

COVID-19 Correlates of Risk Analysis Report
mock Study

USG COVID-19 Response Biostatistics Team

May 19, 2021

Contents

| | |
|--|------------|
| 1 Summary Tables | 25 |
| 1.1 Demographic and Clinical Characteristics at Baseline in the Baseline SARS-CoV-2 Negative Per-Protocol Cohort | 25 |
| 1.2 Demographic and Clinical Characteristics at Baseline in the Baseline SARS-CoV-2 Positive Per-Protocol Cohort | 27 |
| 1.3 Antibody levels in the baseline SARS-CoV-2 negative per-protocol cohort (vaccine recipients) | 28 |
| 1.4 Antibody levels in the baseline SARS-CoV-2 positive per-protocol cohort (vaccine recipients) | 29 |
| 1.5 Antibody levels in the baseline SARS-CoV-2 positive per-protocol cohort (placebo recipients) | 30 |
| 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 | 315 |
| 4.1 Hazard ratios | 315 |
| 4.2 Marginalized risk and controlled vaccine efficacy plots | 320 |
| 5 Univariate CoR: Nonparametric Threshold Modeling | 327 |
| 5.1 Plots and Tables with estimates and pointwise confidence interval for Day 57 | 328 |
| 5.2 Plots and Tables with estimates and pointwise confidence intervals for Day 29 | 333 |
| 5.3 Plots and Tables with estimates and pointwise confidence interval for Day 57 (monotone-corrected) | 338 |
| 5.4 Plots and Tables with estimates and pointwise confidence intervals for Day 29 (monotone-corrected) | 343 |

| | | |
|----------|--|------------|
| 5.5 | Plots and Tables with estimates and simultaneous confidence bands for Day 57 | 348 |
| 5.6 | Plots and Tables with estimates and simultaneous confidence bands for Day 29 | 353 |
| 5.7 | Plots and Tables with estimates and pointwise confidence interval for Day 57 (monotone-corrected) | 358 |
| 5.8 | Plots and Tables with estimates and pointwise confidence intervals for Day 29 (monotone-corrected) | 363 |
| 6 | Appendix | 369 |

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* | 315 |
| 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* | 316 |
| 5.1 | Table of risk estimates for a range of thresholds of Day 57 Spike protein binding antibody levels with pointwise 95% confidence intervals. | 329 |
| 5.2 | Table of risk estimates for a range of thresholds of Day 57 RBD binding antibody levels with pointwise 95% confidence intervals. | 330 |
| 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. | 331 |
| 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. | 332 |
| 5.5 | Table of risk estimates for a range of thresholds of Day 29 Spike protein antibody levels with pointwise 95% confidence intervals. | 334 |
| 5.6 | Table of risk estimates for a range of thresholds of Day 29 RBD binding antibody levels with pointwise 95% confidence intervals. | 335 |
| 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. | 336 |

| | | |
|------|--|-----|
| 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. | 337 |
| 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. | 339 |
| 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. | 340 |
| 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. | 341 |
| 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. | 342 |
| 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. | 344 |
| 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. | 345 |
| 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. | 346 |
| 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. | 347 |
| 5.17 | Table of risk estimates for a range of thresholds of Day 57 Spike protein binding antibody levels with simultaneous 95% confidence intervals. | 349 |
| 5.18 | Table of risk estimates for a range of thresholds of Day 57 RBD binding antibody levels with simultaneous 95% confidence intervals. | 350 |
| 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. | 351 |
| 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. | 352 |
| 5.21 | Table of risk estimates for a range of thresholds of Day 29 Spike protein antibody levels with simultaneous 95% confidence intervals. | 354 |
| 5.22 | Table of risk estimates for a range of thresholds of Day 29 RBD binding antibody levels with simultaneous 95% confidence intervals. | 355 |
| 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. | 356 |
| 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. | 357 |
| 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. | 359 |
| 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. | 360 |
| 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. | 361 |
| 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. | 362 |
| 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. | 364 |

| | |
|---|-----|
| 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. | 365 |
| 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. | 366 |
| 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. | 367 |

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 170 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 170 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod = 0.3, 1.6, 10, 10 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively. | 308 |
| 3.7 Marginalized cumulative risk by Day 170 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 170 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod = 0.3, 1.6, 10, 10 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively. | 309 |
| 3.8 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 = 0.3, 1.6, 10, 10 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively. | 310 |
| 3.9 Marginalized cumulative risk by Day 170 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 170 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod = 0.3, 1.6, 10, 10 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively. | 311 |
| 3.10 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 = 0.3, 1.6, 10, 10 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively. | 312 |
| 3.11 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. | 313 |
| 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. | 317 |
| 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. | 318 |
| 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. | 318 |
| 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. | 319 |
| 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. | 319 |

| | |
|--|-----|
| 4.6 Marginalized cumulative risk by Day 198 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 198 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod = 0.3, 1.6, 10, 10 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively. | 320 |
| 4.7 Marginalized cumulative risk by Day 198 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 198 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod = 0.3, 1.6, 10, 10 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively. | 321 |
| 4.8 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 = 0.3, 1.6, 10, 10 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively. | 322 |
| 4.9 Marginalized cumulative risk by Day 198 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 198 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod = 0.3, 1.6, 10, 10 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively. | 323 |
| 4.10 Controlled VE 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 = 0.3, 1.6, 10, 10 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively. | 324 |
| 4.11 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. | 325 |
| 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. | 329 |
| 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. | 330 |
| 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. | 331 |
| 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. | 332 |
| 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. | 334 |
| 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. | 335 |

| | | |
|------|--|-----|
| 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. | 336 |
| 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. | 337 |
| 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. | 339 |
| 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. | 340 |
| 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. | 341 |
| 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. | 342 |
| 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. | 344 |
| 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. | 345 |
| 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. | 346 |
| 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. | 347 |
| 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. | 349 |
| 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. | 350 |

| | |
|--|-----|
| 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. | 351 |
| 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. | 352 |
| 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. | 354 |
| 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. | 355 |
| 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. | 356 |
| 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. | 357 |
| 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. | 359 |
| 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. | 360 |
| 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. | 361 |
| 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. | 362 |
| 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. | 364 |
| 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. | 365 |

| | |
|--|-----|
| 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. | 366 |
| 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. | 367 |

MOCH

Chapter 1

Summary Tables

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

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

| Characteristics | Vaccine (N = 756) | Placebo (N = 124) | Total (N = 880) |
|---|----------------------|----------------------|--------------------|
| Age | | | |
| Age < 65 | 360 (47.6%) | 61 (49.2%) | 421 (47.8%) |
| Age ≥ 65 | 396 (52.4%) | 63 (50.8%) | 459 (52.2%) |
| Mean (Range) | 58.4 (18.0, 85.0) | 61.3 (18.0, 85.0) | 58.9 (18.0, 85.0) |
| BMI | | | |
| Mean ± SD | 29.9 ± 7.0 | 30.1 ± 7.1 | 30.0 ± 7.0 |
| Risk for Severe Covid-19 | | | |
| At-risk | 378 (50.0%) | 58 (46.8%) | 436 (49.5%) |
| Not at-risk | 378 (50.0%) | 66 (53.2%) | 444 (50.5%) |
| Age, Risk for Severe Covid-19 | | | |
| Age < 65 At-risk | 180 (23.8%) | 29 (23.4%) | 209 (23.8%) |
| Age < 65 Not at-risk | 180 (23.8%) | 32 (25.8%) | 212 (24.1%) |
| Age ≥ 65 | 396 (52.4%) | 63 (50.8%) | 459 (52.2%) |
| Sex | | | |
| Female | 431 (57.0%) | 75 (60.5%) | 506 (57.5%) |
| Male | 325 (43.0%) | 49 (39.5%) | 374 (42.5%) |
| Hispanic or Latino ethnicity | | | |
| Hispanic or Latino | 115 (15.2%) | 16 (12.9%) | 131 (14.9%) |
| Not Hispanic or Latino | 617 (81.6%) | 105 (84.7%) | 722 (82.0%) |
| Not reported and unknown | 24 (3.2%) | 3 (2.4%) | 27 (3.1%) |
| Race | | | |
| White Non-Hispanic | 364 (48.1%) | 64 (51.6%) | 428 (48.6%) |
| Black or African American | 177 (23.4%) | 30 (24.2%) | 207 (23.5%) |
| Asian | 72 (9.5%) | 11 (8.9%) | 83 (9.4%) |
| American Indian or Alaska Native | 23 (3.0%) | 4 (3.2%) | 27 (3.1%) |
| Native Hawaiian or Other Pacific Islander | 9 (1.2%) | 1 (0.8%) | 10 (1.1%) |

(continued)

| Characteristics | Vaccine (N = 756) | Placebo (N = 124) | Total (N = 880) |
|--------------------------|----------------------|----------------------|--------------------|
| Multiracial | 49 (6.5%) | 6 (4.8%) | 55 (6.2%) |
| Other | 26 (3.4%) | 5 (4.0%) | 31 (3.5%) |
| Not reported and unknown | 5 (0.7%) | 1 (0.8%) | 6 (0.7%) |
| Communities of Color | 392 (51.9%) | 60 (48.4%) | 452 (51.4%) |

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).

MOCH

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

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

| Characteristics | Vaccine (N = 231) | Placebo (N = 228) | Total (N = 459) |
|---|----------------------|----------------------|--------------------|
| Age | | | |
| Age < 65 | 120 (51.9%) | 124 (54.4%) | 244 (53.2%) |
| Age ≥ 65 | 111 (48.1%) | 104 (45.6%) | 215 (46.8%) |
| Mean (Range) | 56.4 (18.0, 85.0) | 55.7 (18.0, 85.0) | 56.1 (18.0, 85.0) |
| BMI | | | |
| Mean ± SD | 30.1 ± 7.3 | 29.6 ± 6.5 | 29.8 ± 6.9 |
| Risk for Severe Covid-19 | | | |
| At-risk | 109 (47.2%) | 112 (49.1%) | 221 (48.1%) |
| Not at-risk | 122 (52.8%) | 116 (50.9%) | 238 (51.9%) |
| Age, Risk for Severe Covid-19 | | | |
| Age < 65 At-risk | 59 (25.5%) | 66 (28.9%) | 125 (27.2%) |
| Age < 65 Not at-risk | 61 (26.4%) | 58 (25.4%) | 119 (25.9%) |
| Age ≥ 65 | 111 (48.1%) | 104 (45.6%) | 215 (46.8%) |
| Sex | | | |
| Female | 135 (58.4%) | 122 (53.5%) | 257 (56.0%) |
| Male | 96 (41.6%) | 106 (46.5%) | 202 (44.0%) |
| Hispanic or Latino ethnicity | | | |
| Hispanic or Latino | 29 (12.6%) | 27 (11.8%) | 56 (12.2%) |
| Not Hispanic or Latino | 192 (83.1%) | 197 (86.4%) | 389 (84.7%) |
| Not reported and unknown | 10 (4.3%) | 4 (1.8%) | 14 (3.1%) |
| Race | | | |
| White Non-Hispanic | 123 (53.2%) | 122 (53.5%) | 245 (53.4%) |
| Black or African American | 47 (20.3%) | 43 (18.9%) | 90 (19.6%) |
| Asian | 15 (6.5%) | 22 (9.6%) | 37 (8.1%) |
| American Indian or Alaska Native | 8 (3.5%) | 10 (4.4%) | 18 (3.9%) |
| Native Hawaiian or Other Pacific Islander | 4 (1.7%) | 5 (2.2%) | 9 (2.0%) |
| Multiracial | 16 (6.9%) | 12 (5.3%) | 28 (6.1%) |
| Other | 5 (2.2%) | 7 (3.1%) | 12 (2.6%) |
| Not reported and unknown | 4 (1.7%) | | 4 (0.9%) |
| Communities of Color | 108 (46.8%) | 106 (46.5%) | 214 (46.6%) |

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).

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

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

| Visit | Marker | Baseline SARS-CoV-2 Negative Vaccine Recipients | | | | | | Comparison | |
|--------|------------------------|---|------------------------------------|---------------------------------|-------------------|--|----------------------------------|------------------------|----------------------|
| | | Cases* | | | Non-Cases/Control | | | Resp Rate Difference | GMTR/GMCR |
| | | N | Resp rate | GMT/GMC | N | Resp rate | GMT/GMC | | |
| Day 29 | Pseudovirus-nAb ID80 | 51 | 48/51 = 94.1% (82.9%, 98.1%) | 43.97 (35.67, 54.20) | 759 | 10825.2/11177 = 96.9% (94.3%, 98.3%) | 59.07 (54.65, 63.84) | -0.03 (-0.14, 0.02) | 0.74 (0.60, 0.93) |
| Day 29 | Pseudovirus-nAb ID50 | 51 | 51/51 = 100.0% (100.0%, 100.0%) | 146.33 (117.72, 181.90) | 759 | 11158.3/11177 = 99.8% (99.3%, 100.0%) | 259.24 (238.14, 282.21) | 0 (0, 0.01) | 0.56 (0.45, 0.71) |
| Day 29 | Anti RBD IgG (IU/ml) | 51 | 51/51 = 100.0% (100.0%, 100.0%) | 424.70 (272.93, 660.87) | 759 | 11177/11177 = 100.0% (100.0%, 100.0%) | 480.37 (413.89, 557.54) | 0 (0, 0) | 0.88 (0.55, 1.41) |
| Day 29 | Anti Spike IgG (IU/ml) | 51 | 51/51 = 100.0% (100.0%, 100.0%) | 199.31 (139.24, 285.30) | 759 | 11177/11177 = 100.0% (100.0%, 100.0%) | 307.86 (272.45, 347.87) | 0 (0, 0) | 0.65 (0.44, 0.95) |
| Day 29 | Anti N IgG (IU/ml) | 51 | 51/51 = 100.0% (100.0%, 100.0%) | 25.06 (15.27, 41.12) | 759 | 10770.5/11177 = 96.4% (93.9%, 97.9%) | 43.64 (36.27, 52.51) | 0.04 (0.02, 0.06) | 0.57 (0.34, 0.97) |
| Day 57 | Pseudovirus-nAb ID80 | 51 | 51/51 = 100.0% (100.0%, 100.0%) | 817.23 (671.68, 994.32) | 746 | 11123/11123 = 100.0% (100.0%, 100.0%) | 1343.71 (1248.83, 1445.79) | 0 (0, 0) | 0.61 (0.49, 0.75) |
| Day 57 | Pseudovirus-nAb ID50 | 51 | 51/51 = 100.0% (100.0%, 100.0%) | 3595.84 (2844.47, 4545.67) | 746 | 11123/11123 = 100.0% (100.0%, 100.0%) | 5838.96 (5406.48, 6306.03) | 0 (0, 0) | 0.62 (0.48, 0.79) |
| Day 57 | Anti RBD IgG (IU/ml) | 51 | 51/51 = 100.0% (100.0%, 100.0%) | 10654.37 (6524.76, 17397.65) | 746 | 11123/11123 = 100.0% (100.0%, 100.0%) | 15585.81 (13132.34, 18497.64) | 0 (0, 0) | 0.68 (0.41, 1.15) |
| Day 57 | Anti Spike IgG (IU/ml) | 51 | 51/51 = 100.0% (100.0%, 100.0%) | 4680.49 (3271.09, 6697.15) | 746 | 11123/11123 = 100.0% (100.0%, 100.0%) | 9122.73 (7861.36, 10586.49) | 0 (0, 0) | 0.51 (0.35, 0.76) |
| Day 57 | Anti N IgG (IU/ml) | 51 | 50/51 = 98.0% (86.8%, 99.7%) | 410.50 (218.31, 771.89) | 746 | 11071.8/11123 = 99.5% (97.6%, 99.9%) | 443.60 (356.89, 551.39) | -0.02 (-0.13, 0.01) | 0.93 (0.47, 1.80) |

*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.

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

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 | 0 | - | - | 234 | 1143.4/1150 = 99.4% (97.7%, 99.9%) | 95.87 (85.13, 107.96) | - | - |
| Day 29 | Pseudovirus-nAb ID50 | 0 | - | - | 234 | 1150/1150 = 100.0% (100.0%, 100.0%) | 414.79 (362.03, 475.24) | - | - |
| Day 29 | Anti RBD IgG (IU/ml) | 0 | - | - | 234 | 1150/1150 = 100.0% (100.0%, 100.0%) | 812.90 (592.99, 1114.35) | - | - |
| Day 29 | Anti Spike IgG (IU/ml) | 0 | - | - | 234 | 1150/1150 = 100.0% (100.0%, 100.0%) | 417.36 (328.28, 530.60) | - | - |
| Day 29 | Anti N IgG (IU/ml) | 0 | - | - | 234 | 1150/1150 = 100.0% (100.0%, 100.0%) | 63.92 (47.21, 86.55) | - | - |
| Day 57 | Pseudovirus-nAb ID80 | 0 | - | - | 234 | 1148/1148 = 100.0% (100.0%, 100.0%) | 3015.31 (2636.34, 3448.77) | - | - |
| Day 57 | Pseudovirus-nAb ID50 | 0 | - | - | 234 | 1148/1148 = 100.0% (100.0%, 100.0%) | 14830.76 (12953.59, 16979.96) | - | - |
| Day 57 | Anti RBD IgG (IU/ml) | 0 | - | - | 234 | 1148/1148 = 100.0% (100.0%, 100.0%) | 34997.71 (26871.53, 45581.31) | - | - |
| Day 57 | Anti Spike IgG (IU/ml) | 0 | - | - | 234 | 1148/1148 = 100.0% (100.0%, 100.0%) | 26004.23 (20034.26, 33753.18) | - | - |
| Day 57 | Anti N IgG (IU/ml) | 0 | - | - | 234 | 1144.9/1148 = 99.7% (98.1%, 100.0%) | 1036.64 (699.42, 1536.45) | - | - |

*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.

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

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 | | | | | | 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 | 0 | - | - | 230 | 977.9/1061 = 92.2% (85.6%, 95.9%) | 40.61 (36.01, 45.79) | - | - |
| Day 29 | Pseudovirus-nAb ID50 | 0 | - | - | 230 | 1061/1061 = 100.0% (100.0%, 100.0%) | 180.15 (157.92, 205.51) | - | - |
| Day 29 | Anti RBD IgG (IU/ml) | 0 | - | - | 230 | 1050.1/1061 = 99.0% (92.9%, 99.9%) | 381.50 (291.14, 499.90) | - | - |
| Day 29 | Anti Spike IgG (IU/ml) | 0 | - | - | 230 | 1061/1061 = 100.0% (100.0%, 100.0%) | 175.43 (140.65, 218.81) | - | - |
| Day 29 | Anti N IgG (IU/ml) | 0 | - | - | 230 | 1028.7/1061 = 97.0% (92.9%, 98.7%) | 32.10 (23.70, 43.46) | - | - |
| Day 57 | Pseudovirus-nAb ID80 | 0 | - | - | 230 | 1060/1060 = 100.0% (100.0%, 100.0%) | 1061.75 (941.58, 1197.27) | - | - |
| Day 57 | Pseudovirus-nAb ID50 | 0 | - | - | 230 | 1060/1060 = 100.0% (100.0%, 100.0%) | 4481.65 (3817.29, 5261.63) | - | - |
| Day 57 | Anti RBD IgG (IU/ml) | 0 | - | - | 230 | 1060/1060 = 100.0% (100.0%, 100.0%) | 10765.86 (7862.92, 14740.54) | - | - |
| Day 57 | Anti Spike IgG (IU/ml) | 0 | - | - | 230 | 1060/1060 = 100.0% (100.0%, 100.0%) | 7195.18 (5630.71, 9194.34) | - | - |
| Day 57 | Anti N IgG (IU/ml) | 0 | - | - | 230 | 1056.8/1060 = 99.7% (97.9%, 100.0%) | 346.37 (241.28, 497.21) | - | - |

*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

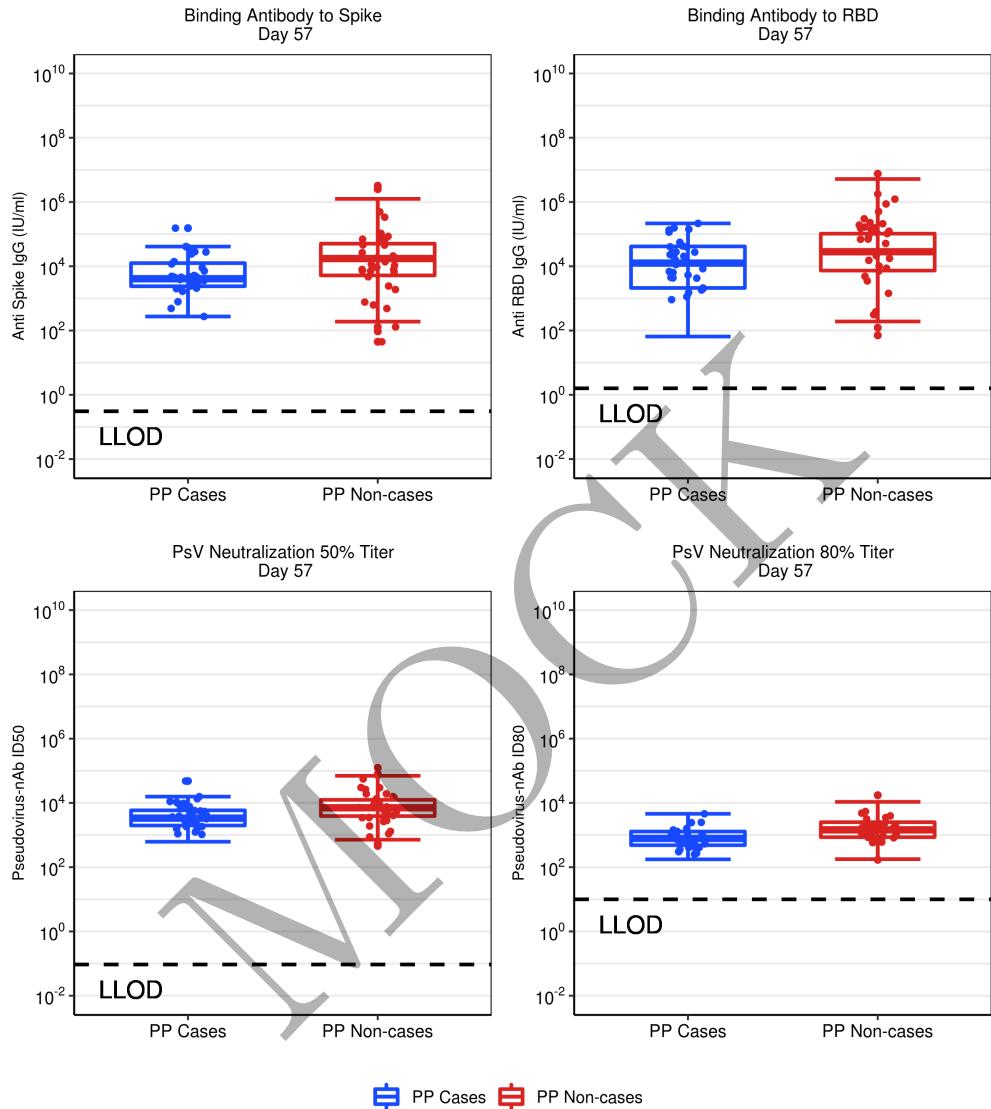


Figure 2.1: Boxplots of D57 Ab markers: baseline negative vaccine arm.

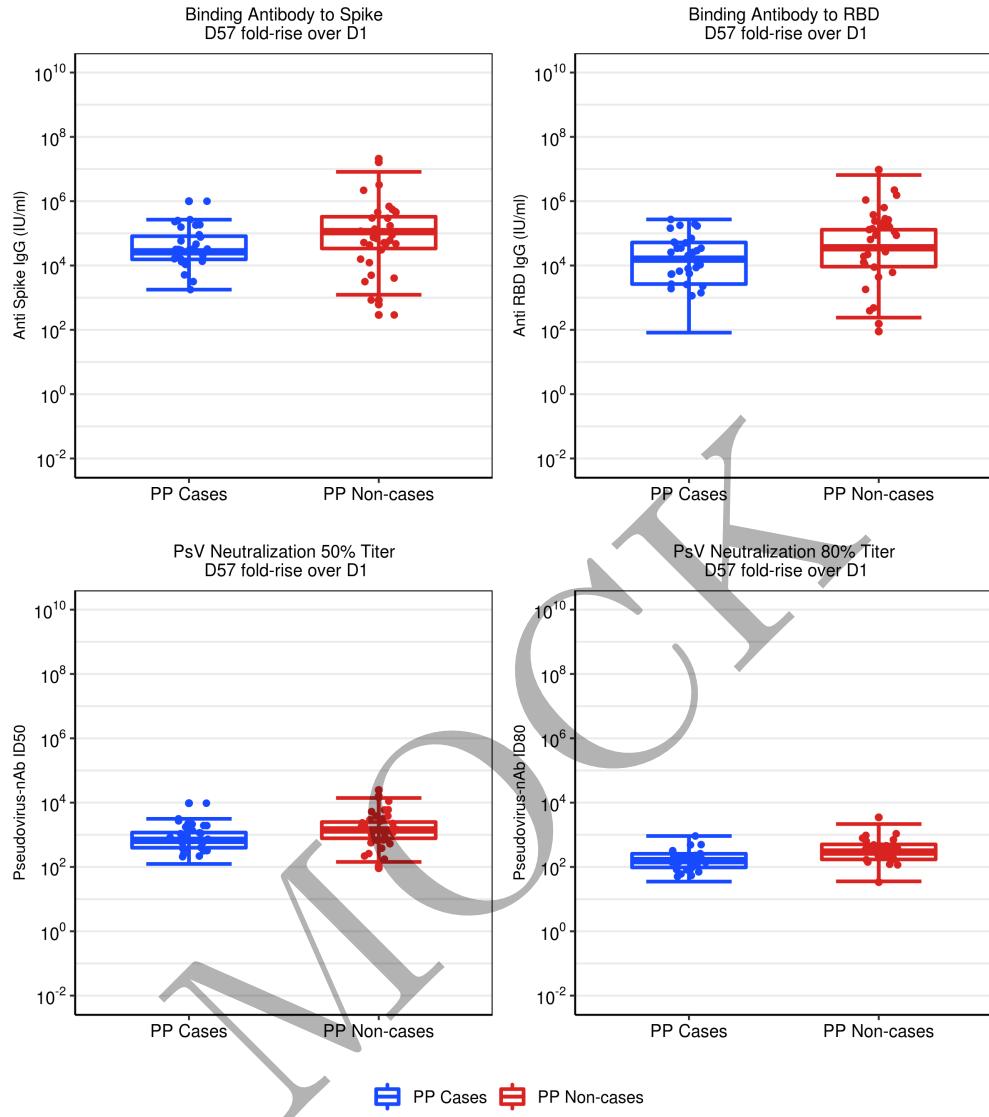


Figure 2.2: Boxplots of D57 fold-rise over D1 Ab markers: baseline negative vaccine arm.

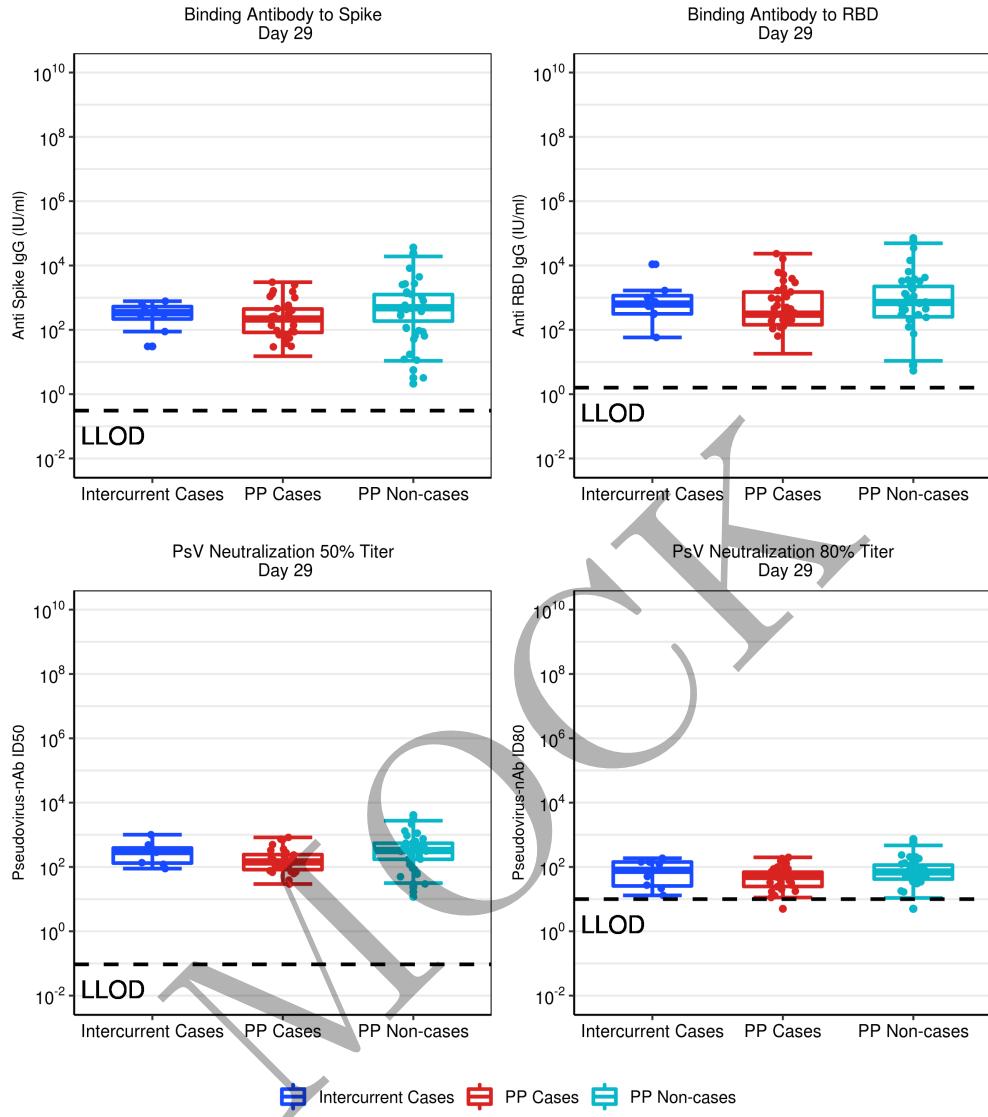


Figure 2.3: Boxplots of D29 Ab markers: baseline negative vaccine arm.

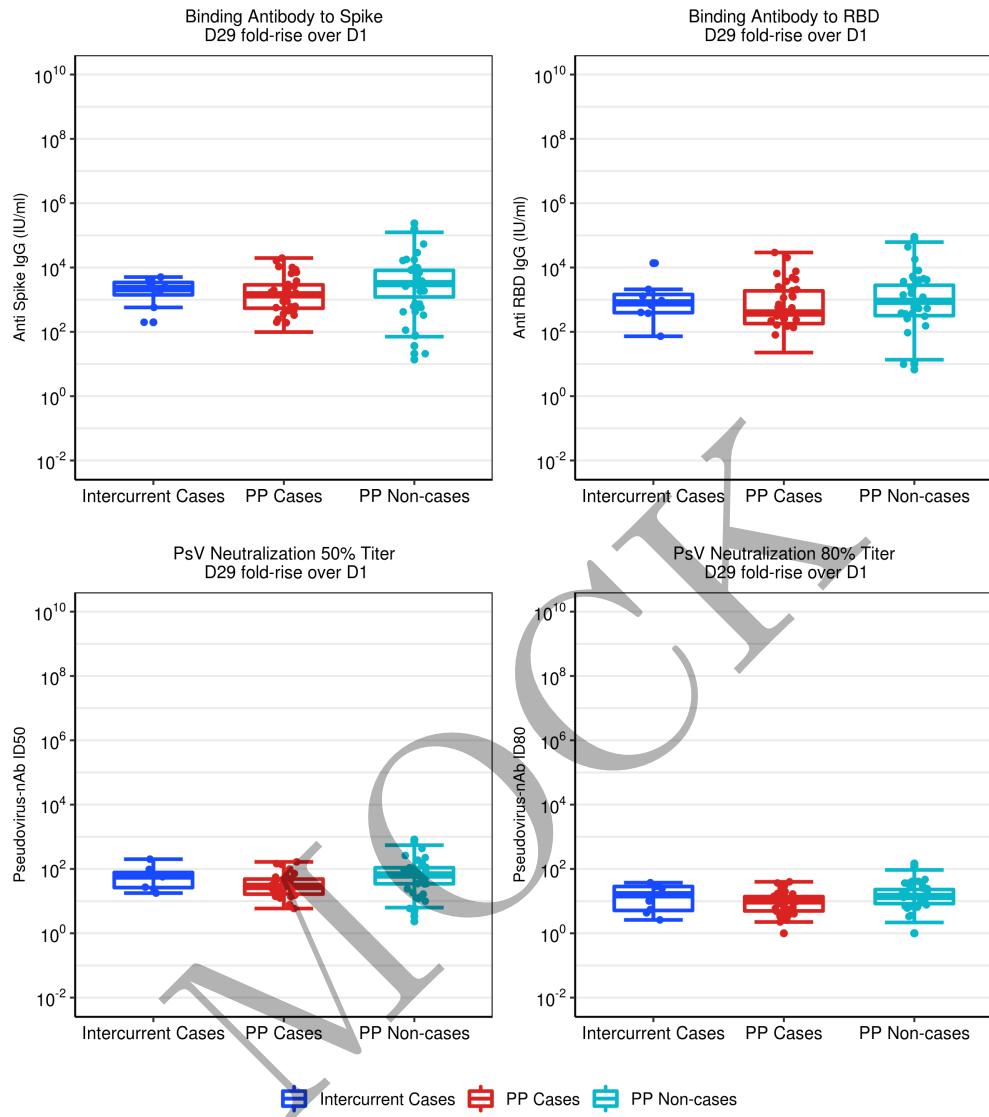


Figure 2.4: Boxplots of D29 fold-rise over D1 Ab markers: baseline negative vaccine arm.

2.1.2 Baseline seropositive

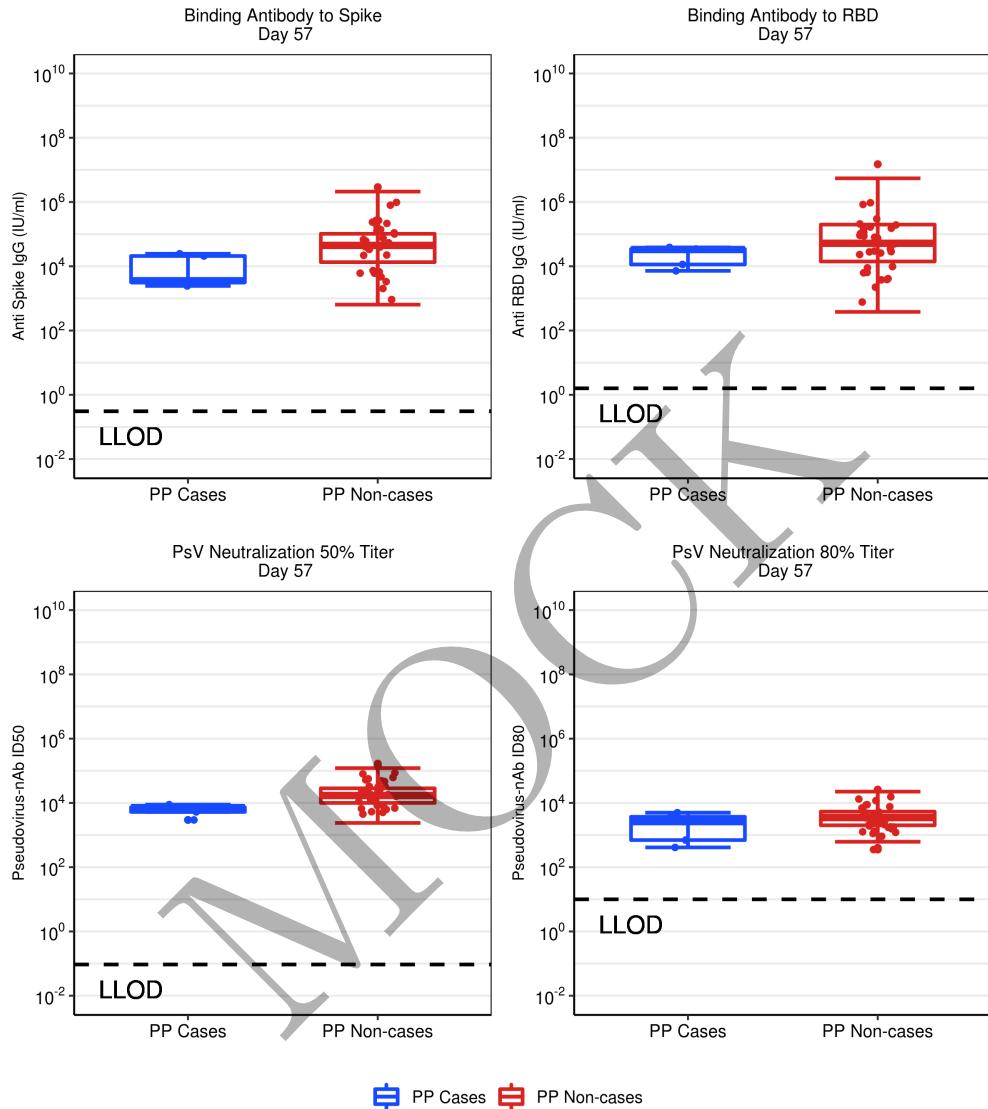


Figure 2.5: Boxplots of D57 Ab markers: baseline positive vaccine arm.

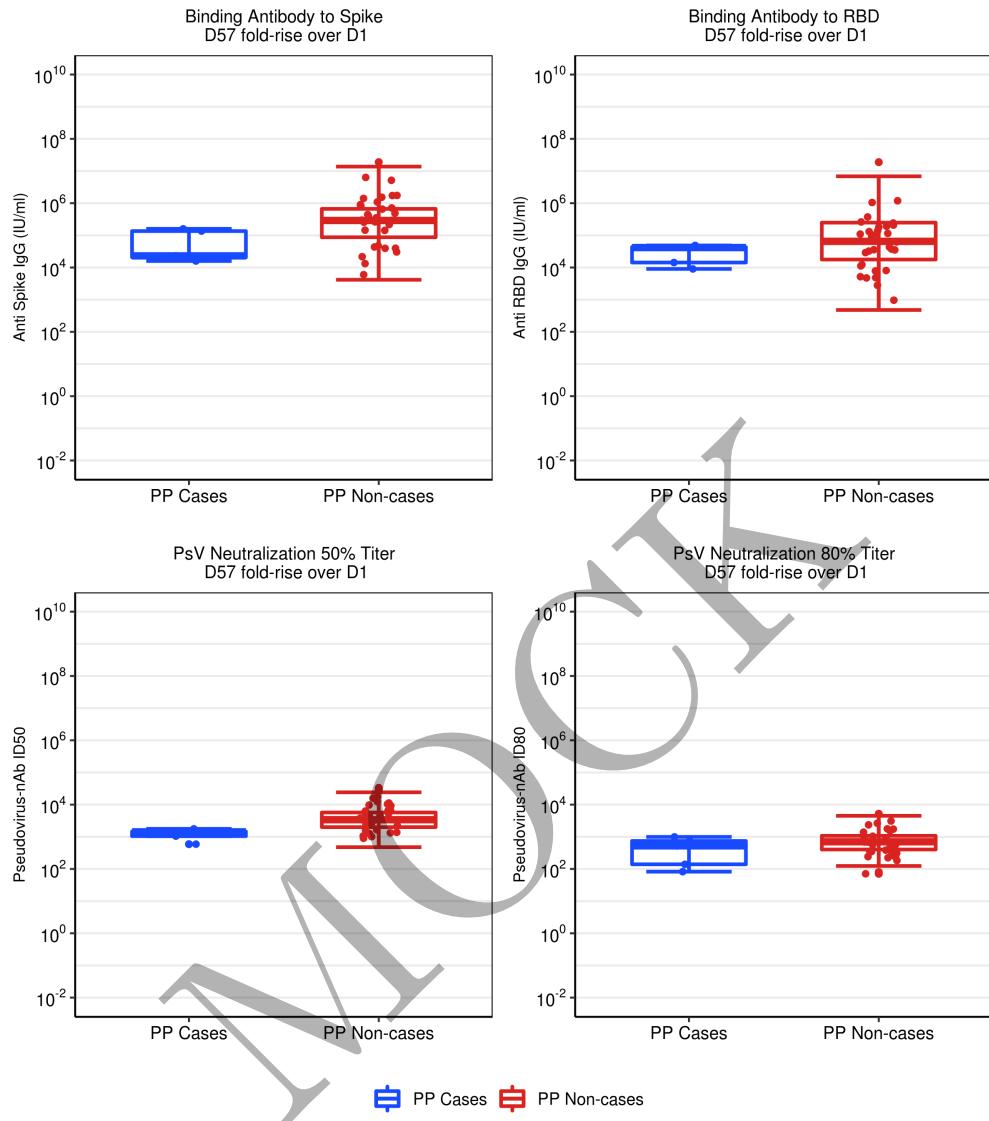


Figure 2.6: Boxplots of D57 fold-rise over D1 Ab markers: baseline positive vaccine arm.

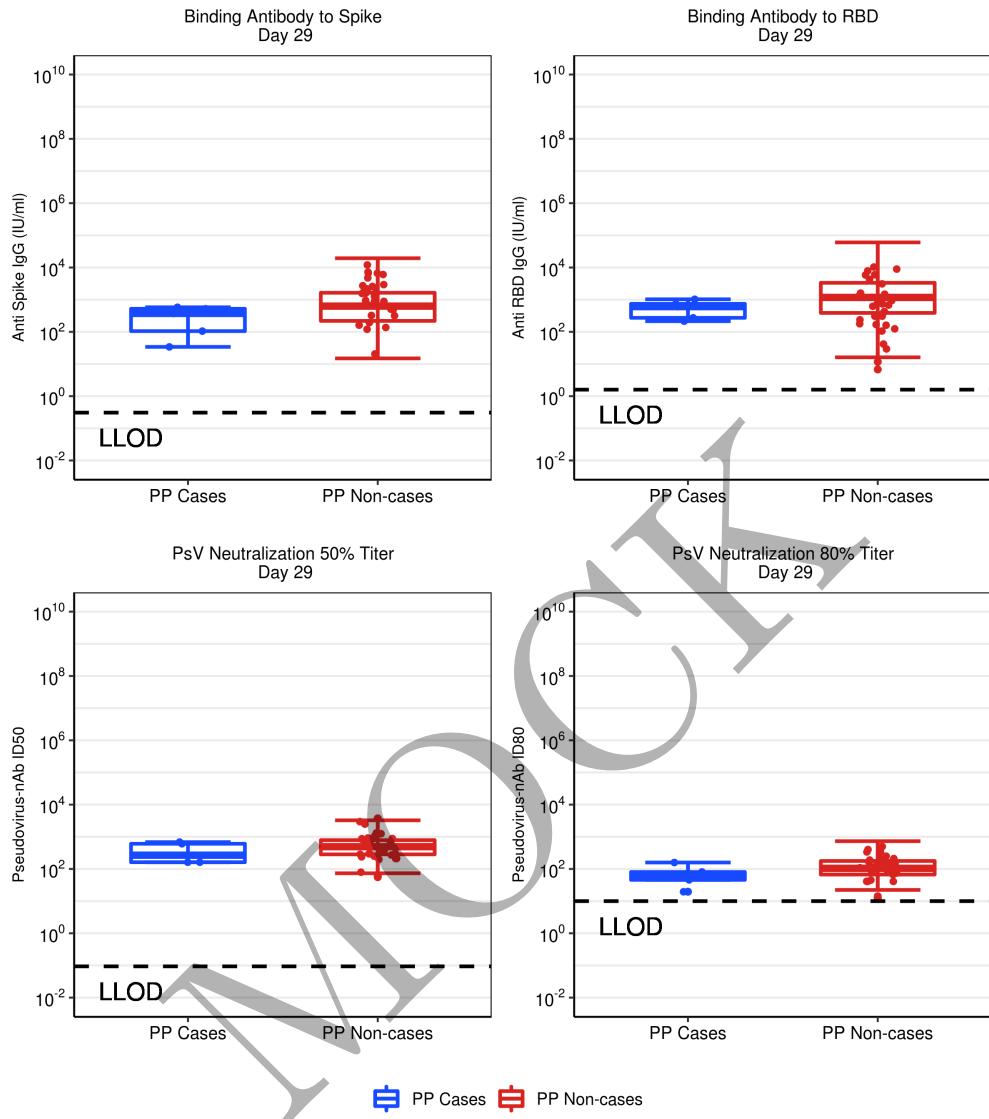


Figure 2.7: Boxplots of D29 Ab markers: baseline positive vaccine arm.

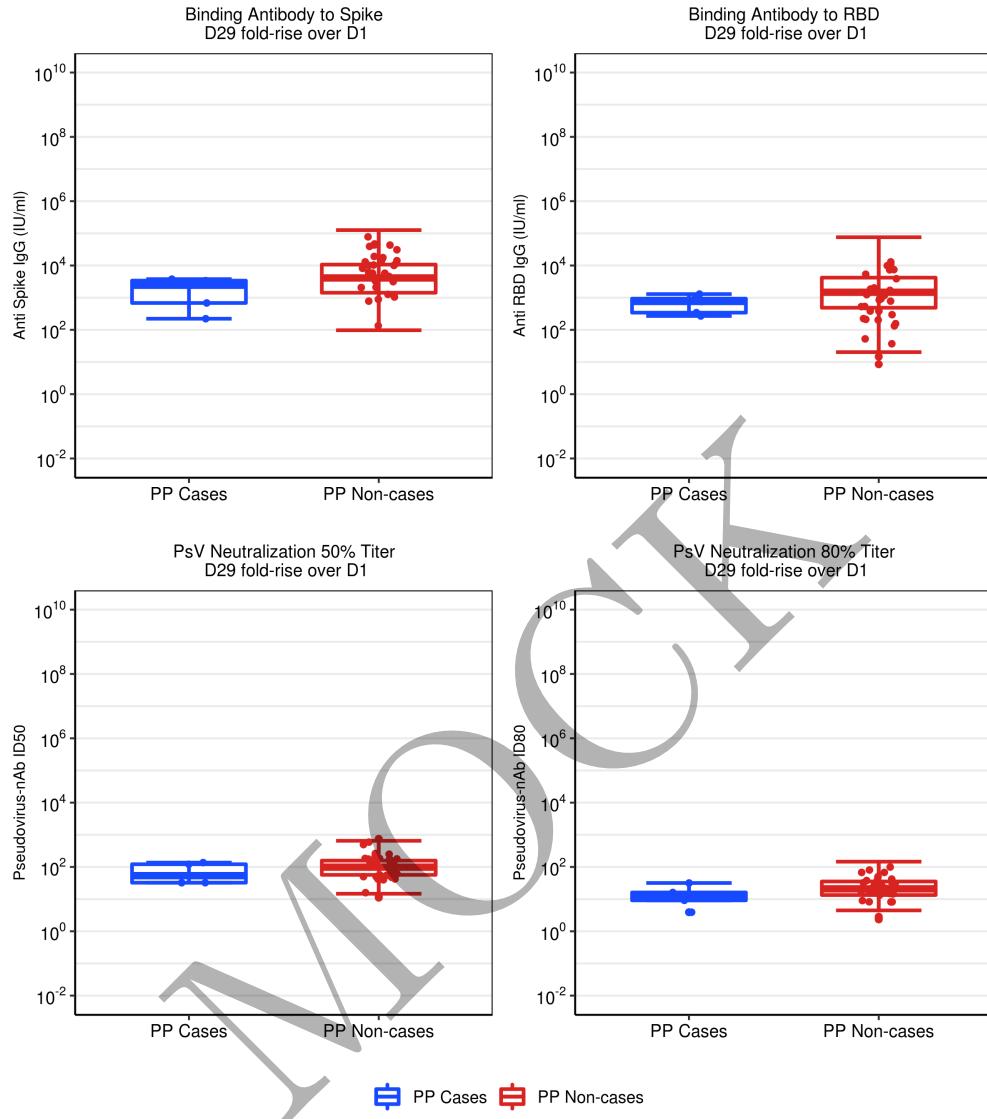


Figure 2.8: Boxplots of D29 fold-rise over D1 Ab markers: baseline positive vaccine arm.

2.2 Weighted RCDF plots

2.2.1 Baseline seronegative

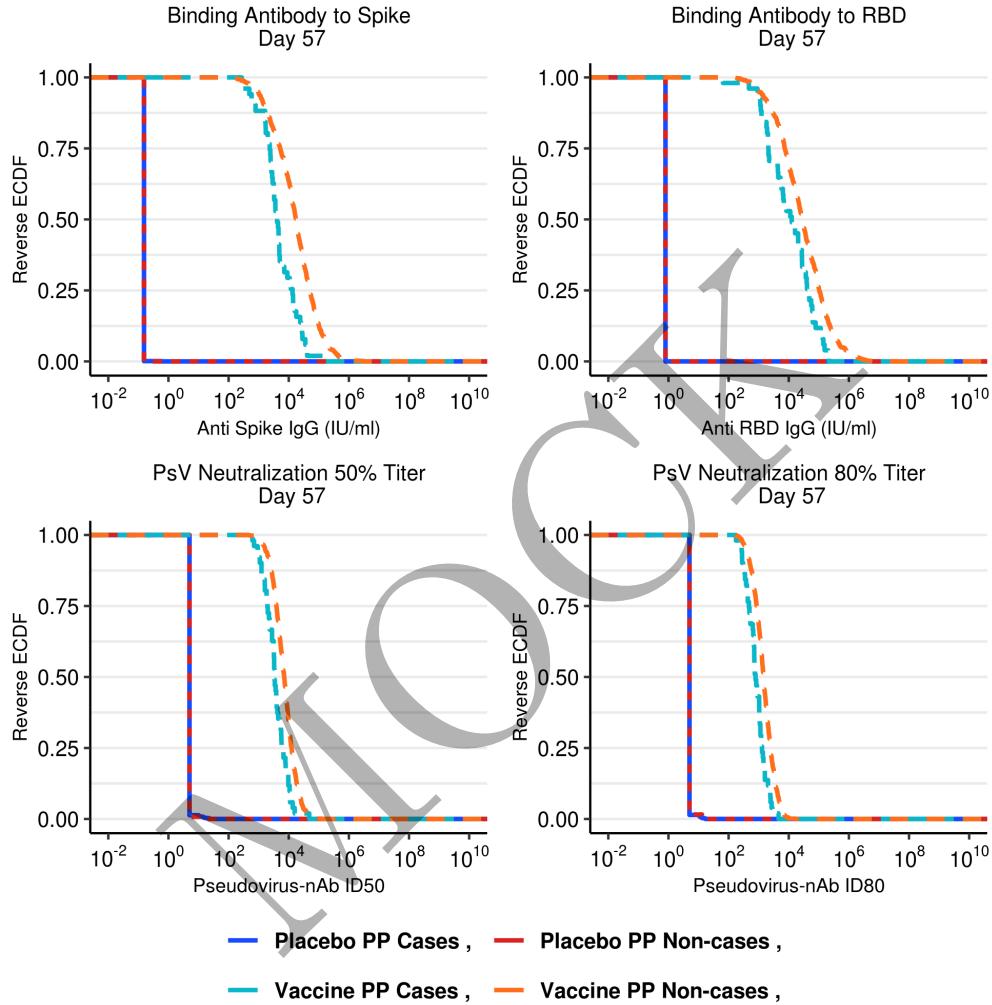


Figure 2.9: RCDF plots for D57 Ab markers: baseline negative by treatment arm.

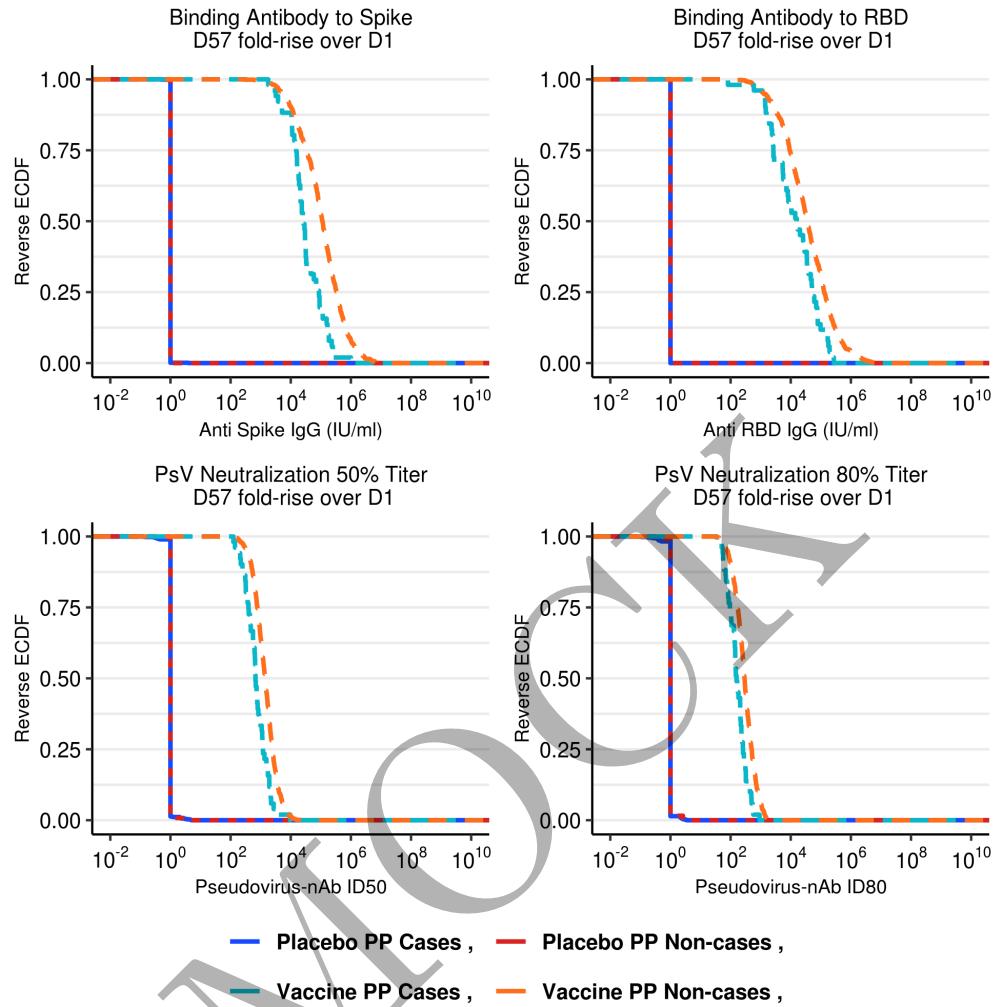


Figure 2.10: RCDF plots for D57 fold-rise over D1 Ab markers: baseline negative by treatment arm.

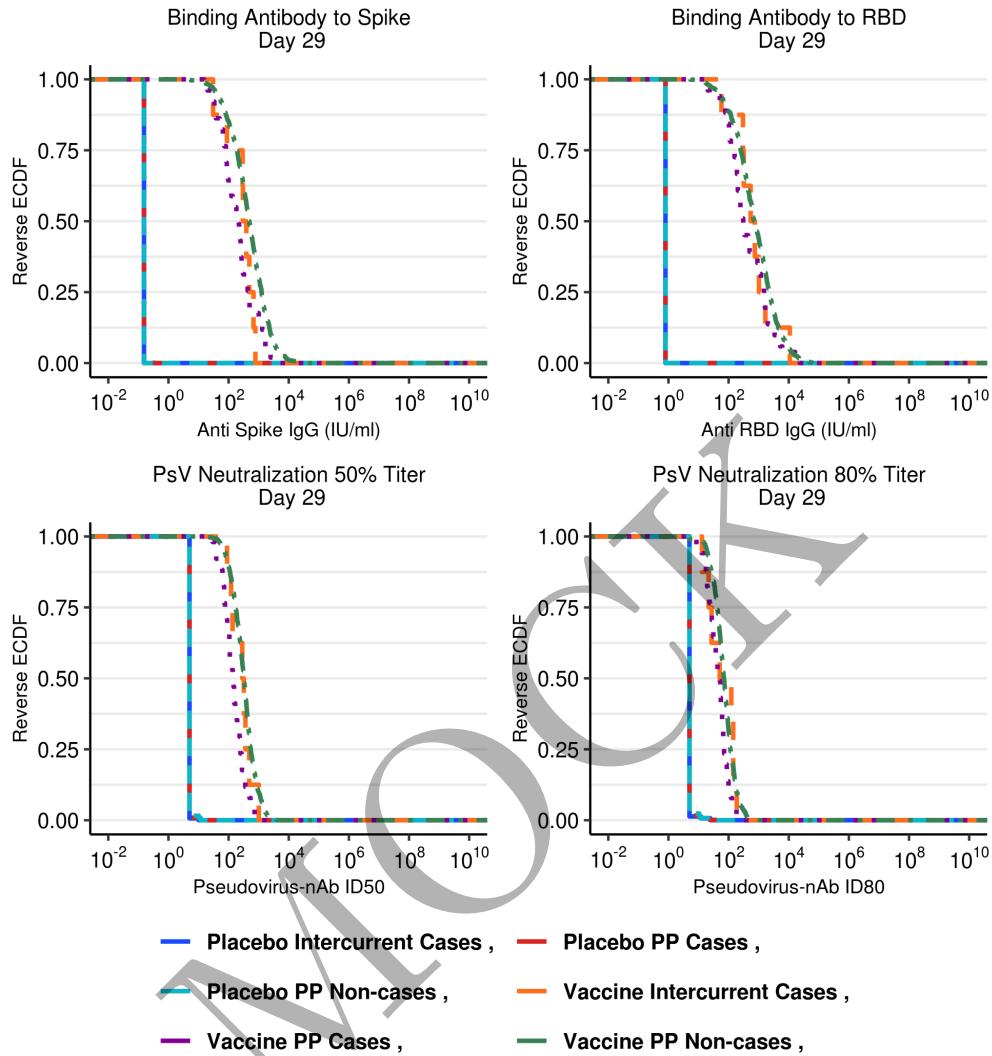


Figure 2.11: RCDF plots for D29 Ab markers: baseline negative by treatment arm.

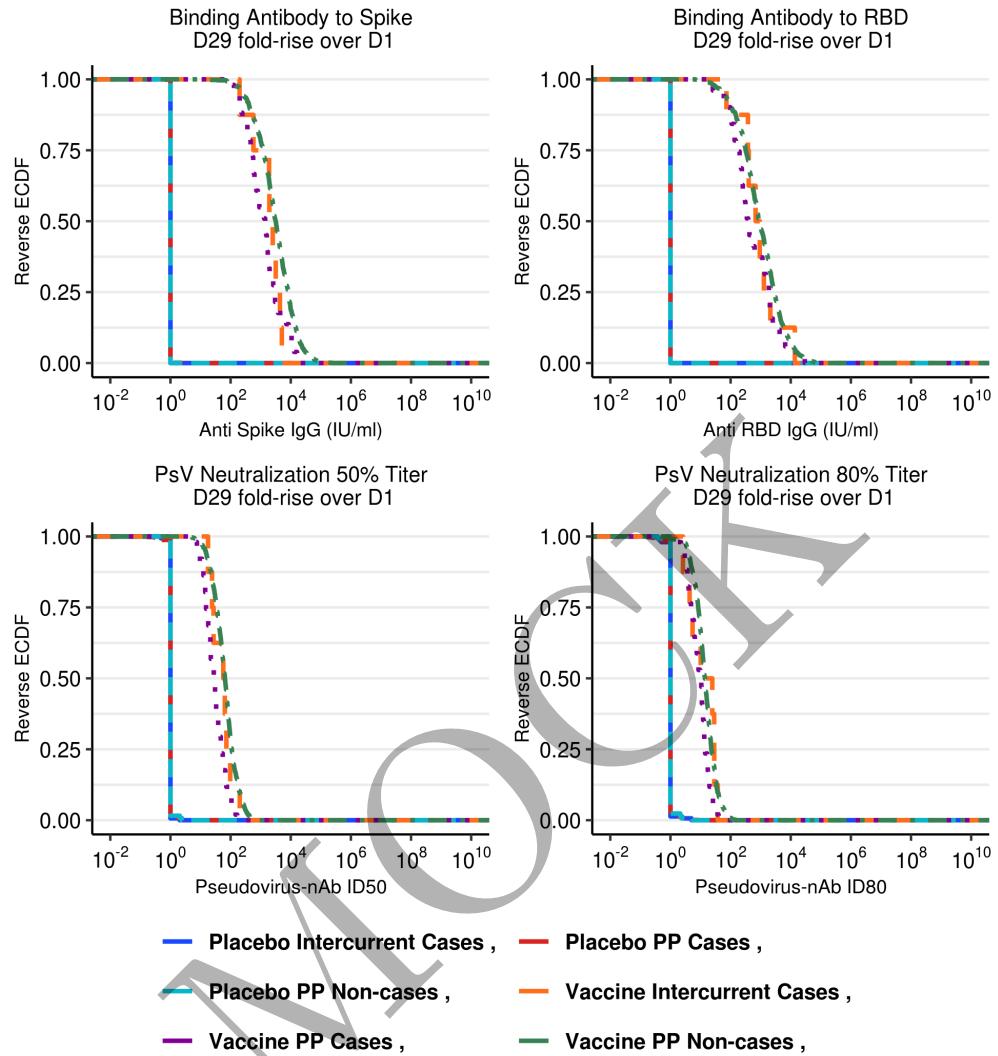


Figure 2.12: RCDF plots for D29 fold-rise over D1 Ab markers: baseline negative by treatment arm.

2.2.2 Baseline seropositive

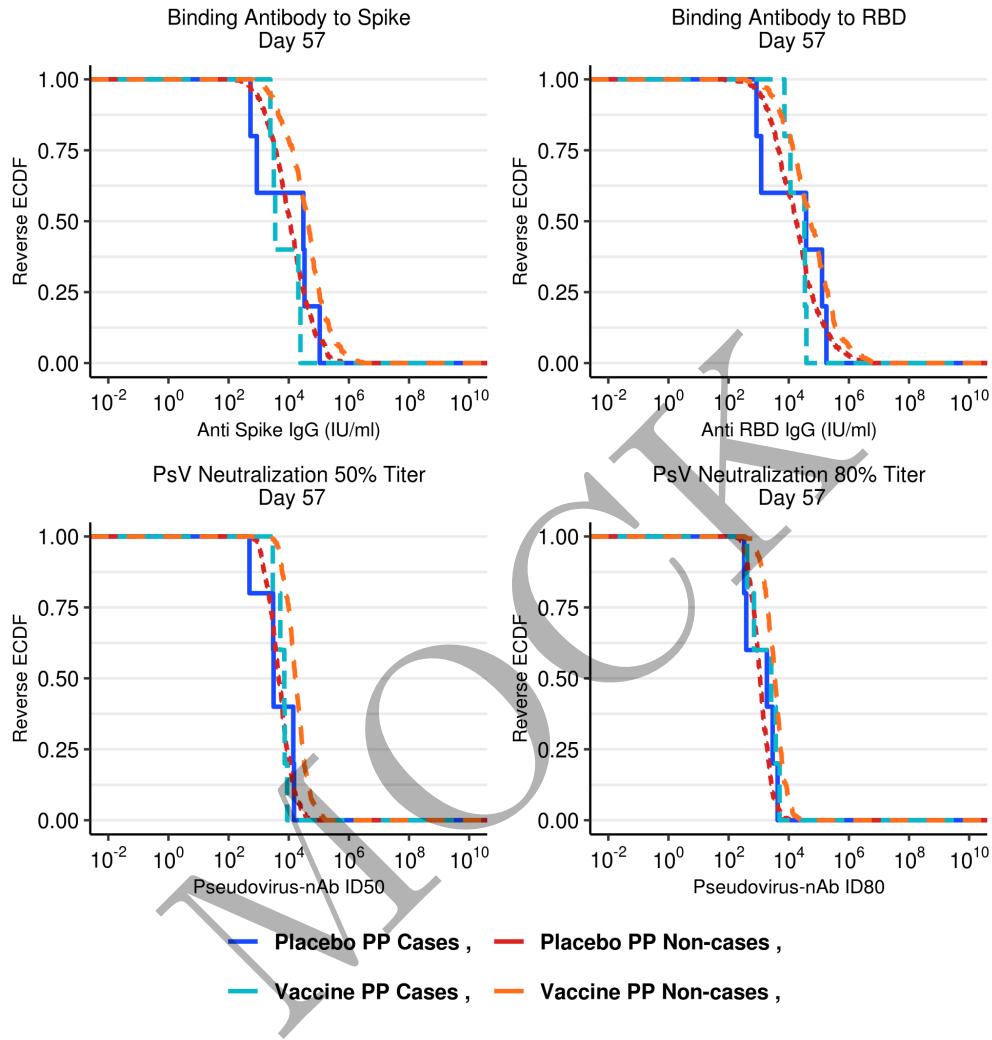


Figure 2.13: RCDF plots for D57 Ab markers: baseline positive by treatment arm.

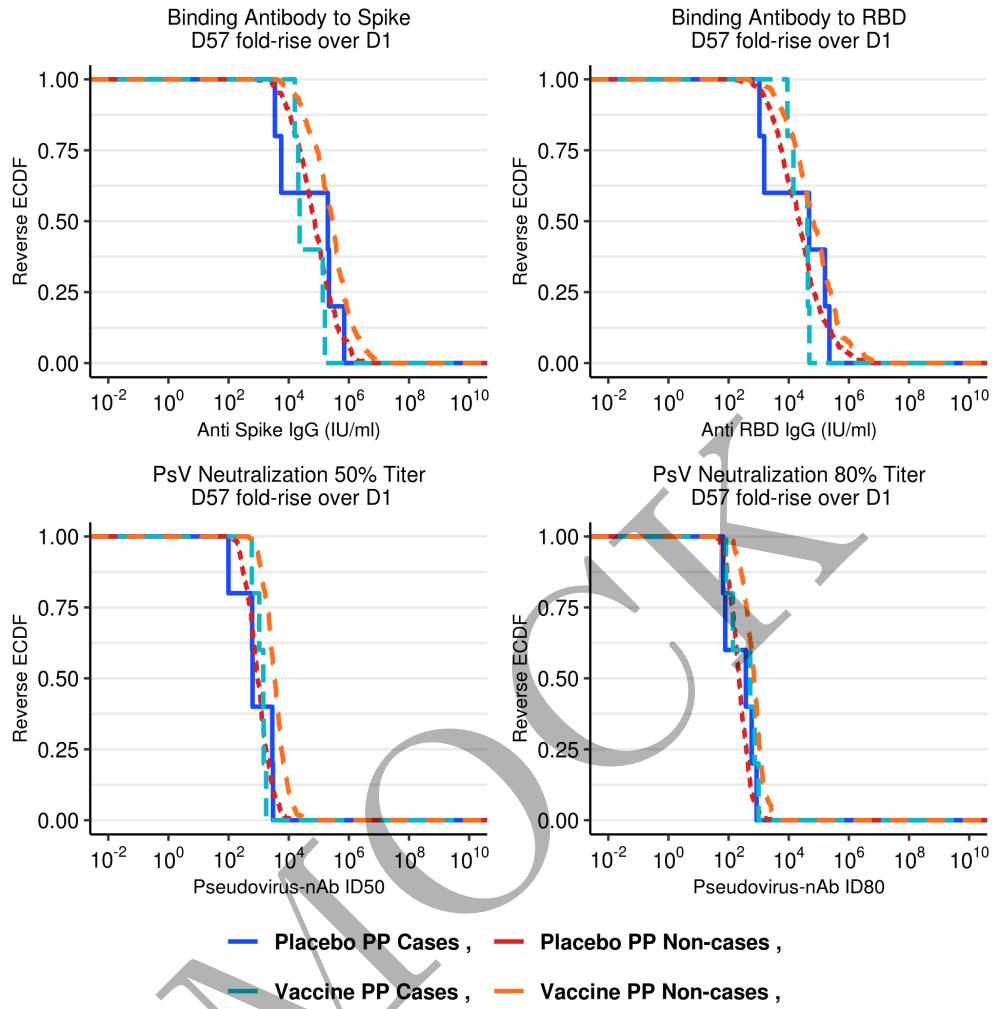


Figure 2.14: RCDF plots for D57 fold-rise over D1 Ab markers: baseline positive by treatment arm.

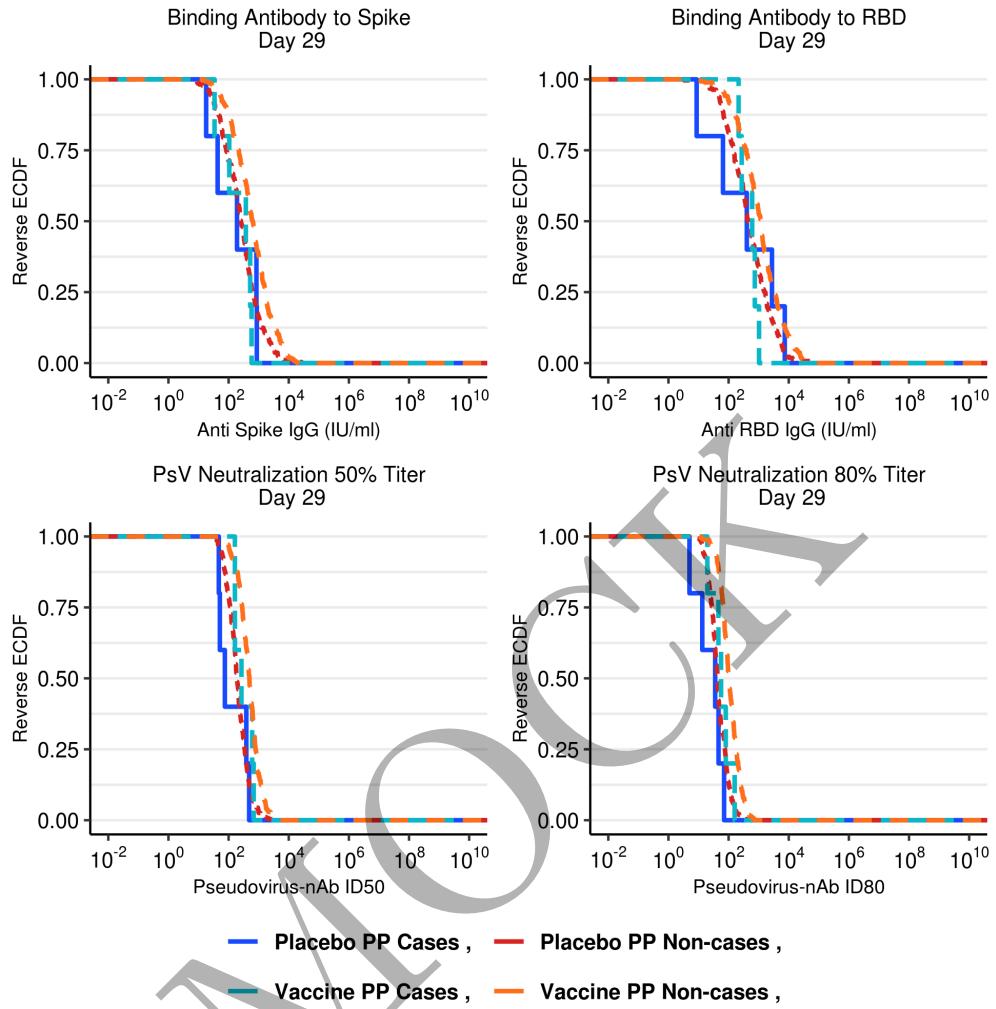


Figure 2.15: RCDF plots for D29 Ab markers: baseline positive by treatment arm.

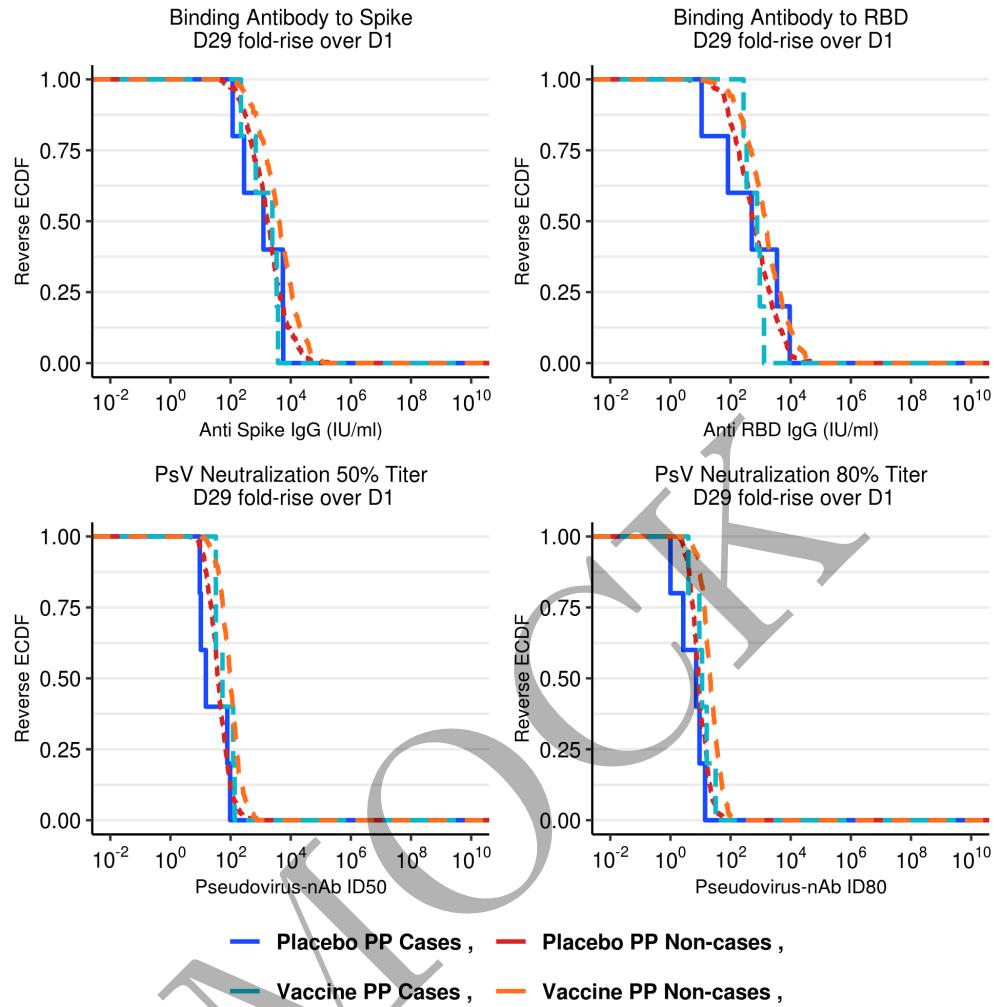


Figure 2.16: RCDF plots for D29 fold-rise over D1 Ab markers: baseline positive by treatment arm.

2.3 Weighted RCDF plots of threshold correlate concentration for vaccine efficacy

2.3.1 Baseline seronegative

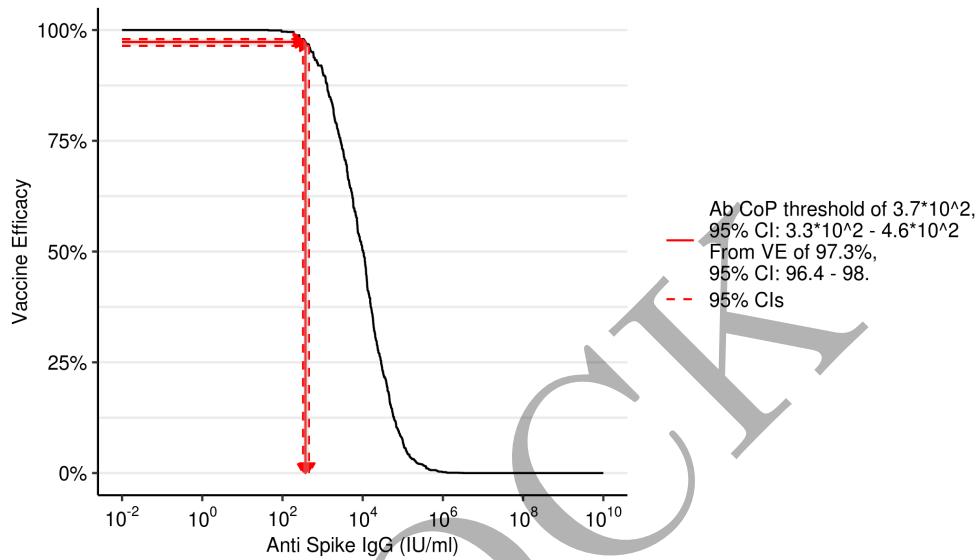


Figure 2.17: Marker RCDF of D57 anti-Spike binding Ab: baseline negative vaccine arm

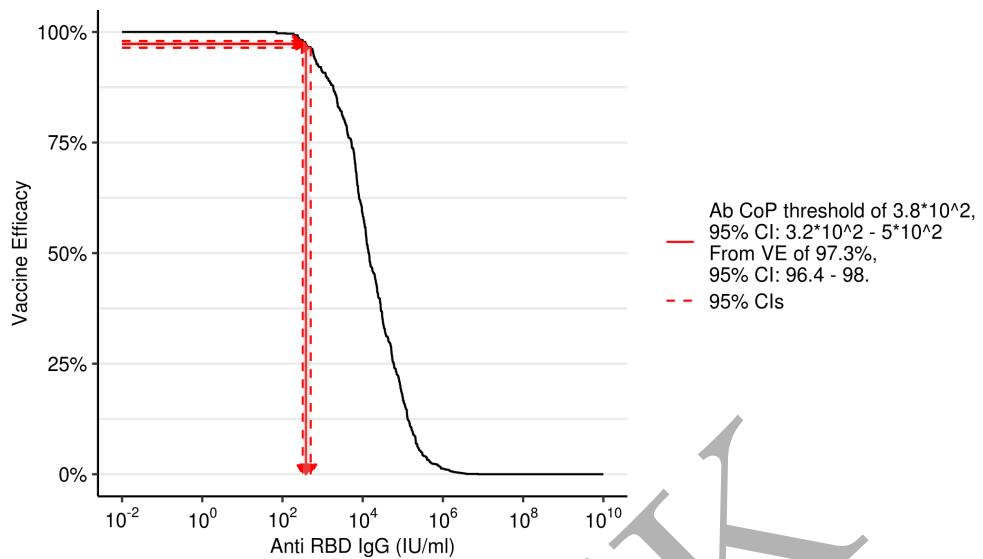


Figure 2.18: Marker RCDF of D57 anti-RBD binding Ab: baseline negative vaccine arm

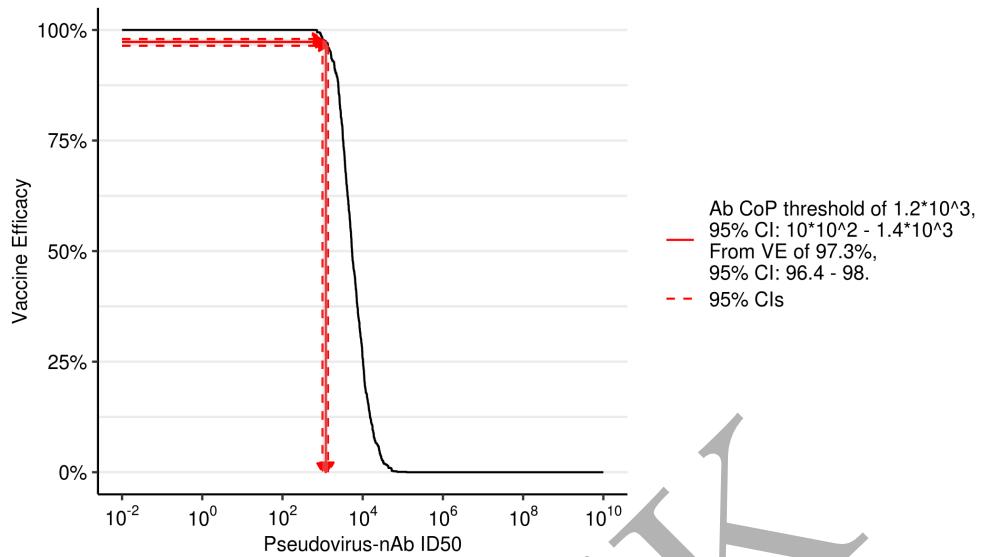


Figure 2.19: Marker RCDF of D57 PsV-nAb ID50: baseline negative vaccine arm

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

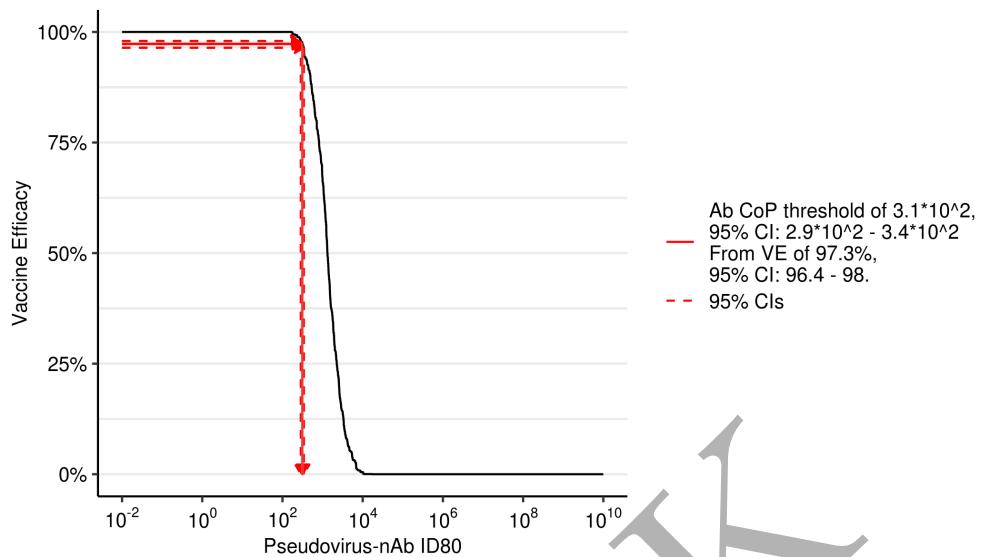


Figure 2.20: Marker RCDF of D57 PsV-nAb ID80: baseline negative vaccine arm

2.4 Spaghetti plots

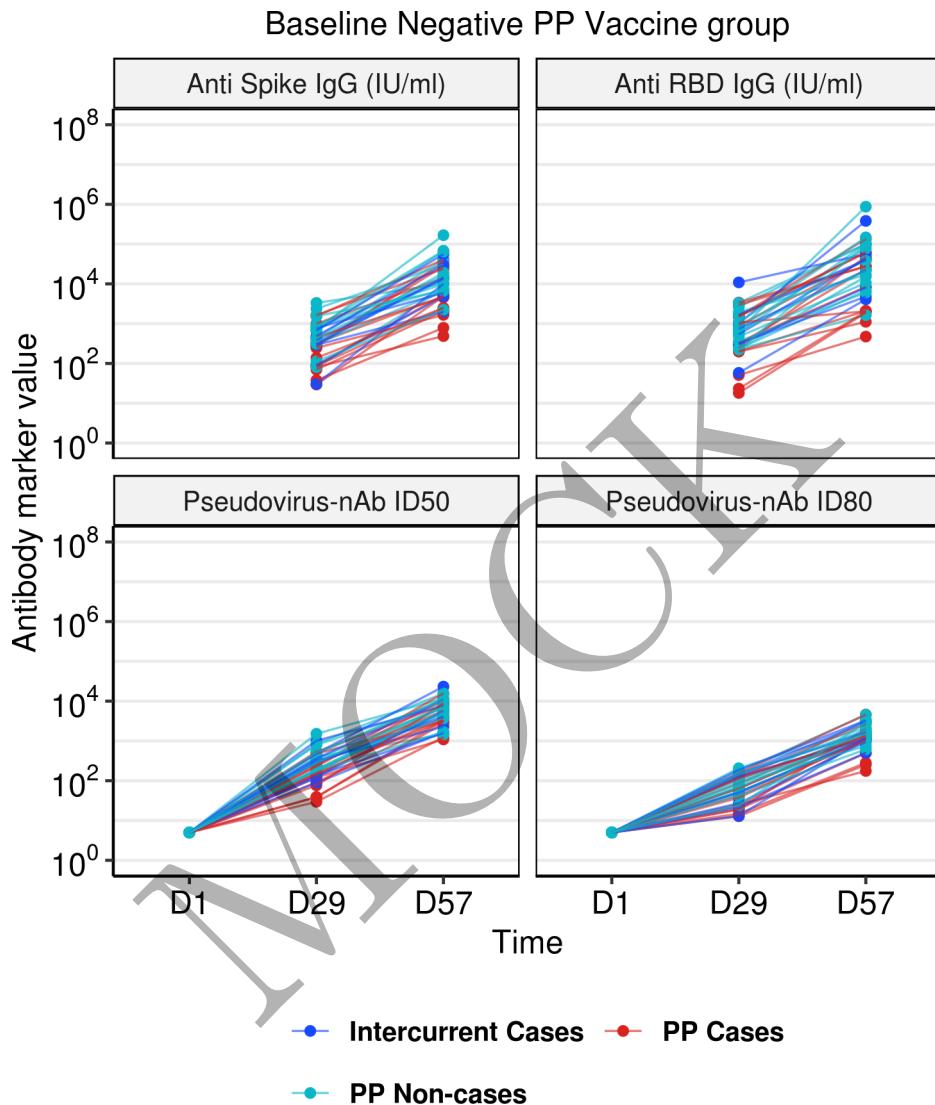


Figure 2.21: Spaghetti Plots of Marker Trajectory: baseline negative vaccine arm

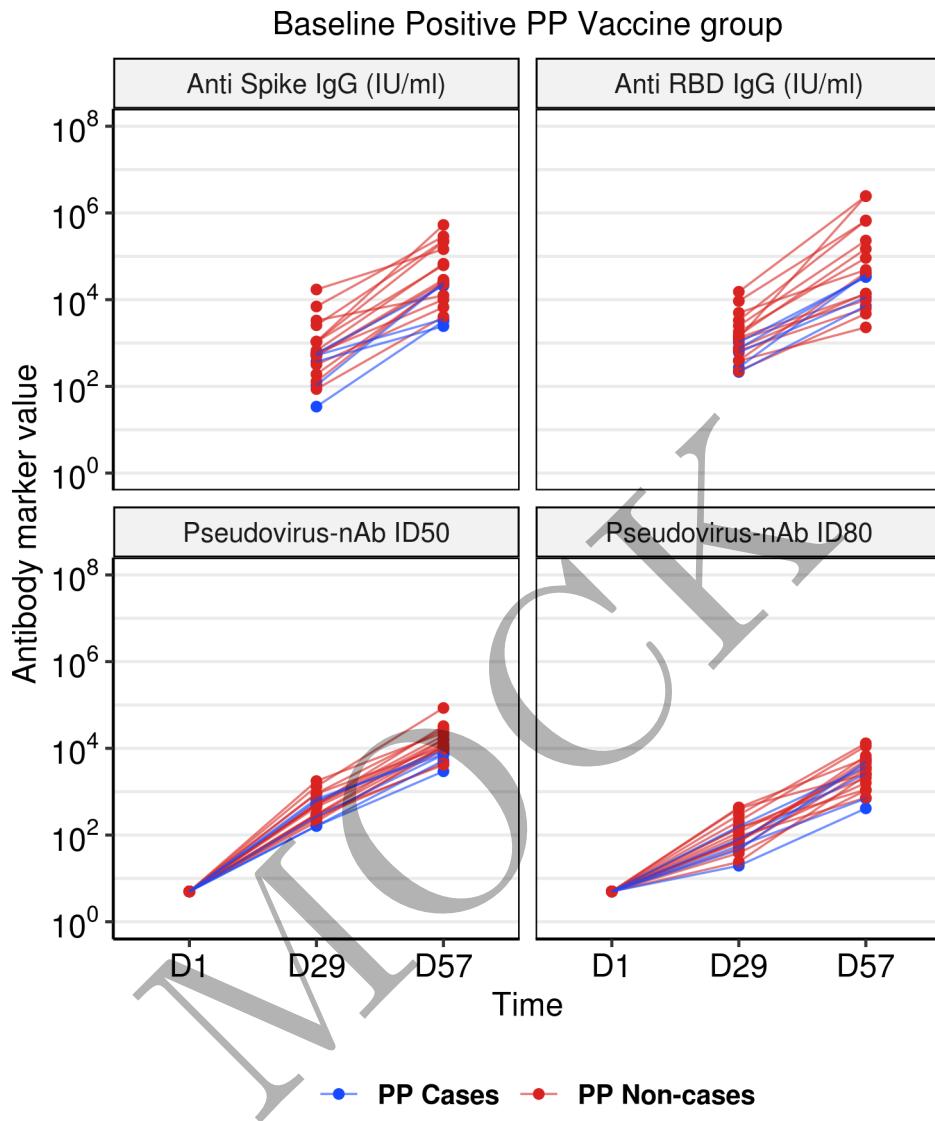


Figure 2.22: Spaghetti Plots of Marker Trajectory: baseline positive vaccine arm

2.5 Violin and line plots

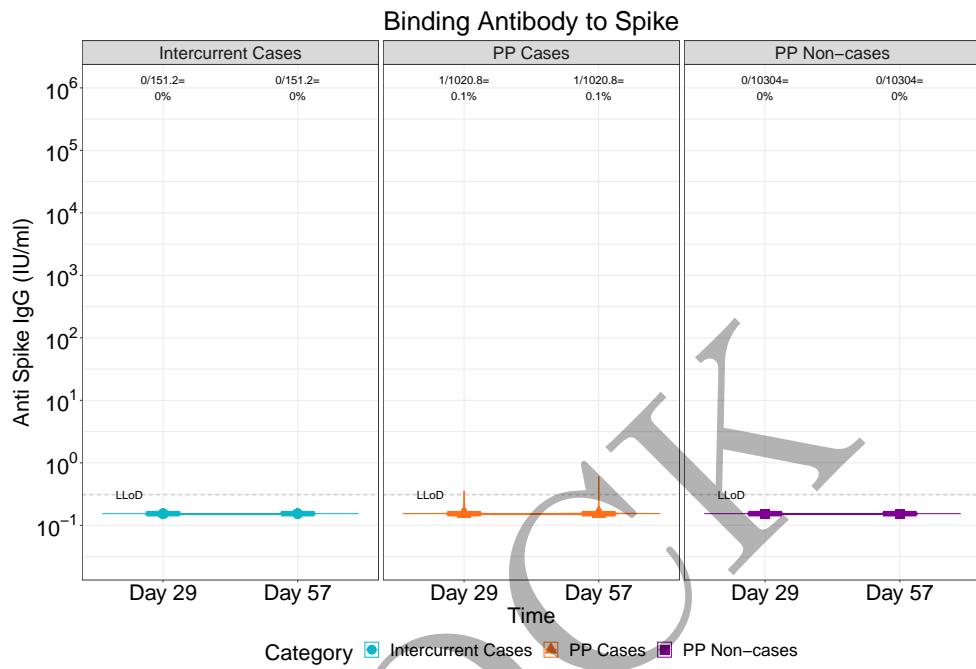


Figure 2.23: lineplots of Binding Antibody to Spike: baseline negative placebo arm (version 1)

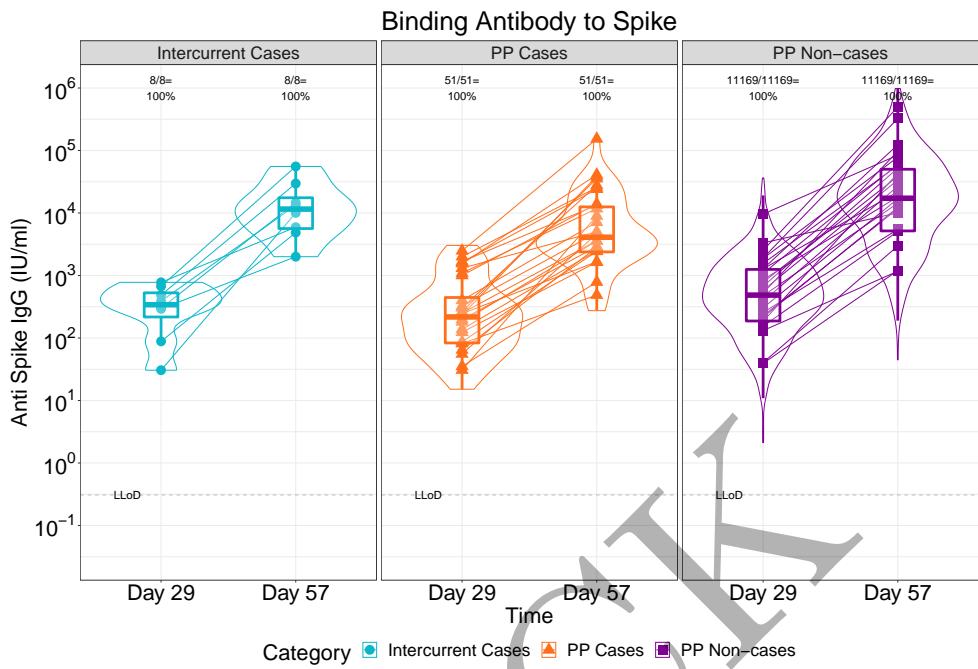


Figure 2.24: lineplots of Binding Antibody to Spike: baseline negative vaccine arm (version 1)

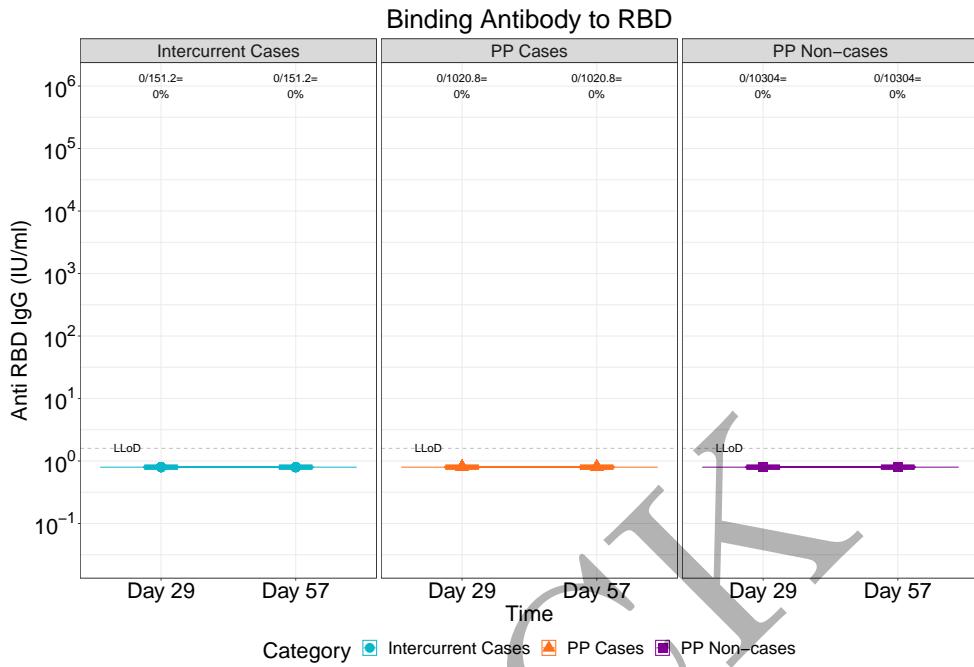


Figure 2.25: lineplots of Binding Antibody to RBD: baseline negative placebo arm (version 1)

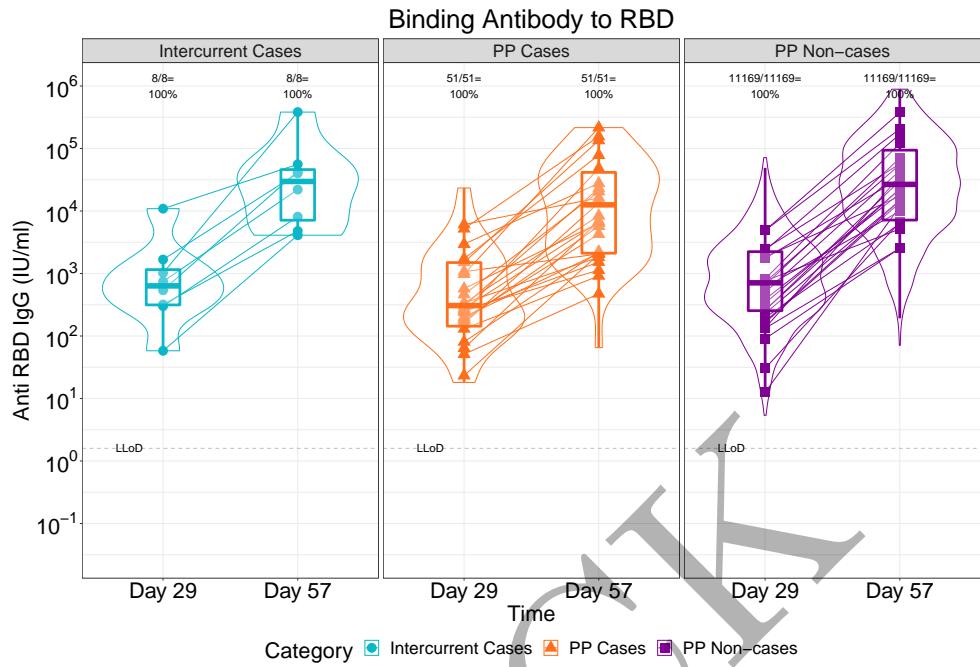


Figure 2.26: lineplots of Binding Antibody to RBD: baseline negative vaccine arm (version 1)

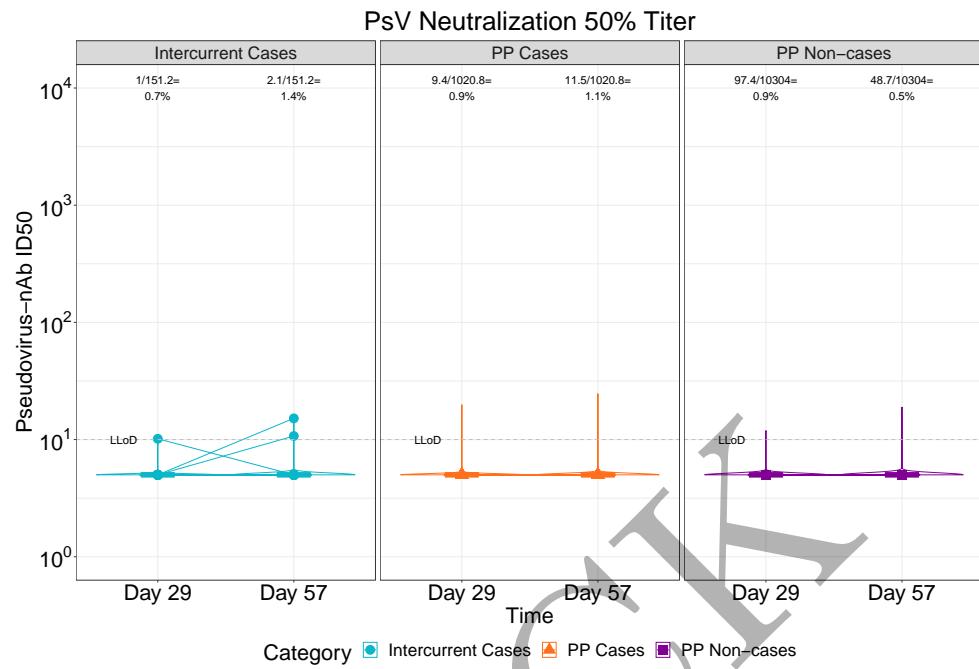


Figure 2.27: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm (version 1)

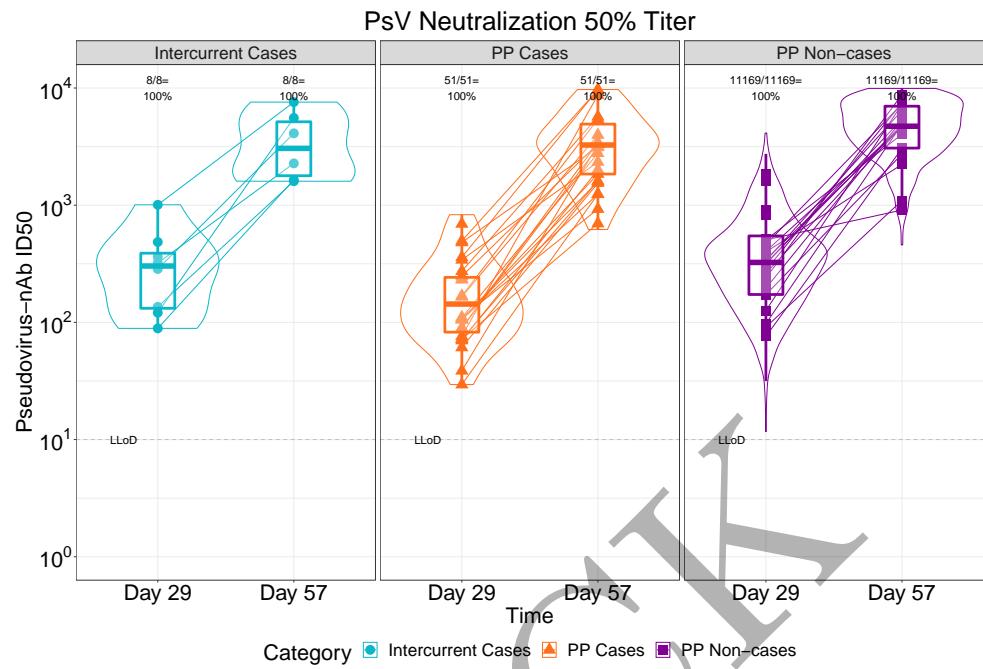


Figure 2.28: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm (version 1)

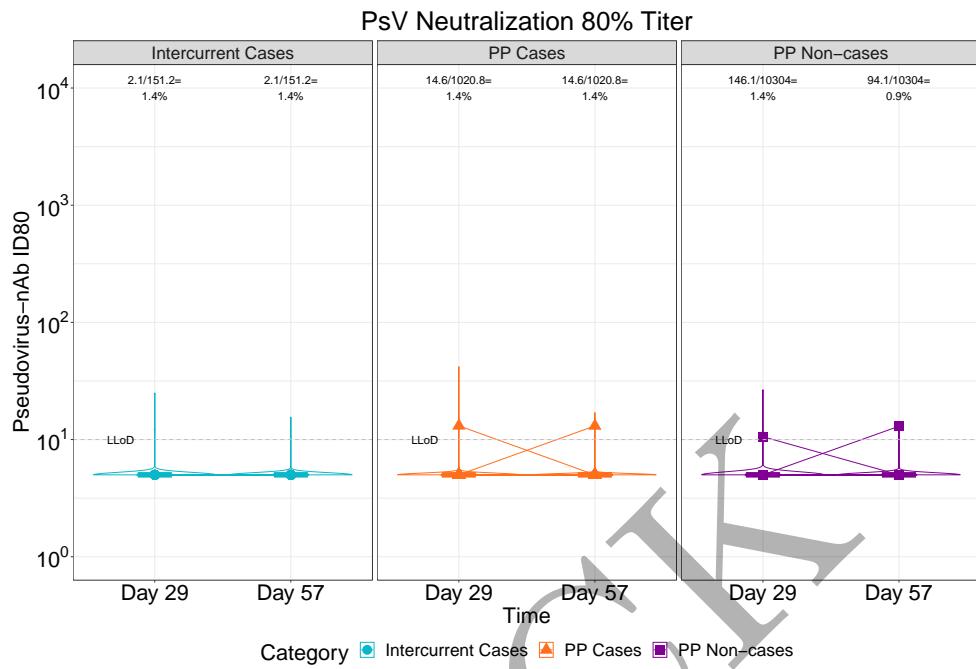


Figure 2.29: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm (version 1)

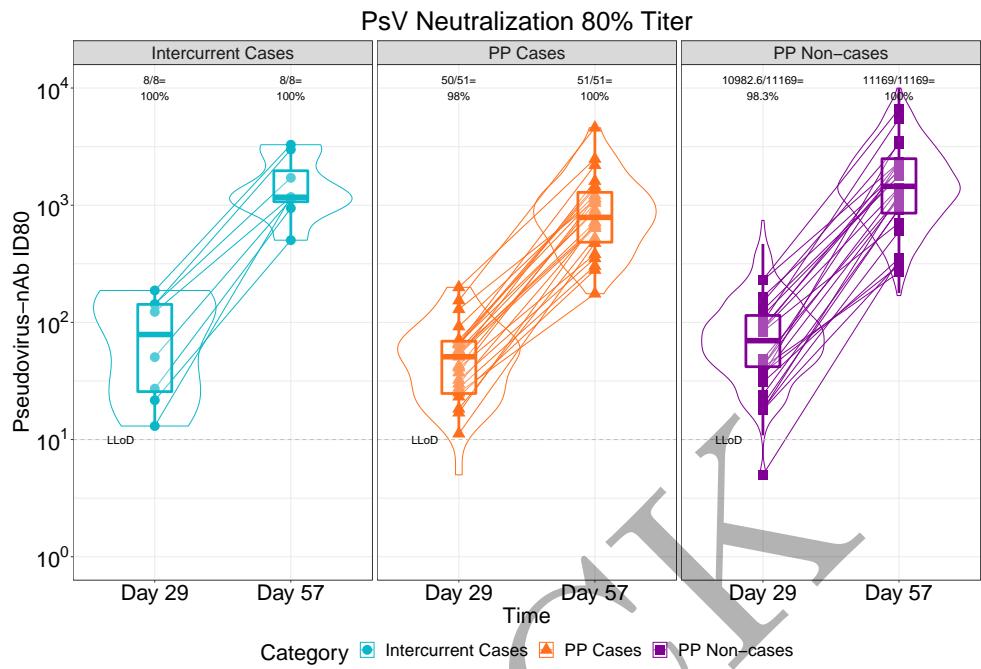


Figure 2.30: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm (version 1)

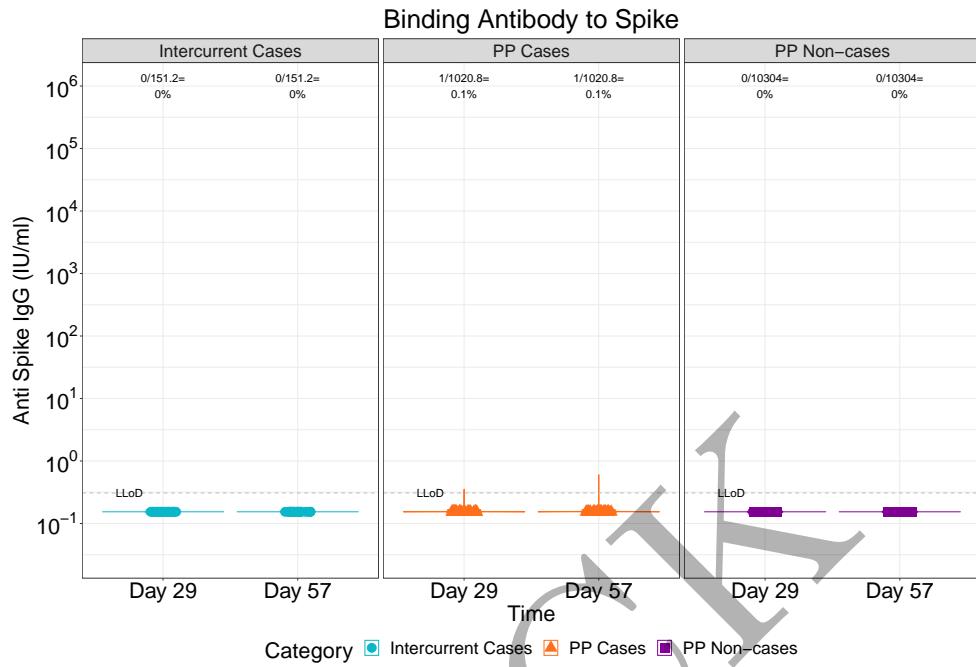


Figure 2.31: violinplots of Binding Antibody to Spike: baseline negative placebo arm (version 1)

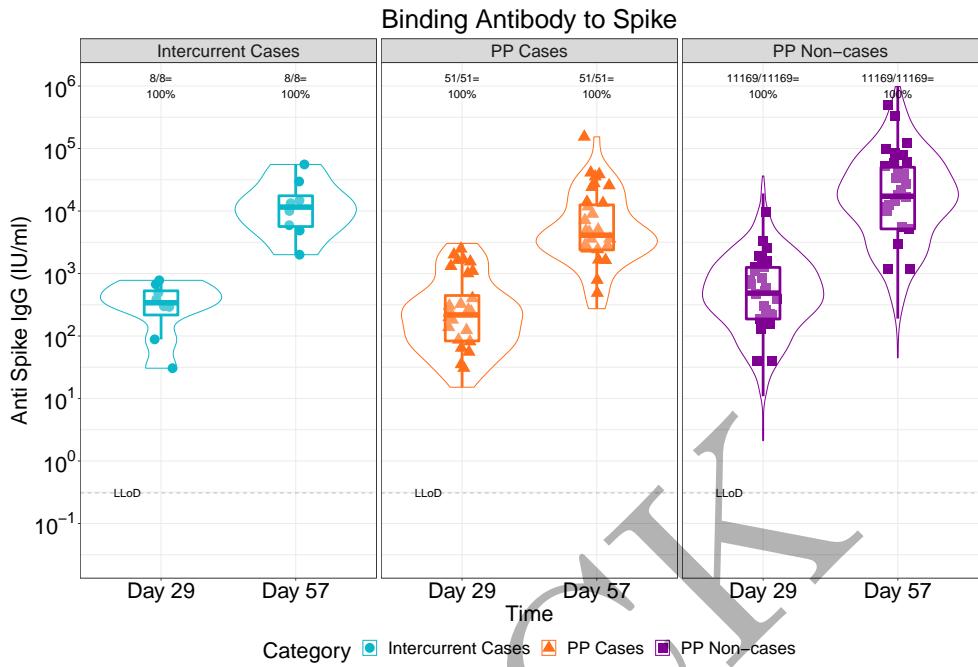


Figure 2.32: violinplots of Binding Antibody to Spike: baseline negative vaccine arm (version 1)

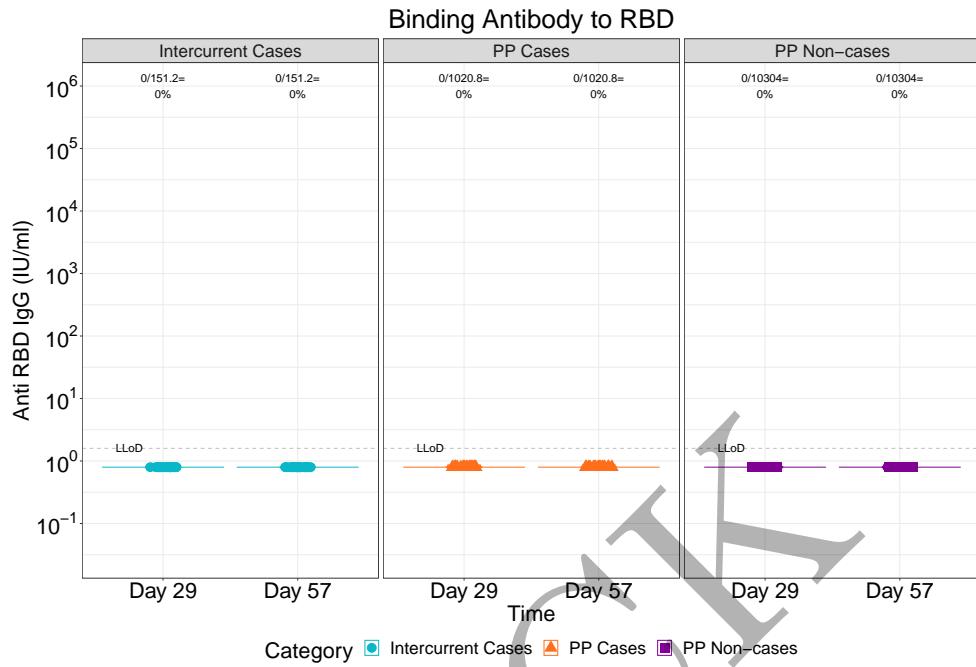


Figure 2.33: violinplots of Binding Antibody to RBD: baseline negative placebo arm (version 1)

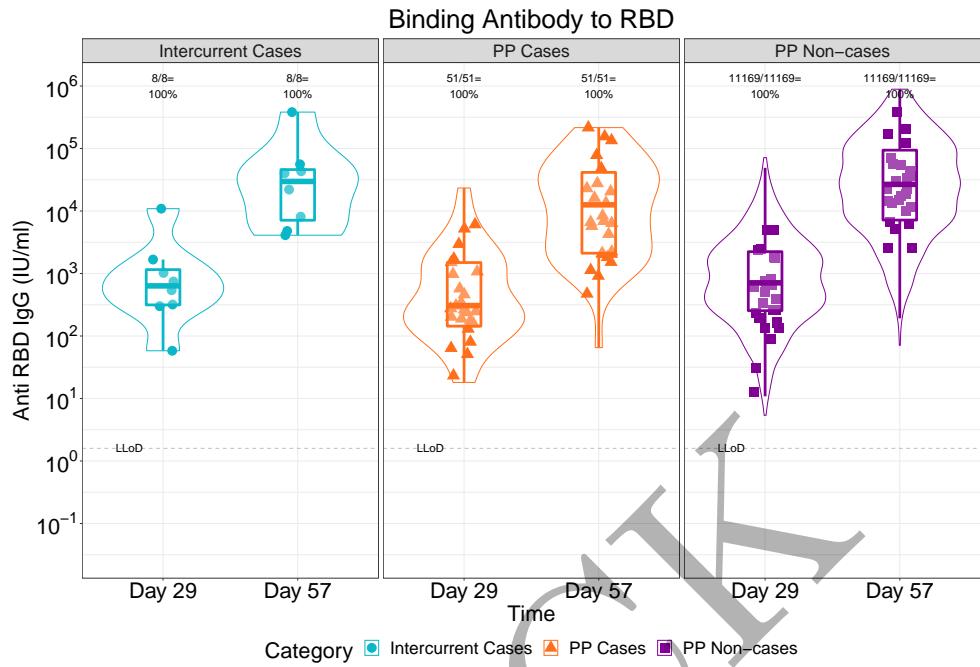


Figure 2.34: violinplots of Binding Antibody to RBD: baseline negative vaccine arm (version 1)

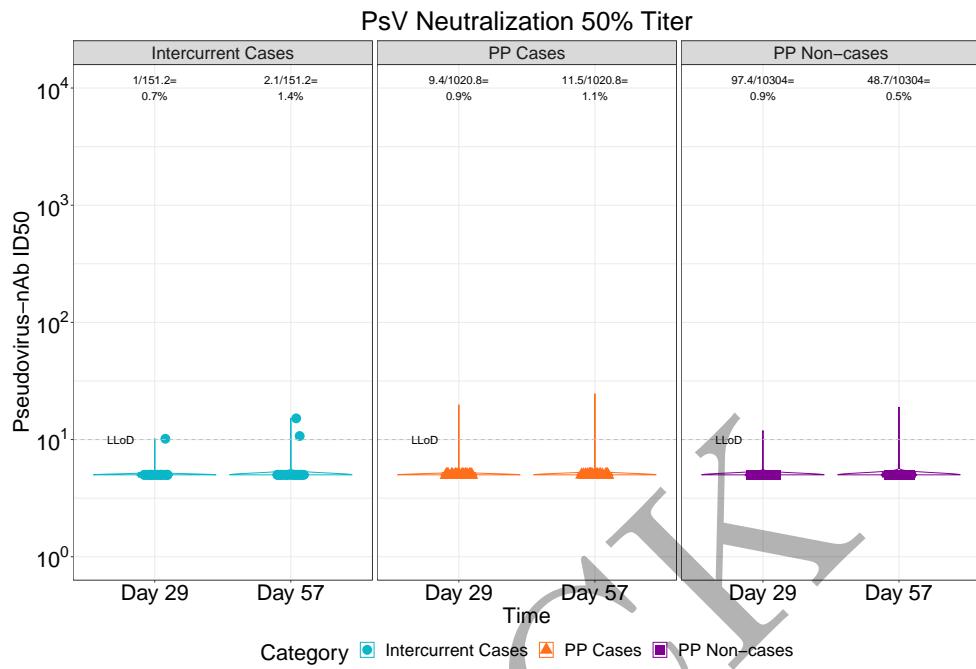


Figure 2.35: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm (version 1)

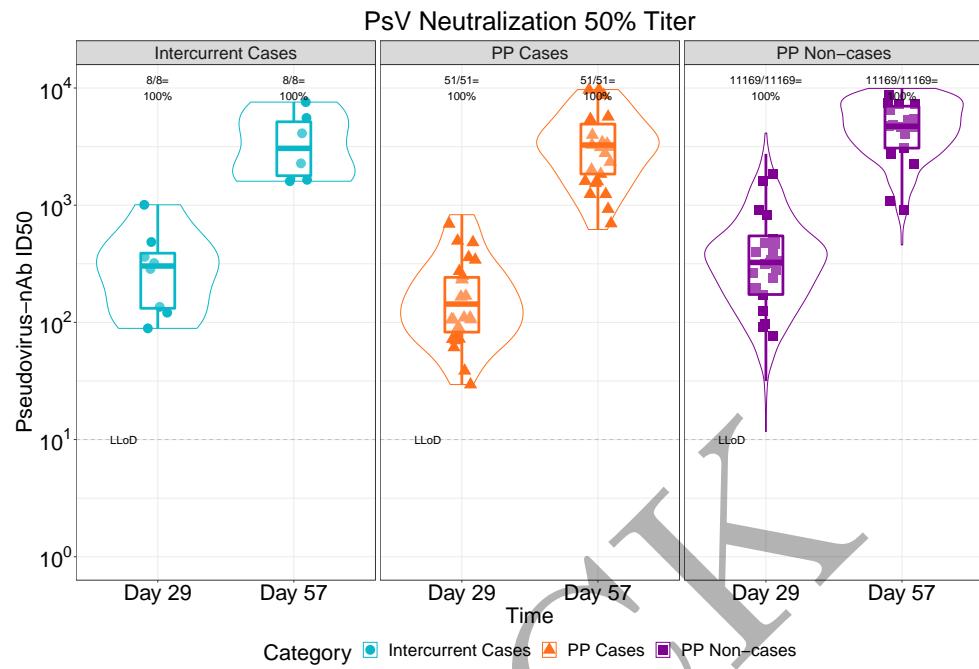


Figure 2.36: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm (version 1)

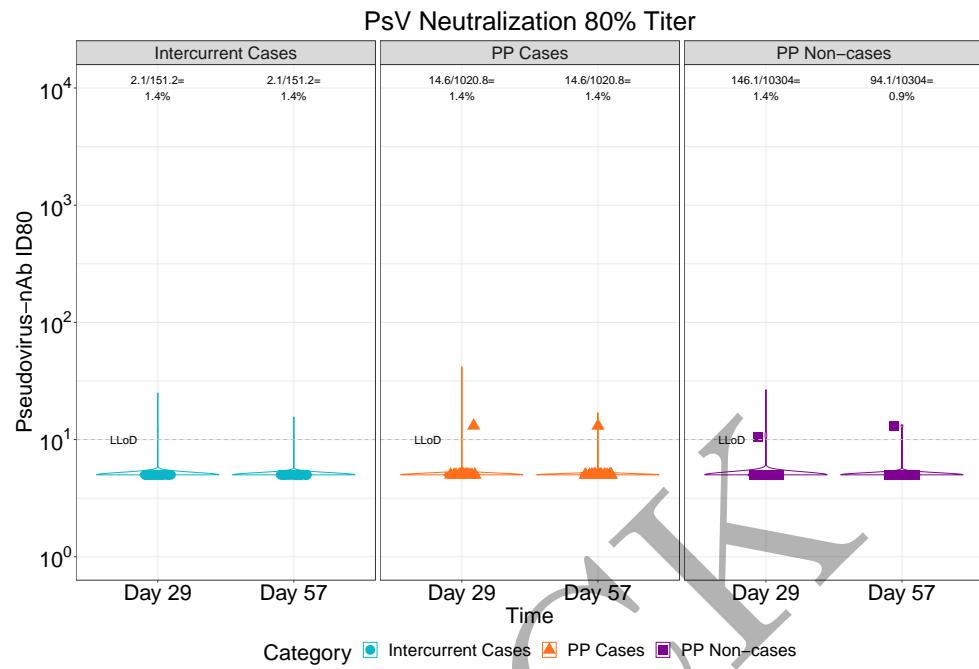


Figure 2.37: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm (version 1)

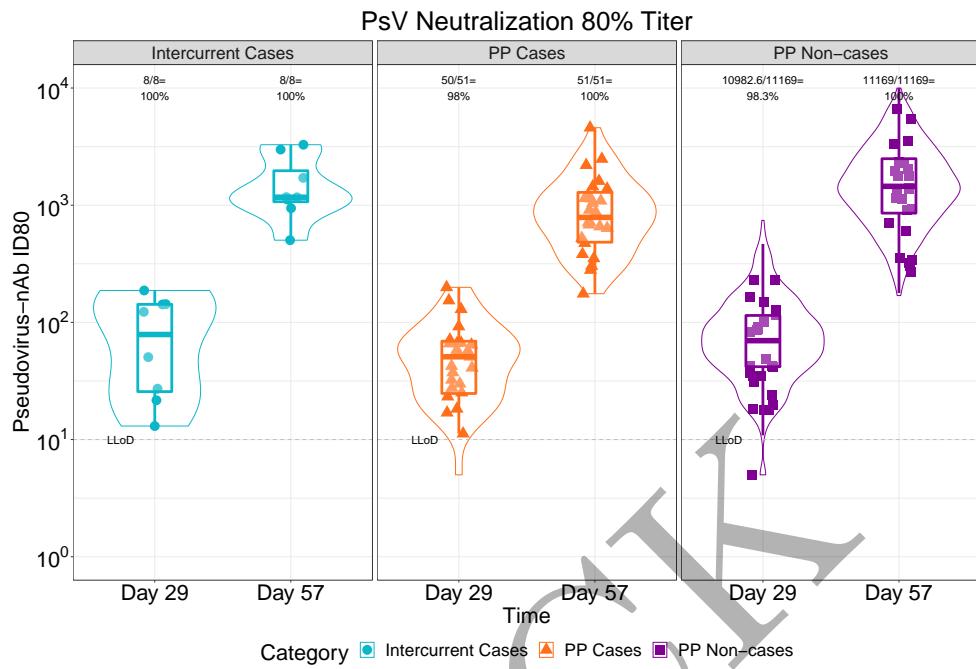


Figure 2.38: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm (version 1)

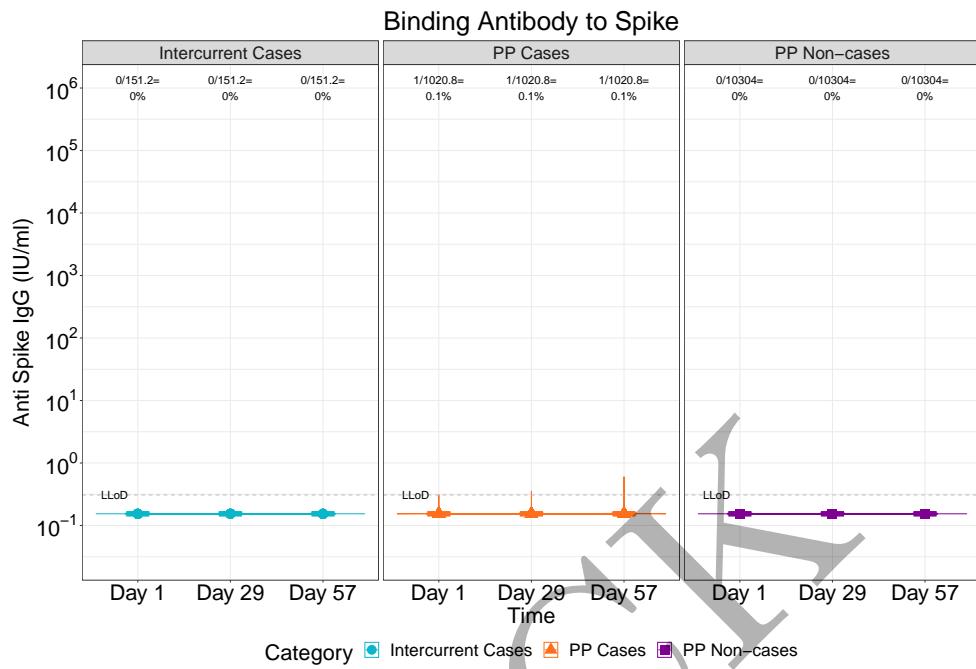


Figure 2.39: lineplots of Binding Antibody to Spike: baseline negative placebo arm (version 2)

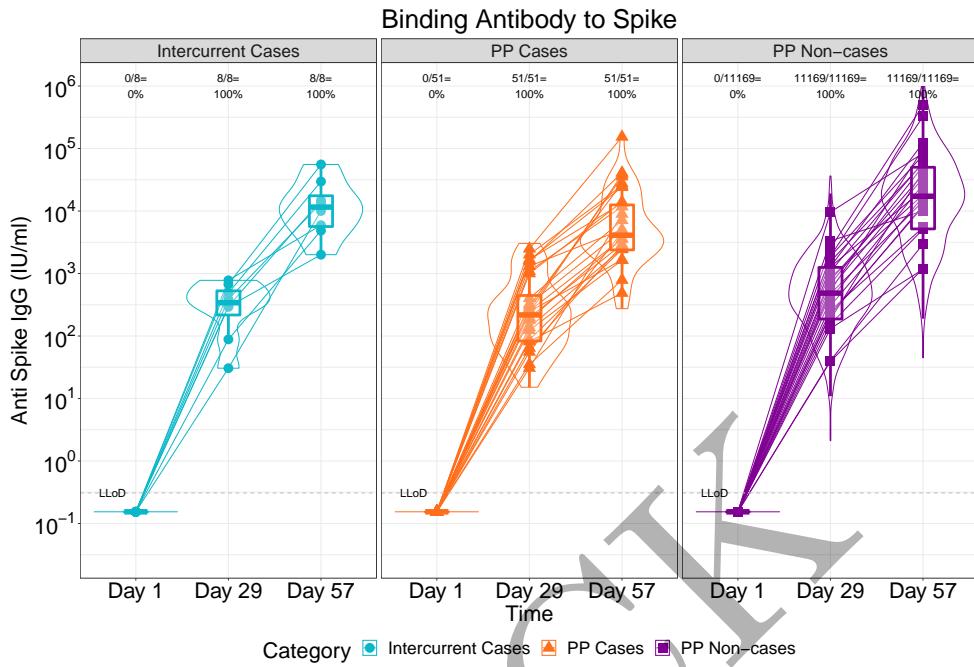


Figure 2.40: lineplots of Binding Antibody to Spike: baseline negative vaccine arm (version 2)

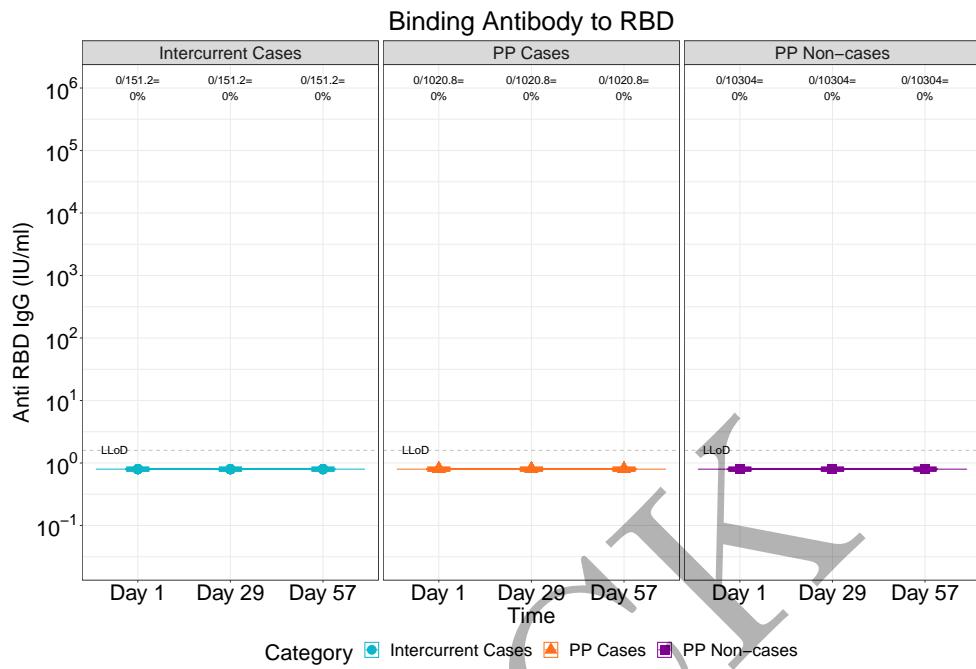


Figure 2.41: lineplots of Binding Antibody to RBD: baseline negative placebo arm (version 2)

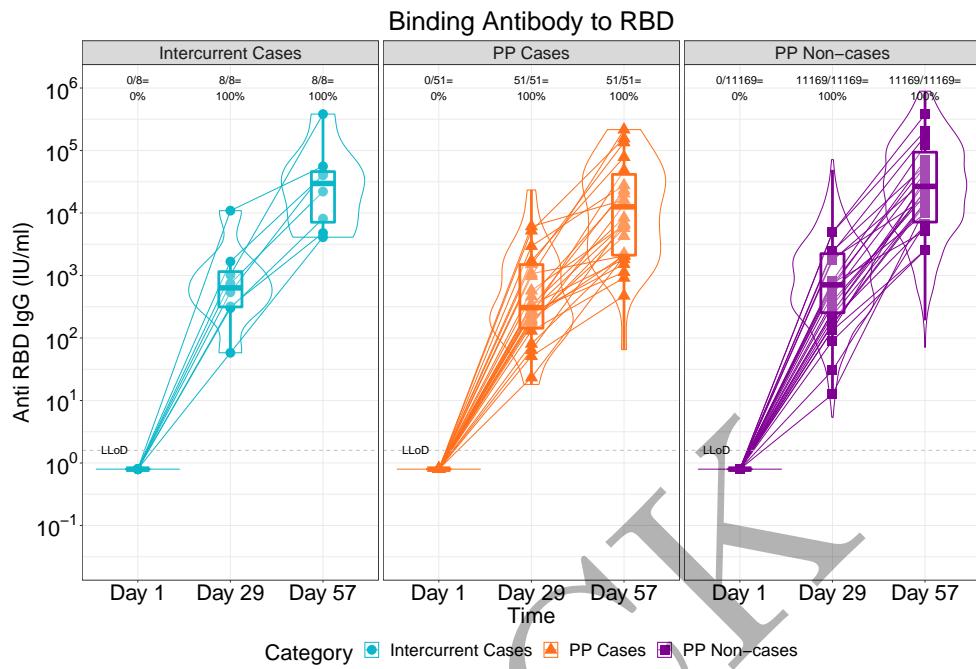


Figure 2.42: lineplots of Binding Antibody to RBD: baseline negative vaccine arm (version 2)

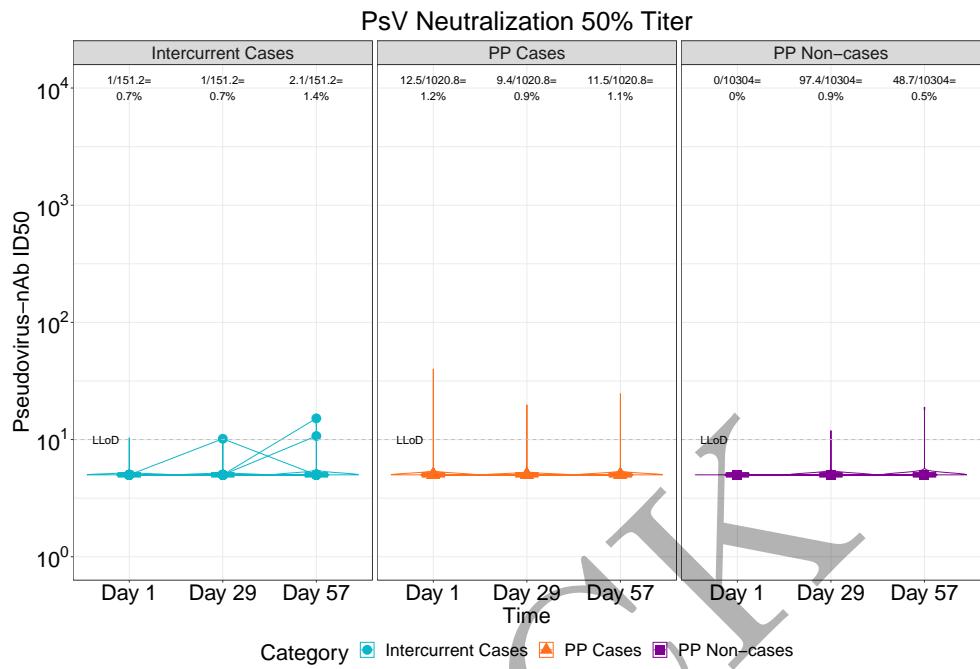


Figure 2.43: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm (version 2)

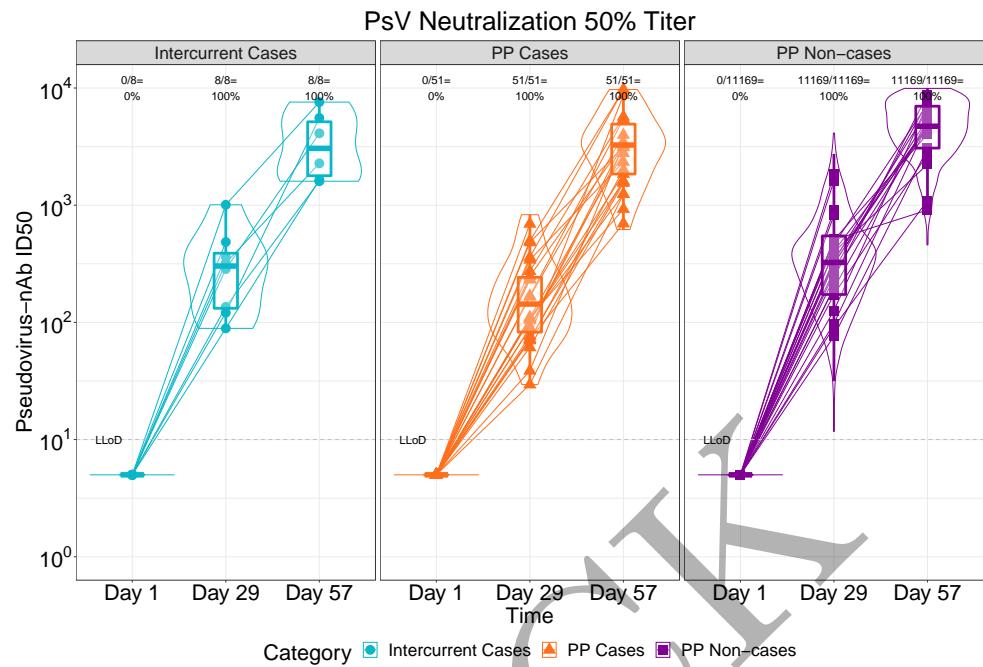


Figure 2.44: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm (version 2)

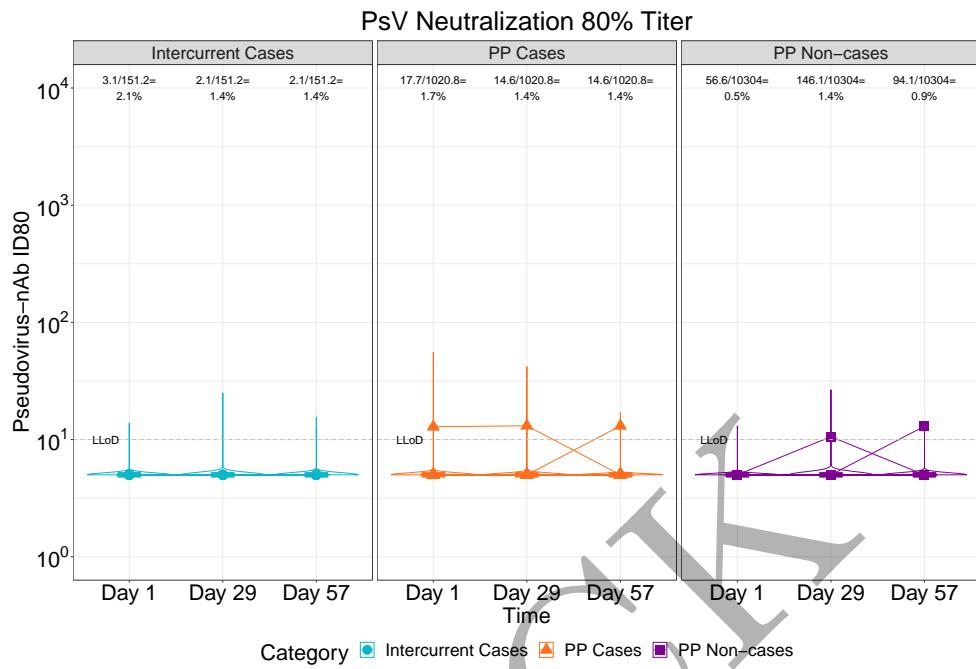


Figure 2.45: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm (version 2)

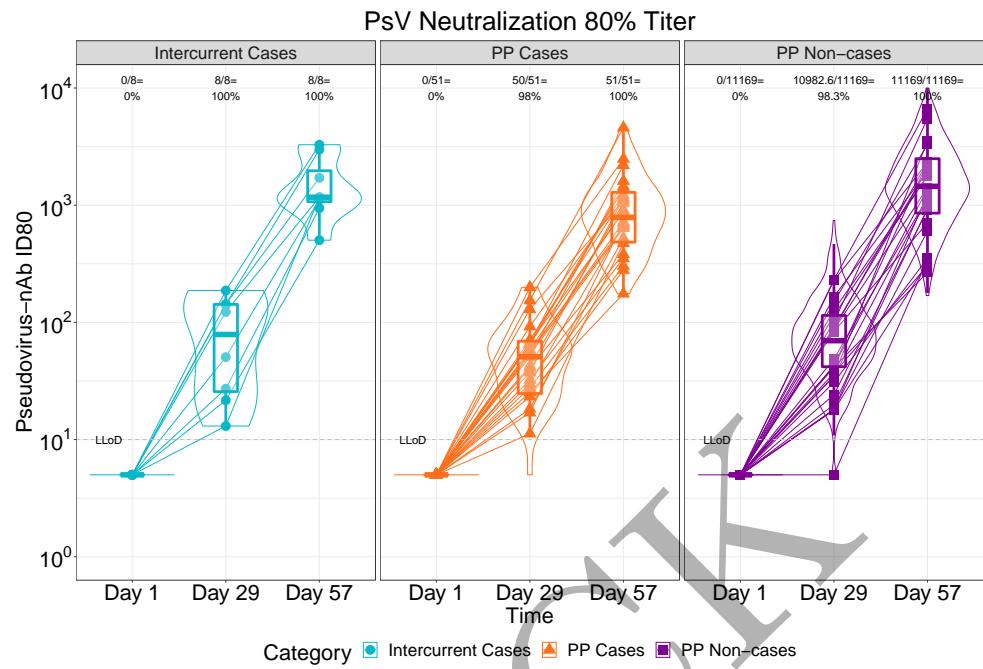


Figure 2.46: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm (version 2)

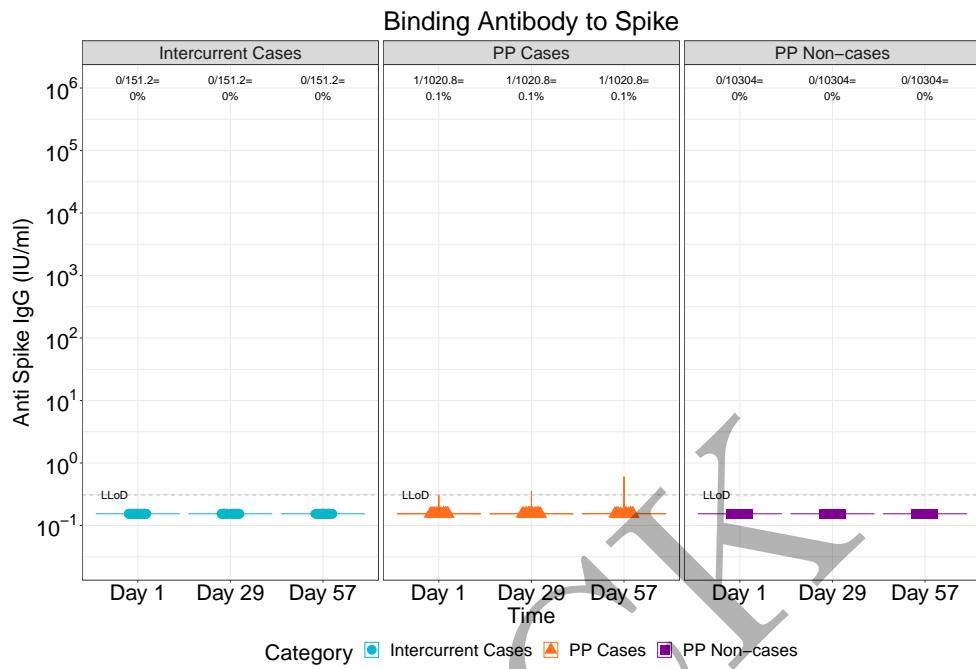


Figure 2.47: violinplots of Binding Antibody to Spike: baseline negative placebo arm (version 2)

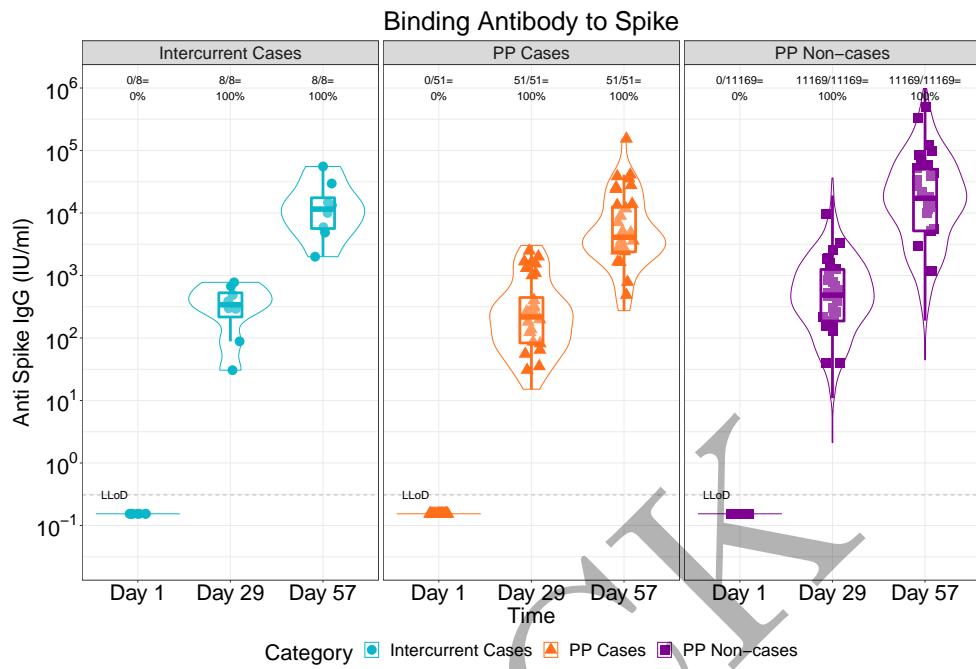


Figure 2.48: violinplots of Binding Antibody to Spike: baseline negative vaccine arm (version 2)

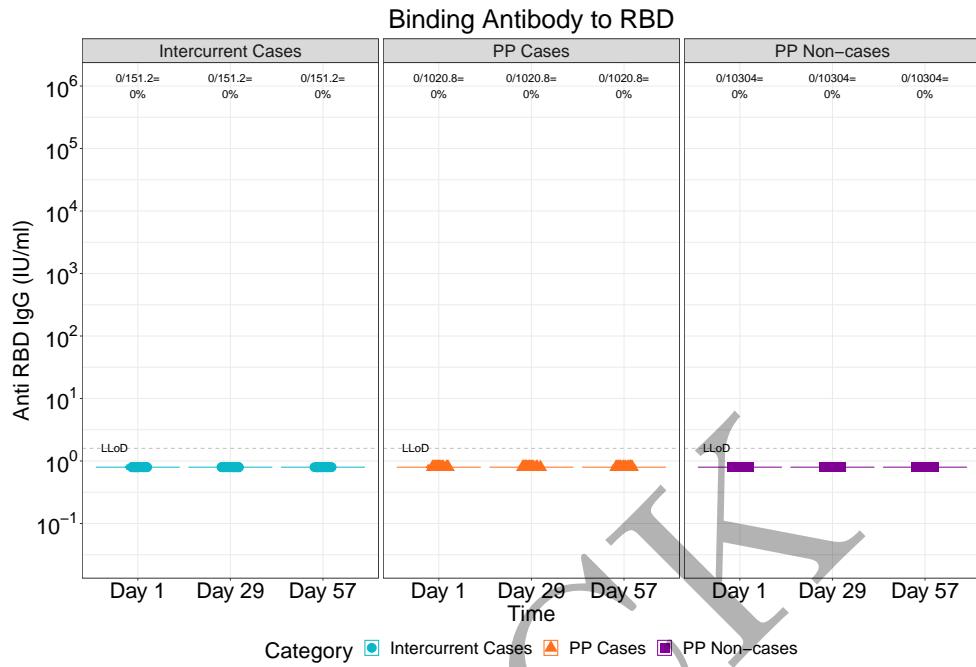


Figure 2.49: violinplots of Binding Antibody to RBD: baseline negative placebo arm (version 2)

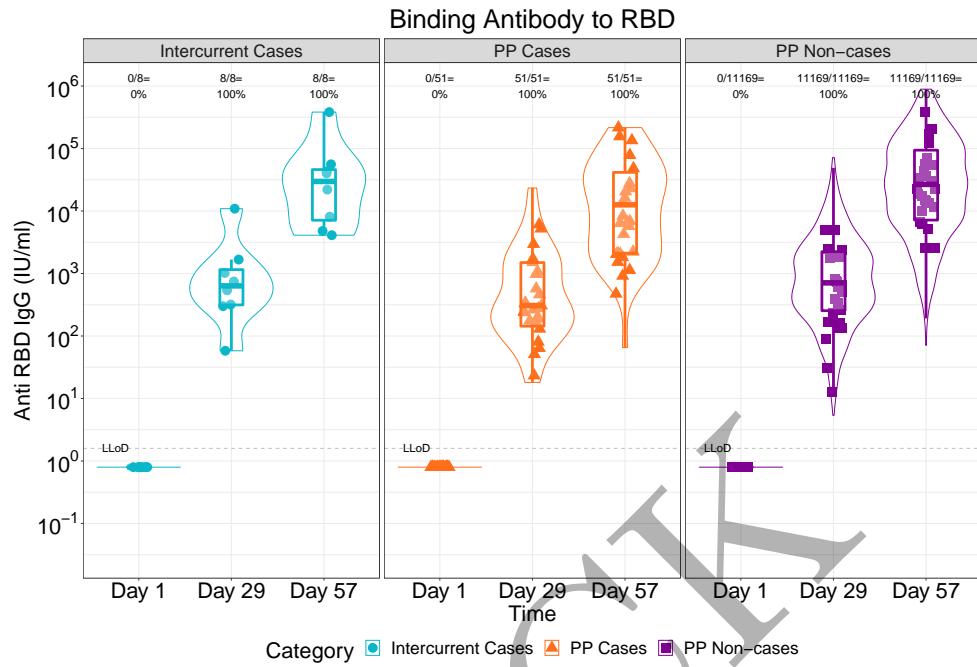


Figure 2.50: violinplots of Binding Antibody to RBD: baseline negative vaccine arm (version 2)

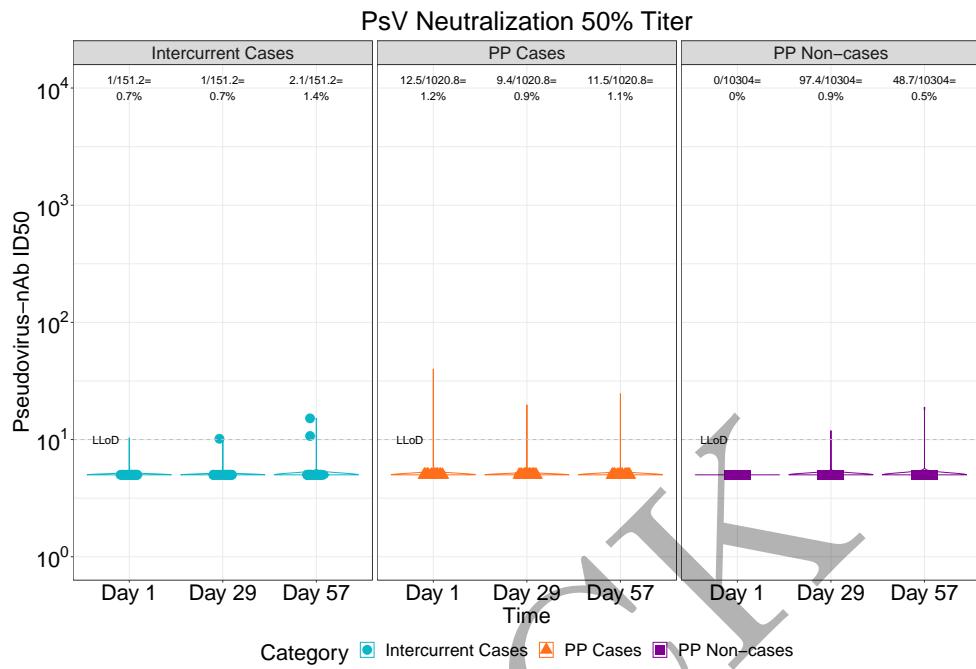


Figure 2.51: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm (version 2)

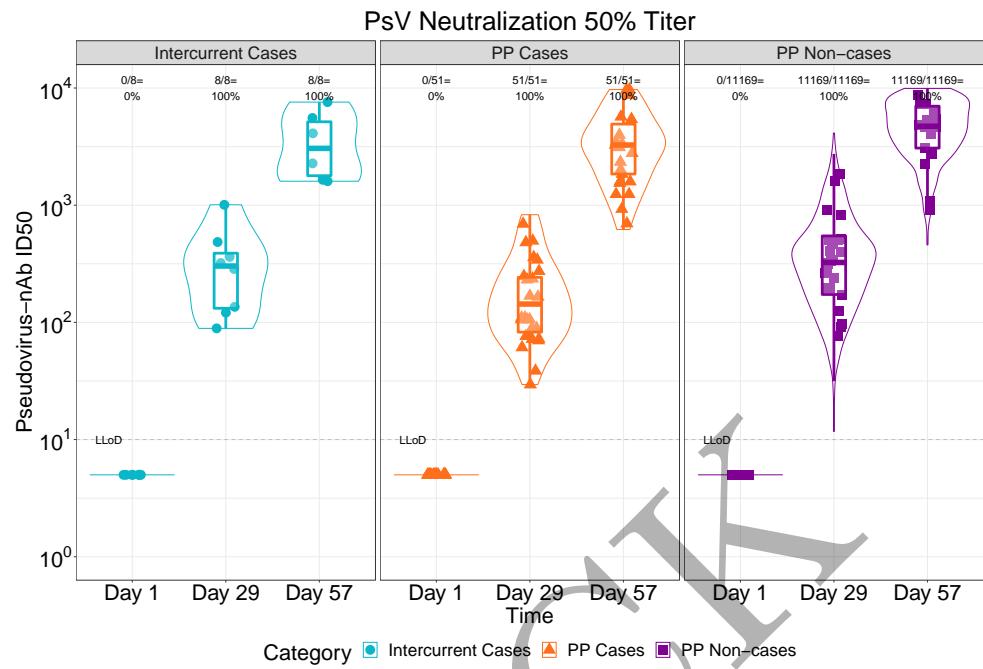


Figure 2.52: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm (version 2)

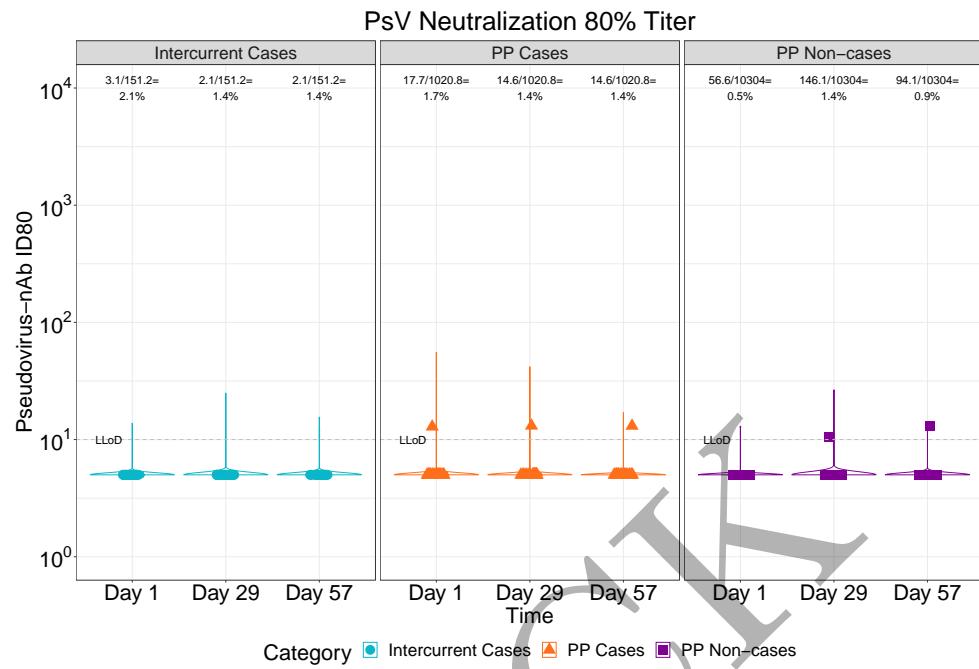


Figure 2.53: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm (version 2)

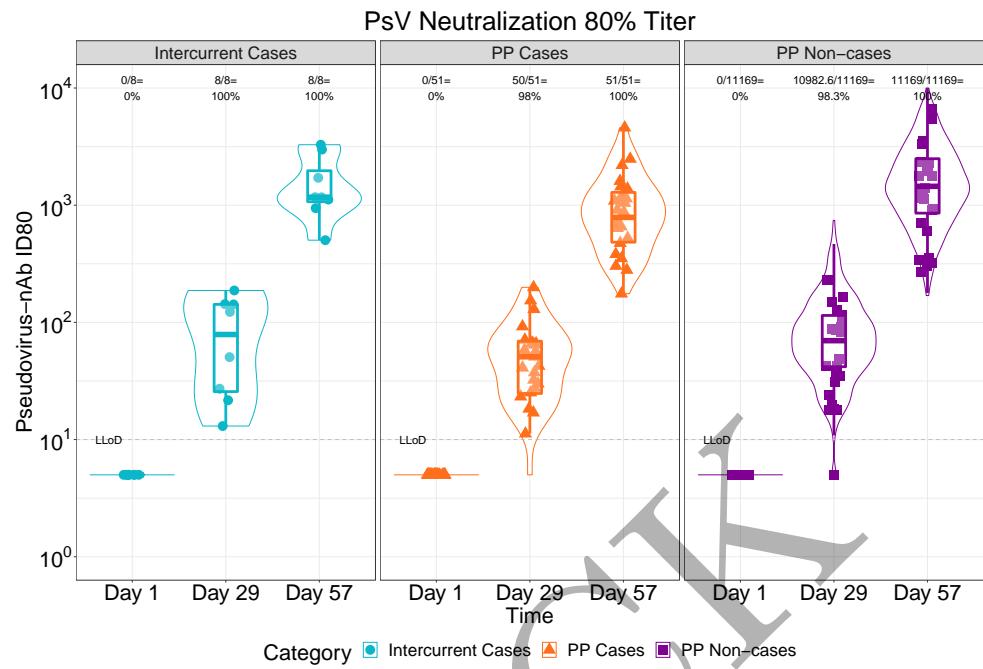


Figure 2.54: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm (version 2)

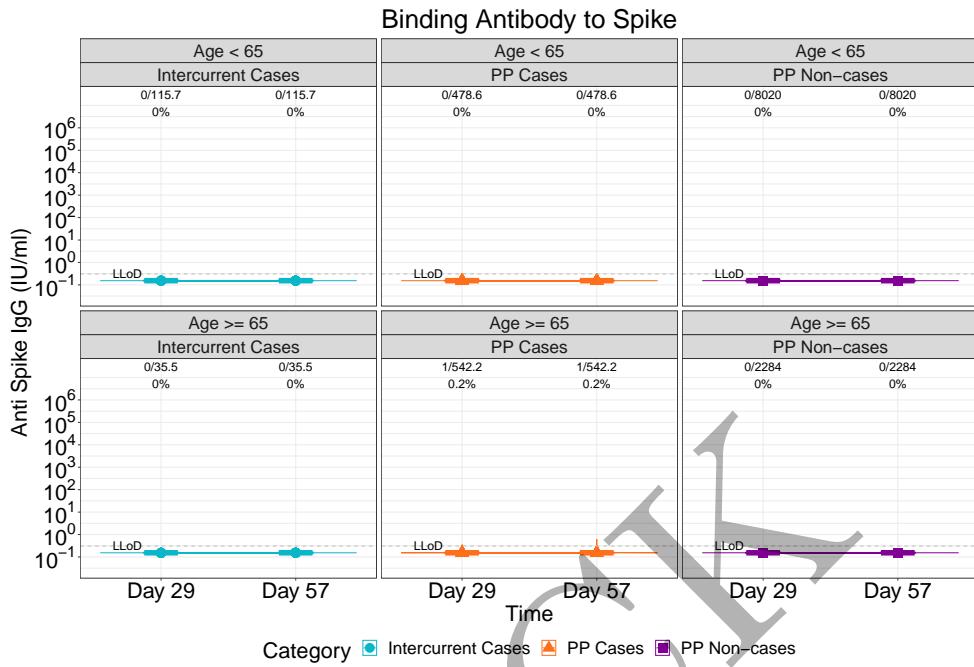


Figure 2.55: lineplots of Binding Antibody to Spike: baseline negative placebo arm by age (version 1)

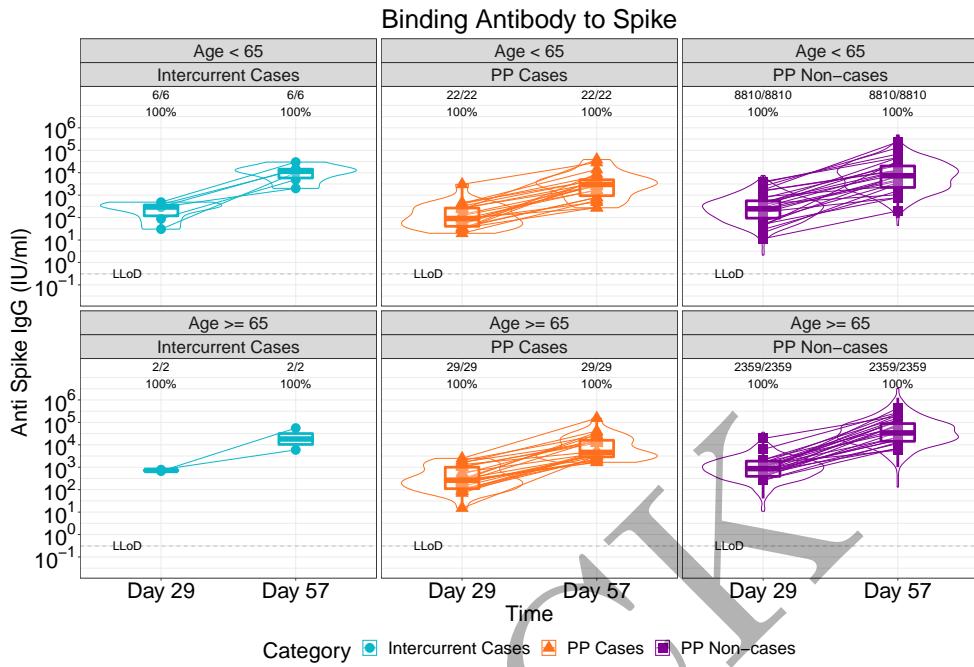


Figure 2.56: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by age (version 1)

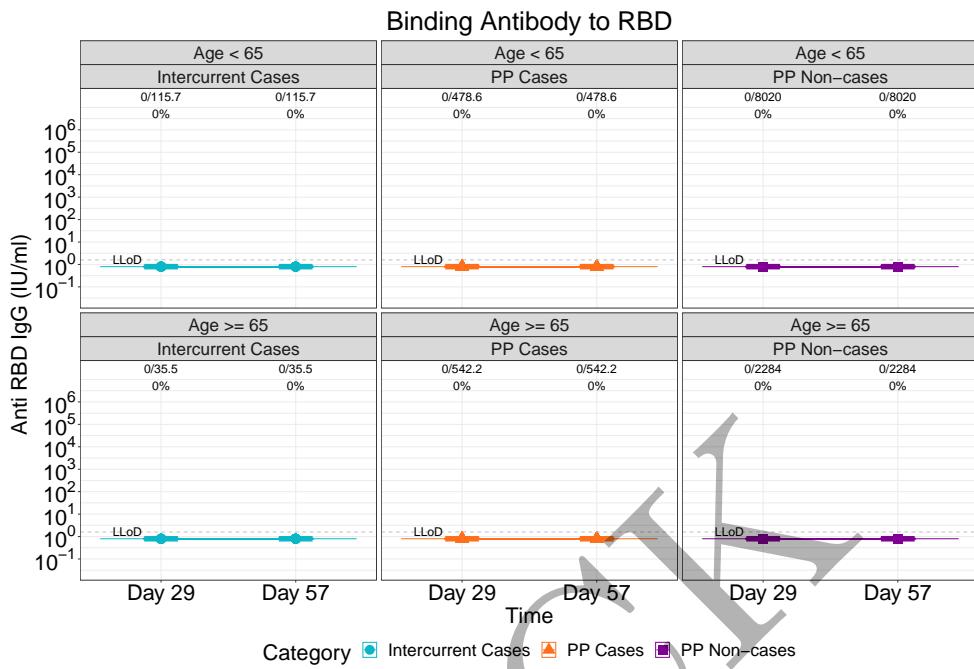


Figure 2.57: lineplots of Binding Antibody to RBD: baseline negative placebo arm by age (version 1)

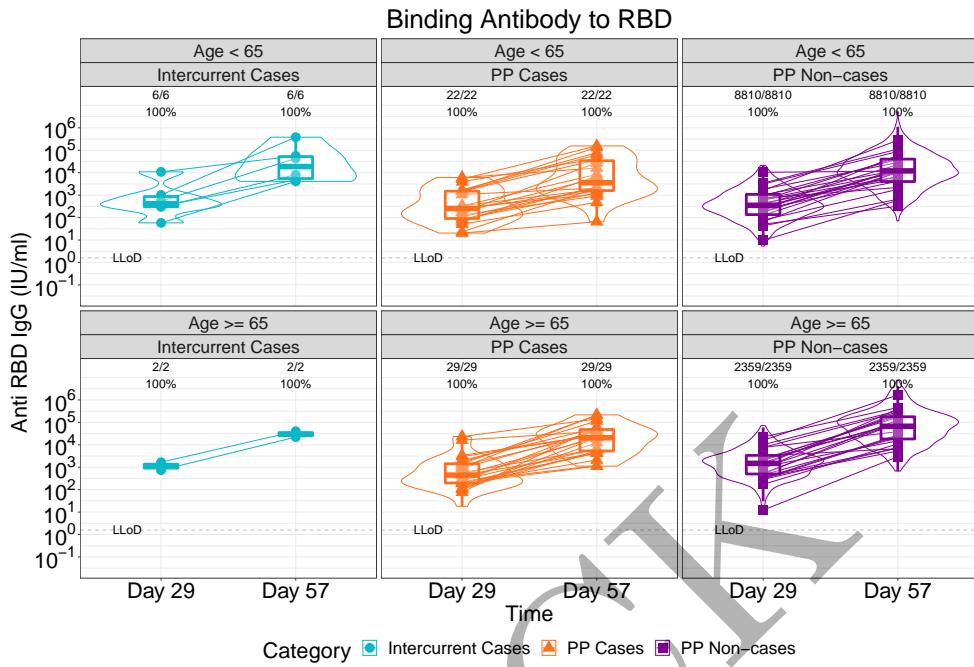


Figure 2.58: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by age (version 1)

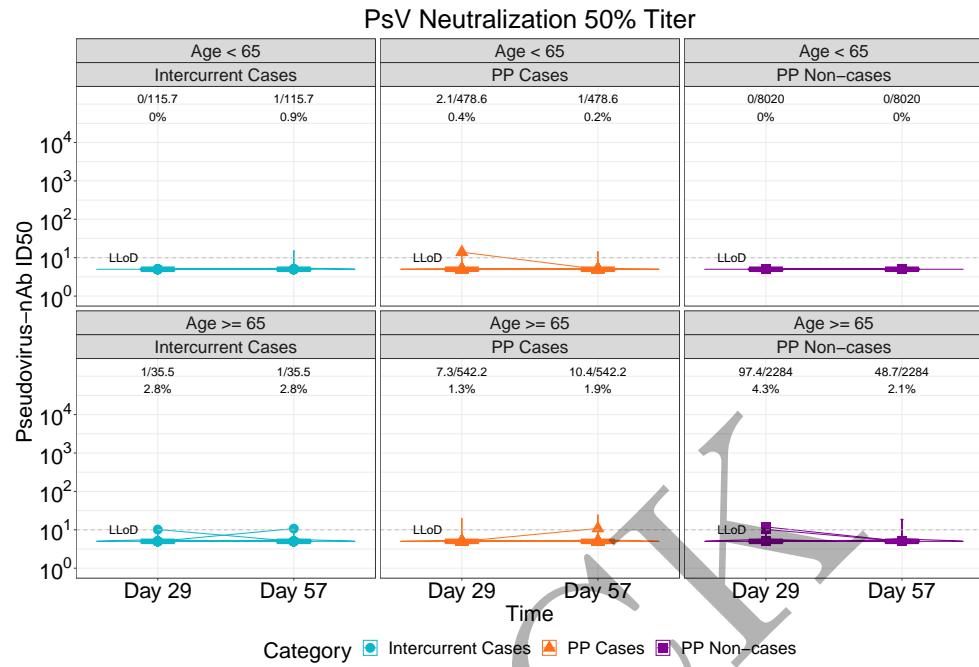


Figure 2.59: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age (version 1)

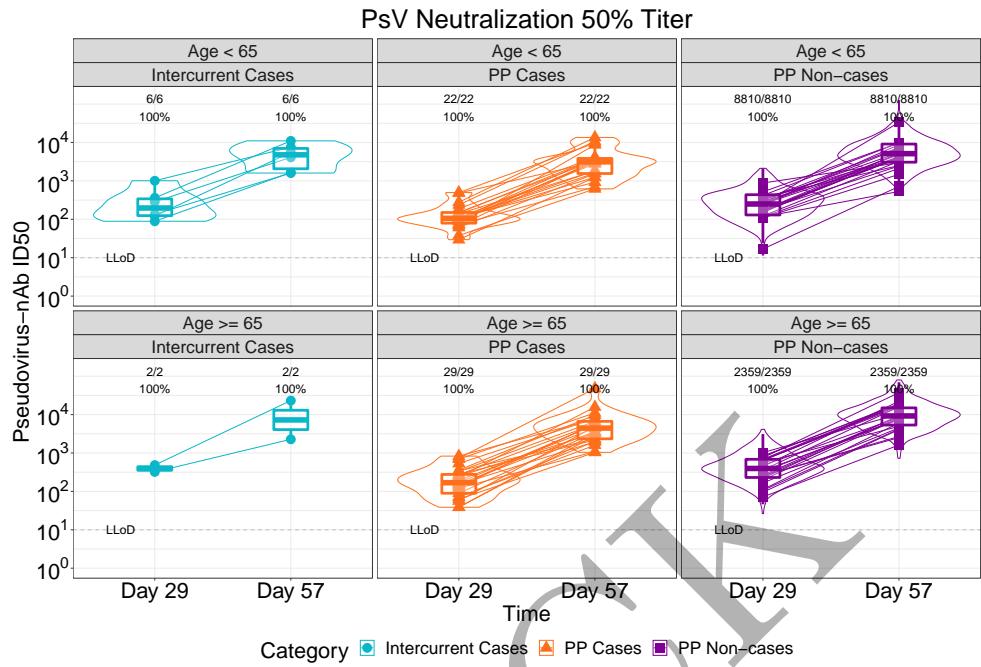


Figure 2.60: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age (version 1)

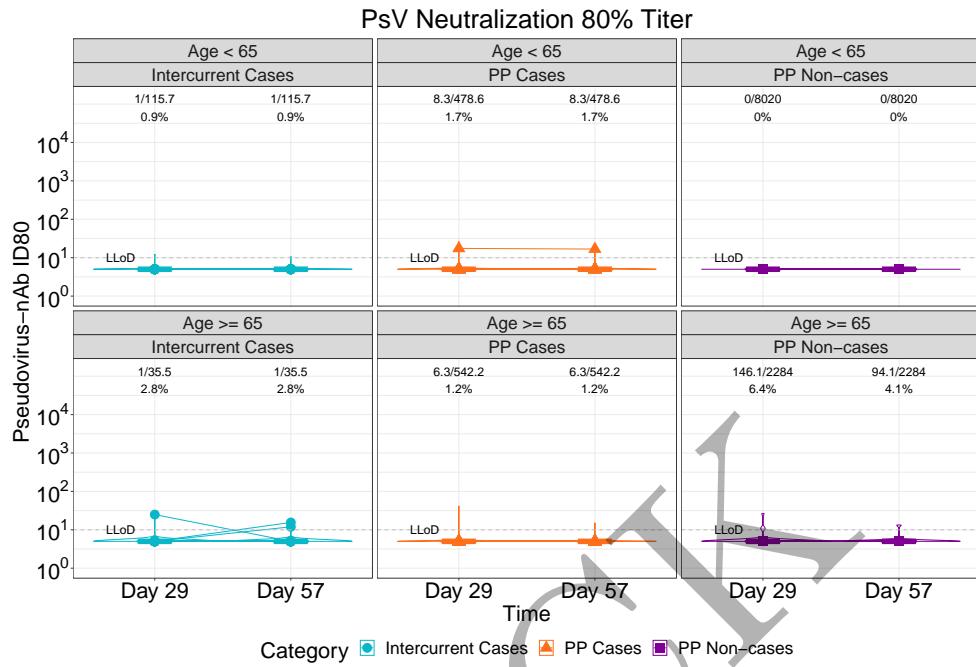


Figure 2.61: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age (version 1)

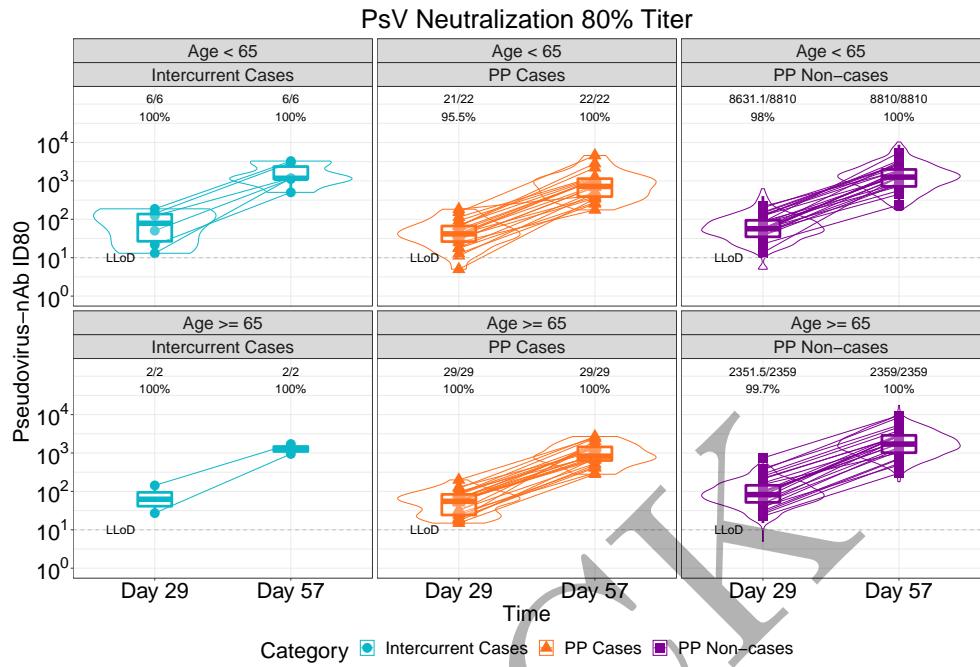


Figure 2.62: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age (version 1)

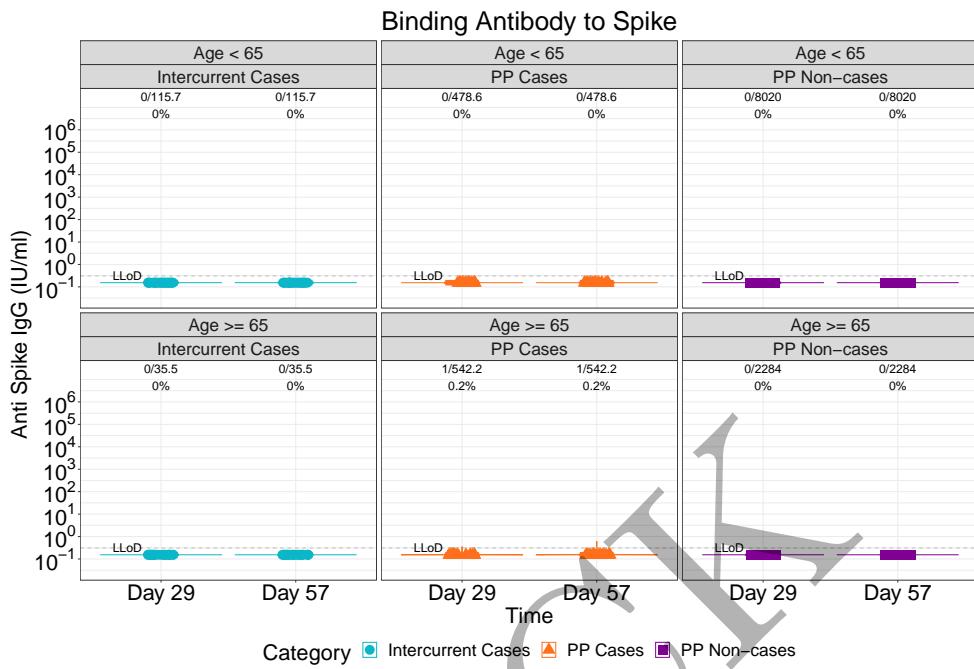


Figure 2.63: violinplots of Binding Antibody to Spike: baseline negative placebo arm by age (version 1)

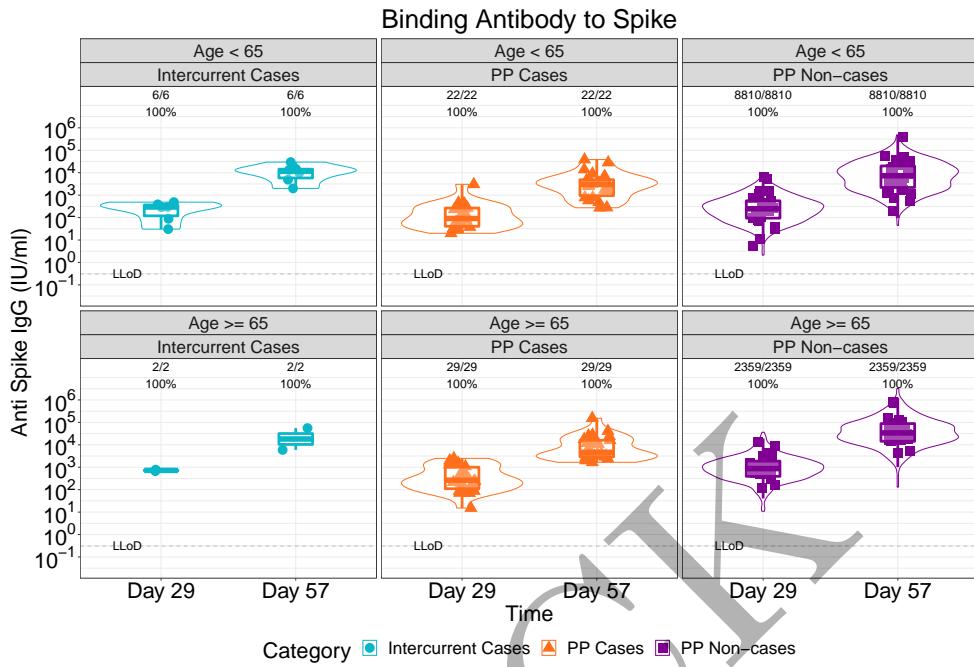


Figure 2.64: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by age (version 1)

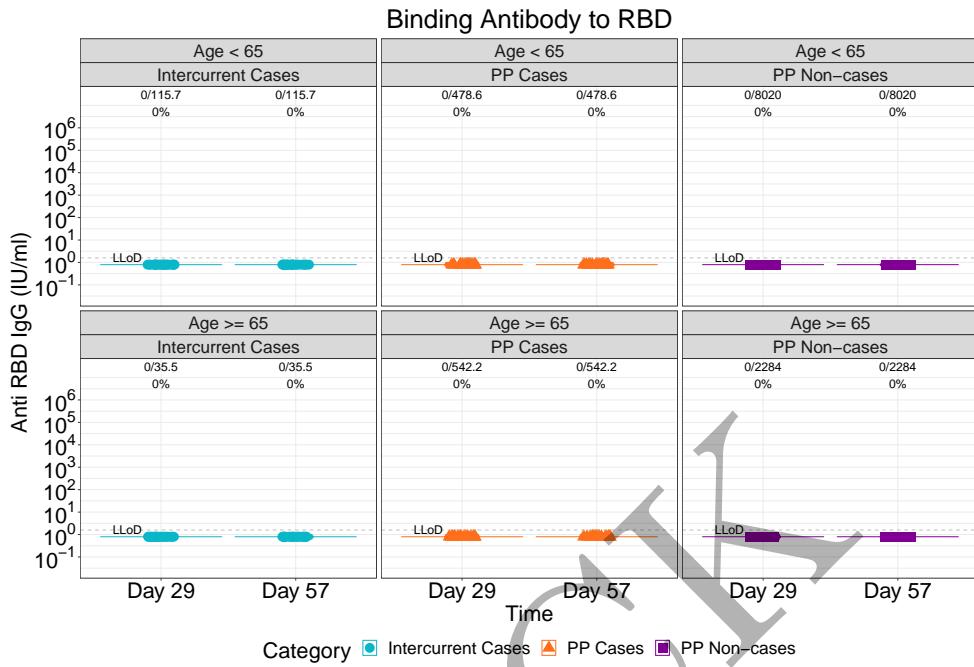


Figure 2.65: violinplots of Binding Antibody to RBD: baseline negative placebo arm by age (version 1)

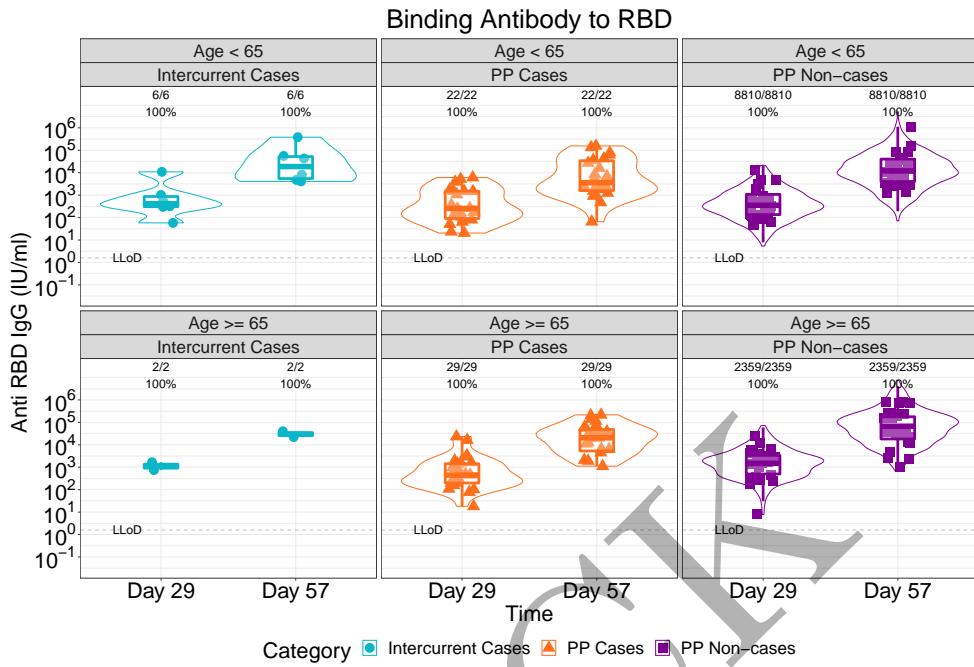


Figure 2.66: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by age (version 1)

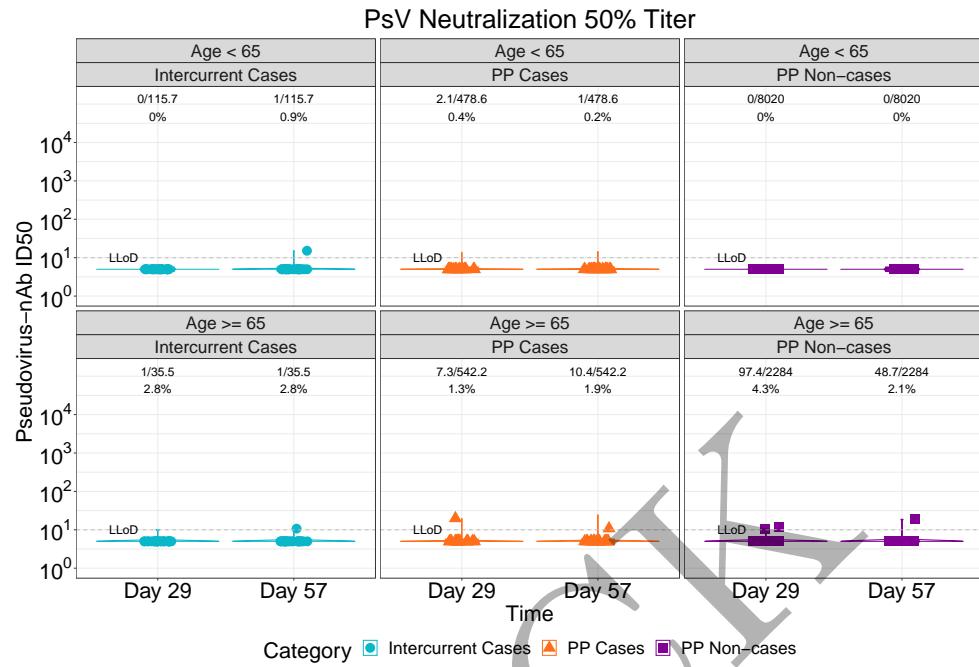


Figure 2.67: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age (version 1)

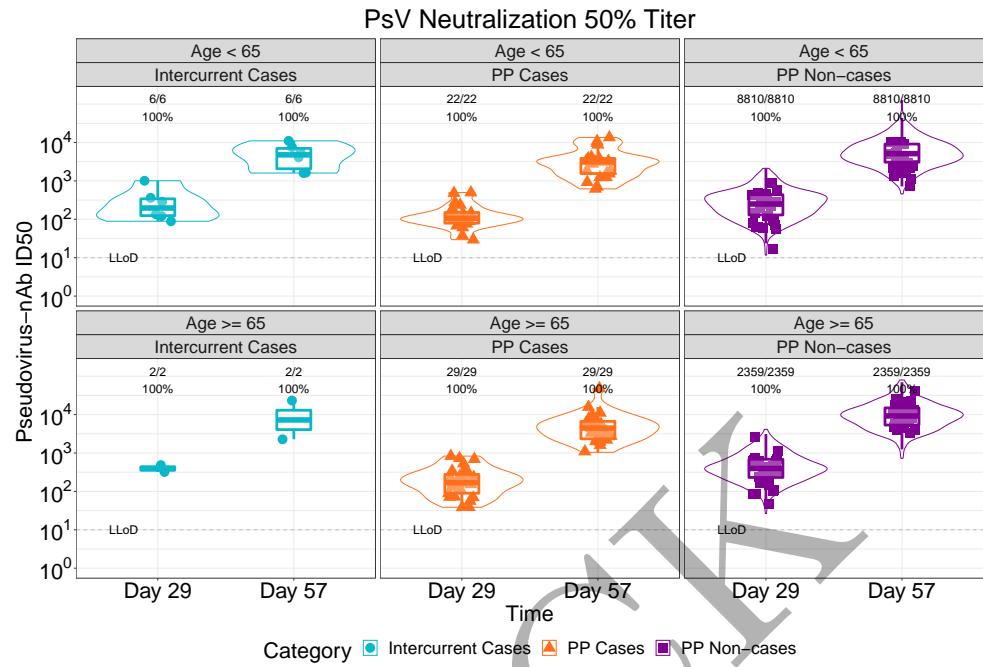


Figure 2.68: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age (version 1)

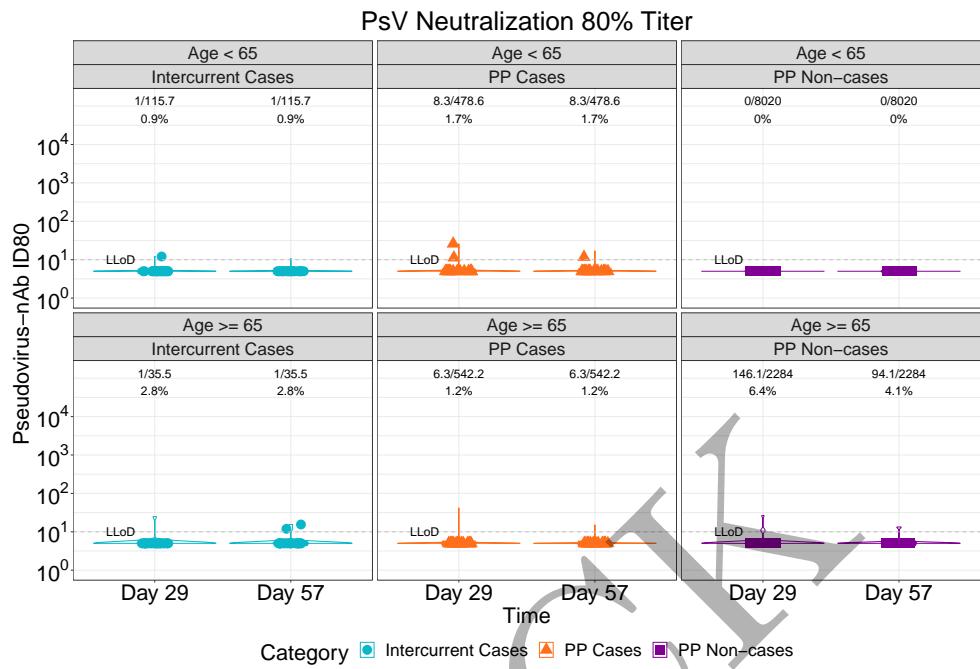


Figure 2.69: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age (version 1)

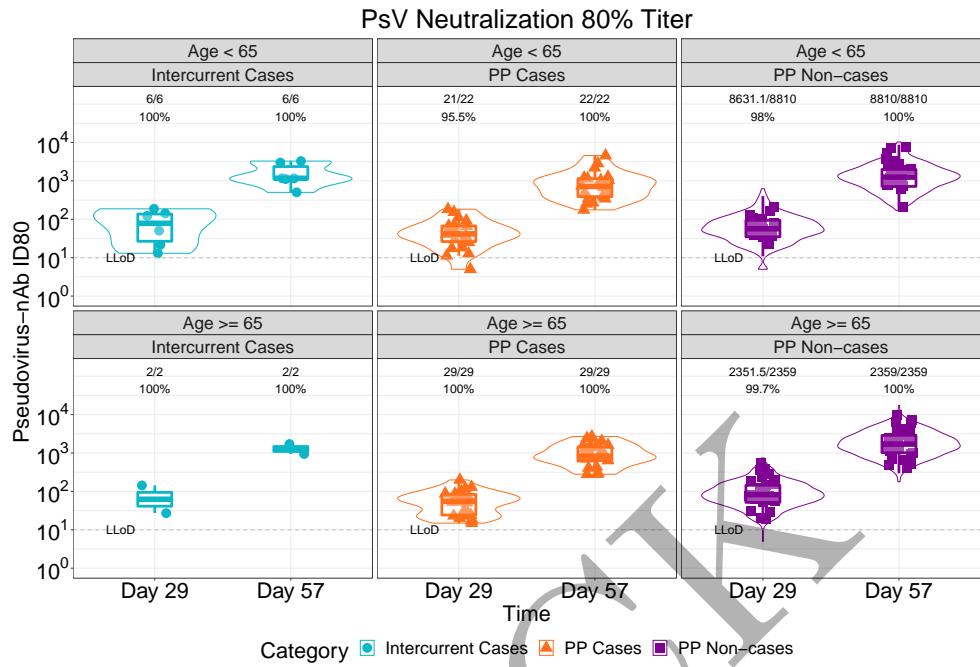


Figure 2.70: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age (version 1)

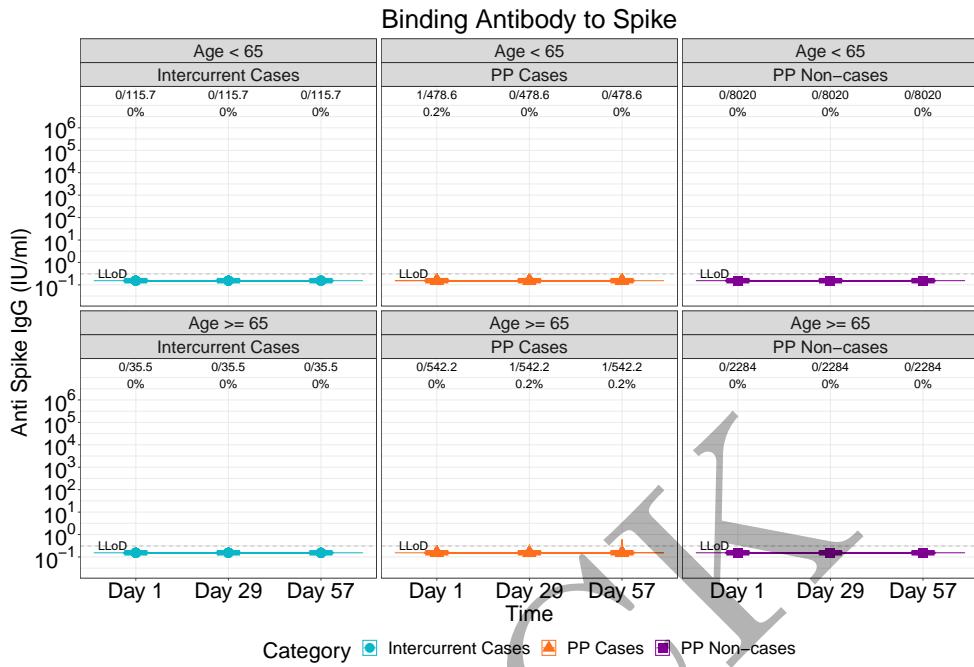


Figure 2.71: lineplots of Binding Antibody to Spike: baseline negative placebo arm by age (version 2)

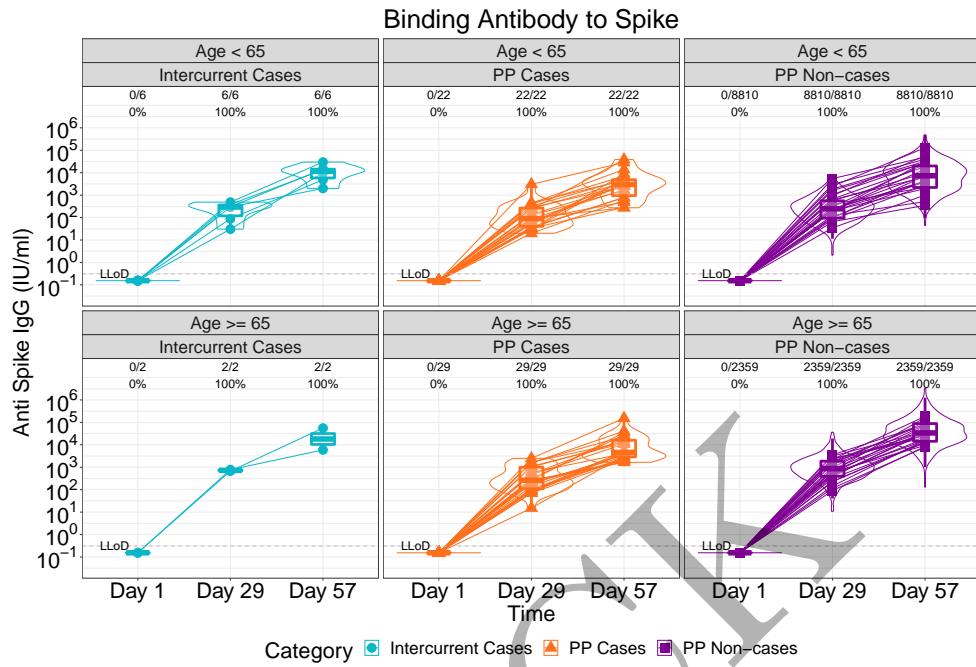


Figure 2.72: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by age (version 2)

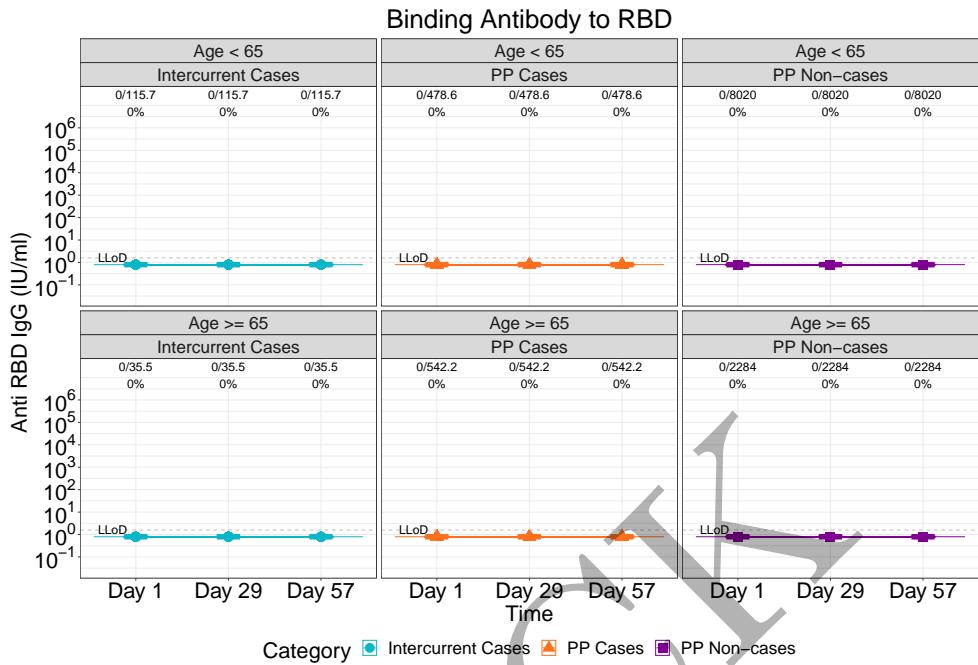


Figure 2.73: lineplots of Binding Antibody to RBD: baseline negative placebo arm by age (version 2)

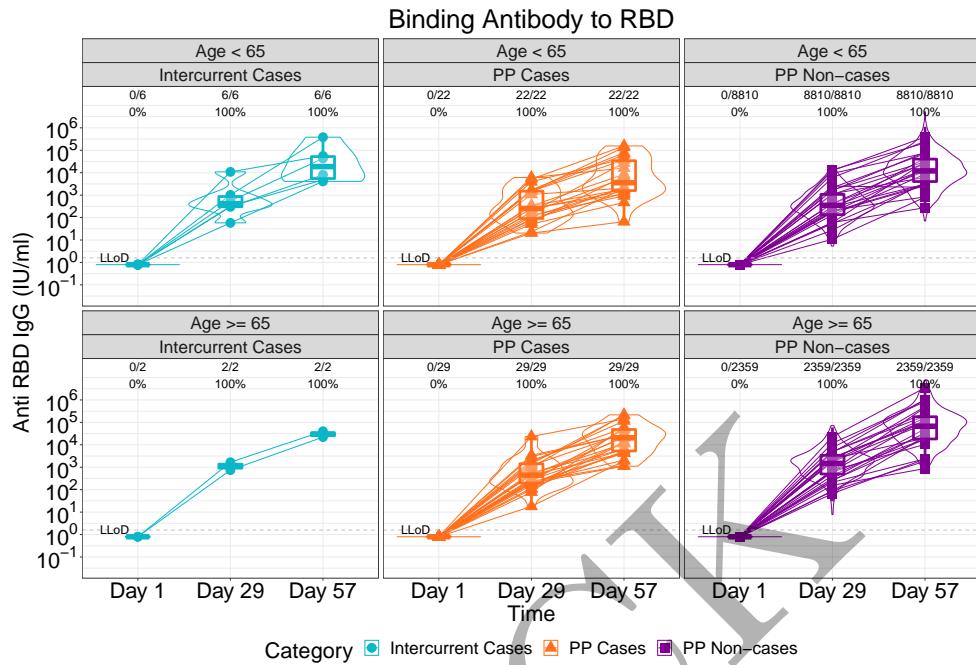


Figure 2.74: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by age (version 2)

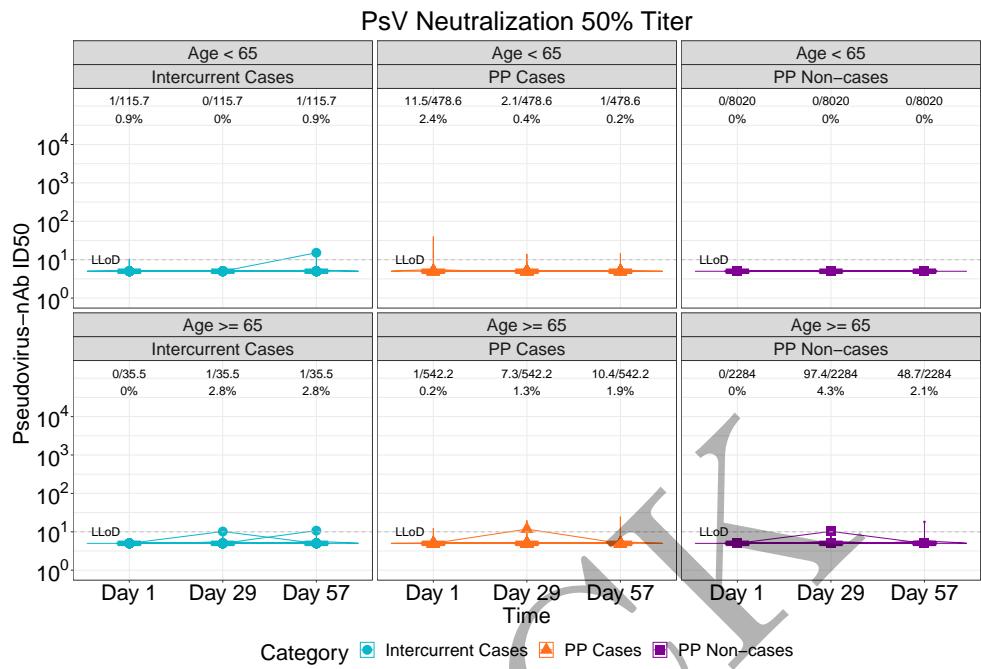


Figure 2.75: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age (version 2)

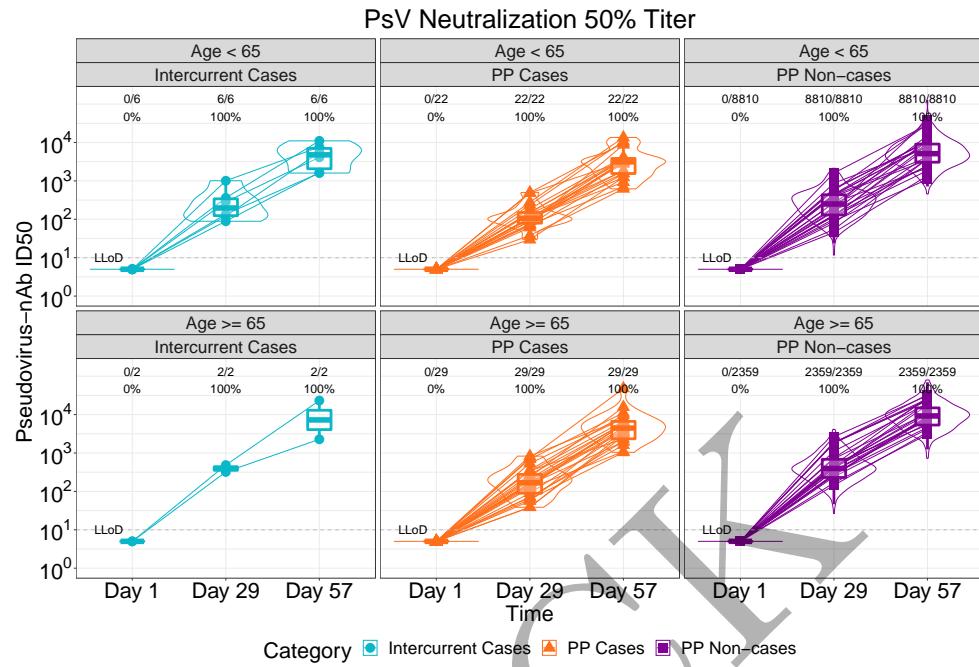


Figure 2.76: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age (version 2)

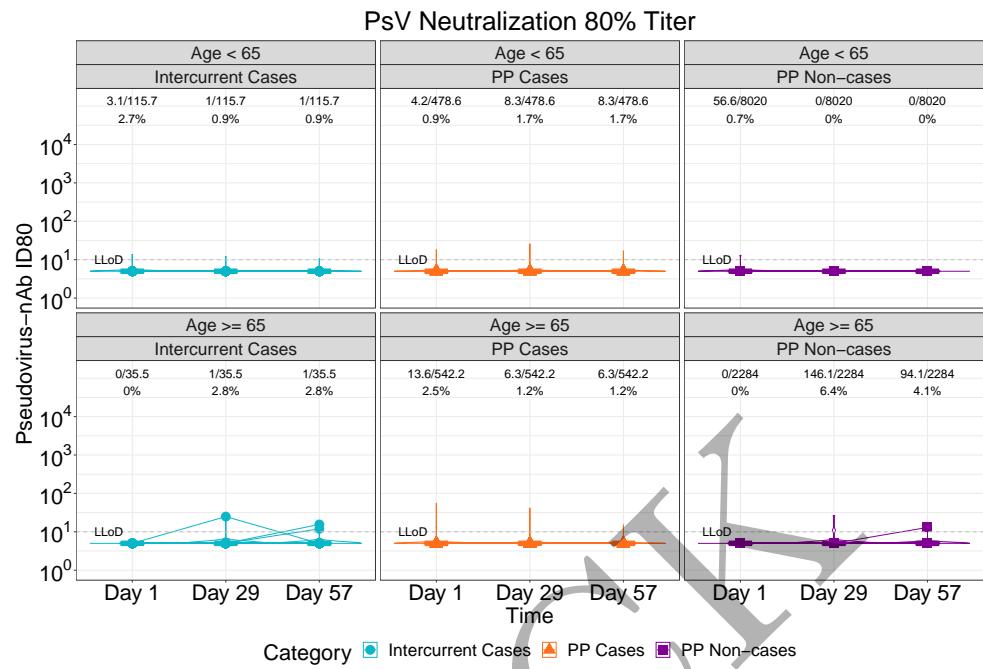


Figure 2.77: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age (version 2)

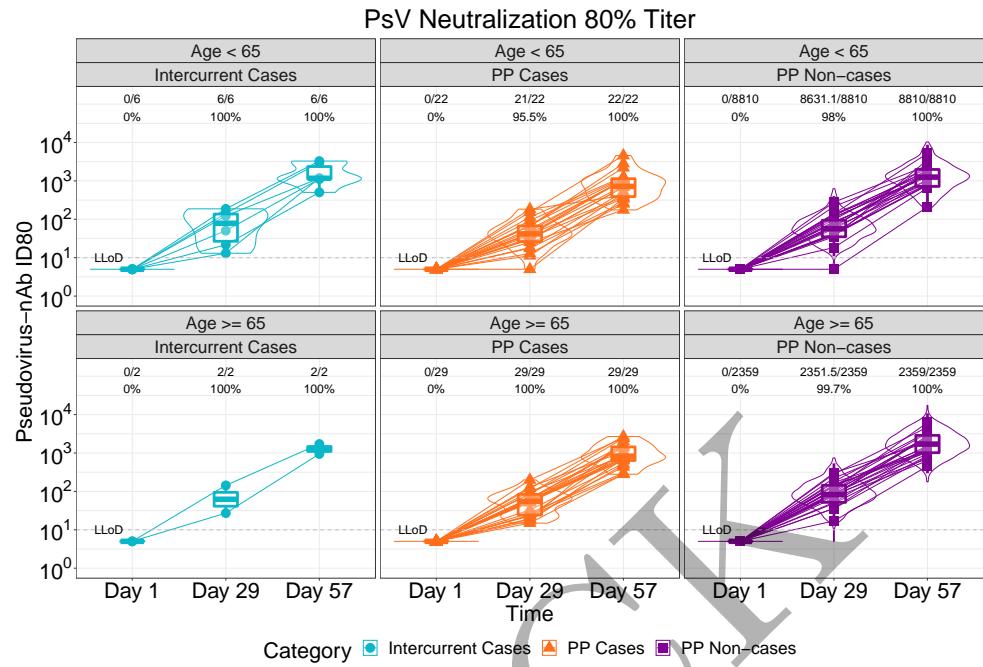


Figure 2.78: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age (version 2)

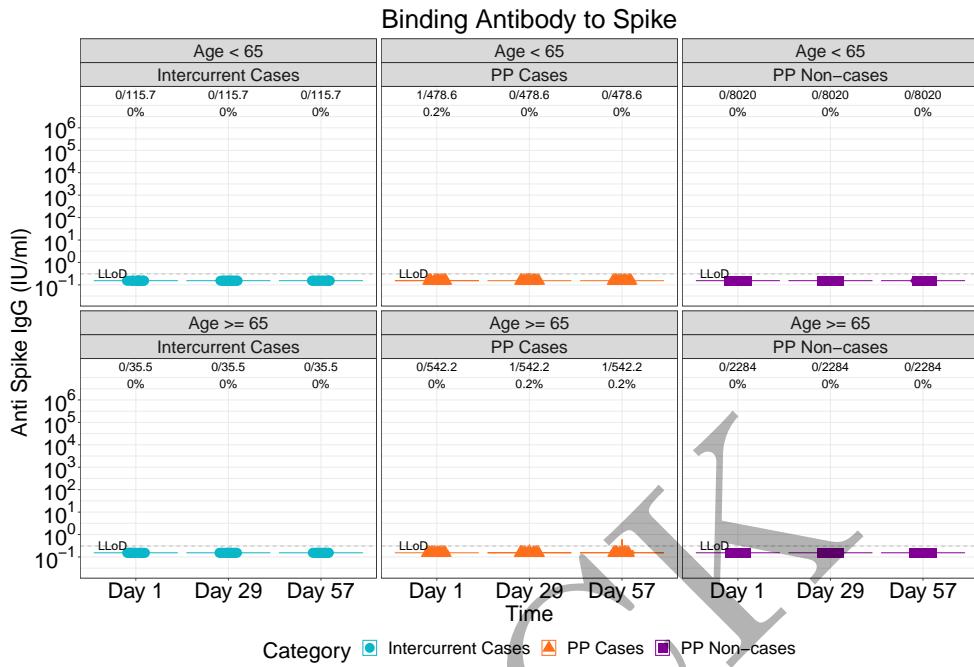


Figure 2.79: violinplots of Binding Antibody to Spike: baseline negative placebo arm by age (version 2)

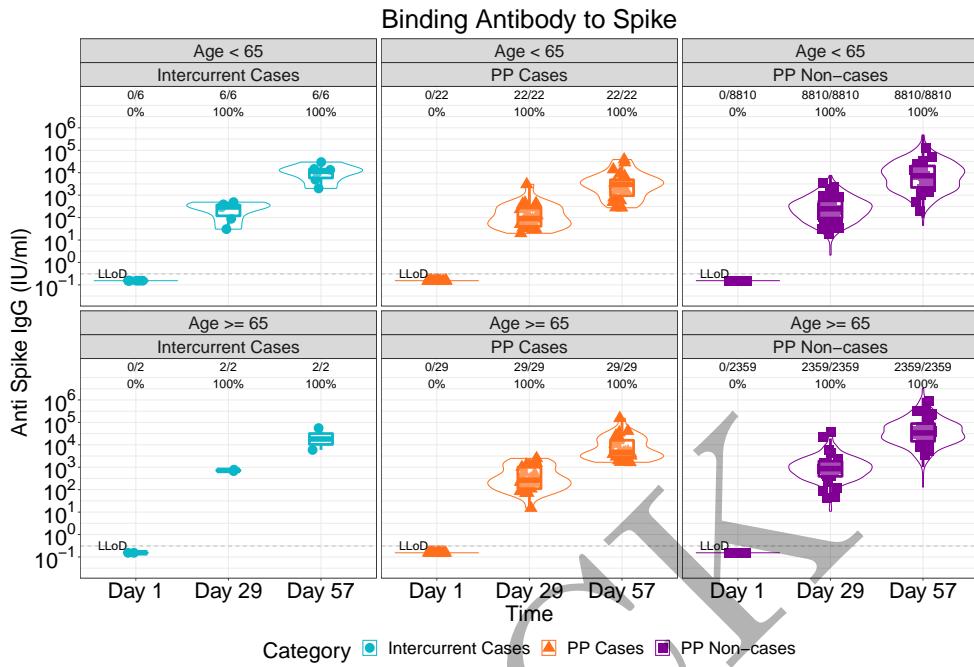


Figure 2.80: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by age (version 2)

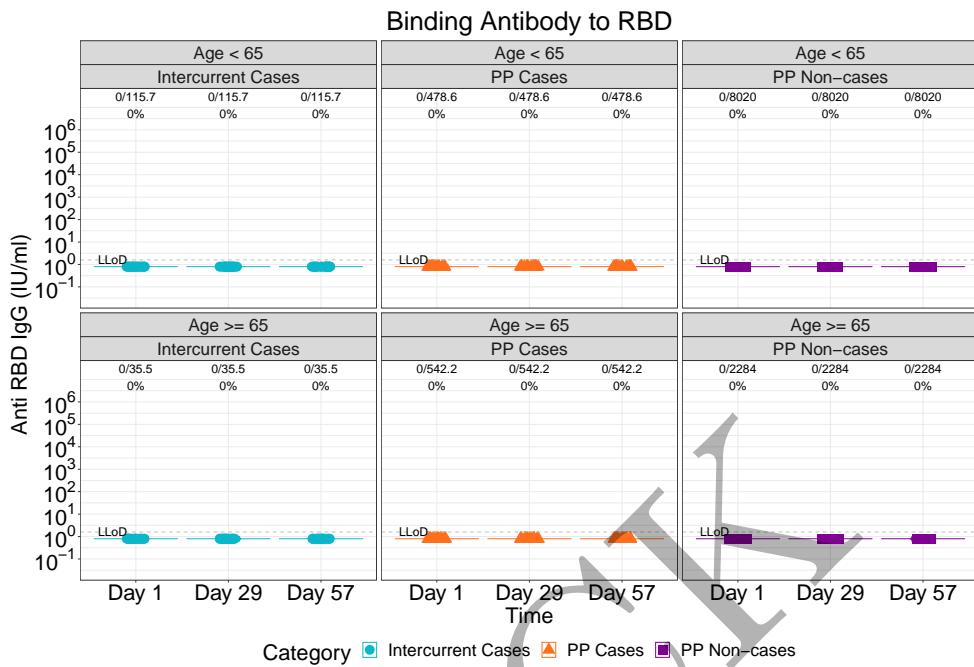


Figure 2.81: violinplots of Binding Antibody to RBD: baseline negative placebo arm by age (version 2)

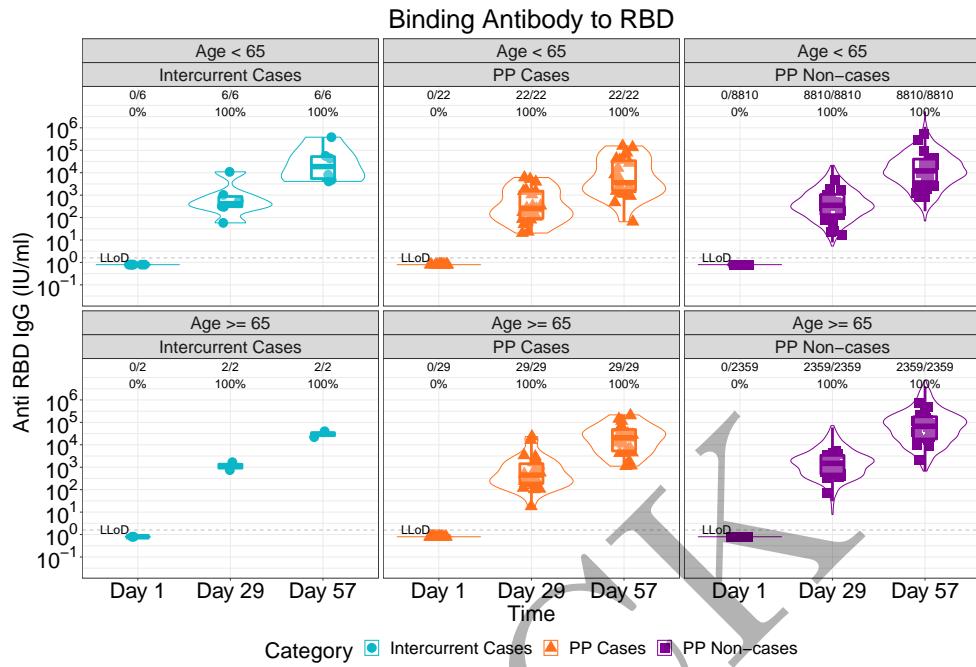


Figure 2.82: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by age (version 2)

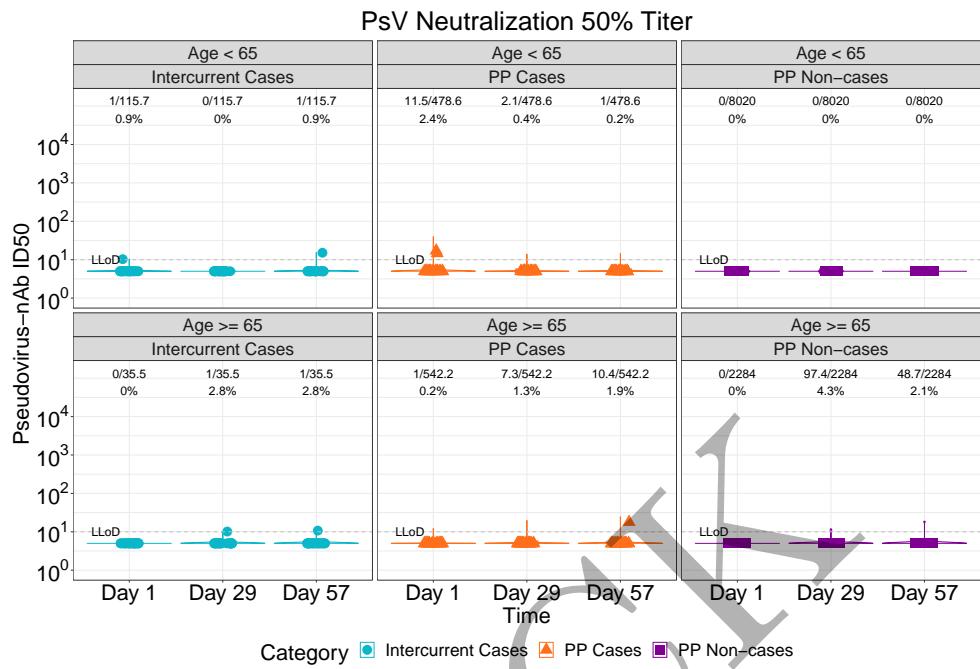


Figure 2.83: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age (version 2)

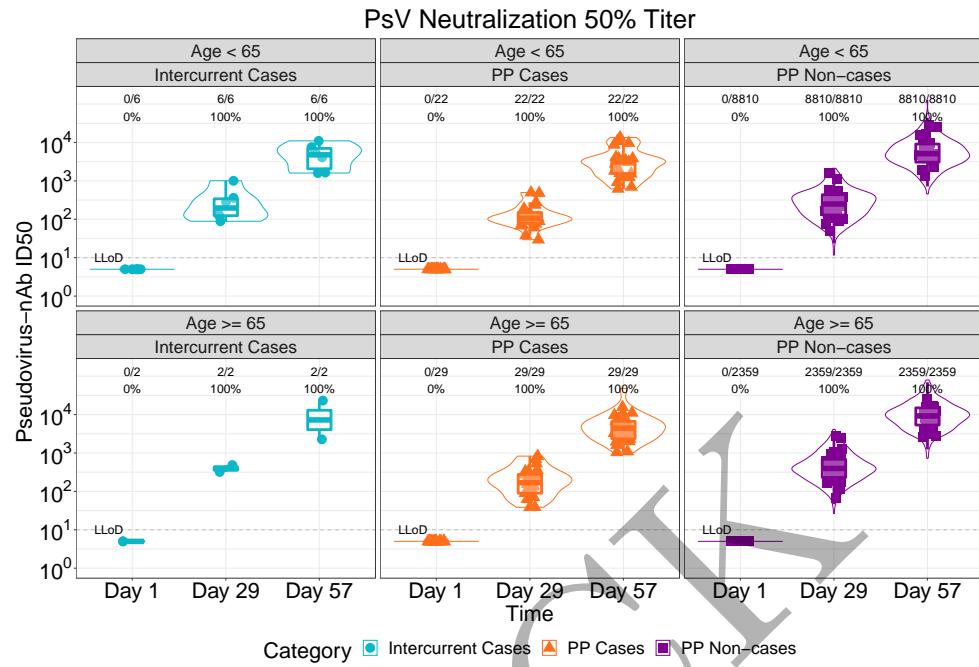


Figure 2.84: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age (version 2)

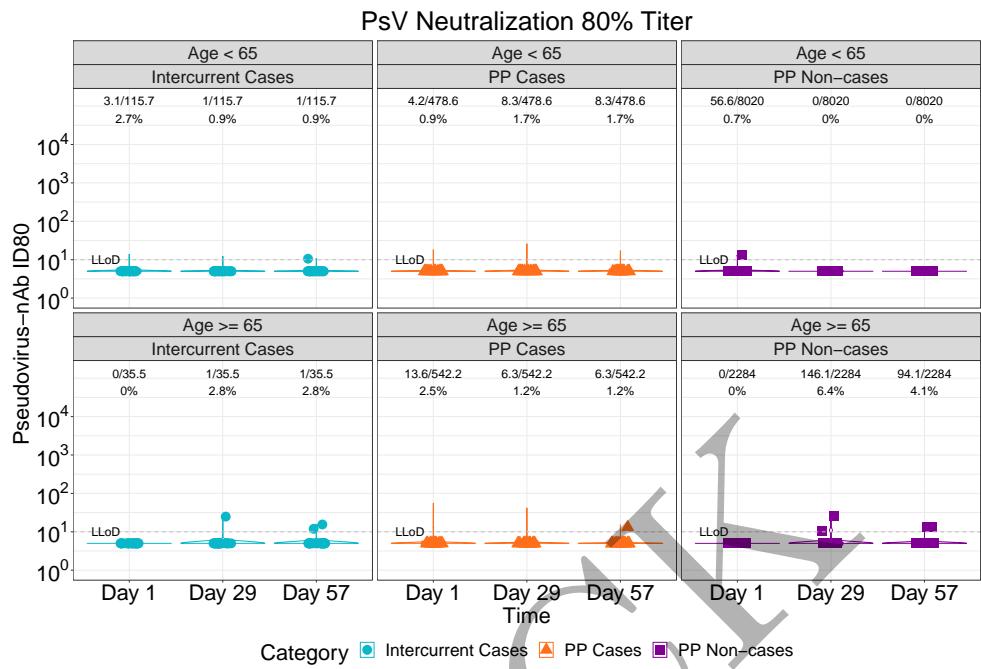


Figure 2.85: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age (version 2)

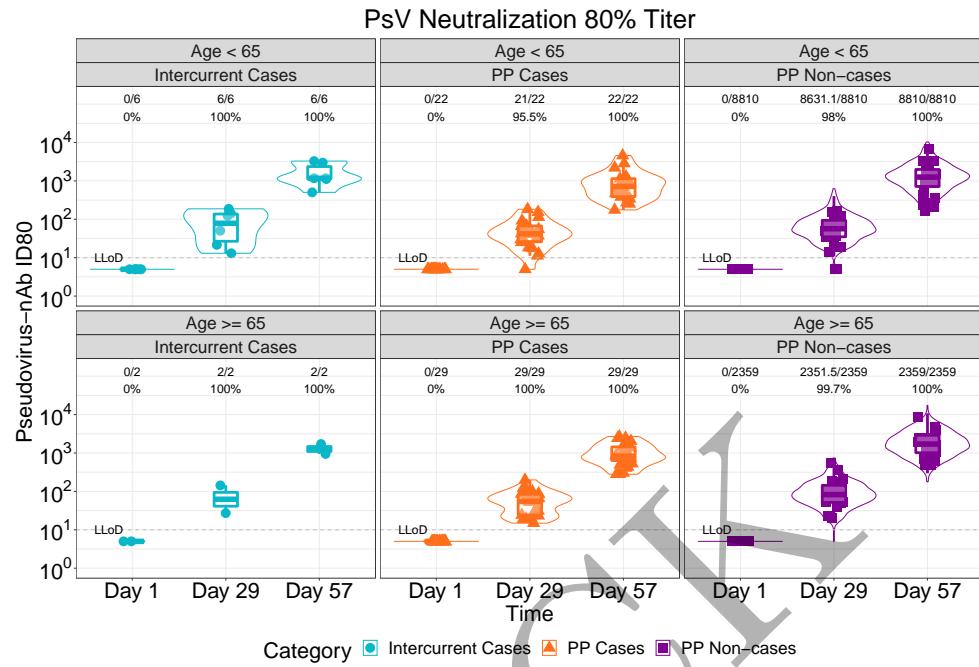


Figure 2.86: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age (version 2)

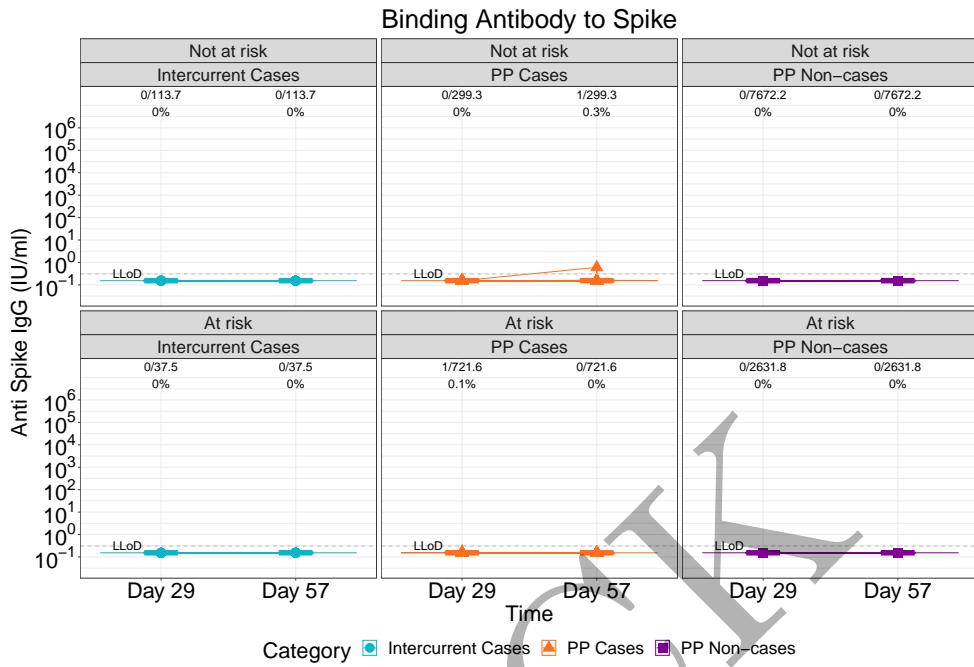


Figure 2.87: lineplots of Binding Antibody to Spike: baseline negative placebo arm by risk condition (version 1)

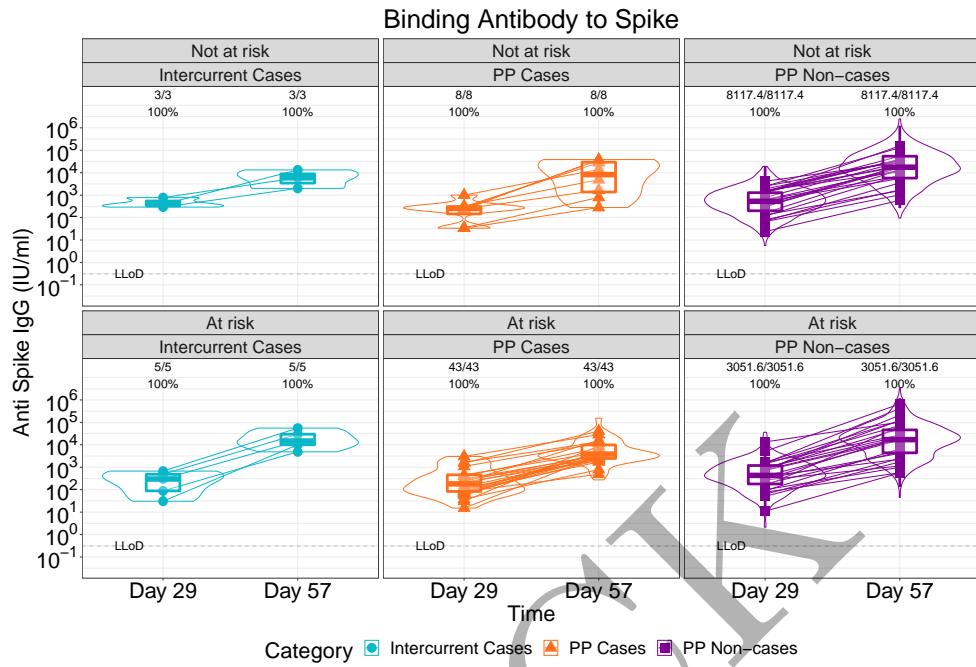


Figure 2.88: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by risk condition (version 1)

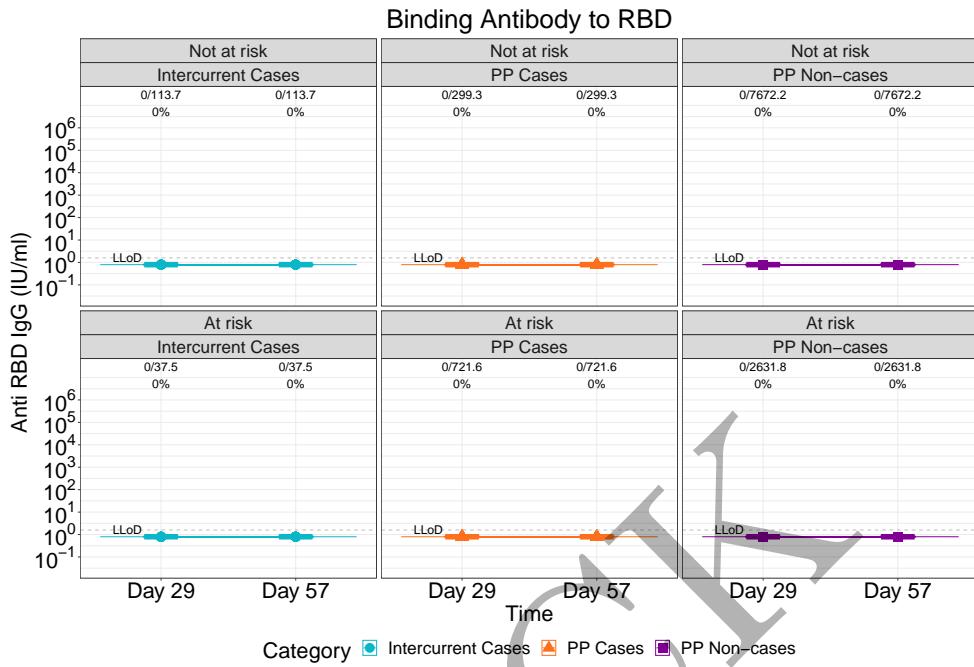


Figure 2.89: lineplots of Binding Antibody to RBD: baseline negative placebo arm by risk condition (version 1)

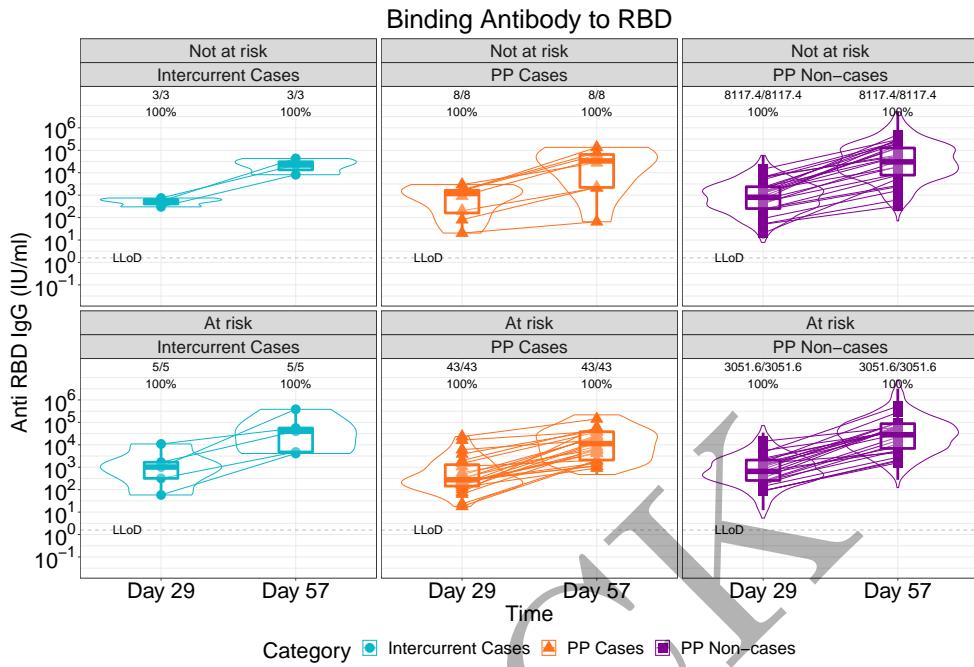


Figure 2.90: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by risk condition (version 1)

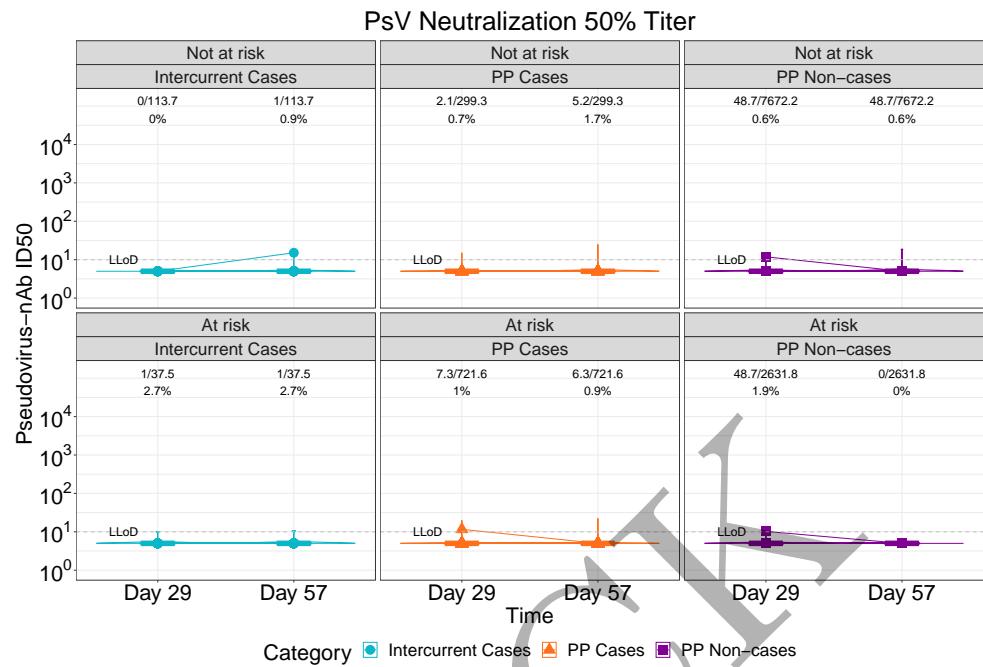


Figure 2.91: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by risk condition (version 1)

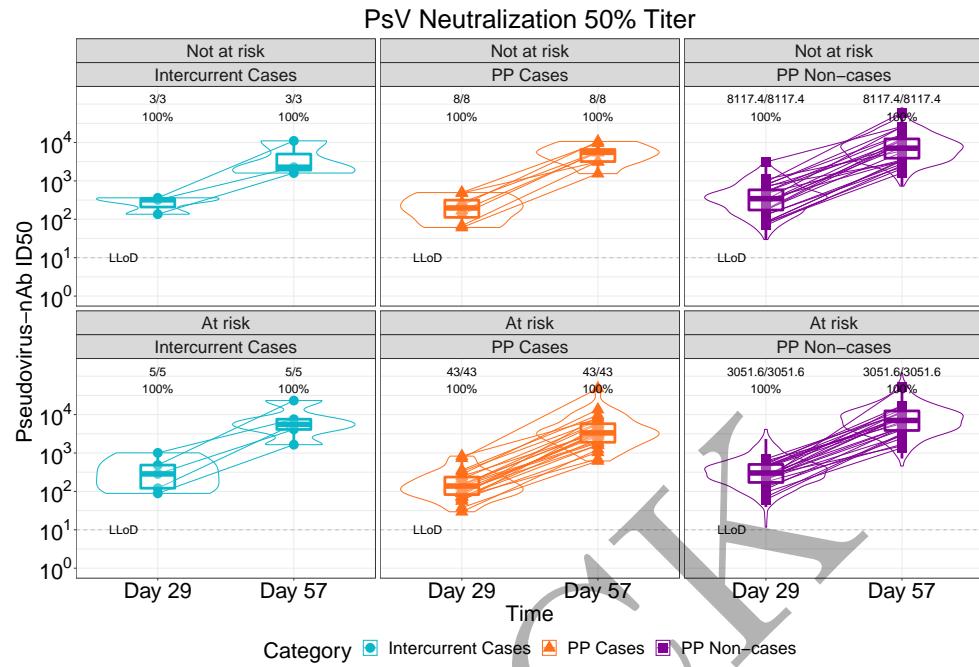


Figure 2.92: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by risk condition (version 1)

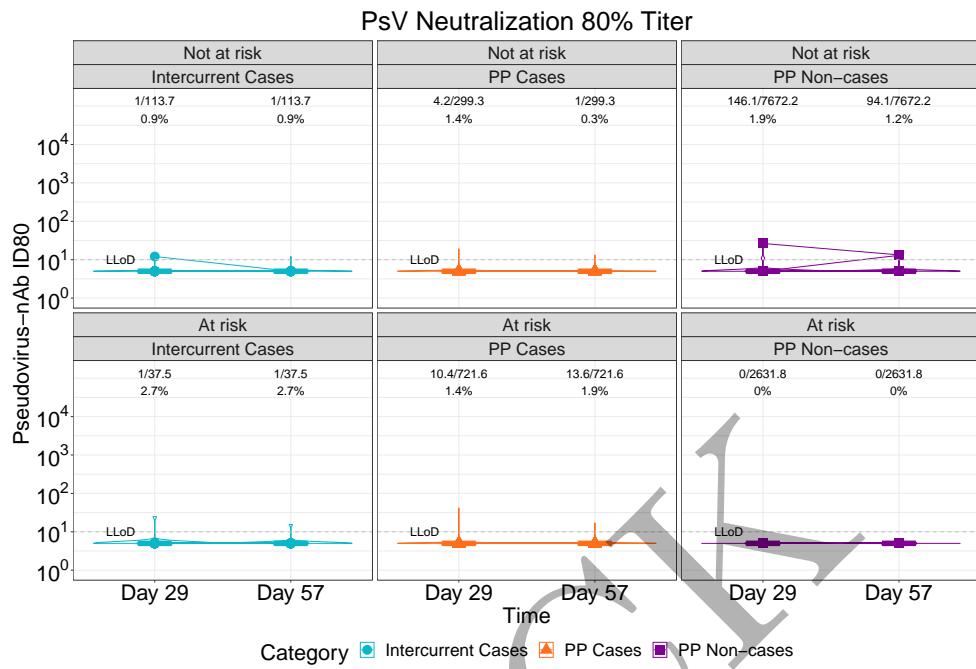


Figure 2.93: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by risk condition (version 1)

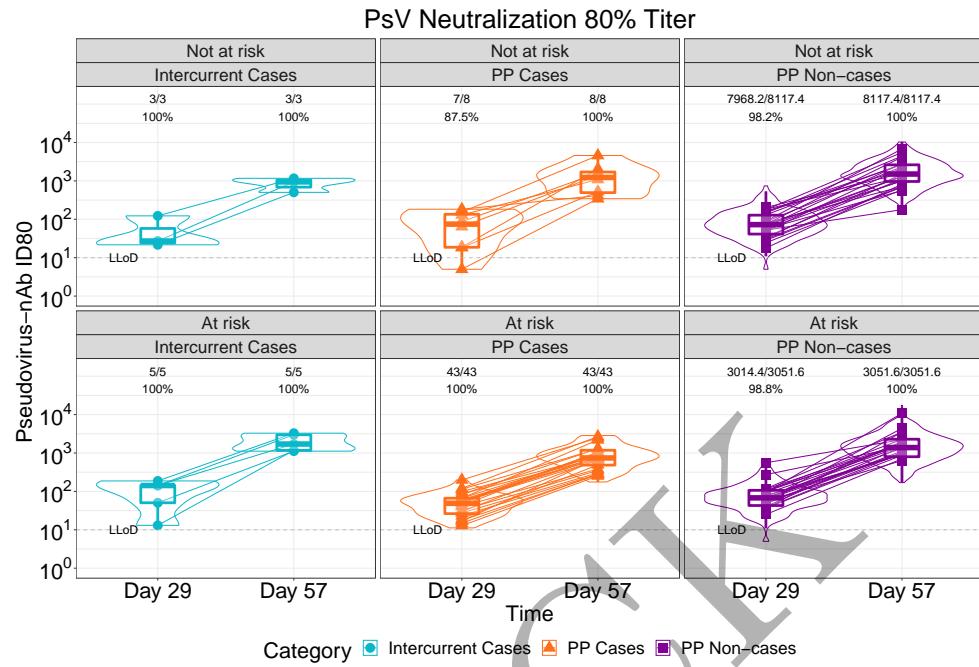


Figure 2.94: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by risk condition (version 1)

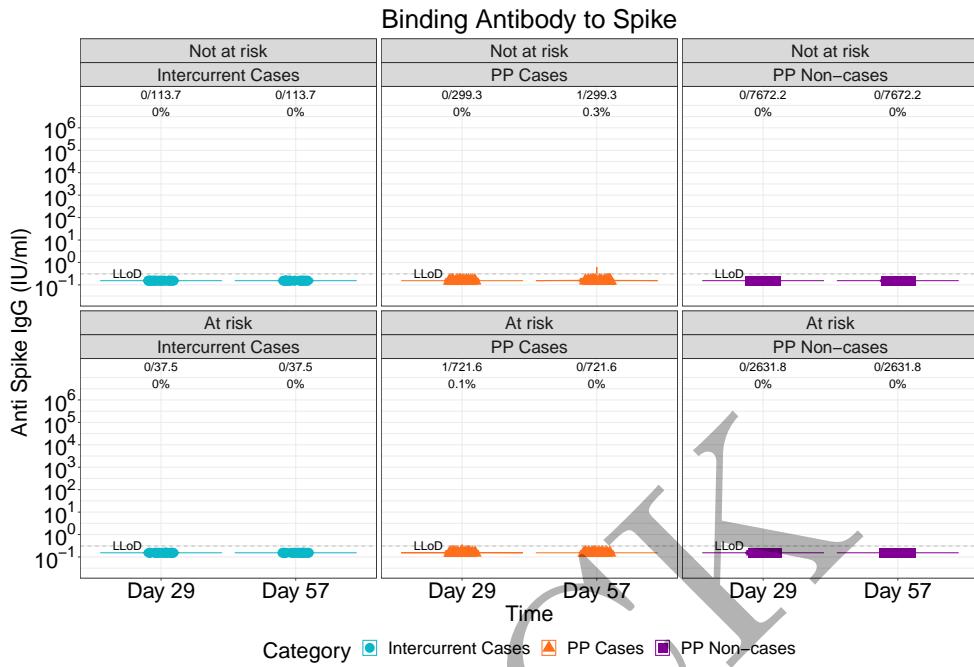


Figure 2.95: violinplots of Binding Antibody to Spike: baseline negative placebo arm by risk condition (version 1)

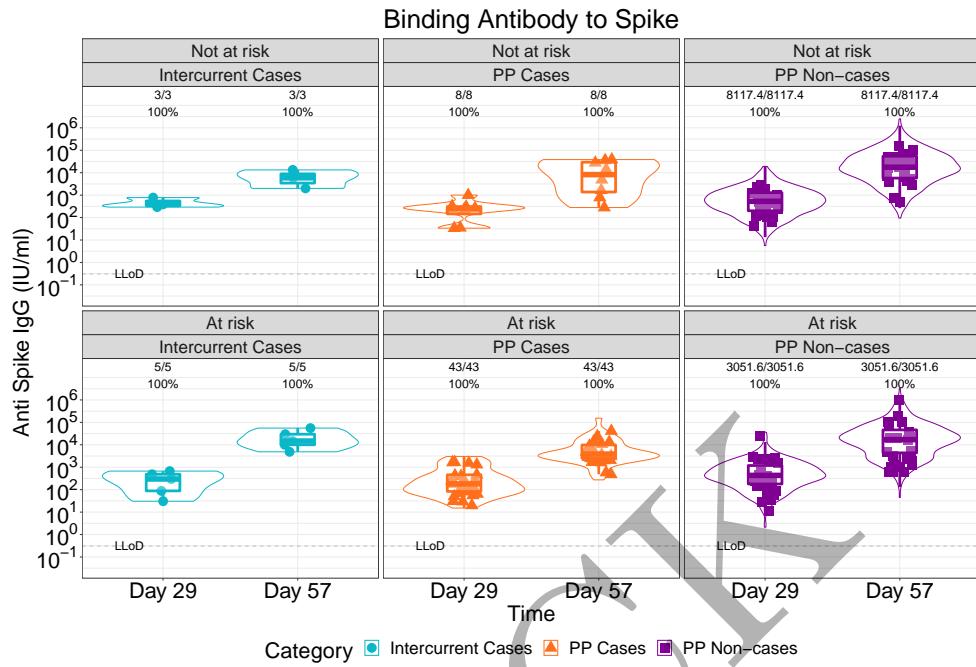


Figure 2.96: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by risk condition (version 1)

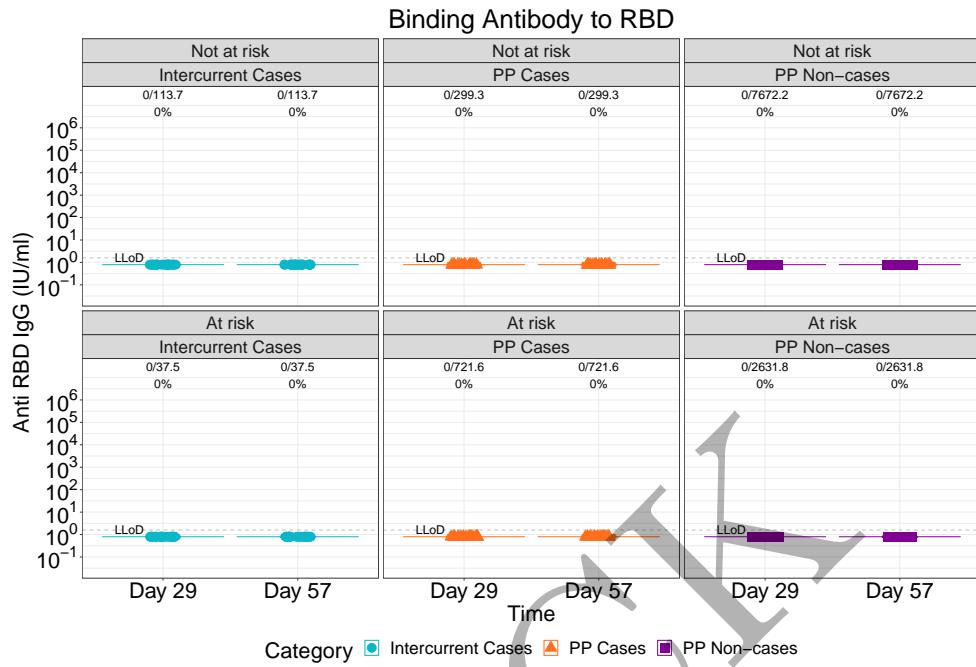


Figure 2.97: violinplots of Binding Antibody to RBD: baseline negative placebo arm by risk condition (version 1)

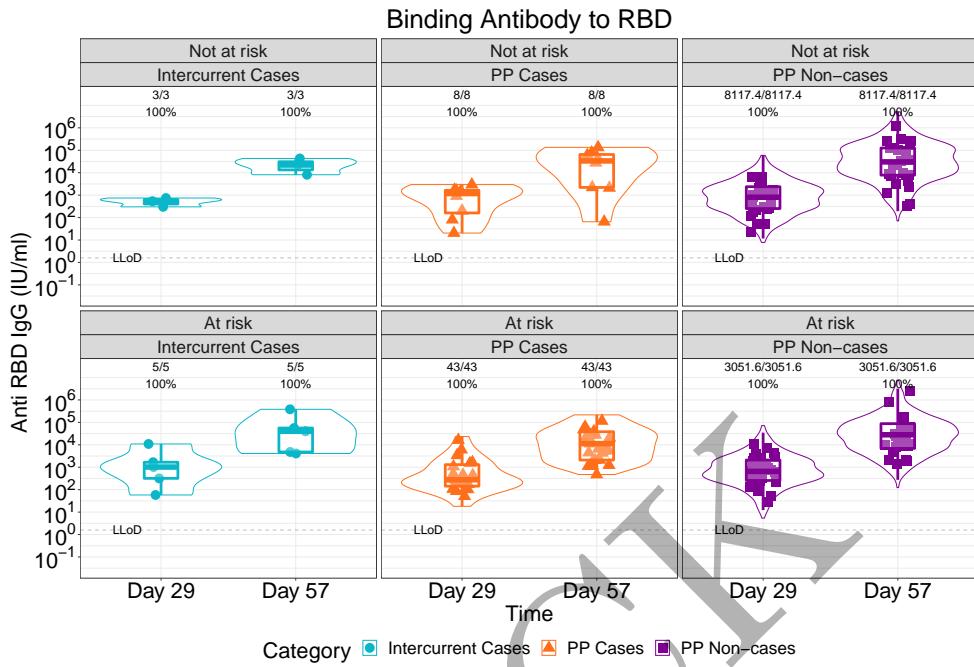


Figure 2.98: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by risk condition (version 1)

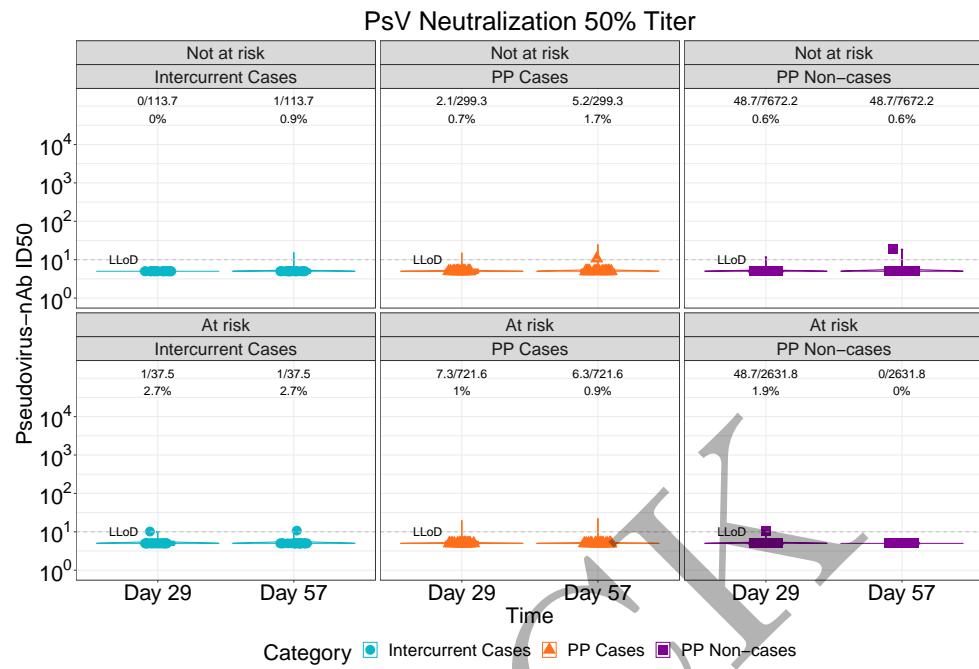


Figure 2.99: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by risk condition (version 1)

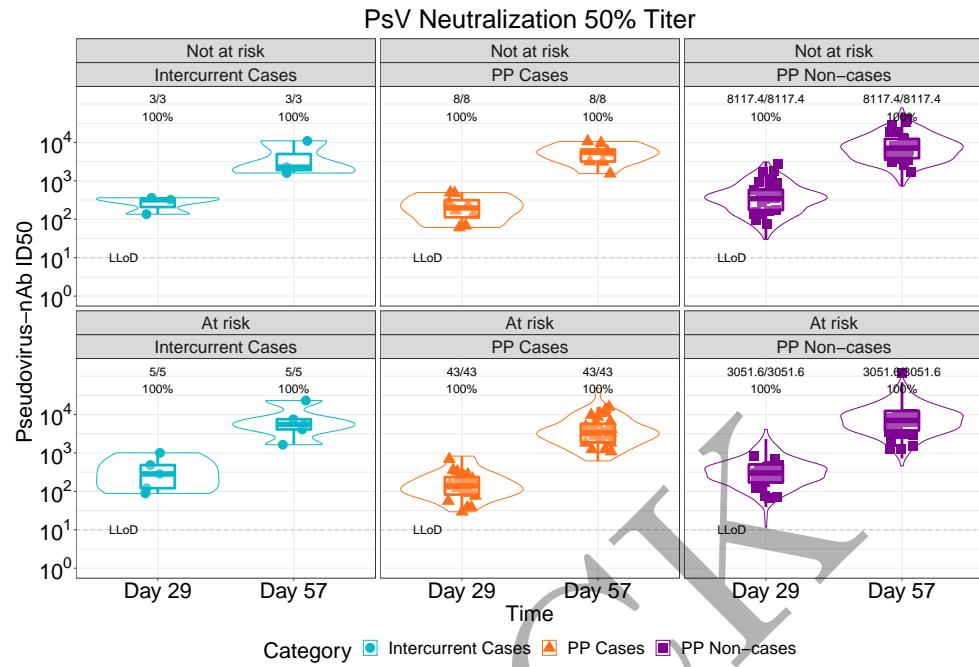


Figure 2.100: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by risk condition (version 1)

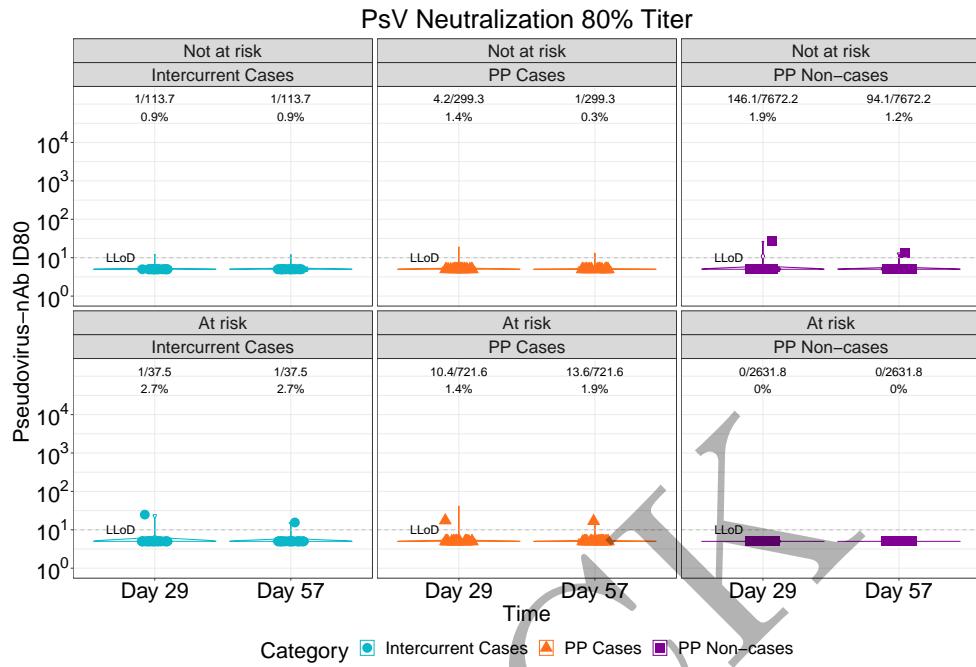


Figure 2.101: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by risk condition (version 1)

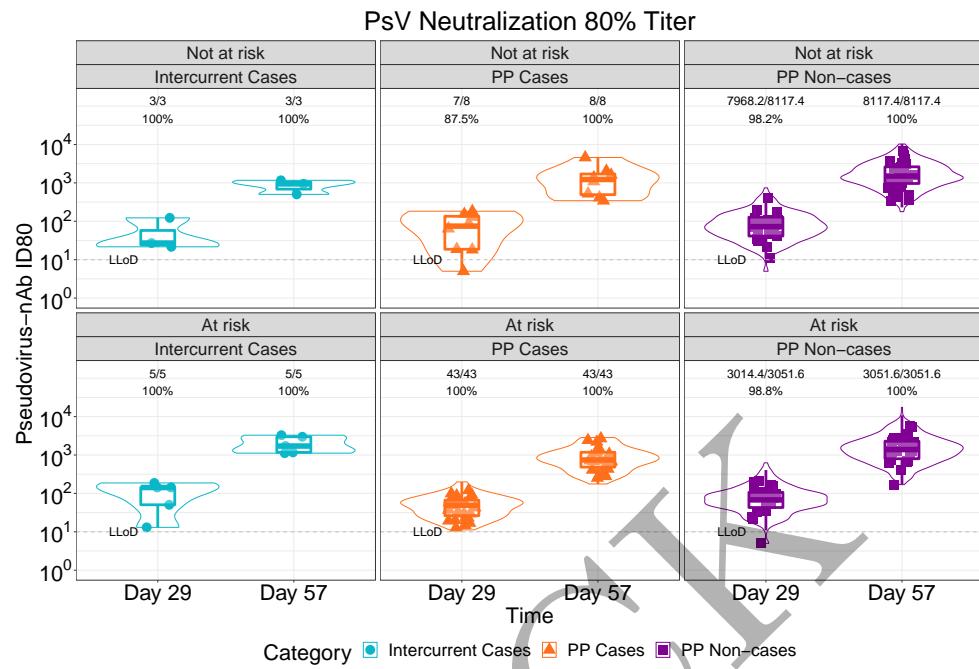


Figure 2.102: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by risk condition (version 1)

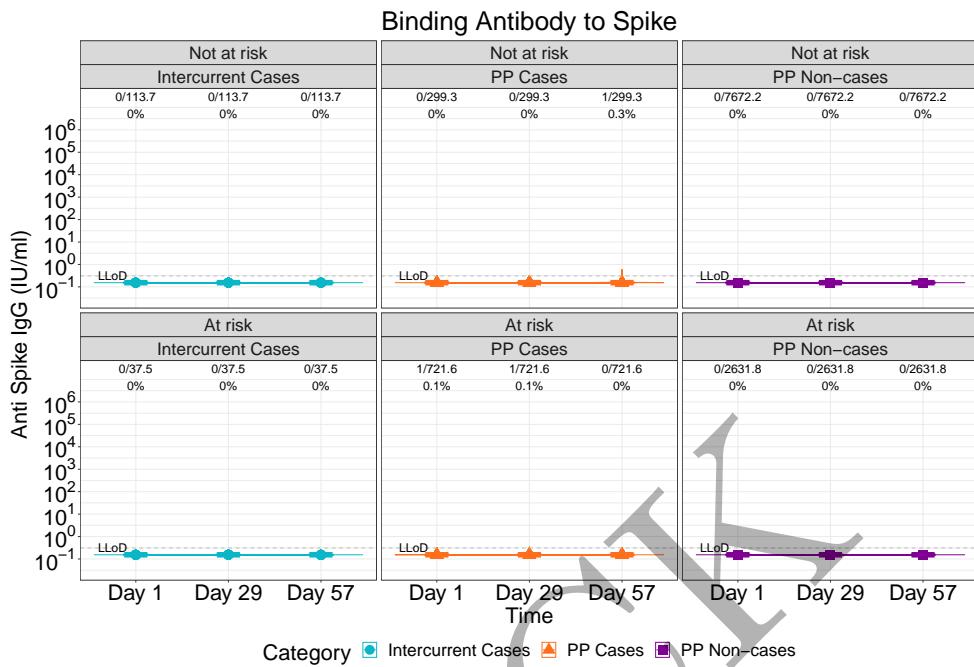


Figure 2.103: lineplots of Binding Antibody to Spike: baseline negative placebo arm by risk condition (version 2)

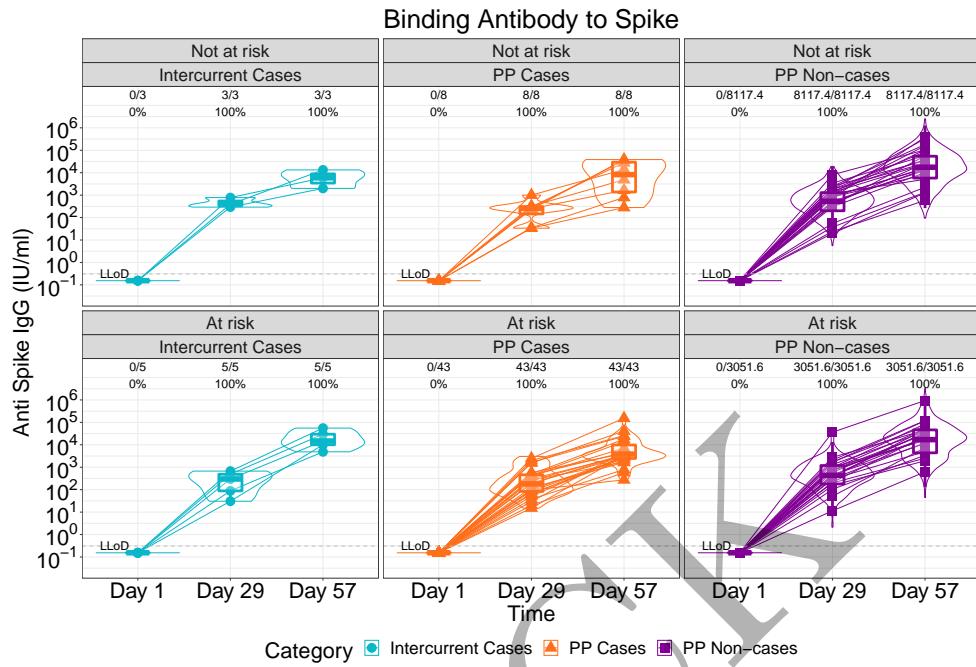


Figure 2.104: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by risk condition (version 2)

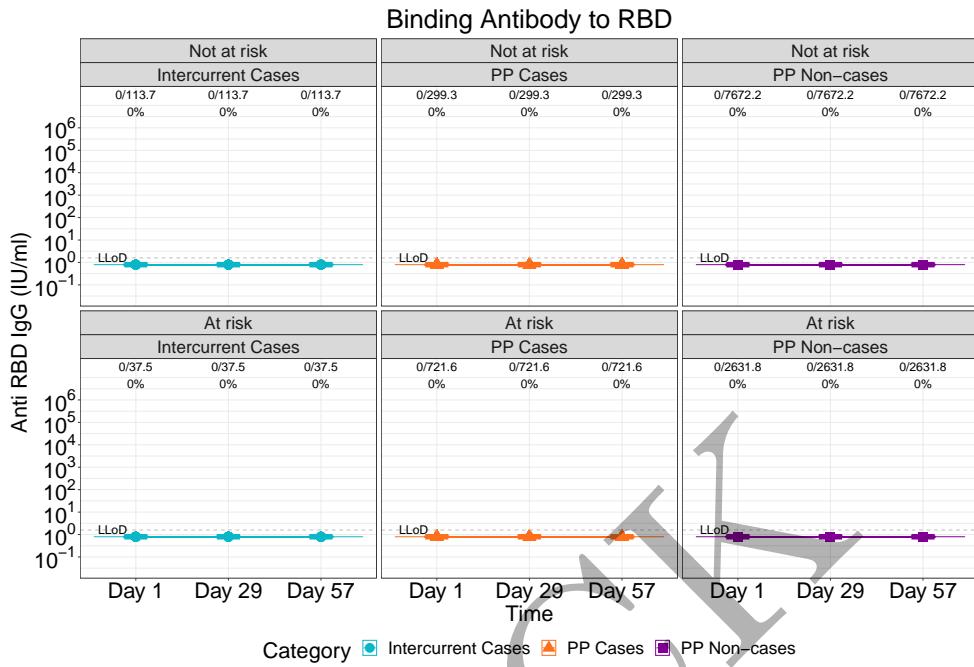


Figure 2.105: lineplots of Binding Antibody to RBD: baseline negative placebo arm by risk condition (version 2)

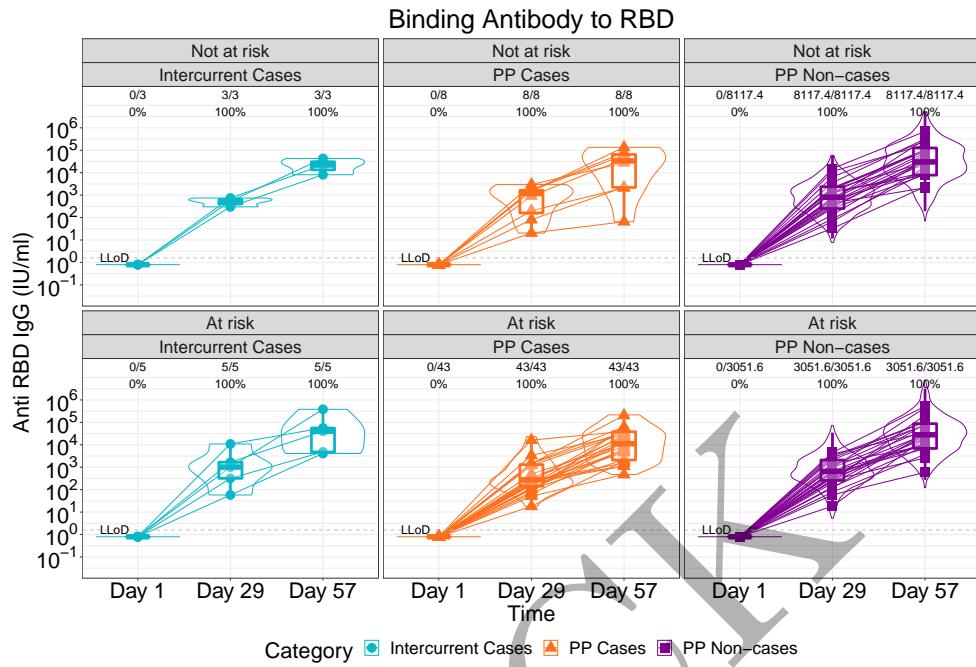


Figure 2.106: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by risk condition (version 2)

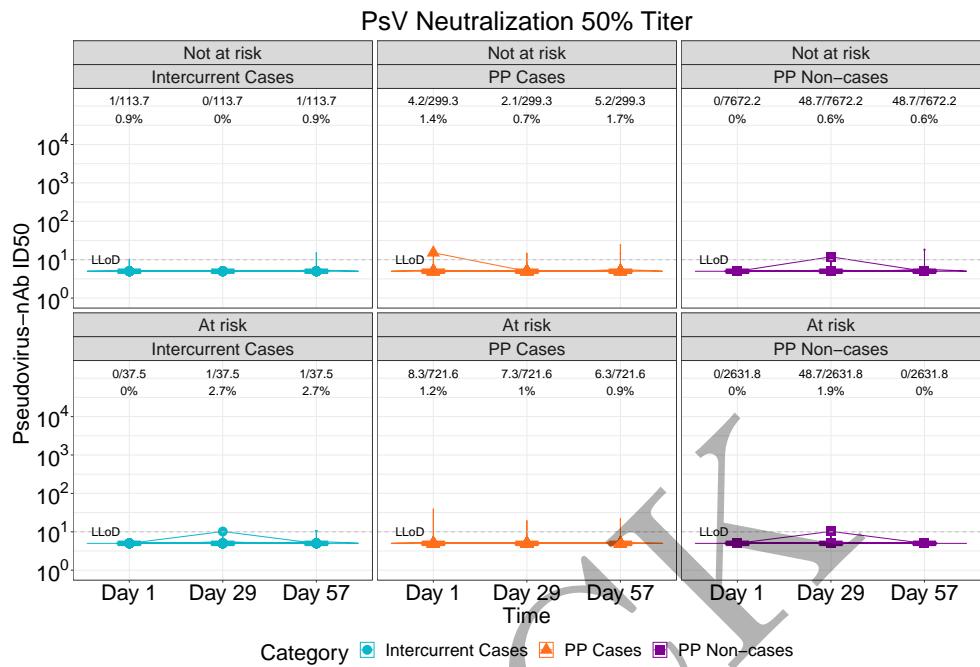


Figure 2.107: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by risk condition (version 2)

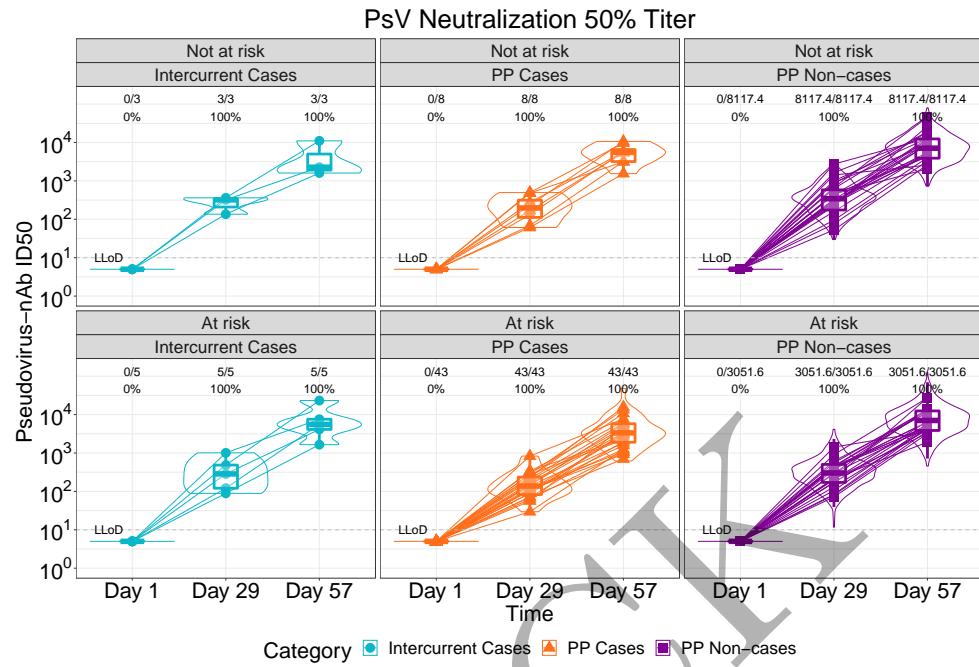


Figure 2.108: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by risk condition (version 2)

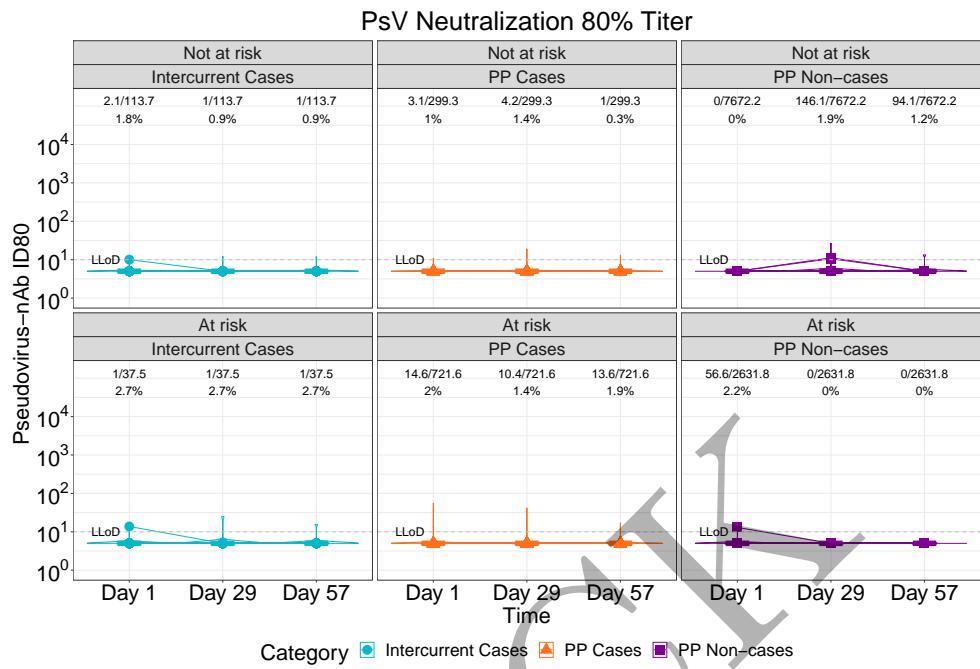


Figure 2.109: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by risk condition (version 2)

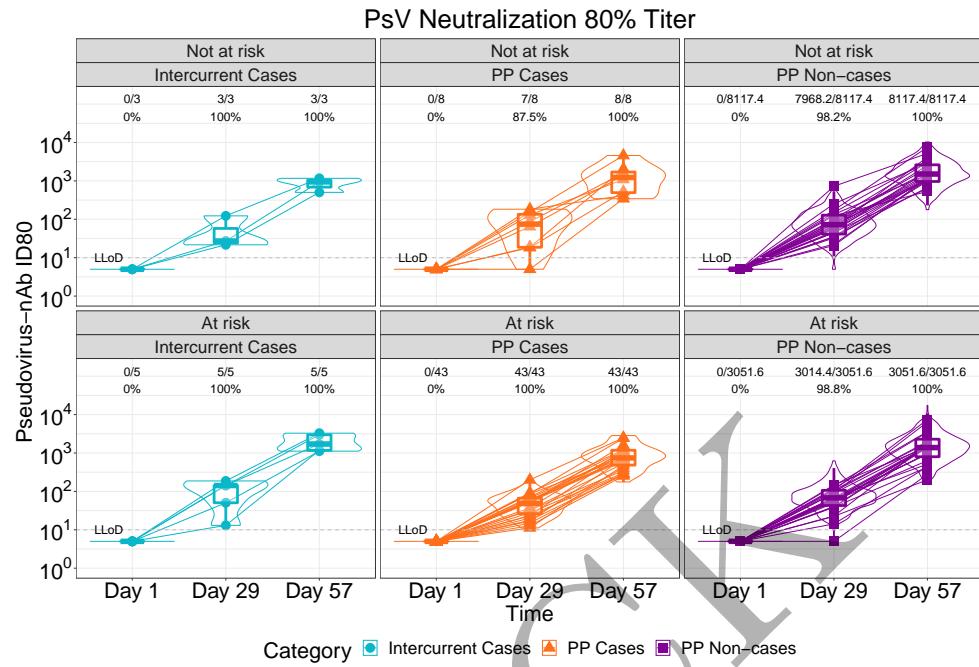


Figure 2.110: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by risk condition (version 2)

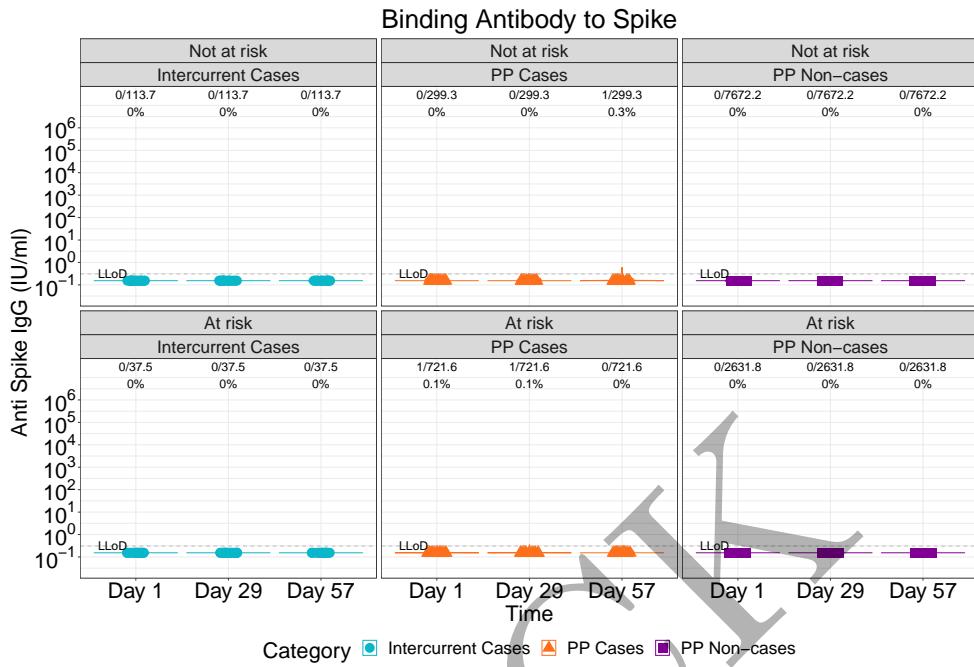


Figure 2.111: violinplots of Binding Antibody to Spike: baseline negative placebo arm by risk condition (version 2)

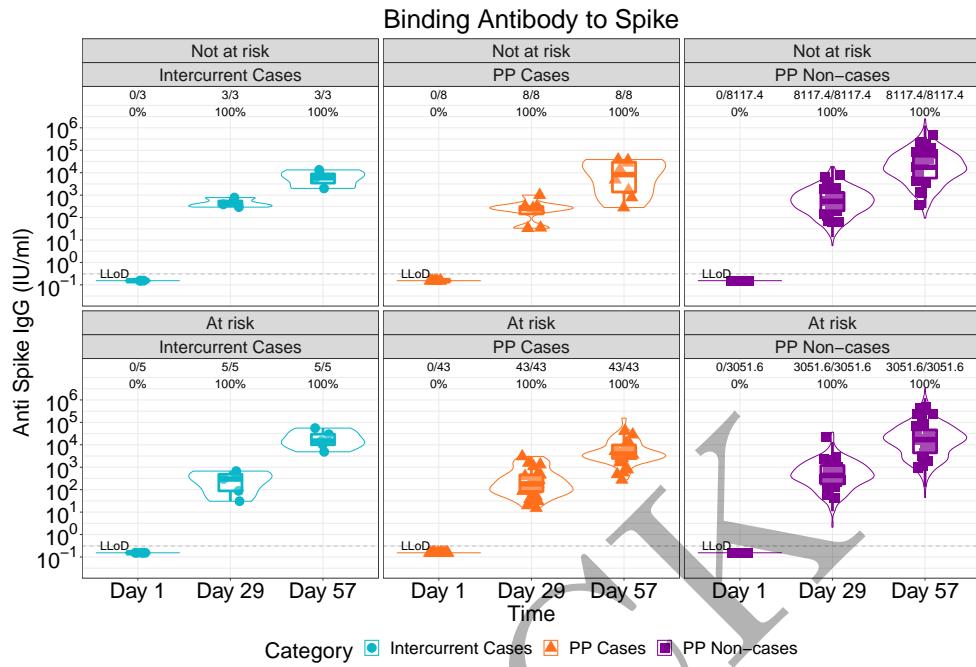


Figure 2.112: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by risk condition (version 2)

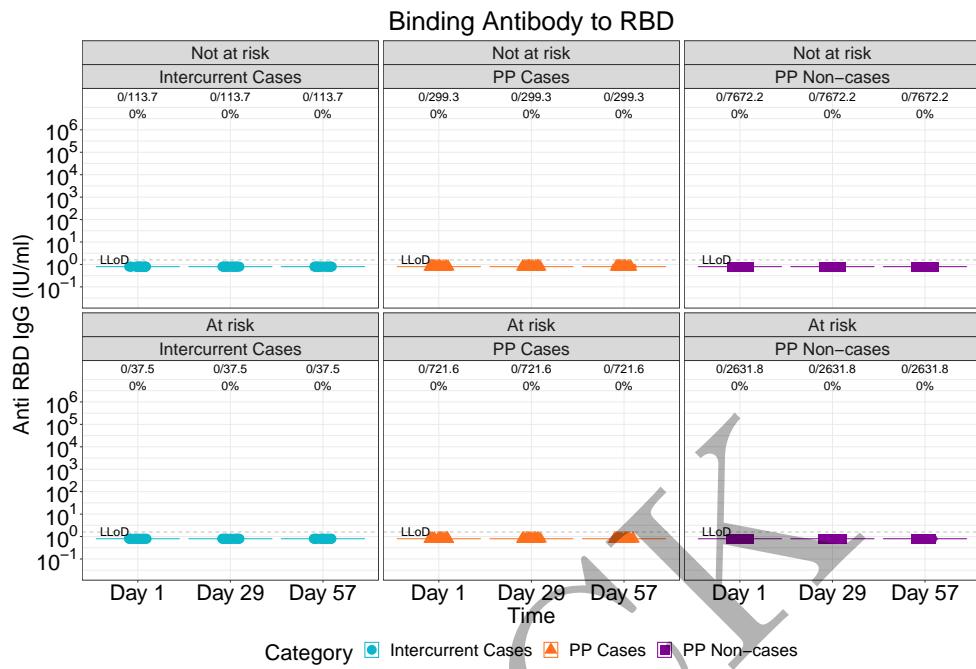


Figure 2.113: violinplots of Binding Antibody to RBD: baseline negative placebo arm by risk condition (version 2)

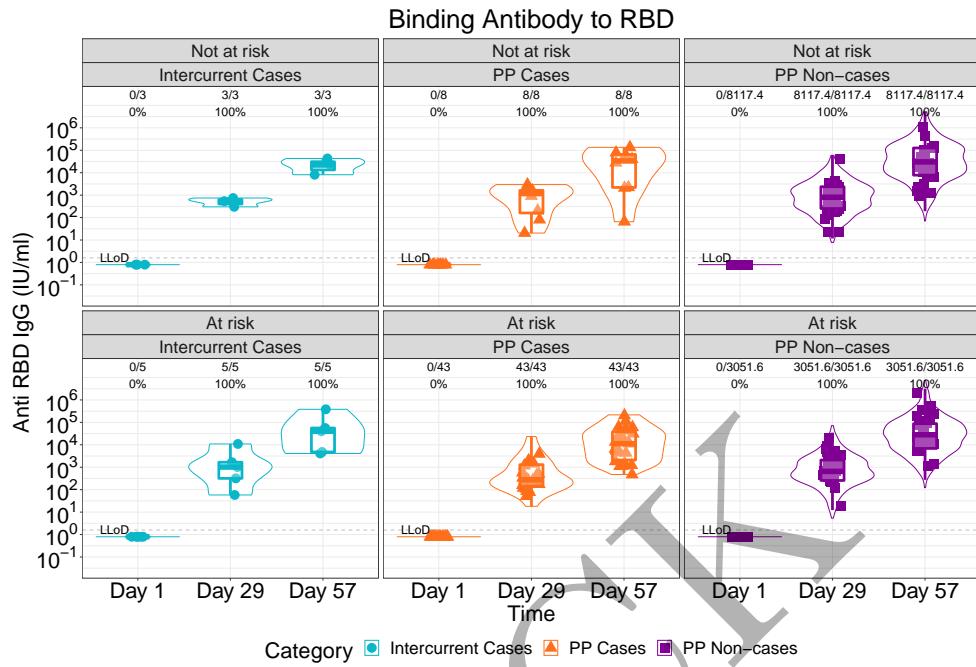


Figure 2.114: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by risk condition (version 2)

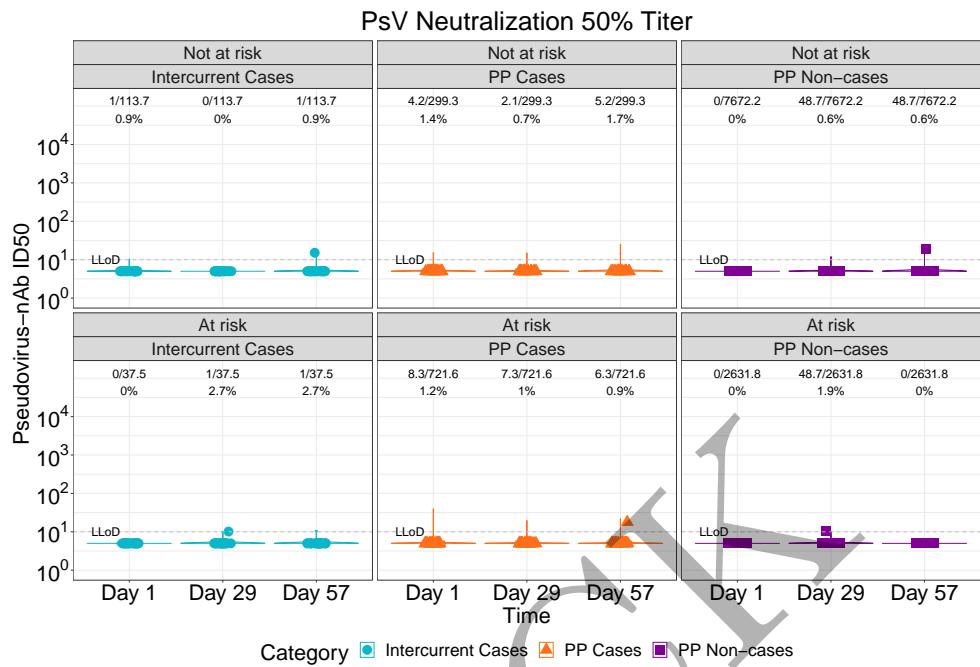


Figure 2.115: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by risk condition (version 2)

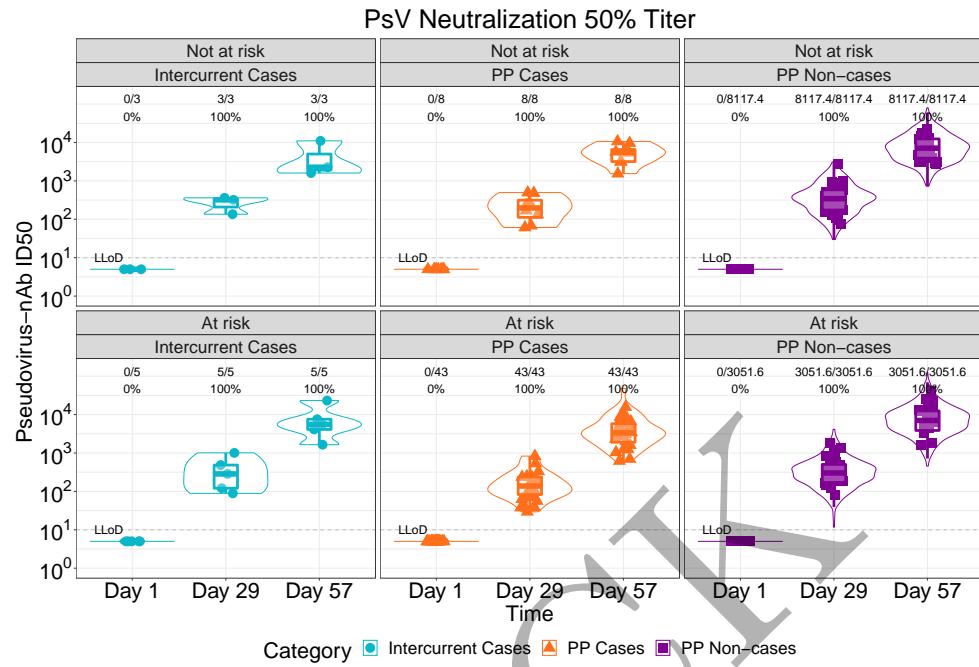


Figure 2.116: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by risk condition (version 2)

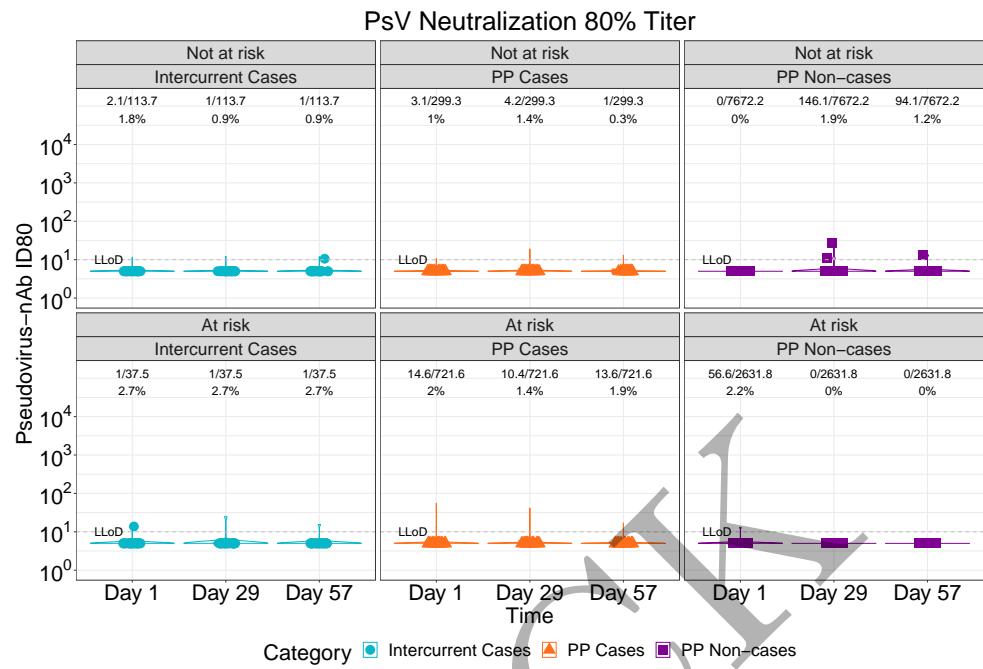


Figure 2.117: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by risk condition (version 2)

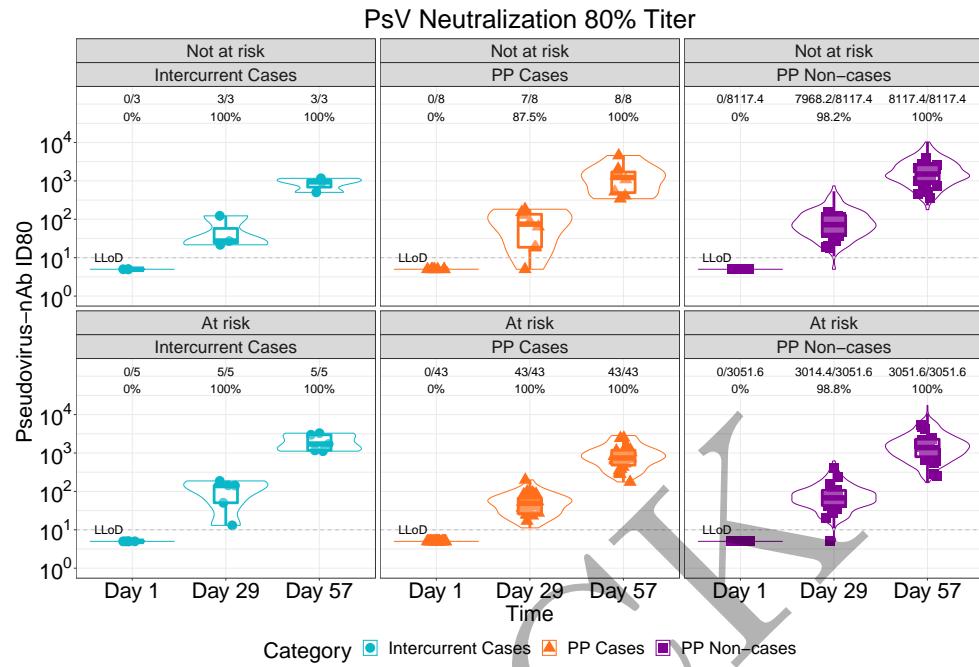


Figure 2.118: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by risk condition (version 2)

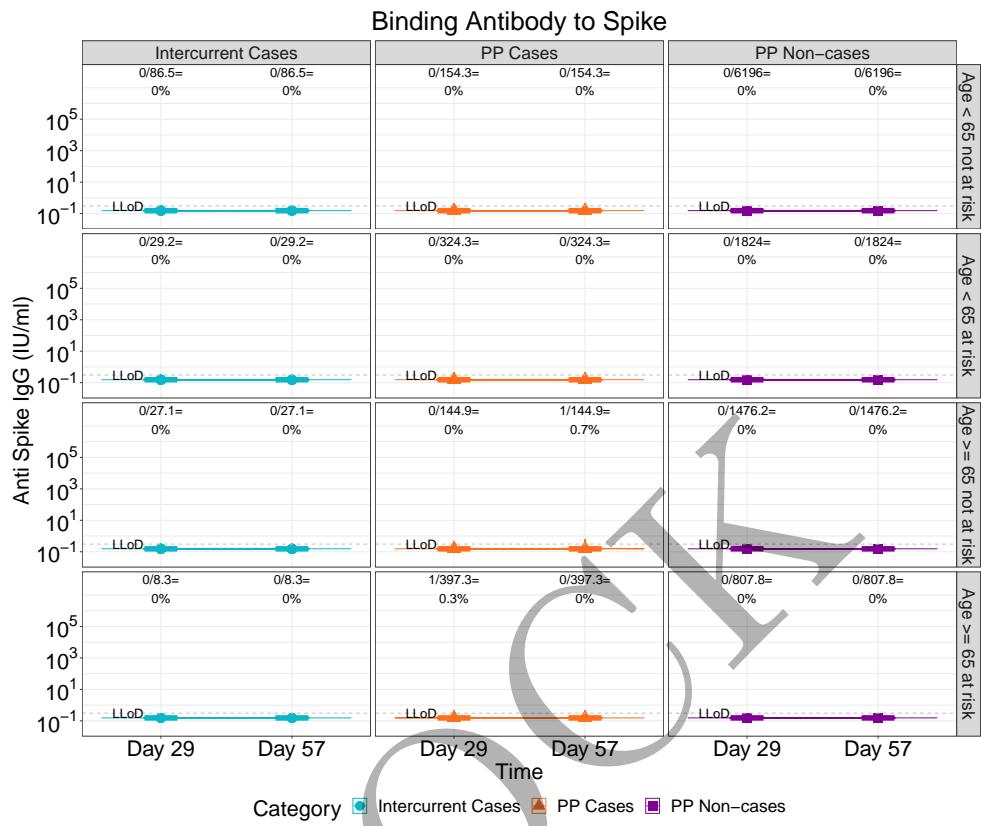


Figure 2.119: lineplots of Binding Antibody to Spike: baseline negative placebo arm by age and risk condition (version 1)

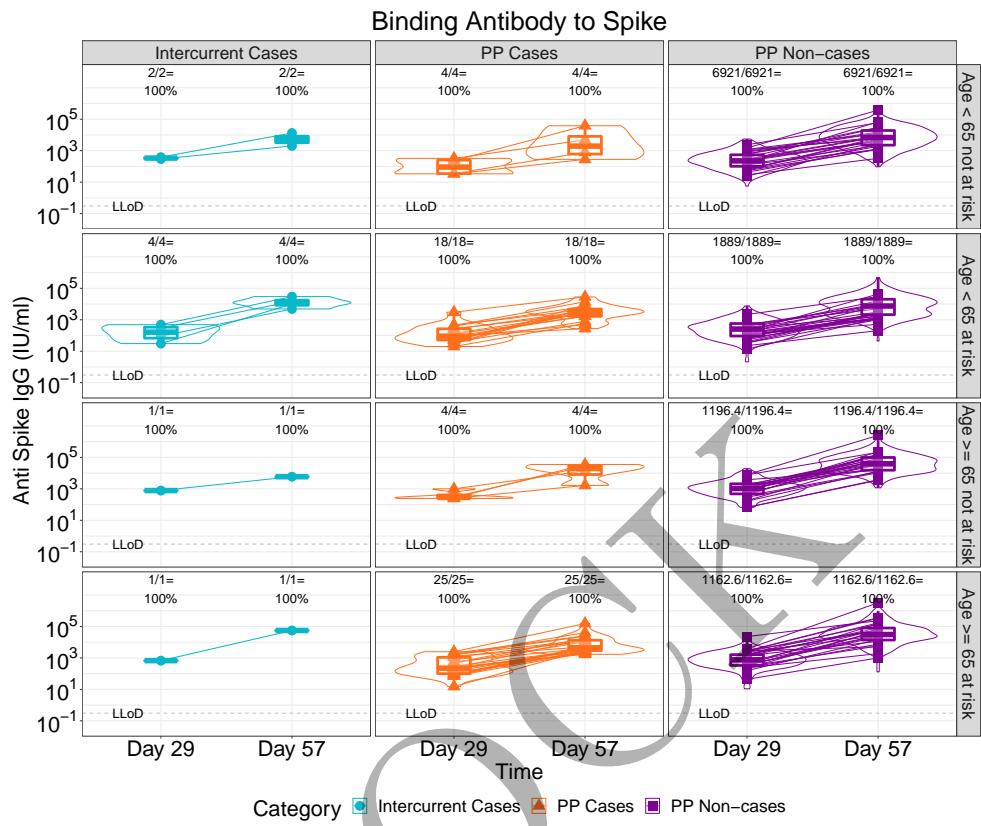


Figure 2.120: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by age and risk condition (version 1)

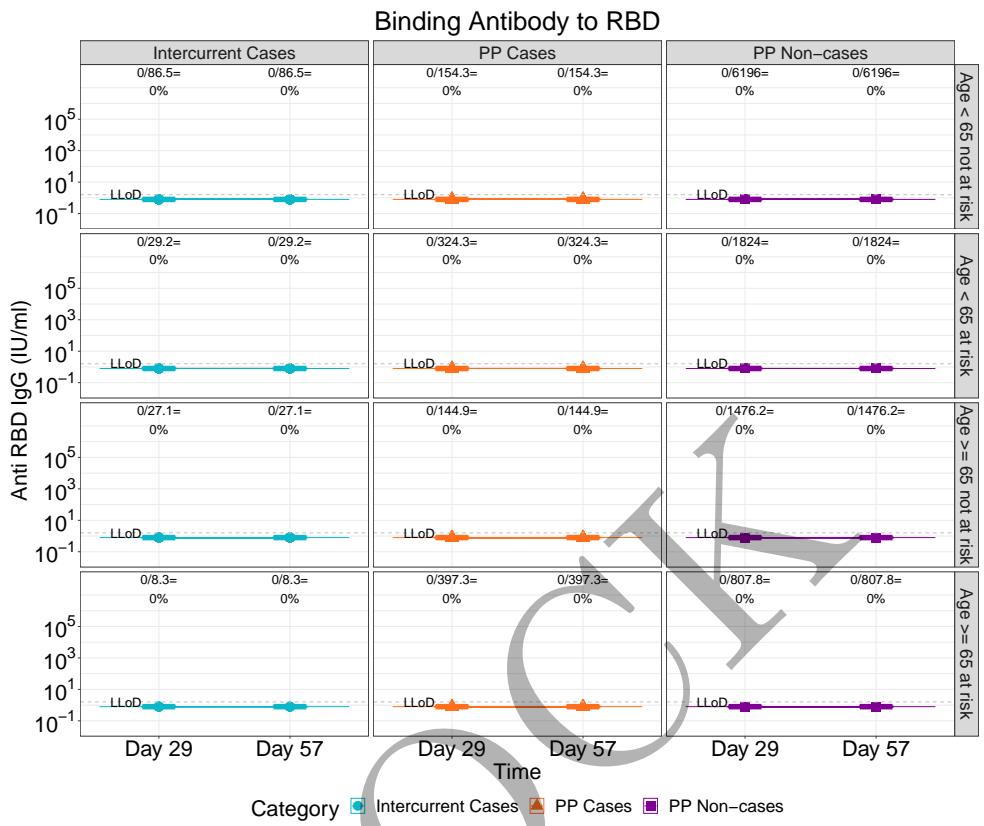


Figure 2.121: lineplots of Binding Antibody to RBD: baseline negative placebo arm by age and risk condition (version 1)

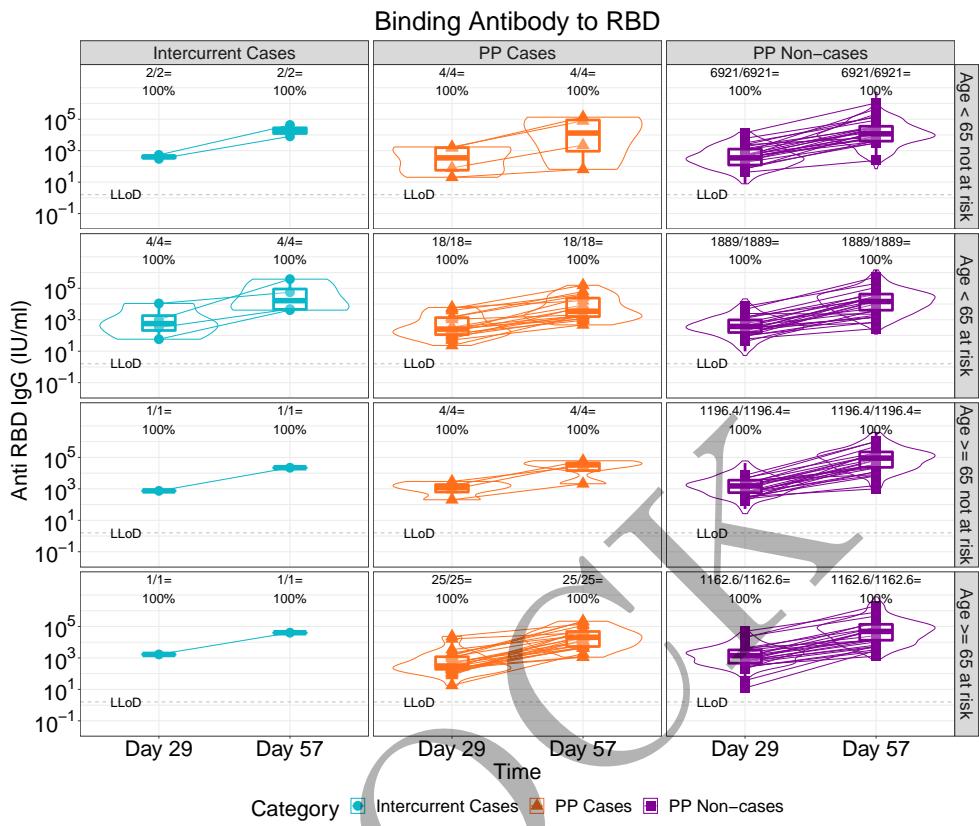


Figure 2.122: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by age and risk condition (version 1)

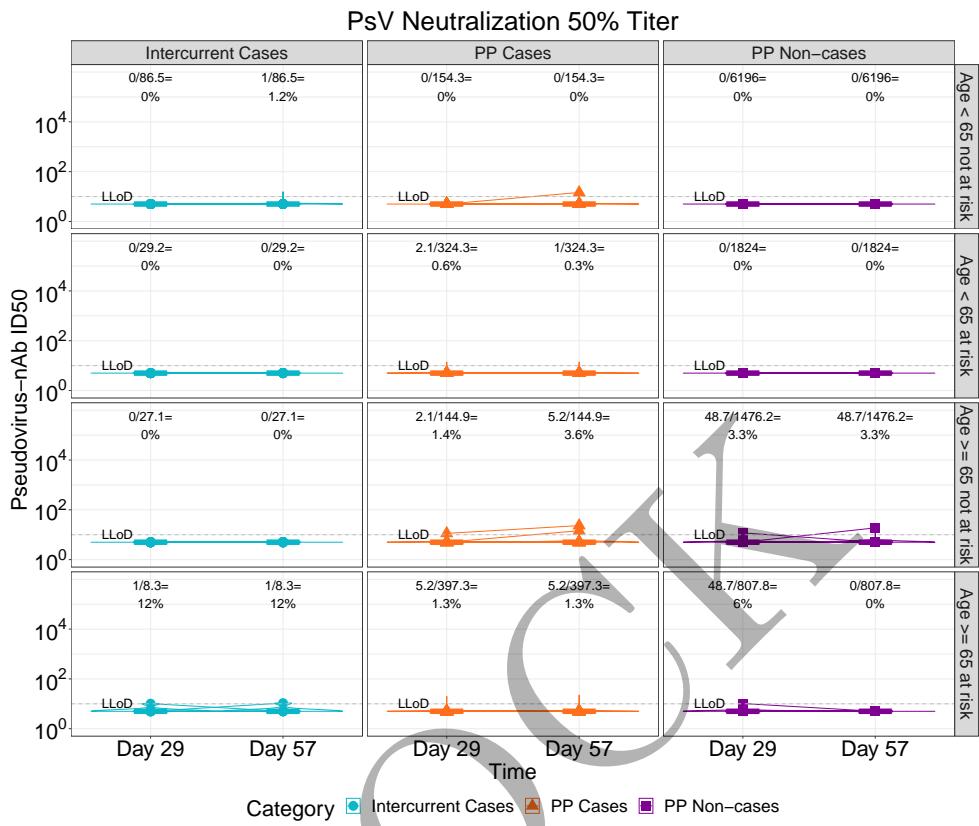


Figure 2.123: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age and risk condition (version 1)

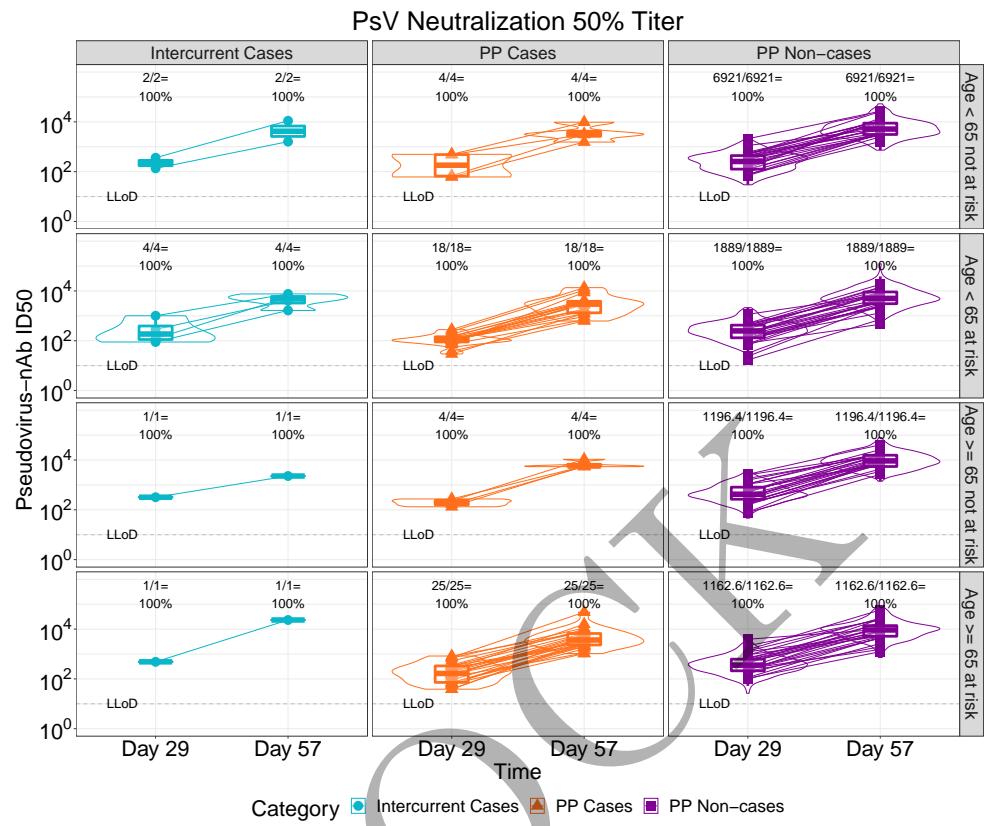


Figure 2.124: lineplots of Pseudovirus Neutralization ID₅₀: baseline negative vaccine arm by age and risk condition (version 1)

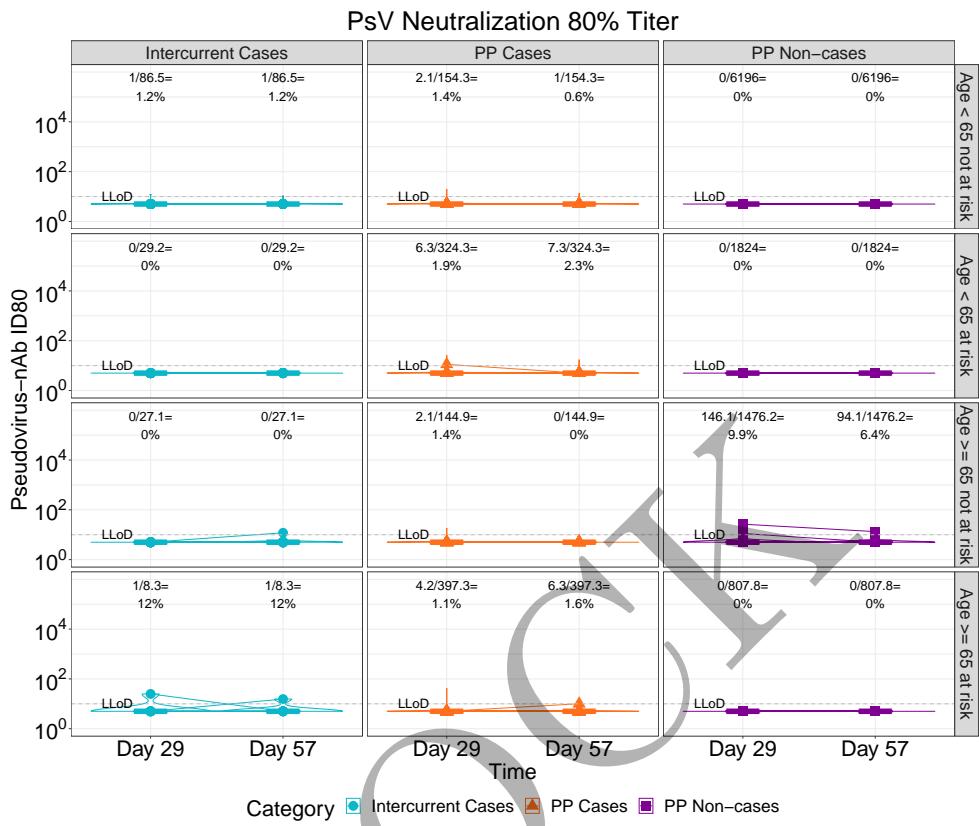


Figure 2.125: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age and risk condition (version 1)

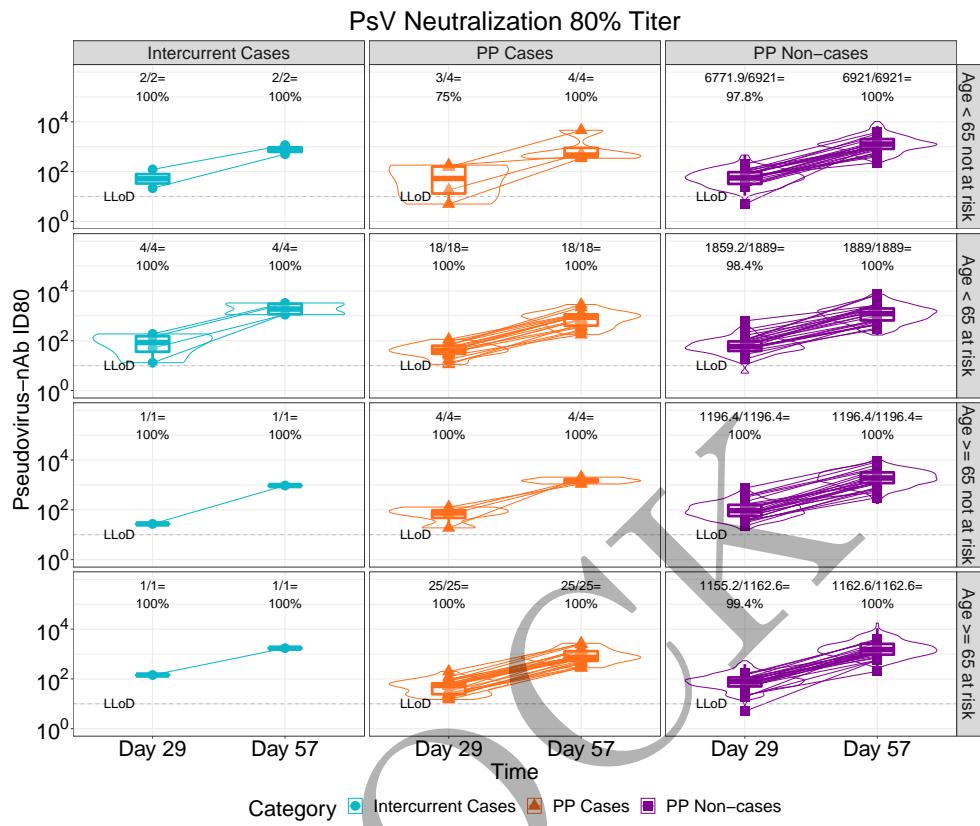


Figure 2.126: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age and risk condition (version 1)

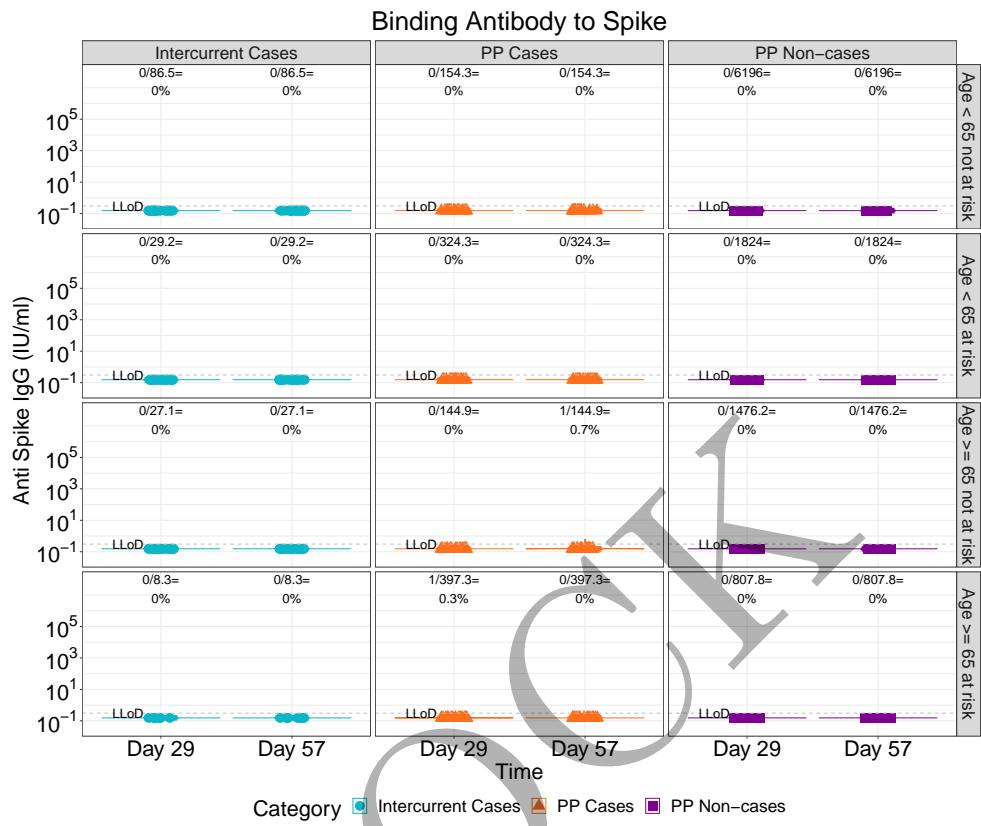


Figure 2.127: violinplots of Binding Antibody to Spike: baseline negative placebo arm by age and risk condition (version 1)

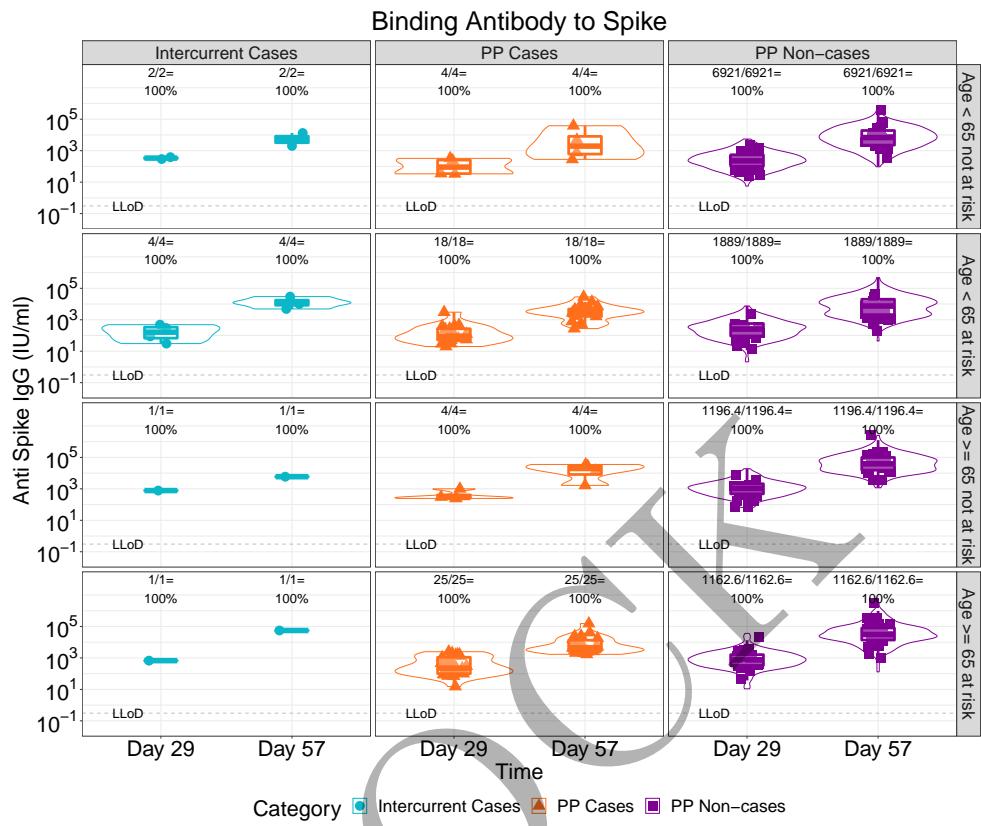


Figure 2.128: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by age and risk condition (version 1)

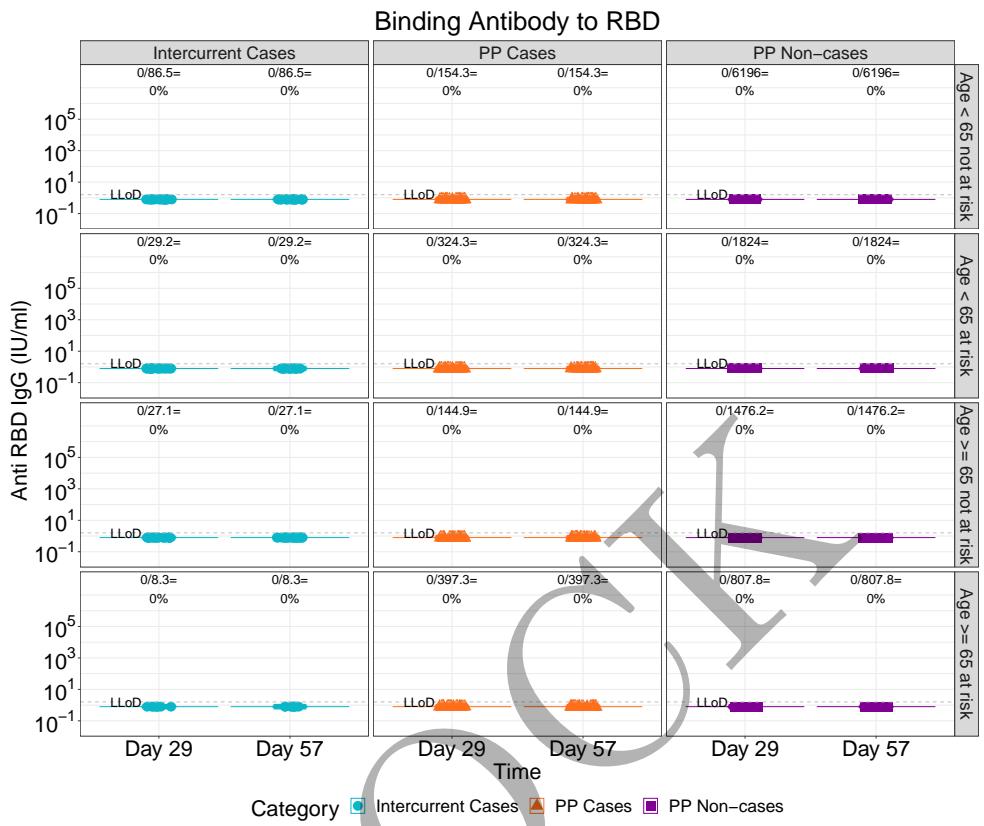


Figure 2.129: violinplots of Binding Antibody to RBD: baseline negative placebo arm by age and risk condition (version 1)

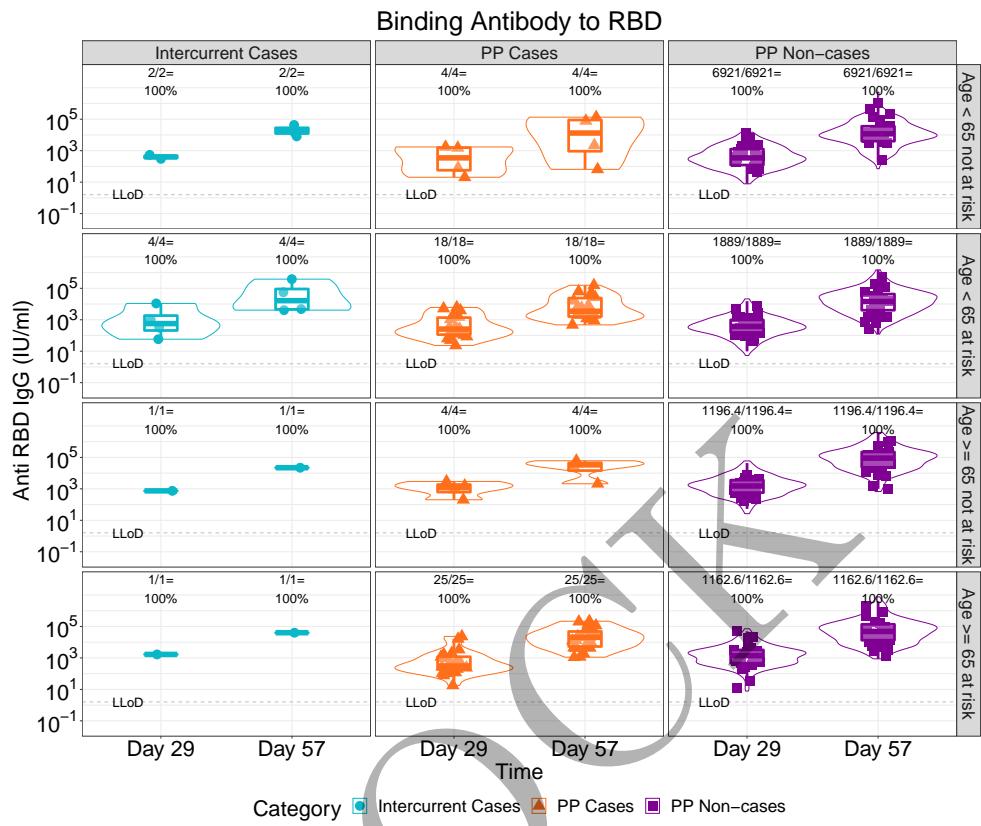


Figure 2.130: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by age and risk condition (version 1)

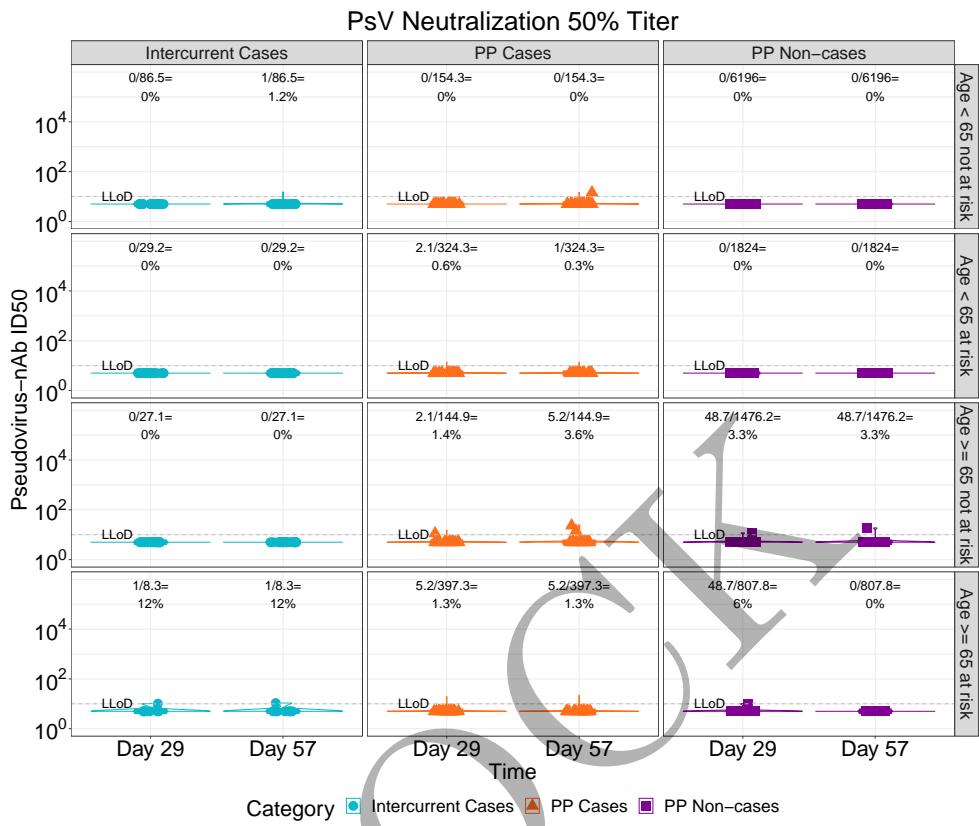


Figure 2.131: violinplots of Pseudovirus Neutralization ID₅₀: baseline negative placebo arm by age and risk condition (version 1)

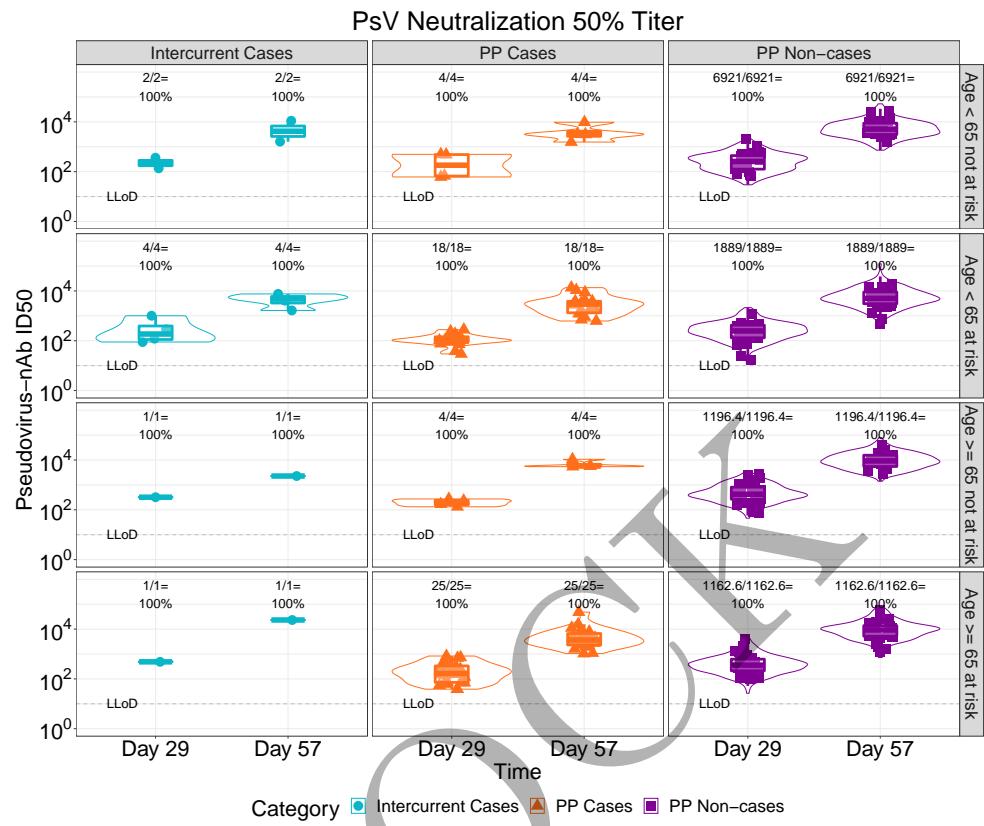


Figure 2.132: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age and risk condition (version 1)

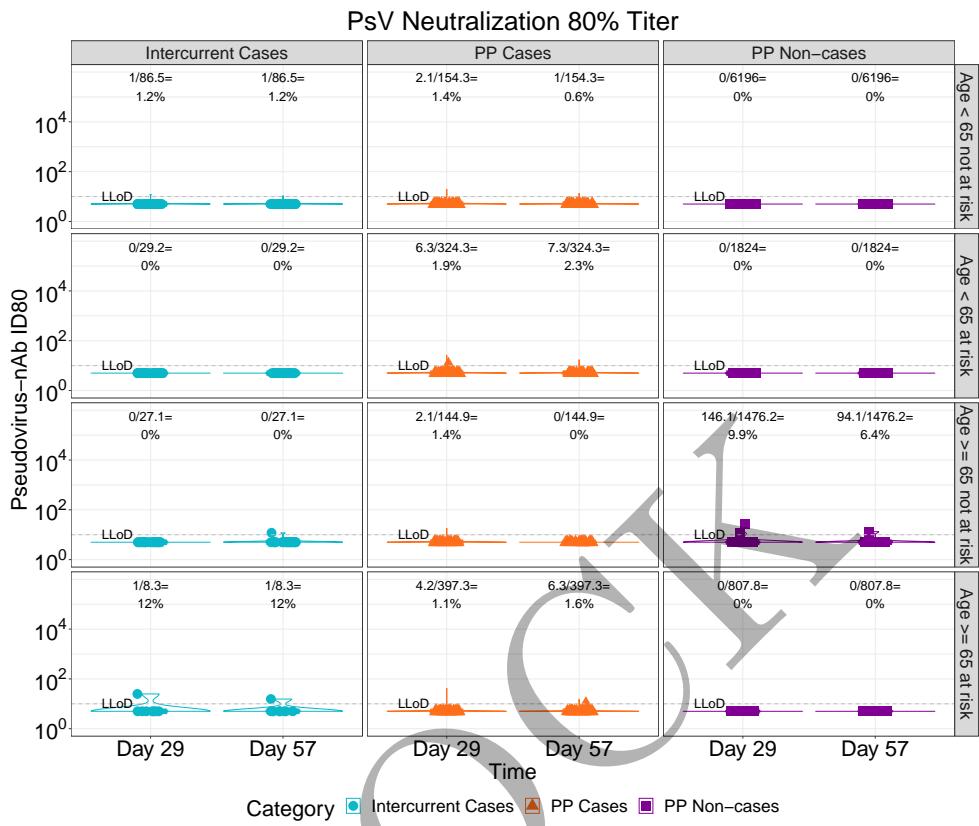


Figure 2.133: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age and risk condition (version 1)

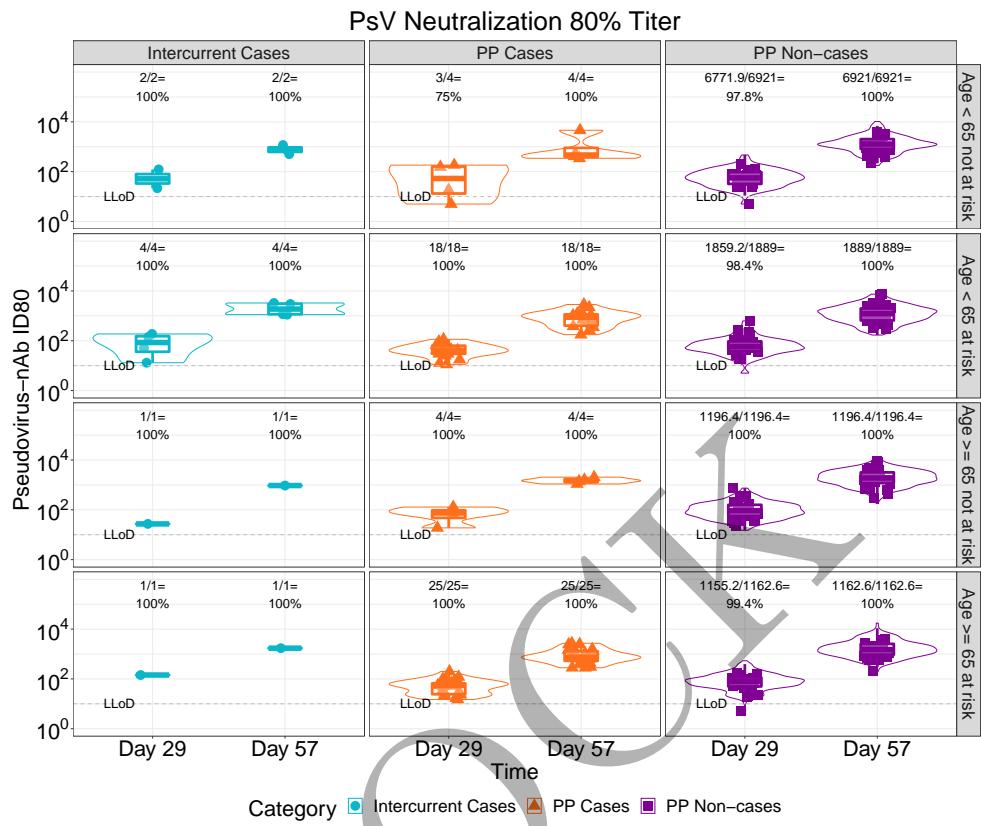


Figure 2.134: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age and risk condition (version 1)

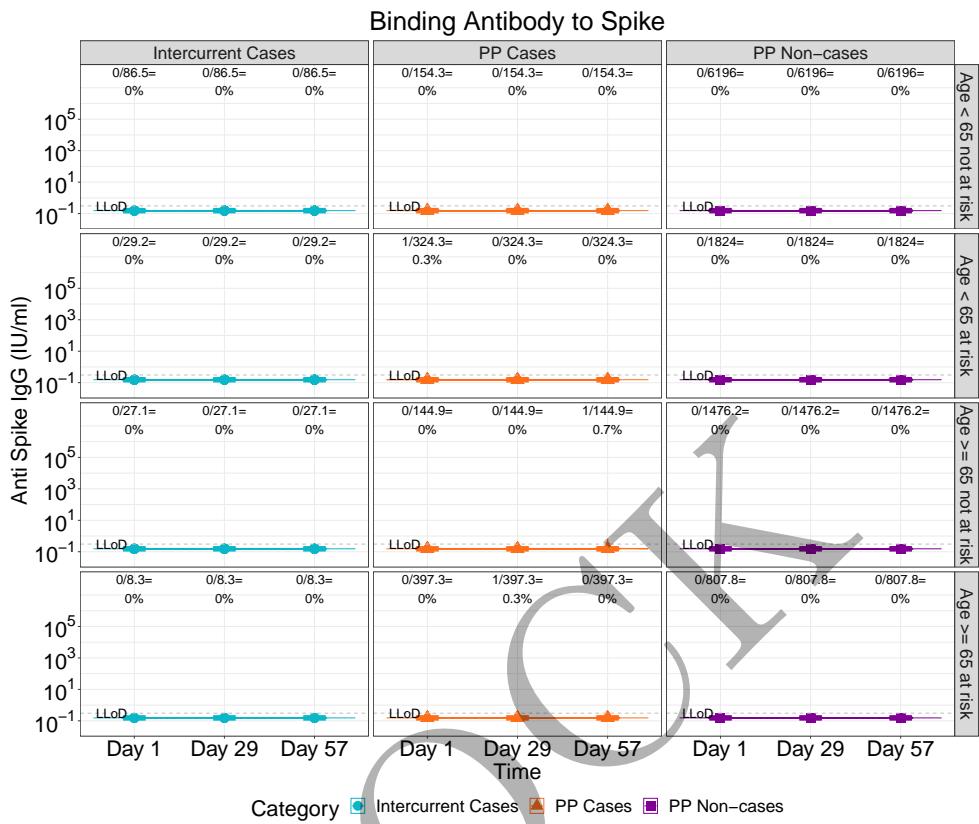


Figure 2.135: lineplots of Binding Antibody to Spike: baseline negative placebo arm by age and risk condition (version 2)

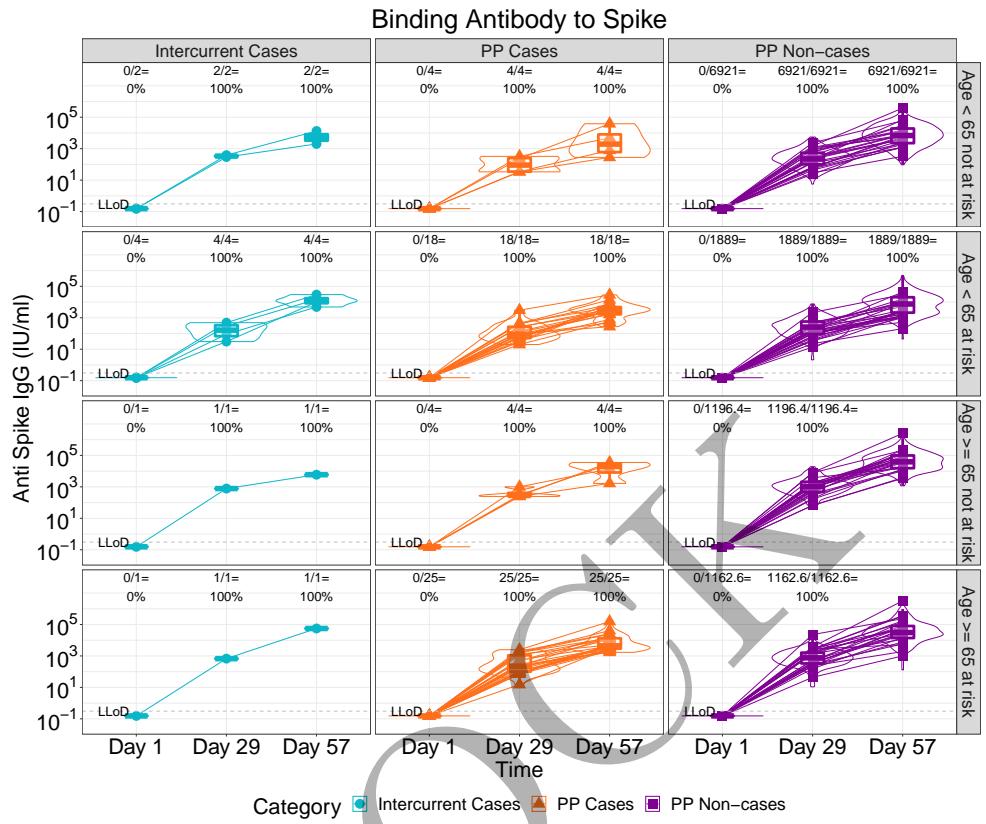


Figure 2.136: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by age and risk condition (version 2)

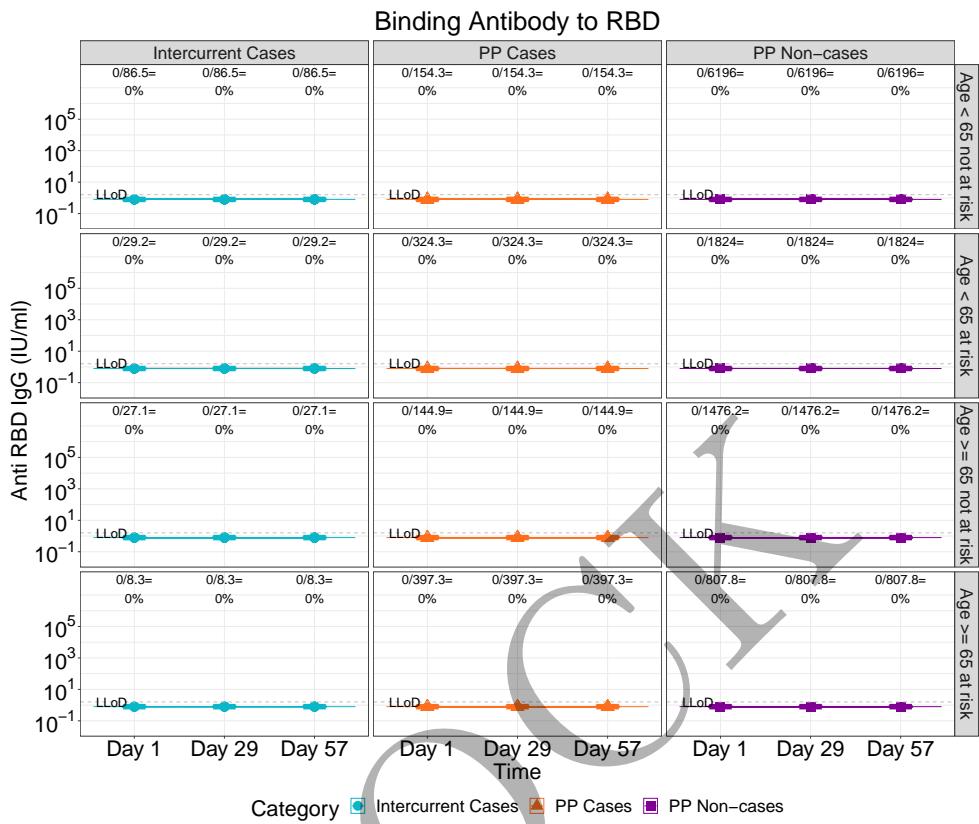


Figure 2.137: lineplots of Binding Antibody to RBD: baseline negative placebo arm by age and risk condition (version 2)

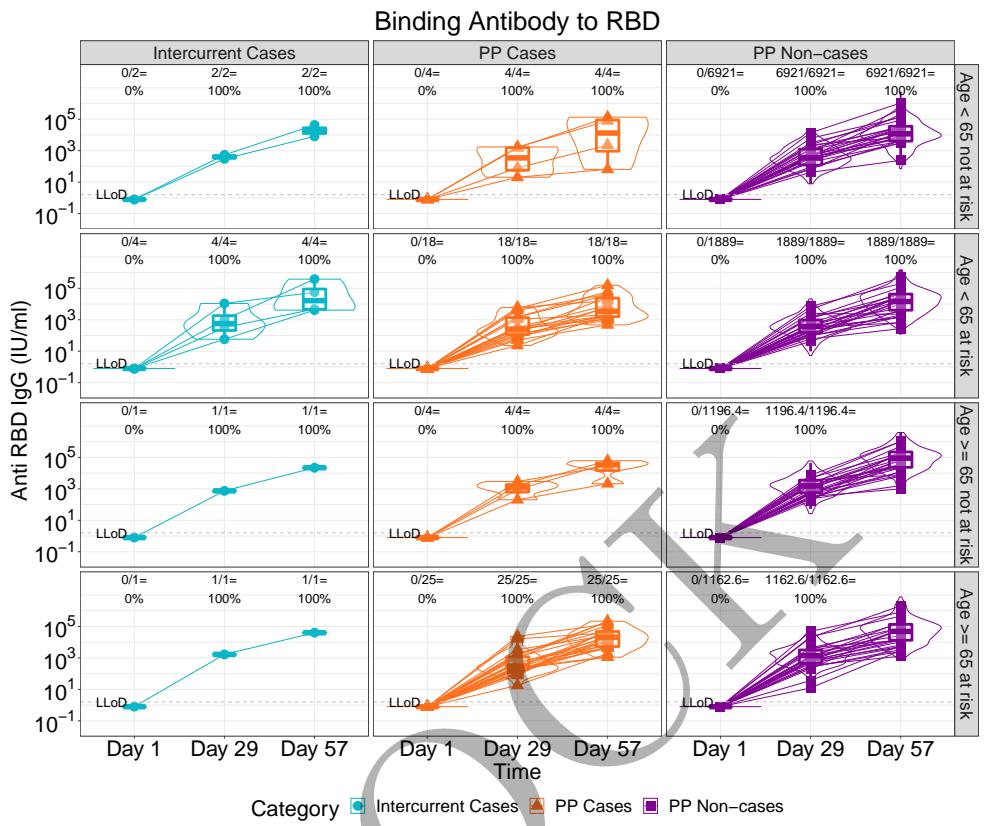


Figure 2.138: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by age and risk condition (version 2)

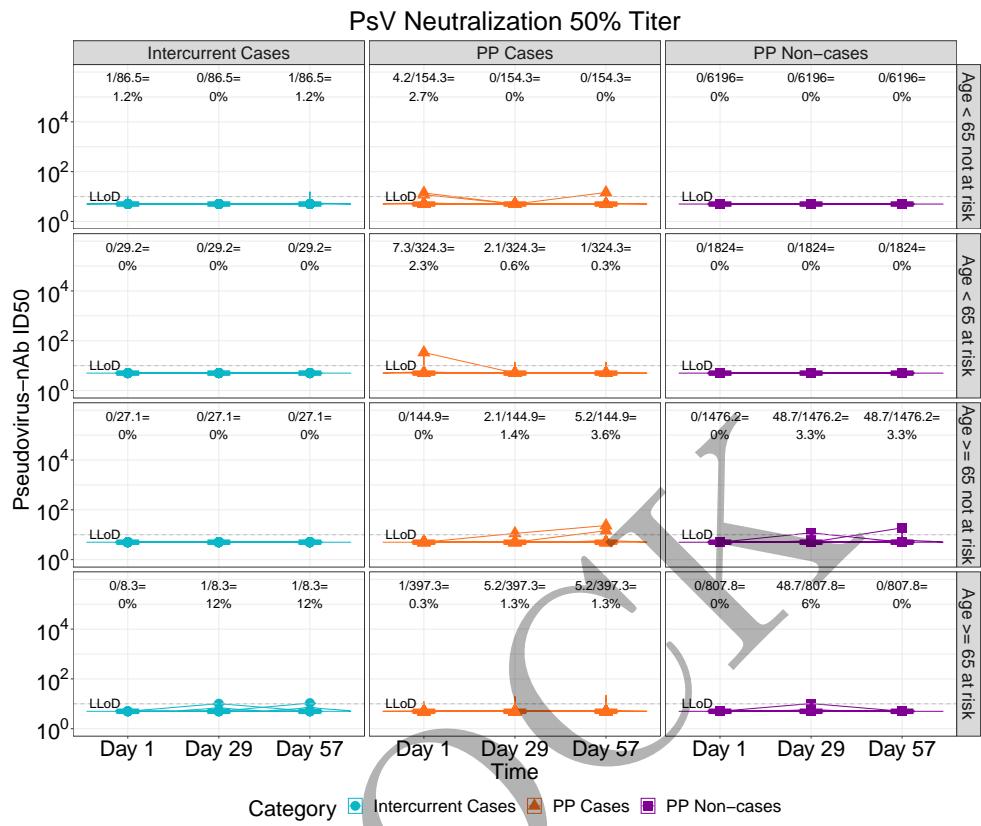


Figure 2.139: lineplots of Pseudovirus Neutralization ID₅₀: baseline negative placebo arm by age and risk condition (version 2)

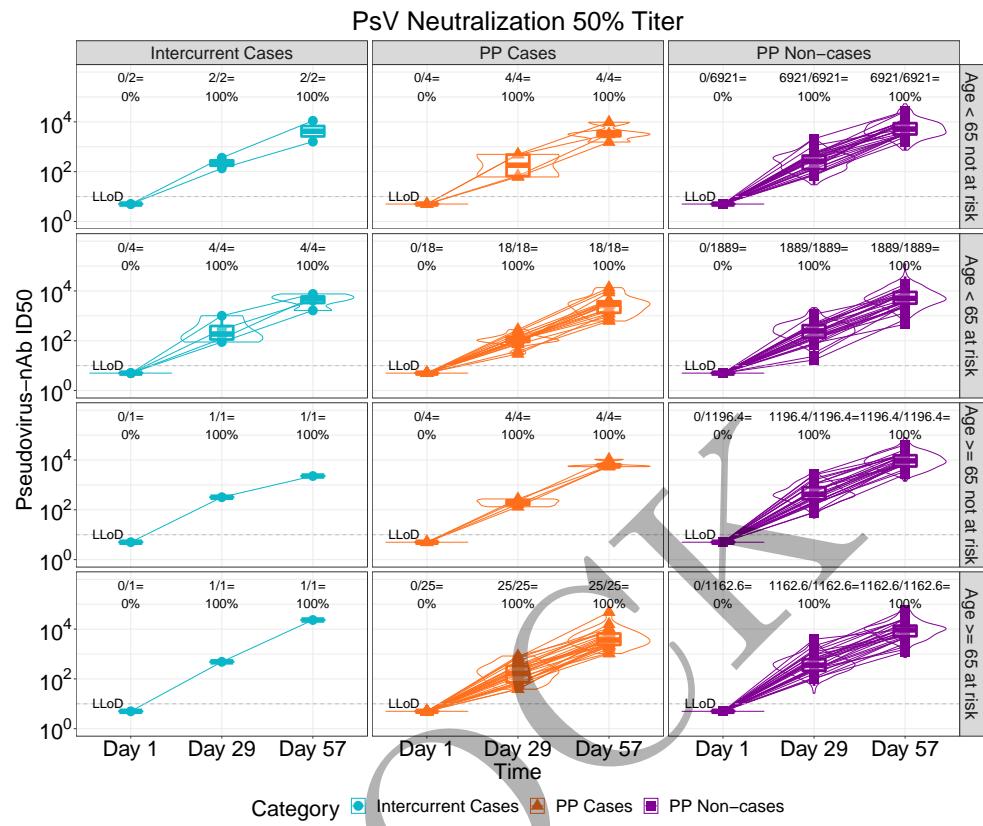


Figure 2.140: lineplots of Pseudovirus Neutralization ID₅₀: baseline negative vaccine arm by age and risk condition (version 2)

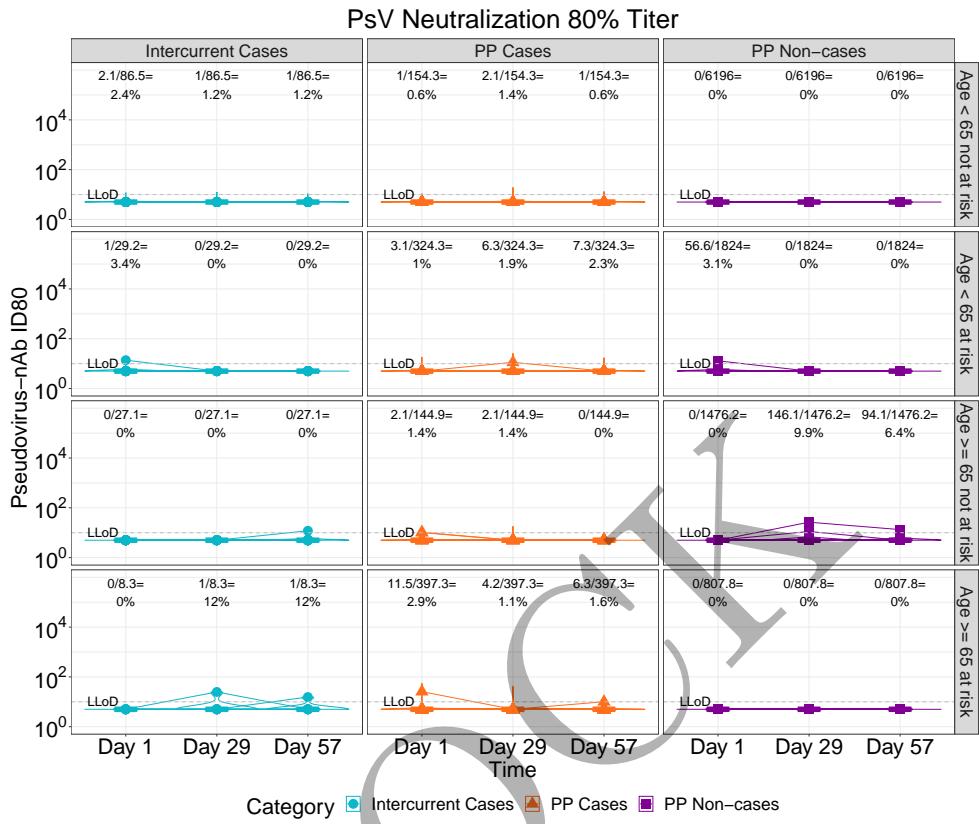


Figure 2.141: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age and risk condition (version 2)

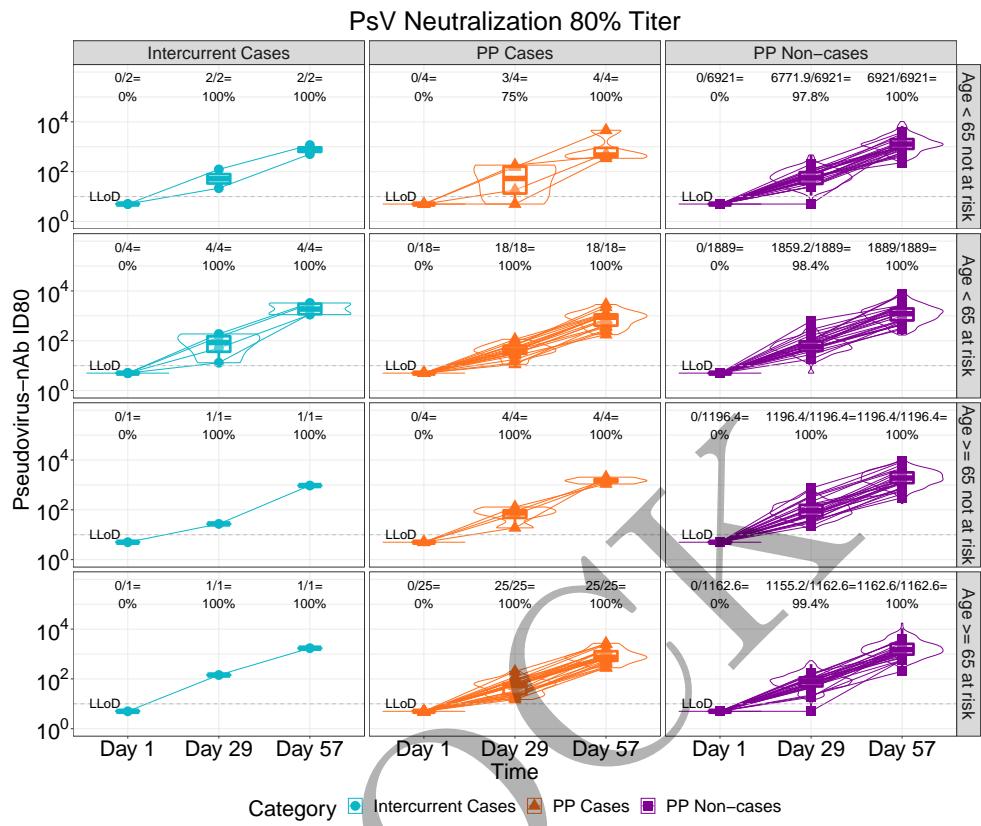


Figure 2.142: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age and risk condition (version 2)

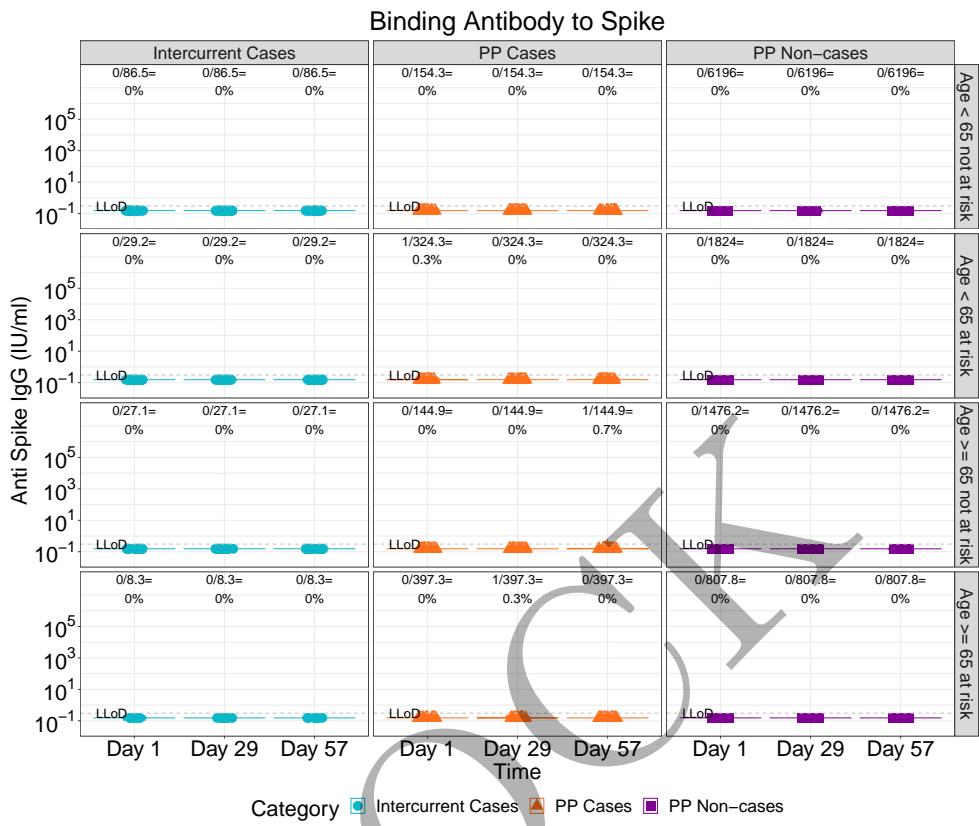


Figure 2.143: violinplots of Binding Antibody to Spike: baseline negative placebo arm by age and risk condition (version 2)

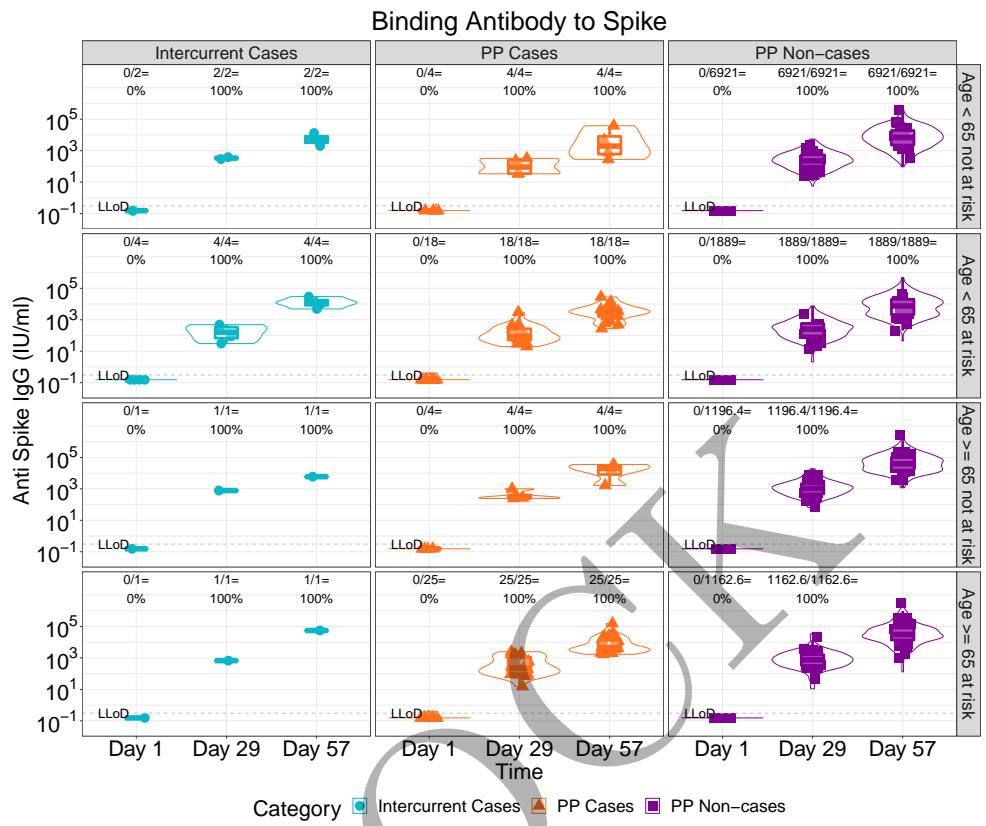


Figure 2.144: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by age and risk condition (version 2)

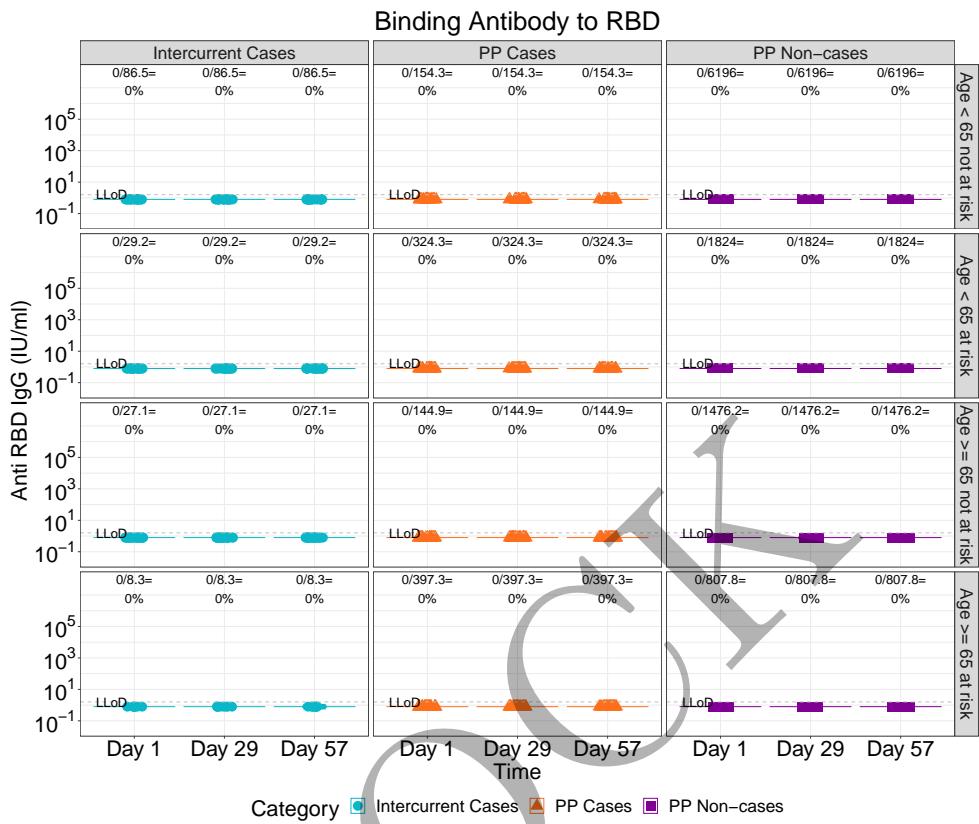


Figure 2.145: violinplots of Binding Antibody to RBD: baseline negative placebo arm by age and risk condition (version 2)

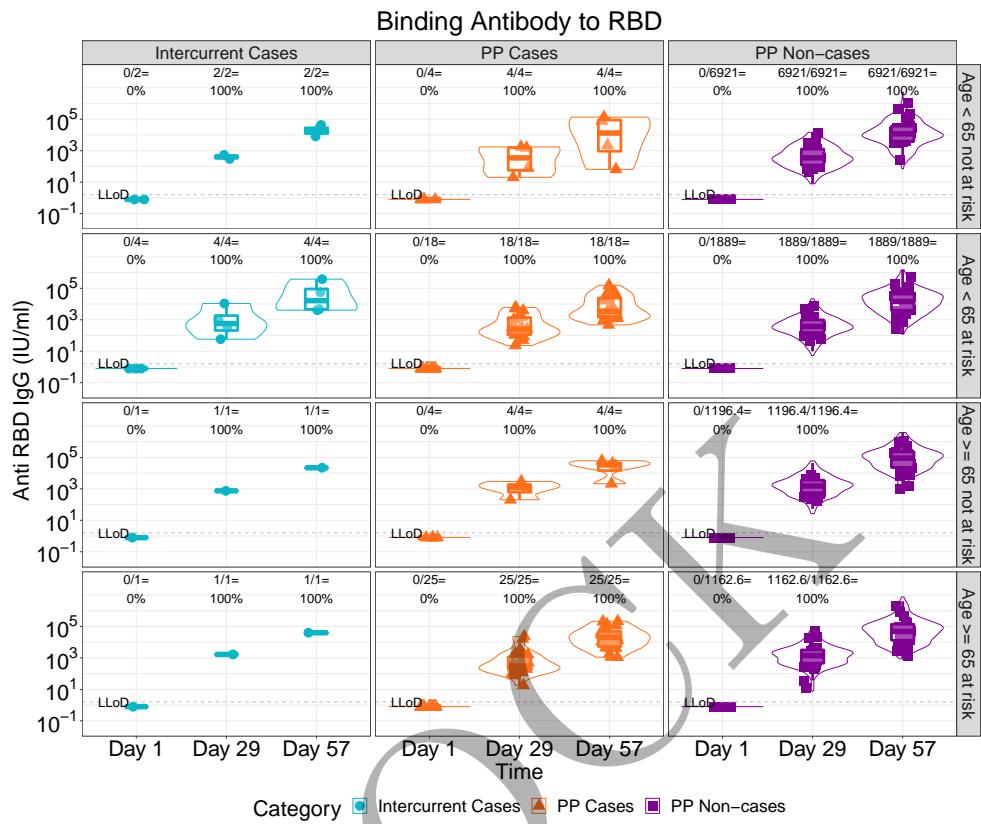


Figure 2.146: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by age and risk condition (version 2)

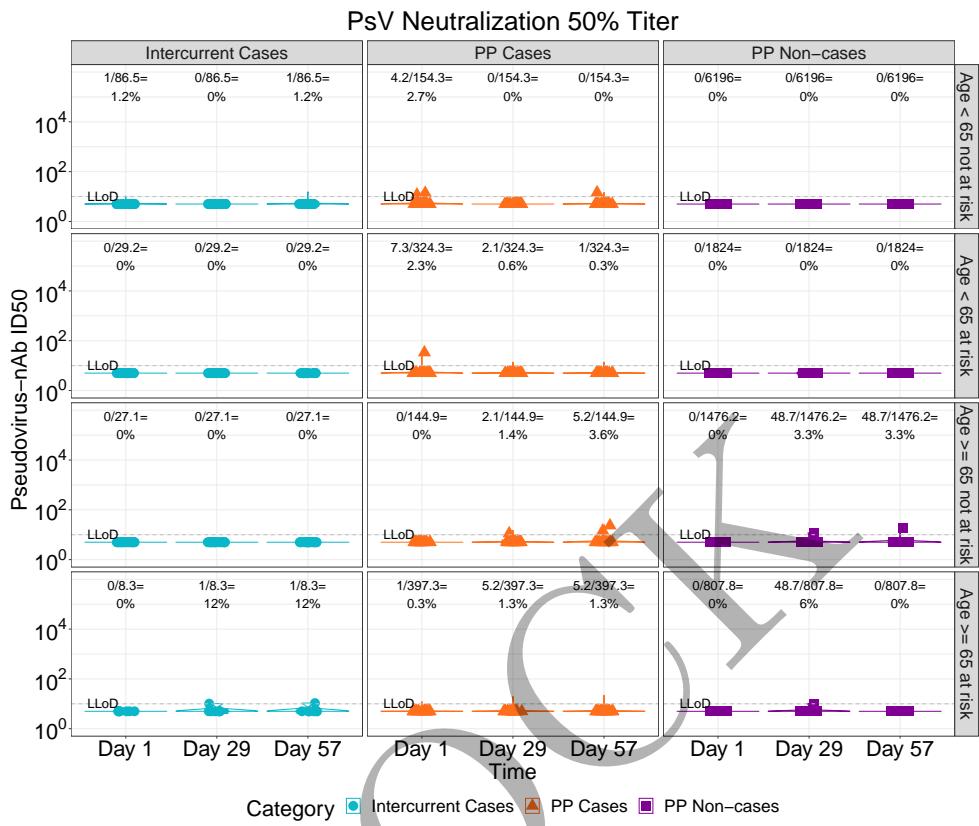


Figure 2.147: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age and risk condition (version 2)

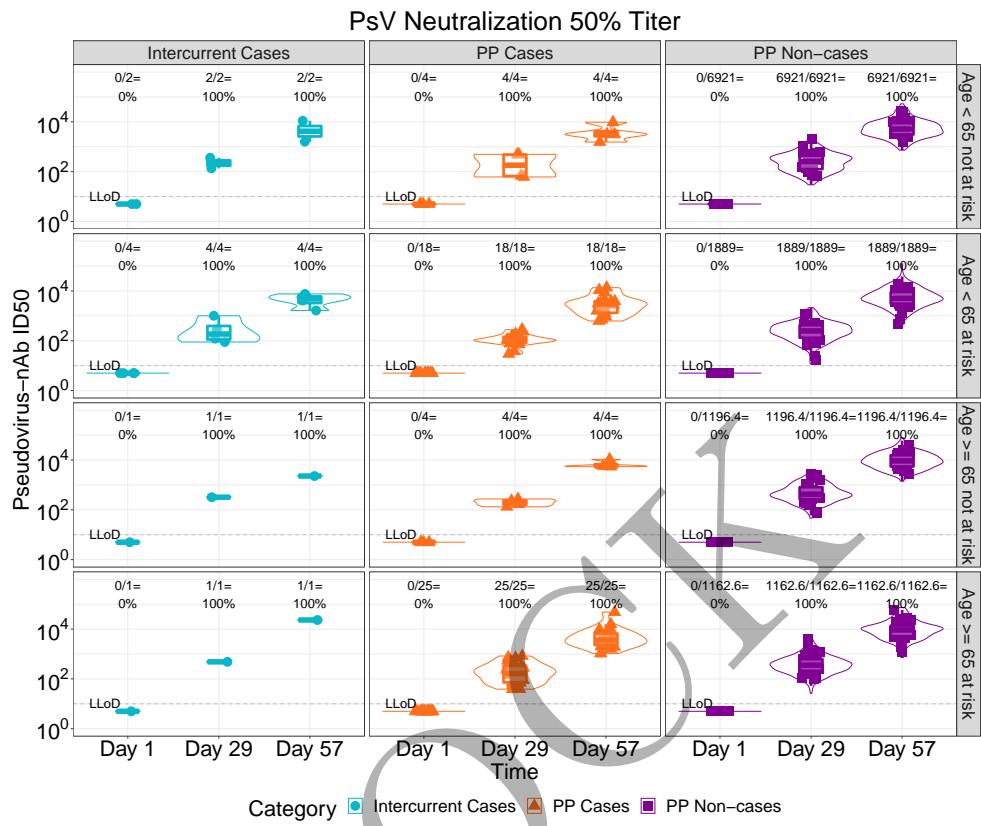


Figure 2.148: violinplots of Pseudovirus Neutralization ID₅₀: baseline negative vaccine arm by age and risk condition (version 2)

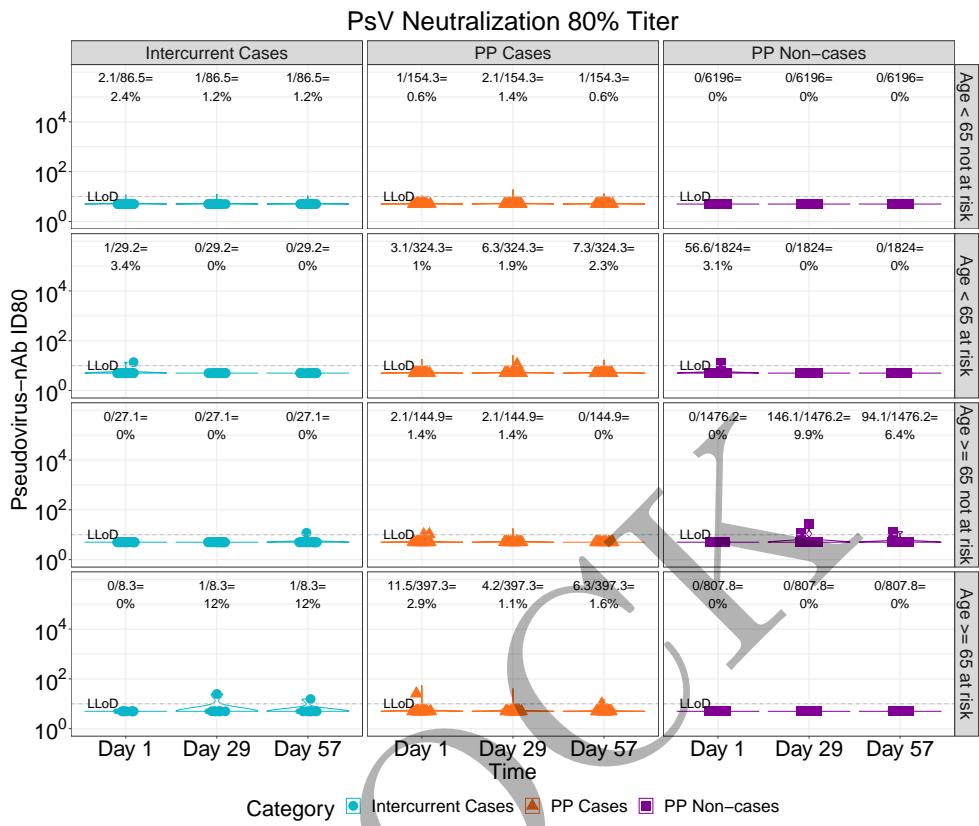


Figure 2.149: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age and risk condition (version 2)

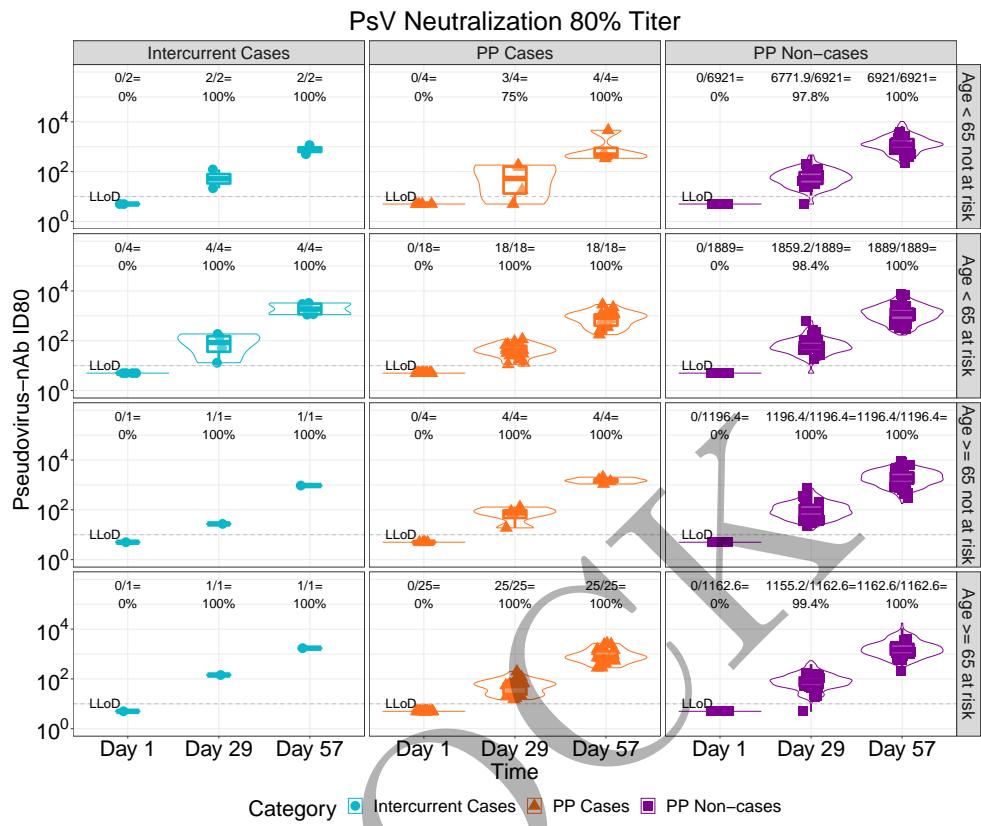


Figure 2.150: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age and risk condition (version 2)

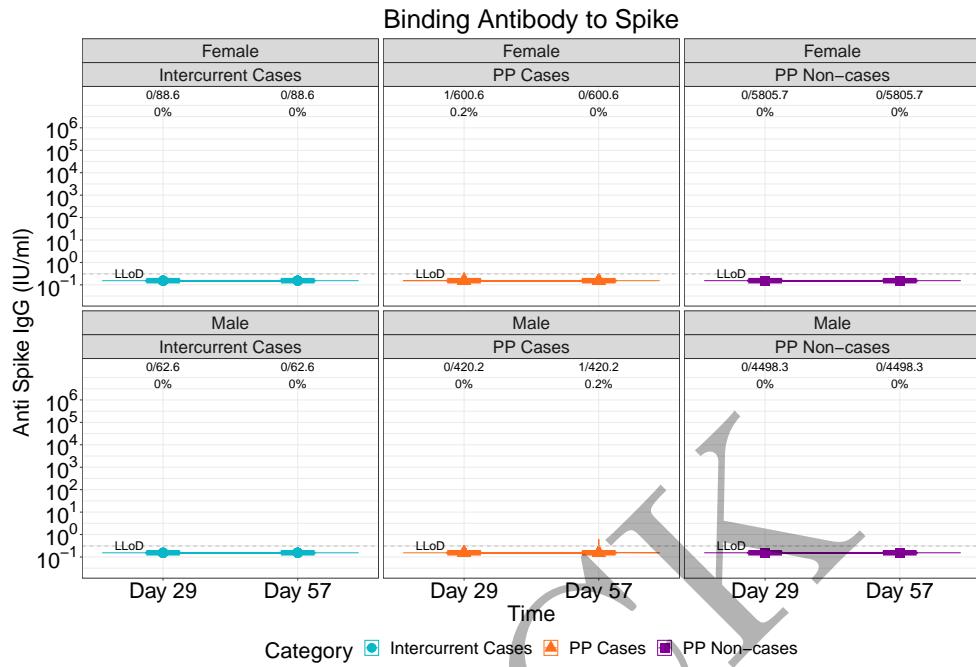


Figure 2.151: lineplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (version 1)

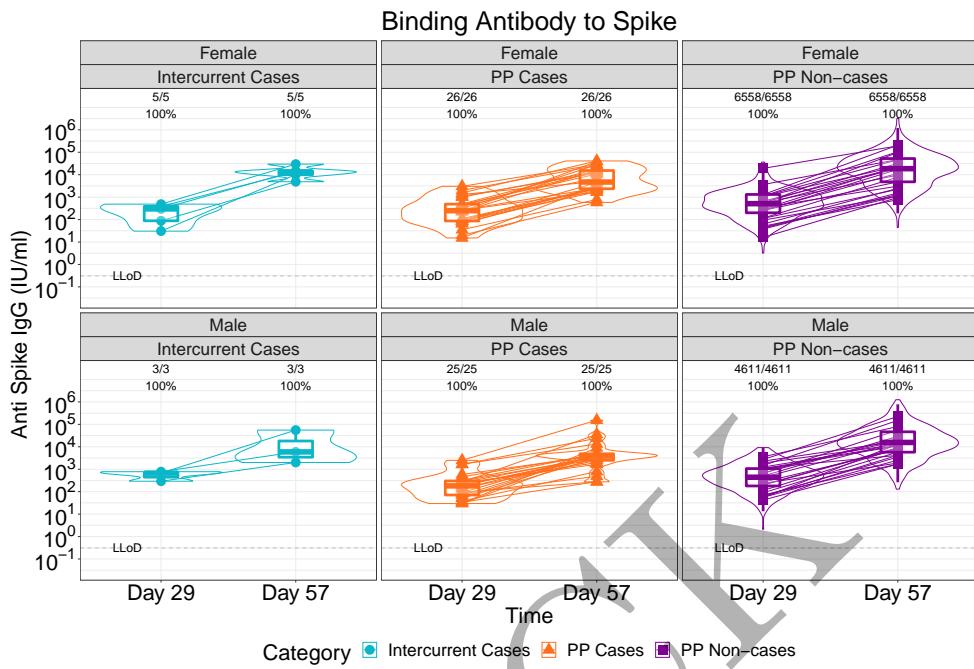


Figure 2.152: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (version 1)

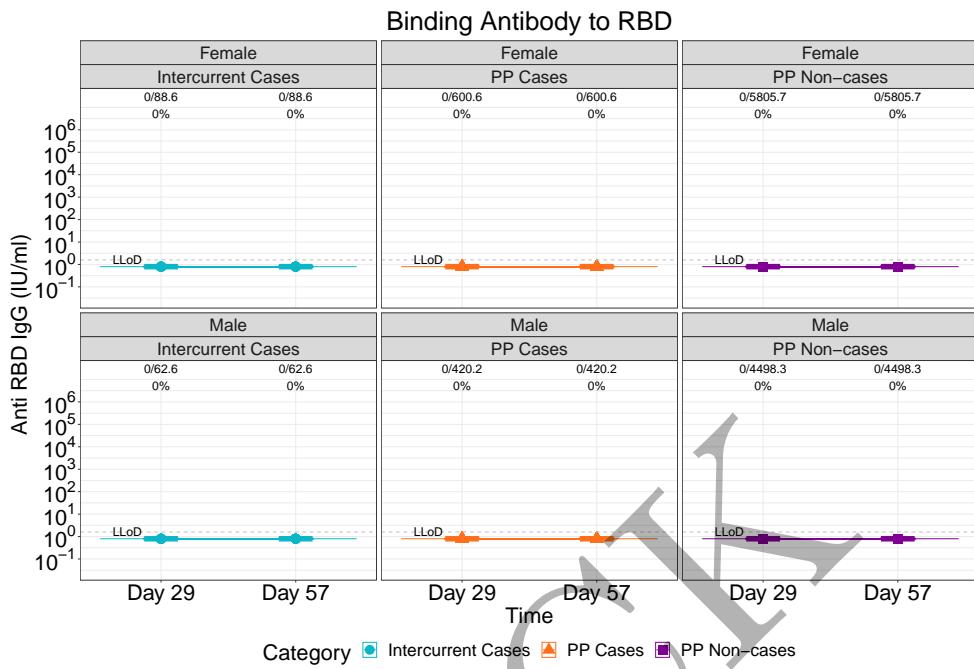


Figure 2.153: lineplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (version 1)

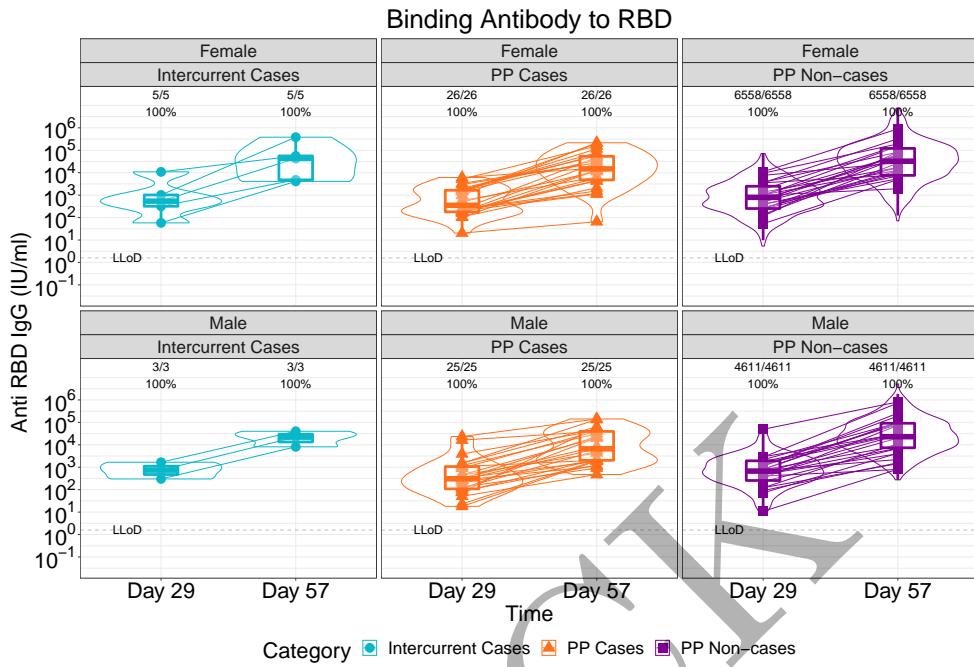


Figure 2.154: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (version 1)

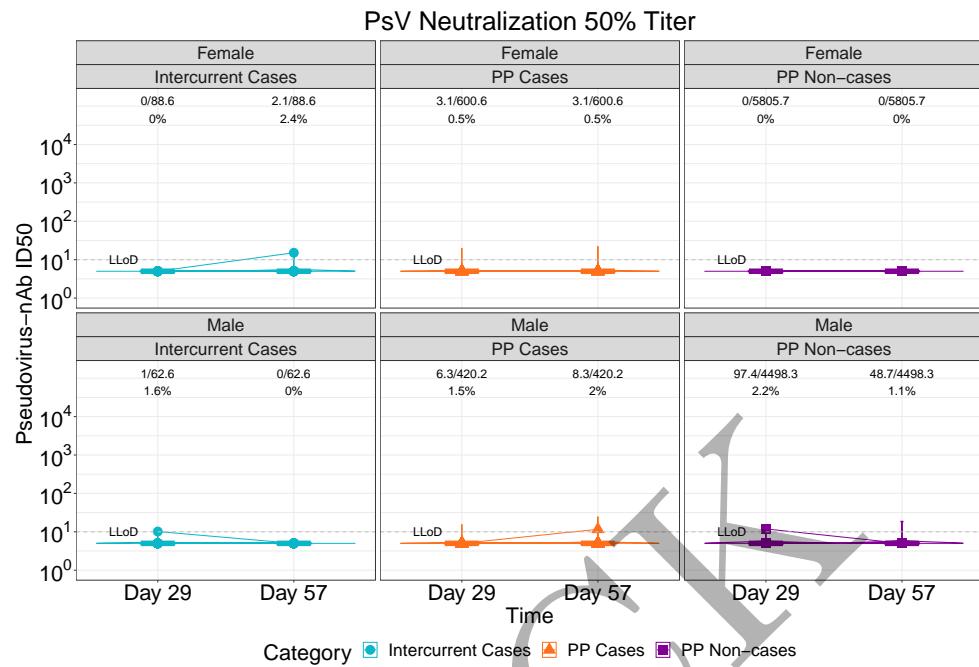


Figure 2.155: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by sex assigned at birth (version 1)

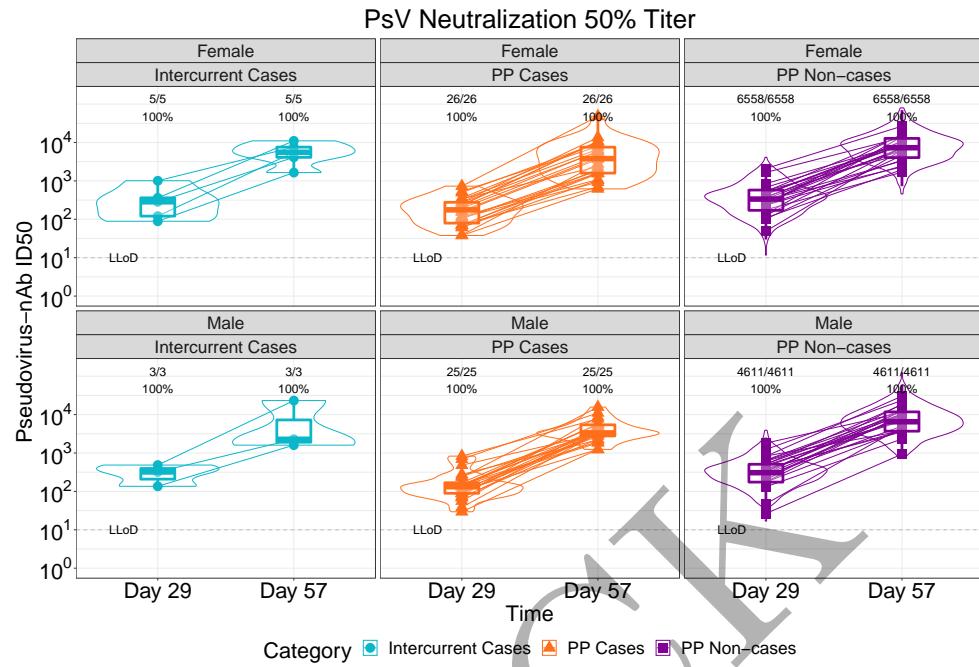


Figure 2.156: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by sex assigned at birth (version 1)

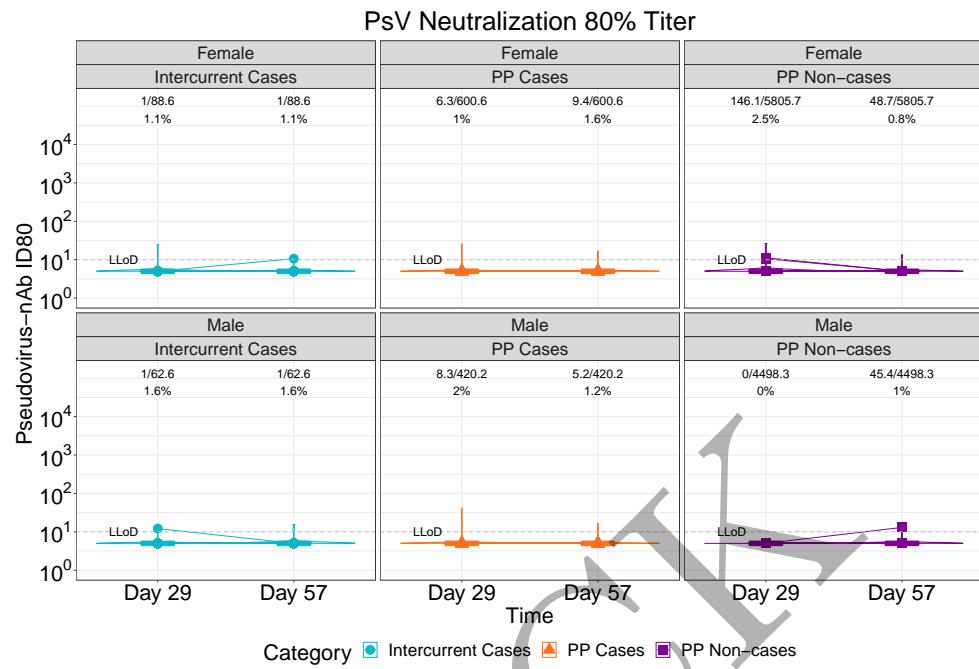


Figure 2.157: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by sex assigned at birth (version 1)

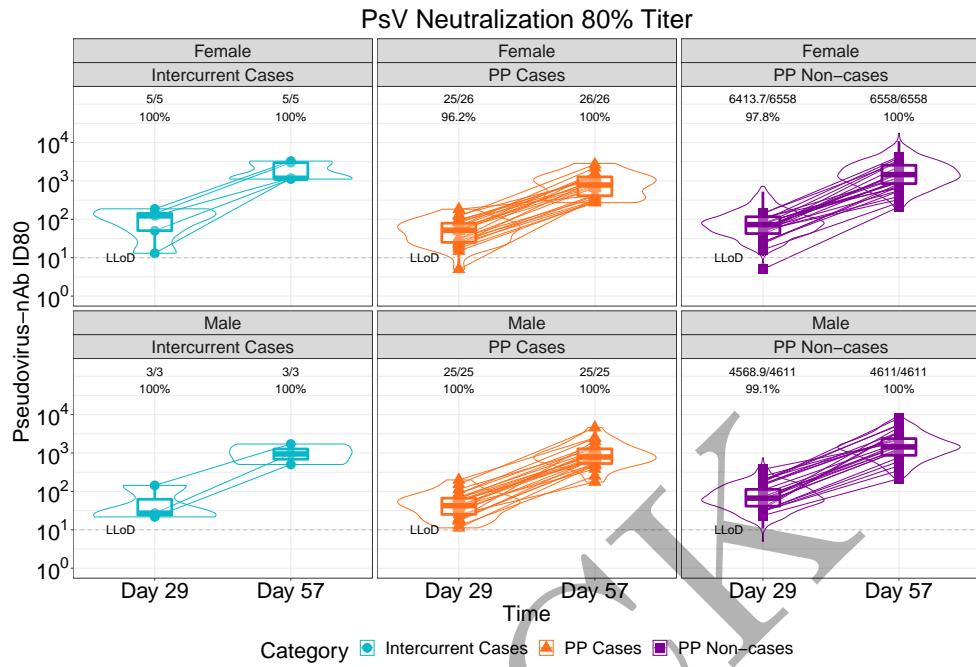


Figure 2.158: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by sex assigned at birth (version 1)

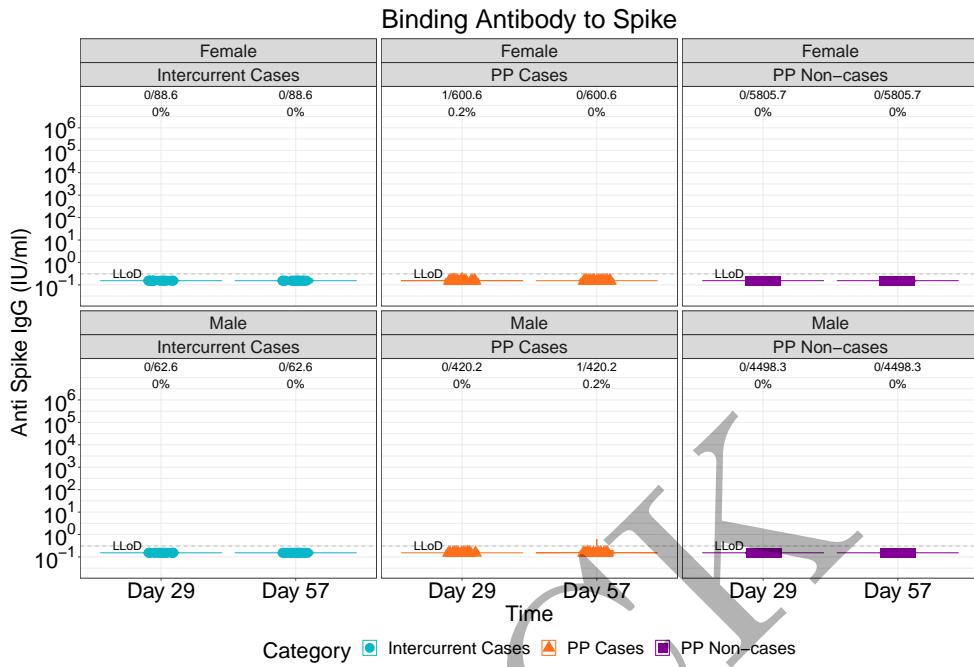


Figure 2.159: violinplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (version 1)

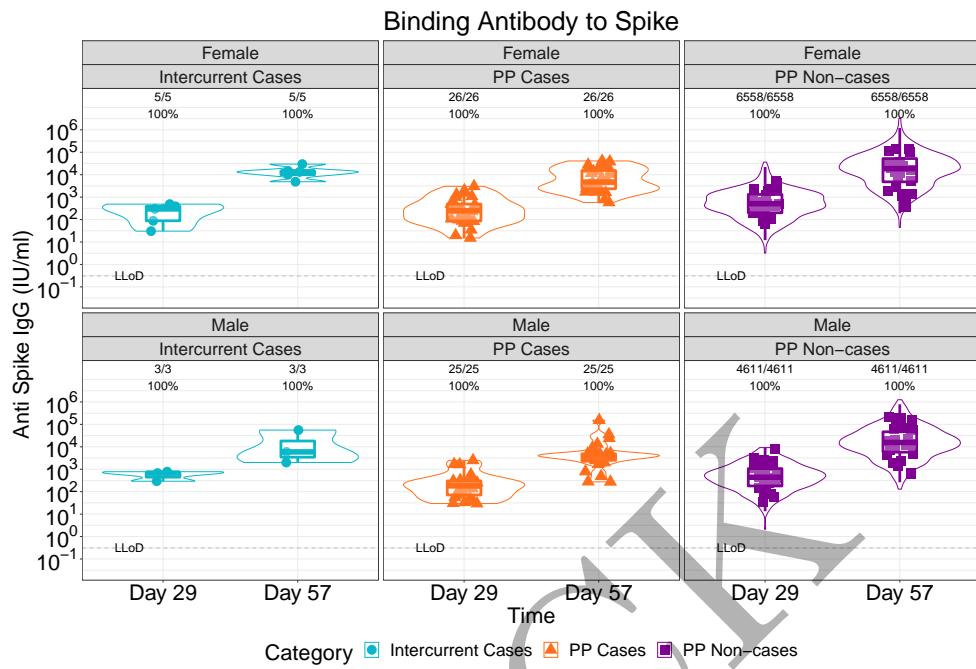


Figure 2.160: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (version 1)

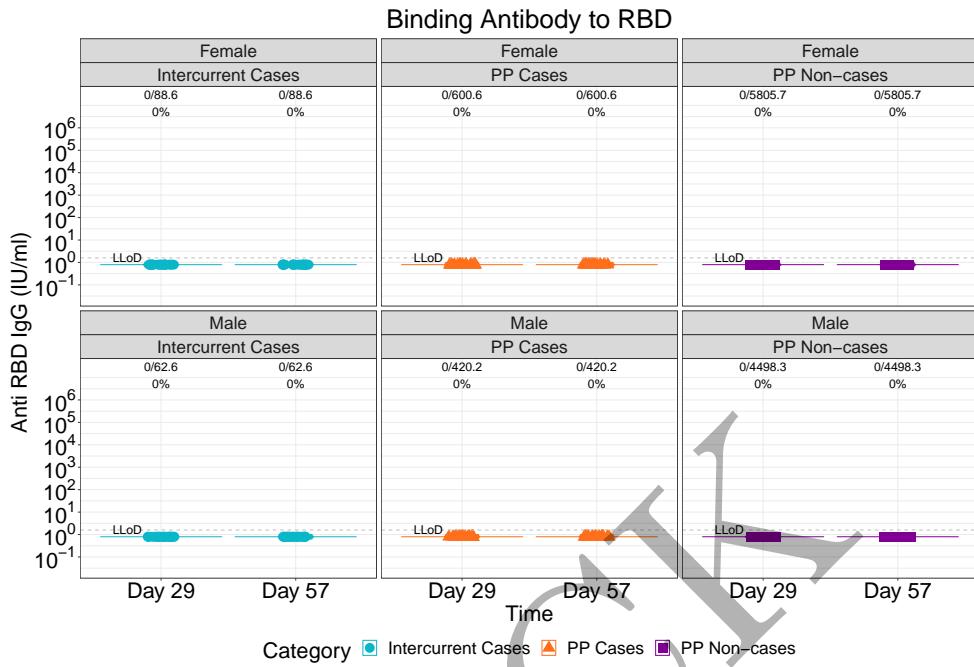


Figure 2.161: violinplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (version 1)

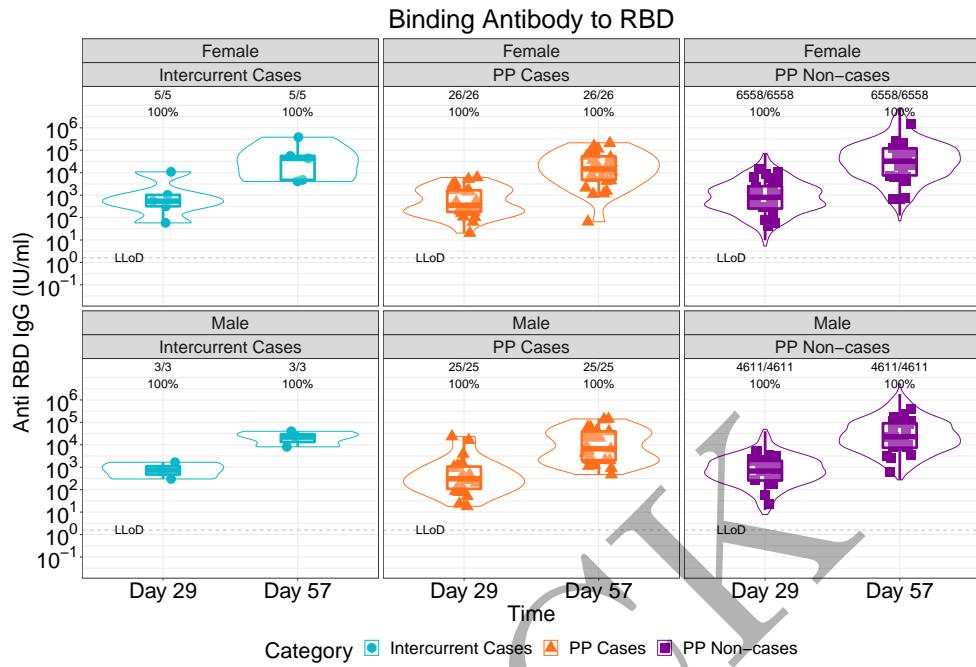


Figure 2.162: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (version 1)

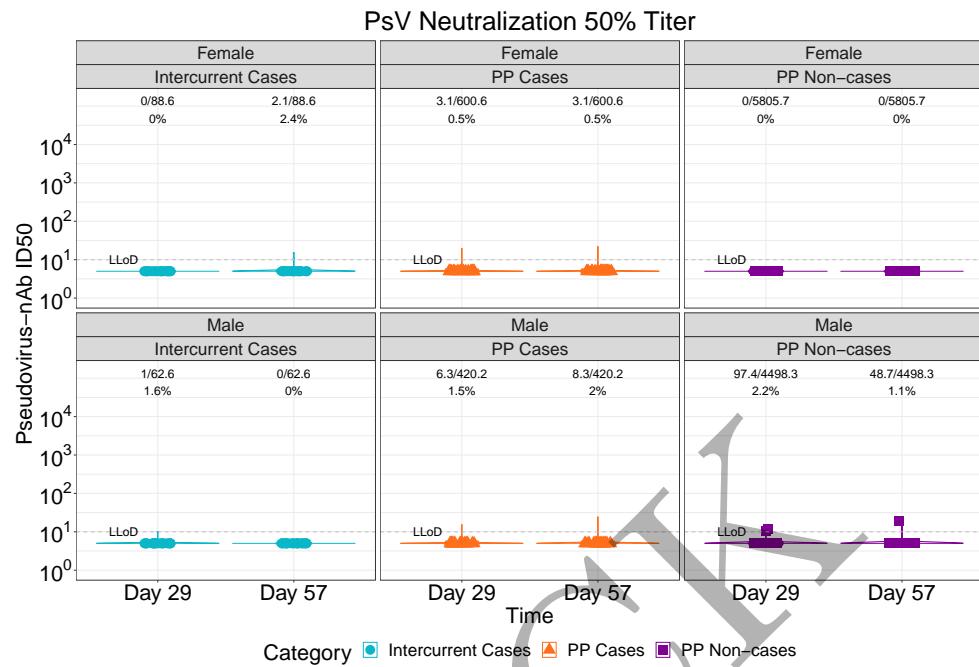


Figure 2.163: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by sex assigned at birth (version 1)

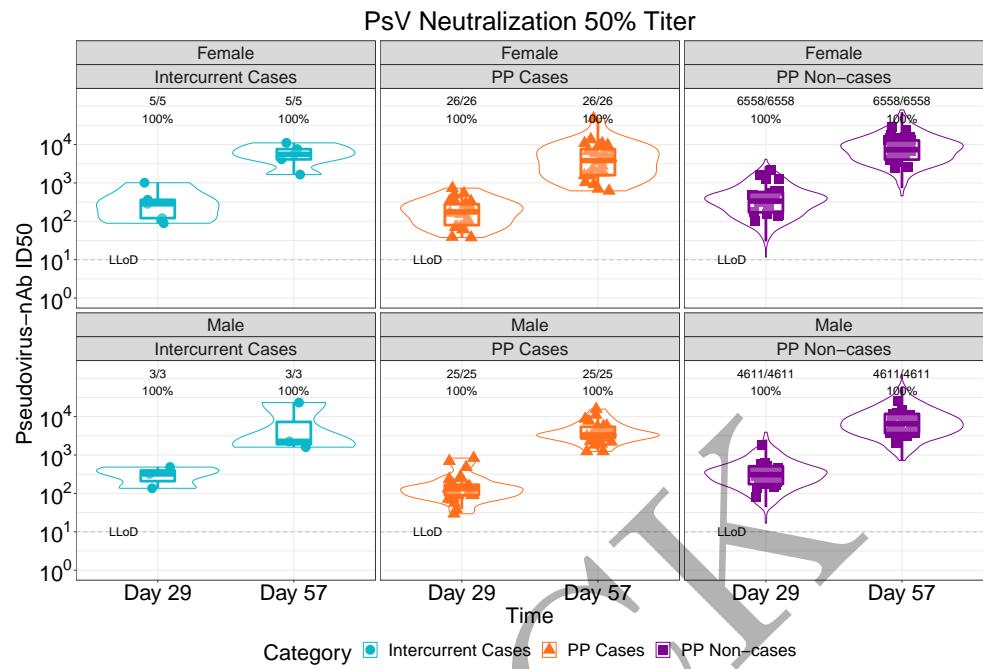


Figure 2.164: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by sex assigned at birth (version 1)

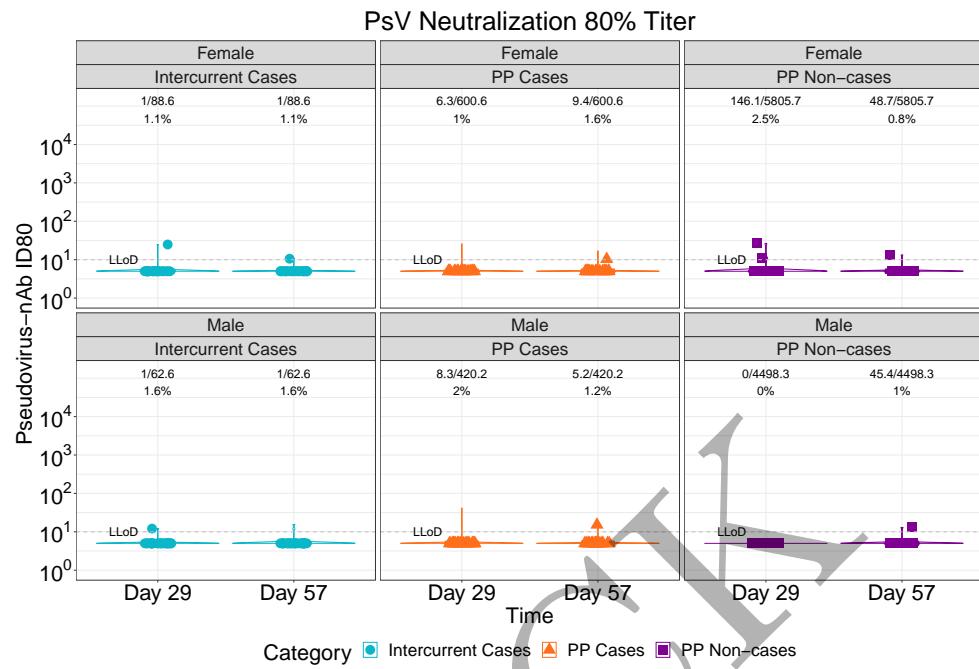


Figure 2.165: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by sex assigned at birth (version 1)

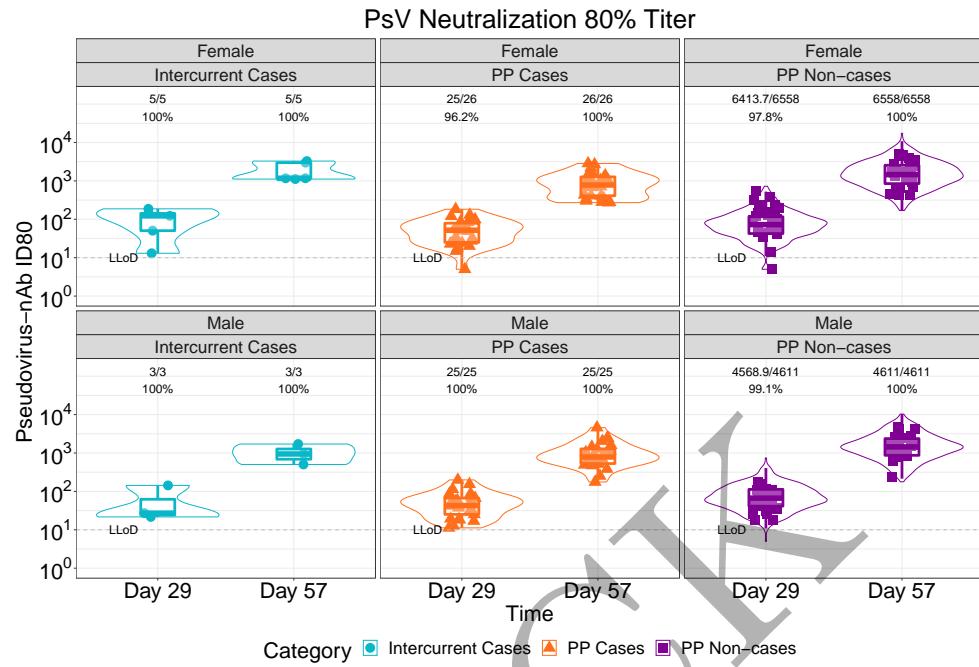


Figure 2.166: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by sex assigned at birth (version 1)

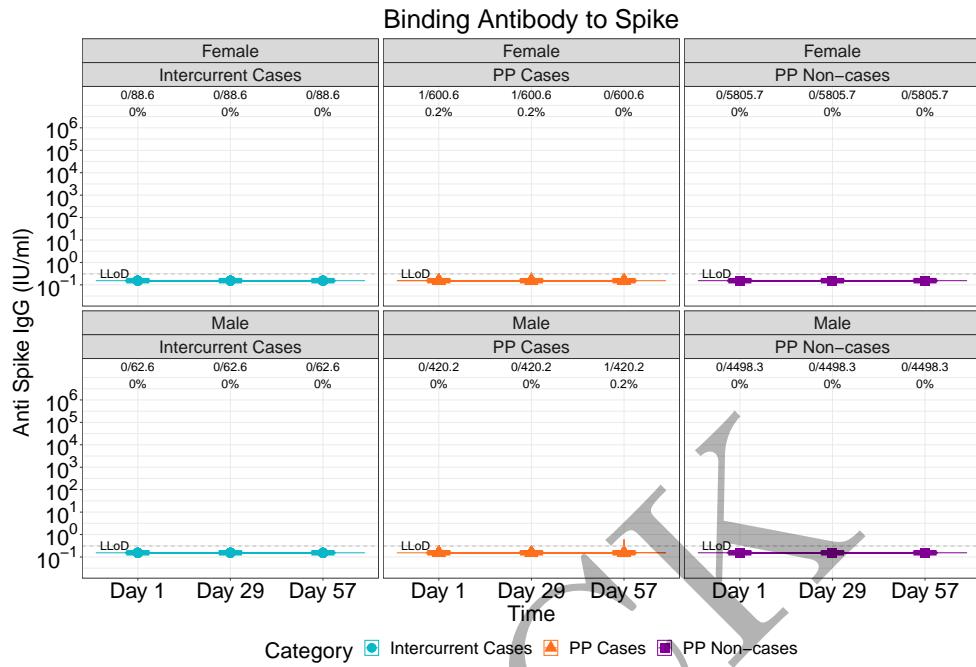


Figure 2.167: lineplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (version 2)

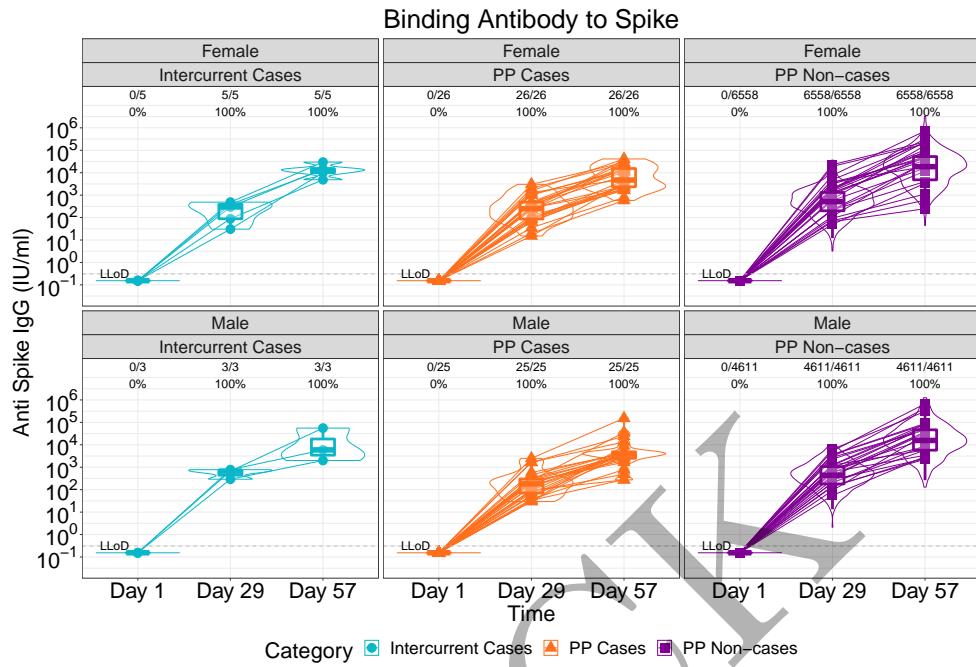


Figure 2.168: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (version 2)

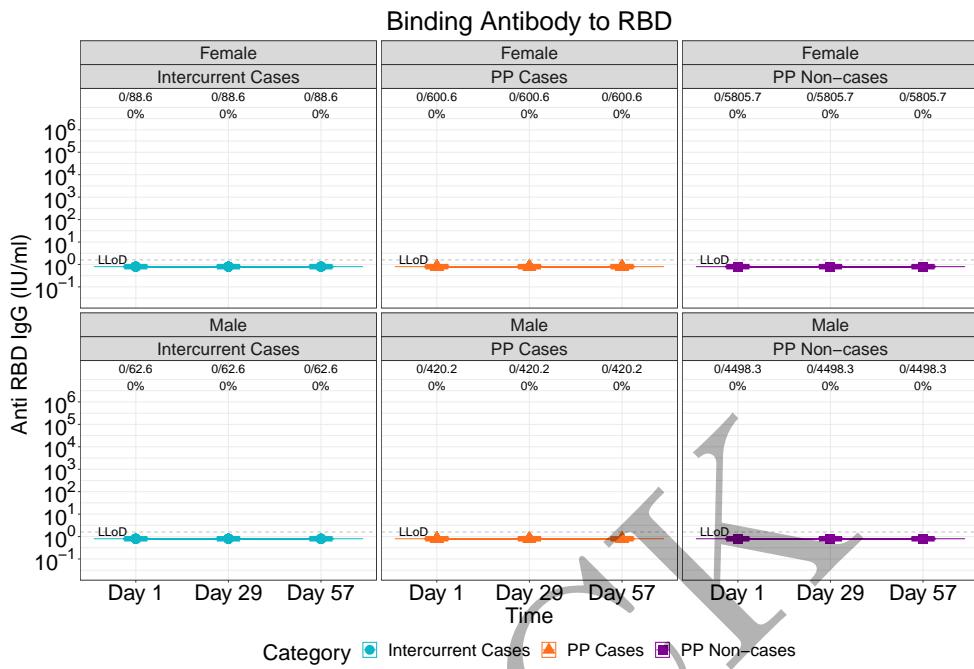


Figure 2.169: lineplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (version 2)

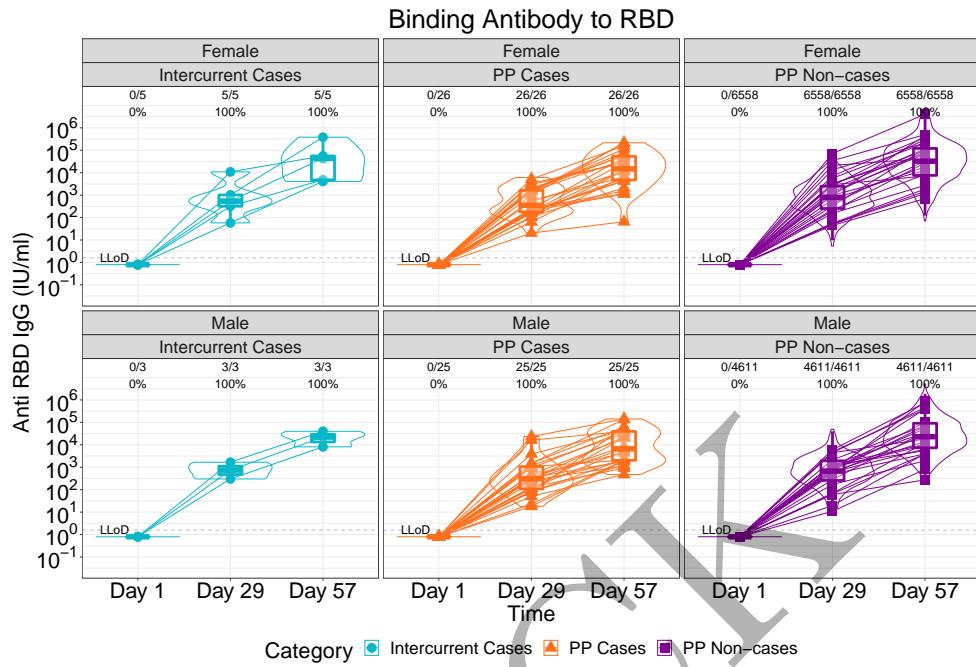


Figure 2.170: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (version 2)

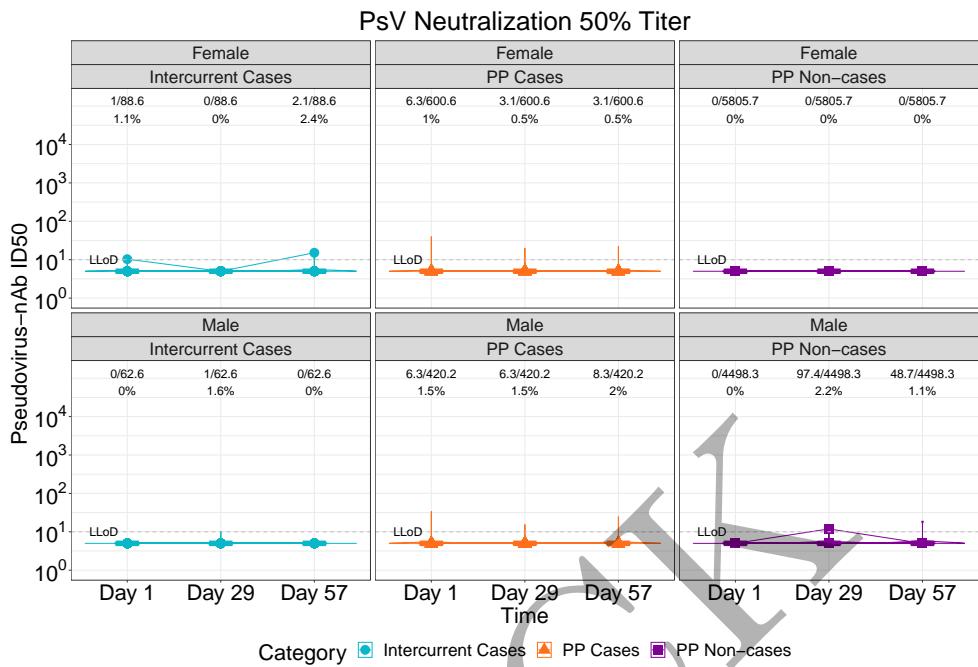


Figure 2.171: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by sex assigned at birth (version 2)

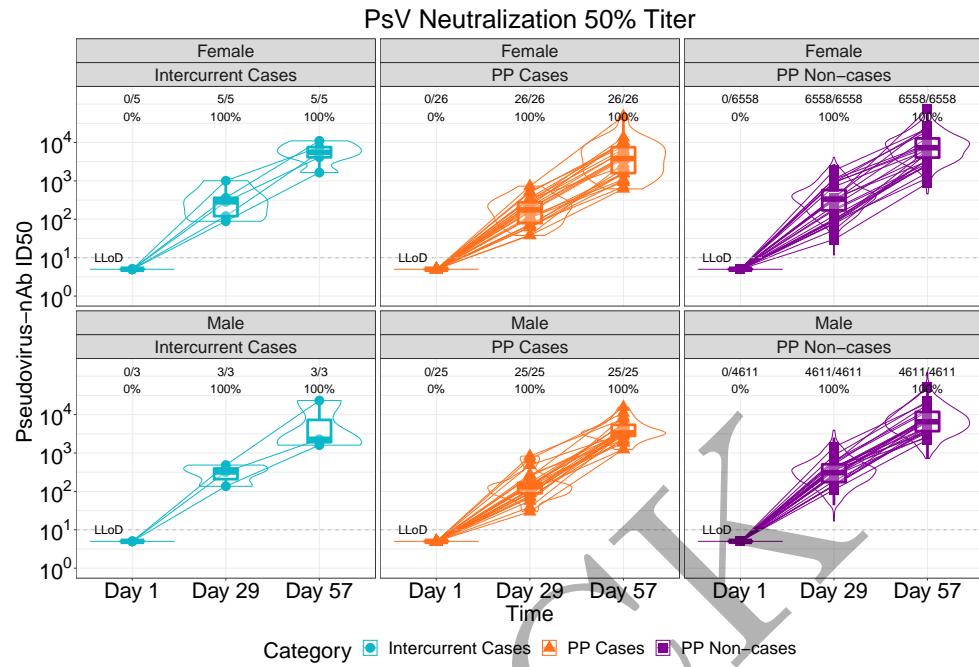


Figure 2.172: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by sex assigned at birth (version 2)

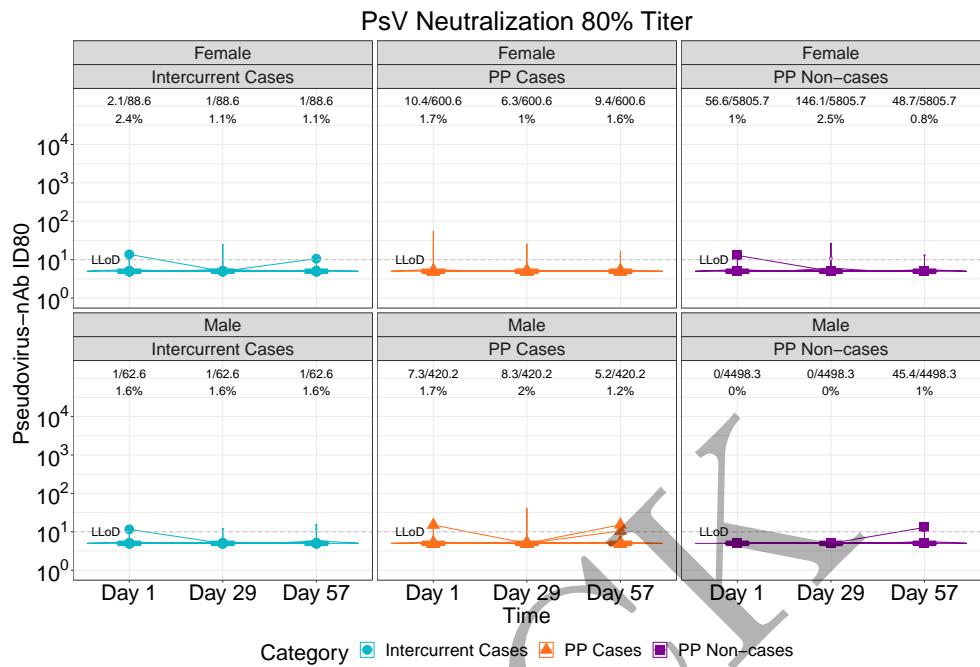


Figure 2.173: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by sex assigned at birth (version 2)

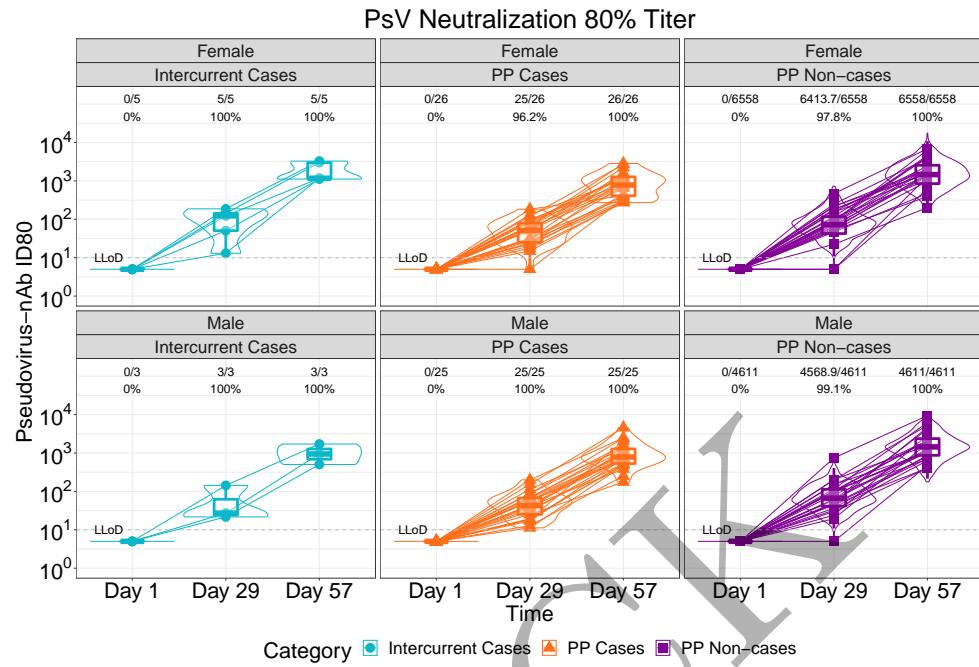


Figure 2.174: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by sex assigned at birth (version 2)

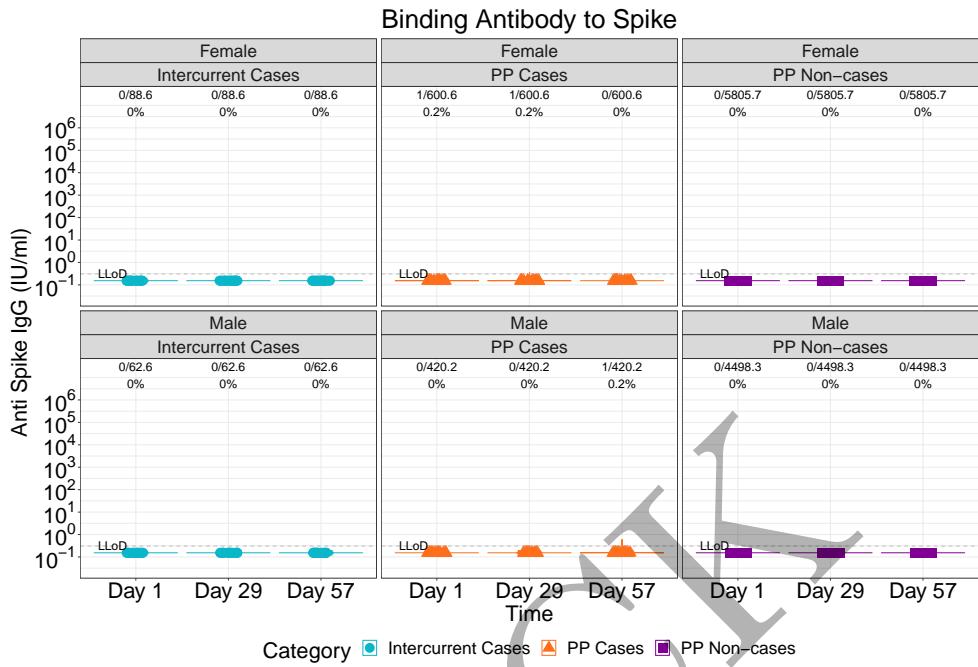


Figure 2.175: violinplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (version 2)

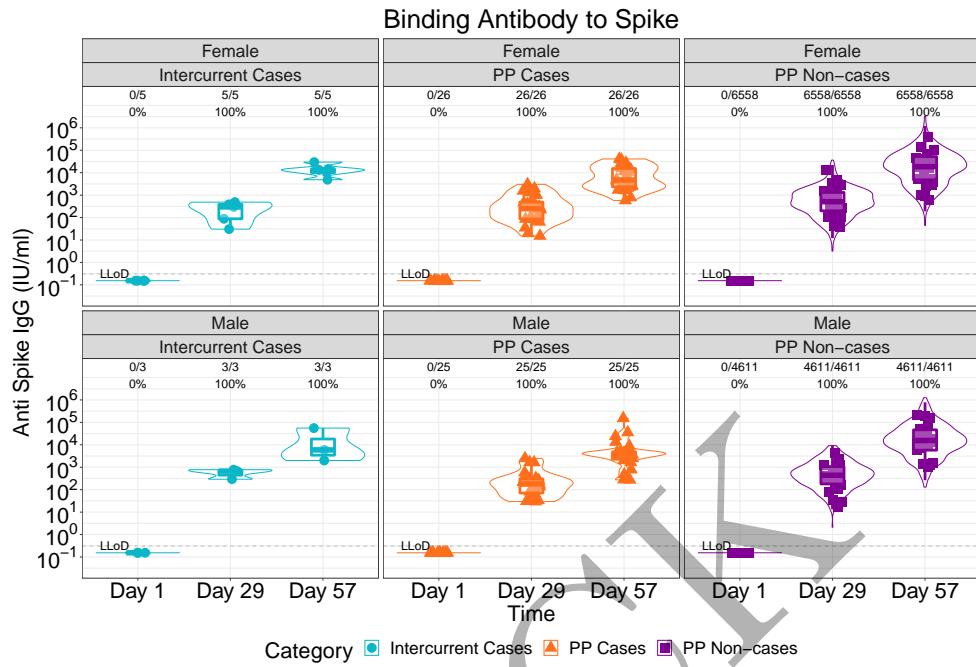


Figure 2.176: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (version 2)

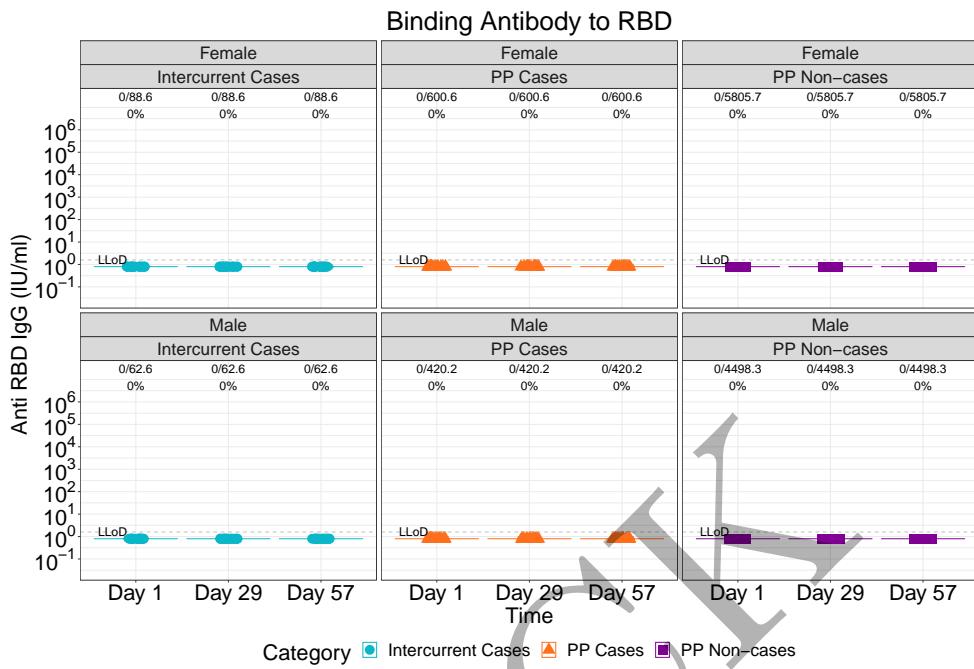


Figure 2.177: violinplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (version 2)

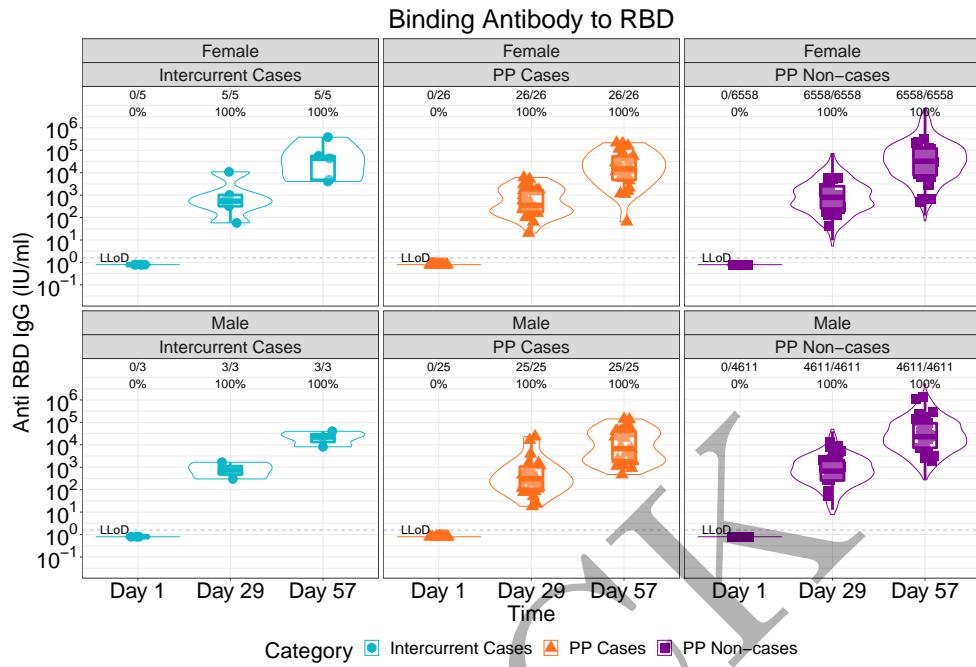


Figure 2.178: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (version 2)

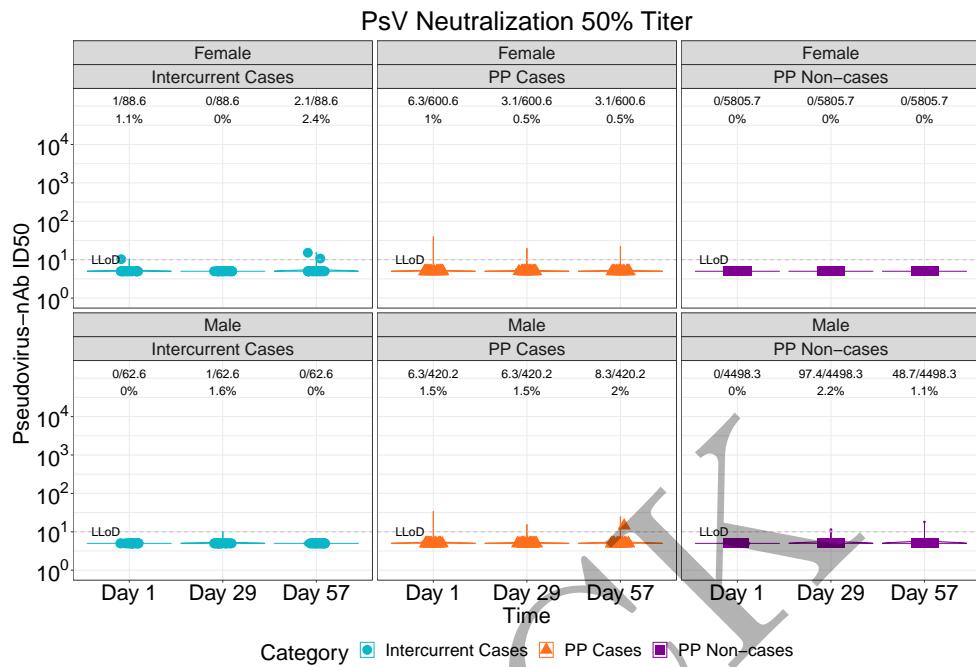


Figure 2.179: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by sex assigned at birth (version 2)

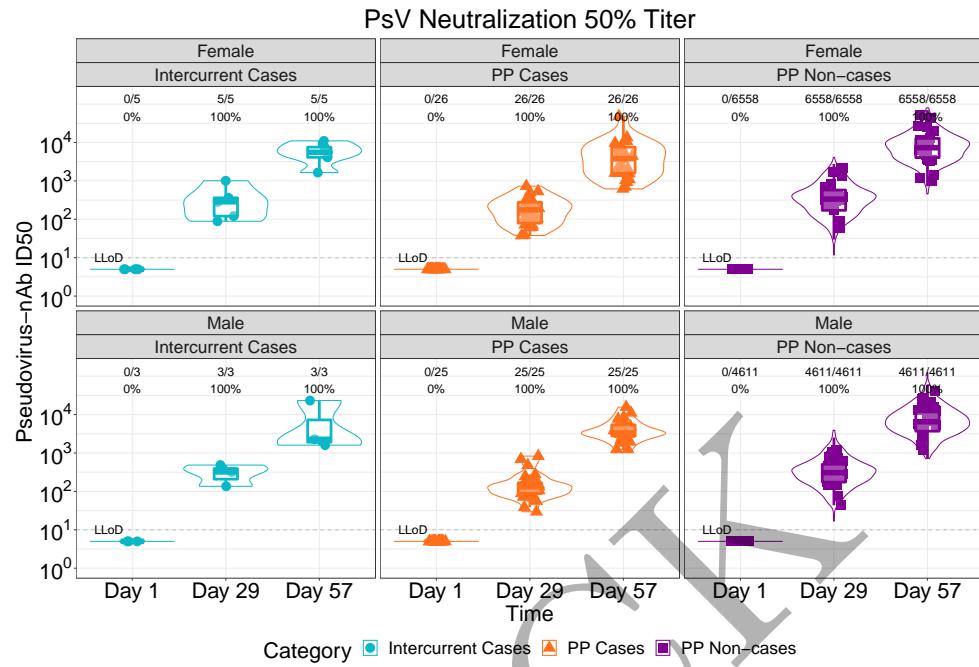


Figure 2.180: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by sex assigned at birth (version 2)

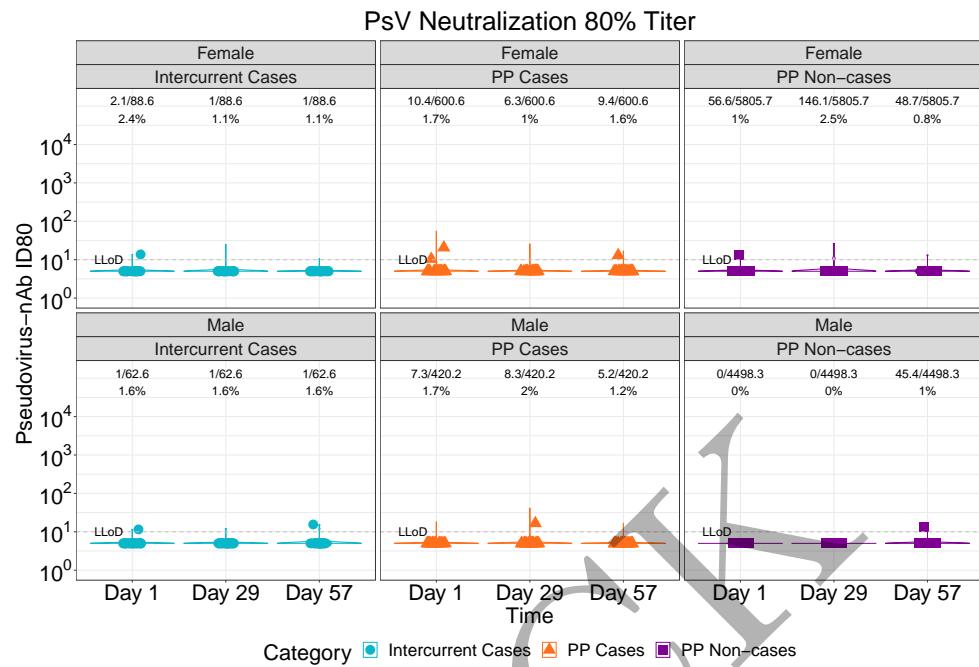


Figure 2.181: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by sex assigned at birth (version 2)

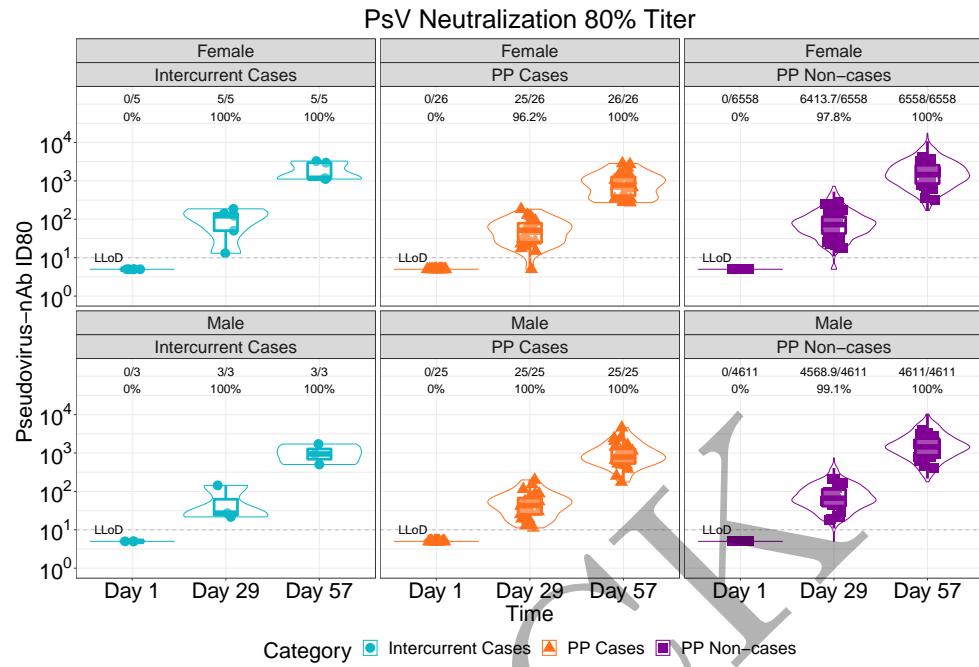


Figure 2.182: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by sex assigned at birth (version 2)

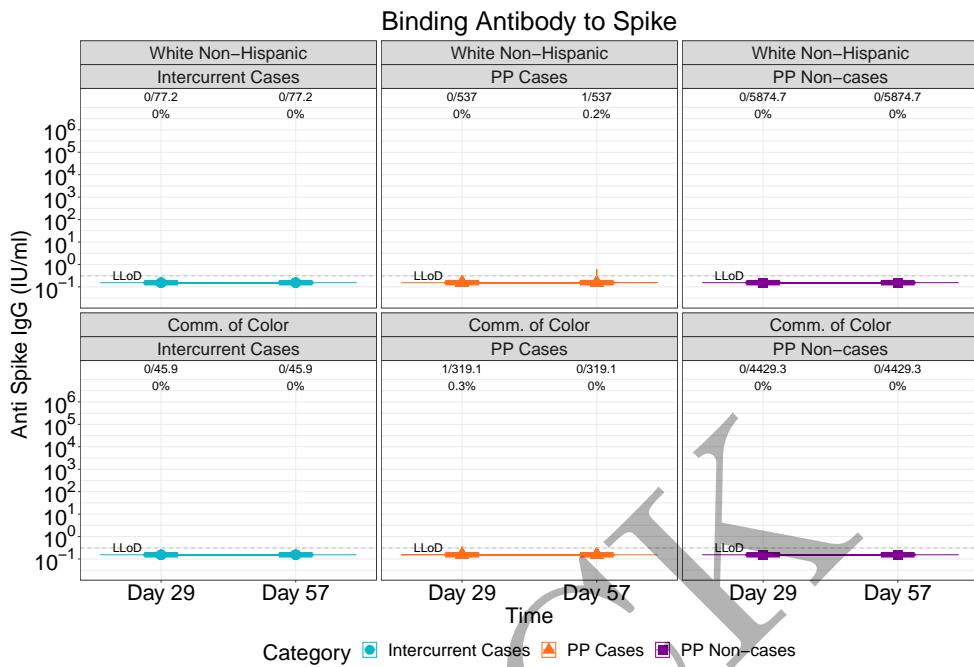


Figure 2.183: lineplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (version 1)

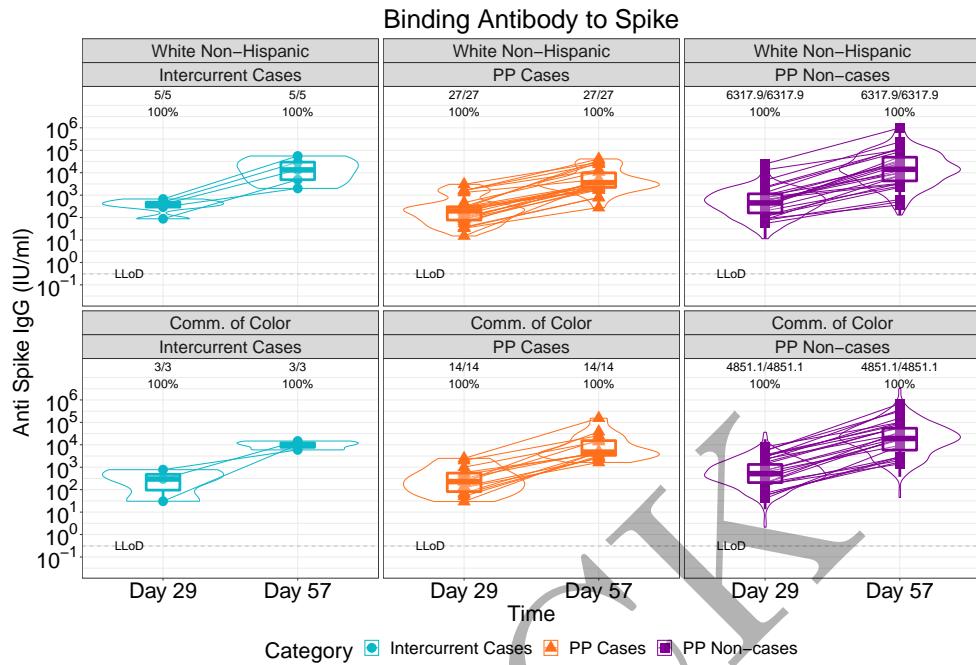


Figure 2.184: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (version 1)

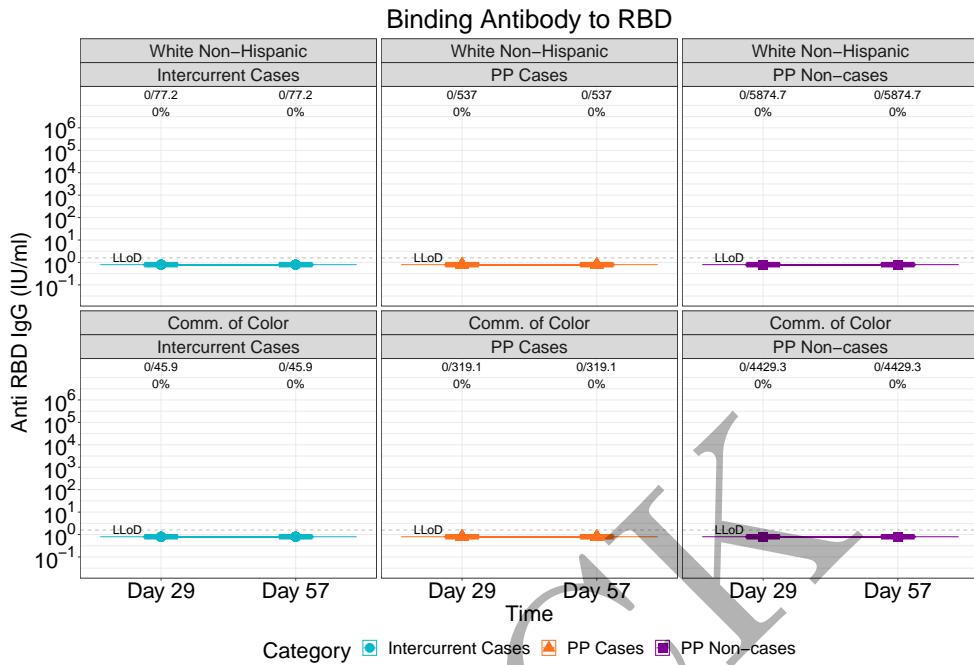


Figure 2.185: lineplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (version 1)

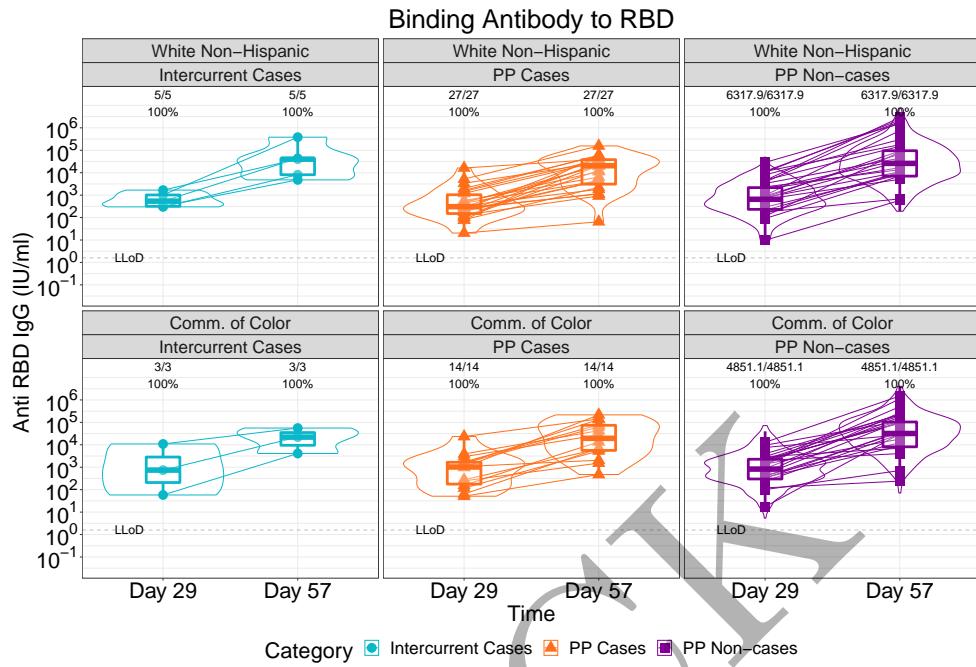


Figure 2.186: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (version 1)

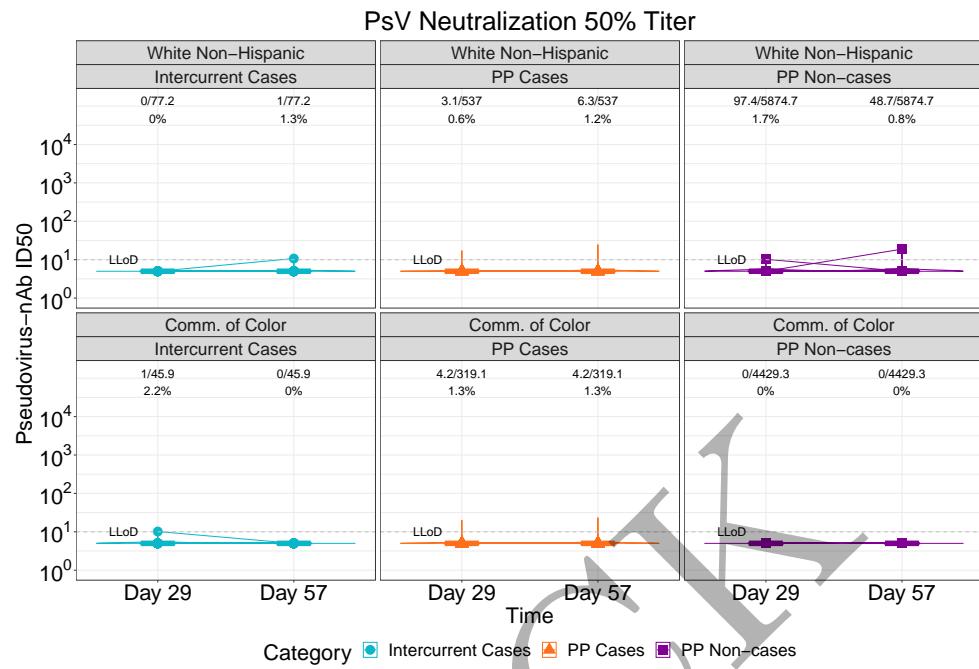


Figure 2.187: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by race and ethnic group (version 1)

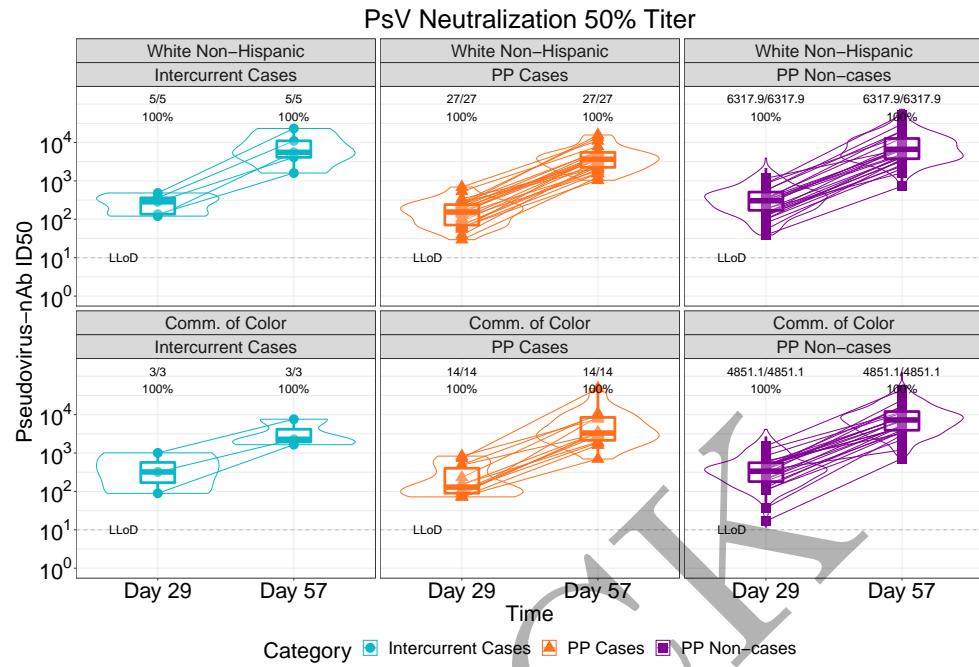


Figure 2.188: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by race and ethnic group (version 1)

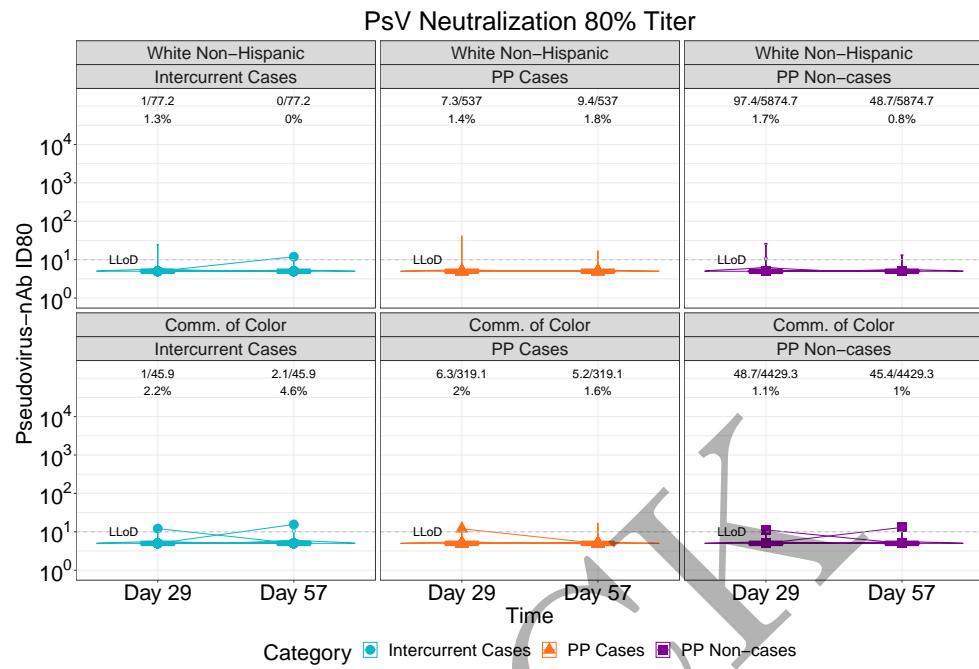


Figure 2.189: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by race and ethnic group (version 1)

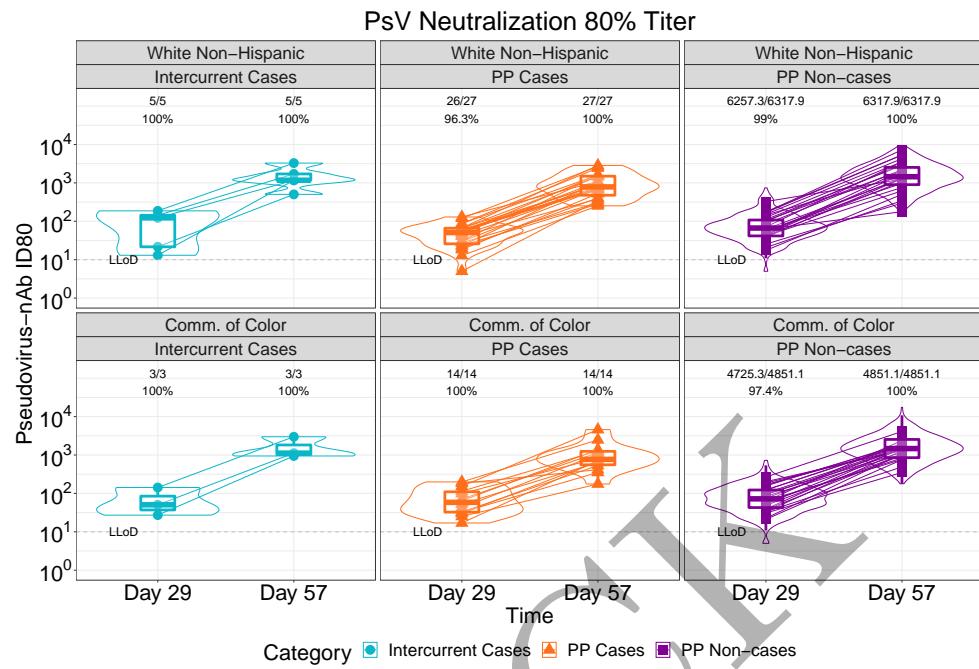


Figure 2.190: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by race and ethnic group (version 1)

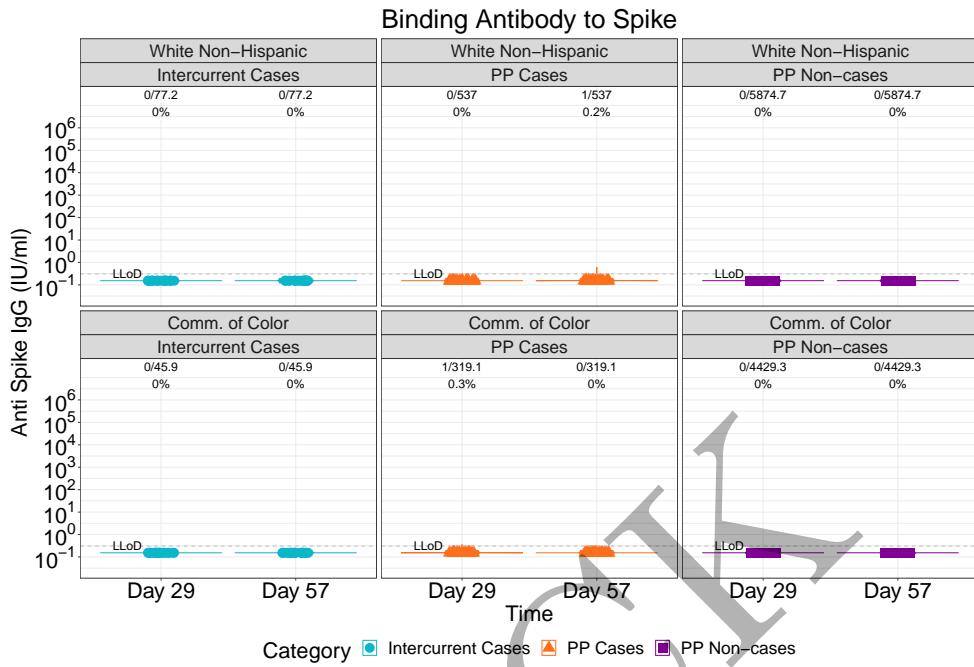


Figure 2.191: violinplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (version 1)

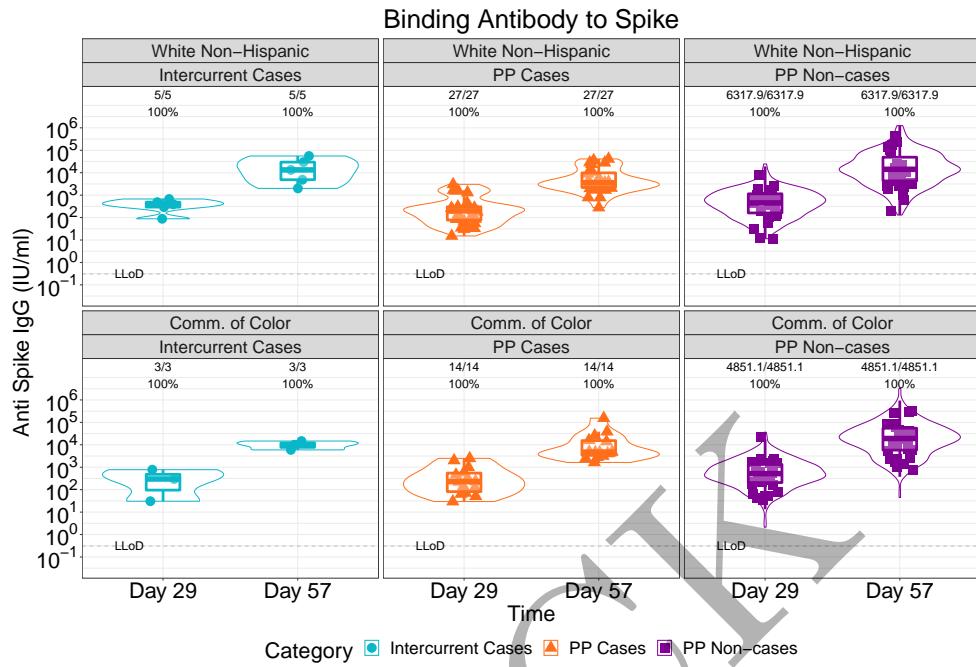


Figure 2.192: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (version 1)

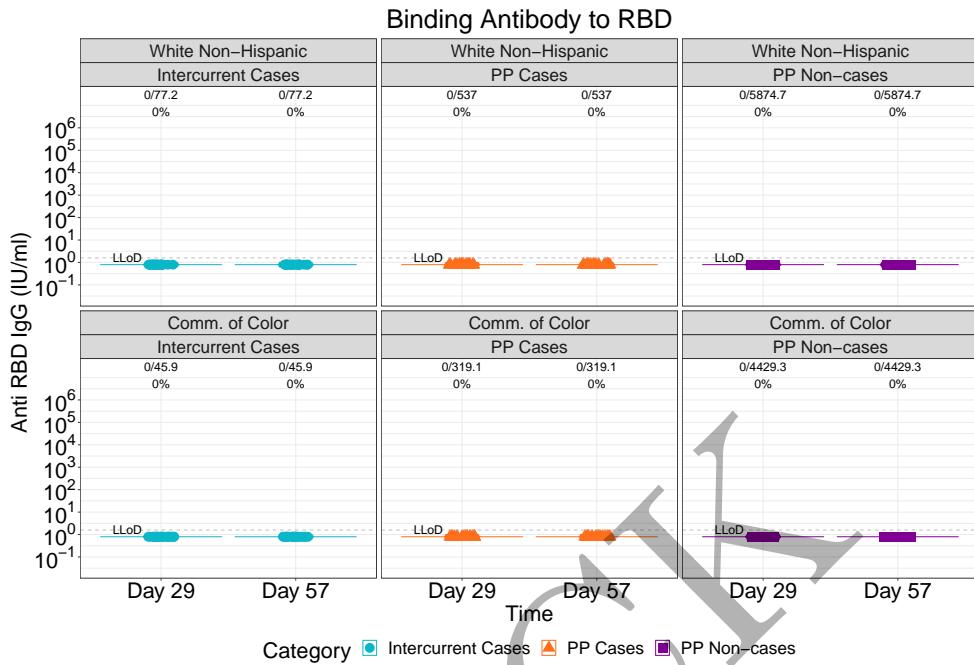


Figure 2.193: violinplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (version 1)

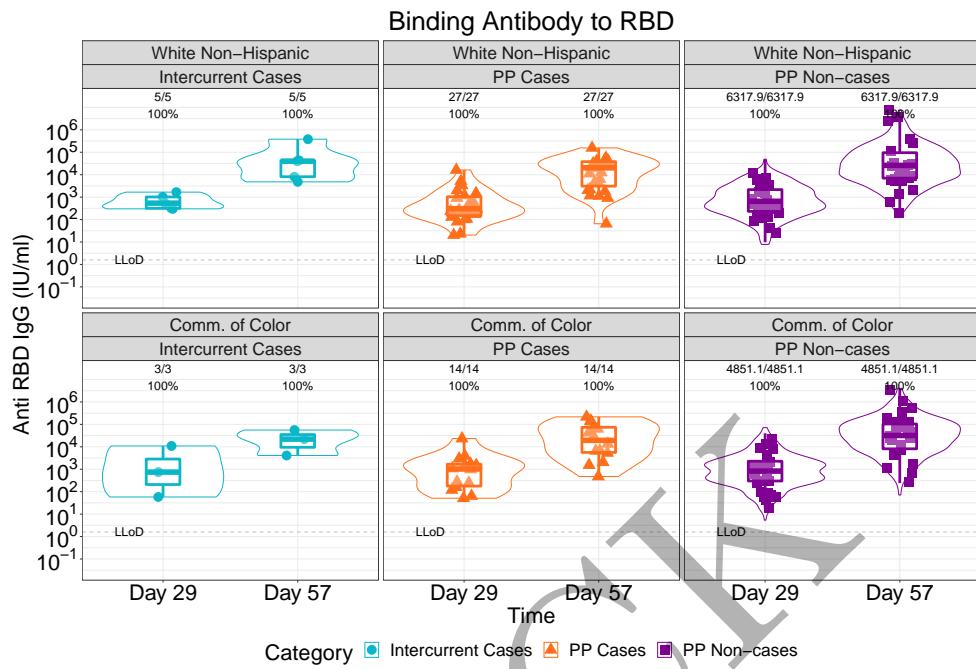


Figure 2.194: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (version 1)

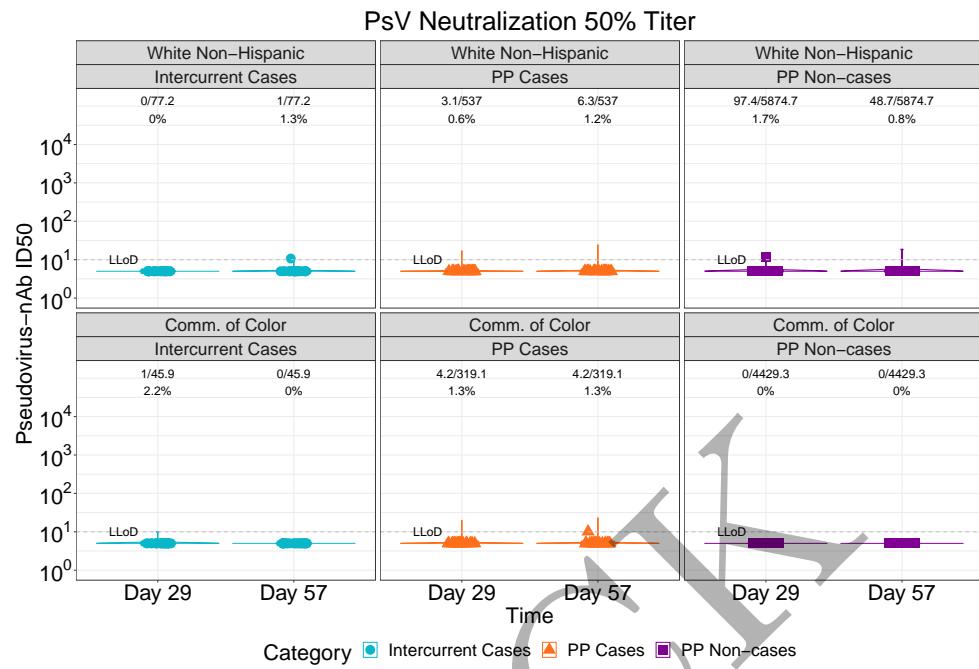


Figure 2.195: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by race and ethnic group (version 1)

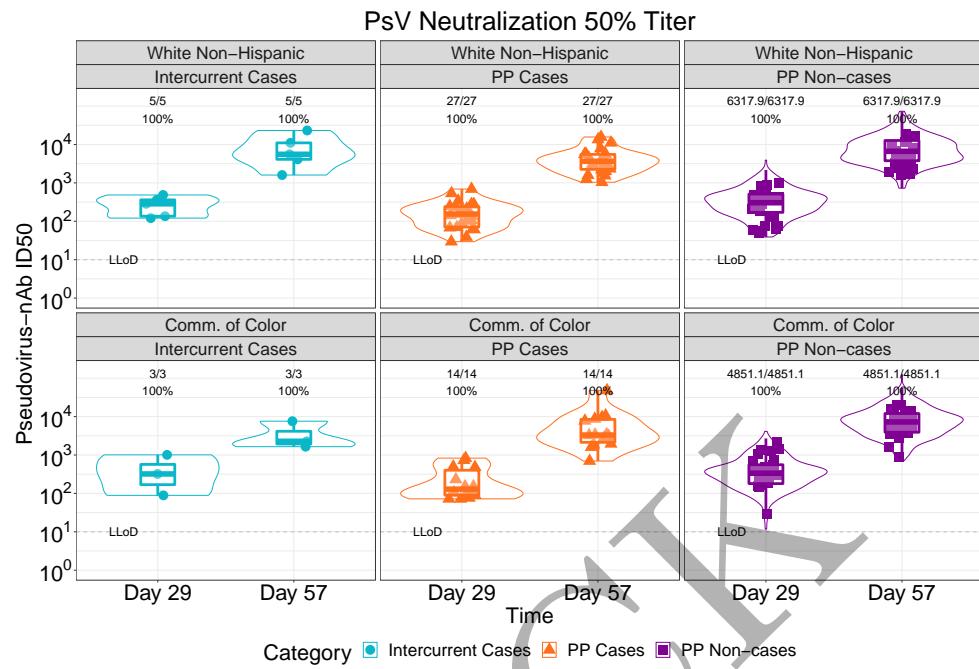


Figure 2.196: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by race and ethnic group (version 1)

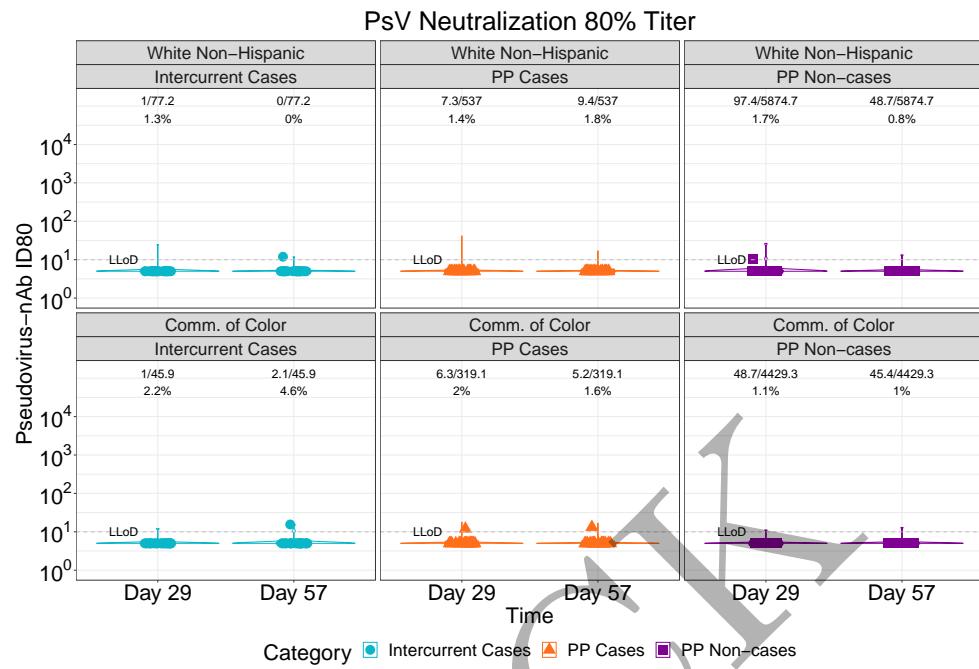


Figure 2.197: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by race and ethnic group (version 1)

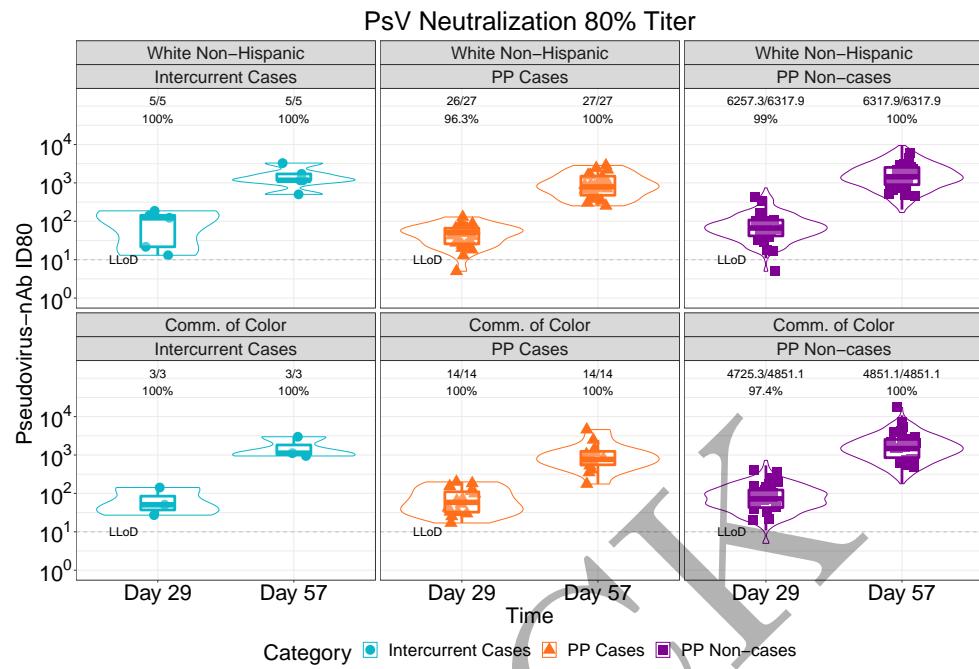


Figure 2.198: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by race and ethnic group (version 1)

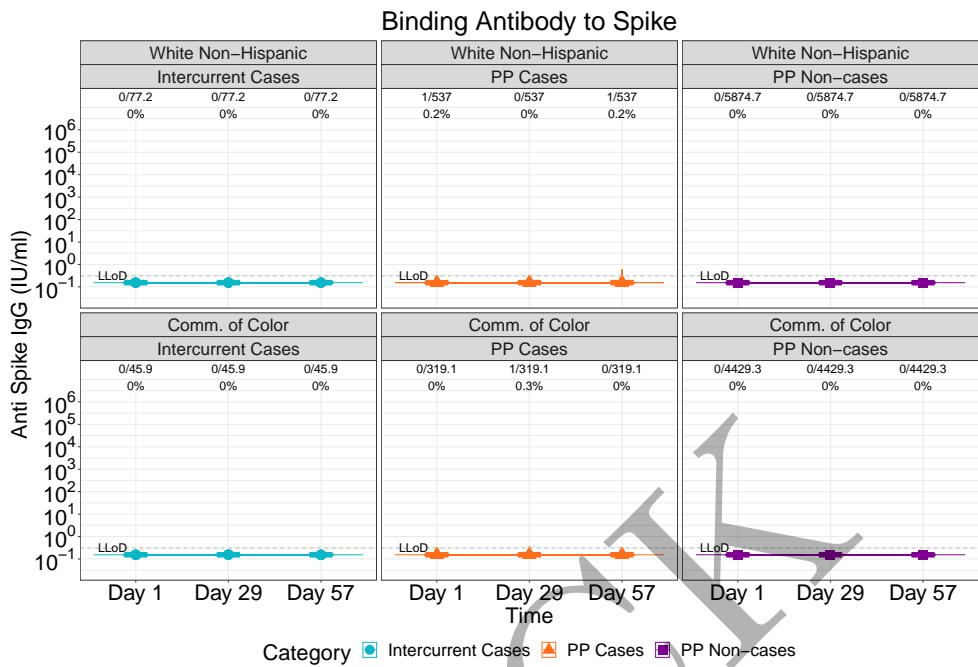


Figure 2.199: lineplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (version 2)

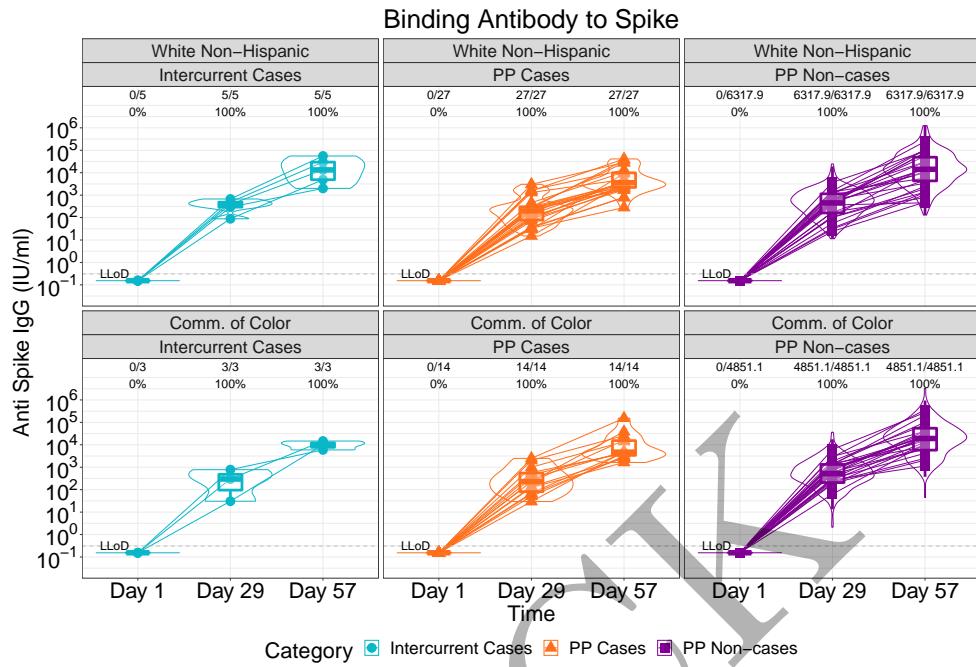


Figure 2.200: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (version 2)

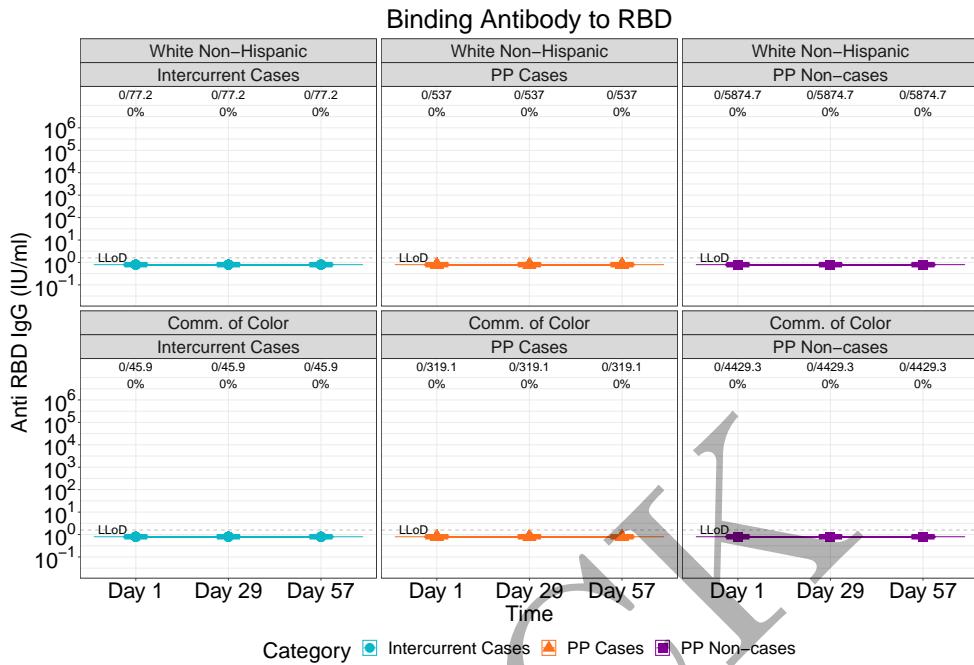


Figure 2.201: lineplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (version 2)

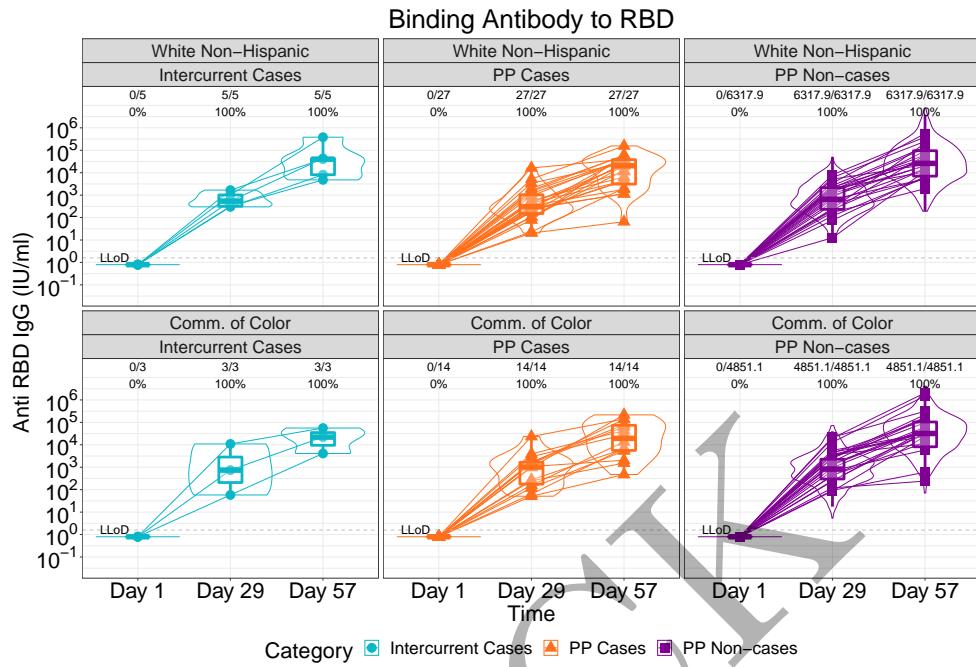


Figure 2.202: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (version 2)

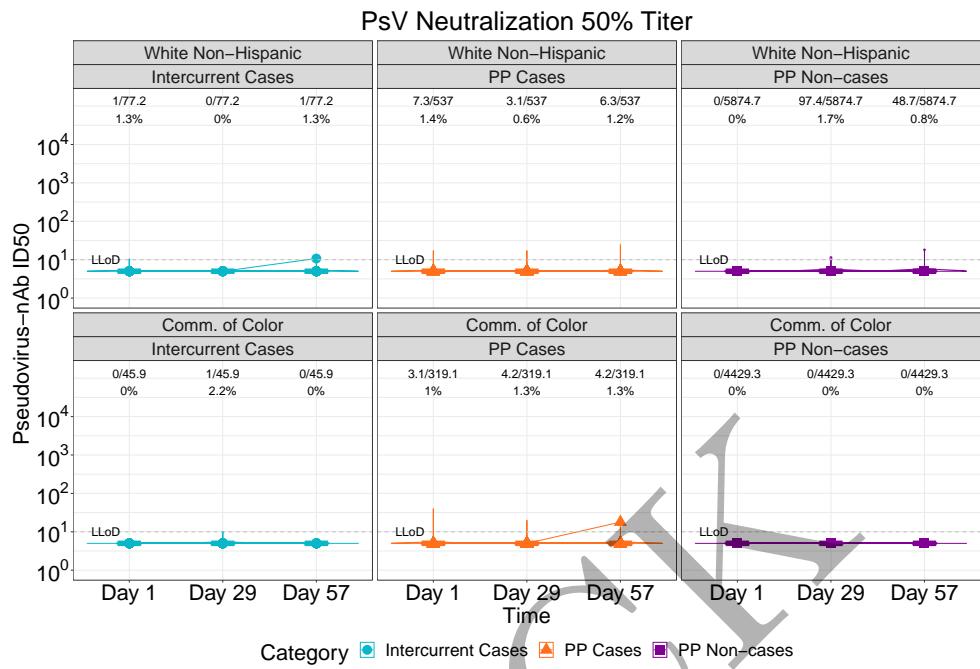


Figure 2.203: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by race and ethnic group (version 2)

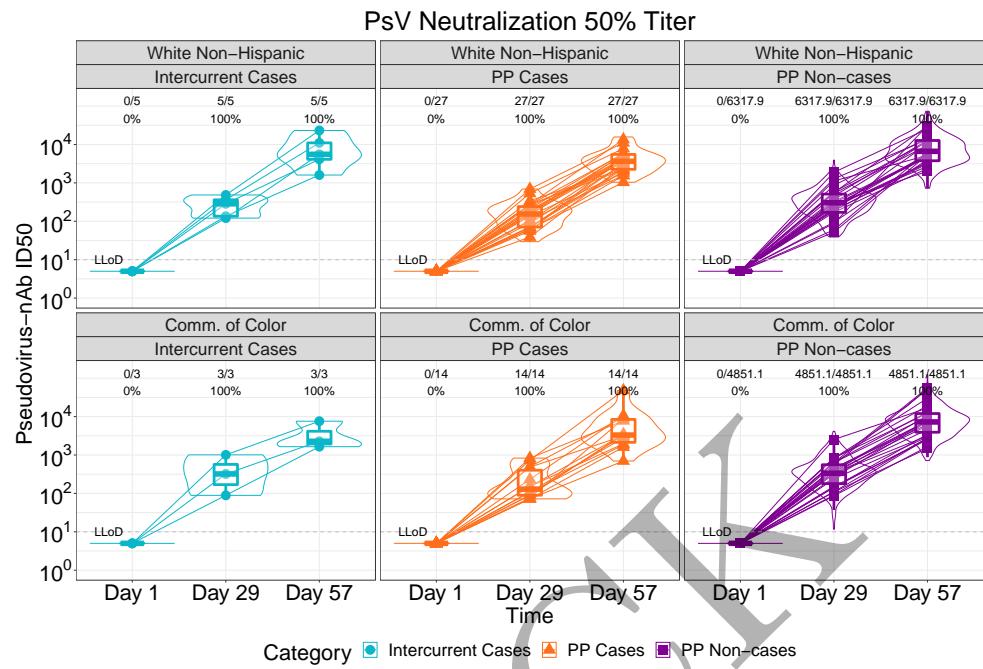


Figure 2.204: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by race and ethnic group (version 2)

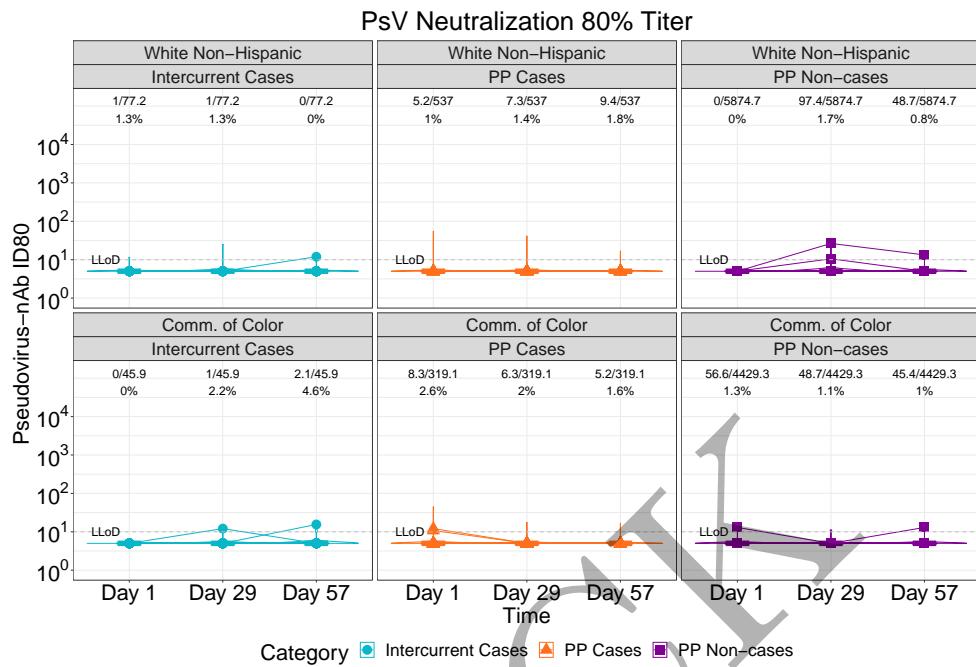


Figure 2.205: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by race and ethnic group (version 2)

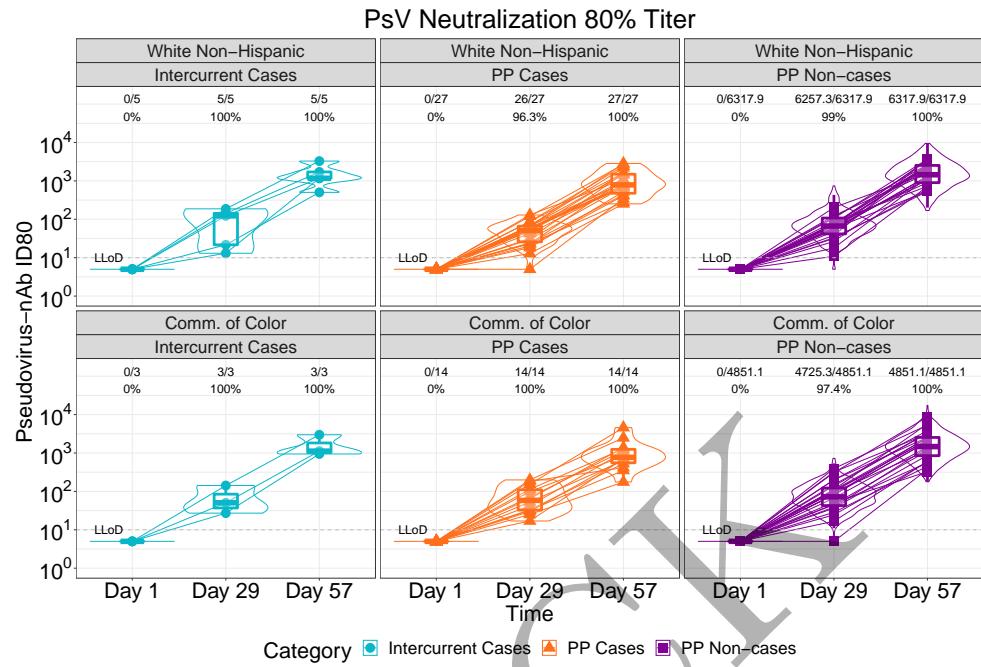


Figure 2.206: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by race and ethnic group (version 2)

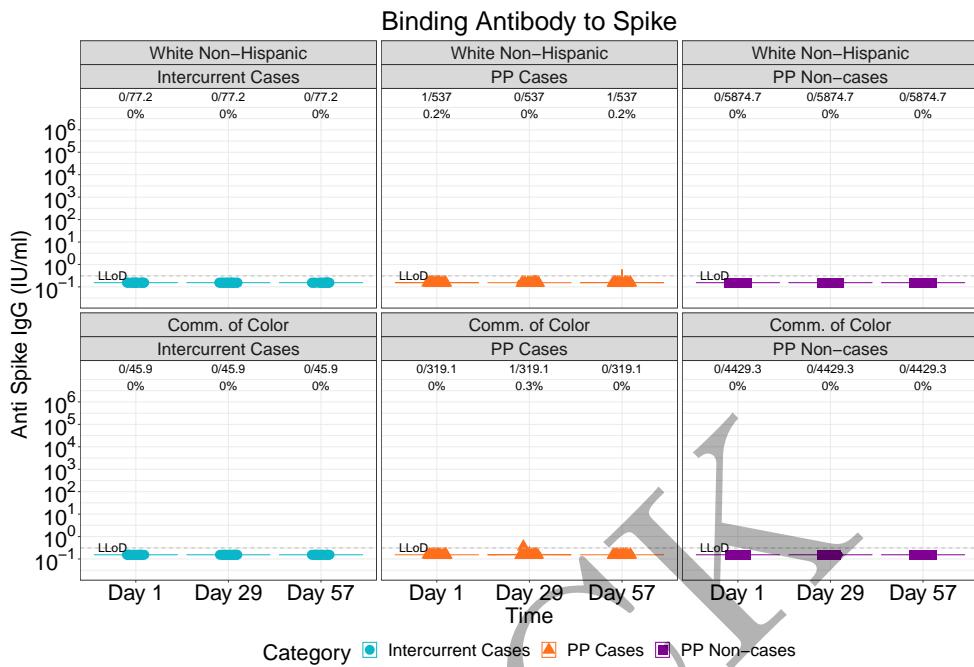


Figure 2.207: violinplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (version 2)

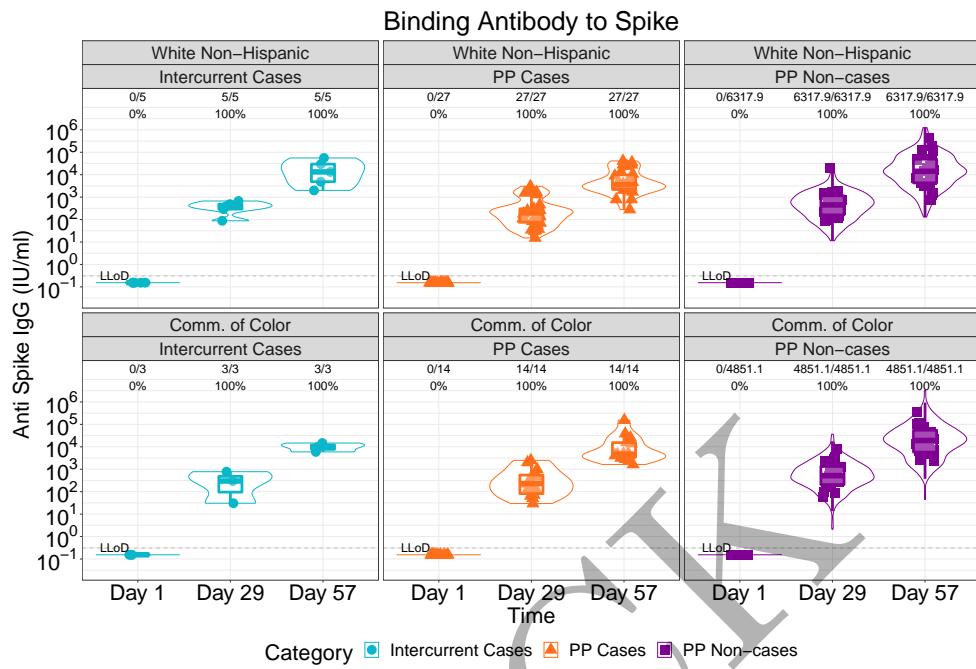


Figure 2.208: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (version 2)

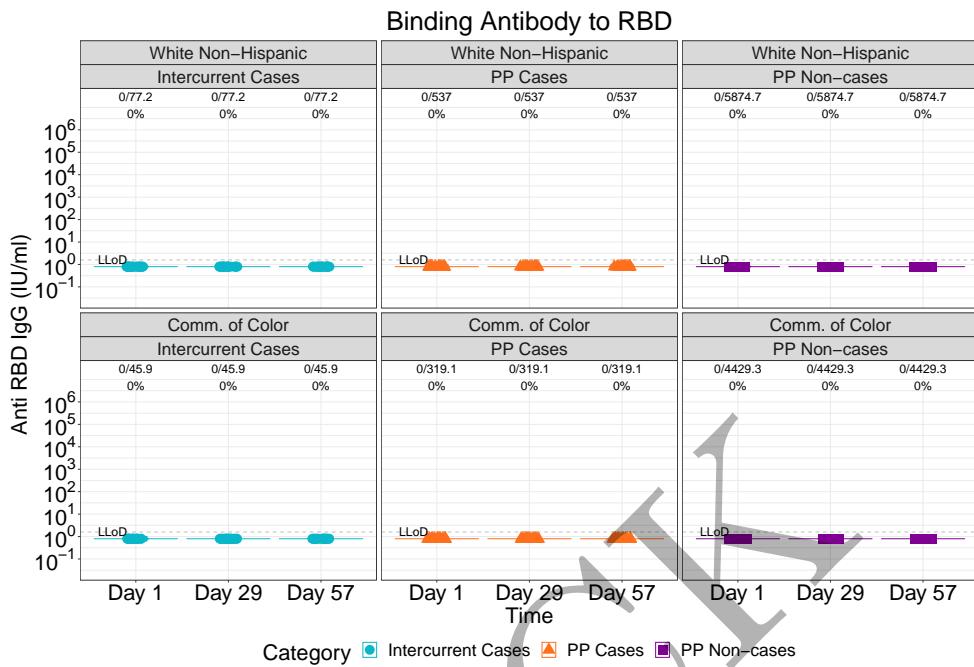


Figure 2.209: violinplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (version 2)

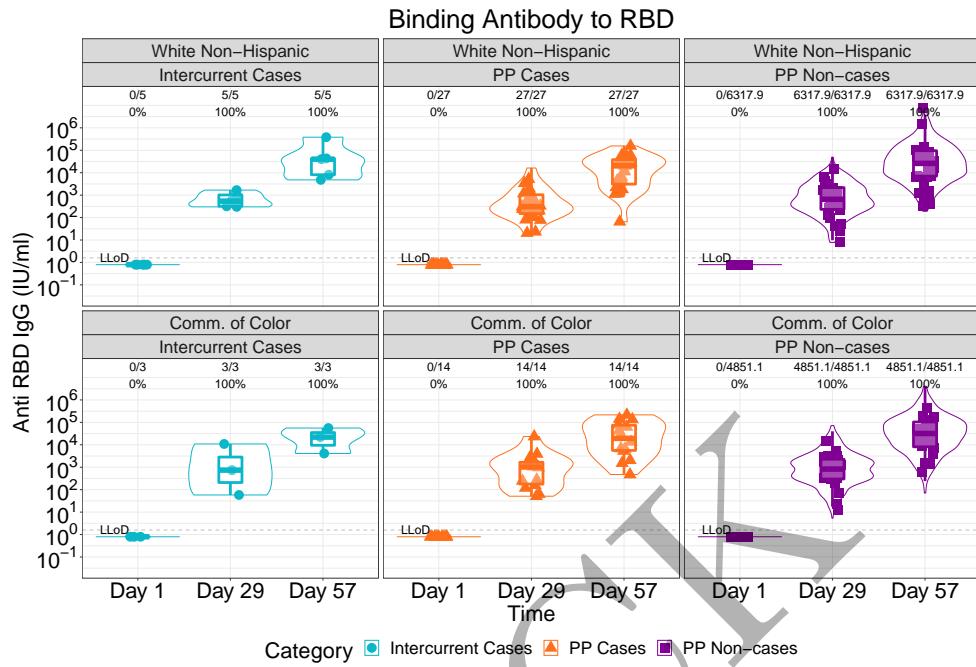


Figure 2.210: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (version 2)

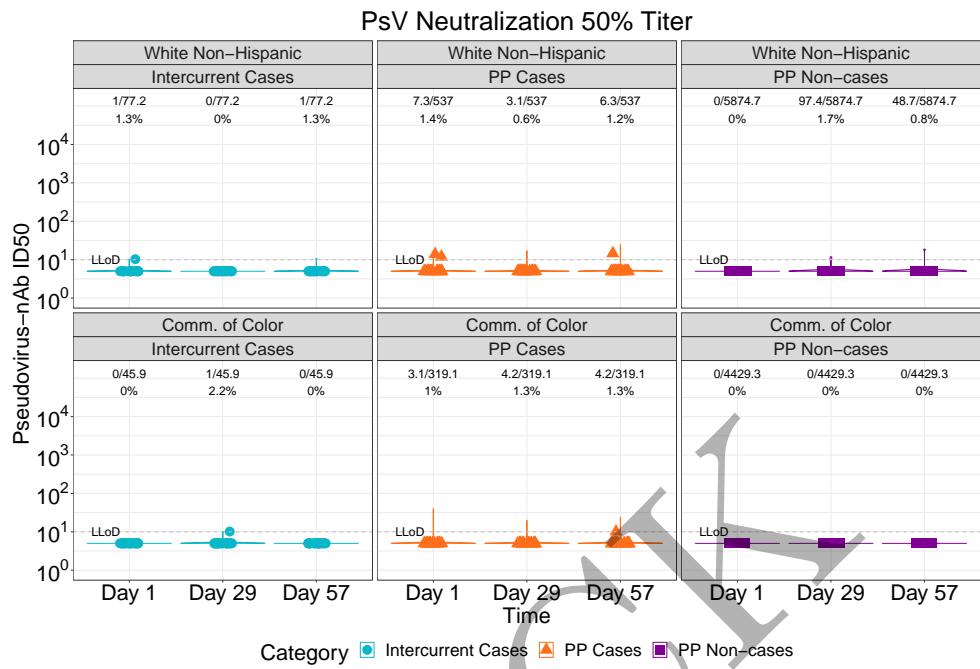


Figure 2.211: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by race and ethnic group (version 2)

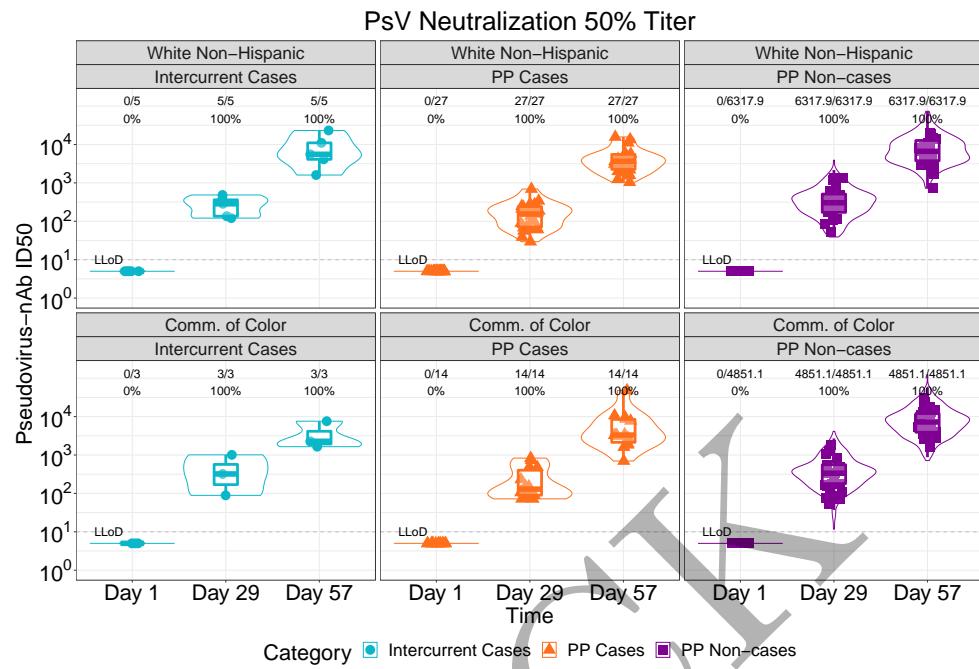


Figure 2.212: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by race and ethnic group (version 2)

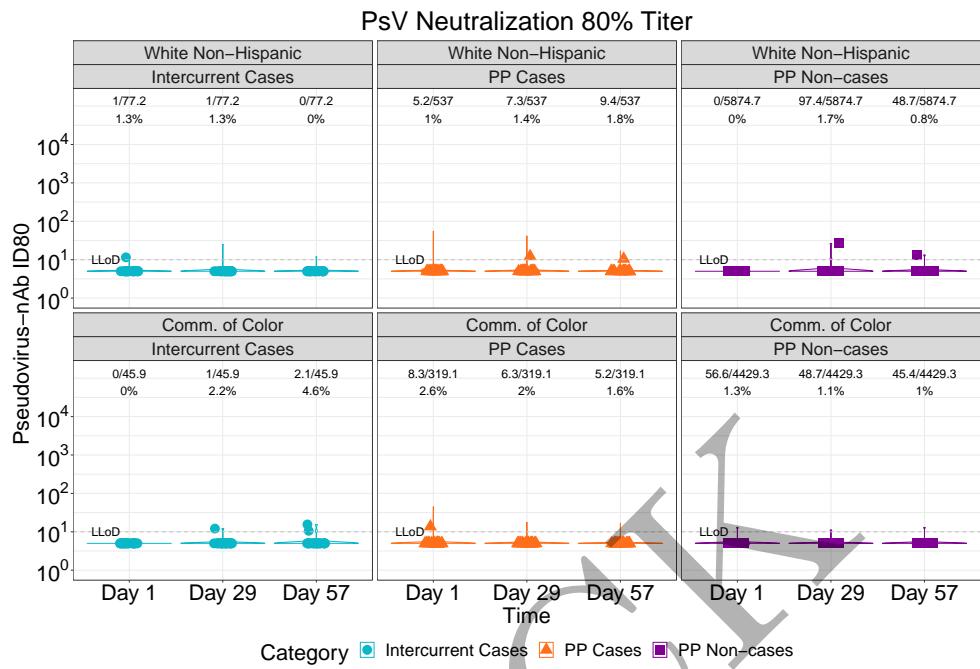


Figure 2.213: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by race and ethnic group (version 2)

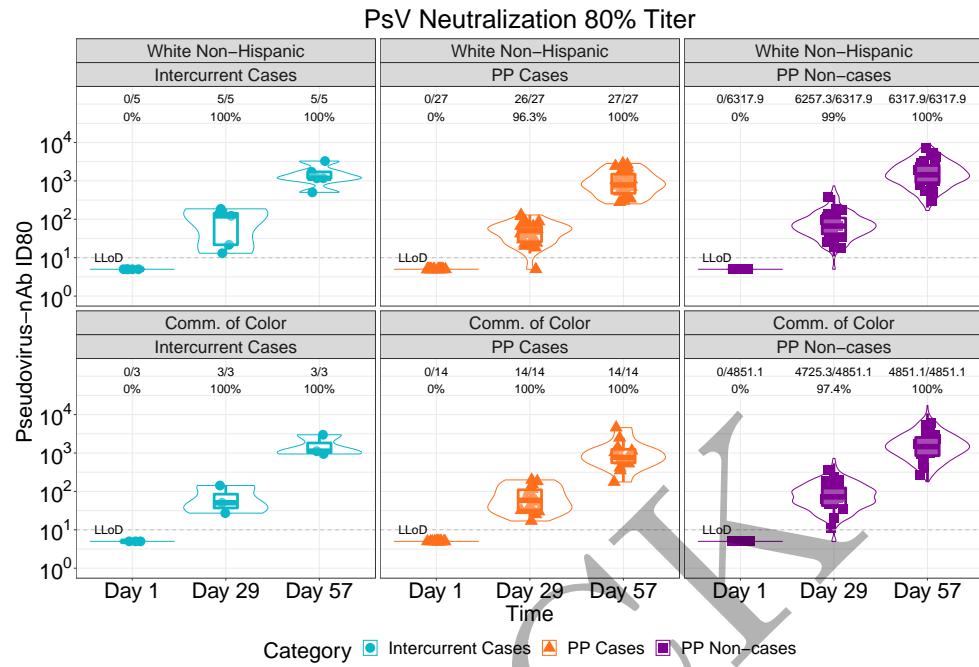


Figure 2.214: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by race and ethnic group (version 2)

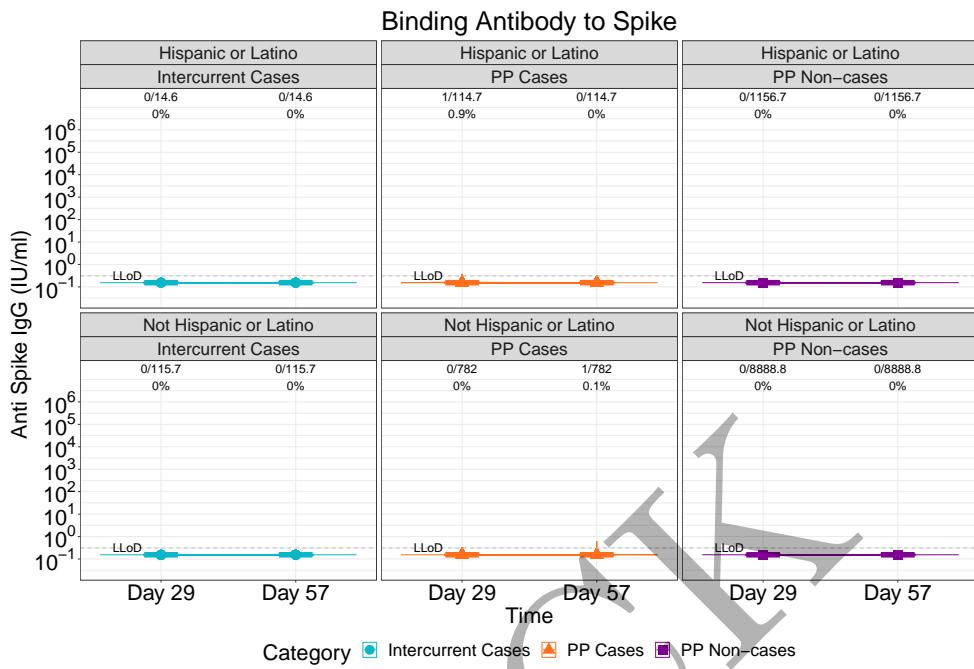


Figure 2.215: lineplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)

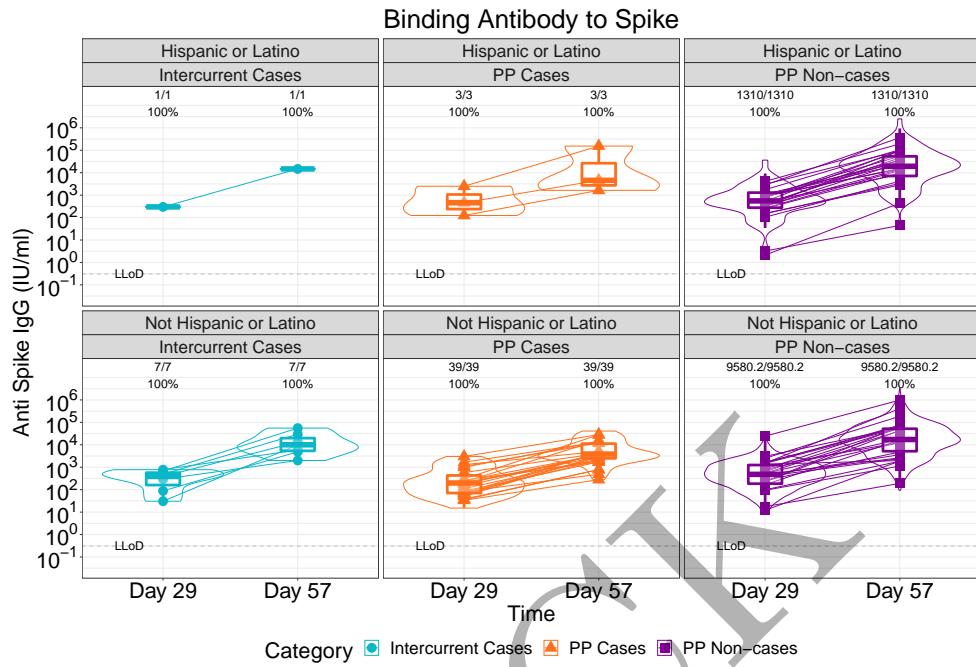


Figure 2.216: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)

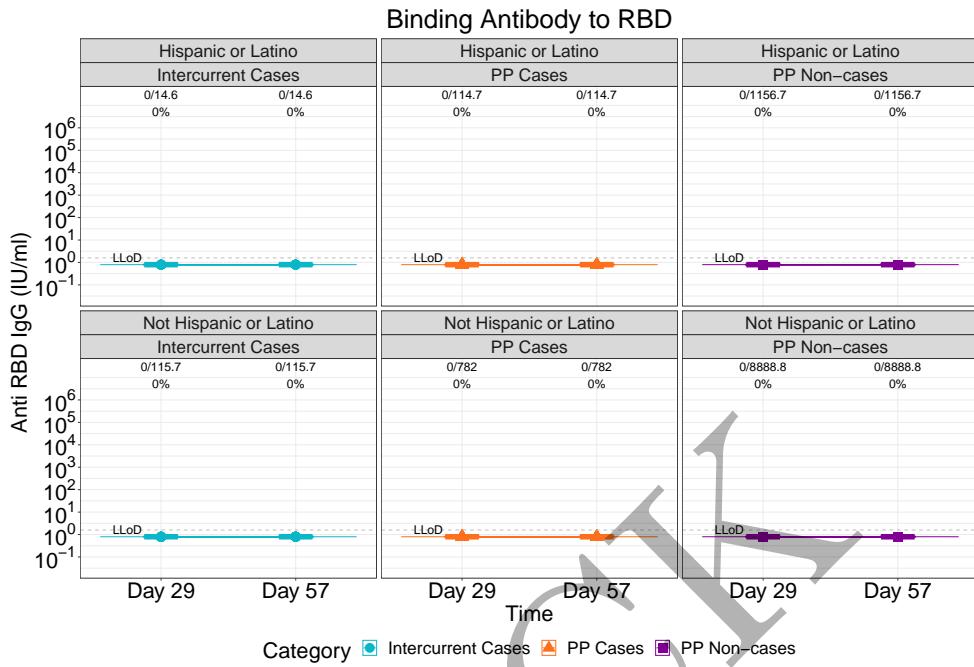


Figure 2.217: lineplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)

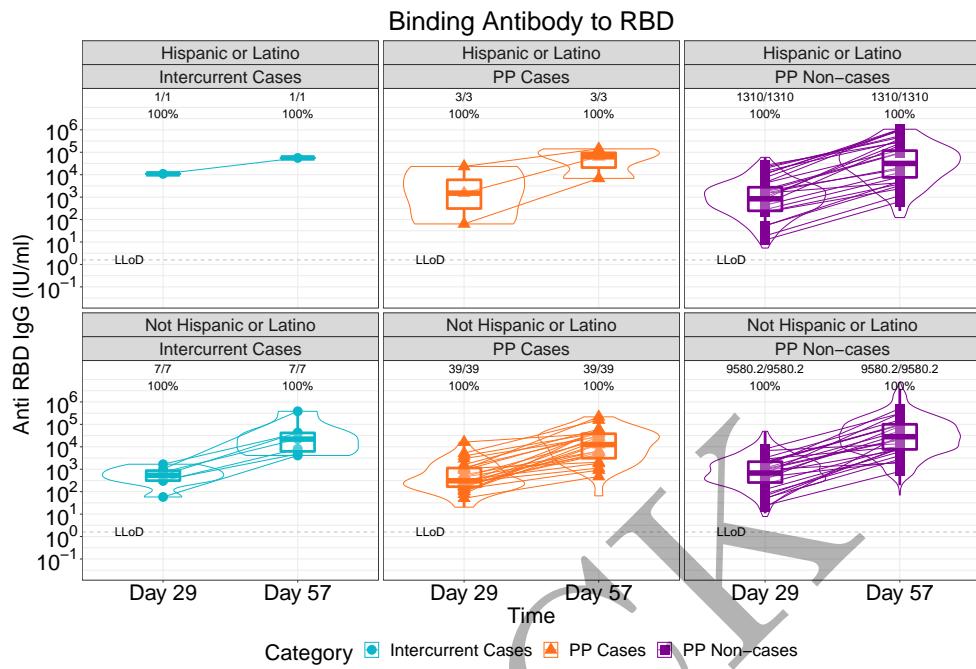


Figure 2.218: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)

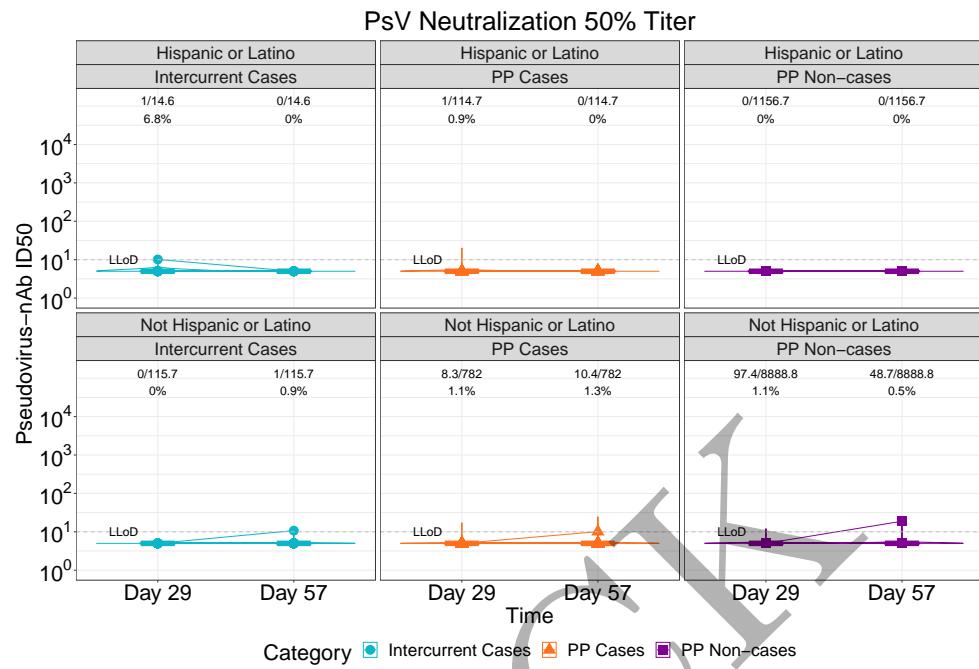


Figure 2.219: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)

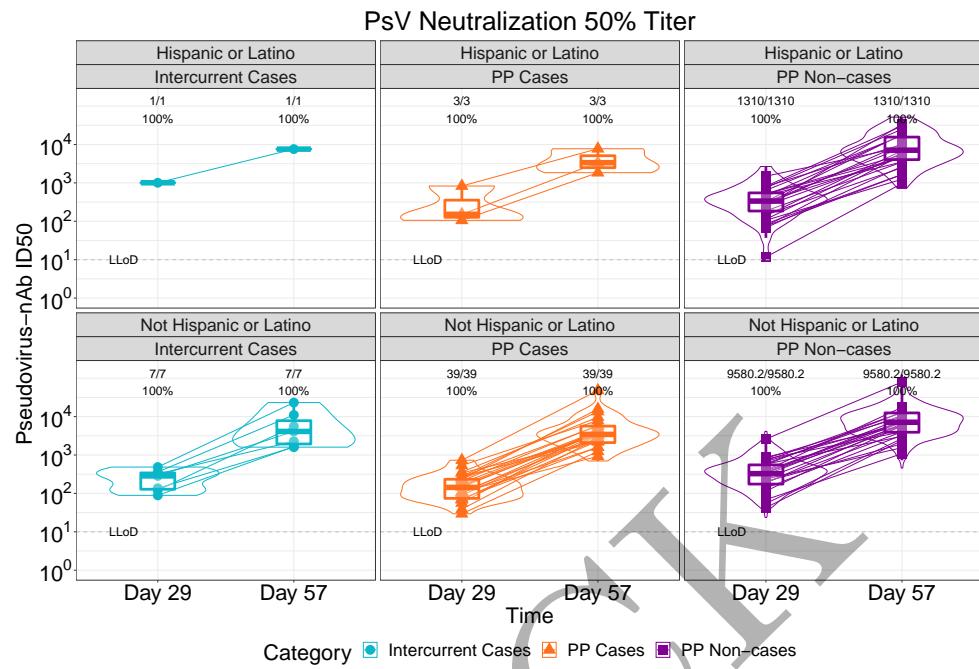


Figure 2.220: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)

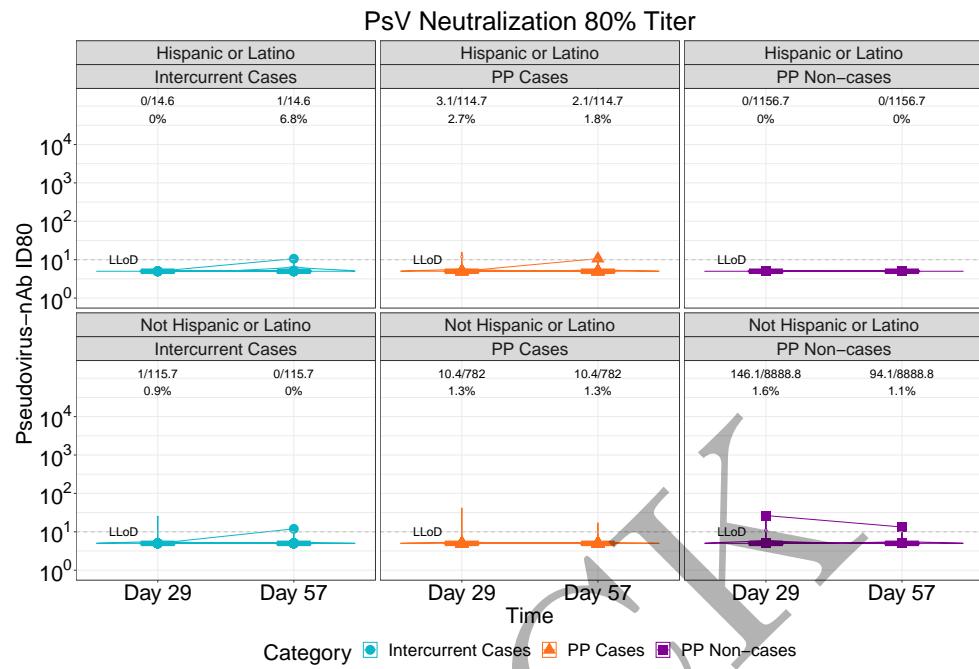


Figure 2.221: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)

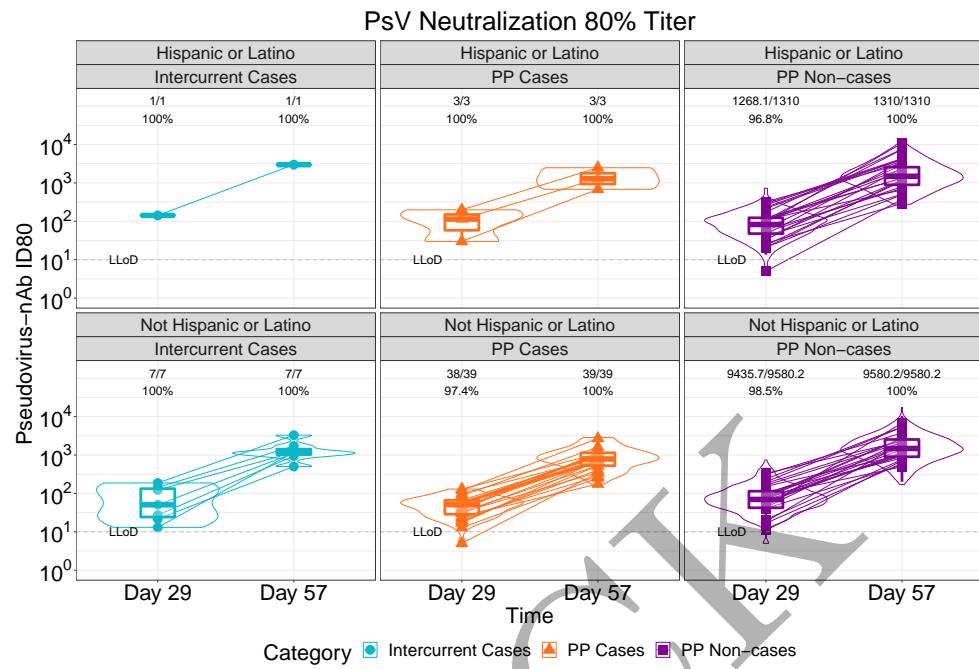


Figure 2.222: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)

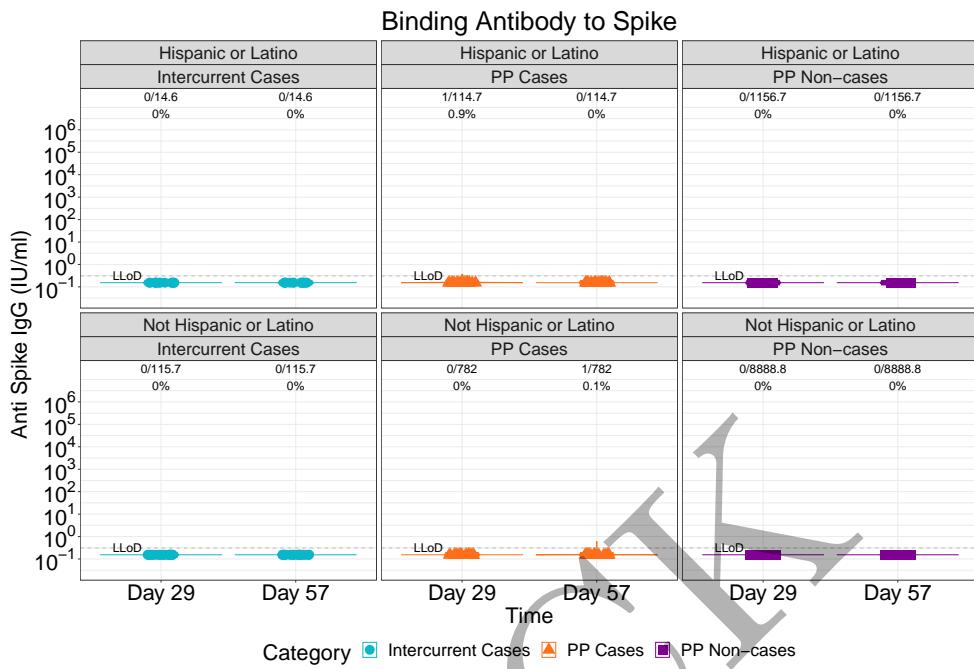


Figure 2.223: violinplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)

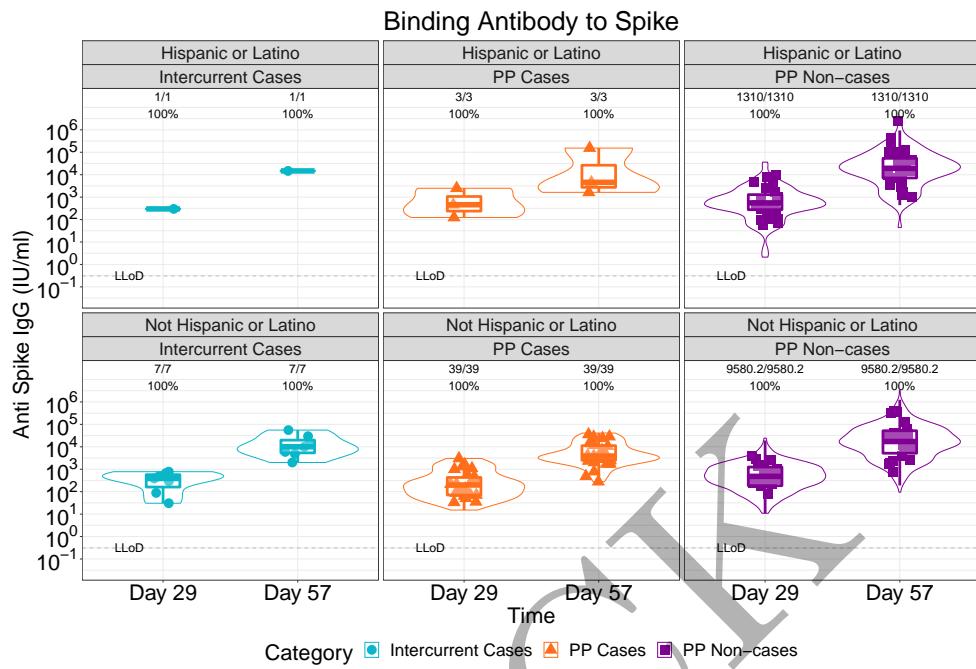


Figure 2.224: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)

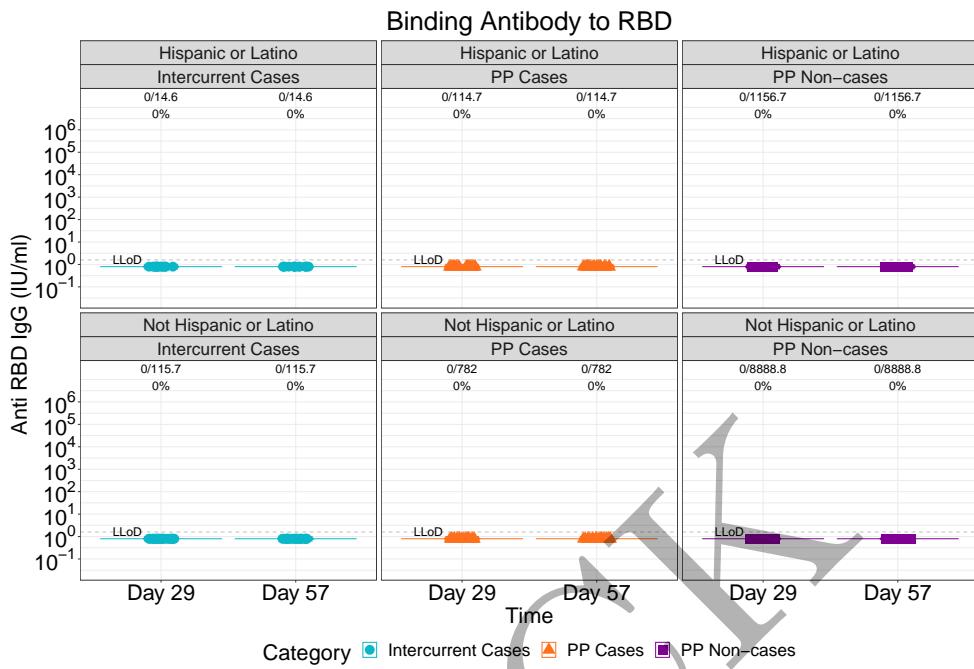


Figure 2.225: violinplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)

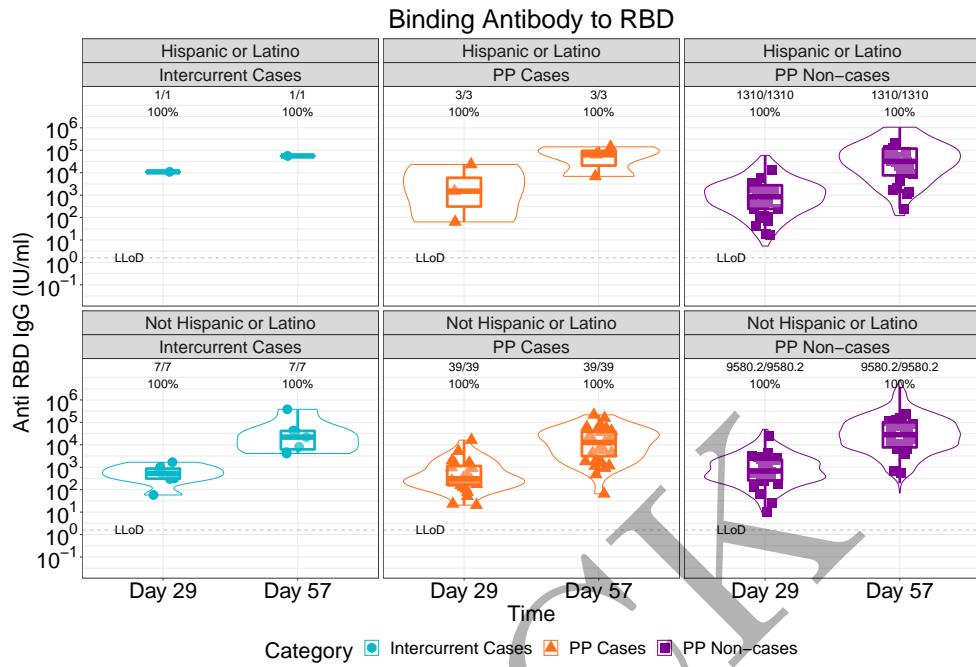


Figure 2.226: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)

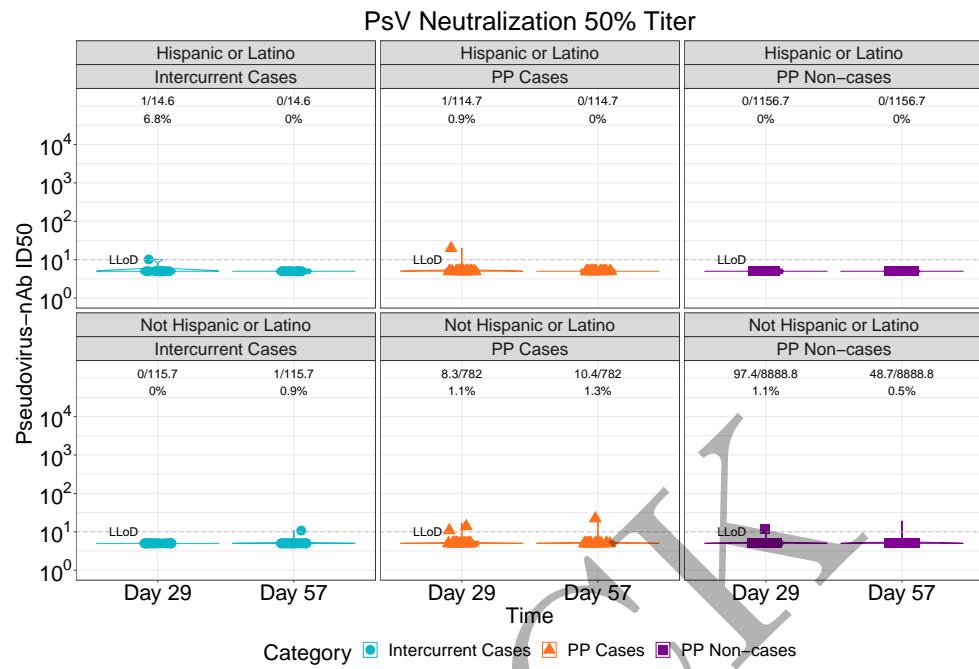


Figure 2.227: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)

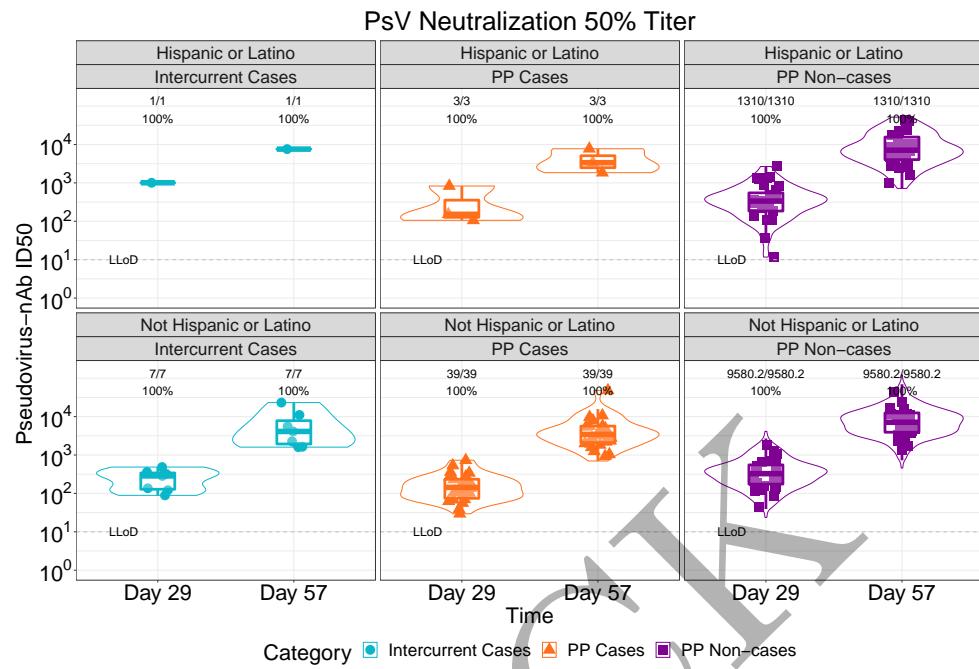


Figure 2.228: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)

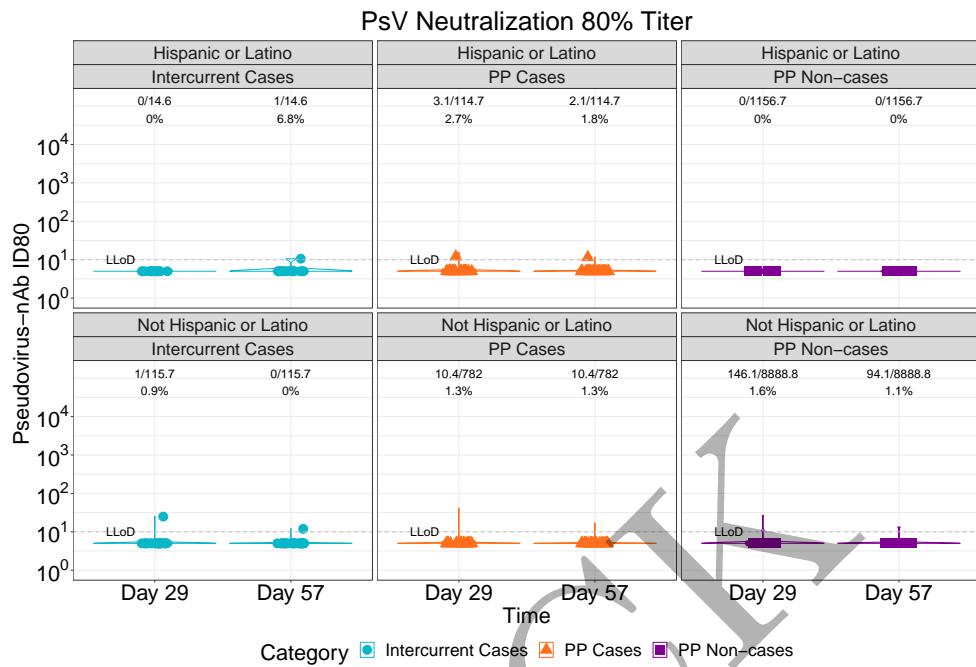


Figure 2.229: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)

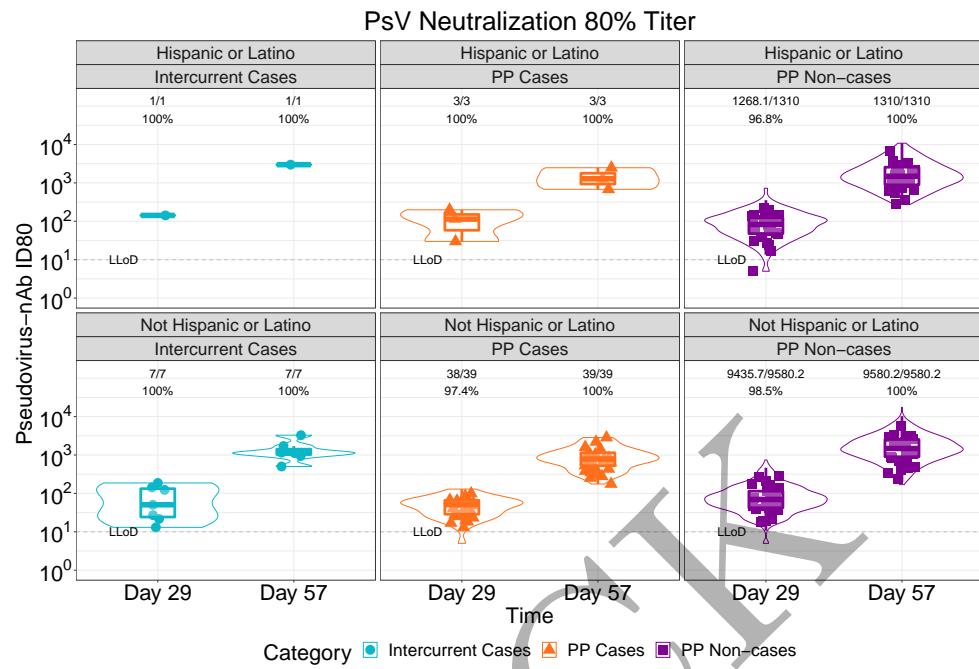


Figure 2.230: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)

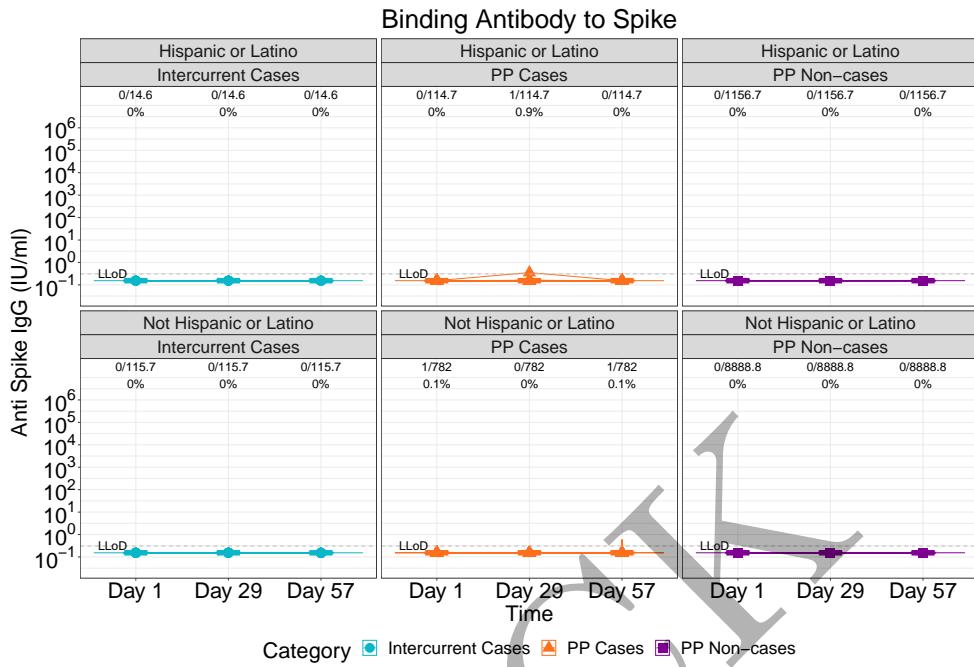


Figure 2.231: lineplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)

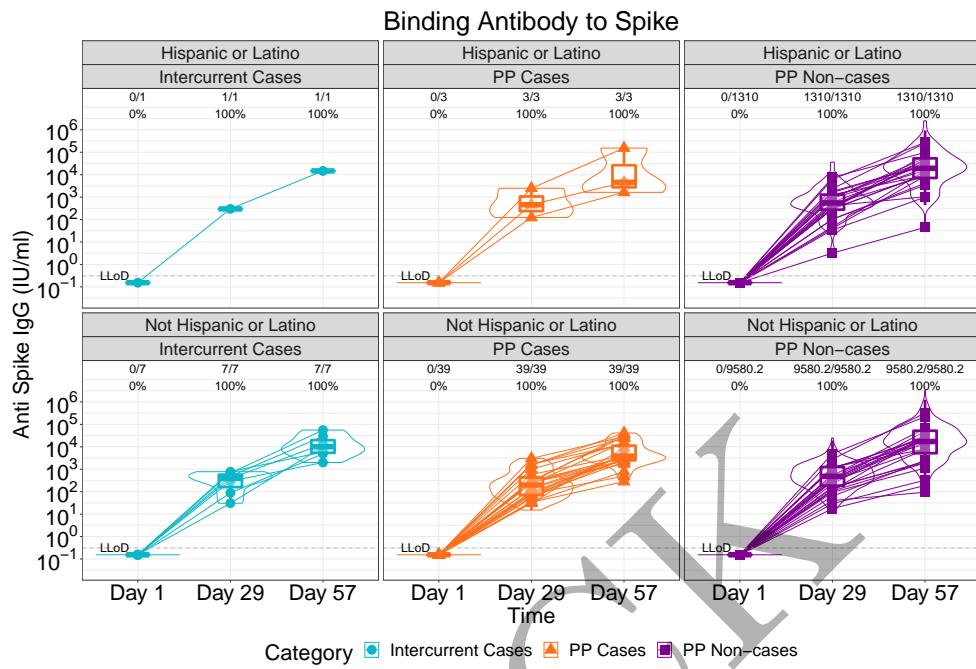


Figure 2.232: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)

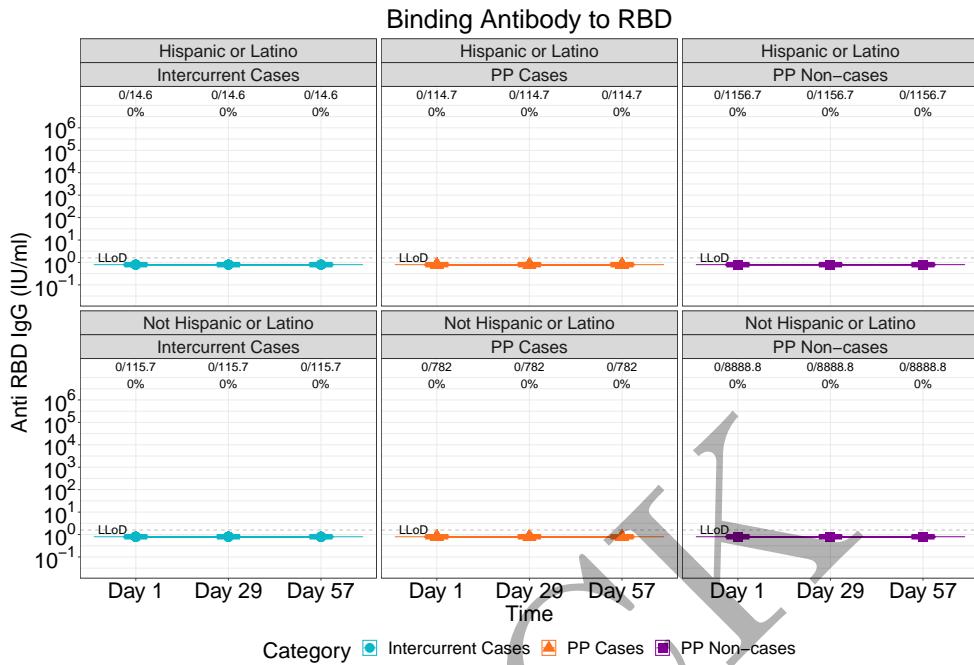


Figure 2.233: lineplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)

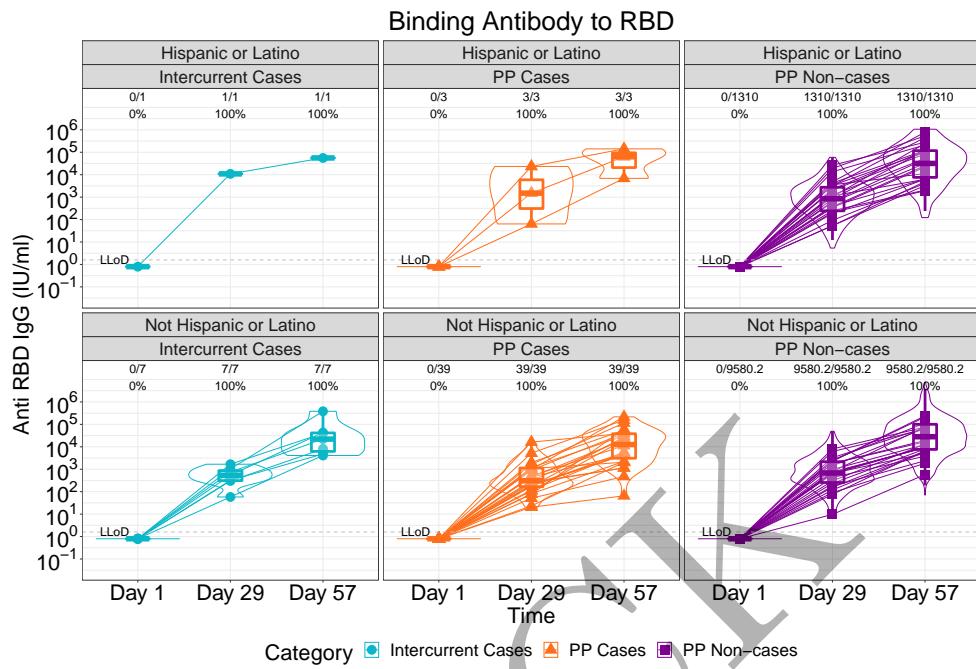


Figure 2.234: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)

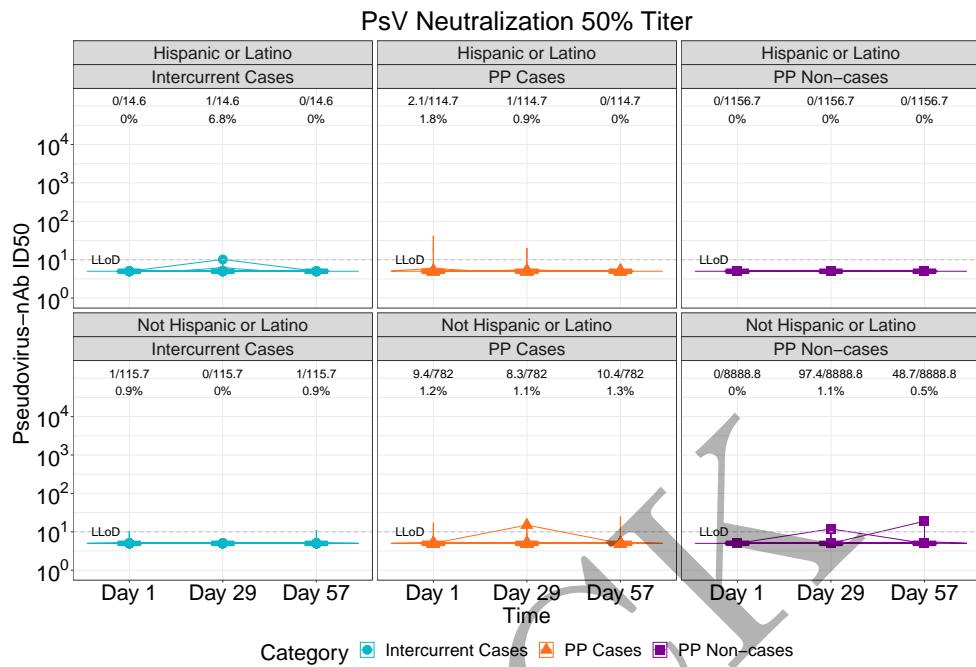


Figure 2.235: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)

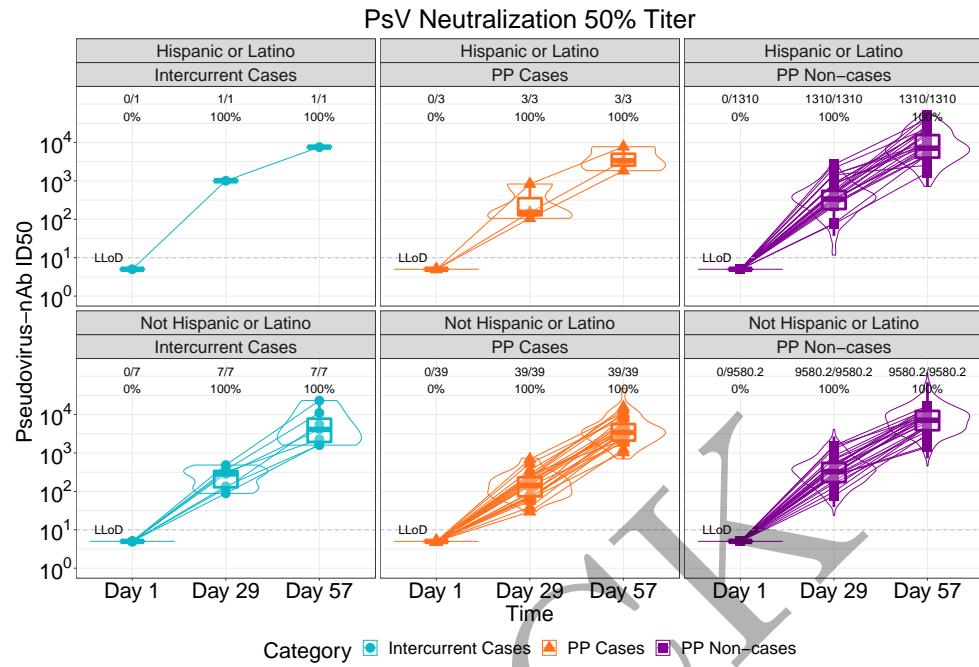


Figure 2.236: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)

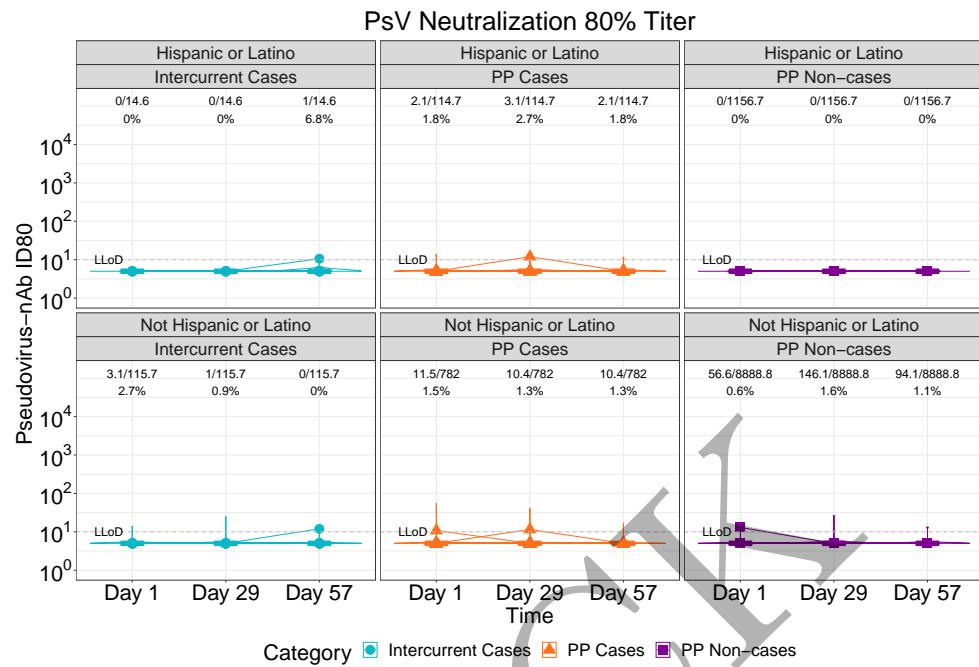


Figure 2.237: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)

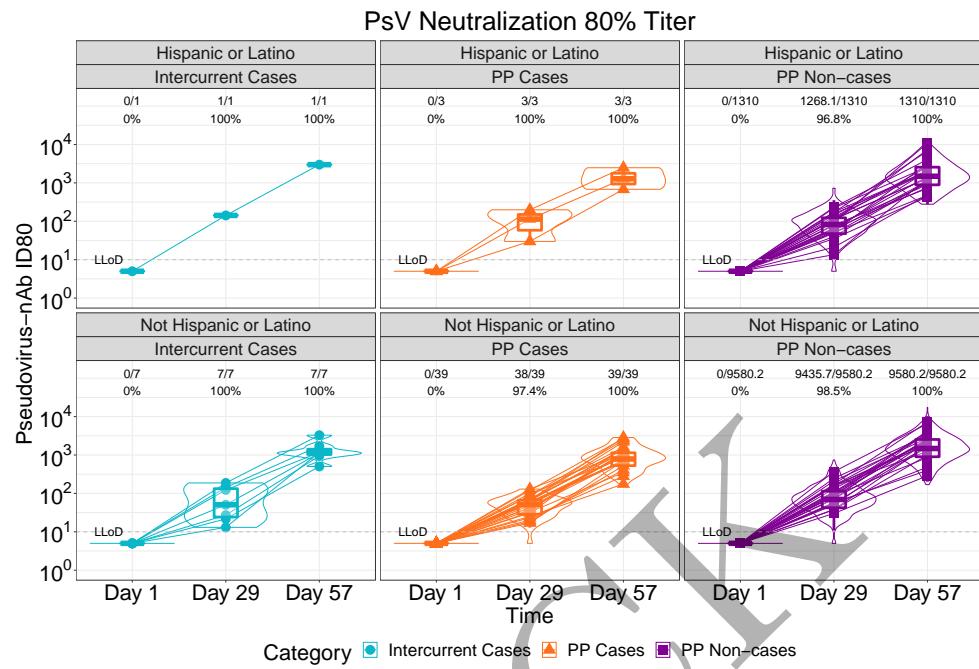


Figure 2.238: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)

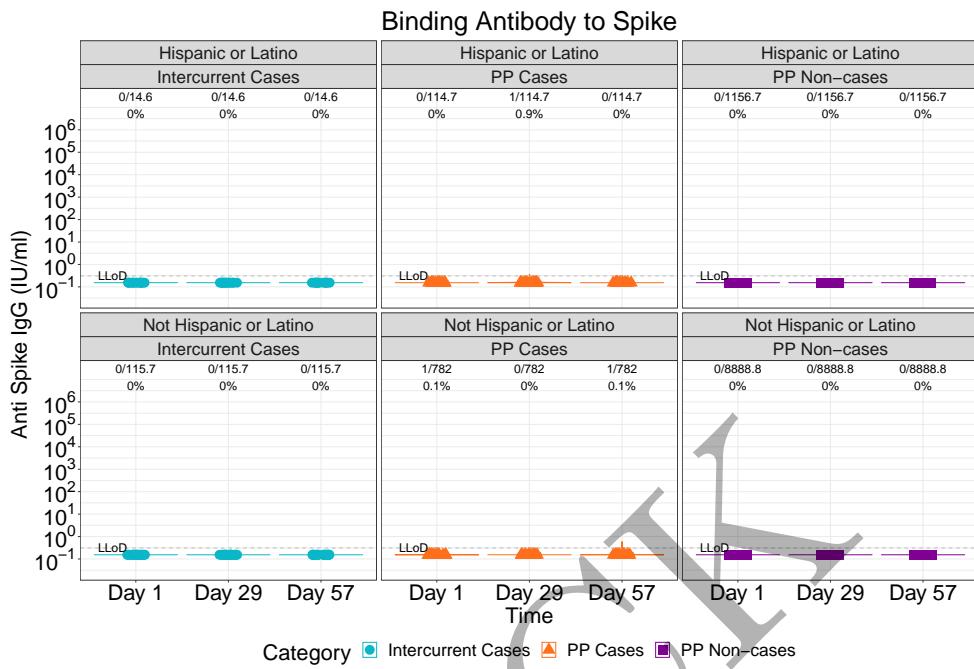


Figure 2.239: violinplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)

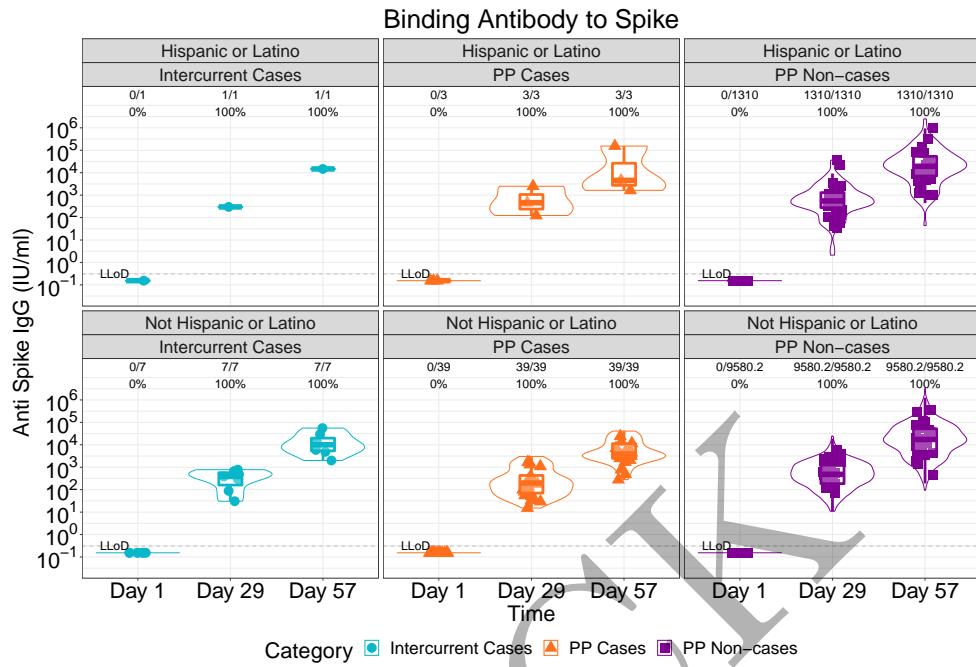


Figure 2.240: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)

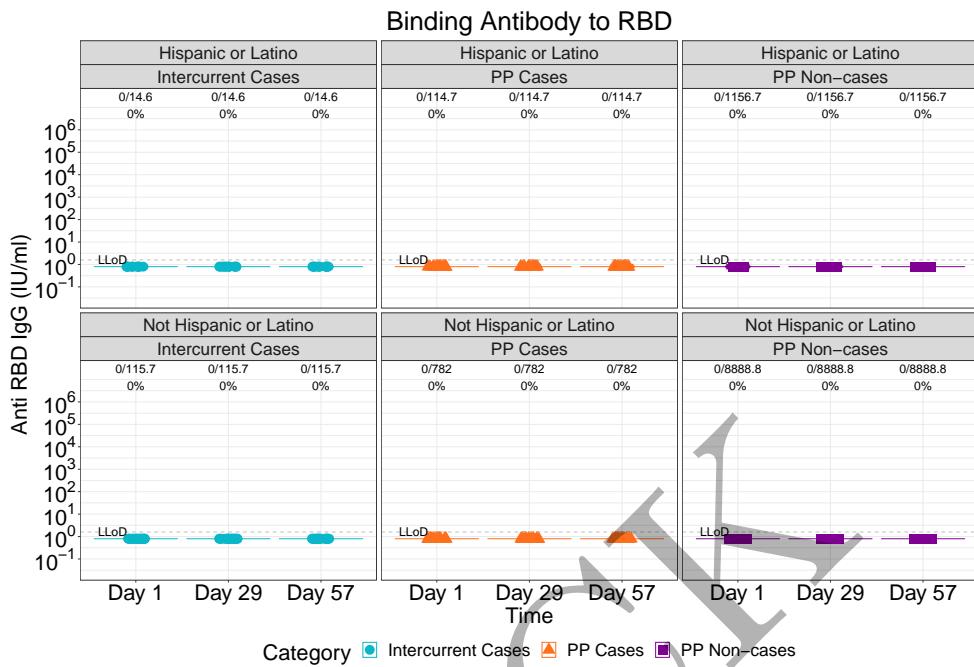


Figure 2.241: violinplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)

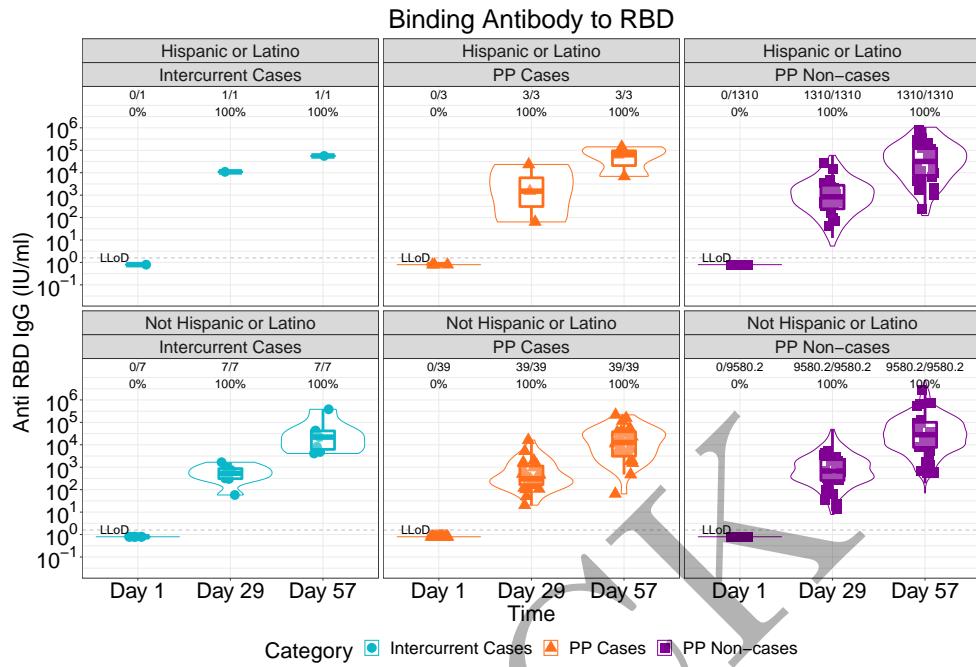


Figure 2.242: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)

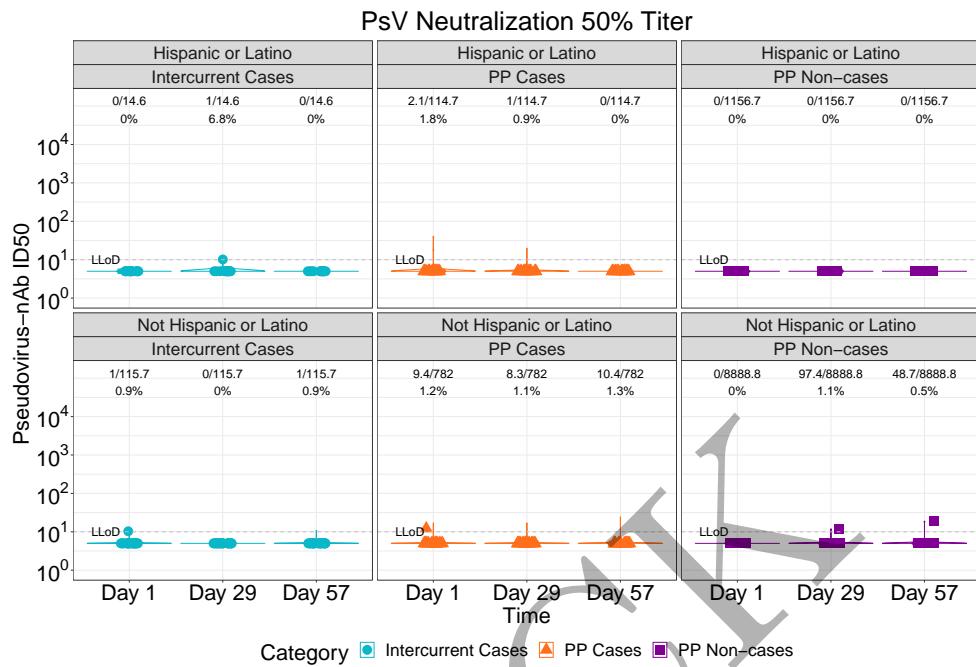


Figure 2.243: violinplots of Pseudovirus Neutralization ID₅₀: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)

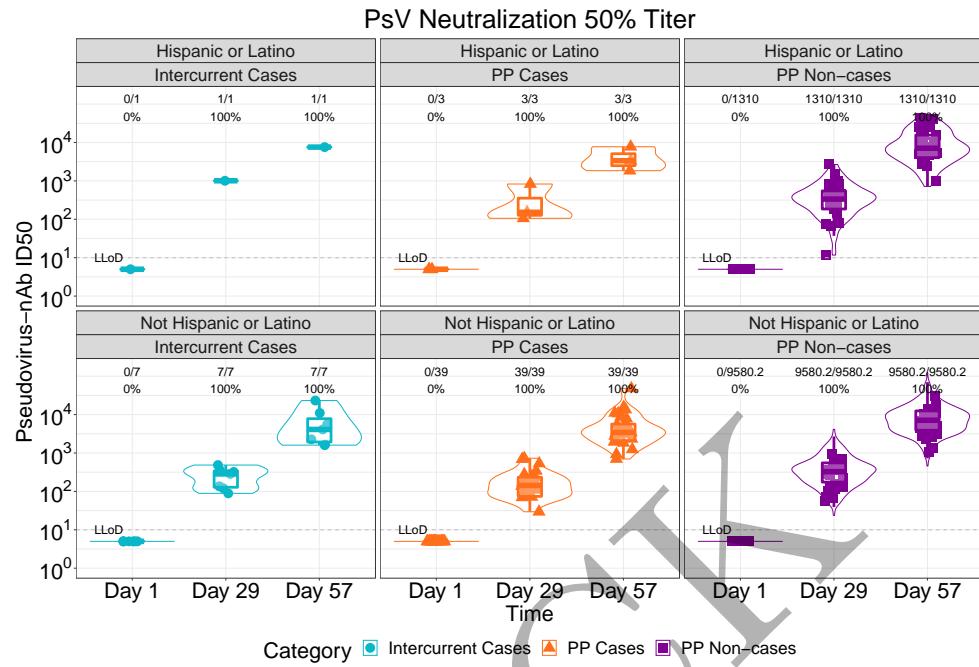


Figure 2.244: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)

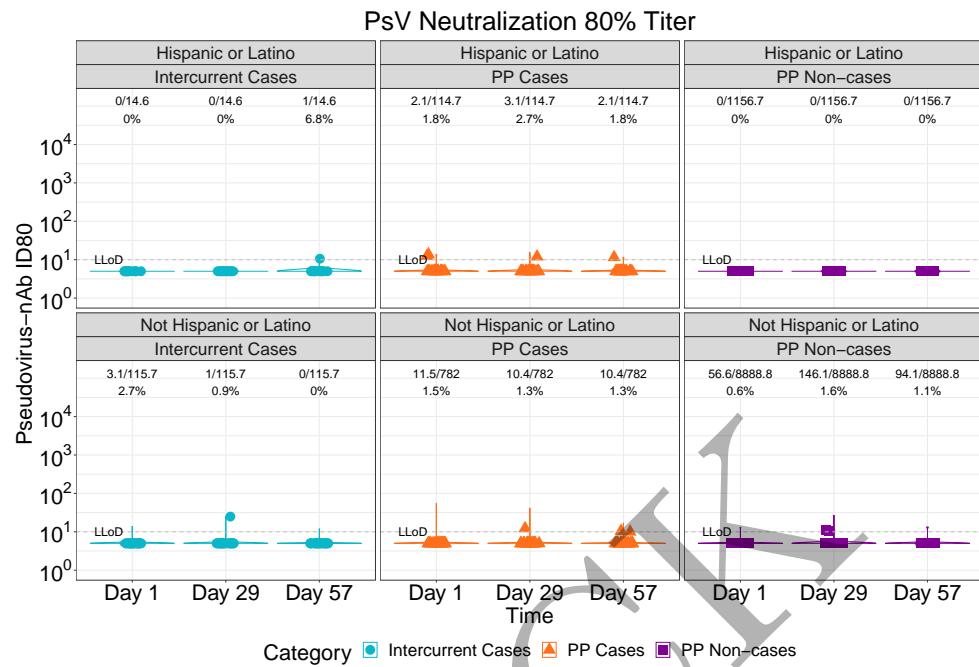


Figure 2.245: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)

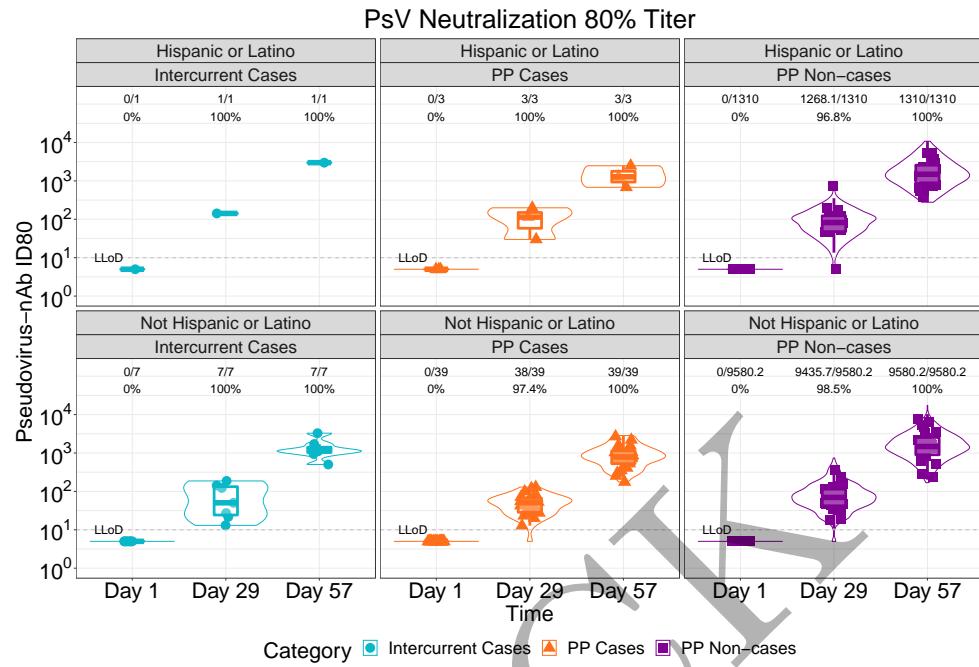


Figure 2.246: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)

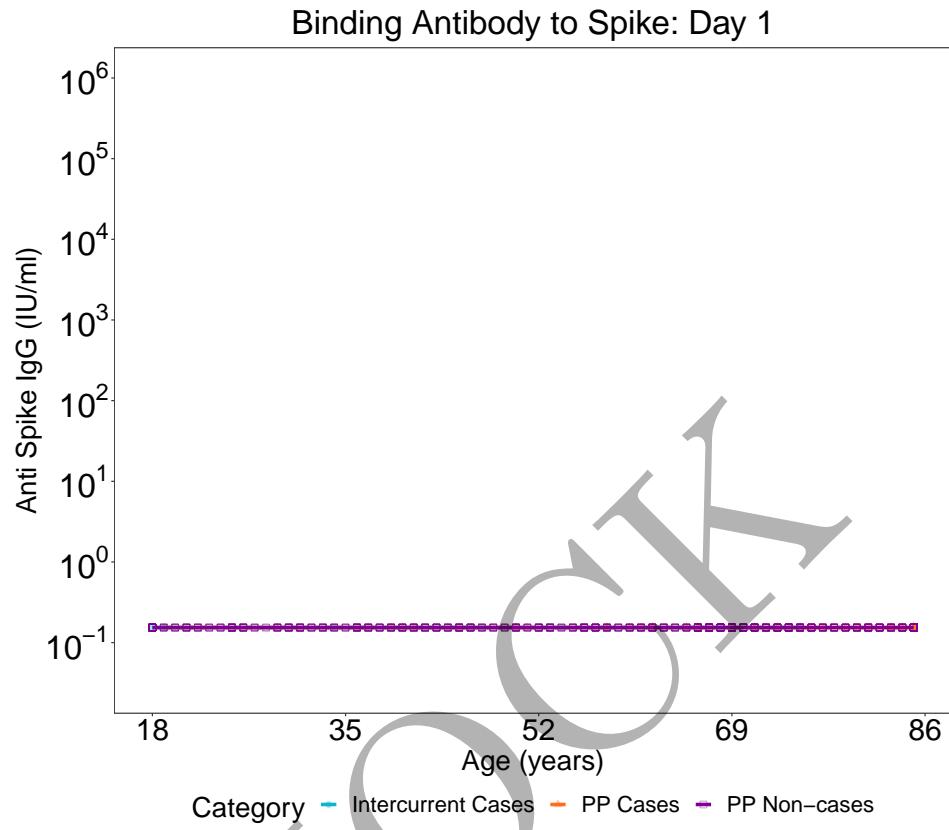


Figure 2.247: scatterplots of Binding Antibody to Spike: baseline negative vaccine arm at day 1

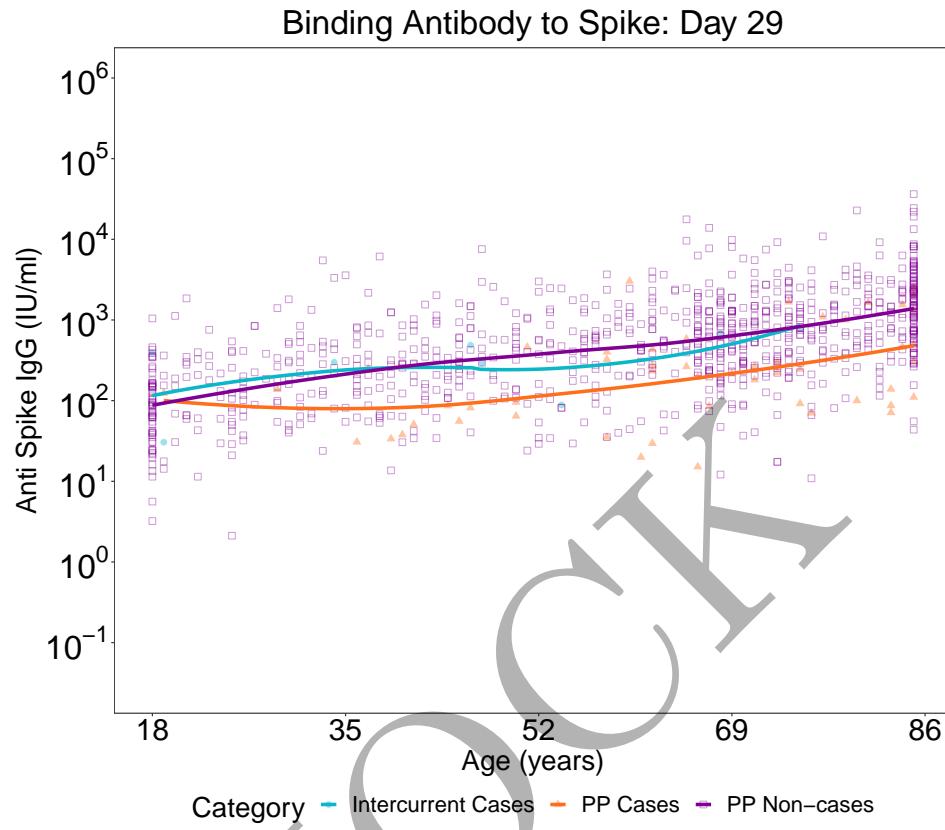


Figure 2.248: scatterplots of Binding Antibody to Spike: baseline negative vaccine arm at day 29

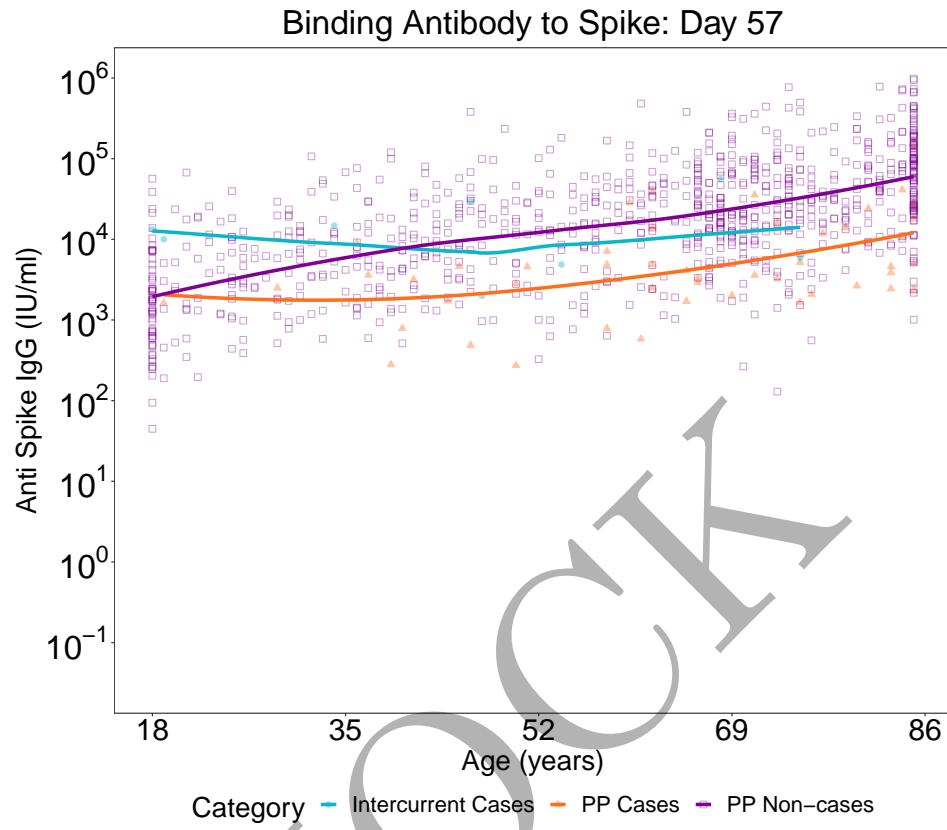


Figure 2.249: scatterplots of Binding Antibody to Spike: baseline negative vaccine arm at day 57

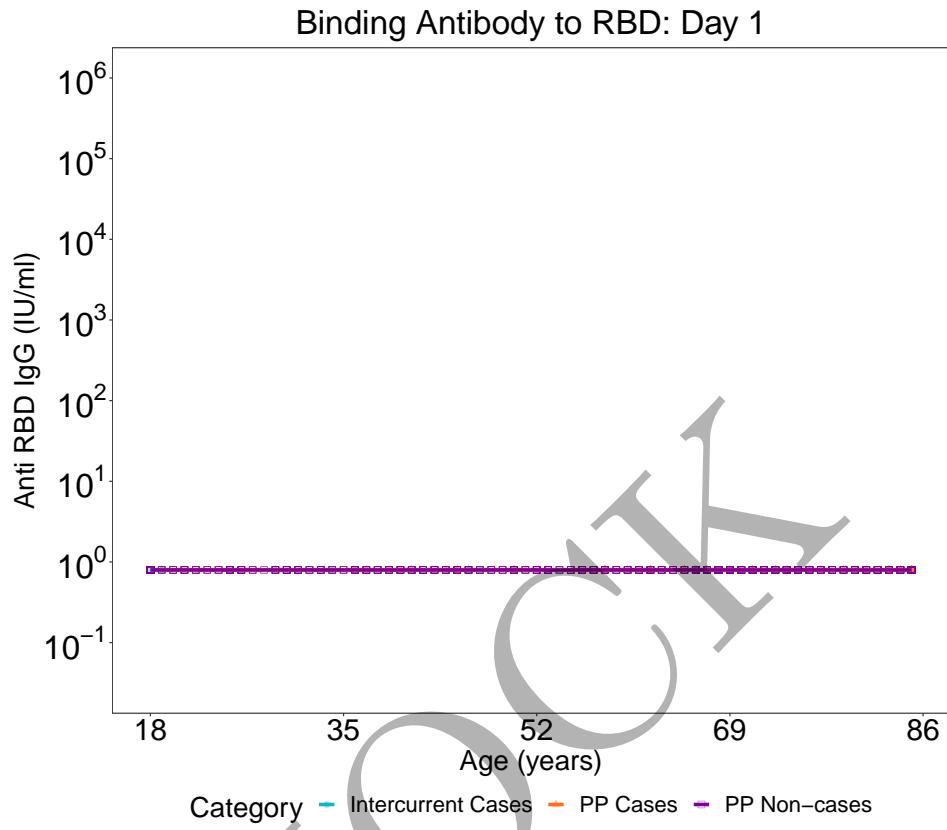


Figure 2.250: scatterplots of Binding Antibody to RBD: baseline negative vaccine arm at day 1

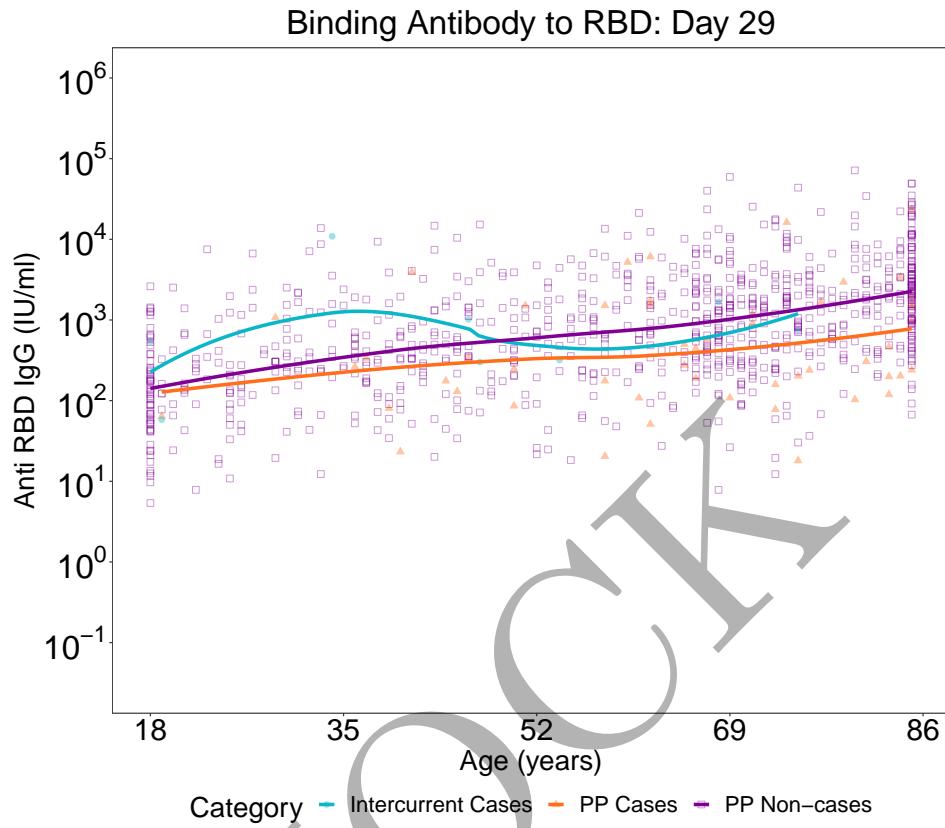


Figure 2.251: scatterplots of Binding Antibody to RBD: baseline negative vaccine arm at day 29

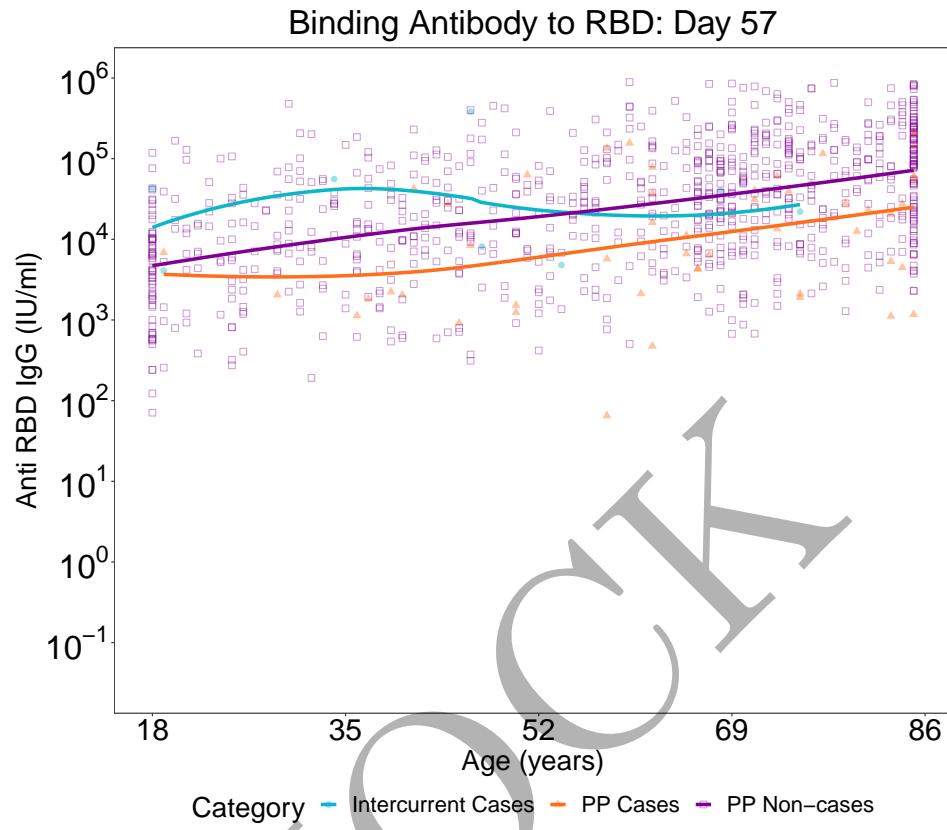


Figure 2.252: scatterplots of Binding Antibody to RBD: baseline negative vaccine arm at day 57

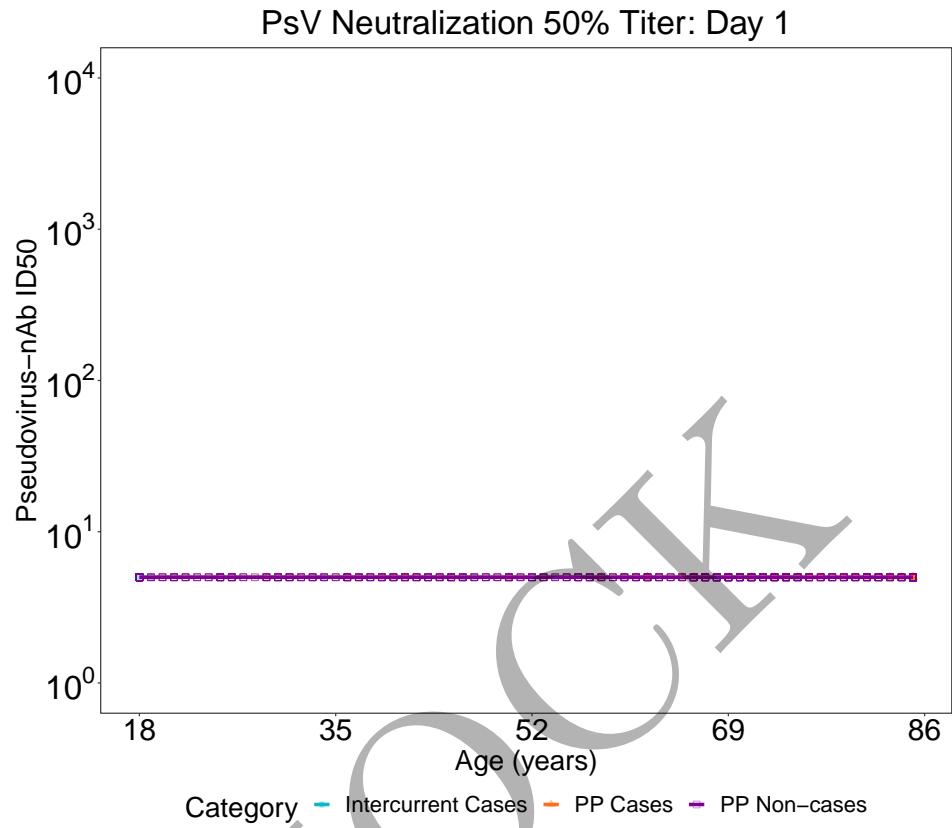


Figure 2.253: scatterplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm at day 1

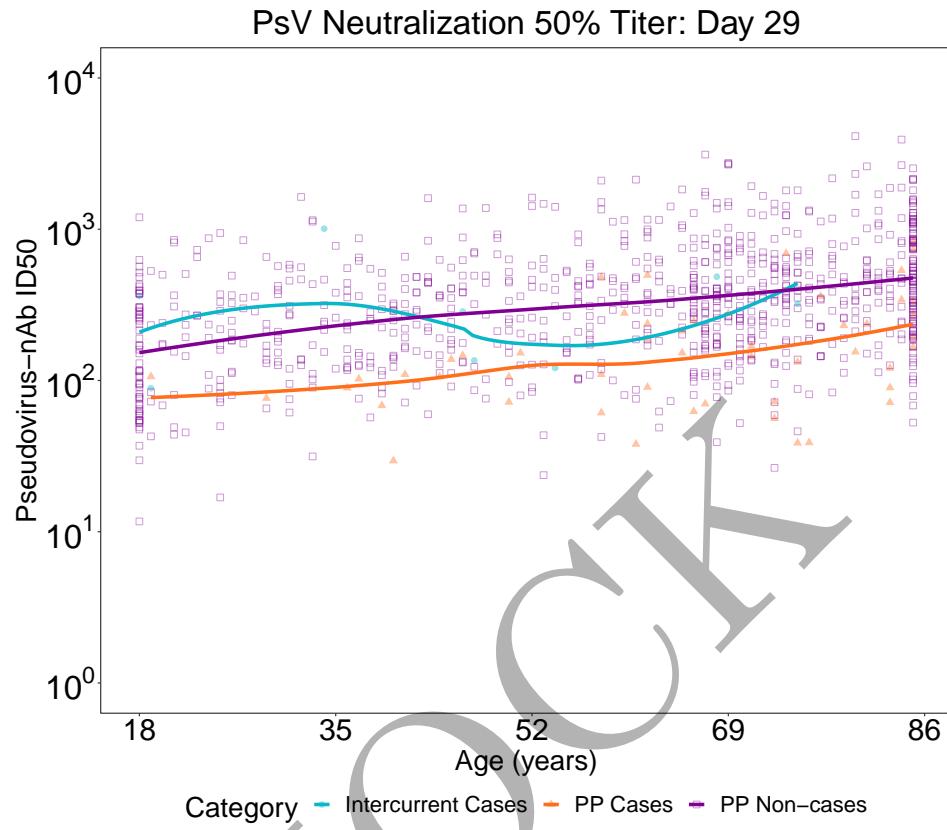


Figure 2.254: scatterplots of Pseudovirus Neutralization ID₅₀: baseline negative vaccine arm at day 29

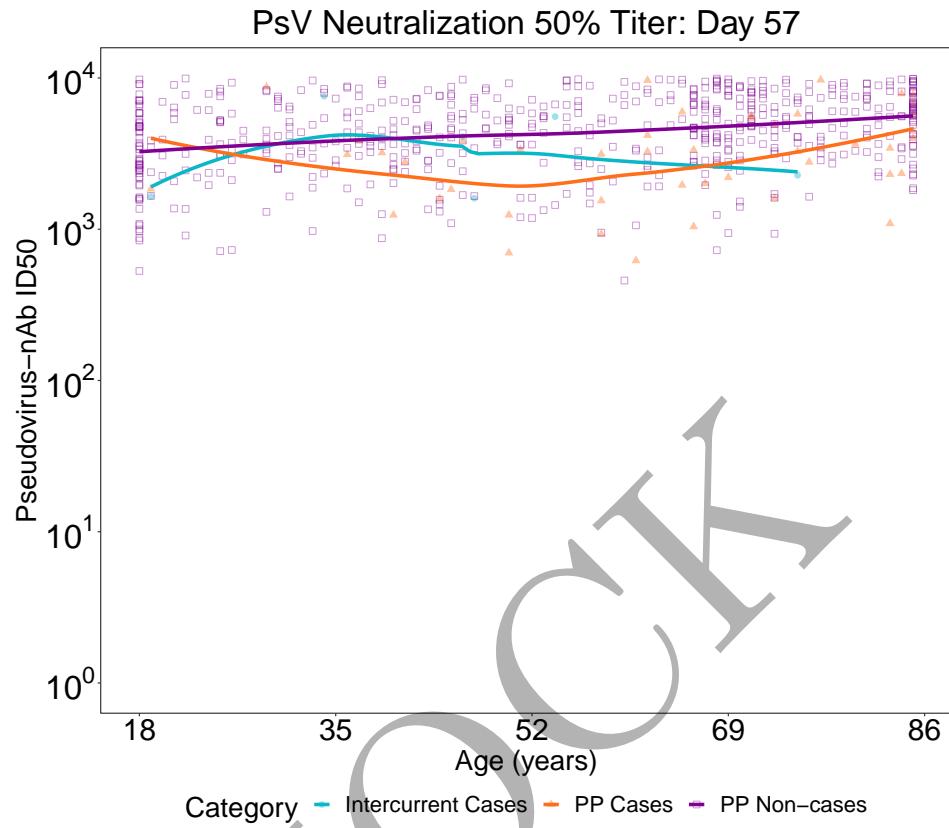


Figure 2.255: scatterplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm at day 57

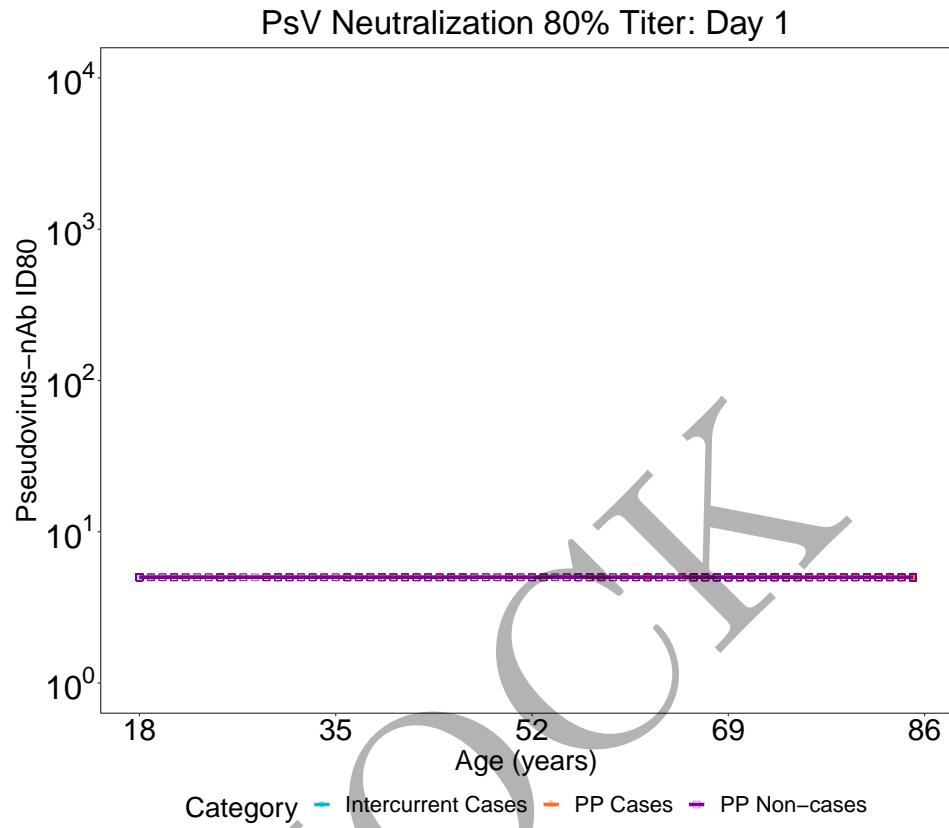


Figure 2.256: scatterplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm at day 1

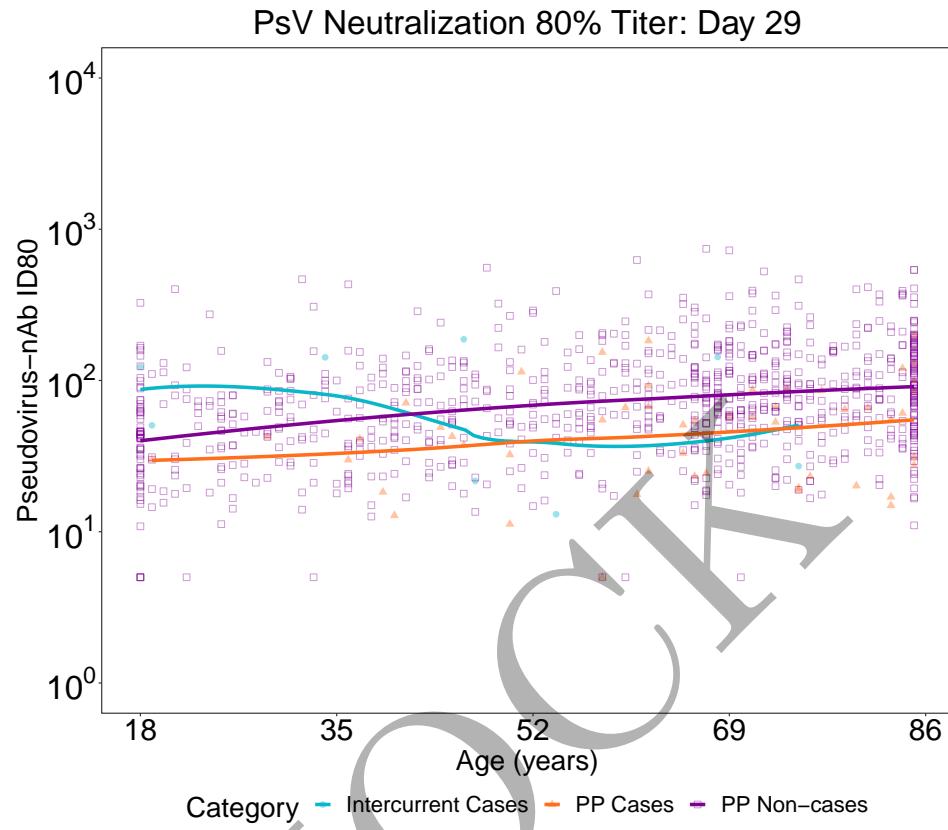


Figure 2.257: scatterplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm at day 29

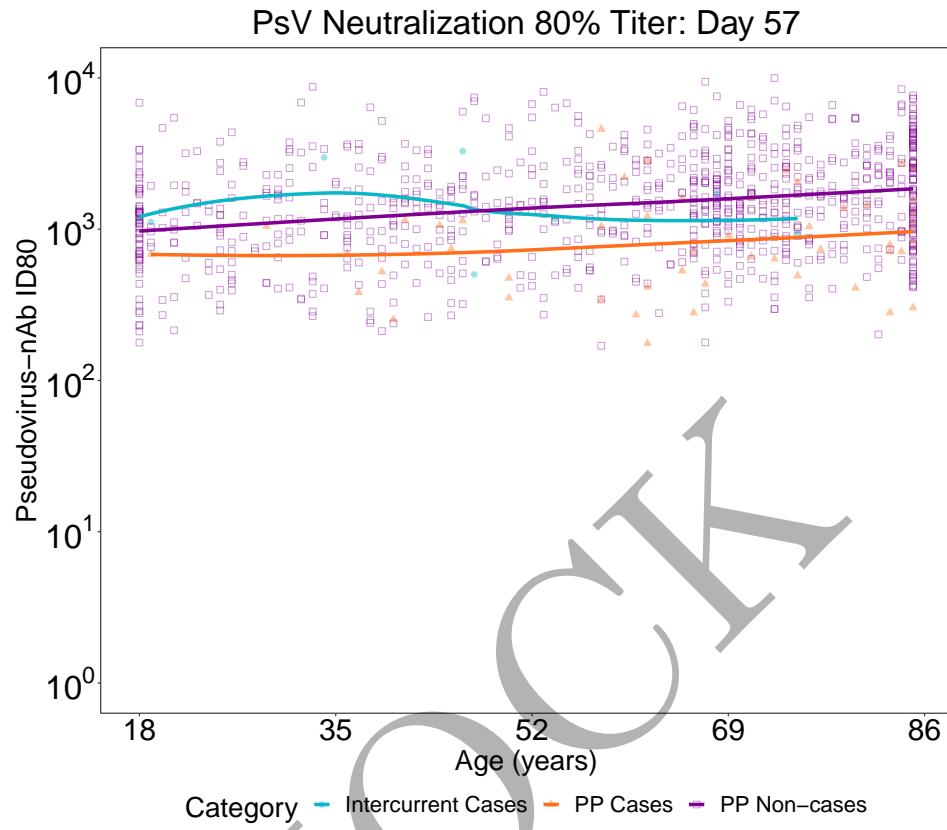


Figure 2.258: scatterplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm at day 57

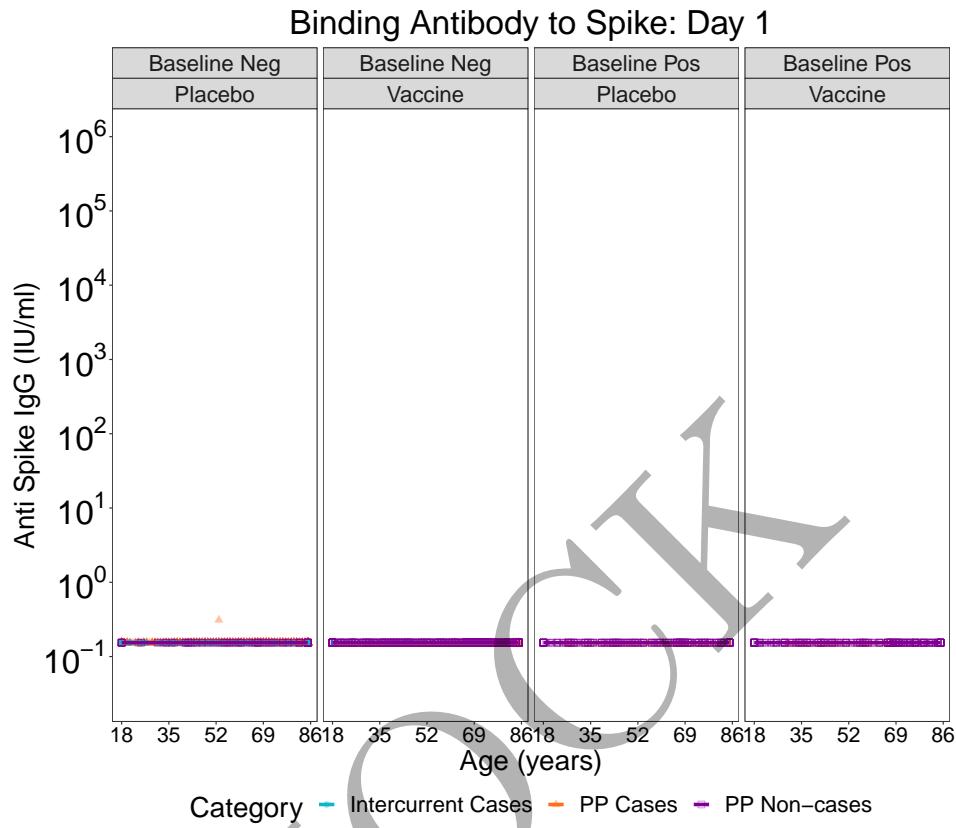


Figure 2.259: scatterplots of Binding Antibody to Spike: by arm at day 1

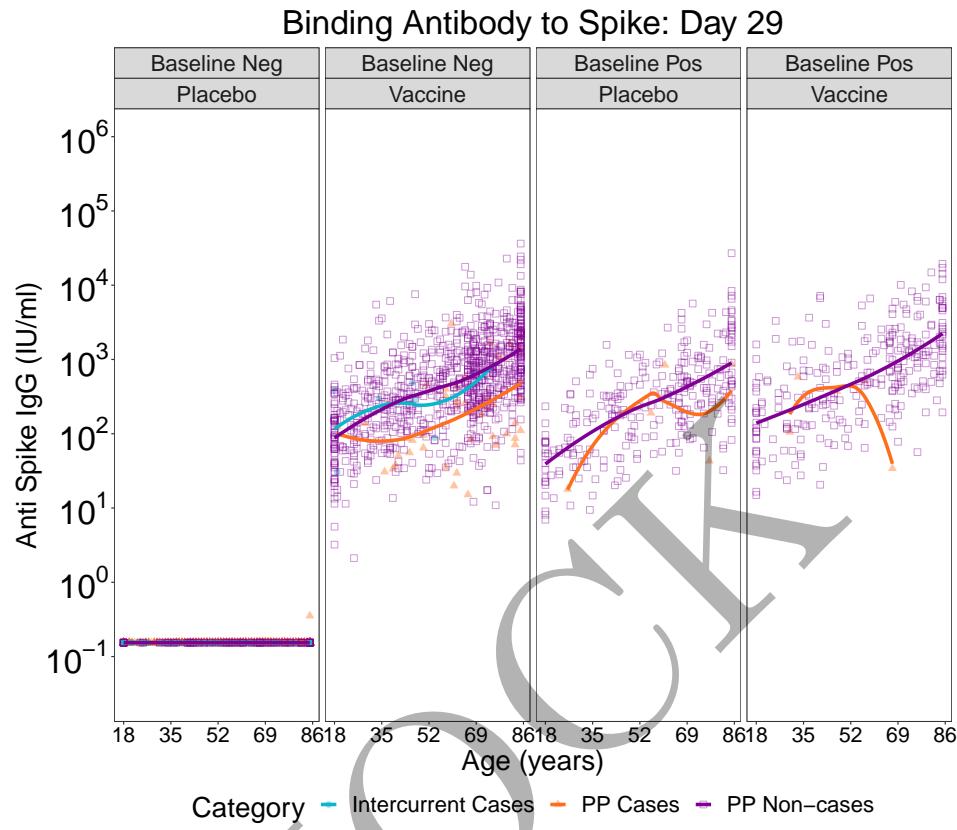


Figure 2.260: scatterplots of Binding Antibody to Spike: by arm at day 29

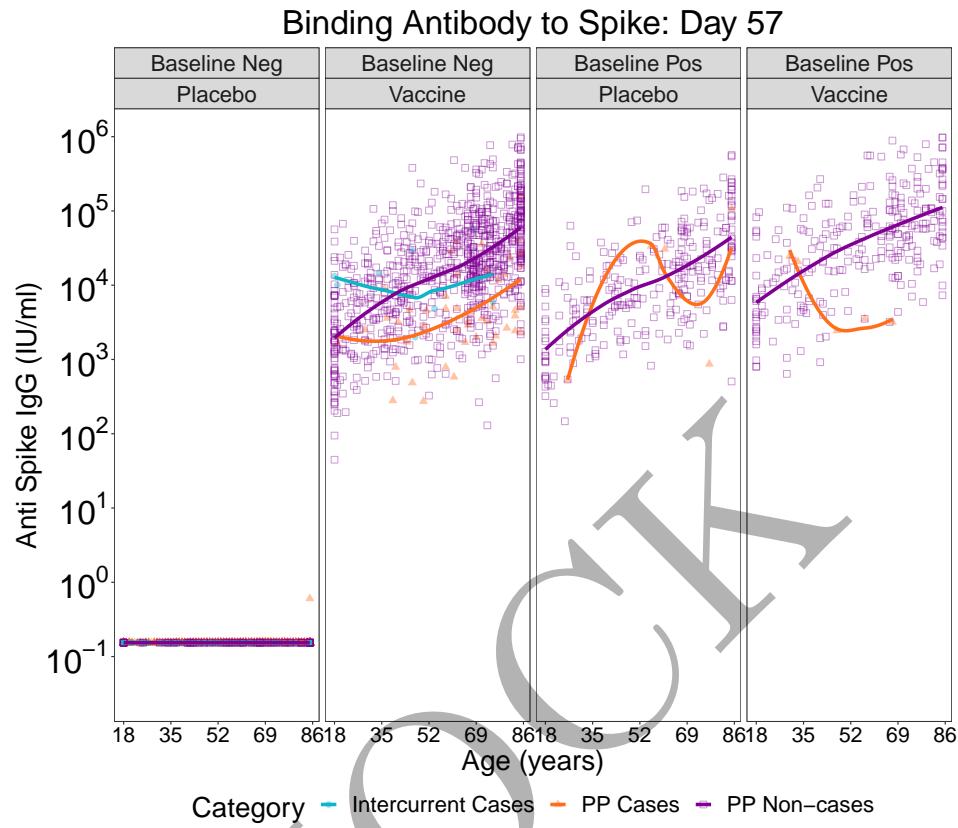


Figure 2.261: scatterplots of Binding Antibody to Spike: by arm at day 57

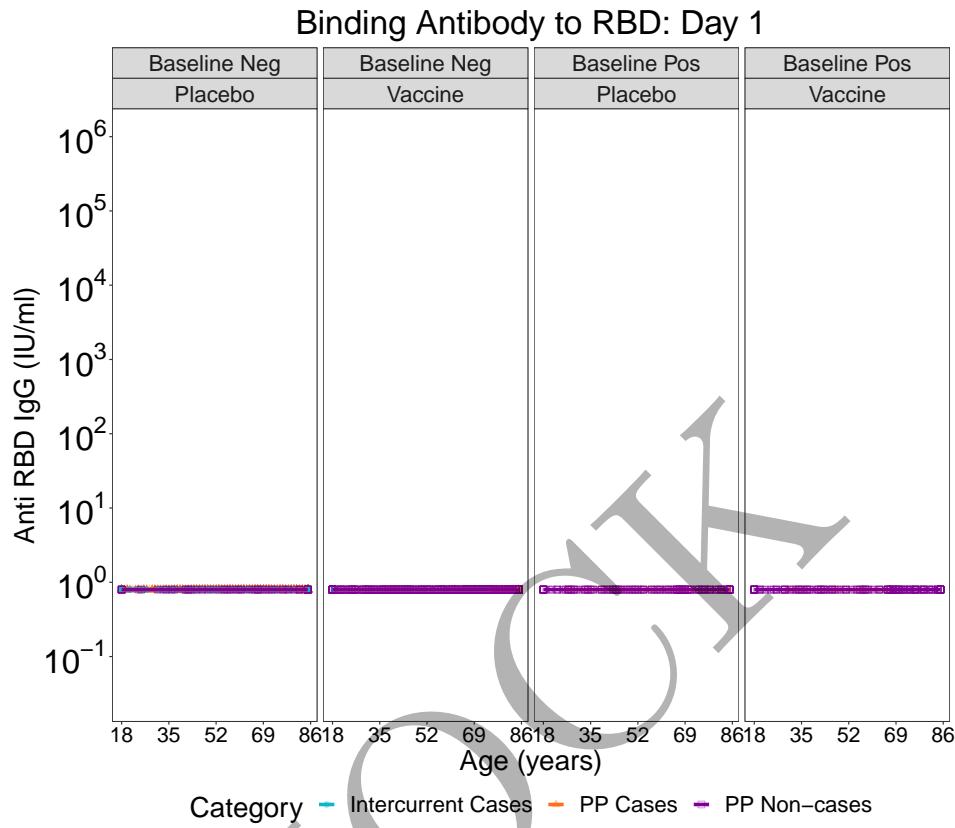


Figure 2.262: scatterplots of Binding Antibody to RBD: by arm at day 1

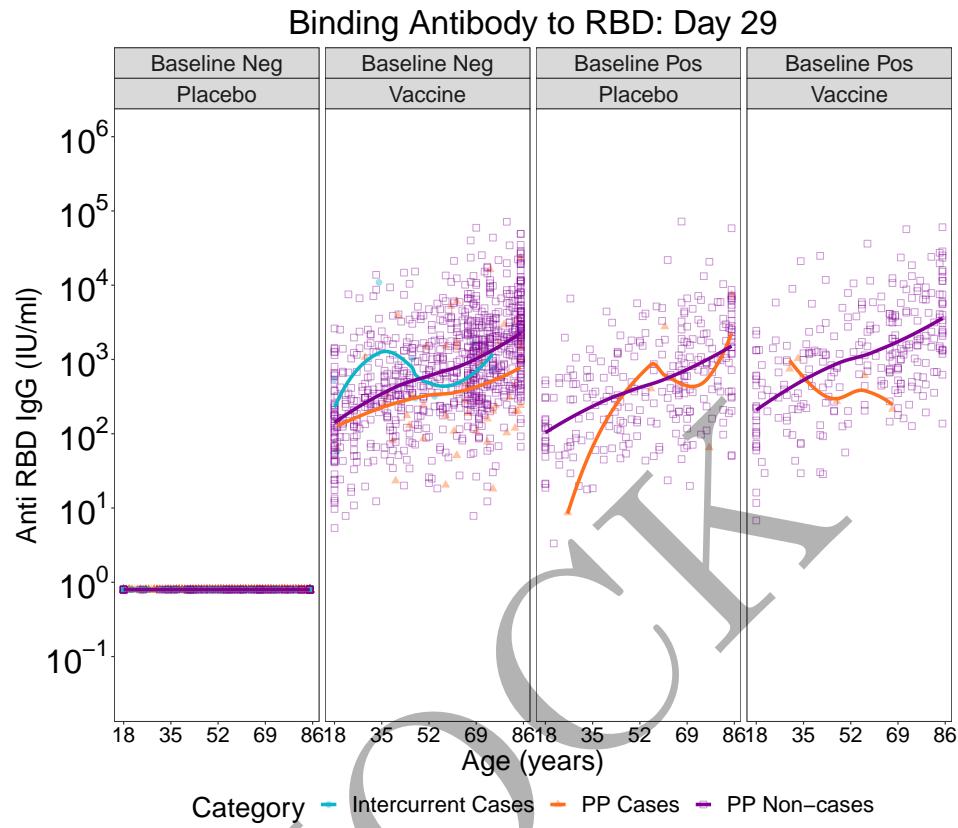


Figure 2.263: scatterplots of Binding Antibody to RBD: by arm at day 29

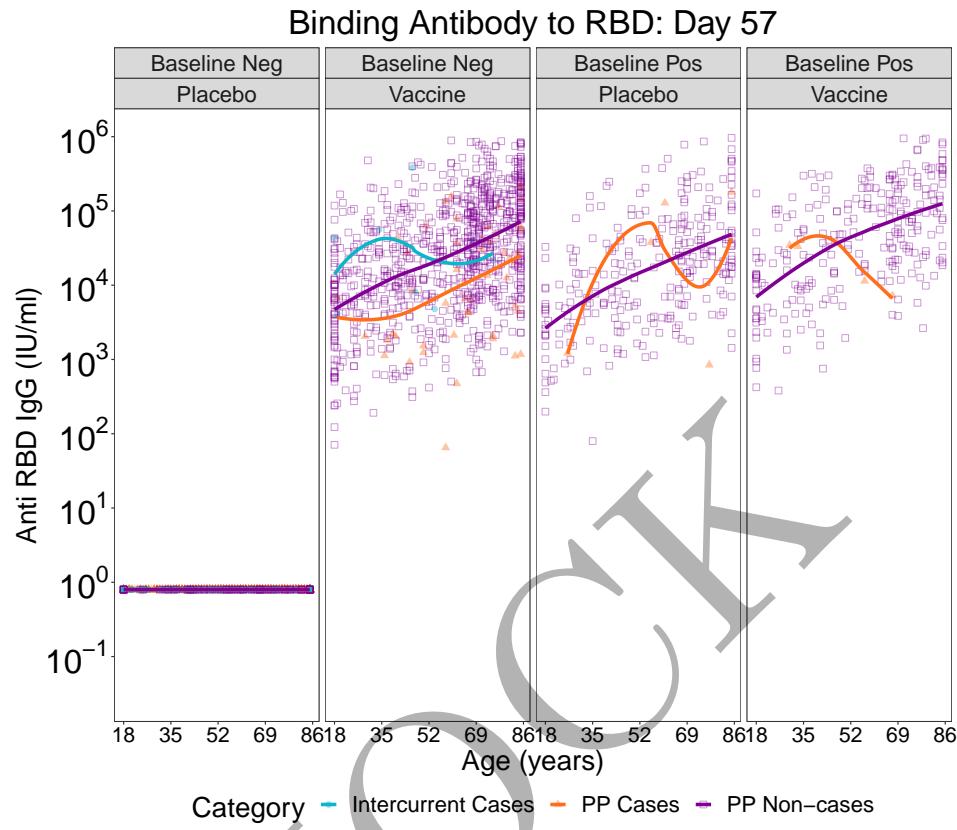


Figure 2.264: scatterplots of Binding Antibody to RBD: by arm at day 57

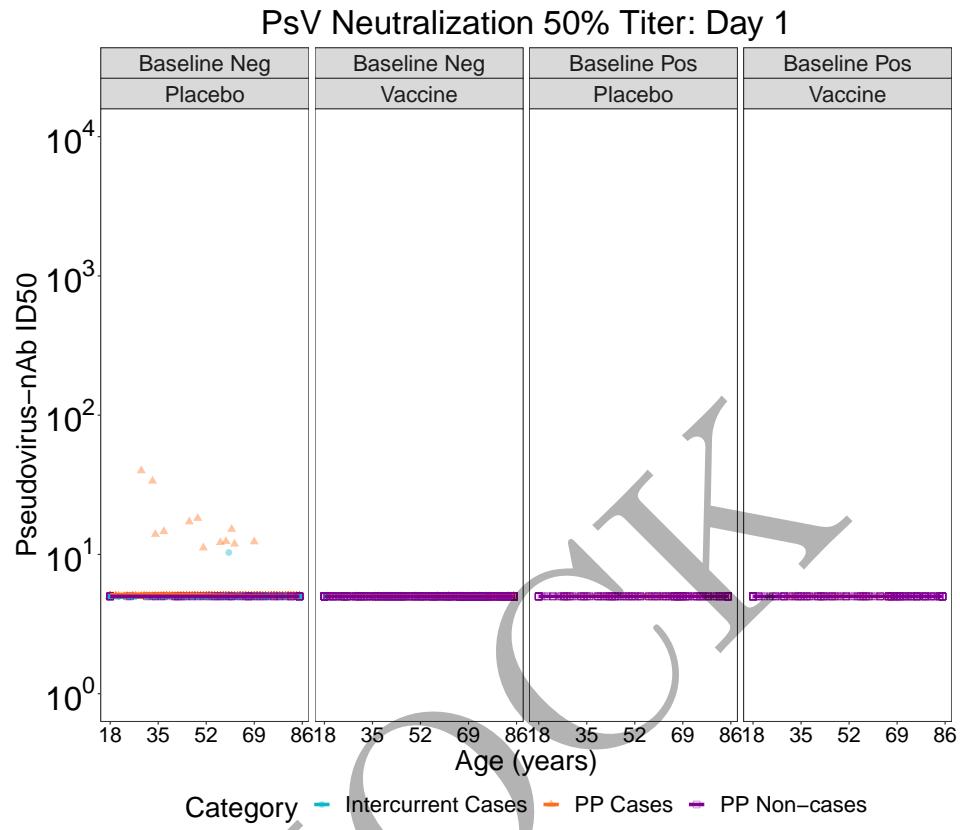


Figure 2.265: scatterplots of Pseudovirus Neutralization ID50: by arm at day 1

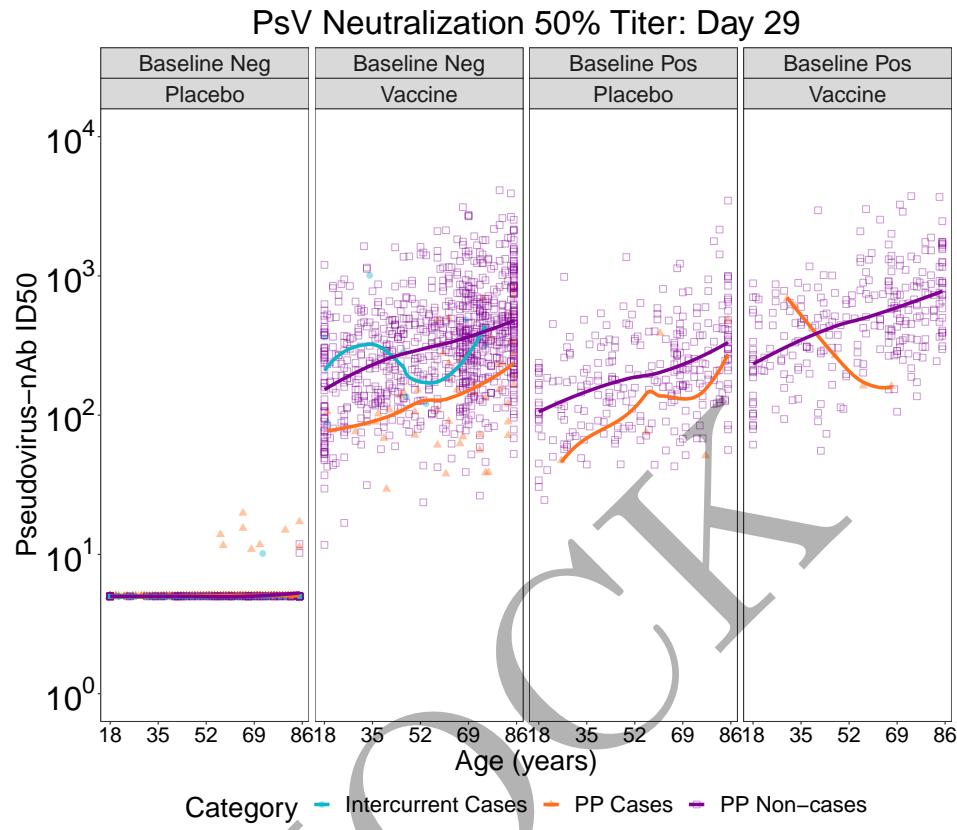


Figure 2.266: scatterplots of Pseudovirus Neutralization ID50: by arm at day 29

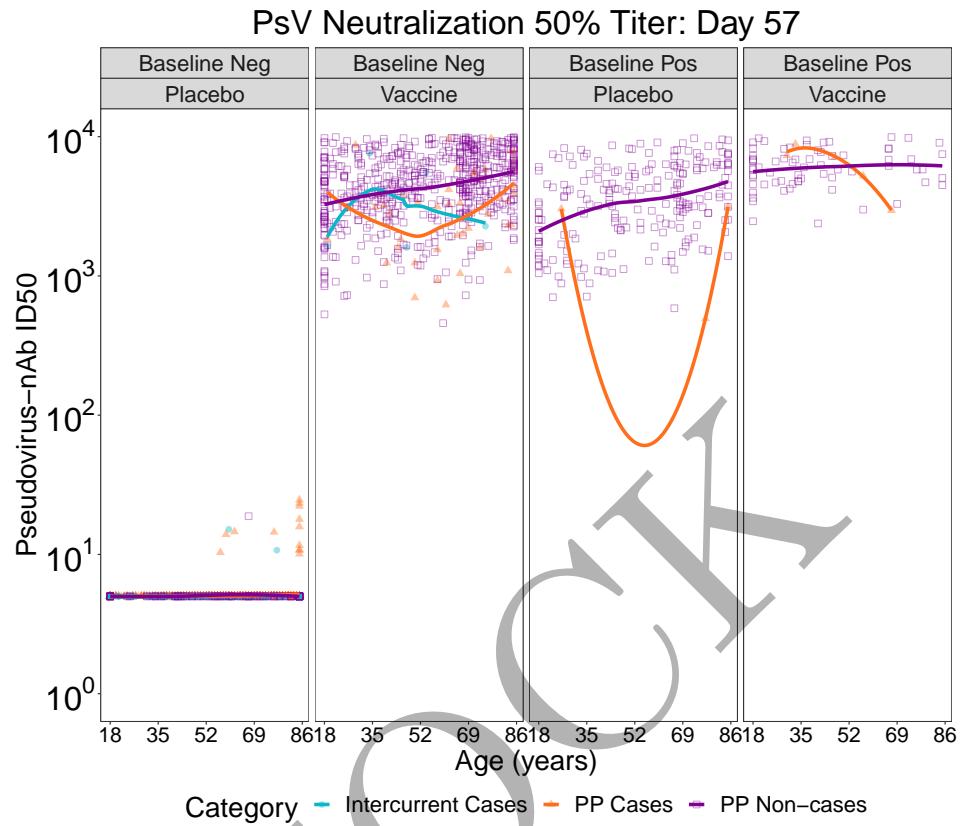


Figure 2.267: scatterplots of Pseudovirus Neutralization ID50: by arm at day 57

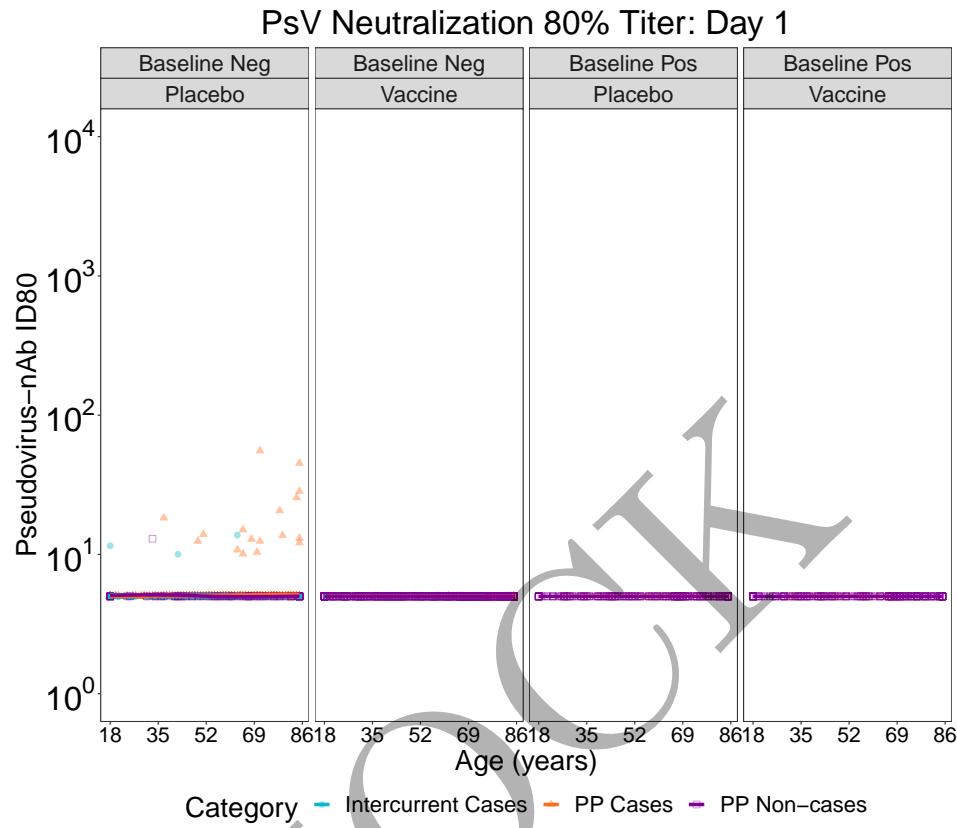


Figure 2.268: scatterplots of Pseudovirus Neutralization ID80: by arm at day 1

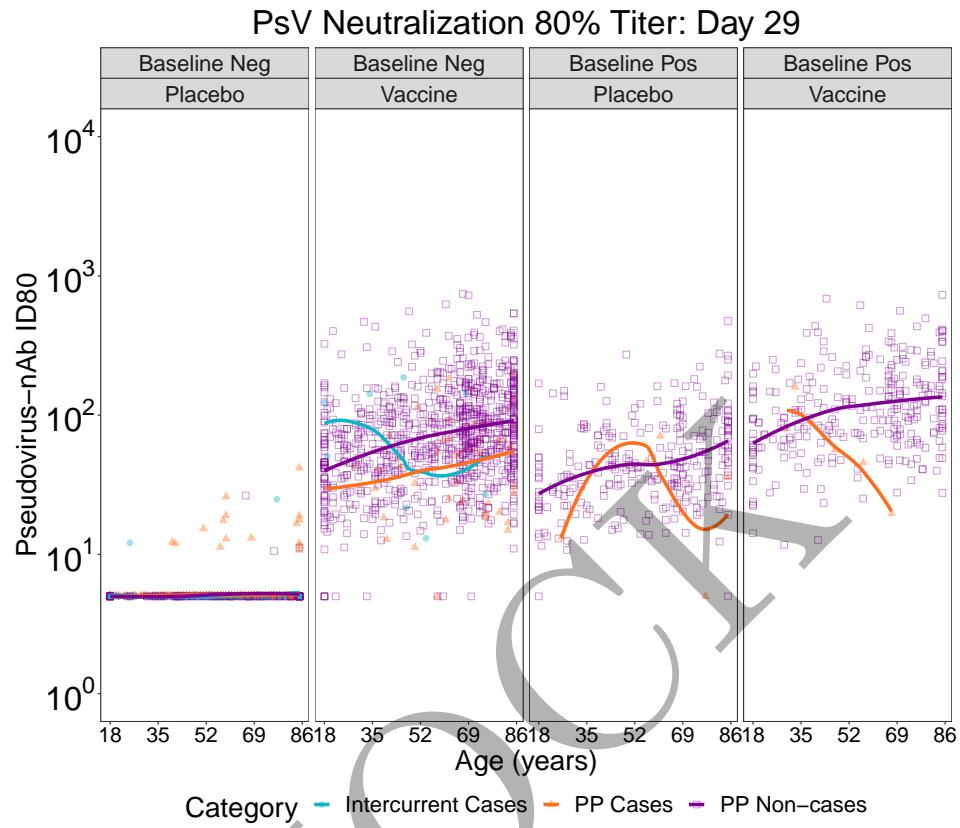


Figure 2.269: scatterplots of Pseudovirus Neutralization ID80: by arm at day 29

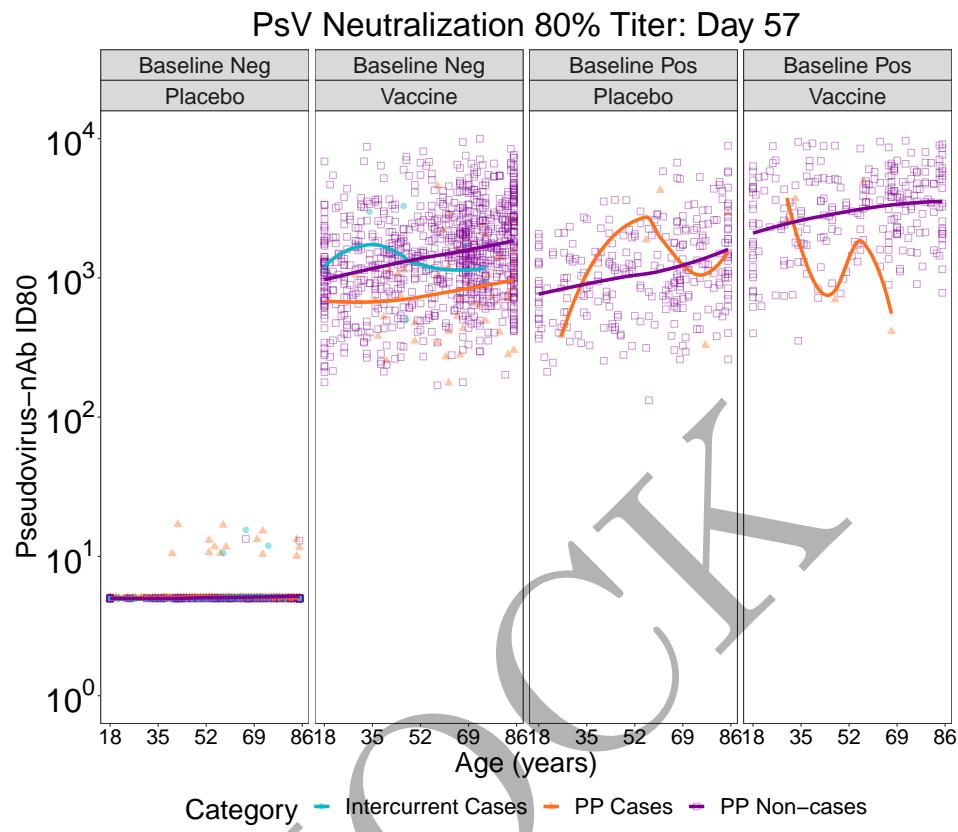


Figure 2.270: scatterplots of Pseudovirus Neutralization ID80: by arm at day 57

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) | 51/11,174 | 0.21 | (0.11-0.40) | <0.001 | <0.001 | <0.001 |
| Anti RBD IgG (IU/ml) | 51/11,174 | 0.22 | (0.10-0.46) | <0.001 | <0.001 | <0.001 |
| Pseudovirus-nAb ID50 | 51/11,174 | 0.02 | (0.00-0.09) | <0.001 | <0.001 | <0.001 |
| Pseudovirus-nAb ID80 | 51/11,174 | 0.05 | (0.02-0.19) | <0.001 | <0.001 | <0.001 |

*Baseline covariates adjusted for: baseline risk score, at risk or not, community of color or not. Maximum failure event time 170 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 | 17/2,765 | 0.0061 | 1 | N/A | N/A | <0.001 | <0.001 | <0.001 |
| | Middle | 19/2,794 | 0.0068 | 0.61 | (0.26-1.42) | 0.251 | | | |
| | Upper | 15/5,616 | 0.0027 | 0.08 | (0.03-0.19) | <0.001 | | | |
| Anti RBD IgG (IU/ml) | Lower | 20/2,964 | 0.0067 | 1 | N/A | N/A | <0.001 | <0.001 | <0.001 |
| | Middle | 8/2,961 | 0.0027 | 0.35 | (0.14-0.86) | 0.022 | | | |
| | Upper | 23/5,249 | 0.0044 | 0.22 | (0.10-0.46) | <0.001 | | | |
| Pseudovirus-nAb ID50 | Lower | 19/2,214 | 0.0086 | 1 | N/A | N/A | <0.001 | <0.001 | <0.001 |
| | Middle | 13/2,200 | 0.0059 | 0.73 | (0.32-1.66) | 0.454 | | | |
| | Upper | 19/6,760 | 0.0028 | 0.14 | (0.07-0.29) | <0.001 | | | |
| Pseudovirus-nAb ID80 | Lower | 26/2,690 | 0.0097 | 1 | N/A | N/A | <0.001 | <0.001 | <0.001 |
| | Middle | 12/2,681 | 0.0045 | 0.38 | (0.18-0.84) | 0.016 | | | |
| | Upper | 13/5,803 | 0.0022 | 0.16 | (0.08-0.33) | <0.001 | | | |
| Placebo | | 1013/11,267 | 0.0899 | | | | | | |

*Baseline covariates adjusted for: baseline risk score, at risk or not, community of color or not. Maximum failure event time 170 days. Cutpoints: Anti Spike IgG (IU/ml) [3.45, 4.01], Anti RBD IgG (IU/ml) [3.77, 4.21], Pseudovirus-nAb ID50 [3.46, 3.64], Pseudovirus-nAb ID80 [2.9, 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.

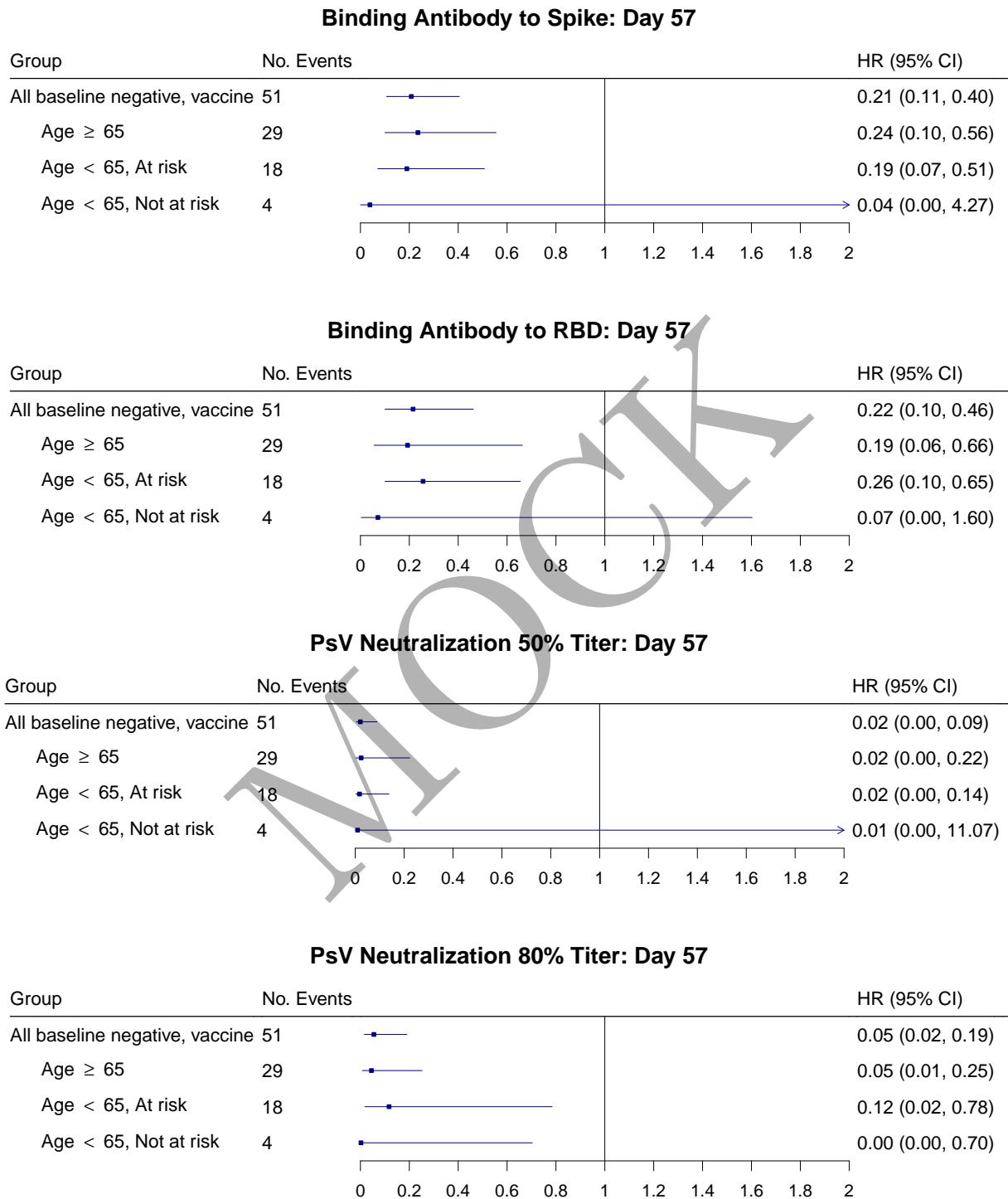


Figure 3.1: Forest plots of hazard ratios per 10-fold increase in the marker among baseline seronegative vaccine recipients and subgroups with 95% point-wise confidence intervals.

Binding Antibody to Spike: Day 57

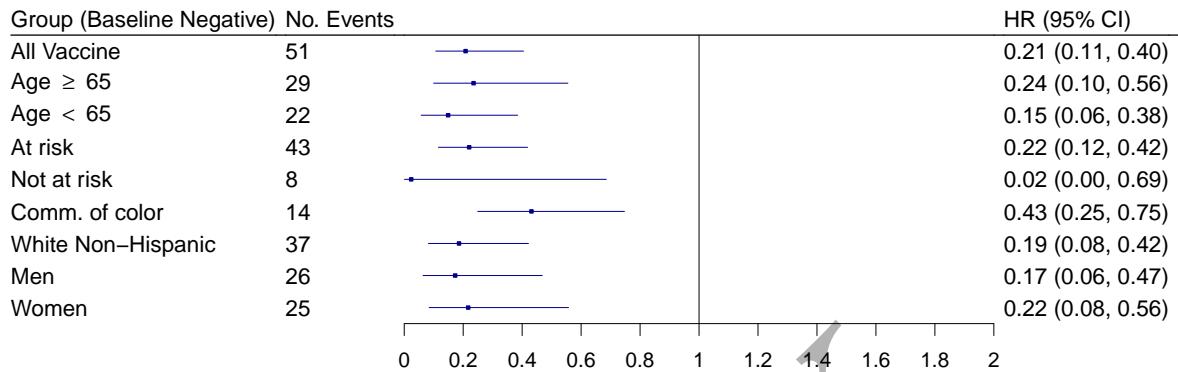


Figure 3.2: Forest plots of hazard ratios per 10-fold increase in the Day 57 binding Ab to spike markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

Binding Antibody to RBD: Day 57

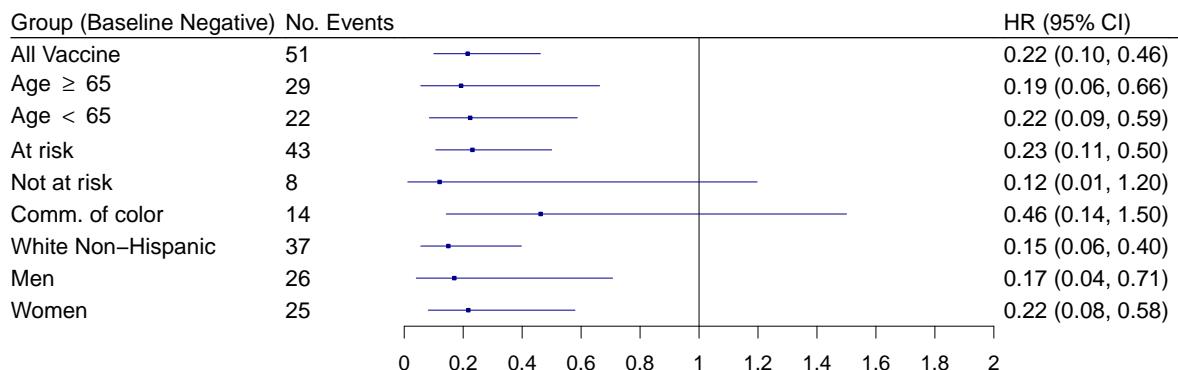


Figure 3.3: Forest plots of hazard ratios per 10-fold increase in the Day 57 binding Ab to RBD markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

PsV Neutralization 50% Titer: Day 57

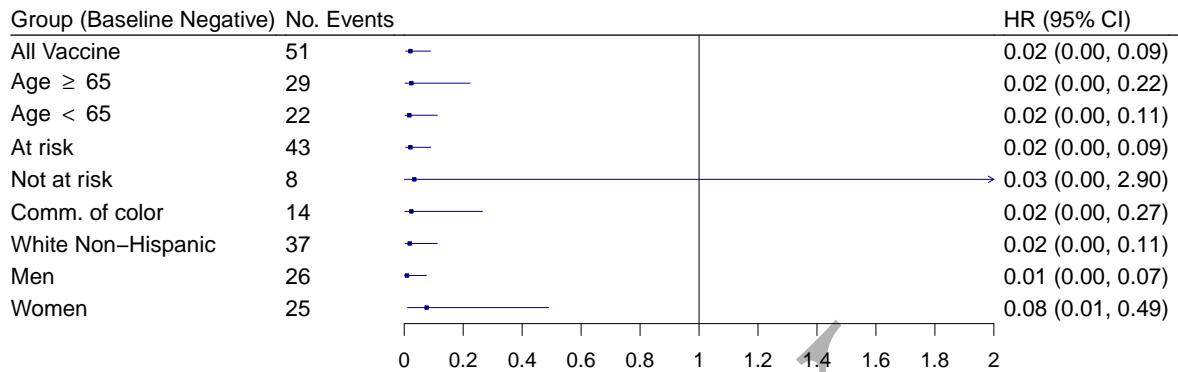


Figure 3.4: Forest plots of hazard ratios per 10-fold increase in the Day 57 pseudo neut ID50 markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

PsV Neutralization 80% Titer: Day 57

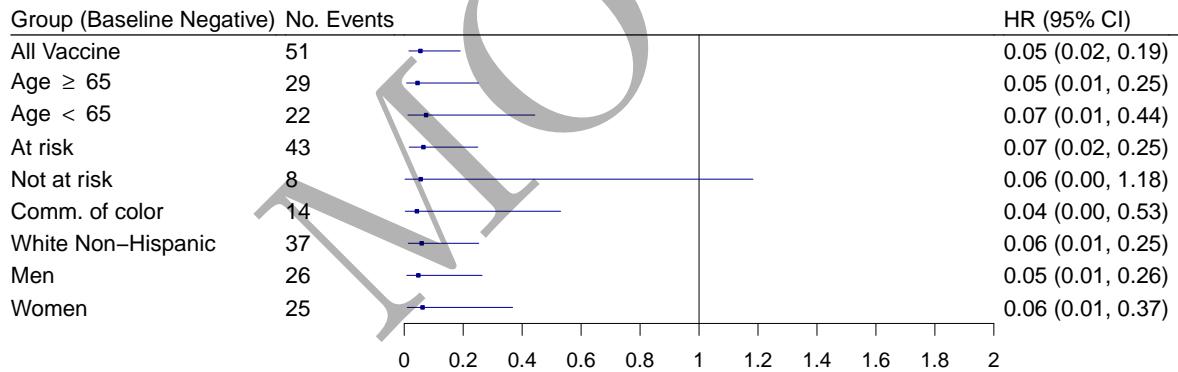


Figure 3.5: Forest plots of hazard ratios per 10-fold increase in the Day 57 pseudo neut ID80 markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

3.2 Marginalized risk and controlled vaccine efficacy plots

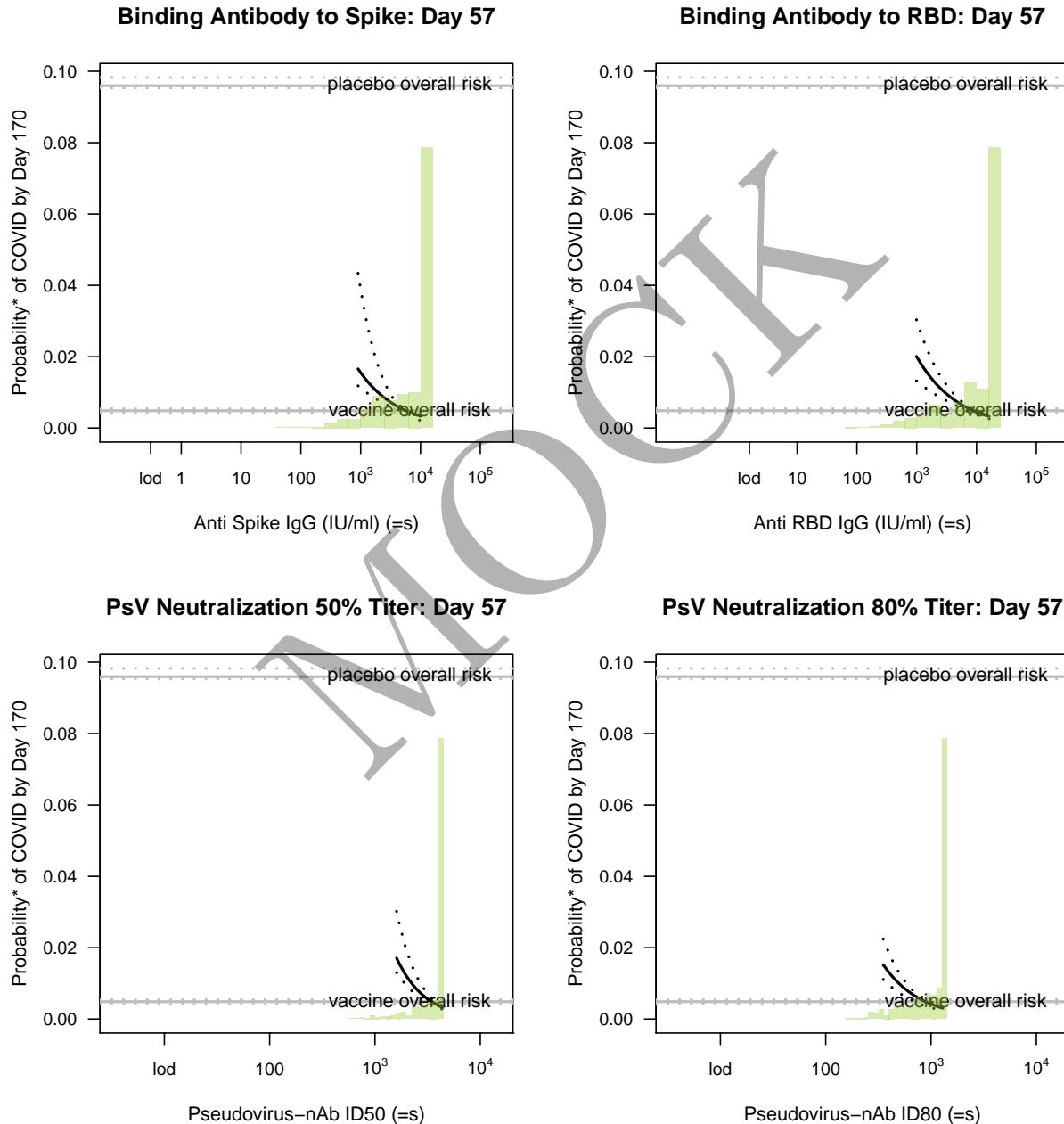


Figure 3.6: Marginalized cumulative risk by Day 170 as functions of Day 57 markers (=s) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. The horizontal lines indicate the overall cumulative risk of the placebo and vaccine arms by Day 170 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod = 0.3, 1.6, 10, 10 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively.

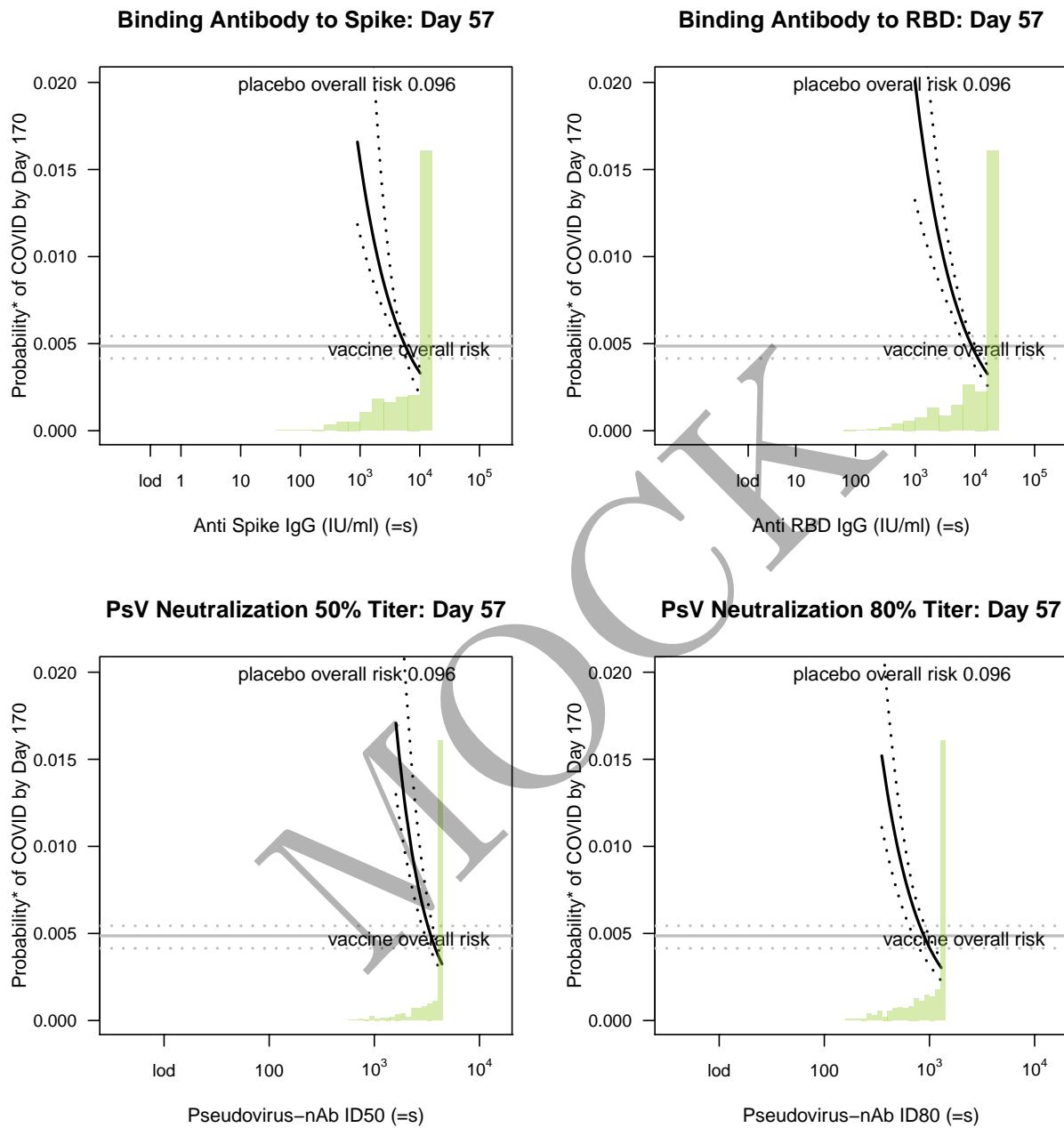


Figure 3.7: Marginalized cumulative risk by Day 170 as functions of Day 57 markers (=s) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. The horizontal lines indicate the overall cumulative risk of the placebo and vaccine arms by Day 170 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod = 0.3, 1.6, 10, 10 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively.

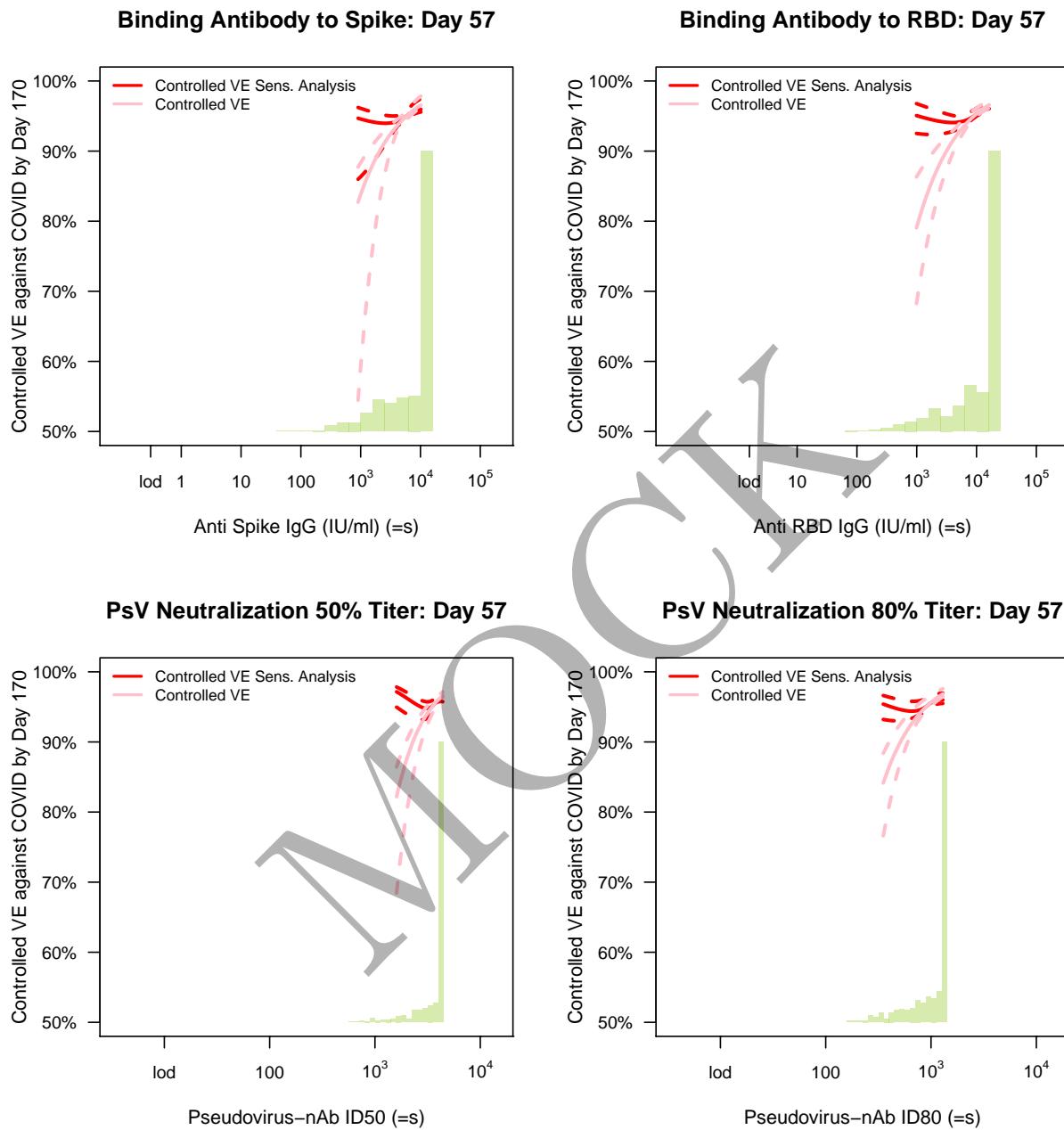


Figure 3.8: Controlled VE with sensitivity analysis as functions of Day 57 markers (=s) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. Histograms of the immunological markers in the vaccine arm are overlaid. lod = 0.3, 1.6, 10, 10 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively.

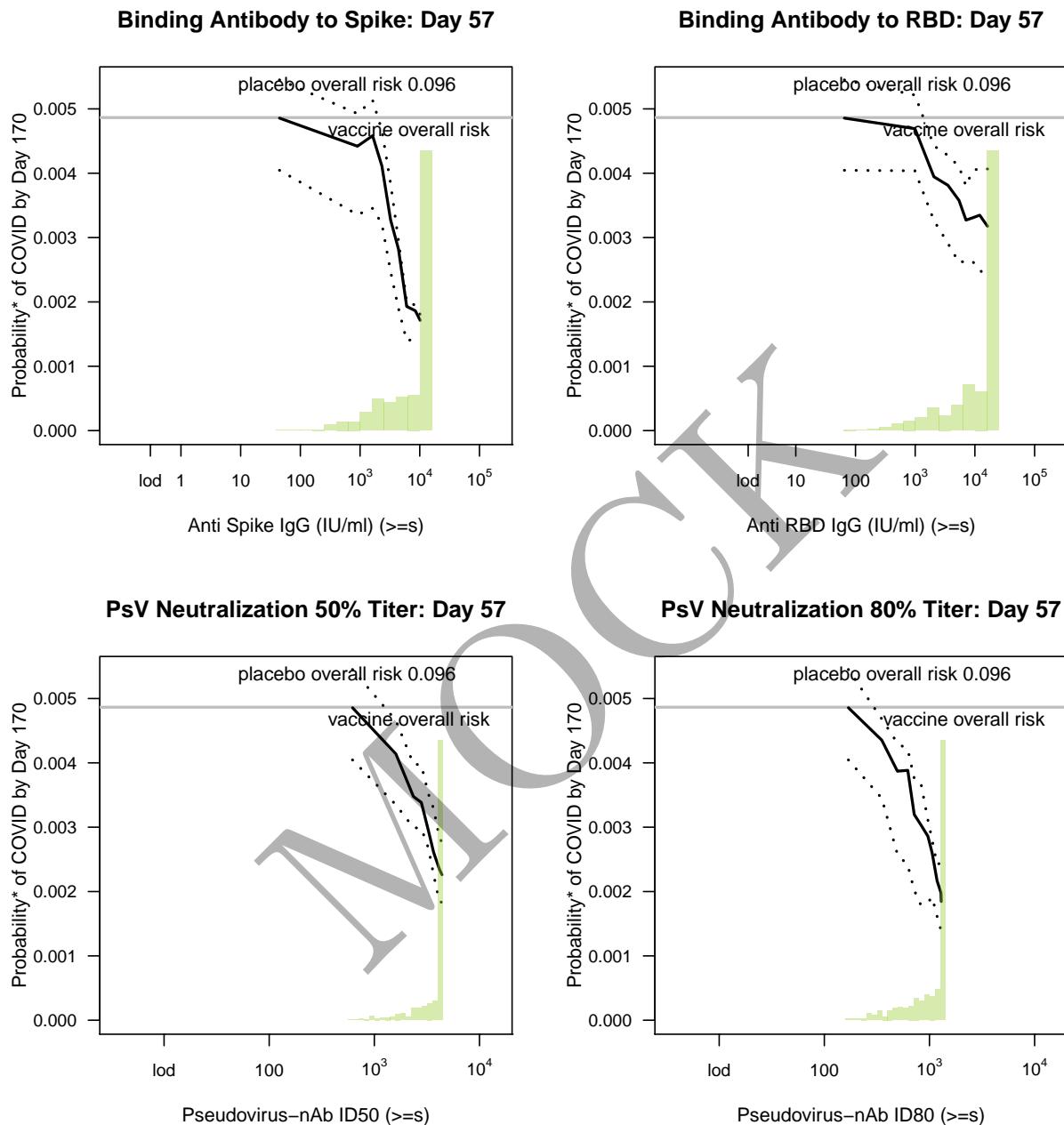


Figure 3.9: Marginalized cumulative risk by Day 170 as functions of Day 57 markers above a threshold ($\geq s$) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands (at least 5 cases are required). The horizontal lines indicate the overall cumulative risk of the vaccine arm by Day 170 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod = 0.3, 1.6, 10, 10 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively.

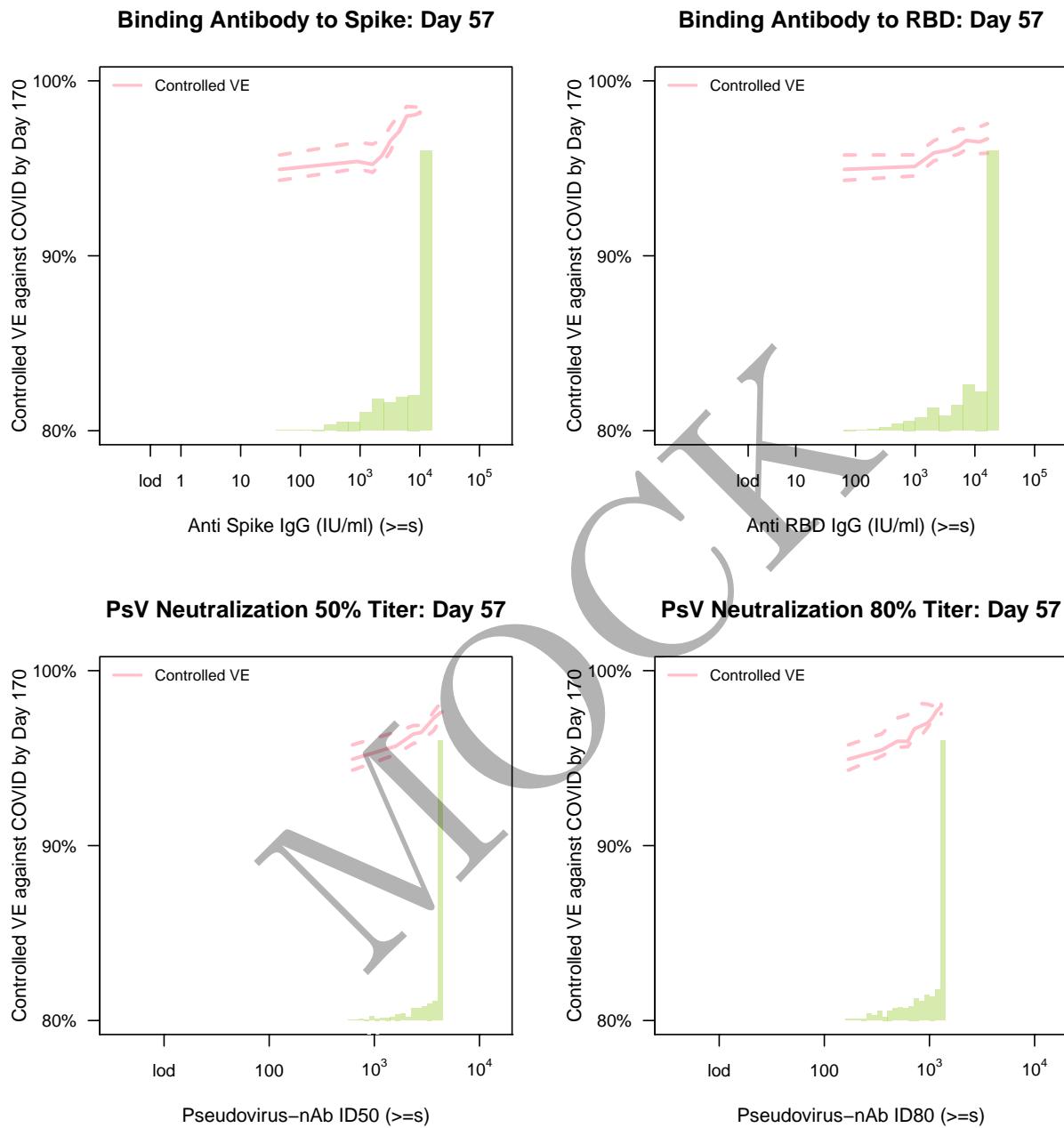


Figure 3.10: Controlled VE as functions of Day 57 markers ($\geq s$) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. Histograms of the immunological markers in the vaccine arm are overlaid. lod = 0.3, 1.6, 10, 10 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively.

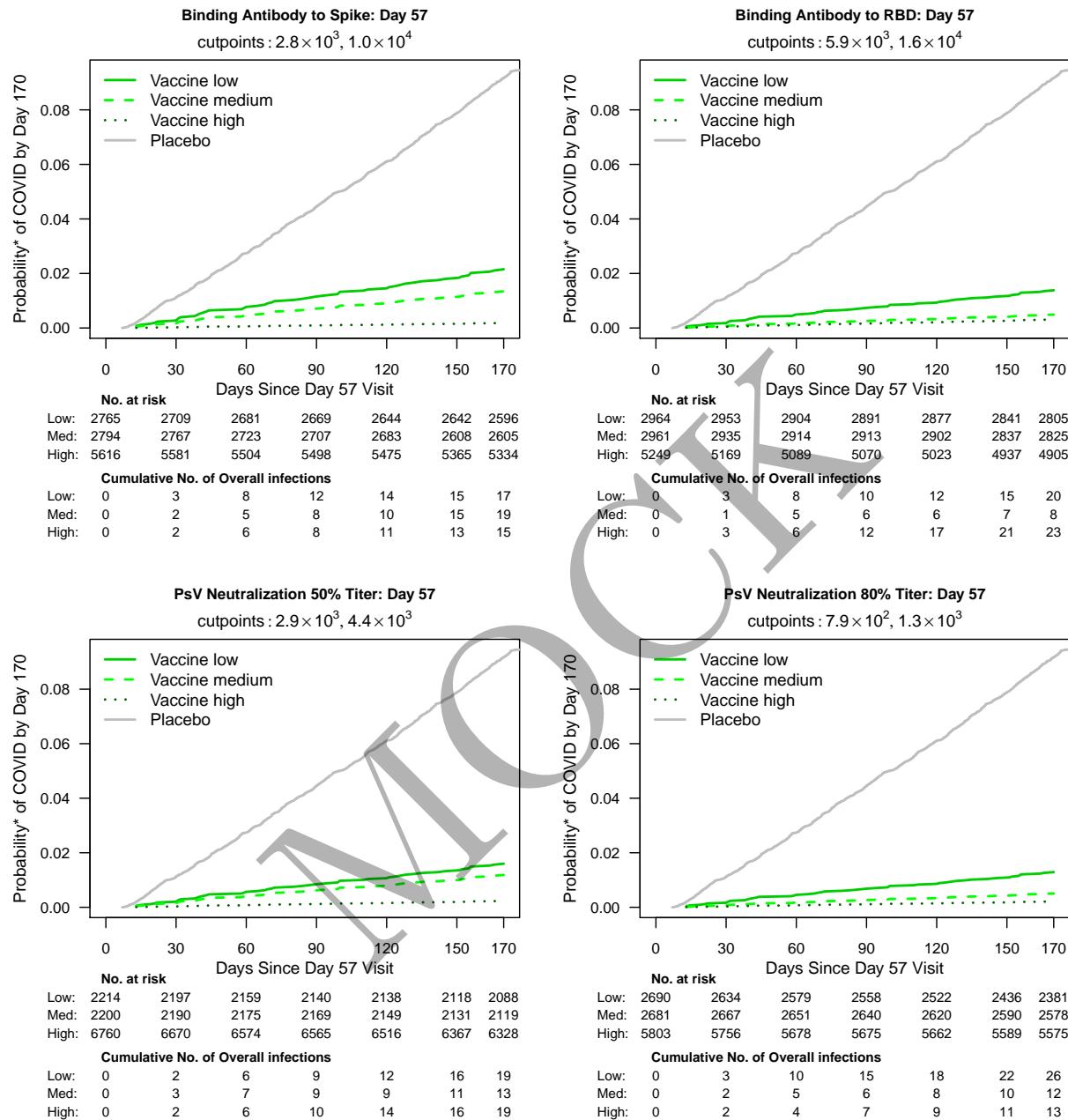


Figure 3.11: Marginalized cumulative incidence rate curves for trichotomized Day 57 markers among baseline seronegative vaccine recipients. The gray line is the overall cumulative incidence rate curve in the placebo arm.

MOCK

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) | 59/11,228 | 0.25 | (0.15-0.41) | <0.001 | <0.001 | <0.001 |
| Anti RBD IgG (IU/ml) | 59/11,228 | 0.47 | (0.29-0.76) | 0.002 | <0.001 | <0.001 |
| Pseudovirus-nAb ID50 | 59/11,228 | 0.10 | (0.05-0.20) | <0.001 | <0.001 | <0.001 |
| Pseudovirus-nAb ID80 | 59/11,228 | 0.21 | (0.10-0.47) | <0.001 | <0.001 | <0.001 |

*Baseline covariates adjusted for: baseline risk score, at risk or not, community of color or not. Maximum failure event time 198 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 | Haz. Ratio Pt. Est. | 95% CI | P-value (2-sided) | Overall P- value*** | Overall q- value | Overall FWER |
|----------------------------|---------|------------------------------|----------------|------------------------|-------------|----------------------|------------------------|---------------------|-----------------|
| Anti Spike IgG (IU/ml) | Lower | 25/3,724 | 0.0067 | 1 | N/A | N/A | <0.001 | <0.001 | <0.001 |
| | Middle | 22/3,732 | 0.0059 | 0.55 | (0.29-1.07) | 0.078 | | | |
| | Upper | 12/3,773 | 0.0032 | 0.11 | (0.05-0.25) | <0.001 | | | |
| Anti RBD IgG (IU/ml) | Lower | 21/3,747 | 0.0056 | 1 | N/A | N/A | 0.018 | <0.001 | .100 |
| | Middle | 19/3,753 | 0.0051 | 0.42 | (0.20-0.91) | 0.028 | | | |
| | Upper | 19/3,728 | 0.0051 | 0.28 | (0.12-0.69) | 0.005 | | | |
| Pseudovirus-nAb ID50 | Lower | 35/3,768 | 0.0093 | 1 | N/A | N/A | <0.001 | <0.001 | <0.001 |
| | Middle | 16/3,719 | 0.0043 | 0.27 | (0.14-0.52) | <0.001 | | | |
| | Upper | 8/3,741 | 0.0021 | 0.09 | (0.04-0.20) | <0.001 | | | |
| Pseudovirus-nAb ID80 | Lower | 26/3,743 | 0.0069 | 1 | N/A | N/A | 0.003 | <0.001 | <0.001 |
| | Middle | 18/3,762 | 0.0048 | 0.43 | (0.23-0.84) | 0.013 | | | |
| | Upper | 15/3,722 | 0.0040 | 0.31 | (0.15-0.64) | 0.001 | | | |
| Placebo | | 1172/11,476 | 0.1021 | | | | | | |

*Baseline covariates adjusted for: baseline risk score, at risk or not, community of color or not. Maximum failure event time 198 days. Cutpoints: Anti Spike IgG (IU/ml) [2.26, 2.75], Anti RBD IgG (IU/ml) [2.38, 3.02], Pseudovirus-nAb ID50 [2.24, 2.58], Pseudovirus-nAb ID80 [1.63, 1.93].

**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.

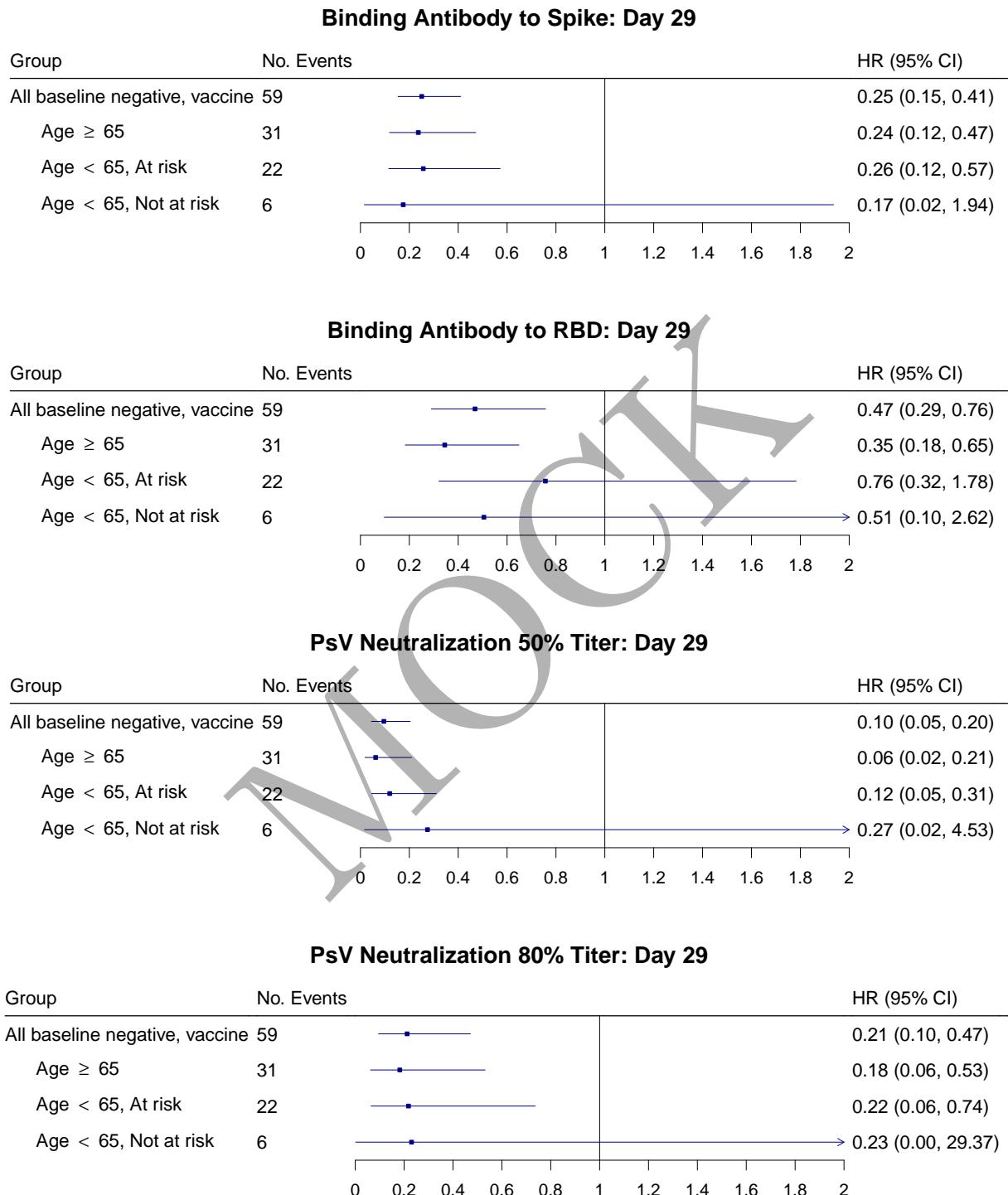


Figure 4.1: Forest plots of hazard ratios per 10-fold increase in the marker among baseline seronegative vaccine recipients and subgroups with 95% point-wise confidence intervals.

Binding Antibody to Spike: Day 29

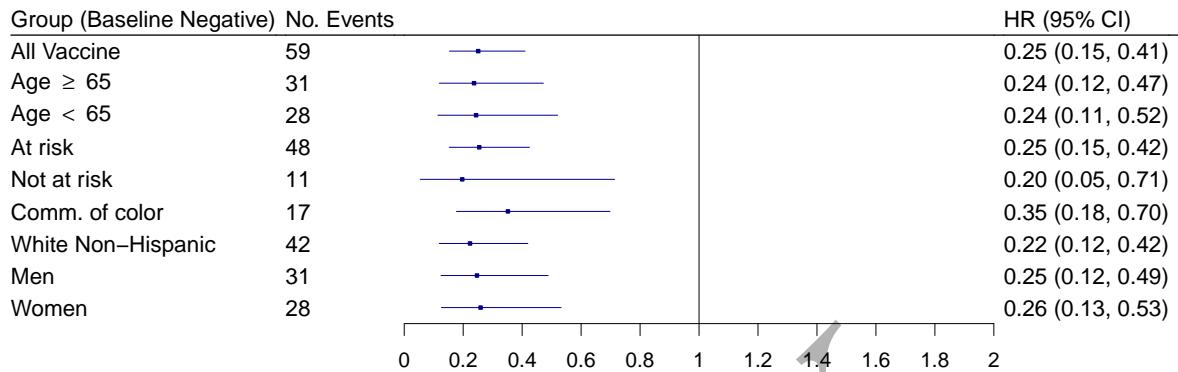


Figure 4.2: Forest plots of hazard ratios per 10-fold increase in the Day 29 binding Ab to spike markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

Binding Antibody to RBD: Day 29

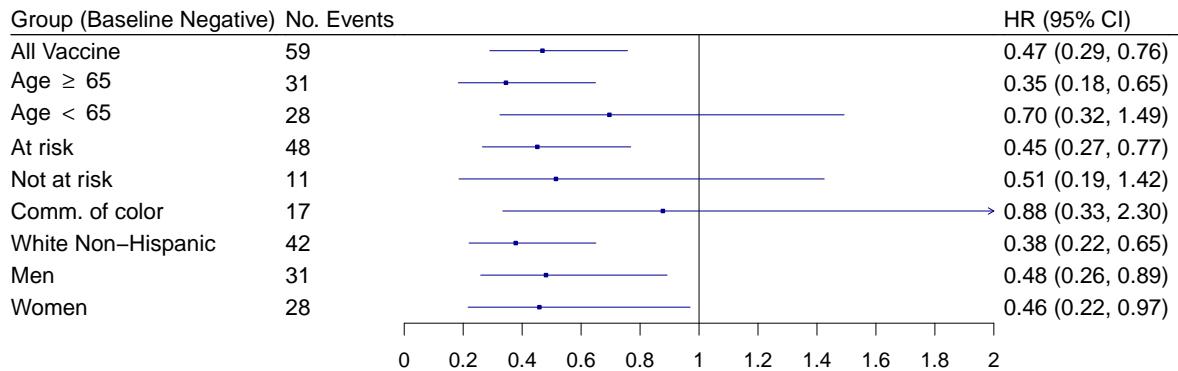


Figure 4.3: Forest plots of hazard ratios per 10-fold increase in the Day 29 binding Ab to RBD markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

PsV Neutralization 50% Titer: Day 29

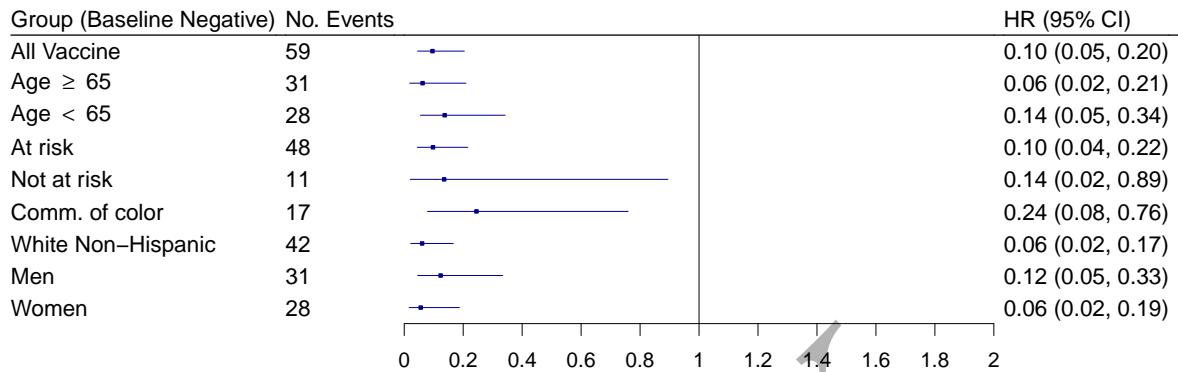


Figure 4.4: Forest plots of hazard ratios per 10-fold increase in the Day 29 pseudo neut ID50 markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

PsV Neutralization 80% Titer: Day 29

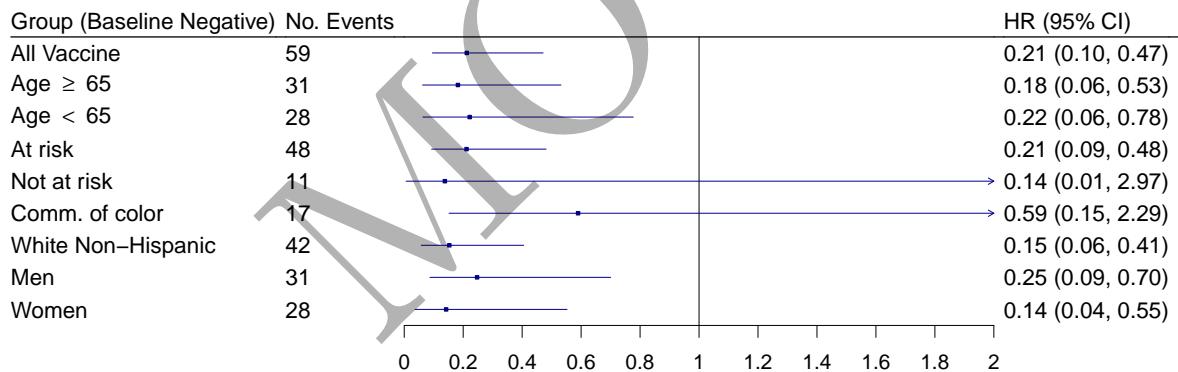


Figure 4.5: Forest plots of hazard ratios per 10-fold increase in the Day 29 pseudo neut ID80 markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

4.2 Marginalized risk and controlled vaccine efficacy plots

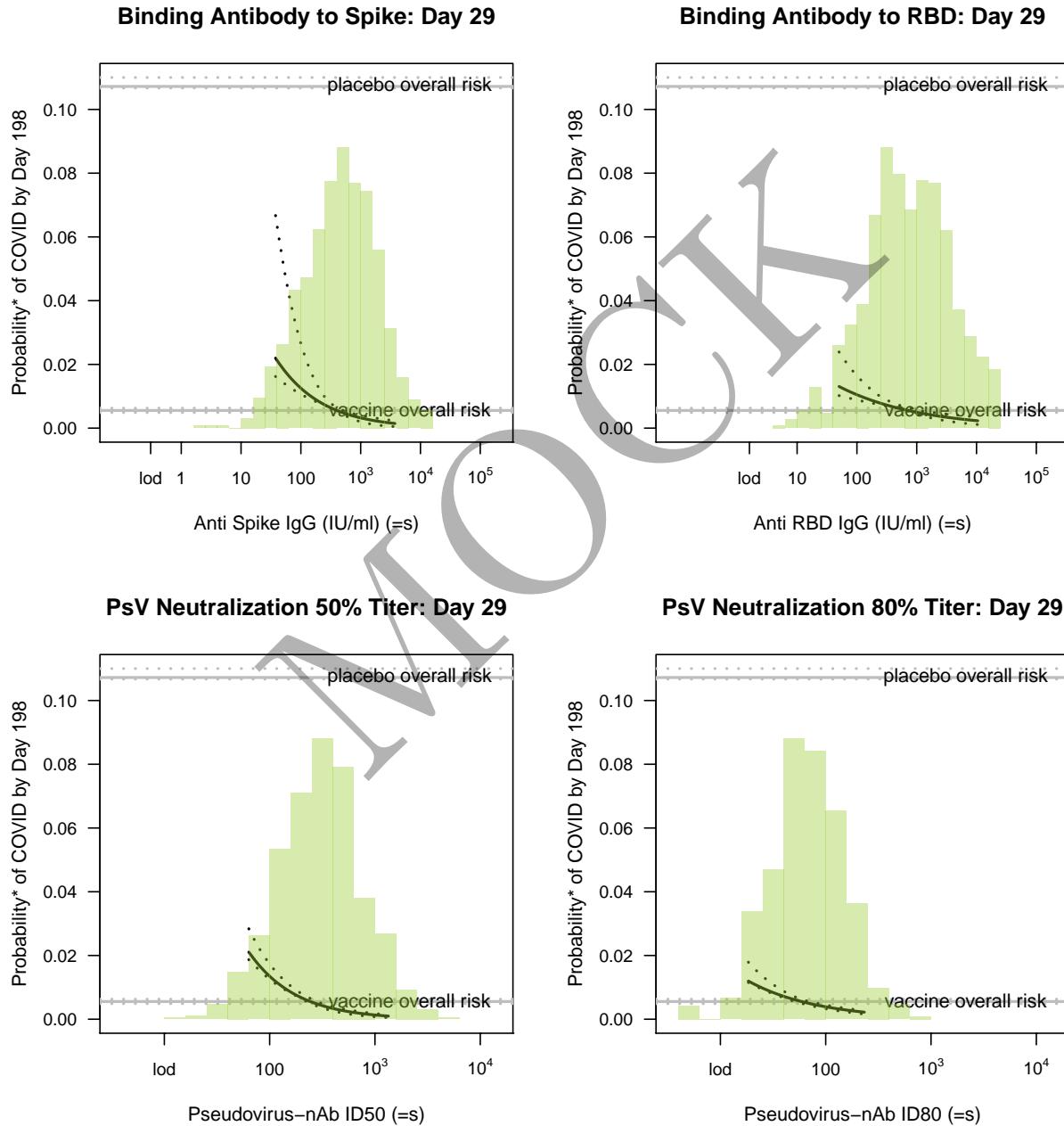


Figure 4.6: Marginalized cumulative risk by Day 198 as functions of Day 29 markers ($=s$) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. The horizontal lines indicate the overall cumulative risk of the placebo and vaccine arms by Day 198 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod = 0.3, 1.6, 10, 10 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively.

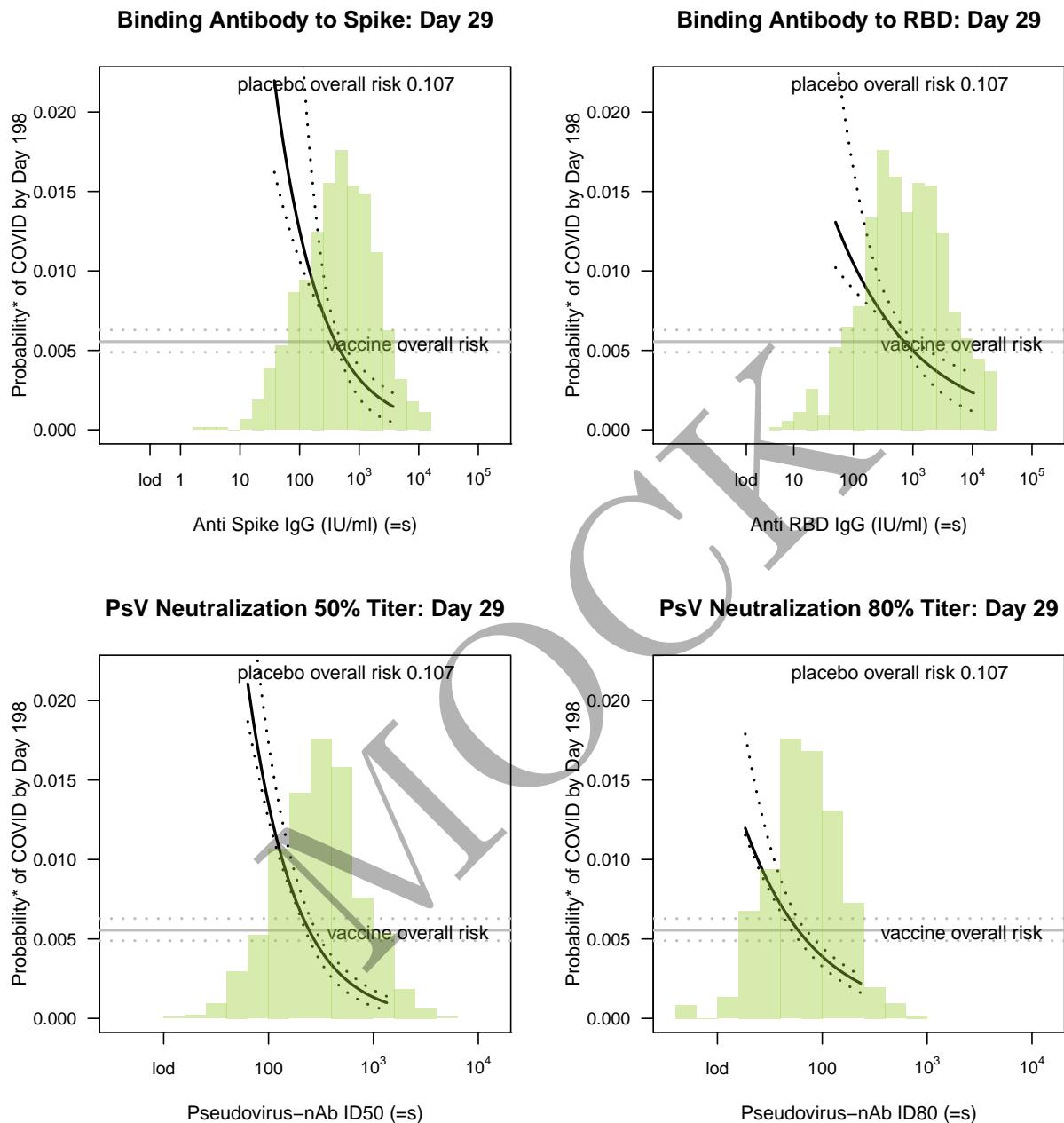


Figure 4.7: Marginalized cumulative risk by Day 198 as functions of Day 29 markers ($=s$) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. The horizontal lines indicate the overall cumulative risk of the placebo and vaccine arms by Day 198 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod = 0.3, 1.6, 10, 10 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively.

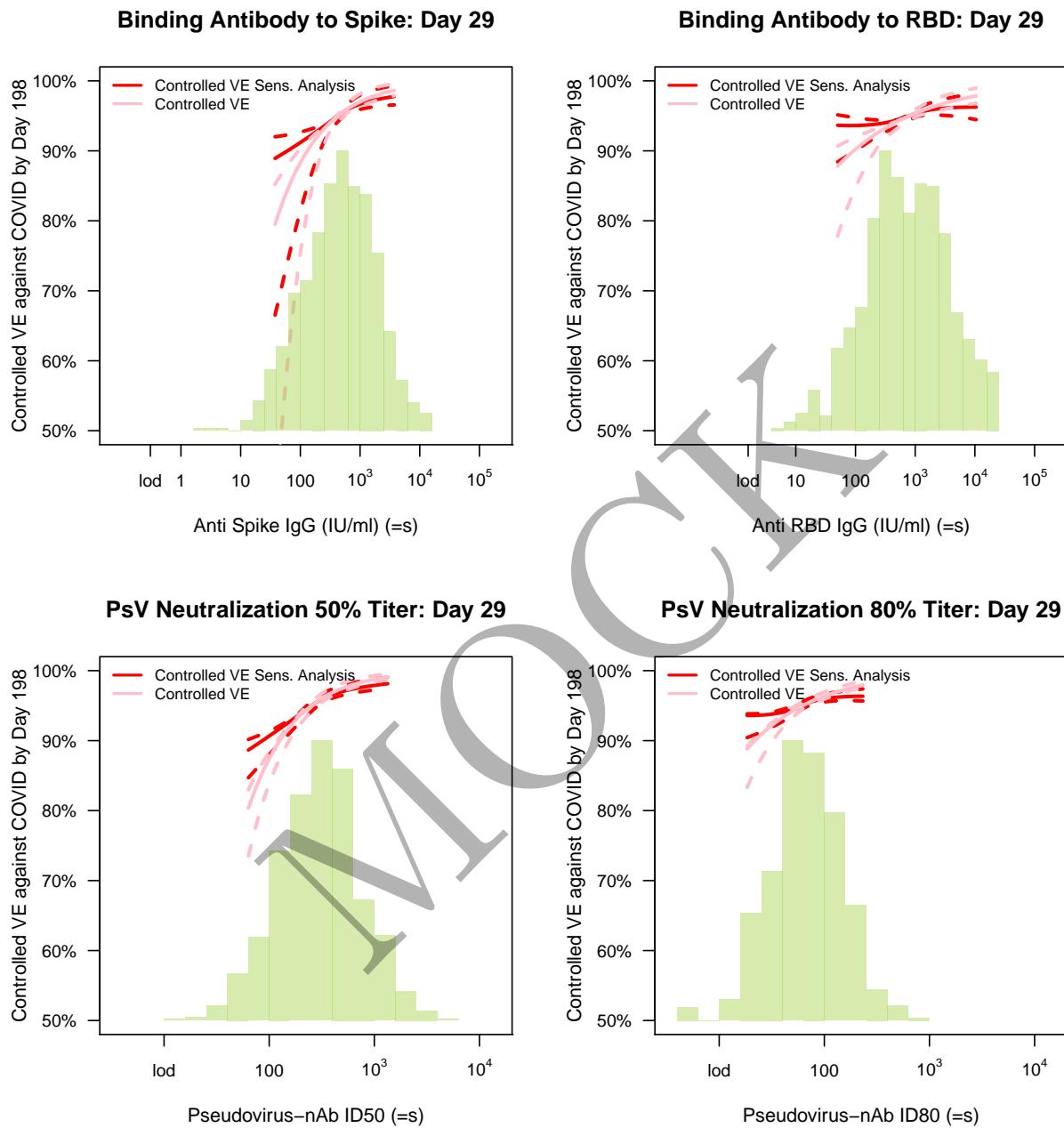


Figure 4.8: Controlled VE with sensitivity analysis as functions of Day 29 markers ($=s$) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. Histograms of the immunological markers in the vaccine arm are overlaid. lod = 0.3, 1.6, 10, 10 for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively.

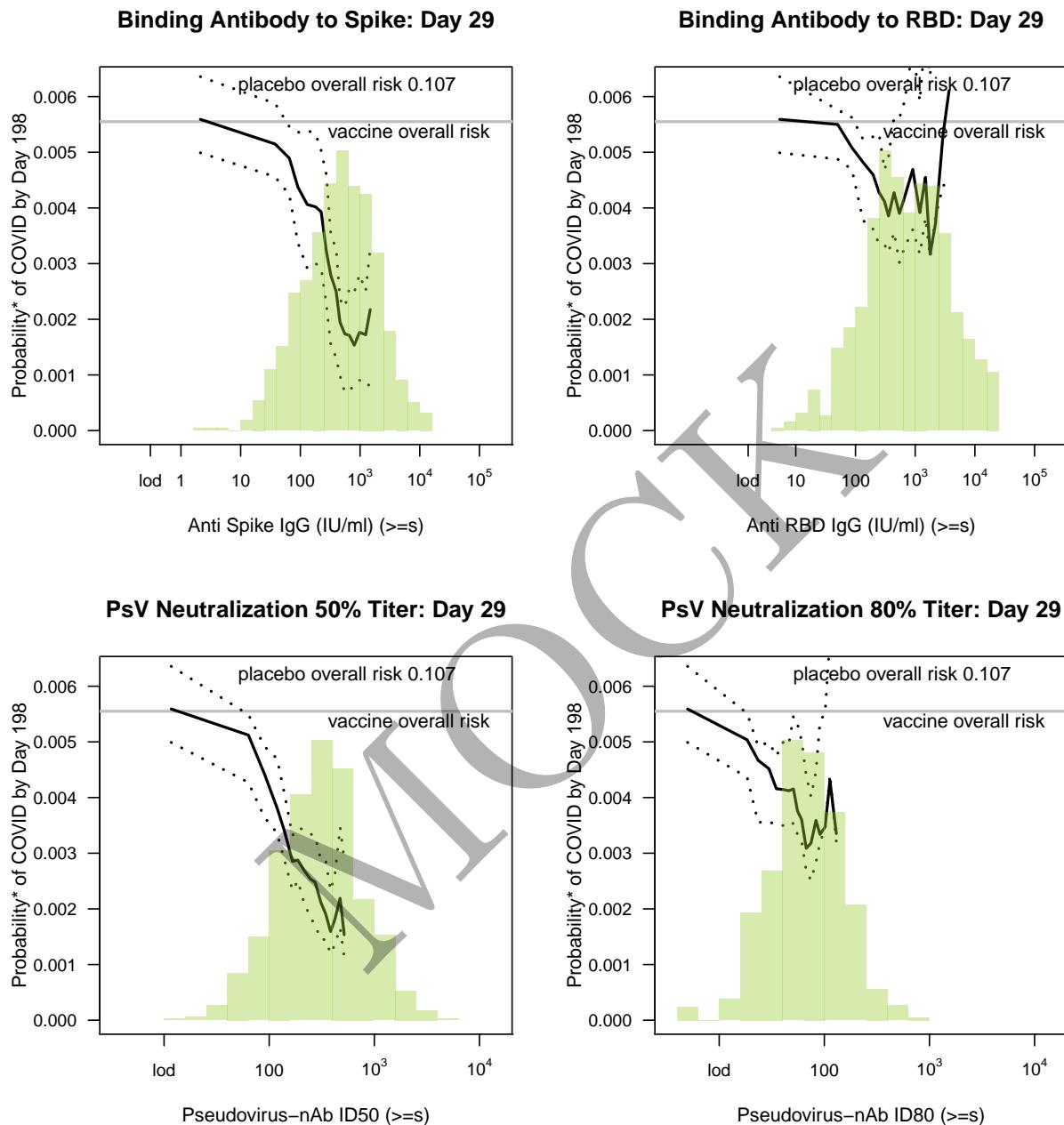


Figure 4.9: Marginalized cumulative risk by Day 198 as functions of Day 29 markers above a threshold ($\geq s$) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands (at least 5 cases are required). The horizontal lines indicate the overall cumulative risk of the vaccine arm by Day 198 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. $l_{od} = 0.3, 1.6, 10, 10$ for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively.

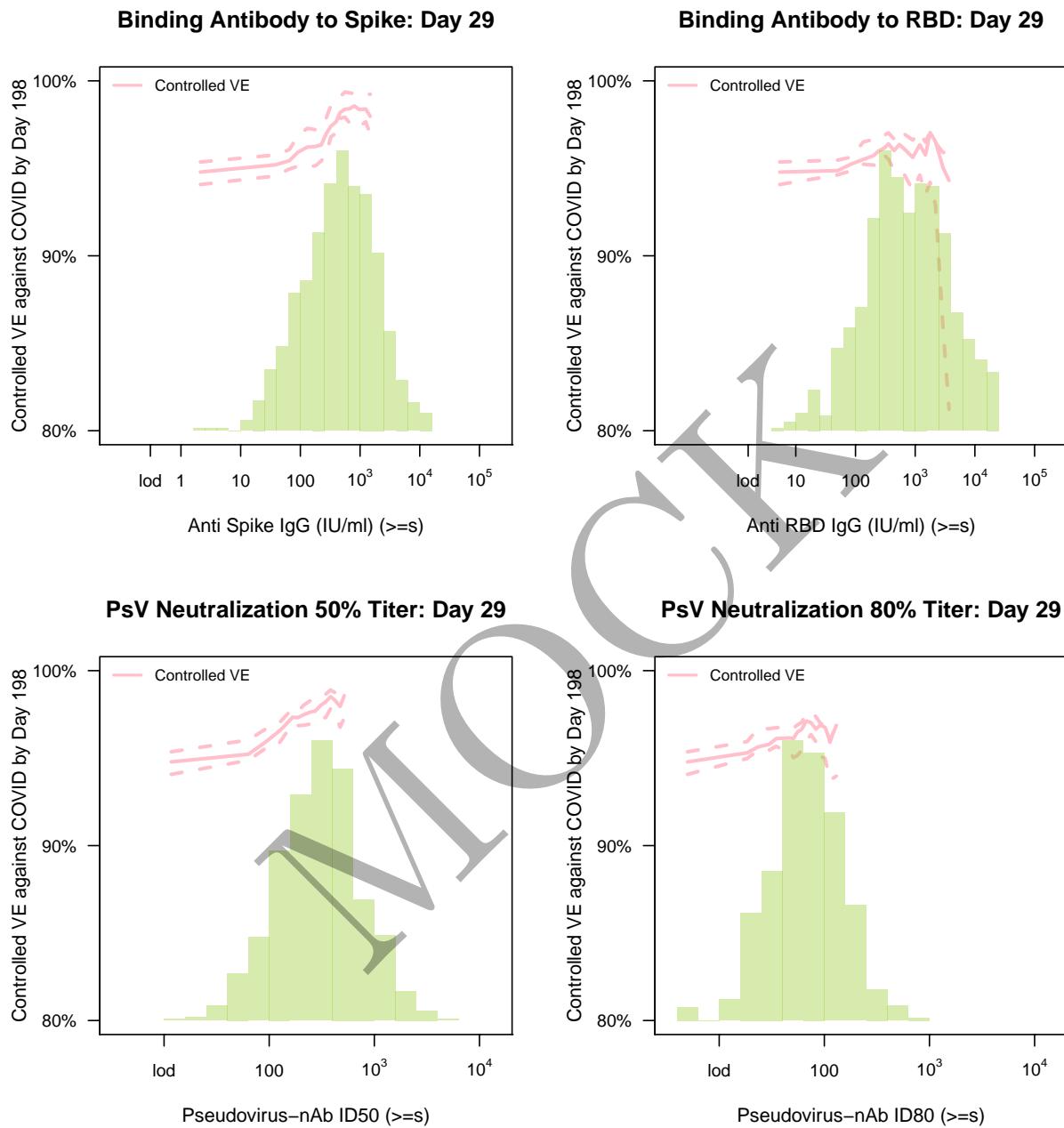


Figure 4.10: Controlled VE as functions of Day 29 markers ($\geq s$) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. Histograms of the immunological markers in the vaccine arm are overlaid. $lod = 0.3, 1.6, 10, 10$ for bAb Spike, bAb RBD, PsV nAb ID50, PsV nAb ID80, respectively.

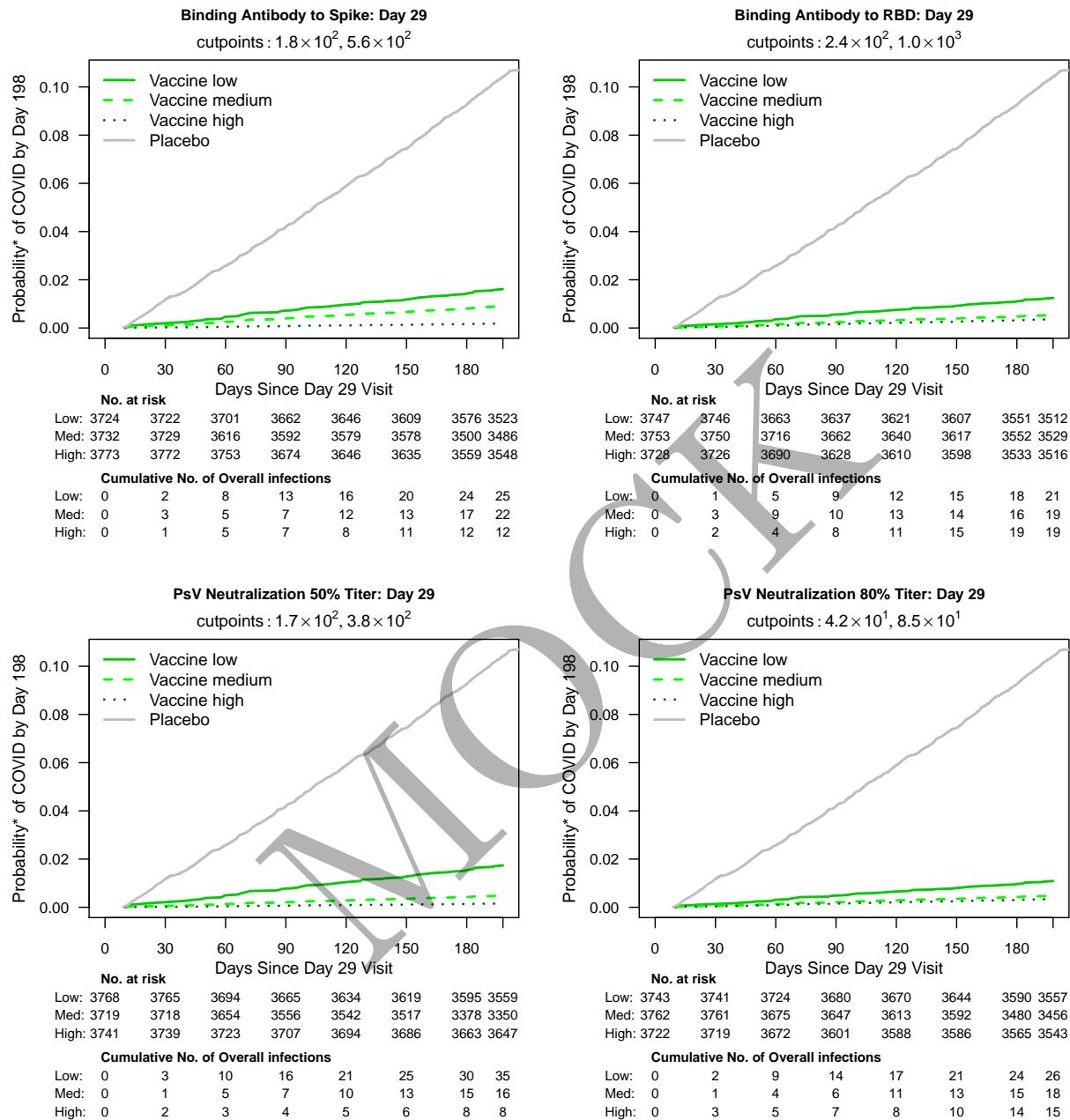


Figure 4.11: Marginalized cumulative incidence rate curves for trichotomized Day 29 markers among baseline seronegative vaccine recipients. The gray line is the overall cumulative incidence rate curve in the placebo arm.

MOCK

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

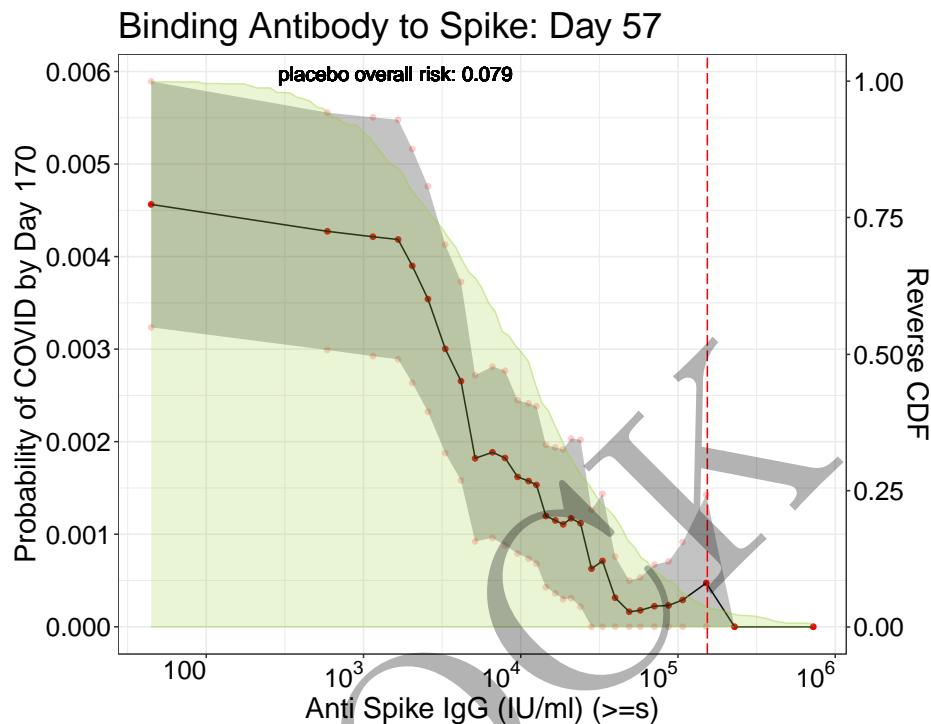


Figure 5.1: Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

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 |
|------------------------|---------------|---------------|---------|----------|
| 1.650 | $4.47 * 10^1$ | 0.00456 | 0.00324 | 0.00589 |
| 3.218 | $1.65 * 10^3$ | 0.00418 | 0.00289 | 0.00548 |
| 3.521 | $3.32 * 10^3$ | 0.00300 | 0.00188 | 0.00413 |
| 3.899 | $7.93 * 10^3$ | 0.00182 | 0.00088 | 0.00277 |
| 4.104 | $1.27 * 10^4$ | 0.00153 | 0.00068 | 0.00238 |
| 4.270 | $1.86 * 10^4$ | 0.00111 | 0.00030 | 0.00192 |
| 4.454 | $2.84 * 10^4$ | 0.00063 | 0.00000 | 0.00126 |
| 4.760 | $5.75 * 10^4$ | 0.00018 | 0.00000 | 0.00053 |
| 5.028 | $1.07 * 10^5$ | 0.00029 | 0.00000 | 0.00091 |
| 5.864 | $7.31 * 10^5$ | 0.00000 | 0.00000 | NA |

5.1.2 Day 57 RBD binding antibody

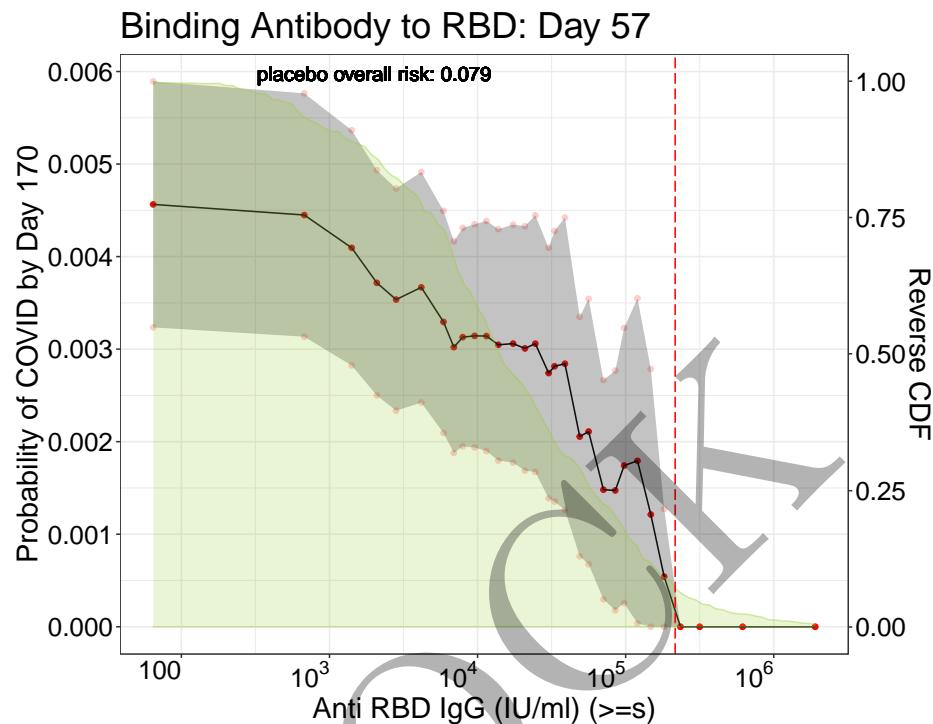


Figure 5.2: Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

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 |
|------------------------|---------------|---------------|---------|----------|
| 1.814 | $6.52 * 10^1$ | 0.00456 | 0.00324 | 0.00589 |
| 3.316 | $2.07 * 10^3$ | 0.00372 | 0.00250 | 0.00493 |
| 3.771 | $5.90 * 10^3$ | 0.00329 | 0.00209 | 0.00450 |
| 4.064 | $1.16 * 10^4$ | 0.00314 | 0.00190 | 0.00438 |
| 4.320 | $2.09 * 10^4$ | 0.00301 | 0.00169 | 0.00433 |
| 4.523 | $3.33 * 10^4$ | 0.00281 | 0.00135 | 0.00428 |
| 4.752 | $5.65 * 10^4$ | 0.00211 | 0.00068 | 0.00354 |
| 5.080 | $1.20 * 10^5$ | 0.00179 | 0.00004 | 0.00355 |
| 5.368 | $2.33 * 10^5$ | 0.00000 | 0.00000 | NA |
| 6.276 | $1.89 * 10^6$ | 0.00000 | 0.00000 | NA |

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

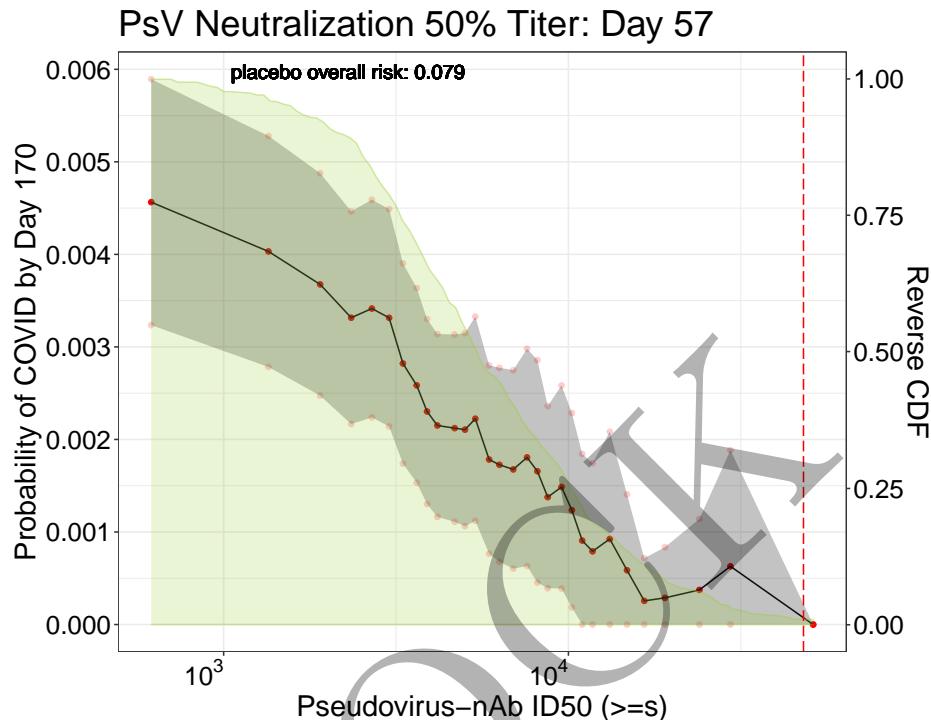


Figure 5.3: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

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 |
|------------------------|---------------|---------------|---------|----------|
| 2.792 | $6.19 * 10^2$ | 0.00456 | 0.00324 | 0.00589 |
| 3.375 | $2.37 * 10^3$ | 0.00332 | 0.00217 | 0.00446 |
| 3.519 | $3.30 * 10^3$ | 0.00282 | 0.00174 | 0.00390 |
| 3.669 | $4.67 * 10^3$ | 0.00212 | 0.00111 | 0.00313 |
| 3.768 | $5.86 * 10^3$ | 0.00178 | 0.00077 | 0.00280 |
| 3.878 | $7.55 * 10^3$ | 0.00181 | 0.00063 | 0.00298 |
| 3.979 | $9.53 * 10^3$ | 0.00149 | 0.00039 | 0.00258 |
| 4.122 | $1.32 * 10^4$ | 0.00092 | 0.00000 | 0.00208 |
| 4.281 | $1.91 * 10^4$ | 0.00029 | 0.00000 | 0.00084 |
| 4.713 | $5.16 * 10^4$ | 0.00000 | 0.00000 | NA |

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

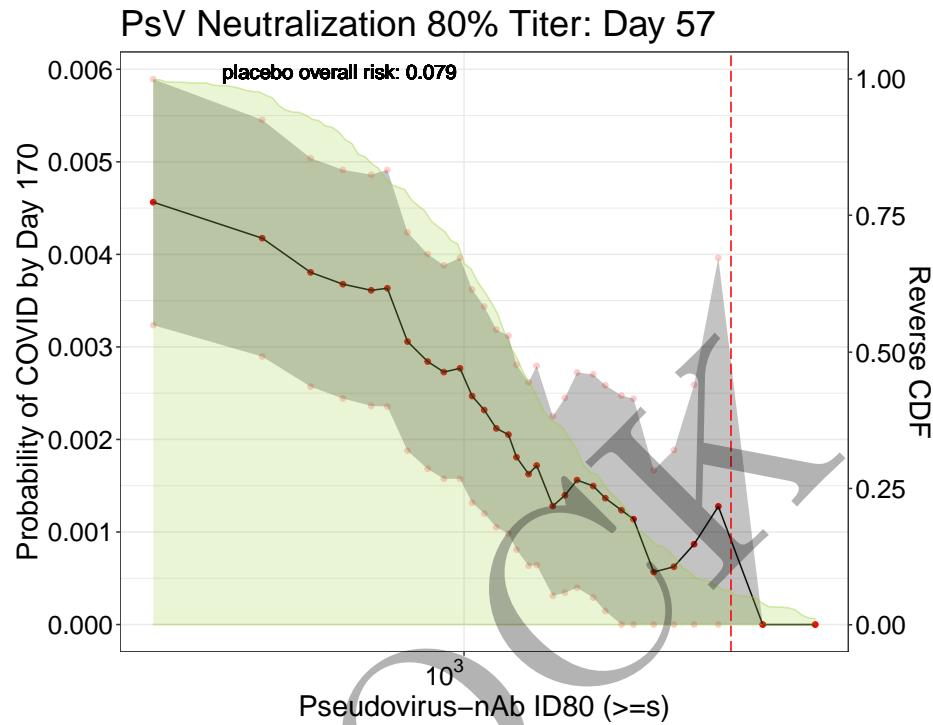


Figure 5.4: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

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 |
|------------------------|---------------|---------------|---------|----------|
| 2.229 | $1.69 * 10^2$ | 0.00456 | 0.00324 | 0.00589 |
| 2.697 | $4.98 * 10^2$ | 0.00368 | 0.00244 | 0.00491 |
| 2.859 | $7.23 * 10^2$ | 0.00306 | 0.00188 | 0.00424 |
| 3.020 | $1.05 * 10^3$ | 0.00247 | 0.00132 | 0.00362 |
| 3.107 | $1.28 * 10^3$ | 0.00205 | 0.00098 | 0.00312 |
| 3.184 | $1.53 * 10^3$ | 0.00172 | 0.00064 | 0.00280 |
| 3.284 | $1.92 * 10^3$ | 0.00156 | 0.00040 | 0.00272 |
| 3.421 | $2.64 * 10^3$ | 0.00114 | 0.00000 | 0.00244 |
| 3.565 | $3.67 * 10^3$ | 0.00087 | 0.00000 | 0.00259 |
| 3.871 | $7.43 * 10^3$ | 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

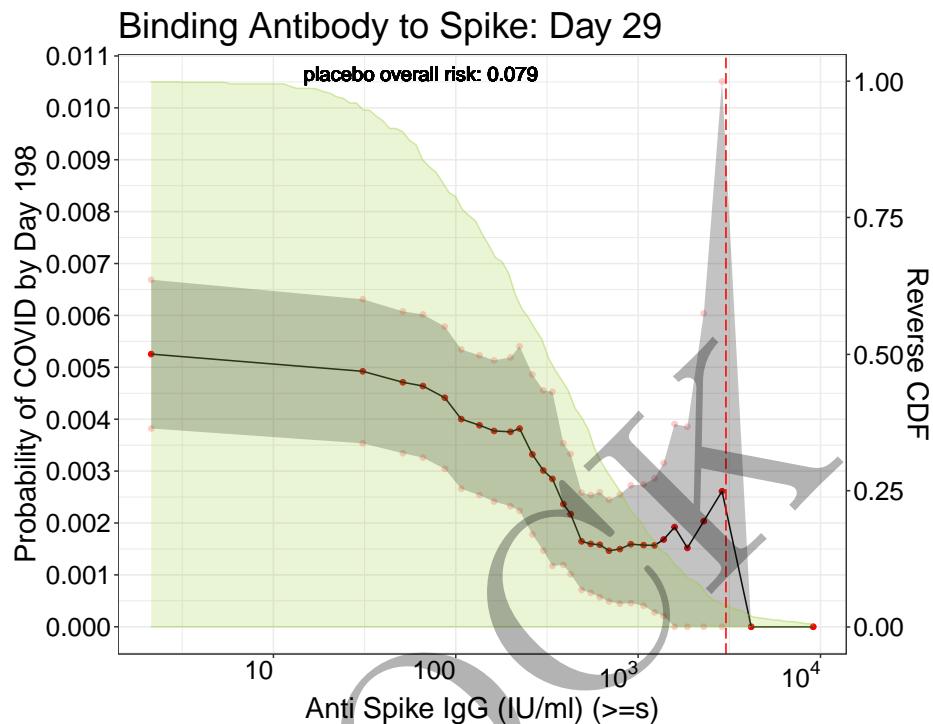


Figure 5.5: Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

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 |
|------------------------|---------------|---------------|---------|----------|
| 0.326 | $2.12 * 10^0$ | 0.00525 | 0.00382 | 0.00669 |
| 1.821 | $6.62 * 10^1$ | 0.00464 | 0.00326 | 0.00602 |
| 2.129 | $1.35 * 10^2$ | 0.00388 | 0.00254 | 0.00523 |
| 2.422 | $2.64 * 10^2$ | 0.00332 | 0.00178 | 0.00486 |
| 2.590 | $3.89 * 10^2$ | 0.00236 | 0.00119 | 0.00354 |
| 2.740 | $5.50 * 10^2$ | 0.00160 | 0.00066 | 0.00254 |
| 2.901 | $7.96 * 10^2$ | 0.00150 | 0.00044 | 0.00255 |
| 3.145 | $1.40 * 10^3$ | 0.00168 | 0.00021 | 0.00316 |
| 3.364 | $2.31 * 10^3$ | 0.00204 | 0.00000 | 0.00604 |
| 3.965 | $9.23 * 10^3$ | 0.00000 | 0.00000 | NA |

5.2.2 Day 29 RBD binding antibody

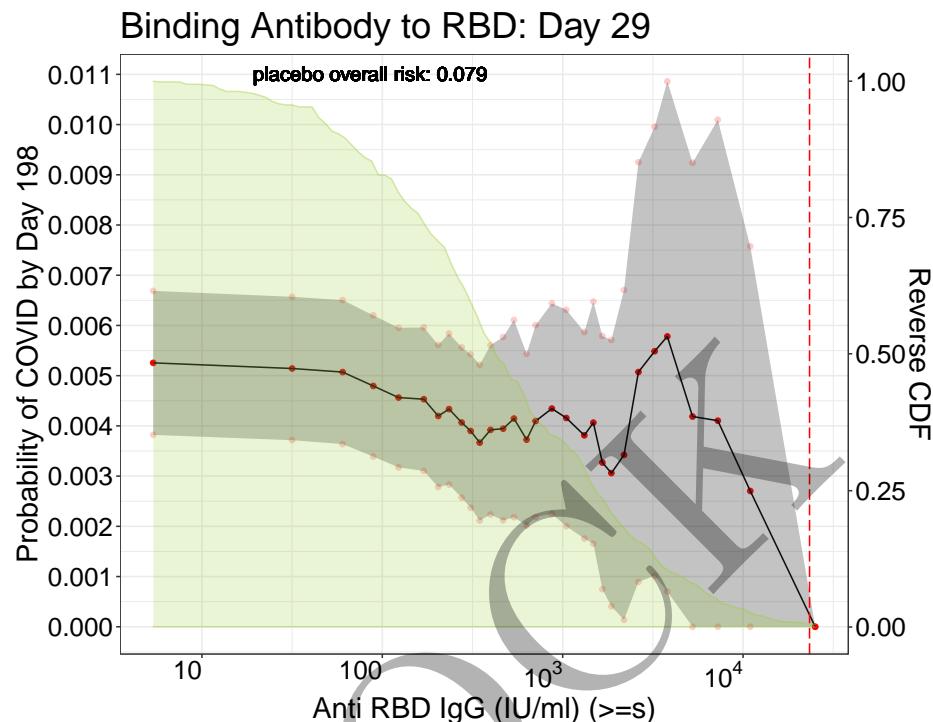


Figure 5.6: Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

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 |
|------------------------|---------------|---------------|---------|----------|
| 0.731 | $5.38 * 10^0$ | 0.00525 | 0.00382 | 0.00669 |
| 1.948 | $8.87 * 10^1$ | 0.00480 | 0.00339 | 0.00620 |
| 2.306 | $2.02 * 10^2$ | 0.00420 | 0.00278 | 0.00561 |
| 2.542 | $3.48 * 10^2$ | 0.00367 | 0.00212 | 0.00522 |
| 2.726 | $5.32 * 10^2$ | 0.00415 | 0.00218 | 0.00611 |
| 2.943 | $8.77 * 10^2$ | 0.00434 | 0.00225 | 0.00644 |
| 3.167 | $1.47 * 10^3$ | 0.00406 | 0.00165 | 0.00647 |
| 3.423 | $2.65 * 10^3$ | 0.00507 | 0.00089 | 0.00925 |
| 3.717 | $5.21 * 10^3$ | 0.00419 | 0.00000 | 0.00924 |
| 4.401 | $2.52 * 10^4$ | 0.00000 | 0.00000 | NA |

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

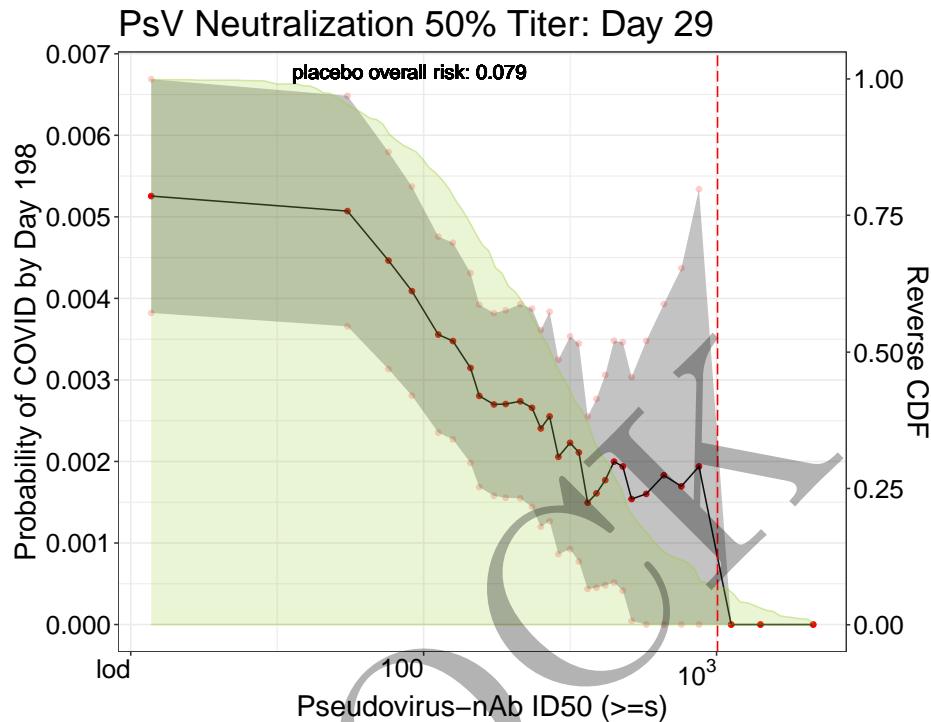


Figure 5.7: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

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 |
|------------------------|---------------|---------------|---------|----------|
| 1.068 | $1.17 * 10^1$ | 0.00525 | 0.00382 | 0.00669 |
| 1.960 | $9.12 * 10^1$ | 0.00409 | 0.00281 | 0.00537 |
| 2.158 | $1.44 * 10^2$ | 0.00315 | 0.00198 | 0.00431 |
| 2.325 | $2.11 * 10^2$ | 0.00274 | 0.00155 | 0.00393 |
| 2.434 | $2.72 * 10^2$ | 0.00255 | 0.00127 | 0.00384 |
| 2.534 | $3.42 * 10^2$ | 0.00211 | 0.00077 | 0.00345 |
| 2.623 | $4.20 * 10^2$ | 0.00177 | 0.00048 | 0.00306 |
| 2.759 | $5.74 * 10^2$ | 0.00160 | 0.00000 | 0.00348 |
| 2.940 | $8.71 * 10^2$ | 0.00194 | 0.00000 | 0.00534 |
| 3.333 | $2.15 * 10^3$ | 0.00000 | 0.00000 | NA |

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

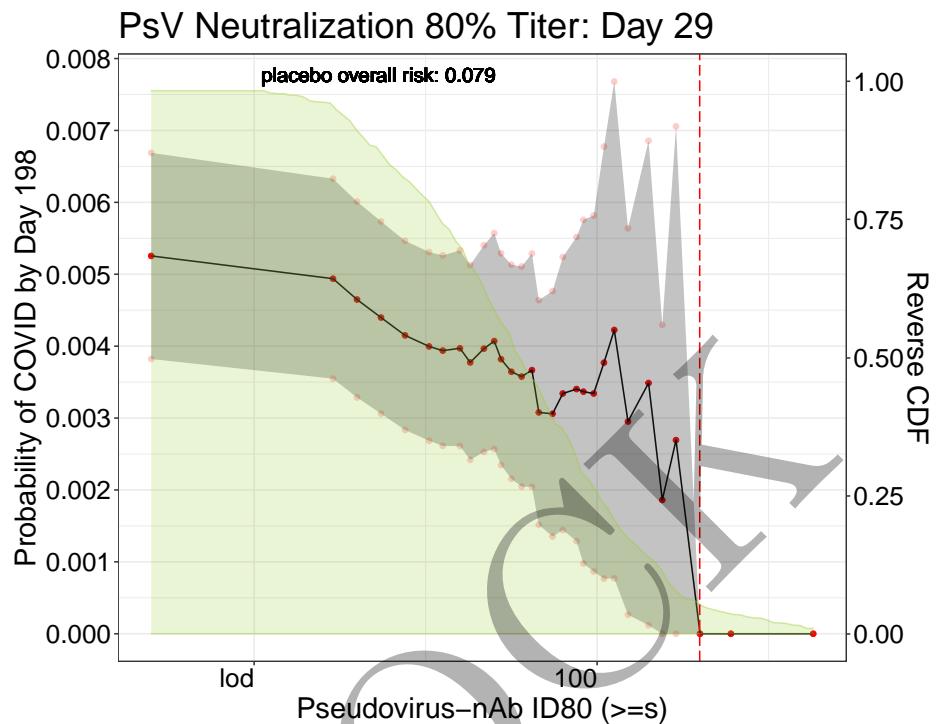


Figure 5.8: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

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 | $5.00 * 10^0$ | 0.00525 | 0.00382 | 0.00669 |
| 1.374 | $2.37 * 10^1$ | 0.00440 | 0.00306 | 0.00573 |
| 1.551 | $3.56 * 10^1$ | 0.00394 | 0.00261 | 0.00526 |
| 1.698 | $4.99 * 10^1$ | 0.00407 | 0.00257 | 0.00557 |
| 1.777 | $5.98 * 10^1$ | 0.00358 | 0.00205 | 0.00511 |
| 1.869 | $7.40 * 10^1$ | 0.00306 | 0.00135 | 0.00477 |
| 1.957 | $9.06 * 10^1$ | 0.00337 | 0.00098 | 0.00576 |
| 2.090 | $1.23 * 10^2$ | 0.00295 | 0.00026 | 0.00564 |
| 2.233 | $1.71 * 10^2$ | 0.00269 | 0.00000 | 0.00706 |
| 2.633 | $4.30 * 10^2$ | 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

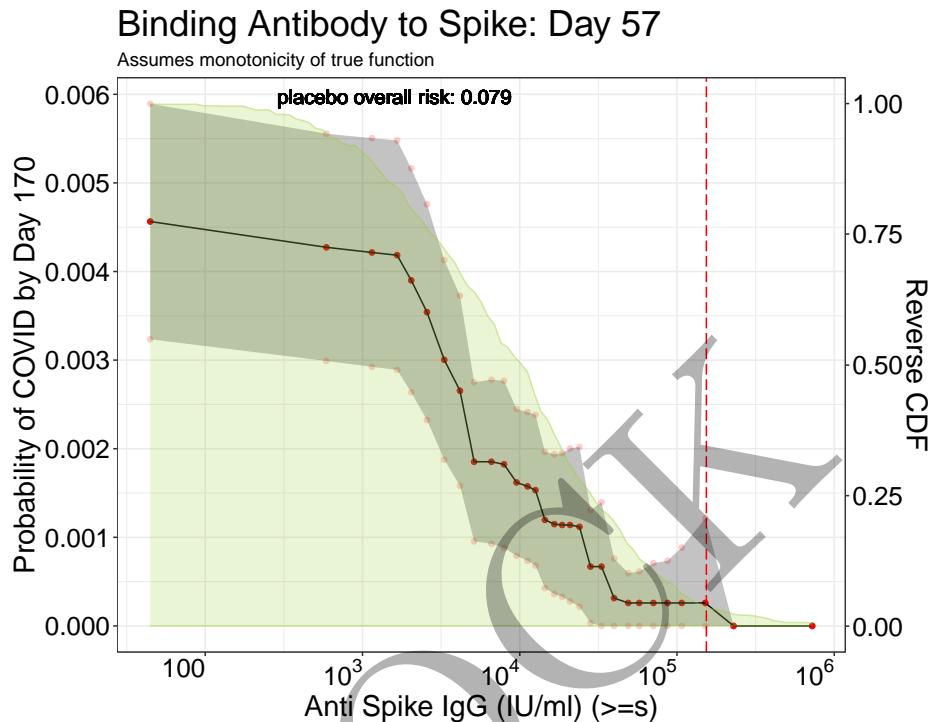


Figure 5.9: Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted 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 |
|------------------------|--------------------|---------------|---------|----------|
| 1.650 | 4.47×10^1 | 0.00456 | 0.00324 | 0.00589 |
| 3.218 | 1.65×10^3 | 0.00418 | 0.00289 | 0.00548 |
| 3.521 | 3.32×10^3 | 0.00300 | 0.00188 | 0.00413 |
| 3.899 | 7.93×10^3 | 0.00182 | 0.00088 | 0.00277 |
| 4.104 | 1.27×10^4 | 0.00153 | 0.00068 | 0.00238 |
| 4.270 | 1.86×10^4 | 0.00114 | 0.00033 | 0.00195 |
| 4.454 | 2.84×10^4 | 0.00067 | 0.00003 | 0.00131 |
| 4.760 | 5.75×10^4 | 0.00026 | 0.00000 | 0.00061 |
| 5.028 | 1.07×10^5 | 0.00026 | 0.00000 | 0.00088 |
| 5.864 | 7.31×10^5 | 0.00000 | 0.00000 | NA |

5.3.2 Day 57 RBD binding antibody

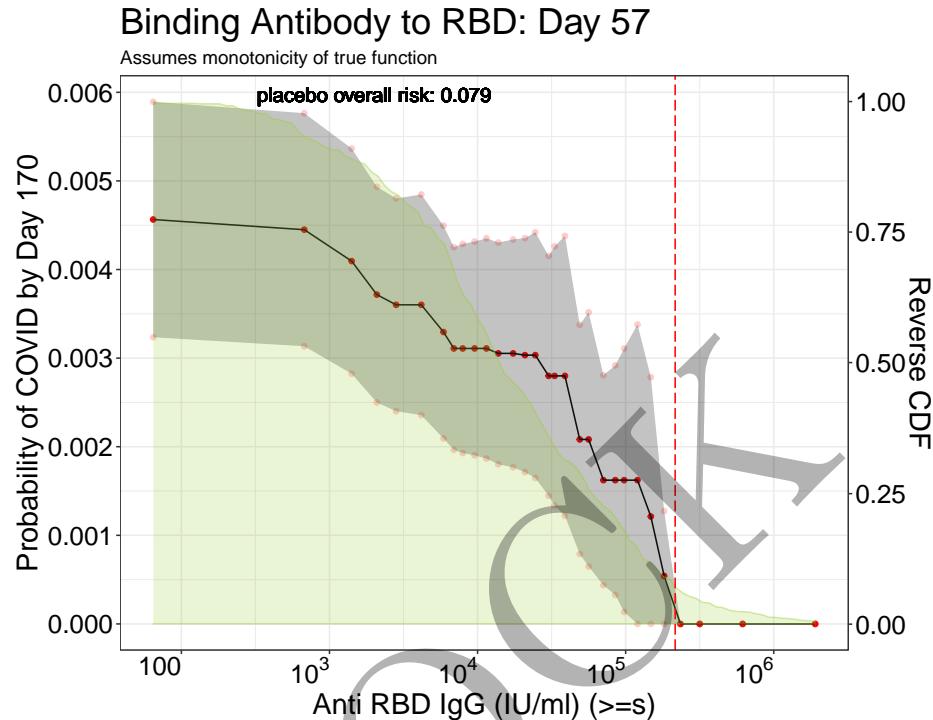


Figure 5.10: Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using 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 |
|------------------------|--------------------|---------------|---------|----------|
| 1.814 | 6.52×10^1 | 0.00456 | 0.00324 | 0.00589 |
| 3.316 | 2.07×10^3 | 0.00372 | 0.00250 | 0.00493 |
| 3.771 | 5.90×10^3 | 0.00329 | 0.00209 | 0.00450 |
| 4.064 | 1.16×10^4 | 0.00311 | 0.00187 | 0.00435 |
| 4.320 | 2.09×10^4 | 0.00303 | 0.00171 | 0.00435 |
| 4.523 | 3.33×10^4 | 0.00280 | 0.00134 | 0.00426 |
| 4.752 | 5.65×10^4 | 0.00208 | 0.00065 | 0.00352 |
| 5.080 | 1.20×10^5 | 0.00162 | 0.00000 | 0.00338 |
| 5.368 | 2.33×10^5 | 0.00000 | 0.00000 | NA |
| 6.276 | 1.89×10^6 | 0.00000 | 0.00000 | NA |

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

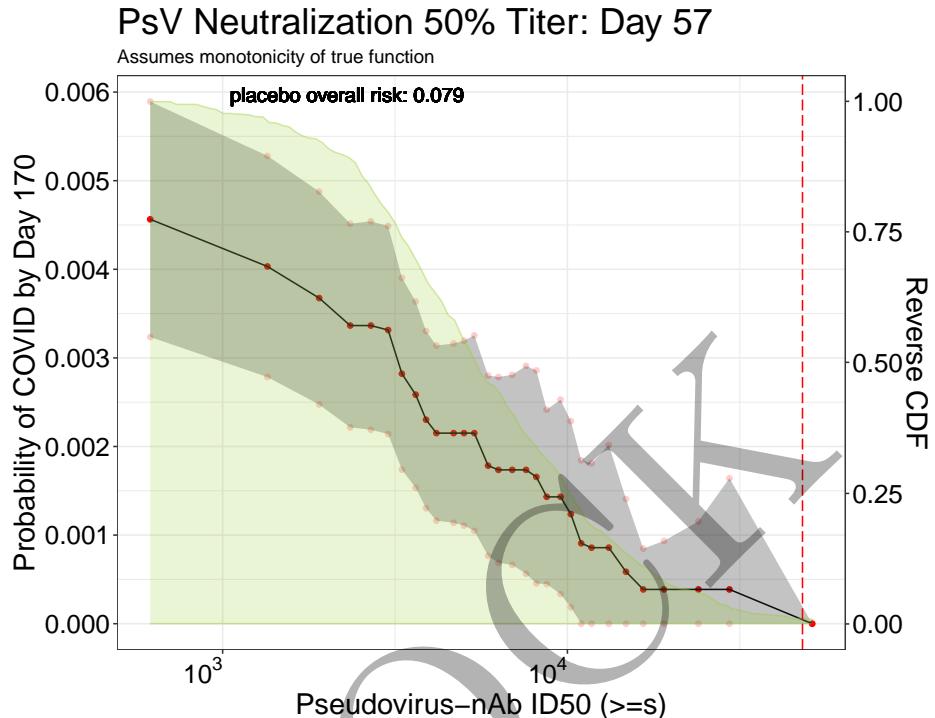


Figure 5.11: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence 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 |
|------------------------|--------------------|---------------|---------|----------|
| 2.792 | 6.19×10^2 | 0.00456 | 0.00324 | 0.00589 |
| 3.375 | 2.37×10^3 | 0.00337 | 0.00222 | 0.00451 |
| 3.519 | 3.30×10^3 | 0.00282 | 0.00174 | 0.00390 |
| 3.669 | 4.67×10^3 | 0.00215 | 0.00114 | 0.00316 |
| 3.768 | 5.86×10^3 | 0.00178 | 0.00077 | 0.00280 |
| 3.878 | 7.55×10^3 | 0.00174 | 0.00056 | 0.00291 |
| 3.979 | 9.53×10^3 | 0.00143 | 0.00033 | 0.00253 |
| 4.122 | 1.32×10^4 | 0.00086 | 0.00000 | 0.00202 |
| 4.281 | 1.91×10^4 | 0.00039 | 0.00000 | 0.00093 |
| 4.713 | 5.16×10^4 | 0.00000 | 0.00000 | NA |

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

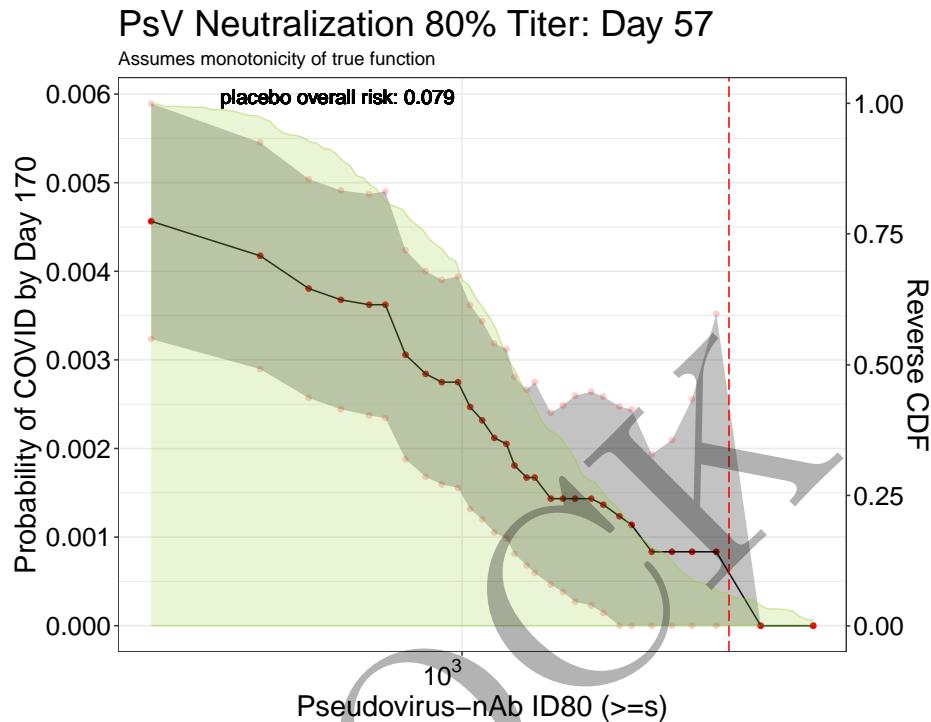


Figure 5.12: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence 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 |
|------------------------|---------------|---------------|---------|----------|
| 2.229 | $1.69 * 10^2$ | 0.00456 | 0.00324 | 0.00589 |
| 2.697 | $4.98 * 10^2$ | 0.00368 | 0.00244 | 0.00491 |
| 2.859 | $7.23 * 10^2$ | 0.00306 | 0.00188 | 0.00424 |
| 3.020 | $1.05 * 10^3$ | 0.00247 | 0.00132 | 0.00362 |
| 3.107 | $1.28 * 10^3$ | 0.00205 | 0.00098 | 0.00312 |
| 3.184 | $1.53 * 10^3$ | 0.00167 | 0.00060 | 0.00275 |
| 3.284 | $1.92 * 10^3$ | 0.00143 | 0.00027 | 0.00260 |
| 3.421 | $2.64 * 10^3$ | 0.00114 | 0.00000 | 0.00244 |
| 3.565 | $3.67 * 10^3$ | 0.00083 | 0.00000 | 0.00256 |
| 3.871 | $7.43 * 10^3$ | 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

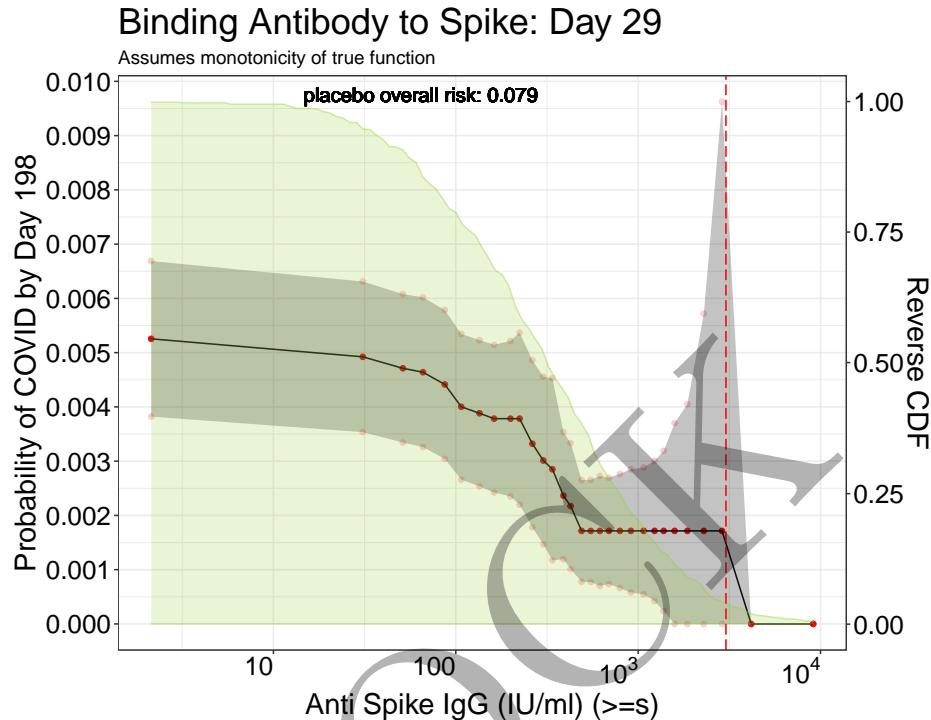


Figure 5.13: Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using 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 |
|------------------------|---------------|---------------|---------|----------|
| 0.326 | $2.12 * 10^0$ | 0.00525 | 0.00382 | 0.00669 |
| 1.821 | $6.62 * 10^1$ | 0.00464 | 0.00326 | 0.00602 |
| 2.129 | $1.35 * 10^2$ | 0.00388 | 0.00254 | 0.00523 |
| 2.422 | $2.64 * 10^2$ | 0.00332 | 0.00178 | 0.00486 |
| 2.590 | $3.89 * 10^2$ | 0.00236 | 0.00119 | 0.00354 |
| 2.740 | $5.50 * 10^2$ | 0.00171 | 0.00077 | 0.00266 |
| 2.901 | $7.96 * 10^2$ | 0.00171 | 0.00066 | 0.00277 |
| 3.145 | $1.40 * 10^3$ | 0.00171 | 0.00024 | 0.00319 |
| 3.364 | $2.31 * 10^3$ | 0.00171 | 0.00000 | 0.00572 |
| 3.965 | $9.23 * 10^3$ | 0.00000 | 0.00000 | NA |

5.4.2 Day 29 RBD binding antibody

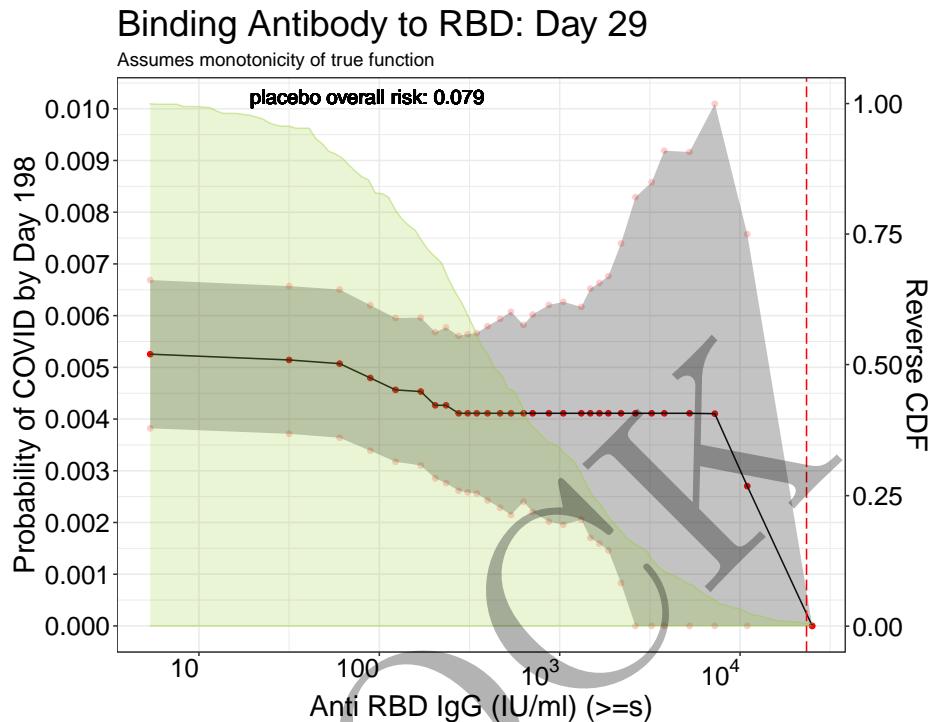


Figure 5.14: Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using 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 |
|------------------------|--------------------|---------------|---------|----------|
| 0.731 | 5.38×10^0 | 0.00525 | 0.00382 | 0.00669 |
| 1.948 | 8.87×10^1 | 0.00480 | 0.00339 | 0.00620 |
| 2.306 | 2.02×10^2 | 0.00427 | 0.00285 | 0.00568 |
| 2.542 | 3.48×10^2 | 0.00411 | 0.00256 | 0.00566 |
| 2.726 | 5.32×10^2 | 0.00411 | 0.00215 | 0.00608 |
| 2.943 | 8.77×10^2 | 0.00411 | 0.00202 | 0.00621 |
| 3.167 | 1.47×10^3 | 0.00411 | 0.00170 | 0.00652 |
| 3.423 | 2.65×10^3 | 0.00411 | 0.00000 | 0.00829 |
| 3.717 | 5.21×10^3 | 0.00411 | 0.00000 | 0.00916 |
| 4.401 | 2.52×10^4 | 0.00000 | 0.00000 | NA |

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

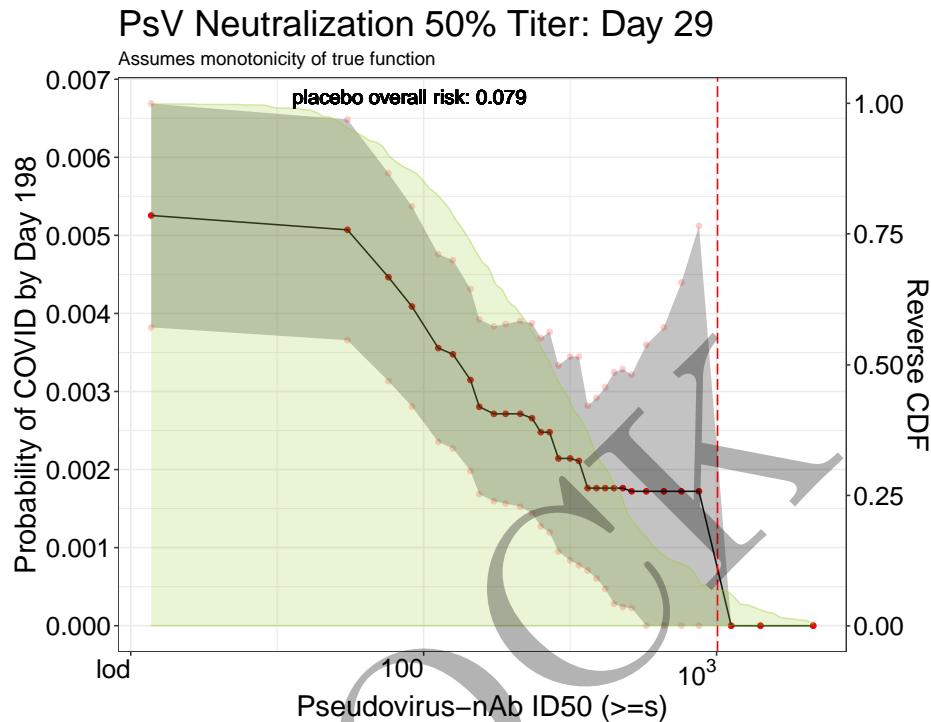


Figure 5.15: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence 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 |
|------------------------|--------------------|---------------|---------|----------|
| 1.068 | 1.17×10^1 | 0.00525 | 0.00382 | 0.00669 |
| 1.960 | 9.12×10^1 | 0.00409 | 0.00281 | 0.00537 |
| 2.158 | 1.44×10^2 | 0.00315 | 0.00198 | 0.00431 |
| 2.325 | 2.11×10^2 | 0.00271 | 0.00152 | 0.00390 |
| 2.434 | 2.72×10^2 | 0.00248 | 0.00119 | 0.00376 |
| 2.534 | 3.42×10^2 | 0.00211 | 0.00077 | 0.00345 |
| 2.623 | 4.20×10^2 | 0.00176 | 0.00047 | 0.00305 |
| 2.759 | 5.74×10^2 | 0.00172 | 0.00000 | 0.00360 |
| 2.940 | 8.71×10^2 | 0.00172 | 0.00000 | 0.00512 |
| 3.333 | 2.15×10^3 | 0.00000 | 0.00000 | NA |

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

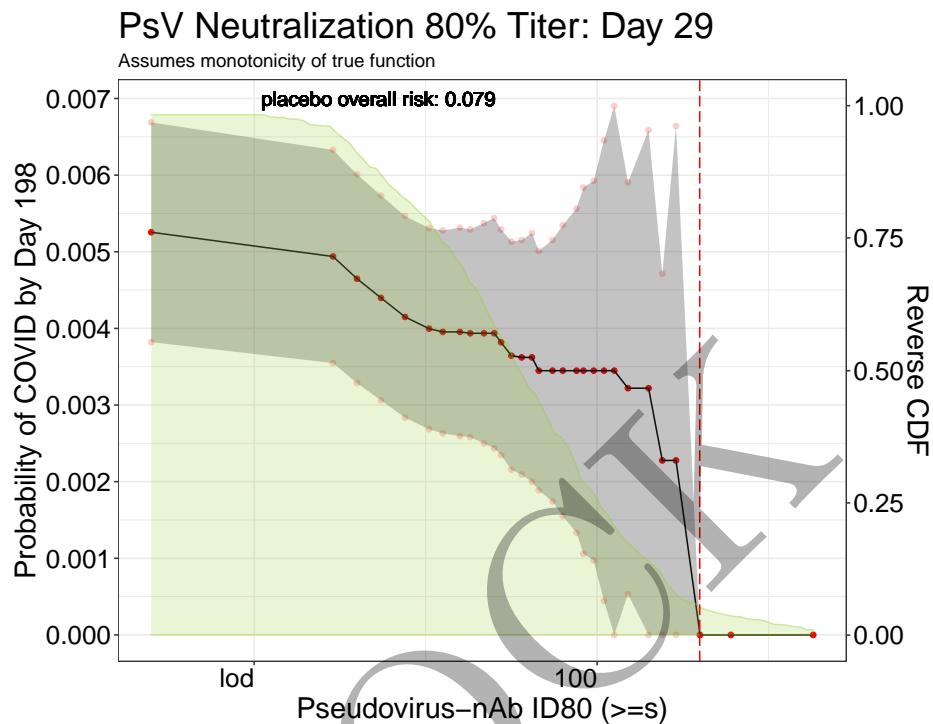


Figure 5.16: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence 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 | $5.00 * 10^0$ | 0.00525 | 0.00382 | 0.00669 |
| 1.374 | $2.37 * 10^1$ | 0.00440 | 0.00306 | 0.00573 |
| 1.551 | $3.56 * 10^1$ | 0.00395 | 0.00263 | 0.00528 |
| 1.698 | $4.99 * 10^1$ | 0.00394 | 0.00243 | 0.00544 |
| 1.777 | $5.98 * 10^1$ | 0.00362 | 0.00209 | 0.00515 |
| 1.869 | $7.40 * 10^1$ | 0.00345 | 0.00174 | 0.00515 |
| 1.957 | $9.06 * 10^1$ | 0.00345 | 0.00106 | 0.00584 |
| 2.090 | $1.23 * 10^2$ | 0.00322 | 0.00053 | 0.00591 |
| 2.233 | $1.71 * 10^2$ | 0.00228 | 0.00000 | 0.00664 |
| 2.633 | $4.30 * 10^2$ | 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

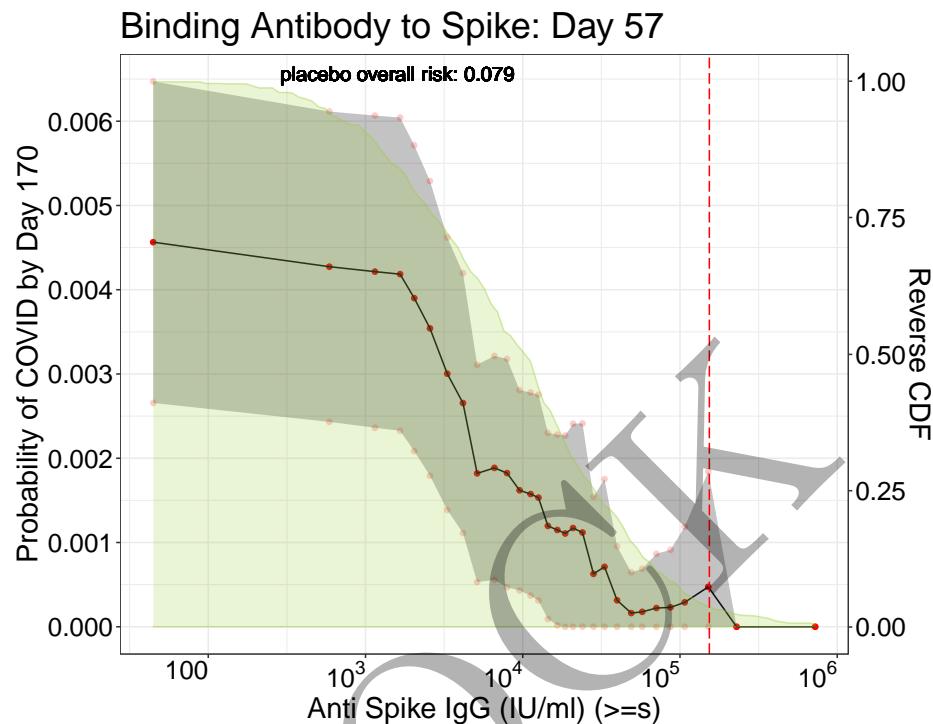


Figure 5.17: Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

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 |
|------------------------|---------------|---------------|---------|----------|
| 1.650 | $4.47 * 10^1$ | 0.00456 | 0.00266 | 0.00647 |
| 3.218 | $1.65 * 10^3$ | 0.00418 | 0.00233 | 0.00604 |
| 3.521 | $3.32 * 10^3$ | 0.00300 | 0.00139 | 0.00462 |
| 3.899 | $7.93 * 10^3$ | 0.00182 | 0.00047 | 0.00318 |
| 4.104 | $1.27 * 10^4$ | 0.00153 | 0.00031 | 0.00275 |
| 4.270 | $1.86 * 10^4$ | 0.00111 | 0.00000 | 0.00227 |
| 4.454 | $2.84 * 10^4$ | 0.00063 | 0.00000 | 0.00154 |
| 4.760 | $5.75 * 10^4$ | 0.00018 | 0.00000 | 0.00069 |
| 5.028 | $1.07 * 10^5$ | 0.00029 | 0.00000 | 0.00119 |
| 5.864 | $7.31 * 10^5$ | 0.00000 | 0.00000 | NA |

5.5.2 Day 57 RBD binding antibody

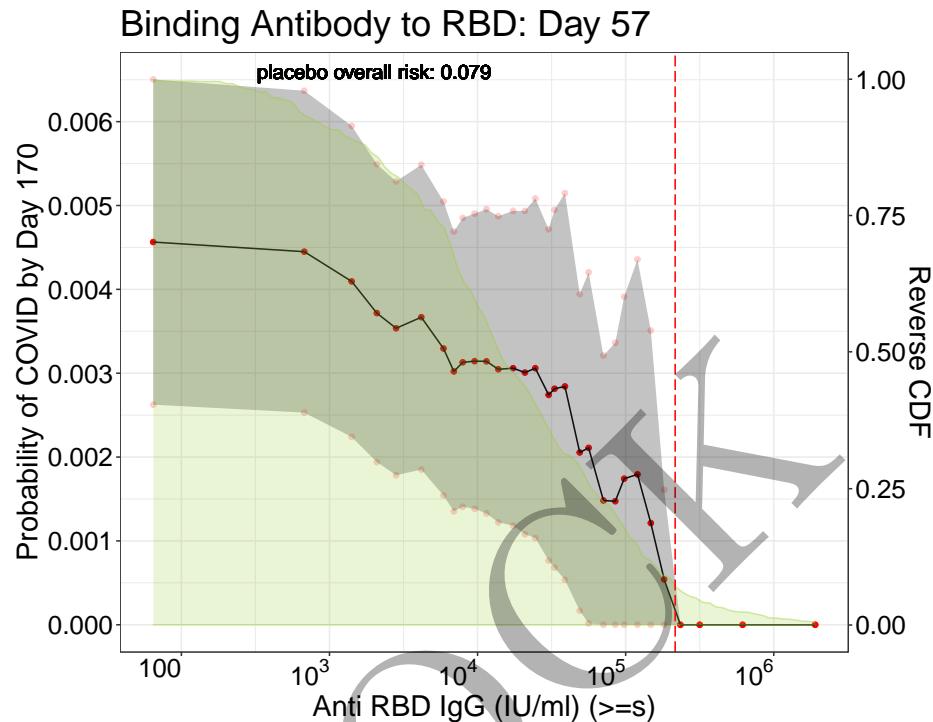


Figure 5.18: Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

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 |
|------------------------|---------------|---------------|---------|----------|
| 1.814 | $6.52 * 10^1$ | 0.00456 | 0.00262 | 0.00650 |
| 3.316 | $2.07 * 10^3$ | 0.00372 | 0.00194 | 0.00549 |
| 3.771 | $5.90 * 10^3$ | 0.00329 | 0.00154 | 0.00505 |
| 4.064 | $1.16 * 10^4$ | 0.00314 | 0.00133 | 0.00496 |
| 4.320 | $2.09 * 10^4$ | 0.00301 | 0.00108 | 0.00494 |
| 4.523 | $3.33 * 10^4$ | 0.00281 | 0.00068 | 0.00495 |
| 4.752 | $5.65 * 10^4$ | 0.00211 | 0.00002 | 0.00420 |
| 5.080 | $1.20 * 10^5$ | 0.00179 | 0.00000 | 0.00436 |
| 5.368 | $2.33 * 10^5$ | 0.00000 | 0.00000 | NA |
| 6.276 | $1.89 * 10^6$ | 0.00000 | 0.00000 | NA |

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

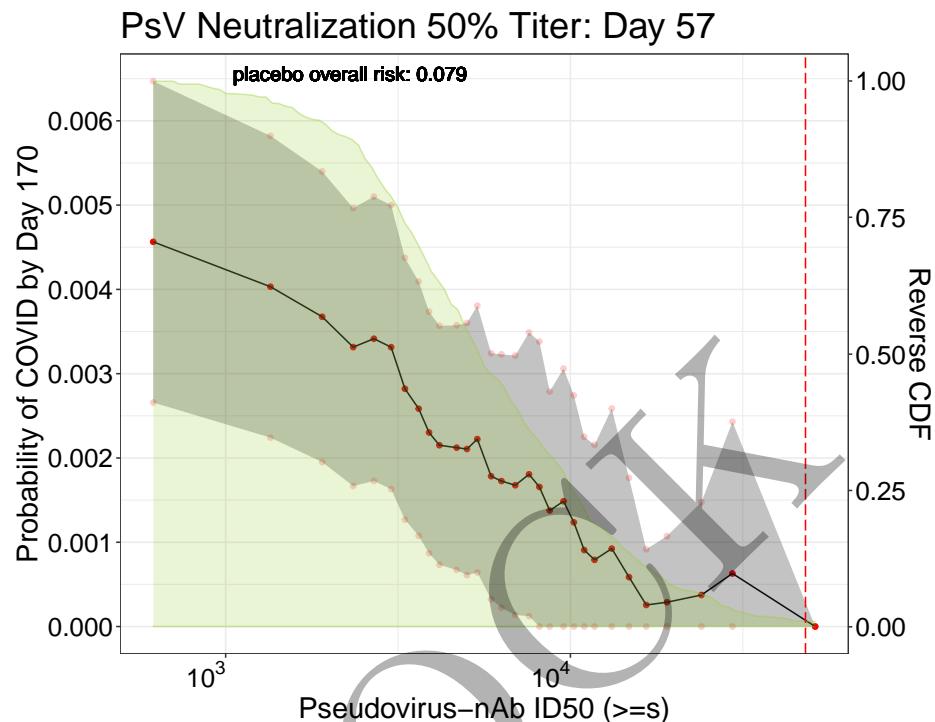


Figure 5.19: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

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 |
|------------------------|--------------------|---------------|---------|----------|
| 2.792 | 6.19×10^2 | 0.00456 | 0.00266 | 0.00647 |
| 3.375 | 2.37×10^3 | 0.00332 | 0.00167 | 0.00496 |
| 3.519 | 3.30×10^3 | 0.00282 | 0.00127 | 0.00437 |
| 3.669 | 4.67×10^3 | 0.00212 | 0.00067 | 0.00357 |
| 3.768 | 5.86×10^3 | 0.00178 | 0.00032 | 0.00324 |
| 3.878 | 7.55×10^3 | 0.00181 | 0.00012 | 0.00349 |
| 3.979 | 9.53×10^3 | 0.00149 | 0.00000 | 0.00306 |
| 4.122 | 1.32×10^4 | 0.00092 | 0.00000 | 0.00259 |
| 4.281 | 1.91×10^4 | 0.00029 | 0.00000 | 0.00107 |
| 4.713 | 5.16×10^4 | 0.00000 | 0.00000 | NA |

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

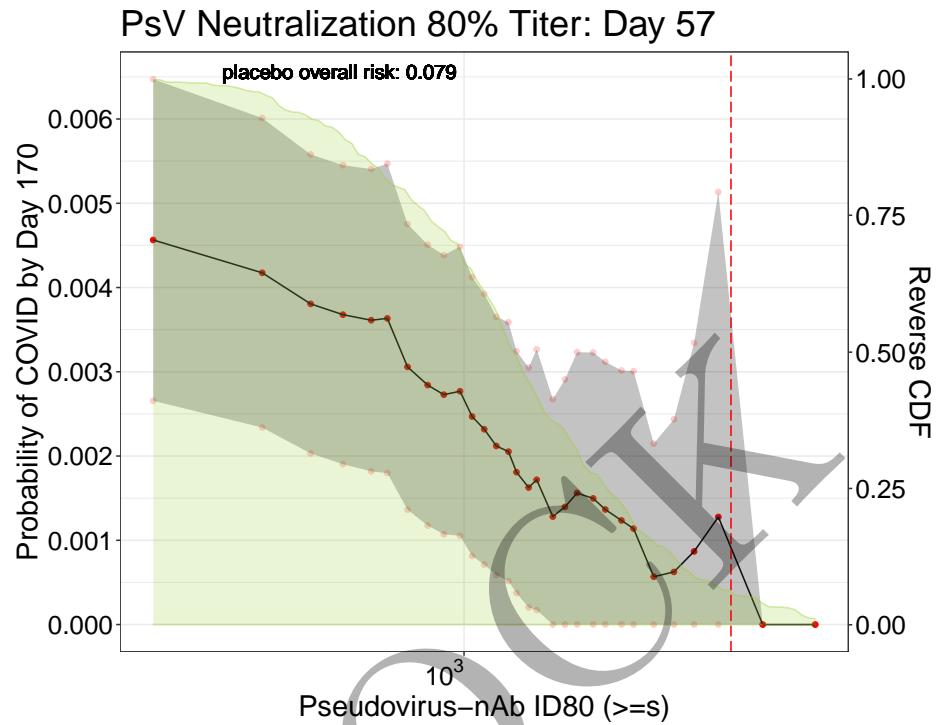


Figure 5.20: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

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 |
|------------------------|---------------|---------------|---------|----------|
| 2.229 | $1.69 * 10^2$ | 0.00456 | 0.00266 | 0.00647 |
| 2.697 | $4.98 * 10^2$ | 0.00368 | 0.00190 | 0.00545 |
| 2.859 | $7.23 * 10^2$ | 0.00306 | 0.00136 | 0.00475 |
| 3.020 | $1.05 * 10^3$ | 0.00247 | 0.00081 | 0.00412 |
| 3.107 | $1.28 * 10^3$ | 0.00205 | 0.00052 | 0.00359 |
| 3.184 | $1.53 * 10^3$ | 0.00172 | 0.00017 | 0.00327 |
| 3.284 | $1.92 * 10^3$ | 0.00156 | 0.00000 | 0.00323 |
| 3.421 | $2.64 * 10^3$ | 0.00114 | 0.00000 | 0.00301 |
| 3.565 | $3.67 * 10^3$ | 0.00087 | 0.00000 | 0.00334 |
| 3.871 | $7.43 * 10^3$ | 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

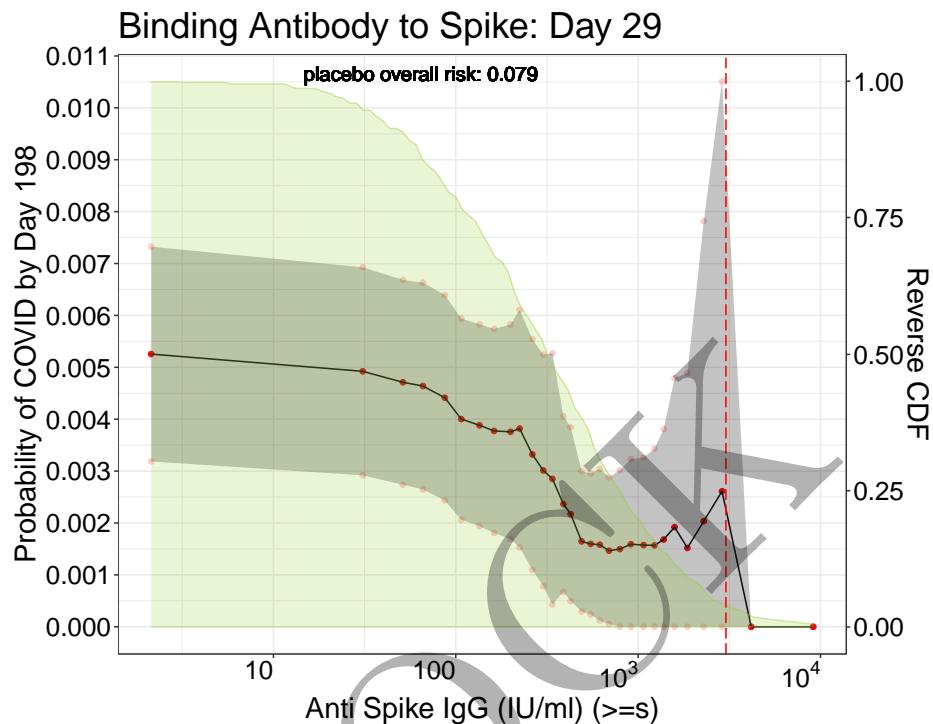


Figure 5.21: Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

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 |
|------------------------|---------------|---------------|---------|----------|
| 0.326 | $2.12 * 10^0$ | 0.00525 | 0.00319 | 0.00732 |
| 1.821 | $6.62 * 10^1$ | 0.00464 | 0.00265 | 0.00663 |
| 2.129 | $1.35 * 10^2$ | 0.00388 | 0.00194 | 0.00583 |
| 2.422 | $2.64 * 10^2$ | 0.00332 | 0.00110 | 0.00554 |
| 2.590 | $3.89 * 10^2$ | 0.00236 | 0.00067 | 0.00406 |
| 2.740 | $5.50 * 10^2$ | 0.00160 | 0.00024 | 0.00296 |
| 2.901 | $7.96 * 10^2$ | 0.00150 | 0.00000 | 0.00302 |
| 3.145 | $1.40 * 10^3$ | 0.00168 | 0.00000 | 0.00381 |
| 3.364 | $2.31 * 10^3$ | 0.00204 | 0.00000 | 0.00782 |
| 3.965 | $9.23 * 10^3$ | 0.00000 | 0.00000 | NA |

5.6.2 Day 29 RBD binding antibody

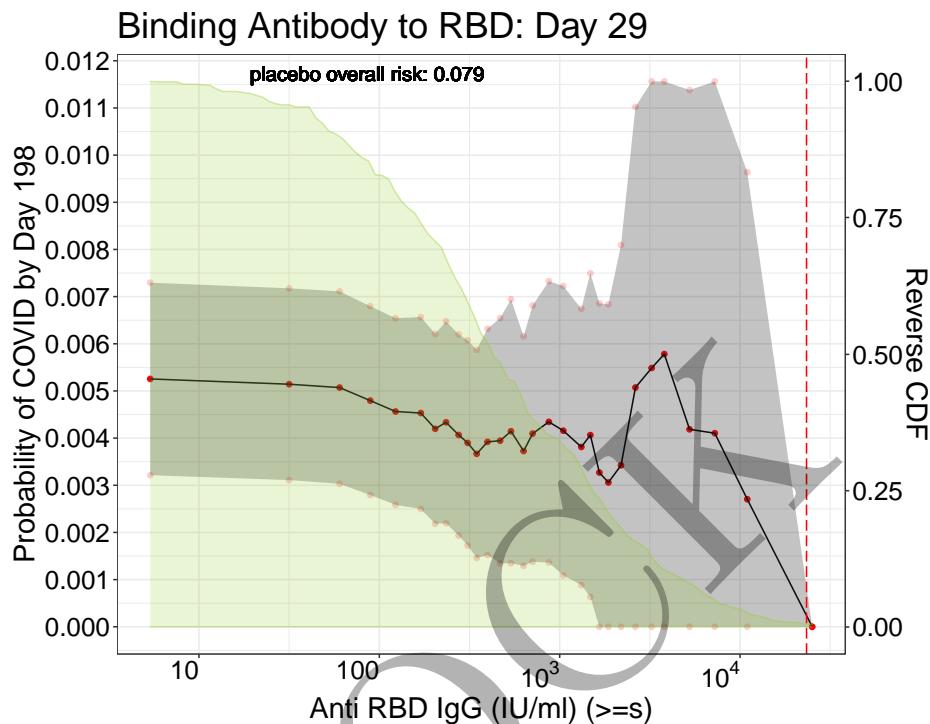


Figure 5.22: Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

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 |
|------------------------|---------------|---------------|---------|----------|
| 0.731 | $5.38 * 10^0$ | 0.00525 | 0.00321 | 0.00730 |
| 1.948 | $8.87 * 10^1$ | 0.00480 | 0.00279 | 0.00680 |
| 2.306 | $2.02 * 10^2$ | 0.00420 | 0.00218 | 0.00621 |
| 2.542 | $3.48 * 10^2$ | 0.00367 | 0.00146 | 0.00587 |
| 2.726 | $5.32 * 10^2$ | 0.00415 | 0.00135 | 0.00694 |
| 2.943 | $8.77 * 10^2$ | 0.00434 | 0.00136 | 0.00733 |
| 3.167 | $1.47 * 10^3$ | 0.00406 | 0.00063 | 0.00750 |
| 3.423 | $2.65 * 10^3$ | 0.00507 | 0.00000 | 0.01102 |
| 3.717 | $5.21 * 10^3$ | 0.00419 | 0.00000 | 0.01138 |
| 4.401 | $2.52 * 10^4$ | 0.00000 | 0.00000 | NA |

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

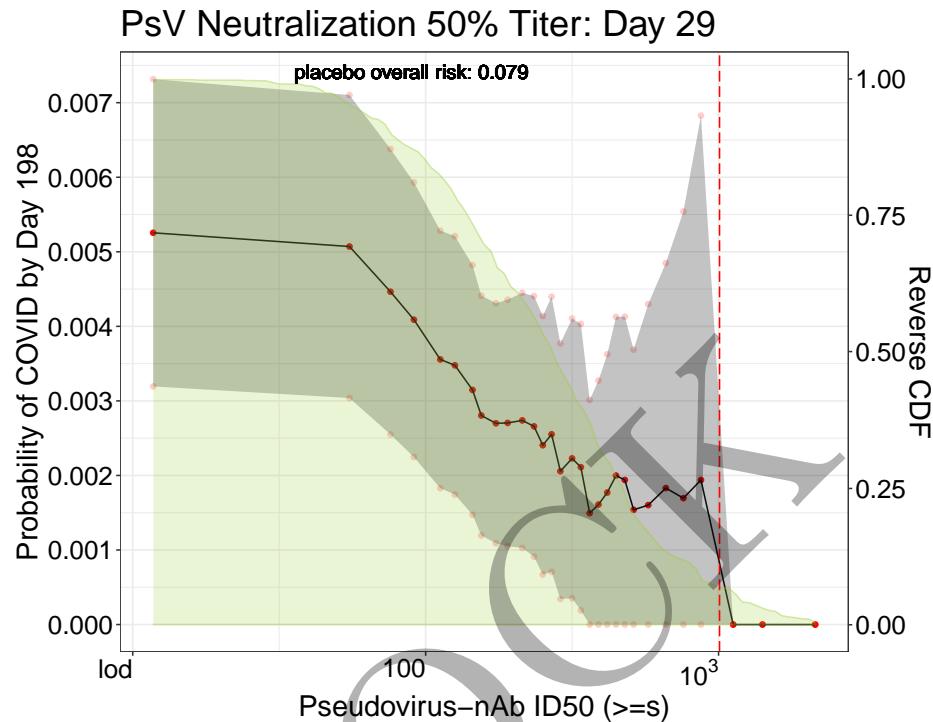


Figure 5.23: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

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 |
|------------------------|---------------|---------------|---------|----------|
| 1.068 | $1.17 * 10^1$ | 0.00525 | 0.00319 | 0.00732 |
| 1.960 | $9.12 * 10^1$ | 0.00409 | 0.00225 | 0.00593 |
| 2.158 | $1.44 * 10^2$ | 0.00315 | 0.00147 | 0.00482 |
| 2.325 | $2.11 * 10^2$ | 0.00274 | 0.00103 | 0.00445 |
| 2.434 | $2.72 * 10^2$ | 0.00255 | 0.00071 | 0.00440 |
| 2.534 | $3.42 * 10^2$ | 0.00211 | 0.00019 | 0.00403 |
| 2.623 | $4.20 * 10^2$ | 0.00177 | 0.00000 | 0.00363 |
| 2.759 | $5.74 * 10^2$ | 0.00160 | 0.00000 | 0.00430 |
| 2.940 | $8.71 * 10^2$ | 0.00194 | 0.00000 | 0.00683 |
| 3.333 | $2.15 * 10^3$ | 0.00000 | 0.00000 | NA |

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

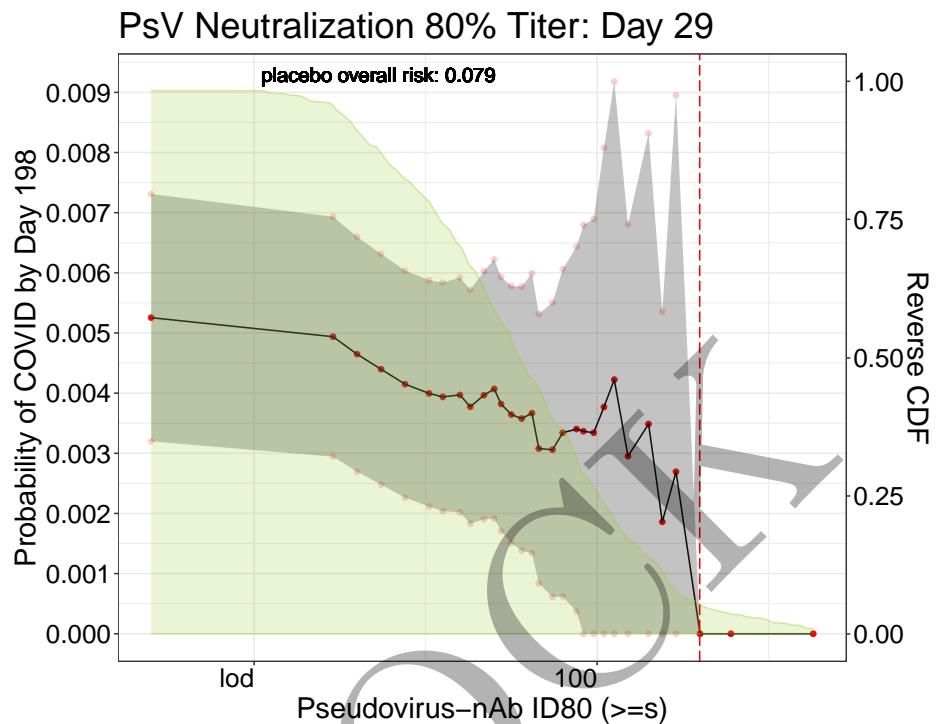


Figure 5.24: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

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 | $5.00 * 10^0$ | 0.00525 | 0.00320 | 0.00731 |
| 1.374 | $2.37 * 10^1$ | 0.00440 | 0.00248 | 0.00631 |
| 1.551 | $3.56 * 10^1$ | 0.00394 | 0.00204 | 0.00584 |
| 1.698 | $4.99 * 10^1$ | 0.00407 | 0.00192 | 0.00622 |
| 1.777 | $5.98 * 10^1$ | 0.00358 | 0.00138 | 0.00577 |
| 1.869 | $7.40 * 10^1$ | 0.00306 | 0.00061 | 0.00551 |
| 1.957 | $9.06 * 10^1$ | 0.00337 | 0.00000 | 0.00679 |
| 2.090 | $1.23 * 10^2$ | 0.00295 | 0.00000 | 0.00681 |
| 2.233 | $1.71 * 10^2$ | 0.00269 | 0.00000 | 0.00895 |
| 2.633 | $4.30 * 10^2$ | 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

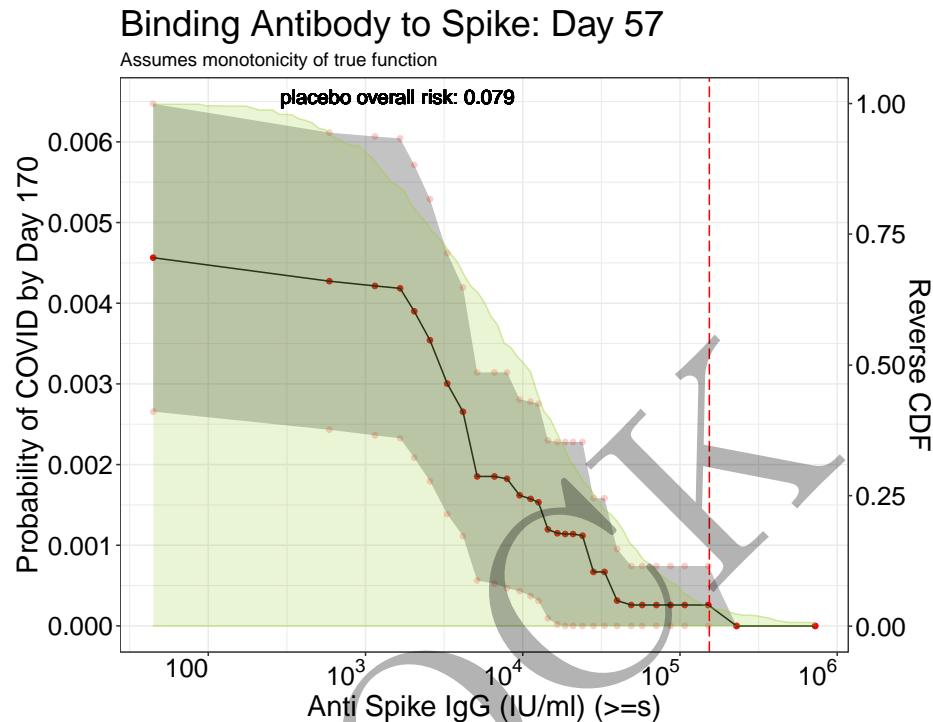


Figure 5.25: Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are 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 |
|------------------------|---------------|---------------|---------|----------|
| 1.650 | $4.47 * 10^1$ | 0.00456 | 0.00266 | 0.00647 |
| 3.218 | $1.65 * 10^3$ | 0.00418 | 0.00233 | 0.00604 |
| 3.521 | $3.32 * 10^3$ | 0.00300 | 0.00139 | 0.00462 |
| 3.899 | $7.93 * 10^3$ | 0.00182 | 0.00047 | 0.00318 |
| 4.104 | $1.27 * 10^4$ | 0.00153 | 0.00031 | 0.00275 |
| 4.270 | $1.86 * 10^4$ | 0.00114 | 0.00000 | 0.00230 |
| 4.454 | $2.84 * 10^4$ | 0.00067 | 0.00000 | 0.00158 |
| 4.760 | $5.75 * 10^4$ | 0.00026 | 0.00000 | 0.00077 |
| 5.028 | $1.07 * 10^5$ | 0.00026 | 0.00000 | 0.00116 |
| 5.864 | $7.31 * 10^5$ | 0.00000 | 0.00000 | NA |

5.7.2 Day 57 RBD binding antibody

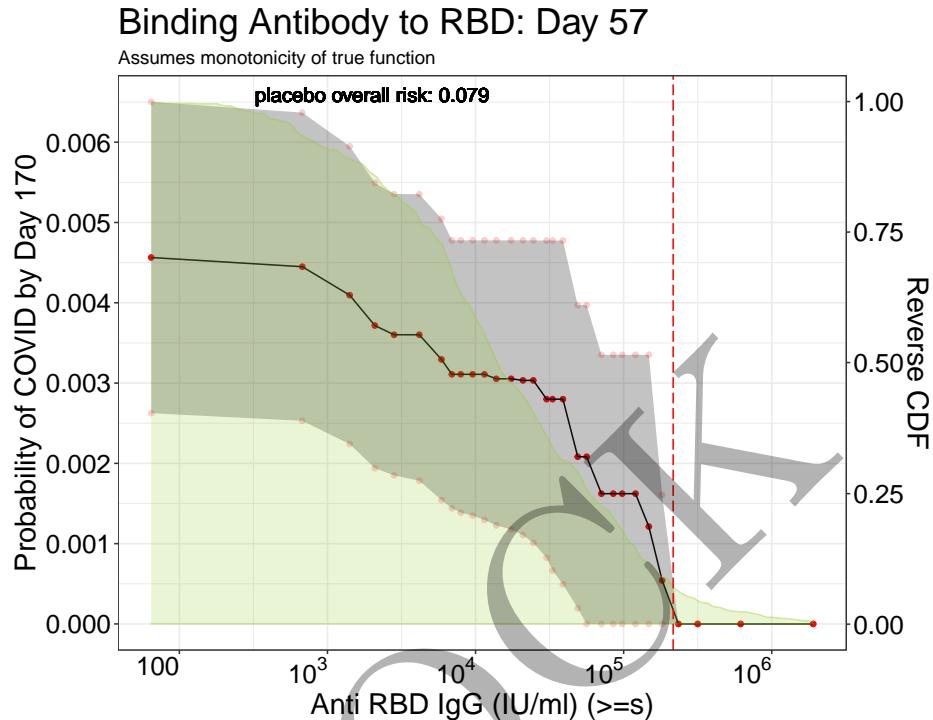


Figure 5.26: Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted 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 |
|------------------------|---------------|---------------|---------|----------|
| 1.814 | $6.52 * 10^1$ | 0.00456 | 0.00262 | 0.00650 |
| 3.316 | $2.07 * 10^3$ | 0.00372 | 0.00194 | 0.00549 |
| 3.771 | $5.90 * 10^3$ | 0.00329 | 0.00154 | 0.00505 |
| 4.064 | $1.16 * 10^4$ | 0.00311 | 0.00130 | 0.00492 |
| 4.320 | $2.09 * 10^4$ | 0.00303 | 0.00111 | 0.00496 |
| 4.523 | $3.33 * 10^4$ | 0.00280 | 0.00067 | 0.00493 |
| 4.752 | $5.65 * 10^4$ | 0.00208 | 0.00000 | 0.00418 |
| 5.080 | $1.20 * 10^5$ | 0.00162 | 0.00000 | 0.00419 |
| 5.368 | $2.33 * 10^5$ | 0.00000 | 0.00000 | NA |
| 6.276 | $1.89 * 10^6$ | 0.00000 | 0.00000 | NA |

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

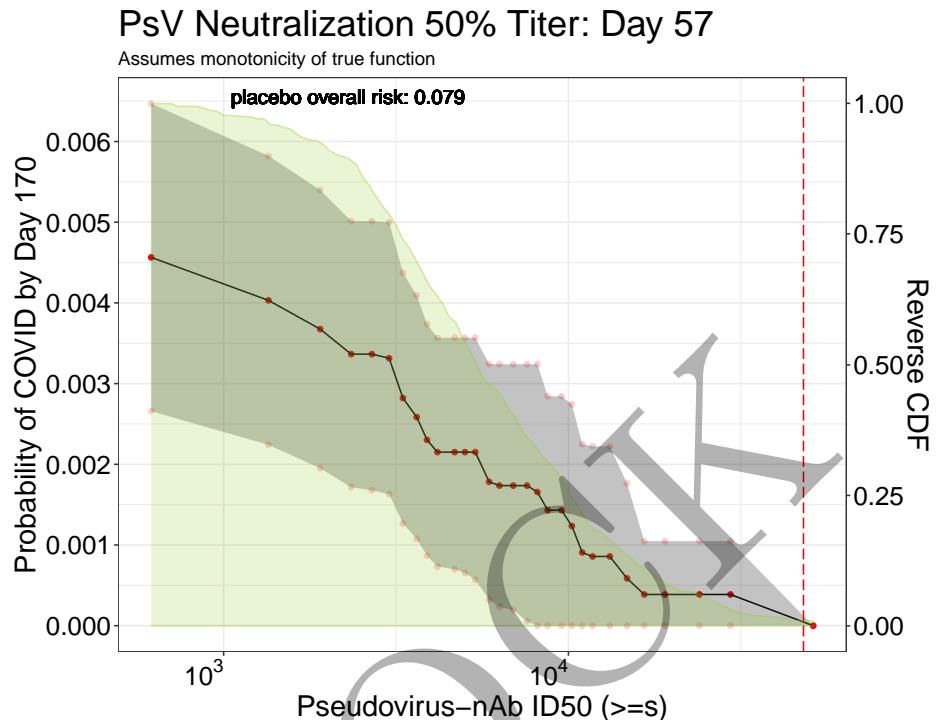


Figure 5.27: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence 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 |
|------------------------|--------------------|---------------|---------|----------|
| 2.792 | 6.19×10^2 | 0.00456 | 0.00266 | 0.00647 |
| 3.375 | 2.37×10^3 | 0.00337 | 0.00172 | 0.00501 |
| 3.519 | 3.30×10^3 | 0.00282 | 0.00127 | 0.00437 |
| 3.669 | 4.67×10^3 | 0.00215 | 0.00070 | 0.00360 |
| 3.768 | 5.86×10^3 | 0.00178 | 0.00032 | 0.00324 |
| 3.878 | 7.55×10^3 | 0.00174 | 0.00005 | 0.00342 |
| 3.979 | 9.53×10^3 | 0.00143 | 0.00000 | 0.00301 |
| 4.122 | 1.32×10^4 | 0.00086 | 0.00000 | 0.00252 |
| 4.281 | 1.91×10^4 | 0.00039 | 0.00000 | 0.00117 |
| 4.713 | 5.16×10^4 | 0.00000 | 0.00000 | NA |

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

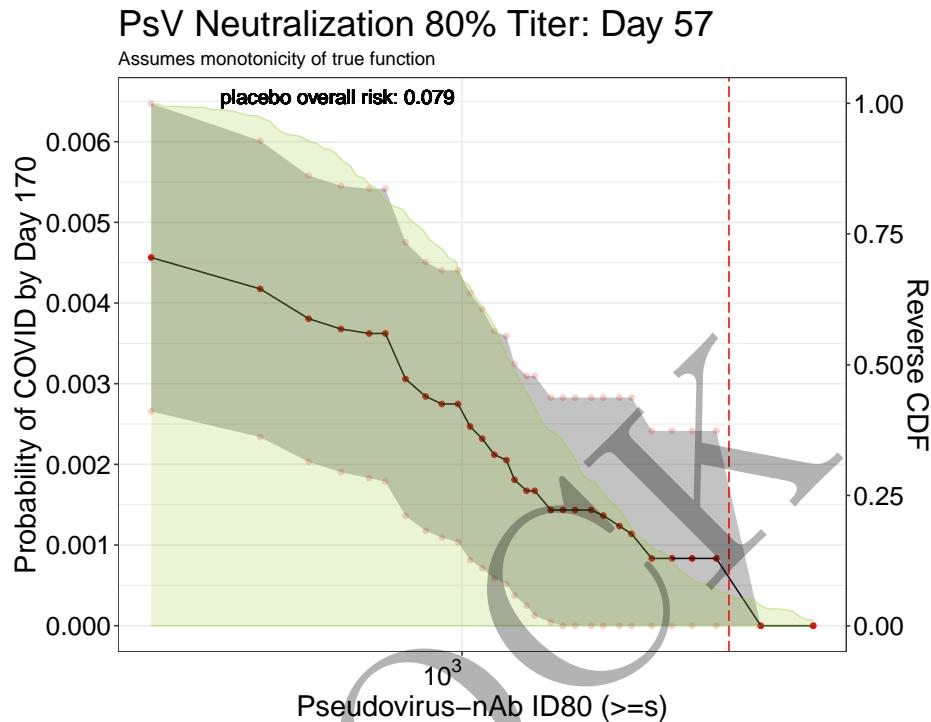


Figure 5.28: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence 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 |
|------------------------|---------------|---------------|---------|----------|
| 2.229 | $1.69 * 10^2$ | 0.00456 | 0.00266 | 0.00647 |
| 2.697 | $4.98 * 10^2$ | 0.00368 | 0.00190 | 0.00545 |
| 2.859 | $7.23 * 10^2$ | 0.00306 | 0.00136 | 0.00475 |
| 3.020 | $1.05 * 10^3$ | 0.00247 | 0.00081 | 0.00412 |
| 3.107 | $1.28 * 10^3$ | 0.00205 | 0.00052 | 0.00359 |
| 3.184 | $1.53 * 10^3$ | 0.00167 | 0.00013 | 0.00322 |
| 3.284 | $1.92 * 10^3$ | 0.00143 | 0.00000 | 0.00310 |
| 3.421 | $2.64 * 10^3$ | 0.00114 | 0.00000 | 0.00301 |
| 3.565 | $3.67 * 10^3$ | 0.00083 | 0.00000 | 0.00331 |
| 3.871 | $7.43 * 10^3$ | 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

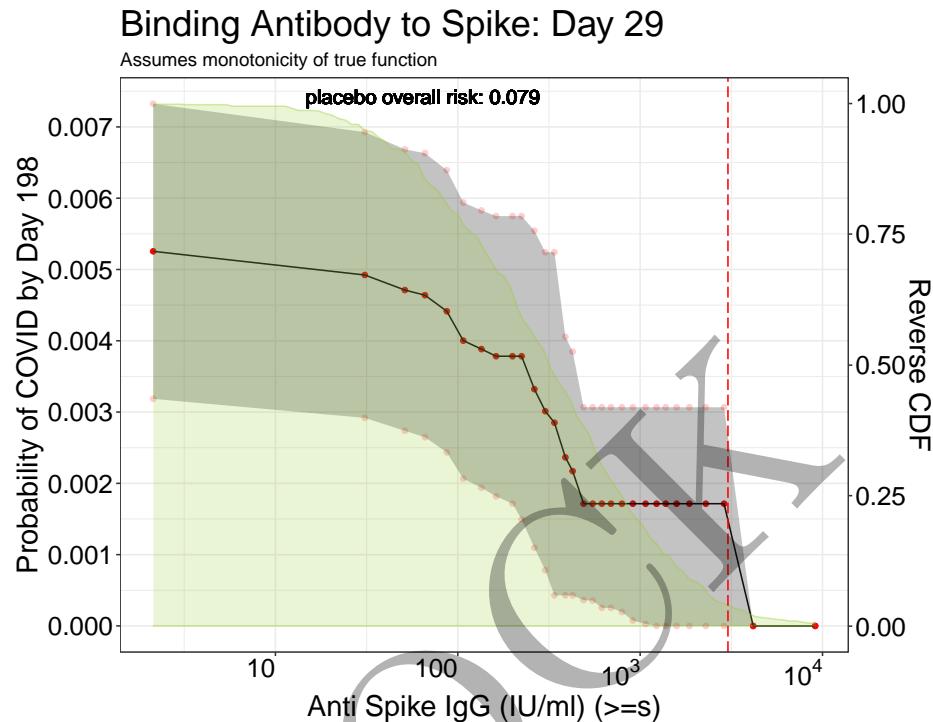


Figure 5.29: Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted 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 |
|------------------------|---------------|---------------|---------|----------|
| 0.326 | $2.12 * 10^0$ | 0.00525 | 0.00319 | 0.00732 |
| 1.821 | $6.62 * 10^1$ | 0.00464 | 0.00265 | 0.00663 |
| 2.129 | $1.35 * 10^2$ | 0.00388 | 0.00194 | 0.00583 |
| 2.422 | $2.64 * 10^2$ | 0.00332 | 0.00110 | 0.00554 |
| 2.590 | $3.89 * 10^2$ | 0.00236 | 0.00067 | 0.00406 |
| 2.740 | $5.50 * 10^2$ | 0.00171 | 0.00036 | 0.00307 |
| 2.901 | $7.96 * 10^2$ | 0.00171 | 0.00019 | 0.00323 |
| 3.145 | $1.40 * 10^3$ | 0.00171 | 0.00000 | 0.00384 |
| 3.364 | $2.31 * 10^3$ | 0.00171 | 0.00000 | 0.00749 |
| 3.965 | $9.23 * 10^3$ | 0.00000 | 0.00000 | NA |

5.8.2 Day 29 RBD binding antibody

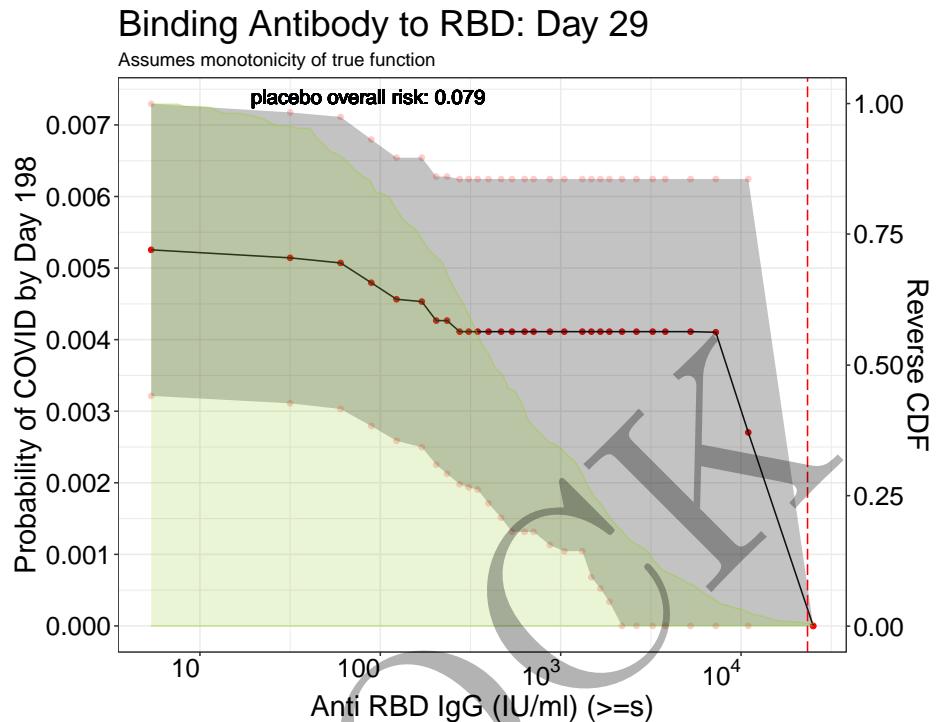


Figure 5.30: Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted 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 |
|------------------------|--------------------|---------------|---------|----------|
| 0.731 | 5.38×10^0 | 0.00525 | 0.00321 | 0.00730 |
| 1.948 | 8.87×10^1 | 0.00480 | 0.00279 | 0.00680 |
| 2.306 | 2.02×10^2 | 0.00427 | 0.00225 | 0.00628 |
| 2.542 | 3.48×10^2 | 0.00411 | 0.00190 | 0.00632 |
| 2.726 | 5.32×10^2 | 0.00411 | 0.00131 | 0.00691 |
| 2.943 | 8.77×10^2 | 0.00411 | 0.00113 | 0.00709 |
| 3.167 | 1.47×10^3 | 0.00411 | 0.00068 | 0.00754 |
| 3.423 | 2.65×10^3 | 0.00411 | 0.00000 | 0.01006 |
| 3.717 | 5.21×10^3 | 0.00411 | 0.00000 | 0.01131 |
| 4.401 | 2.52×10^4 | 0.00000 | 0.00000 | NA |

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

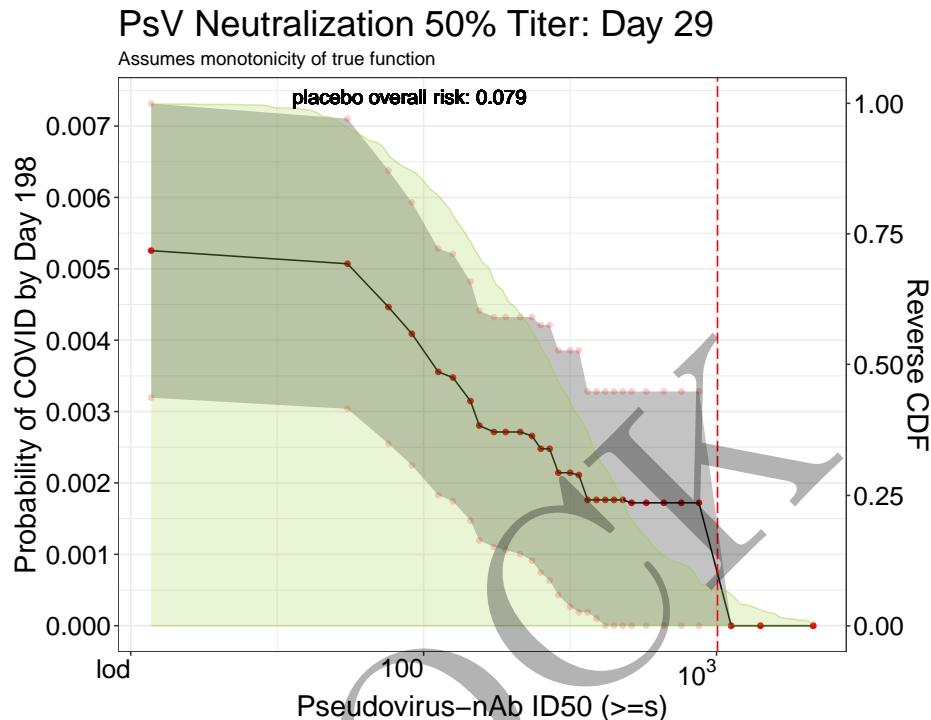


Figure 5.31: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence 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 |
|------------------------|--------------------|---------------|---------|----------|
| 1.068 | 1.17×10^1 | 0.00525 | 0.00319 | 0.00732 |
| 1.960 | 9.12×10^1 | 0.00409 | 0.00225 | 0.00593 |
| 2.158 | 1.44×10^2 | 0.00315 | 0.00147 | 0.00482 |
| 2.325 | 2.11×10^2 | 0.00271 | 0.00100 | 0.00442 |
| 2.434 | 2.72×10^2 | 0.00248 | 0.00063 | 0.00432 |
| 2.534 | 3.42×10^2 | 0.00211 | 0.00019 | 0.00403 |
| 2.623 | 4.20×10^2 | 0.00176 | 0.00000 | 0.00362 |
| 2.759 | 5.74×10^2 | 0.00172 | 0.00000 | 0.00442 |
| 2.940 | 8.71×10^2 | 0.00172 | 0.00000 | 0.00661 |
| 3.333 | 2.15×10^3 | 0.00000 | 0.00000 | NA |

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

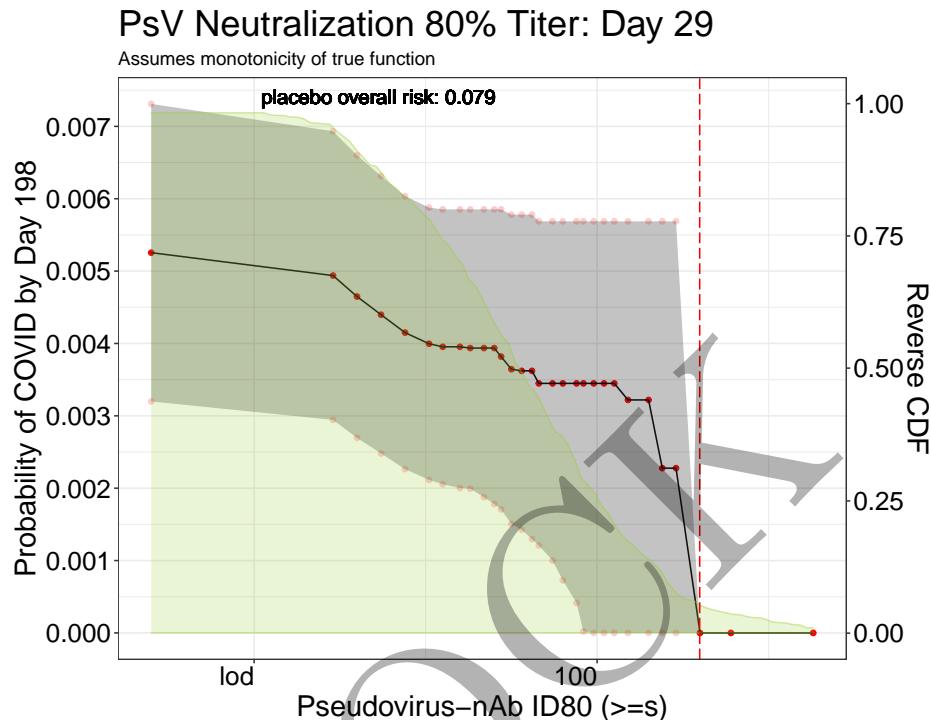


Figure 5.32: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence 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 | $5.00 * 10^0$ | 0.00525 | 0.00320 | 0.00731 |
| 1.374 | $2.37 * 10^1$ | 0.00440 | 0.00248 | 0.00631 |
| 1.551 | $3.56 * 10^1$ | 0.00395 | 0.00205 | 0.00585 |
| 1.698 | $4.99 * 10^1$ | 0.00394 | 0.00178 | 0.00609 |
| 1.777 | $5.98 * 10^1$ | 0.00362 | 0.00143 | 0.00582 |
| 1.869 | $7.40 * 10^1$ | 0.00345 | 0.00100 | 0.00590 |
| 1.957 | $9.06 * 10^1$ | 0.00345 | 0.00002 | 0.00688 |
| 2.090 | $1.23 * 10^2$ | 0.00322 | 0.00000 | 0.00707 |
| 2.233 | $1.71 * 10^2$ | 0.00228 | 0.00000 | 0.00854 |
| 2.633 | $4.30 * 10^2$ | 0.00000 | 0.00000 | NA |

MOCK

Chapter 6

Appendix

- This report was built from the [CoVPN/correlates_reporting](#) repository with commit hash 1e58586a8581da55c5b84d278351065b832ab884. A diff of the changes introduced by that commit may be viewed at https://github.com/CoVPN/correlates_reporting/commit/1e58586a8581da55c5b84d278351065b832ab884
- The sha256 hash sum of the raw input file, “COVID_VEtiral_practicedata_primarystage1.csv”: 45ff85033ffbc717462d678b41bc4060a12c7bc60952e2cb72297bb5500b97b9
- The sha256 hash sum of the processed file, “practice_data.csv”: 8de0bf2f66901eb123908b42ec8dd87cf9304412ca180aff8a