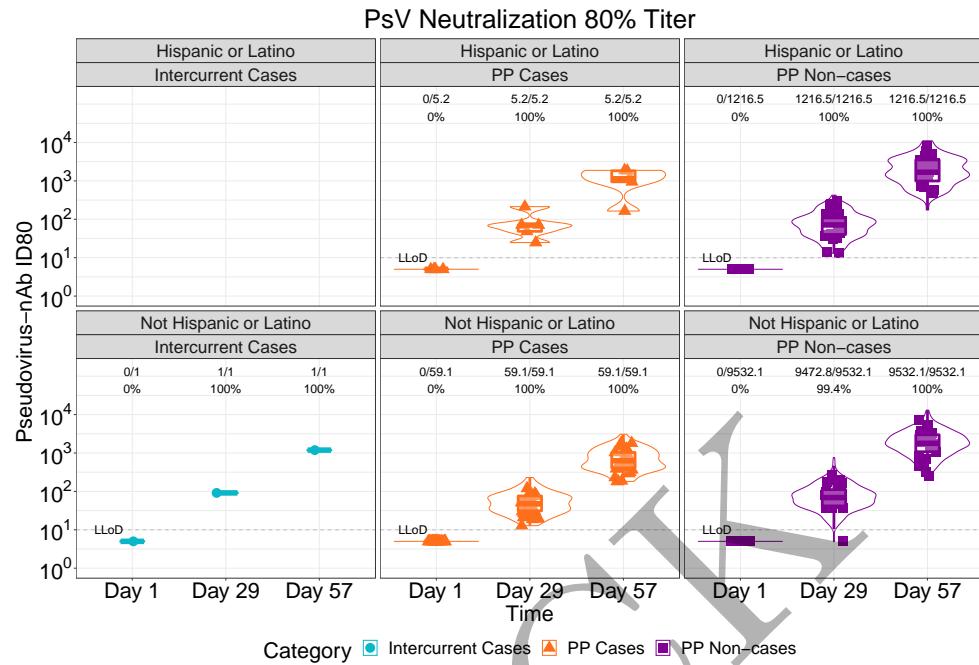


Figure 2.246: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)

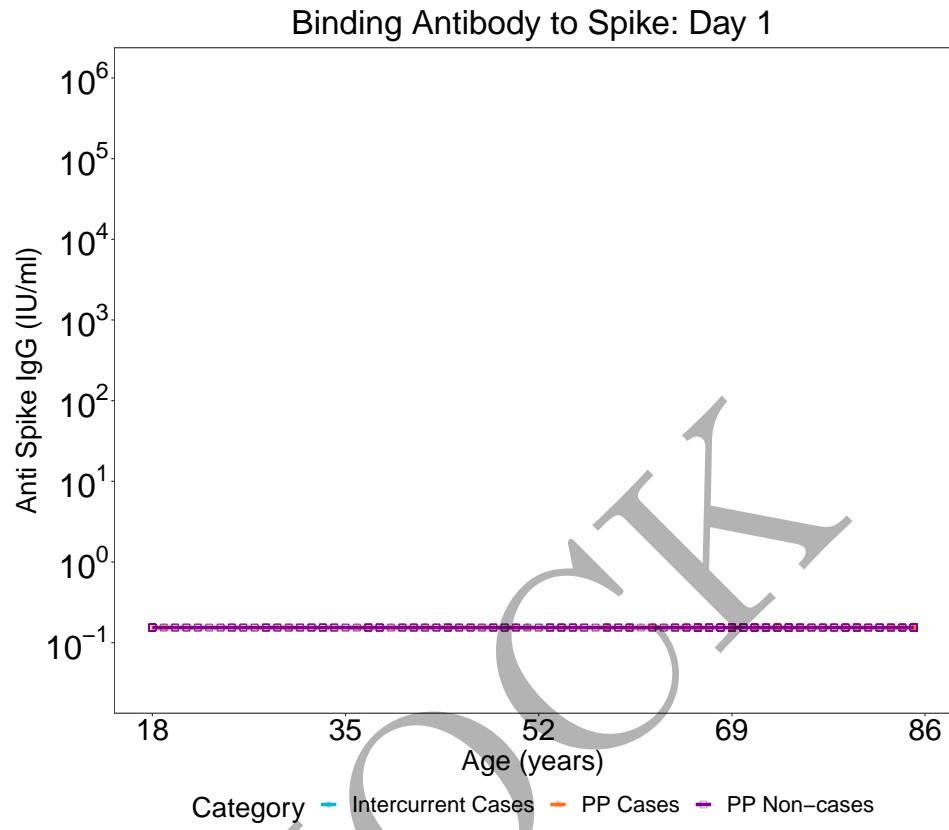


Figure 2.247: scatterplots of Binding Antibody to Spike: baseline negative vaccine arm at day 1

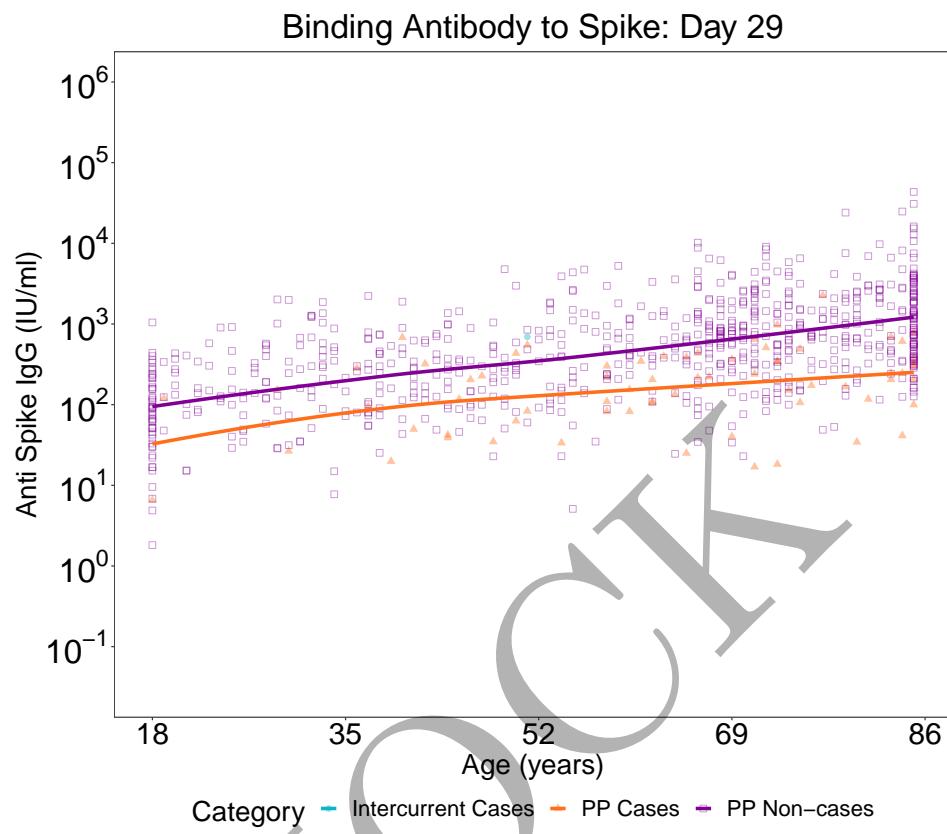


Figure 2.248: scatterplots of Binding Antibody to Spike: baseline negative vaccine arm at day 29

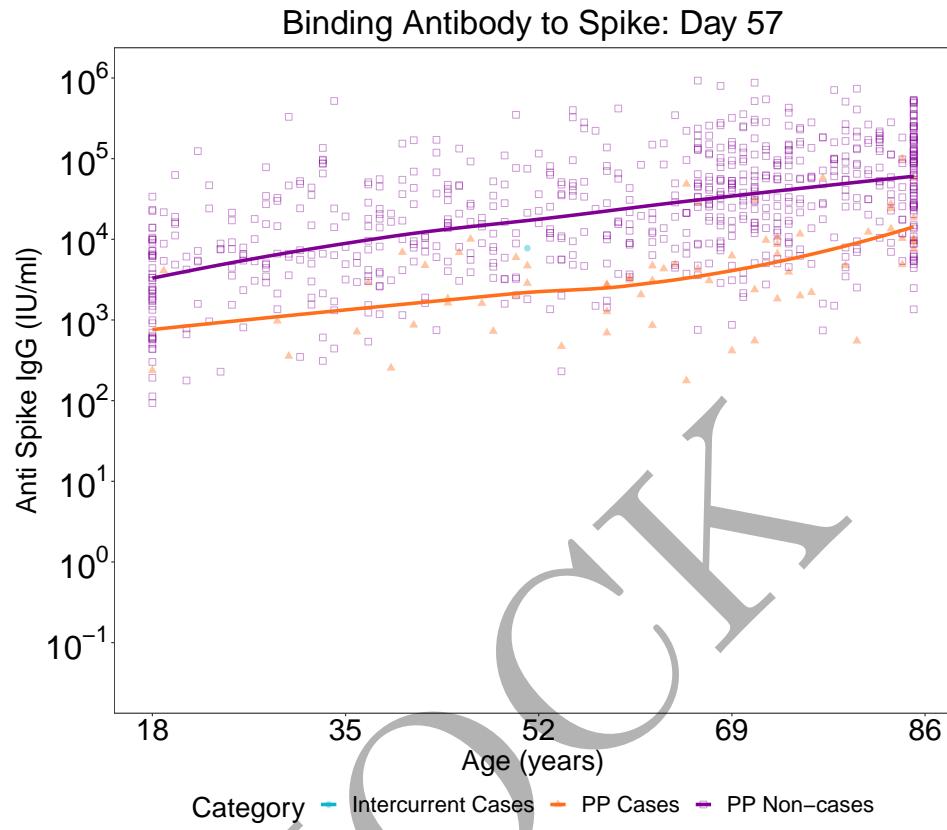


Figure 2.249: scatterplots of Binding Antibody to Spike: baseline negative vaccine arm at day 57

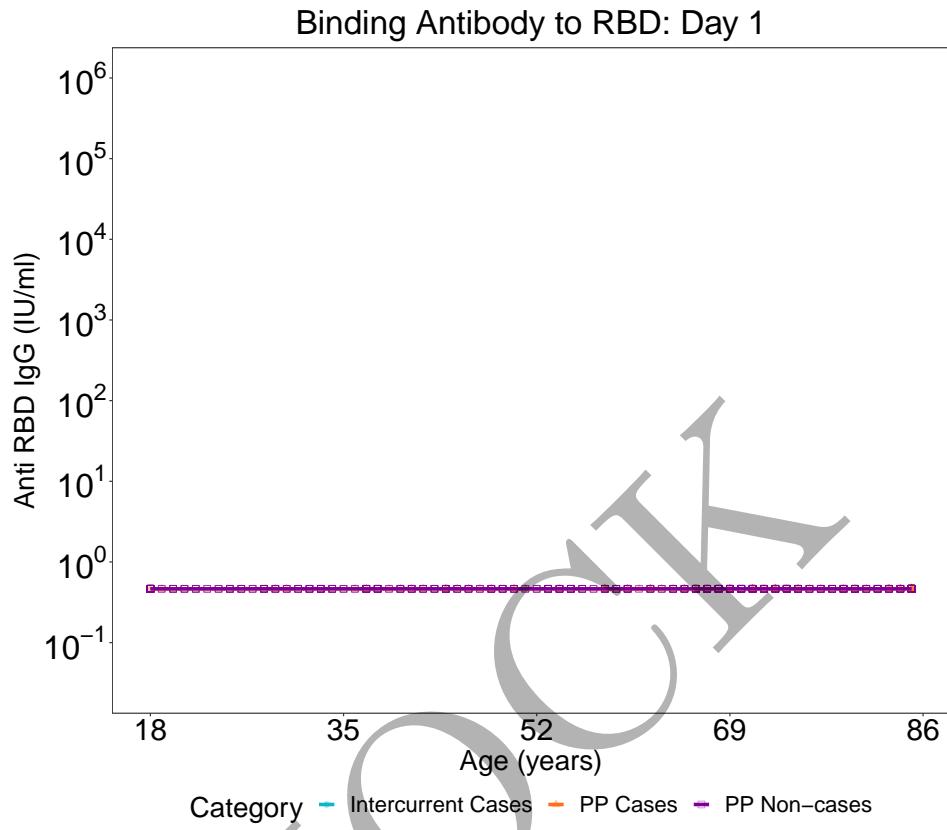


Figure 2.250: scatterplots of Binding Antibody to RBD: baseline negative vaccine arm at day 1

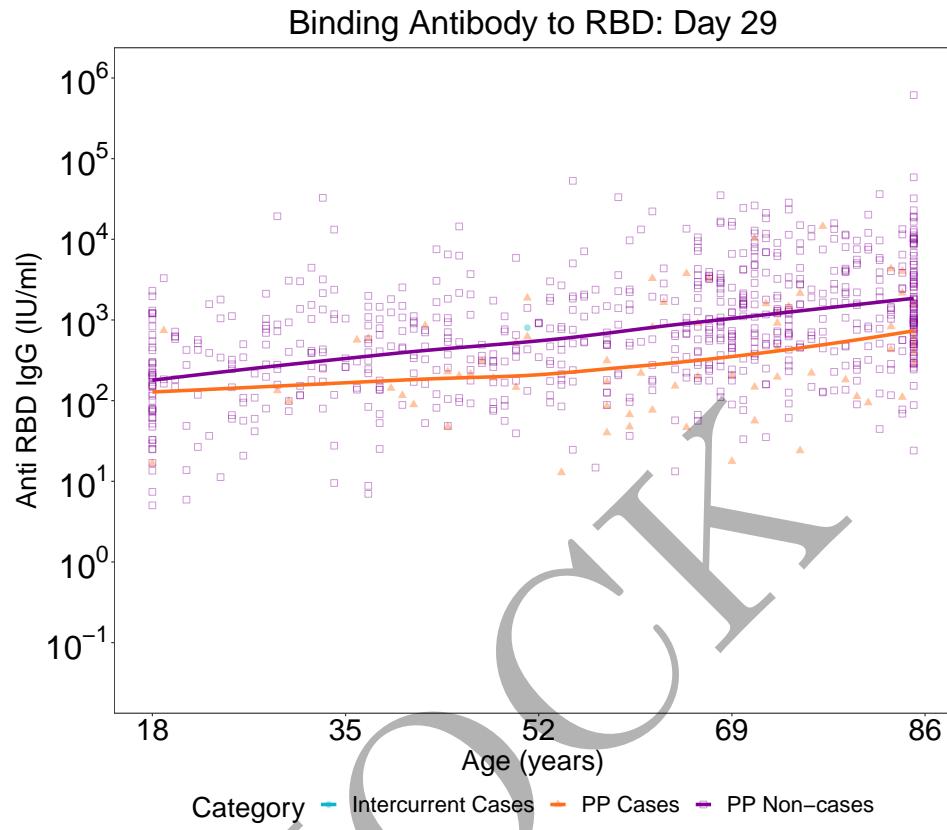


Figure 2.251: scatterplots of Binding Antibody to RBD: baseline negative vaccine arm at day 29

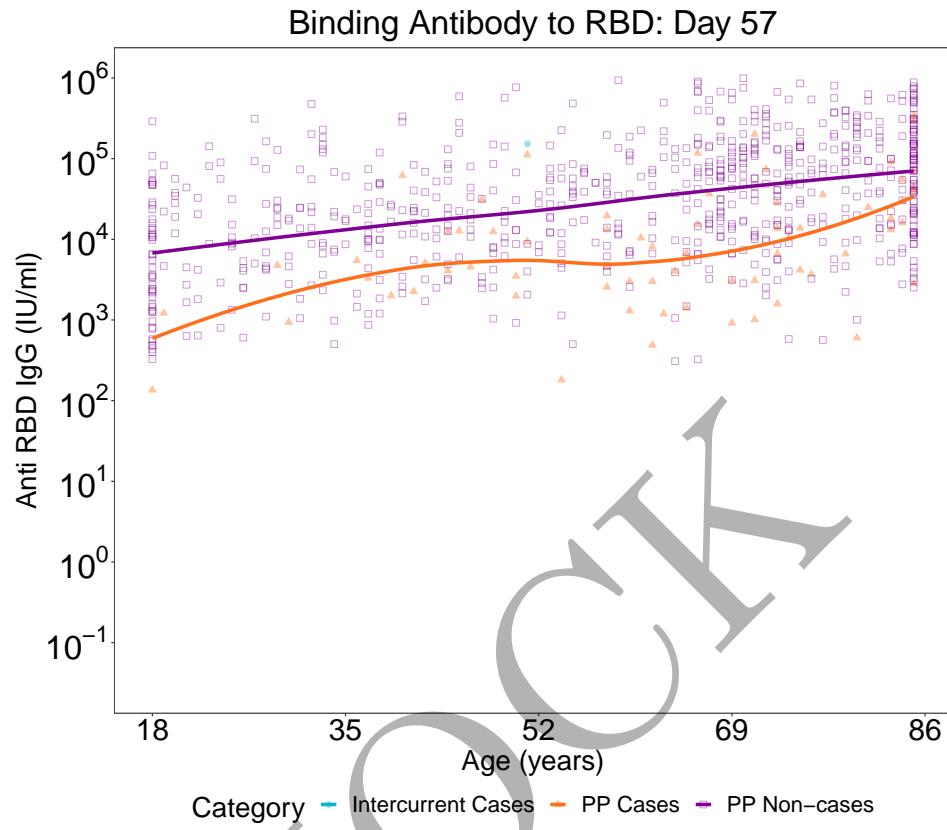


Figure 2.252: scatterplots of Binding Antibody to RBD: baseline negative vaccine arm at day 57

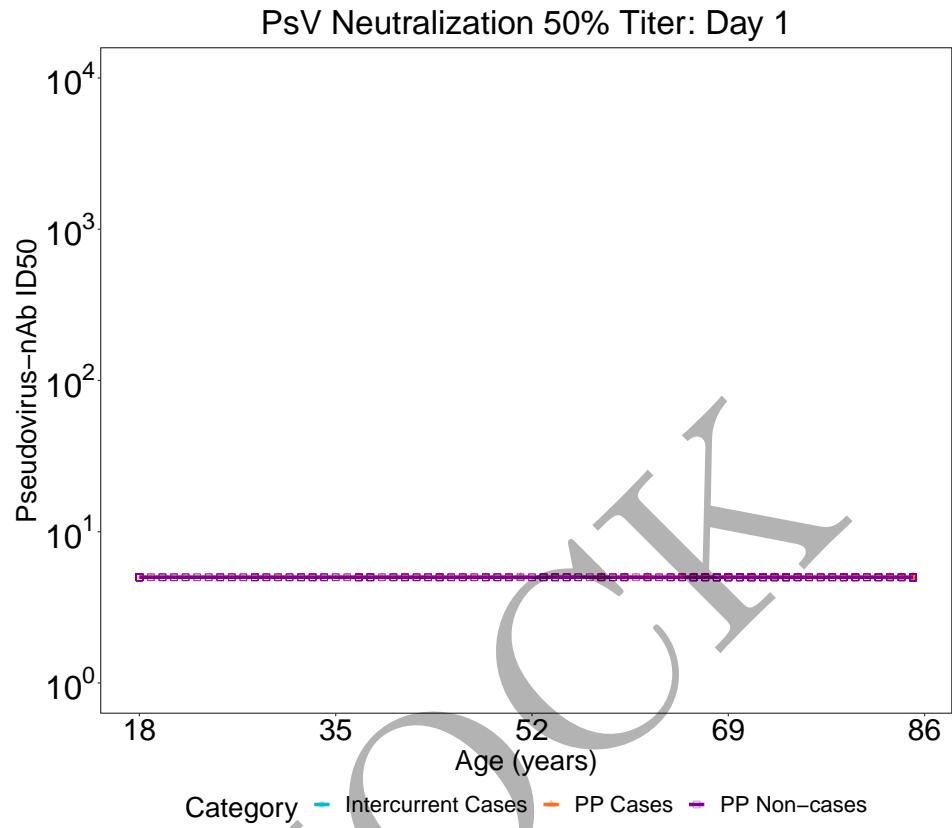


Figure 2.253: scatterplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm at day 1

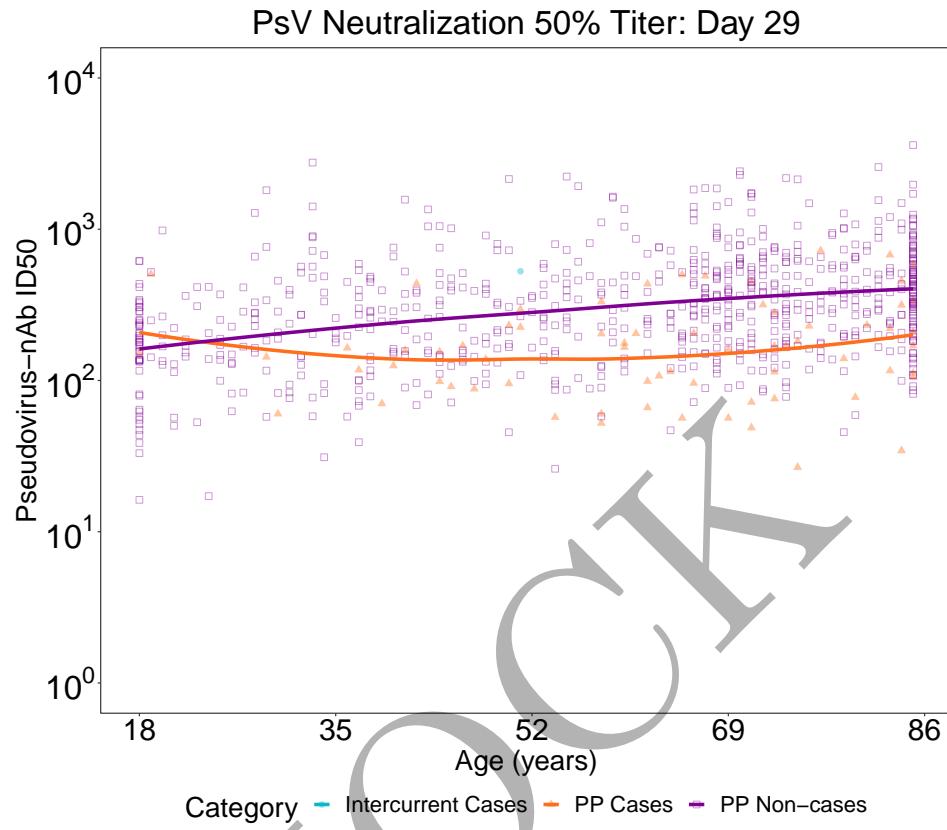


Figure 2.254: scatterplots of Pseudovirus Neutralization ID₅₀: baseline negative vaccine arm at day 29

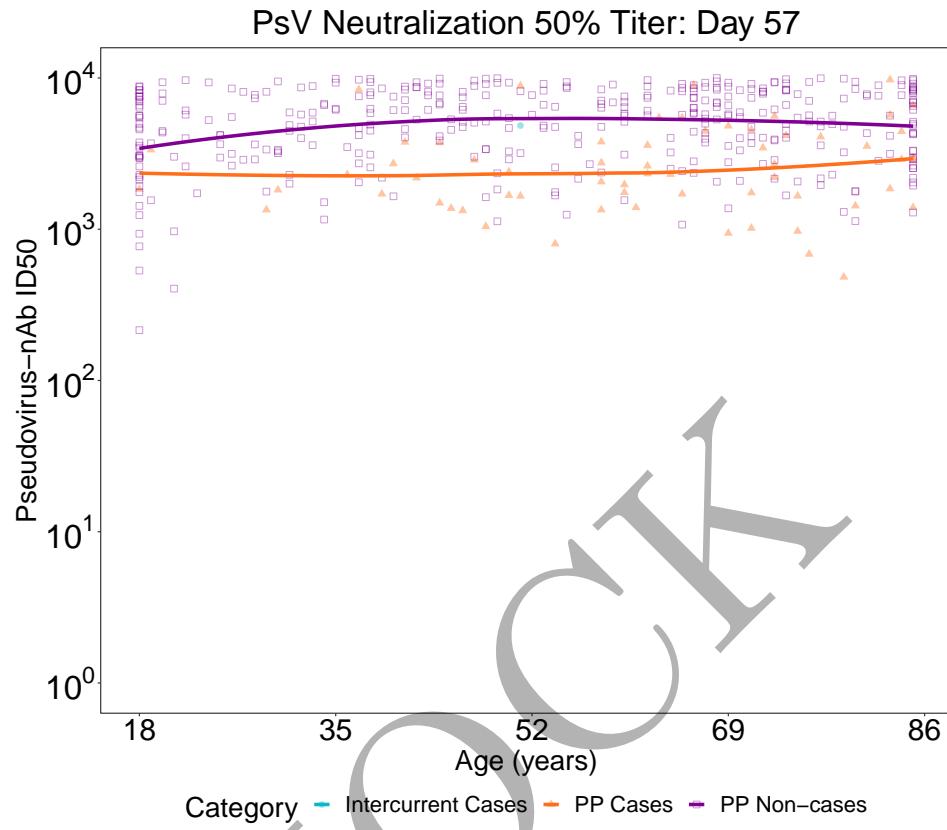


Figure 2.255: scatterplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm at day 57

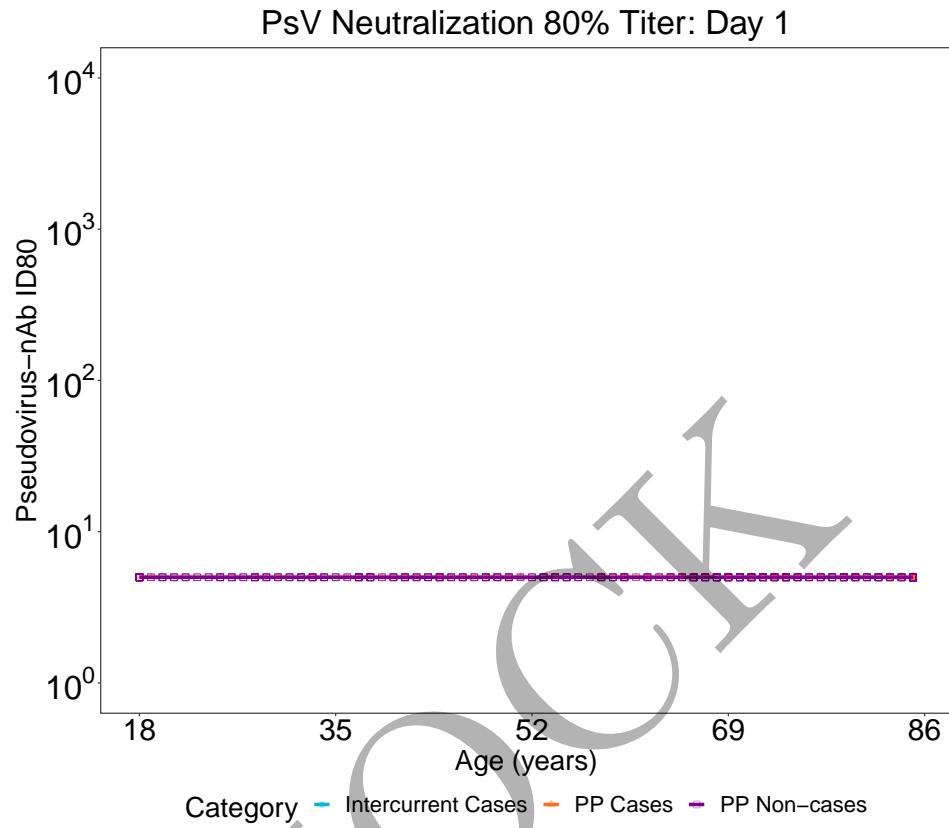


Figure 2.256: scatterplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm at day 1

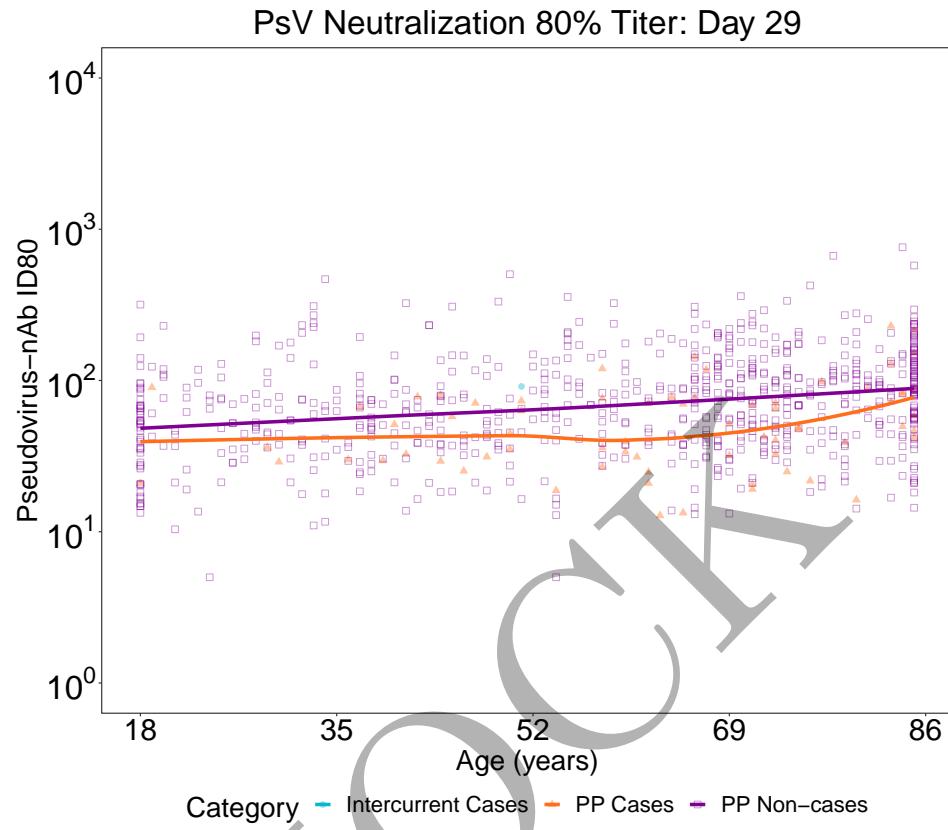


Figure 2.257: scatterplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm at day 29

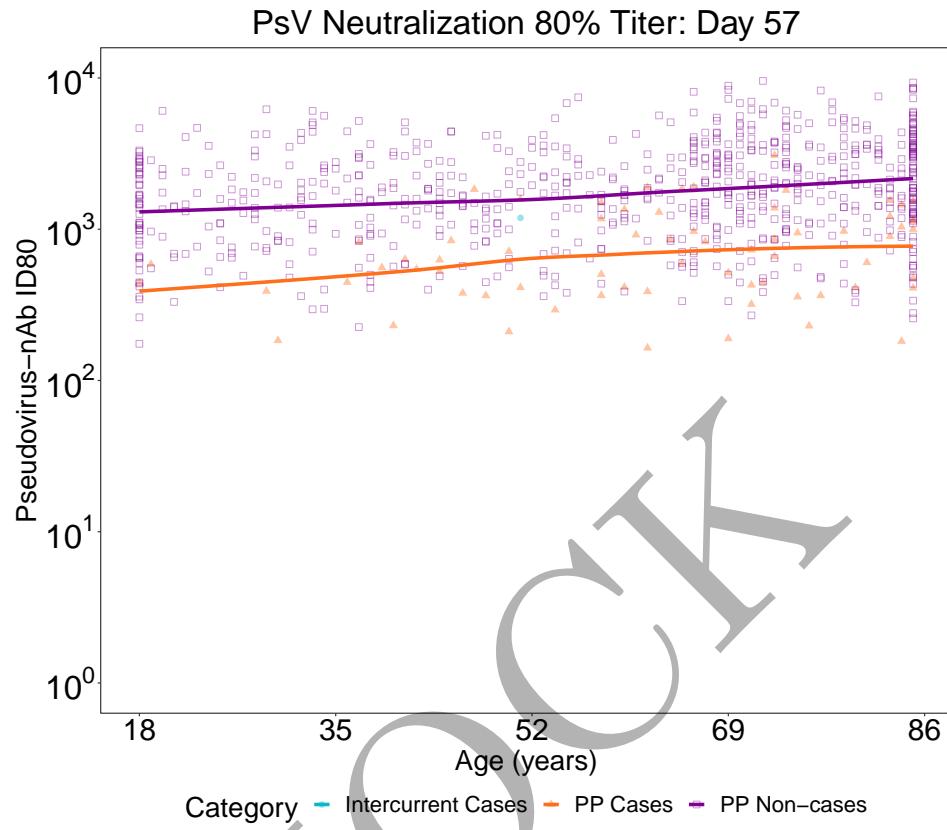


Figure 2.258: scatterplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm at day 57

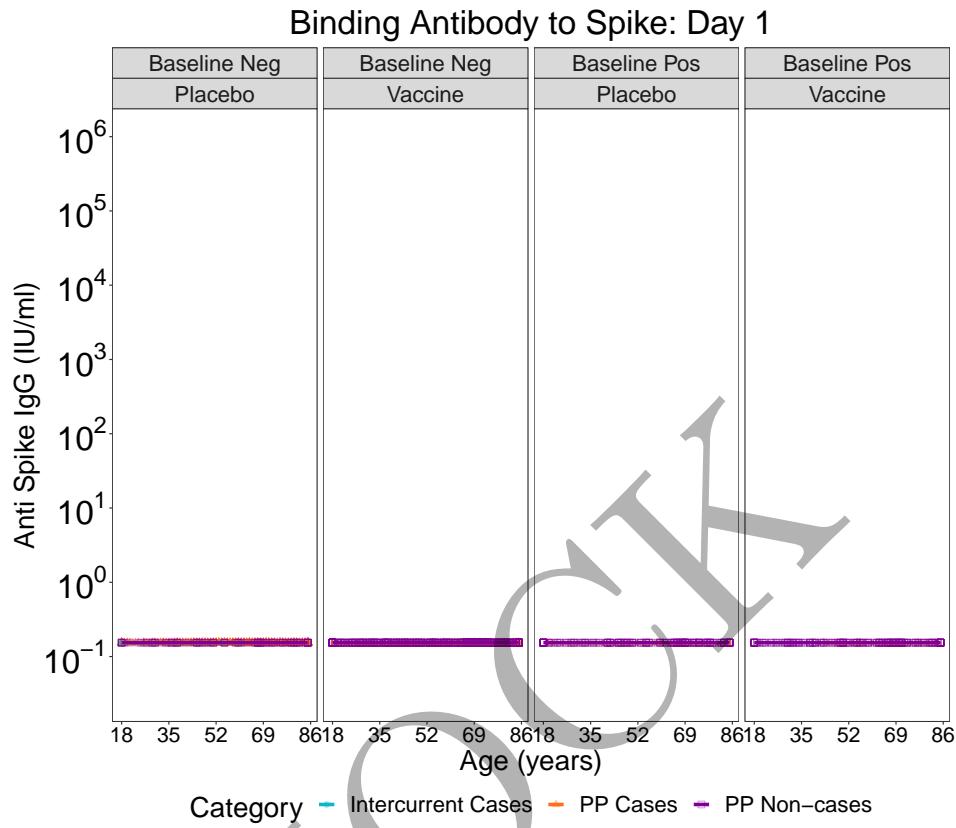


Figure 2.259: scatterplots of Binding Antibody to Spike: by arm at day 1

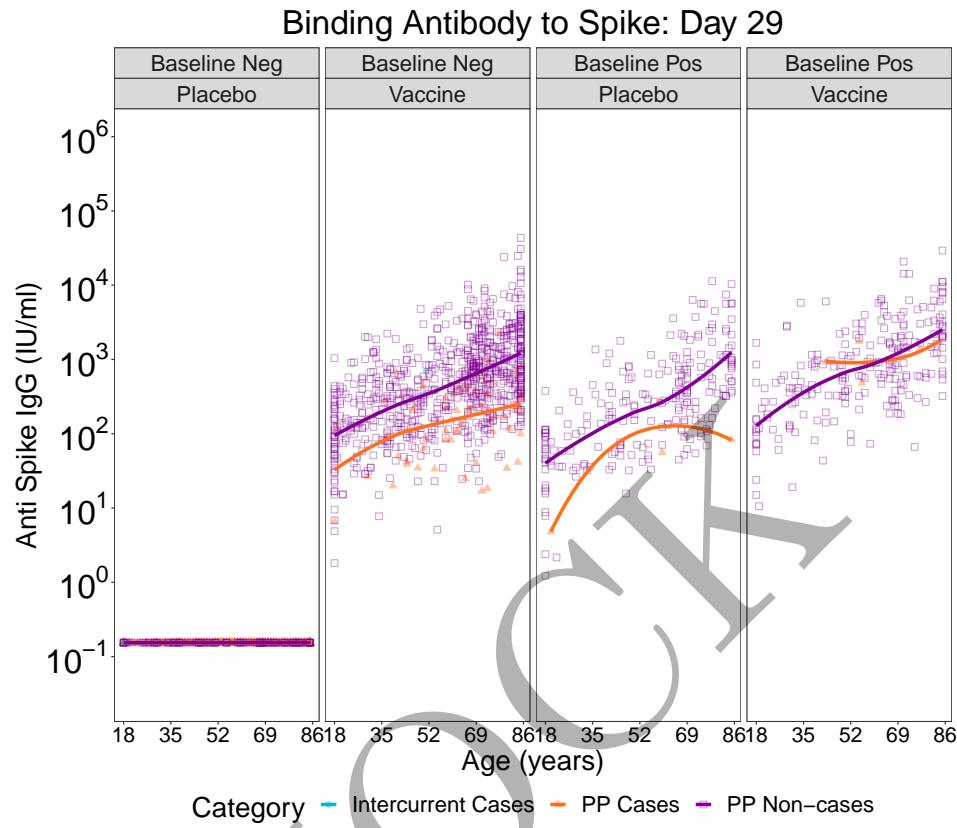


Figure 2.260: scatterplots of Binding Antibody to Spike: by arm at day 29

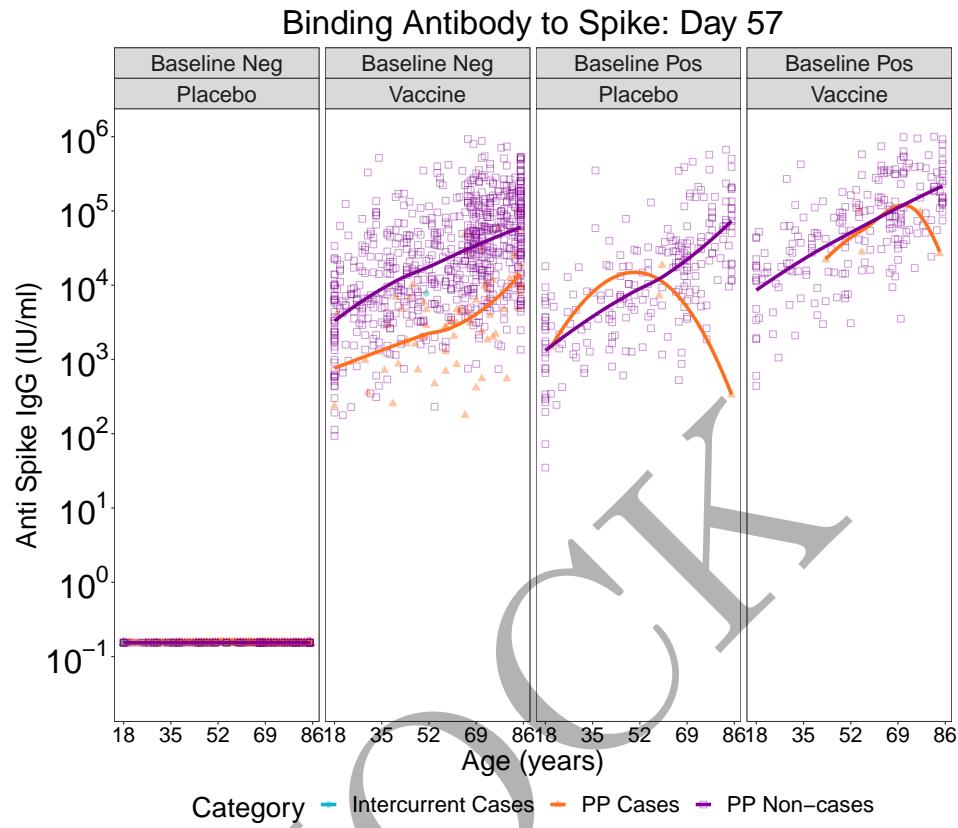


Figure 2.261: scatterplots of Binding Antibody to Spike: by arm at day 57

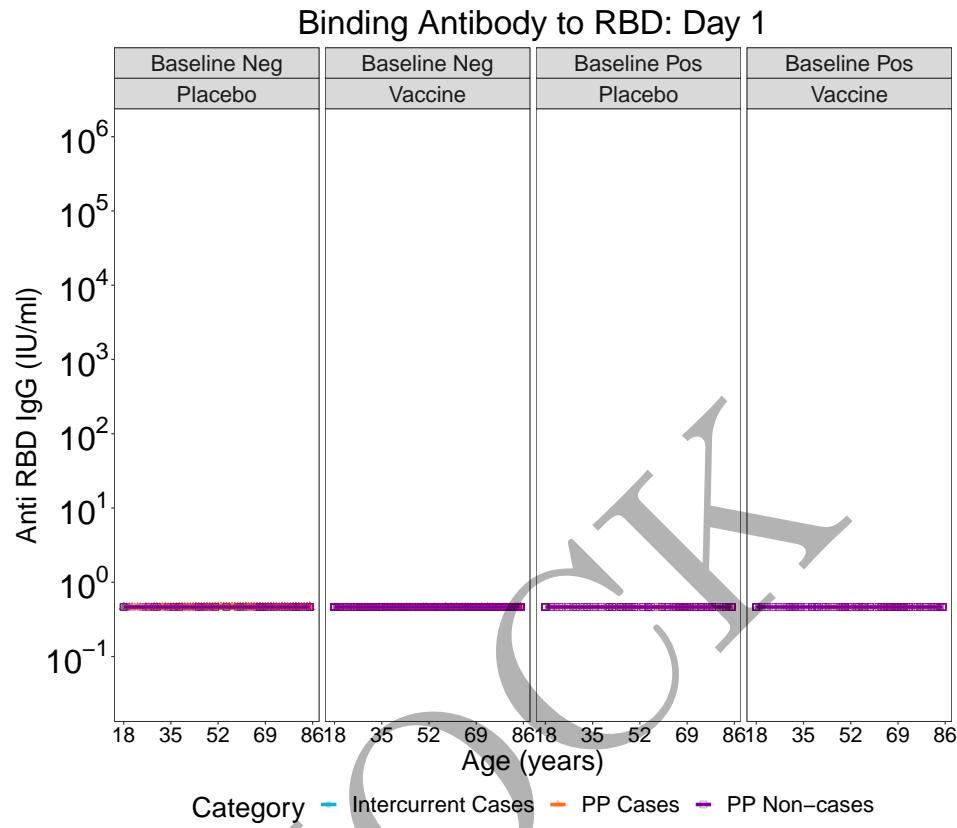


Figure 2.262: scatterplots of Binding Antibody to RBD: by arm at day 1

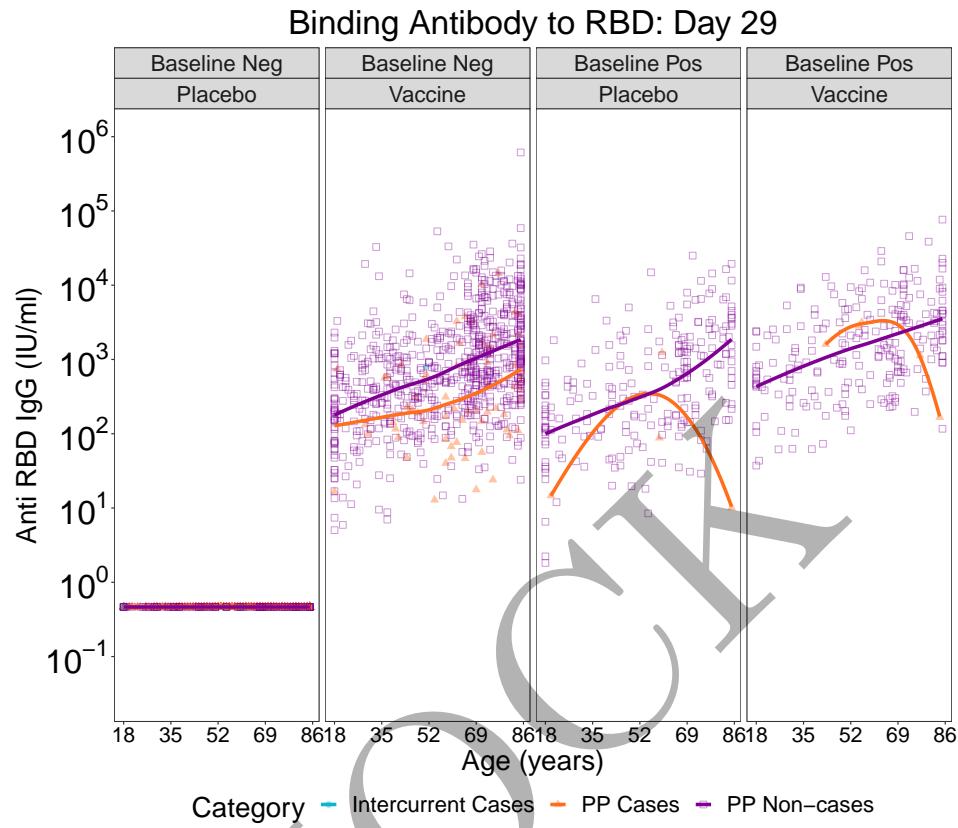


Figure 2.263: scatterplots of Binding Antibody to RBD: by arm at day 29

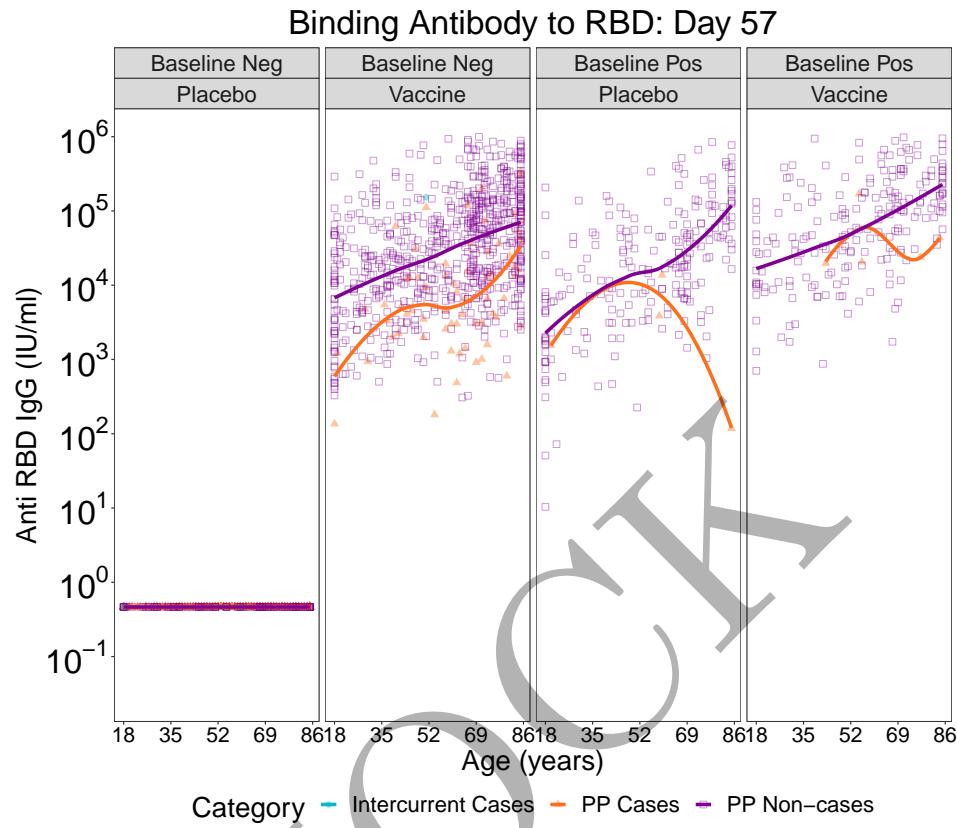


Figure 2.264: scatterplots of Binding Antibody to RBD: by arm at day 57

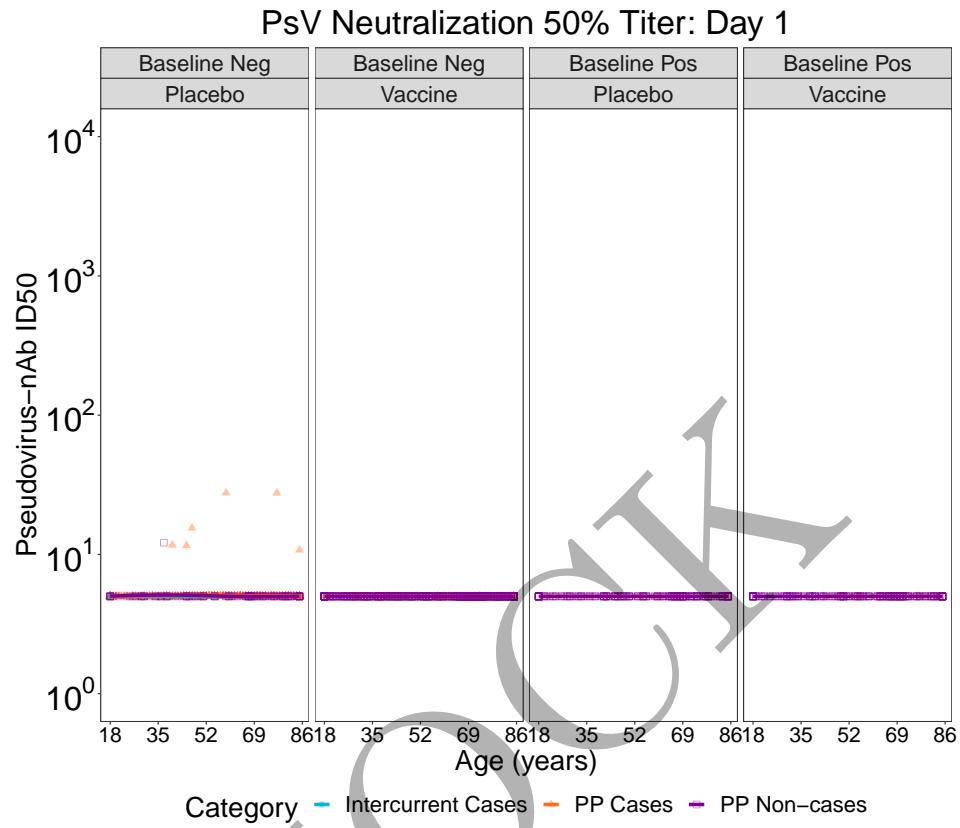


Figure 2.265: scatterplots of Pseudovirus Neutralization ID50: by arm at day 1

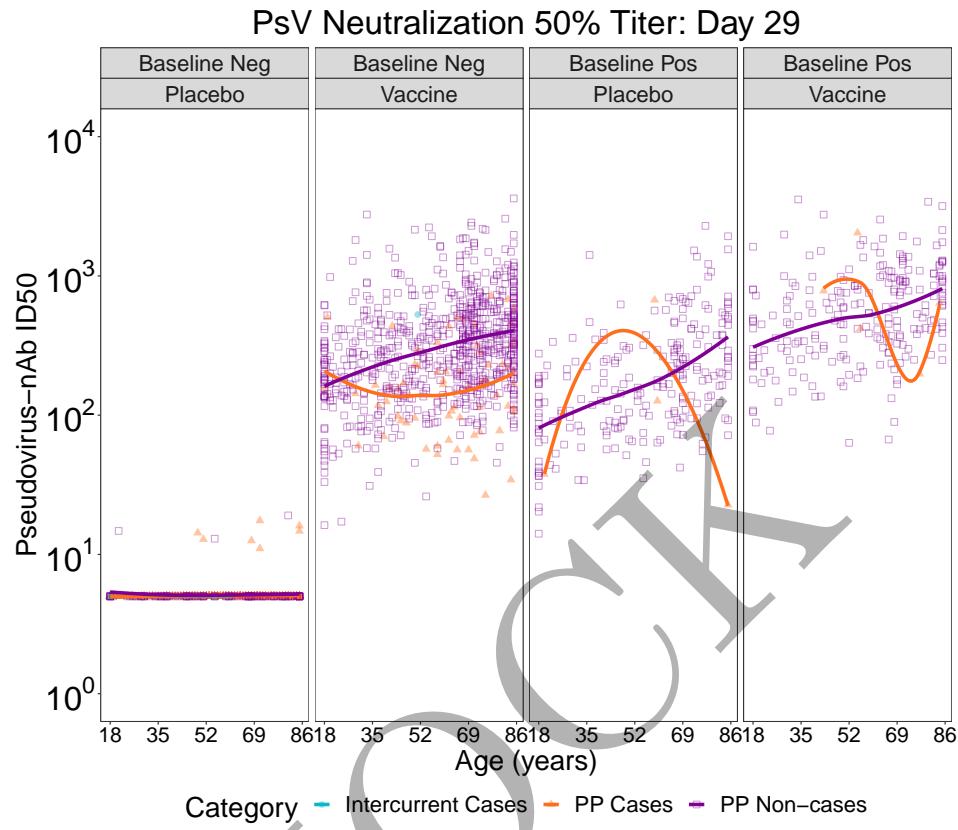


Figure 2.266: scatterplots of Pseudovirus Neutralization ID50: by arm at day 29

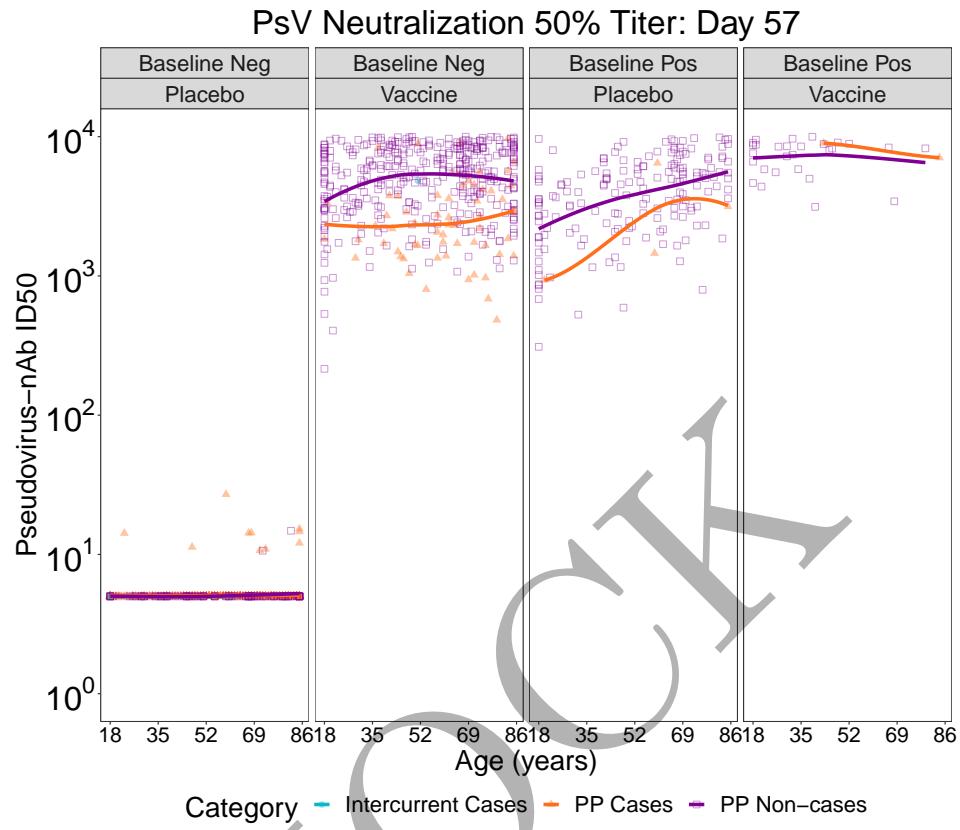


Figure 2.267: scatterplots of Pseudovirus Neutralization ID50: by arm at day 57

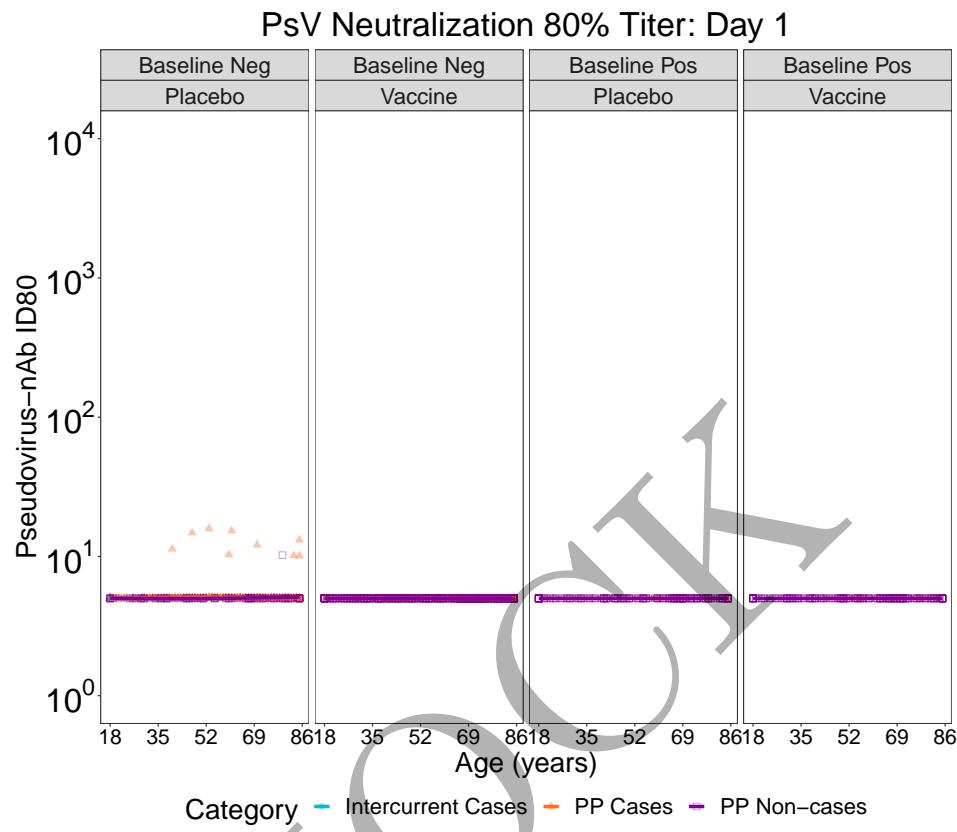


Figure 2.268: scatterplots of Pseudovirus Neutralization ID80: by arm at day 1

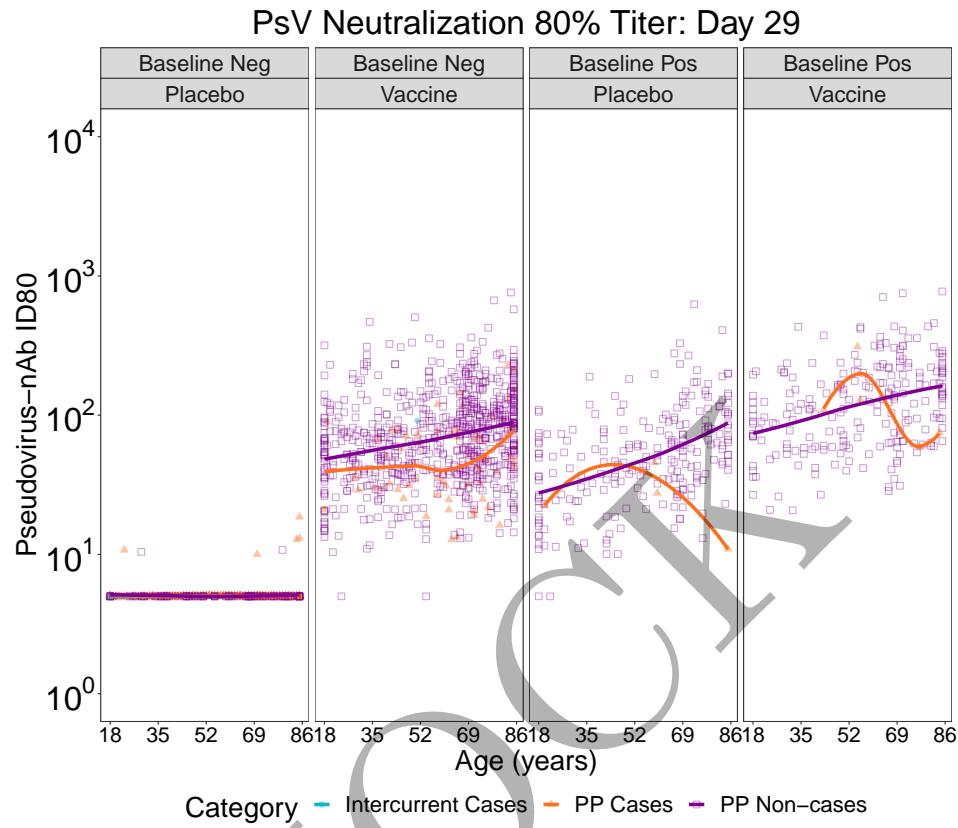


Figure 2.269: scatterplots of Pseudovirus Neutralization ID80: by arm at day 29

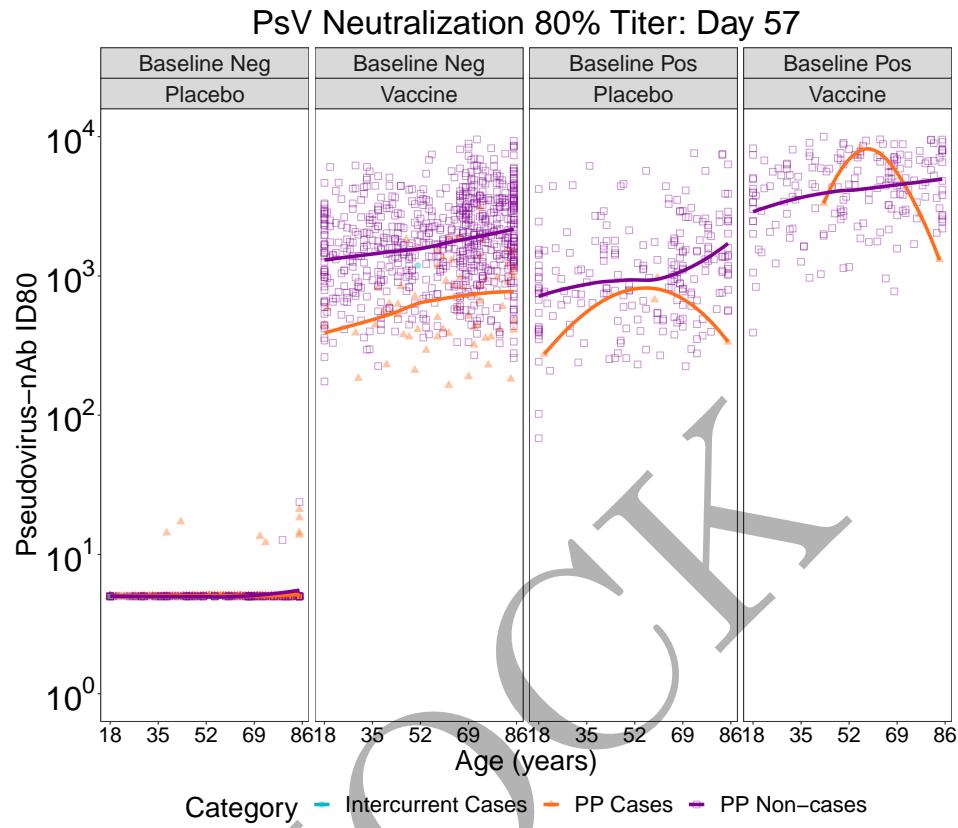


Figure 2.270: scatterplots of Pseudovirus Neutralization ID80: by arm at day 57

MOCK

Chapter 3

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.

3.1 Hazard ratios

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*

Mock 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)	71/11,071	0.06	(0.03-0.11)	<0.001	<0.001	<0.001
Anti RBD IgG (IU/ml)	71/11,071	0.17	(0.11-0.28)	<0.001	<0.001	<0.001
Pseudovirus-nAb ID50	71/11,071	0.00	(0.00-0.01)	<0.001	<0.001	<0.001
Pseudovirus-nAb ID80	71/11,071	0.00	(0.00-0.02)	<0.001	<0.001	<0.001

*Baseline covariates adjusted for: baseline risk score, at risk or not, community of color or not. Average follow-up time 173 days, maximum follow-up time 185 days.

**No. at-risk = number of per-protocol baseline negative vaccine recipients at-risk for COVID; no. cases = number of this cohort with an observed COVID endpoints starting 7 days post Day 57 visit.

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*

Mock Immunologic Marker	Tertile	No. cases / No. at-risk**	Attack rate	Haz. Ratio Pt. Est.	95% CI	P-value (2-sided)	Overall P- value***	Overall q- value	Overall FWER
Anti Spike IgG (IU/ml)	Lower	38/2,508	0.0152	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	18/2,513	0.0072	0.29	(0.14-0.60)	0.001			
	Upper	16/6,050	0.0026	0.05	(0.02-0.09)	<0.001			
Anti RBD IgG (IU/ml)	Lower	38/3,178	0.0120	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	18/3,159	0.0057	0.29	(0.15-0.56)	<0.001			
	Upper	16/4,734	0.0034	0.10	(0.05-0.21)	<0.001			
Pseudovirus-nAb ID50	Lower	42/1,199	0.0350	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	10/1,174	0.0085	0.34	(0.15-0.79)	0.013			
	Upper	19/8,699	0.0022	0.04	(0.02-0.08)	<0.001			
Pseudovirus-nAb ID80	Lower	42/2,065	0.0203	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	15/2,014	0.0074	0.36	(0.18-0.74)	0.005			
	Upper	15/6,991	0.0021	0.07	(0.04-0.14)	<0.001			
Placebo		704/11,254	0.0626						

*Baseline covariates adjusted for: baseline risk score, at risk or not, community of color or not. Average follow-up time 173 days, maximum follow-up time 185 days. Cutpoints: Anti Spike IgG (IU/ml) [3.64, 4.01), Anti RBD IgG (IU/ml) [3.92, 4.49), Pseudovirus-nAb ID50 [3.47, 3.64), Pseudovirus-nAb ID80 [2.92, 3.11).

**No. at-risk = number of per-protocol baseline negative vaccine recipients at-risk for COVID at 7 days post Day 57 visit; no. cases = number of this cohort with an observed COVID endpoints.

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

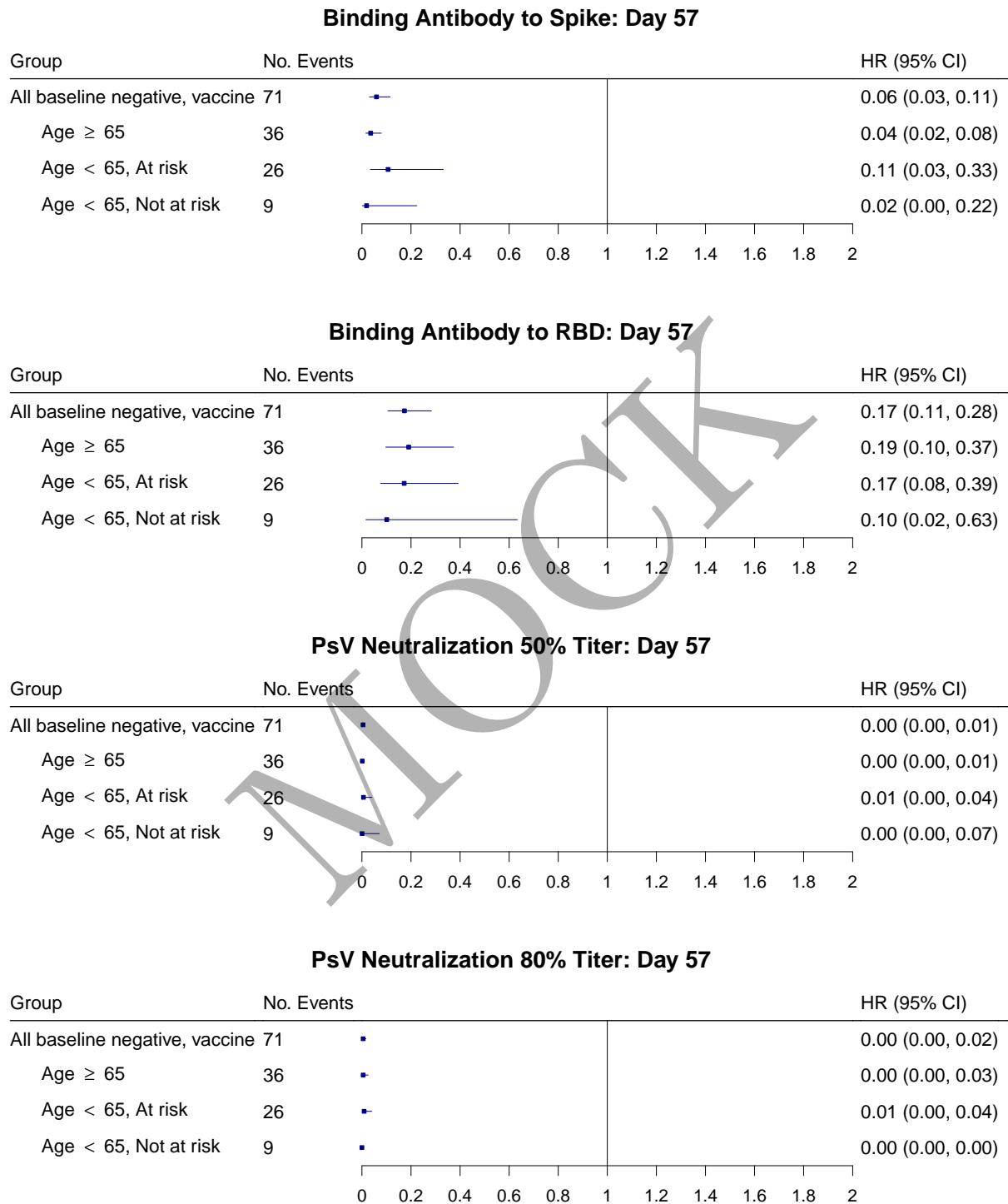


Figure 3.1: Forest plots of hazard ratios per 10-fold increase in the marker among baseline seronegative vaccine recipients and subgroups with 95% point-wise confidence intervals.

Binding Antibody to Spike: Day 57

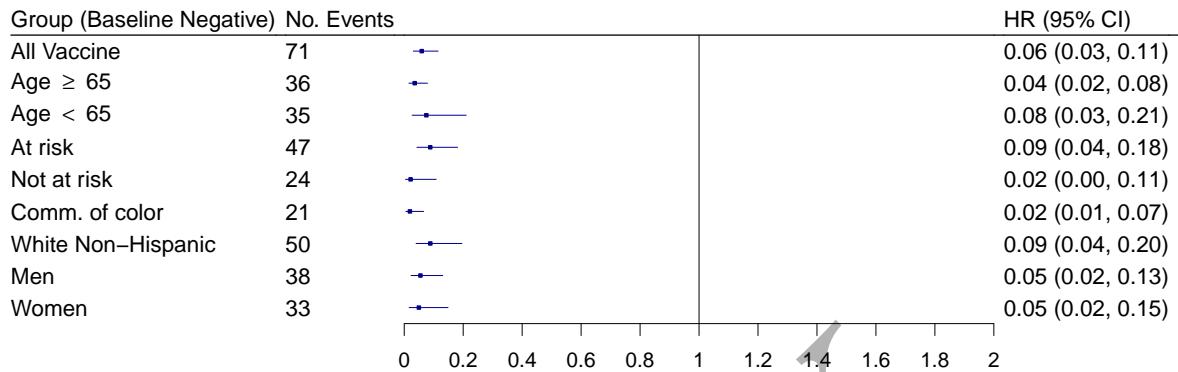


Figure 3.2: Forest plots of hazard ratios per 10-fold increase in the Day 57 binding Ab to spike markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

Binding Antibody to RBD: Day 57

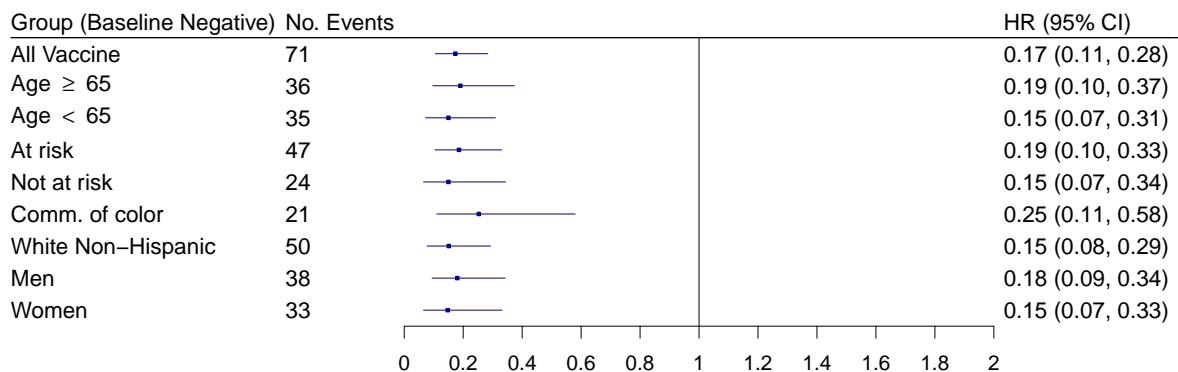


Figure 3.3: Forest plots of hazard ratios per 10-fold increase in the Day 57 binding Ab to RBD markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

PsV Neutralization 50% Titer: Day 57

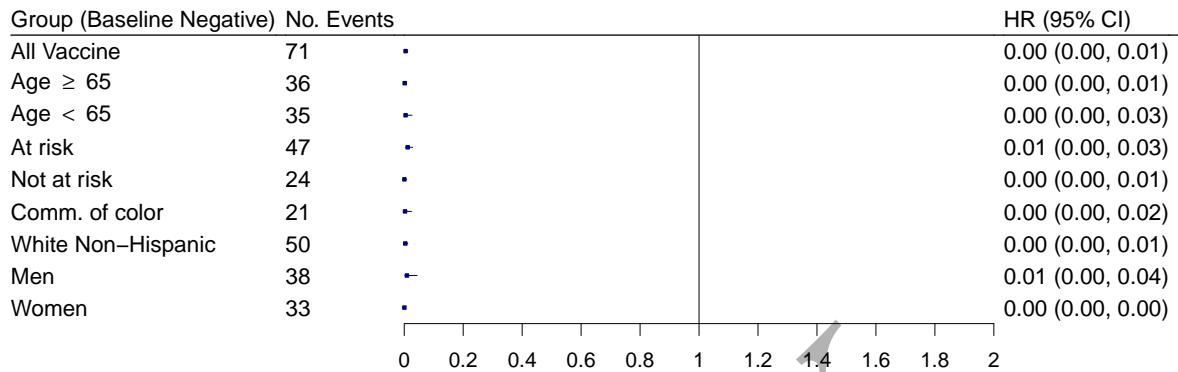


Figure 3.4: Forest plots of hazard ratios per 10-fold increase in the Day 57 pseudo neut ID50 markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

PsV Neutralization 80% Titer: Day 57

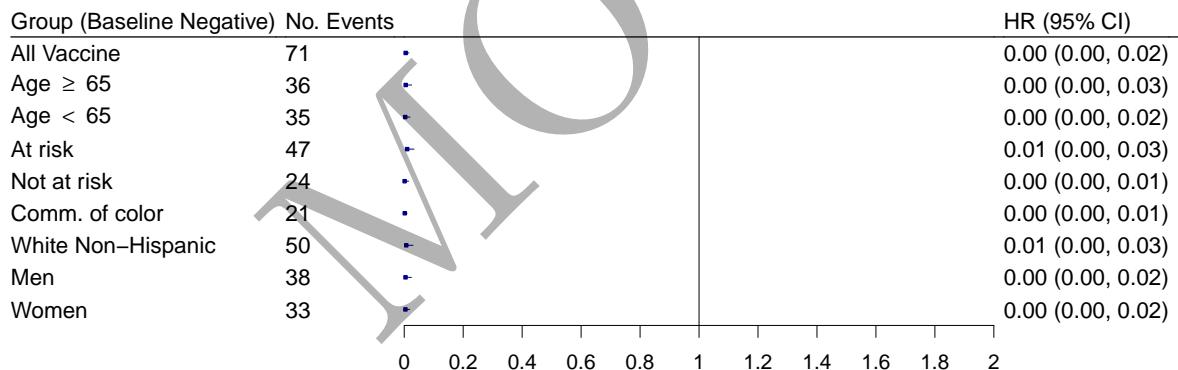


Figure 3.5: Forest plots of hazard ratios per 10-fold increase in the Day 57 pseudo neut ID80 markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

3.2 Marginalized risk and controlled vaccine efficacy plots

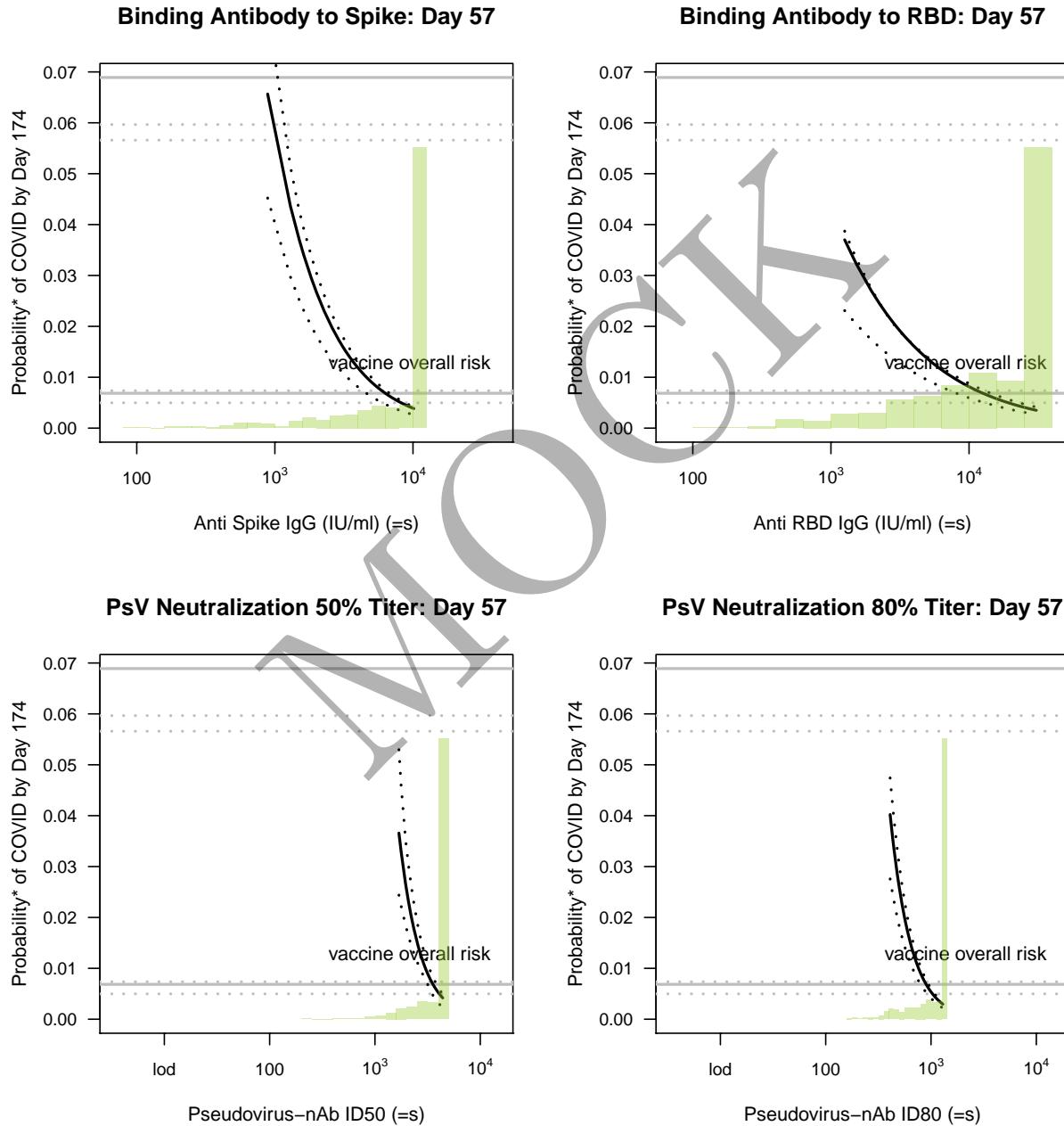


Figure 3.6: Marginalized cumulative risk by Day 174 as functions of Day 57 markers (=s) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. The horizontal lines indicate the overall cumulative risk of the placebo and vaccine arms by Day 174 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.

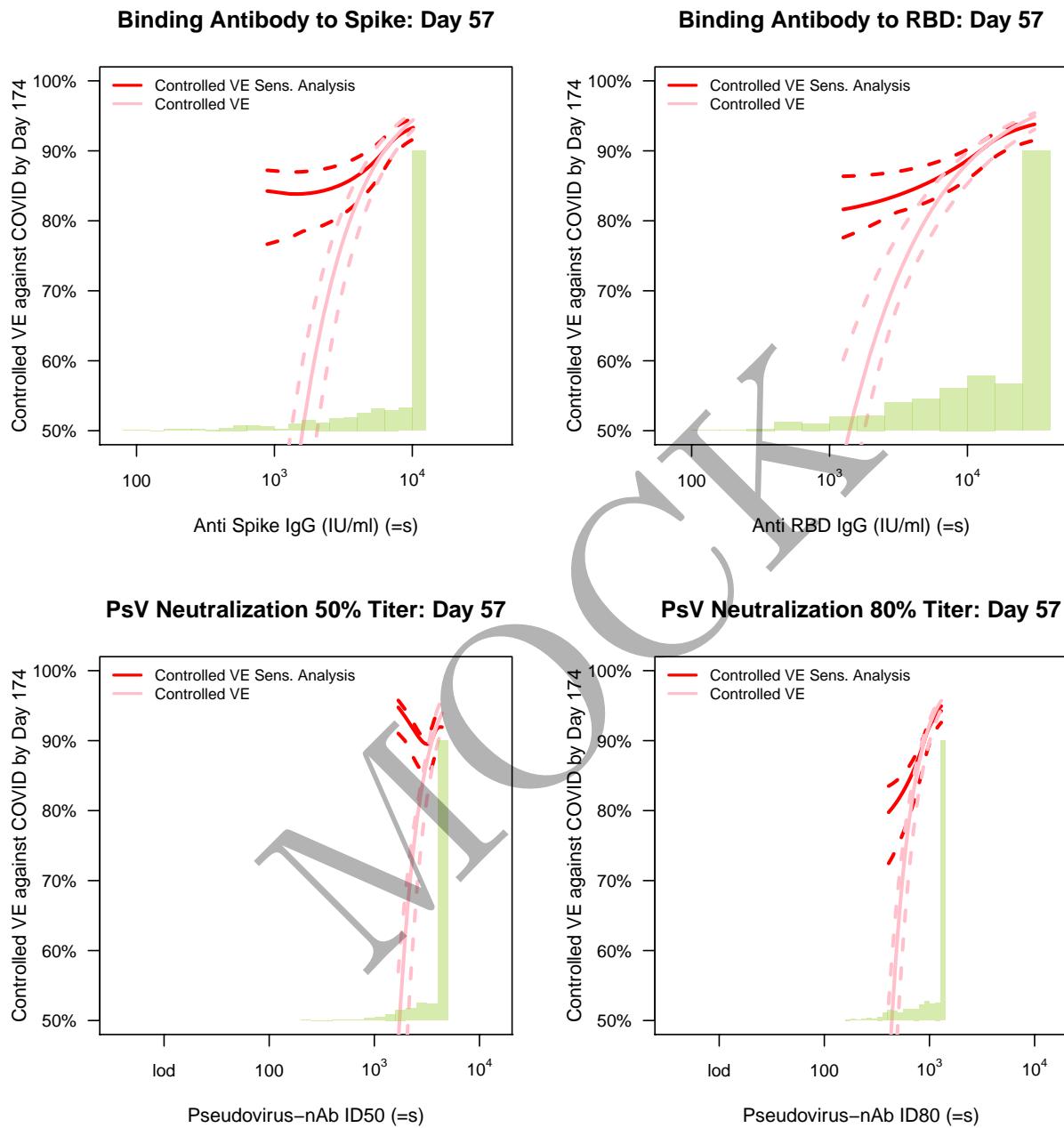


Figure 3.7: Controlled VE with sensitivity analysis as functions of Day 57 markers (=s) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.

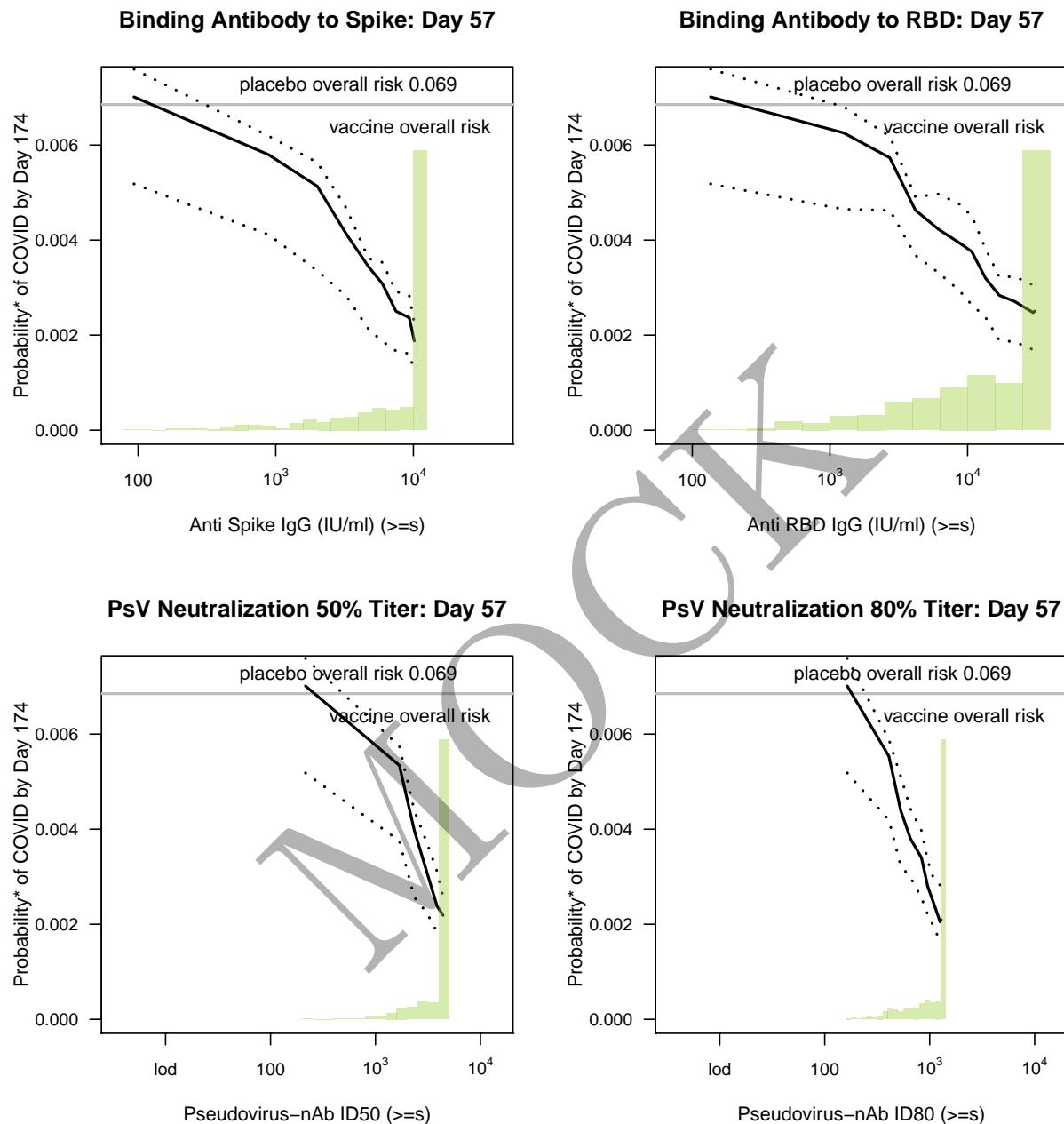


Figure 3.8: Marginalized cumulative risk by Day 174 as functions of Day 57 markers above a threshold ($\geq s$) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands (at least 5 cases are required). The horizontal lines indicate the overall cumulative risk of the vaccine arm by Day 174 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.

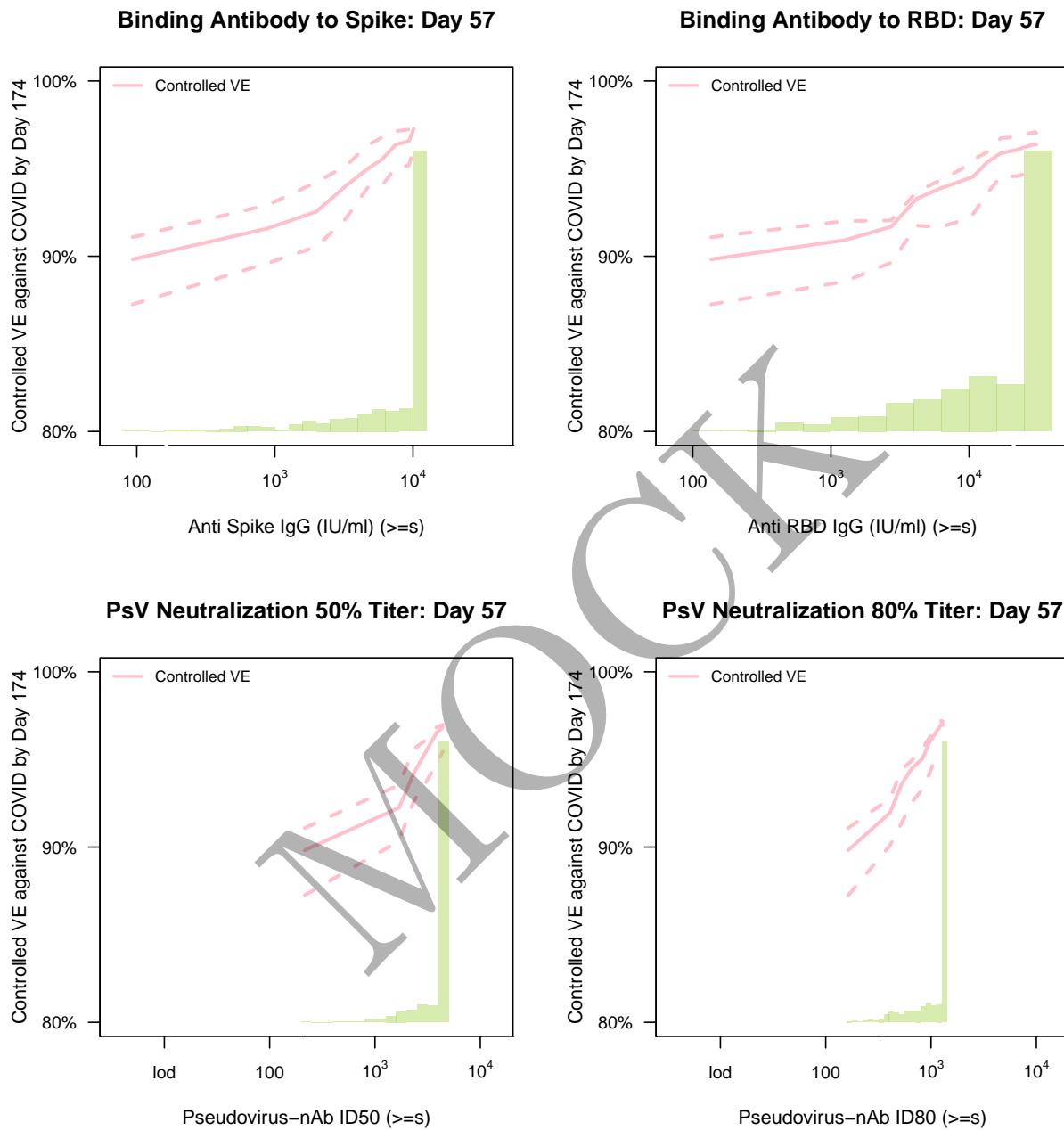


Figure 3.9: Controlled VE as functions of Day 57 markers ($\geq s$) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.

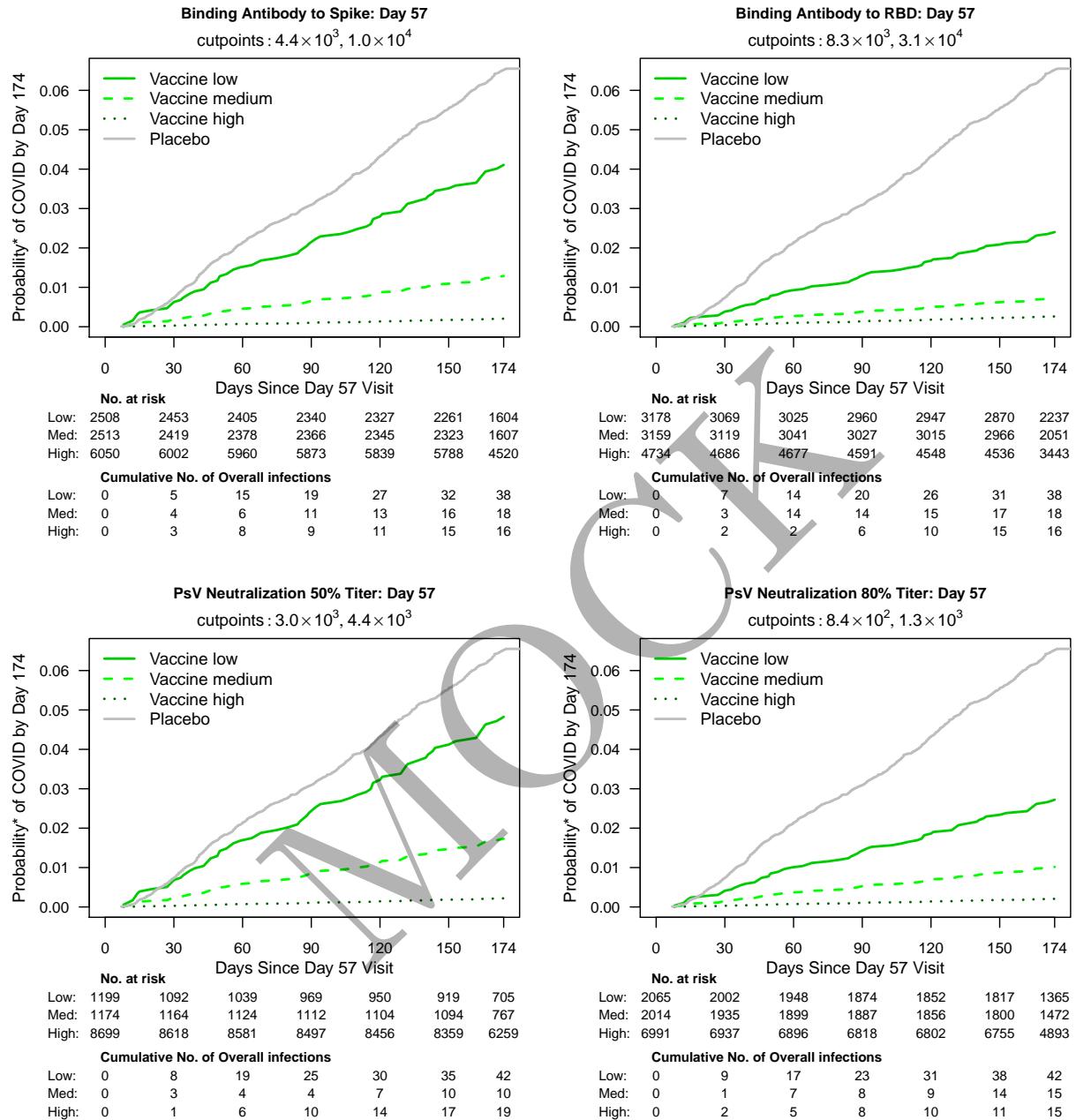


Figure 3.10: Marginalized cumulative incidence rate curves for trichotomized Day 57 markers among baseline seronegative vaccine recipients. The gray line is the overall cumulative incidence rate curve in the placebo arm.

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

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*

Mock 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)	83/11,110	0.19	(0.12-0.30)	<0.001	<0.001	<0.001
Anti RBD IgG (IU/ml)	83/11,110	0.49	(0.32-0.73)	0.001	<0.001	<0.001
Pseudovirus-nAb ID50	83/11,110	0.10	(0.05-0.23)	<0.001	<0.001	<0.001
Pseudovirus-nAb ID80	83/11,110	0.26	(0.13-0.54)	<0.001	<0.001	<0.001

*Baseline covariates adjusted for: baseline risk score, at risk or not, community of color or not. Average follow-up time 200 days, maximum follow-up time 213 days.

**No. at-risk = number of per-protocol baseline negative vaccine recipients at-risk for COVID; no. cases = number of this cohort with an observed COVID endpoints starting 7 days post Day 29 visit.

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*

Mock 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	34/3,697	0.0092	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	34/3,717	0.0091	0.53	(0.30-0.95)	0.034			
	Upper	15/3,696	0.0041	0.11	(0.05-0.24)	<0.001			
Anti RBD IgG (IU/ml)	Lower	37/3,705	0.0100	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	24/3,703	0.0065	0.46	(0.26-0.84)	0.011			
	Upper	22/3,702	0.0059	0.27	(0.14-0.51)	<0.001			
Pseudovirus-nAb ID50	Lower	45/3,712	0.0121	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	20/3,729	0.0054	0.27	(0.15-0.49)	<0.001			
	Upper	19/3,669	0.0052	0.19	(0.10-0.38)	<0.001			
Pseudovirus-nAb ID80	Lower	34/3,705	0.0092	1	N/A	N/A	0.007	<0.001	<0.001
	Middle	27/3,735	0.0072	0.73	(0.41-1.28)	0.268			
	Upper	22/3,670	0.0060	0.38	(0.21-0.69)	0.002			
Placebo		815/11,408	0.0714						

*Baseline covariates adjusted for: baseline risk score, at risk or not, community of color or not. Average follow-up time 200 days, maximum follow-up time 213 days. Cutpoints: Anti Spike IgG (IU/ml) [2.24, 2.74), Anti RBD IgG (IU/ml) [2.42, 2.96), Pseudovirus-nAb ID50 [2.23, 2.57), Pseudovirus-nAb ID80 [1.66, 1.91).

**No. at-risk = number of per-protocol baseline negative vaccine recipients at-risk for COVID at 7 days post Day 29 visit; no. cases = number of this cohort with an observed COVID endpoints.

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

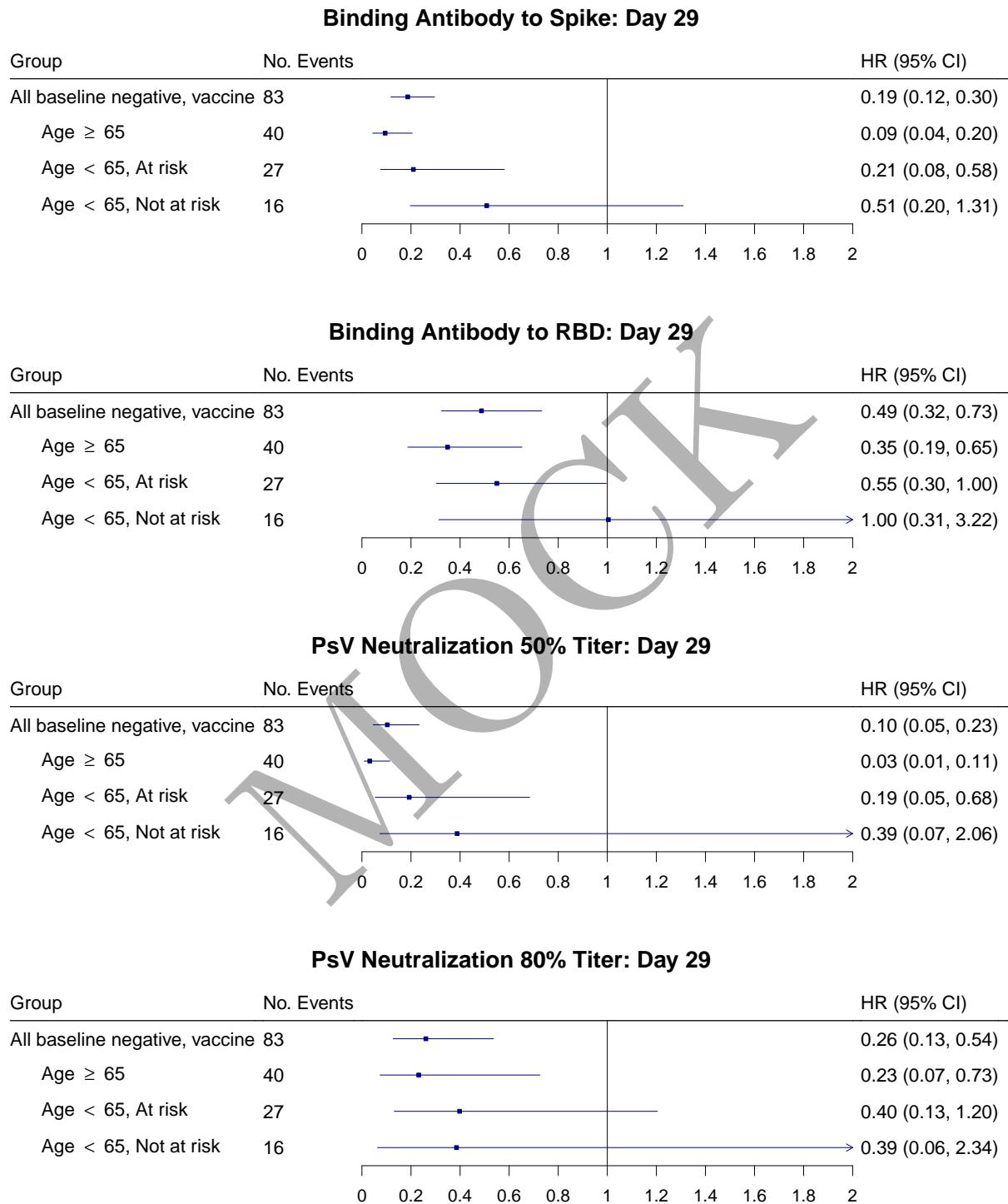


Figure 4.1: Forest plots of hazard ratios per 10-fold increase in the marker among baseline seronegative vaccine recipients and subgroups with 95% point-wise confidence intervals.

Binding Antibody to Spike: Day 29

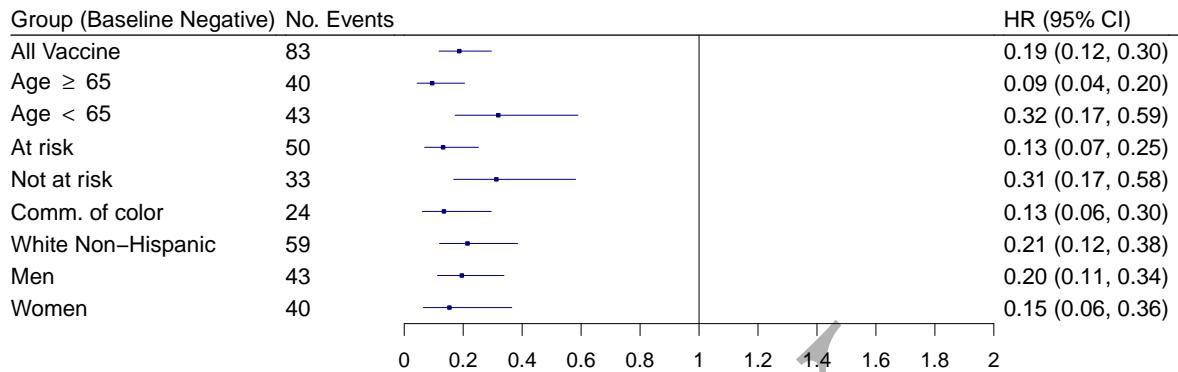


Figure 4.2: Forest plots of hazard ratios per 10-fold increase in the Day 29 binding Ab to spike markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

Binding Antibody to RBD: Day 29

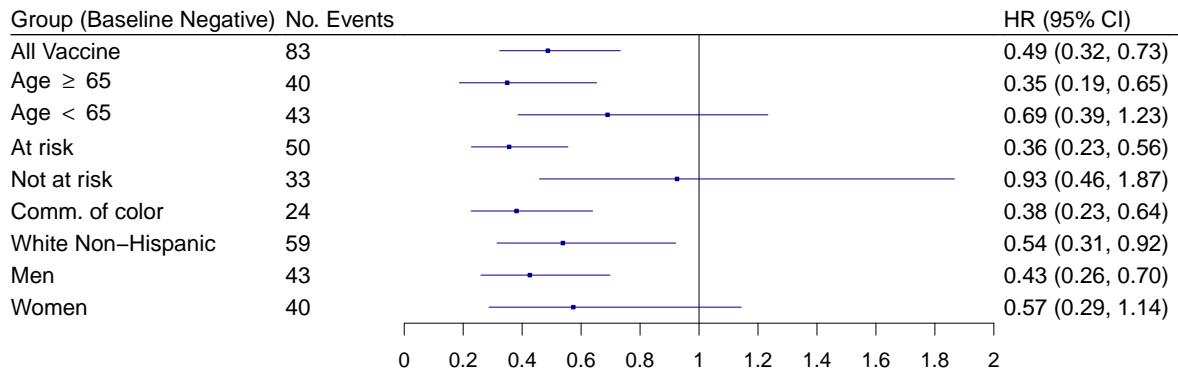


Figure 4.3: Forest plots of hazard ratios per 10-fold increase in the Day 29 binding Ab to RBD markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

PsV Neutralization 50% Titer: Day 29

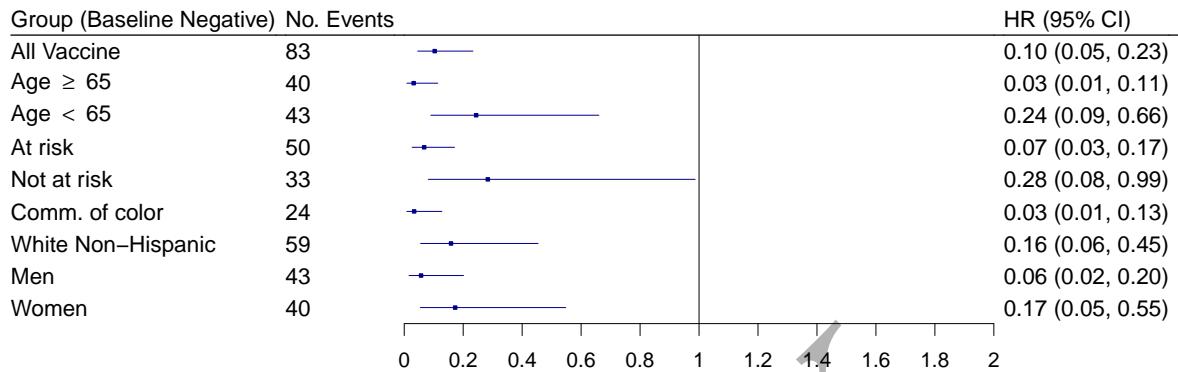


Figure 4.4: Forest plots of hazard ratios per 10-fold increase in the Day 29 pseudo neut ID50 markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

PsV Neutralization 80% Titer: Day 29

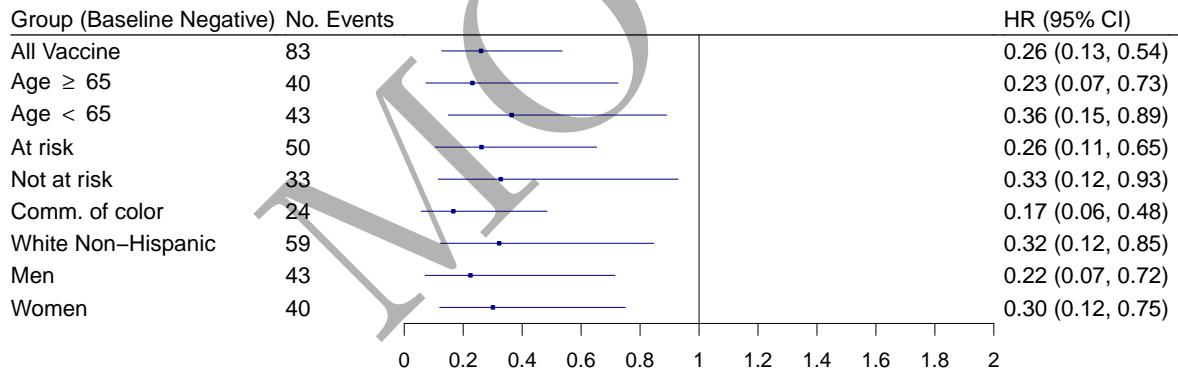


Figure 4.5: Forest plots of hazard ratios per 10-fold increase in the Day 29 pseudo neut ID80 markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

4.2 Marginalized risk and controlled vaccine efficacy plots

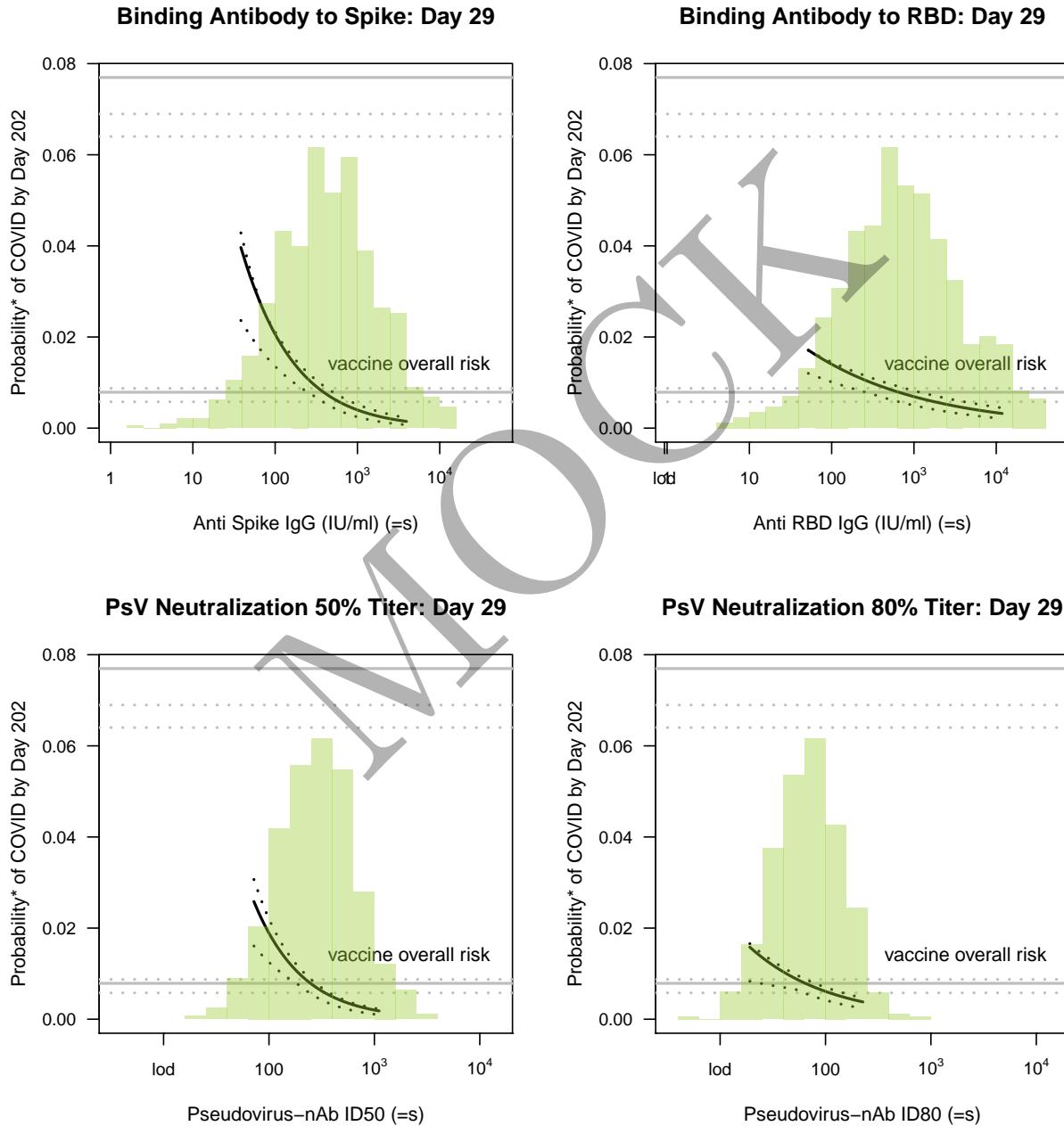


Figure 4.6: Marginalized cumulative risk by Day 202 as functions of Day 29 markers ($=s$) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. The horizontal lines indicate the overall cumulative risk of the placebo and vaccine arms by Day 202 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.

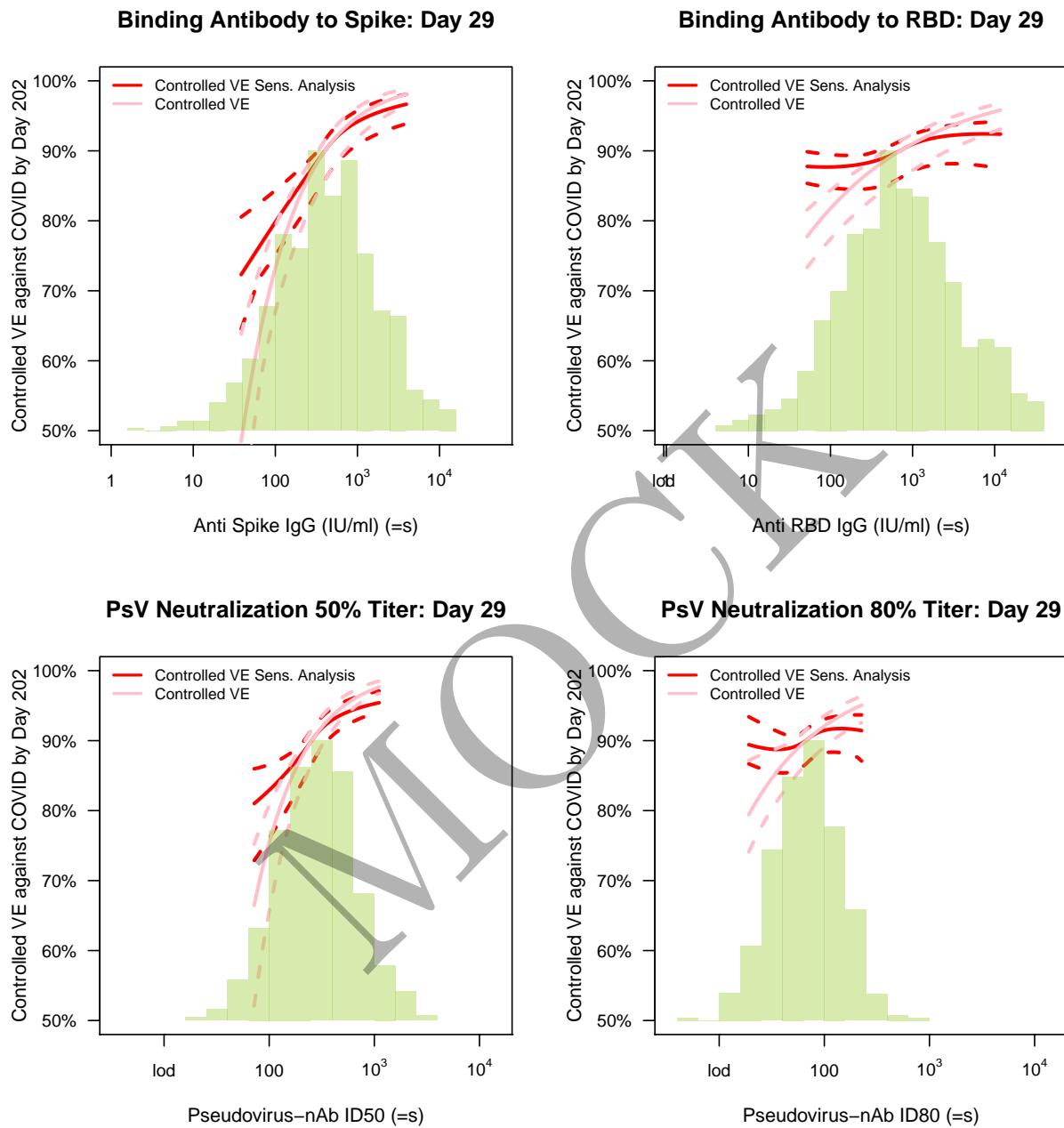


Figure 4.7: Controlled VE with sensitivity analysis as functions of Day 29 markers (=s) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.

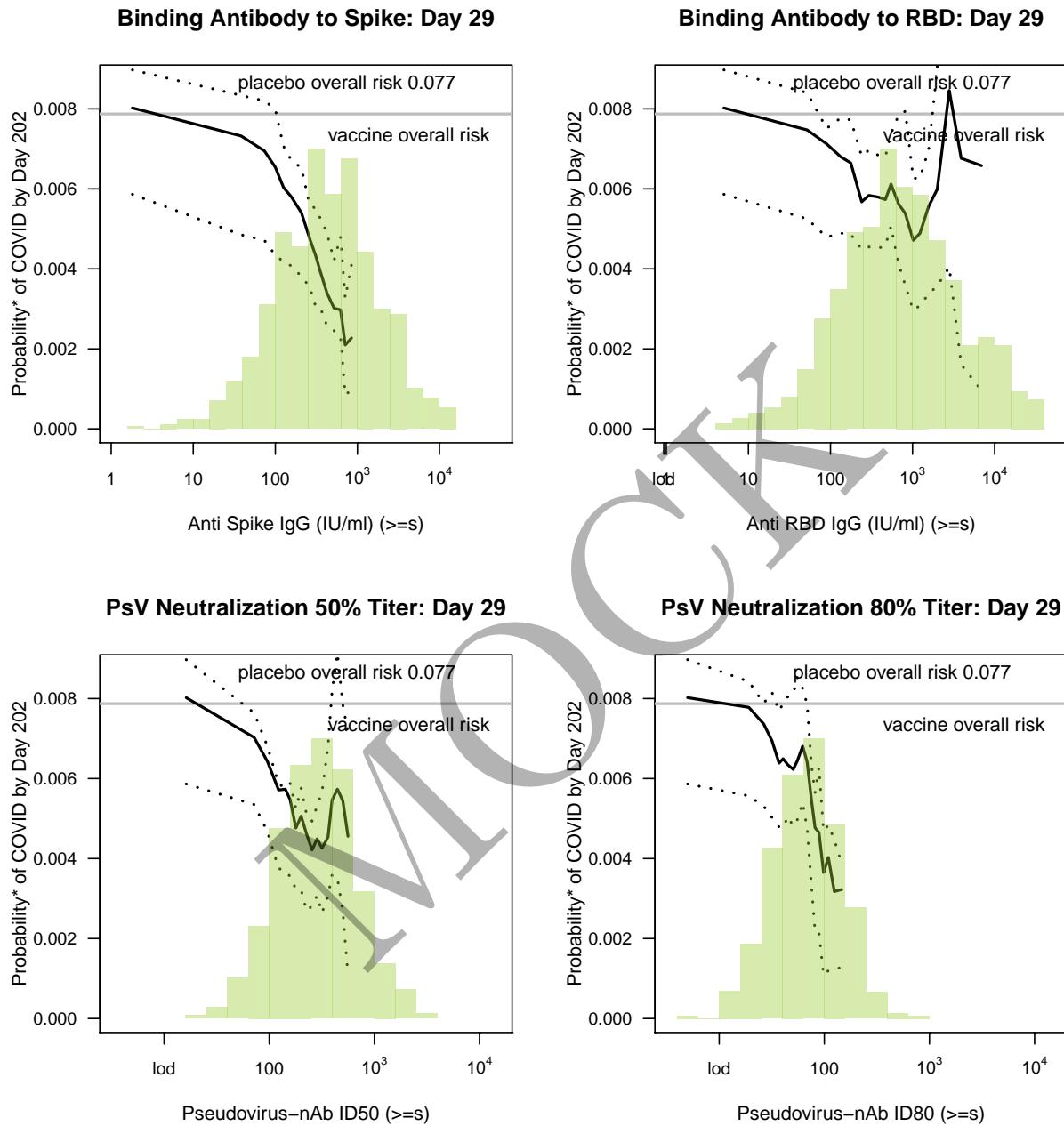


Figure 4.8: Marginalized cumulative risk by Day 202 as functions of Day 29 markers above a threshold ($\geq s$) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands (at least 5 cases are required). The horizontal lines indicate the overall cumulative risk of the vaccine arm by Day 202 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.

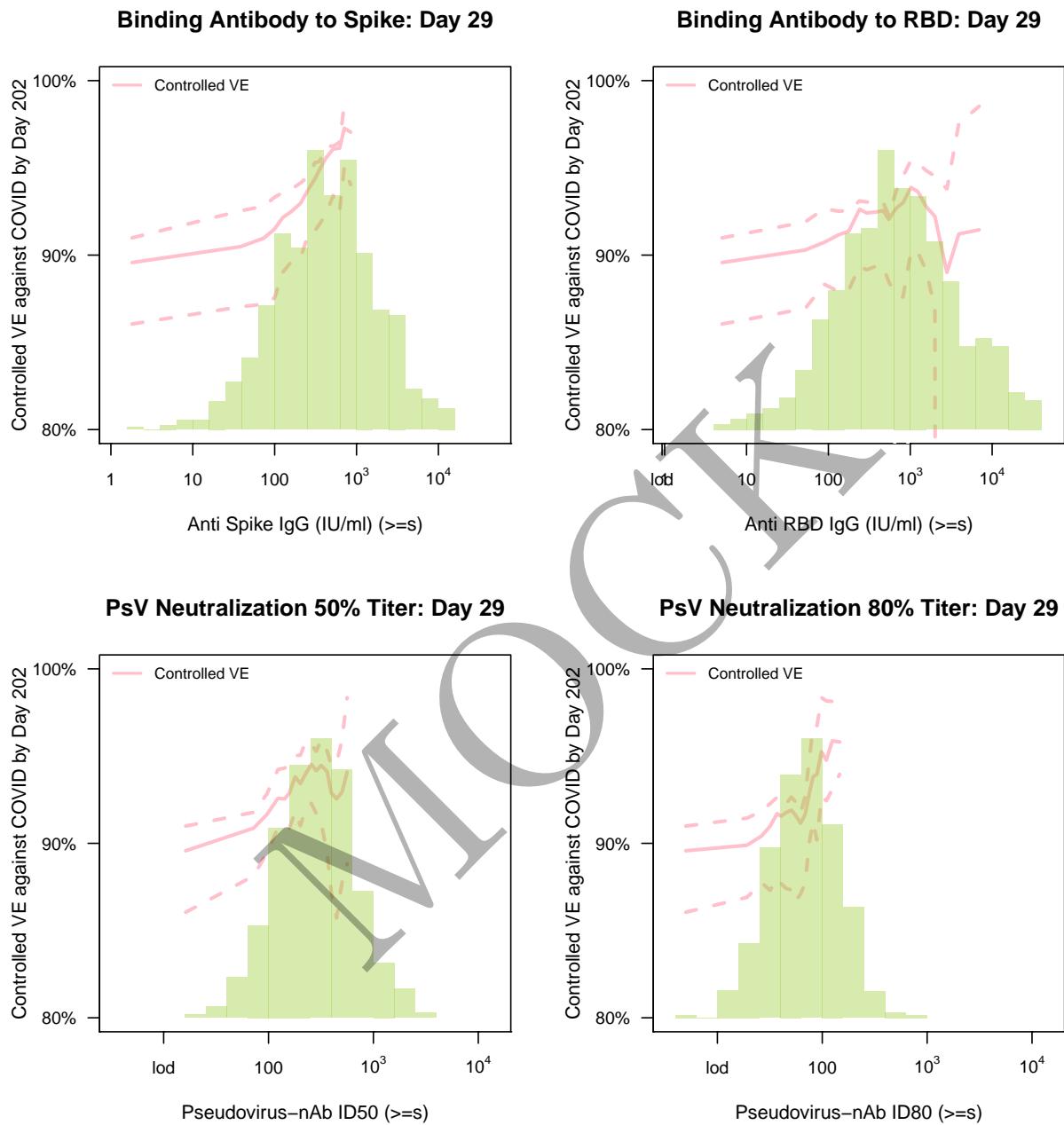


Figure 4.9: Controlled VE as functions of Day 29 markers ($\geq s$) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.

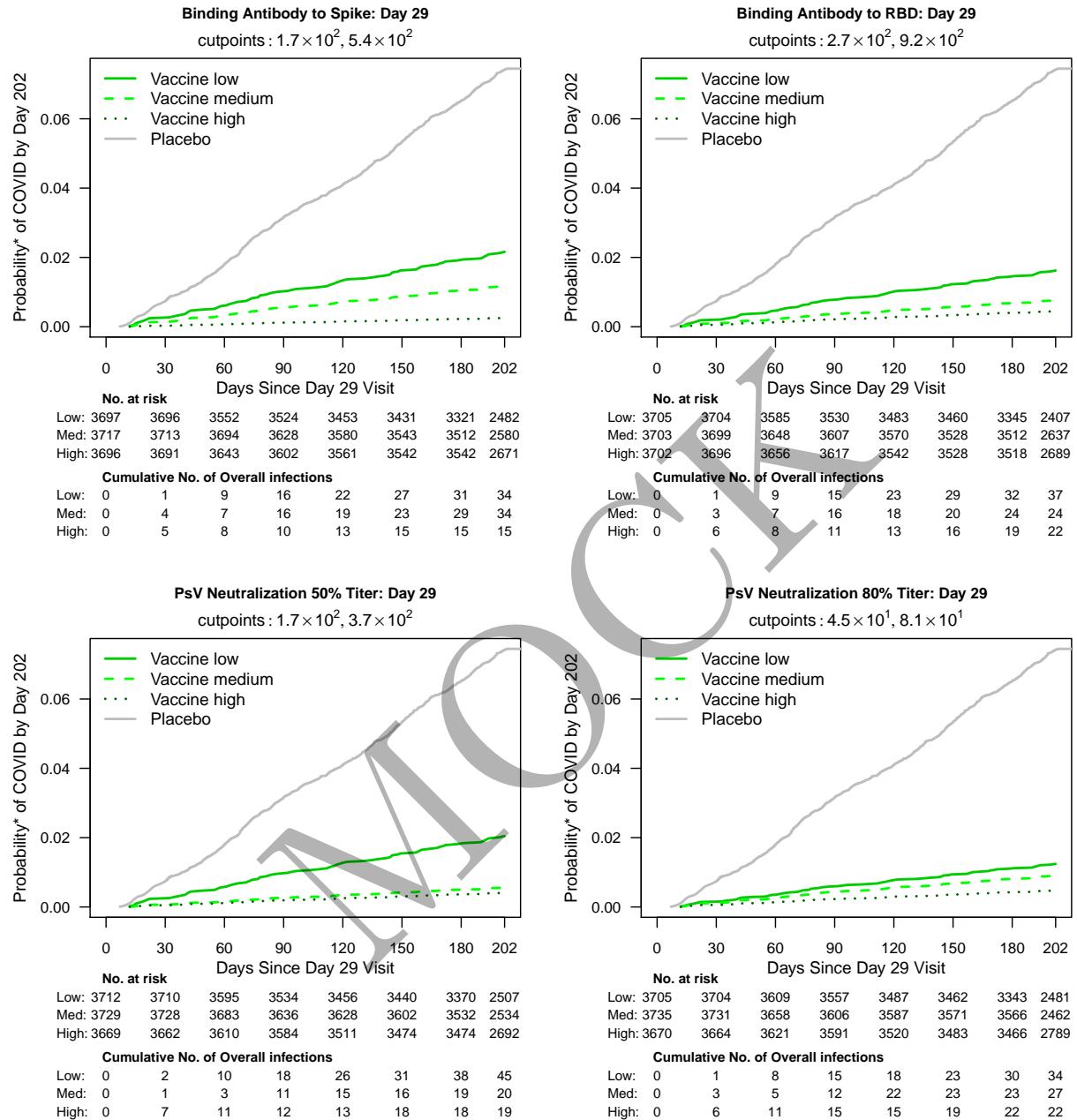


Figure 4.10: Marginalized cumulative incidence rate curves for trichotomized Day 29 markers among baseline seronegative vaccine recipients. The gray line is the overall cumulative incidence rate curve in the placebo arm.

Chapter 5

Univariate CoR: Nonparametric Threshold Modeling

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.

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

MOCK

5.1.1 Day 57 Spike protein binding antibody

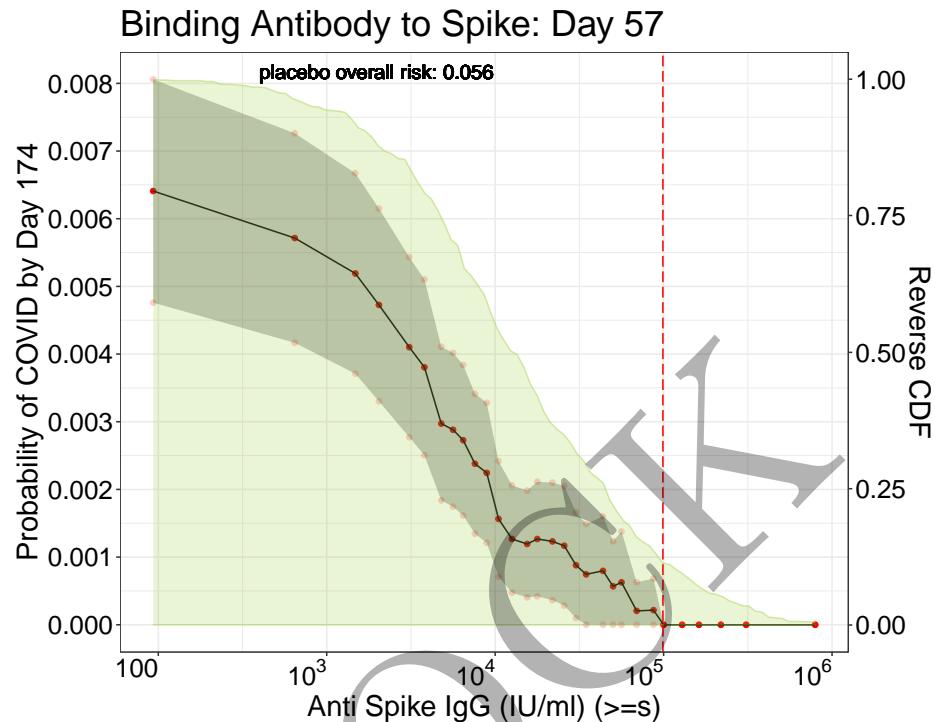


Figure 5.1: Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table 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
1.970	$9.33 * 10^1$	0.00641	0.00476	0.00806
3.312	$2.05 * 10^3$	0.00473	0.00330	0.00615
3.683	$4.82 * 10^3$	0.00297	0.00184	0.00411
3.953	$8.97 * 10^3$	0.00224	0.00121	0.00328
4.190	$1.55 * 10^4$	0.00119	0.00040	0.00198
4.413	$2.59 * 10^4$	0.00117	0.00028	0.00205
4.642	$4.39 * 10^4$	0.00080	0.00000	0.00160
4.939	$8.69 * 10^4$	0.00022	0.00000	0.00068
5.206	$1.61 * 10^5$	0.00000	0.00000	NA
5.899	$7.93 * 10^5$	0.00000	0.00000	NA

5.1.2 Day 57 RBD binding antibody

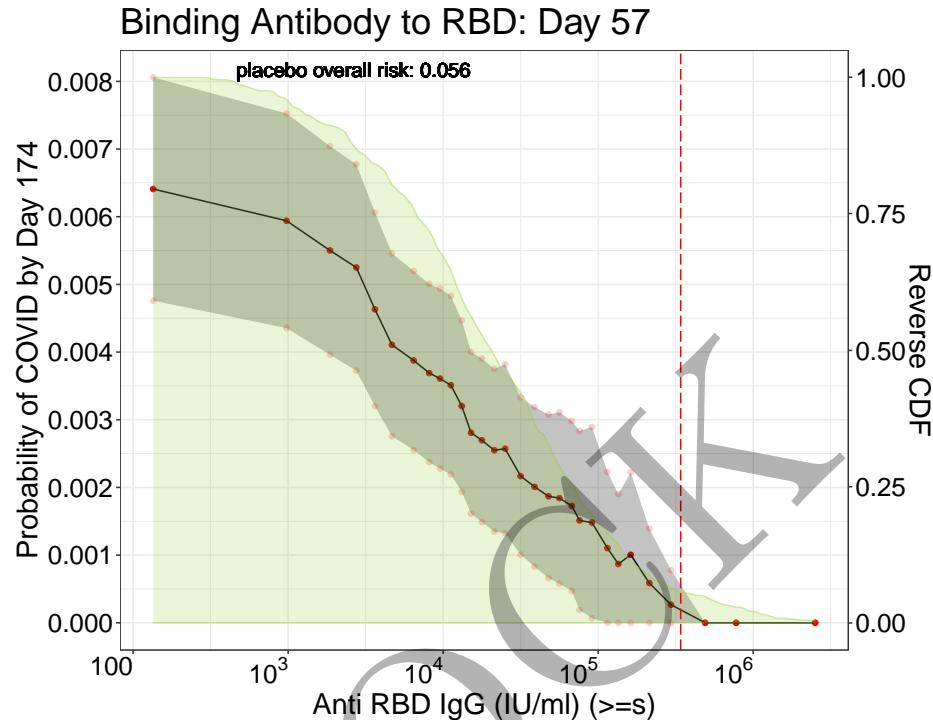


Figure 5.2: Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table 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
2.133	$1.36 * 10^2$	0.00641	0.00476	0.00806
3.441	$2.76 * 10^3$	0.00525	0.00373	0.00677
3.814	$6.52 * 10^3$	0.00388	0.00255	0.00520
4.119	$1.32 * 10^4$	0.00320	0.00194	0.00447
4.332	$2.15 * 10^4$	0.00255	0.00135	0.00375
4.591	$3.90 * 10^4$	0.00201	0.00083	0.00319
4.830	$6.76 * 10^4$	0.00173	0.00047	0.00298
5.135	$1.36 * 10^5$	0.00087	0.00000	0.00190
5.473	$2.97 * 10^5$	0.00027	0.00000	0.00078
6.399	$2.51 * 10^6$	0.00000	0.00000	NA

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

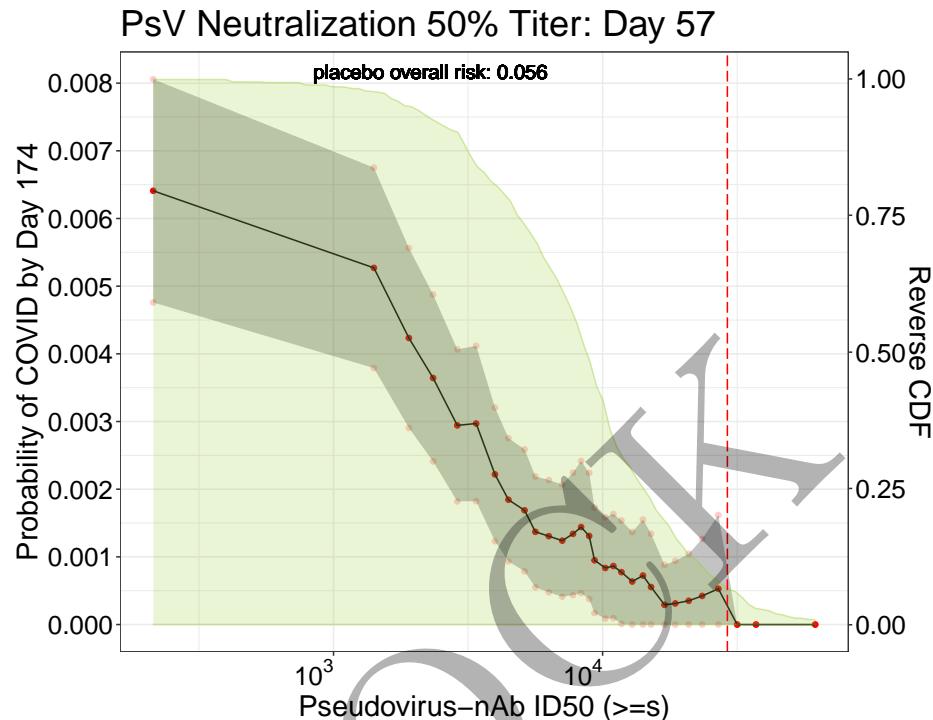


Figure 5.3: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table 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
2.333	$2.15 * 10^2$	0.00641	0.00476	0.00806
3.374	$2.37 * 10^3$	0.00364	0.00241	0.00488
3.602	$4.00 * 10^3$	0.00222	0.00123	0.00321
3.800	$6.31 * 10^3$	0.00131	0.00048	0.00214
3.923	$8.38 * 10^3$	0.00144	0.00046	0.00242
4.005	$1.01 * 10^4$	0.00084	0.00009	0.00159
4.115	$1.30 * 10^4$	0.00064	0.00000	0.00137
4.270	$1.86 * 10^4$	0.00031	0.00000	0.00094
4.425	$2.66 * 10^4$	0.00053	0.00000	0.00162
4.786	$6.11 * 10^4$	0.00000	0.00000	NA

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

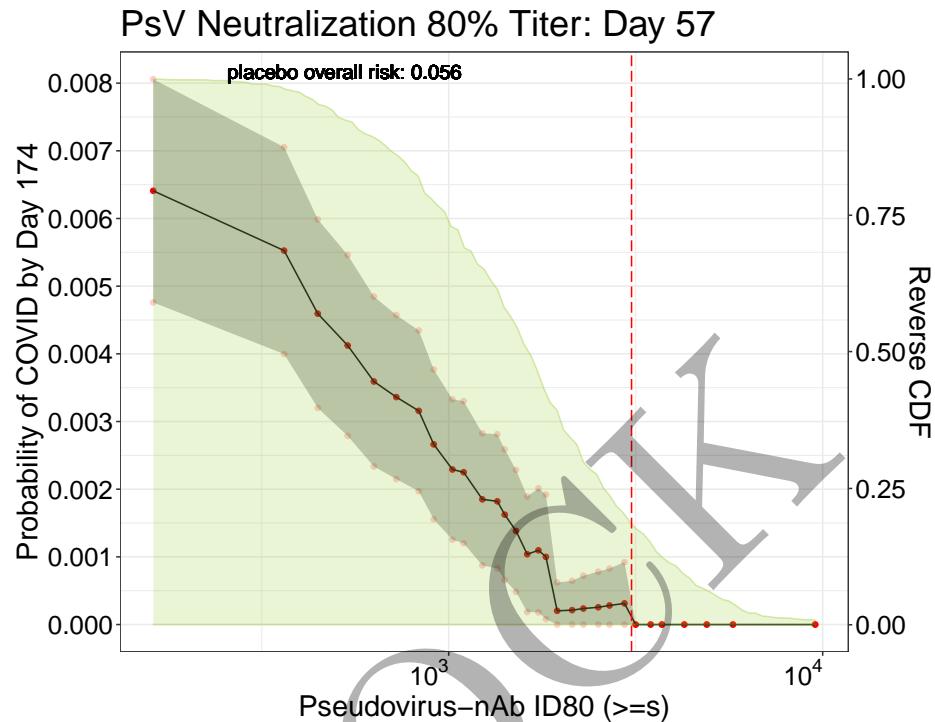


Figure 5.4: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table 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
2.215	$1.64 * 10^2$	0.00641	0.00476	0.00806
2.734	$5.42 * 10^2$	0.00412	0.00279	0.00546
2.924	$8.39 * 10^2$	0.00316	0.00197	0.00435
3.086	$1.22 * 10^3$	0.00185	0.00087	0.00283
3.179	$1.51 * 10^3$	0.00138	0.00048	0.00228
3.263	$1.83 * 10^3$	0.00100	0.00008	0.00192
3.357	$2.28 * 10^3$	0.00024	0.00000	0.00072
3.503	$3.18 * 10^3$	0.00000	0.00000	NA
3.630	$4.27 * 10^3$	0.00000	0.00000	NA
3.980	$9.55 * 10^3$	0.00000	0.00000	NA

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

MOCK

5.2.1 Day 29 Spike protein antibody

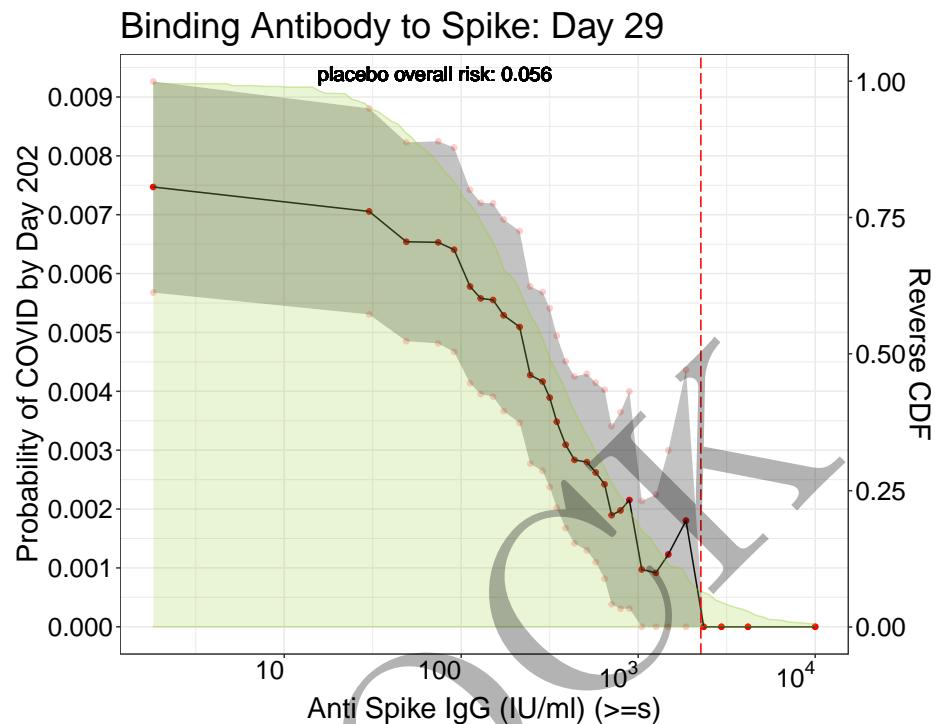


Figure 5.5: Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table 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
0.259	$1.82 * 10^0$	0.00747	0.00568	0.00926
1.869	$7.40 * 10^1$	0.00653	0.00481	0.00825
2.108	$1.28 * 10^2$	0.00558	0.00395	0.00720
2.395	$2.48 * 10^2$	0.00428	0.00277	0.00578
2.544	$3.50 * 10^2$	0.00348	0.00202	0.00494
2.708	$5.11 * 10^2$	0.00280	0.00130	0.00430
2.850	$7.08 * 10^2$	0.00190	0.00038	0.00341
3.099	$1.26 * 10^3$	0.00092	0.00000	0.00225
3.373	$2.36 * 10^3$	0.00000	0.00000	NA
4.004	$1.01 * 10^4$	0.00000	0.00000	NA

5.2.2 Day 29 RBD binding antibody

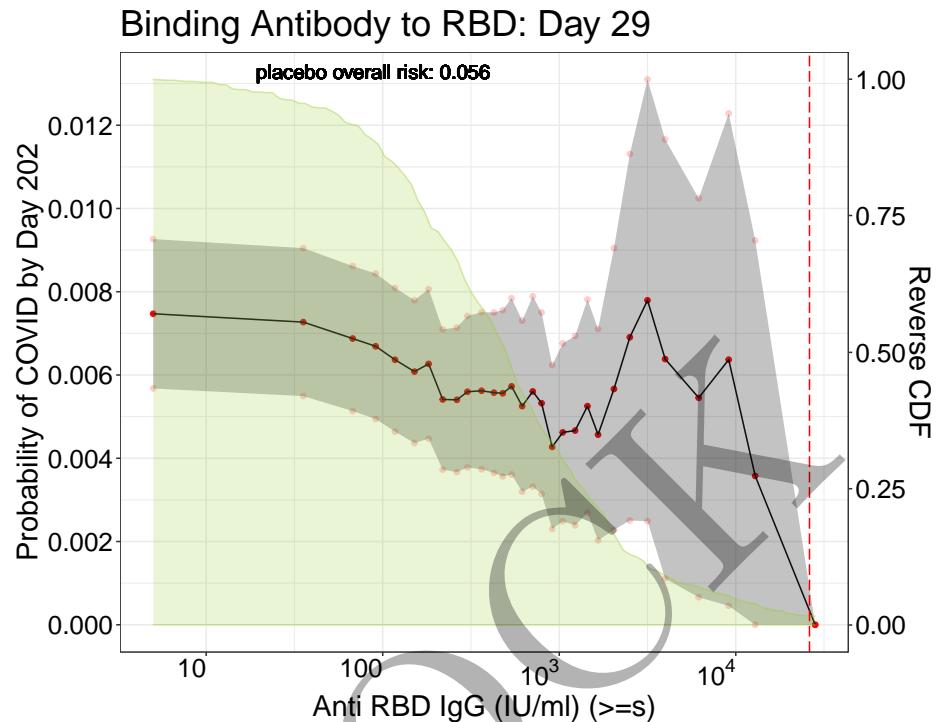


Figure 5.6: Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table 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
0.702	5.04×10^0	0.00747	0.00568	0.00926
1.965	9.23×10^1	0.00669	0.00494	0.00844
2.257	1.81×10^2	0.00627	0.00447	0.00806
2.556	3.60×10^2	0.00562	0.00374	0.00751
2.729	5.36×10^2	0.00573	0.00361	0.00785
2.899	7.93×10^2	0.00532	0.00314	0.00750
3.087	1.22×10^3	0.00466	0.00239	0.00694
3.395	2.48×10^3	0.00691	0.00250	0.01131
3.786	6.11×10^3	0.00545	0.00066	0.01024
4.448	2.81×10^4	0.00000	0.00000	NA

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

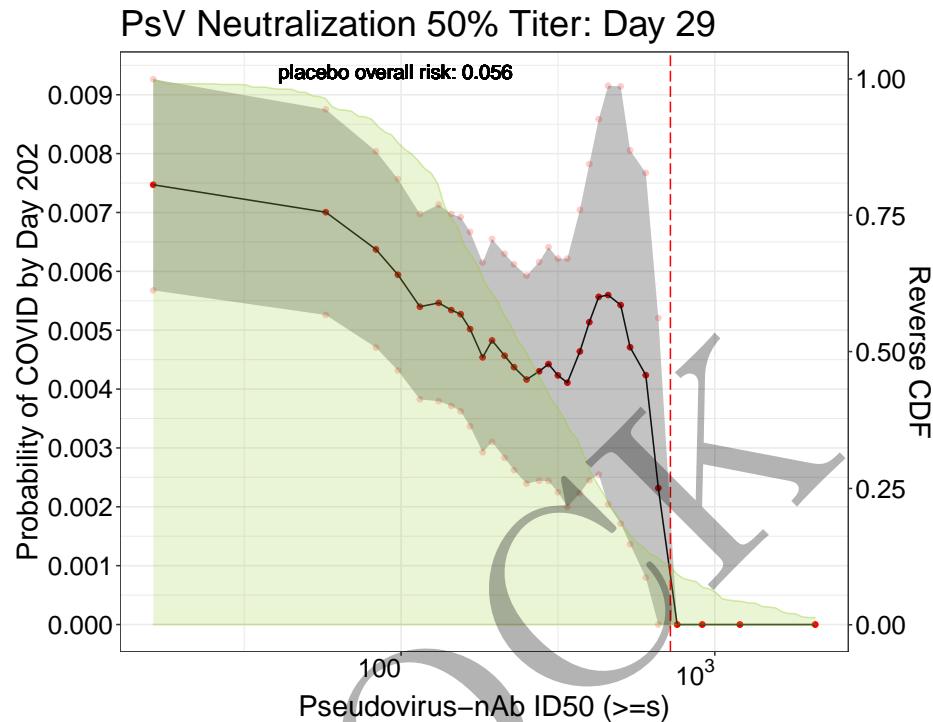


Figure 5.7: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table 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
1.211	1.63×10^1	0.00747	0.00568	0.00926
1.993	9.84×10^1	0.00594	0.00432	0.00757
2.157	1.44×10^2	0.00534	0.00371	0.00697
2.293	1.96×10^2	0.00483	0.00310	0.00655
2.401	2.52×10^2	0.00416	0.00239	0.00593
2.500	3.16×10^2	0.00423	0.00225	0.00622
2.597	3.95×10^2	0.00514	0.00245	0.00782
2.731	5.38×10^2	0.00471	0.00136	0.00806
2.879	7.57×10^2	0.00000	0.00000	NA
3.323	2.10×10^3	0.00000	0.00000	NA

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

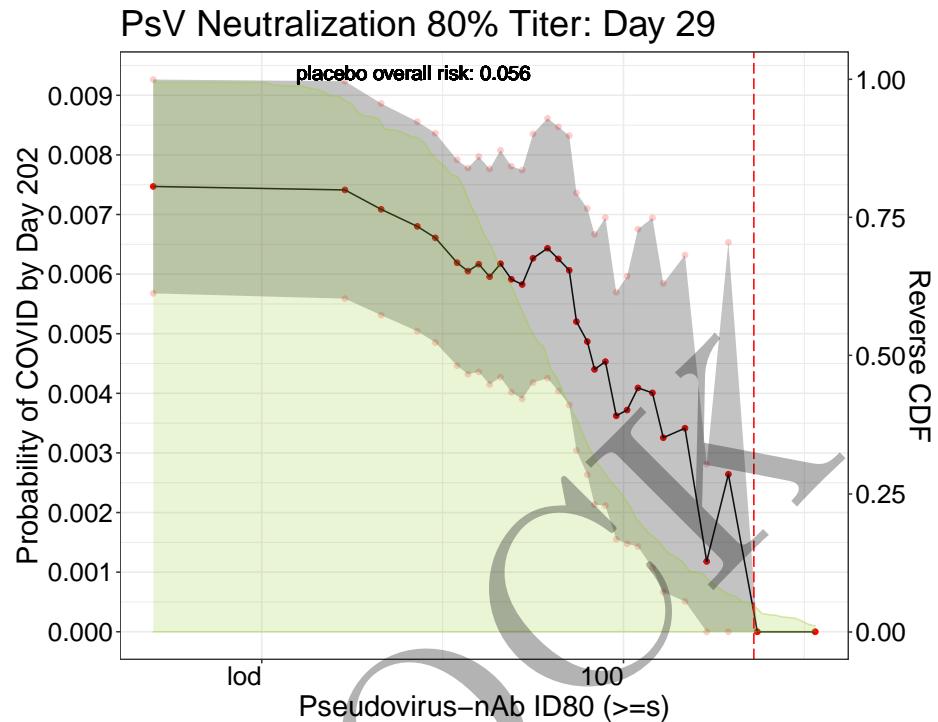


Figure 5.8: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table 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
0.699	$5.00 * 10^0$	0.00747	0.00568	0.00926
1.432	$2.70 * 10^1$	0.00680	0.00504	0.00856
1.571	$3.72 * 10^1$	0.00605	0.00432	0.00778
1.694	$4.94 * 10^1$	0.00591	0.00402	0.00781
1.785	$6.10 * 10^1$	0.00643	0.00425	0.00861
1.873	$7.46 * 10^1$	0.00520	0.00304	0.00736
1.949	$8.89 * 10^1$	0.00453	0.00212	0.00695
2.080	$1.20 * 10^2$	0.00401	0.00107	0.00694
2.232	$1.71 * 10^2$	0.00118	0.00000	0.00281
2.526	$3.36 * 10^2$	0.00000	0.00000	NA

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

MOCK

5.3.1 Day 57 Spike protein binding antibody

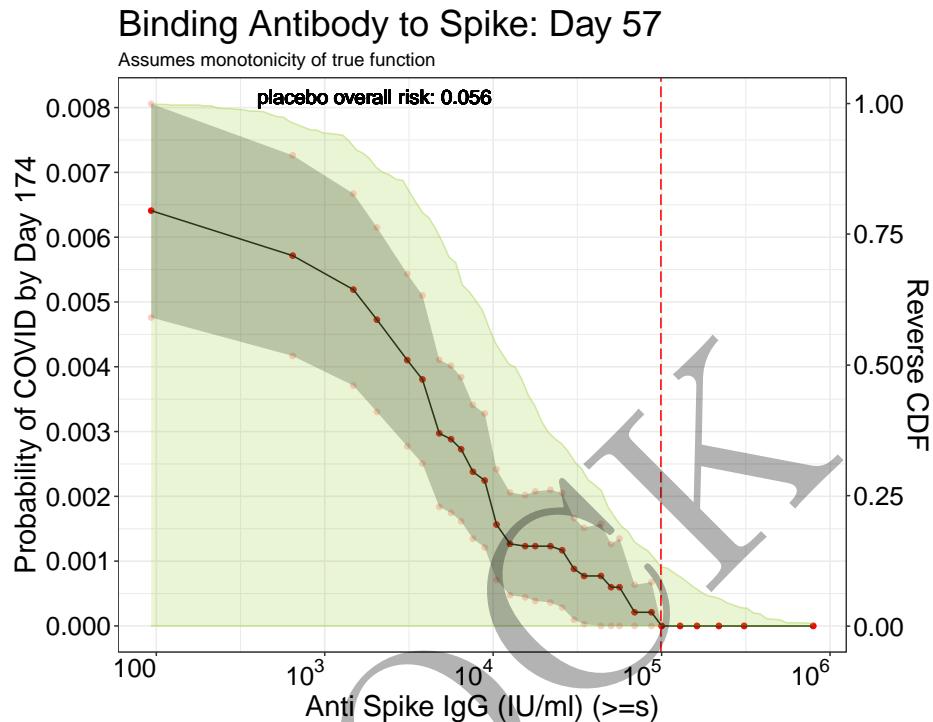


Figure 5.9: Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 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
1.970	$9.33 * 10^1$	0.00641	0.00476	0.00806
3.312	$2.05 * 10^3$	0.00473	0.00330	0.00615
3.683	$4.82 * 10^3$	0.00297	0.00184	0.00411
3.953	$8.97 * 10^3$	0.00224	0.00121	0.00328
4.190	$1.55 * 10^4$	0.00123	0.00044	0.00202
4.413	$2.59 * 10^4$	0.00117	0.00028	0.00205
4.642	$4.39 * 10^4$	0.00077	0.00000	0.00158
4.939	$8.69 * 10^4$	0.00021	0.00000	0.00068
5.206	$1.61 * 10^5$	0.00000	0.00000	NA
5.899	$7.93 * 10^5$	0.00000	0.00000	NA

5.3.2 Day 57 RBD binding antibody

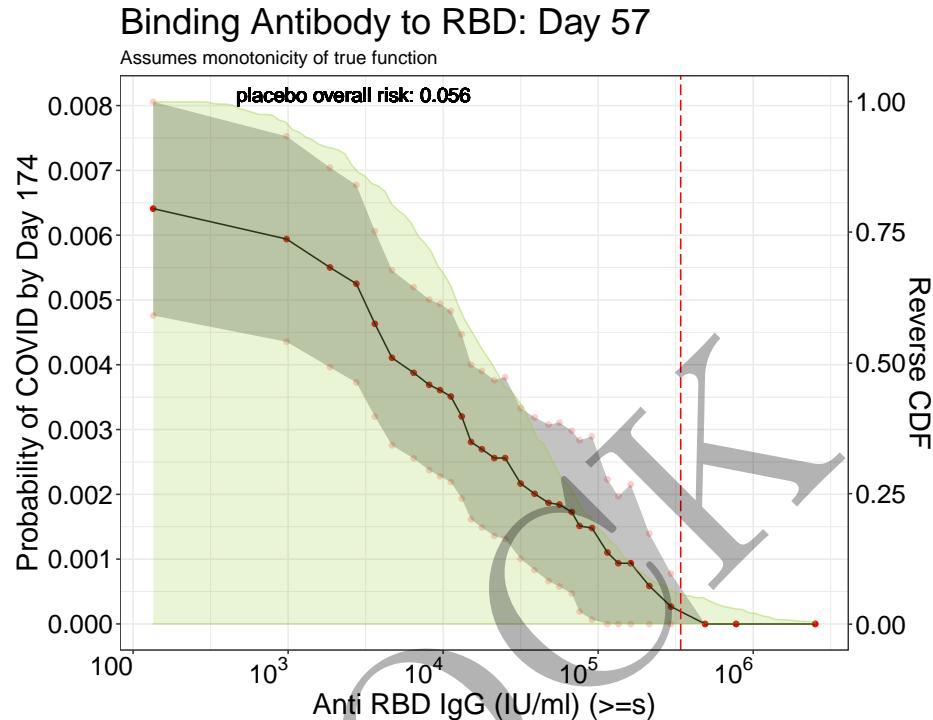


Figure 5.10: Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 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
2.133	1.36×10^2	0.00641	0.00476	0.00806
3.441	2.76×10^3	0.00525	0.00373	0.00677
3.814	6.52×10^3	0.00388	0.00255	0.00520
4.119	1.32×10^4	0.00320	0.00194	0.00447
4.332	2.15×10^4	0.00256	0.00136	0.00376
4.591	3.90×10^4	0.00201	0.00083	0.00319
4.830	6.76×10^4	0.00173	0.00047	0.00298
5.135	1.36×10^5	0.00094	0.00000	0.00197
5.473	2.97×10^5	0.00027	0.00000	0.00078
6.399	2.51×10^6	0.00000	0.00000	NA

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

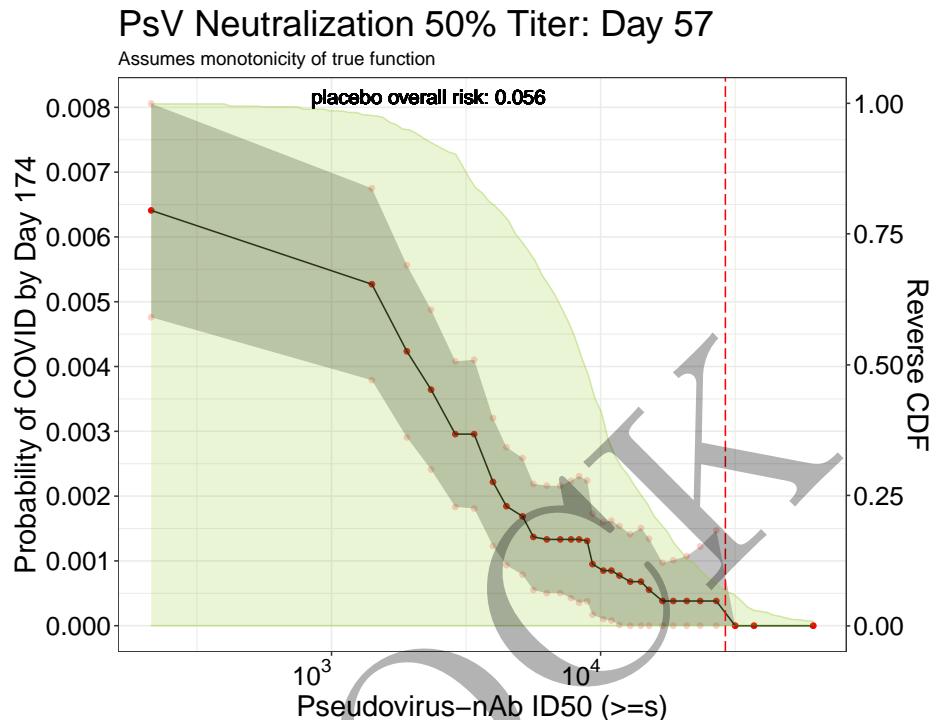


Figure 5.11: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 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
2.333	$2.15 * 10^2$	0.00641	0.00476	0.00806
3.374	$2.37 * 10^3$	0.00364	0.00241	0.00488
3.602	$4.00 * 10^3$	0.00222	0.00123	0.00321
3.800	$6.31 * 10^3$	0.00133	0.00050	0.00216
3.923	$8.38 * 10^3$	0.00133	0.00036	0.00231
4.005	$1.01 * 10^4$	0.00085	0.00010	0.00160
4.115	$1.30 * 10^4$	0.00068	0.00000	0.00141
4.270	$1.86 * 10^4$	0.00038	0.00000	0.00101
4.425	$2.66 * 10^4$	0.00038	0.00000	0.00147
4.786	$6.11 * 10^4$	0.00000	0.00000	NA

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

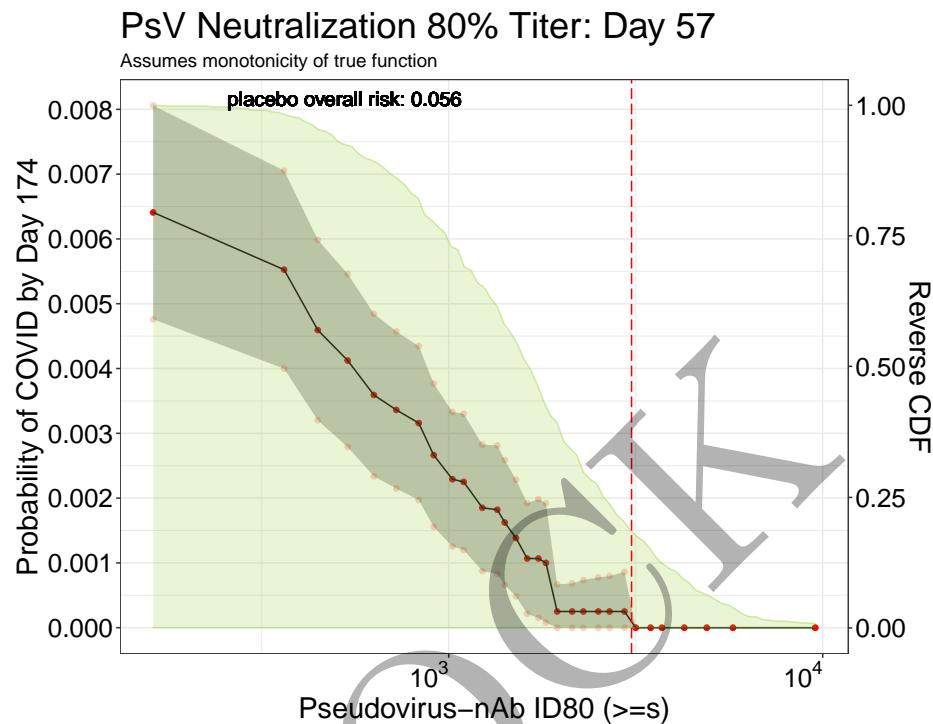


Figure 5.12: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 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
2.215	$1.64 * 10^2$	0.00641	0.00476	0.00806
2.734	$5.42 * 10^2$	0.00412	0.00279	0.00546
2.924	$8.39 * 10^2$	0.00316	0.00197	0.00435
3.086	$1.22 * 10^3$	0.00185	0.00087	0.00283
3.179	$1.51 * 10^3$	0.00138	0.00048	0.00228
3.263	$1.83 * 10^3$	0.00100	0.00008	0.00192
3.357	$2.28 * 10^3$	0.00025	0.00000	0.00074
3.503	$3.18 * 10^3$	0.00000	0.00000	NA
3.630	$4.27 * 10^3$	0.00000	0.00000	NA
3.980	$9.55 * 10^3$	0.00000	0.00000	NA

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

MOCK

5.4.1 Day 29 Spike protein antibody

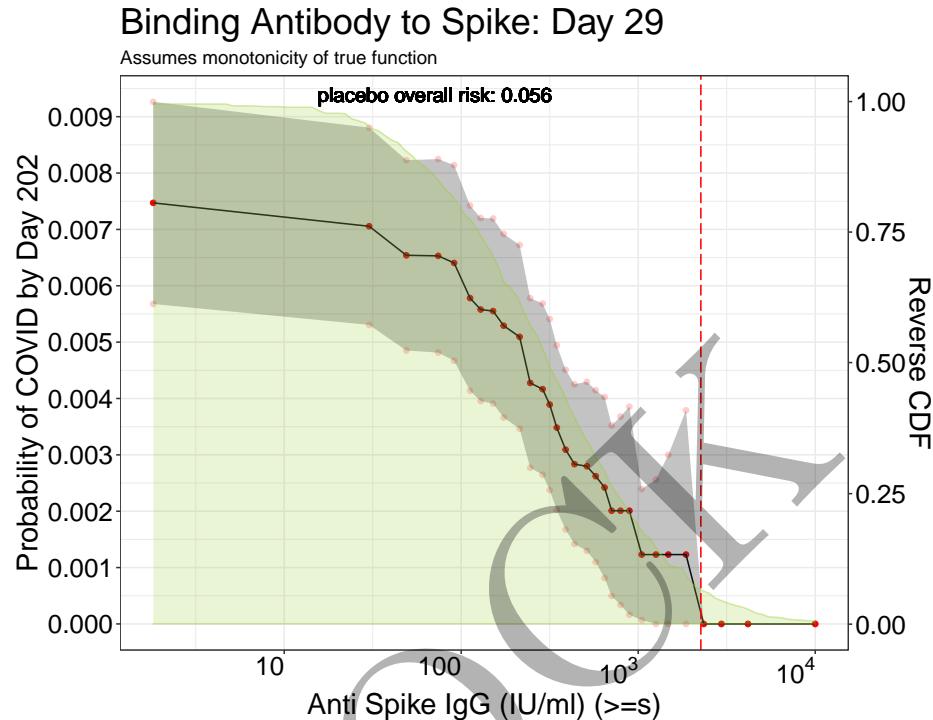


Figure 5.13: Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 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
0.259	1.82×10^0	0.00747	0.00568	0.00926
1.869	7.40×10^1	0.00653	0.00481	0.00825
2.108	1.28×10^2	0.00558	0.00395	0.00720
2.395	2.48×10^2	0.00428	0.00277	0.00578
2.544	3.50×10^2	0.00348	0.00202	0.00494
2.708	5.11×10^2	0.00280	0.00130	0.00430
2.850	7.08×10^2	0.00201	0.00050	0.00352
3.099	1.26×10^3	0.00123	0.00000	0.00256
3.373	2.36×10^3	0.00000	0.00000	NA
4.004	1.01×10^4	0.00000	0.00000	NA

5.4.2 Day 29 RBD binding antibody

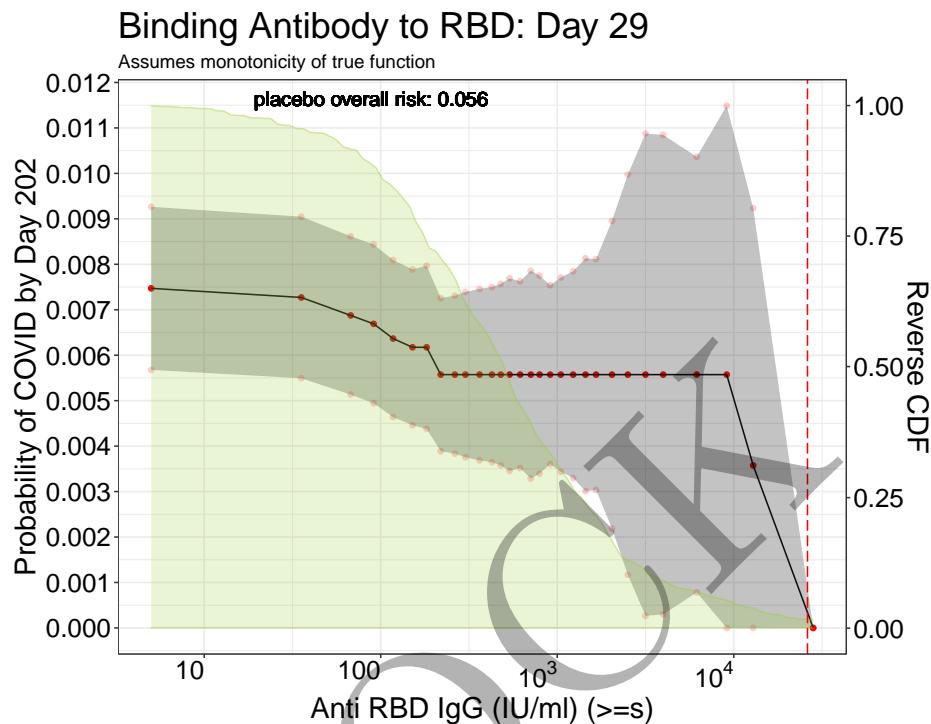


Figure 5.14: Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 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
0.702	5.04×10^0	0.00747	0.00568	0.00926
1.965	9.23×10^1	0.00669	0.00494	0.00844
2.257	1.81×10^2	0.00617	0.00438	0.00797
2.556	3.60×10^2	0.00557	0.00369	0.00746
2.729	5.36×10^2	0.00557	0.00345	0.00769
2.899	7.93×10^2	0.00557	0.00339	0.00775
3.087	1.22×10^3	0.00557	0.00330	0.00785
3.395	2.48×10^3	0.00557	0.00117	0.00998
3.786	6.11×10^3	0.00557	0.00078	0.01036
4.448	2.81×10^4	0.00000	0.00000	NA

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

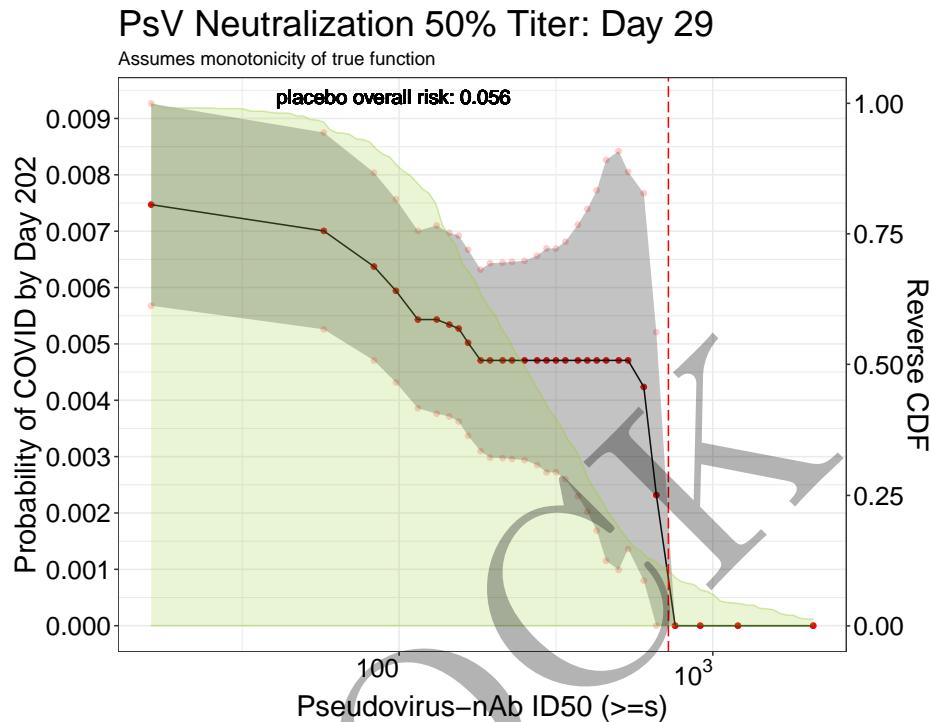


Figure 5.15: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 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
1.211	$1.63 * 10^1$	0.00747	0.00568	0.00926
1.993	$9.84 * 10^1$	0.00594	0.00432	0.00757
2.157	$1.44 * 10^2$	0.00534	0.00371	0.00697
2.293	$1.96 * 10^2$	0.00471	0.00298	0.00643
2.401	$2.52 * 10^2$	0.00471	0.00294	0.00647
2.500	$3.16 * 10^2$	0.00471	0.00272	0.00669
2.597	$3.95 * 10^2$	0.00471	0.00202	0.00739
2.731	$5.38 * 10^2$	0.00471	0.00136	0.00805
2.879	$7.57 * 10^2$	0.00000	0.00000	NA
3.323	$2.10 * 10^3$	0.00000	0.00000	NA

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

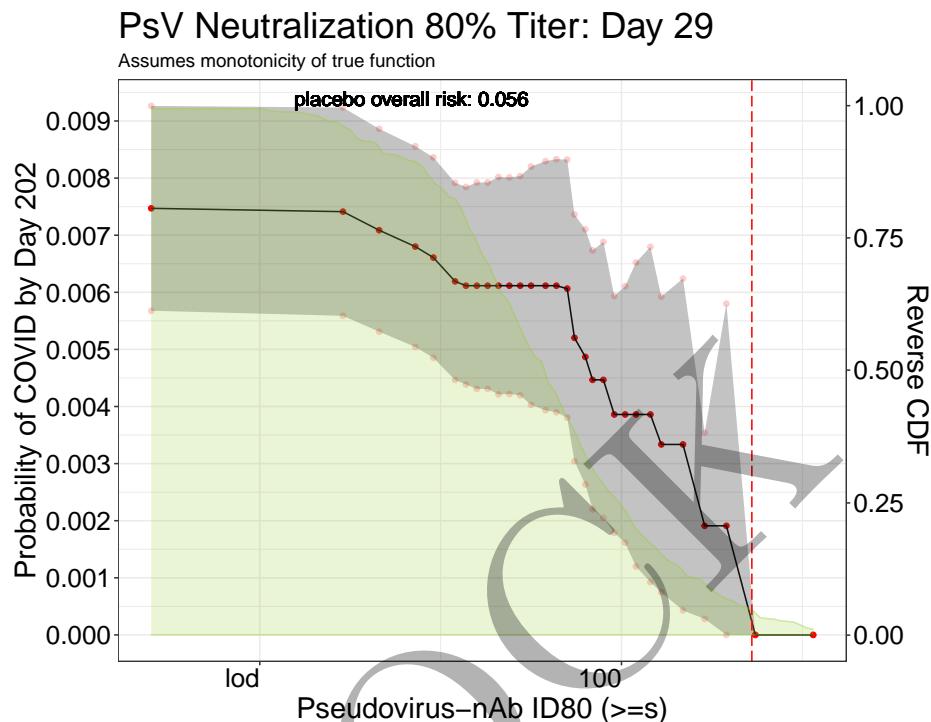


Figure 5.16: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 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
0.699	$5.00 * 10^0$	0.00747	0.00568	0.00926
1.432	$2.70 * 10^1$	0.00680	0.00504	0.00856
1.571	$3.72 * 10^1$	0.00612	0.00439	0.00785
1.694	$4.94 * 10^1$	0.00612	0.00422	0.00801
1.785	$6.10 * 10^1$	0.00612	0.00394	0.00830
1.873	$7.46 * 10^1$	0.00520	0.00304	0.00736
1.949	$8.89 * 10^1$	0.00447	0.00205	0.00688
2.080	$1.20 * 10^2$	0.00386	0.00092	0.00680
2.232	$1.71 * 10^2$	0.00191	0.00028	0.00354
2.526	$3.36 * 10^2$	0.00000	0.00000	NA

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

MOCK

5.5.1 Day 57 Spike protein binding antibody

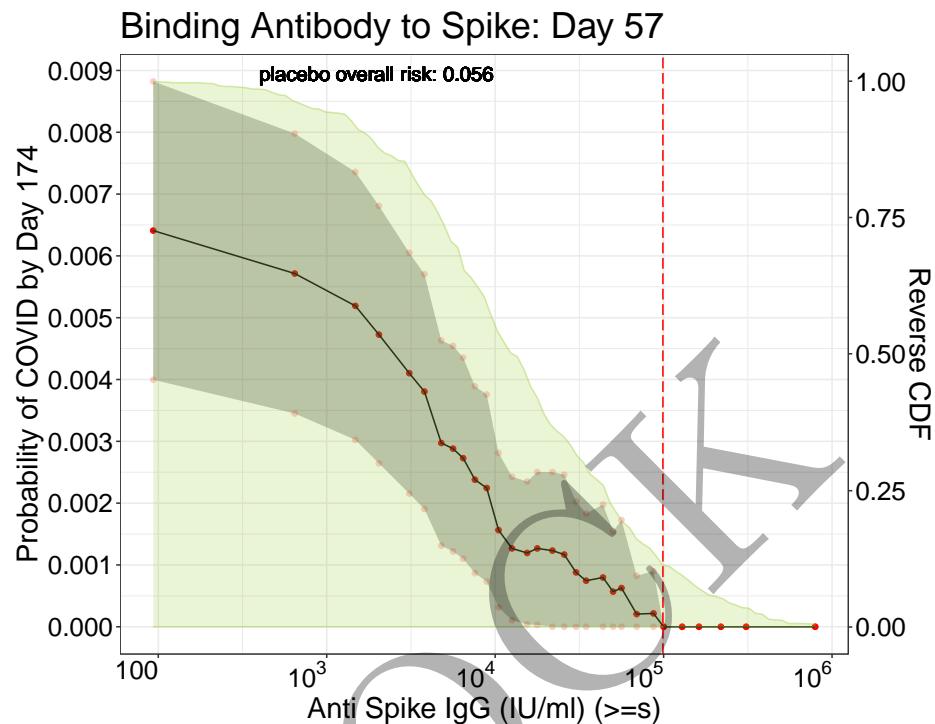


Figure 5.17: Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table 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
1.970	9.33×10^1	0.00641	0.00400	0.00882
3.312	2.05×10^3	0.00473	0.00264	0.00681
3.683	4.82×10^3	0.00297	0.00131	0.00463
3.953	8.97×10^3	0.00224	0.00073	0.00376
4.190	1.55×10^4	0.00119	0.00004	0.00235
4.413	2.59×10^4	0.00117	0.00000	0.00246
4.642	4.39×10^4	0.00080	0.00000	0.00198
4.939	8.69×10^4	0.00022	0.00000	0.00090
5.206	1.61×10^5	0.00000	0.00000	NA
5.899	7.93×10^5	0.00000	0.00000	NA

5.5.2 Day 57 RBD binding antibody

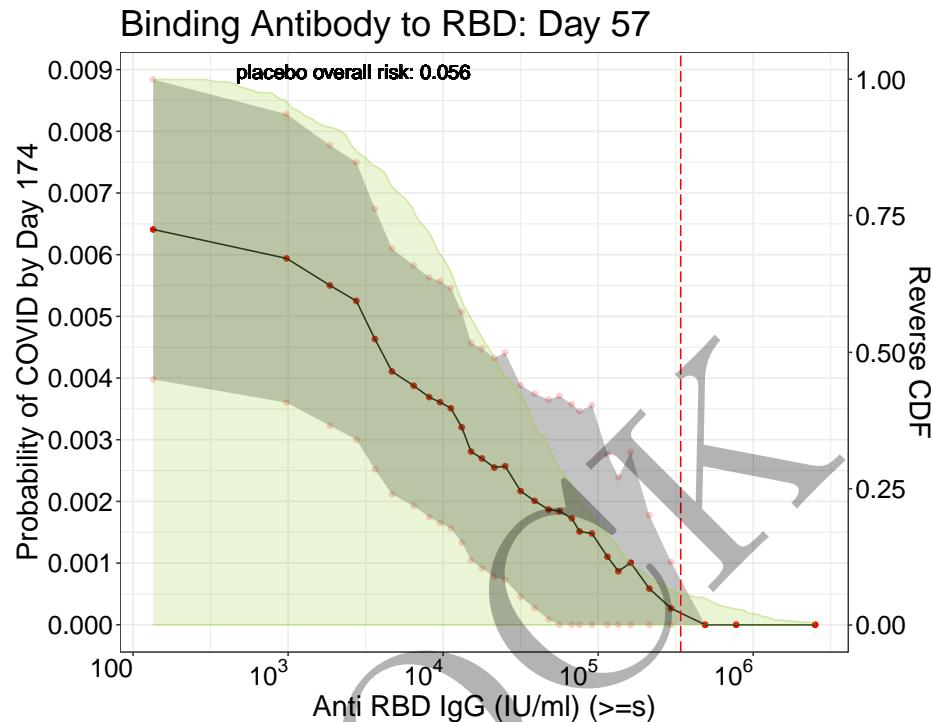


Figure 5.18: Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table 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
2.133	$1.36 * 10^2$	0.00641	0.00398	0.00884
3.441	$2.76 * 10^3$	0.00525	0.00300	0.00750
3.814	$6.52 * 10^3$	0.00388	0.00193	0.00583
4.119	$1.32 * 10^4$	0.00320	0.00133	0.00507
4.332	$2.15 * 10^4$	0.00255	0.00078	0.00432
4.591	$3.90 * 10^4$	0.00201	0.00027	0.00375
4.830	$6.76 * 10^4$	0.00173	0.00000	0.00358
5.135	$1.36 * 10^5$	0.00087	0.00000	0.00239
5.473	$2.97 * 10^5$	0.00027	0.00000	0.00102
6.399	$2.51 * 10^6$	0.00000	0.00000	NA

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

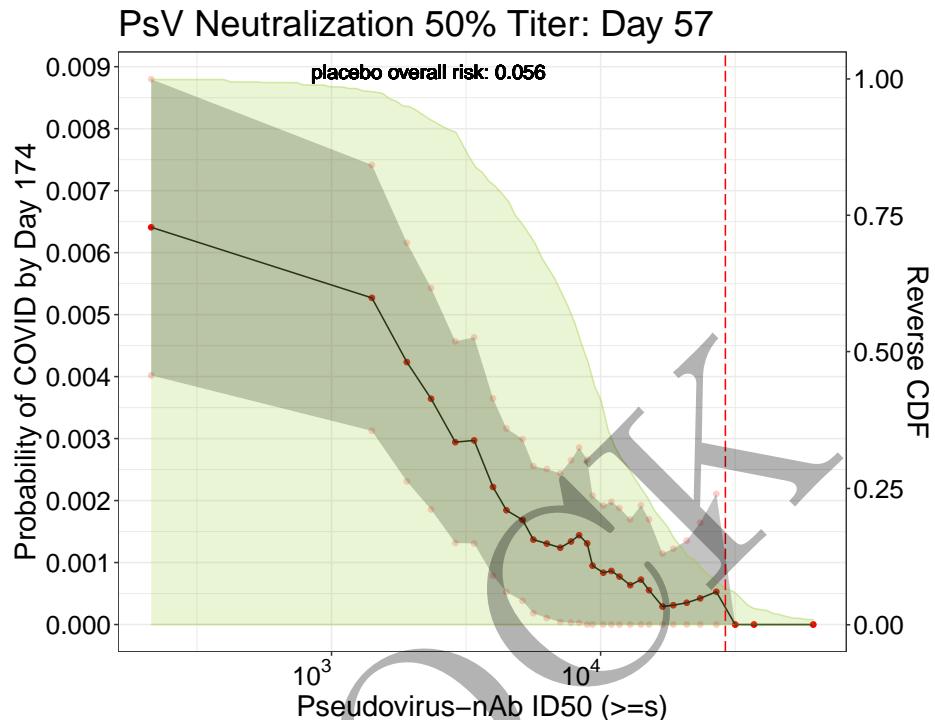


Figure 5.19: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table 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
2.333	$2.15 * 10^2$	0.00641	0.00402	0.00880
3.374	$2.37 * 10^3$	0.00364	0.00186	0.00543
3.602	$4.00 * 10^3$	0.00222	0.00079	0.00365
3.800	$6.31 * 10^3$	0.00131	0.00010	0.00251
3.923	$8.38 * 10^3$	0.00144	0.00003	0.00285
4.005	$1.01 * 10^4$	0.00084	0.00000	0.00192
4.115	$1.30 * 10^4$	0.00064	0.00000	0.00170
4.270	$1.86 * 10^4$	0.00031	0.00000	0.00122
4.425	$2.66 * 10^4$	0.00053	0.00000	0.00211
4.786	$6.11 * 10^4$	0.00000	0.00000	NA

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

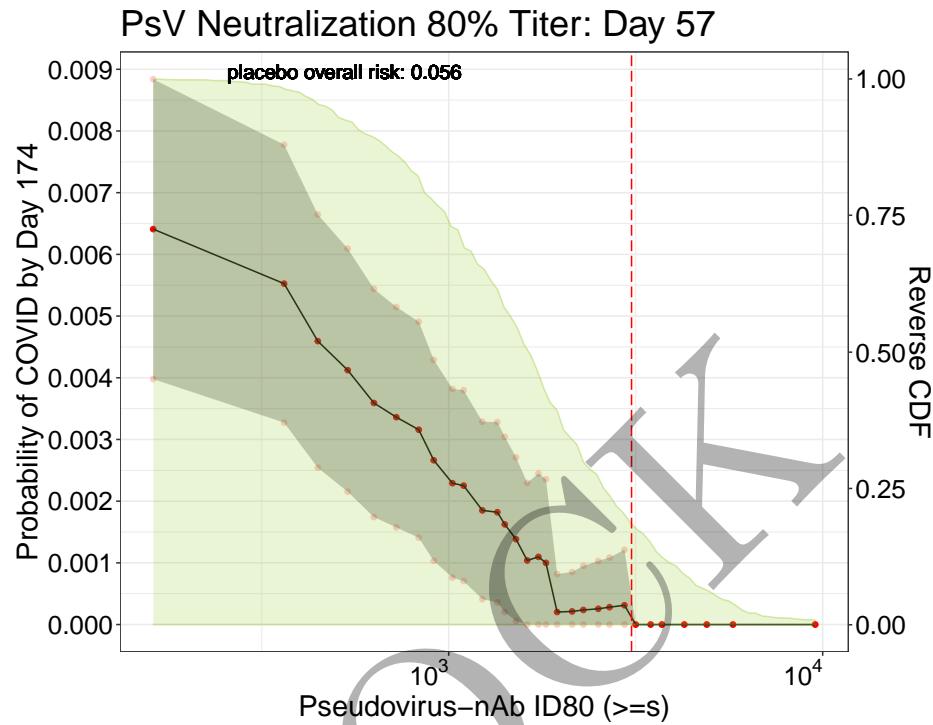


Figure 5.20: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table 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
2.215	$1.64 * 10^2$	0.00641	0.00398	0.00884
2.734	$5.42 * 10^2$	0.00412	0.00215	0.00609
2.924	$8.39 * 10^2$	0.00316	0.00141	0.00491
3.086	$1.22 * 10^3$	0.00185	0.00041	0.00329
3.179	$1.51 * 10^3$	0.00138	0.00006	0.00271
3.263	$1.83 * 10^3$	0.00100	0.00000	0.00236
3.357	$2.28 * 10^3$	0.00024	0.00000	0.00095
3.503	$3.18 * 10^3$	0.00000	0.00000	NA
3.630	$4.27 * 10^3$	0.00000	0.00000	NA
3.980	$9.55 * 10^3$	0.00000	0.00000	NA

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

MOCK

5.6.1 Day 29 Spike protein antibody

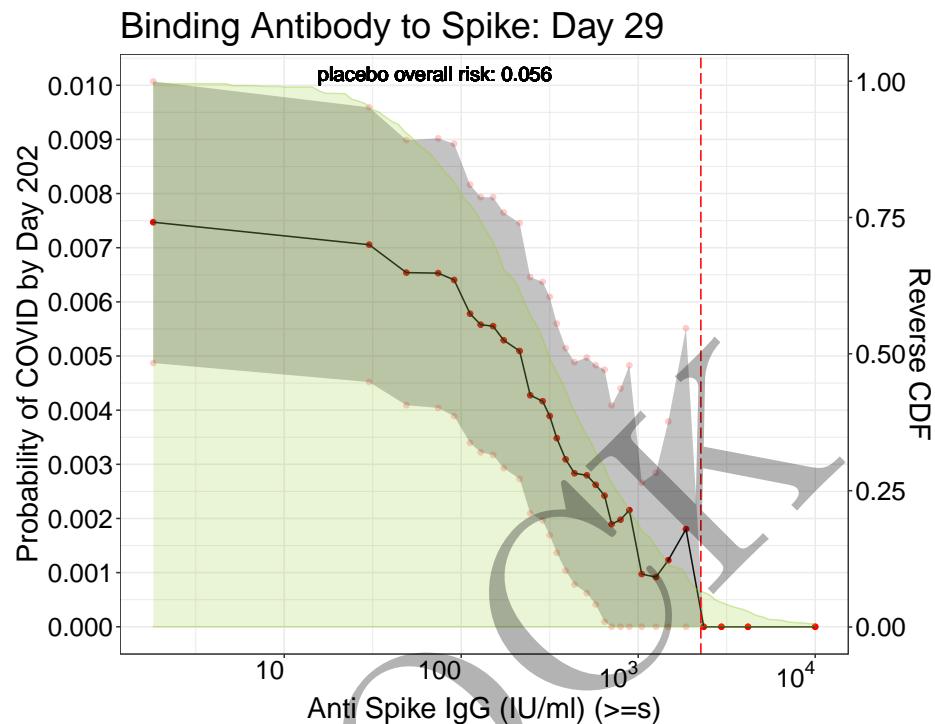


Figure 5.21: Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table 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
0.259	$1.82 * 10^0$	0.00747	0.00487	0.01007
1.869	$7.40 * 10^1$	0.00653	0.00404	0.00902
2.108	$1.28 * 10^2$	0.00558	0.00322	0.00793
2.395	$2.48 * 10^2$	0.00428	0.00209	0.00646
2.544	$3.50 * 10^2$	0.00348	0.00137	0.00560
2.708	$5.11 * 10^2$	0.00280	0.00062	0.00497
2.850	$7.08 * 10^2$	0.00190	0.00000	0.00409
3.099	$1.26 * 10^3$	0.00092	0.00000	0.00284
3.373	$2.36 * 10^3$	0.00000	0.00000	NA
4.004	$1.01 * 10^4$	0.00000	0.00000	NA

5.6.2 Day 29 RBD binding antibody

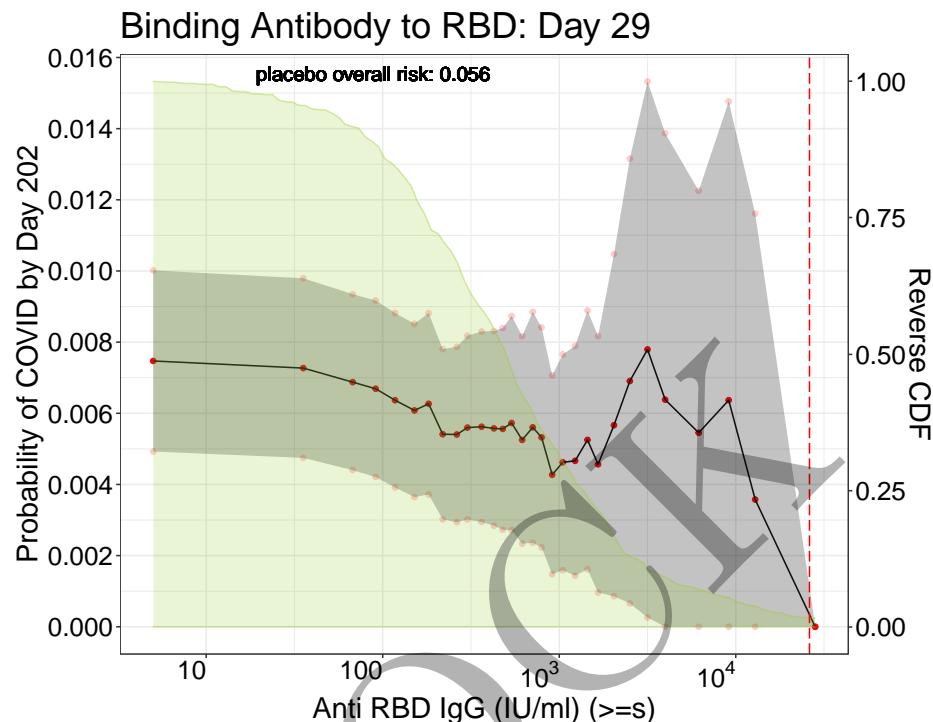


Figure 5.22: Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table 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
0.702	5.04×10^0	0.00747	0.00492	0.01002
1.965	9.23×10^1	0.00669	0.00421	0.00917
2.257	1.81×10^2	0.00627	0.00372	0.00882
2.556	3.60×10^2	0.00562	0.00294	0.00830
2.729	5.36×10^2	0.00573	0.00272	0.00874
2.899	7.93×10^2	0.00532	0.00223	0.00841
3.087	1.22×10^3	0.00466	0.00144	0.00789
3.395	2.48×10^3	0.00691	0.00066	0.01316
3.786	6.11×10^3	0.00545	0.00000	0.01225
4.448	2.81×10^4	0.00000	0.00000	NA

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

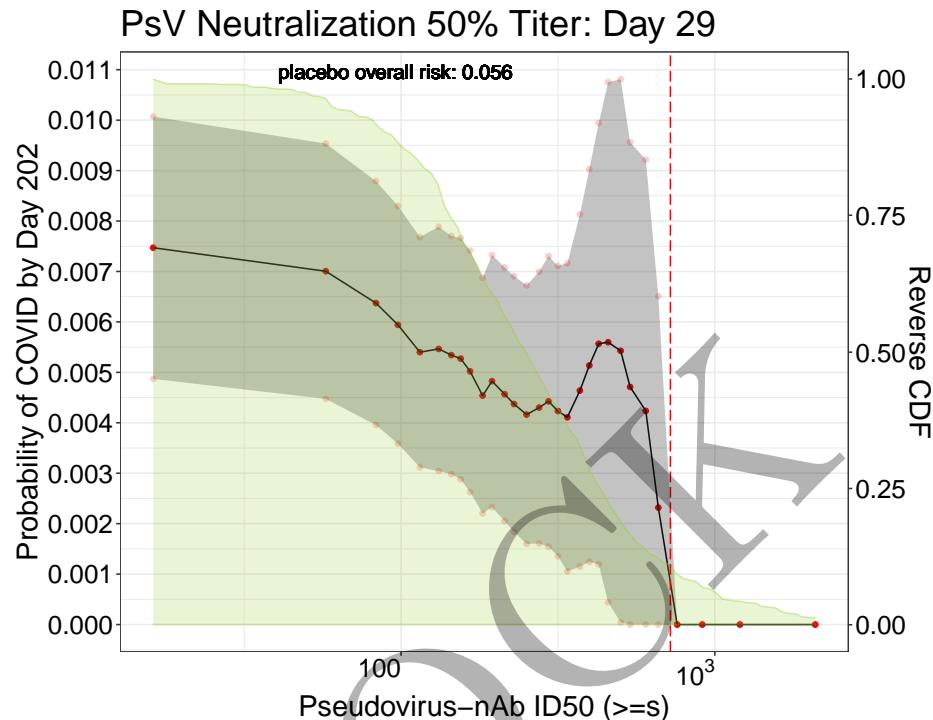


Figure 5.23: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table 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
1.211	$1.63 * 10^1$	0.00747	0.00487	0.01007
1.993	$9.84 * 10^1$	0.00594	0.00358	0.00830
2.157	$1.44 * 10^2$	0.00534	0.00298	0.00770
2.293	$1.96 * 10^2$	0.00483	0.00233	0.00733
2.401	$2.52 * 10^2$	0.00416	0.00160	0.00672
2.500	$3.16 * 10^2$	0.00423	0.00135	0.00711
2.597	$3.95 * 10^2$	0.00514	0.00124	0.00903
2.731	$5.38 * 10^2$	0.00471	0.00000	0.00956
2.879	$7.57 * 10^2$	0.00000	0.00000	NA
3.323	$2.10 * 10^3$	0.00000	0.00000	NA

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

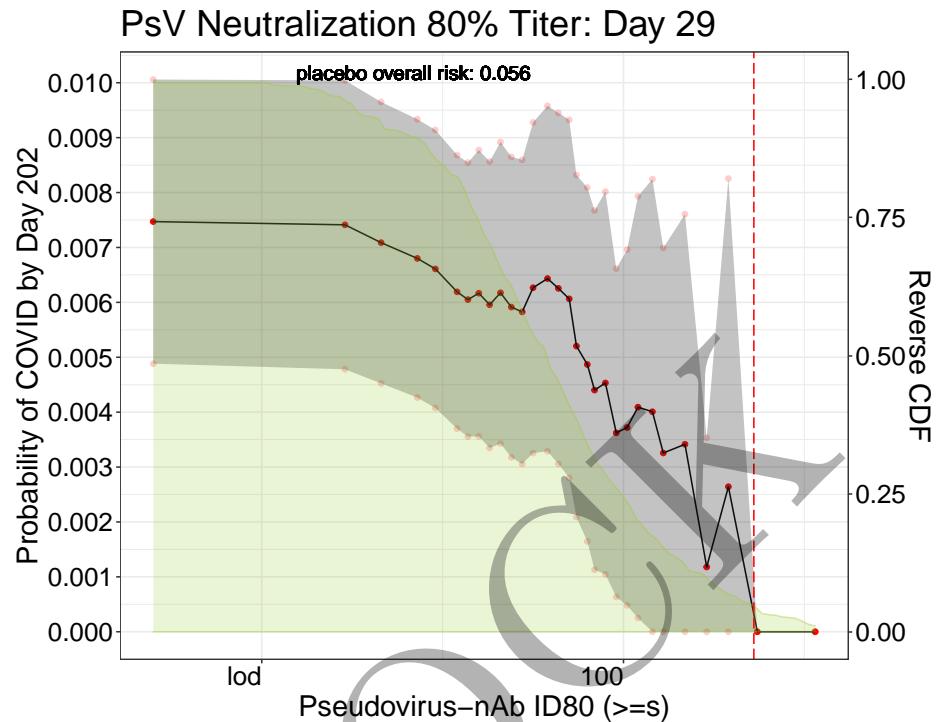


Figure 5.24: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table 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
0.699	$5.00 * 10^0$	0.00747	0.00488	0.01006
1.432	$2.70 * 10^1$	0.00680	0.00427	0.00934
1.571	$3.72 * 10^1$	0.00605	0.00355	0.00855
1.694	$4.94 * 10^1$	0.00591	0.00318	0.00865
1.785	$6.10 * 10^1$	0.00643	0.00329	0.00958
1.873	$7.46 * 10^1$	0.00520	0.00209	0.00832
1.949	$8.89 * 10^1$	0.00453	0.00105	0.00802
2.080	$1.20 * 10^2$	0.00401	0.00000	0.00824
2.232	$1.71 * 10^2$	0.00118	0.00000	0.00353
2.526	$3.36 * 10^2$	0.00000	0.00000	NA

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

MOCK

5.7.1 Day 57 Spike protein binding antibody

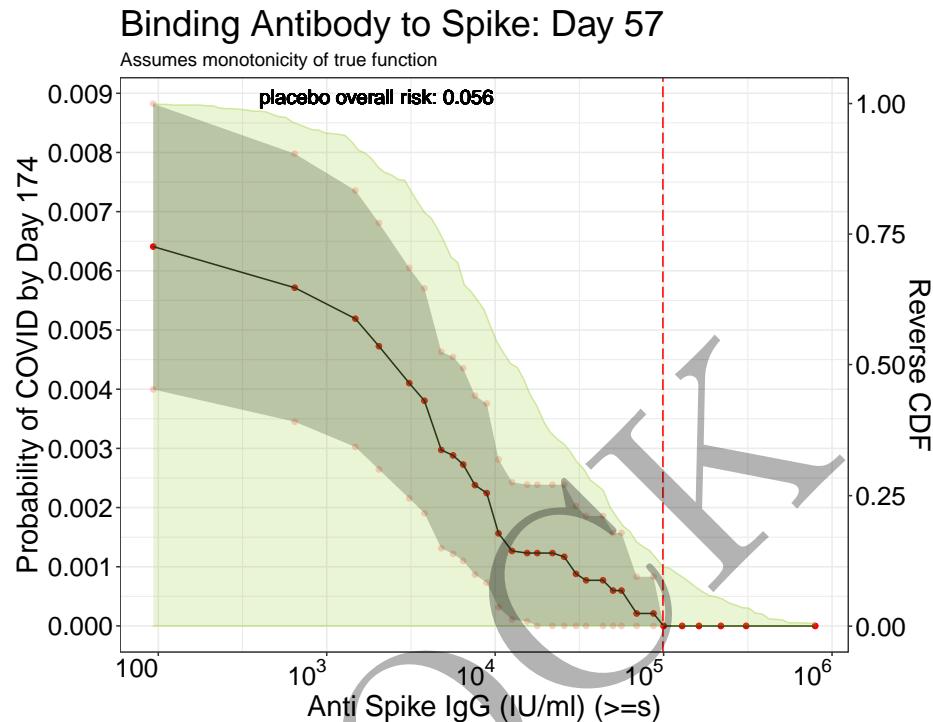


Figure 5.25: Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 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
1.970	9.33×10^1	0.00641	0.00400	0.00882
3.312	2.05×10^3	0.00473	0.00264	0.00681
3.683	4.82×10^3	0.00297	0.00131	0.00463
3.953	8.97×10^3	0.00224	0.00073	0.00376
4.190	1.55×10^4	0.00123	0.00008	0.00239
4.413	2.59×10^4	0.00117	0.00000	0.00246
4.642	4.39×10^4	0.00077	0.00000	0.00195
4.939	8.69×10^4	0.00021	0.00000	0.00089
5.206	1.61×10^5	0.00000	0.00000	NA
5.899	7.93×10^5	0.00000	0.00000	NA

5.7.2 Day 57 RBD binding antibody

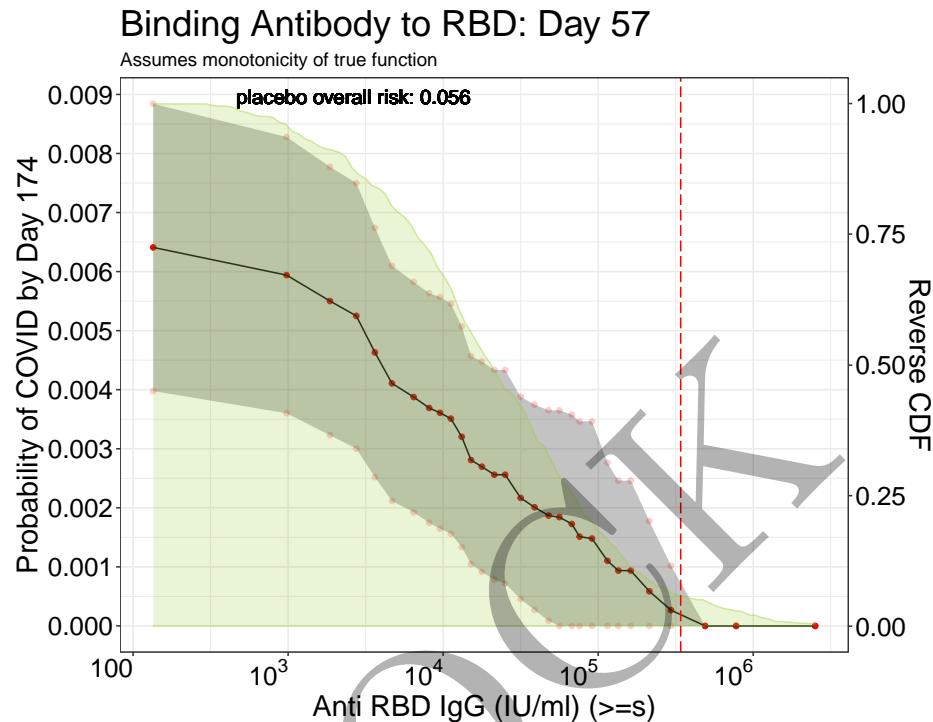


Figure 5.26: Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 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
2.133	1.36×10^2	0.00641	0.00398	0.00884
3.441	2.76×10^3	0.00525	0.00300	0.00750
3.814	6.52×10^3	0.00388	0.00193	0.00583
4.119	1.32×10^4	0.00320	0.00133	0.00507
4.332	2.15×10^4	0.00256	0.00079	0.00433
4.591	3.90×10^4	0.00201	0.00027	0.00375
4.830	6.76×10^4	0.00173	0.00000	0.00358
5.135	1.36×10^5	0.00094	0.00000	0.00246
5.473	2.97×10^5	0.00027	0.00000	0.00102
6.399	2.51×10^6	0.00000	0.00000	NA

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

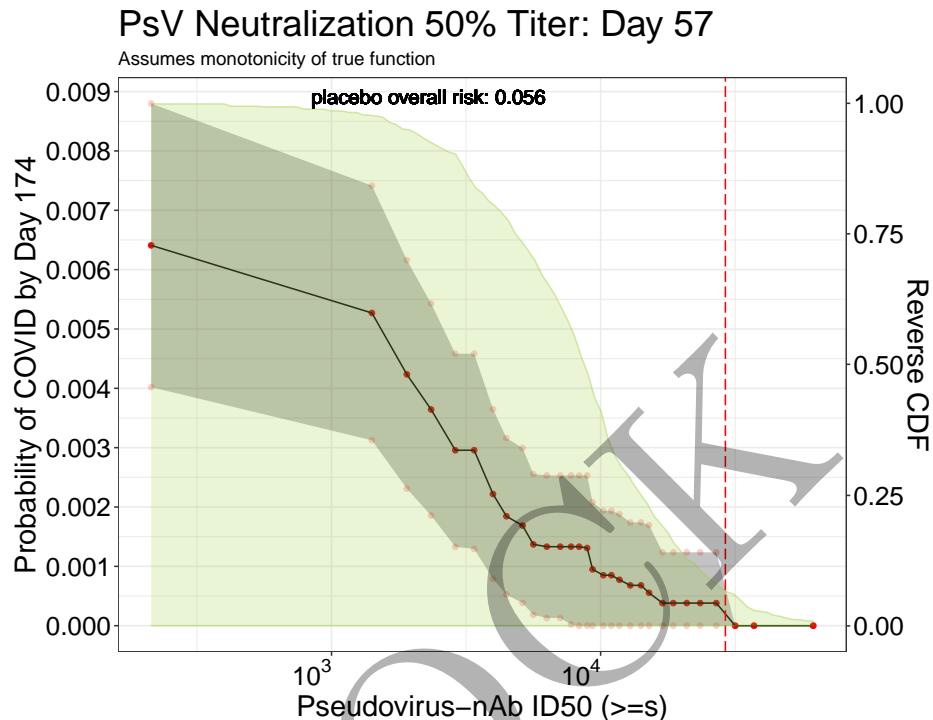


Figure 5.27: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 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
2.333	2.15×10^2	0.00641	0.00402	0.00880
3.374	2.37×10^3	0.00364	0.00186	0.00543
3.602	4.00×10^3	0.00222	0.00079	0.00365
3.800	6.31×10^3	0.00133	0.00013	0.00253
3.923	8.38×10^3	0.00133	0.00000	0.00275
4.005	1.01×10^4	0.00085	0.00000	0.00194
4.115	1.30×10^4	0.00068	0.00000	0.00174
4.270	1.86×10^4	0.00038	0.00000	0.00129
4.425	2.66×10^4	0.00038	0.00000	0.00196
4.786	6.11×10^4	0.00000	0.00000	NA

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

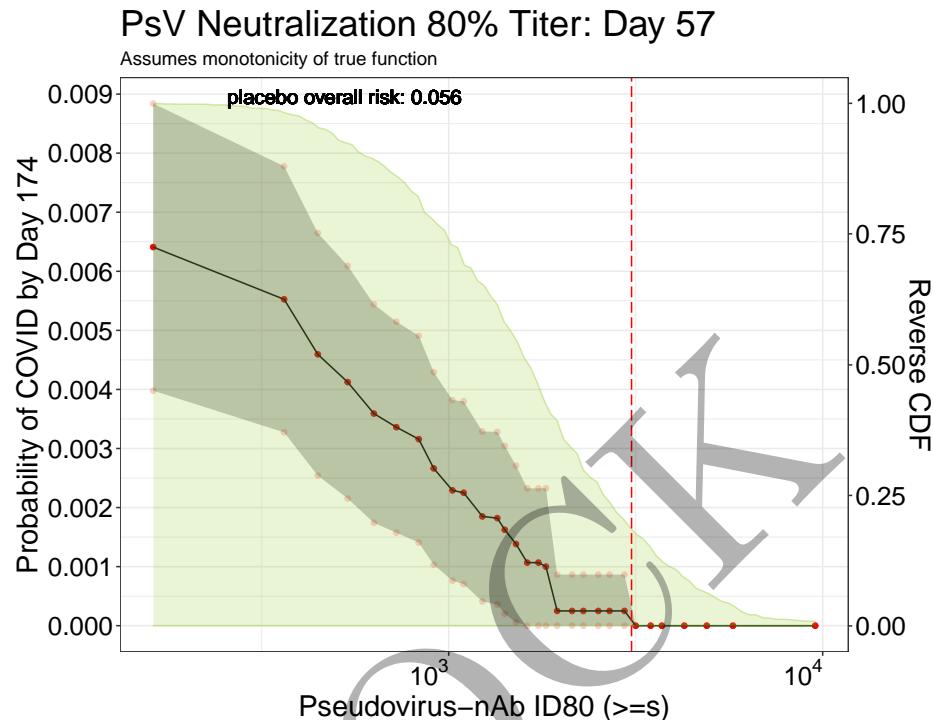


Figure 5.28: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 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
2.215	1.64×10^2	0.00641	0.00398	0.00884
2.734	5.42×10^2	0.00412	0.00215	0.00609
2.924	8.39×10^2	0.00316	0.00141	0.00491
3.086	1.22×10^3	0.00185	0.00041	0.00329
3.179	1.51×10^3	0.00138	0.00006	0.00271
3.263	1.83×10^3	0.00100	0.00000	0.00236
3.357	2.28×10^3	0.00025	0.00000	0.00097
3.503	3.18×10^3	0.00000	0.00000	NA
3.630	4.27×10^3	0.00000	0.00000	NA
3.980	9.55×10^3	0.00000	0.00000	NA

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

MOCK

5.8.1 Day 29 Spike protein antibody

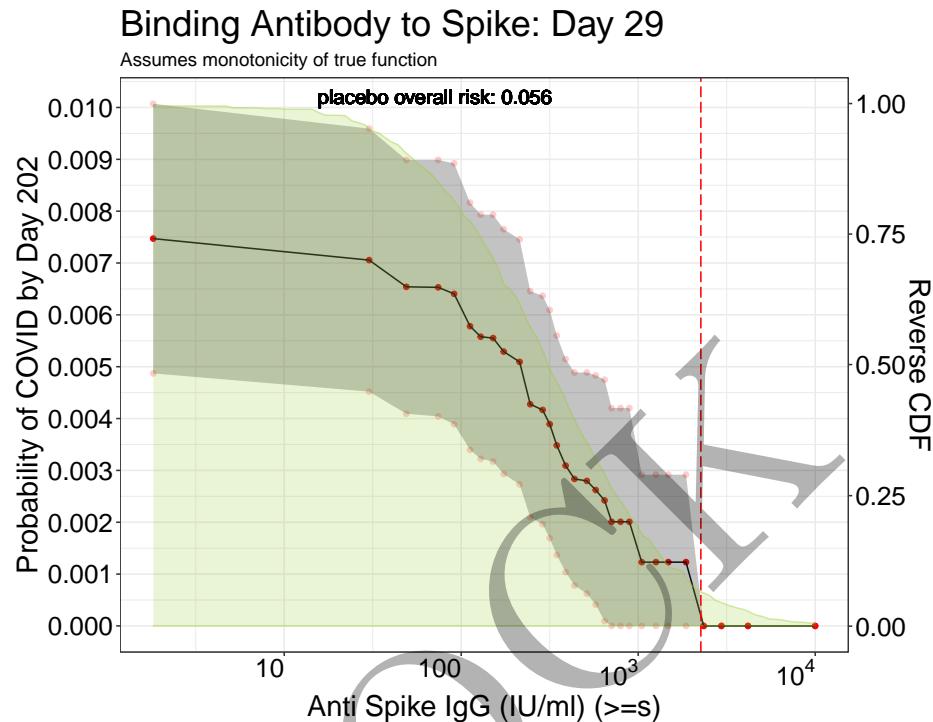


Figure 5.29: Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 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
0.259	$1.82 * 10^0$	0.00747	0.00487	0.01007
1.869	$7.40 * 10^1$	0.00653	0.00404	0.00902
2.108	$1.28 * 10^2$	0.00558	0.00322	0.00793
2.395	$2.48 * 10^2$	0.00428	0.00209	0.00646
2.544	$3.50 * 10^2$	0.00348	0.00137	0.00560
2.708	$5.11 * 10^2$	0.00280	0.00062	0.00497
2.850	$7.08 * 10^2$	0.00201	0.00000	0.00420
3.099	$1.26 * 10^3$	0.00123	0.00000	0.00316
3.373	$2.36 * 10^3$	0.00000	0.00000	NA
4.004	$1.01 * 10^4$	0.00000	0.00000	NA

5.8.2 Day 29 RBD binding antibody

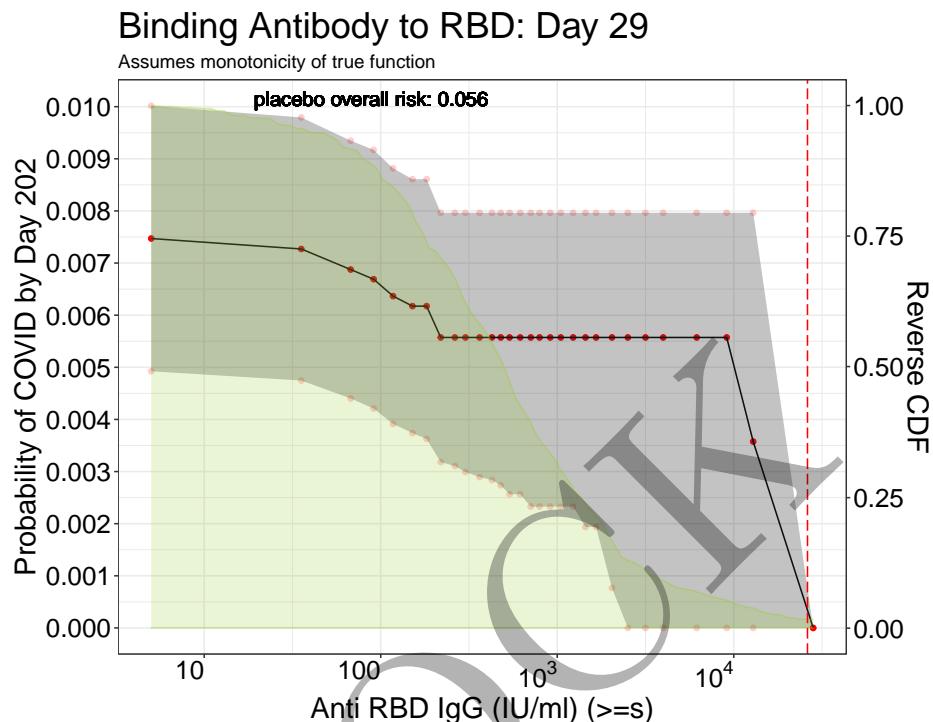


Figure 5.30: Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 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
0.702	5.04×10^0	0.00747	0.00492	0.01002
1.965	9.23×10^1	0.00669	0.00421	0.00917
2.257	1.81×10^2	0.00617	0.00362	0.00872
2.556	3.60×10^2	0.00557	0.00289	0.00825
2.729	5.36×10^2	0.00557	0.00257	0.00858
2.899	7.93×10^2	0.00557	0.00248	0.00866
3.087	1.22×10^3	0.00557	0.00234	0.00880
3.395	2.48×10^3	0.00557	0.00000	0.01182
3.786	6.11×10^3	0.00557	0.00000	0.01238
4.448	2.81×10^4	0.00000	0.00000	NA

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

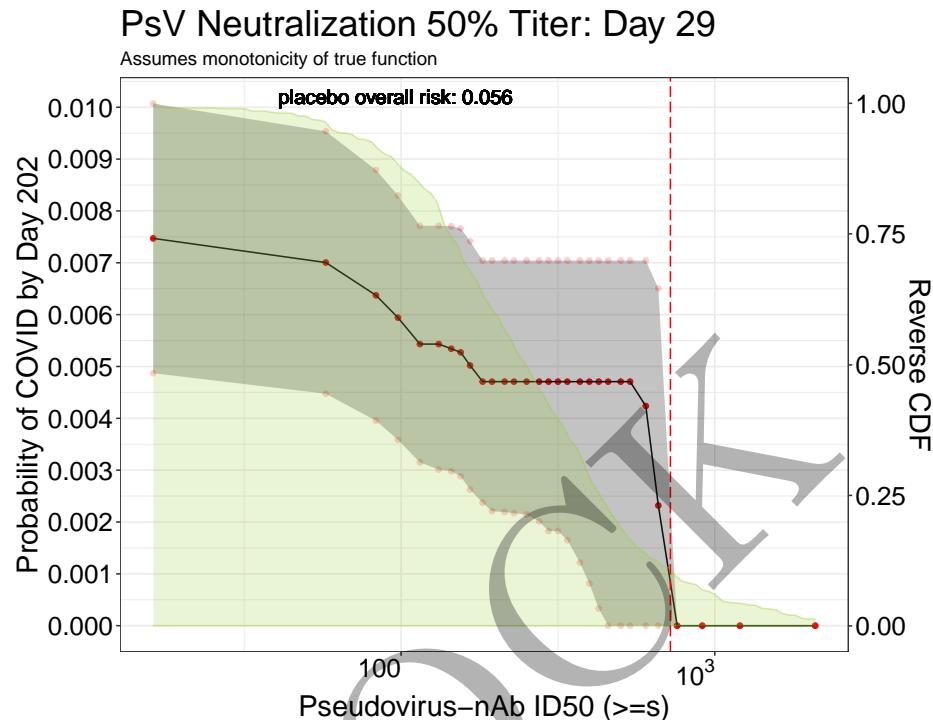


Figure 5.31: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 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
1.211	$1.63 * 10^1$	0.00747	0.00487	0.01007
1.993	$9.84 * 10^1$	0.00594	0.00358	0.00830
2.157	$1.44 * 10^2$	0.00534	0.00298	0.00770
2.293	$1.96 * 10^2$	0.00471	0.00221	0.00721
2.401	$2.52 * 10^2$	0.00471	0.00214	0.00727
2.500	$3.16 * 10^2$	0.00471	0.00183	0.00759
2.597	$3.95 * 10^2$	0.00471	0.00081	0.00860
2.731	$5.38 * 10^2$	0.00471	0.00000	0.00956
2.879	$7.57 * 10^2$	0.00000	0.00000	NA
3.323	$2.10 * 10^3$	0.00000	0.00000	NA

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

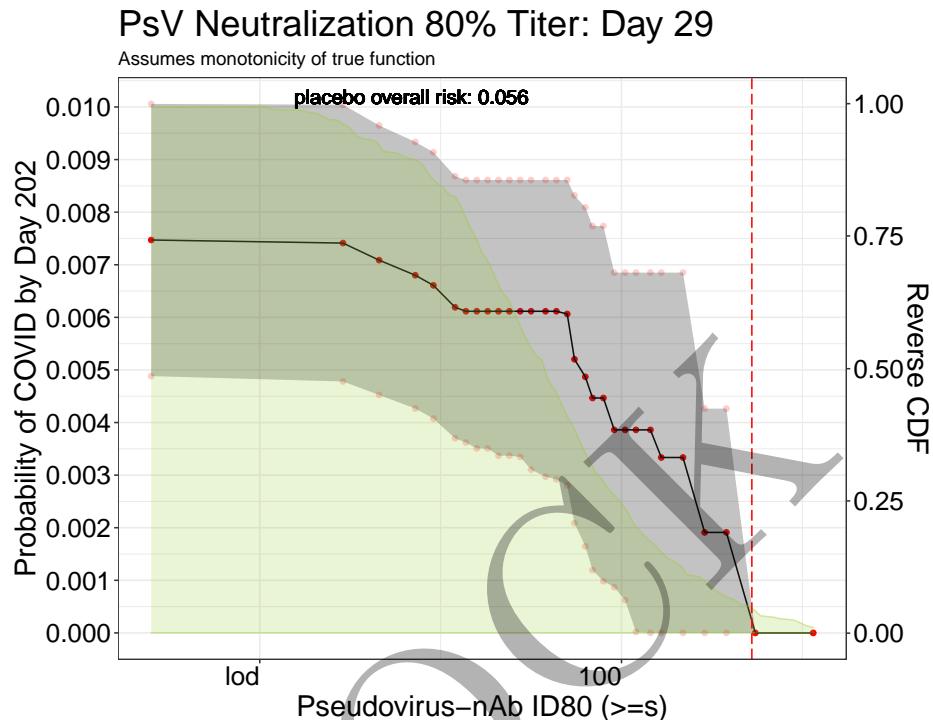


Figure 5.32: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 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
0.699	$5.00 * 10^0$	0.00747	0.00488	0.01006
1.432	$2.70 * 10^1$	0.00680	0.00427	0.00934
1.571	$3.72 * 10^1$	0.00612	0.00362	0.00861
1.694	$4.94 * 10^1$	0.00612	0.00338	0.00885
1.785	$6.10 * 10^1$	0.00612	0.00297	0.00926
1.873	$7.46 * 10^1$	0.00520	0.00209	0.00832
1.949	$8.89 * 10^1$	0.00447	0.00098	0.00795
2.080	$1.20 * 10^2$	0.00386	0.00000	0.00810
2.232	$1.71 * 10^2$	0.00191	0.00000	0.00426
2.526	$3.36 * 10^2$	0.00000	0.00000	NA

MOCK

Chapter 6

Appendix

- This report was built from the [CoVPN/correlates_reporting](#) repository with commit hash 49f6c091f6f6e6fa7b625a45ceec3c2f131e66e0. A diff of the changes introduced by that commit may be viewed at https://github.com/CoVPN/correlates_reporting/commit/49f6c091f6f6e6fa7b625a45ceec3c2f131e66e0
- The sha256 hash sum of the raw input file, “COVID_VEtiral_practicedata_primarystage1.csv”: 2353971c2e14399ede55ef6ba0d4e624626433dc15ec507c2482bb886210019a
- The sha256 hash sum of the processed file, “practice_data.csv”: 6250066f886245b78f7aa29fefc615ba5d10118448f298c39ec