

COVID-19 Correlates of Risk Analysis Report
mock Study

USG COVID-19 Response Biostatistics Team

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Chapter 1

Summary Tables

Table 1. Demographic and Clinical Characteristics at Baseline in the baseline SARS-CoV-2 negative per-protocol cohort

Characteristics	Vaccine (N = 13258)	Placebo (N = 13373)	Total (N = 26631)
Age			
Age < 65	10440 (78.7%)	10226 (76.5%)	20666 (77.6%)
Age ≥ 65	2818 (21.3%)	3147 (23.5%)	5965 (22.4%)
Mean (Range)	47.1 (18.0, 85.0)	48.5 (18.0, 85.0)	47.8 (18.0, 85.0)
BMI			
Mean ± SD	30.0 ± 6.9	30.0 ± 7.1	30.0 ± 7.0
Risk for Severe Covid-19			
At-risk	2928 (22.1%)	3465 (25.9%)	6393 (24.0%)
Not at-risk	10330 (77.9%)	9908 (74.1%)	20238 (76.0%)
Age, Risk for Severe Covid-19			
Age < 65 At-risk	2260 (17.0%)	2460 (18.4%)	4720 (17.7%)
Age < 65 Not at-risk	8180 (61.7%)	7766 (58.1%)	15946 (59.9%)
Age ≥ 65	2818 (21.3%)	3147 (23.5%)	5965 (22.4%)
Sex			
Female	7396 (55.8%)	7566 (56.6%)	14962 (56.2%)
Male	5862 (44.2%)	5807 (43.4%)	11669 (43.8%)
Hispanic or Latino ethnicity			
Hispanic or Latino	1498 (11.3%)	1507 (11.3%)	3005 (11.3%)
Not Hispanic or Latino	10711 (80.8%)	10889 (81.4%)	21600 (81.1%)
Not reported and unknown	1049 (7.9%)	977 (7.3%)	2026 (7.6%)
Race			
White Non-Hispanic	7343 (55.4%)	7498 (56.1%)	14841 (55.7%)
Black or African American	1830 (13.8%)	1823 (13.6%)	3653 (13.7%)
Asian	672 (5.1%)	655 (4.9%)	1327 (5.0%)
American Indian or Alaska Native	206 (1.6%)	226 (1.7%)	432 (1.6%)
Native Hawaiian or Other Pacific Islander	141 (1.1%)	153 (1.1%)	294 (1.1%)
Multiracial	561 (4.2%)	570 (4.3%)	1131 (4.2%)
Other	234 (1.8%)	218 (1.6%)	452 (1.7%)
Not reported and unknown	921 (6.9%)	943 (7.1%)	1864 (7.0%)

(continued)

Characteristics	Vaccine (N = 13258)	Placebo (N = 13373)	Total (N = 26631)
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This table summarises the per-protocol individuals without a COVID failure event < 7 days post Day 57.

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Table 2. Demographic and Clinical Characteristics at Baseline in the baseline SARS-CoV-2 positive per-protocol cohort

Characteristics	Vaccine (N = 1436)	Placebo (N = 1286)	Total (N = 2722)
Age			
Age < 65	1154 (80.4%)	1034 (80.4%)	2188 (80.4%)
Age ≥ 65	282 (19.6%)	252 (19.6%)	534 (19.6%)
Mean (Range)	46.8 (18.0, 85.0)	46.7 (18.0, 85.0)	46.7 (18.0, 85.0)
BMI			
Mean ± SD	29.8 ± 7.0	29.8 ± 6.9	29.8 ± 7.0
Risk for Severe Covid-19			
At-risk	268 (18.7%)	266 (20.7%)	534 (19.6%)
Not at-risk	1168 (81.3%)	1020 (79.3%)	2188 (80.4%)
Age, Risk for Severe Covid-19			
Age < 65 At-risk	207 (14.4%)	223 (17.3%)	430 (15.8%)
Age < 65 Not at-risk	947 (65.9%)	811 (63.1%)	1758 (64.6%)
Age ≥ 65	282 (19.6%)	252 (19.6%)	534 (19.6%)
Sex			
Female	815 (56.8%)	712 (55.4%)	1527 (56.1%)
Male	621 (43.2%)	574 (44.6%)	1195 (43.9%)
Hispanic or Latino ethnicity			
Hispanic or Latino	145 (10.1%)	137 (10.7%)	282 (10.4%)
Not Hispanic or Latino	1196 (83.3%)	1058 (82.3%)	2254 (82.8%)
Not reported and unknown	95 (6.6%)	91 (7.1%)	186 (6.8%)
Race			
White Non-Hispanic	801 (55.8%)	730 (56.8%)	1531 (56.2%)
Black or African American	226 (15.7%)	168 (13.1%)	394 (14.5%)
Asian	90 (6.3%)	69 (5.4%)	159 (5.8%)
American Indian or Alaska Native	31 (2.2%)	18 (1.4%)	49 (1.8%)
Native Hawaiian or Other Pacific Islander	14 (1.0%)	17 (1.3%)	31 (1.1%)
Multiracial	60 (4.2%)	44 (3.4%)	104 (3.8%)
Other	18 (1.3%)	22 (1.7%)	40 (1.5%)
Not reported and unknown	87 (6.1%)	97 (7.5%)	184 (6.8%)

This table summarises the per-protocol individuals without a COVID failure event < 7 days post Day 57.

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							
		Cases*			Non-Cases/Control			Comparison	
N	Resp rate	GMT/GMC	N	Resp rate	GMT/GMC	Resp Rate Difference	GMTR/GMCR		
Day 29	Pseudovirus-nAb ID80	70 66.6/71.8 = 92.9% (83.7%, 97.0%)	124 (87, 177)	902 12600/13206.2 = 95.4% (92.8%, 97.1%)	203 (175, 236)	-2.6% (-11.8%, 2.4%)	0.61 (0.42, 0.90)		
Day 29	Pseudovirus-nAb ID50	70 55.3/71.8 = 77.1% (65.7%, 85.6%)	37 (26, 53)	902 12115.4/13206.2 = 91.7% (88.7%, 94.0%)	115 (99, 133)	-14.6% (-26.3%, -5.6%)	0.32 (0.22, 0.48)		
Day 29	Anti RBD IgG (IU/ml)	70 71.8/71.8 = 100.0% (100.0%, 100.0%)	10561 (7476, 14920)	902 13206.2/13206.2 = 100.0% (100.0%, 100.0%)	24558 (21233, 28403)	0% (0%, 0%)	0.43 (0.30, 0.63)		
Day 29	Anti Spike IgG (IU/ml)	70 71.8/71.8 = 100.0% (100.0%, 100.0%)	12526 (9467, 16573)	902 13206.2/13206.2 = 100.0% (100.0%, 100.0%)	43997 (38898, 49765)	0% (0%, 0%)	0.28 (0.21, 0.39)		
Day 29	Anti N IgG (IU/ml)	70 71.8/71.8 = 100.0% (100.0%, 100.0%)	11376 (7592, 17046)	902 13206.2/13206.2 = 100.0% (100.0%, 100.0%)	26157 (22378, 30575)	0% (0%, 0%)	0.43 (0.28, 0.67)		
Day 57	Pseudovirus-nAb ID80	70 70.7/71.8 = 98.6% (90.2%, 99.8%)	435 (314, 603)	899 13130.9/13186.2 = 99.6% (97.7%, 99.9%)	790 (722, 864)	-1% (-9.3%, 1.2%)	0.55 (0.39, 0.77)		
Day 57	Pseudovirus-nAb ID50	70 62.5/71.8 = 87.1% (76.9%, 93.3%)	162 (101, 261)	899 13080.4/13186.2 = 99.2% (97.7%, 99.7%)	1158 (1004, 1335)	-12.1% (-22.3%, -5.8%)	0.14 (0.09, 0.23)		
Day 57	Anti RBD IgG (IU/ml)	70 71.8/71.8 = 100.0% (100.0%, 100.0%)	238890 (158541, 359962)	899 13186.2/13186.2 = 100.0% (100.0%, 100.0%)	1181181 (1009002, 1382742)	0% (0%, 0%)	0.20 (0.13, 0.31)		
Day 57	Anti Spike IgG (IU/ml)	70 71.8/71.8 = 100.0% (100.0%, 100.0%)	230380 (165152, 321372)	899 13186.2/13186.2 = 100.0% (100.0%, 100.0%)	2353932 (2049571, 2703492)	0% (0%, 0%)	0.10 (0.07, 0.14)		
Day 57	Anti N IgG (IU/ml)	70 71.8/71.8 = 100.0% (100.0%, 100.0%)	68782 (42731, 110716)	899 13186.2/13186.2 = 100.0% (100.0%, 100.0%)	408256 (335305, 497080)	0% (0%, 0%)	0.17 (0.10, 0.28)		

*Cases are baseline negative per-protocol vaccine recipients with the symptomatic infection COVID-19 primary endpoint diagnosed starting 7 days after the Day 57 study visit. Non-cases/Controls are baseline negative per-protocol vaccine recipients sampled into the random subcohort with no evidence of SARS-CoV-2 infection up to the time of data cut.

Table 4. Antibody levels in the baseline SARS-CoV-2 positive per-protocol cohort (vaccine recipients)

Visit	Marker	Baseline SARS-CoV-2 Positive Vaccine Recipients						Comparison	
		Cases*			Non-Cases/Control			Resp Rate Difference	GMTR/GMCR
N	Resp rate	GMT/GMC	N	Resp rate	GMT/GMC				
Day 29	Pseudovirus-nAb ID80	5 5/5 = 100.0% (100.0%, 100.0%)	416 (237, 730)	281	1372.5/1434 = 95.7% (90.5%, 98.1%)	243 (189, 312)	4.3% (1.9%, 9.5%)	1.71 (0.93, 3.17)	
Day 29	Pseudovirus-nAb ID50	5 5/5 = 100.0% (100.0%, 100.0%)	97 (32, 300)	281	1358.6/1434 = 94.7% (89.4%, 97.5%)	148 (114, 193)	5.3% (2.5%, 10.6%)	0.66 (0.21, 2.09)	
Day 29	Anti RBD IgG (IU/ml)	5 5/5 = 100.0% (100.0%, 100.0%)	34489 (16902, 70377)	281	1434/1434 = 100.0% (100.0%, 100.0%)	33757 (26047, 43750)	0% (0%, 0%)	1.02 (0.48, 2.18)	
Day 29	Anti Spike IgG (IU/ml)	5 5/5 = 100.0% (100.0%, 100.0%)	119729 (59800, 239719)	281	1434/1434 = 100.0% (100.0%, 100.0%)	69408 (55631, 86598)	0% (0%, 0%)	1.72 (0.83, 3.57)	
Day 29	Anti N IgG (IU/ml)	5 5/5 = 100.0% (100.0%, 100.0%)	37629 (8842, 160140)	281	1434/1434 = 100.0% (100.0%, 100.0%)	34685 (26636, 45167)	0% (0%, 0%)	1.08 (0.25, 4.73)	
Day 57	Pseudovirus-nAb ID80	5 5/5 = 100.0% (100.0%, 100.0%)	1295 (1295, 1295)	279	1431/1431 = 100.0% (100.0%, 100.0%)	967 (837, 1116)	0% (0%, 0%)	1.34 (1.16, 1.55)	
Day 57	Pseudovirus-nAb ID50	5 5/5 = 100.0% (100.0%, 100.0%)	1119 (565, 2216)	279	1417.1/1431 = 99.0% (93.5%, 99.9%)	1784 (1428, 2227)	1% (0.1%, 6.5%)	0.63 (0.31, 1.29)	
Day 57	Anti RBD IgG (IU/ml)	5 5/5 = 100.0% (100.0%, 100.0%)	1493688 (427212, 5222482)	279	1431/1431 = 100.0% (100.0%, 100.0%)	2387095 (1820218, 3130518)	0% (0%, 0%)	0.63 (0.17, 2.25)	
Day 57	Anti Spike IgG (IU/ml)	5 5/5 = 100.0% (100.0%, 100.0%)	3120901 (1055232, 9230216)	279	1431/1431 = 100.0% (100.0%, 100.0%)	5016998 (4154063, 6059194)	0% (0%, 0%)	0.62 (0.21, 1.87)	
Day 57	Anti N IgG (IU/ml)	5 5/5 = 100.0% (100.0%, 100.0%)	1082032 (269879, 4338206)	279	1431/1431 = 100.0% (100.0%, 100.0%)	780336 (563384, 1080835)	0% (0%, 0%)	1.39 (0.33, 5.77)	

*Cases are baseline positive per-protocol vaccine recipients with the symptomatic infection COVID-19 primary endpoint diagnosed starting 7 days after the Day 57 study visit. Non-cases/Controls are baseline negative per-protocol vaccine recipients sampled into the random subcohort with no evidence of SARS-CoV-2 infection up to the time of data cut.

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

Visit	Marker	Baseline SARS-CoV-2 Positive Placebo Recipients							
		Cases*				Non-Cases/Control			Comparison
		N	Resp rate	GMT/GMC	N	Resp rate	GMT/GMC	Resp Rate Difference	GMTR/GMCR
Day 29	Pseudovirus-nAb ID80	5	4/5 = 80.0% (15.2%, 98.9%)	46 (12, 179)	263	1168.4/1281 = 91.2% (85.1%, 95.0%)	116 (91, 147)	-11.2% (-76.1%, 8.7%)	0.40 (0.10, 1.58)
Day 29	Pseudovirus-nAb ID50	5	3/5 = 60.0% (10.6%, 95.0%)	20 (6, 68)	263	987.9/1281 = 77.1% (69.4%, 83.3%)	54 (41, 71)	-17.1% (-66.9%, 18.7%)	0.37 (0.11, 1.31)
Day 29	Anti RBD IgG (IU/ml)	5	5/5 = 100.0% (100.0%, 100.0%)	4989 (1271, 19589)	263	1281/1281 = 100.0% (100.0%, 100.0%)	13809 (10955, 17408)	0% (0%, 0%)	0.36 (0.09, 1.45)
Day 29	Anti Spike IgG (IU/ml)	5	5/5 = 100.0% (100.0%, 100.0%)	11746 (2396, 57585)	263	1281/1281 = 100.0% (100.0%, 100.0%)	19848 (16200, 24319)	0% (0%, 0%)	0.59 (0.12, 2.94)
Day 29	Anti N IgG (IU/ml)	5	5/5 = 100.0% (100.0%, 100.0%)	3274 (734, 14600)	263	1281/1281 = 100.0% (100.0%, 100.0%)	13419 (10340, 17416)	0% (0%, 0%)	0.24 (0.05, 1.11)
Day 57	Pseudovirus-nAb ID80	5	4/5 = 80.0% (15.2%, 98.9%)	118 (22, 639)	263	1273.1/1281 = 99.4% (95.8%, 99.9%)	610 (519, 716)	-19.4% (-84.2%, -0.2%)	0.19 (0.04, 1.06)
Day 57	Pseudovirus-nAb ID50	5	4/5 = 80.0% (15.2%, 98.9%)	106 (18, 625)	263	1232.7/1281 = 96.2% (91.1%, 98.5%)	504 (365, 695)	-16.2% (-81.1%, 3.3%)	0.21 (0.03, 1.28)
Day 57	Anti RBD IgG (IU/ml)	5	5/5 = 100.0% (100.0%, 100.0%)	259968 (54625, 1237231)	263	1281/1281 = 100.0% (100.0%, 100.0%)	395918 (295146, 531096)	0% (0%, 0%)	0.66 (0.13, 3.21)
Day 57	Anti Spike IgG (IU/ml)	5	5/5 = 100.0% (100.0%, 100.0%)	363563 (107367, 1231089)	263	1281/1281 = 100.0% (100.0%, 100.0%)	720549 (564910, 919068)	0% (0%, 0%)	0.50 (0.15, 1.75)
Day 57	Anti N IgG (IU/ml)	5	5/5 = 100.0% (100.0%, 100.0%)	48344 (9345, 250095)	263	1281/1281 = 100.0% (100.0%, 100.0%)	143737 (103916, 198817)	0% (0%, 0%)	0.34 (0.06, 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.

Chapter 2

Graphical Descriptions of Antibody Marker Data

2.1 Boxplots

2.1.1 Baseline seronegative

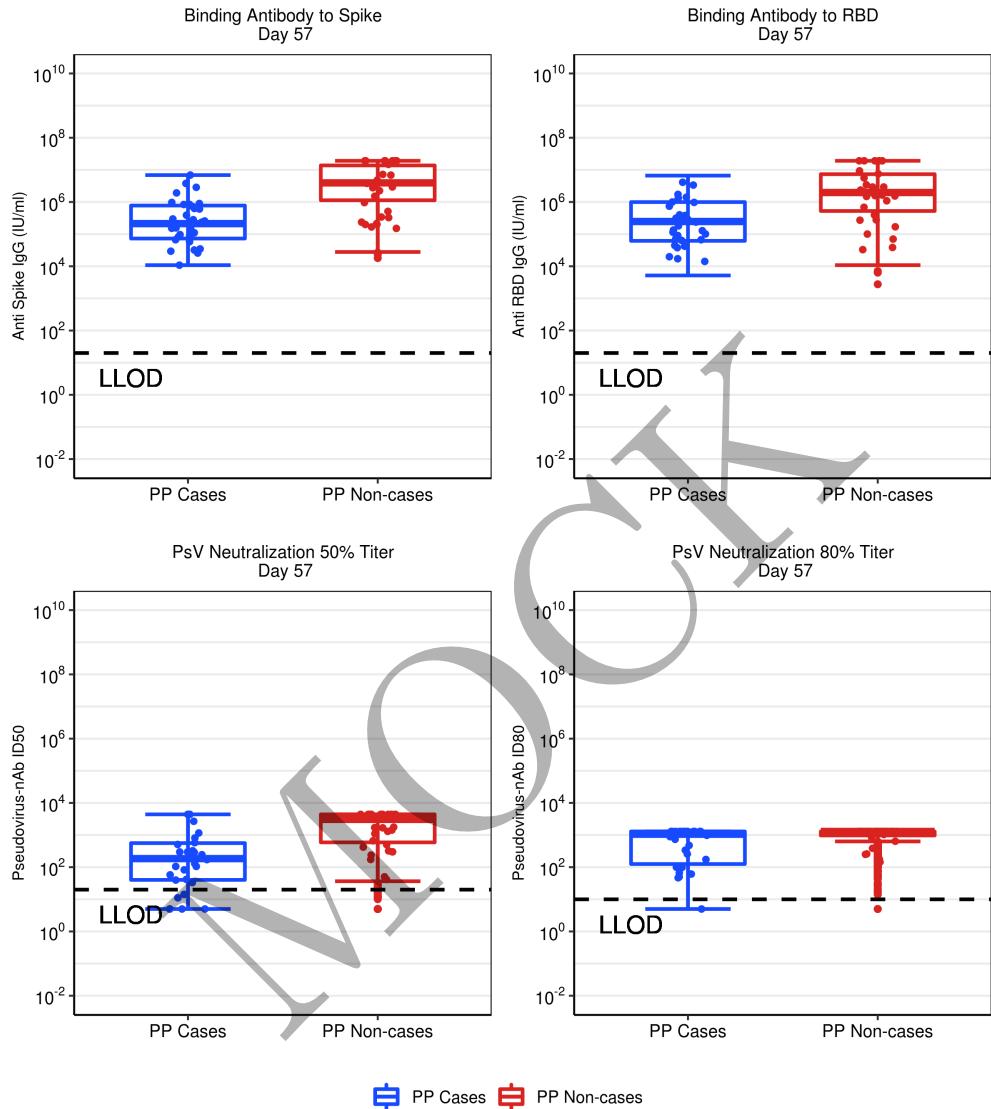


Figure 2.1: Boxplots of D57 Ab markers: baseline negative vaccine arm.

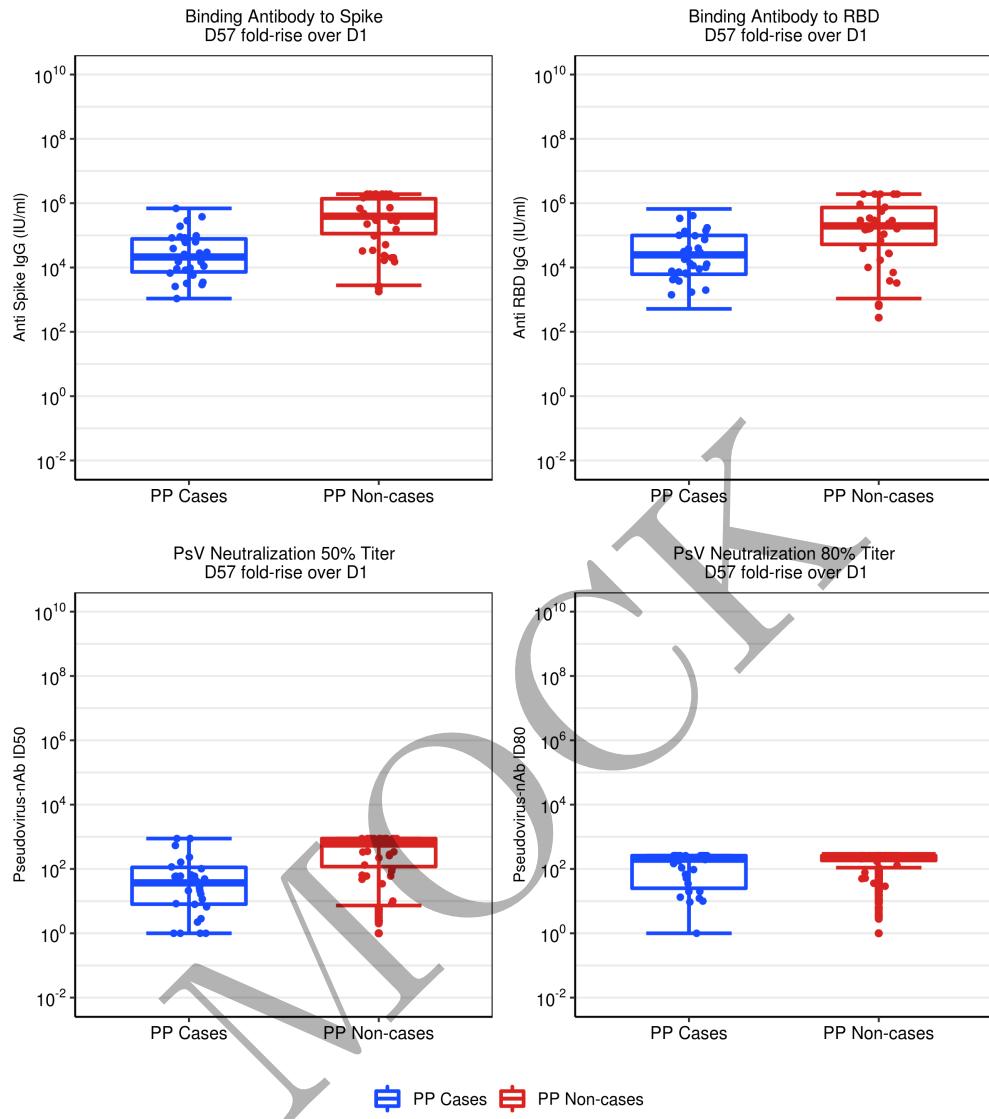


Figure 2.2: Boxplots of D57 fold-rise over D1 Ab markers: baseline negative vaccine arm.

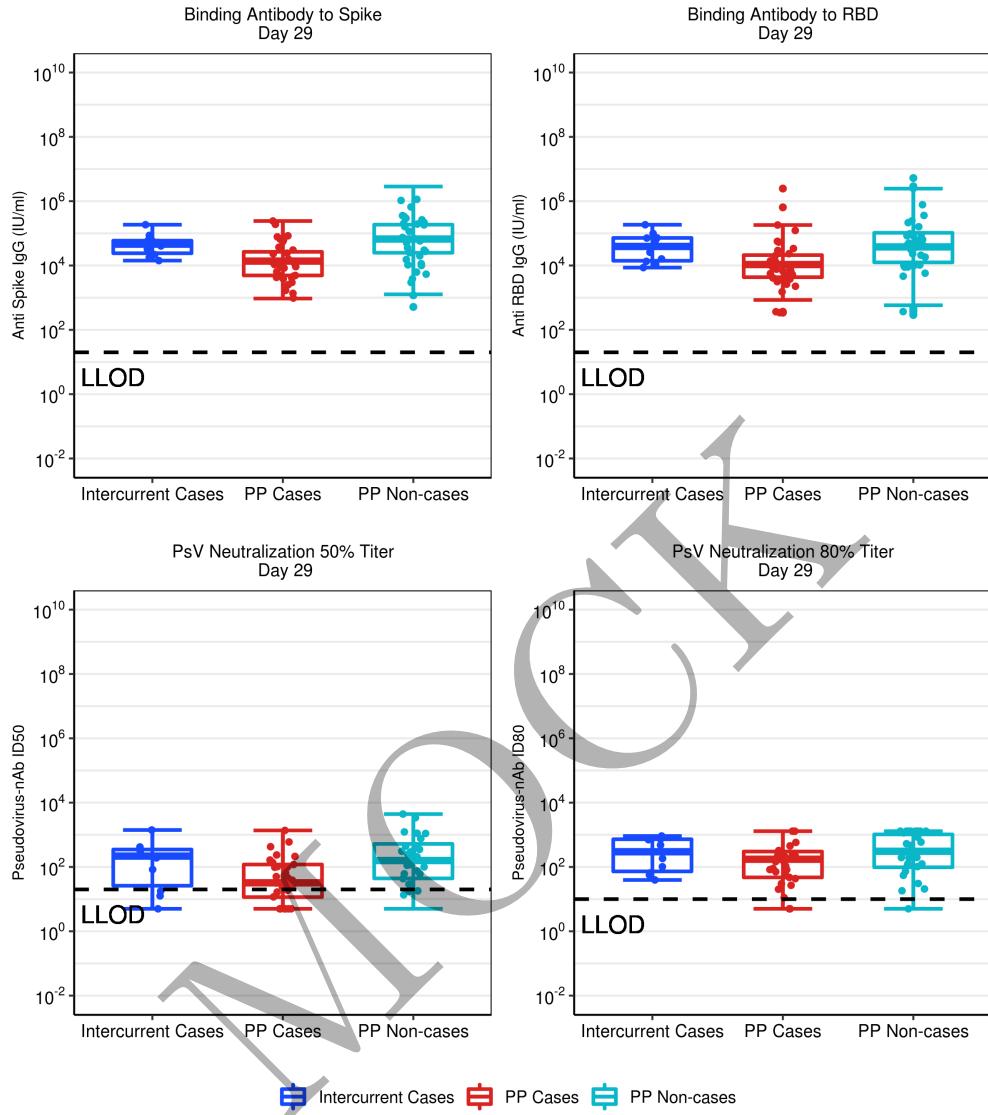


Figure 2.3: Boxplots of D29 Ab markers: baseline negative vaccine arm.

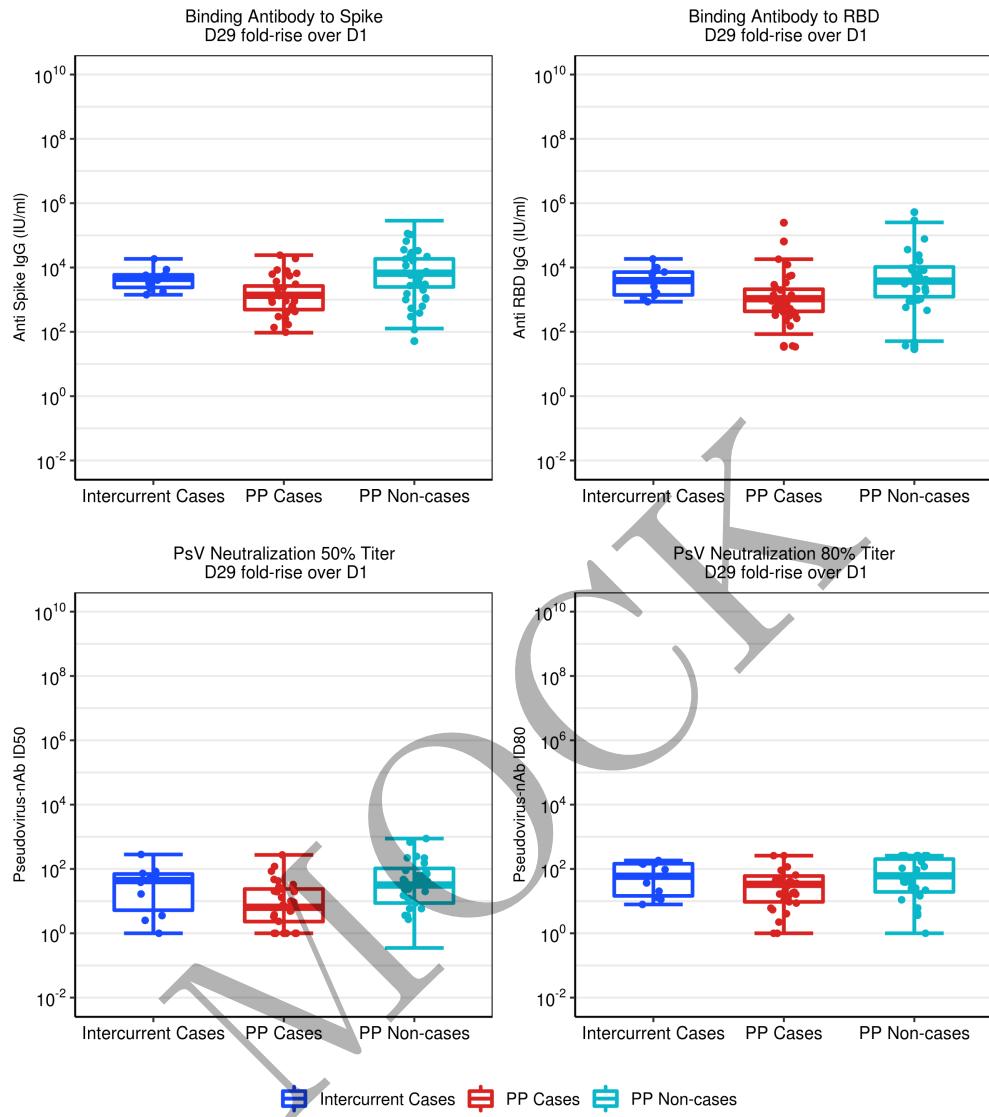


Figure 2.4: Boxplots of D29 fold-rise over D1 Ab markers: baseline negative vaccine arm.

2.1.2 Baseline seropositive

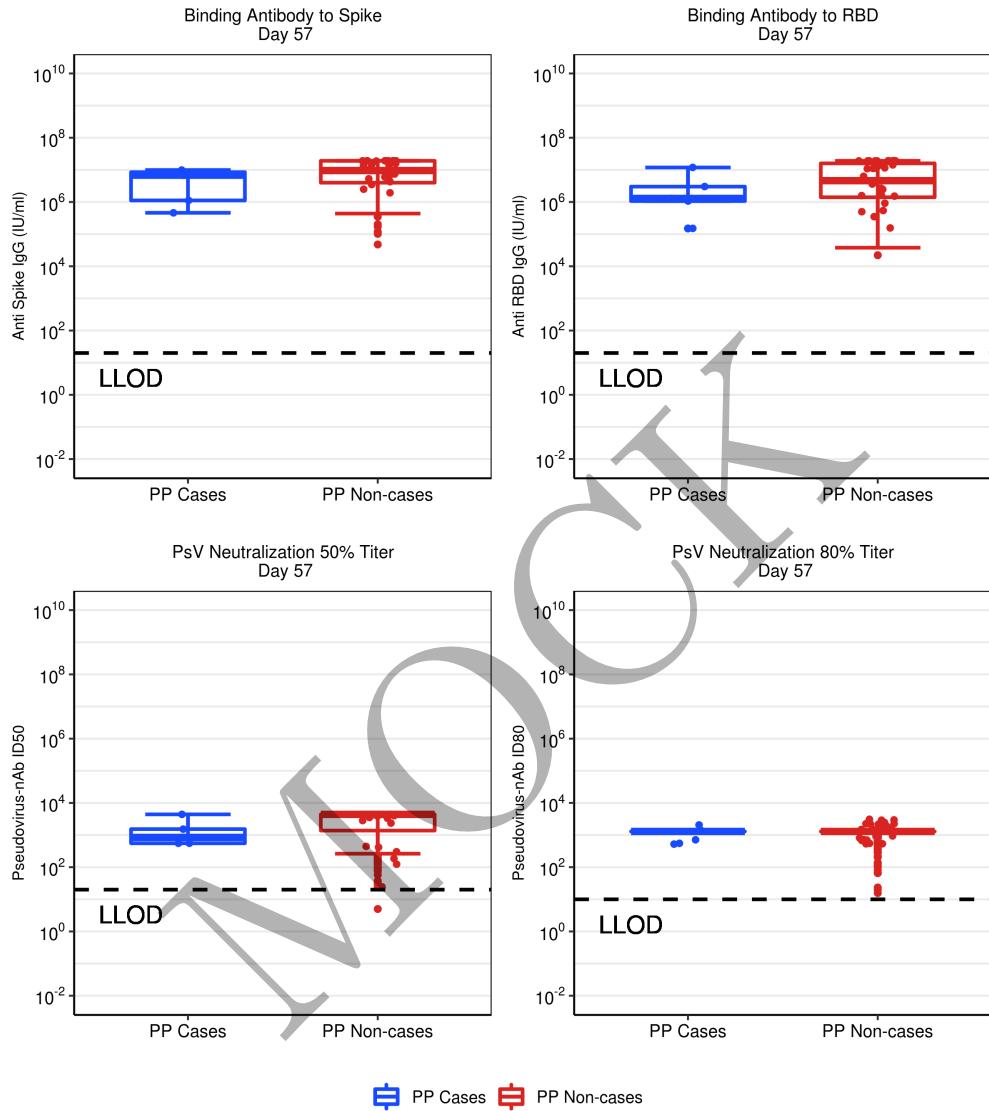


Figure 2.5: Boxplots of D57 Ab markers: baseline positive vaccine arm.

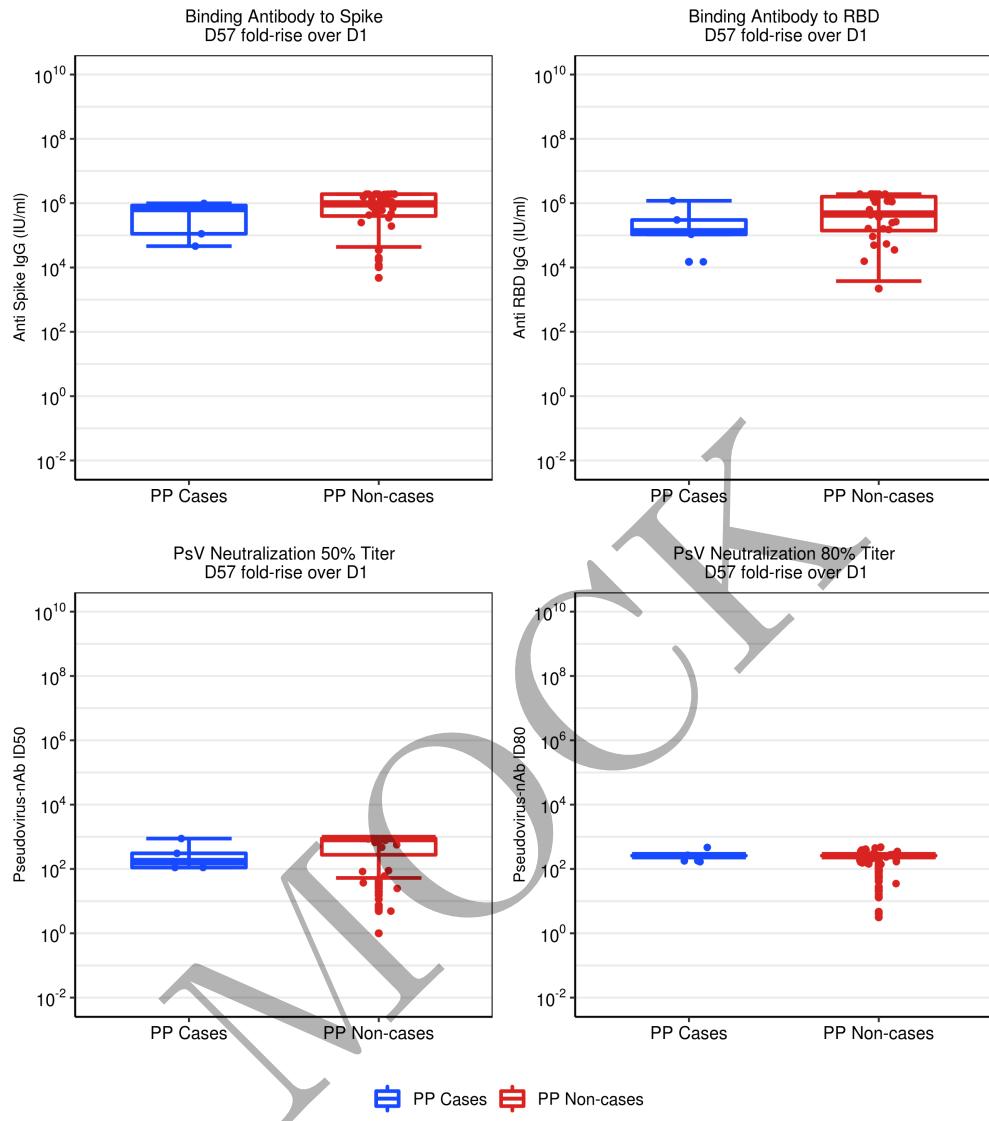


Figure 2.6: Boxplots of D57 fold-rise over D1 Ab markers: baseline positive vaccine arm.

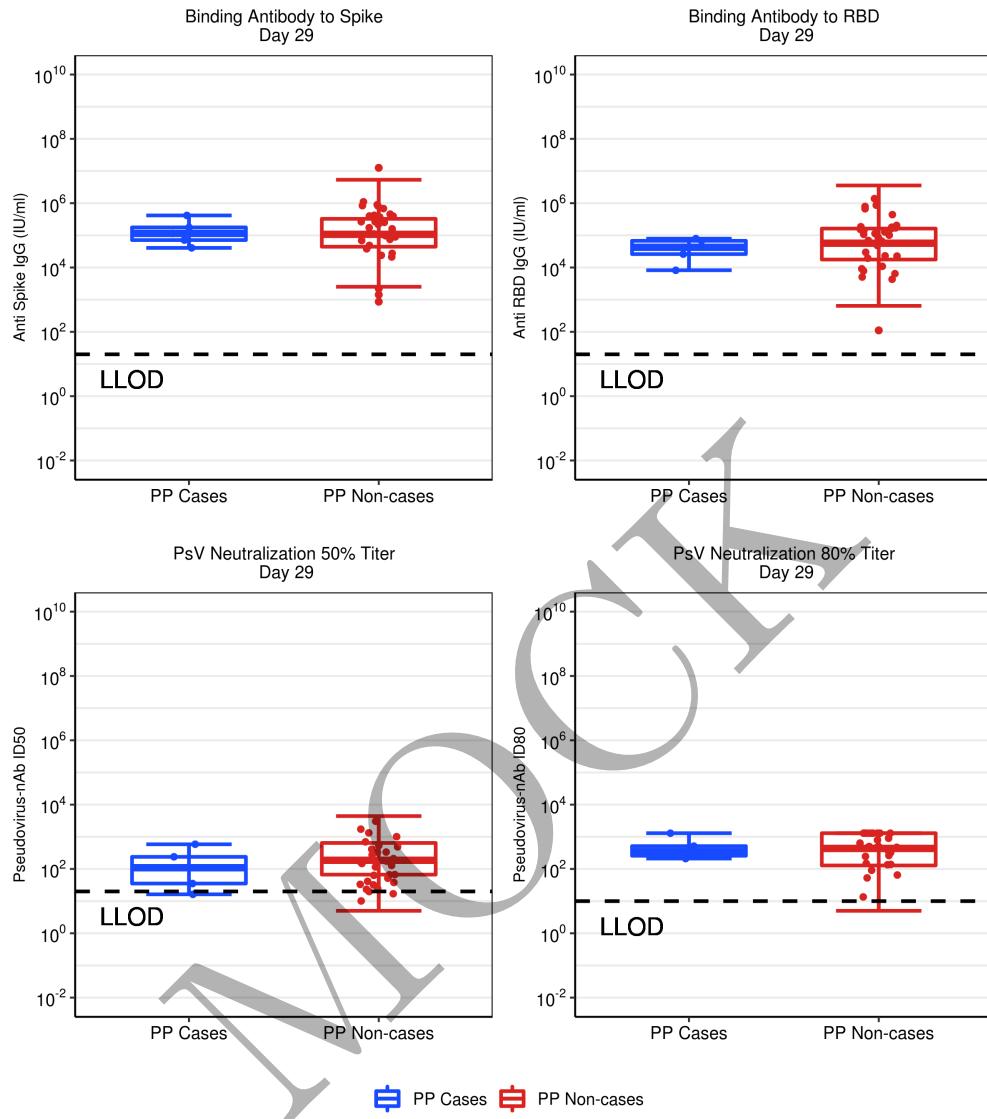


Figure 2.7: Boxplots of D29 Ab markers: baseline positive vaccine arm.

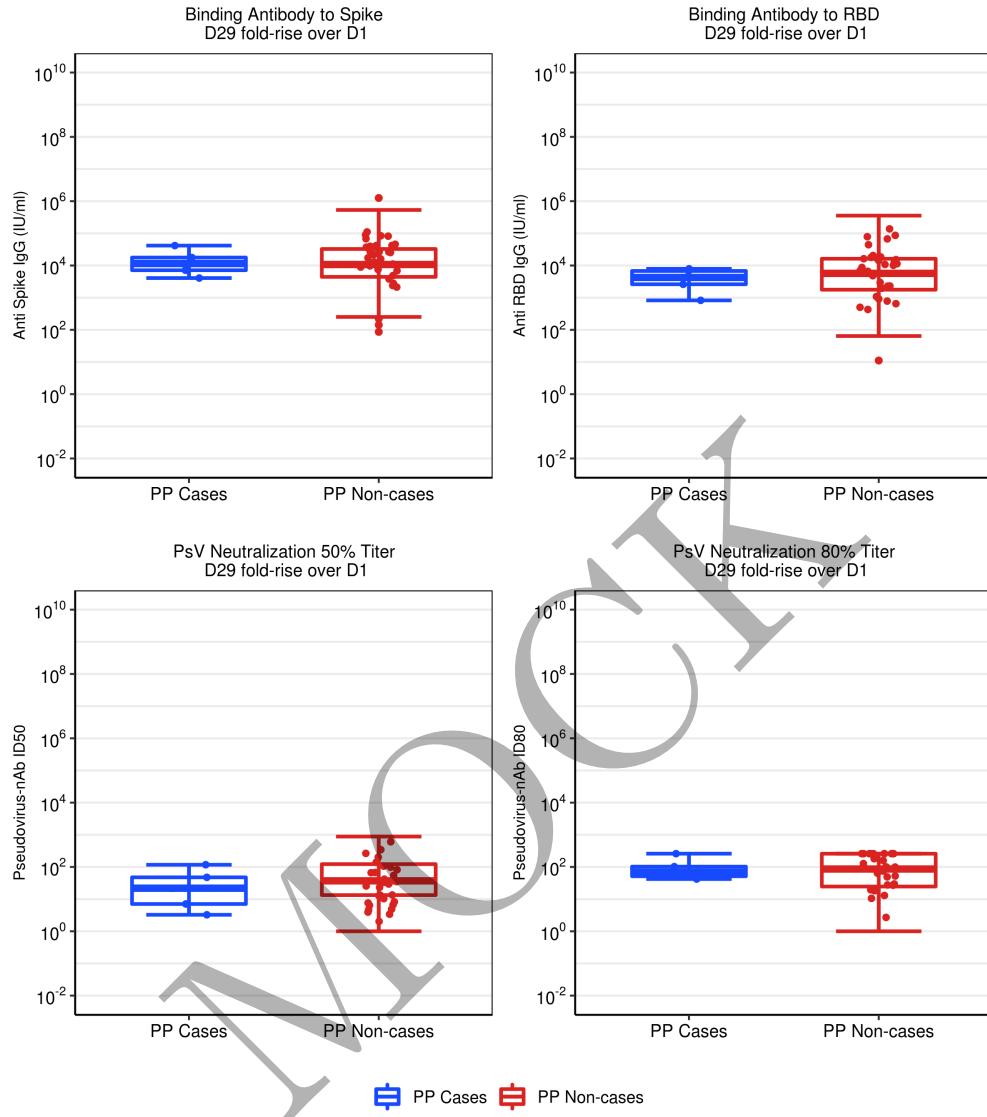


Figure 2.8: Boxplots of D29 fold-rise over D1 Ab markers: baseline positive vaccine arm.

2.2 Weighted RCDF plots

2.2.1 Baseline seronegative

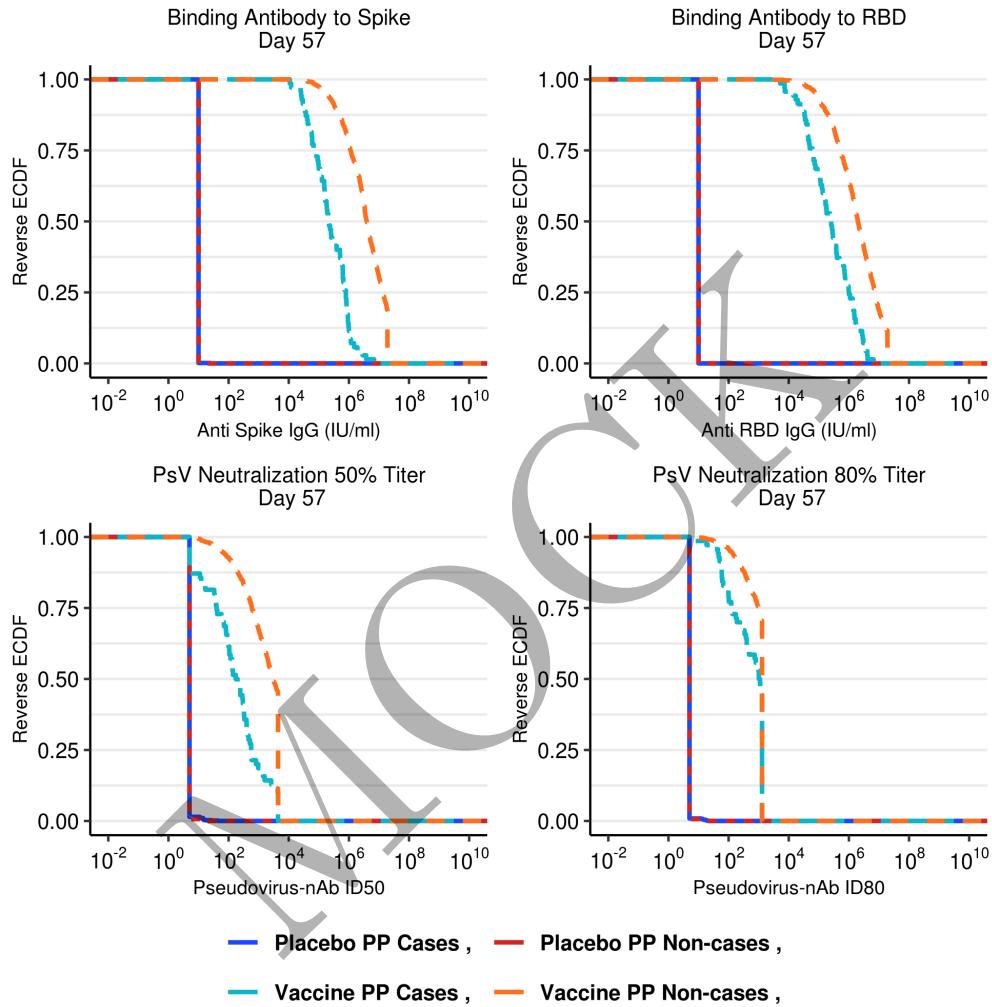


Figure 2.9: RCDF plots for D57 Ab markers: baseline negative by treatment arm.

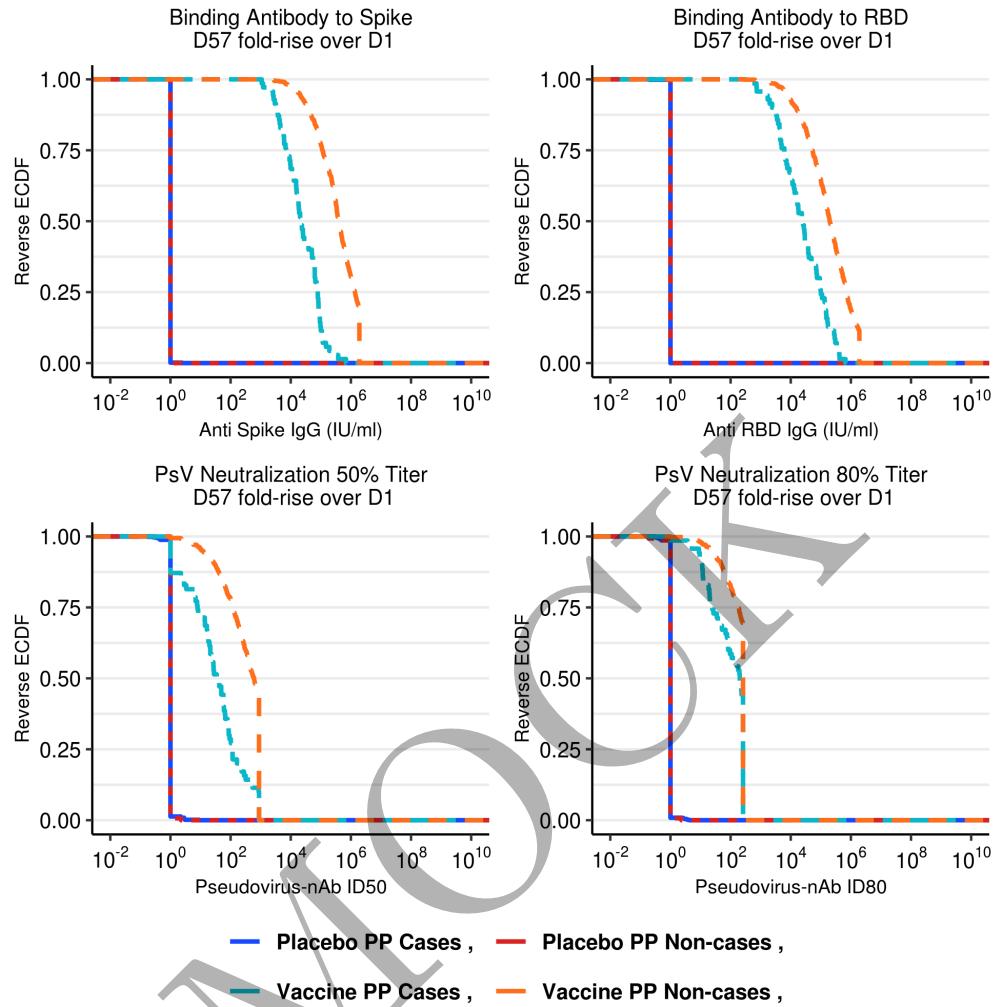


Figure 2.10: RCDF plots for D57 fold-rise over D1 Ab markers: baseline negative by treatment arm.

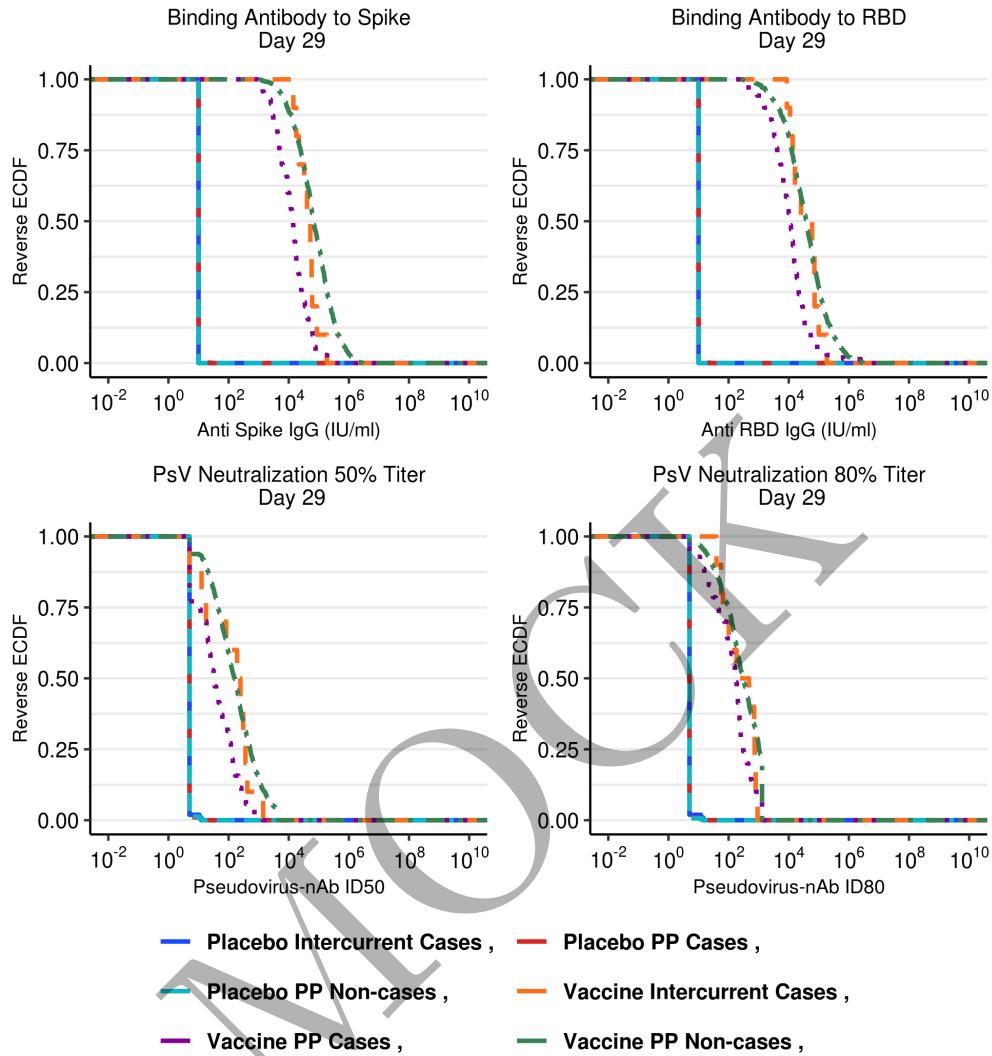


Figure 2.11: RCDF plots for D29 Ab markers: baseline negative by treatment arm.

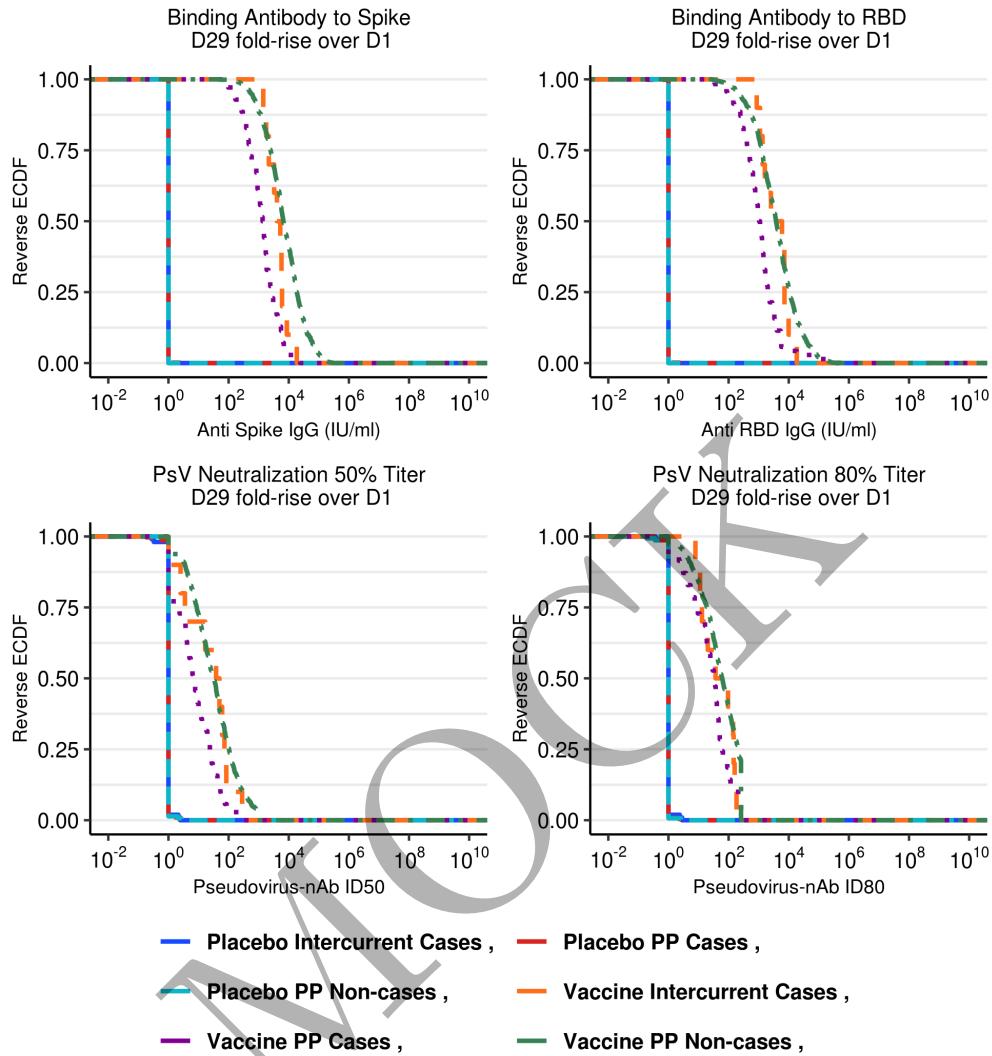


Figure 2.12: RCDF plots for D29 fold-rise over D1 Ab markers: baseline negative by treatment arm.

2.2.2 Baseline seropositive

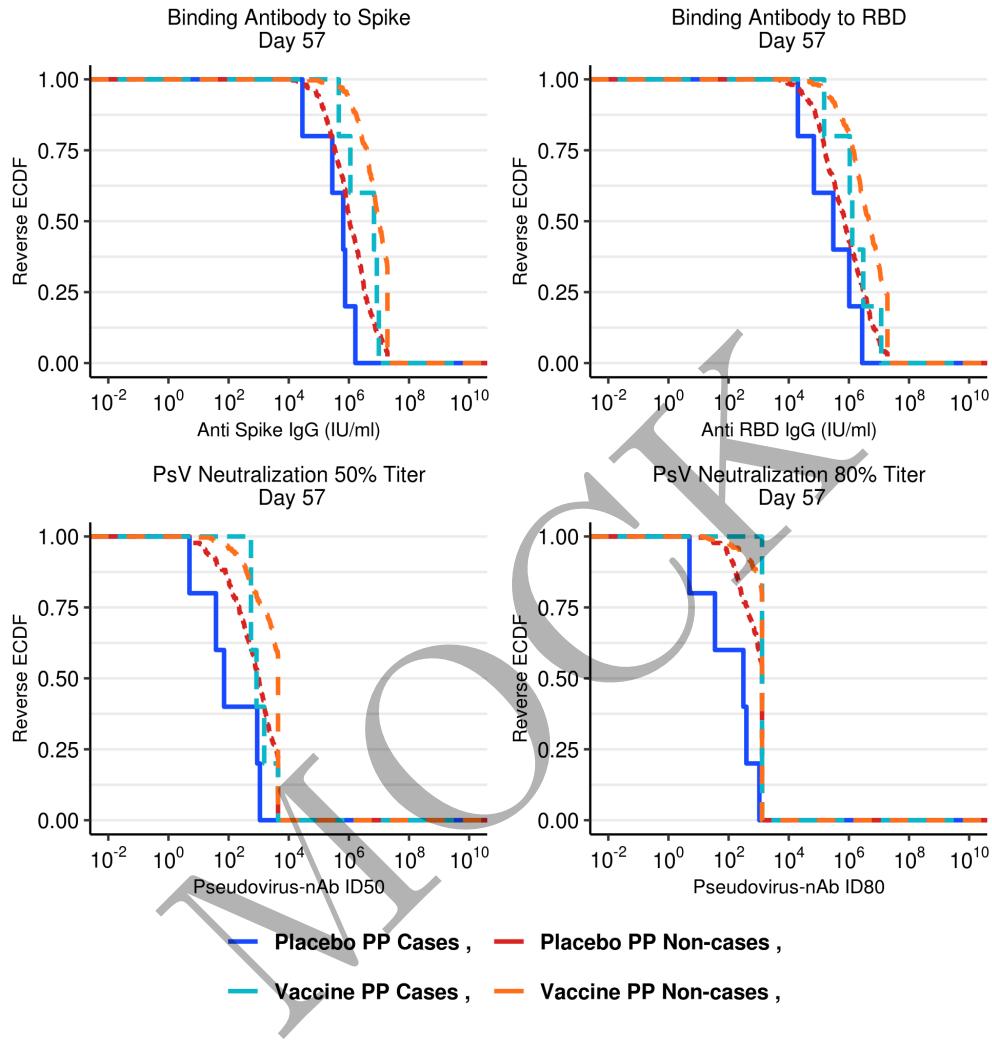


Figure 2.13: RCDF plots for D57 Ab markers: baseline positive by treatment arm.

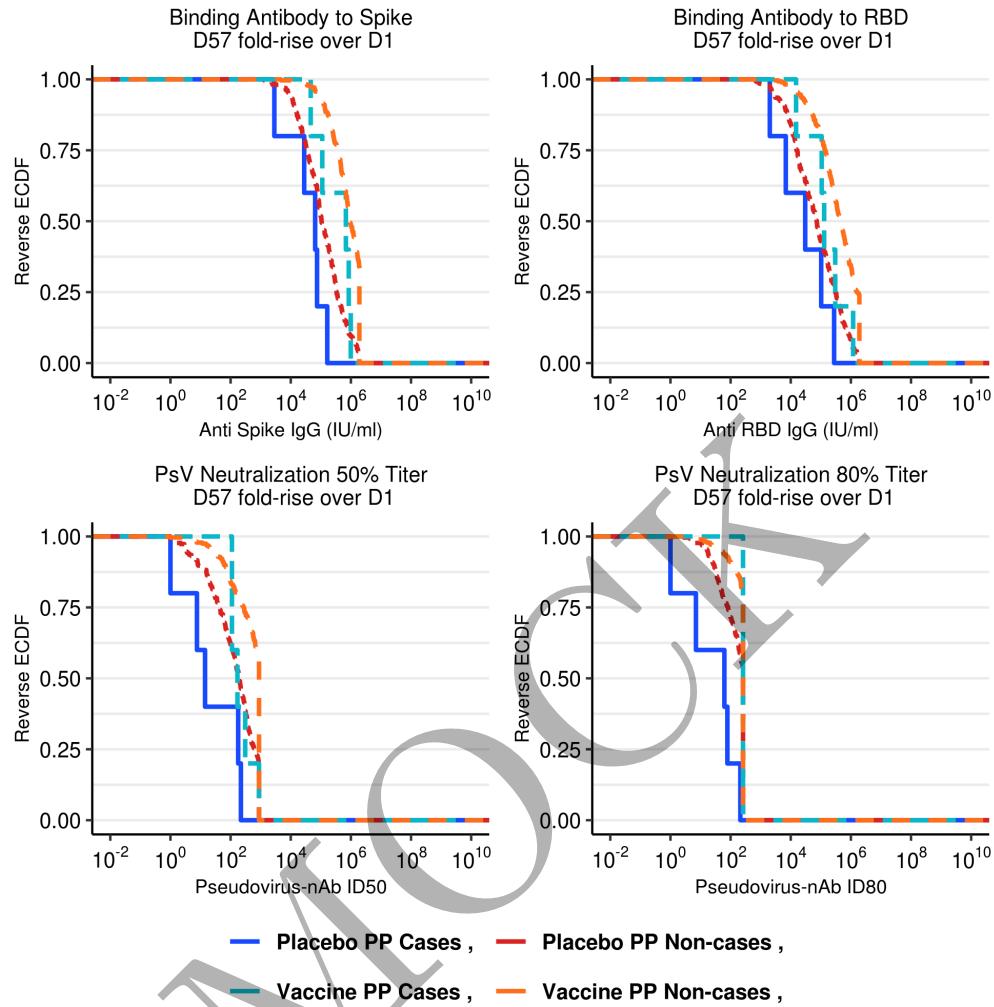


Figure 2.14: RCDF plots for D57 fold-rise over D1 Ab markers: baseline positive by treatment arm.

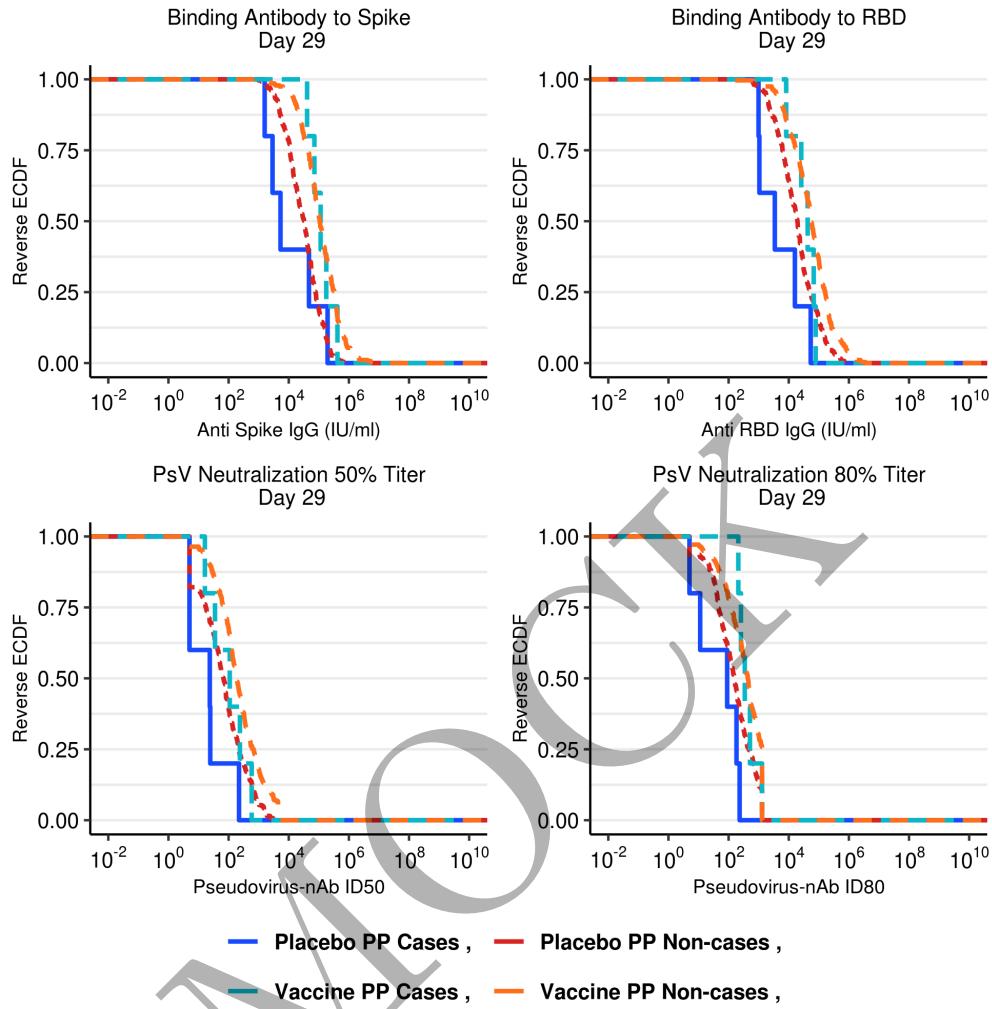


Figure 2.15: RCDF plots for D29 Ab markers: baseline positive by treatment arm.

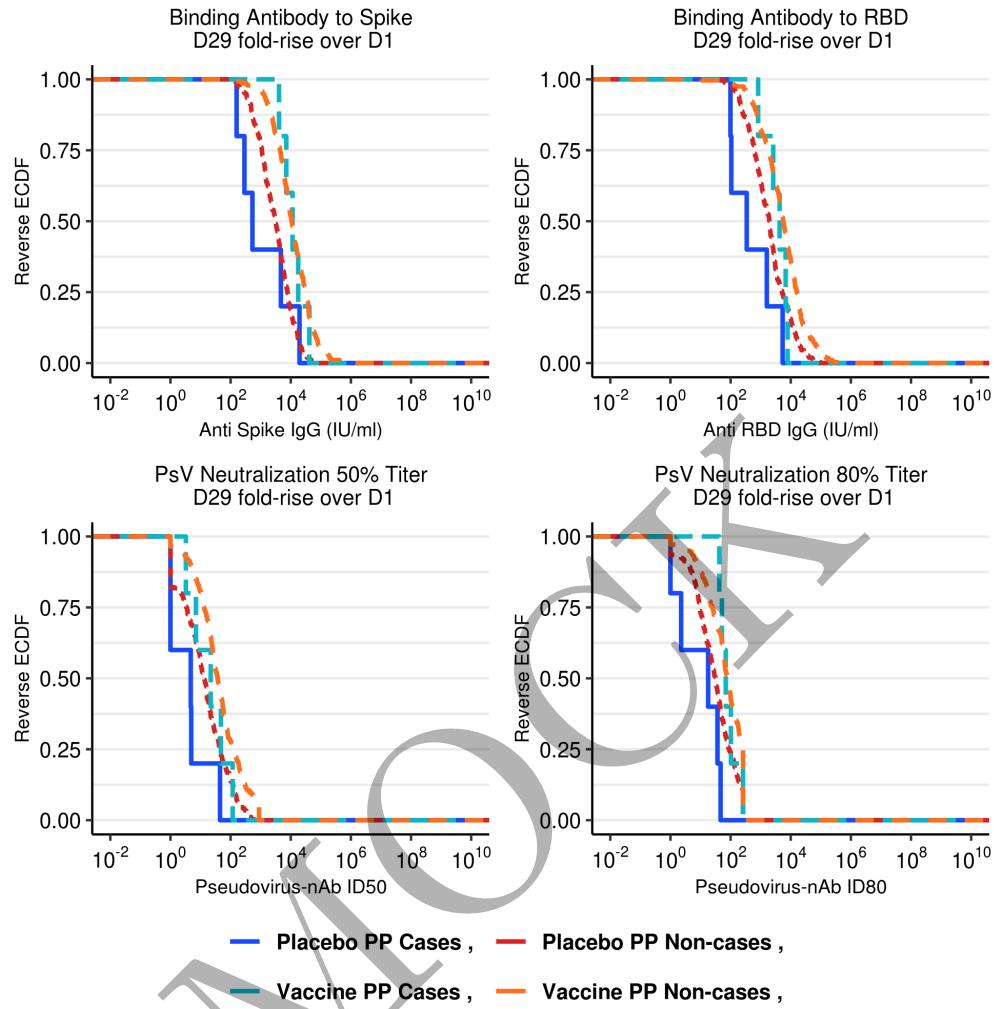


Figure 2.16: RCDF plots for D29 fold-rise over D1 Ab markers: baseline positive by treatment arm.

2.3 Weighted RCDF plots of threshold correlate concentration for vaccine efficacy

2.3.1 Baseline seronegative

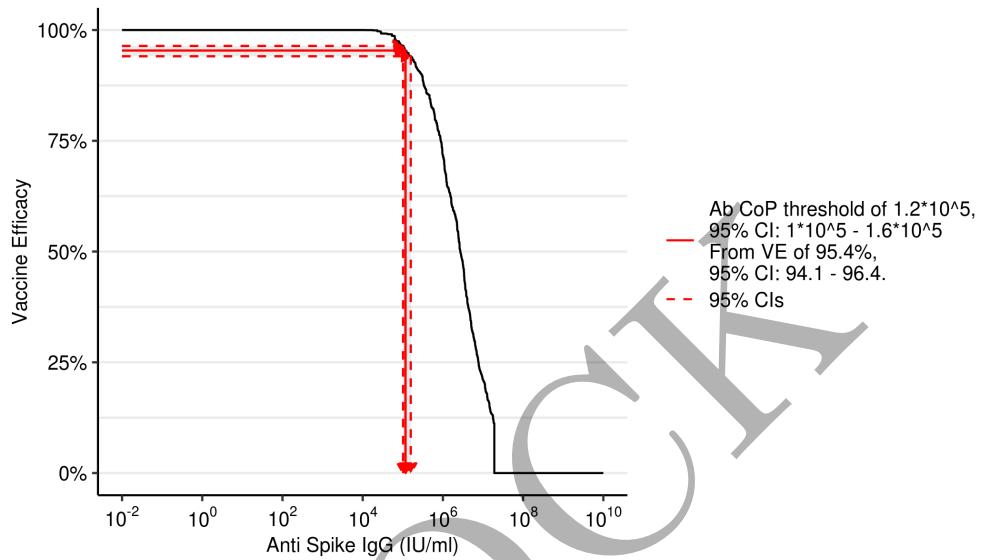


Figure 2.17: Marker RCDF of D57 anti-Spike binding Ab: baseline negative vaccine arm

2.3. WEIGHTED RCDF PLOTS OF THRESHOLD CORRELATE CONCENTRATION FOR VACCINE EFFICACY49

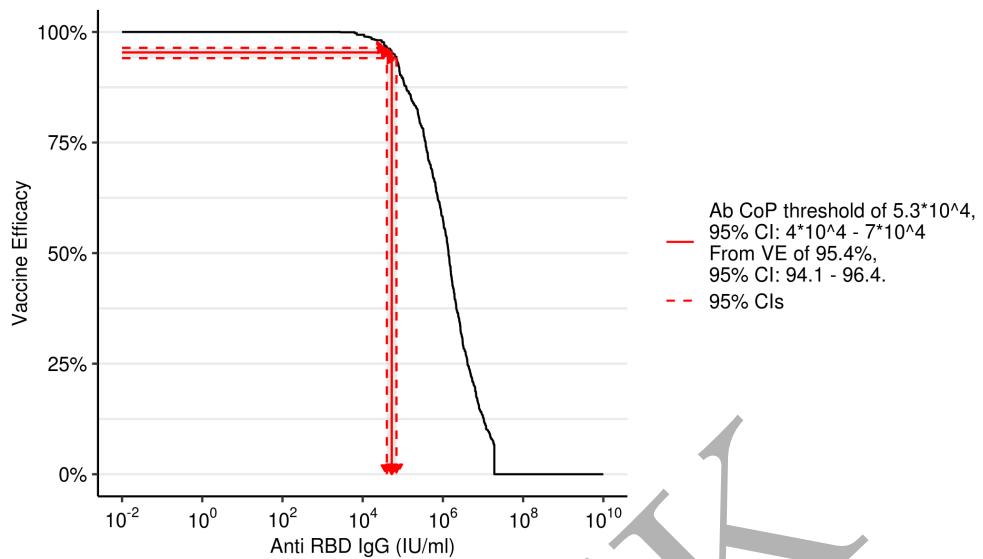


Figure 2.18: Marker RCDF of D57 anti-RBD binding Ab: baseline negative vaccine arm

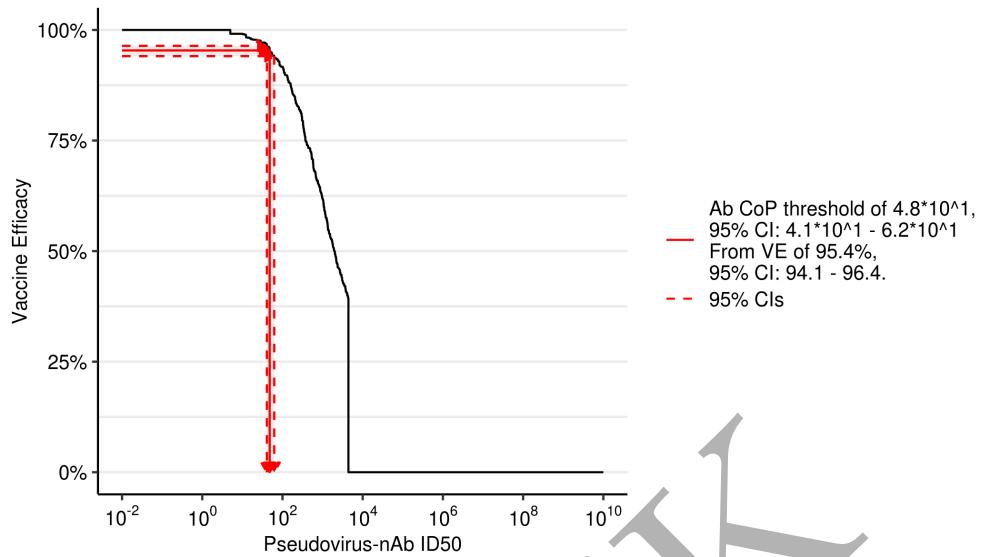


Figure 2.19: Marker RCDF of D57 PsV-nAb ID50: baseline negative vaccine arm

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

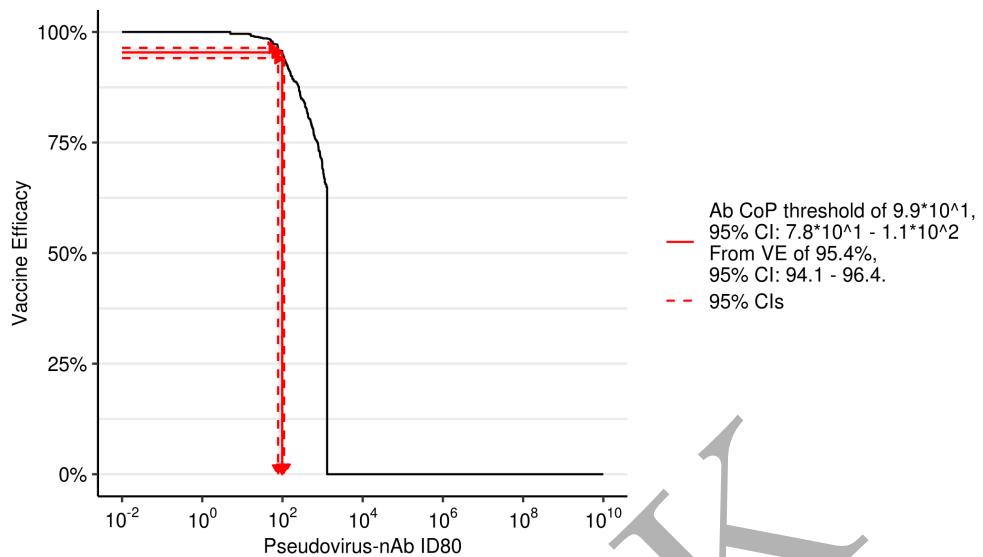


Figure 2.20: Marker RCDF of D57 PsV-nAb ID80: baseline negative vaccine arm

2.4 Spaghetti plots

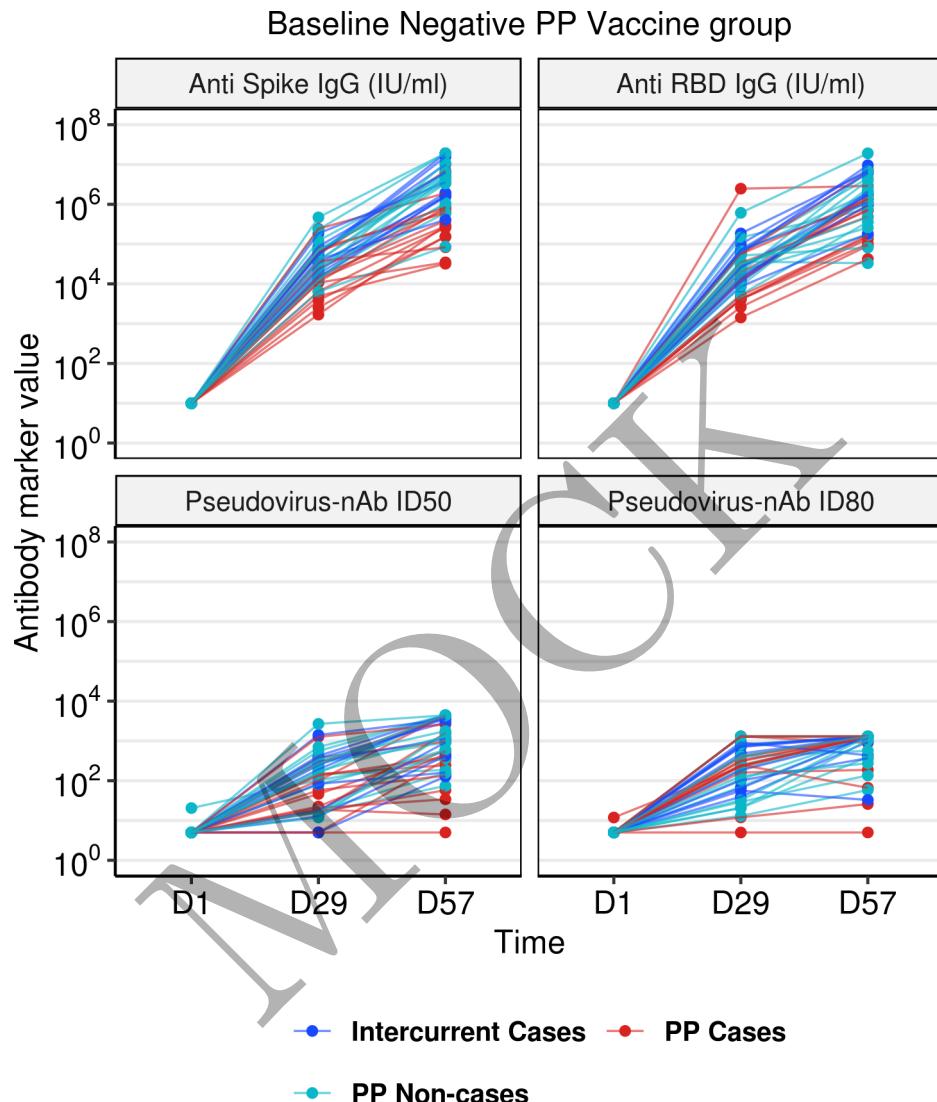


Figure 2.21: Spaghetti Plots of Marker Trajectory: baseline negative vaccine arm

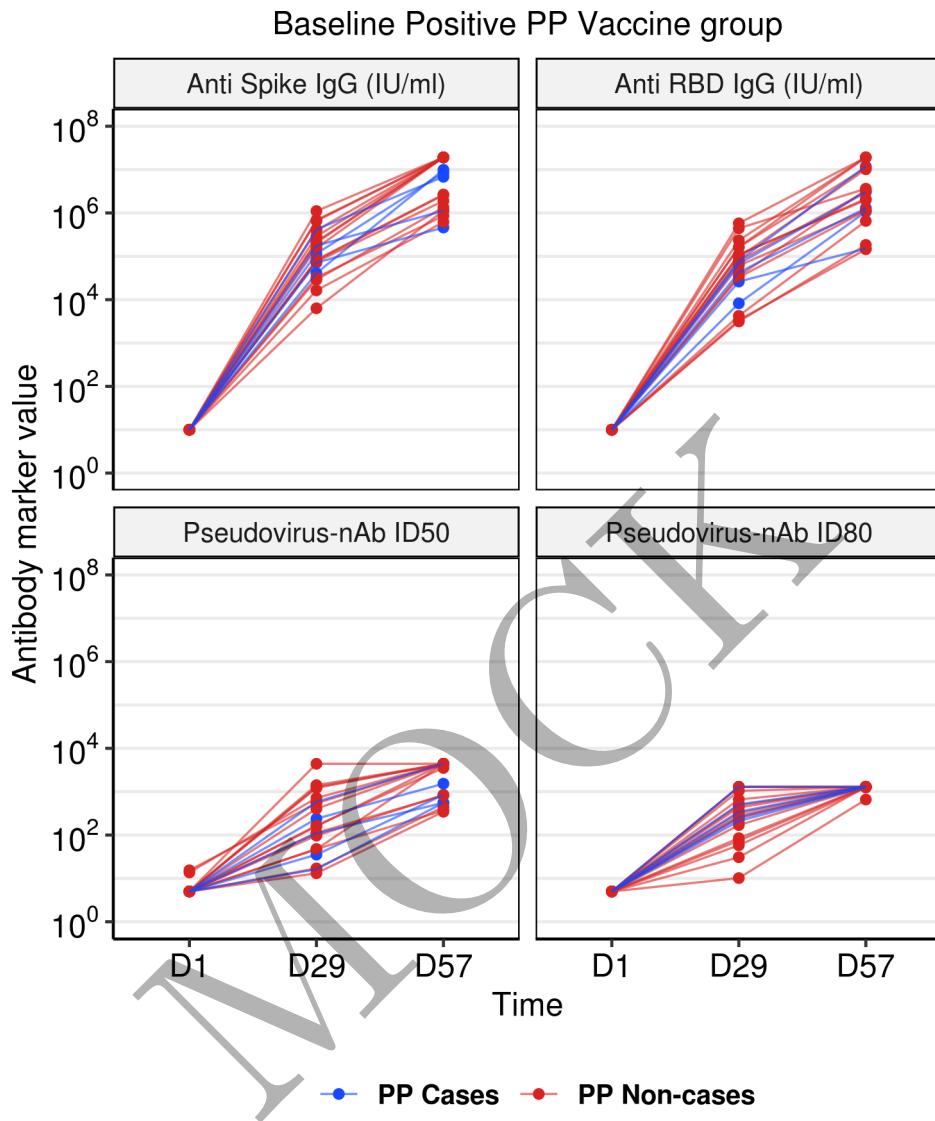


Figure 2.22: Spaghetti Plots of Marker Trajectory: baseline positive vaccine arm

2.5 Violin and line plots

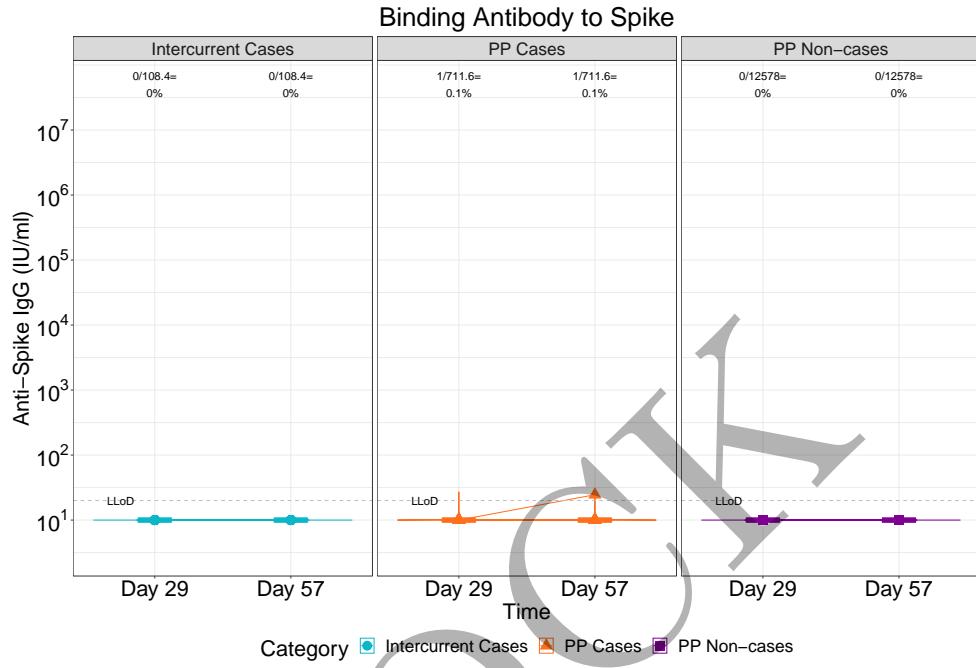


Figure 2.23: lineplots of Binding Antibody to Spike: baseline negative placebo arm (2 timepoints)

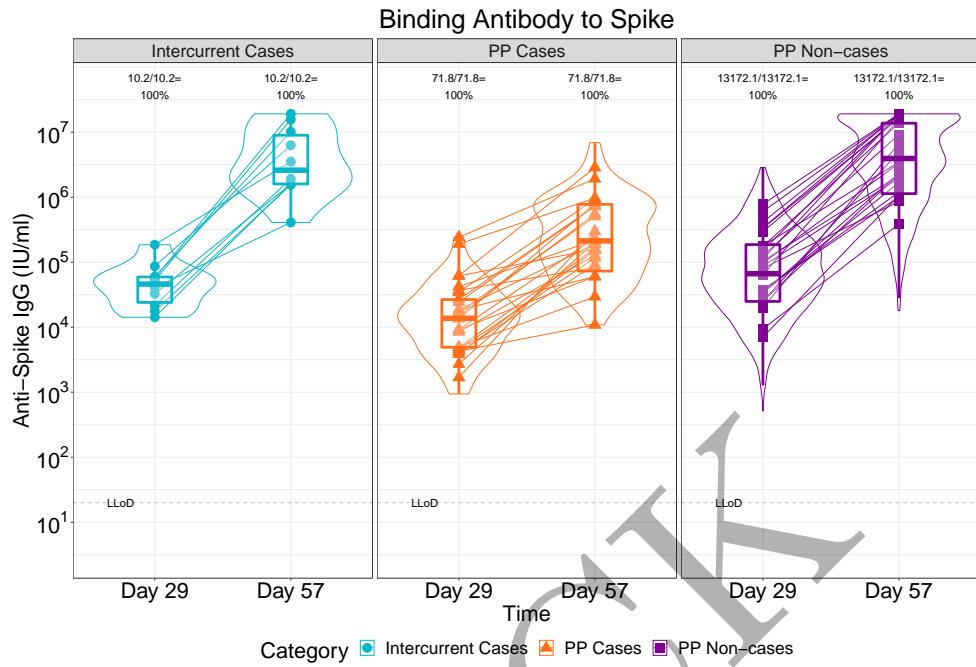


Figure 2.24: lineplots of Binding Antibody to Spike: baseline negative vaccine arm (2 timepoints)

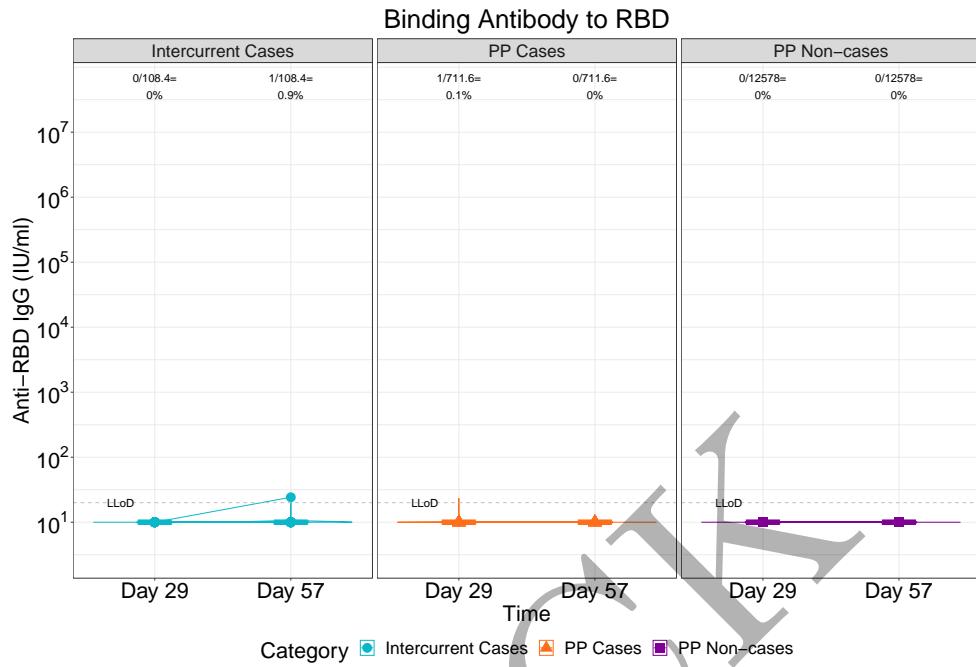


Figure 2.25: lineplots of Binding Antibody to RBD: baseline negative placebo arm (2 timepoints)

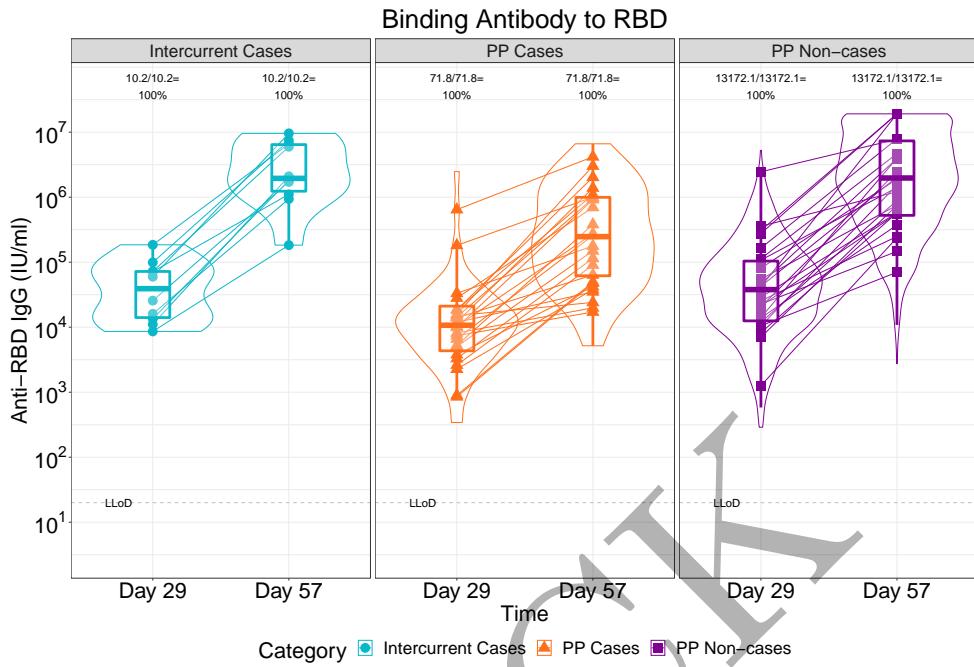


Figure 2.26: lineplots of Binding Antibody to RBD: baseline negative vaccine arm (2 timepoints)

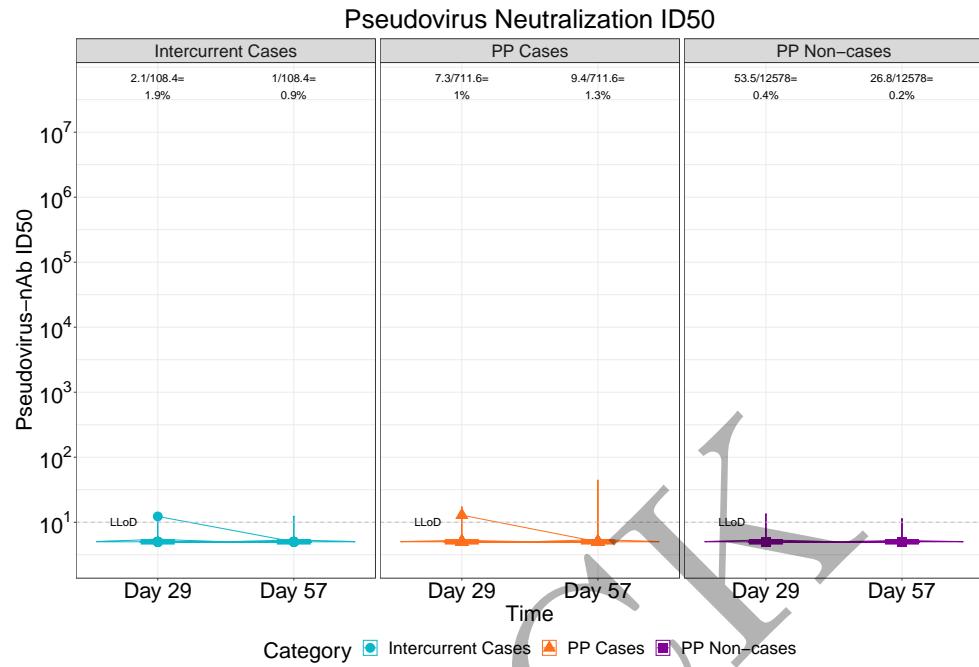


Figure 2.27: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm (2 timepoints)

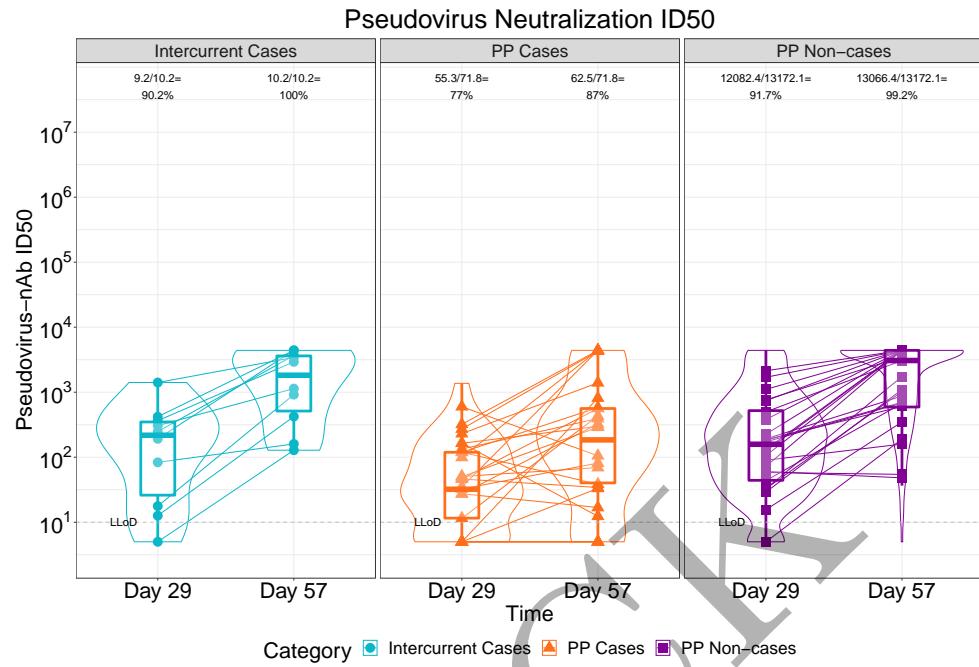


Figure 2.28: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm (2 timepoints)

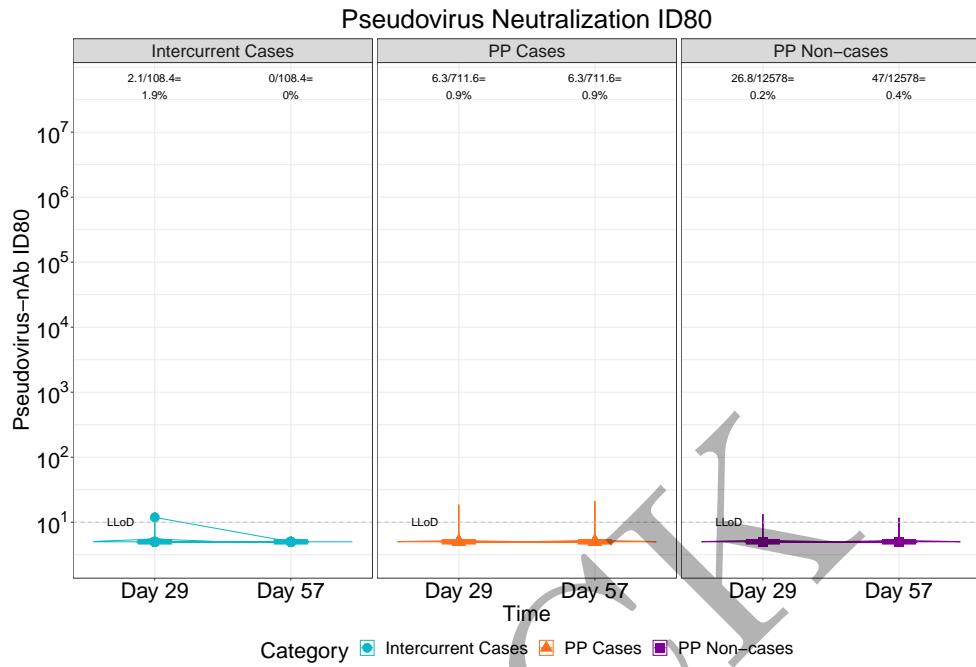


Figure 2.29: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm (2 timepoints)

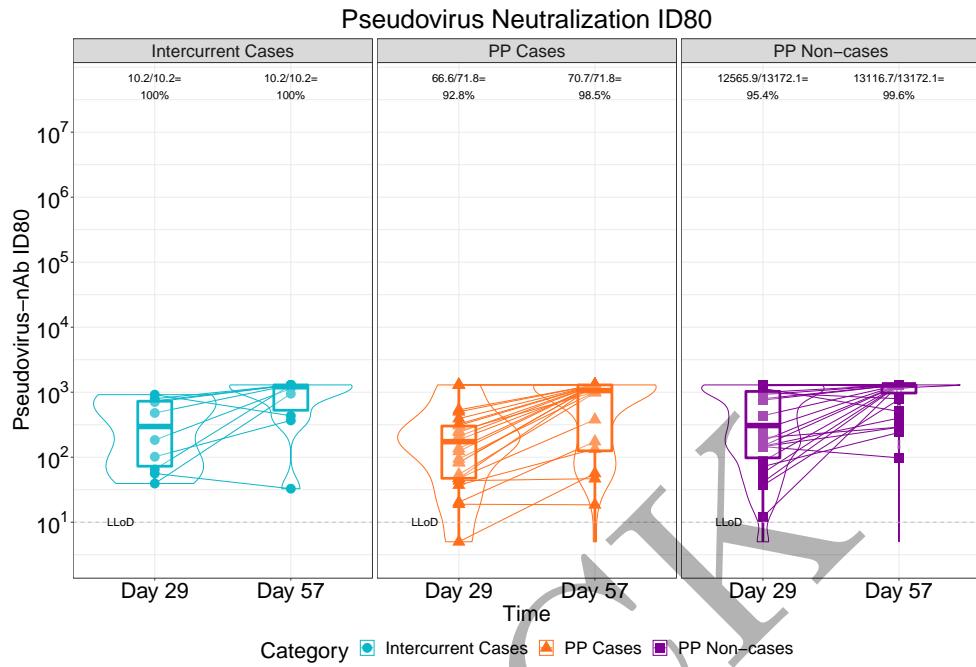


Figure 2.30: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm (2 timepoints)

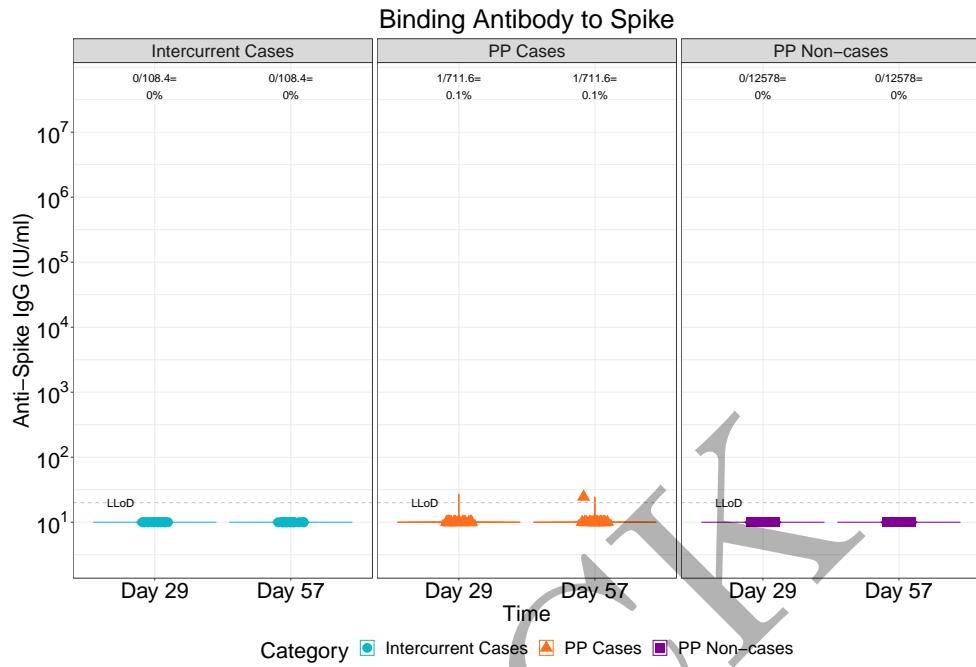


Figure 2.31: violinplots of Binding Antibody to Spike: baseline negative placebo arm (2 timepoints)

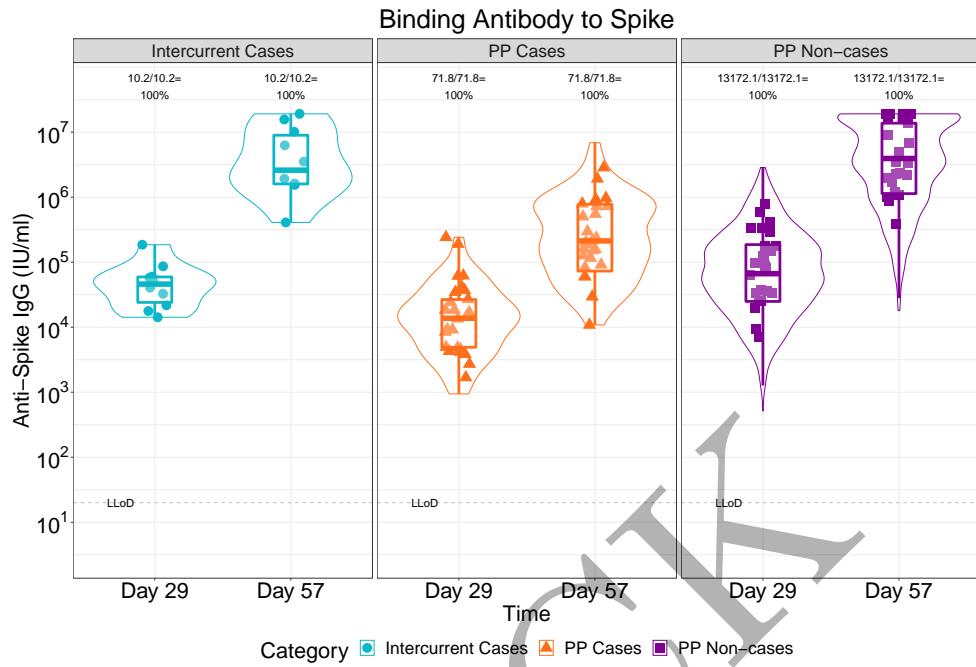


Figure 2.32: violinplots of Binding Antibody to Spike: baseline negative vaccine arm (2 timepoints)

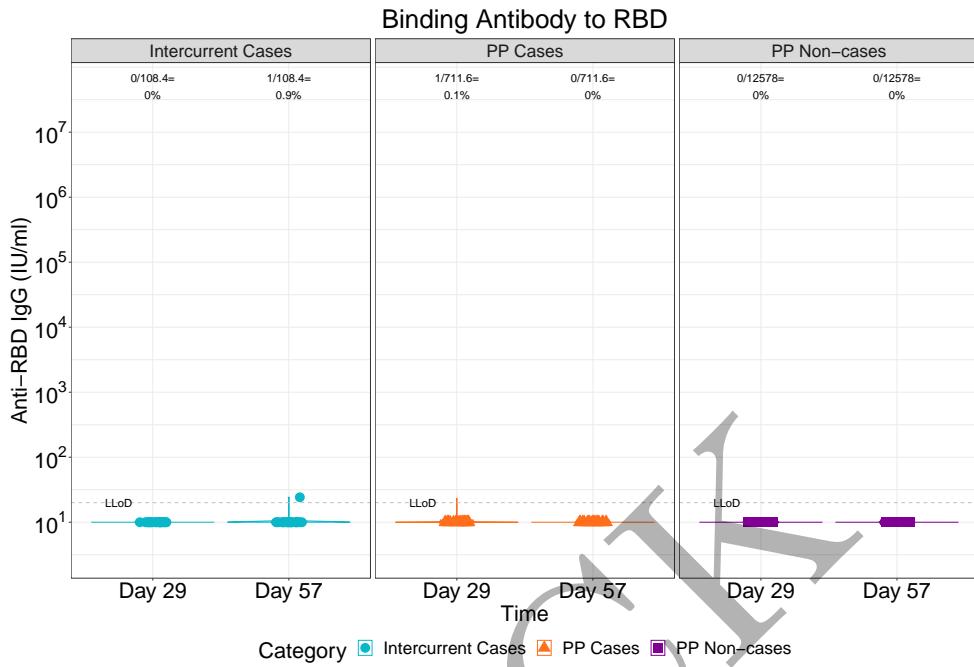


Figure 2.33: violinplots of Binding Antibody to RBD: baseline negative placebo arm (2 timepoints)

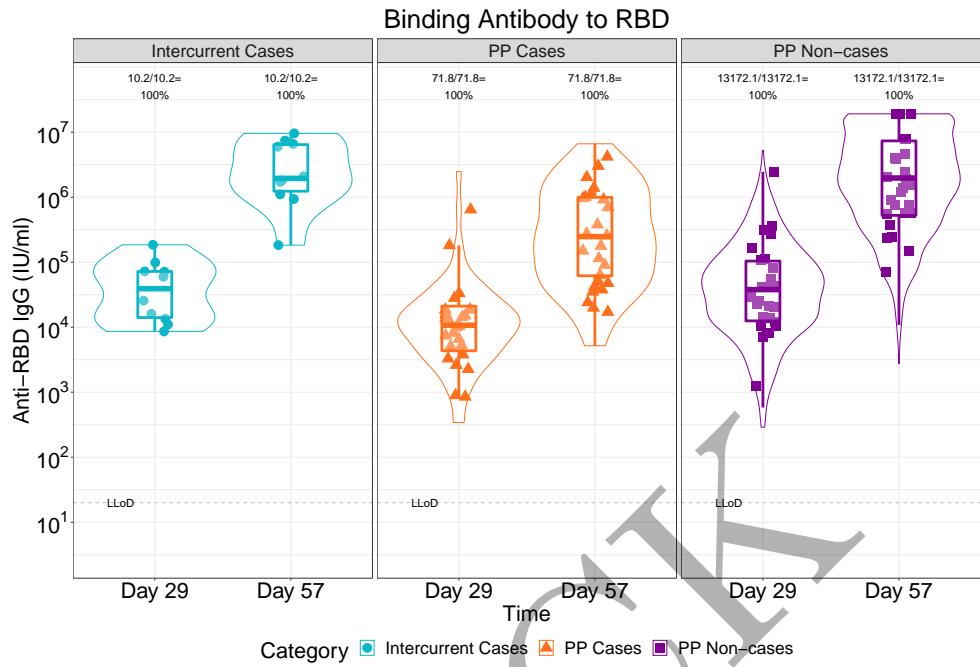


Figure 2.34: violinplots of Binding Antibody to RBD: baseline negative vaccine arm (2 timepoints)

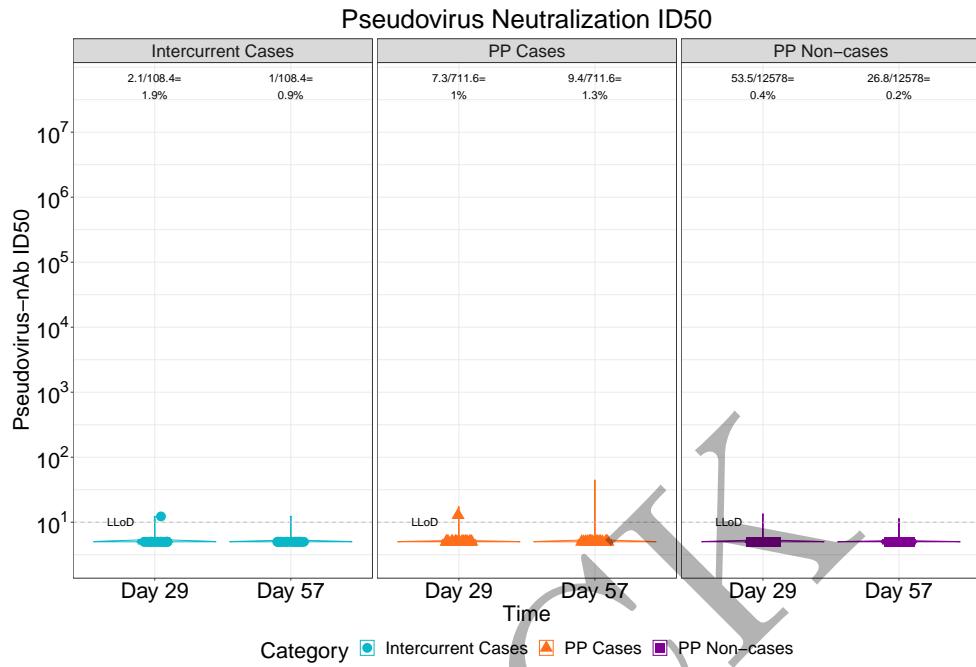


Figure 2.35: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm (2 timepoints)

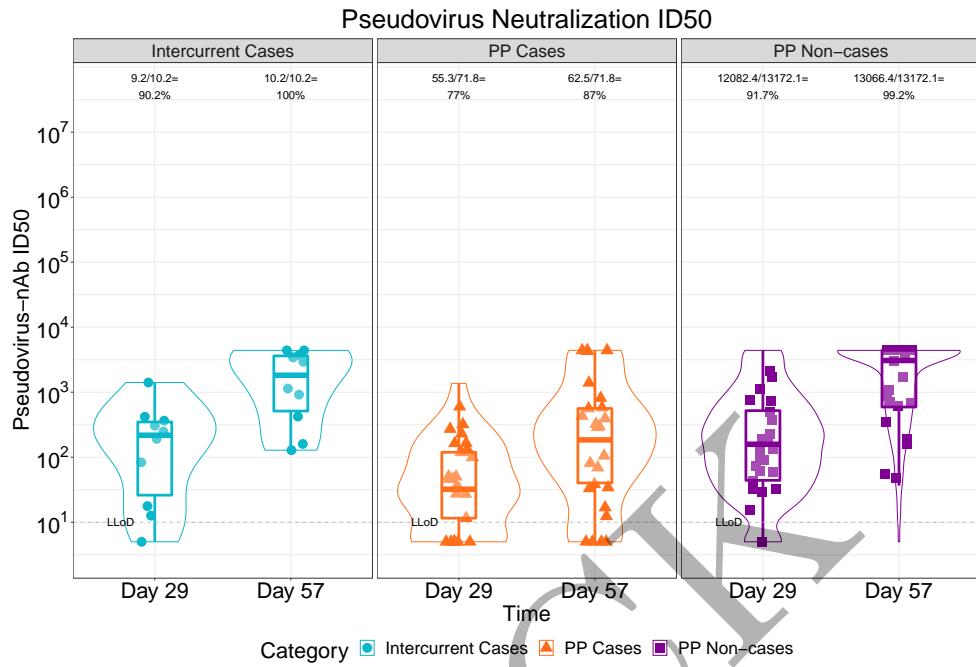


Figure 2.36: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm (2 timepoints)

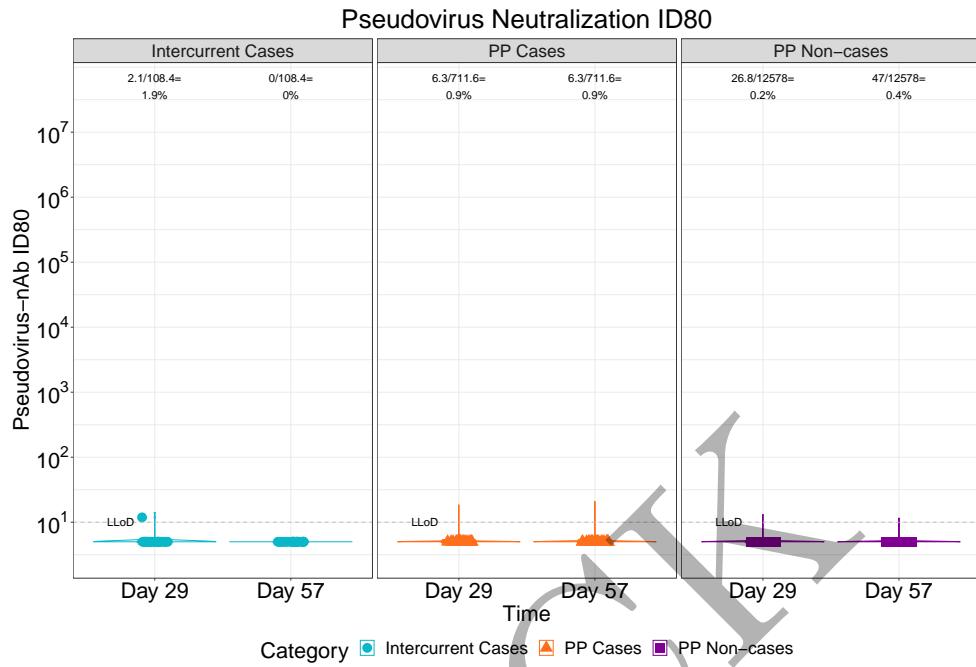


Figure 2.37: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm (2 timepoints)

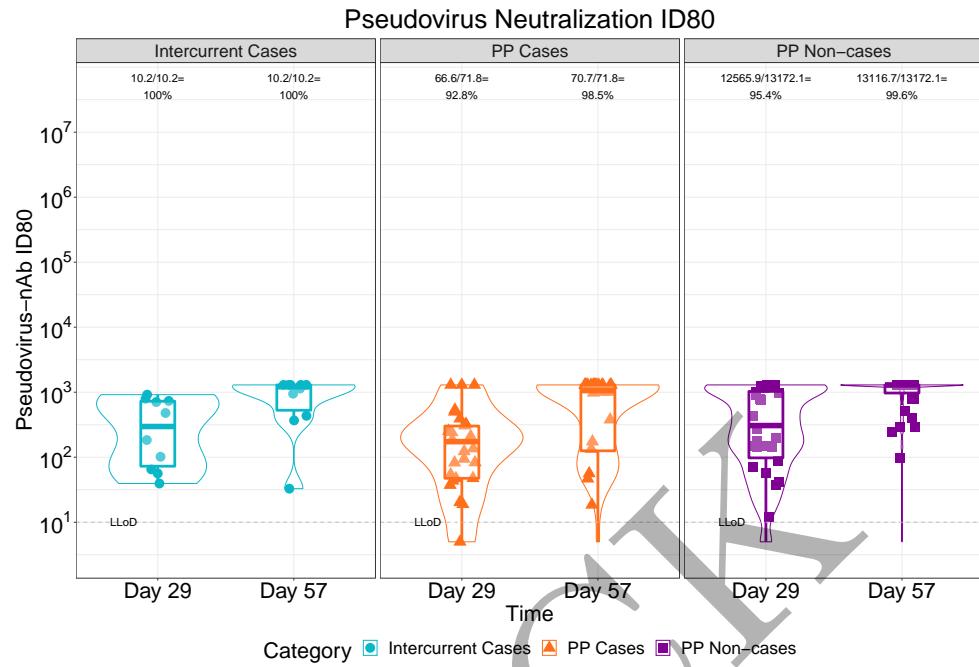


Figure 2.38: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm (2 timepoints)

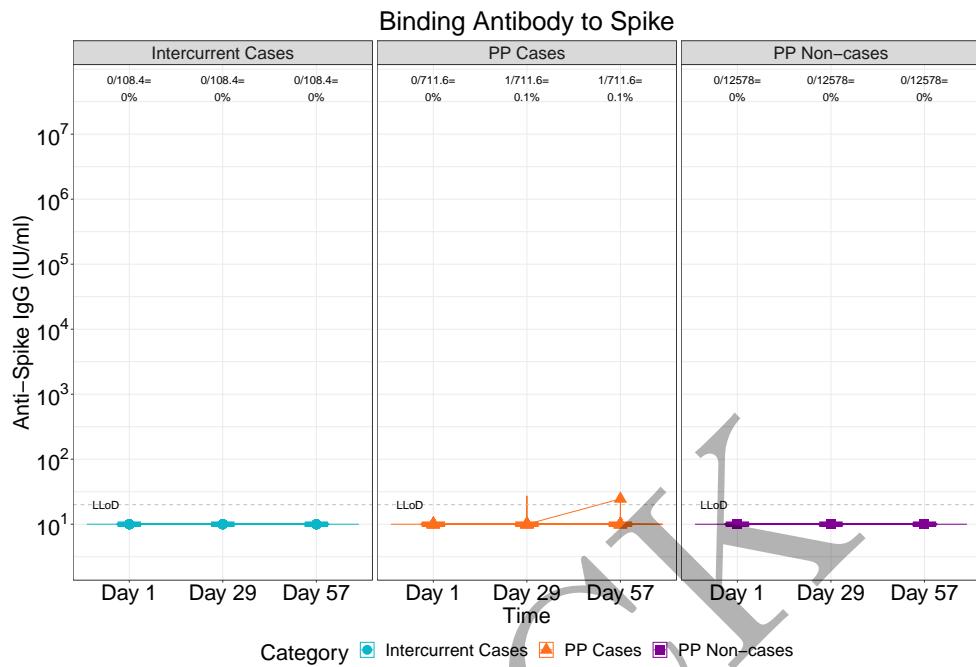


Figure 2.39: lineplots of Binding Antibody to Spike: baseline negative placebo arm (3 timepoints)

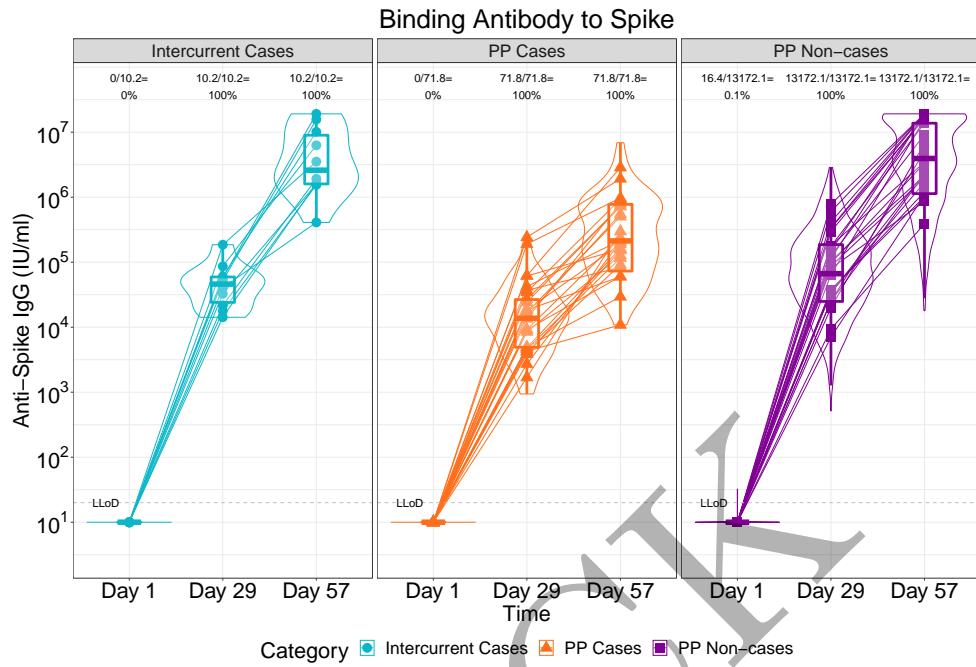


Figure 2.40: lineplots of Binding Antibody to Spike: baseline negative vaccine arm (3 timepoints)

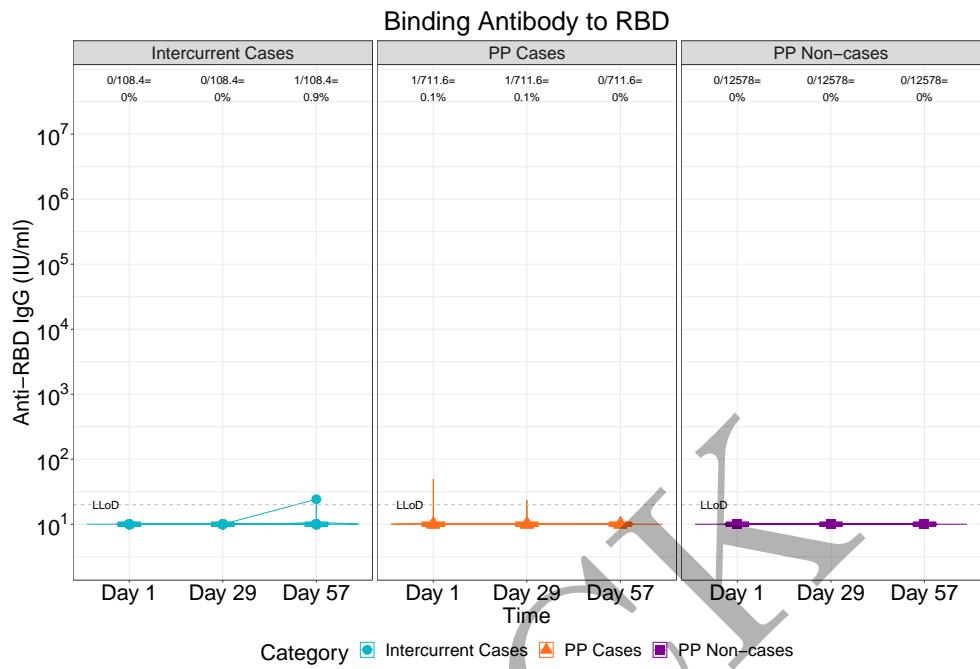


Figure 2.41: lineplots of Binding Antibody to RBD: baseline negative placebo arm (3 timepoints)

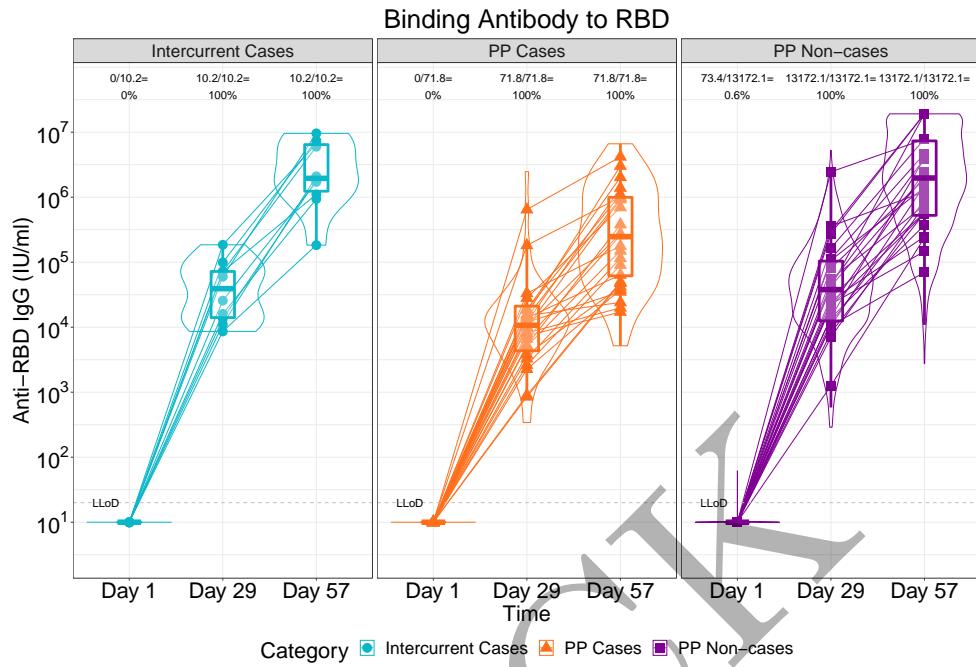


Figure 2.42: lineplots of Binding Antibody to RBD: baseline negative vaccine arm (3 timepoints)

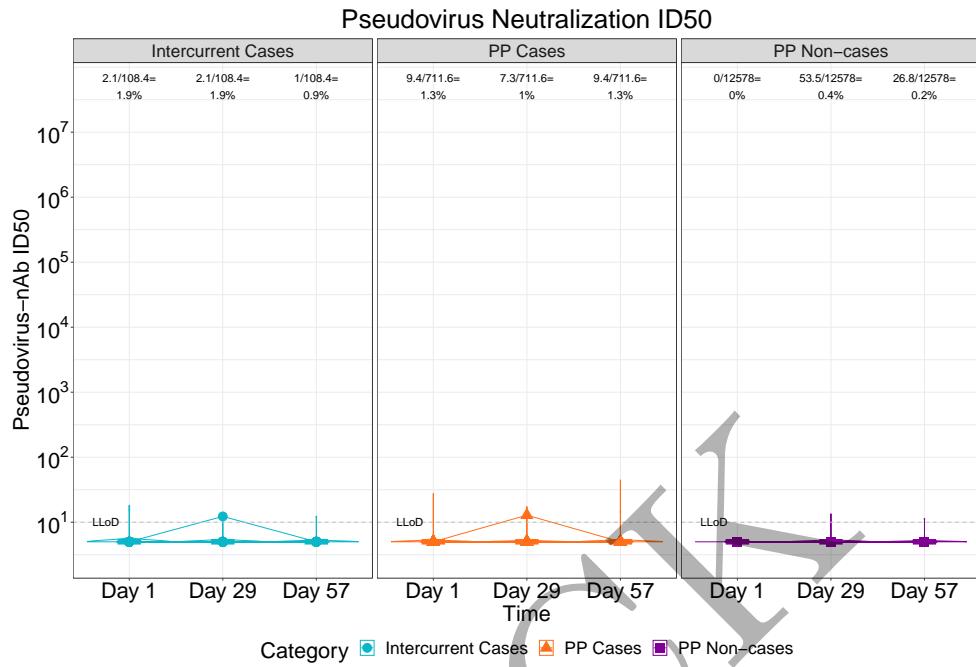


Figure 2.43: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm (3 timepoints)

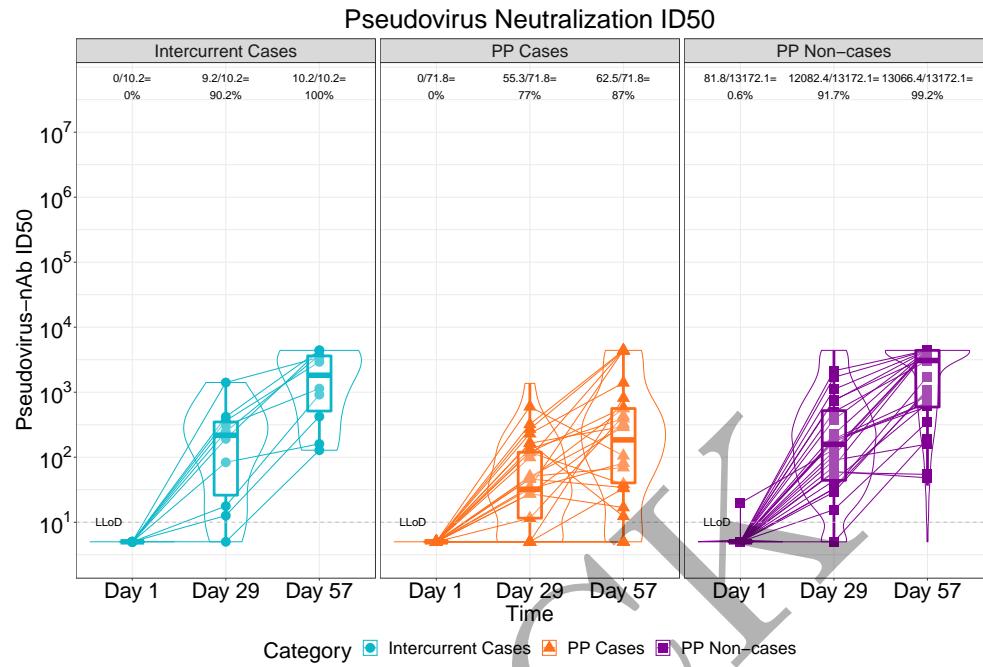


Figure 2.44: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm (3 timepoints)

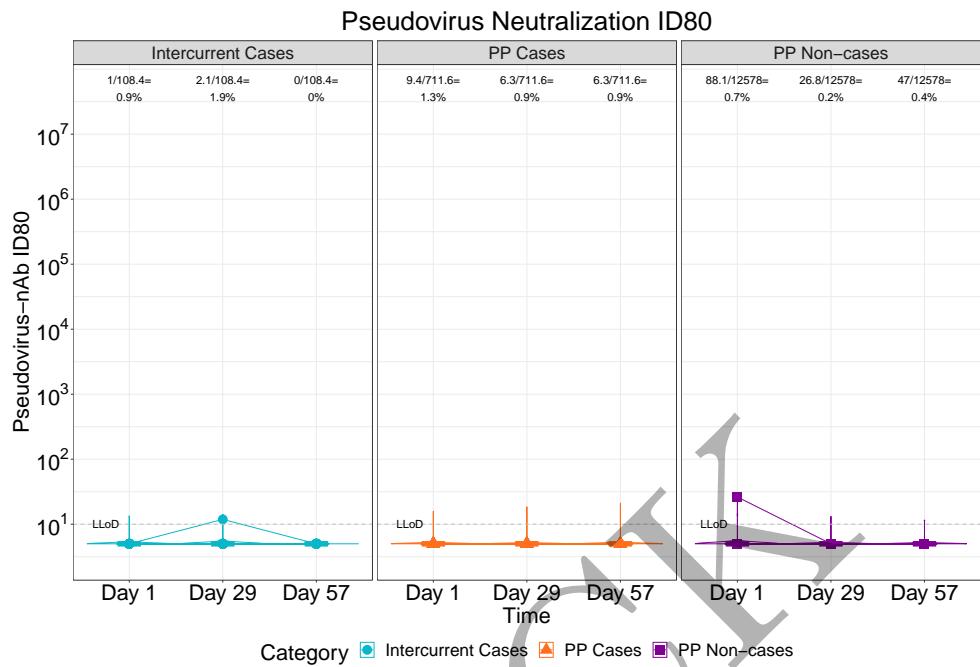


Figure 2.45: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm (3 timepoints)

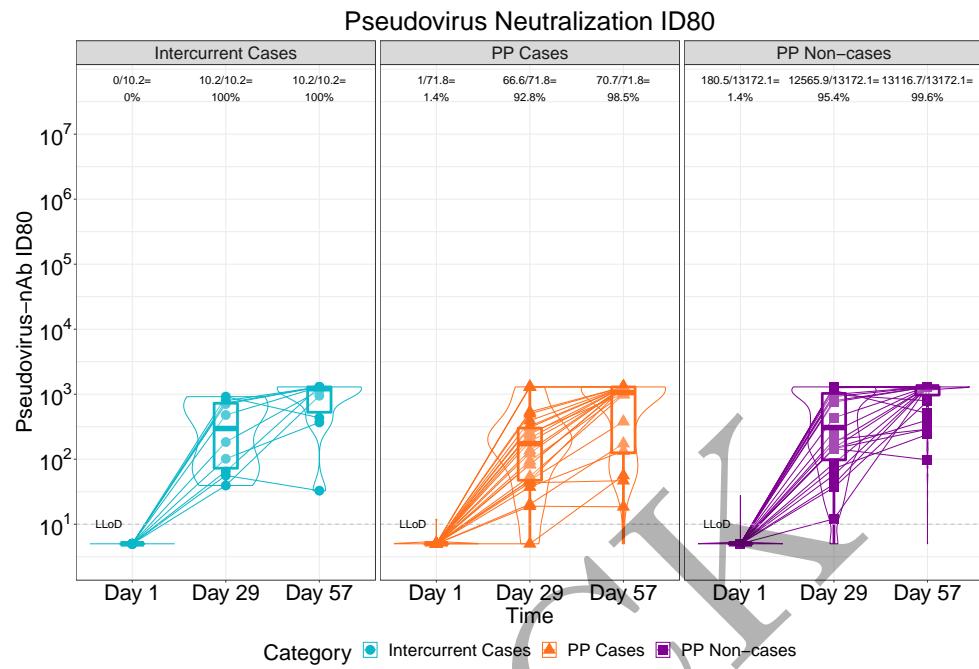


Figure 2.46: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm (3 timepoints)

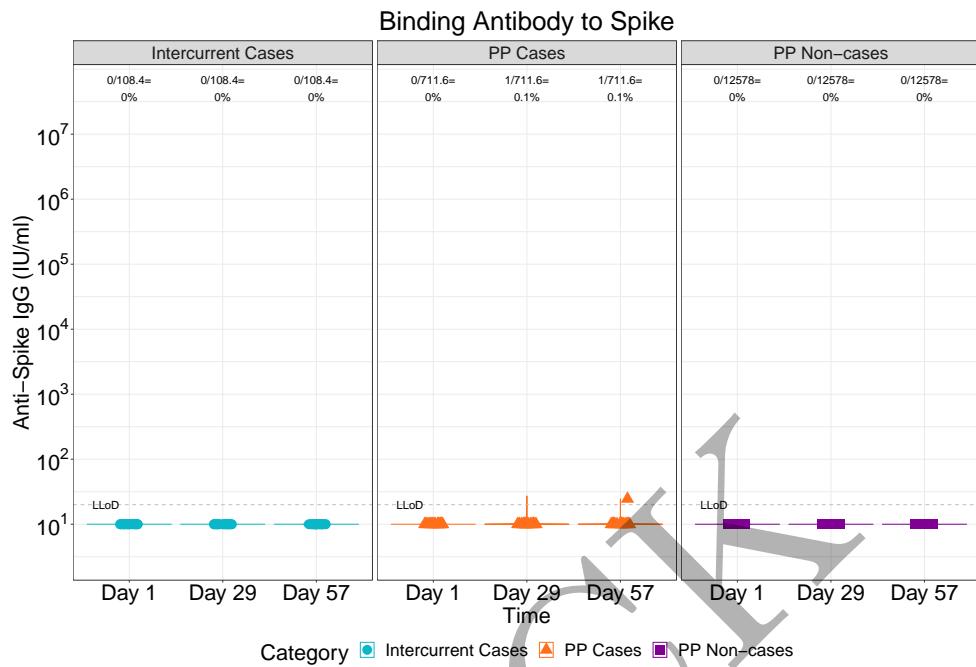


Figure 2.47: violinplots of Binding Antibody to Spike: baseline negative placebo arm (3 timepoints)

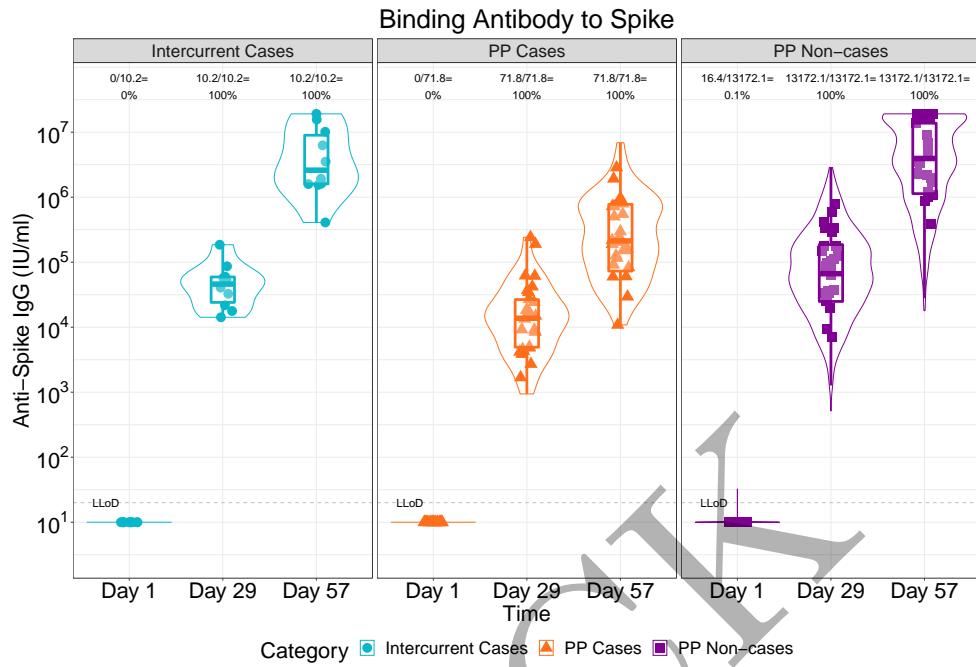


Figure 2.48: violinplots of Binding Antibody to Spike: baseline negative vaccine arm (3 timepoints)

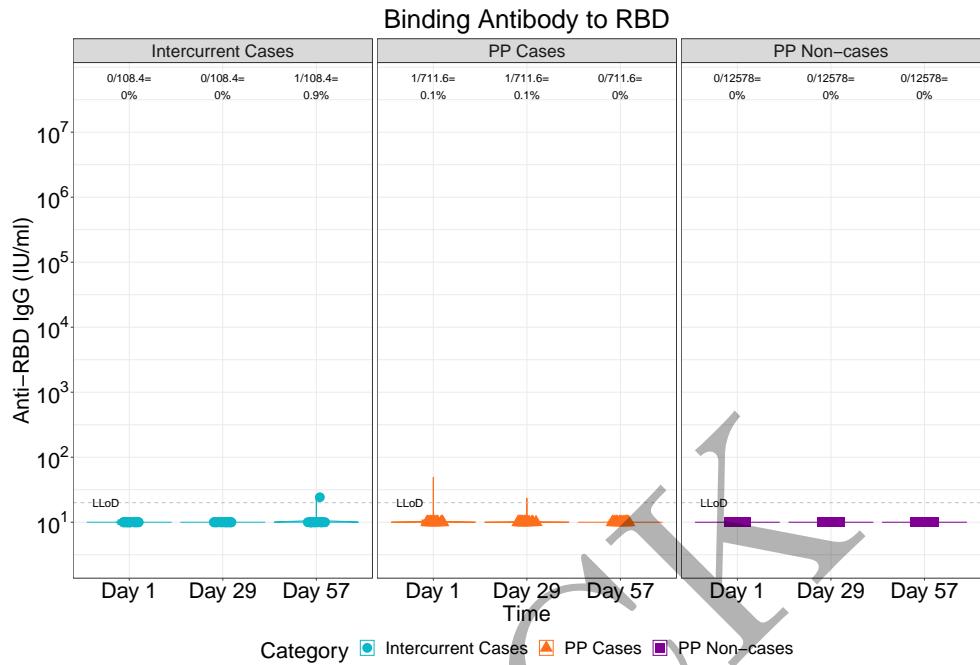


Figure 2.49: violinplots of Binding Antibody to RBD: baseline negative placebo arm (3 timepoints)

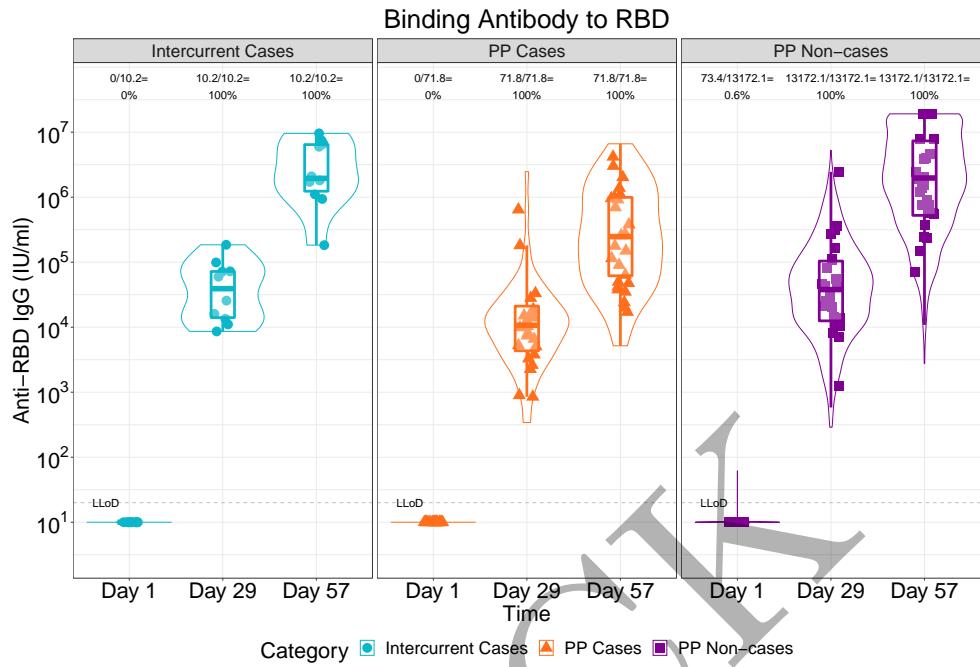


Figure 2.50: violinplots of Binding Antibody to RBD: baseline negative vaccine arm (3 timepoints)

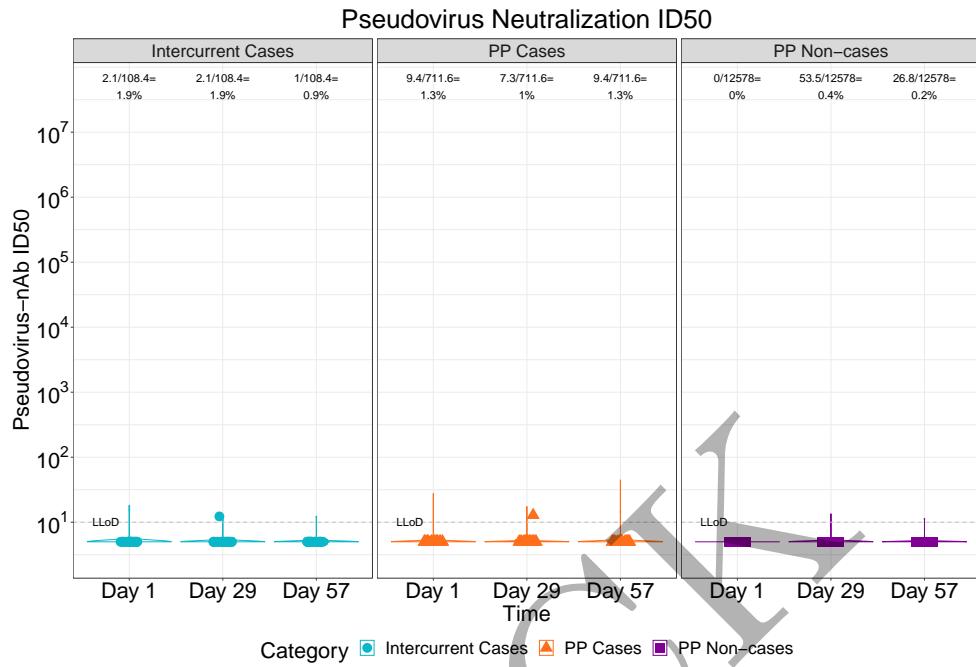


Figure 2.51: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm (3 timepoints)

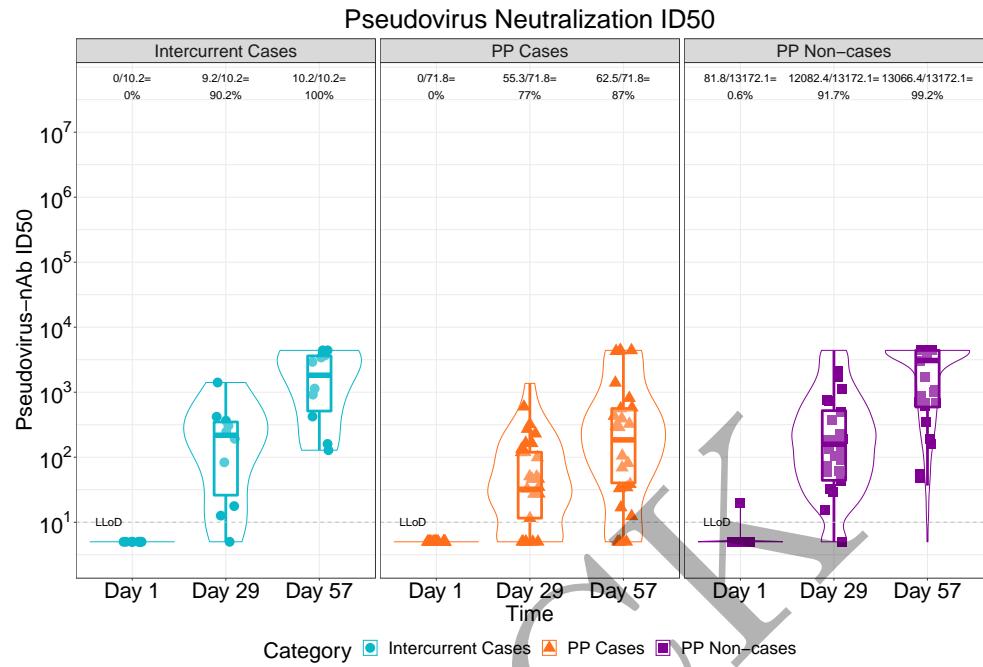


Figure 2.52: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm (3 timepoints)

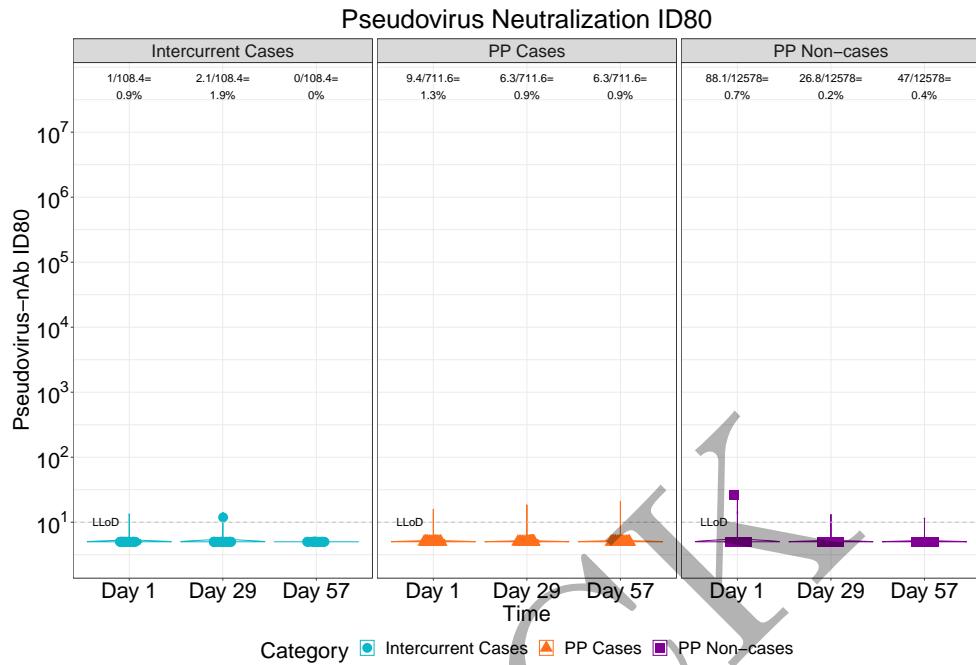


Figure 2.53: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm (3 timepoints)

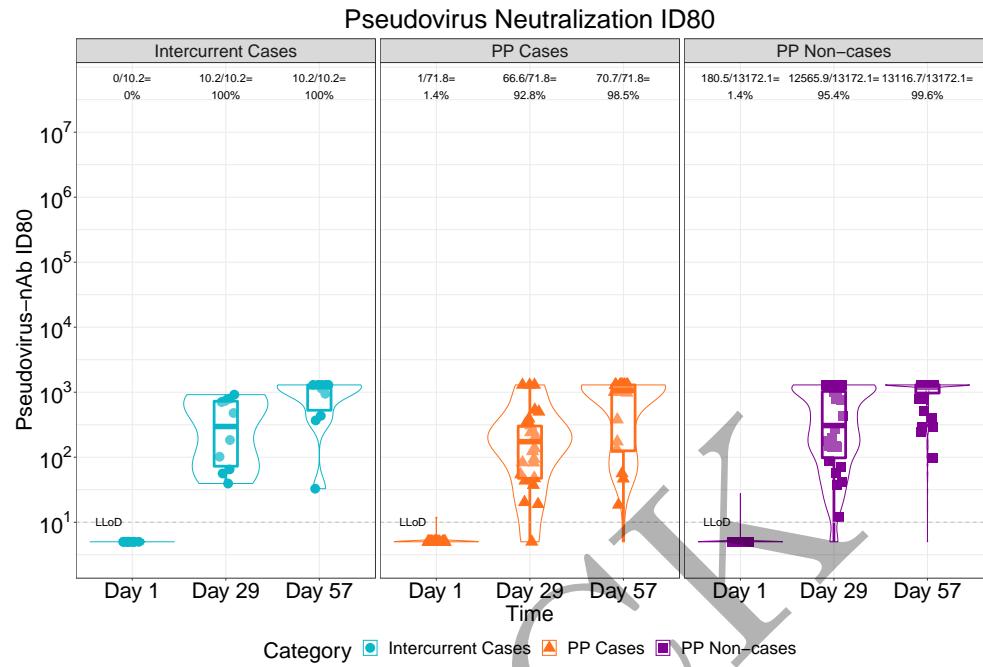


Figure 2.54: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm (3 timepoints)

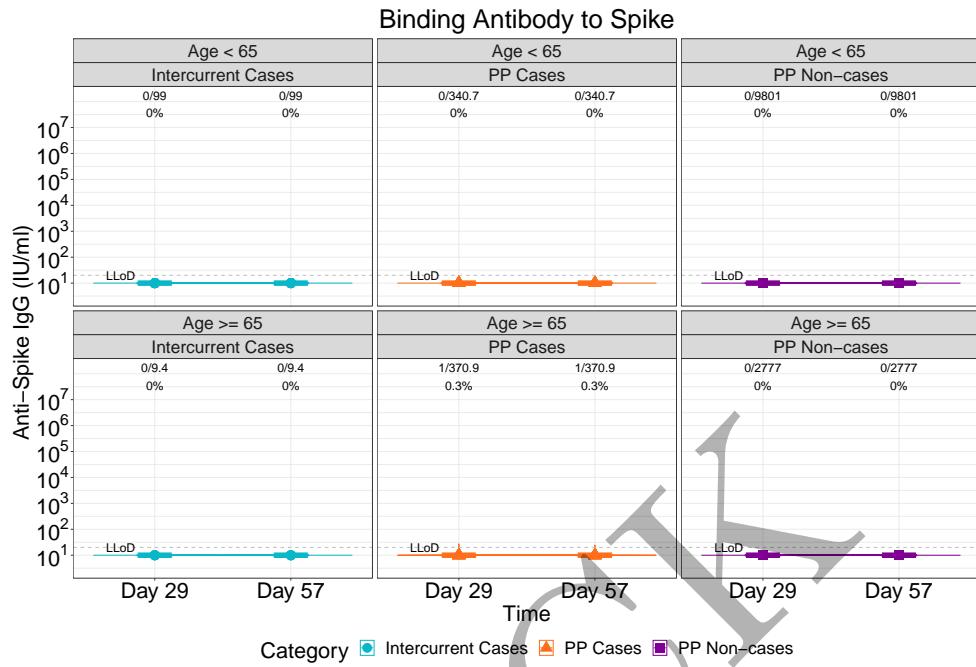


Figure 2.55: lineplots of Binding Antibody to Spike: baseline negative placebo arm by age (2 timepoints)

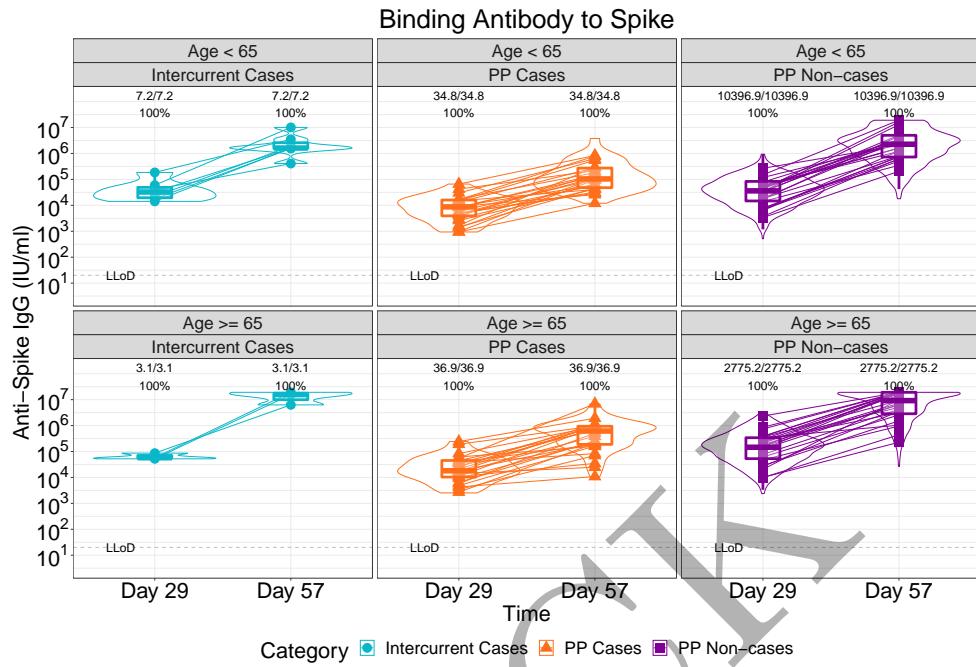


Figure 2.56: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by age (2 timepoints)

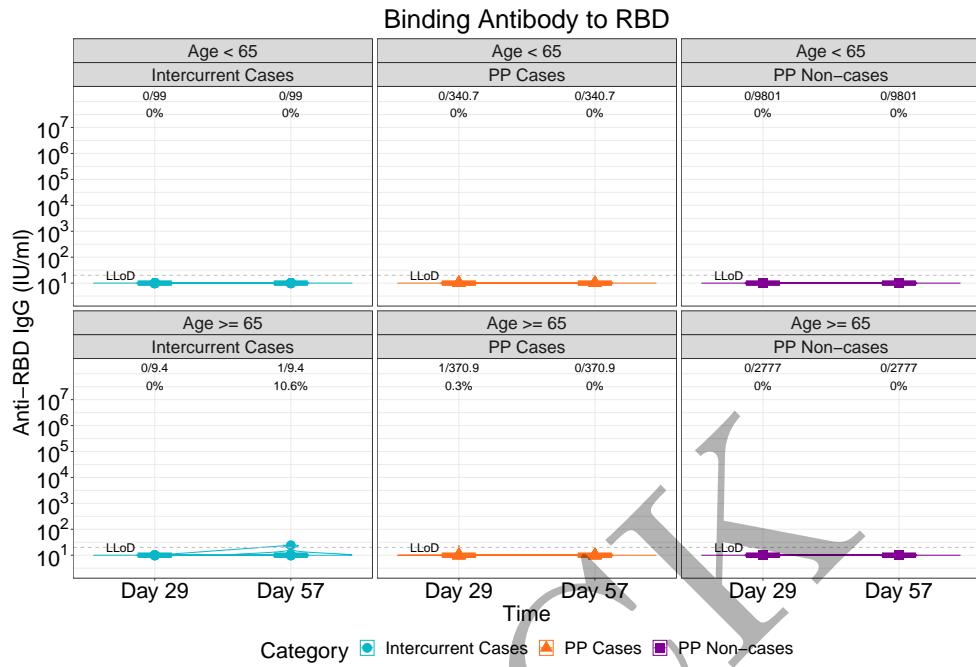


Figure 2.57: lineplots of Binding Antibody to RBD: baseline negative placebo arm by age (2 timepoints)

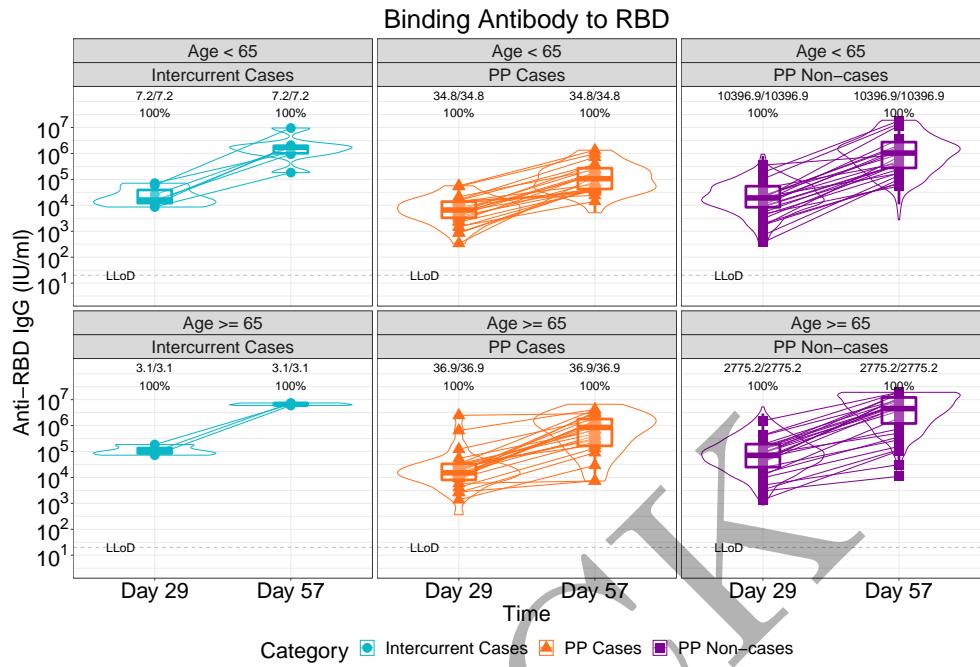


Figure 2.58: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by age (2 timepoints)

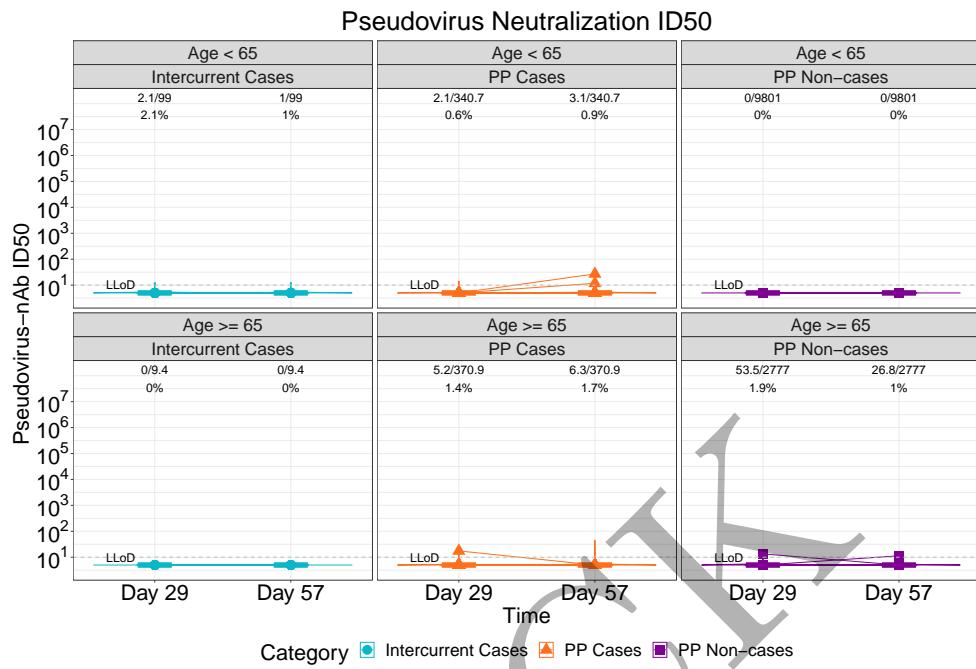


Figure 2.59: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age (2 timepoints)

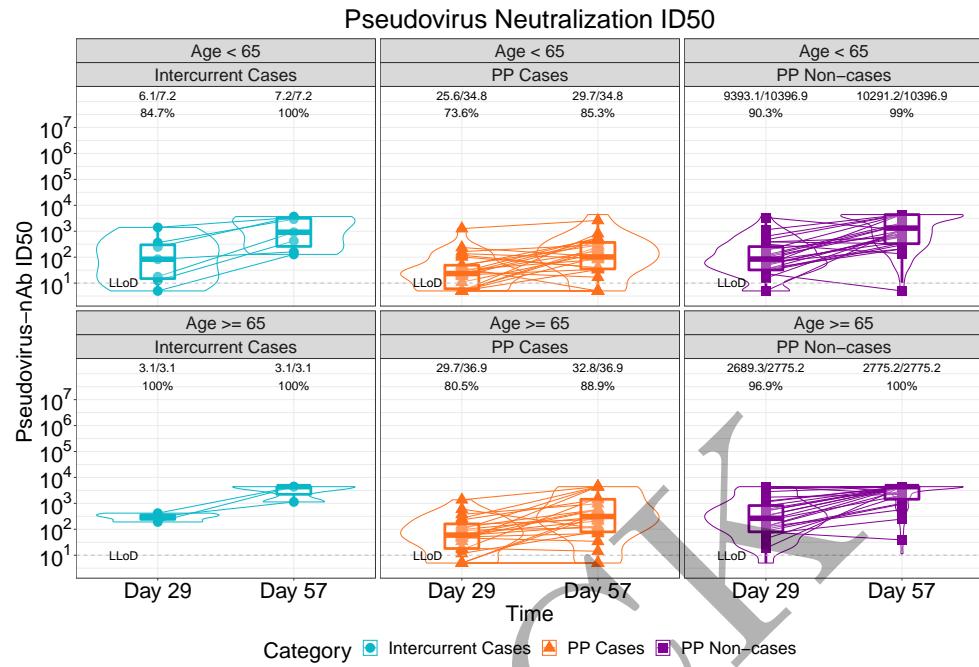


Figure 2.60: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age (2 timepoints)

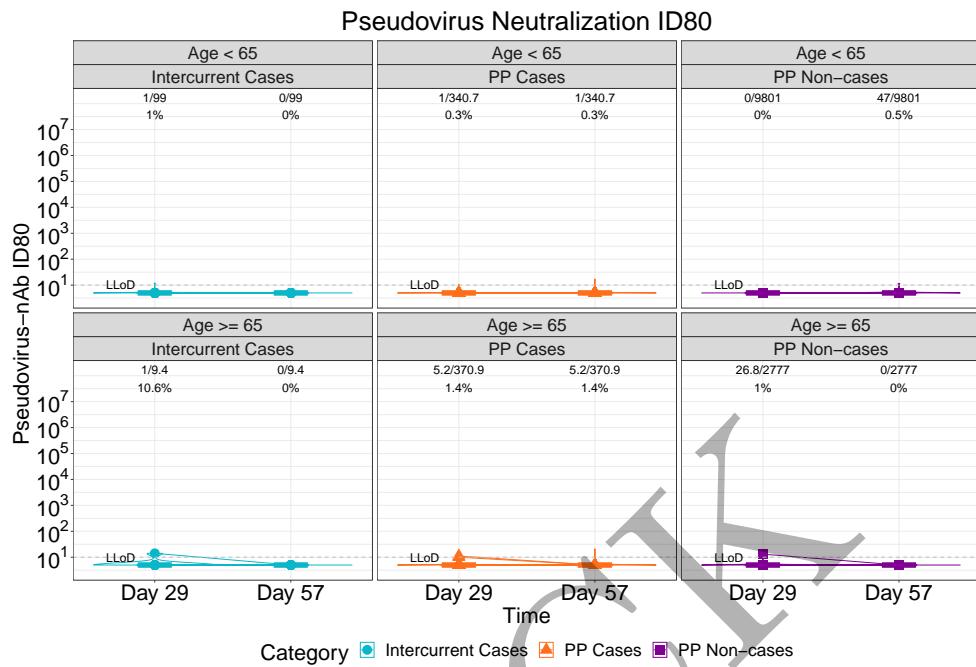


Figure 2.61: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age (2 timepoints)

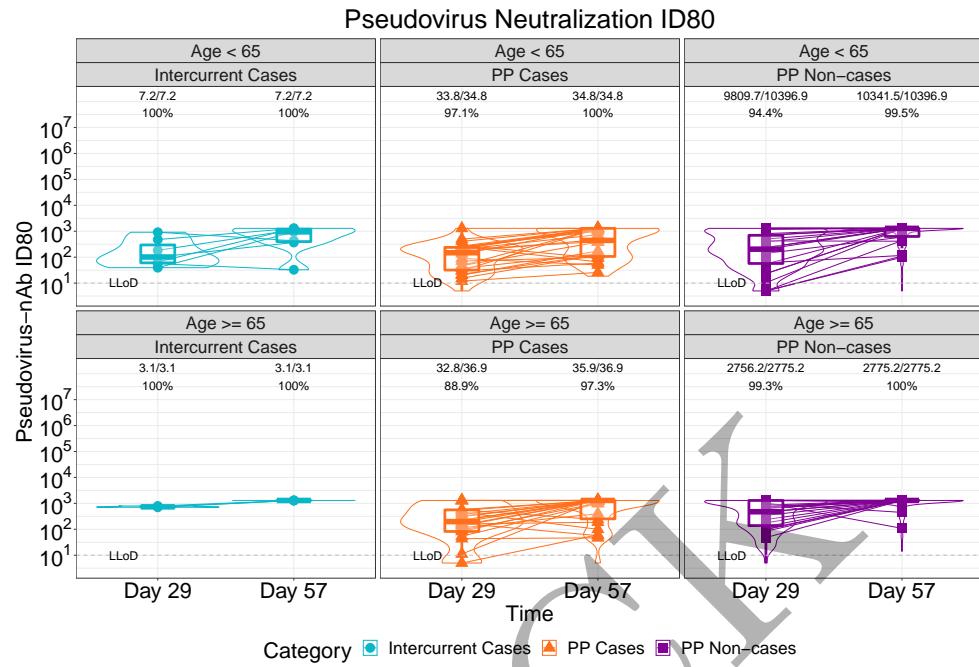


Figure 2.62: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age (2 timepoints)

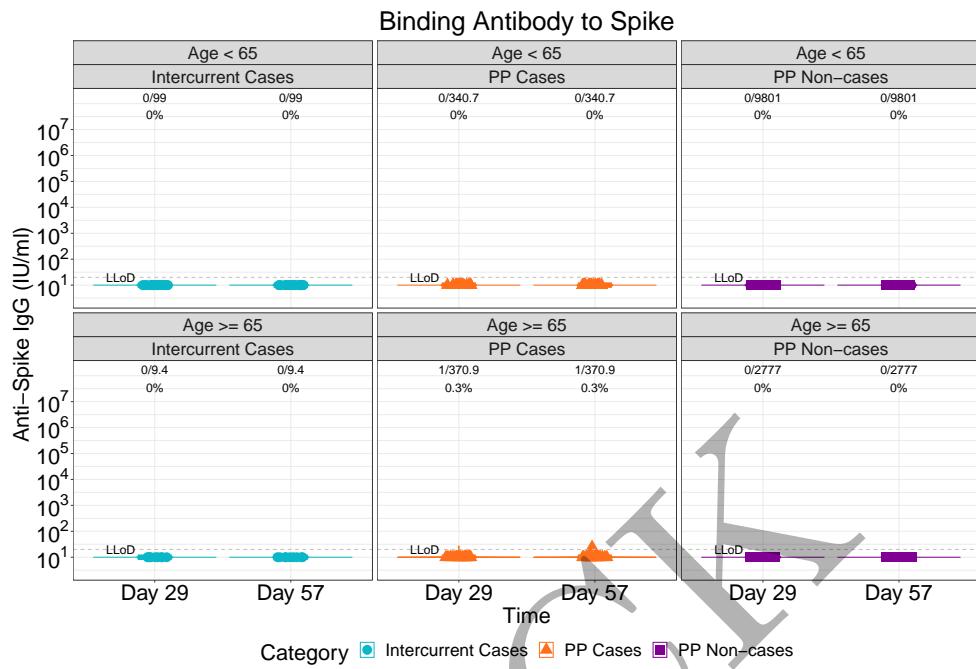


Figure 2.63: violinplots of Binding Antibody to Spike: baseline negative placebo arm by age (2 timepoints)

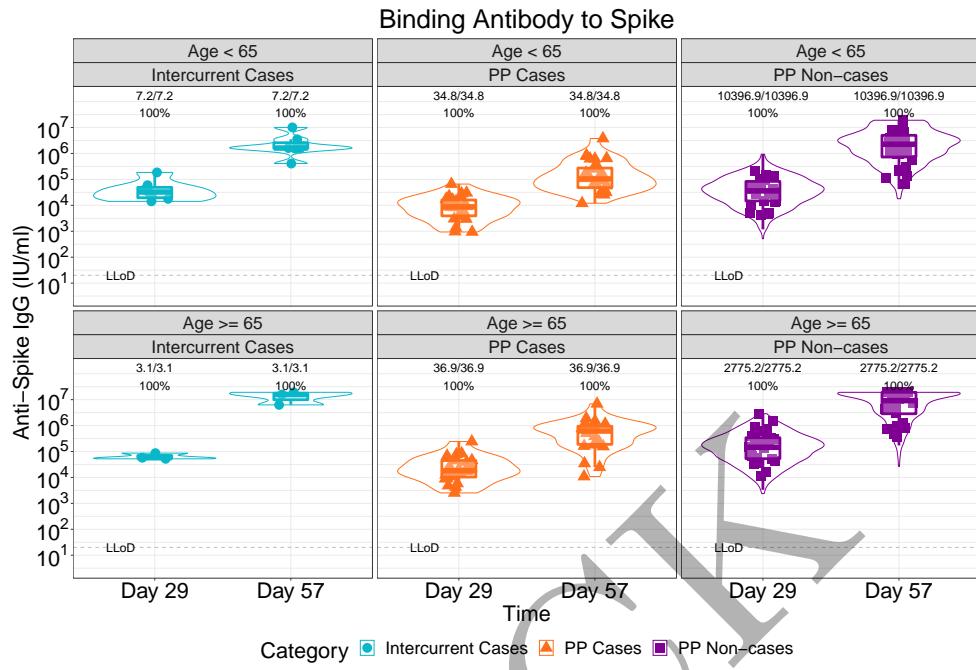


Figure 2.64: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by age (2 timepoints)

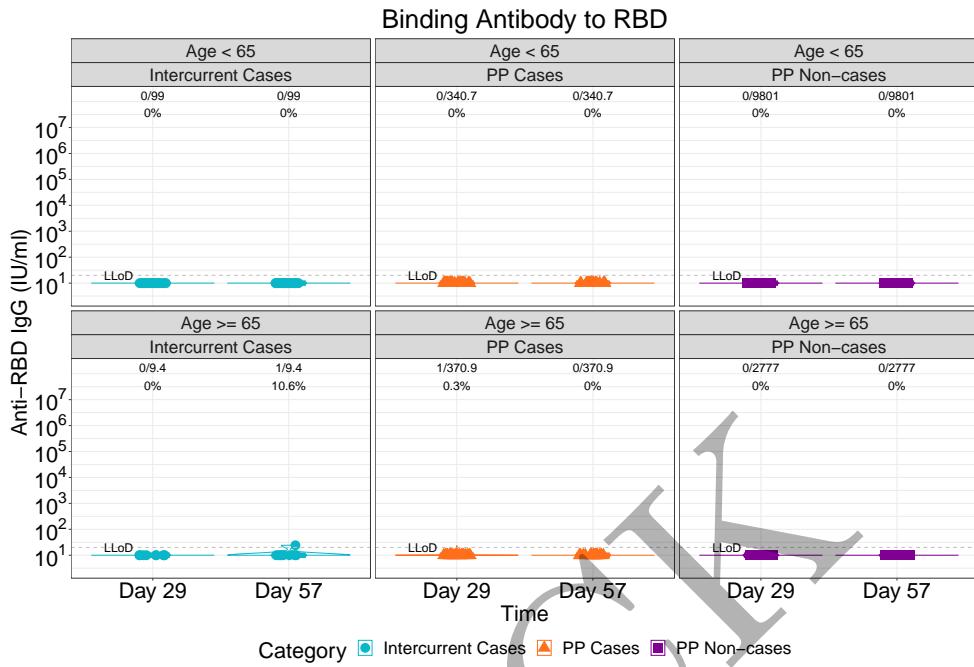


Figure 2.65: violinplots of Binding Antibody to RBD: baseline negative placebo arm by age (2 timepoints)

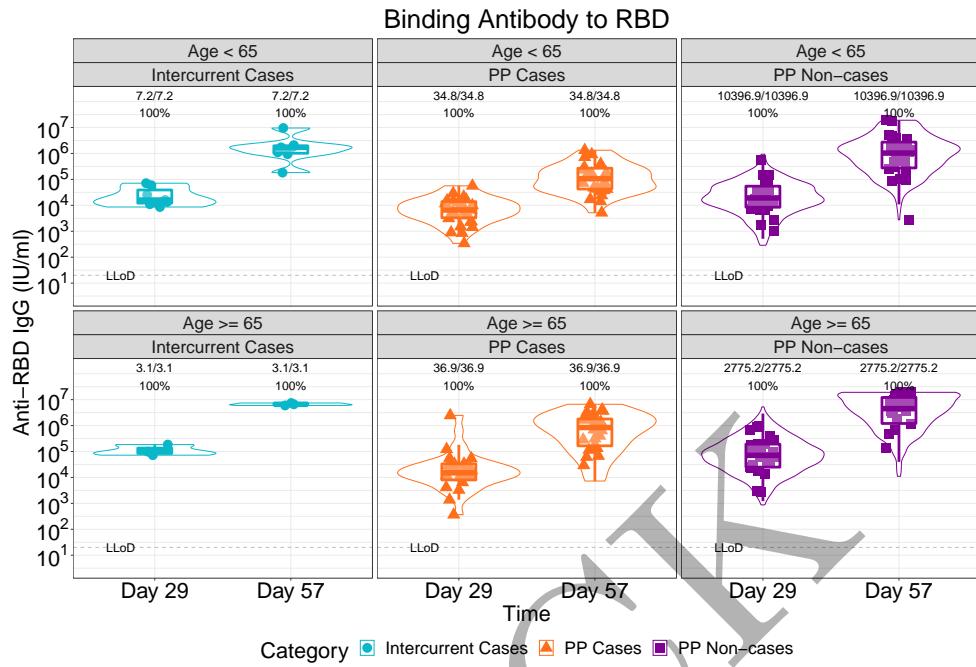


Figure 2.66: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by age (2 timepoints)

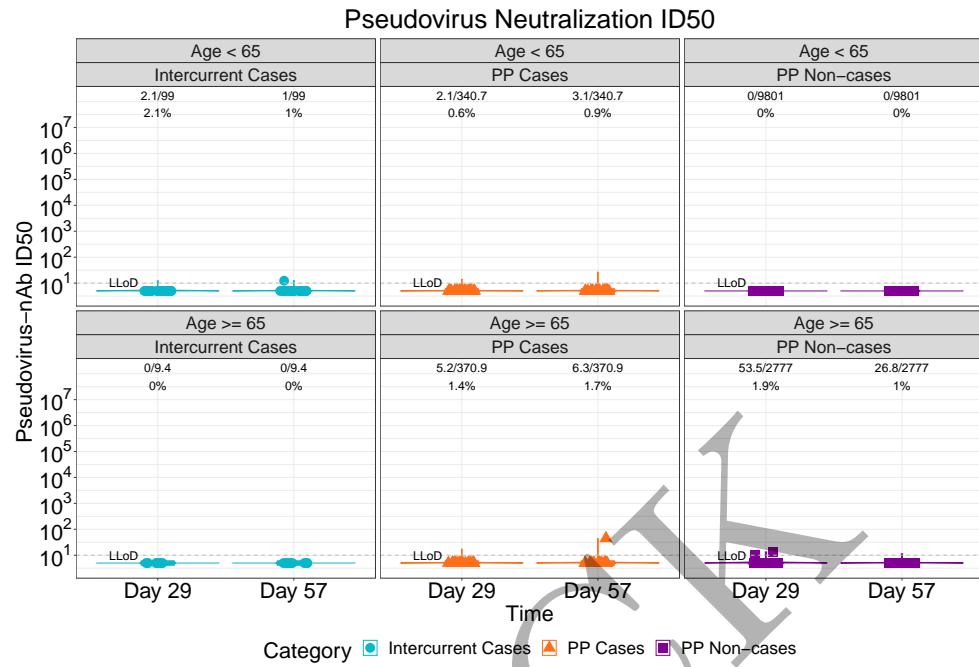


Figure 2.67: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age (2 timepoints)

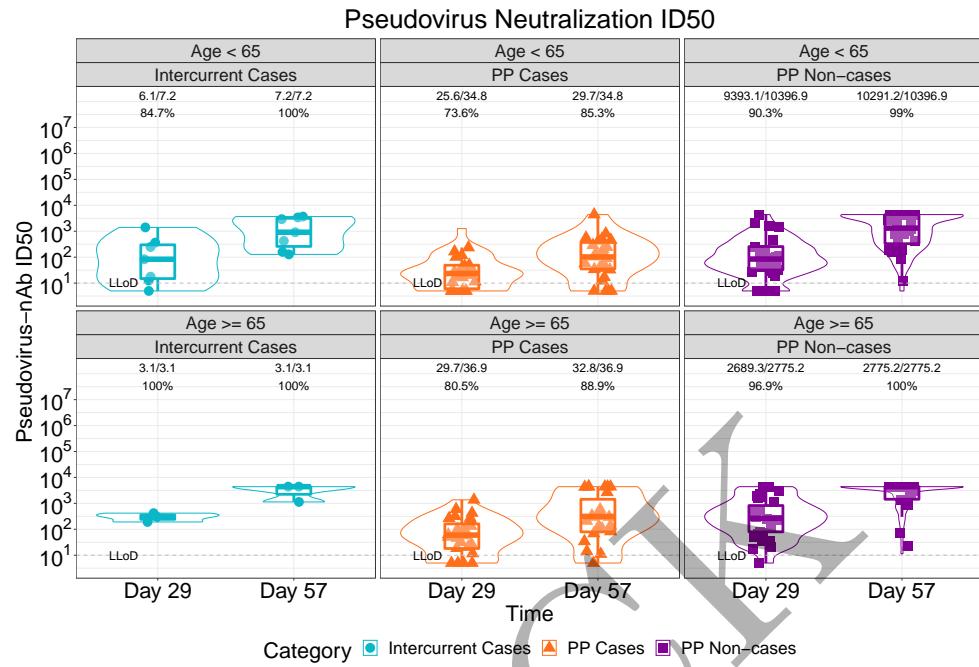


Figure 2.68: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age (2 timepoints)

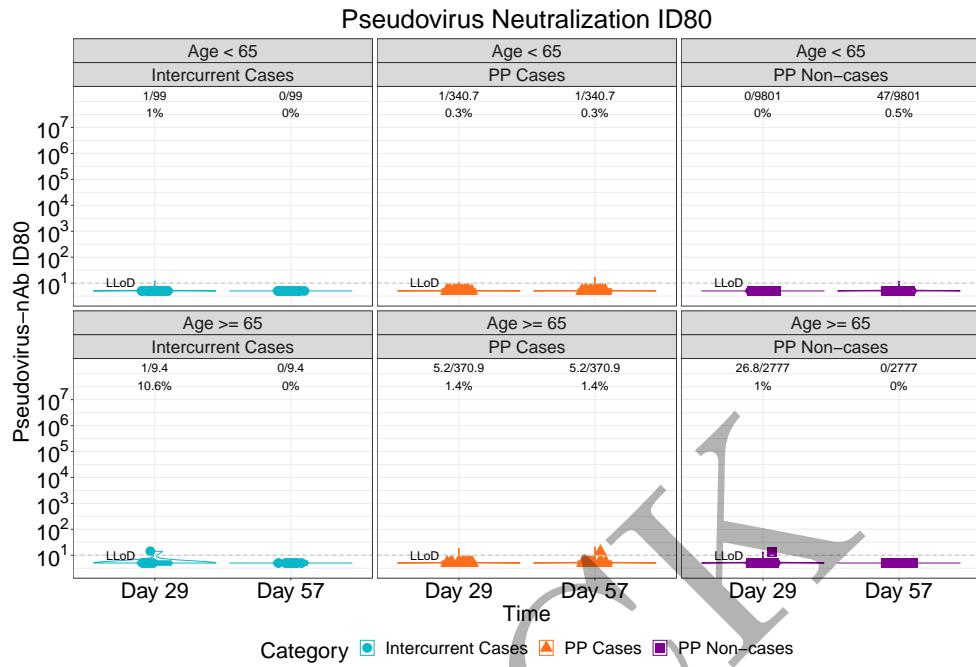


Figure 2.69: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age (2 timepoints)

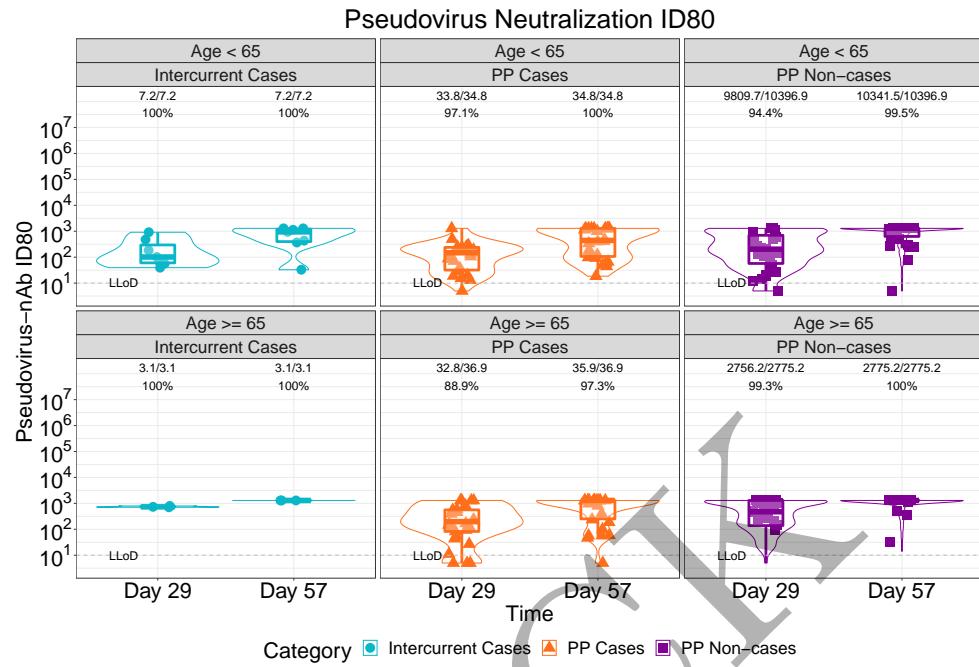


Figure 2.70: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age (2 timepoints)

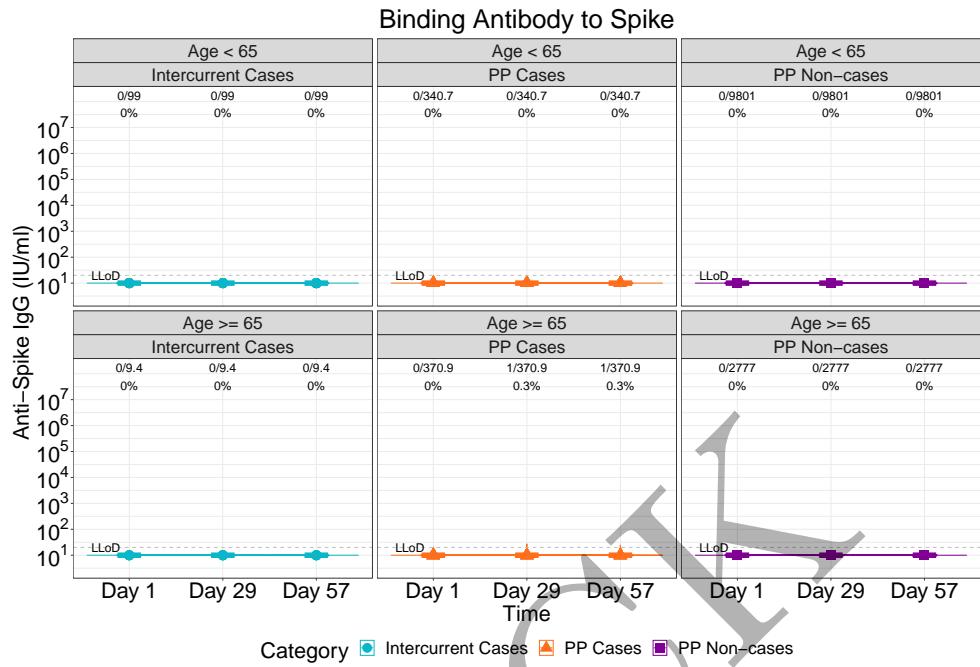


Figure 2.71: lineplots of Binding Antibody to Spike: baseline negative placebo arm by age (3 timepoints)

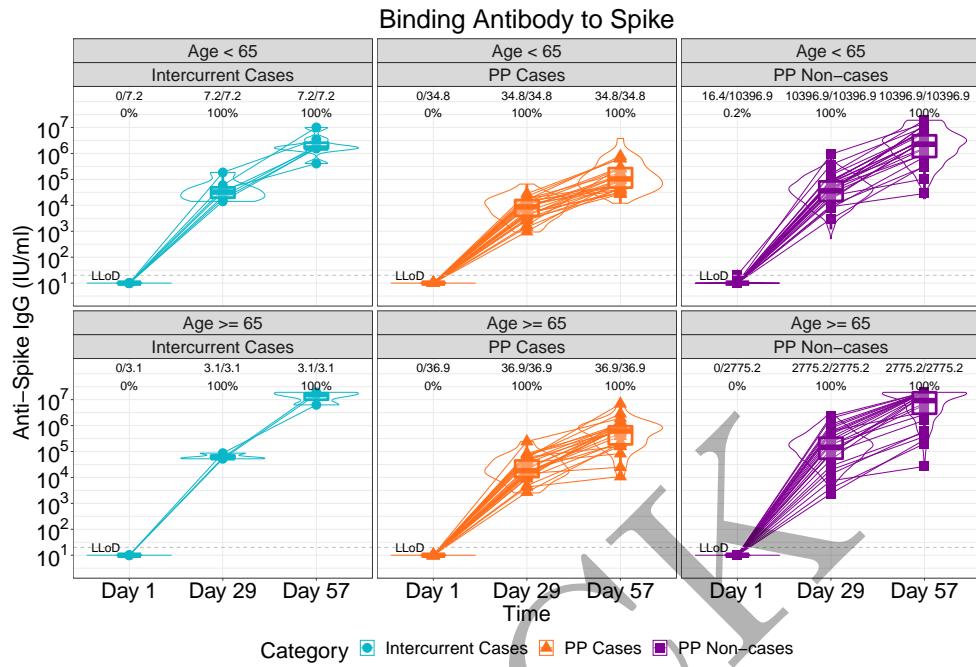


Figure 2.72: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by age (3 timepoints)

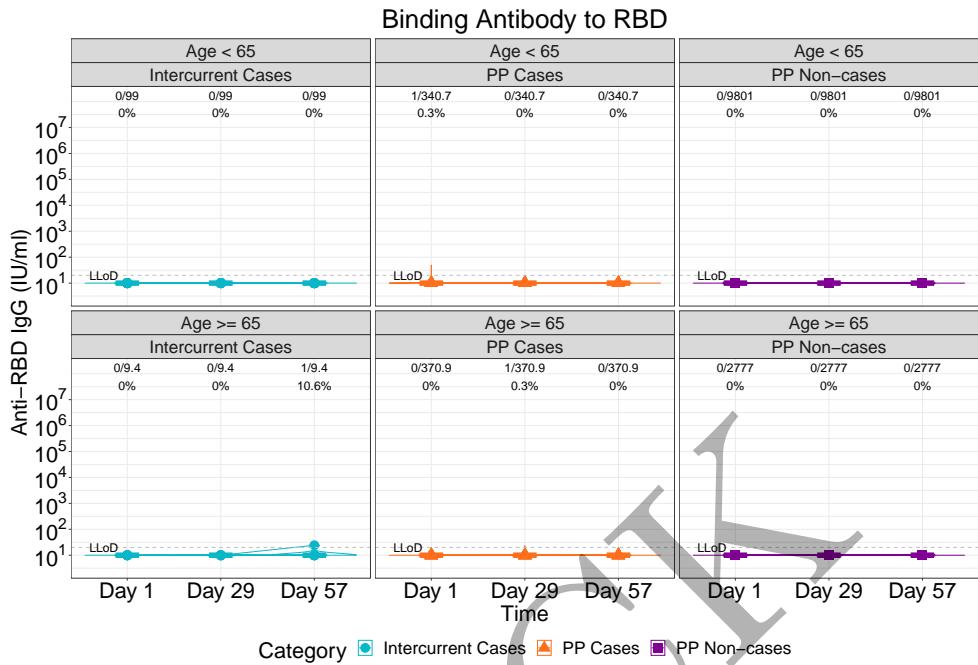


Figure 2.73: lineplots of Binding Antibody to RBD: baseline negative placebo arm by age (3 timepoints)

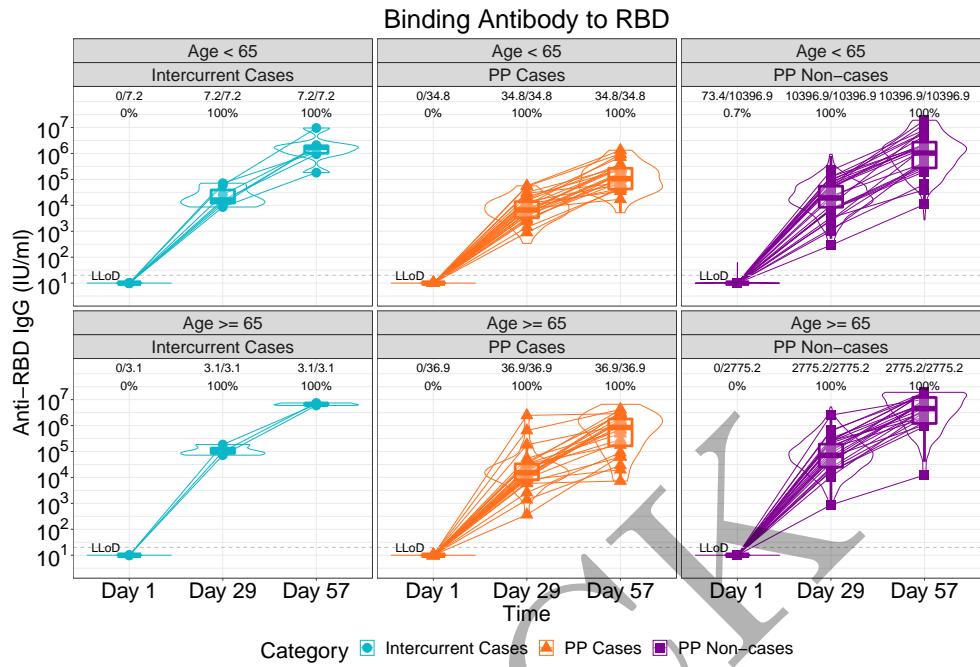


Figure 2.74: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by age (3 timepoints)

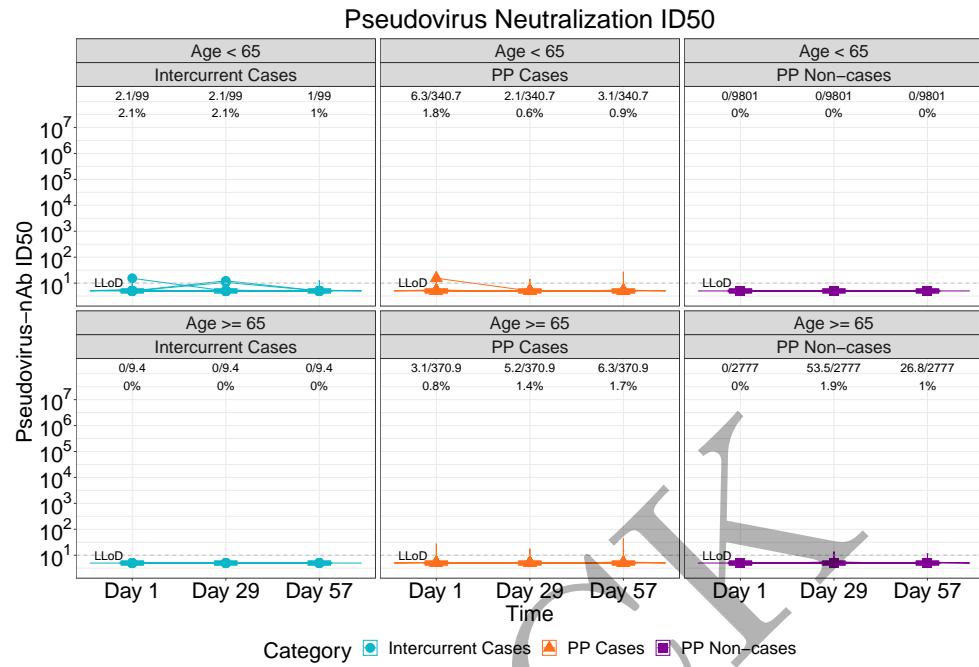


Figure 2.75: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age (3 timepoints)

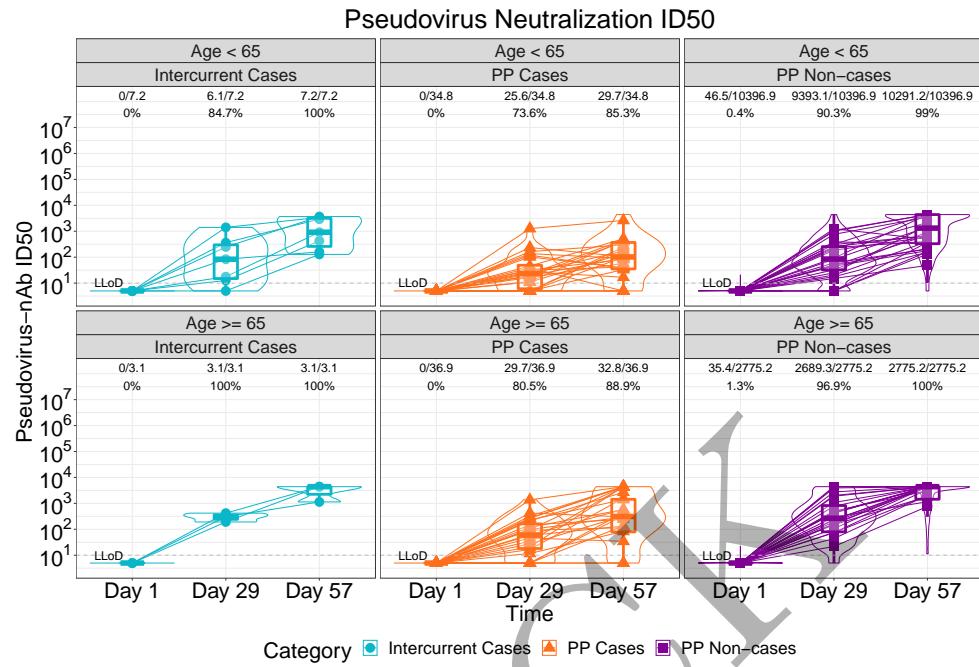


Figure 2.76: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age (3 timepoints)

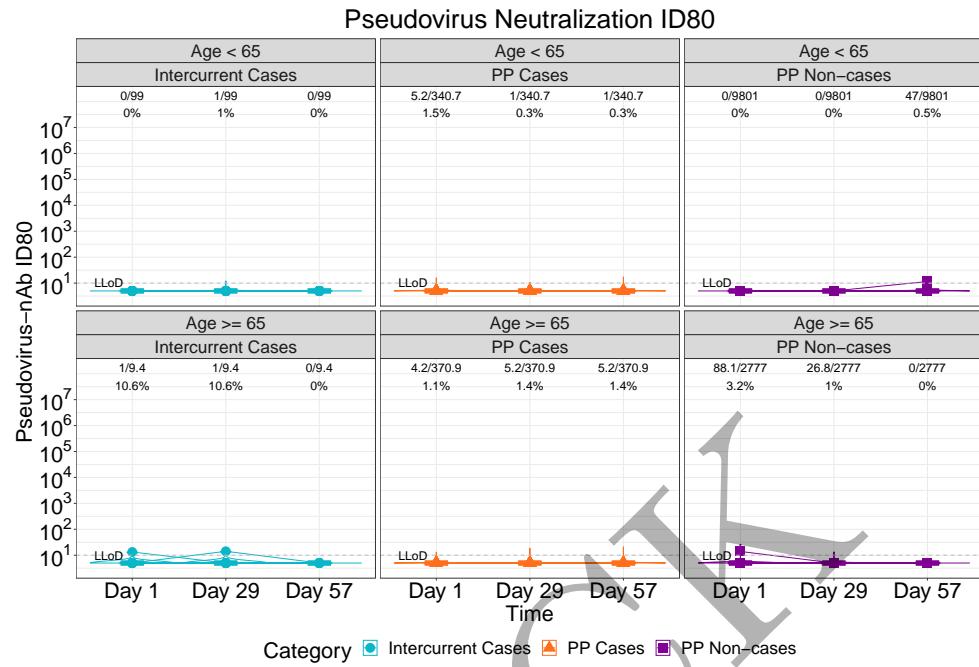


Figure 2.77: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age (3 timepoints)

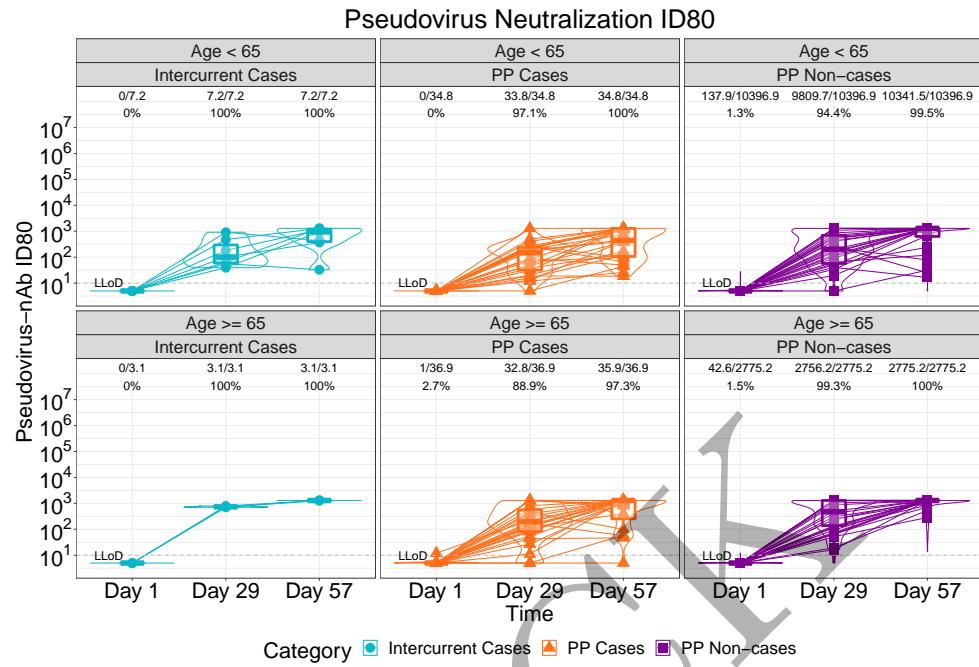


Figure 2.78: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age (3 timepoints)

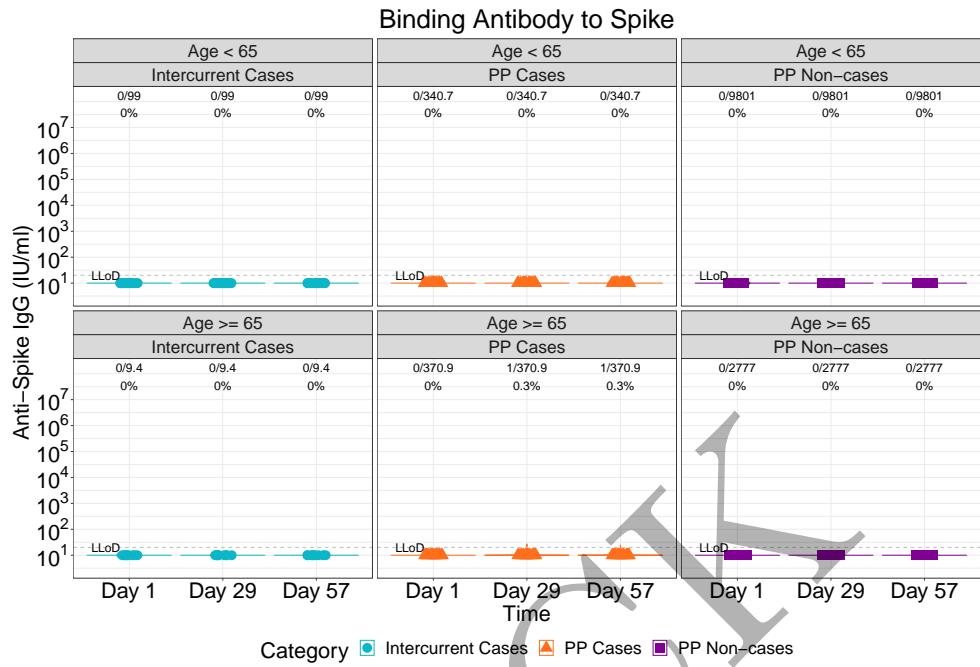


Figure 2.79: violinplots of Binding Antibody to Spike: baseline negative placebo arm by age (3 timepoints)

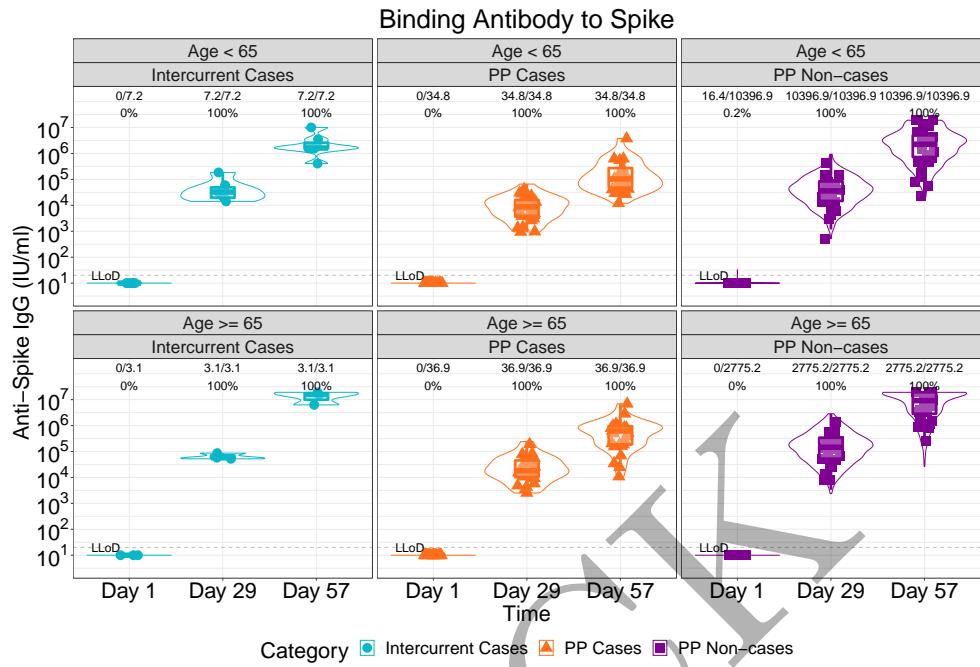


Figure 2.80: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by age (3 timepoints)

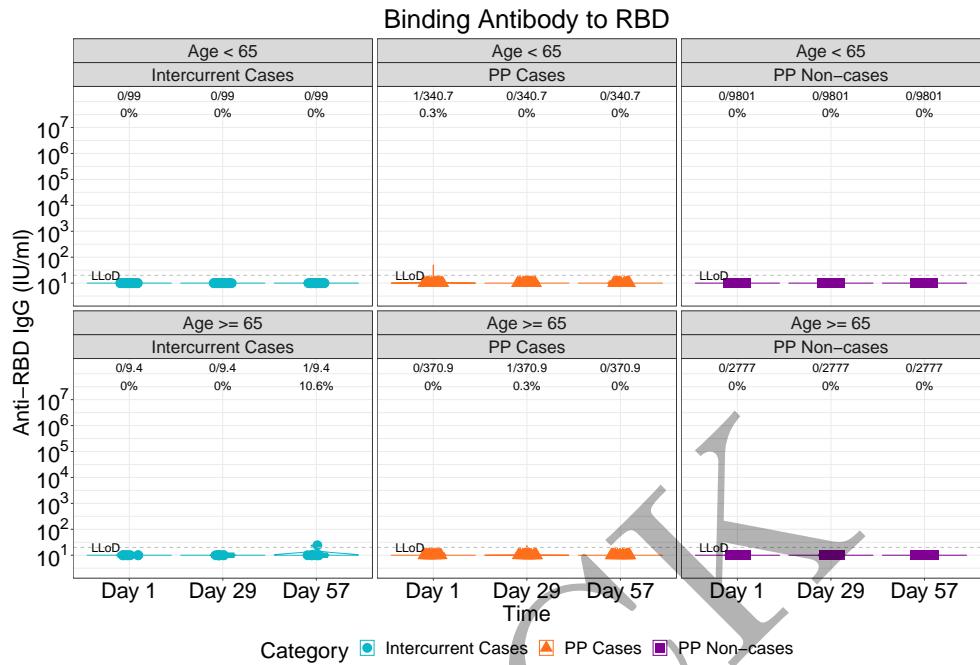


Figure 2.81: violinplots of Binding Antibody to RBD: baseline negative placebo arm by age (3 timepoints)

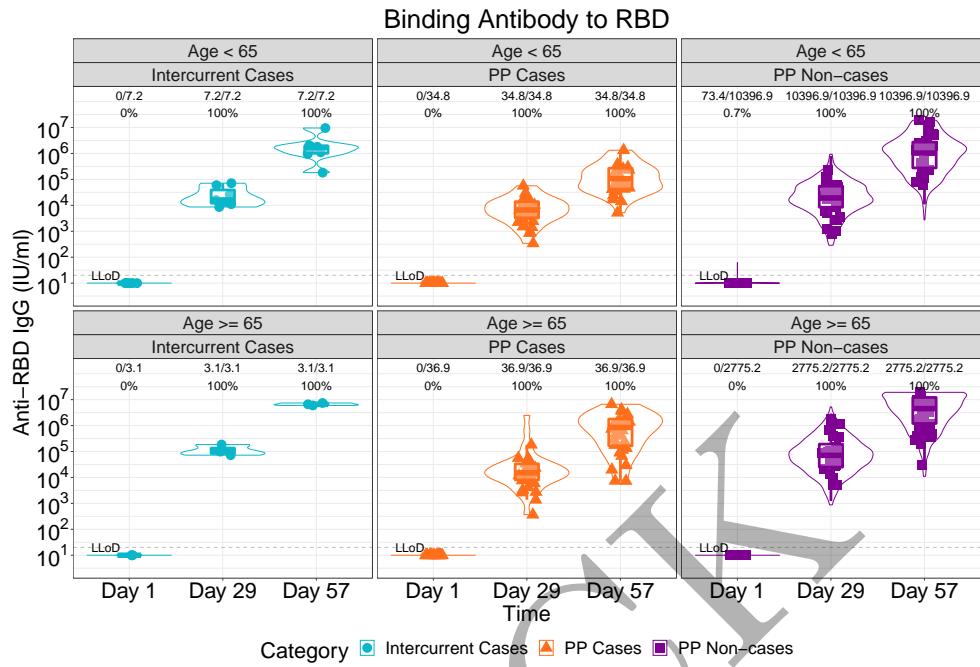


Figure 2.82: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by age (3 timepoints)

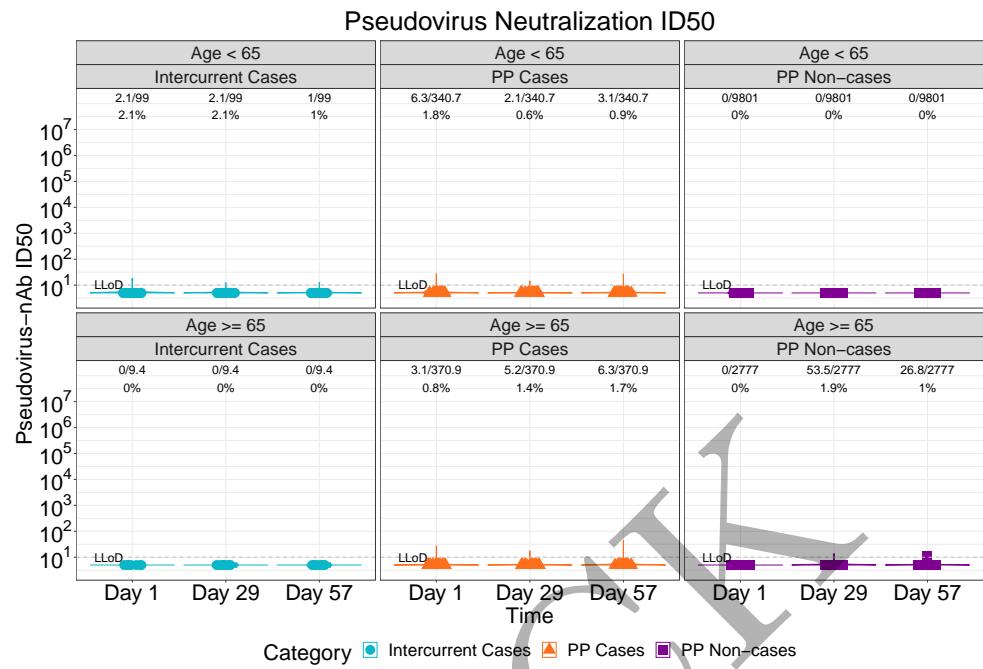


Figure 2.83: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age (3 timepoints)

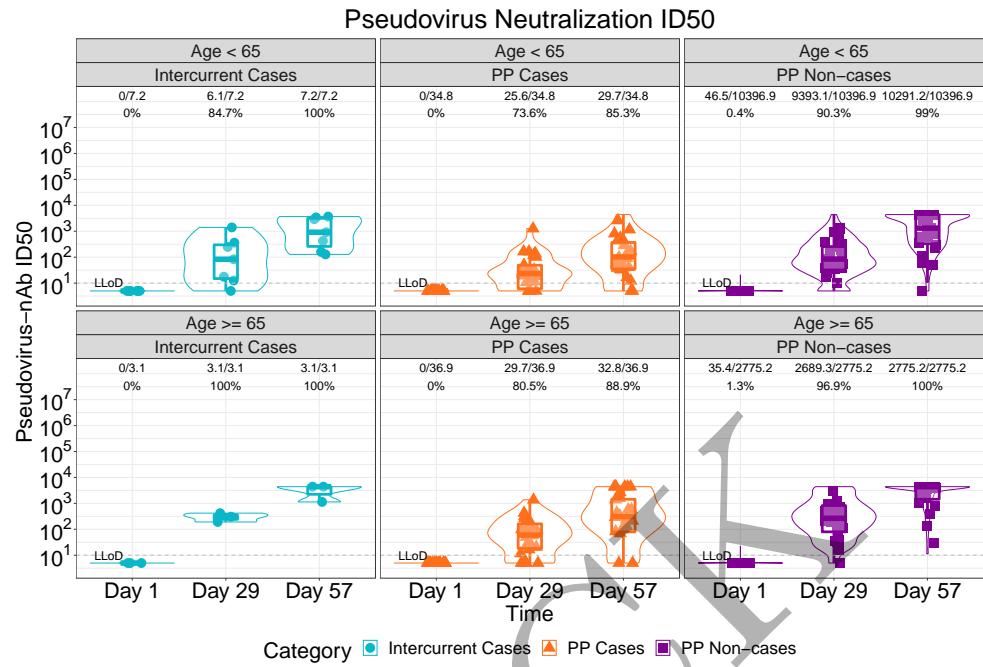


Figure 2.84: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age (3 timepoints)

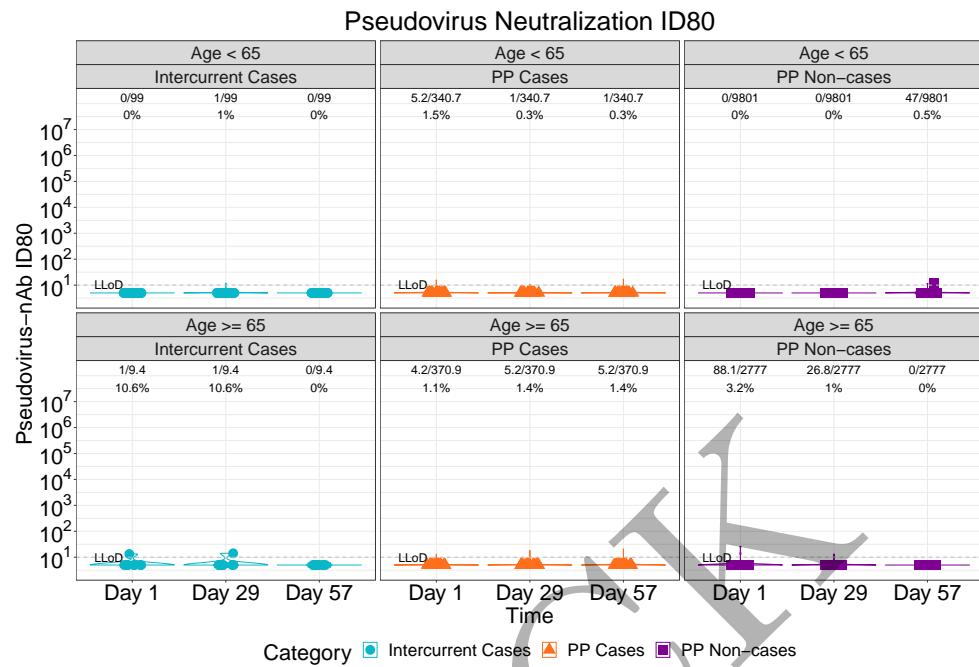


Figure 2.85: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age (3 timepoints)

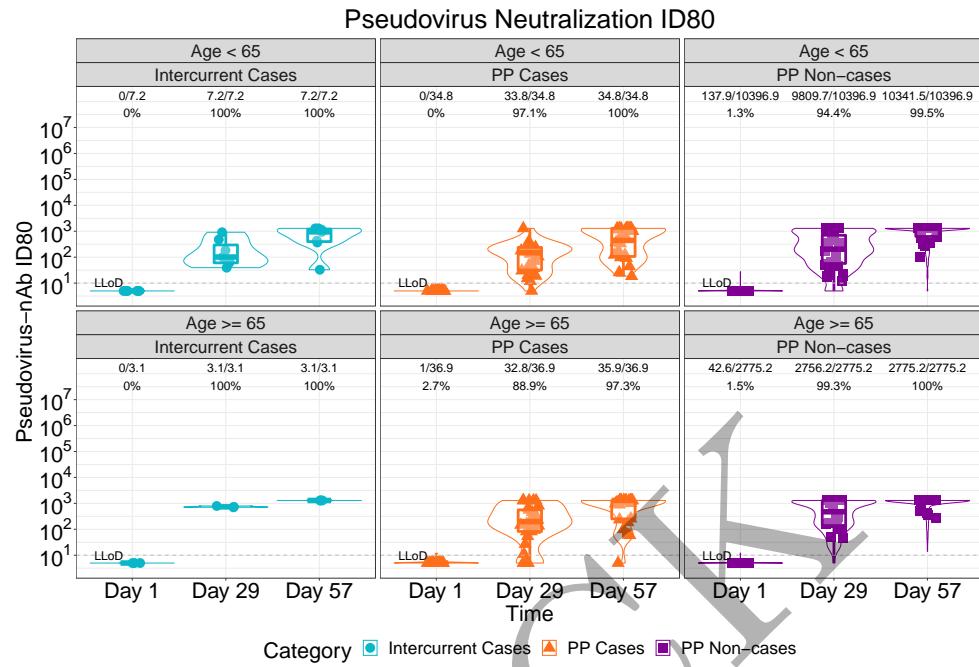


Figure 2.86: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age (3 timepoints)

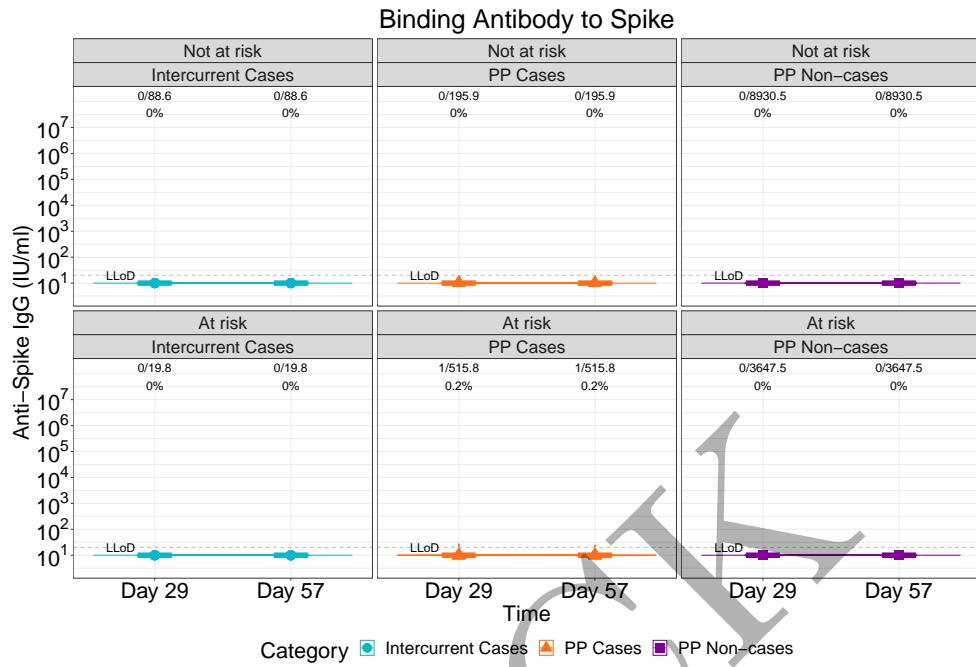


Figure 2.87: lineplots of Binding Antibody to Spike: baseline negative placebo arm by risk condition (2 timepoints)

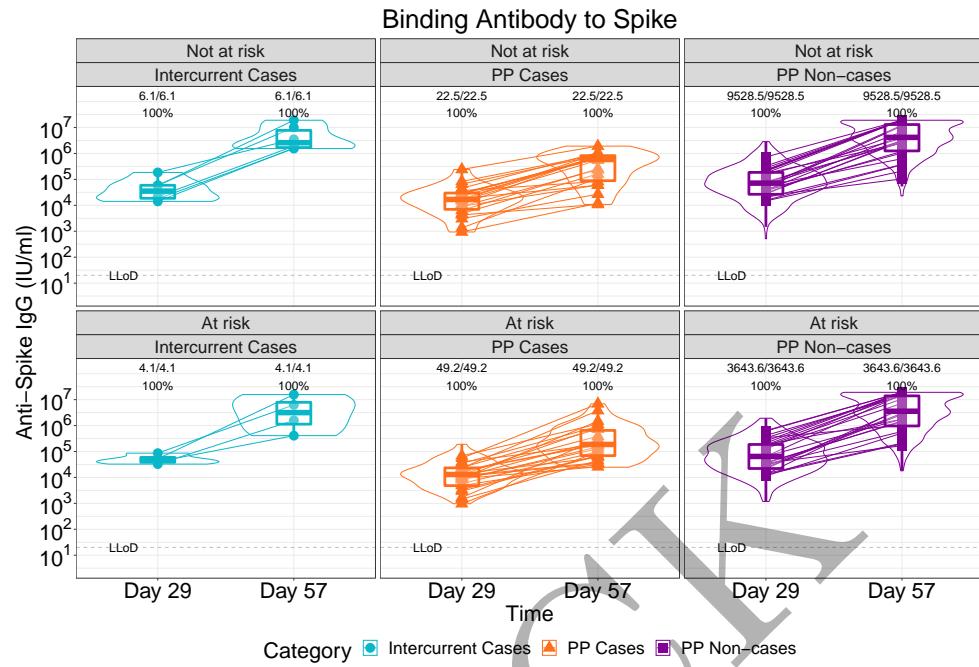


Figure 2.88: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by risk condition (2 timepoints)

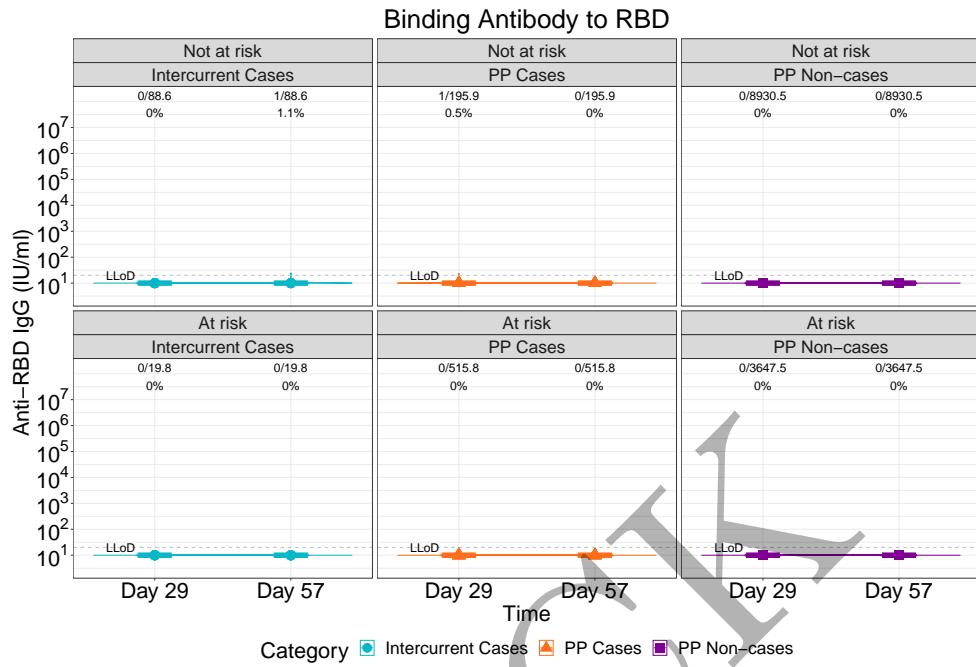


Figure 2.89: lineplots of Binding Antibody to RBD: baseline negative placebo arm by risk condition (2 timepoints)

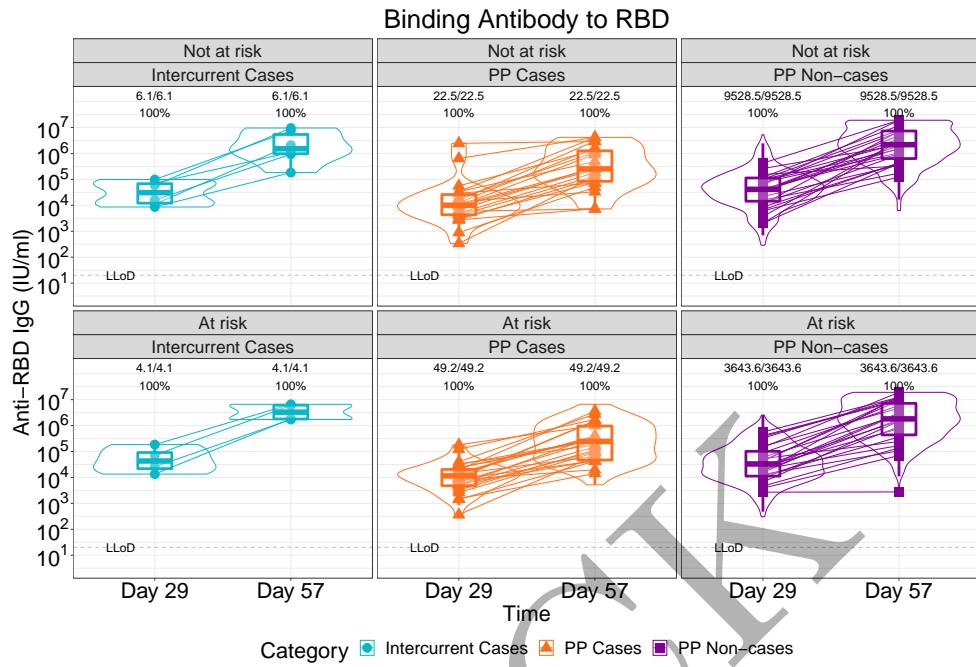


Figure 2.90: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by risk condition (2 timepoints)

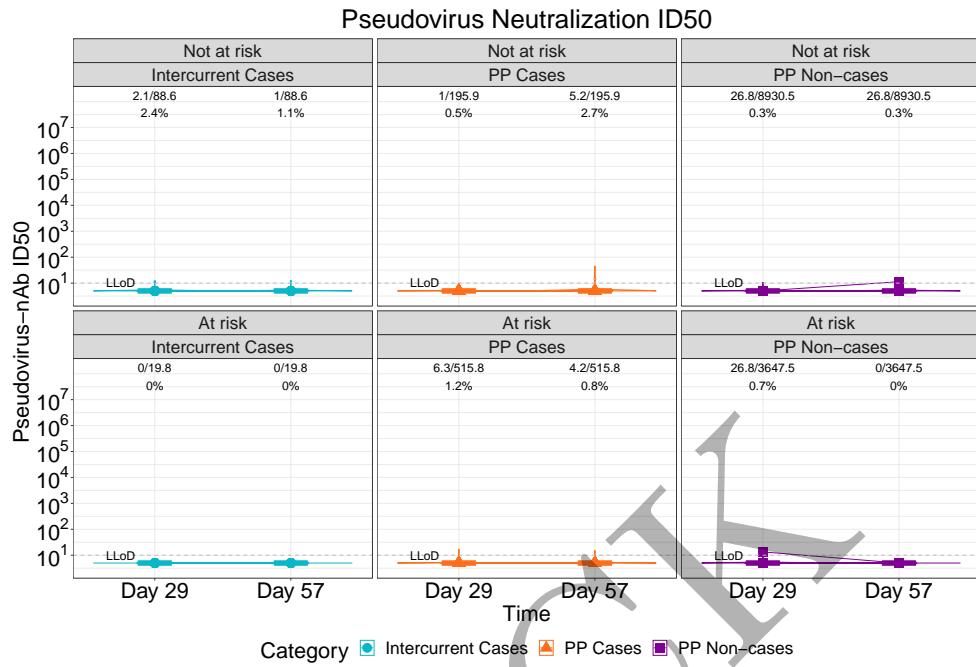


Figure 2.91: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by risk condition (2 timepoints)

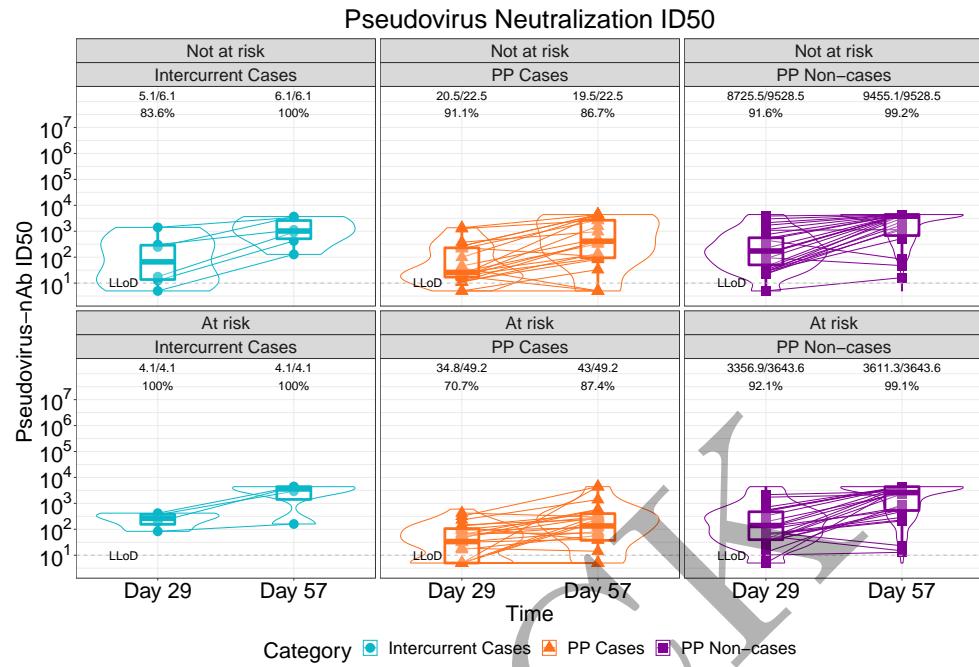


Figure 2.92: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by risk condition (2 timepoints)

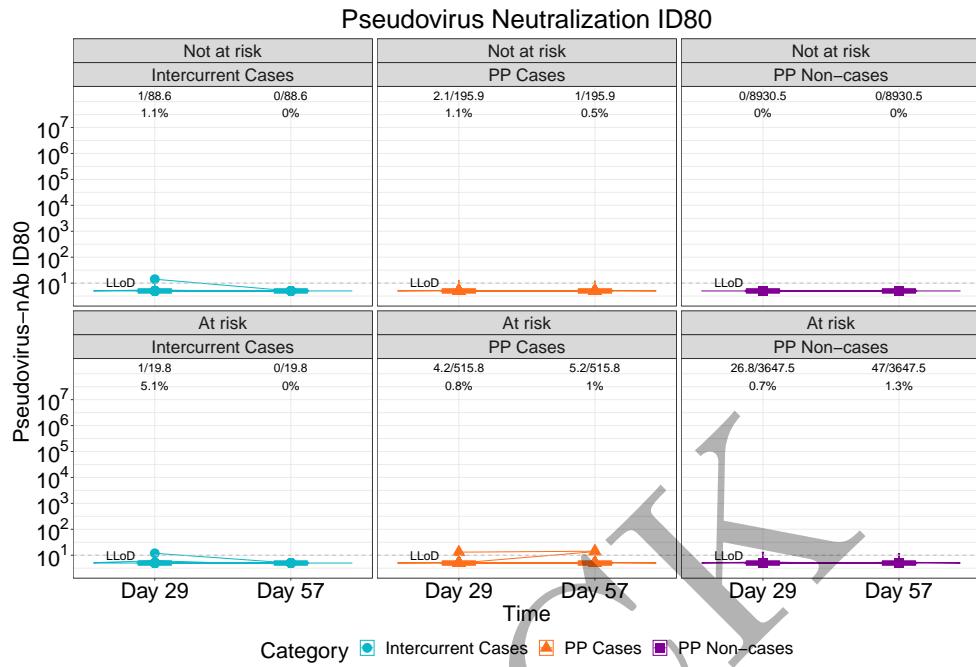


Figure 2.93: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by risk condition (2 timepoints)

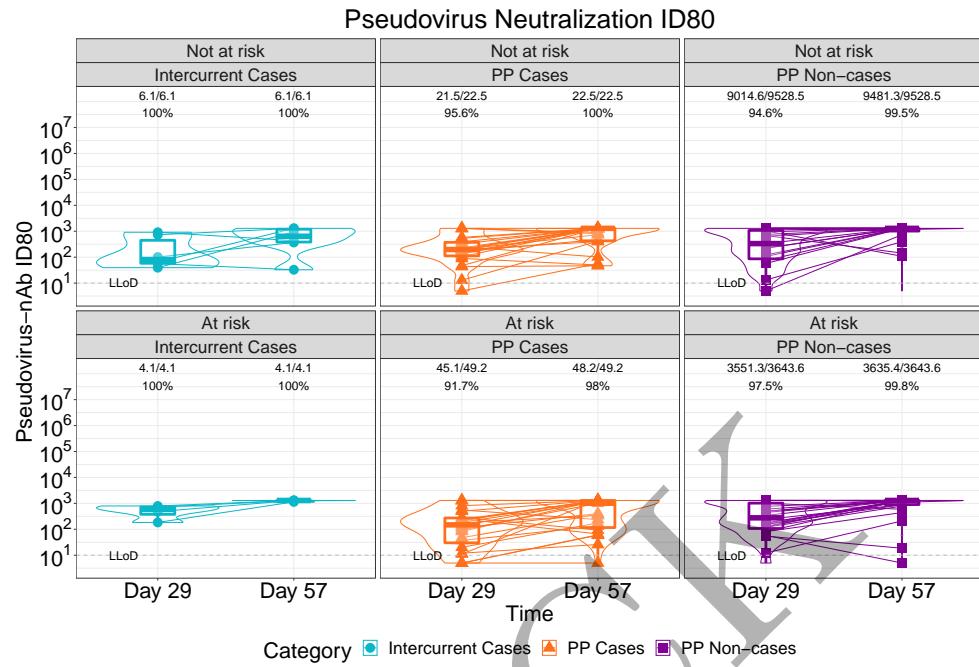


Figure 2.94: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by risk condition (2 timepoints)

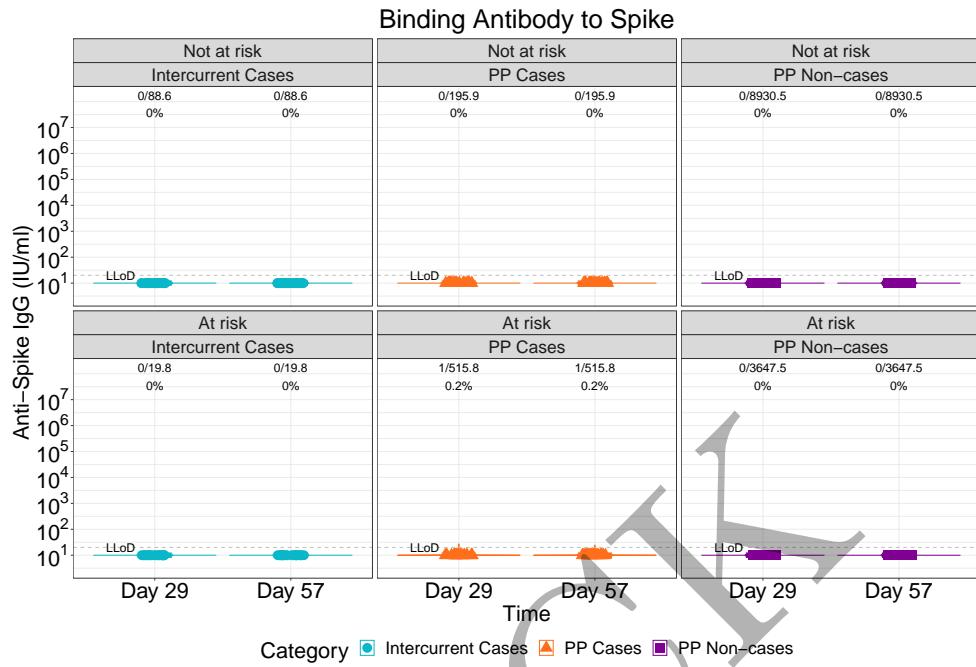


Figure 2.95: violinplots of Binding Antibody to Spike: baseline negative placebo arm by risk condition (2 timepoints)

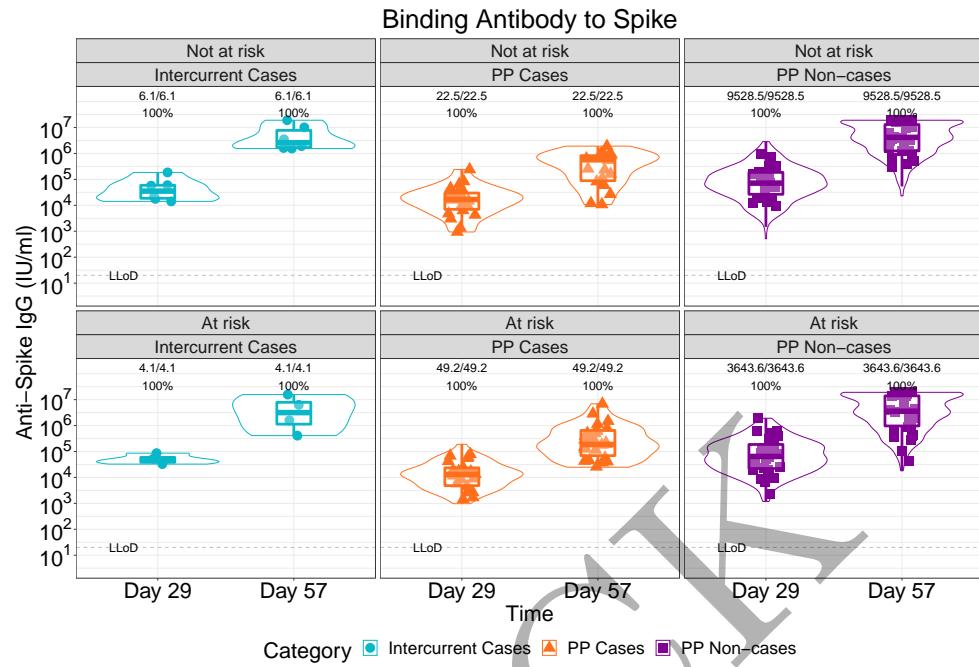


Figure 2.96: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by risk condition (2 timepoints)

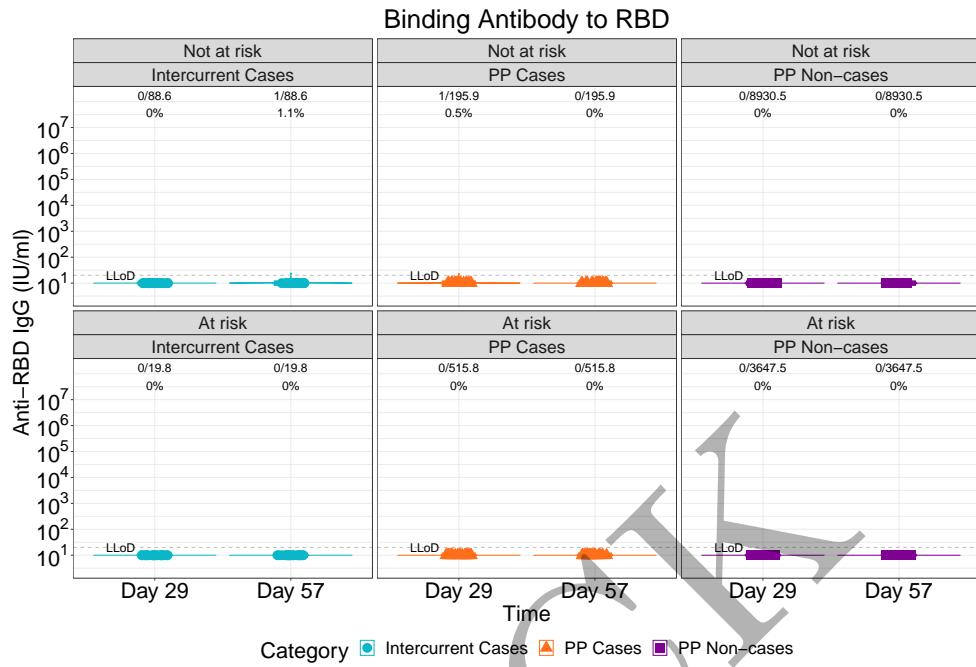


Figure 2.97: violinplots of Binding Antibody to RBD: baseline negative placebo arm by risk condition (2 timepoints)

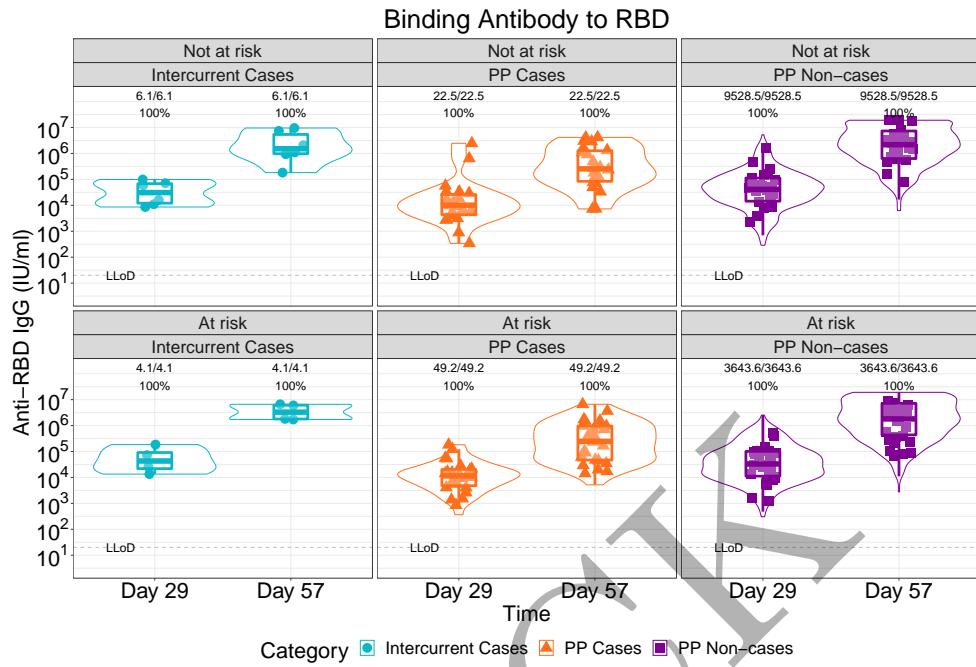


Figure 2.98: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by risk condition (2 timepoints)

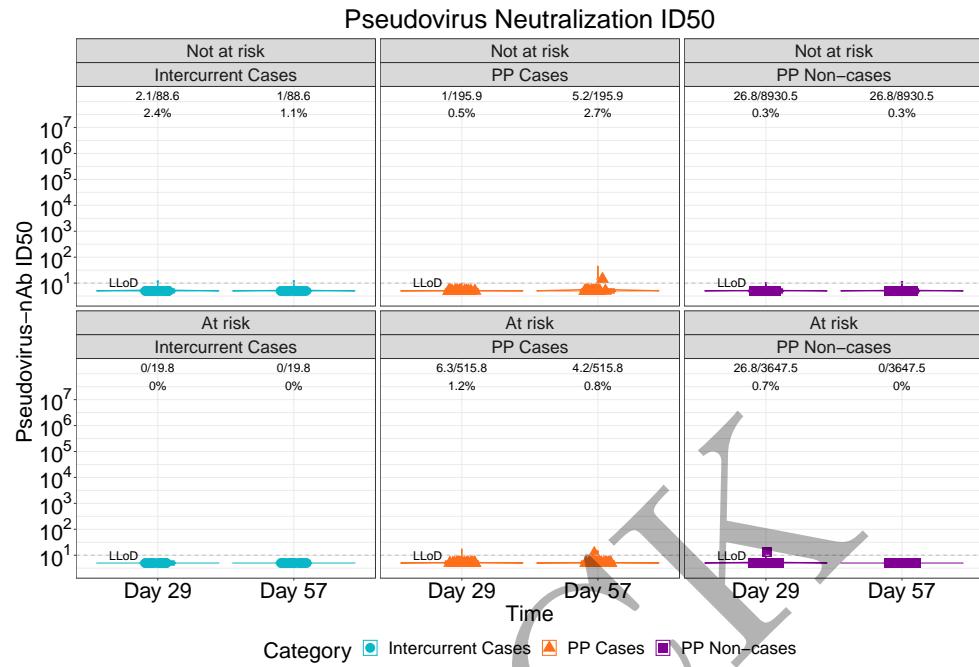


Figure 2.99: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by risk condition (2 timepoints)

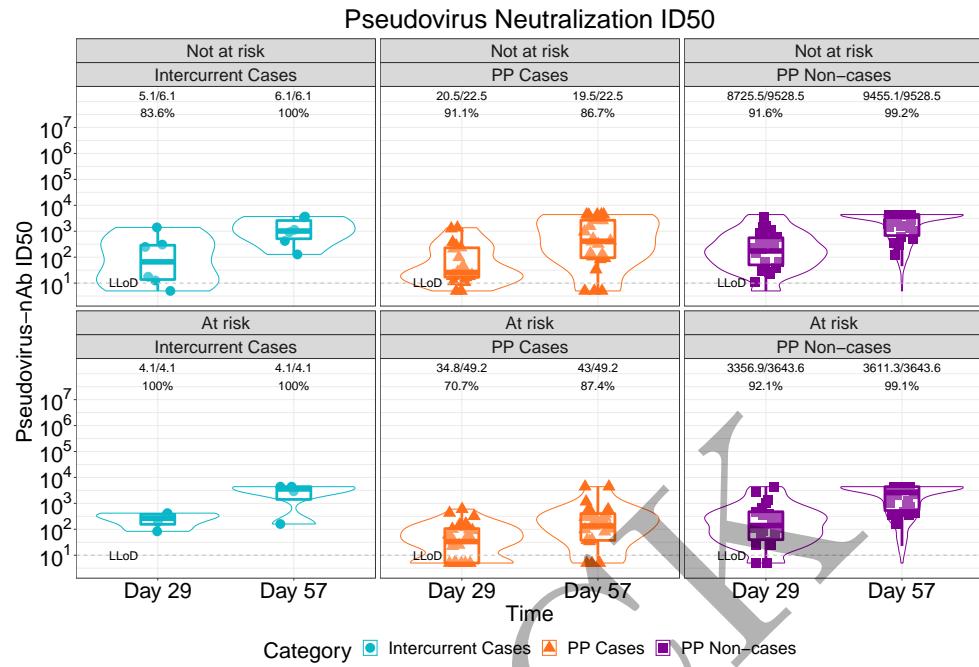


Figure 2.100: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by risk condition (2 timepoints)

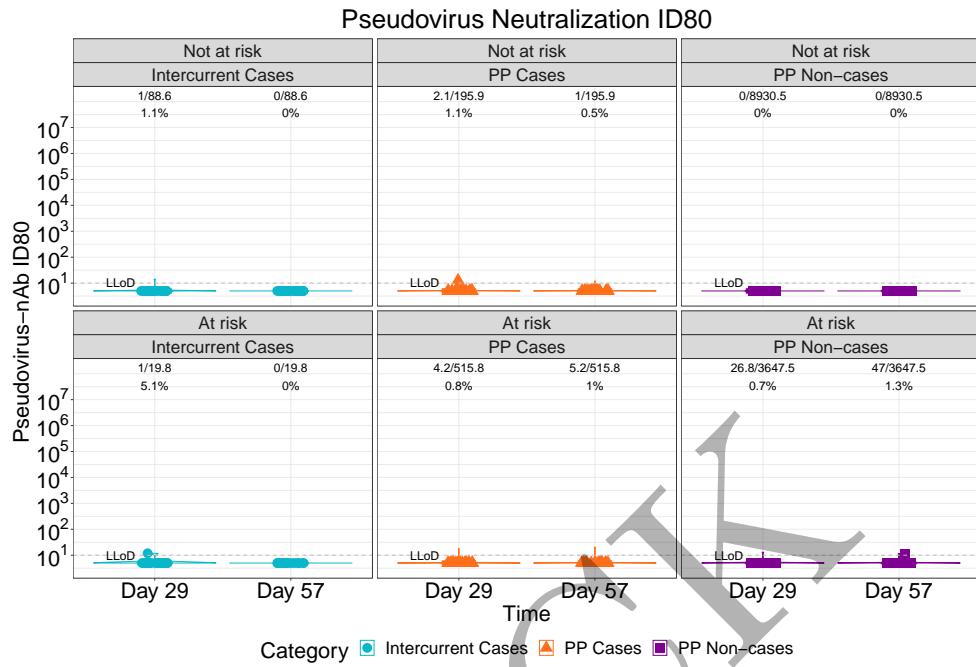


Figure 2.101: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by risk condition (2 timepoints)

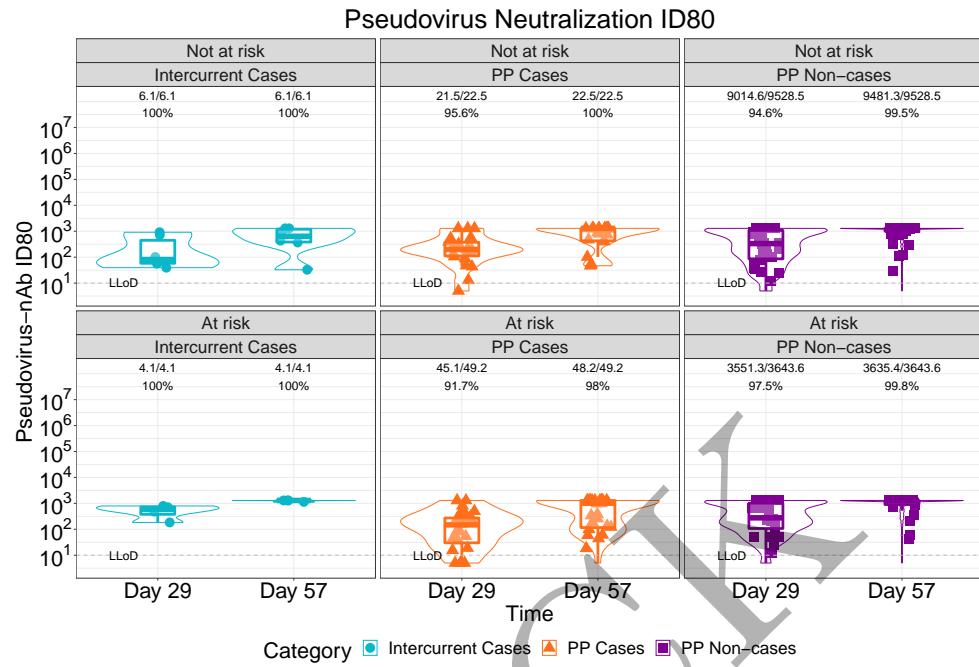


Figure 2.102: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by risk condition (2 timepoints)

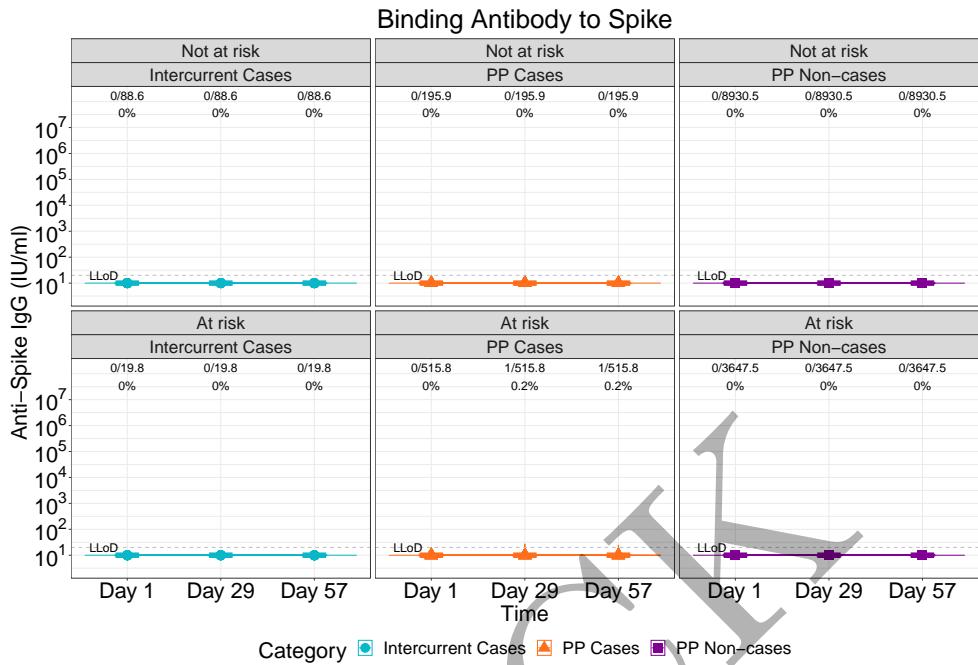


Figure 2.103: lineplots of Binding Antibody to Spike: baseline negative placebo arm by risk condition (3 timepoints)

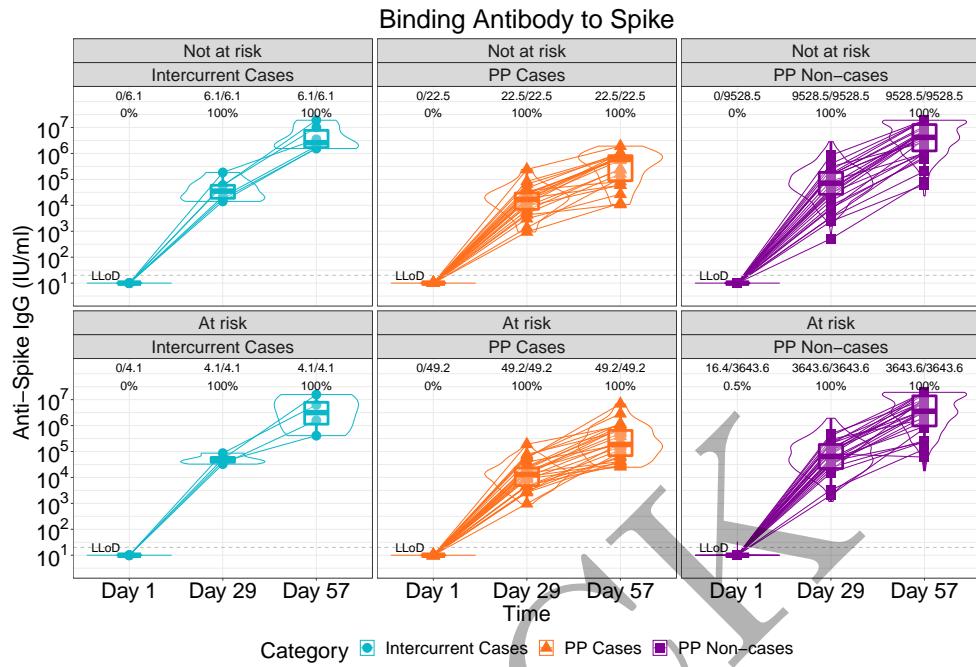


Figure 2.104: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by risk condition (3 timepoints)

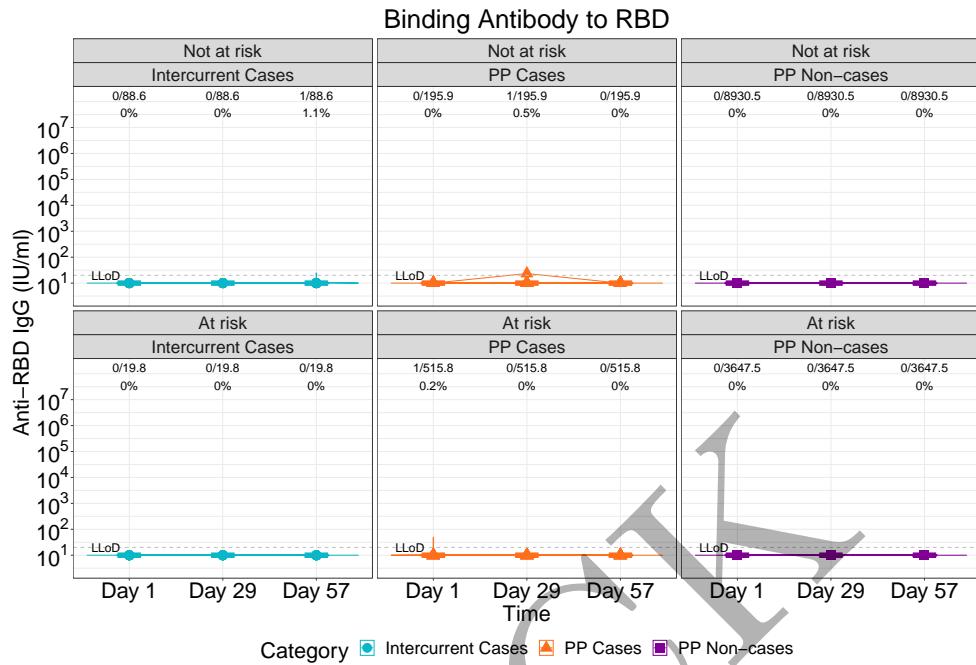


Figure 2.105: lineplots of Binding Antibody to RBD: baseline negative placebo arm by risk condition (3 timepoints)

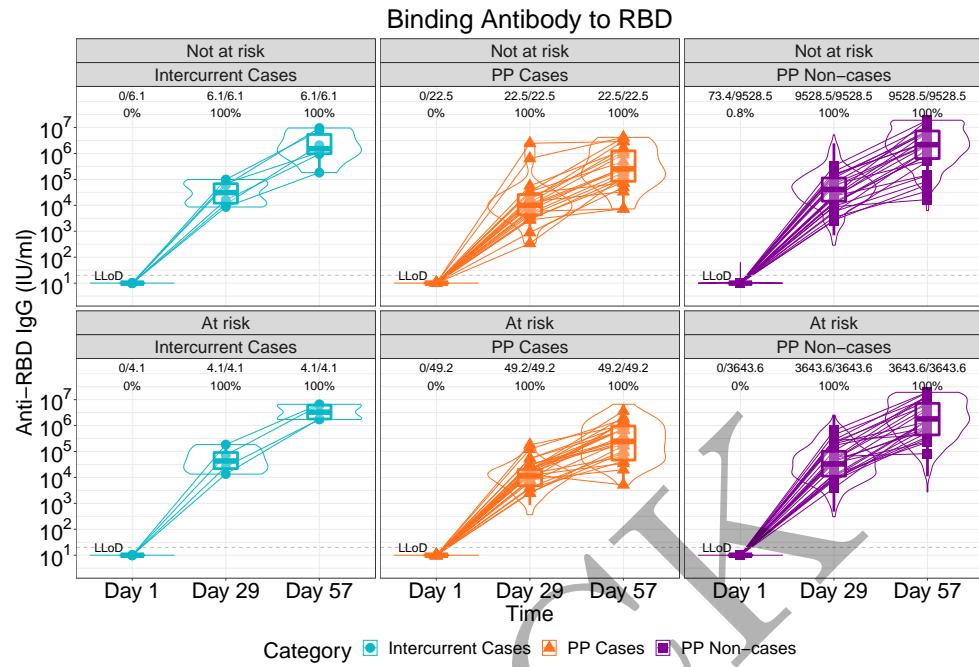


Figure 2.106: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by risk condition (3 timepoints)

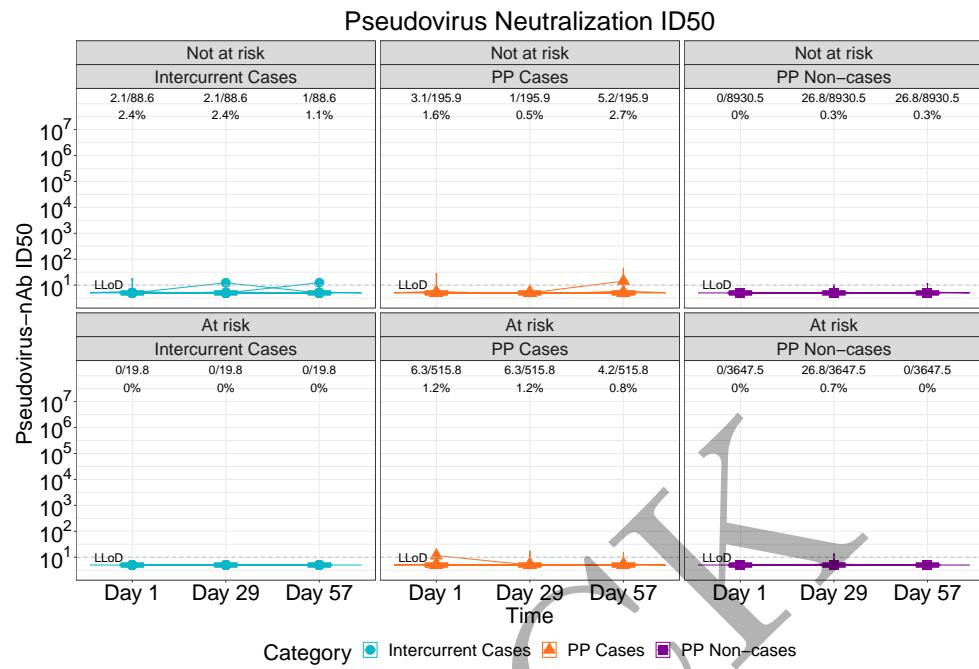


Figure 2.107: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by risk condition (3 timepoints)

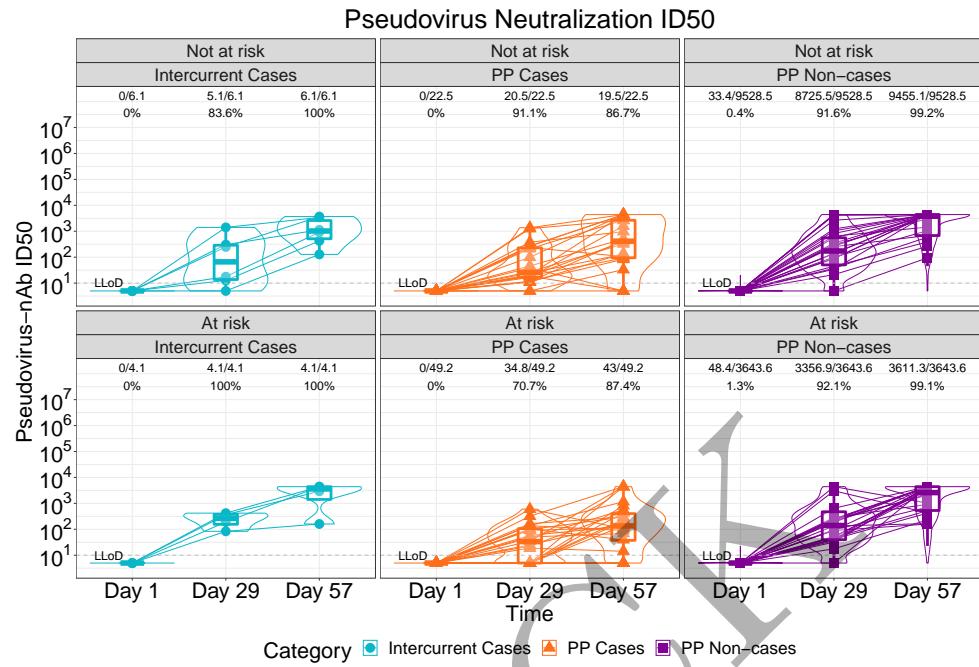


Figure 2.108: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by risk condition (3 timepoints)

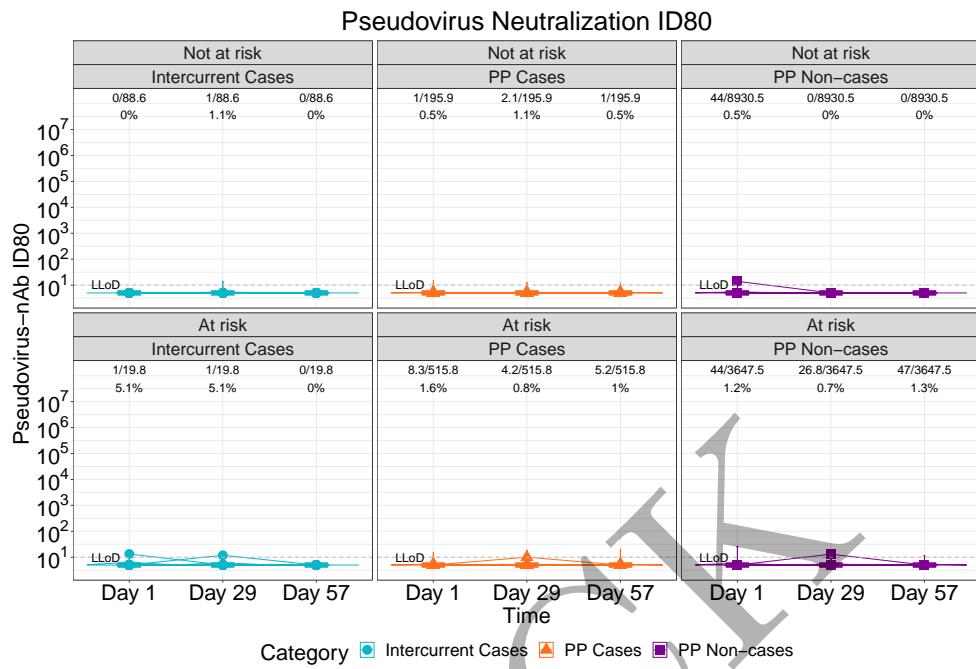


Figure 2.109: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by risk condition (3 timepoints)

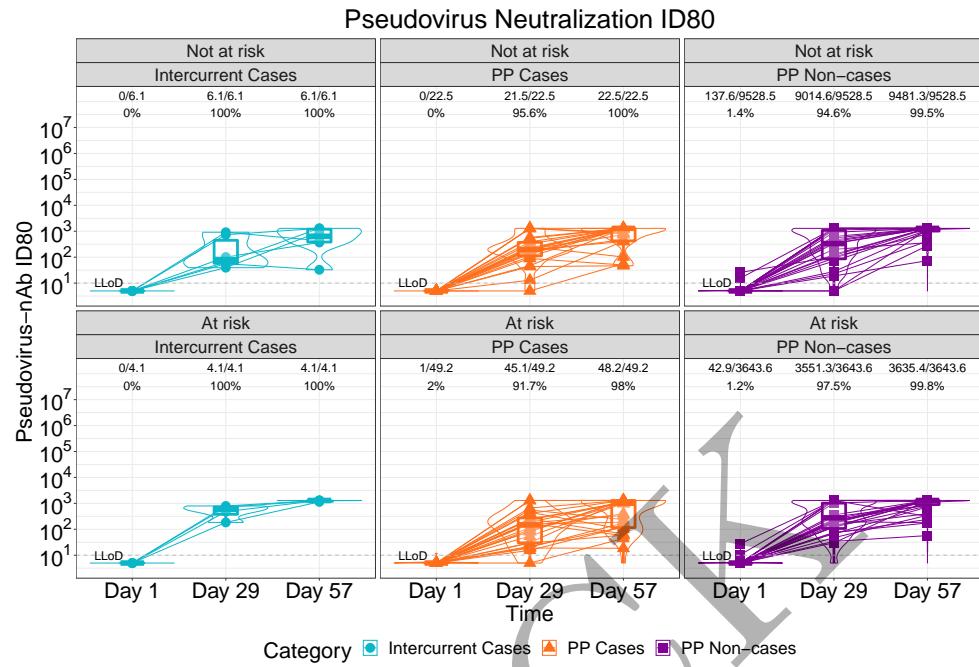


Figure 2.110: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by risk condition (3 timepoints)

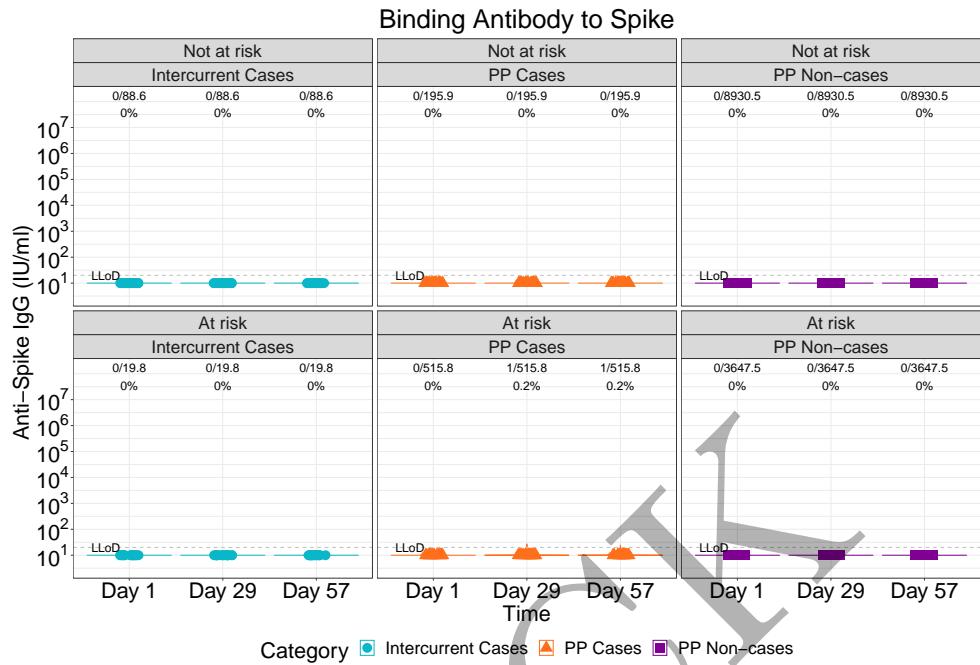


Figure 2.111: violinplots of Binding Antibody to Spike: baseline negative placebo arm by risk condition (3 timepoints)

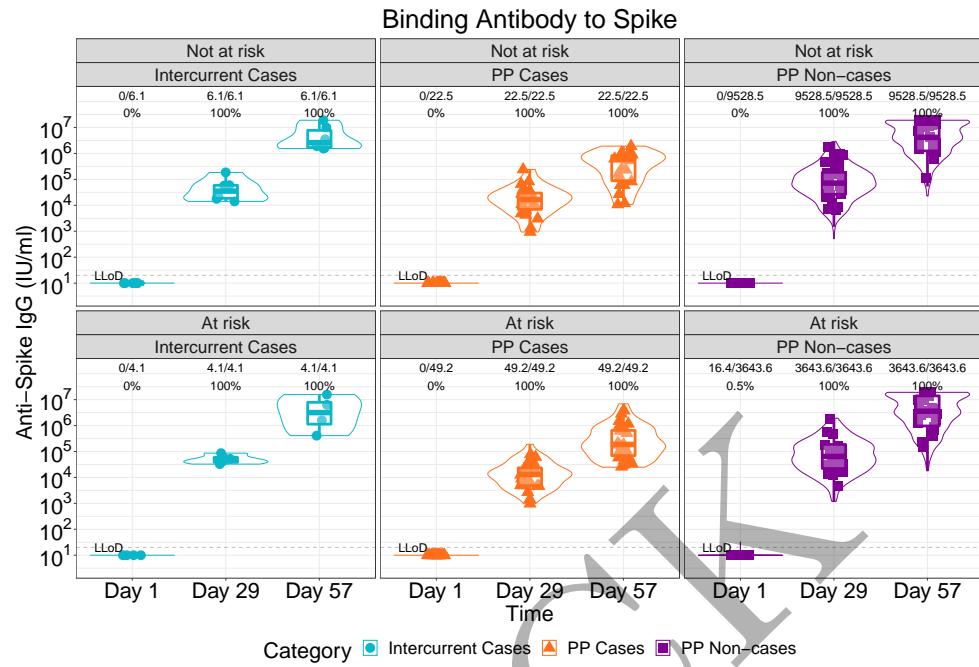


Figure 2.112: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by risk condition (3 timepoints)

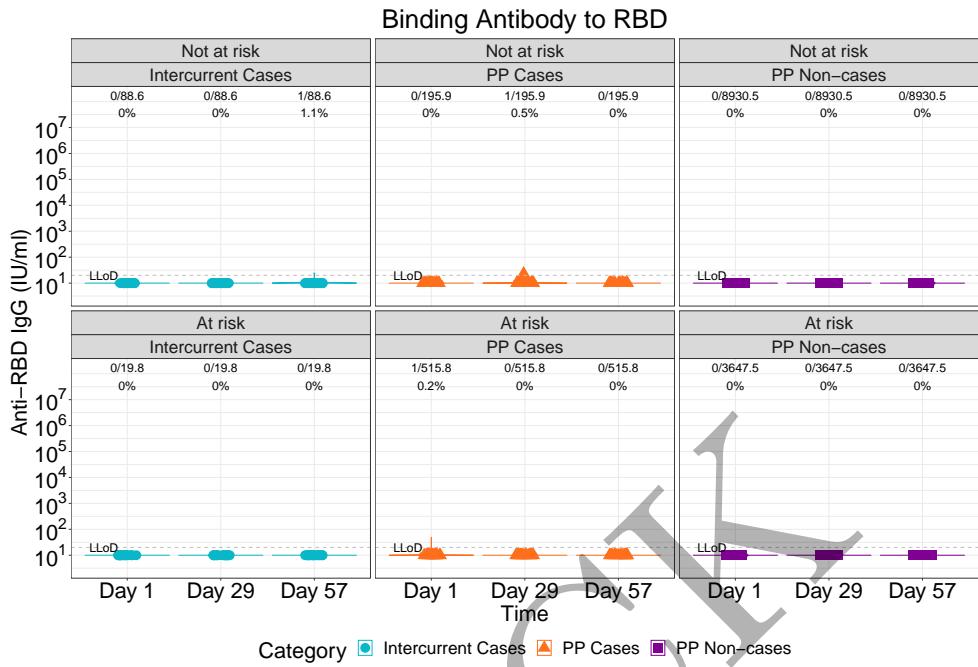


Figure 2.113: violinplots of Binding Antibody to RBD: baseline negative placebo arm by risk condition (3 timepoints)

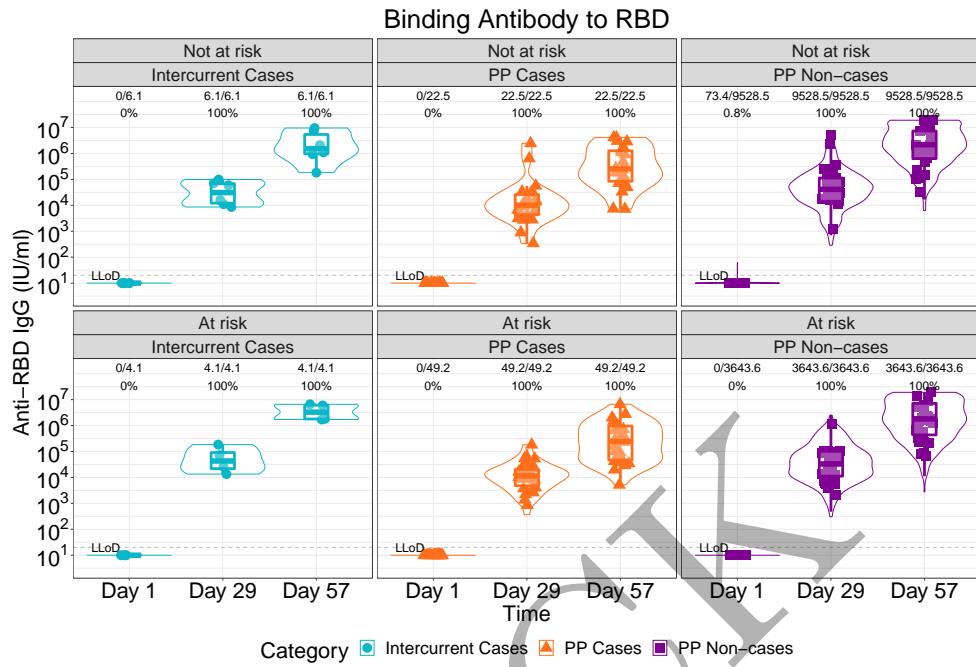


Figure 2.114: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by risk condition (3 timepoints)

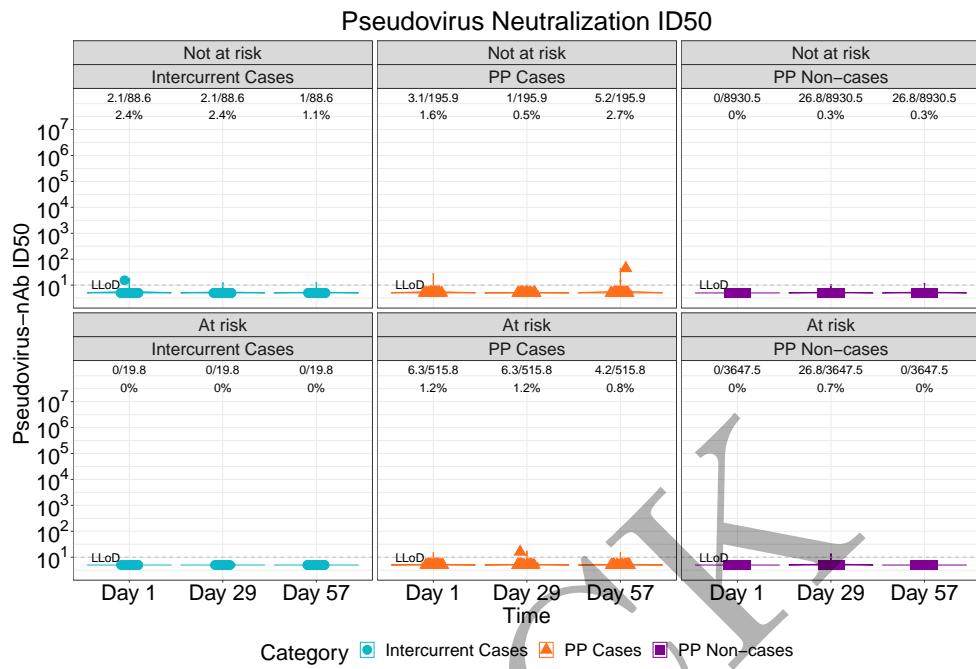


Figure 2.115: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by risk condition (3 timepoints)

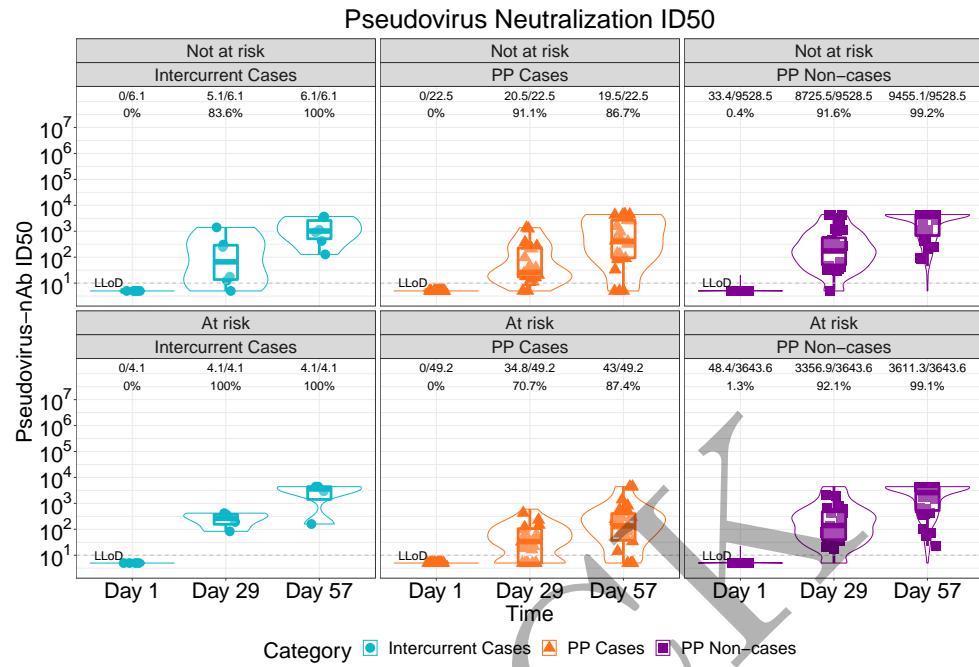


Figure 2.116: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by risk condition (3 timepoints)

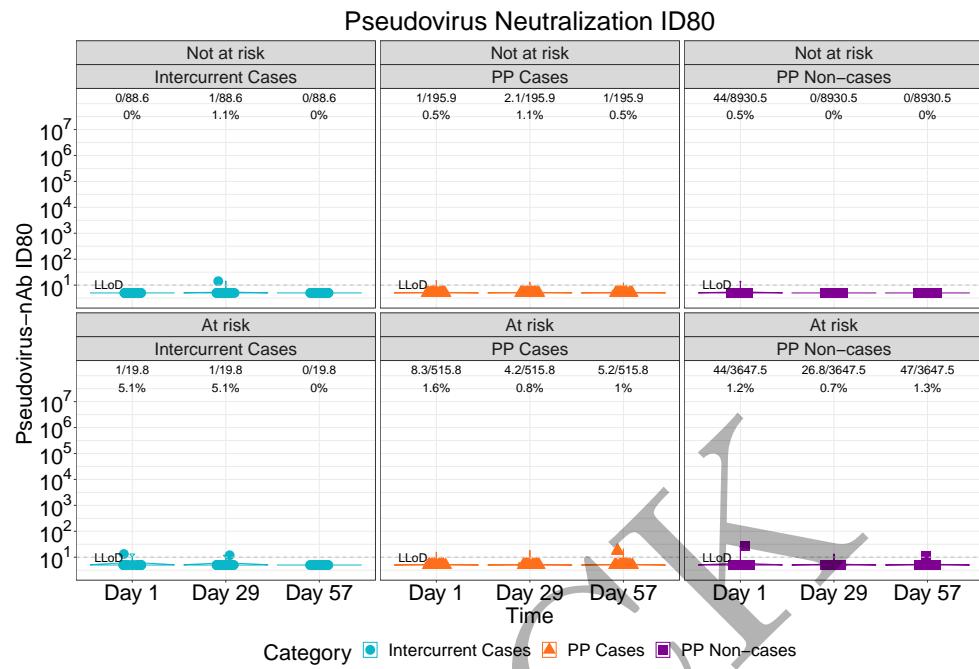


Figure 2.117: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by risk condition (3 timepoints)

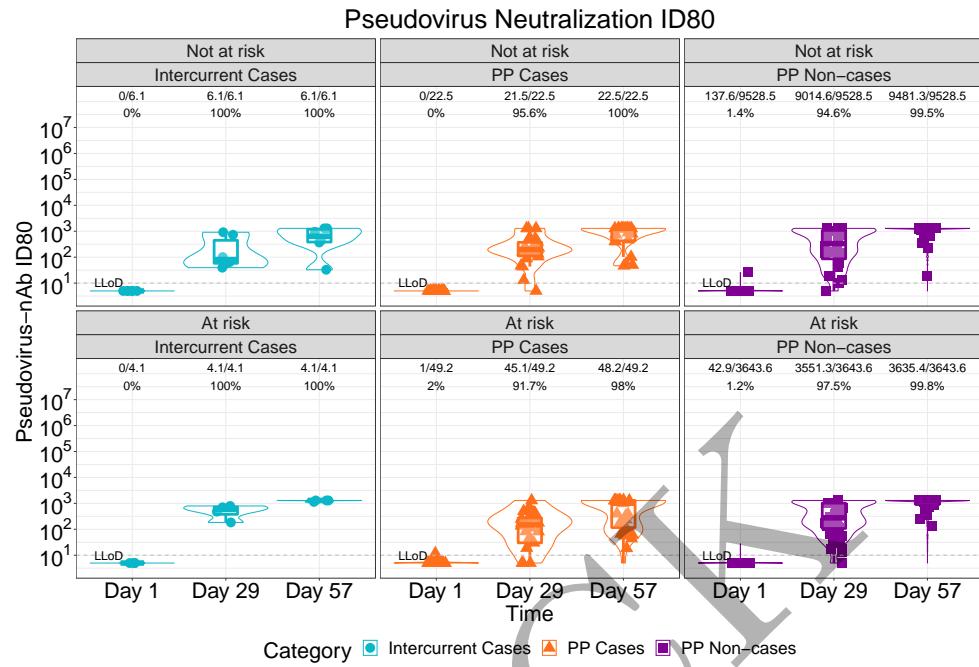


Figure 2.118: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by risk condition (3 timepoints)

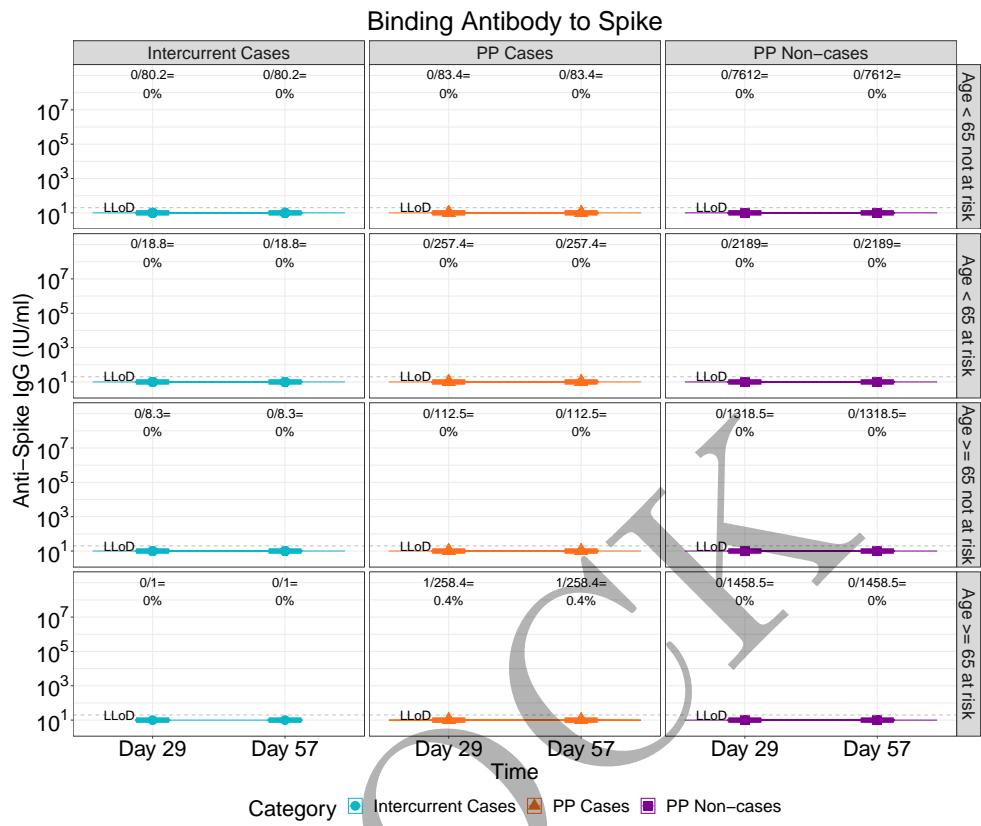


Figure 2.119: lineplots of Binding Antibody to Spike: baseline negative placebo arm by age and risk condition (2 timepoints)

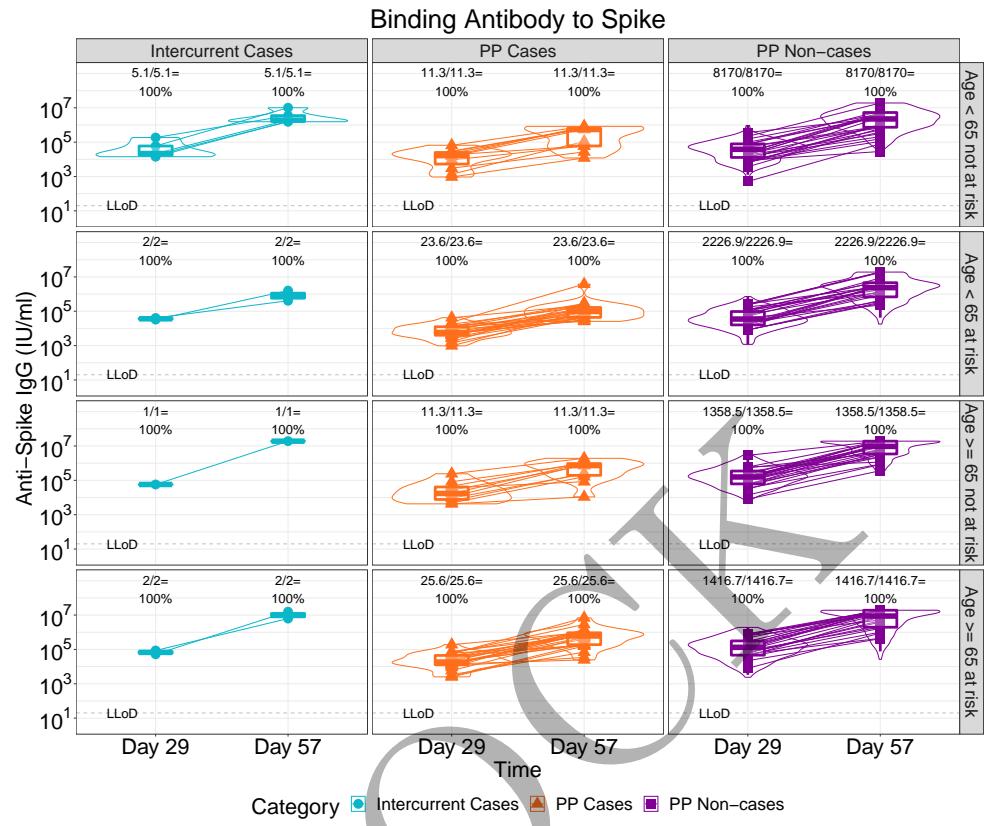


Figure 2.120: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by age and risk condition (2 timepoints)

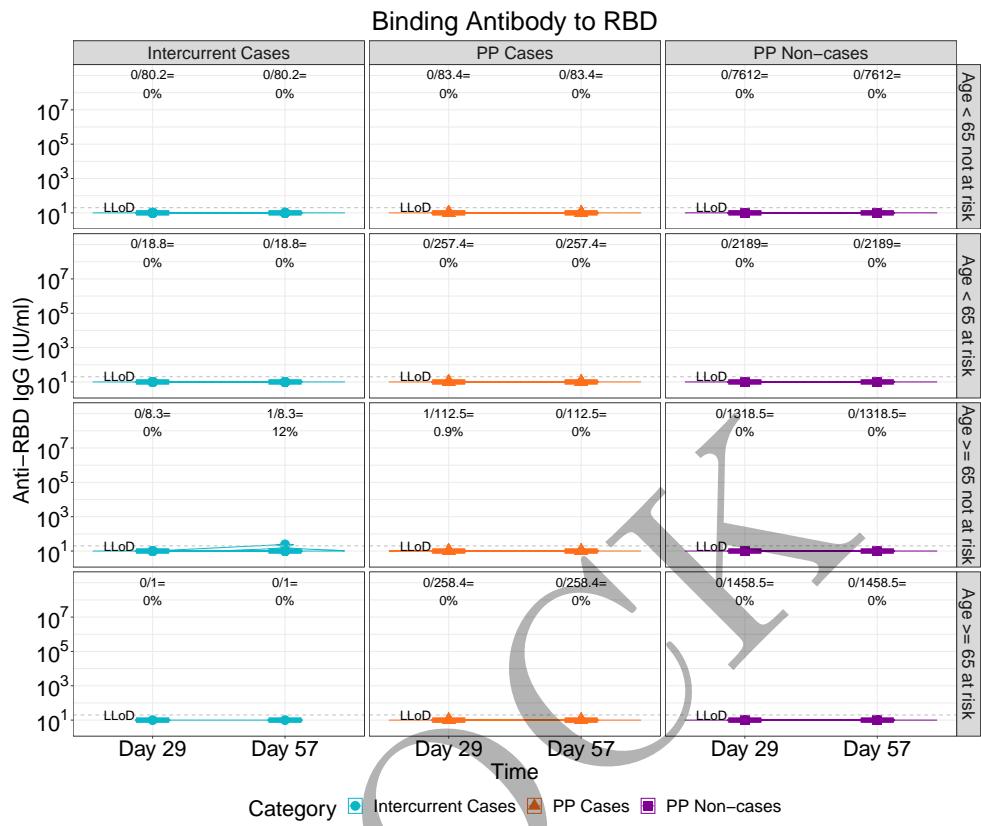


Figure 2.121: lineplots of Binding Antibody to RBD: baseline negative placebo arm by age and risk condition (2 timepoints)

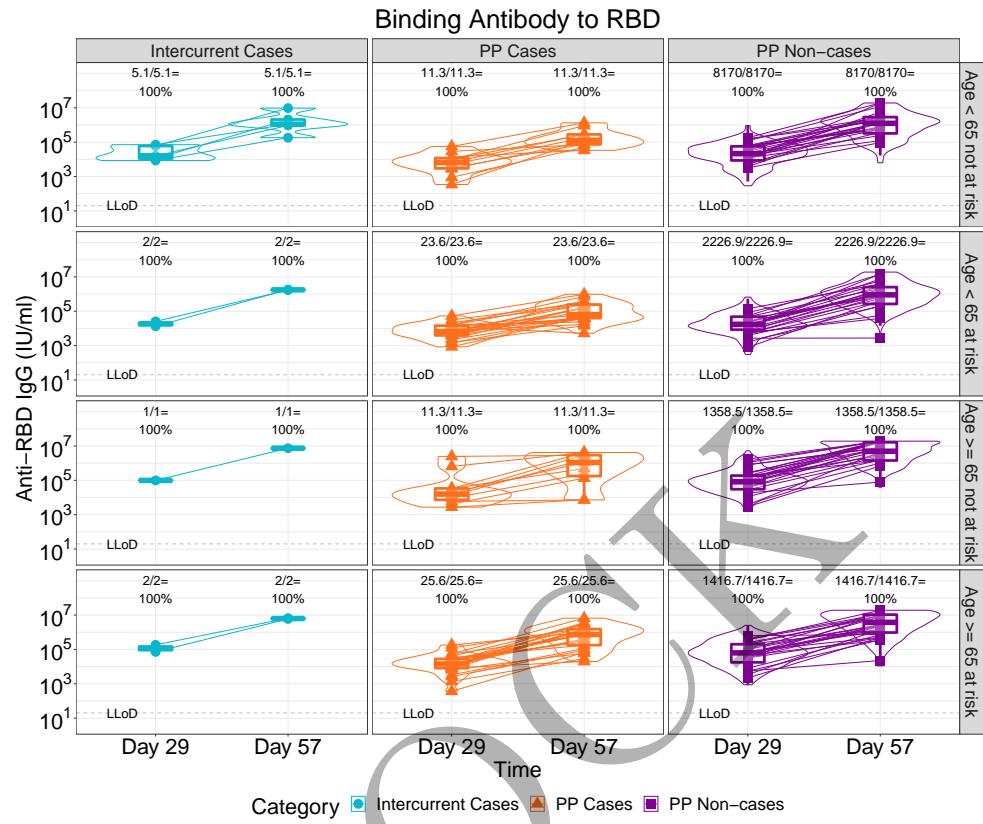


Figure 2.122: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by age and risk condition (2 timepoints)

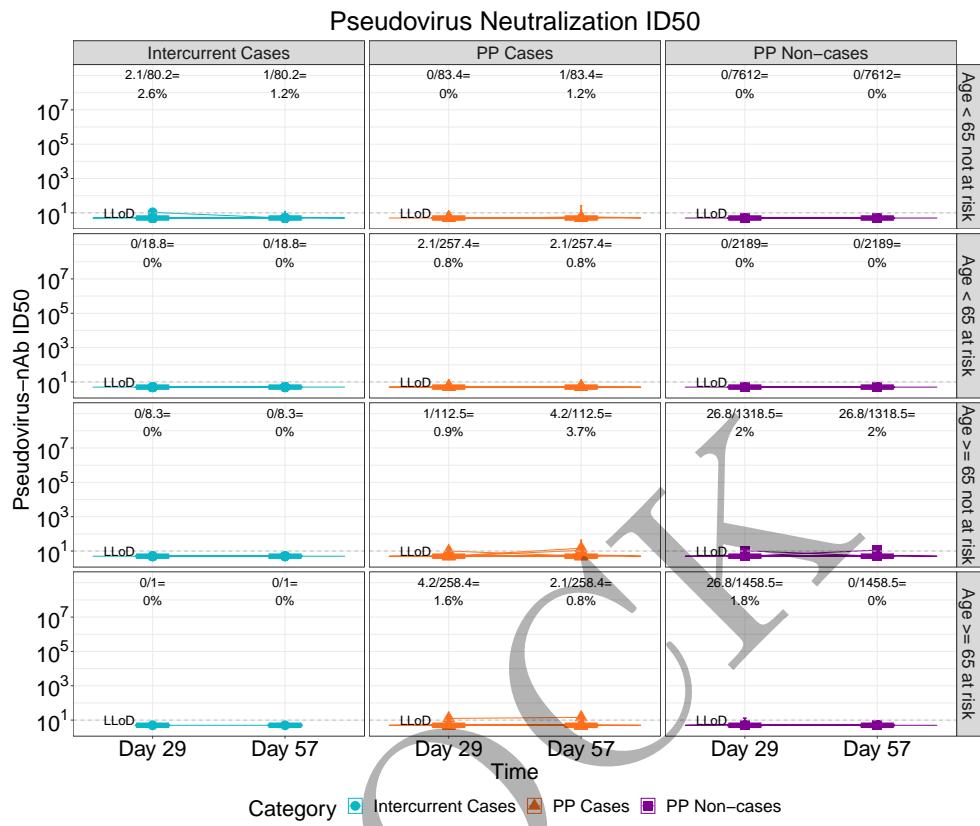


Figure 2.123: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age and risk condition (2 timepoints)

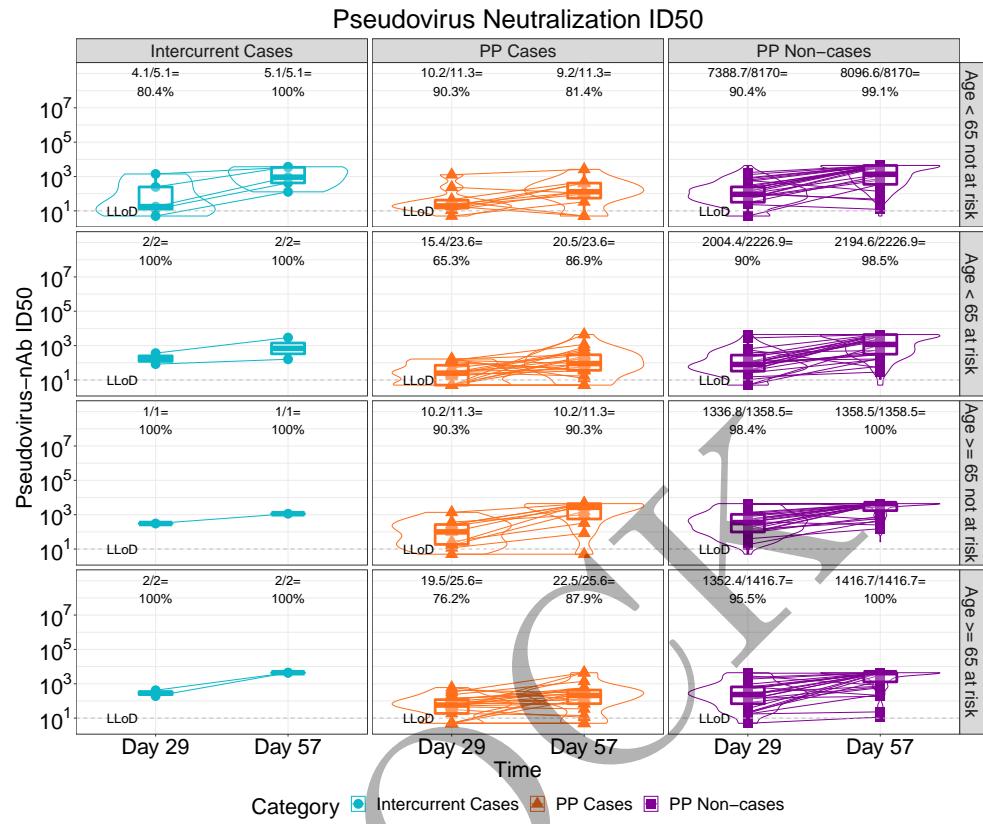


Figure 2.124: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age and risk condition (2 timepoints)

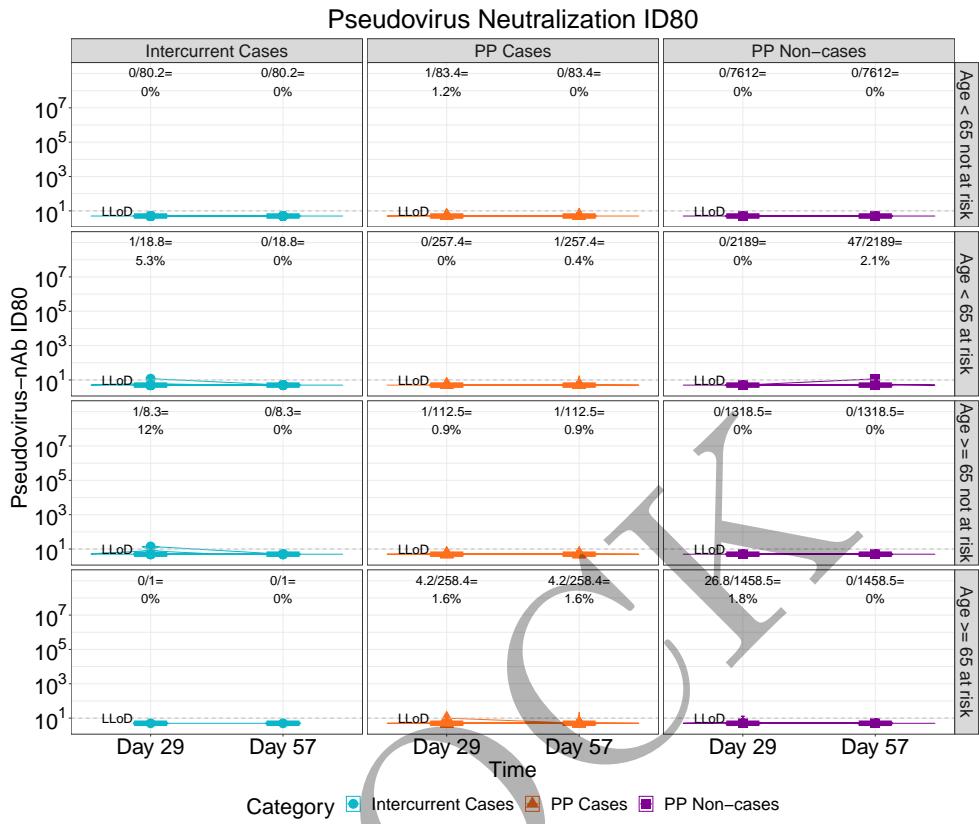


Figure 2.125: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age and risk condition (2 timepoints)

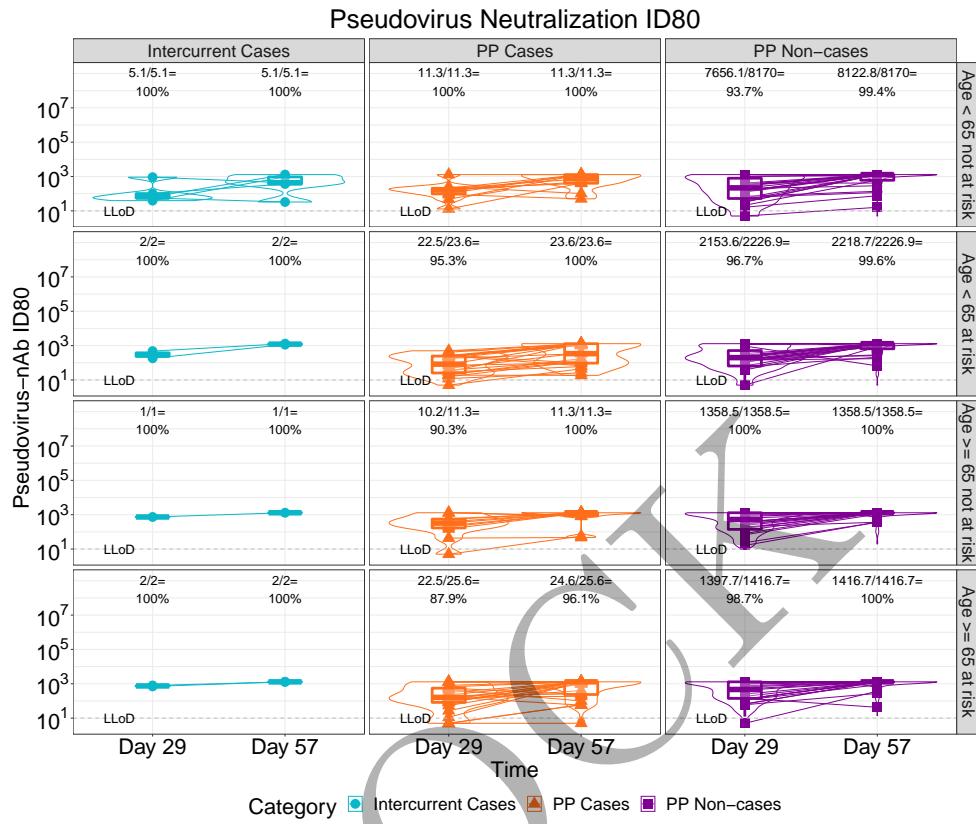


Figure 2.126: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age and risk condition (2 timepoints)

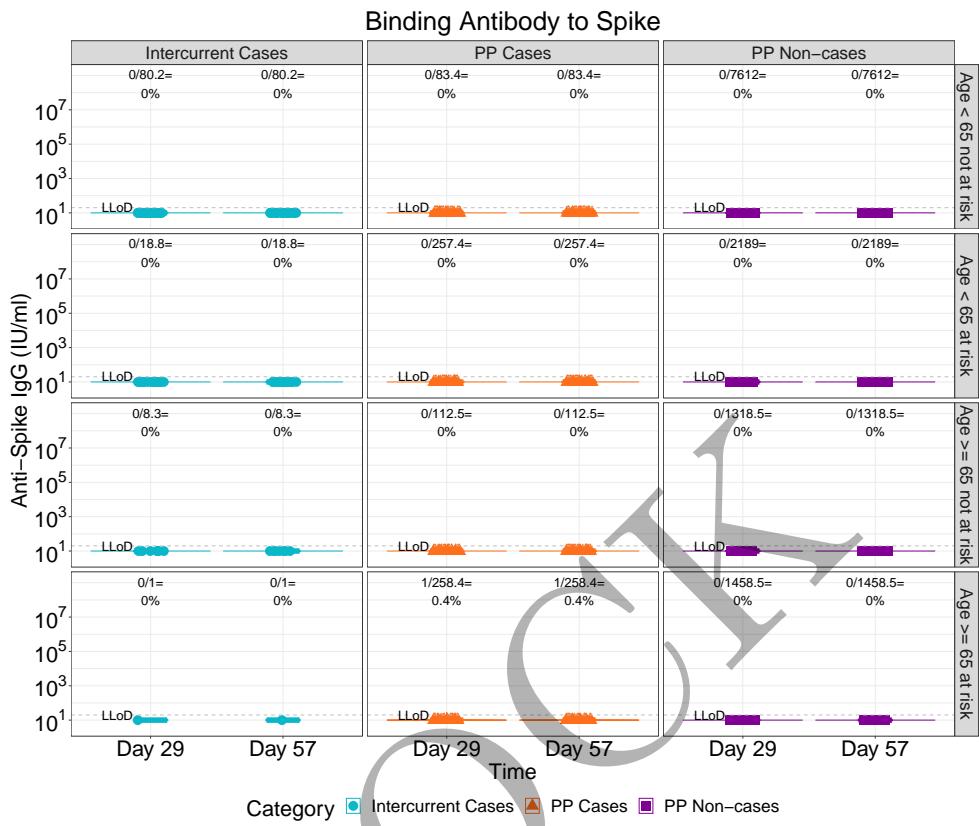


Figure 2.127: violinplots of Binding Antibody to Spike: baseline negative placebo arm by age and risk condition (2 timepoints)

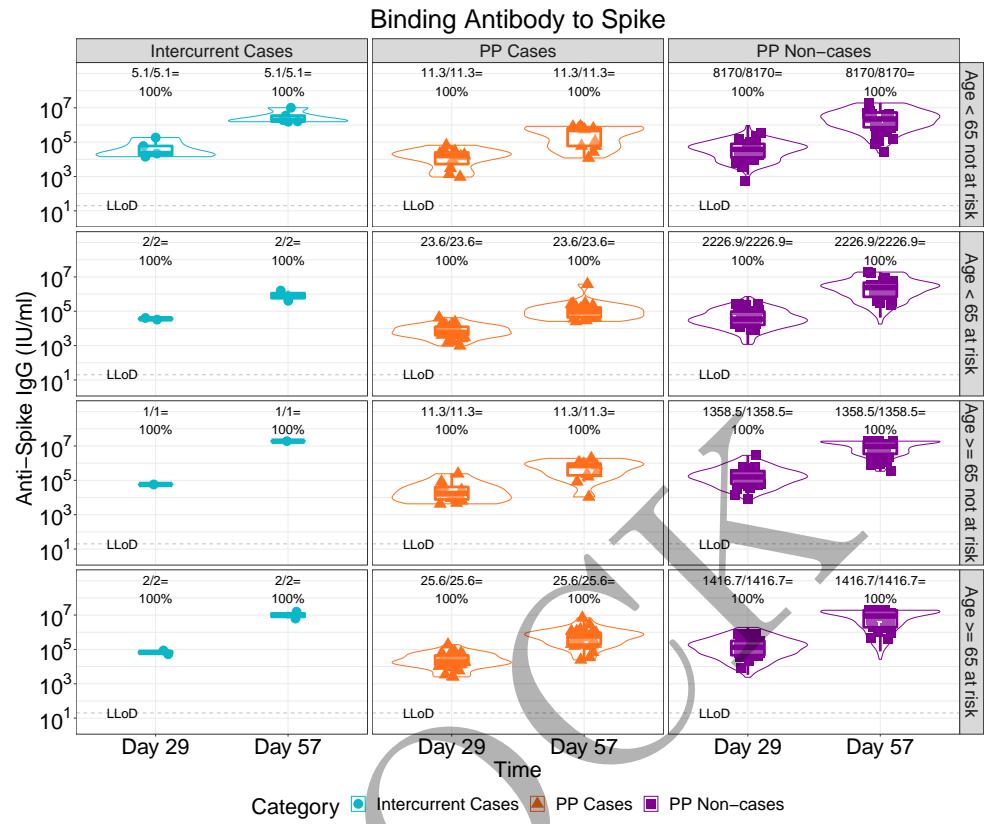


Figure 2.128: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by age and risk condition (2 timepoints)

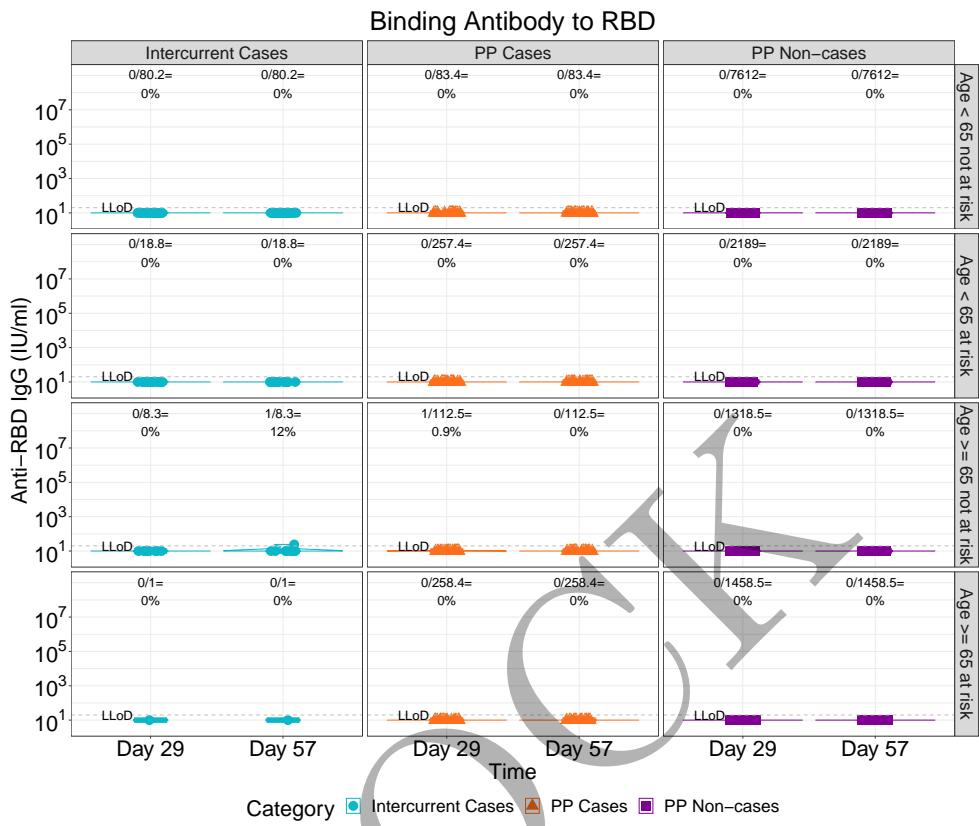


Figure 2.129: violinplots of Binding Antibody to RBD: baseline negative placebo arm by age and risk condition (2 timepoints)

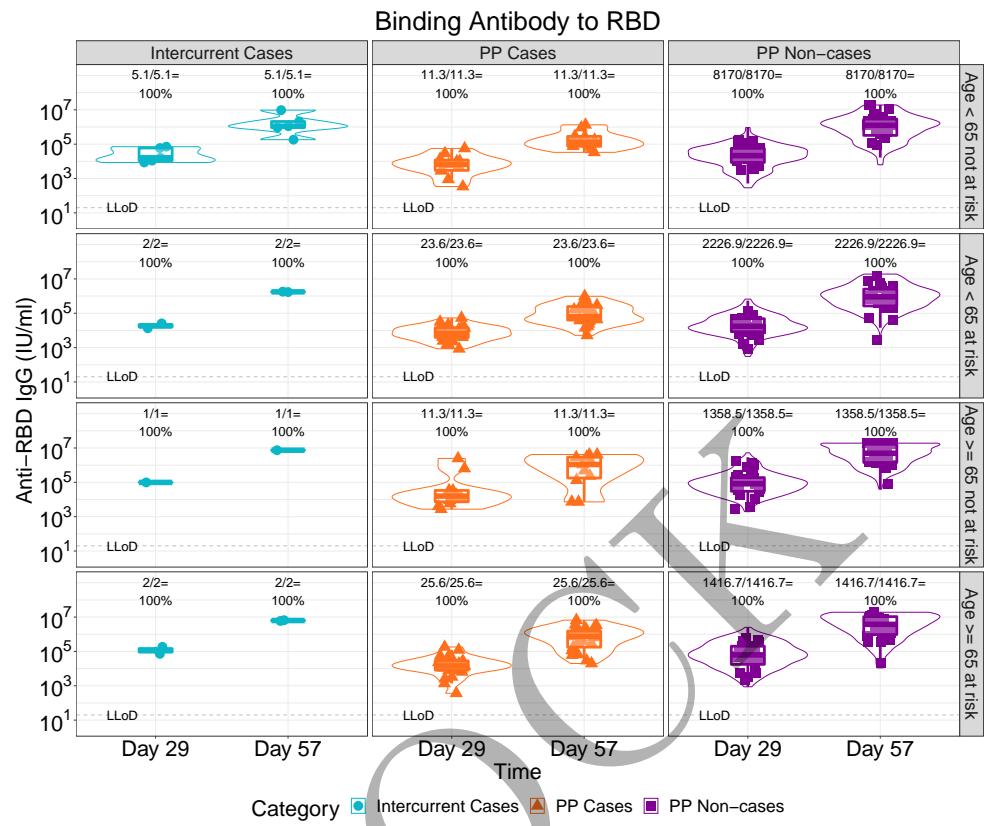


Figure 2.130: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by age and risk condition (2 timepoints)

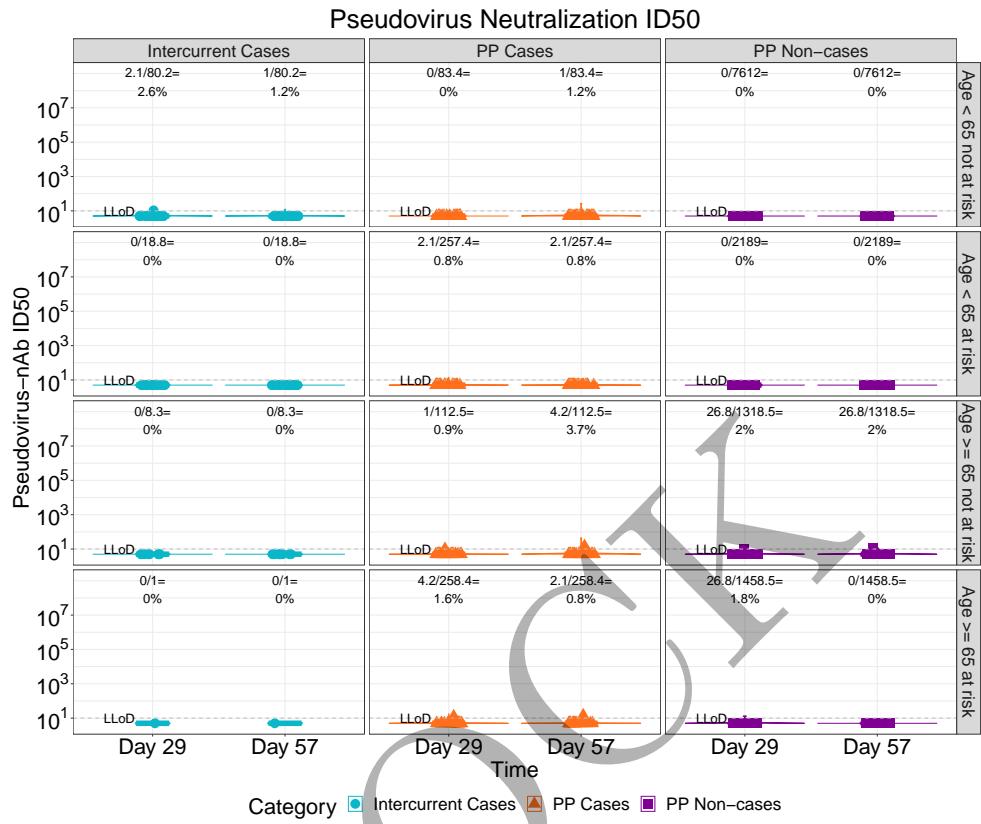


Figure 2.131: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age and risk condition (2 timepoints)

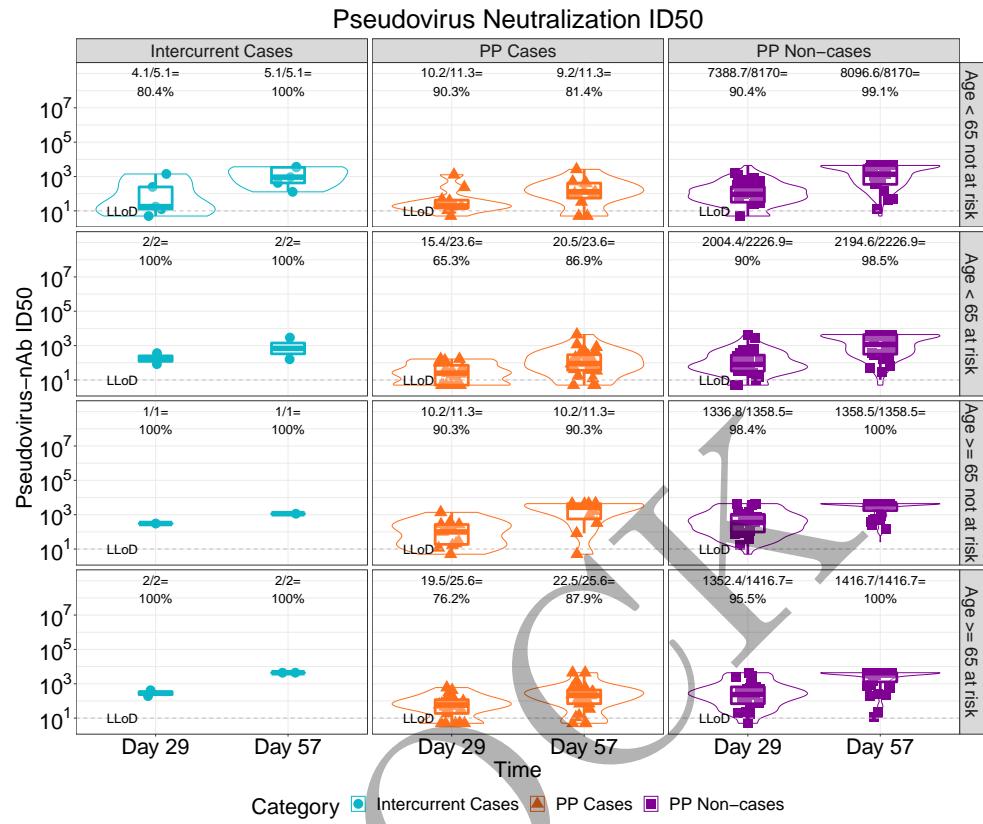


Figure 2.132: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age and risk condition (2 timepoints)

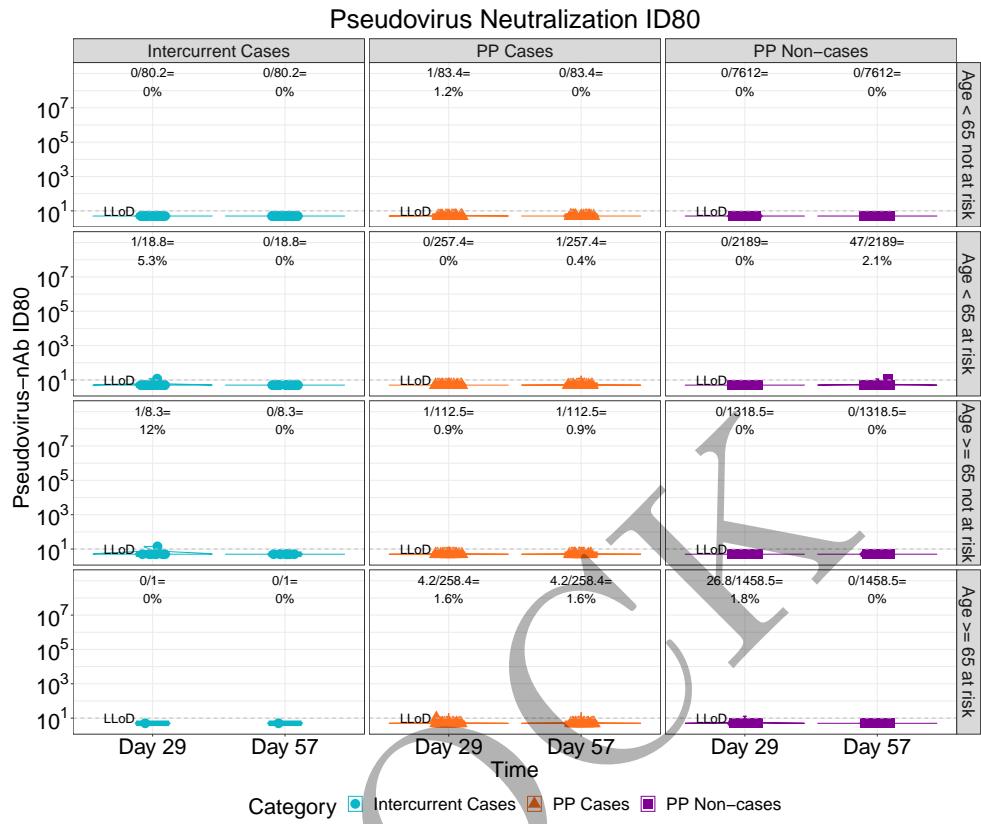


Figure 2.133: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age and risk condition (2 timepoints)

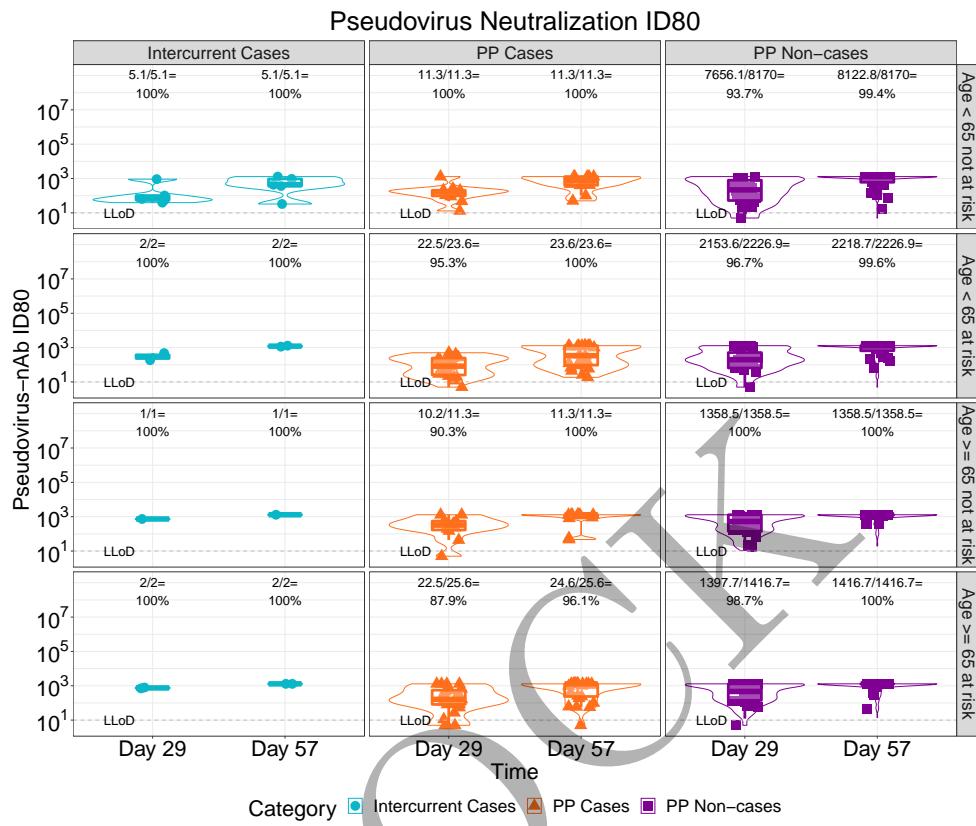


Figure 2.134: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age and risk condition (2 timepoints)

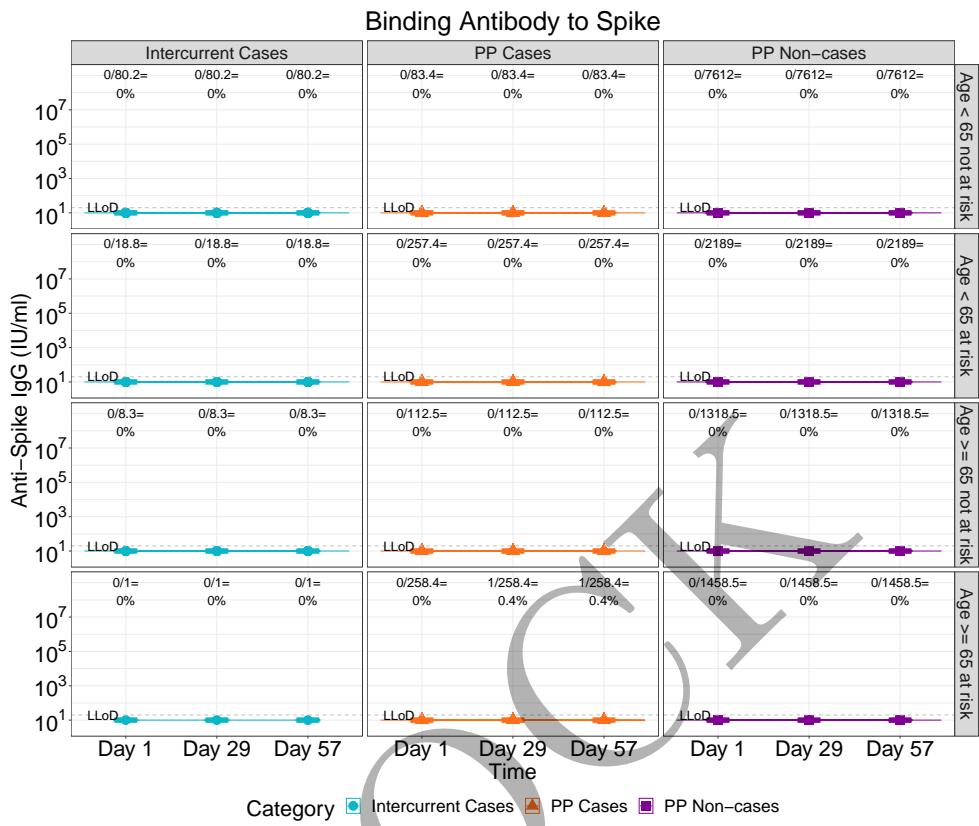


Figure 2.135: lineplots of Binding Antibody to Spike: baseline negative placebo arm by age and risk condition (3 timepoints)

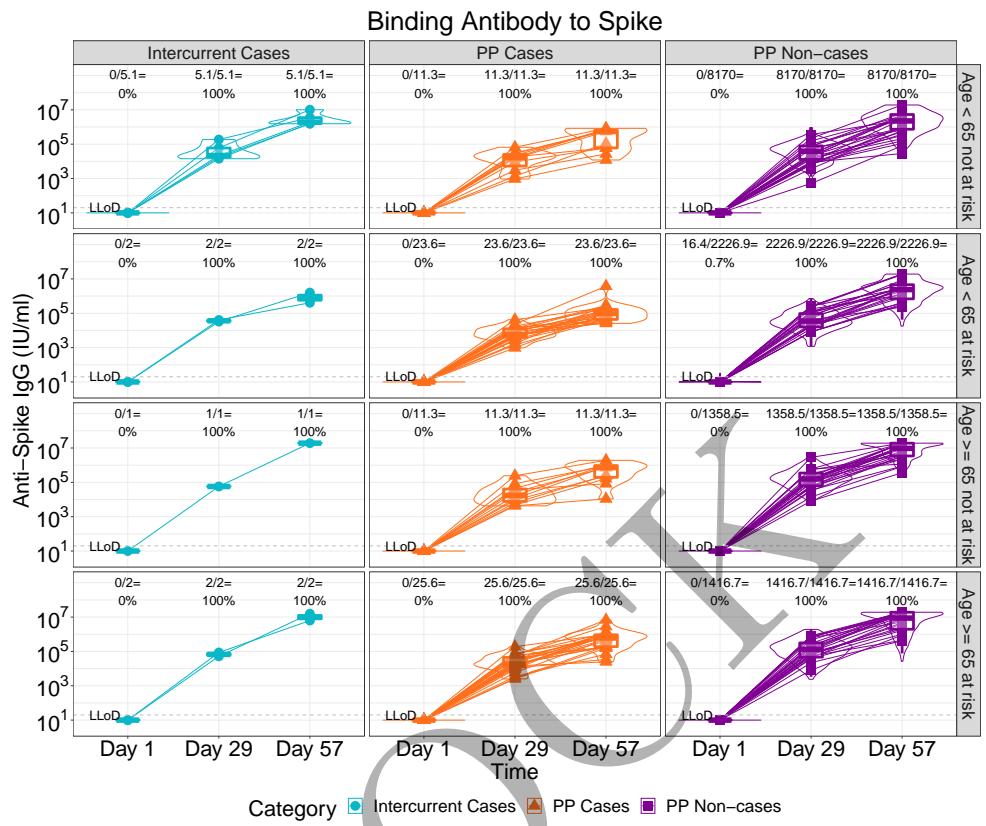


Figure 2.136: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by age and risk condition (3 timepoints)

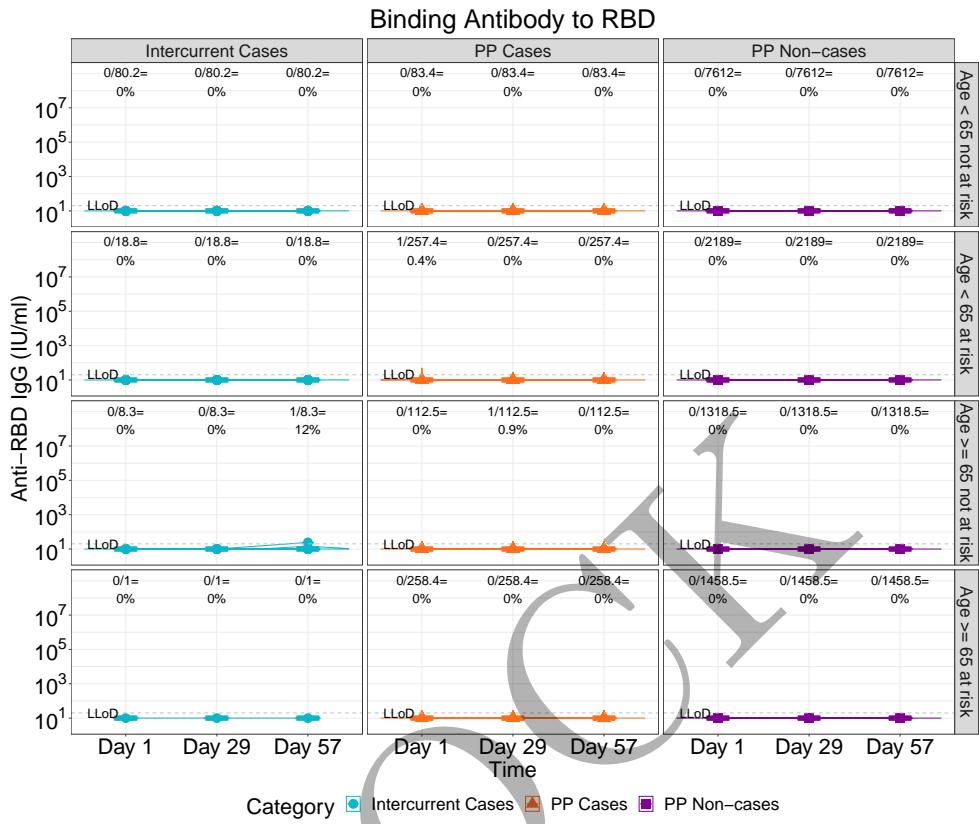


Figure 2.137: lineplots of Binding Antibody to RBD: baseline negative placebo arm by age and risk condition (3 timepoints)

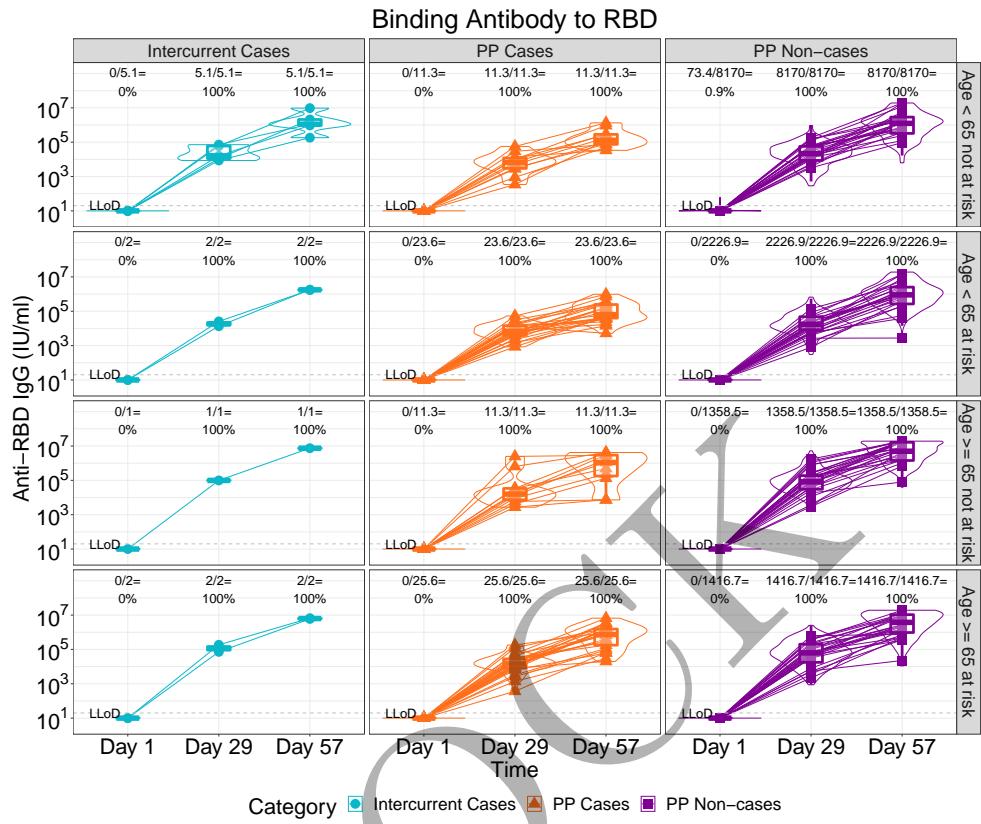


Figure 2.138: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by age and risk condition (3 timepoints)

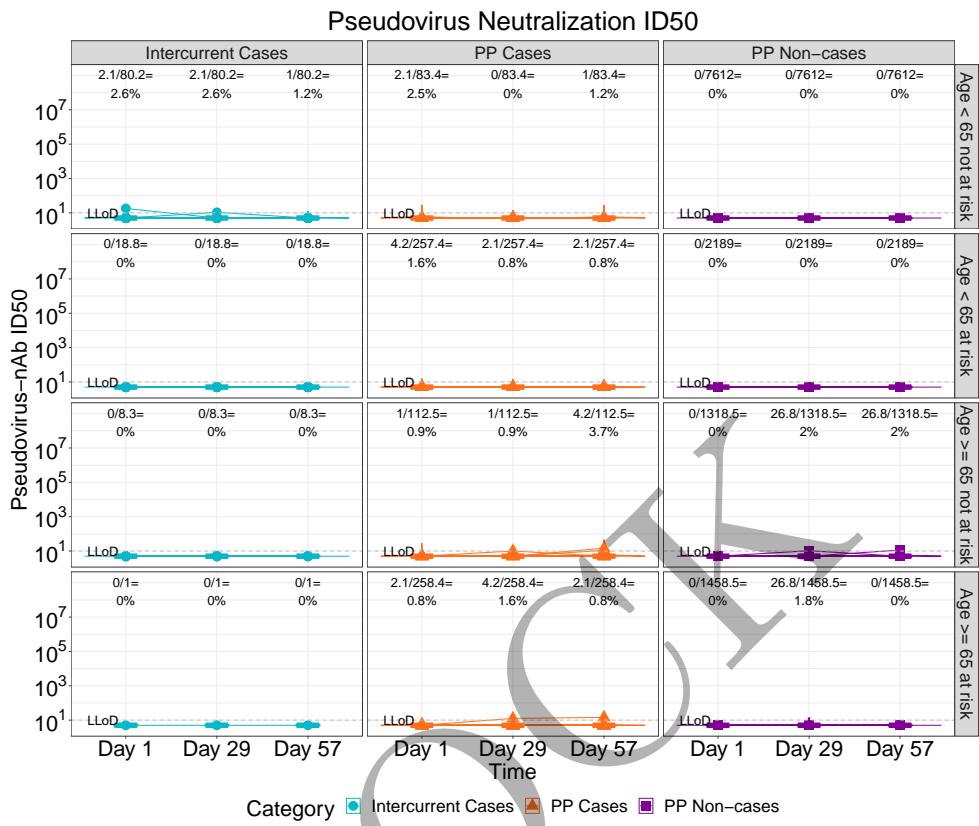


Figure 2.139: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age and risk condition (3 timepoints)

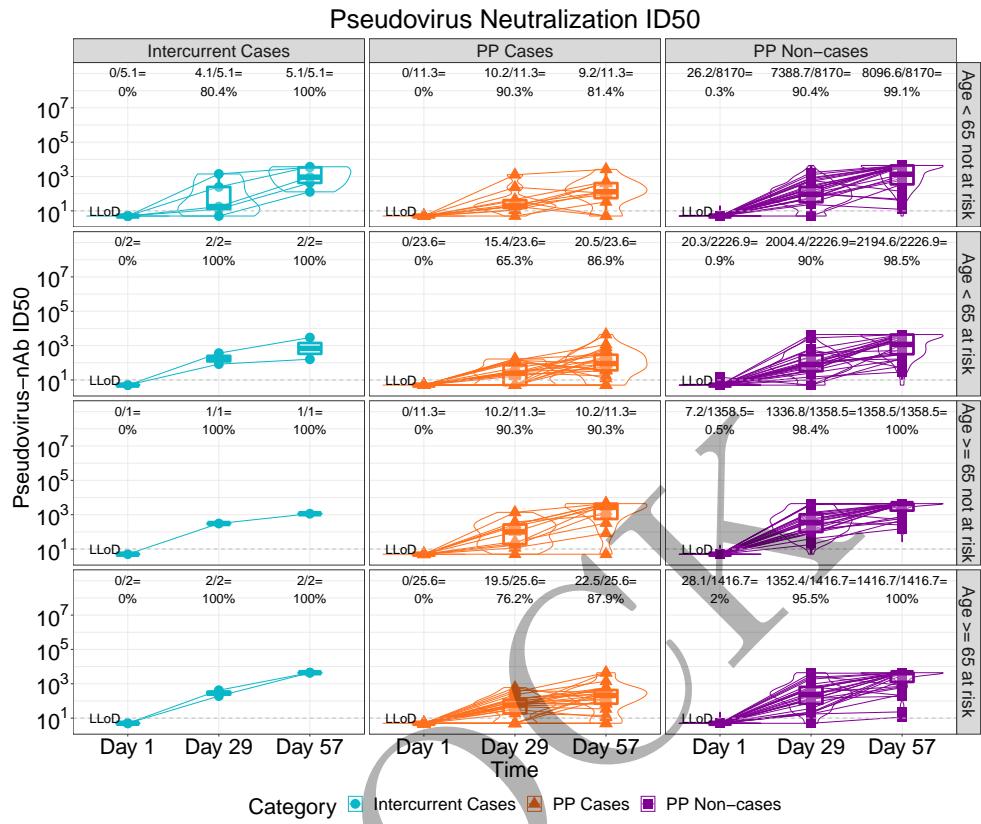


Figure 2.140: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age and risk condition (3 timepoints)

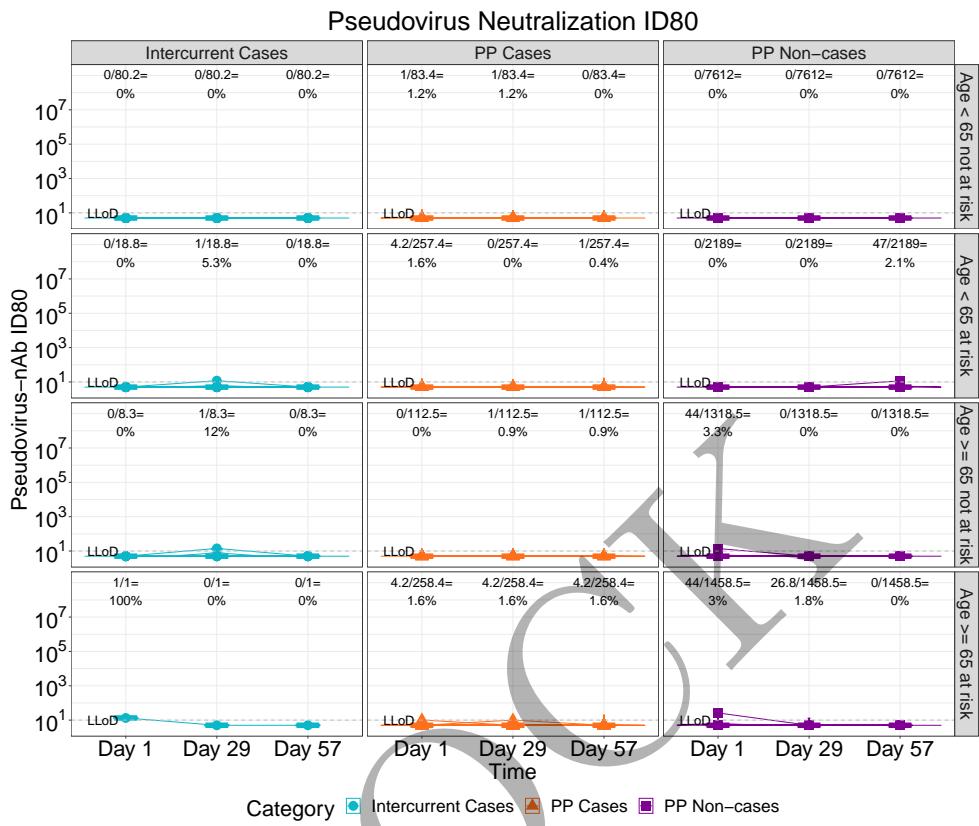


Figure 2.141: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age and risk condition (3 timepoints)

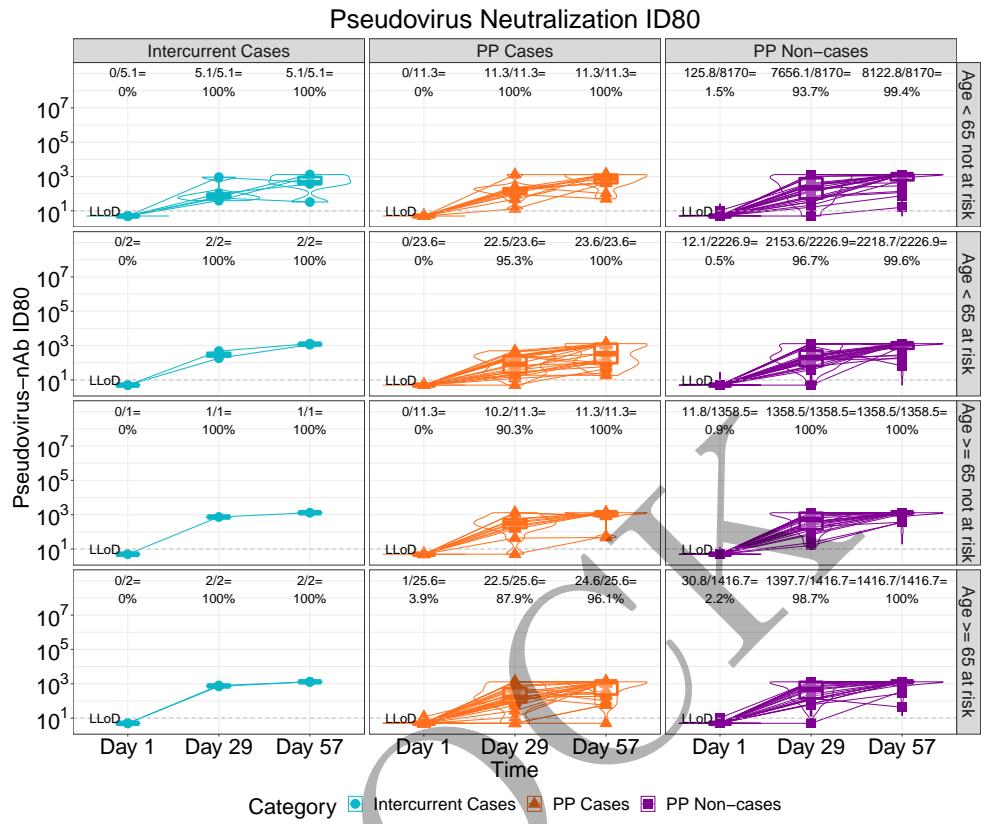


Figure 2.142: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age and risk condition (3 timepoints)

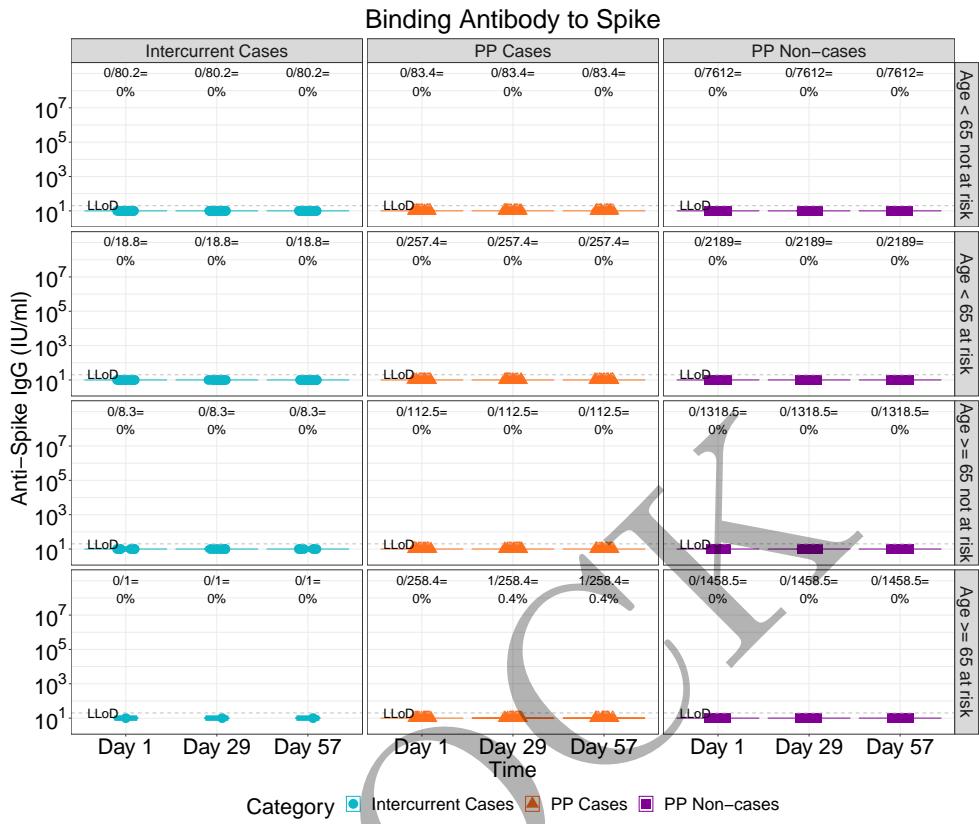


Figure 2.143: violinplots of Binding Antibody to Spike: baseline negative placebo arm by age and risk condition (3 timepoints)

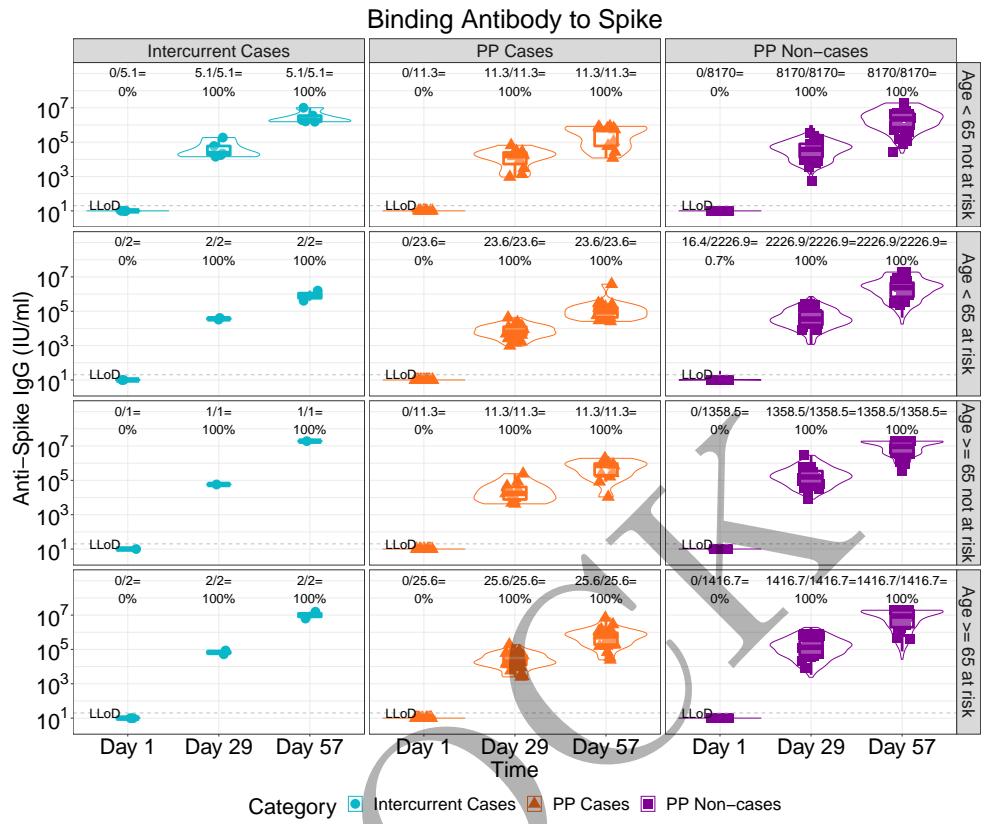


Figure 2.144: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by age and risk condition (3 timepoints)

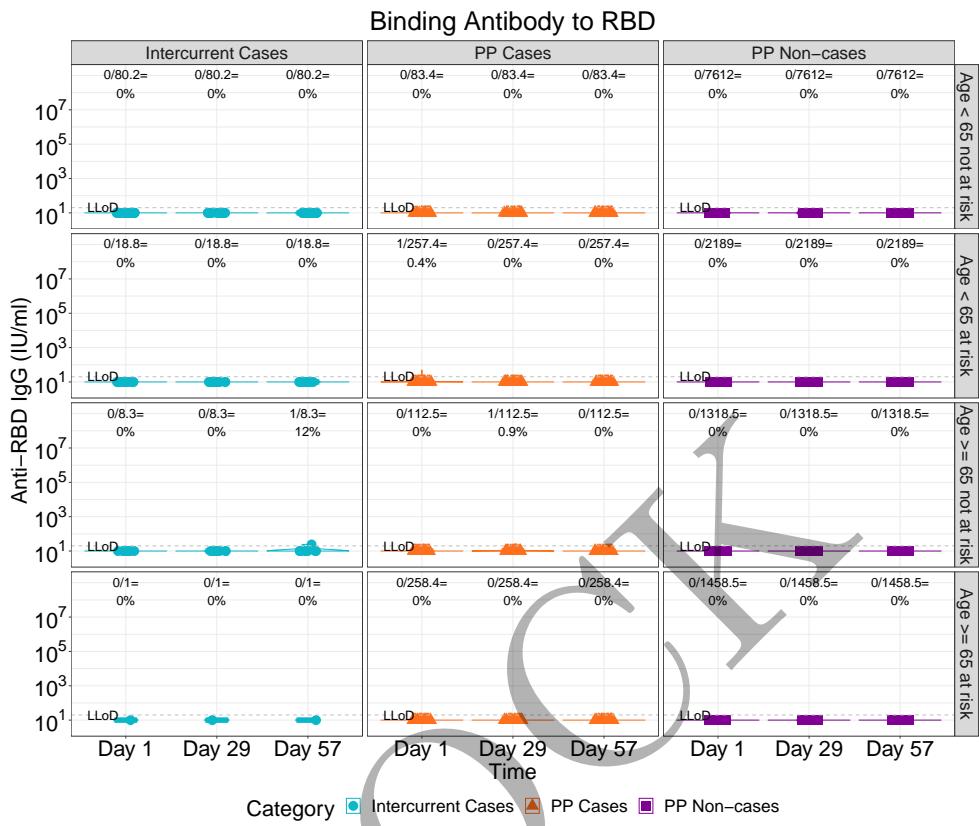


Figure 2.145: violinplots of Binding Antibody to RBD: baseline negative placebo arm by age and risk condition (3 timepoints)

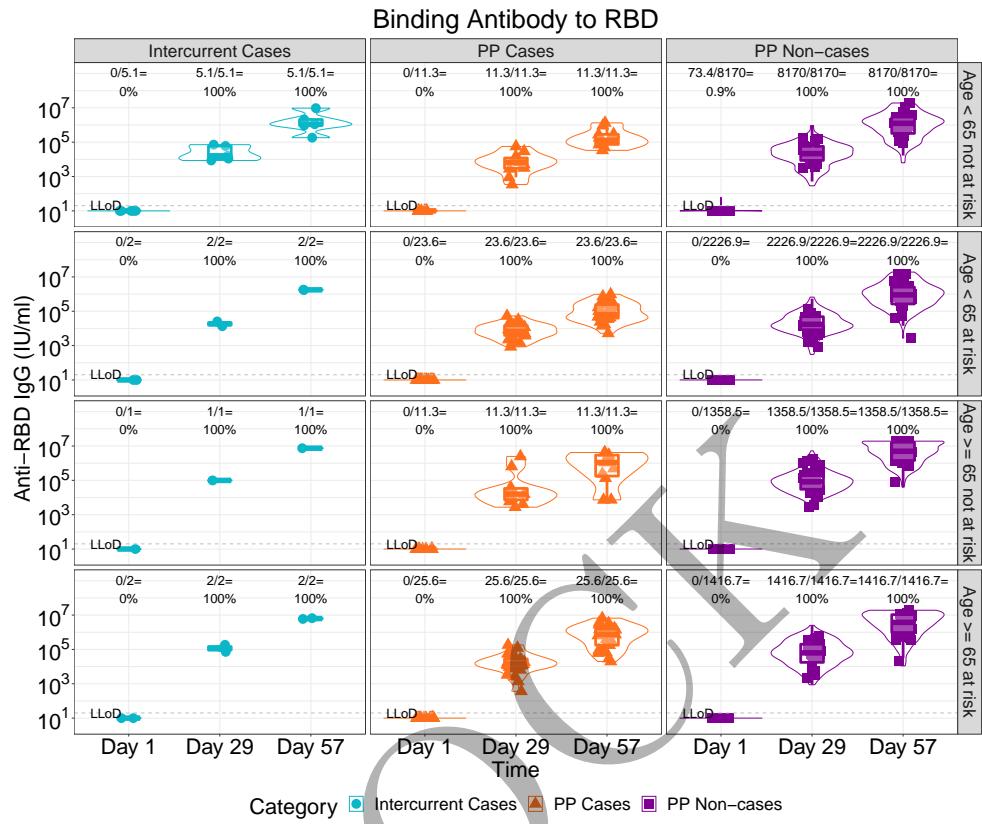


Figure 2.146: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by age and risk condition (3 timepoints)

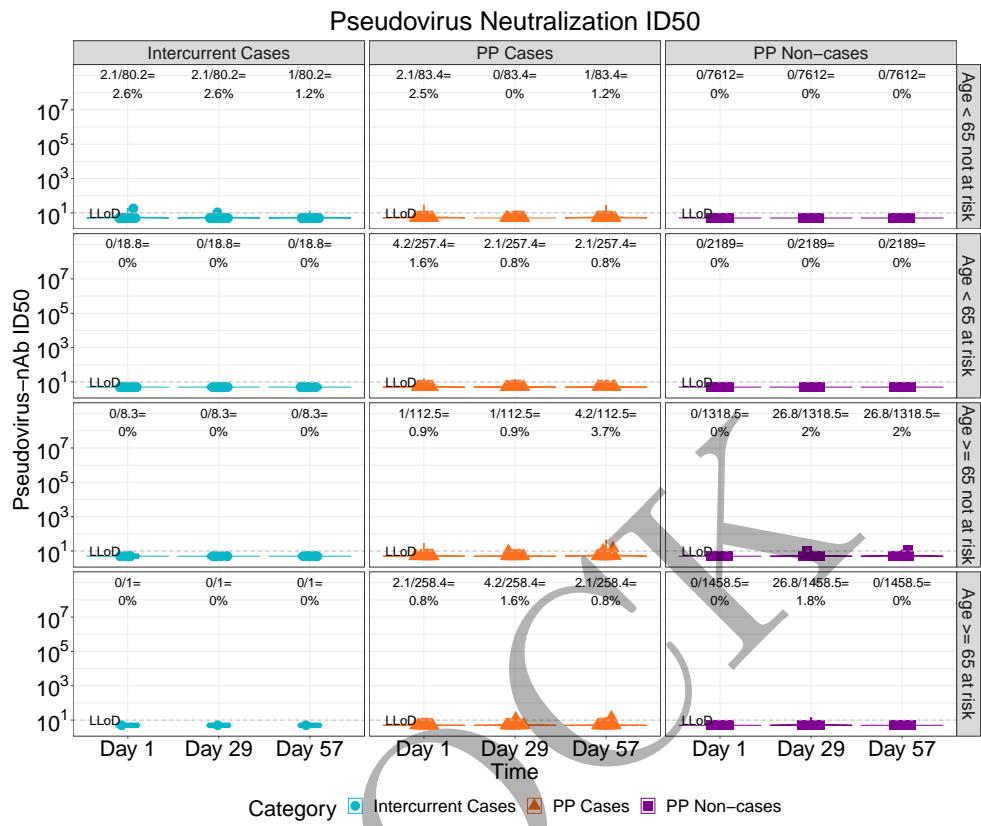


Figure 2.147: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age and risk condition (3 timepoints)

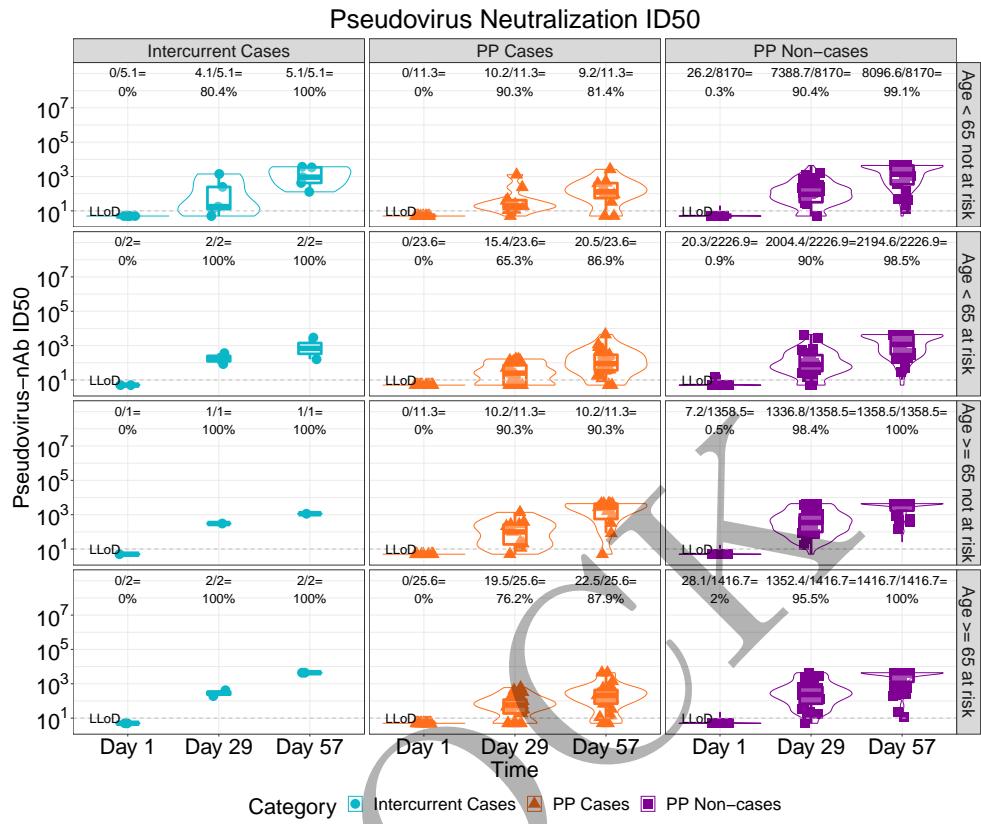


Figure 2.148: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age and risk condition (3 timepoints)

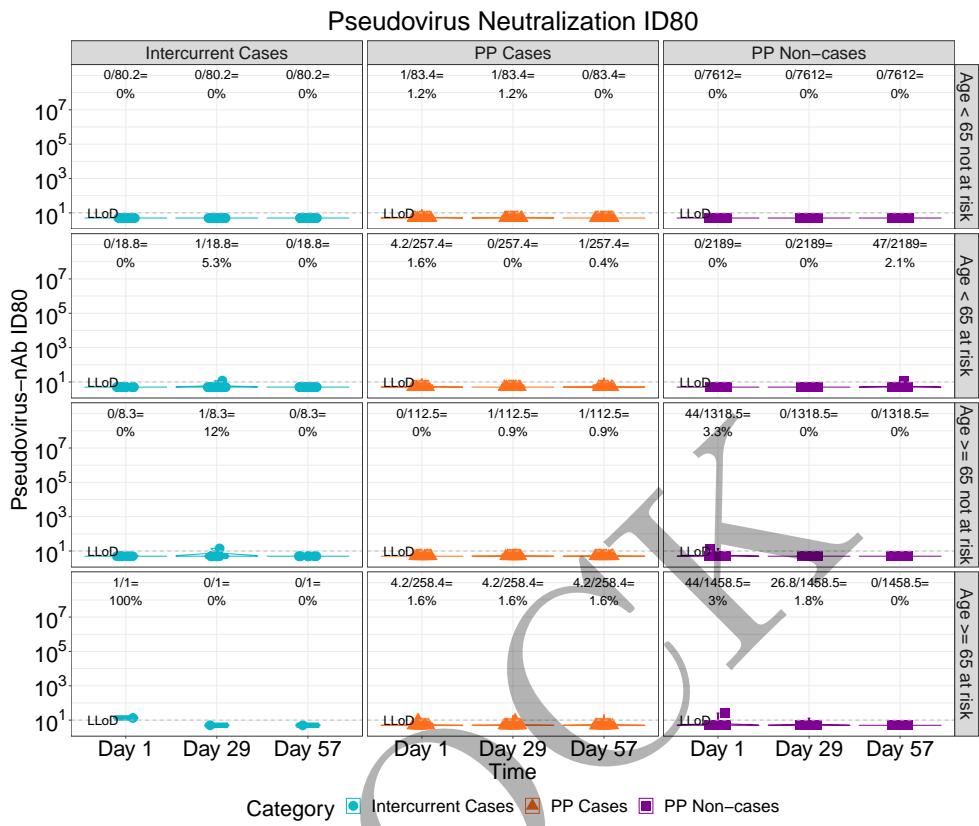


Figure 2.149: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age and risk condition (3 timepoints)

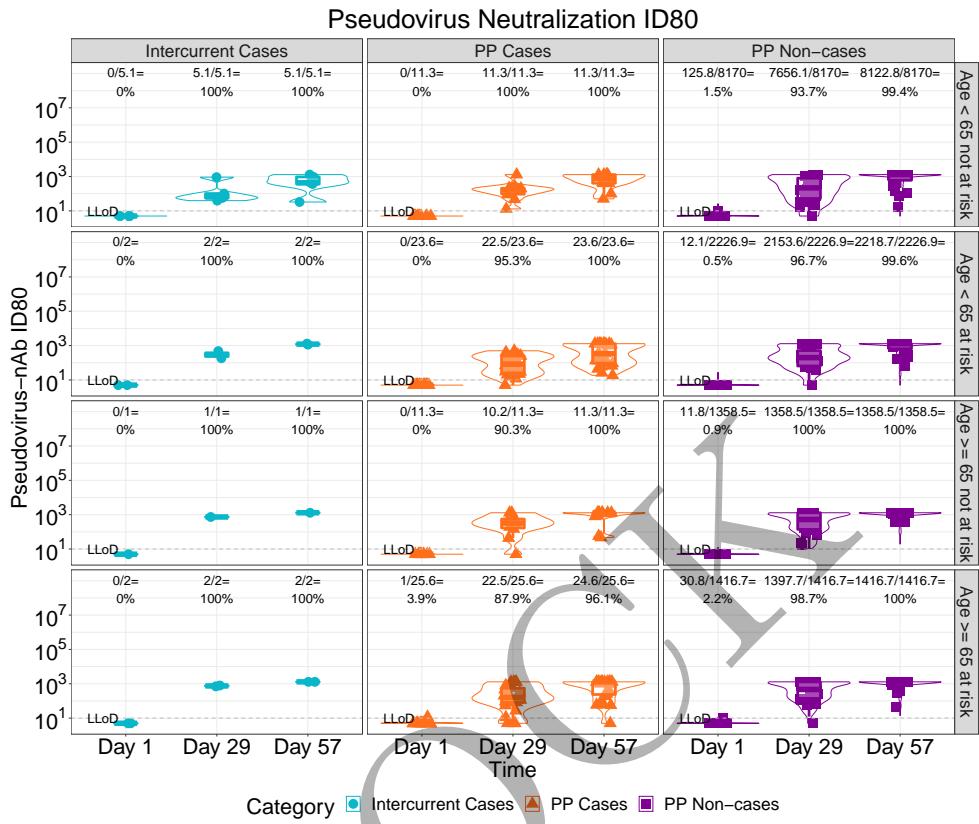


Figure 2.150: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age and risk condition (3 timepoints)

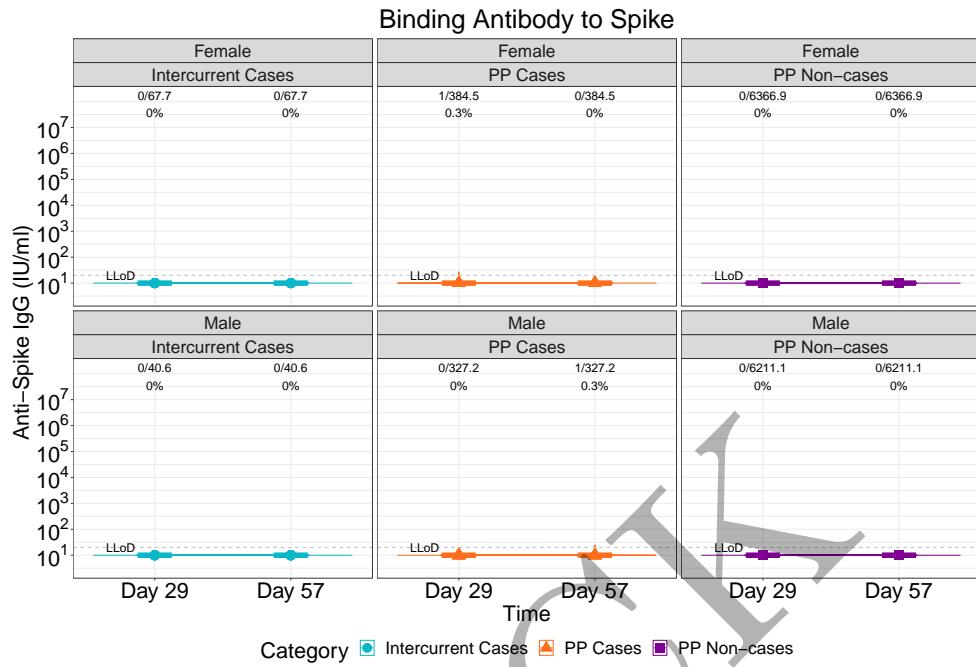


Figure 2.151: lineplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (2 timepoints)

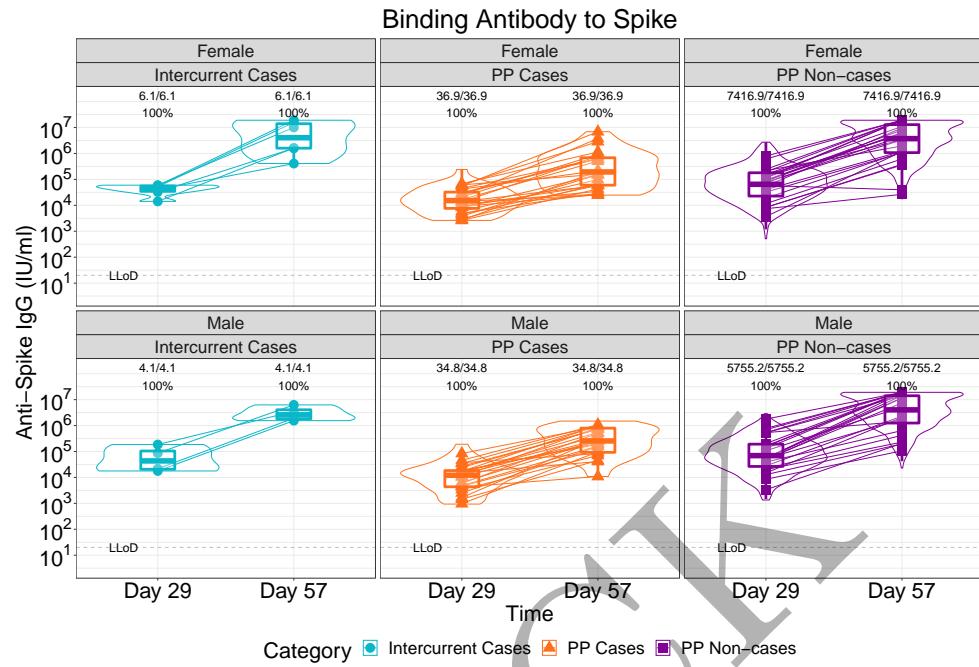


Figure 2.152: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (2 timepoints)

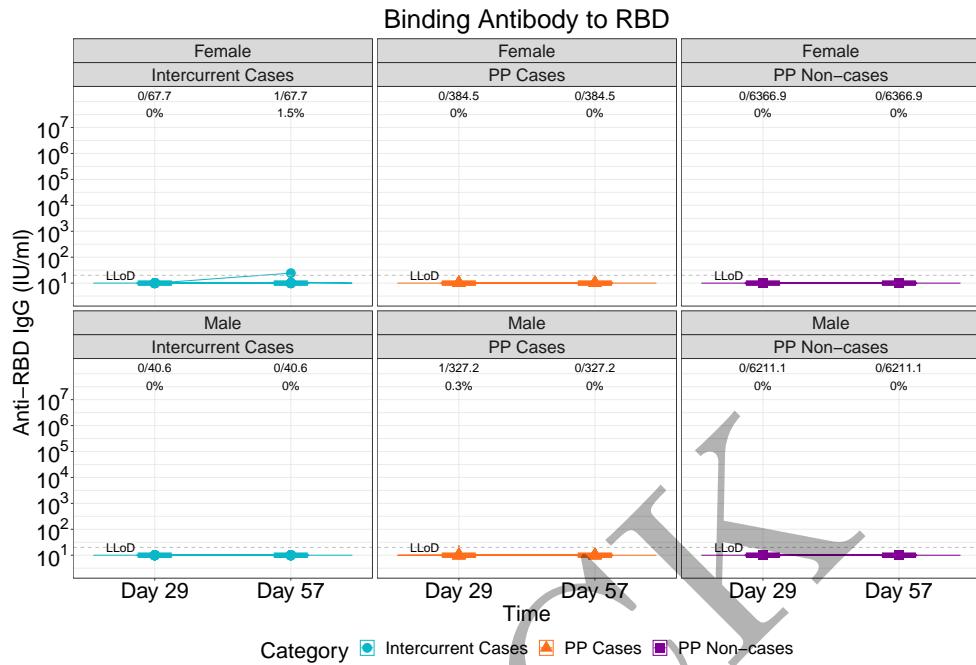


Figure 2.153: lineplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (2 timepoints)

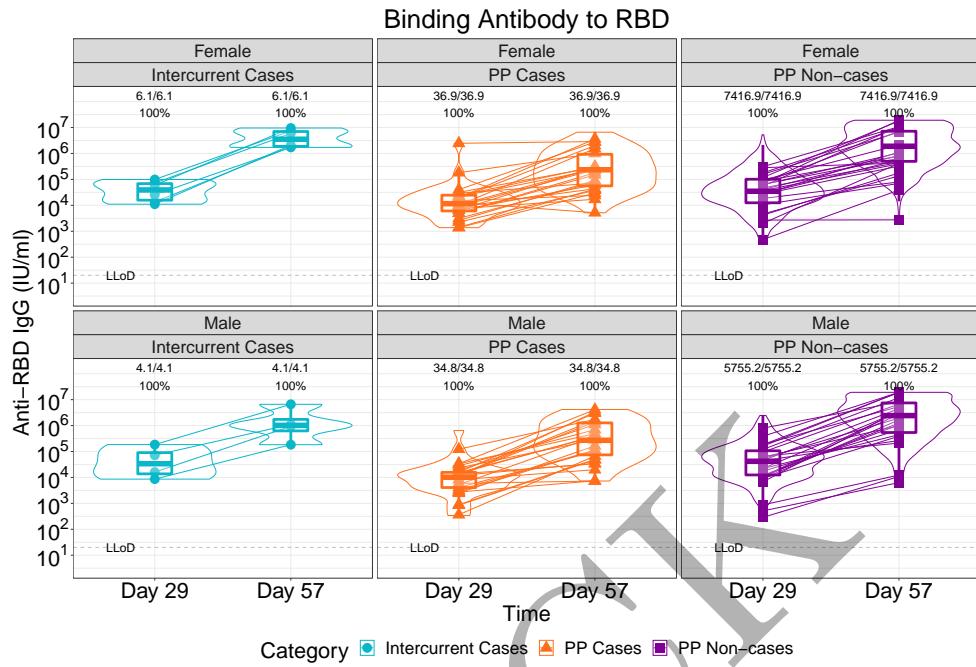


Figure 2.154: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (2 timepoints)

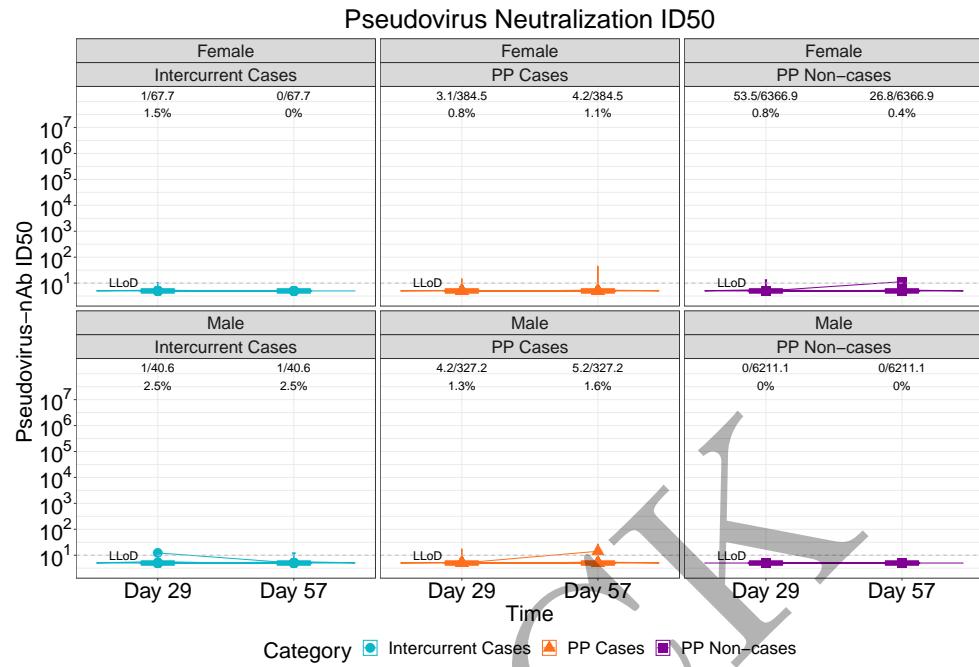


Figure 2.155: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by sex assigned at birth (2 timepoints)

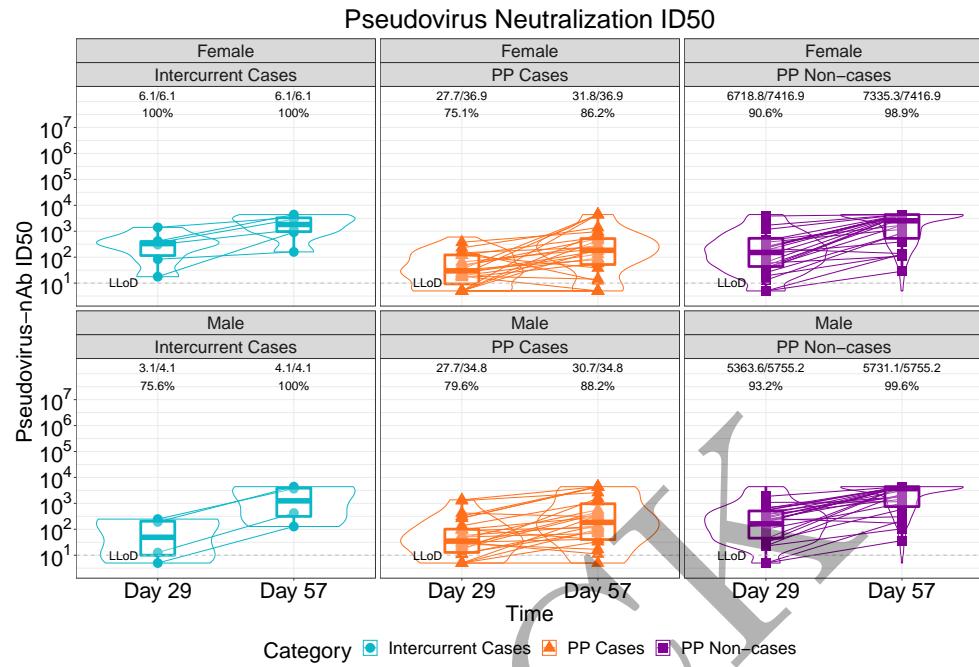


Figure 2.156: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by sex assigned at birth (2 timepoints)

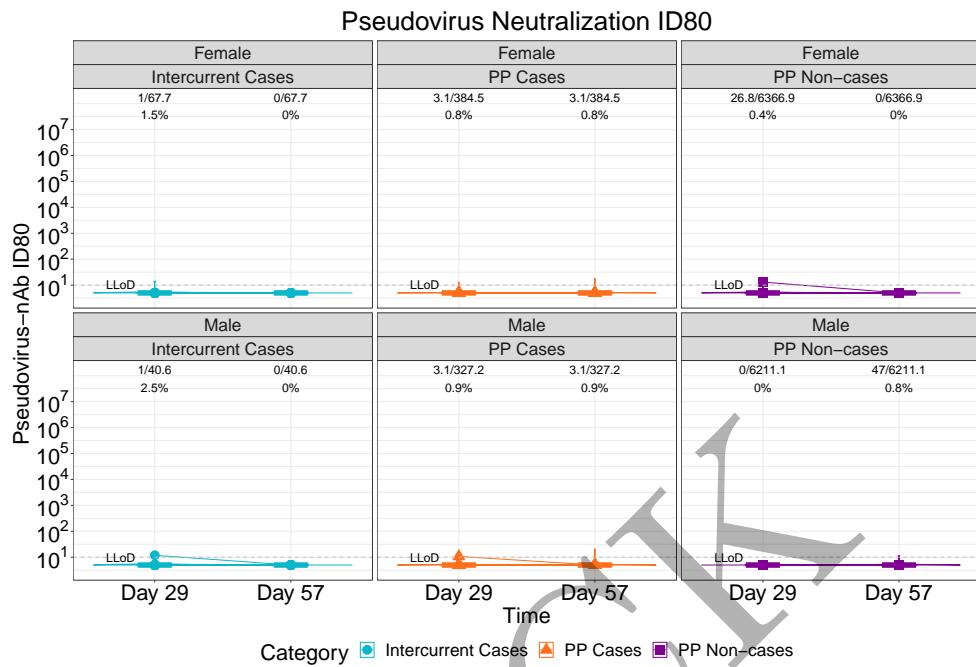


Figure 2.157: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by sex assigned at birth (2 timepoints)

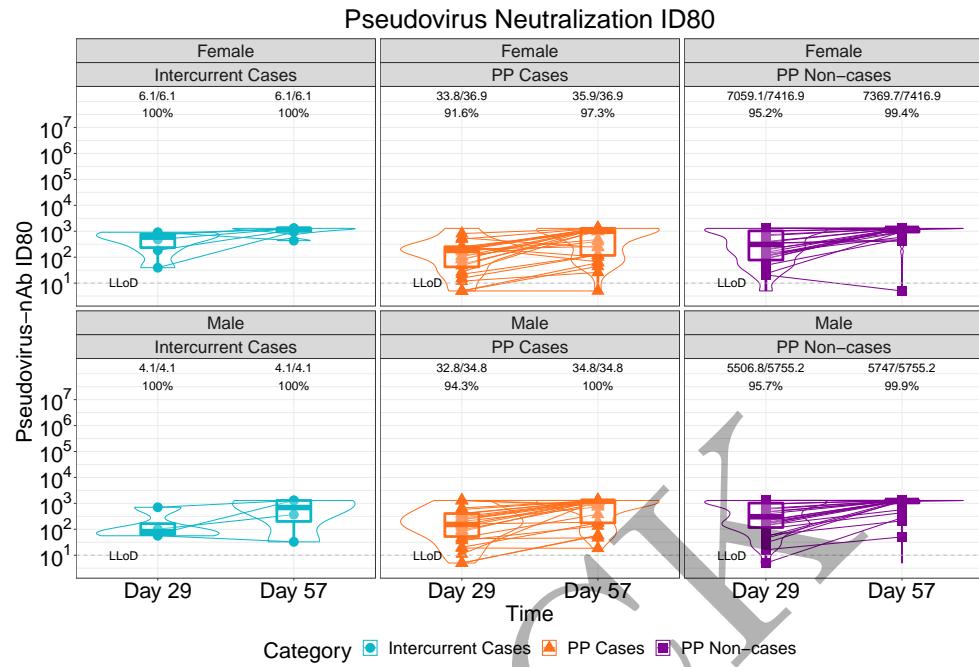


Figure 2.158: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by sex assigned at birth (2 timepoints)

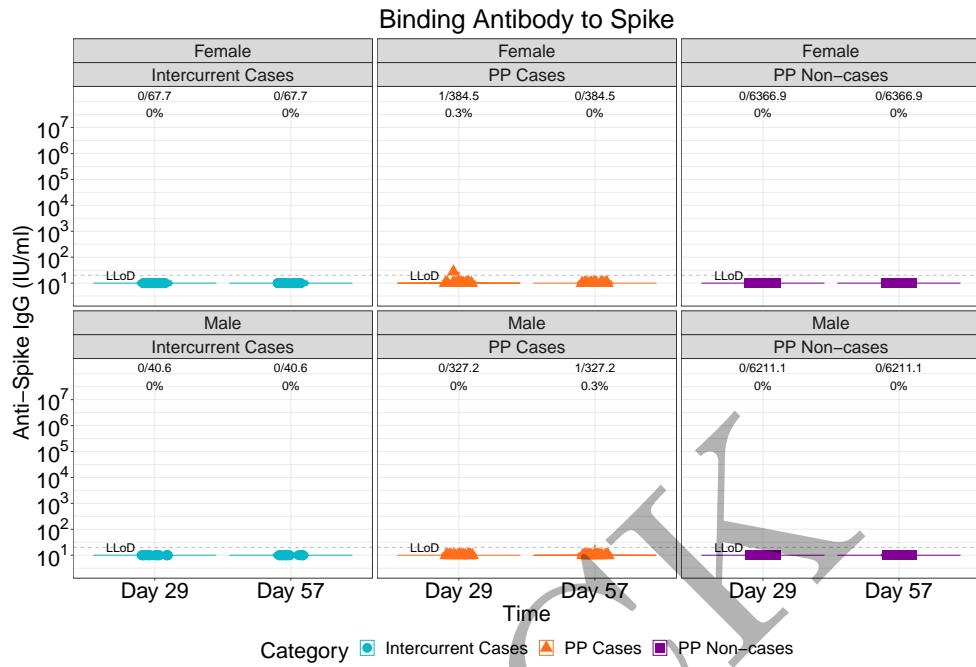


Figure 2.159: violinplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (2 timepoints)

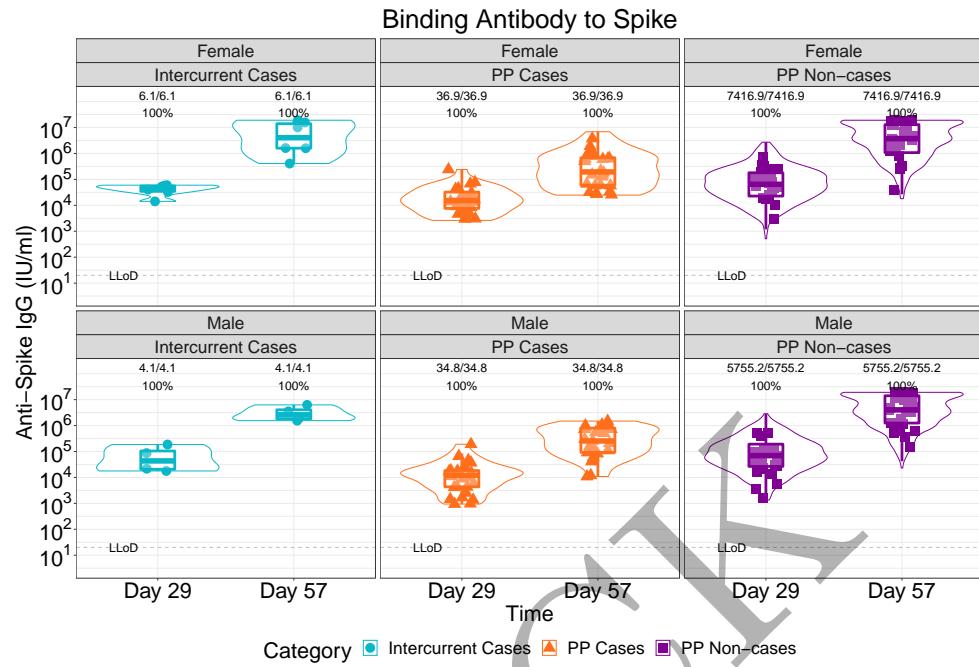


Figure 2.160: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (2 timepoints)

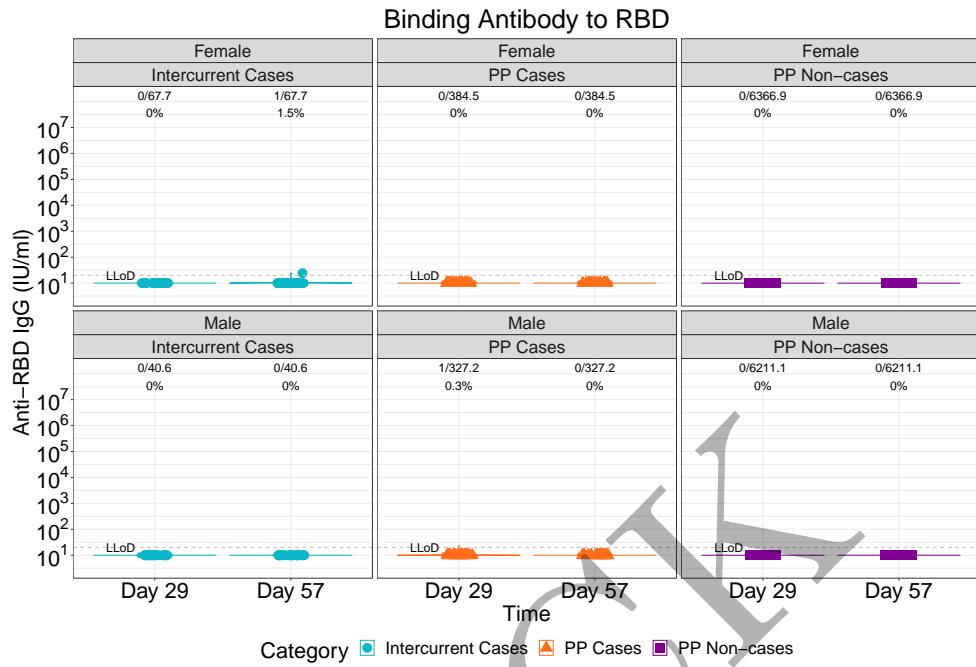


Figure 2.161: violinplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (2 timepoints)

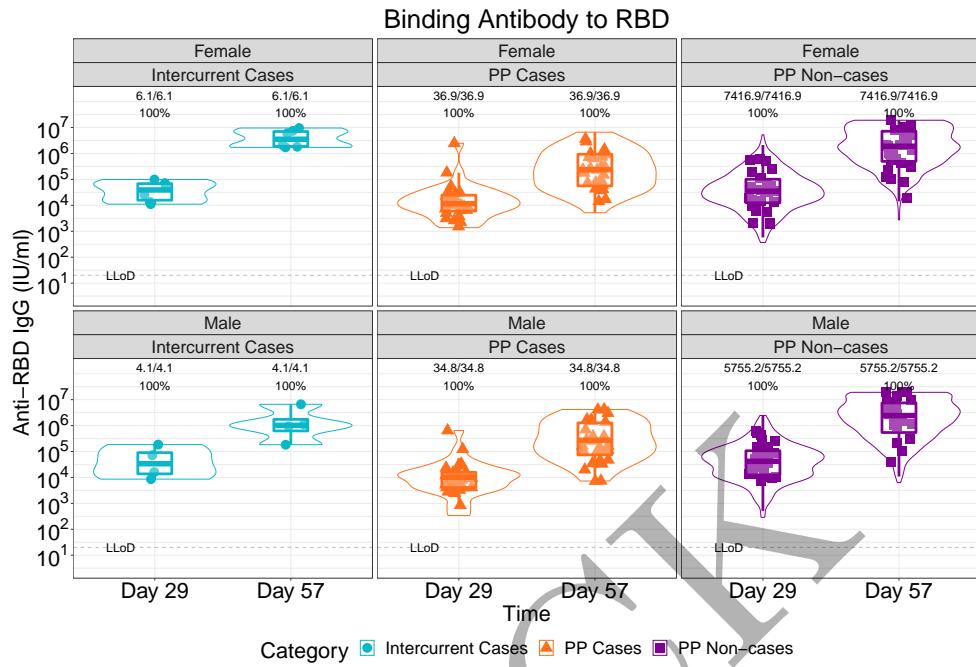


Figure 2.162: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (2 timepoints)

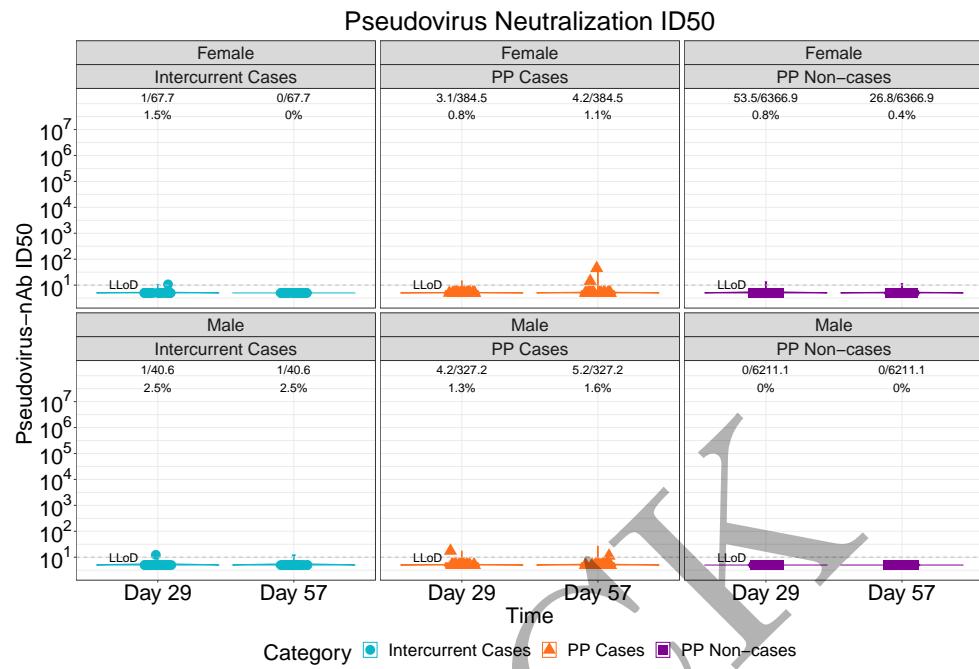


Figure 2.163: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by sex assigned at birth (2 timepoints)

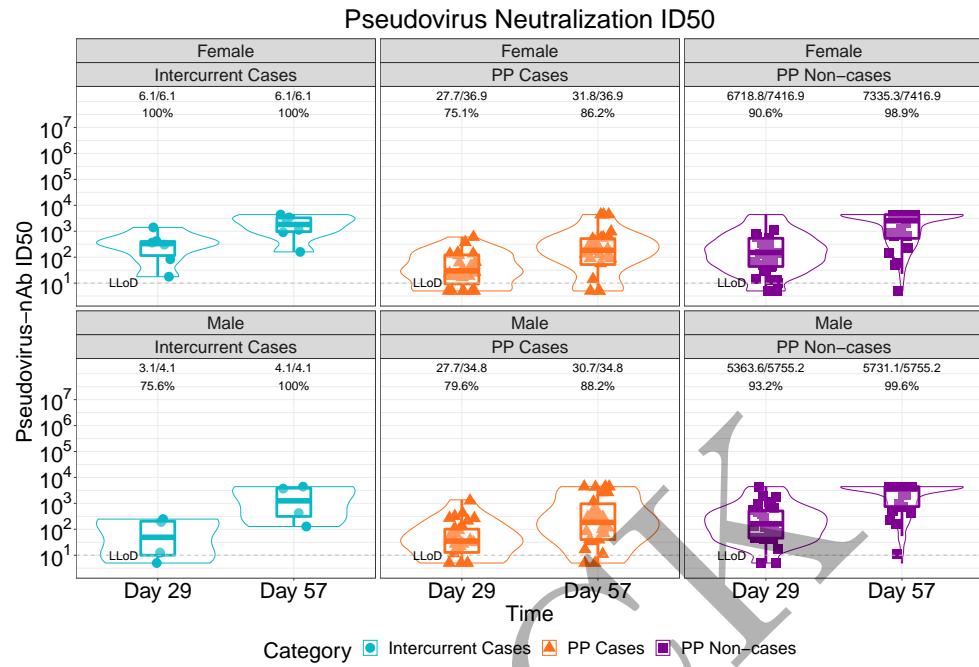


Figure 2.164: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by sex assigned at birth (2 timepoints)

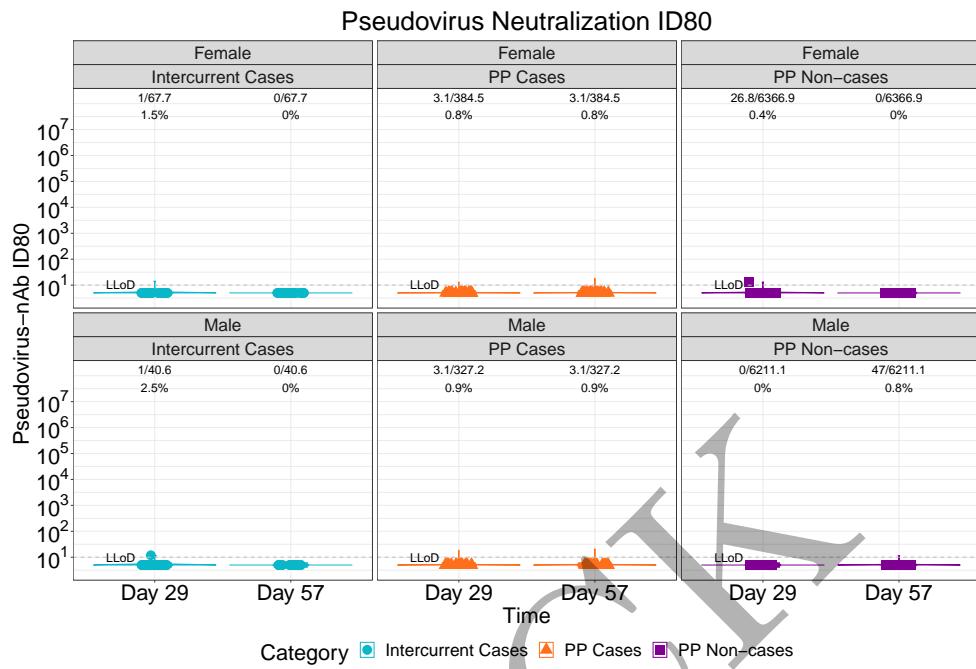


Figure 2.165: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by sex assigned at birth (2 timepoints)

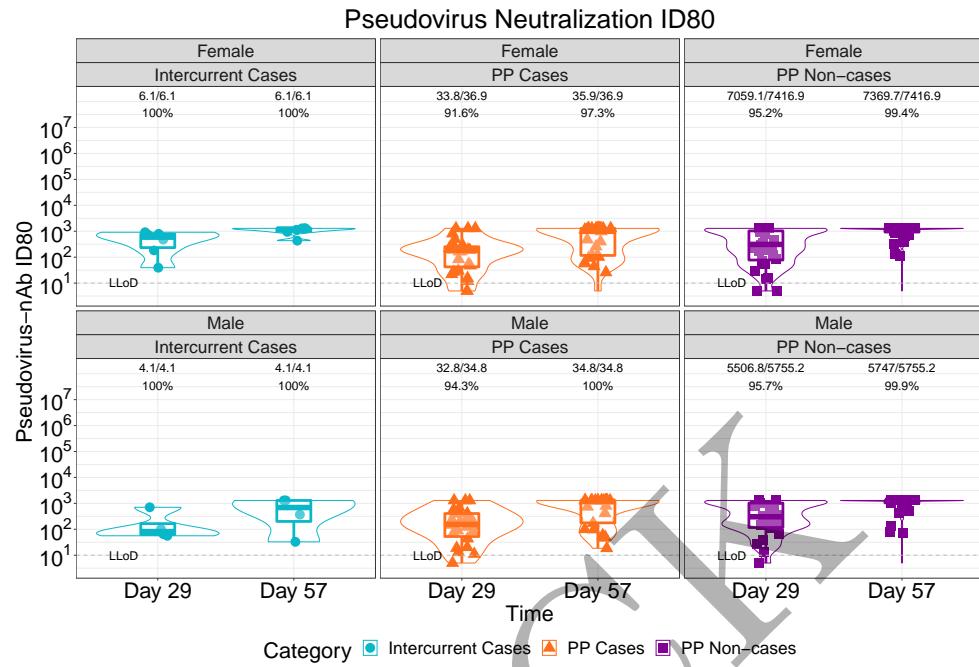


Figure 2.166: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by sex assigned at birth (2 timepoints)

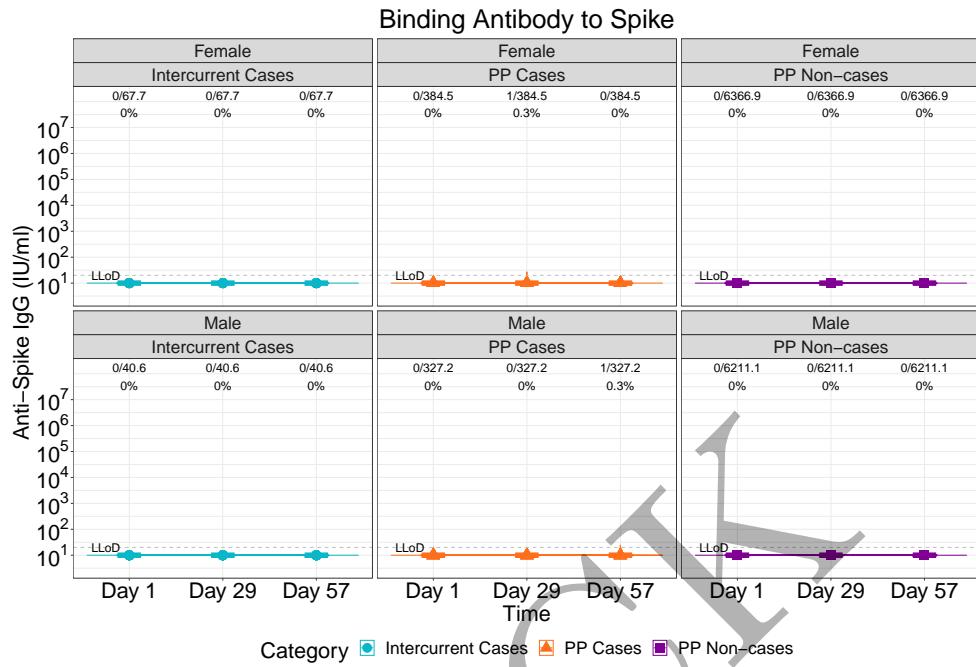


Figure 2.167: lineplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (3 timepoints)

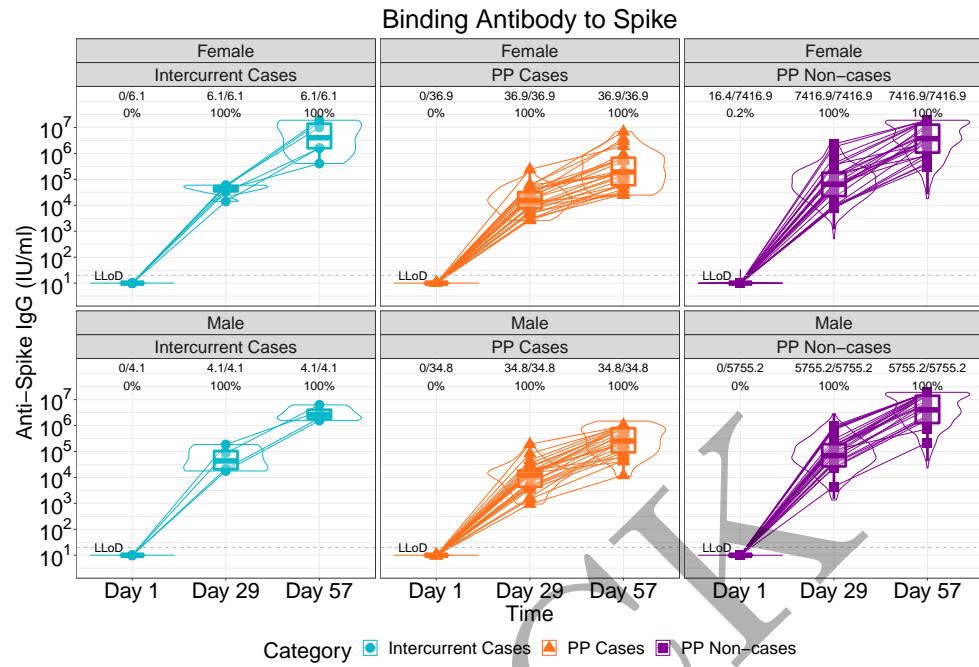


Figure 2.168: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (3 timepoints)

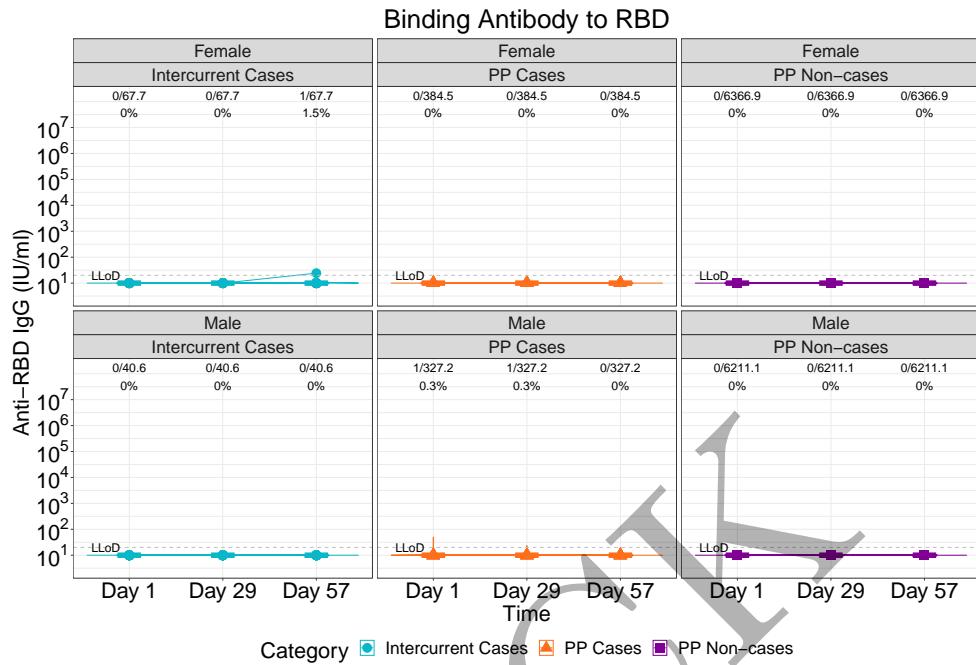


Figure 2.169: lineplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (3 timepoints)

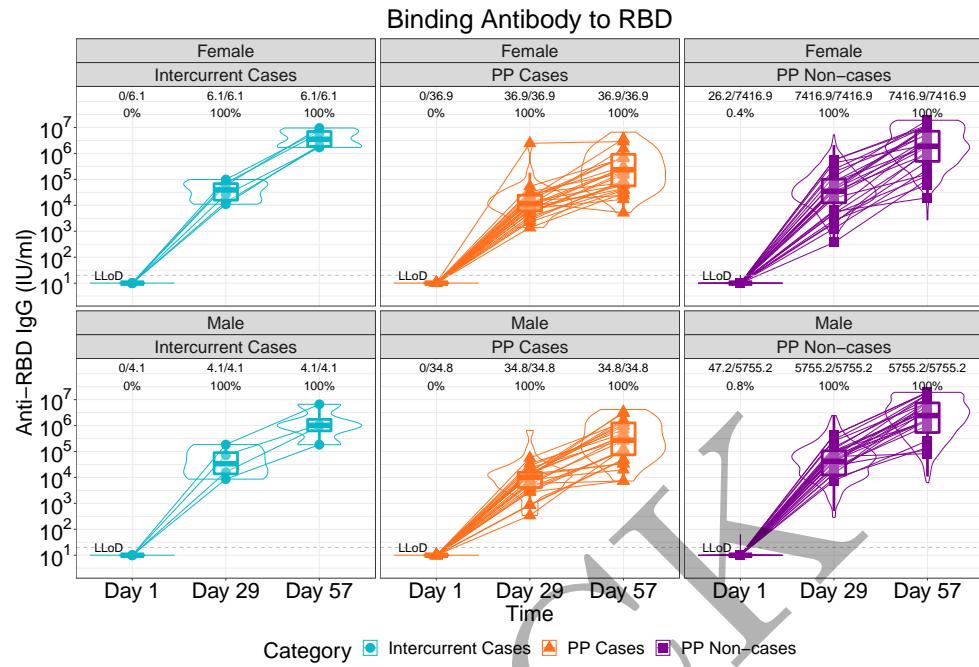


Figure 2.170: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (3 timepoints)

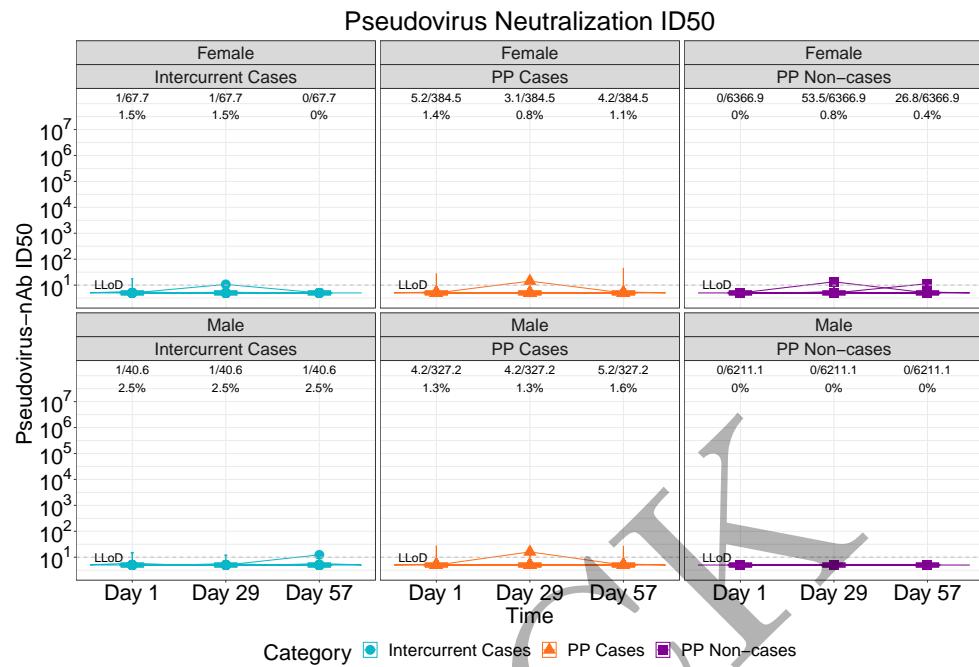


Figure 2.171: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by sex assigned at birth (3 timepoints)

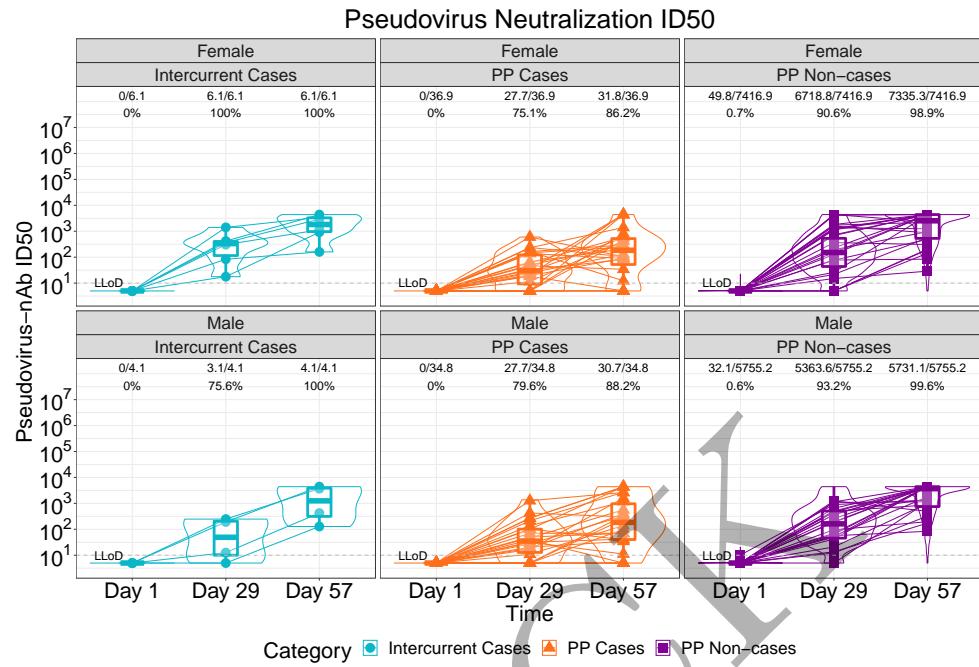


Figure 2.172: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by sex assigned at birth (3 timepoints)

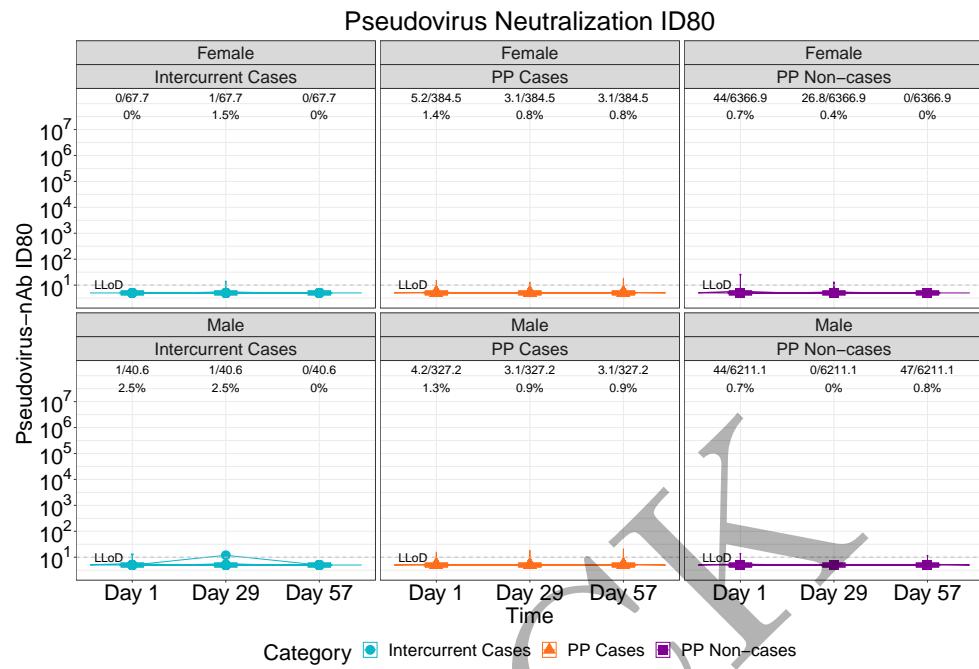


Figure 2.173: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by sex assigned at birth (3 timepoints)

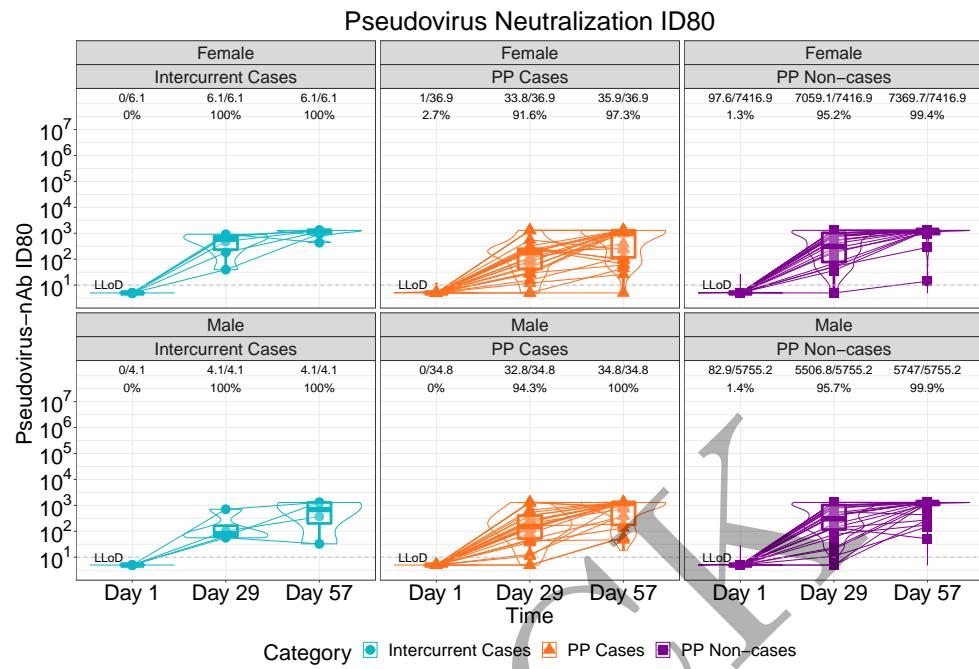


Figure 2.174: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by sex assigned at birth (3 timepoints)

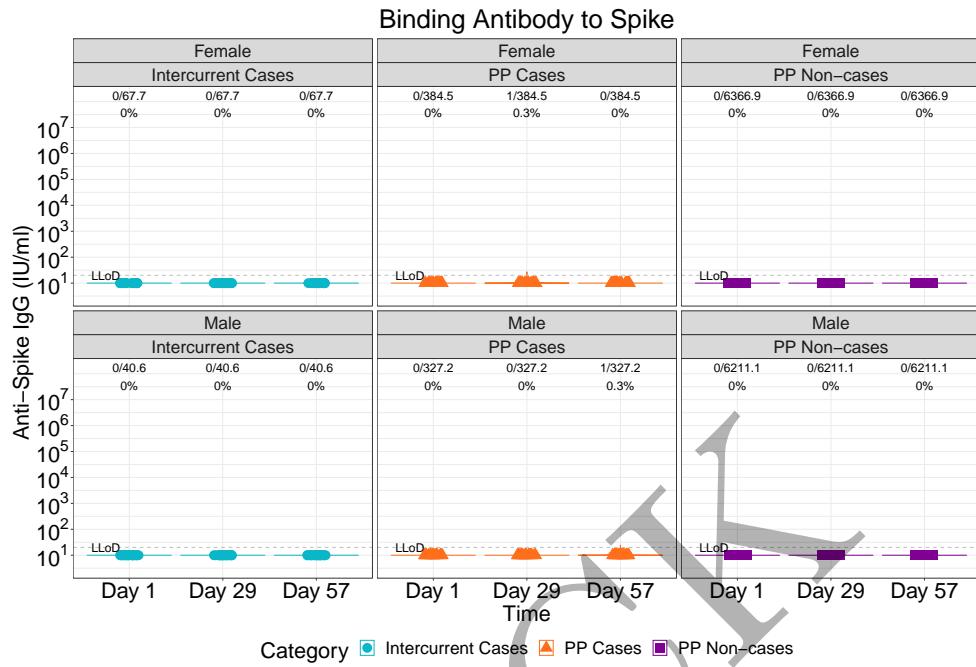


Figure 2.175: violinplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (3 timepoints)

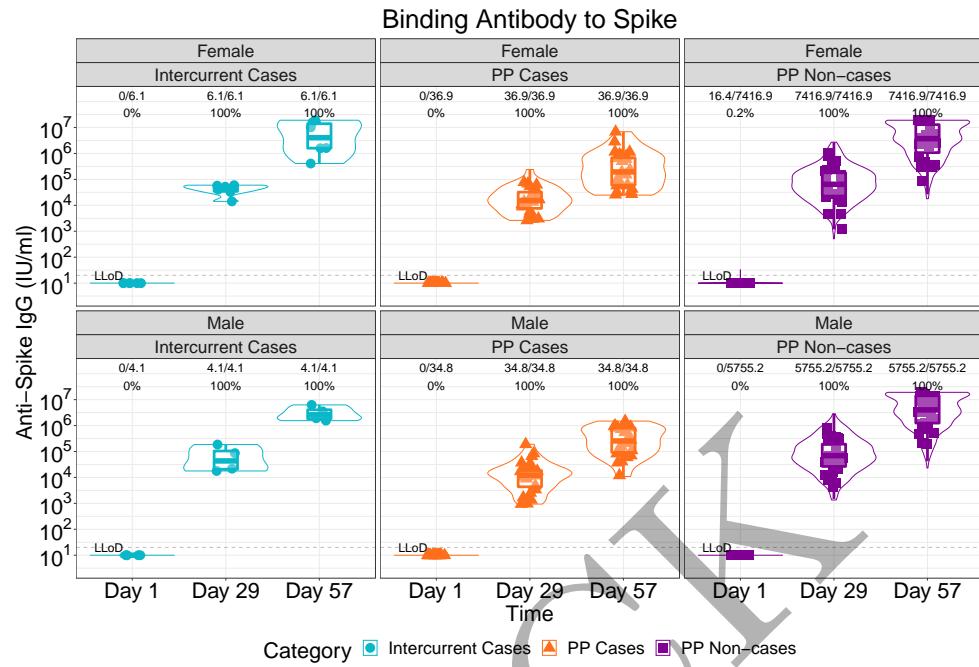


Figure 2.176: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (3 timepoints)

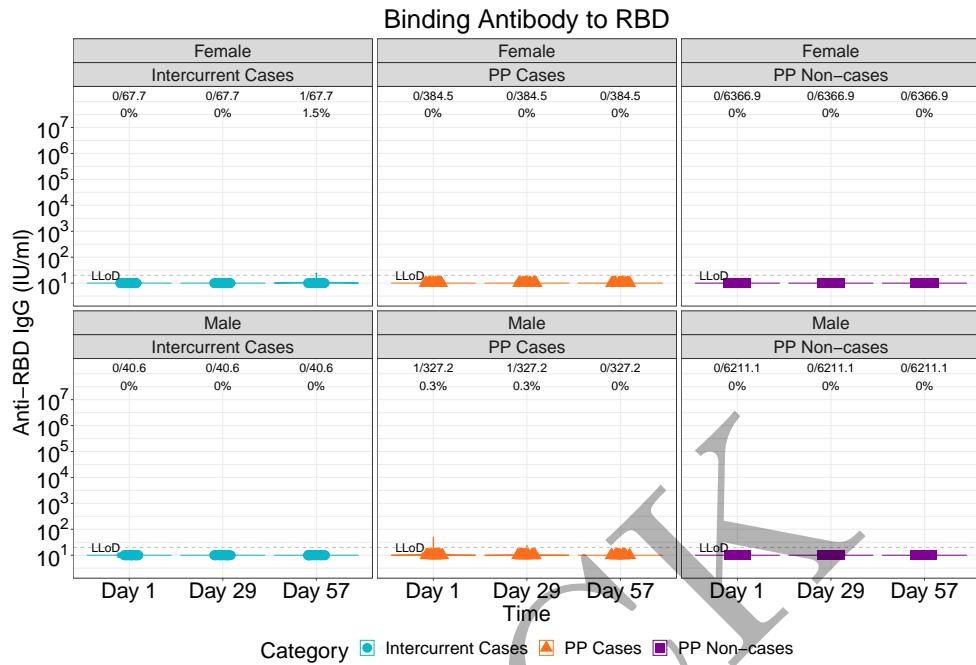


Figure 2.177: violinplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (3 timepoints)

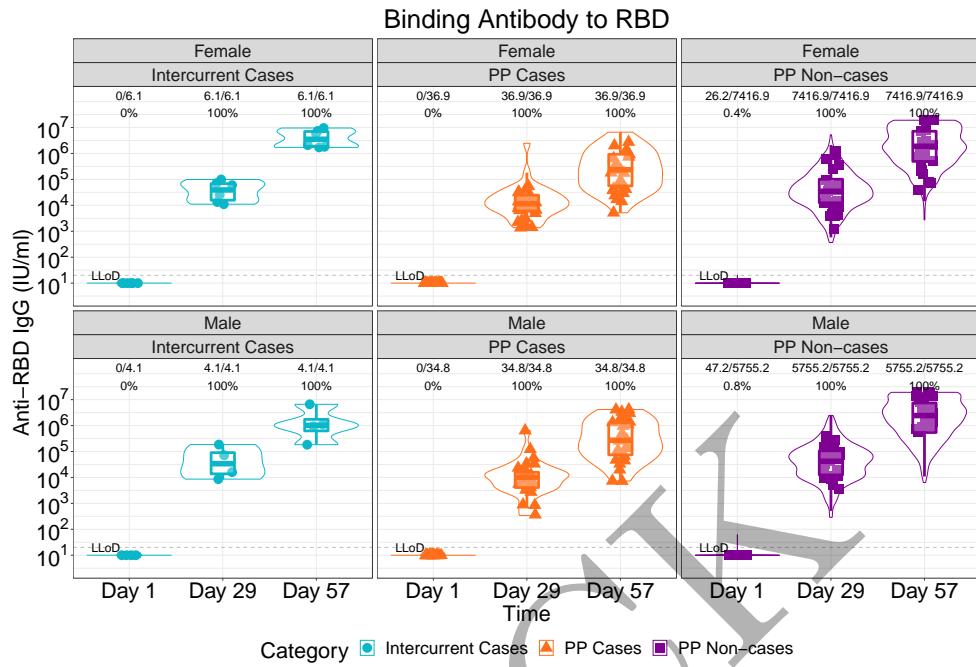


Figure 2.178: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (3 timepoints)

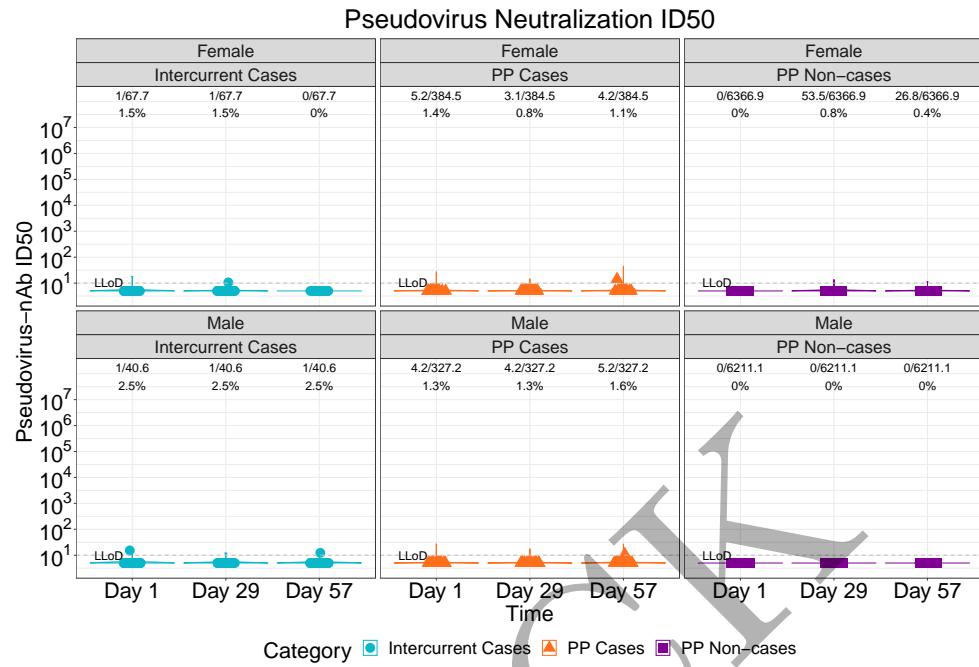


Figure 2.179: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by sex assigned at birth (3 timepoints)

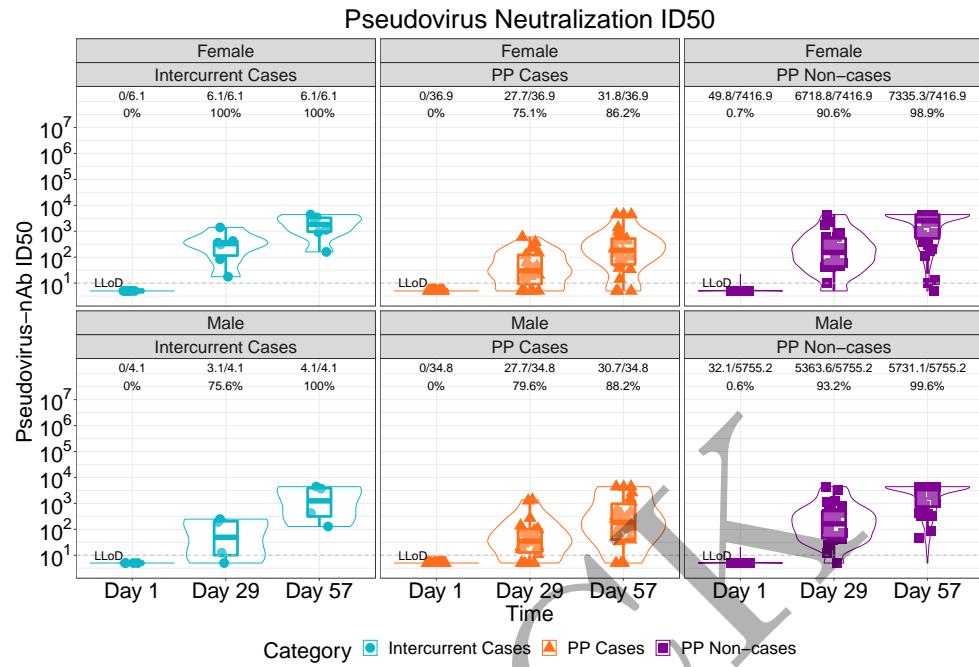


Figure 2.180: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by sex assigned at birth (3 timepoints)

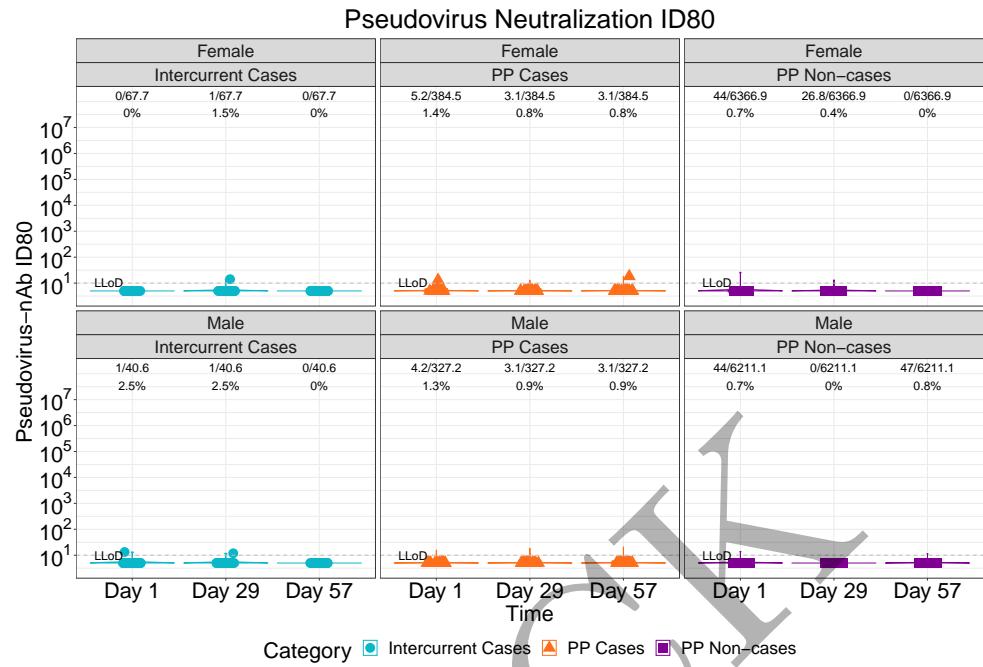


Figure 2.181: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by sex assigned at birth (3 timepoints)

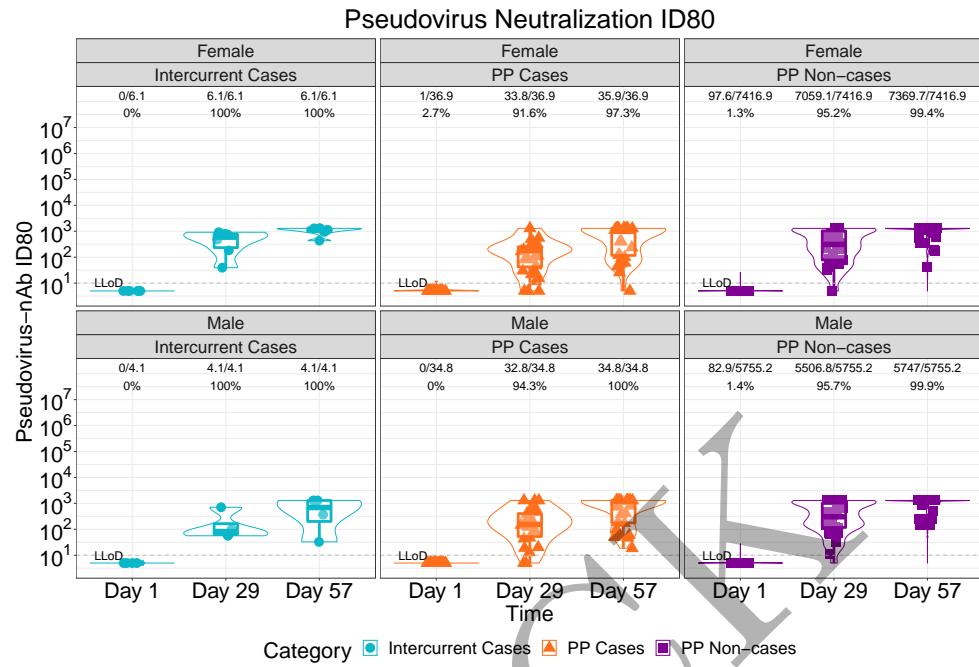


Figure 2.182: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by sex assigned at birth (3 timepoints)

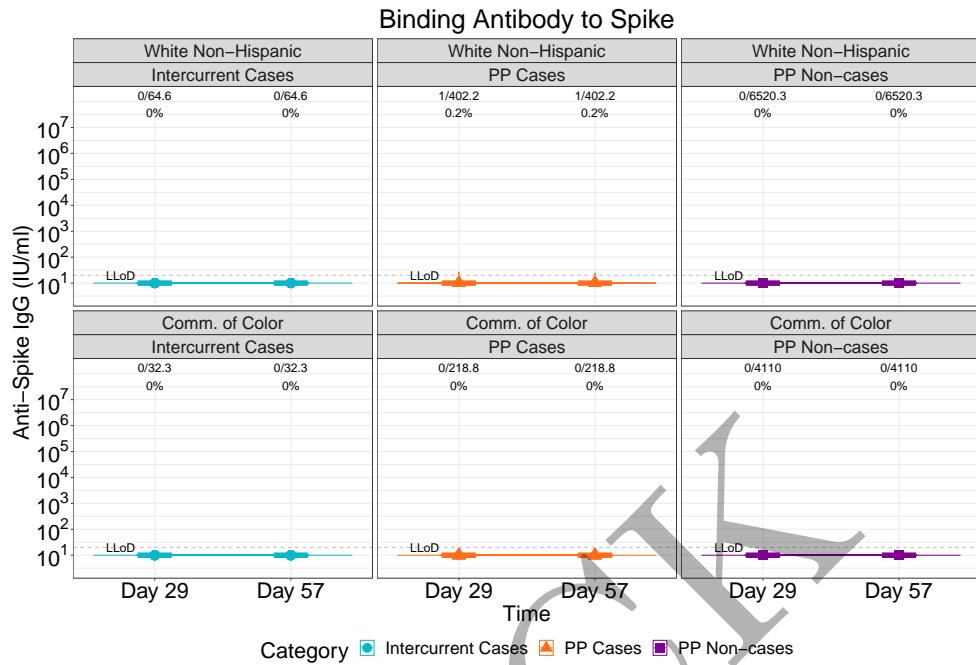


Figure 2.183: lineplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (2 timepoints)

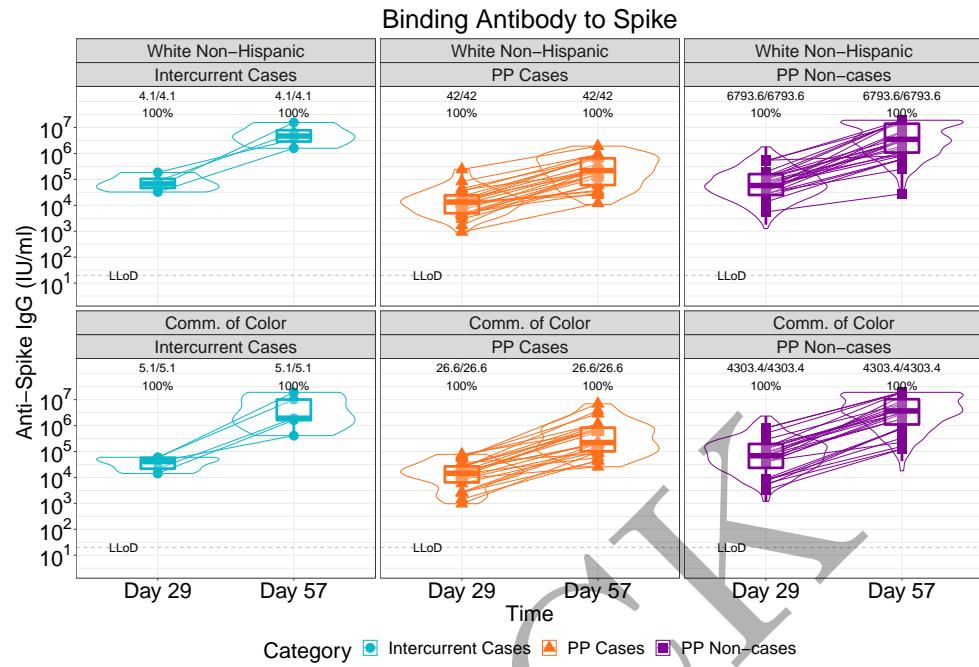


Figure 2.184: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (2 timepoints)

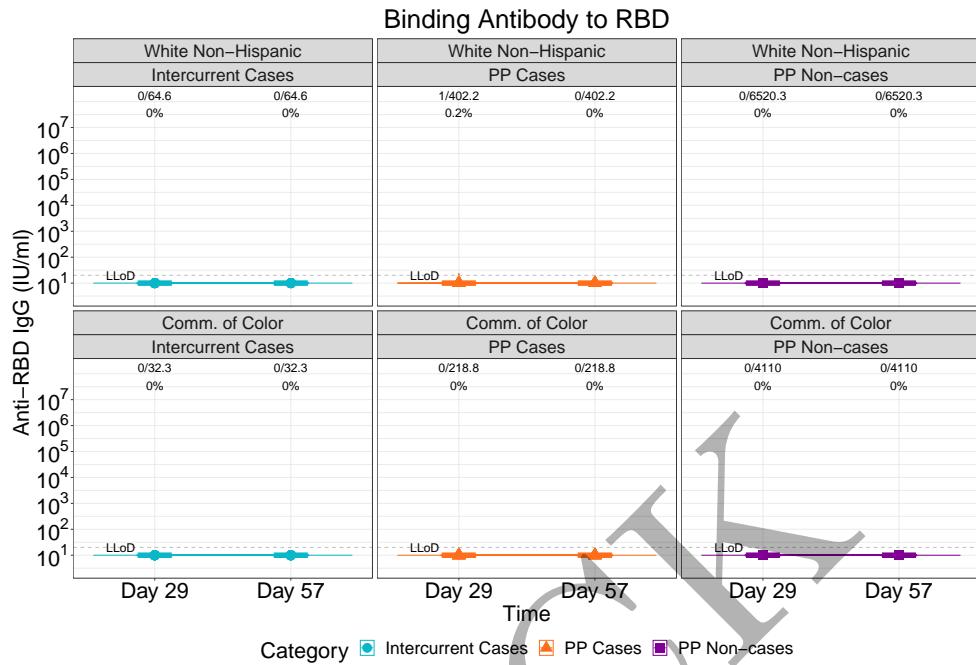


Figure 2.185: lineplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (2 timepoints)

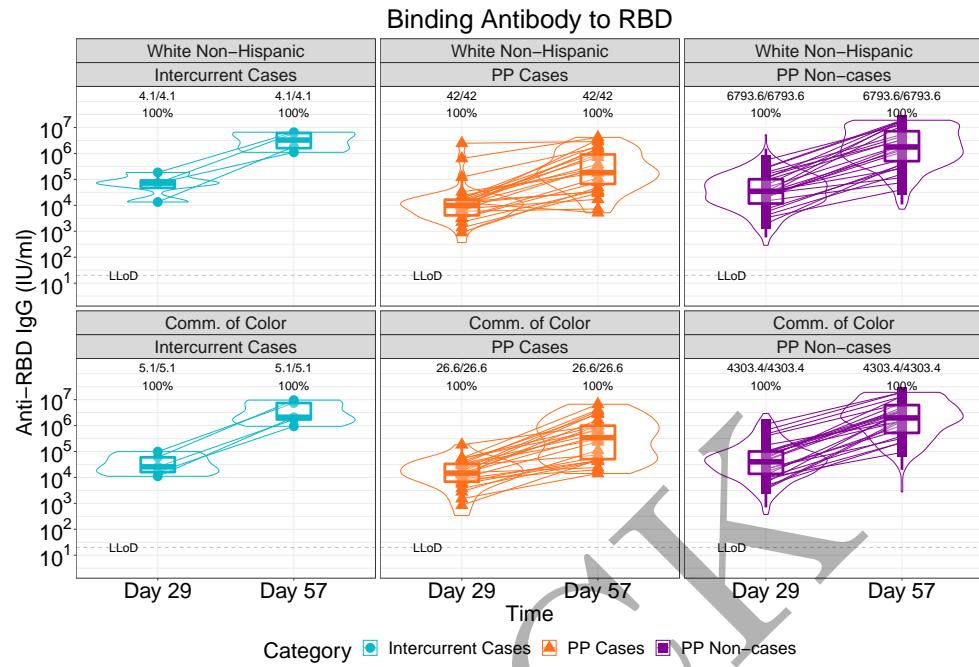


Figure 2.186: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (2 timepoints)

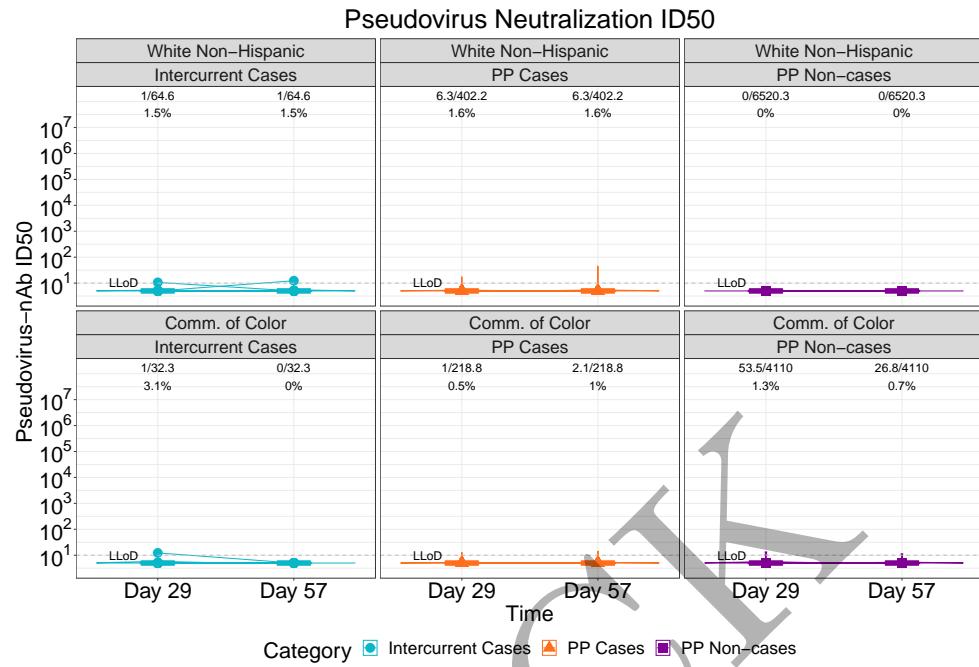


Figure 2.187: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by race and ethnic group (2 timepoints)

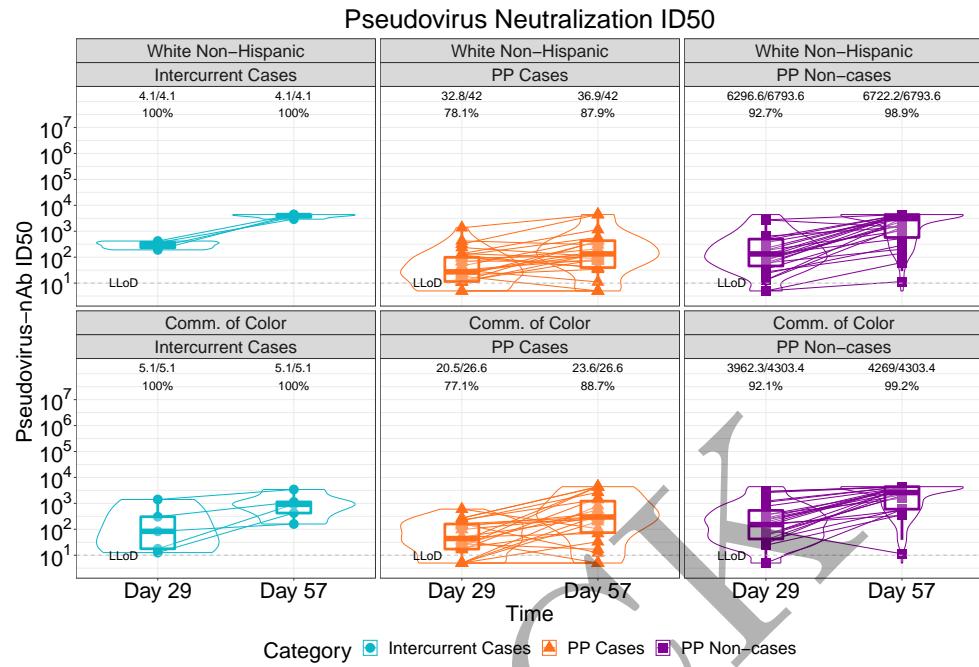


Figure 2.188: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by race and ethnic group (2 timepoints)

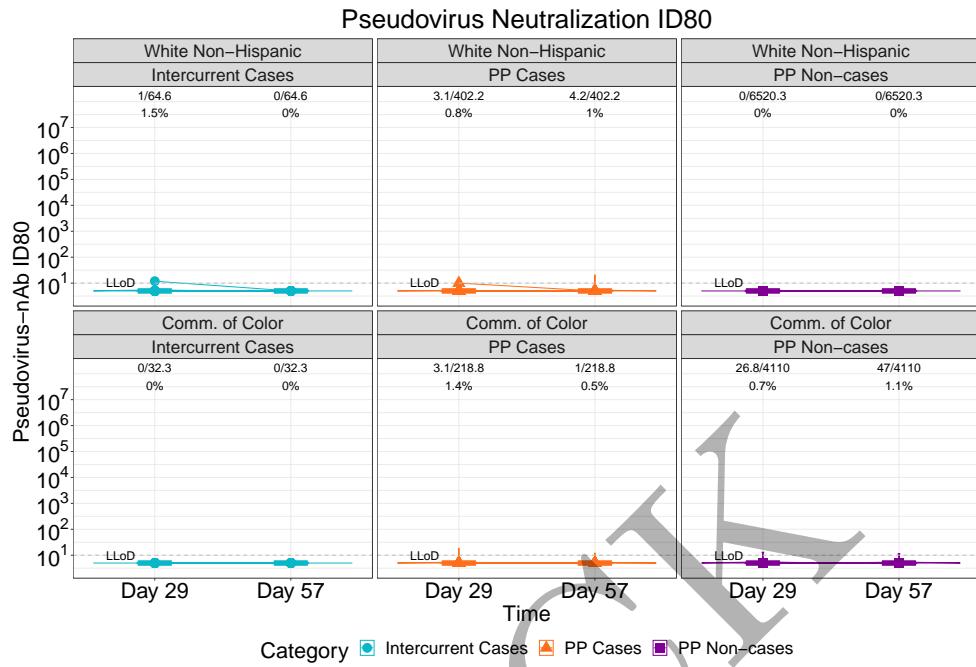


Figure 2.189: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by race and ethnic group (2 timepoints)

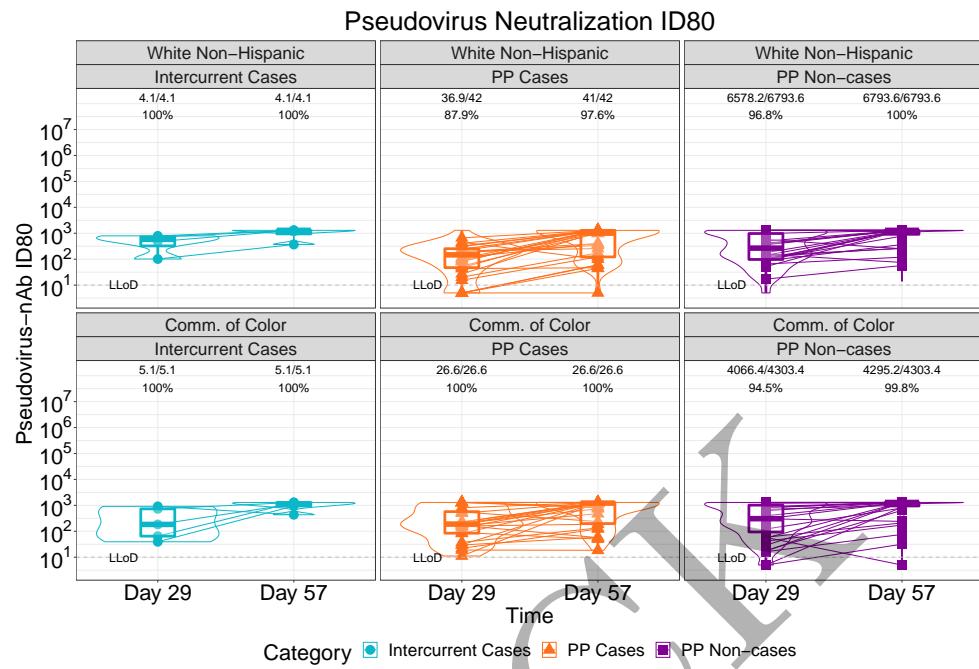


Figure 2.190: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by race and ethnic group (2 timepoints)

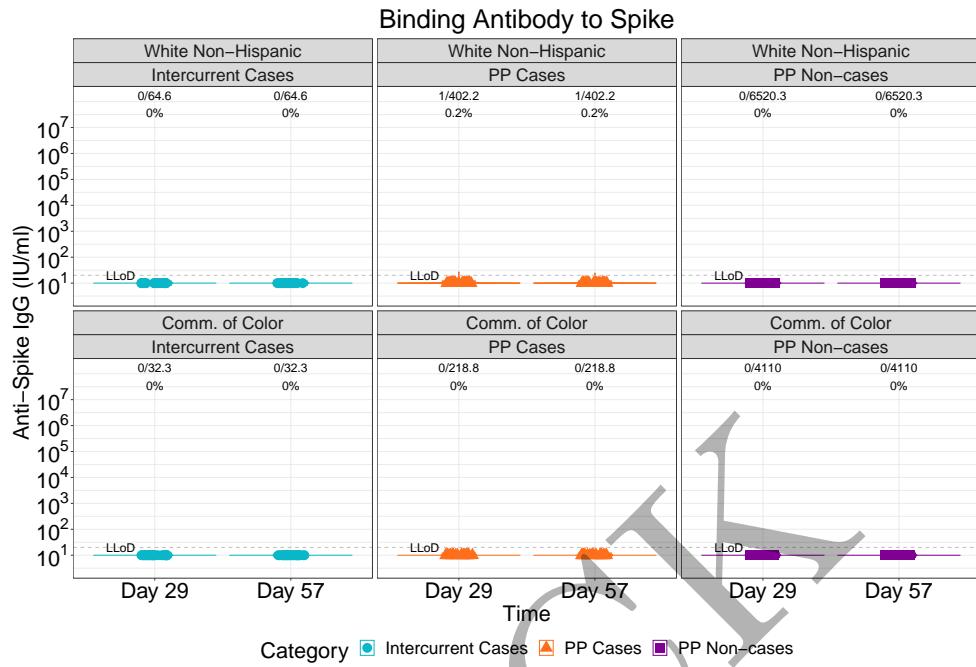


Figure 2.191: violinplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (2 timepoints)

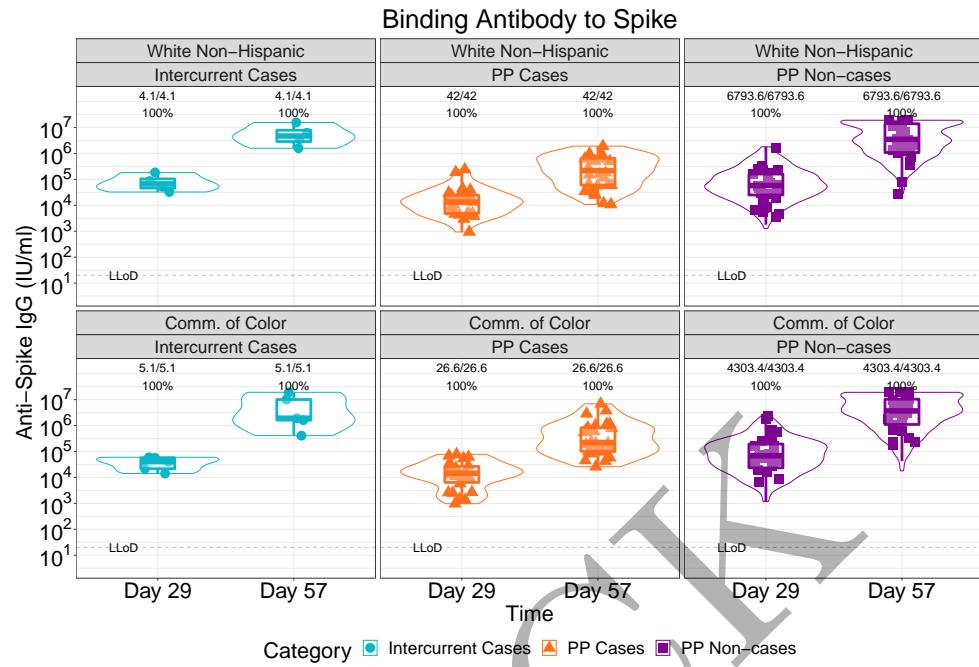


Figure 2.192: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (2 timepoints)

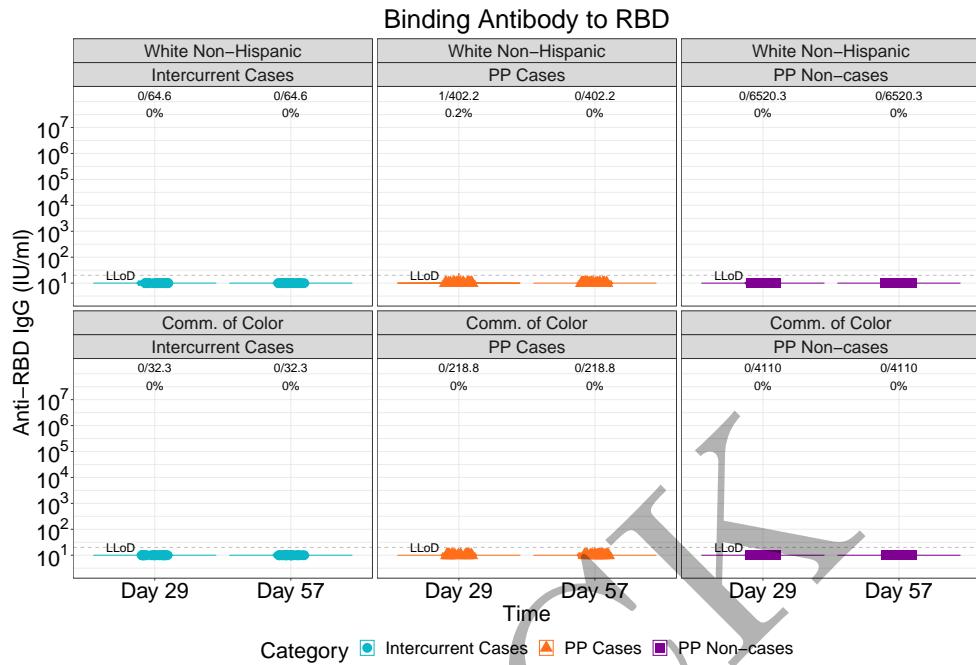


Figure 2.193: violinplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (2 timepoints)

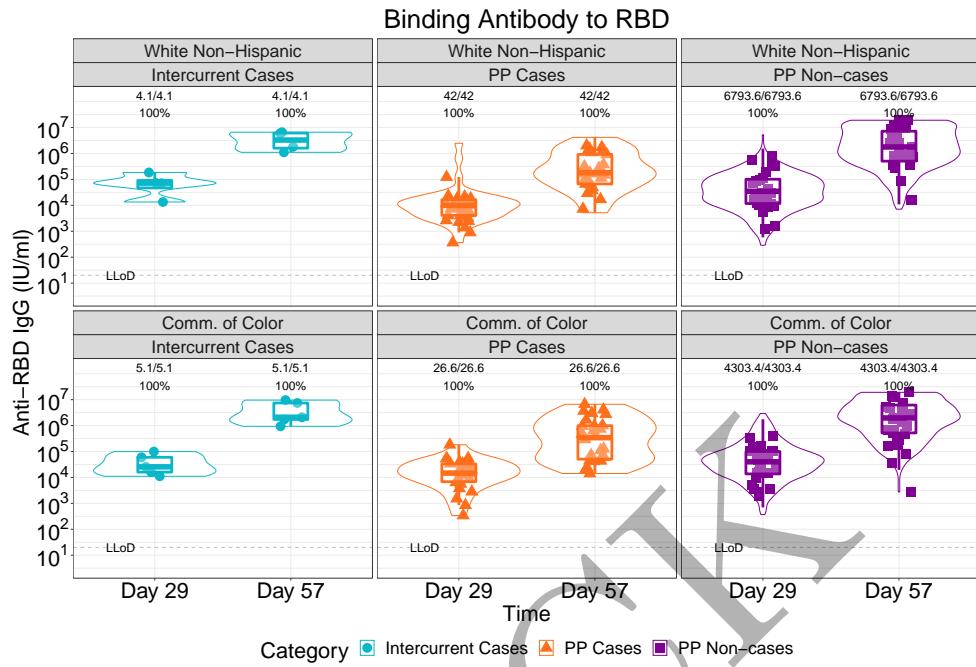


Figure 2.194: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (2 timepoints)

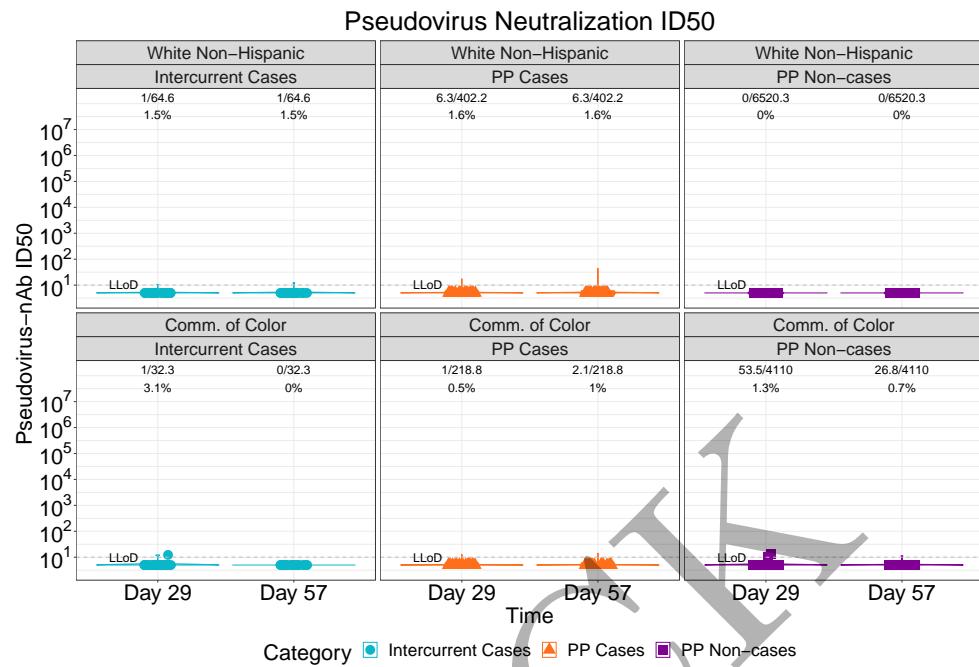


Figure 2.195: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by race and ethnic group (2 timepoints)

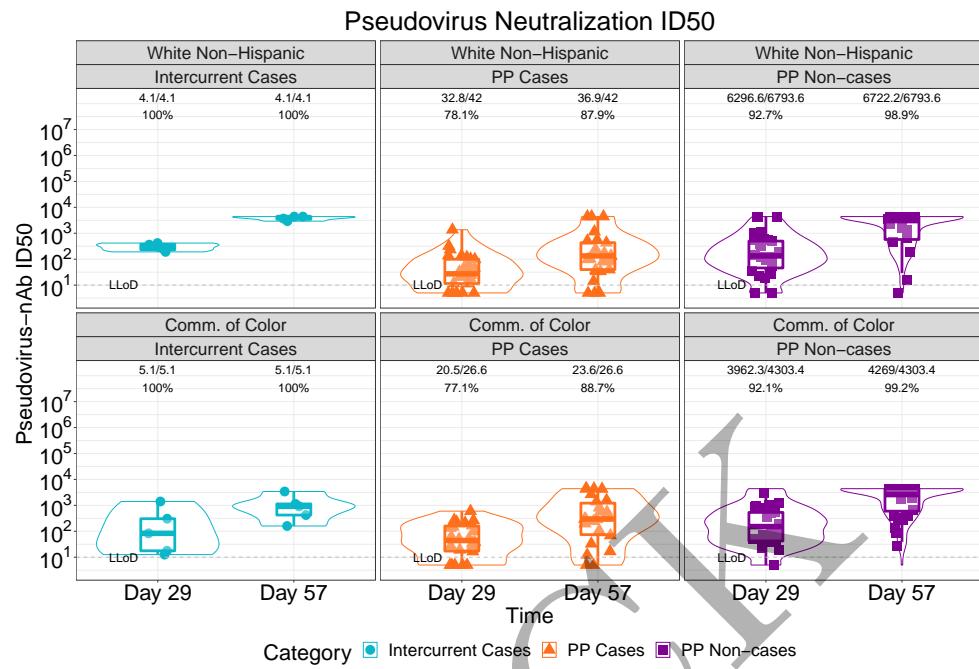


Figure 2.196: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by race and ethnic group (2 timepoints)

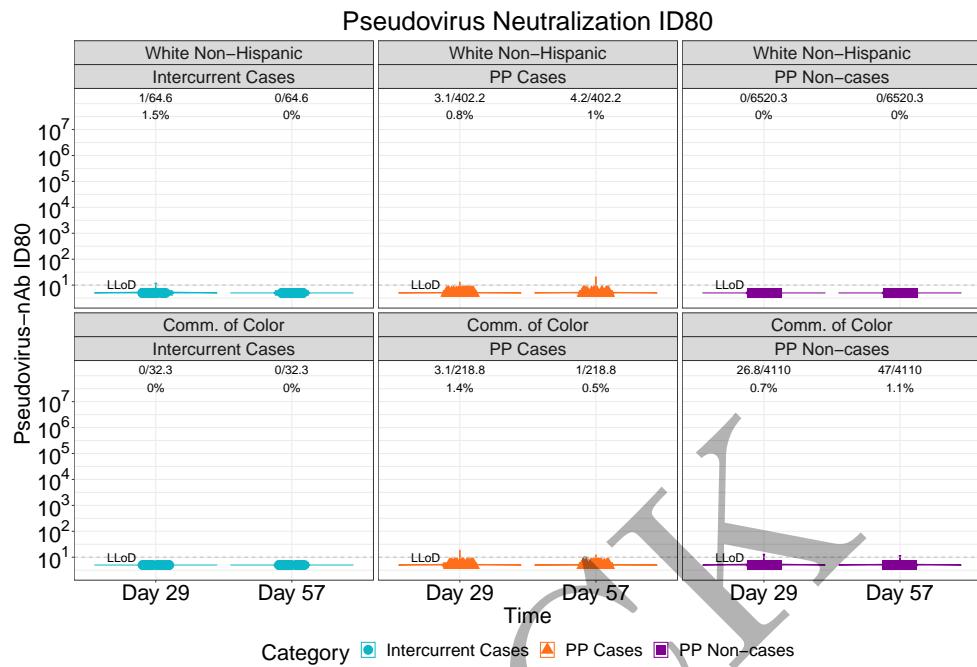


Figure 2.197: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by race and ethnic group (2 timepoints)

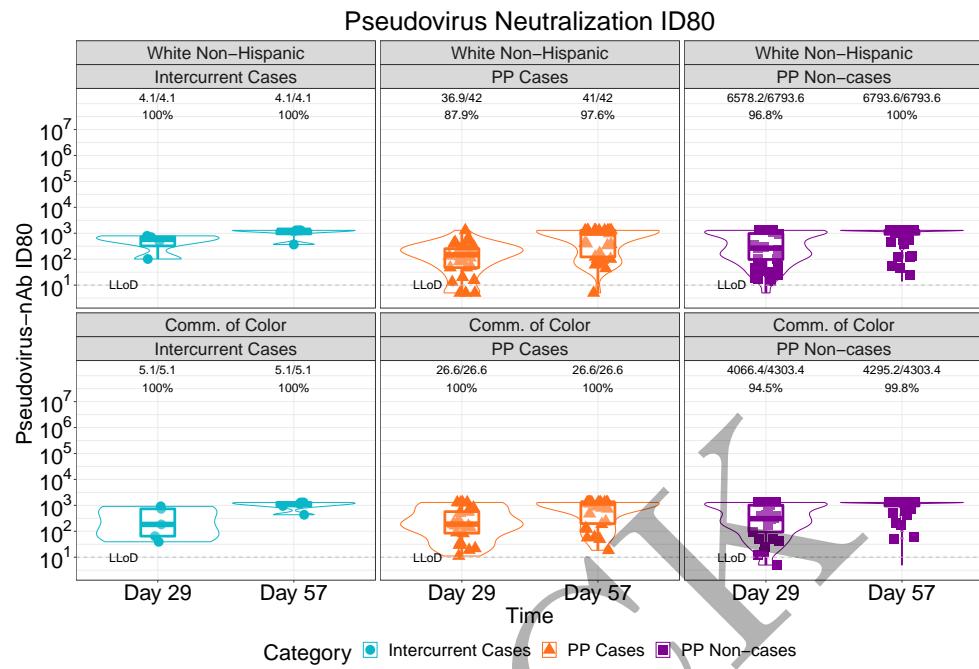


Figure 2.198: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by race and ethnic group (2 timepoints)

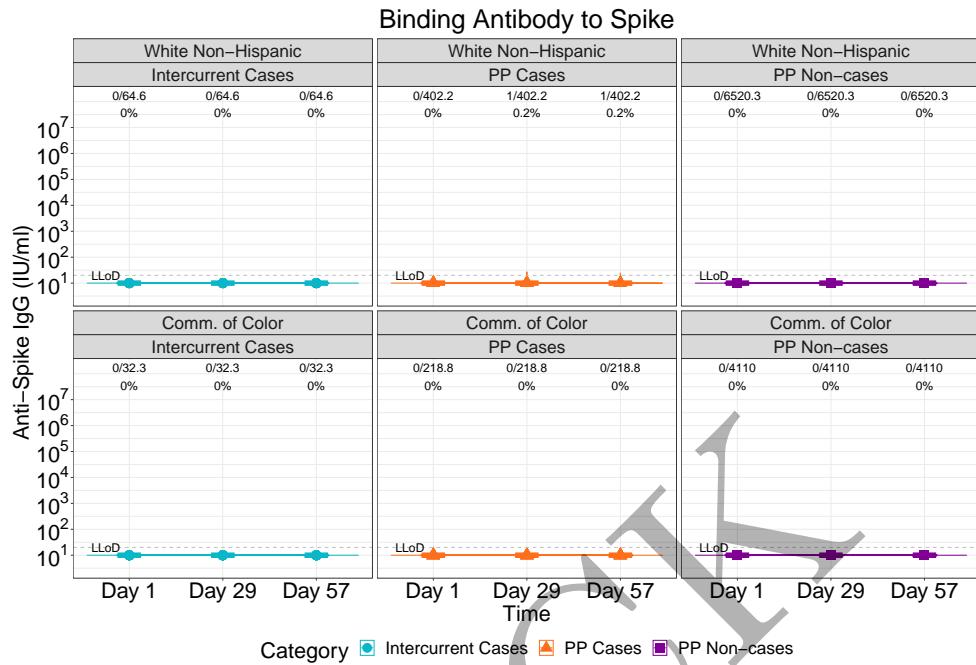


Figure 2.199: lineplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (3 timepoints)

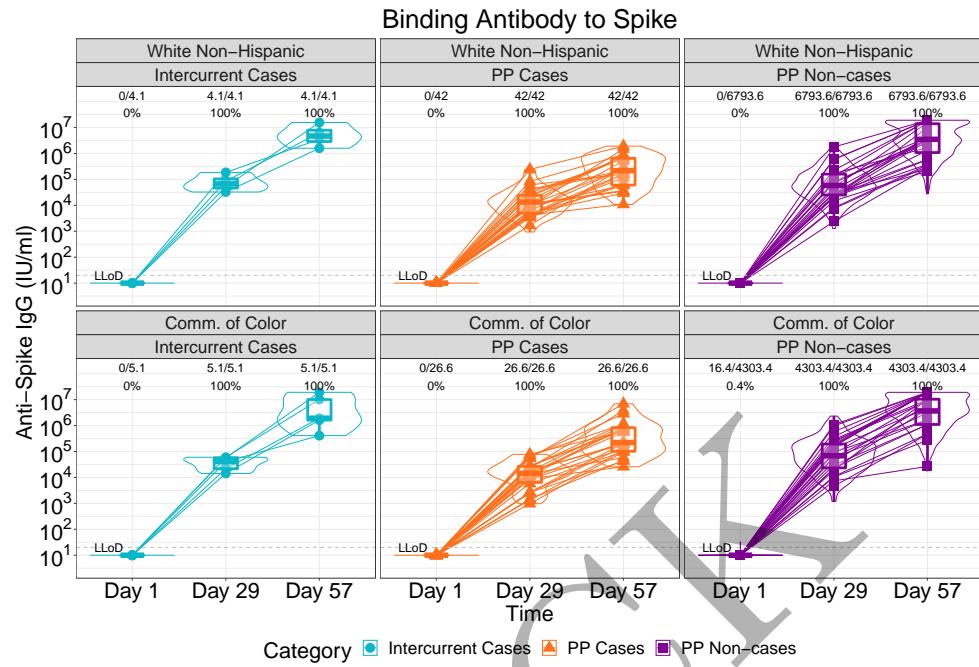


Figure 2.200: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (3 timepoints)

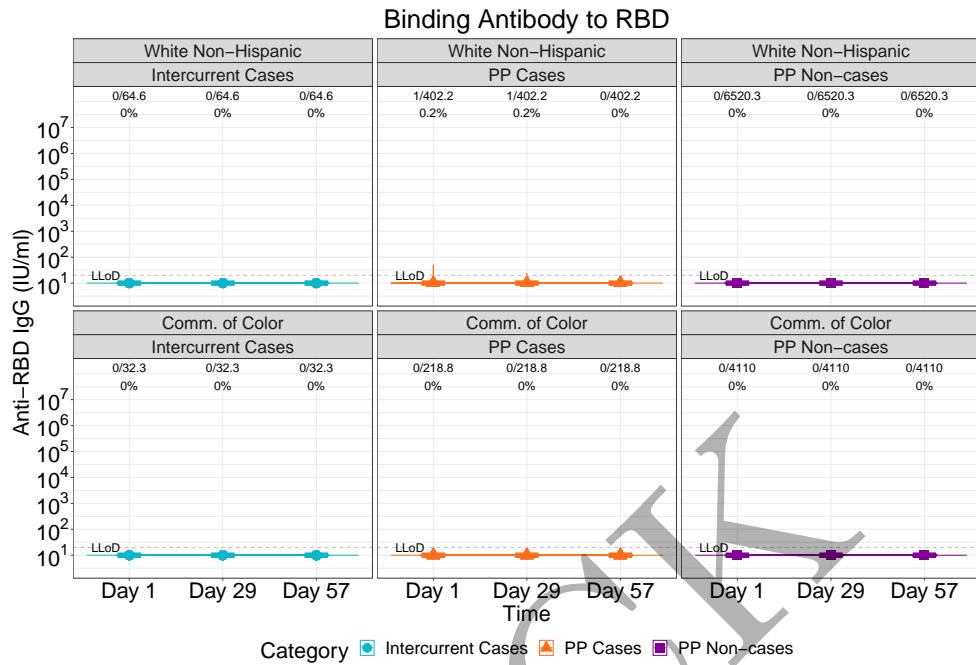


Figure 2.201: lineplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (3 timepoints)

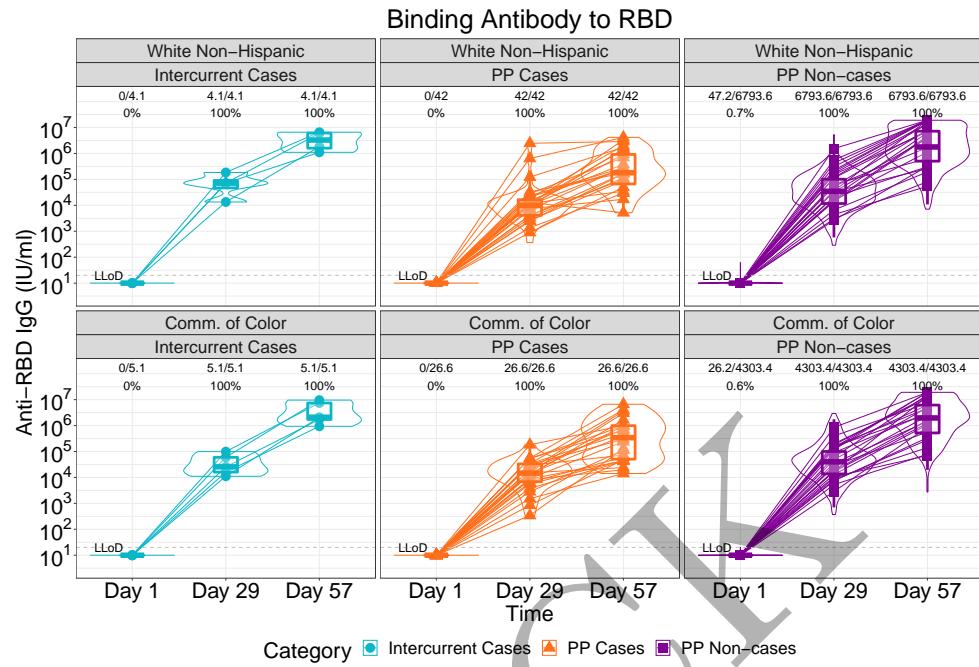


Figure 2.202: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (3 timepoints)

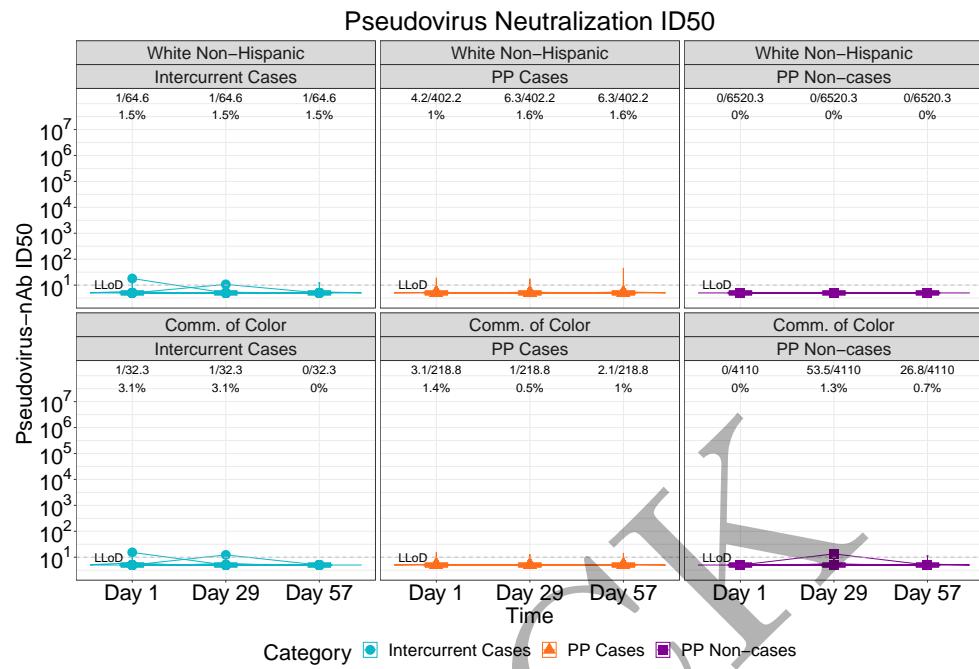


Figure 2.203: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by race and ethnic group (3 timepoints)

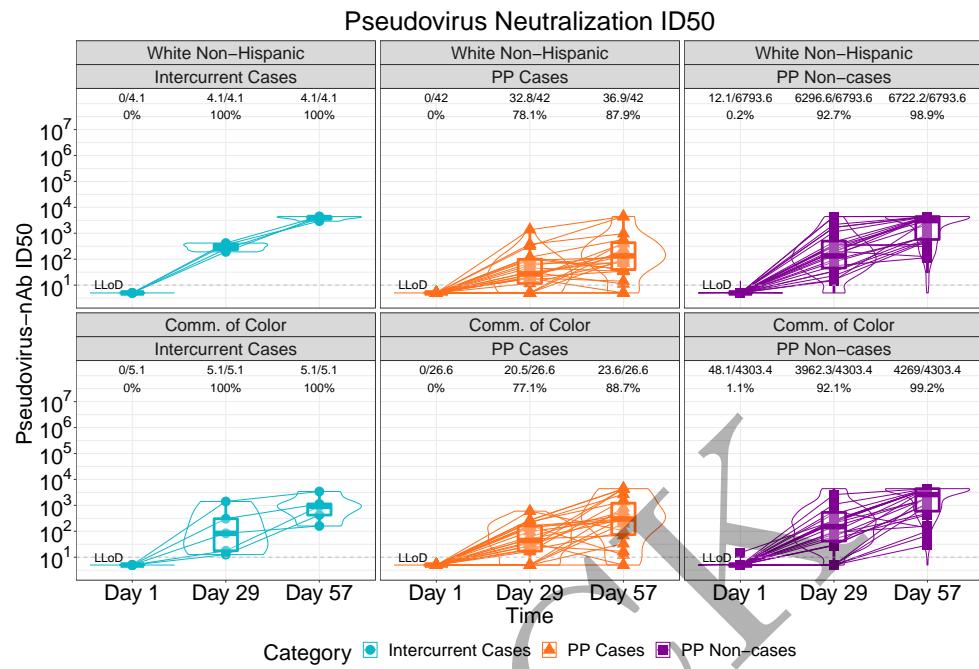


Figure 2.204: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by race and ethnic group (3 timepoints)

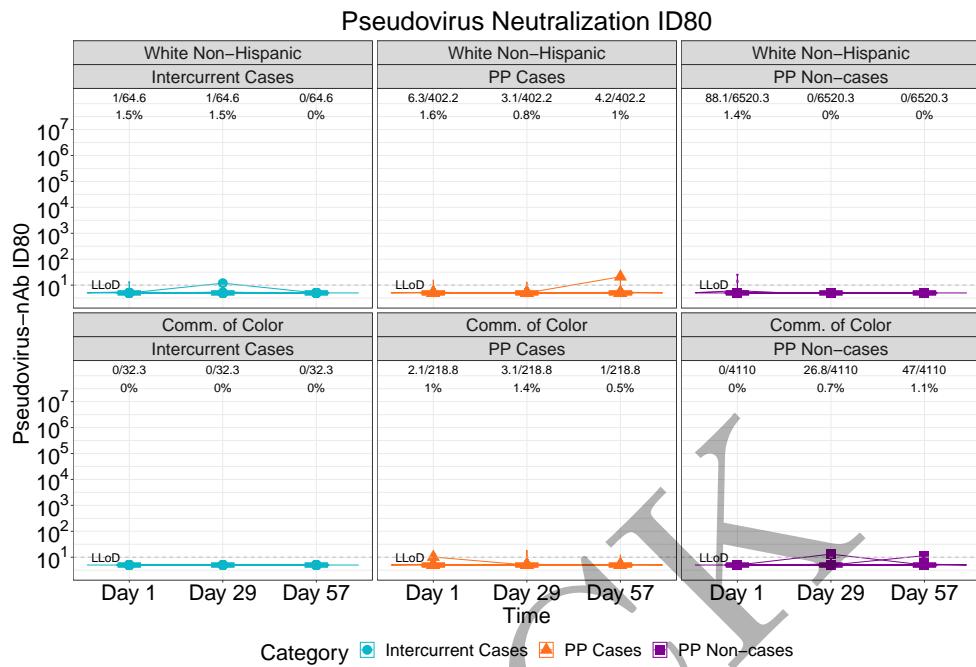


Figure 2.205: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by race and ethnic group (3 timepoints)

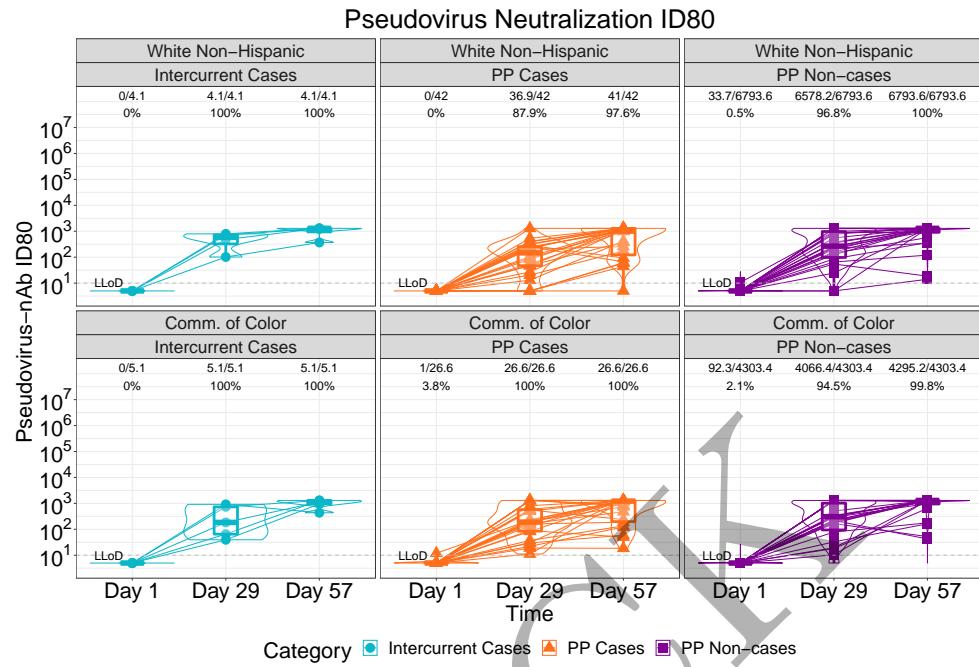


Figure 2.206: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by race and ethnic group (3 timepoints)

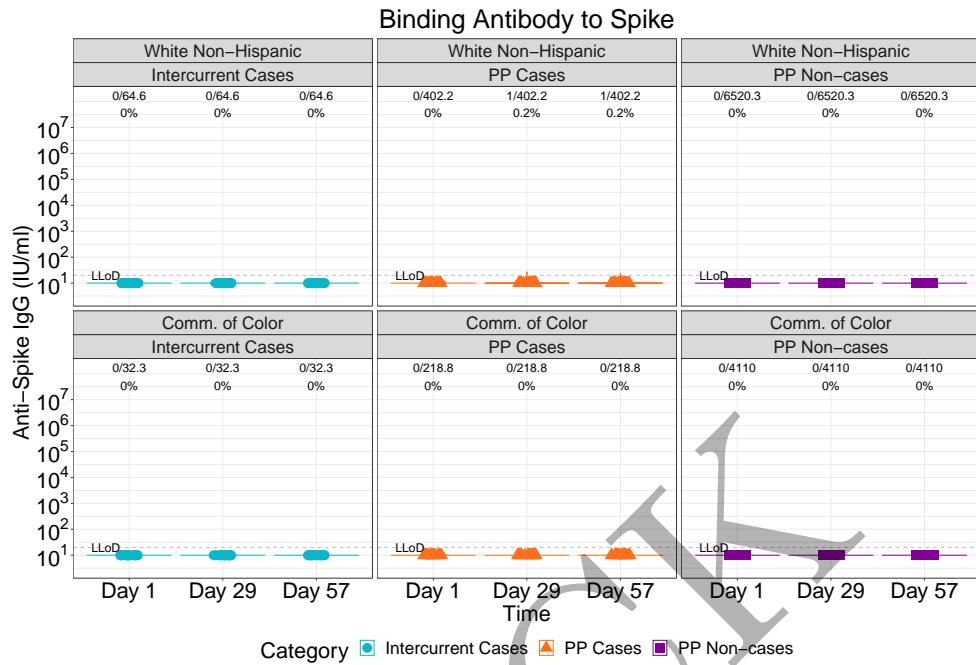


Figure 2.207: violinplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (3 timepoints)

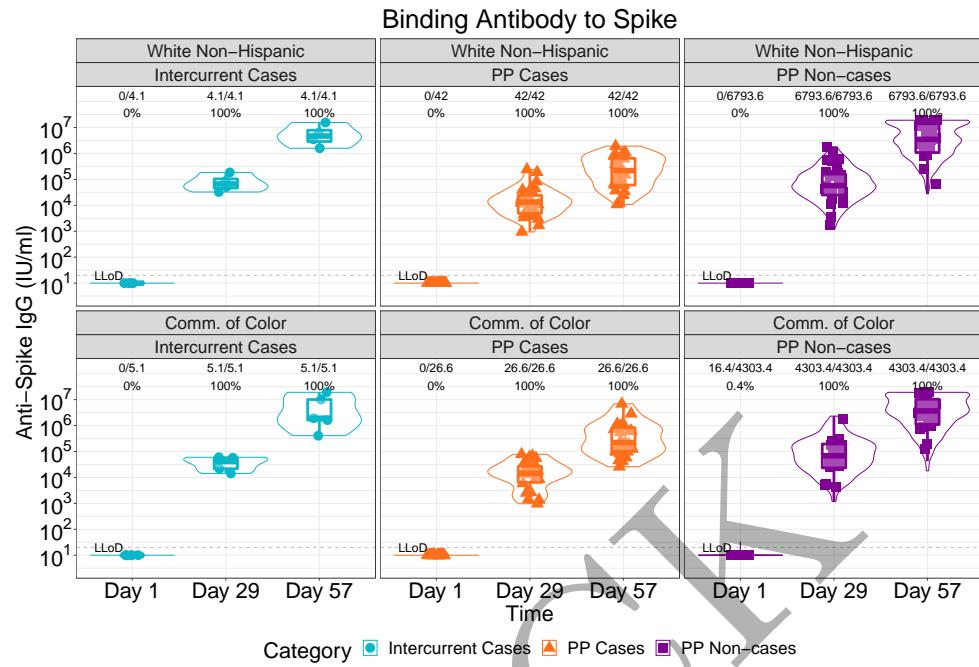


Figure 2.208: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (3 timepoints)

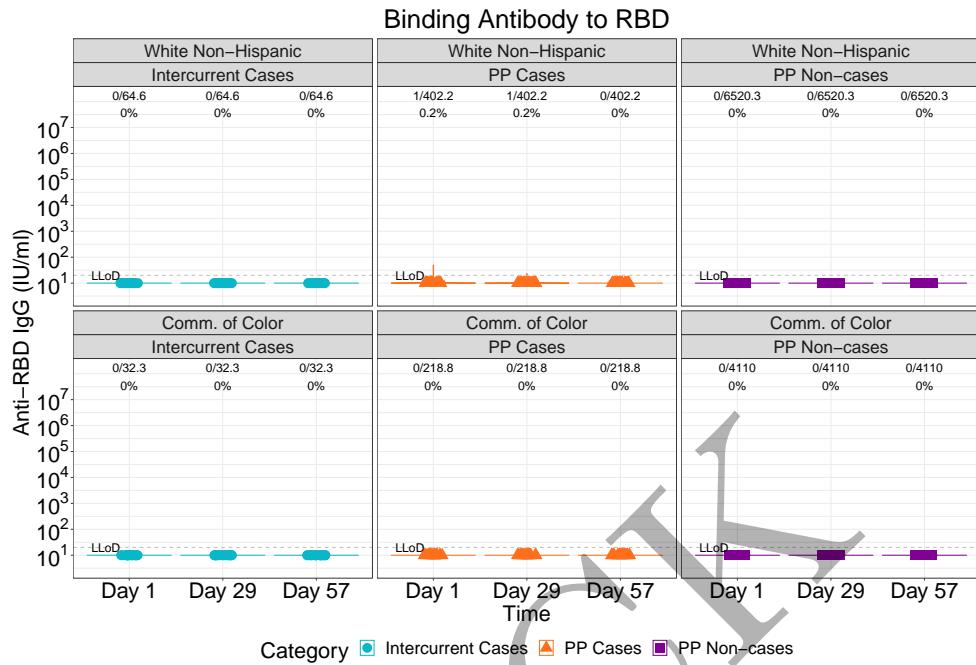


Figure 2.209: violinplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (3 timepoints)

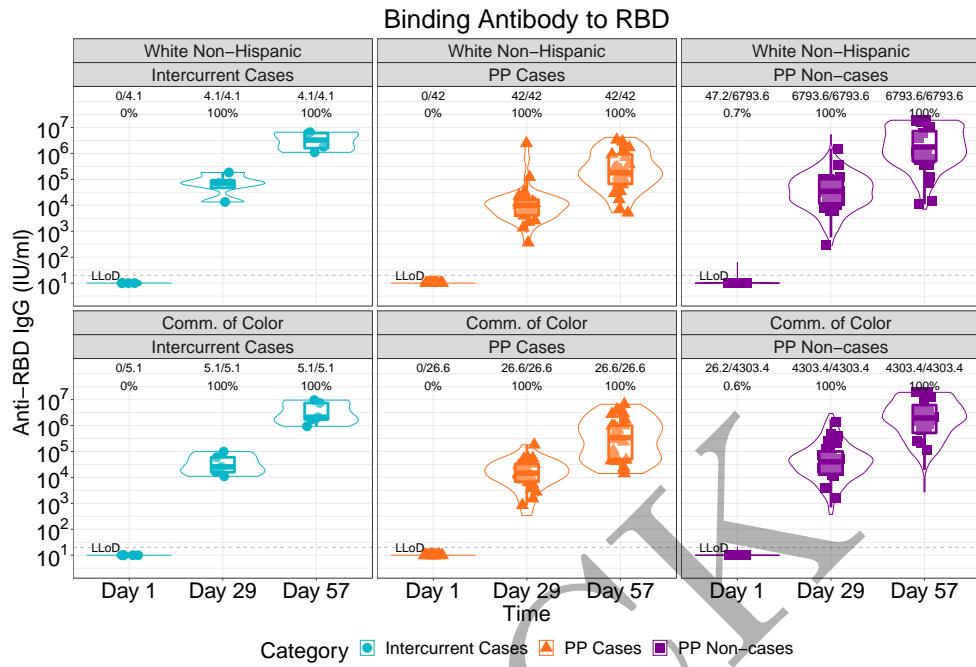


Figure 2.210: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (3 timepoints)

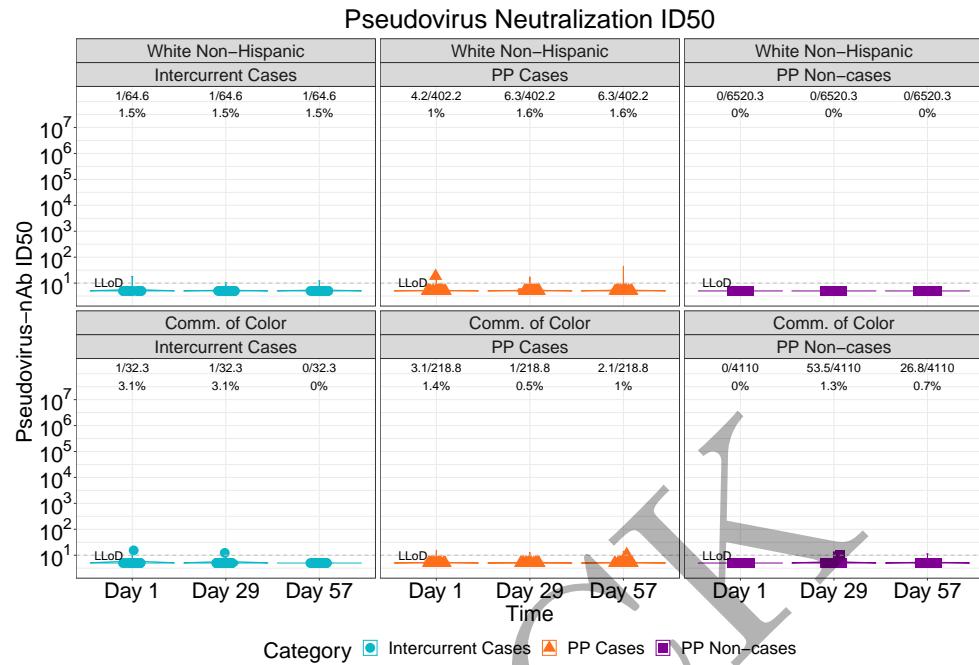


Figure 2.211: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by race and ethnic group (3 timepoints)

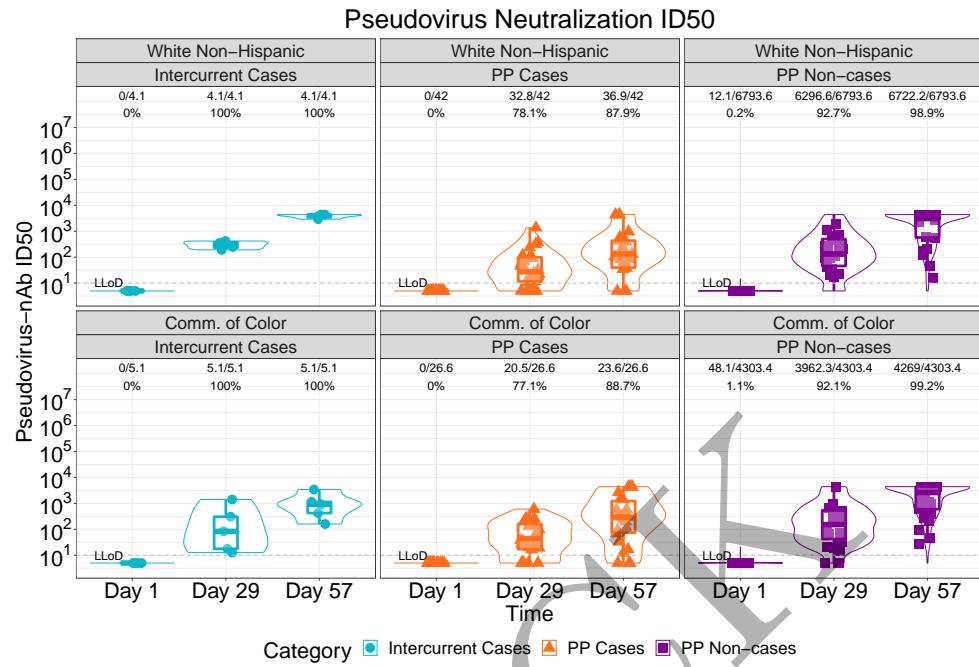


Figure 2.212: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by race and ethnic group (3 timepoints)

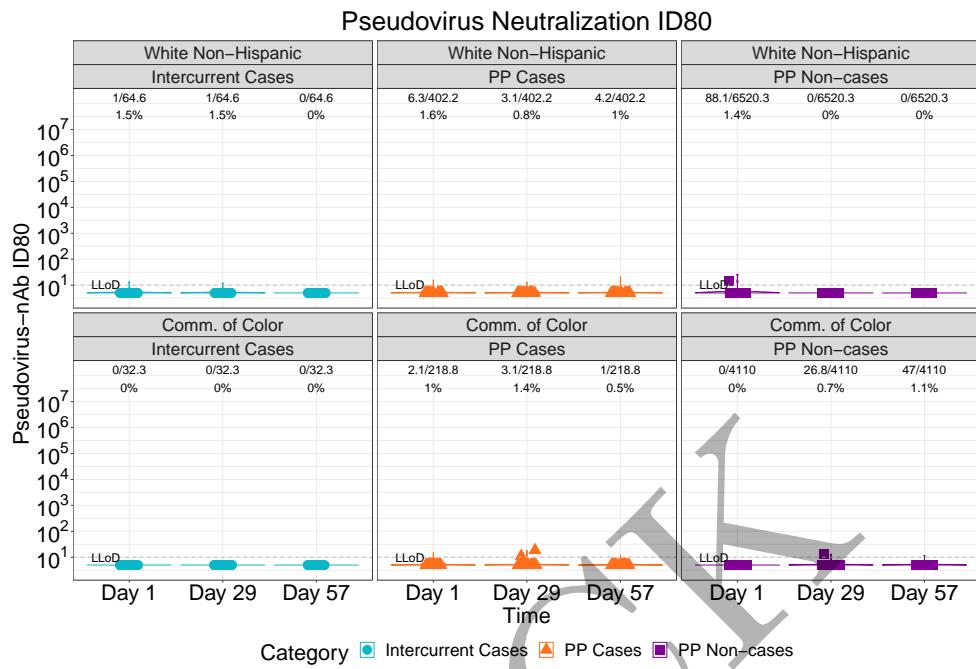


Figure 2.213: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by race and ethnic group (3 timepoints)

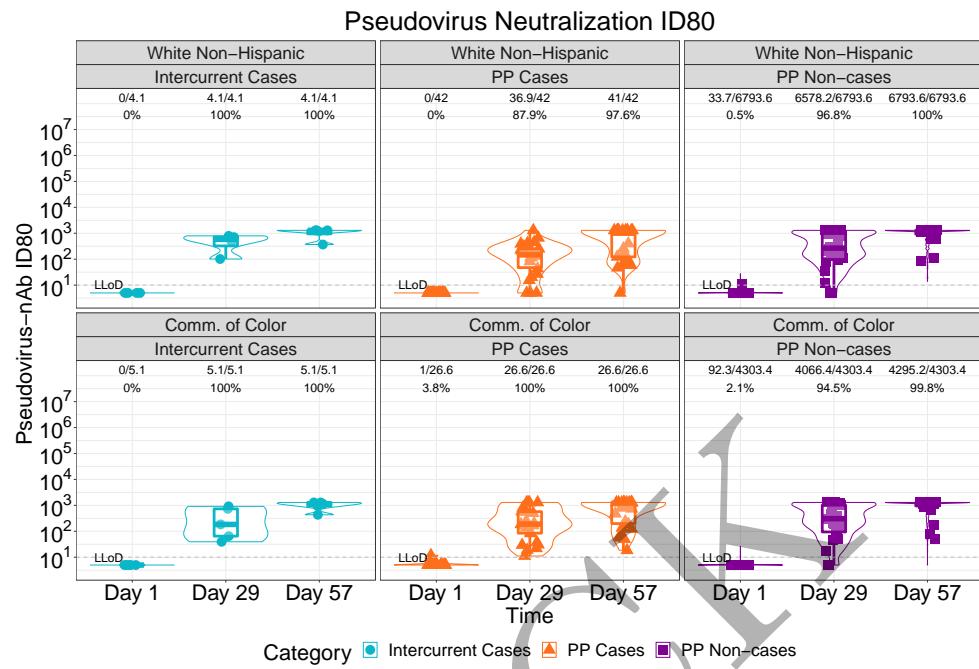


Figure 2.214: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by race and ethnic group (3 timepoints)

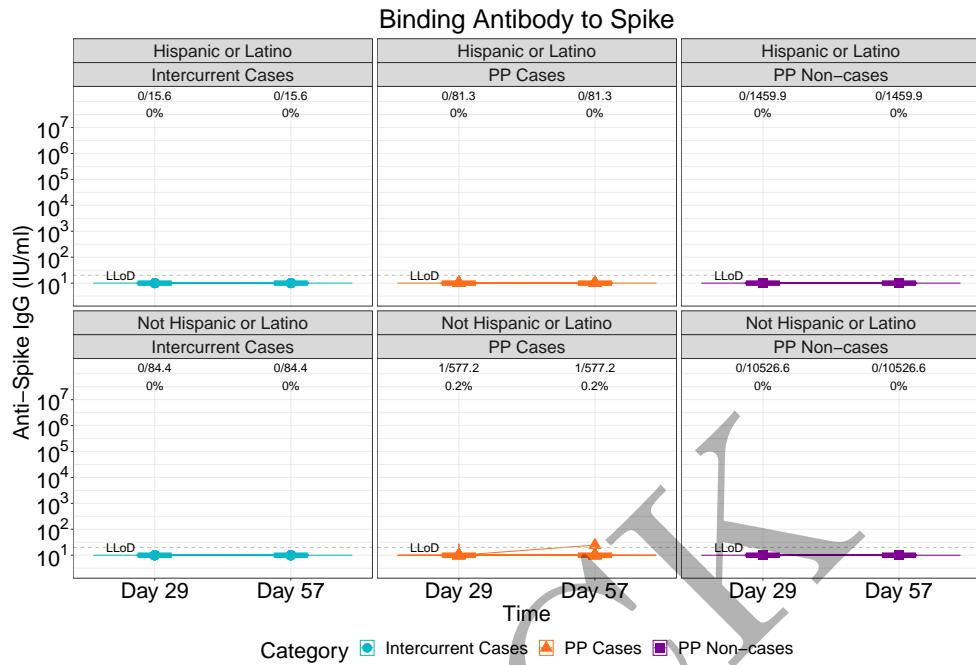


Figure 2.215: lineplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (2 timepoints)

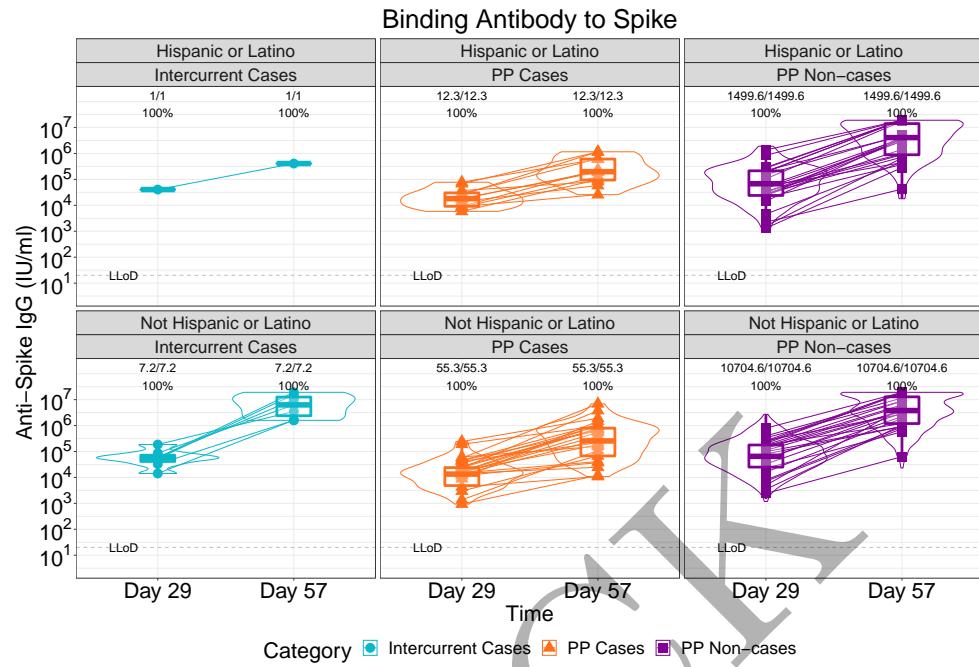


Figure 2.216: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (2 timepoints)

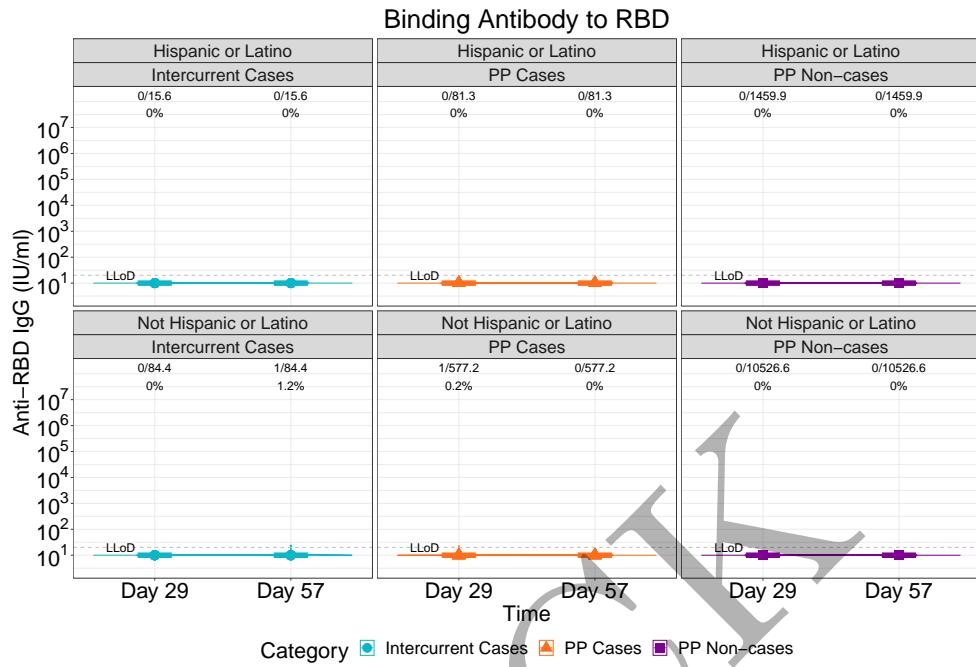


Figure 2.217: lineplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (2 timepoints)

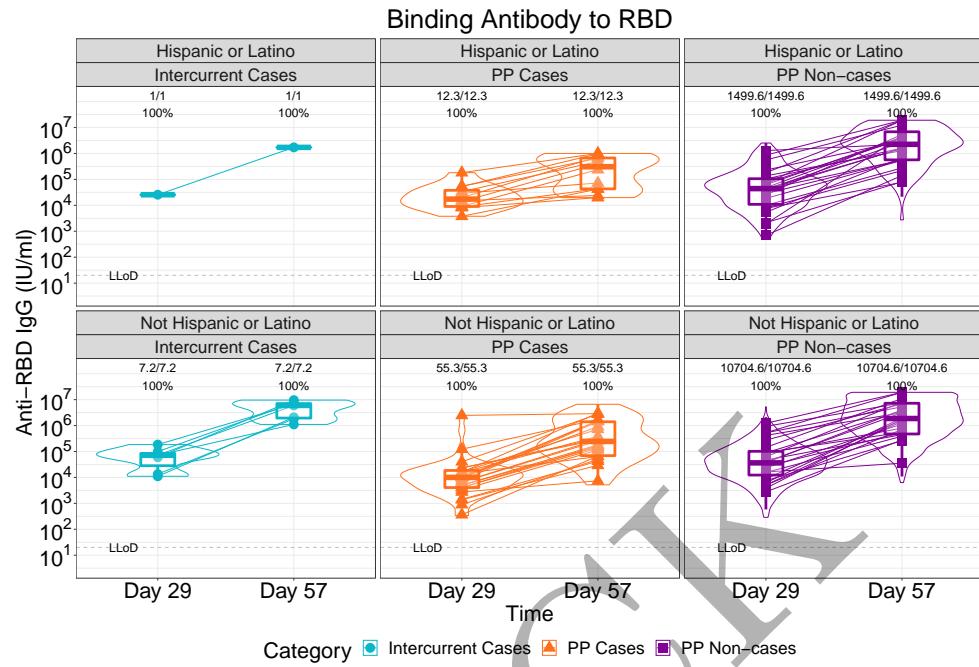


Figure 2.218: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (2 timepoints)

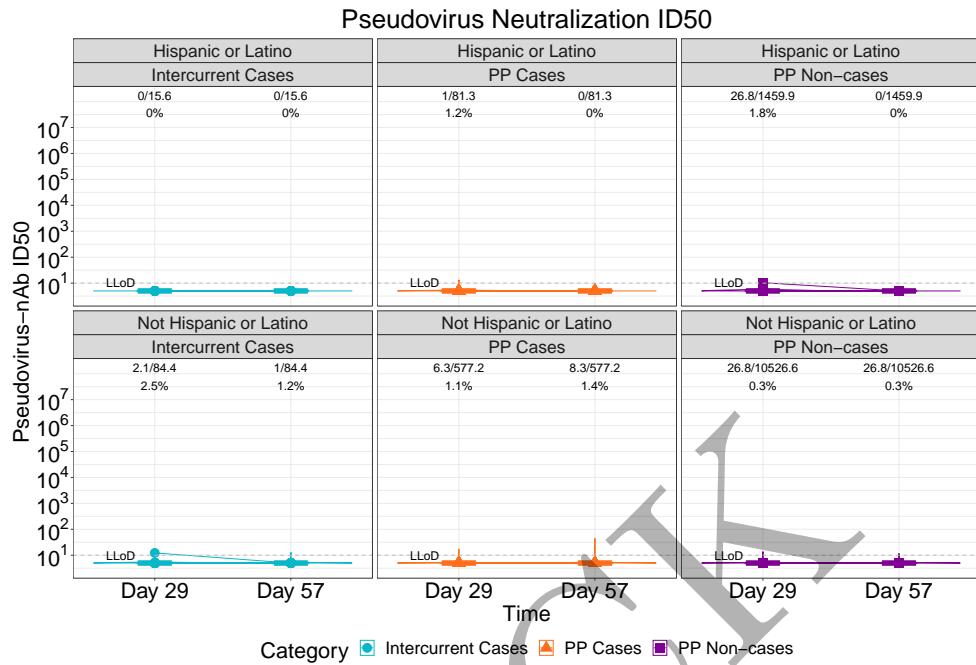


Figure 2.219: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by dichotomous classification of race and ethnic group (2 timepoints)

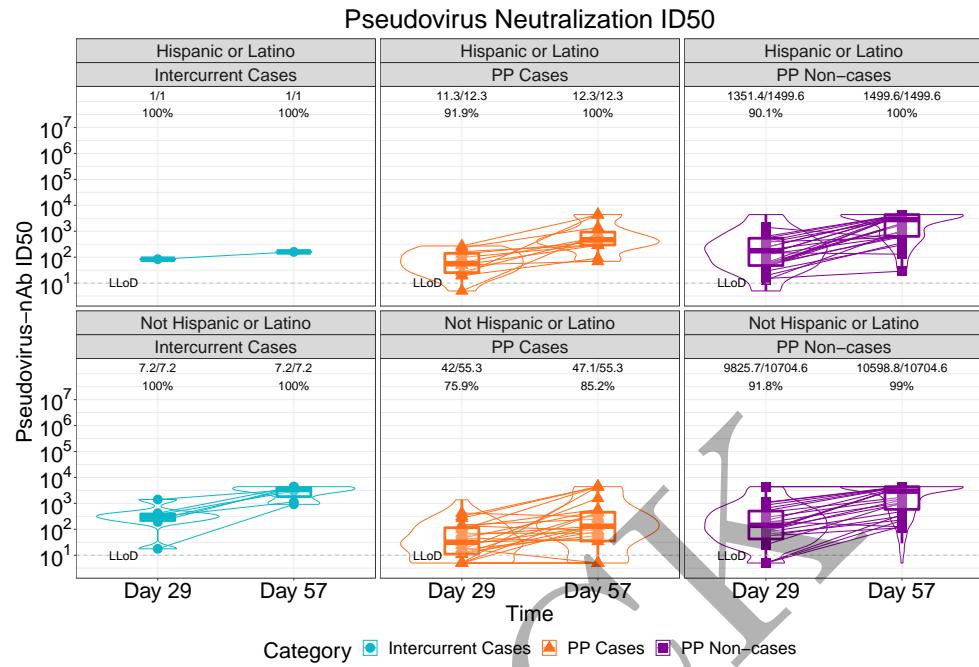


Figure 2.220: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by dichotomous classification of race and ethnic group (2 timepoints)

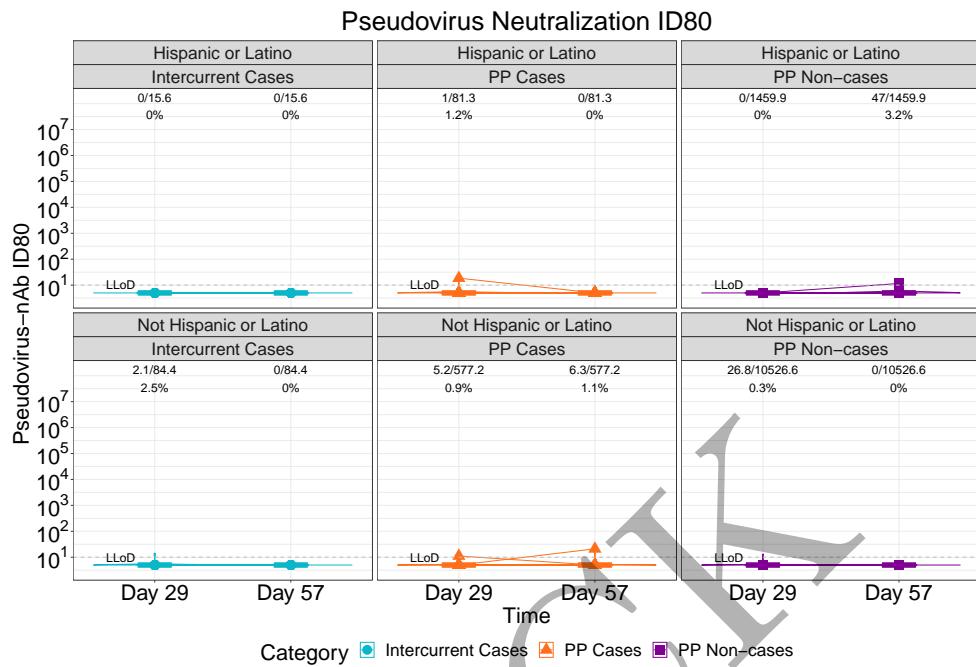


Figure 2.221: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by dichotomous classification of race and ethnic group (2 timepoints)

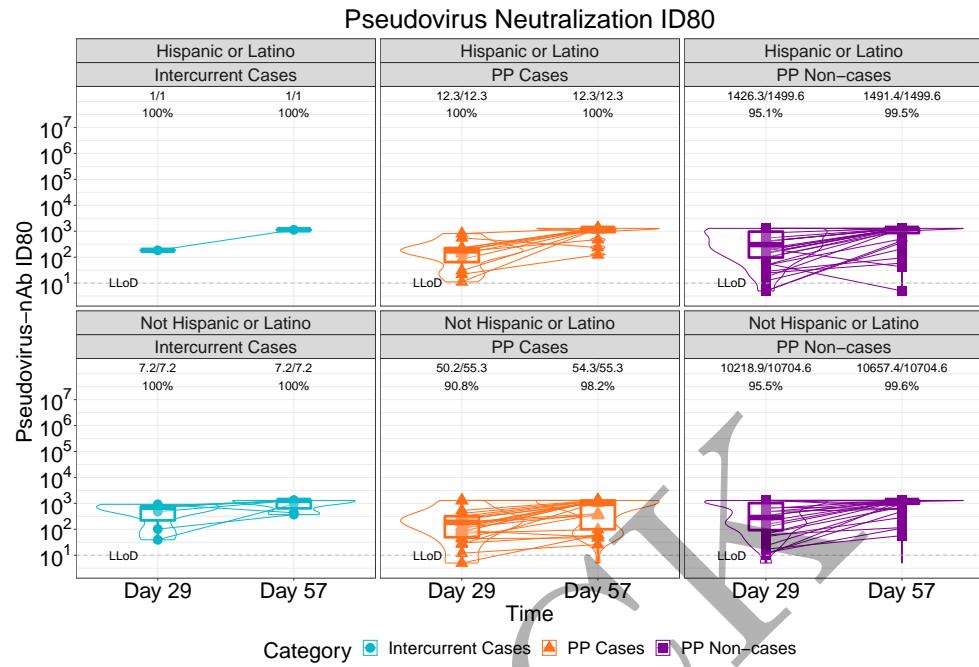


Figure 2.222: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by dichotomous classification of race and ethnic group (2 timepoints)

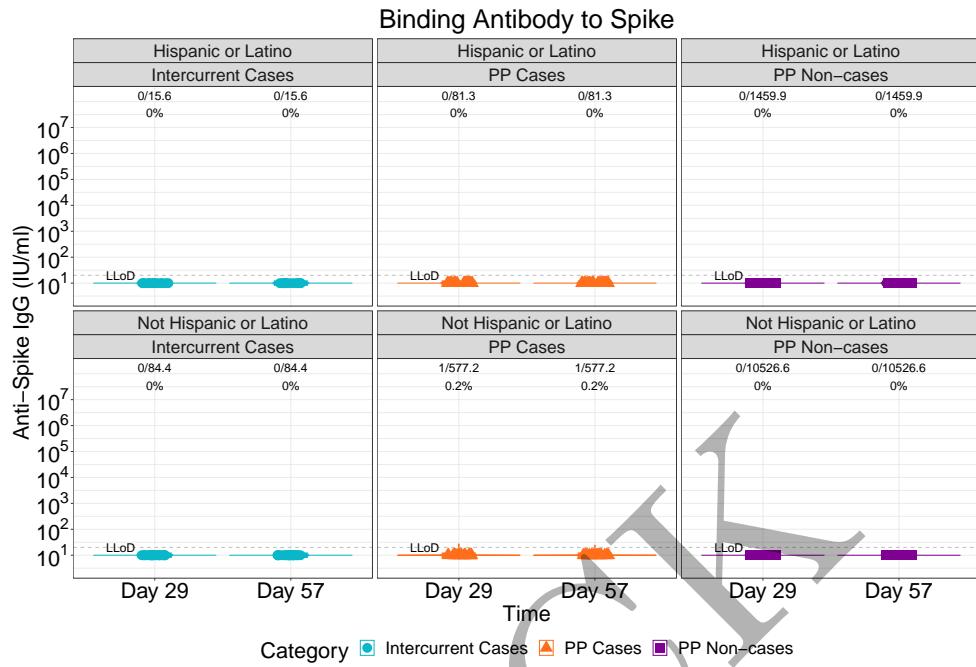


Figure 2.223: violinplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (2 timepoints)

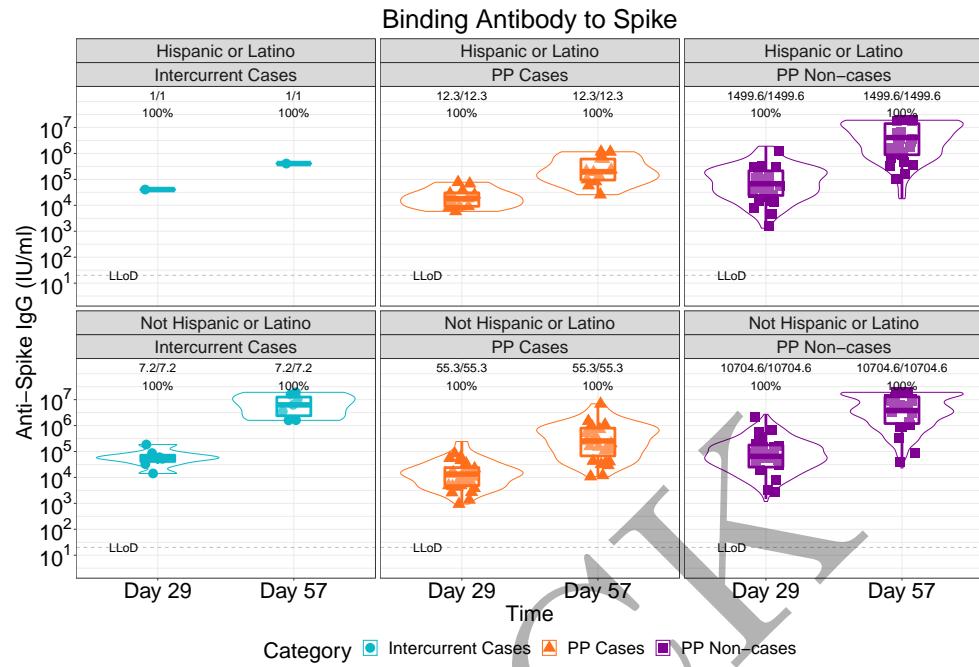


Figure 2.224: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (2 timepoints)

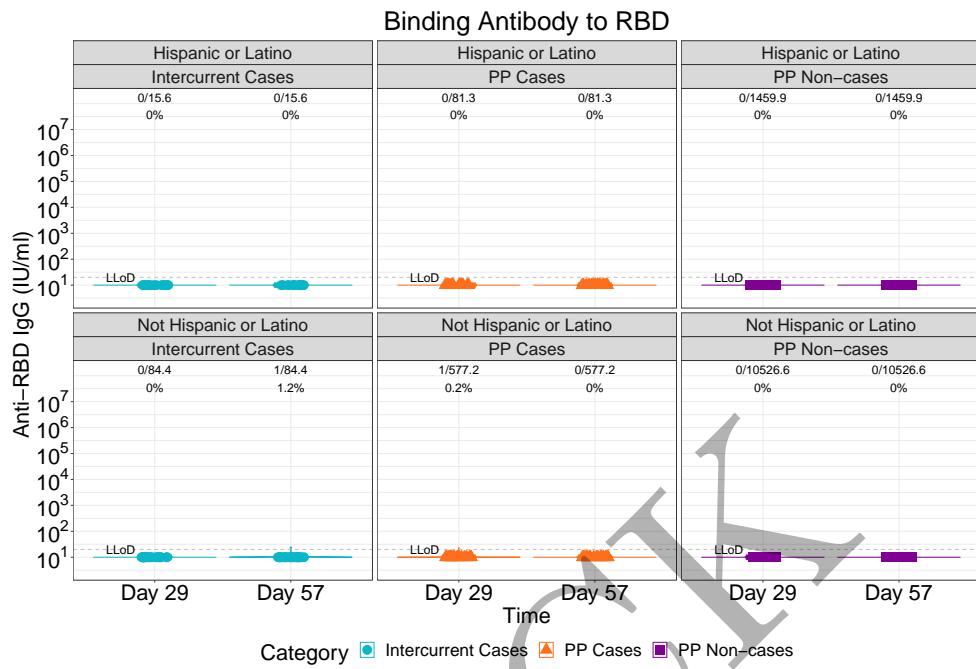


Figure 2.225: violinplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (2 timepoints)

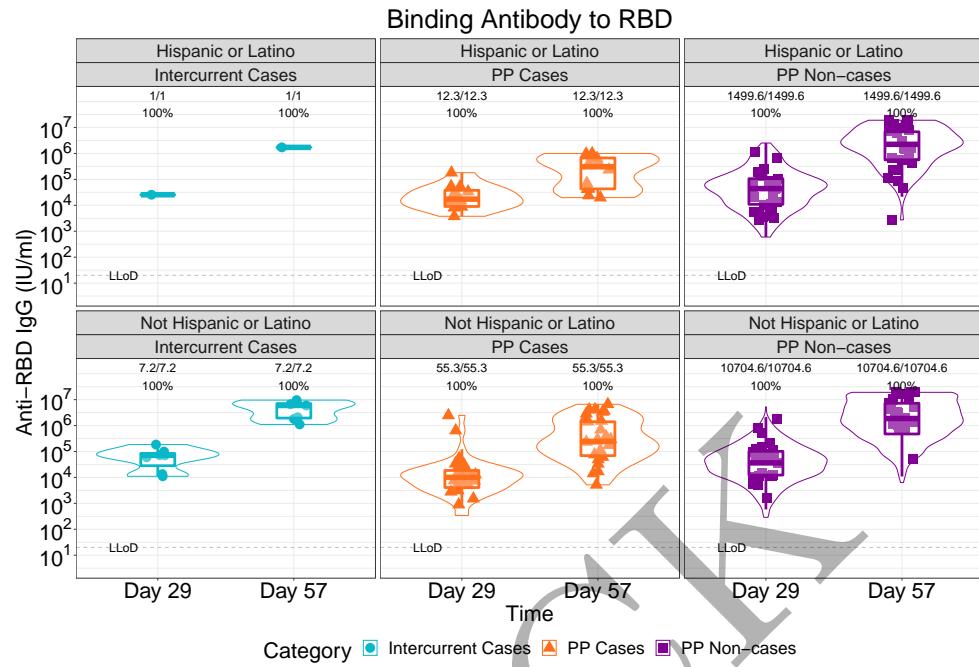


Figure 2.226: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (2 timepoints)

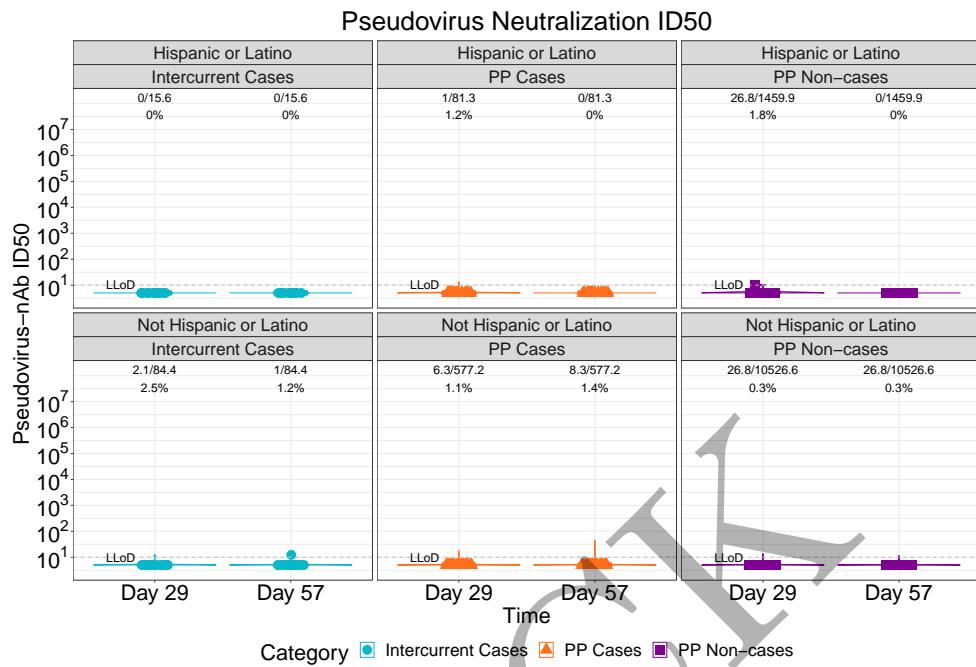


Figure 2.227: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by dichotomous classification of race and ethnic group (2 timepoints)

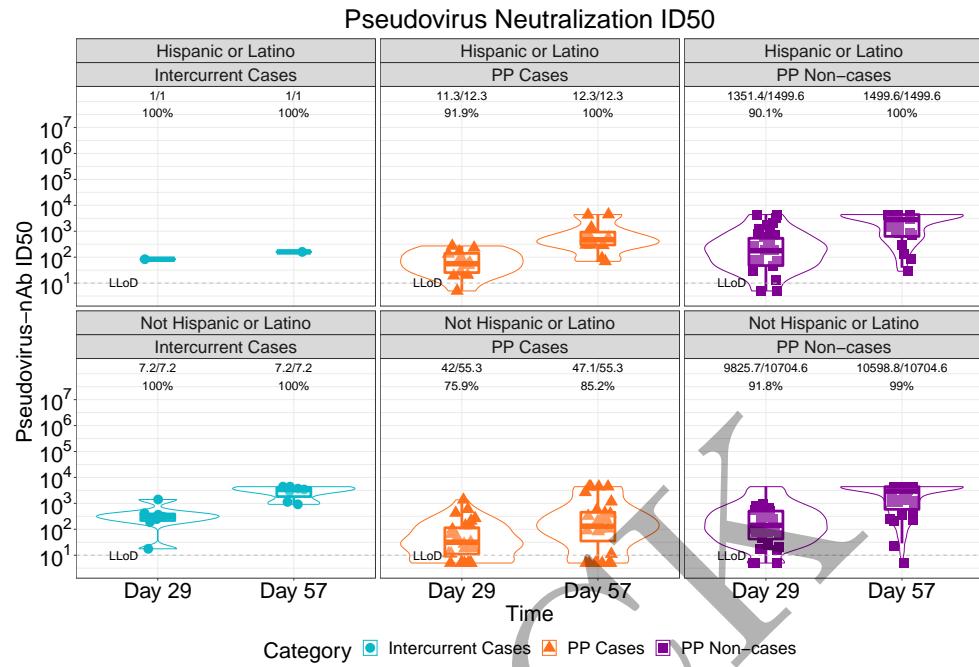


Figure 2.228: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by dichotomous classification of race and ethnic group (2 timepoints)

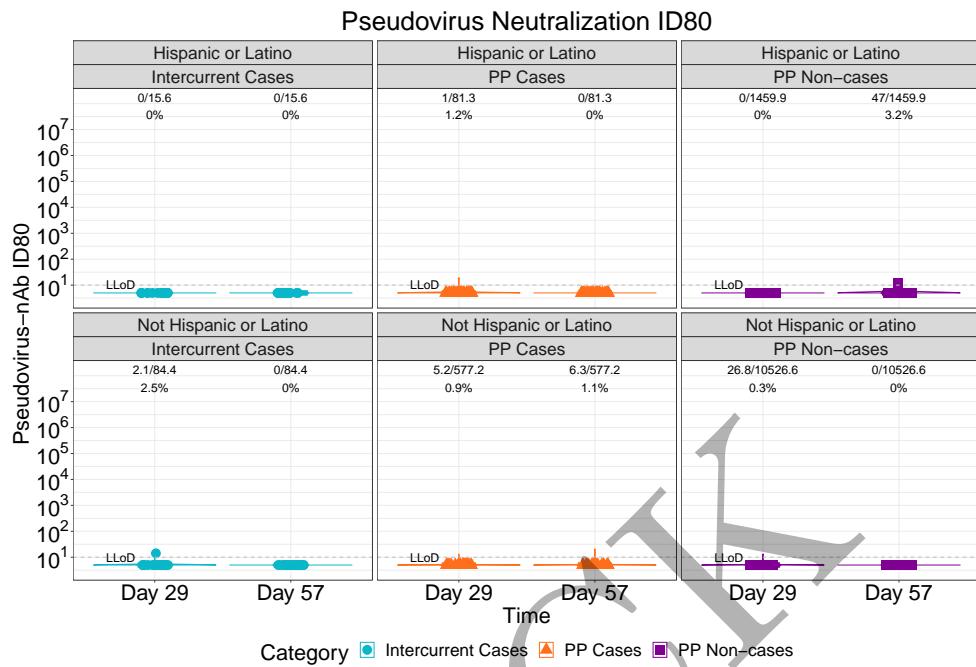


Figure 2.229: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by dichotomous classification of race and ethnic group (2 timepoints)

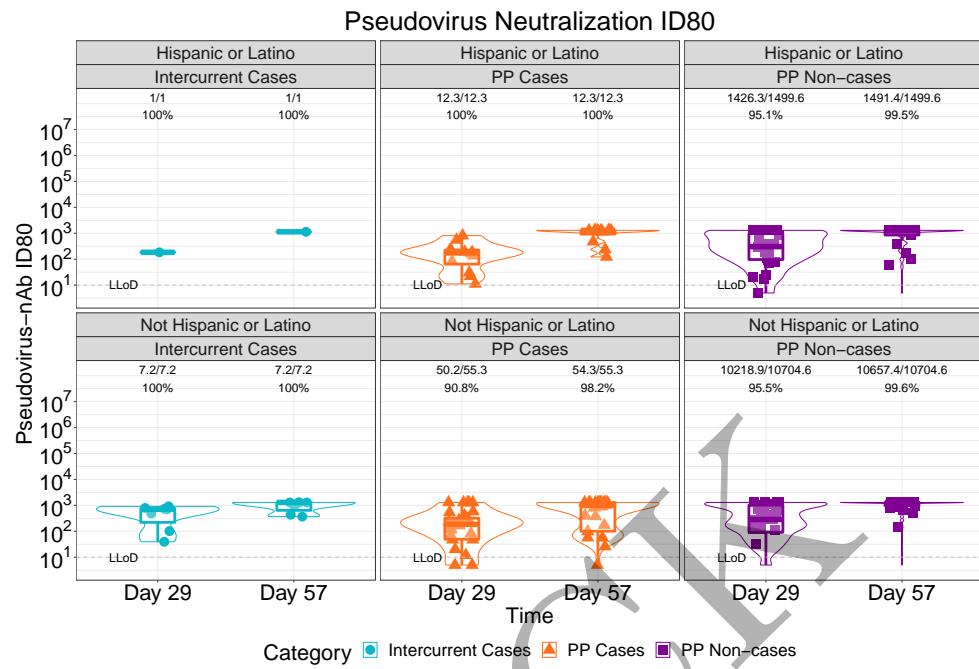


Figure 2.230: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by dichotomous classification of race and ethnic group (2 timepoints)

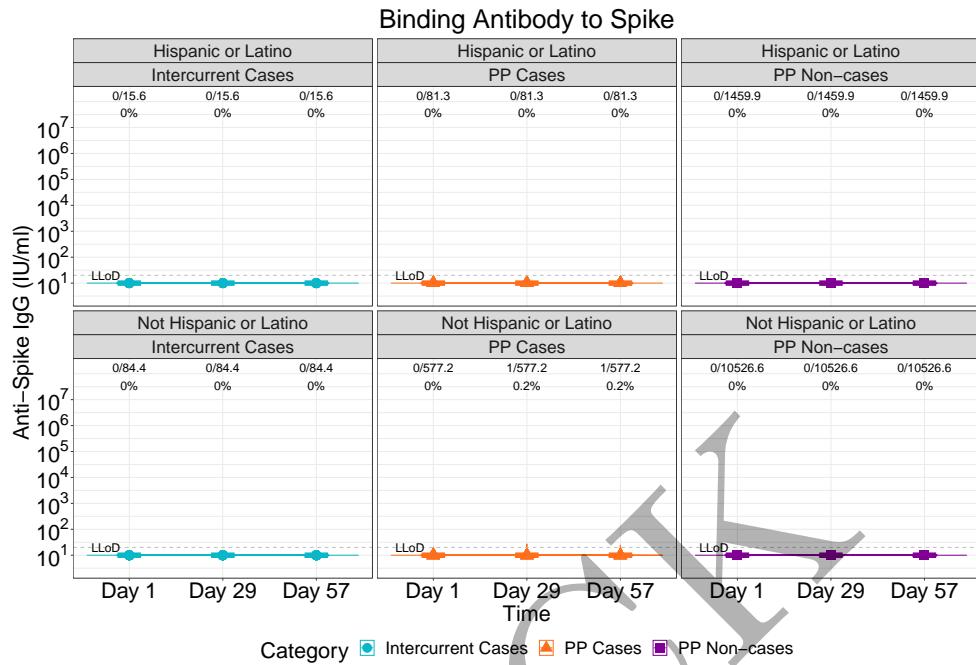


Figure 2.231: lineplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (3 timepoints)

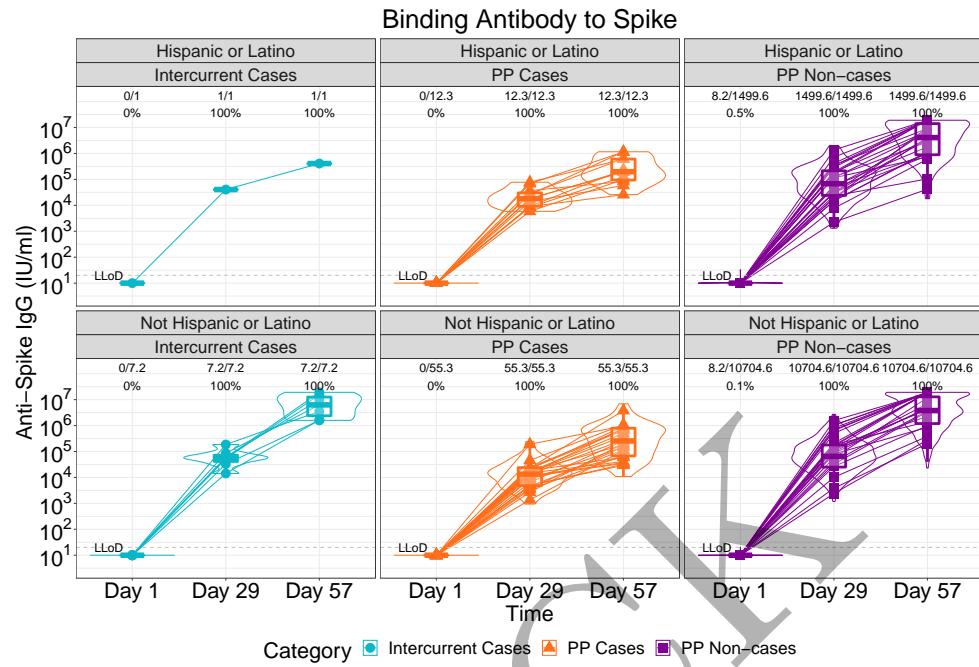


Figure 2.232: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (3 timepoints)

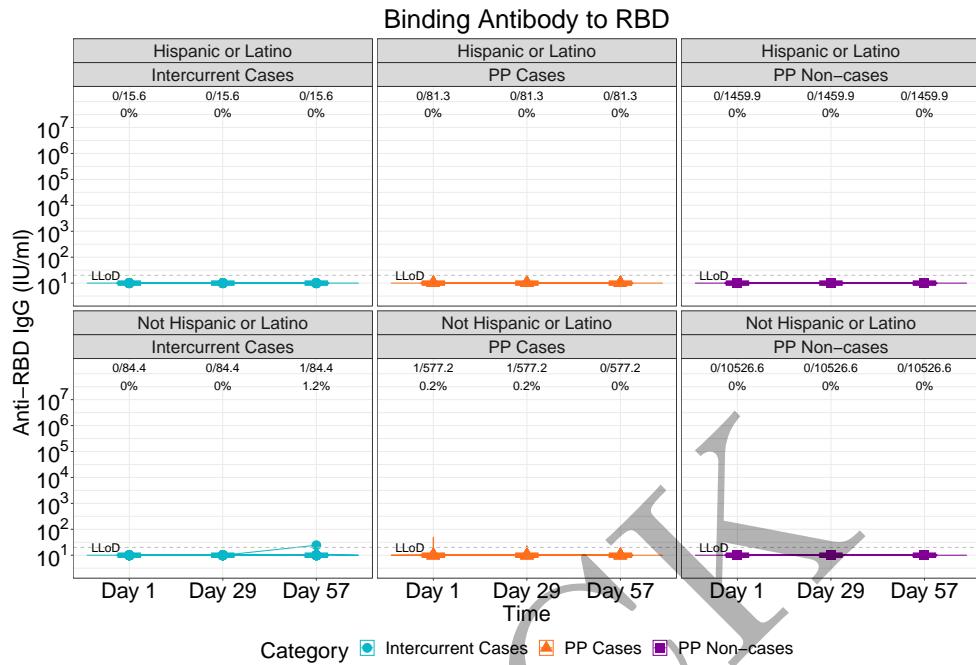


Figure 2.233: lineplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (3 timepoints)

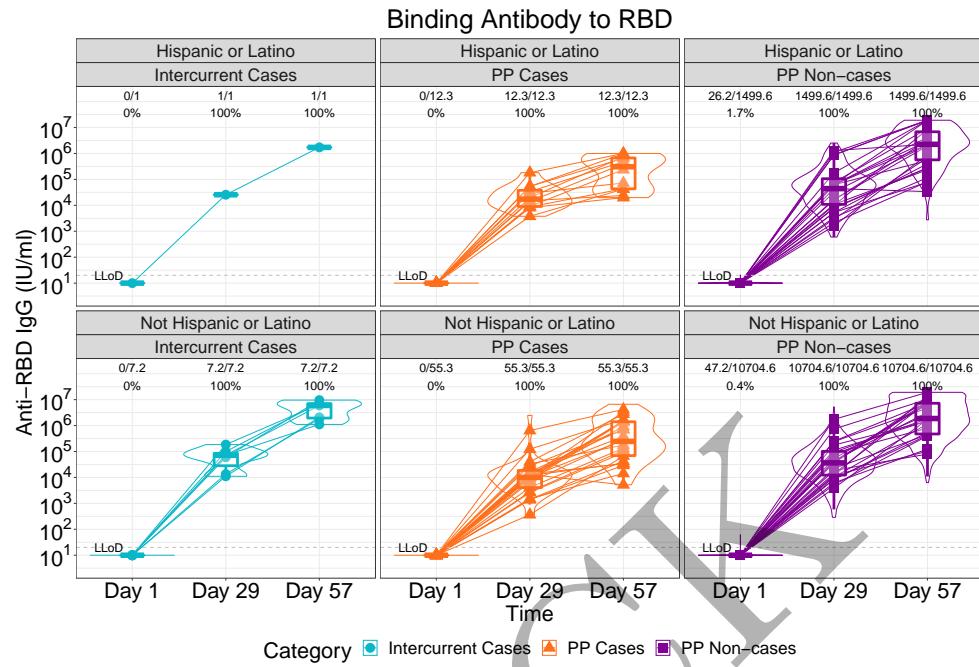


Figure 2.234: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (3 timepoints)

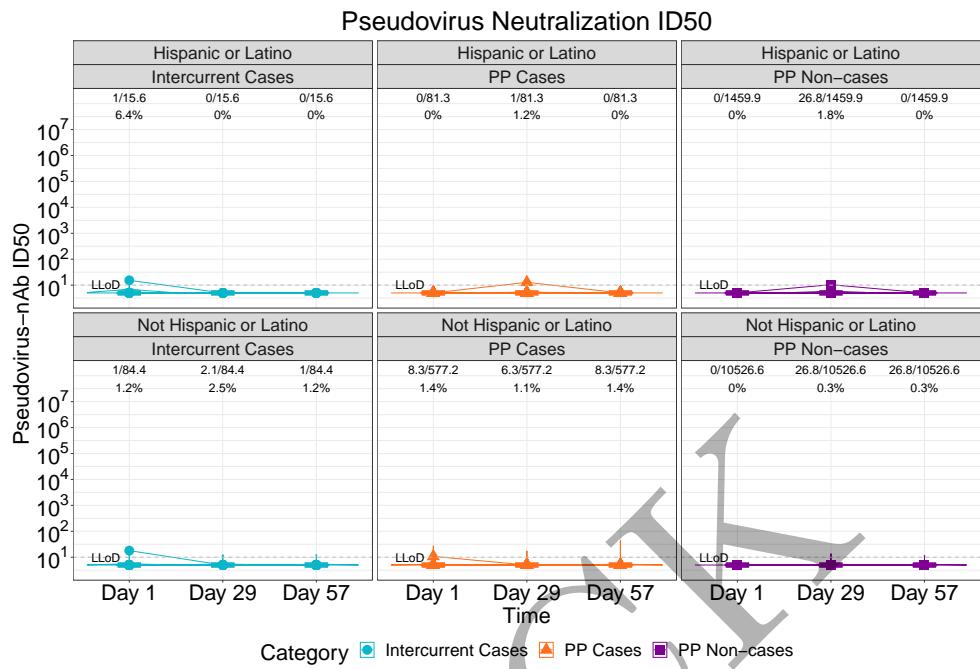


Figure 2.235: lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by dichotomous classification of race and ethnic group (3 timepoints)

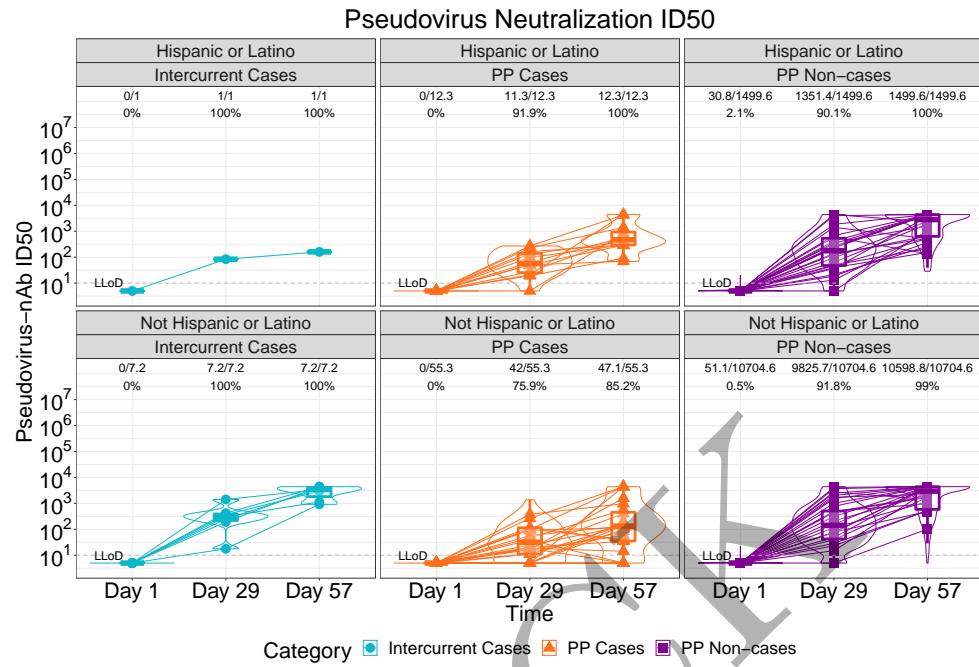


Figure 2.236: lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by dichotomous classification of race and ethnic group (3 timepoints)

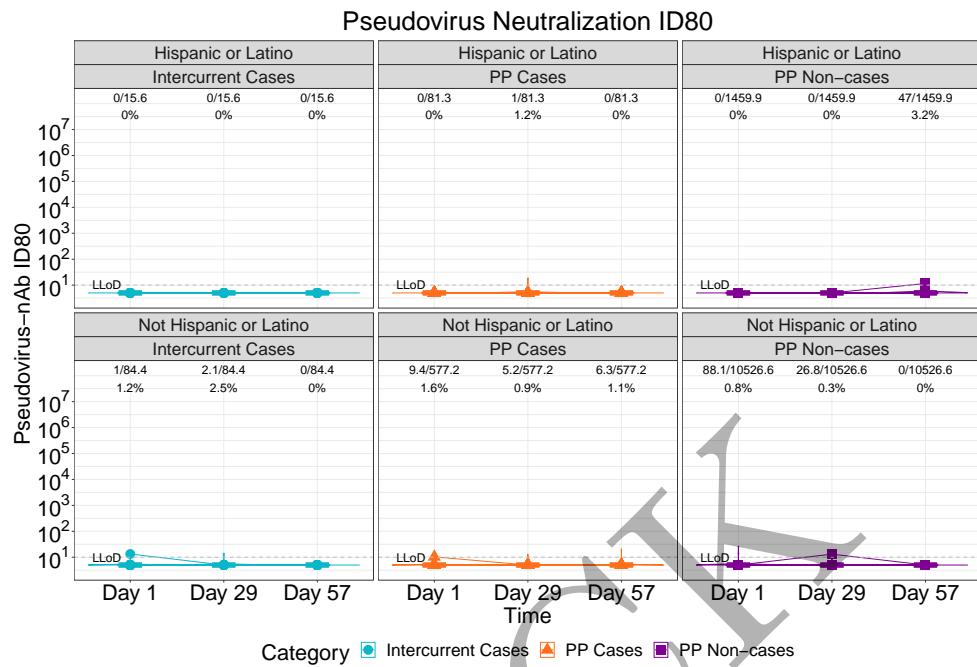


Figure 2.237: lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by dichotomous classification of race and ethnic group (3 timepoints)

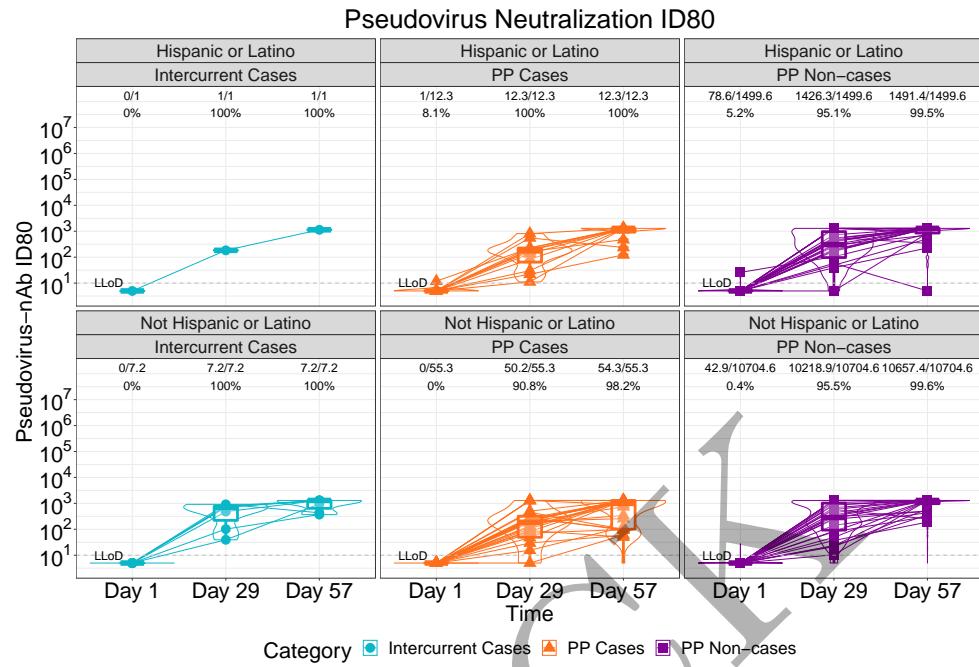


Figure 2.238: lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by dichotomous classification of race and ethnic group (3 timepoints)

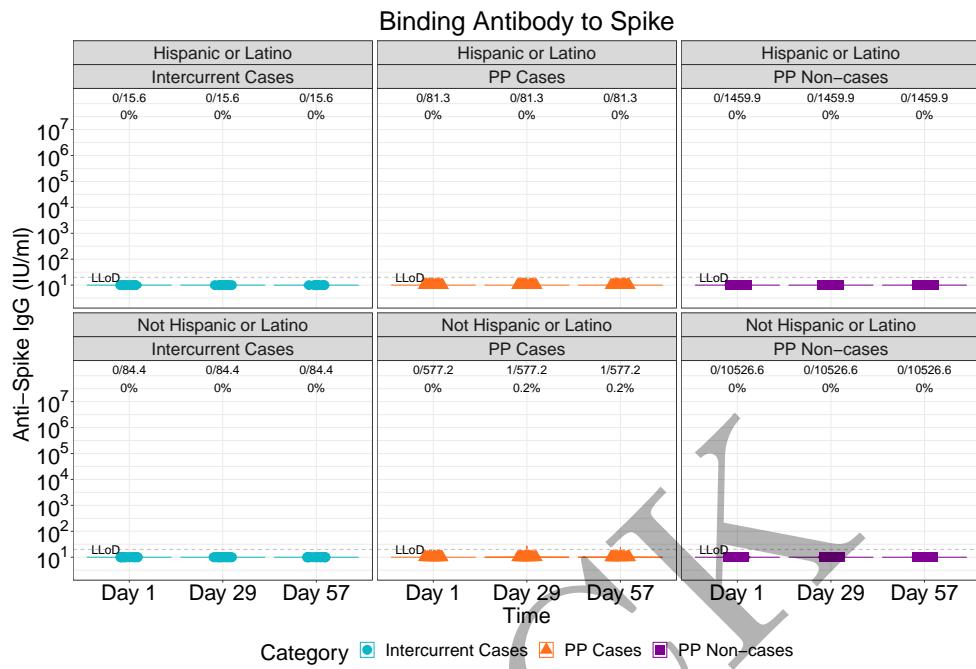


Figure 2.239: violinplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (3 timepoints)

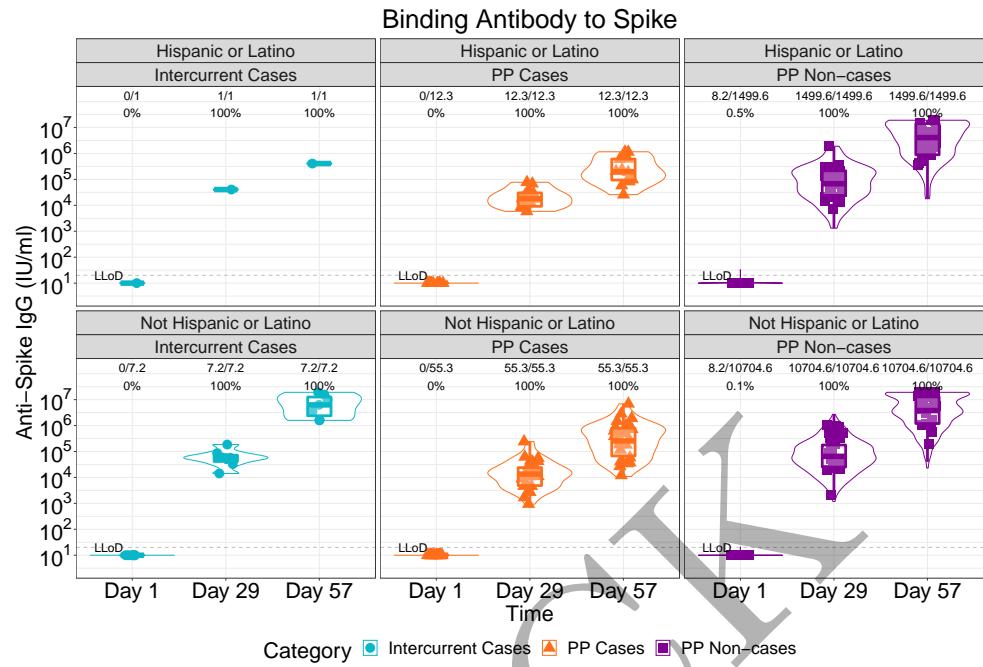


Figure 2.240: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (3 timepoints)

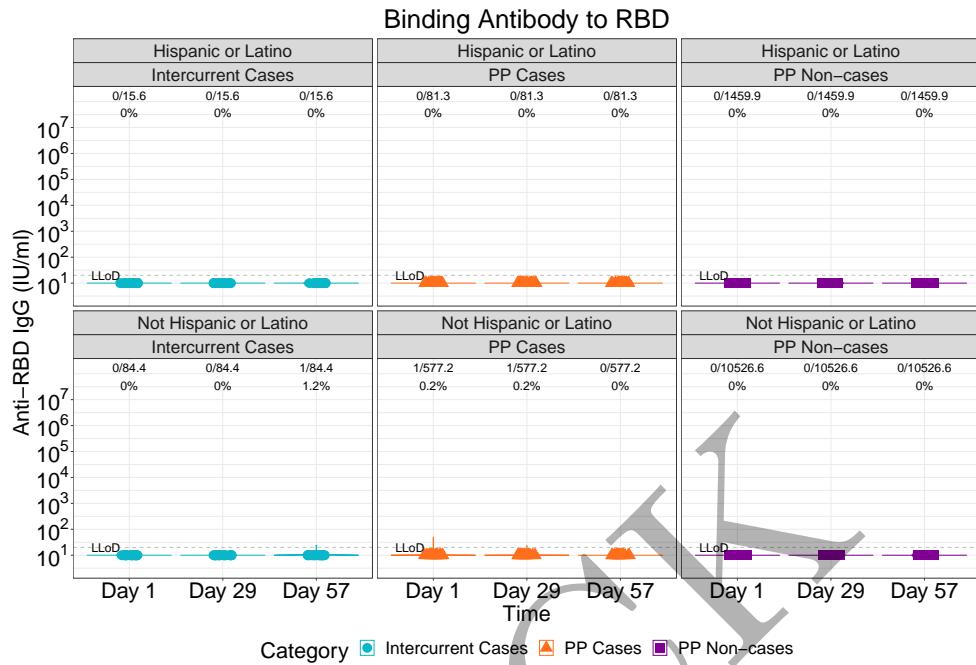


Figure 2.241: violinplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (3 timepoints)

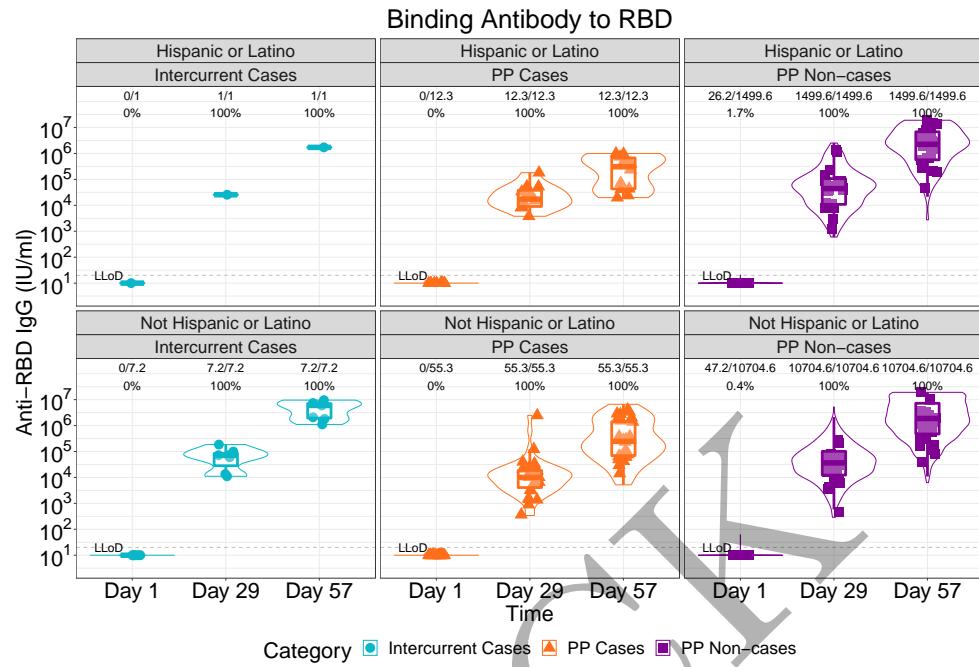


Figure 2.242: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (3 timepoints)

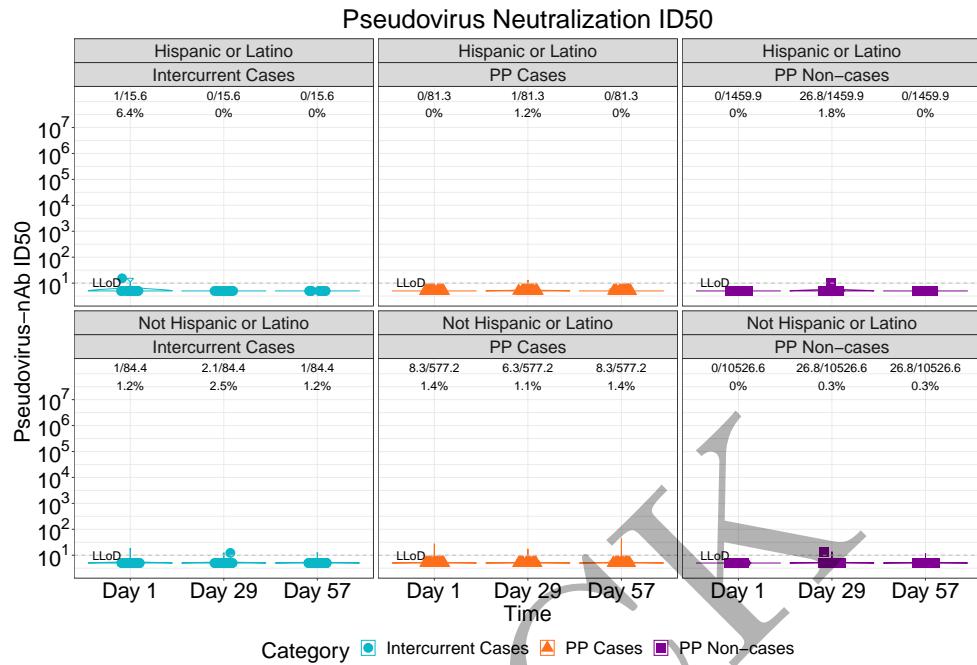


Figure 2.243: violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by dichotomous classification of race and ethnic group (3 timepoints)

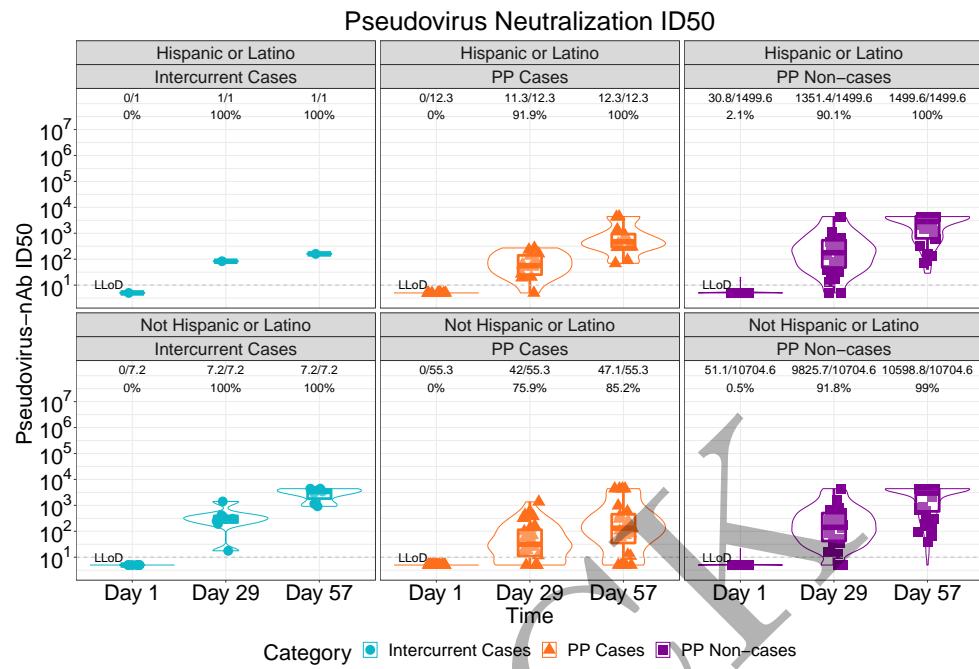


Figure 2.244: violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by dichotomous classification of race and ethnic group (3 timepoints)

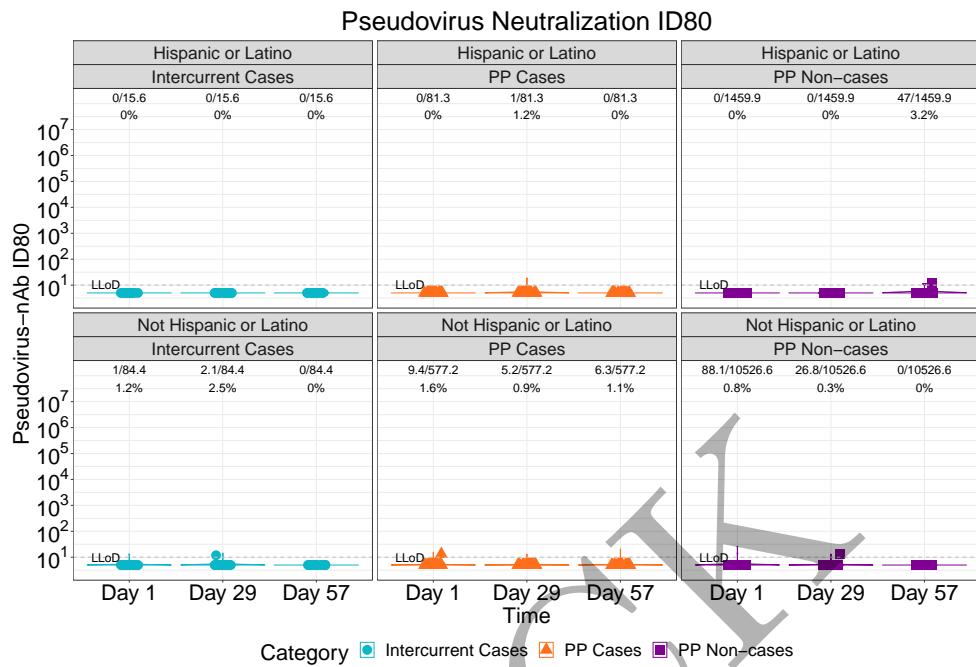


Figure 2.245: violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by dichotomous classification of race and ethnic group (3 timepoints)

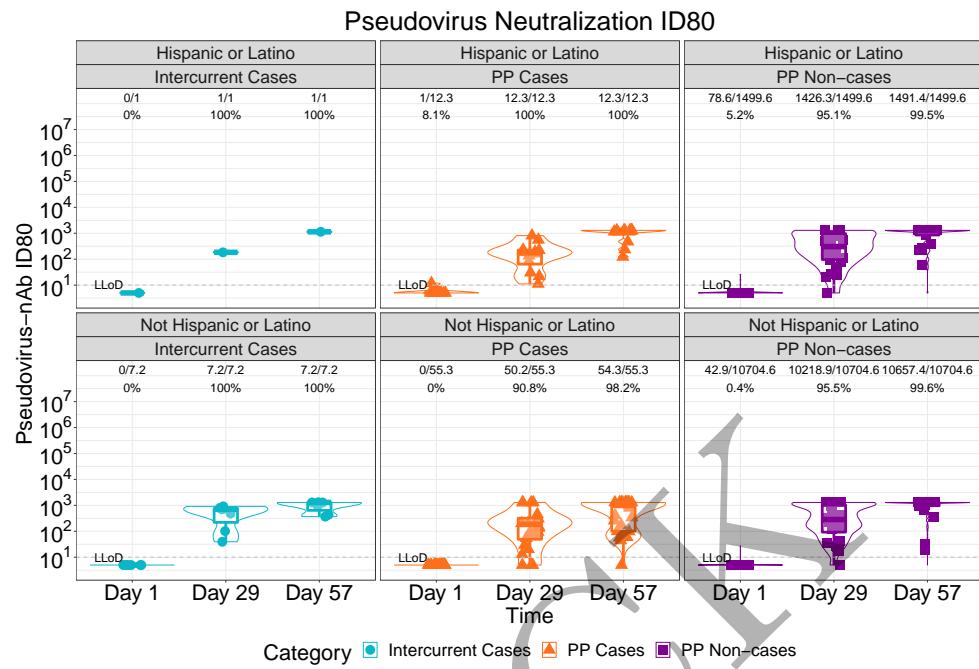


Figure 2.246: violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by dichotomous classification of race and ethnic group (3 timepoints)

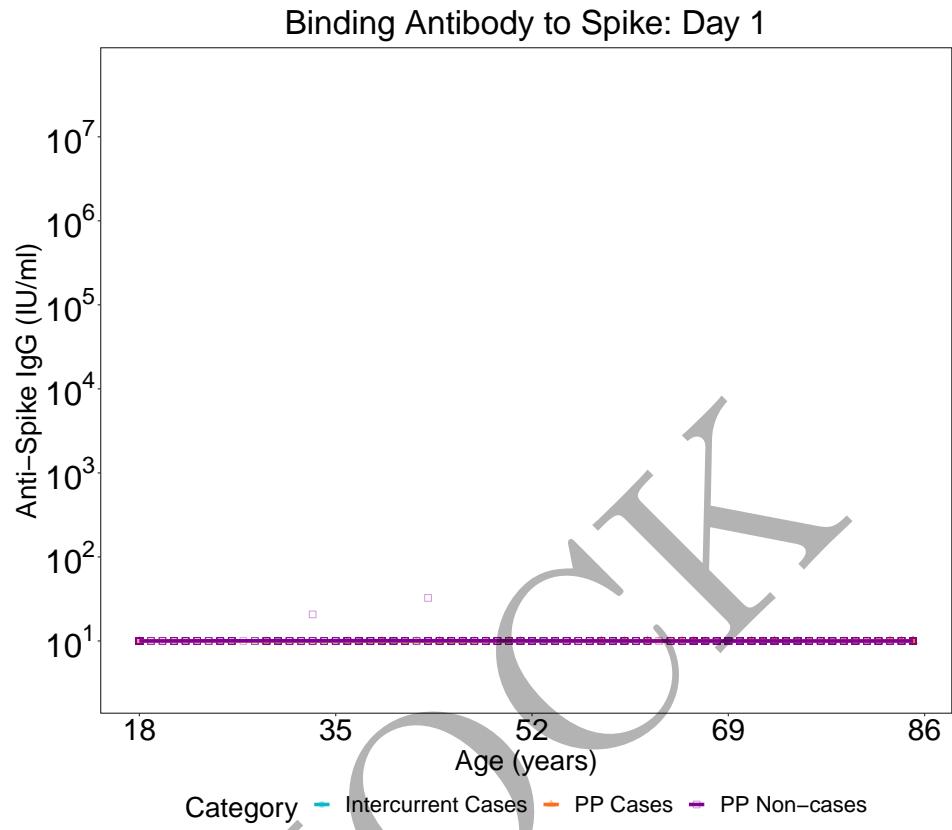


Figure 2.247: scatterplots of Binding Antibody to Spike: baseline negative vaccine arm at day 1

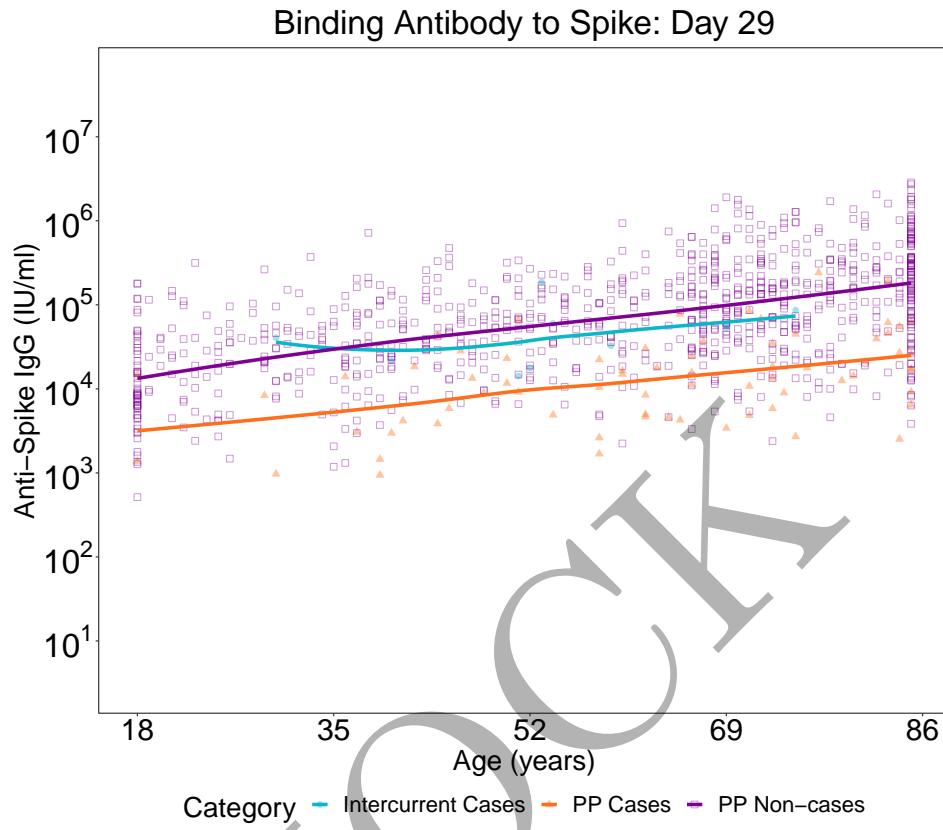


Figure 2.248: scatterplots of Binding Antibody to Spike: baseline negative vaccine arm at day 29

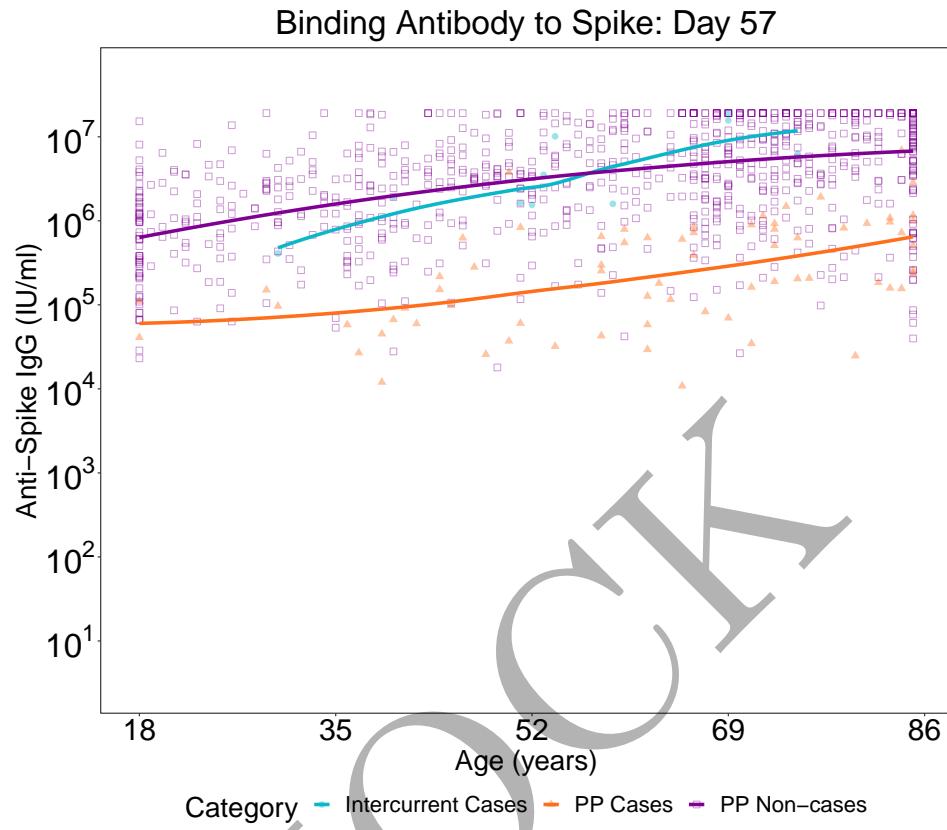


Figure 2.249: scatterplots of Binding Antibody to Spike: baseline negative vaccine arm at day 57

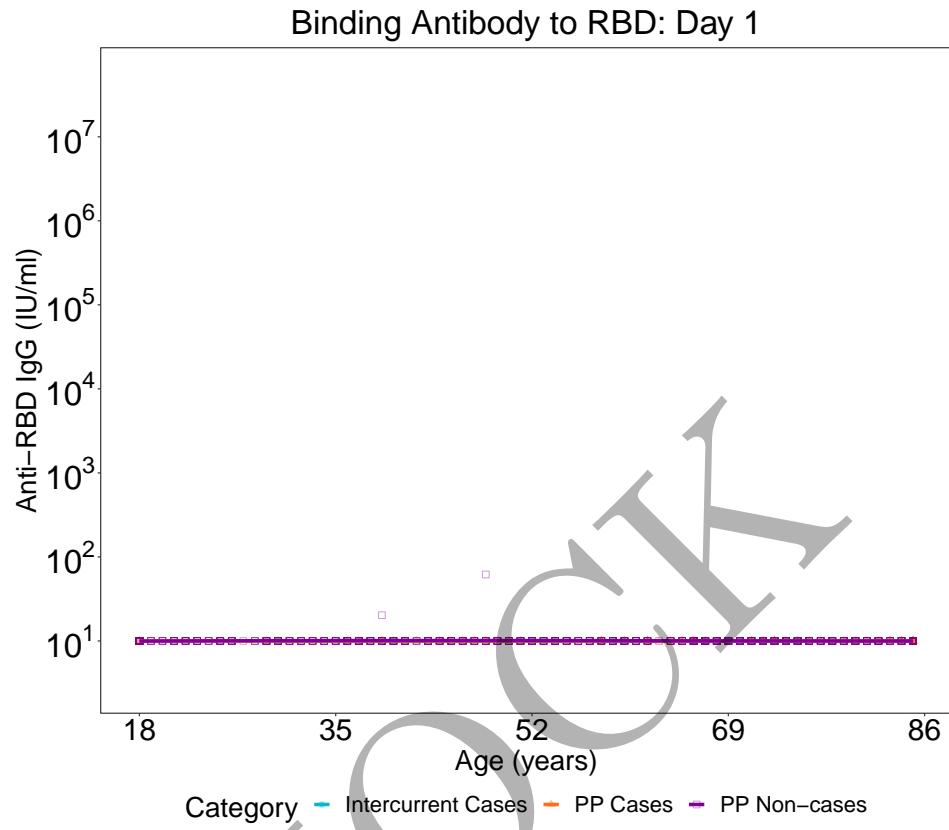


Figure 2.250: scatterplots of Binding Antibody to RBD: baseline negative vaccine arm at day 1

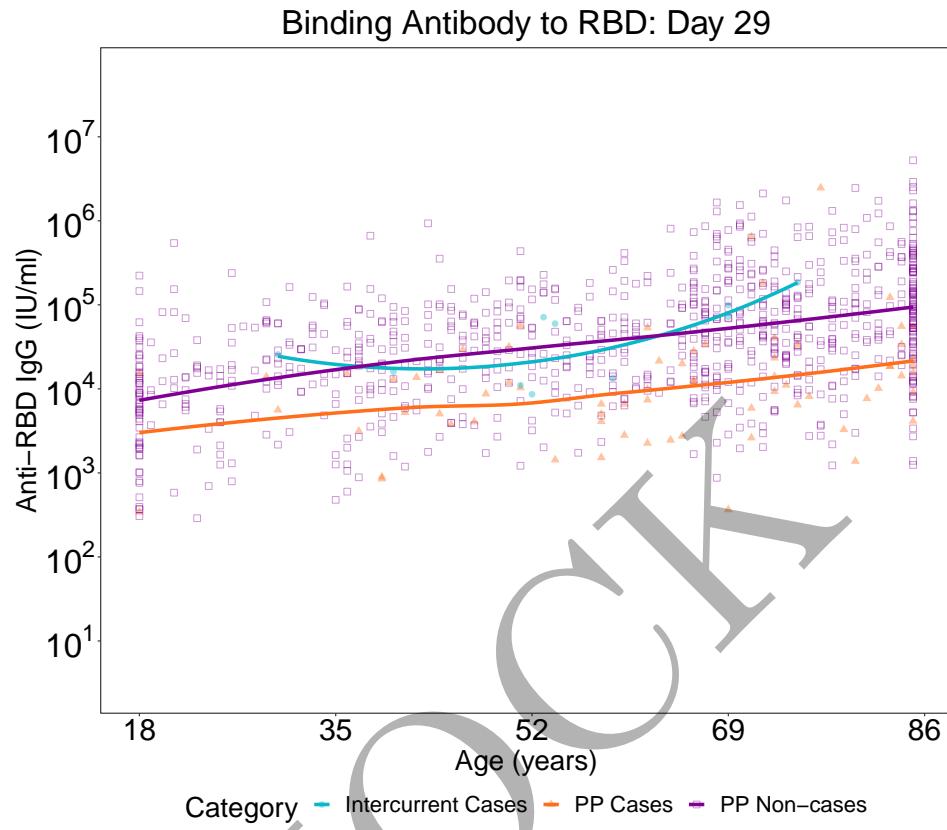


Figure 2.251: scatterplots of Binding Antibody to RBD: baseline negative vaccine arm at day 29

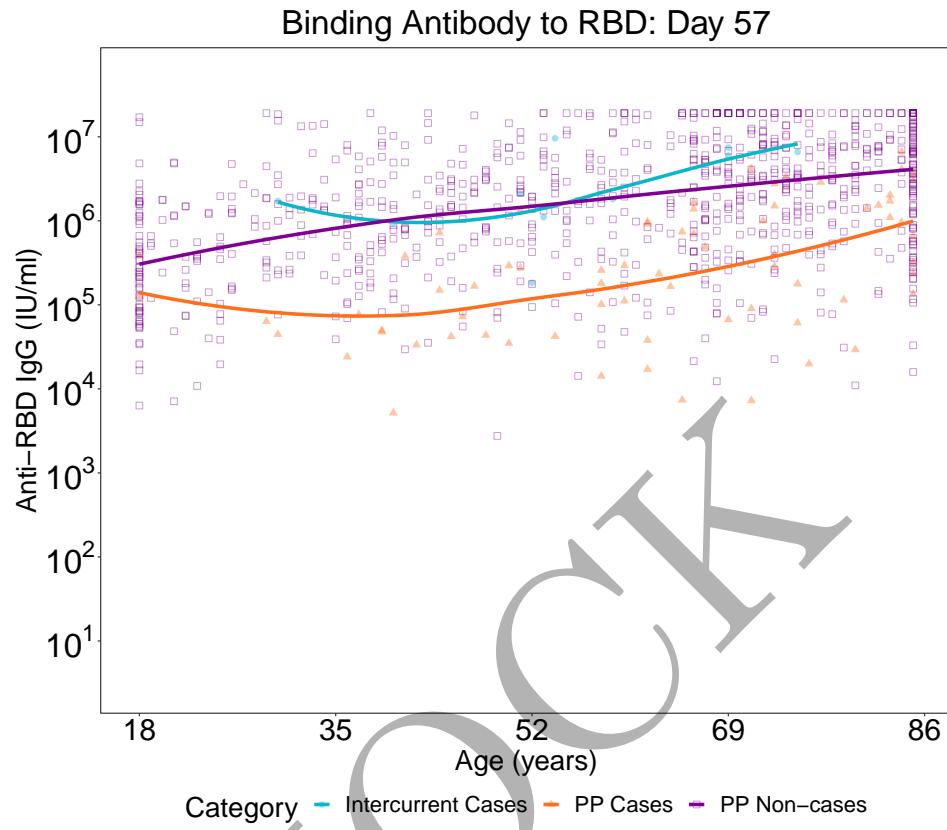


Figure 2.252: scatterplots of Binding Antibody to RBD: baseline negative vaccine arm at day 57

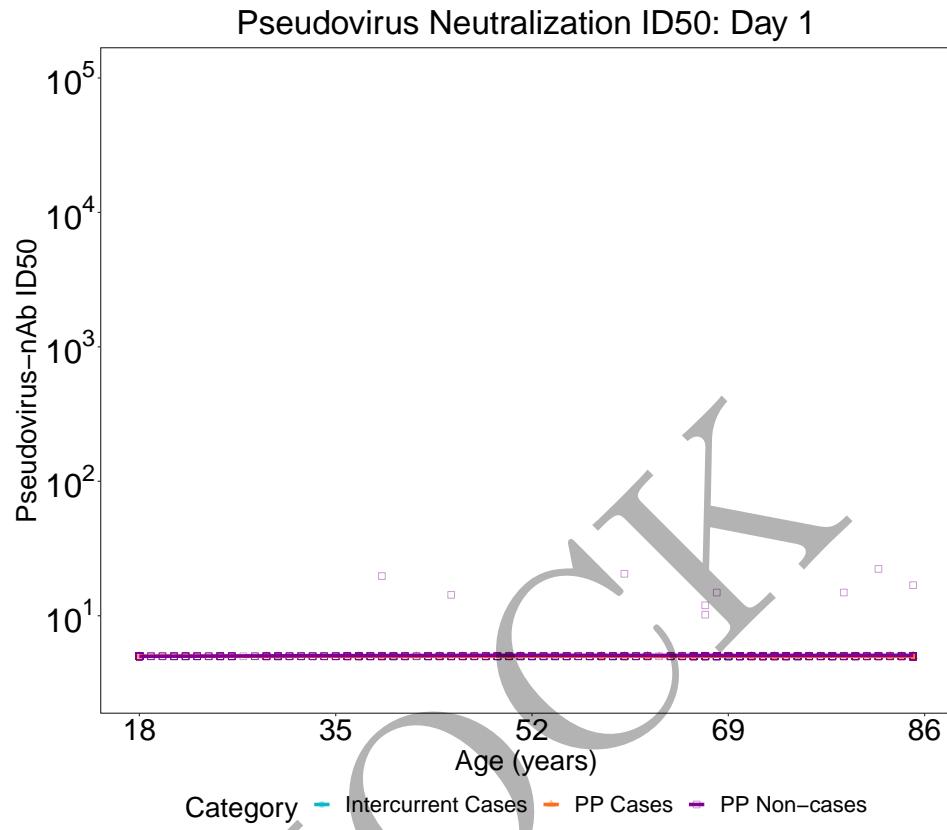


Figure 2.253: scatterplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm at day 1

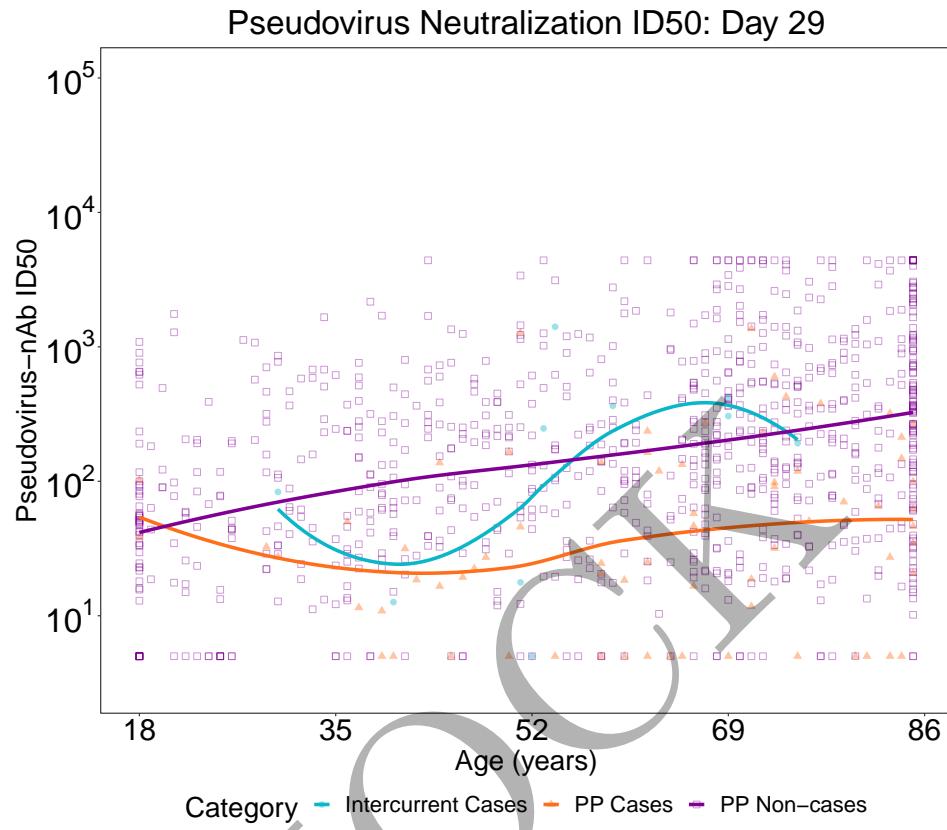


Figure 2.254: scatterplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm at day 29

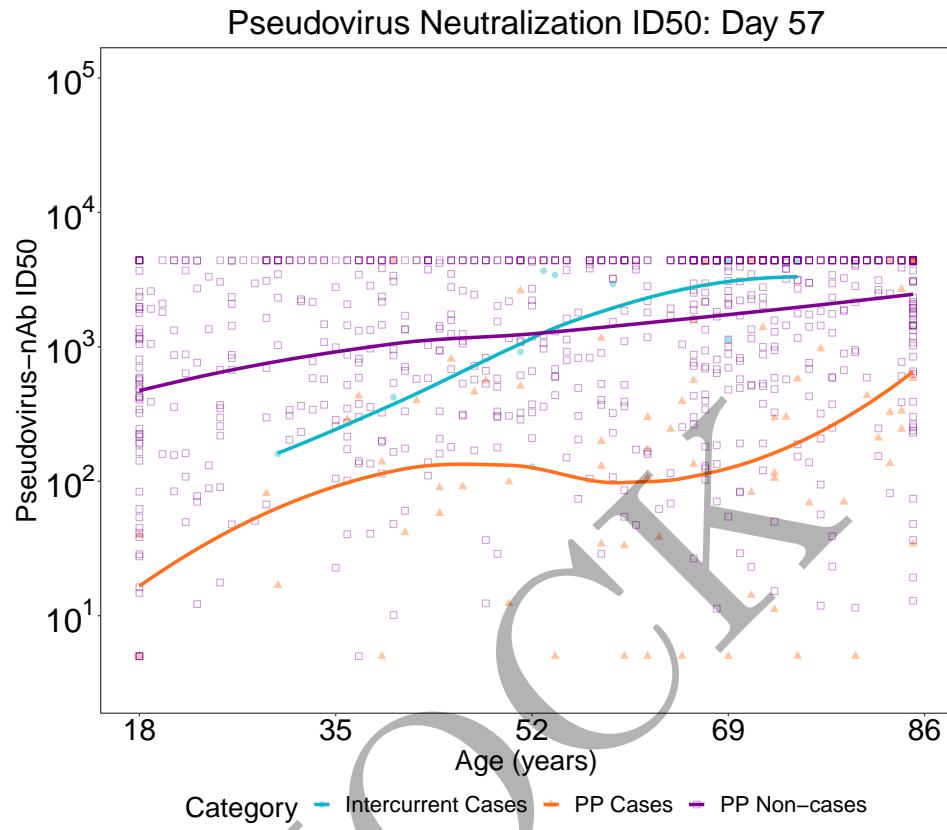


Figure 2.255: scatterplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm at day 57

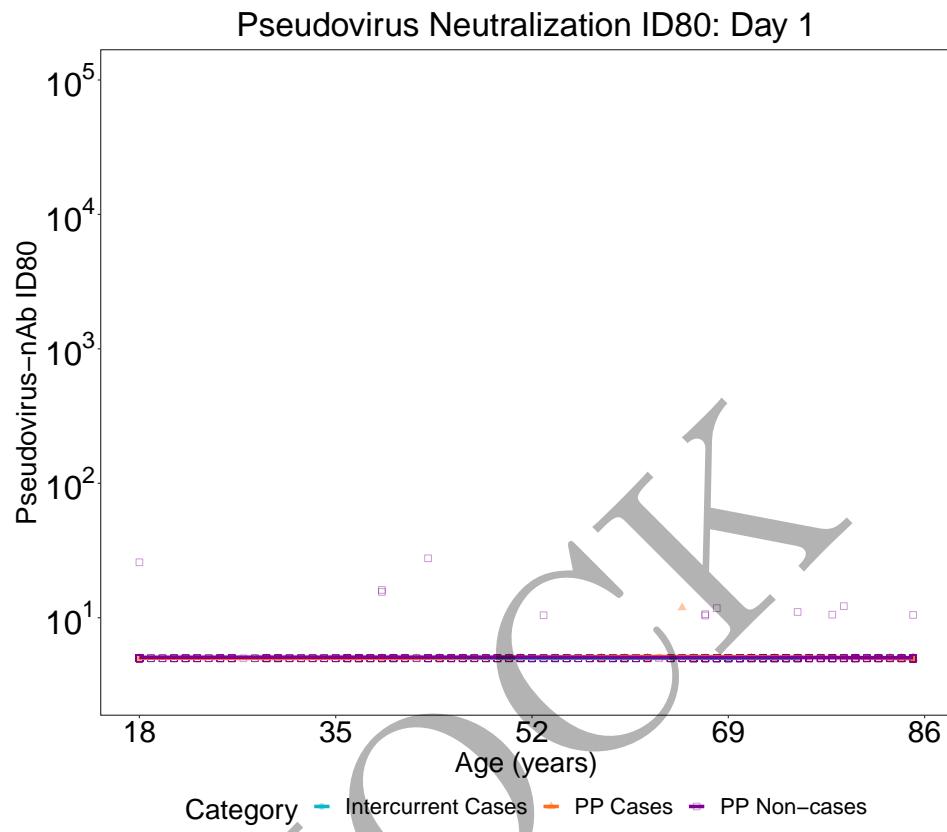


Figure 2.256: scatterplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm at day 1

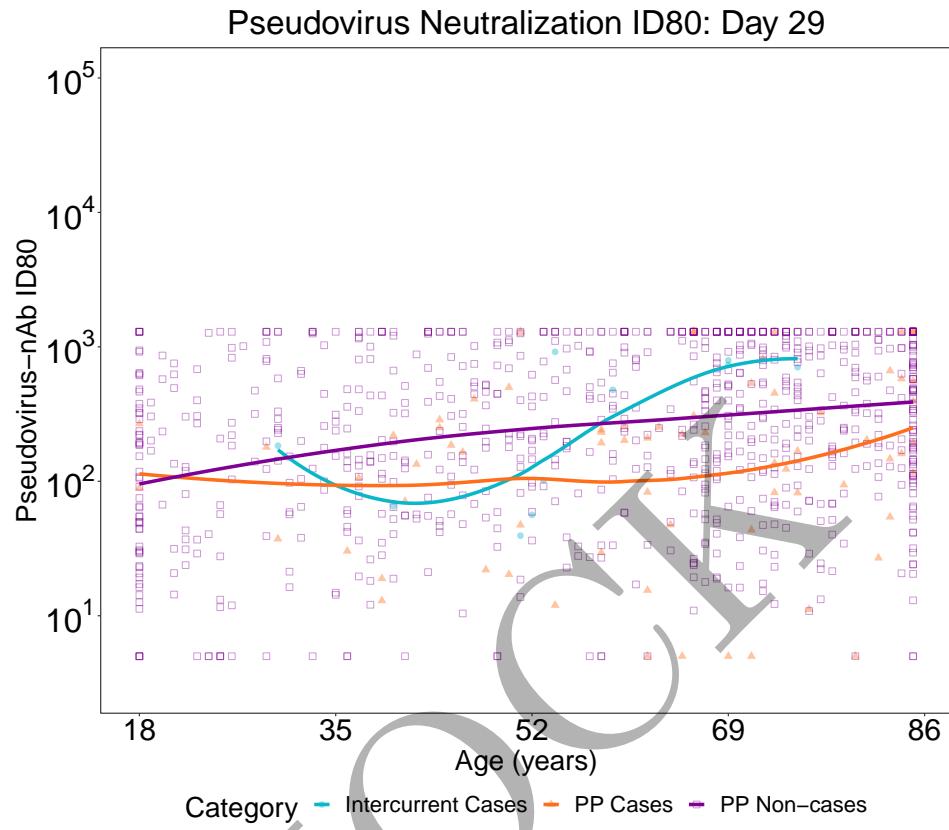


Figure 2.257: scatterplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm at day 29

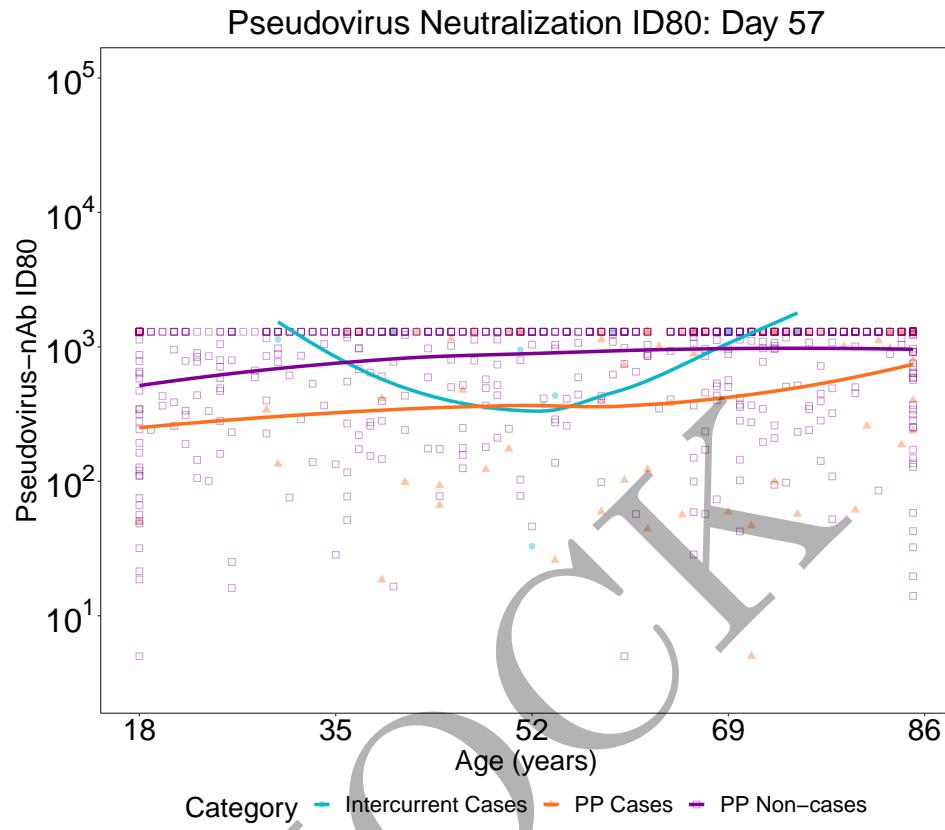


Figure 2.258: scatterplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm at day 57

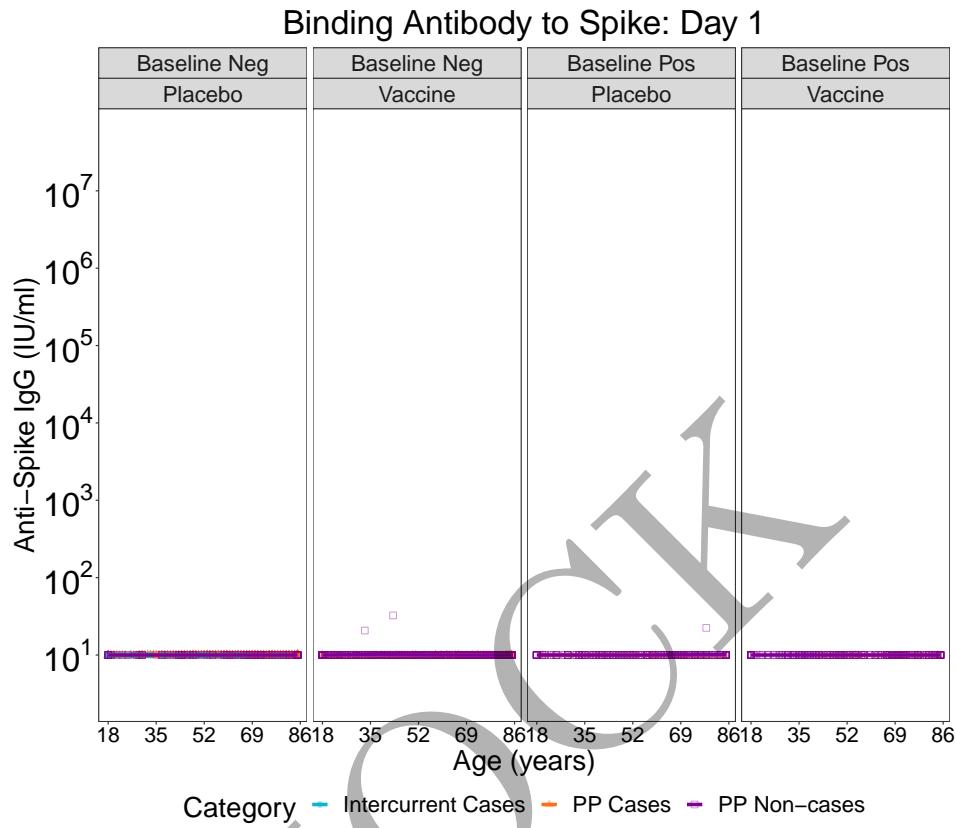


Figure 2.259: scatterplots of Binding Antibody to Spike: by arm at day 1

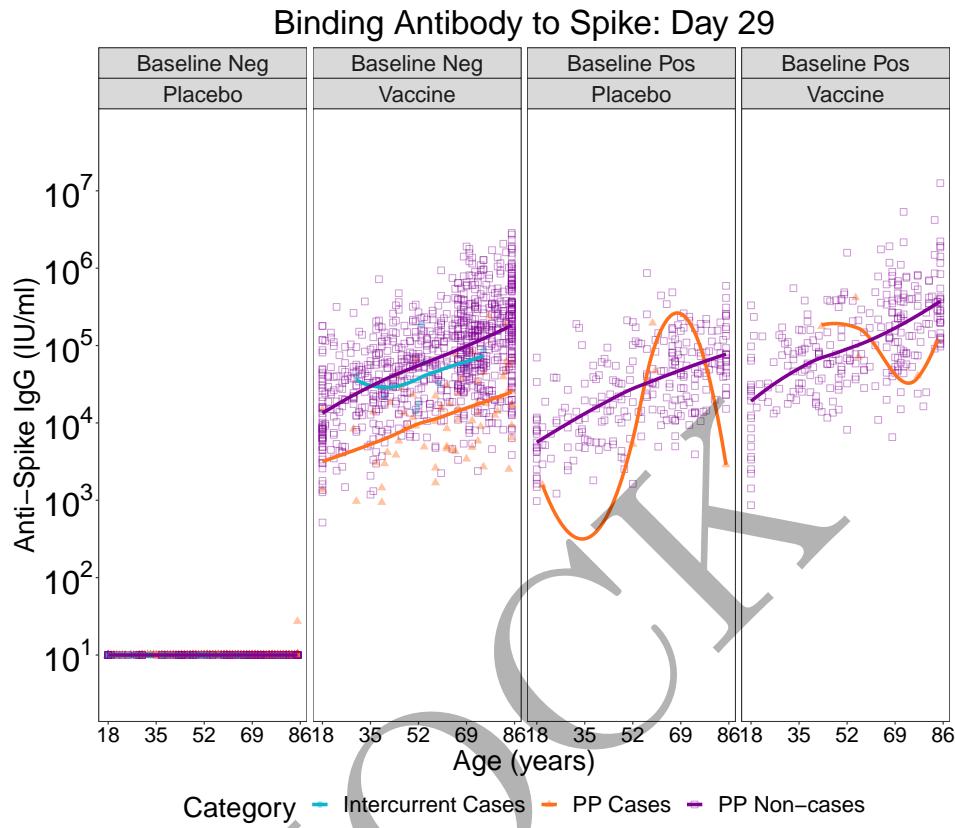


Figure 2.260: scatterplots of Binding Antibody to Spike: by arm at day 29

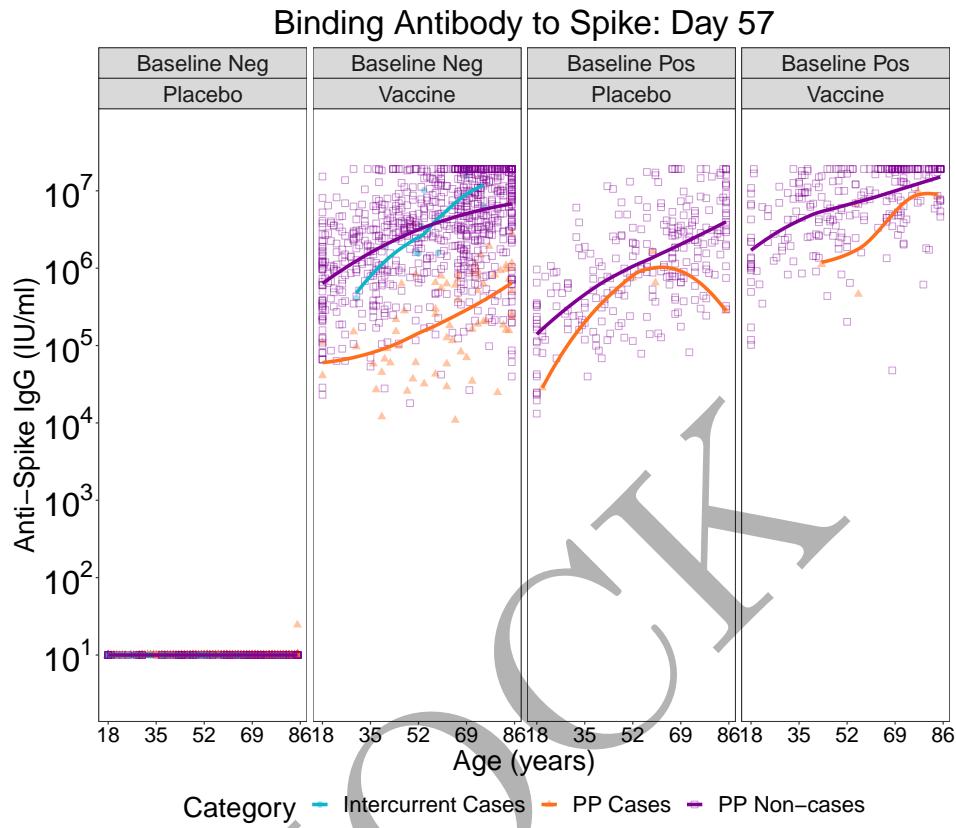


Figure 2.261: scatterplots of Binding Antibody to Spike: by arm at day 57

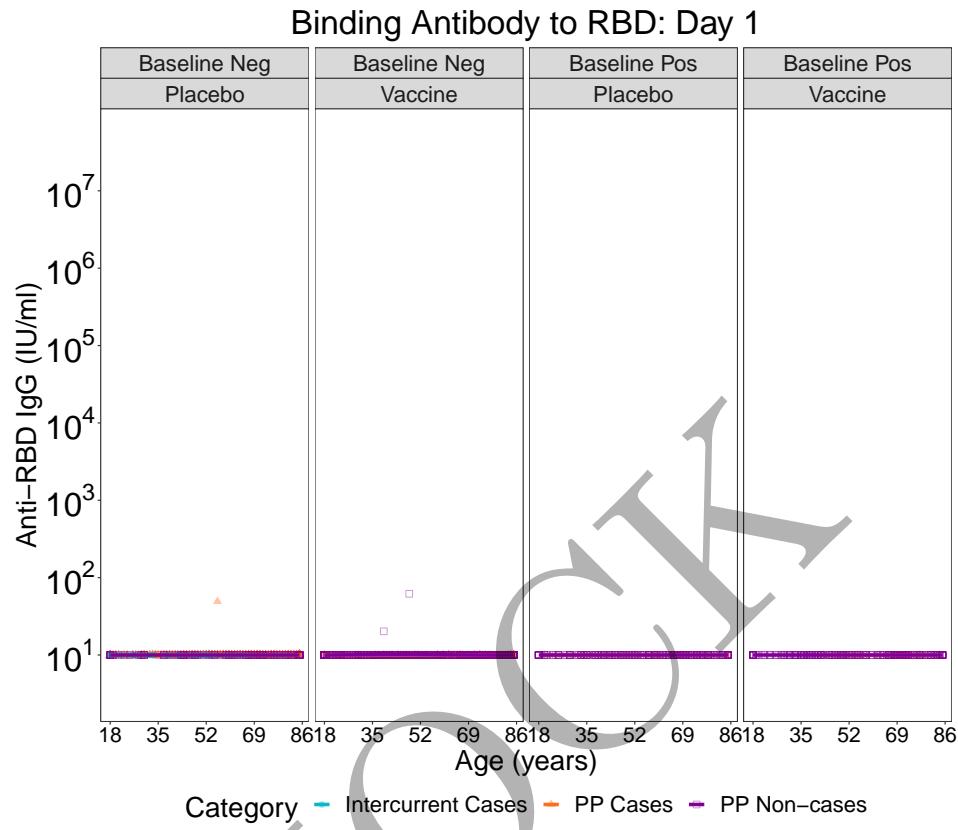


Figure 2.262: scatterplots of Binding Antibody to RBD: by arm at day 1

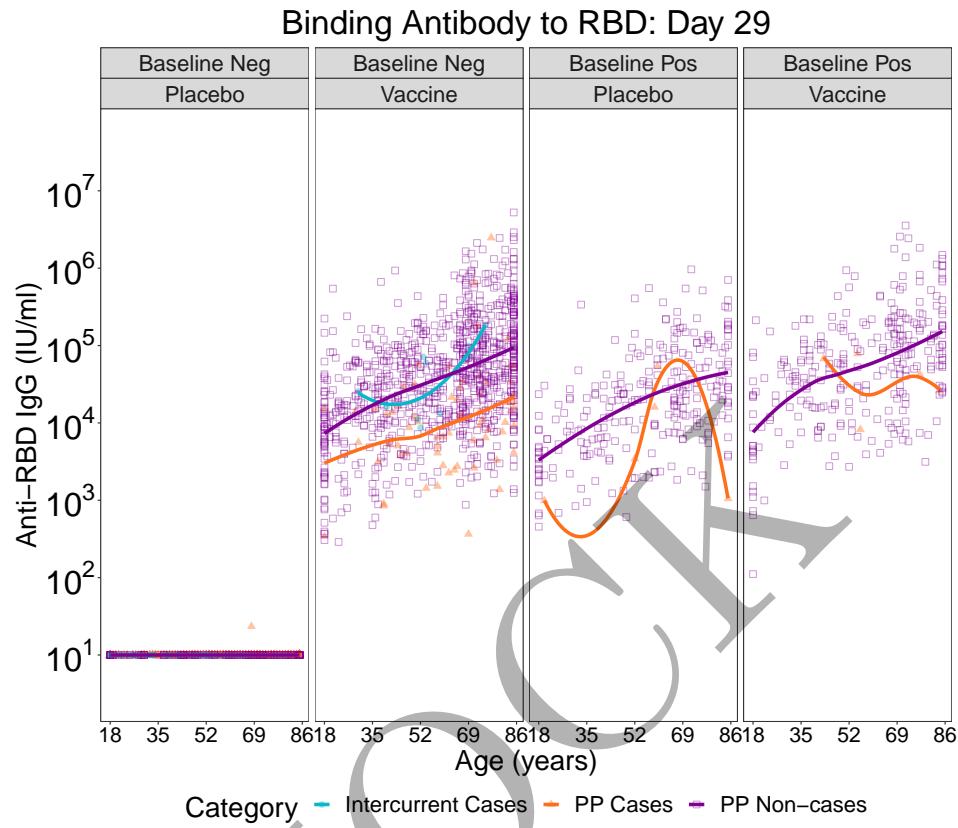


Figure 2.263: scatterplots of Binding Antibody to RBD: by arm at day 29

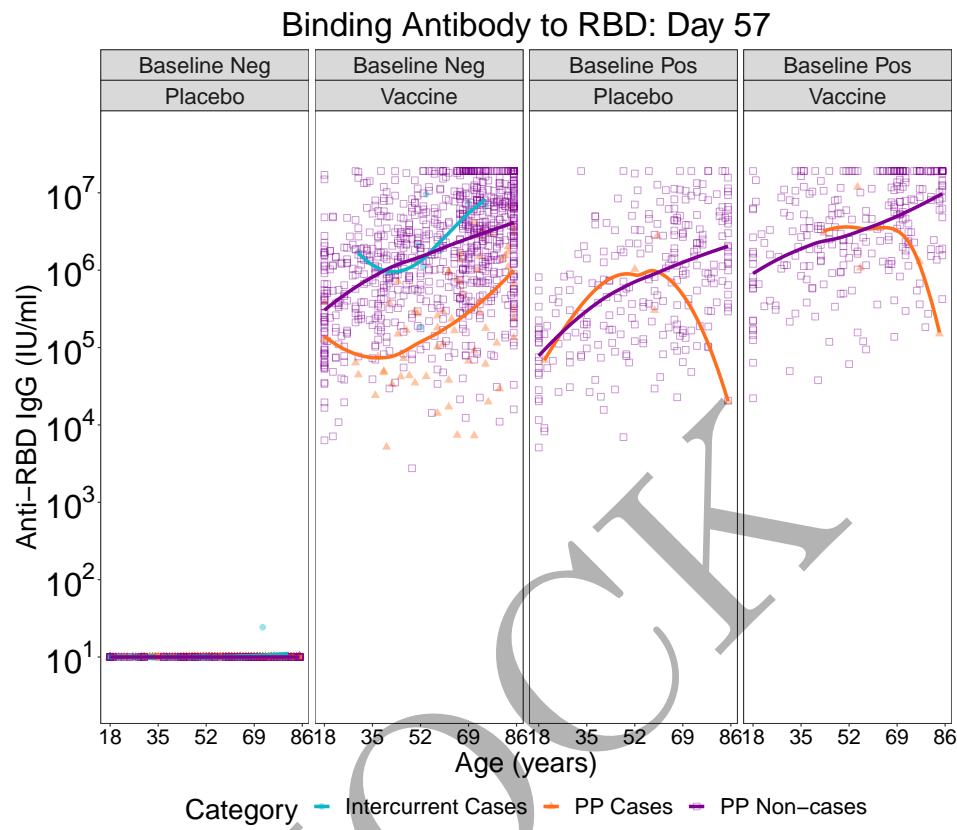


Figure 2.264: scatterplots of Binding Antibody to RBD: by arm at day 57

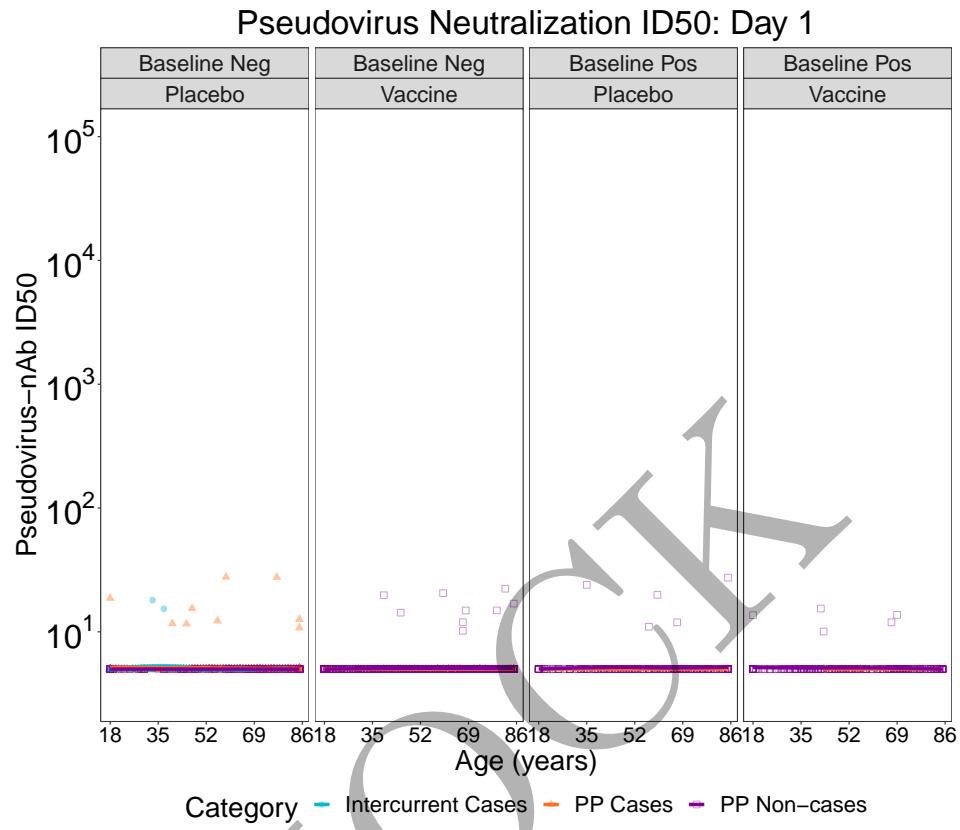


Figure 2.265: scatterplots of Pseudovirus Neutralization ID50: by arm at day 1

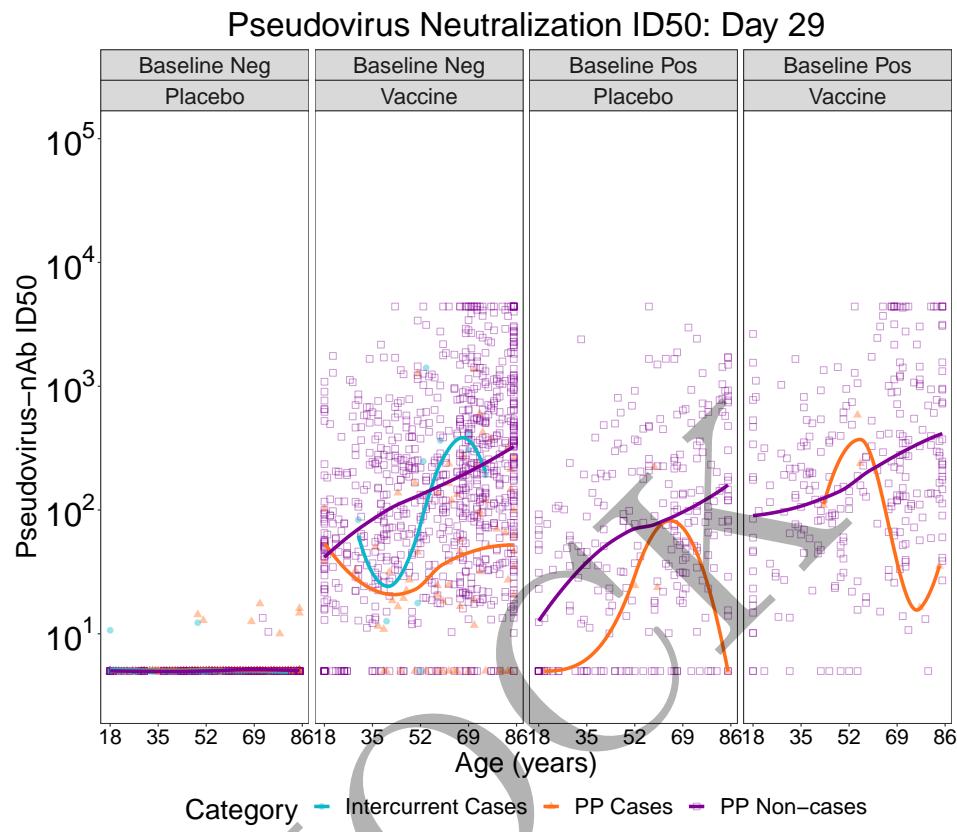


Figure 2.266: scatterplots of Pseudovirus Neutralization ID50: by arm at day 29

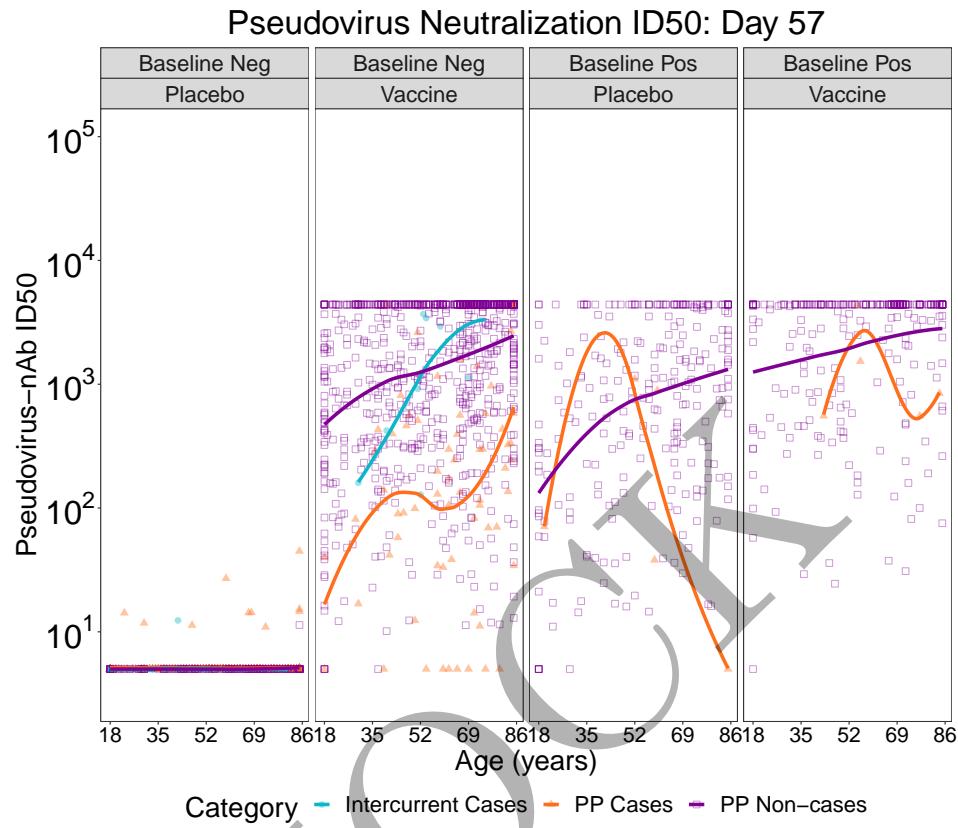


Figure 2.267: scatterplots of Pseudovirus Neutralization ID50: by arm at day 57

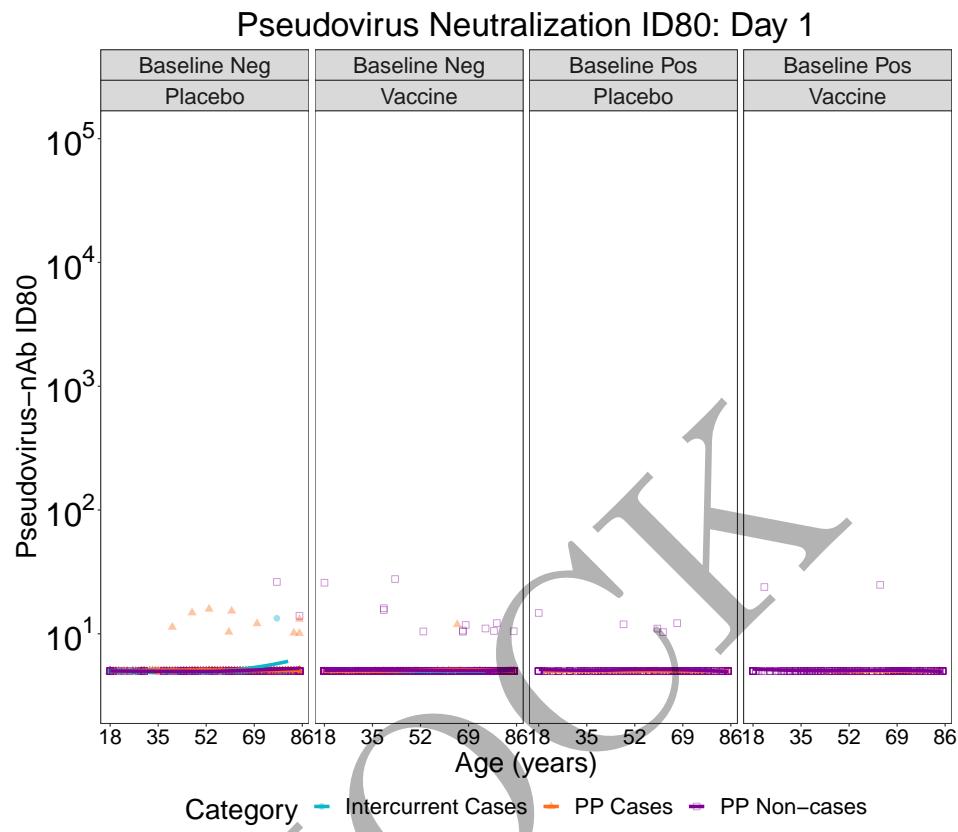


Figure 2.268: scatterplots of Pseudovirus Neutralization ID80: by arm at day 1

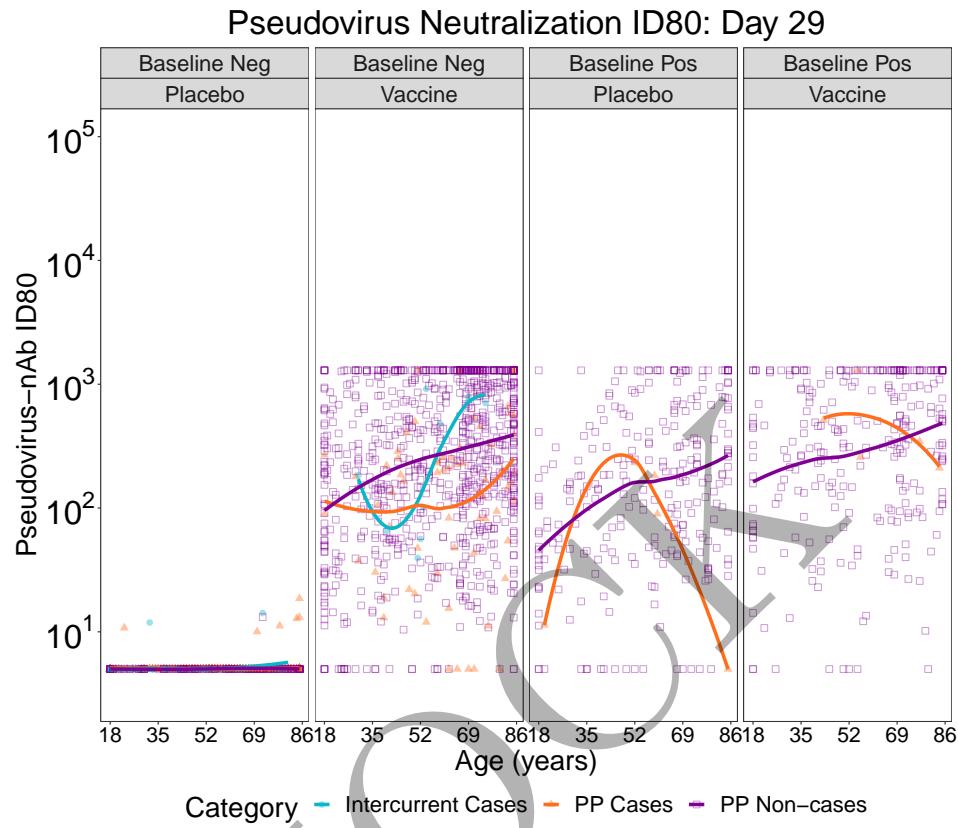


Figure 2.269: scatterplots of Pseudovirus Neutralization ID80: by arm at day 29

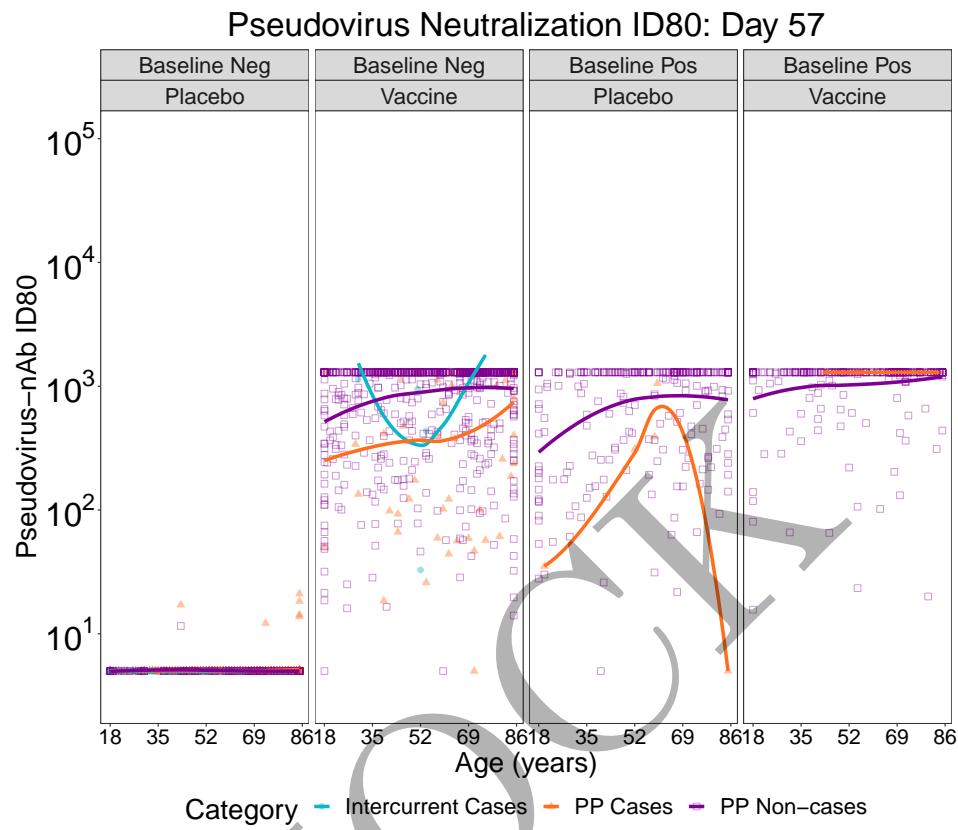


Figure 2.270: scatterplots of Pseudovirus Neutralization ID80: by arm at day 57

MOCK

Chapter 3

Day 57 Univariate CoR: Cox Models of Risk

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

3.1 Hazard ratios

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

Mock Immunologic Marker	No. cases / No. at-risk**	HR per 10-fold incr. Pt. Est.	95% CI	P-value (2-sided)	q-value	FWER
Anti Spike IgG (IU/ml)	71/13,258	0.07	(0.05-0.11)	<0.001	<0.001	<0.001
Anti RBD IgG (IU/ml)	71/13,258	0.24	(0.18-0.33)	<0.001	<0.001	<0.001
Pseudovirus-nAb ID50	71/13,258	0.21	(0.16-0.28)	<0.001	<0.001	<0.001
Pseudovirus-nAb ID80	71/13,258	0.26	(0.17-0.41)	<0.001	<0.001	<0.001

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

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

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

Mock Immunologic Marker	Tertile	No. cases / No. at-risk**	Attack rate	Pt. Est.	Haz. Ratio 95% CI	P-value (2-sided)	Overall P- value***	Overall q- value	Overall FWER
Anti Spike IgG (IU/ml)	Lower	67/4,444	0.0151	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	4/4,389	0.0009	0.04	(0.01-0.12)	<0.001			
	Upper	1/4,426	0.0002	0.00	(0.00-0.03)	<0.001			
Anti RBD IgG (IU/ml)	Lower	46/4,445	0.0103	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	17/4,389	0.0039	0.31	(0.17-0.56)	<0.001			
	Upper	8/4,424	0.0018	0.07	(0.03-0.15)	<0.001			
Pseudovirus-nAb ID50	Lower	56/4,420	0.0127	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	8/3,644	0.0022	0.13	(0.06-0.27)	<0.001			
	Upper	7/5,194	0.0013	0.05	(0.02-0.12)	<0.001			
Pseudovirus-nAb ID80	Lower	38/4,453	0.0085	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	2/ 201	0.0100	1.10	(0.22-5.42)	0.903			
	Upper	32/8,604	0.0037	0.29	(0.17-0.49)	<0.001			
Placebo		711/13,373	0.0532						

*Baseline covariates adjusted for: baseline risk score, at risk or not, community of color or not. Average follow-up time 173 days, maximum follow-up time 185 days. Cutpoints: Anti Spike IgG (IU/ml) [6.08, 6.71), Anti RBD IgG (IU/ml) [5.78, 6.44), Pseudovirus-nAb ID50 [2.83, 3.64), Pseudovirus-nAb ID80 [3.05, 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.

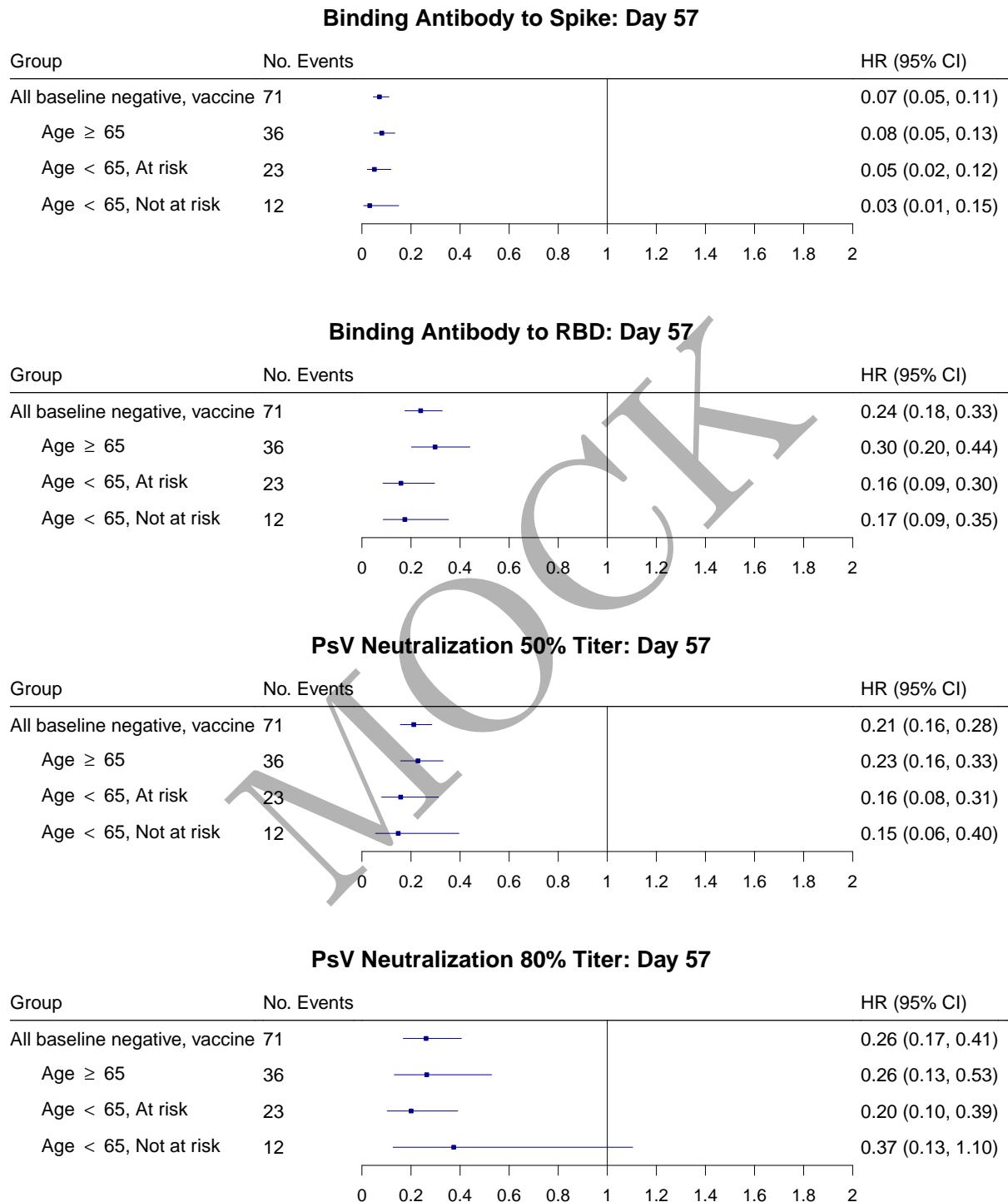


Figure 3.1: Forest plots of hazard ratios per 10-fold increase in the marker among baseline seronegative vaccine recipients and subgroups with 95% point-wise confidence intervals.

Binding Antibody to Spike: Day 57

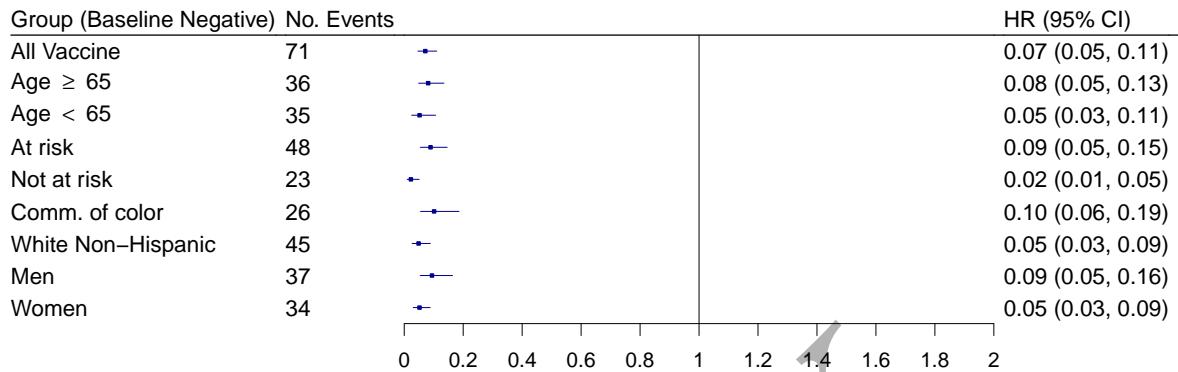


Figure 3.2: Forest plots of hazard ratios per 10-fold increase in the Day 57 binding Ab to spike markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

Binding Antibody to RBD: Day 57

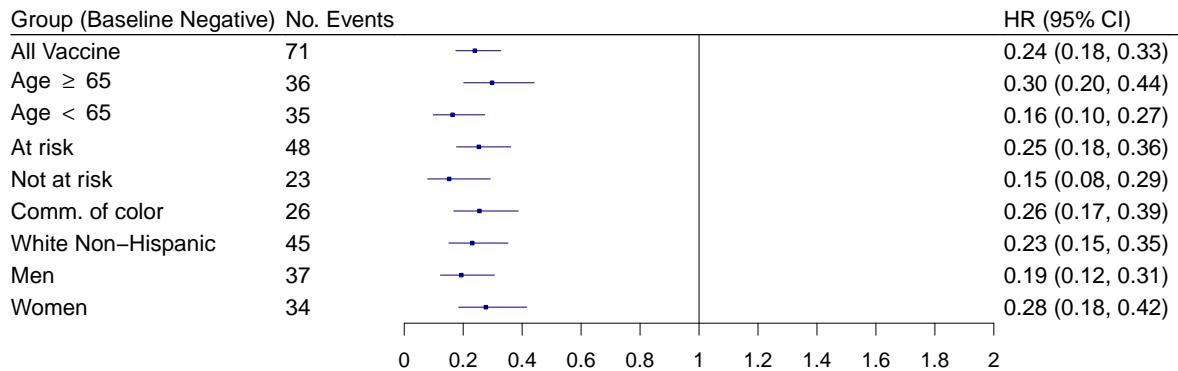


Figure 3.3: Forest plots of hazard ratios per 10-fold increase in the Day 57 binding Ab to RBD markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

PsV Neutralization 50% Titer: Day 57

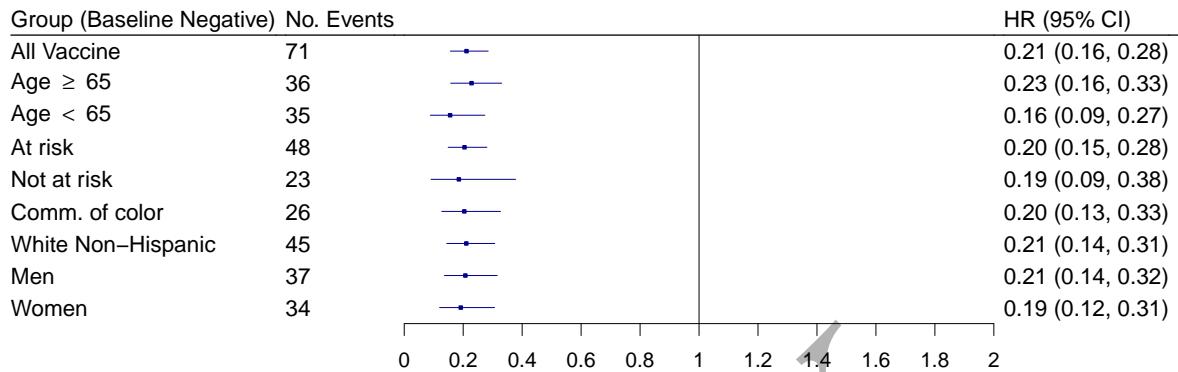


Figure 3.4: Forest plots of hazard ratios per 10-fold increase in the Day 57 pseudo neut ID50 markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

PsV Neutralization 80% Titer: Day 57

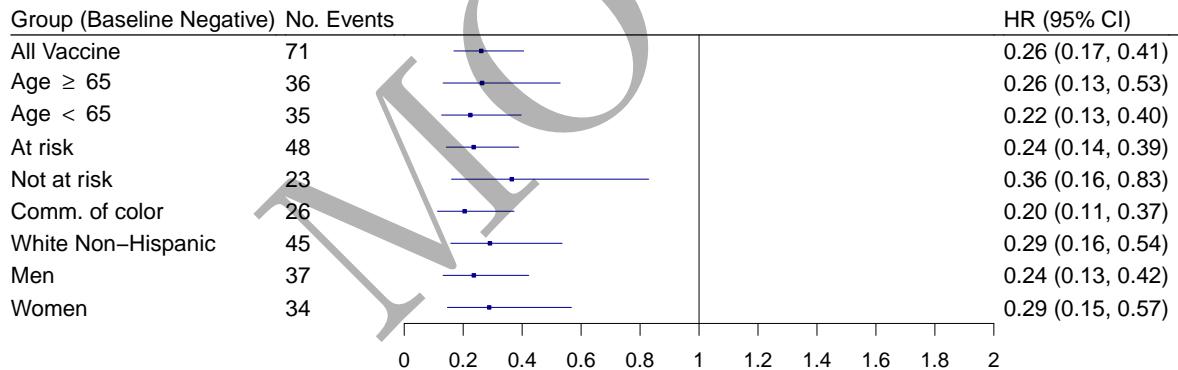


Figure 3.5: Forest plots of hazard ratios per 10-fold increase in the Day 57 pseudo neut ID80 markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

3.2 Marginalized risk and controlled vaccine efficacy plots

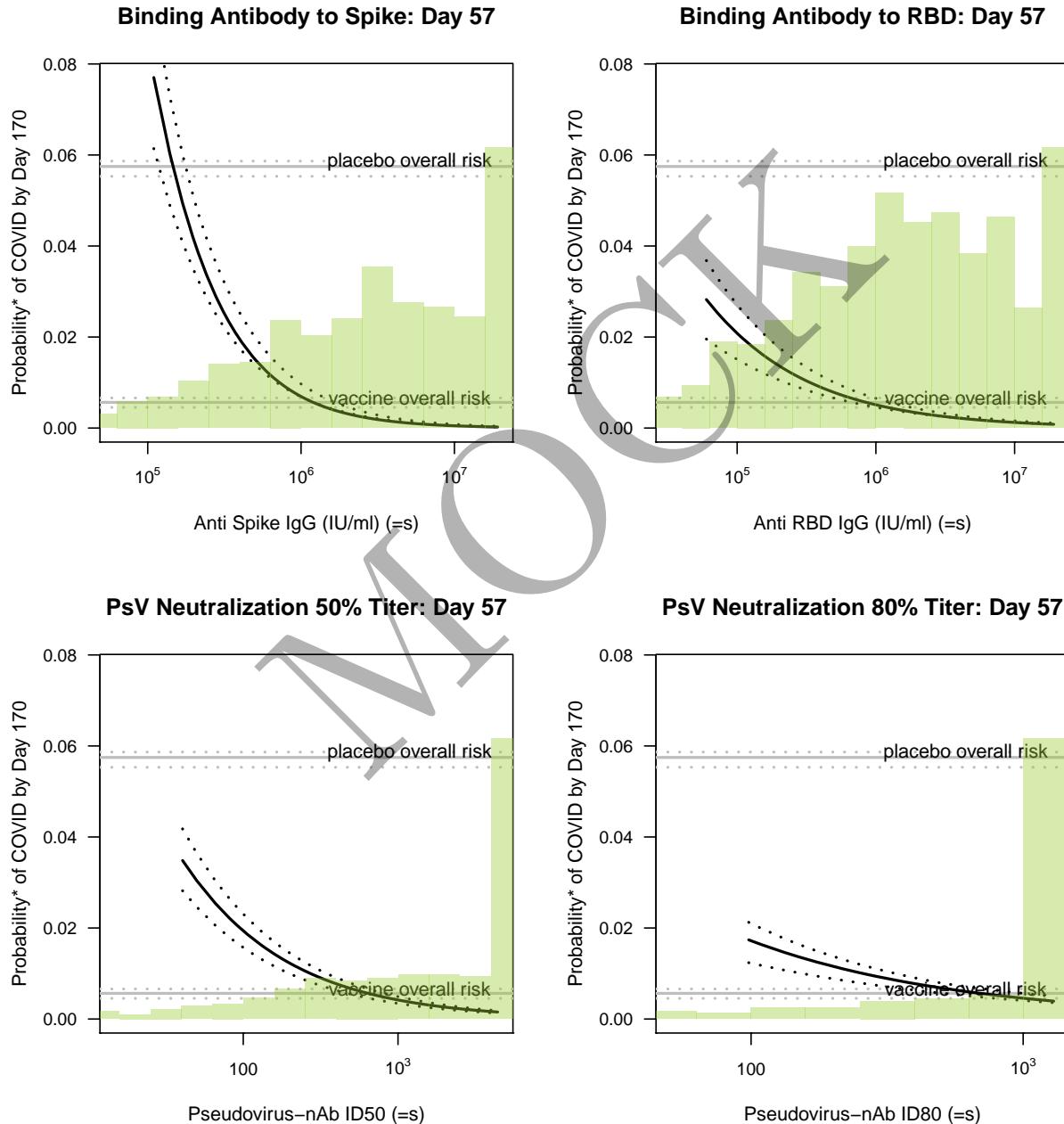


Figure 3.6: Marginalized cumulative risk by Day 170 as functions of Day 57 markers ($=s$) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. The horizontal lines indicate the overall cumulative risk of the placebo and vaccine arms by Day 170 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.

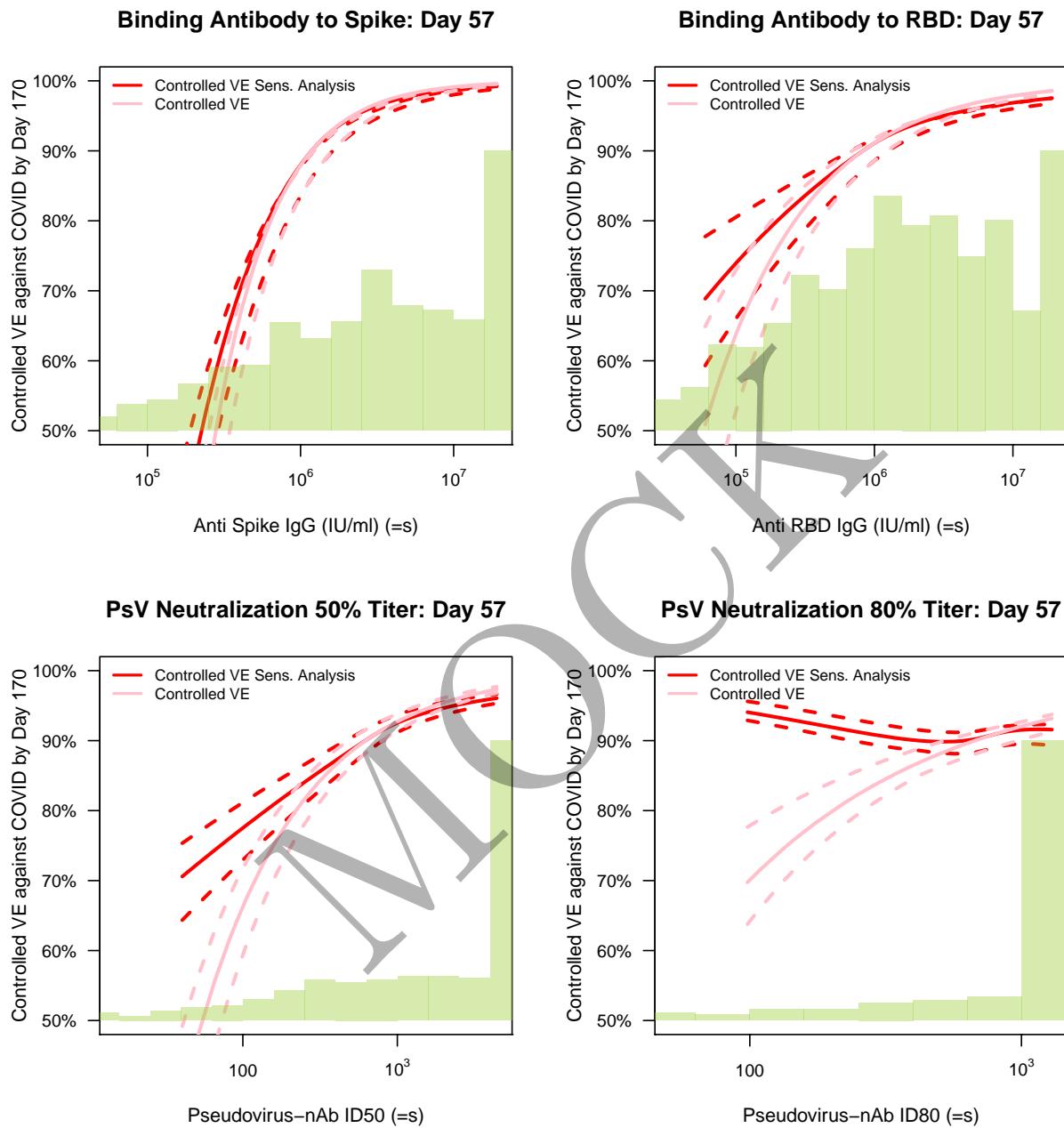


Figure 3.7: Controlled VE with sensitivity analysis as functions of Day 57 markers ($=s$) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.

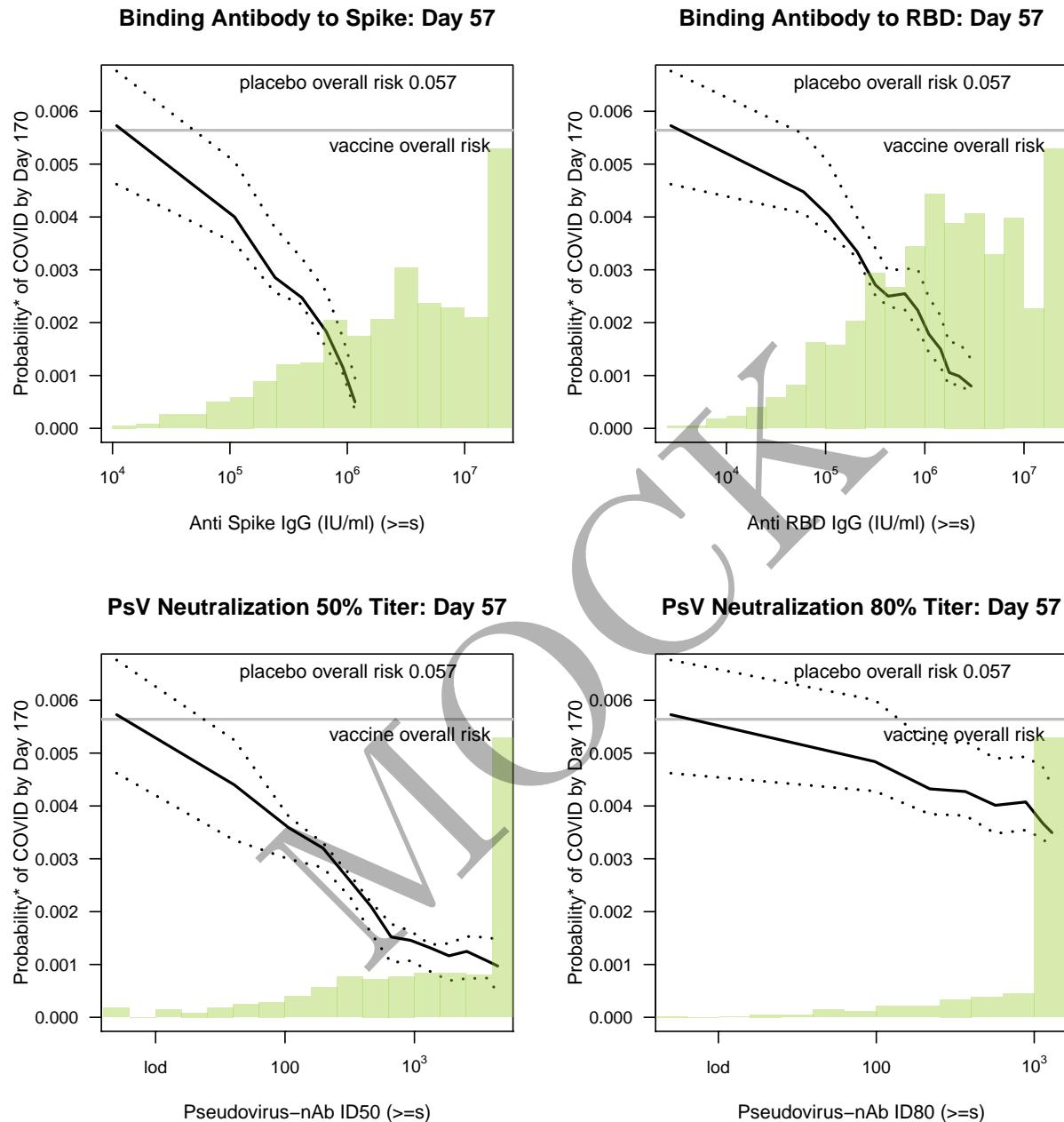


Figure 3.8: Marginalized cumulative risk by Day 170 as functions of Day 57 markers above a threshold ($\geq s$) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands (at least 5 cases are required). The horizontal lines indicate the overall cumulative risk of the vaccine arm by Day 170 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.

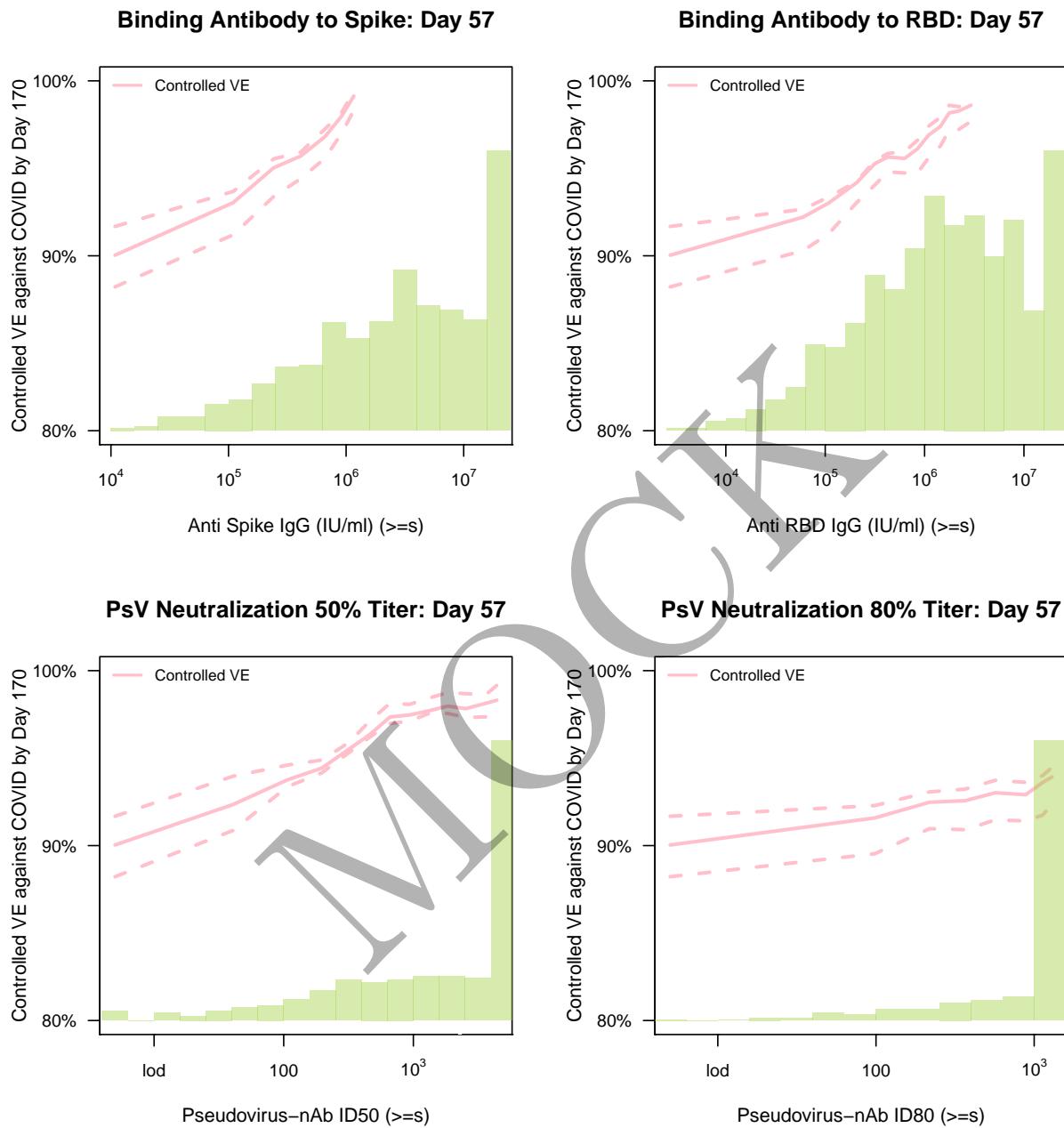


Figure 3.9: Controlled VE as functions of Day 57 markers ($\geq s$) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.

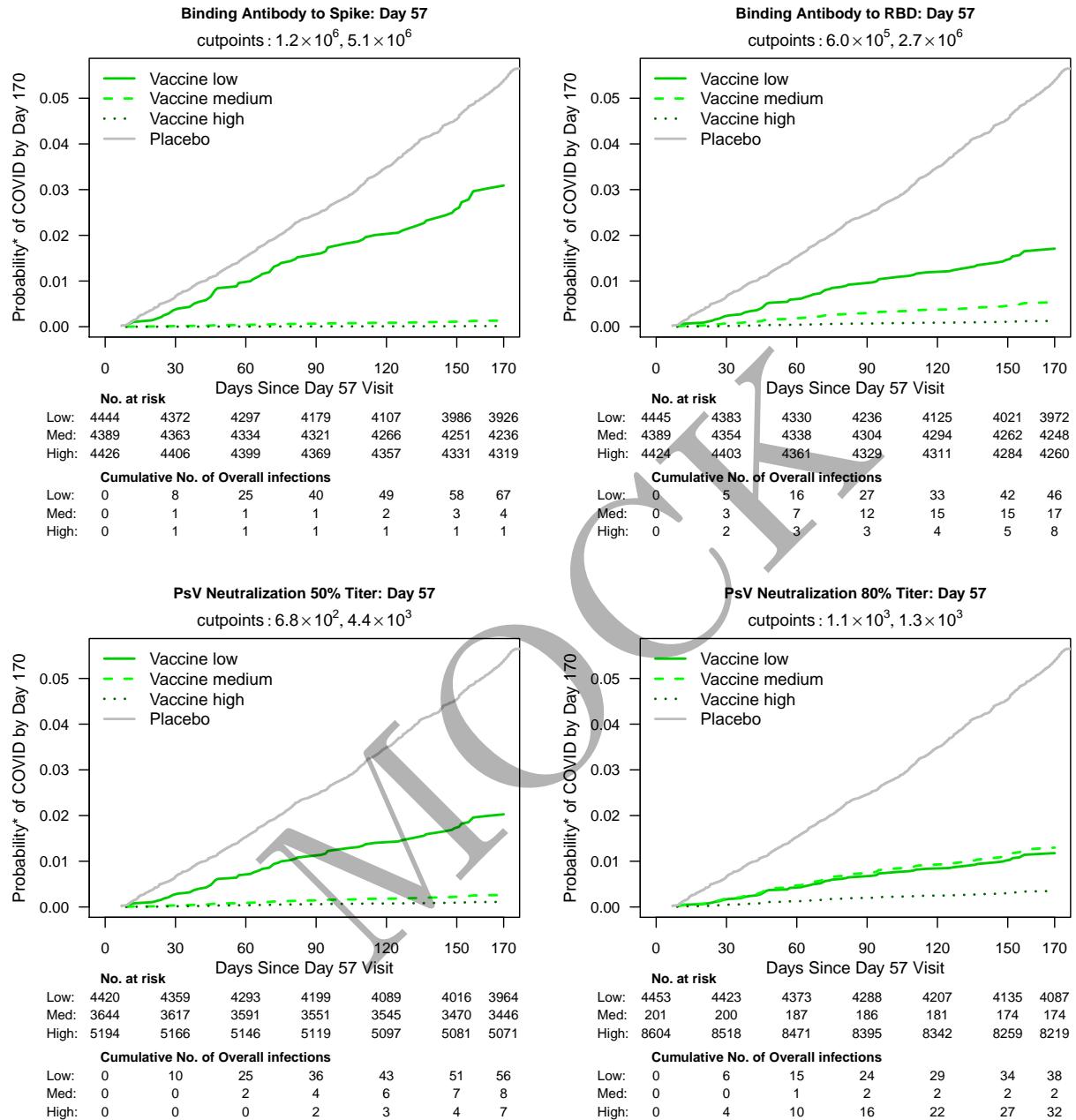


Figure 3.10: Marginalized cumulative incidence rate curves for trichotomized Day 57 markers among baseline seronegative vaccine recipients. The gray line is the overall cumulative incidence rate curve in the placebo arm.

Chapter 4

Day 29 Univariate CoR: Cox Models of Risk

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

4.1 Hazard ratios

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

Mock Immunologic Marker	No. cases / No. at-risk**	HR per 10-fold incr. Pt. Est.	95% CI	P-value (2-sided)	q-value	FWER
Anti Spike IgG (IU/ml)	82/13,278	0.10	(0.07-0.17)	<0.001	<0.001	<0.001
Anti RBD IgG (IU/ml)	82/13,278	0.29	(0.20-0.42)	<0.001	<0.001	<0.001
Pseudovirus-nAb ID50	82/13,278	0.30	(0.21-0.43)	<0.001	<0.001	<0.001
Pseudovirus-nAb ID80	82/13,278	0.48	(0.34-0.66)	<0.001	<0.001	<0.001

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

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

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

Mock Immunologic Marker	Tertile	No. cases / No. at-risk**	Attack rate	Haz. Ratio Pt. Est.	95% CI	P-value (2-sided)	Overall P- value***	Overall q- value	Overall FWER
Anti Spike IgG (IU/ml)	Lower	55/4,435	0.0124	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	22/4,371	0.0050	0.27	(0.16-0.47)	<0.001			
	Upper	5/4,472	0.0011	0.03	(0.01-0.08)	<0.001			
Anti RBD IgG (IU/ml)	Lower	43/4,429	0.0097	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	27/4,383	0.0062	0.43	(0.25-0.75)	0.003			
	Upper	12/4,467	0.0027	0.13	(0.06-0.26)	<0.001			
Pseudovirus-nAb ID50	Lower	47/4,436	0.0106	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	20/4,415	0.0045	0.35	(0.19-0.61)	<0.001			
	Upper	14/4,427	0.0032	0.17	(0.09-0.32)	<0.001			
Pseudovirus-nAb ID80	Lower	33/4,430	0.0074	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	36/4,414	0.0082	0.76	(0.45-1.29)	0.313			
	Upper	13/4,435	0.0029	0.26	(0.13-0.50)	<0.001			
Placebo		820/13,398	0.0612						

*Baseline covariates adjusted for: baseline risk score, at risk or not, community of color or not. Average follow-up time 200 days, maximum follow-up time 213 days. Cutpoints: Anti Spike IgG (IU/ml) [4.4, 4.9], Anti RBD IgG (IU/ml) [4.12, 4.73], Pseudovirus-nAb ID50 [1.74, 2.37], Pseudovirus-nAb ID80 [2.08, 2.77].

**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.

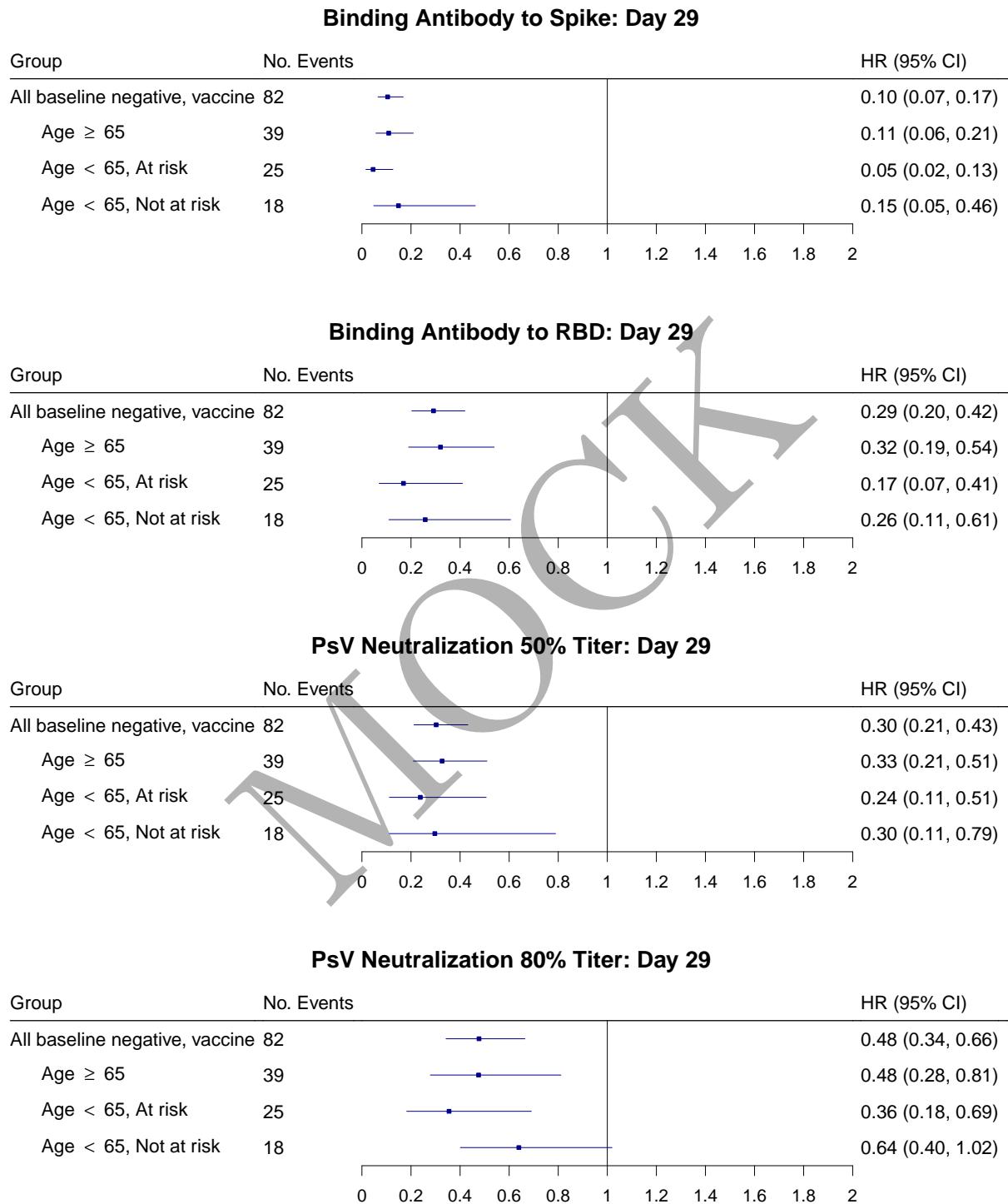


Figure 4.1: Forest plots of hazard ratios per 10-fold increase in the marker among baseline seronegative vaccine recipients and subgroups with 95% point-wise confidence intervals.

Binding Antibody to Spike: Day 29

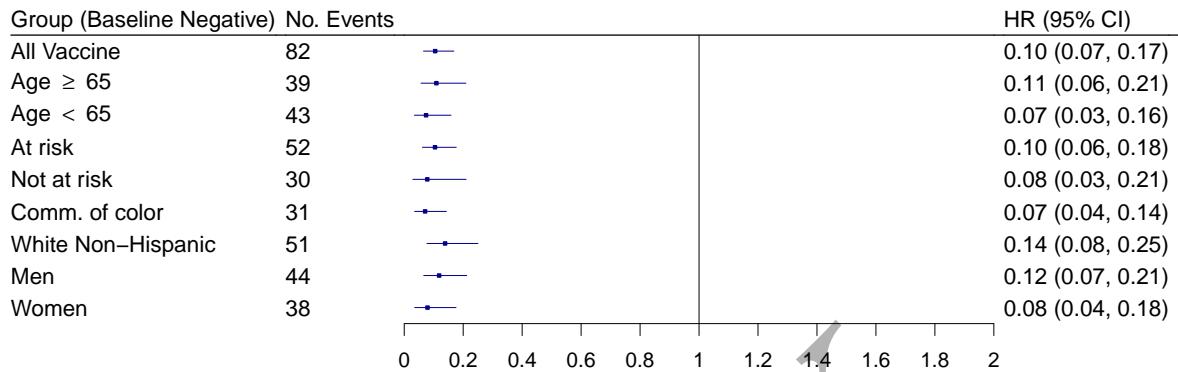


Figure 4.2: Forest plots of hazard ratios per 10-fold increase in the Day 29 binding Ab to spike markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

Binding Antibody to RBD: Day 29

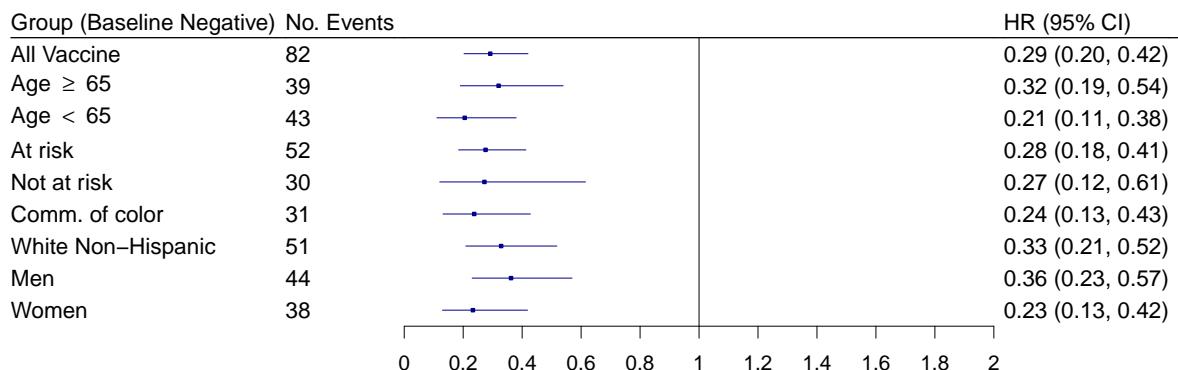


Figure 4.3: Forest plots of hazard ratios per 10-fold increase in the Day 29 binding Ab to RBD markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

PsV Neutralization 50% Titer: Day 29

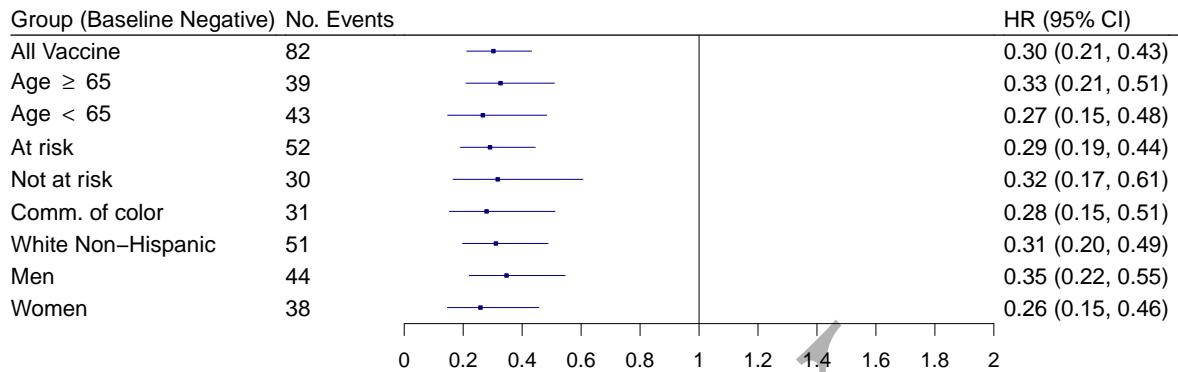


Figure 4.4: Forest plots of hazard ratios per 10-fold increase in the Day 29 pseudo neut ID50 markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

PsV Neutralization 80% Titer: Day 29

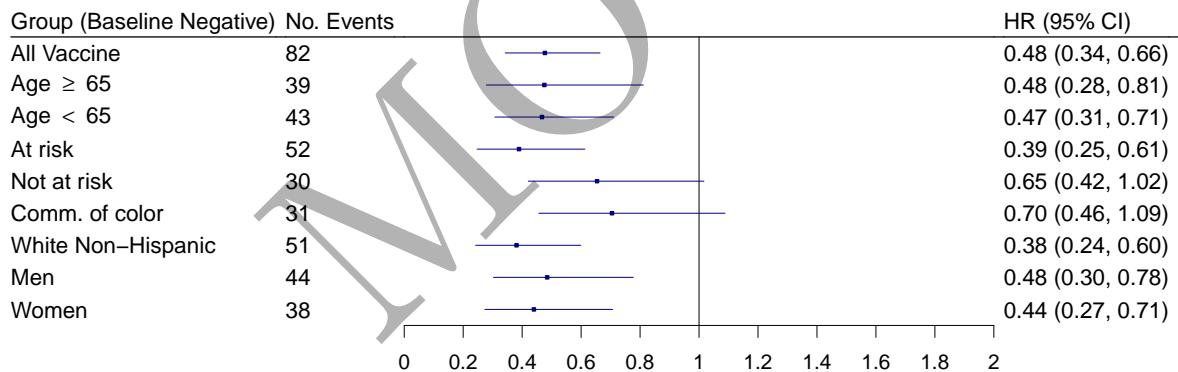


Figure 4.5: Forest plots of hazard ratios per 10-fold increase in the Day 29 pseudo neut ID80 markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

4.2 Marginalized risk and controlled vaccine efficacy plots

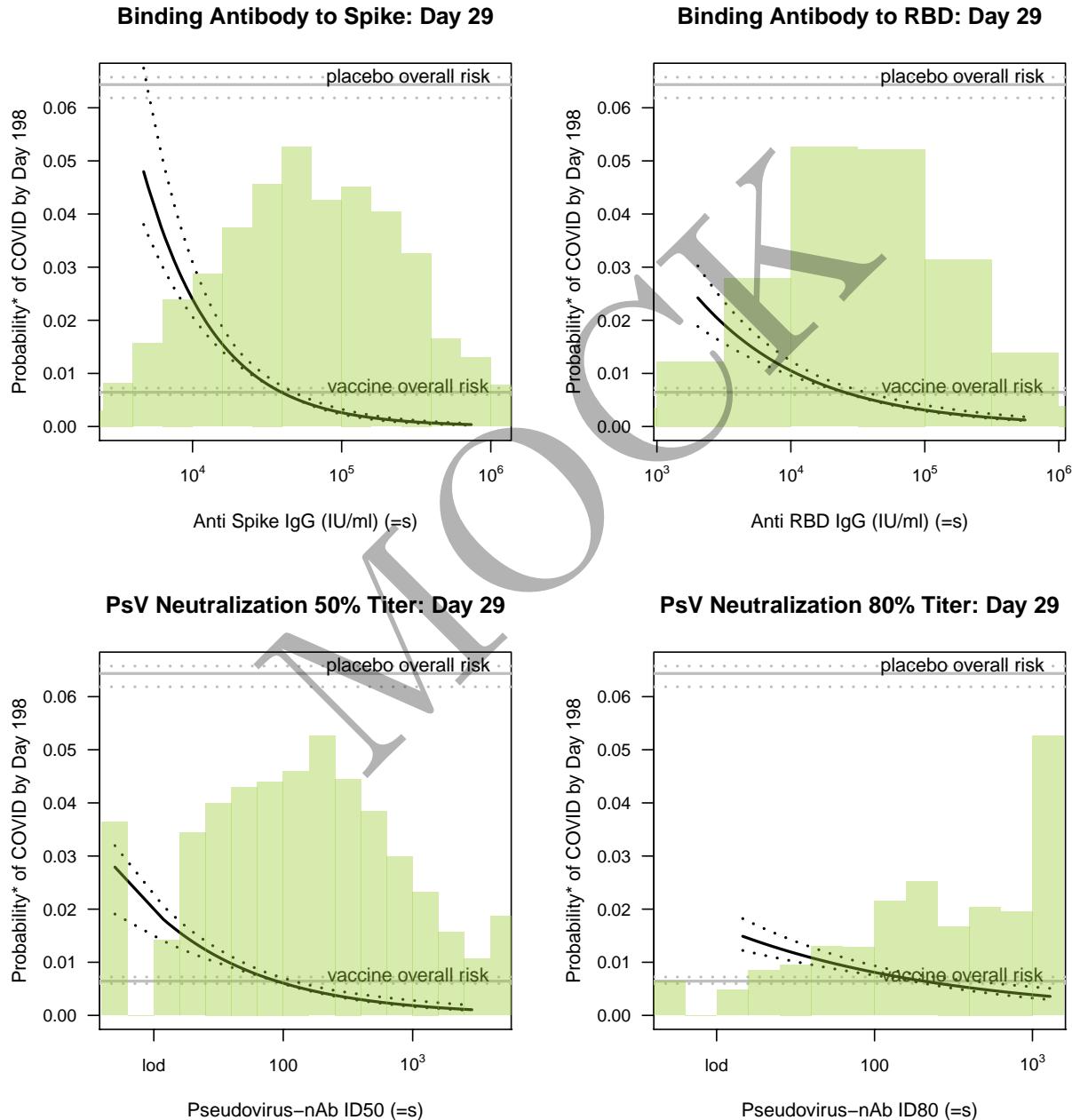


Figure 4.6: Marginalized cumulative risk by Day 198 as functions of Day 29 markers ($=s$) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. The horizontal lines indicate the overall cumulative risk of the placebo and vaccine arms by Day 198 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.

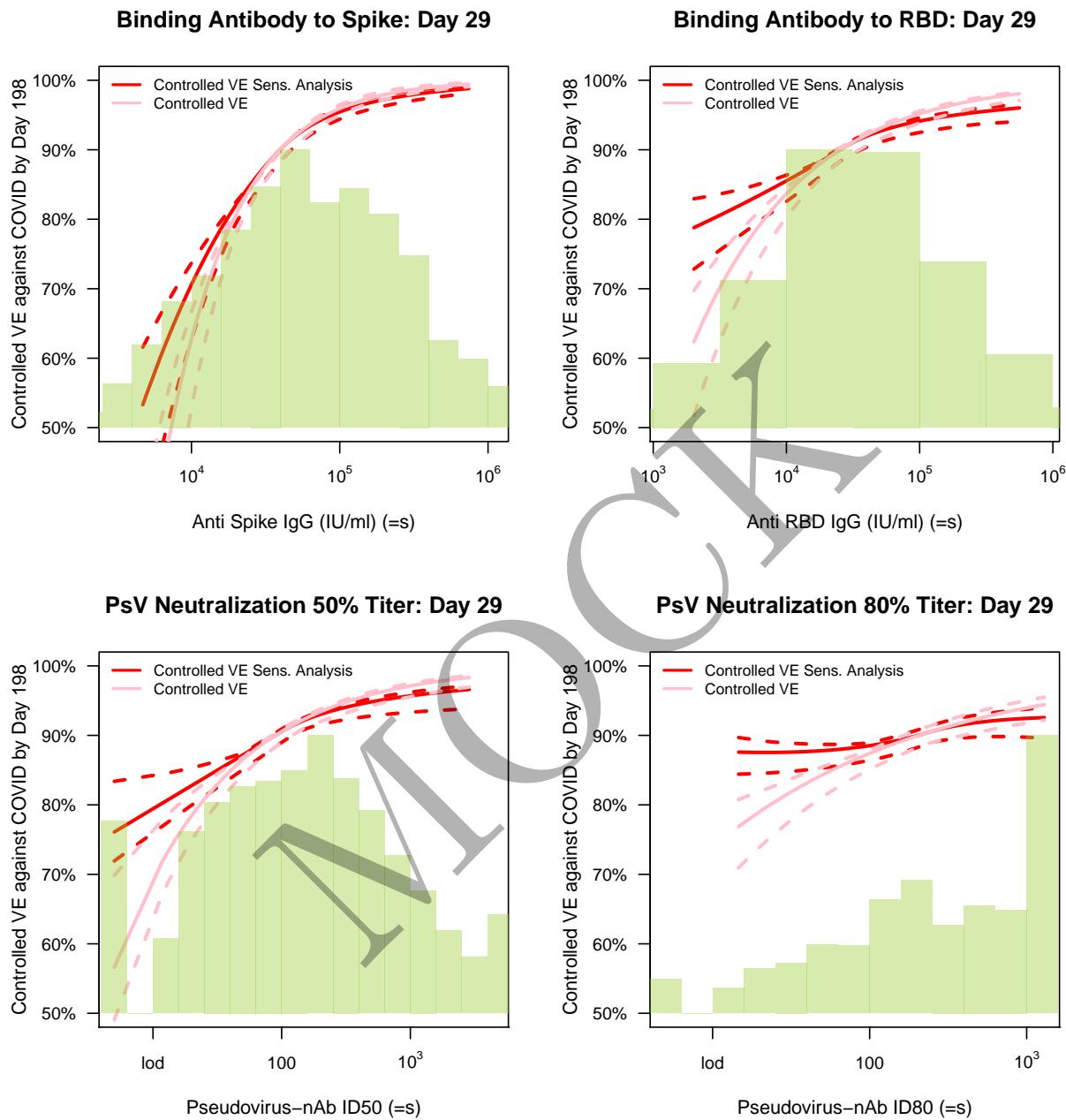


Figure 4.7: Controlled VE with sensitivity analysis as functions of Day 29 markers ($=s$) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.

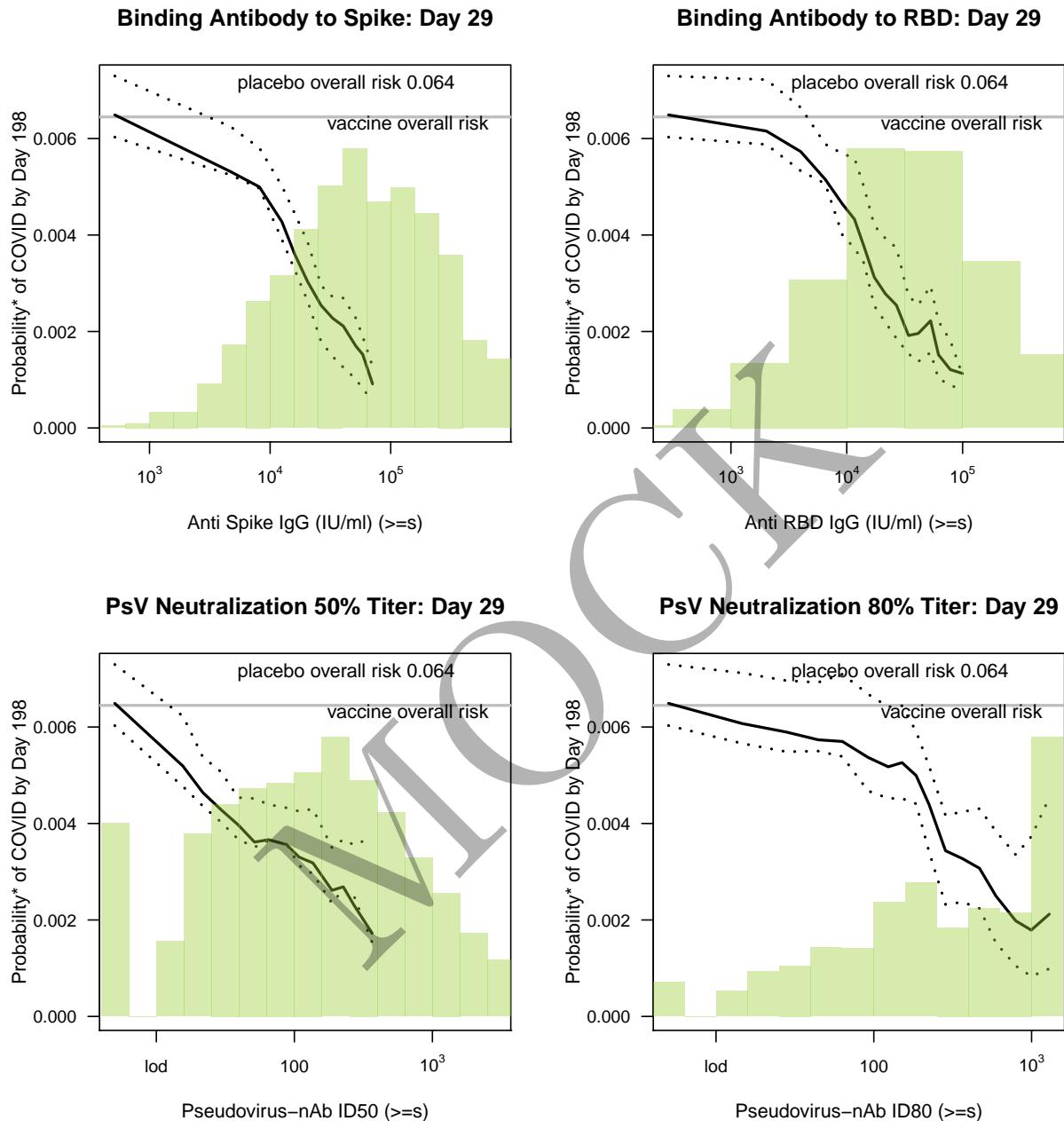


Figure 4.8: Marginalized cumulative risk by Day 198 as functions of Day 29 markers above a threshold ($\geq s$) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands (at least 5 cases are required). The horizontal lines indicate the overall cumulative risk of the vaccine arm by Day 198 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.

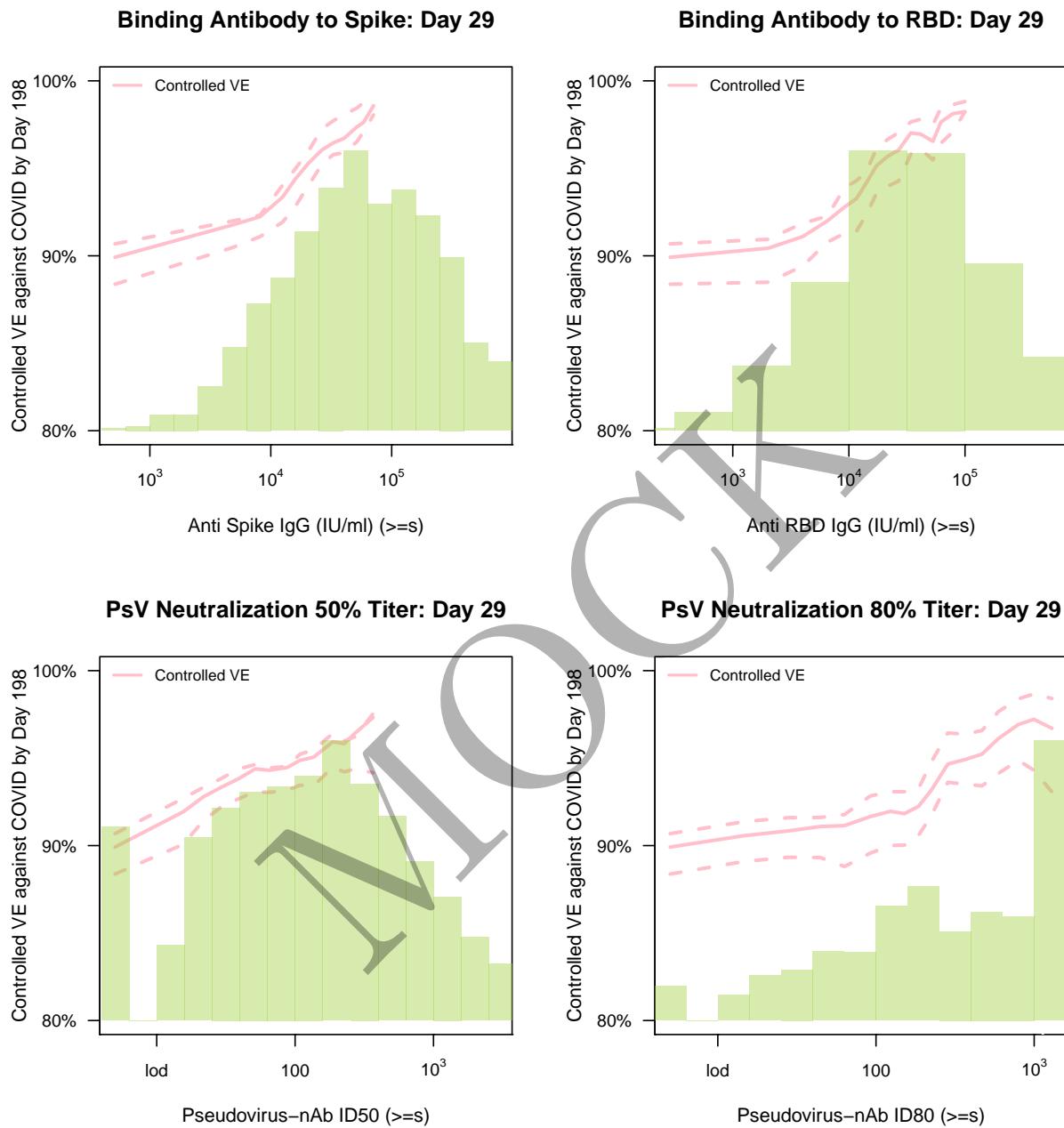


Figure 4.9: Controlled VE as functions of Day 29 markers ($\geq s$) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.

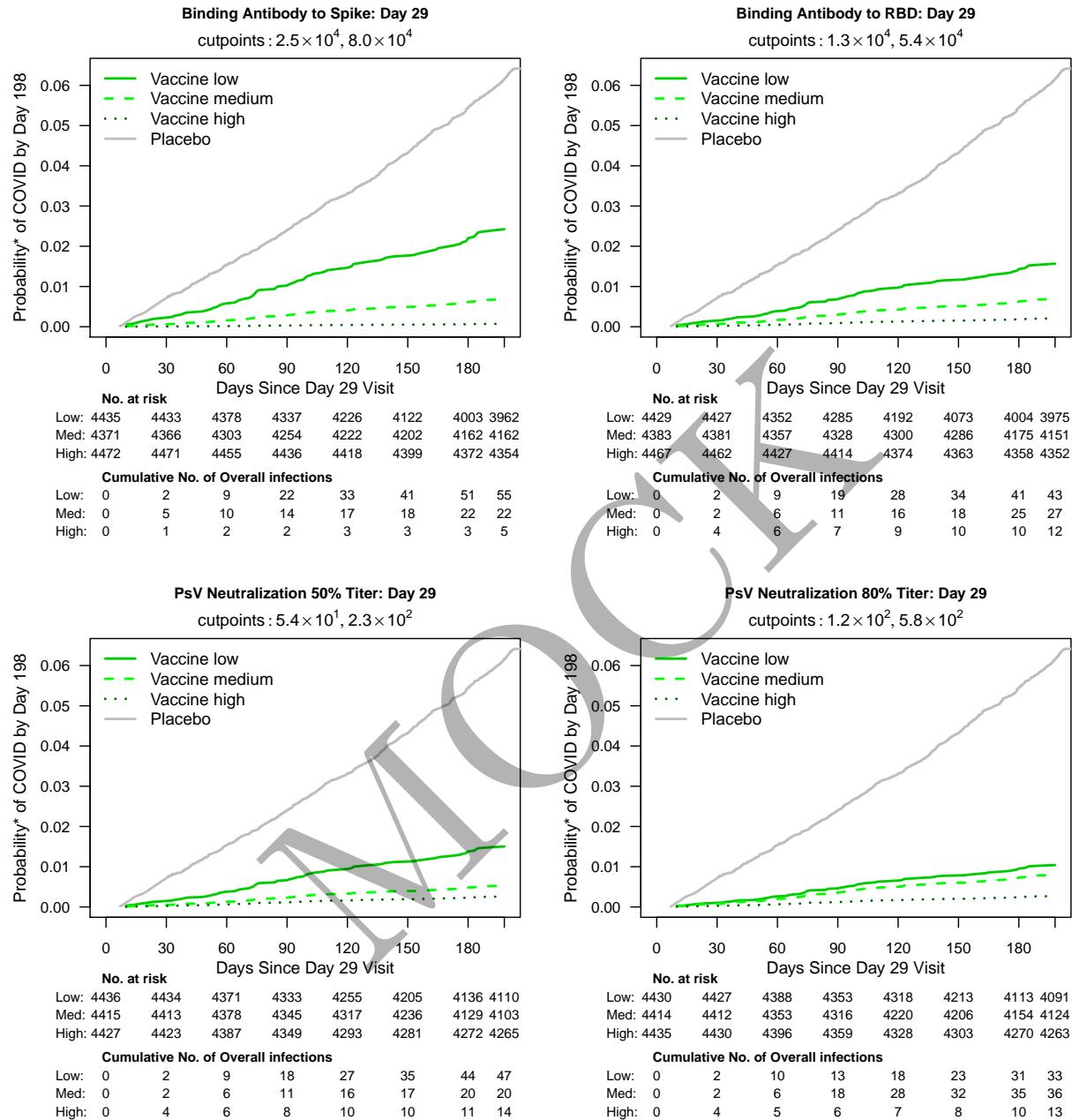


Figure 4.10: Marginalized cumulative incidence rate curves for trichotomized Day 29 markers among baseline seronegative vaccine recipients. The gray line is the overall cumulative incidence rate curve in the placebo arm.

Chapter 5

Univariate CoR: Nonparametric Threshold Modeling

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

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

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

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

MOCK

5.1.1 Day 57 Spike protein binding antibody

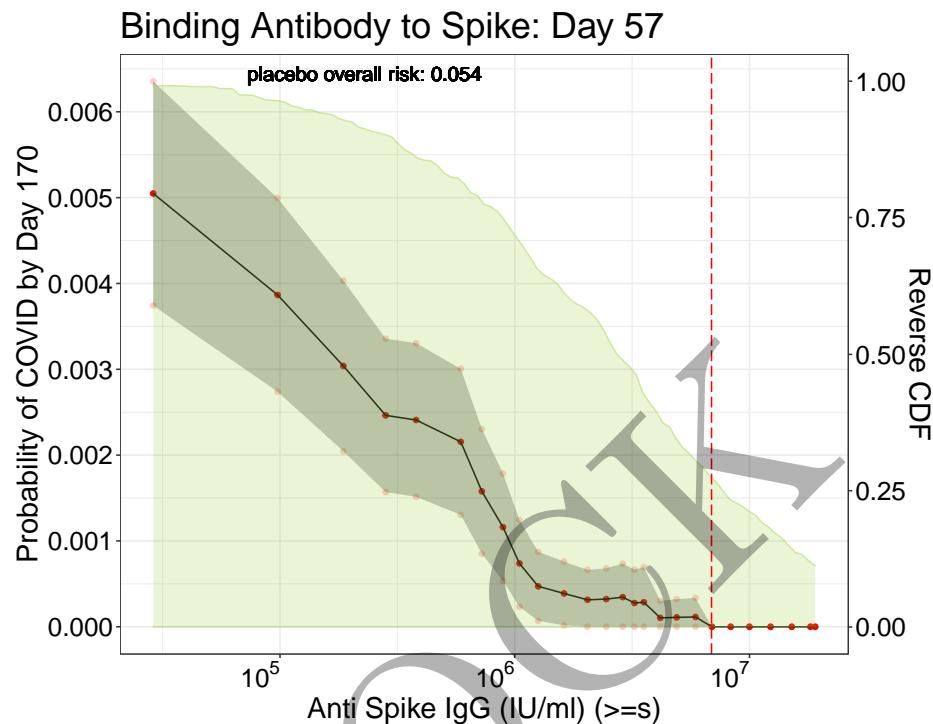


Figure 5.1: Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

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

\log_{10} -Threshold	Threshold	Risk estimate	CI left	CI right
4.465	$2.92 * 10^4$	0.00505	0.00374	0.00635
5.450	$2.82 * 10^5$	0.00246	0.00157	0.00336
5.864	$7.31 * 10^5$	0.00158	0.00085	0.00230
6.020	$1.05 * 10^6$	0.00074	0.00023	0.00124
6.307	$2.03 * 10^6$	0.00031	0.00000	0.00066
6.512	$3.25 * 10^6$	0.00028	0.00000	0.00066
6.688	$4.88 * 10^6$	0.00011	0.00000	0.00032
6.842	$6.95 * 10^6$	0.00000	0.00000	NA
7.092	$1.24 * 10^7$	0.00000	0.00000	NA
7.282	$1.91 * 10^7$	0.00000	0.00000	NA

5.1.2 Day 57 RBD binding antibody

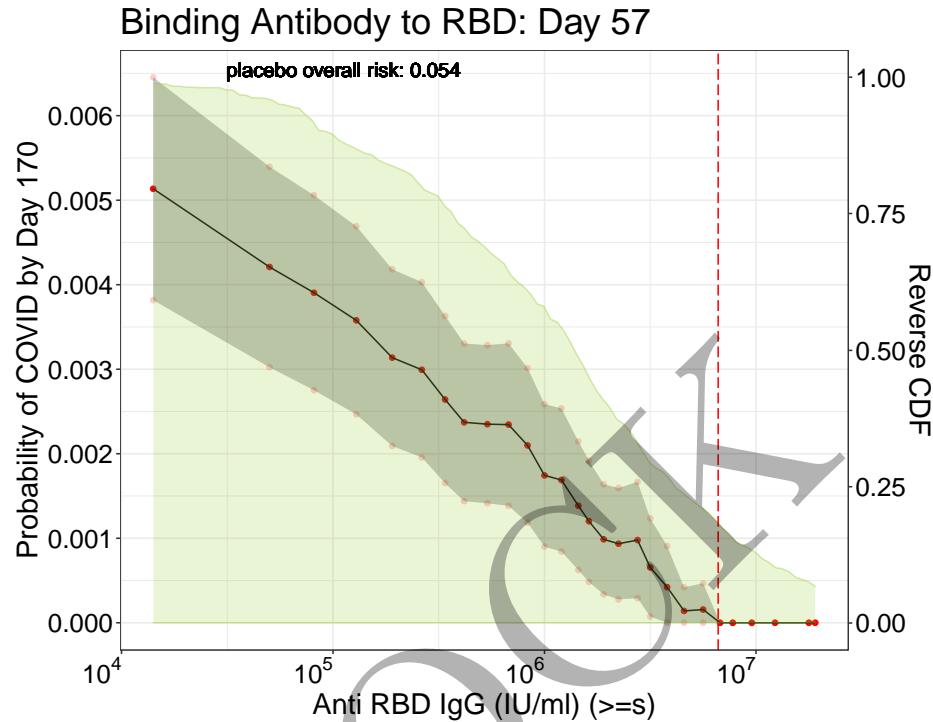


Figure 5.2: Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

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
4.154	$1.43 * 10^4$	0.00514	0.00382	0.00645
5.109	$1.29 * 10^5$	0.00358	0.00247	0.00469
5.534	$3.42 * 10^5$	0.00264	0.00165	0.00363
5.831	$6.78 * 10^5$	0.00234	0.00138	0.00331
6.084	$1.21 * 10^6$	0.00169	0.00084	0.00254
6.284	$1.92 * 10^6$	0.00099	0.00034	0.00164
6.497	$3.14 * 10^6$	0.00065	0.00007	0.00124
6.753	$5.66 * 10^6$	0.00016	0.00000	0.00047
6.977	$9.48 * 10^6$	0.00000	0.00000	NA
7.282	$1.91 * 10^7$	0.00000	0.00000	NA

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

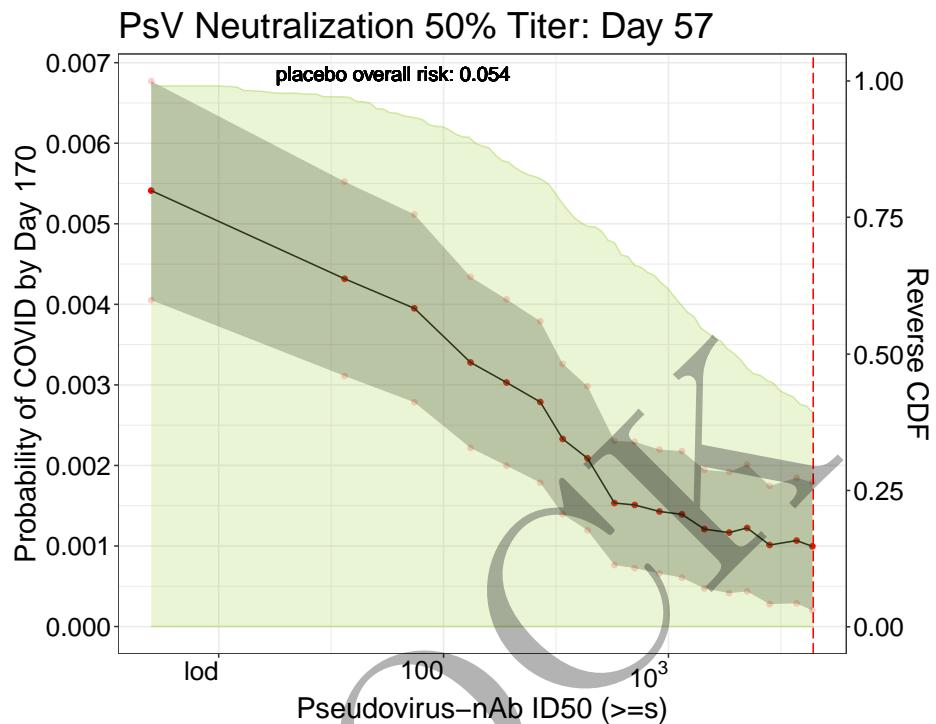


Figure 5.3: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

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
0.699	5.00×10^0	0.00541	0.00405	0.00677
1.872	7.45×10^1	0.00395	0.00278	0.00512
2.277	1.89×10^2	0.00303	0.00200	0.00406
2.533	3.41×10^2	0.00233	0.00140	0.00326
2.764	5.81×10^2	0.00153	0.00076	0.00230
2.853	7.13×10^2	0.00151	0.00073	0.00229
3.061	1.15×10^3	0.00139	0.00061	0.00218
3.266	1.85×10^3	0.00117	0.00041	0.00192
3.453	2.84×10^3	0.00101	0.00028	0.00175
3.644	4.41×10^3	0.00100	0.00020	0.00179

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

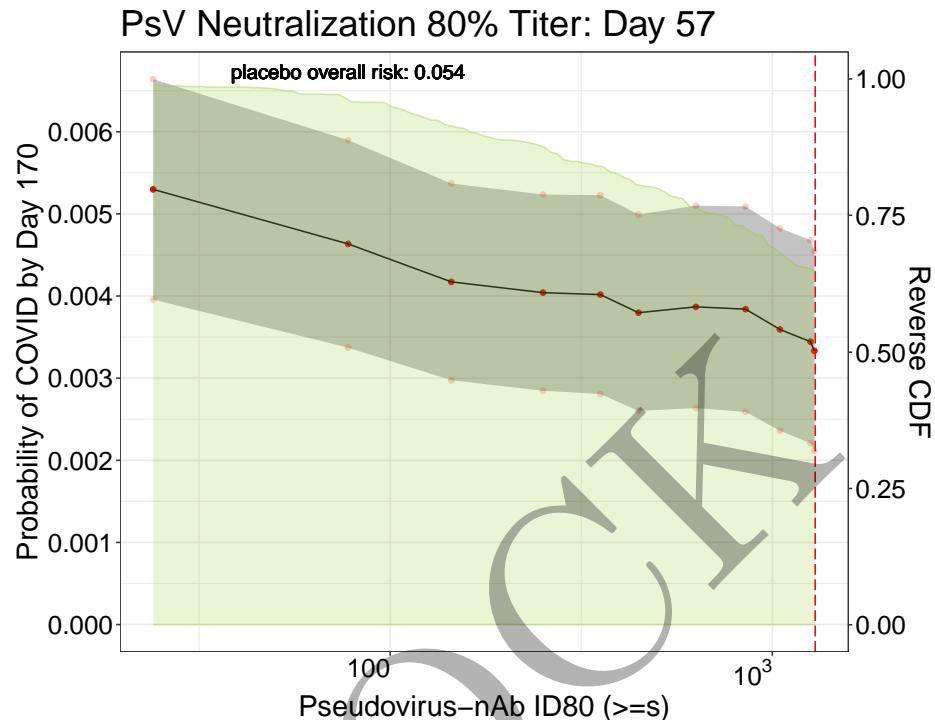


Figure 5.4: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

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
1.378	$2.39 * 10^1$	0.00530	0.00396	0.00664
1.889	$7.74 * 10^1$	0.00463	0.00337	0.00590
2.161	$1.45 * 10^2$	0.00417	0.00297	0.00537
2.396	$2.49 * 10^2$	0.00404	0.00285	0.00524
2.547	$3.52 * 10^2$	0.00402	0.00281	0.00523
2.802	$6.34 * 10^2$	0.00387	0.00264	0.00510
2.935	$8.61 * 10^2$	0.00384	0.00259	0.00509
3.016	$1.04 * 10^3$	0.00359	0.00236	0.00483
3.100	$1.26 * 10^3$	0.00344	0.00221	0.00468
3.112	$1.29 * 10^3$	0.00333	0.00212	0.00455

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

MOCK

5.2.1 Day 29 Spike protein antibody

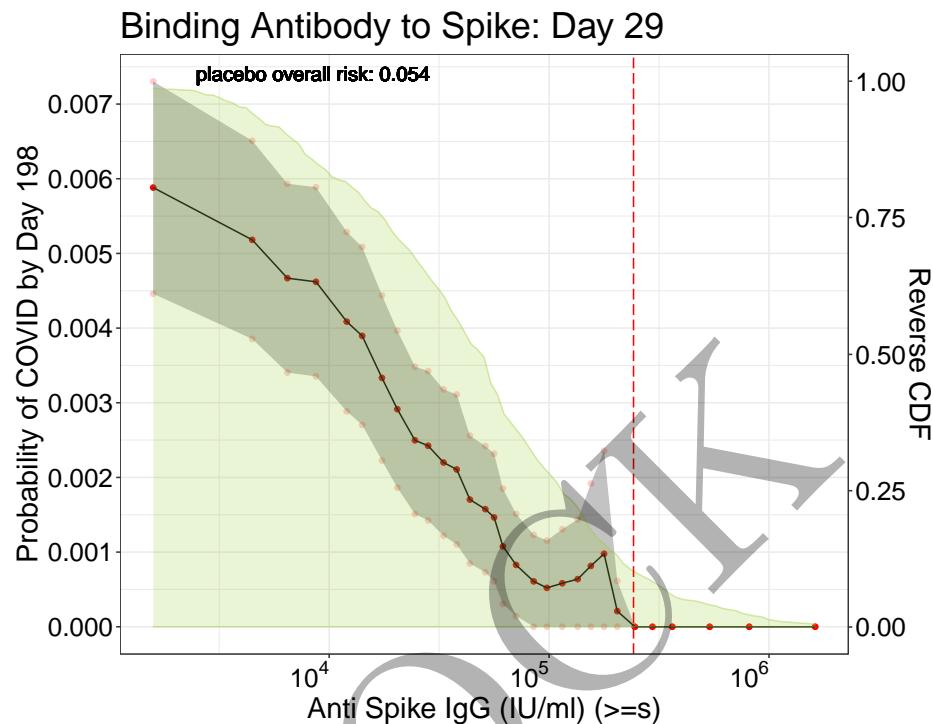


Figure 5.5: Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

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
3.196	$1.57 * 10^3$	0.00588	0.00446	0.00730
3.938	$8.67 * 10^3$	0.00462	0.00335	0.00589
4.236	$1.72 * 10^4$	0.00333	0.00223	0.00444
4.516	$3.28 * 10^4$	0.00220	0.00122	0.00318
4.711	$5.14 * 10^4$	0.00157	0.00073	0.00242
4.852	$7.11 * 10^4$	0.00083	0.00014	0.00151
5.064	$1.16 * 10^5$	0.00058	0.00000	0.00131
5.312	$2.05 * 10^5$	0.00021	0.00000	0.00062
5.560	$3.63 * 10^5$	0.00000	0.00000	NA
6.214	$1.64 * 10^6$	0.00000	0.00000	NA

5.2.2 Day 29 RBD binding antibody

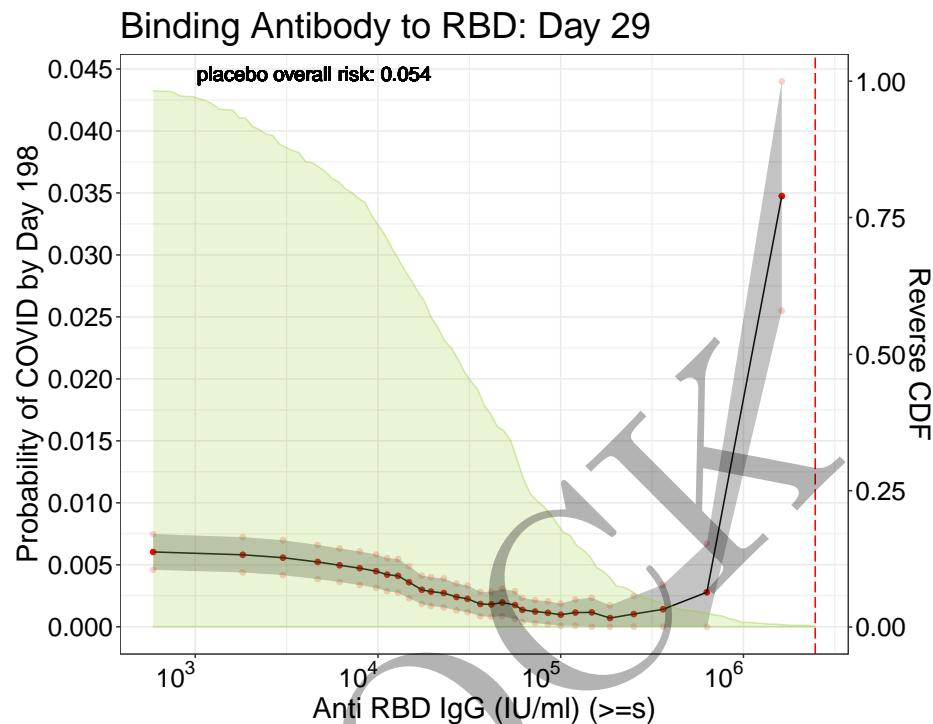


Figure 5.6: Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

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
2.774	5.94×10^2	0.00604	0.00459	0.00748
3.669	4.67×10^3	0.00523	0.00385	0.00660
3.986	9.68×10^3	0.00448	0.00313	0.00583
4.236	1.72×10^4	0.00298	0.00183	0.00413
4.428	2.68×10^4	0.00240	0.00132	0.00349
4.619	4.16×10^4	0.00181	0.00080	0.00282
4.793	6.21×10^4	0.00136	0.00039	0.00234
5.076	1.19×10^5	0.00114	0.00008	0.00221
5.403	2.53×10^5	0.00103	0.00000	0.00249
6.212	1.63×10^6	0.03475	0.02550	0.04400

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

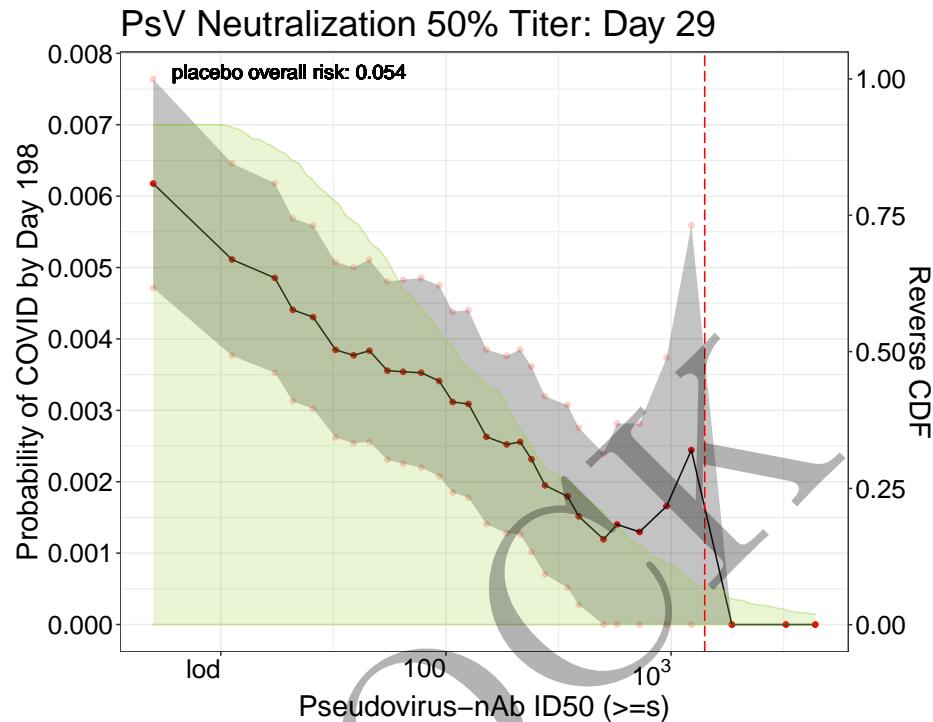


Figure 5.7: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

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
0.699	$5.00 * 10^0$	0.00618	0.00471	0.00764
1.323	$2.10 * 10^1$	0.00441	0.00313	0.00569
1.589	$3.88 * 10^1$	0.00377	0.00254	0.00500
1.808	$6.43 * 10^1$	0.00354	0.00225	0.00483
2.031	$1.07 * 10^2$	0.00312	0.00185	0.00438
2.327	$2.12 * 10^2$	0.00256	0.00126	0.00385
2.540	$3.47 * 10^2$	0.00179	0.00052	0.00307
2.759	$5.74 * 10^2$	0.00140	0.00000	0.00281
3.089	$1.23 * 10^3$	0.00244	0.00000	0.00559
3.644	$4.41 * 10^3$	0.00000	0.00000	NA

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

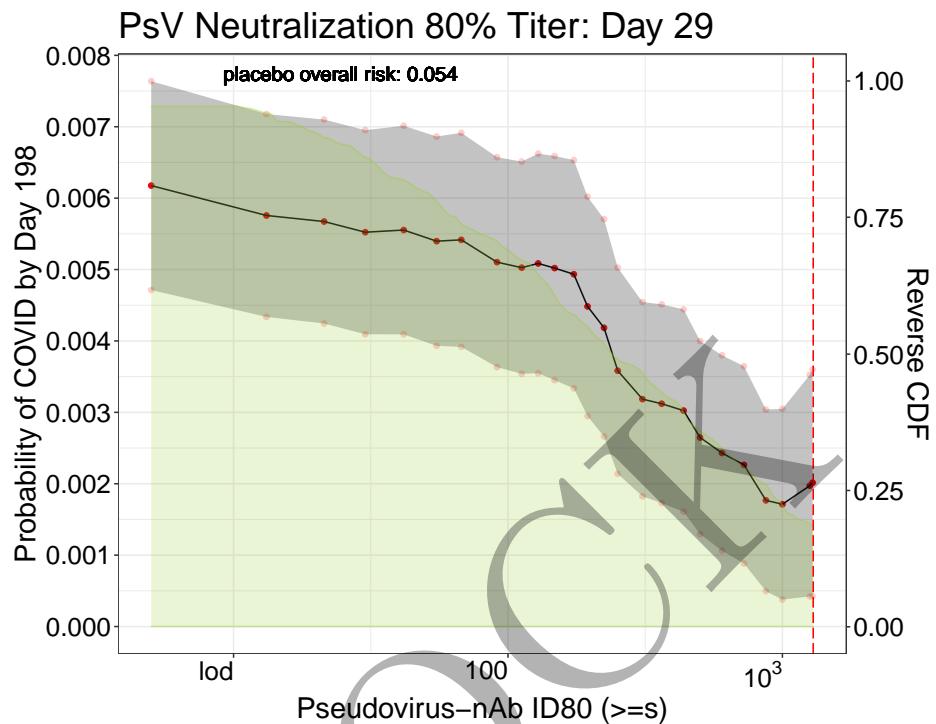


Figure 5.8: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

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	$5.00 * 10^0$	0.00618	0.00471	0.00764
1.482	$3.03 * 10^1$	0.00552	0.00409	0.00695
1.744	$5.55 * 10^1$	0.00540	0.00393	0.00686
2.046	$1.11 * 10^2$	0.00503	0.00354	0.00651
2.238	$1.73 * 10^2$	0.00493	0.00334	0.00653
2.348	$2.23 * 10^2$	0.00418	0.00266	0.00571
2.564	$3.66 * 10^2$	0.00312	0.00173	0.00451
2.779	$6.01 * 10^2$	0.00243	0.00106	0.00380
2.938	$8.67 * 10^2$	0.00177	0.00050	0.00304
3.112	$1.29 * 10^3$	0.00201	0.00043	0.00360

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

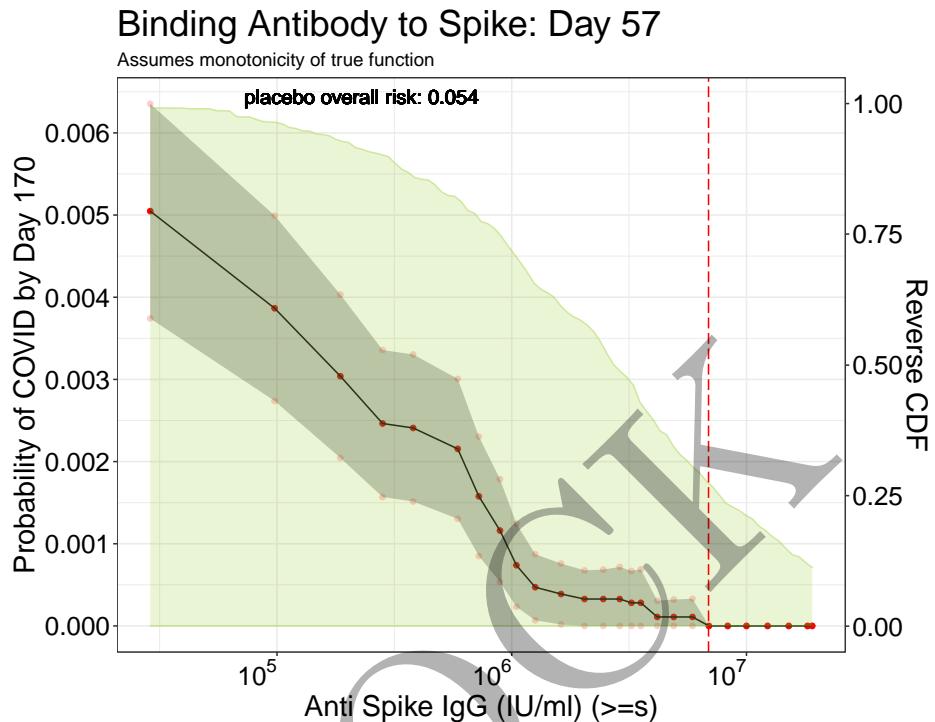


Figure 5.9: Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted 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
4.465	2.92 * 10 ⁴	0.00505	0.00374	0.00635
5.450	2.82 * 10 ⁵	0.00246	0.00157	0.00336
5.864	7.31 * 10 ⁵	0.00158	0.00085	0.00230
6.020	1.05 * 10 ⁶	0.00074	0.00023	0.00124
6.307	2.03 * 10 ⁶	0.00033	0.00000	0.00068
6.512	3.25 * 10 ⁶	0.00028	0.00000	0.00067
6.688	4.88 * 10 ⁶	0.00011	0.00000	0.00032
6.842	6.95 * 10 ⁶	0.00000	0.00000	NA
7.092	1.24 * 10 ⁷	0.00000	0.00000	NA
7.282	1.91 * 10 ⁷	0.00000	0.00000	NA

5.3.2 Day 57 RBD binding antibody

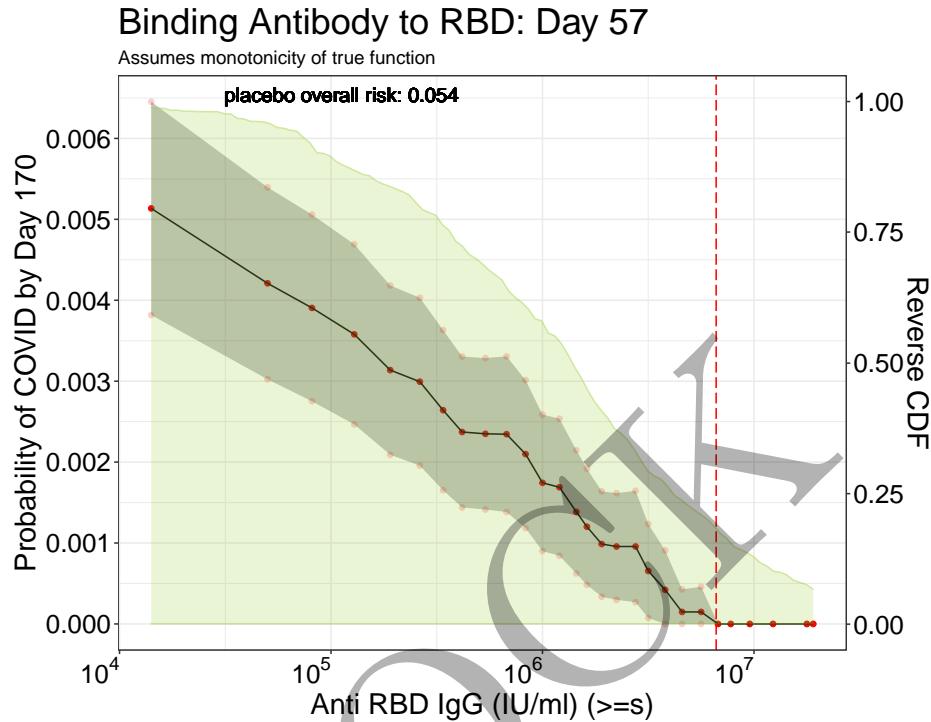


Figure 5.10: Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using 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
4.154	$1.43 * 10^4$	0.00514	0.00382	0.00645
5.109	$1.29 * 10^5$	0.00358	0.00247	0.00469
5.534	$3.42 * 10^5$	0.00264	0.00165	0.00363
5.831	$6.78 * 10^5$	0.00234	0.00138	0.00331
6.084	$1.21 * 10^6$	0.00169	0.00084	0.00254
6.284	$1.92 * 10^6$	0.00099	0.00034	0.00164
6.497	$3.14 * 10^6$	0.00065	0.00007	0.00124
6.753	$5.66 * 10^6$	0.00015	0.00000	0.00046
6.977	$9.48 * 10^6$	0.00000	0.00000	NA
7.282	$1.91 * 10^7$	0.00000	0.00000	NA

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

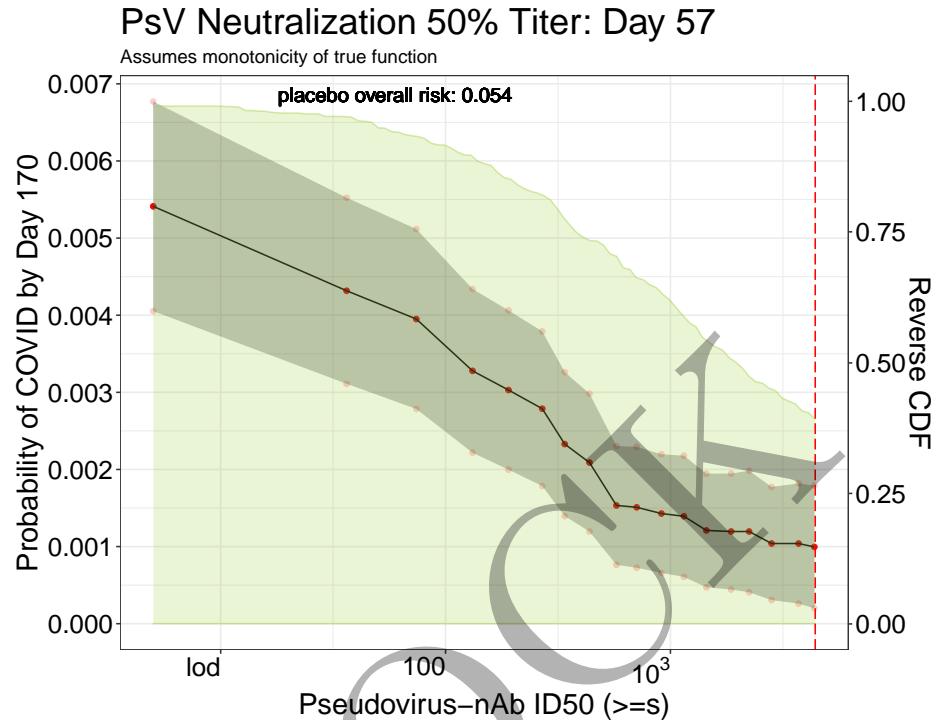


Figure 5.11: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence 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
0.699	$5.00 * 10^0$	0.00541	0.00405	0.00677
1.872	$7.45 * 10^1$	0.00395	0.00278	0.00512
2.277	$1.89 * 10^2$	0.00303	0.00200	0.00406
2.533	$3.41 * 10^2$	0.00233	0.00140	0.00326
2.764	$5.81 * 10^2$	0.00153	0.00076	0.00230
2.853	$7.13 * 10^2$	0.00151	0.00073	0.00229
3.061	$1.15 * 10^3$	0.00139	0.00061	0.00218
3.266	$1.85 * 10^3$	0.00120	0.00044	0.00195
3.453	$2.84 * 10^3$	0.00104	0.00031	0.00177
3.644	$4.41 * 10^3$	0.00100	0.00020	0.00179

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

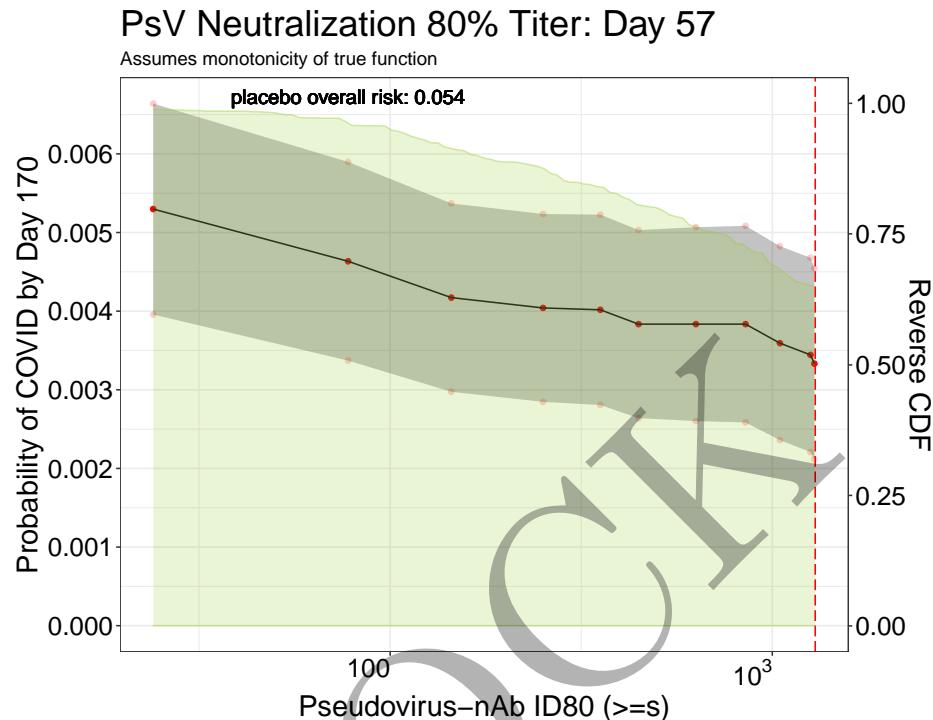


Figure 5.12: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence 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
1.378	$2.39 * 10^1$	0.00530	0.00396	0.00664
1.889	$7.74 * 10^1$	0.00463	0.00337	0.00590
2.161	$1.45 * 10^2$	0.00417	0.00297	0.00537
2.396	$2.49 * 10^2$	0.00404	0.00285	0.00524
2.547	$3.52 * 10^2$	0.00402	0.00281	0.00523
2.802	$6.34 * 10^2$	0.00384	0.00260	0.00507
2.935	$8.61 * 10^2$	0.00384	0.00258	0.00509
3.016	$1.04 * 10^3$	0.00359	0.00236	0.00483
3.100	$1.26 * 10^3$	0.00344	0.00221	0.00468
3.112	$1.29 * 10^3$	0.00333	0.00212	0.00455

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

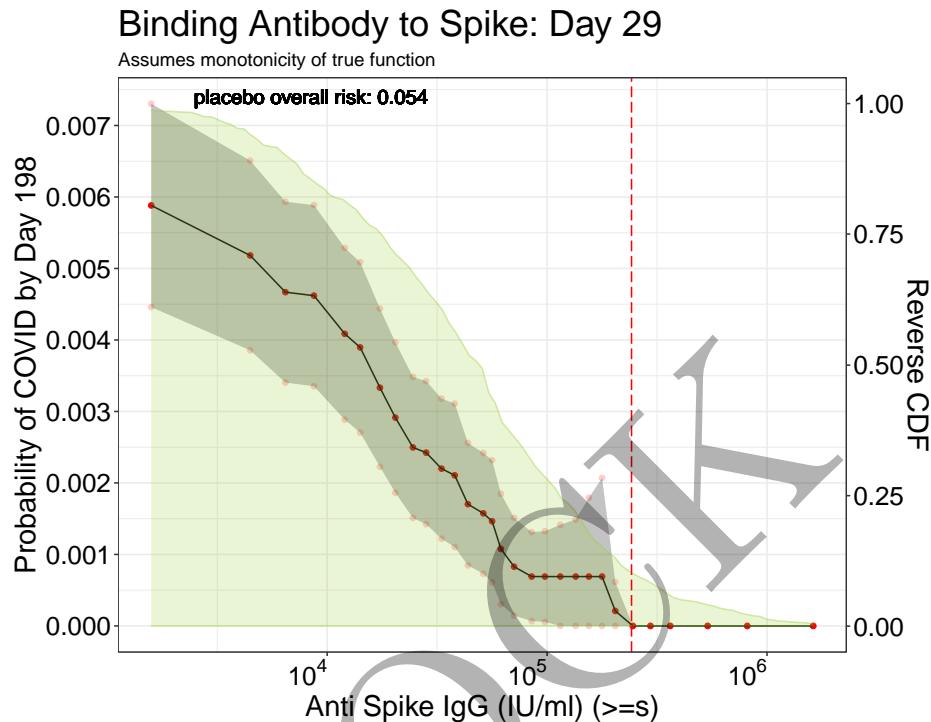


Figure 5.13: Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using 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
3.196	1.57×10^3	0.00588	0.00446	0.00730
3.938	8.67×10^3	0.00462	0.00335	0.00589
4.236	1.72×10^4	0.00333	0.00223	0.00444
4.516	3.28×10^4	0.00220	0.00122	0.00318
4.711	5.14×10^4	0.00157	0.00073	0.00242
4.852	7.11×10^4	0.00083	0.00014	0.00151
5.064	1.16×10^5	0.00069	0.00000	0.00141
5.312	2.05×10^5	0.00021	0.00000	0.00062
5.560	3.63×10^5	0.00000	0.00000	NA
6.214	1.64×10^6	0.00000	0.00000	NA

5.4.2 Day 29 RBD binding antibody

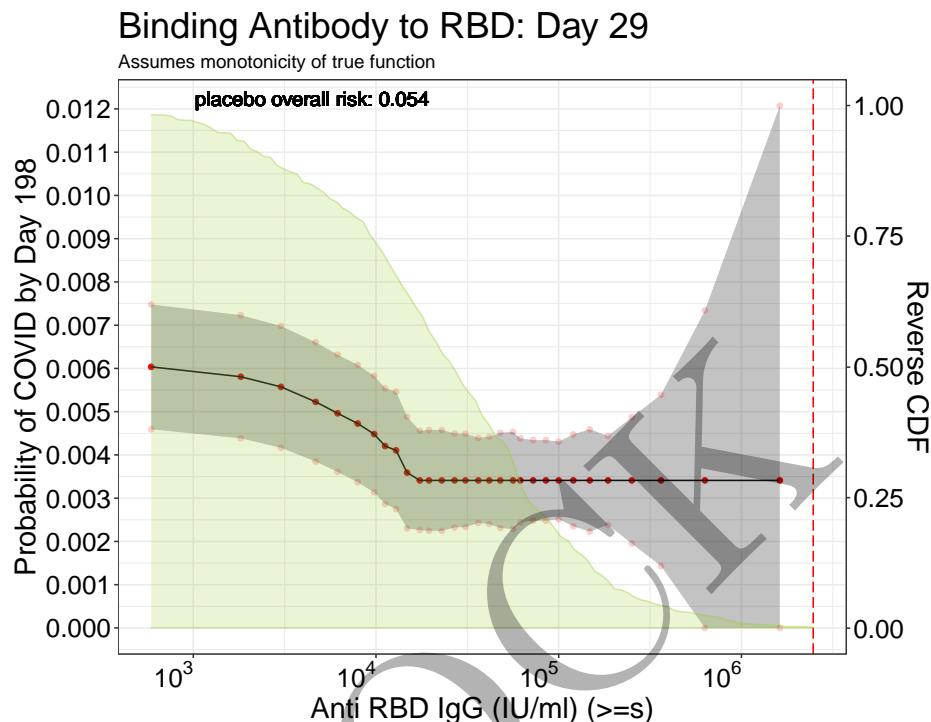


Figure 5.14: Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using 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
2.774	5.94×10^2	0.00604	0.00459	0.00748
3.669	4.67×10^3	0.00523	0.00385	0.00660
3.986	9.68×10^3	0.00448	0.00313	0.00583
4.236	1.72×10^4	0.00341	0.00226	0.00456
4.428	2.68×10^4	0.00341	0.00232	0.00450
4.619	4.16×10^4	0.00341	0.00240	0.00442
4.793	6.21×10^4	0.00341	0.00244	0.00438
5.076	1.19×10^5	0.00341	0.00235	0.00447
5.403	2.53×10^5	0.00341	0.00195	0.00487
6.212	1.63×10^6	0.00341	0.00000	0.01266

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

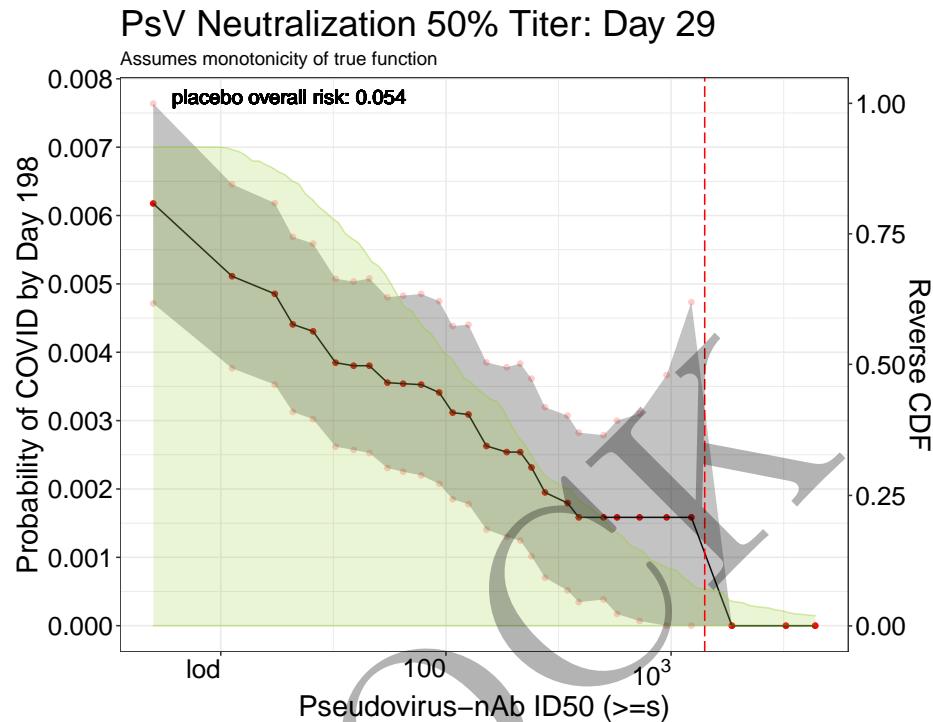


Figure 5.15: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence 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
0.699	$5.00 * 10^0$	0.00618	0.00471	0.00764
1.323	$2.10 * 10^1$	0.00441	0.00313	0.00569
1.589	$3.88 * 10^1$	0.00380	0.00257	0.00503
1.808	$6.43 * 10^1$	0.00354	0.00225	0.00483
2.031	$1.07 * 10^2$	0.00312	0.00185	0.00438
2.327	$2.12 * 10^2$	0.00254	0.00125	0.00383
2.540	$3.47 * 10^2$	0.00179	0.00052	0.00307
2.759	$5.74 * 10^2$	0.00158	0.00017	0.00300
3.089	$1.23 * 10^3$	0.00158	0.00000	0.00473
3.644	$4.41 * 10^3$	0.00000	0.00000	NA

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

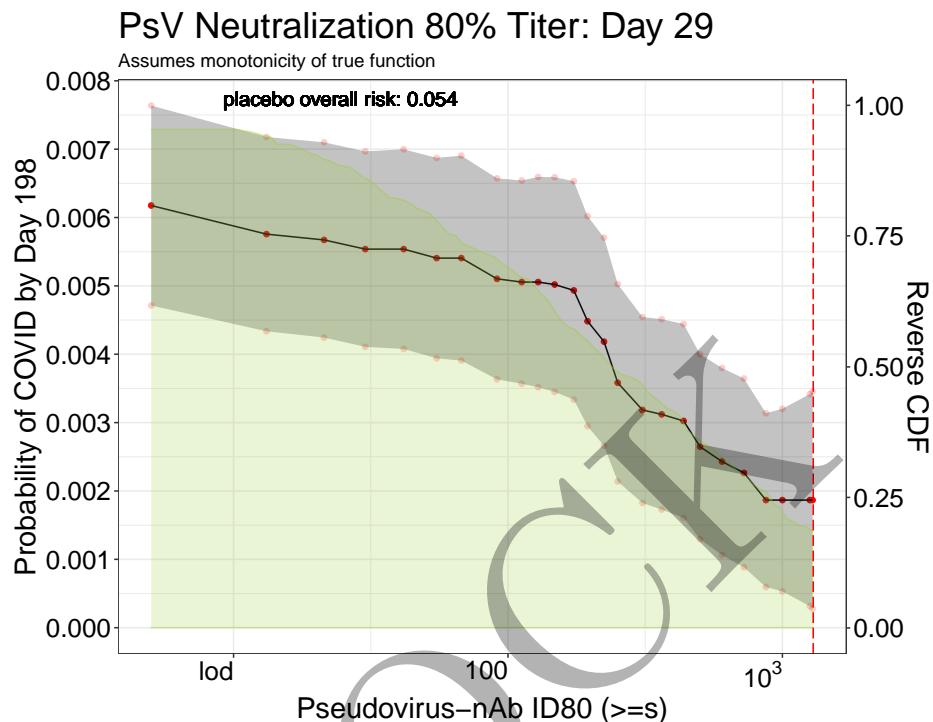


Figure 5.16: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence 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	$5.00 * 10^0$	0.00618	0.00471	0.00764
1.482	$3.03 * 10^1$	0.00554	0.00411	0.00697
1.744	$5.55 * 10^1$	0.00541	0.00394	0.00687
2.046	$1.11 * 10^2$	0.00506	0.00357	0.00654
2.238	$1.73 * 10^2$	0.00493	0.00334	0.00653
2.348	$2.23 * 10^2$	0.00418	0.00266	0.00571
2.564	$3.66 * 10^2$	0.00312	0.00173	0.00451
2.779	$6.01 * 10^2$	0.00243	0.00106	0.00380
2.938	$8.67 * 10^2$	0.00187	0.00060	0.00314
3.112	$1.29 * 10^3$	0.00187	0.00028	0.00345

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

MOCK

5.5.1 Day 57 Spike protein binding antibody

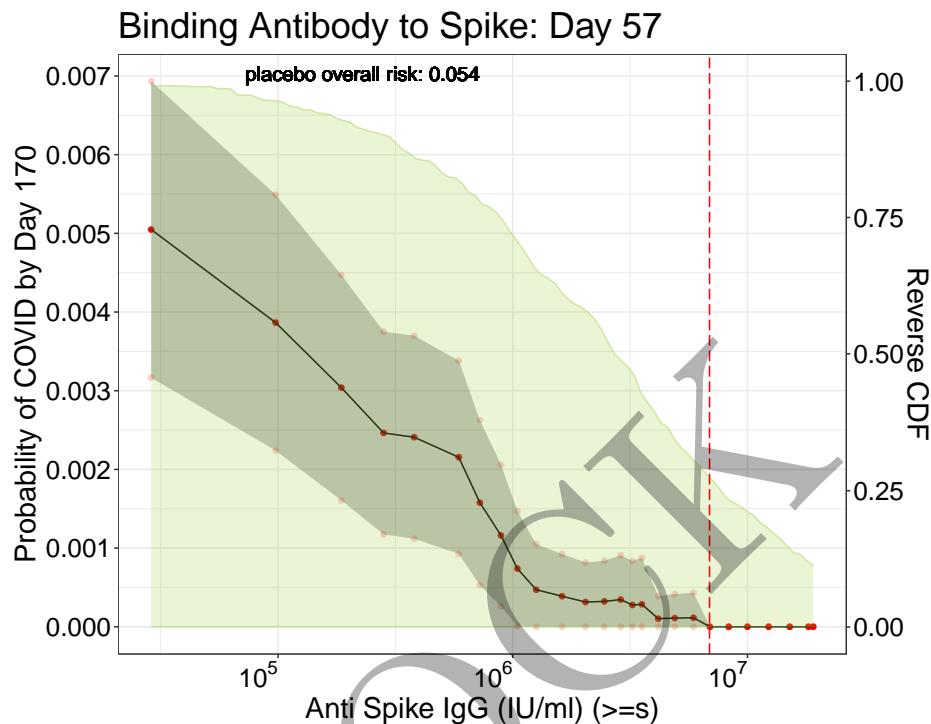


Figure 5.17: Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

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
4.465	$2.92 * 10^4$	0.00505	0.00317	0.00693
5.450	$2.82 * 10^5$	0.00246	0.00117	0.00375
5.864	$7.31 * 10^5$	0.00158	0.00053	0.00262
6.020	$1.05 * 10^6$	0.00074	0.00001	0.00147
6.307	$2.03 * 10^6$	0.00031	0.00000	0.00082
6.512	$3.25 * 10^6$	0.00028	0.00000	0.00084
6.688	$4.88 * 10^6$	0.00011	0.00000	0.00042
6.842	$6.95 * 10^6$	0.00000	0.00000	NA
7.092	$1.24 * 10^7$	0.00000	0.00000	NA
7.282	$1.91 * 10^7$	0.00000	0.00000	NA

5.5.2 Day 57 RBD binding antibody

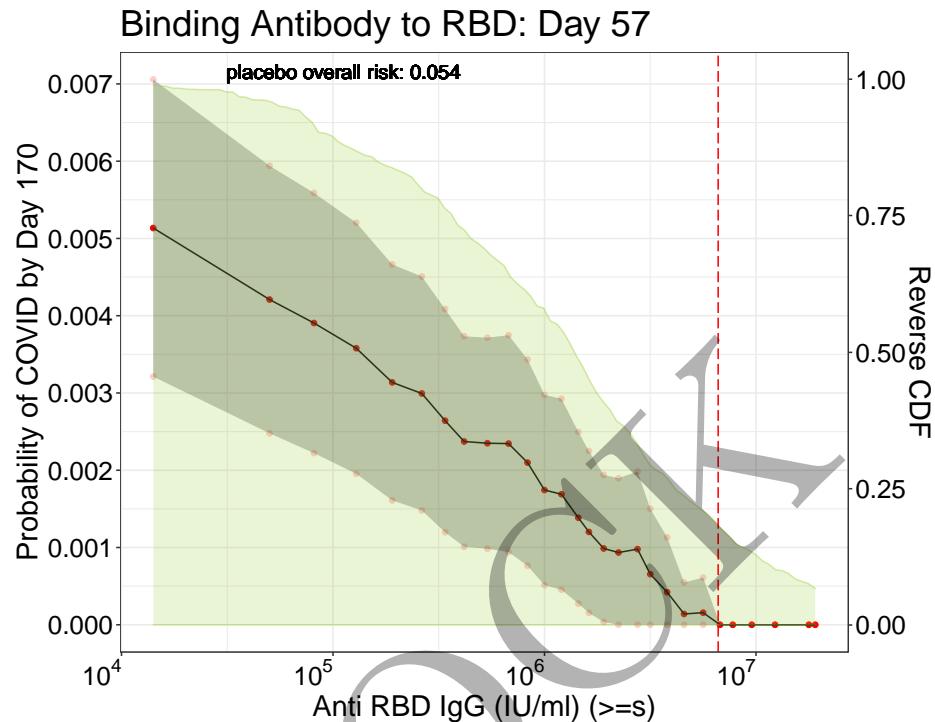


Figure 5.18: Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

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
4.154	$1.43 * 10^4$	0.00514	0.00321	0.00706
5.109	$1.29 * 10^5$	0.00358	0.00195	0.00520
5.534	$3.42 * 10^5$	0.00264	0.00120	0.00409
5.831	$6.78 * 10^5$	0.00234	0.00094	0.00375
6.084	$1.21 * 10^6$	0.00169	0.00045	0.00293
6.284	$1.92 * 10^6$	0.00099	0.00004	0.00194
6.497	$3.14 * 10^6$	0.00065	0.00000	0.00150
6.753	$5.66 * 10^6$	0.00016	0.00000	0.00061
6.977	$9.48 * 10^6$	0.00000	0.00000	NA
7.282	$1.91 * 10^7$	0.00000	0.00000	NA

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

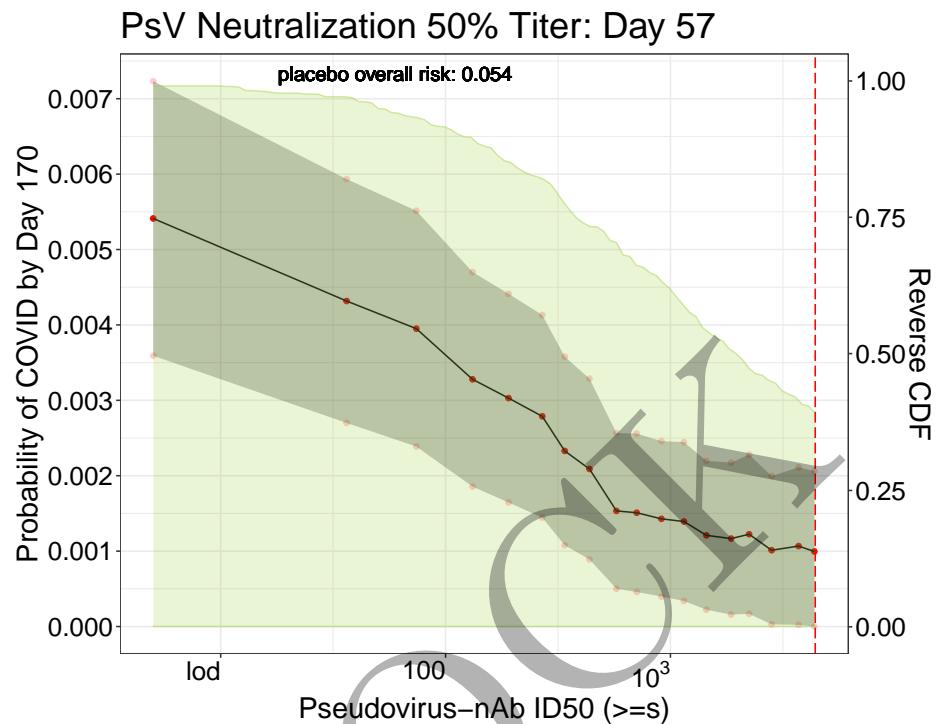


Figure 5.19: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

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
0.699	$5.00 * 10^0$	0.00541	0.00359	0.00723
1.872	$7.45 * 10^1$	0.00395	0.00239	0.00551
2.277	$1.89 * 10^2$	0.00303	0.00165	0.00441
2.533	$3.41 * 10^2$	0.00233	0.00108	0.00358
2.764	$5.81 * 10^2$	0.00153	0.00050	0.00257
2.853	$7.13 * 10^2$	0.00151	0.00046	0.00256
3.061	$1.15 * 10^3$	0.00139	0.00034	0.00245
3.266	$1.85 * 10^3$	0.00117	0.00016	0.00217
3.453	$2.84 * 10^3$	0.00101	0.00003	0.00200
3.644	$4.41 * 10^3$	0.00100	0.00000	0.00206

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

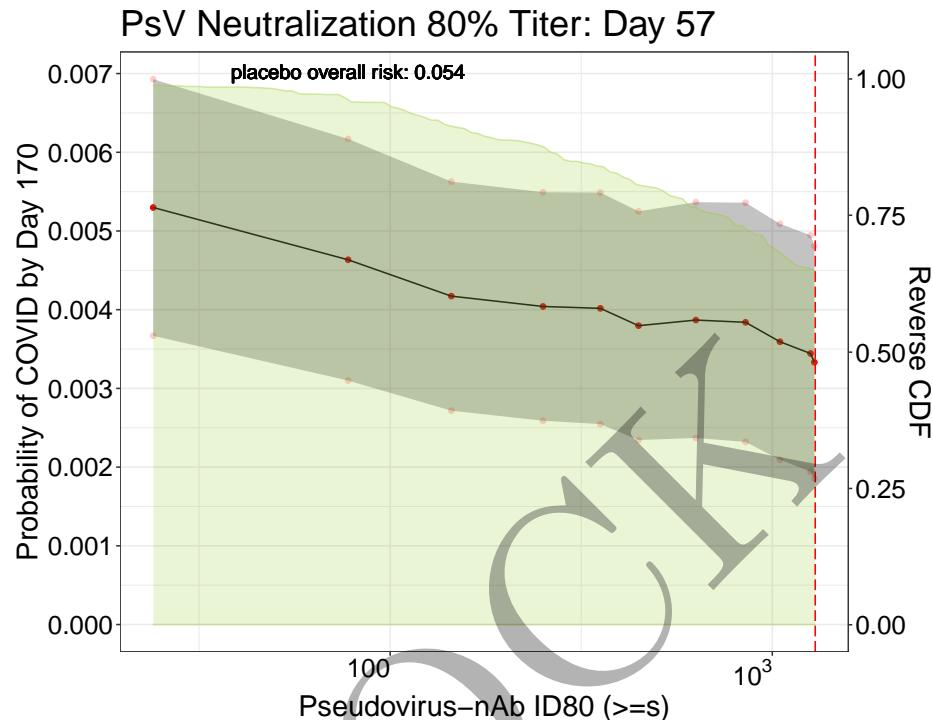


Figure 5.20: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

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
1.378	2.39×10^1	0.00530	0.00367	0.00693
1.889	7.74×10^1	0.00463	0.00310	0.00617
2.161	1.45×10^2	0.00417	0.00272	0.00563
2.396	2.49×10^2	0.00404	0.00259	0.00549
2.547	3.52×10^2	0.00402	0.00255	0.00549
2.802	6.34×10^2	0.00387	0.00237	0.00537
2.935	8.61×10^2	0.00384	0.00232	0.00536
3.016	1.04×10^3	0.00359	0.00209	0.00509
3.100	1.26×10^3	0.00344	0.00194	0.00495
3.112	1.29×10^3	0.00333	0.00186	0.00481

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

MOCK

5.6.1 Day 29 Spike protein antibody

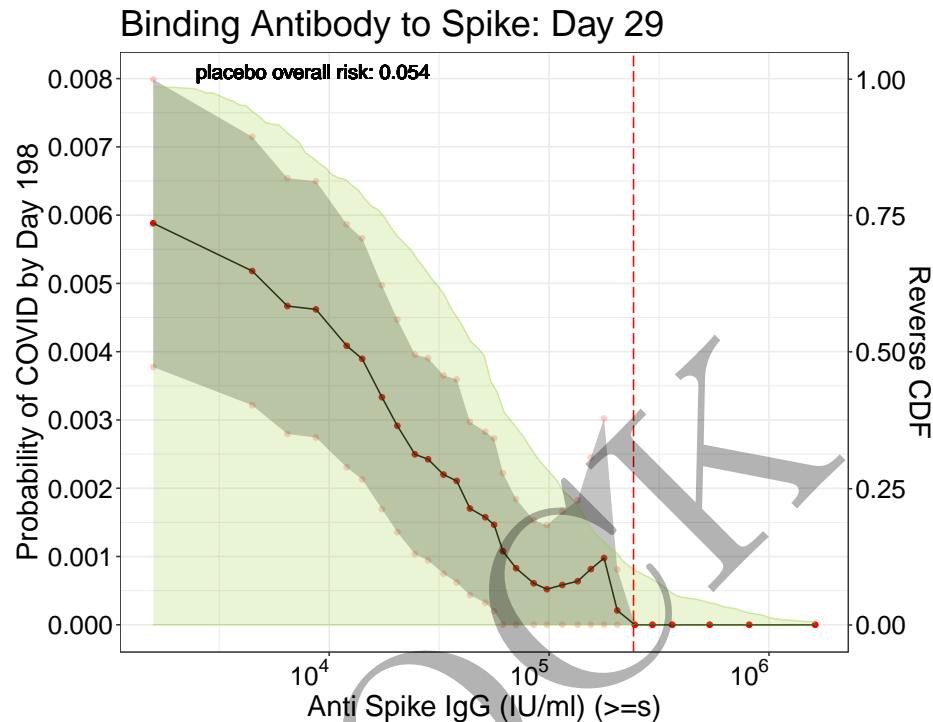


Figure 5.21: Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

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
3.196	$1.57 * 10^3$	0.00588	0.00378	0.00799
3.938	$8.67 * 10^3$	0.00462	0.00274	0.00650
4.236	$1.72 * 10^4$	0.00333	0.00169	0.00497
4.516	$3.28 * 10^4$	0.00220	0.00075	0.00365
4.711	$5.14 * 10^4$	0.00157	0.00032	0.00283
4.852	$7.11 * 10^4$	0.00083	0.00000	0.00184
5.064	$1.16 * 10^5$	0.00058	0.00000	0.00166
5.312	$2.05 * 10^5$	0.00021	0.00000	0.00081
5.560	$3.63 * 10^5$	0.00000	0.00000	NA
6.214	$1.64 * 10^6$	0.00000	0.00000	NA

5.6.2 Day 29 RBD binding antibody

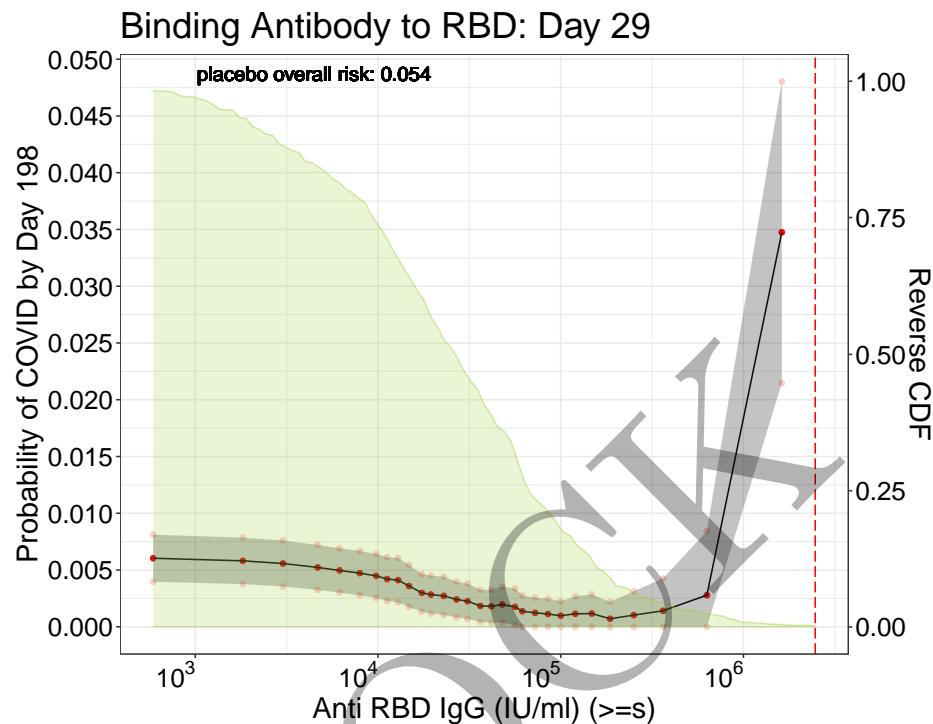


Figure 5.22: Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

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
2.774	5.94×10^2	0.00604	0.00396	0.00811
3.669	4.67×10^3	0.00523	0.00325	0.00721
3.986	9.68×10^3	0.00448	0.00255	0.00642
4.236	1.72×10^4	0.00298	0.00133	0.00463
4.428	2.68×10^4	0.00240	0.00084	0.00397
4.619	4.16×10^4	0.00181	0.00036	0.00326
4.793	6.21×10^4	0.00136	0.00000	0.00276
5.076	1.19×10^5	0.00114	0.00000	0.00267
5.403	2.53×10^5	0.00103	0.00000	0.00313
6.212	1.63×10^6	0.03475	0.02145	0.04804

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

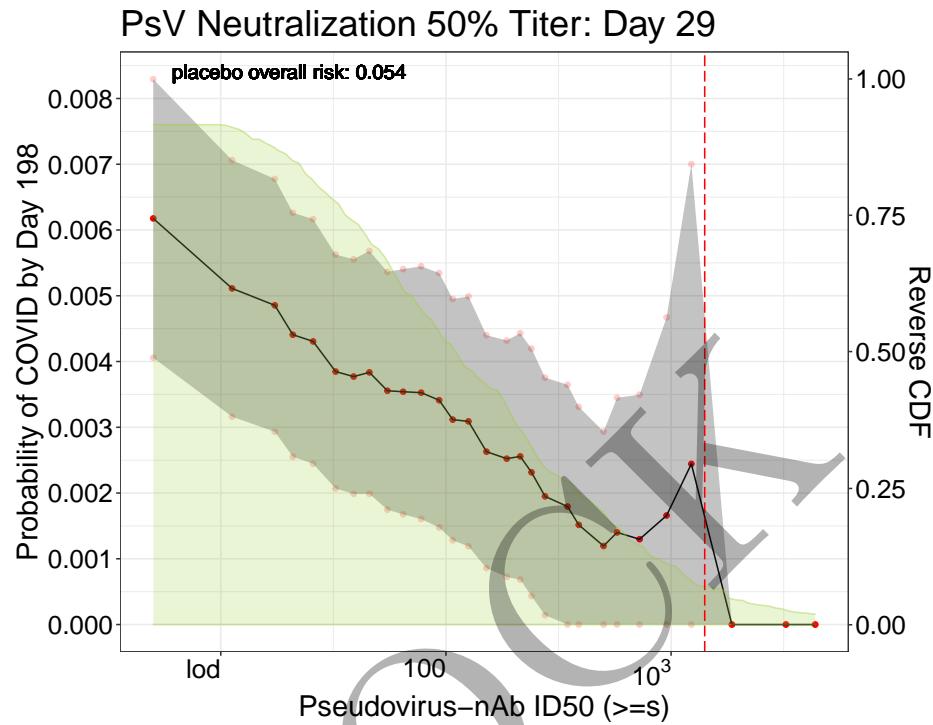


Figure 5.23: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

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
0.699	$5.00 * 10^0$	0.00618	0.00406	0.00829
1.323	$2.10 * 10^1$	0.00441	0.00255	0.00626
1.589	$3.88 * 10^1$	0.00377	0.00199	0.00556
1.808	$6.43 * 10^1$	0.00354	0.00168	0.00541
2.031	$1.07 * 10^2$	0.00312	0.00128	0.00495
2.327	$2.12 * 10^2$	0.00256	0.00068	0.00443
2.540	$3.47 * 10^2$	0.00179	0.00000	0.00365
2.759	$5.74 * 10^2$	0.00140	0.00000	0.00345
3.089	$1.23 * 10^3$	0.00244	0.00000	0.00700
3.644	$4.41 * 10^3$	0.00000	0.00000	NA

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

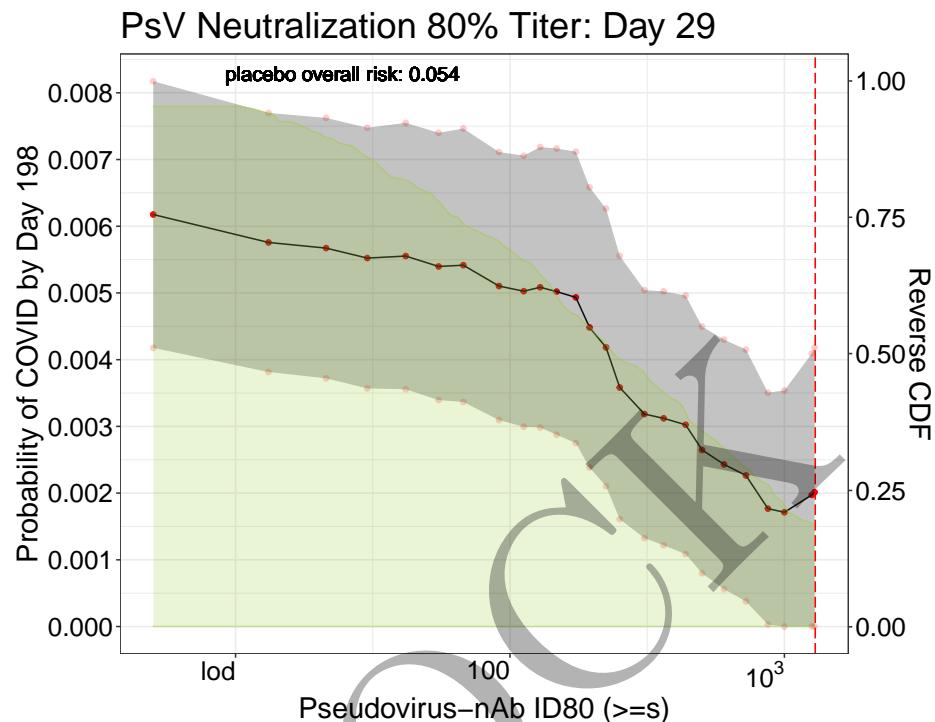


Figure 5.24: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

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	$5.00 * 10^0$	0.00618	0.00418	0.00817
1.482	$3.03 * 10^1$	0.00552	0.00357	0.00748
1.744	$5.55 * 10^1$	0.00540	0.00339	0.00740
2.046	$1.11 * 10^2$	0.00503	0.00300	0.00706
2.238	$1.73 * 10^2$	0.00493	0.00275	0.00712
2.348	$2.23 * 10^2$	0.00418	0.00210	0.00626
2.564	$3.66 * 10^2$	0.00312	0.00122	0.00502
2.779	$6.01 * 10^2$	0.00243	0.00056	0.00430
2.938	$8.67 * 10^2$	0.00177	0.00003	0.00351
3.112	$1.29 * 10^3$	0.00201	0.00000	0.00418

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

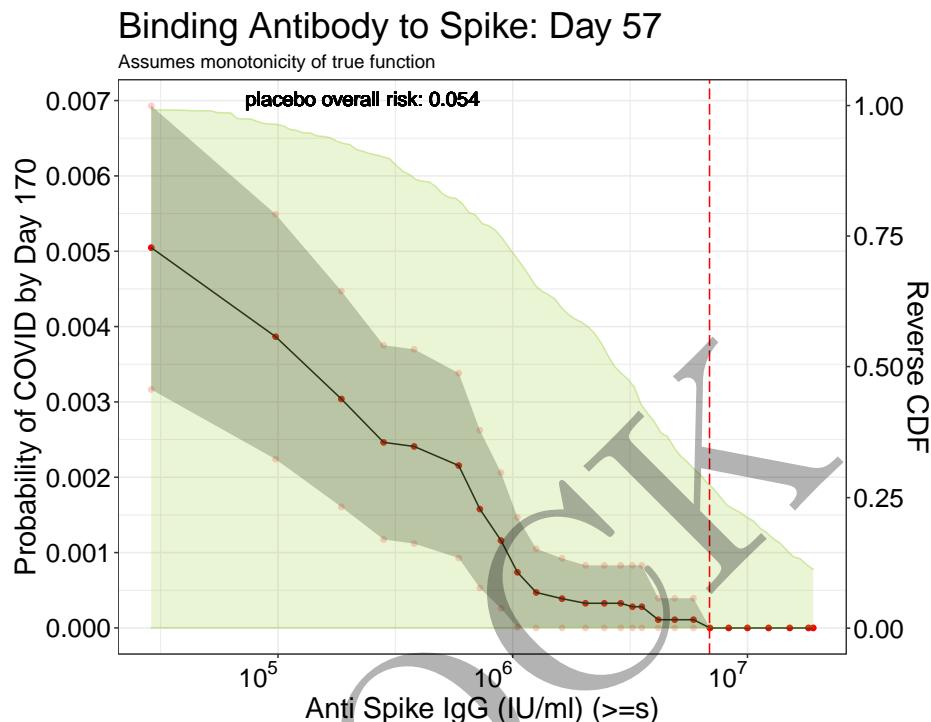


Figure 5.25: Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are 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
4.465	$2.92 * 10^4$	0.00505	0.00317	0.00693
5.450	$2.82 * 10^5$	0.00246	0.00117	0.00375
5.864	$7.31 * 10^5$	0.00158	0.00053	0.00262
6.020	$1.05 * 10^6$	0.00074	0.00001	0.00147
6.307	$2.03 * 10^6$	0.00033	0.00000	0.00083
6.512	$3.25 * 10^6$	0.00028	0.00000	0.00084
6.688	$4.88 * 10^6$	0.00011	0.00000	0.00041
6.842	$6.95 * 10^6$	0.00000	0.00000	NA
7.092	$1.24 * 10^7$	0.00000	0.00000	NA
7.282	$1.91 * 10^7$	0.00000	0.00000	NA

5.7.2 Day 57 RBD binding antibody

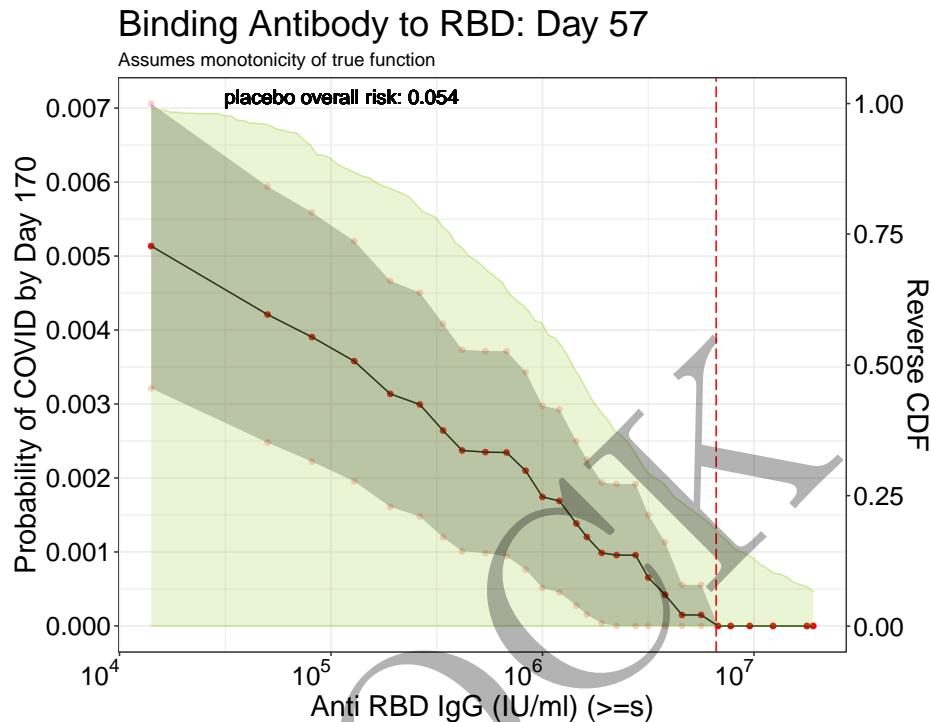


Figure 5.26: Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted 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
4.154	1.43×10^4	0.00514	0.00321	0.00706
5.109	1.29×10^5	0.00358	0.00195	0.00520
5.534	3.42×10^5	0.00264	0.00120	0.00409
5.831	6.78×10^5	0.00234	0.00094	0.00375
6.084	1.21×10^6	0.00169	0.00045	0.00293
6.284	1.92×10^6	0.00099	0.00004	0.00194
6.497	3.14×10^6	0.00065	0.00000	0.00150
6.753	5.66×10^6	0.00015	0.00000	0.00060
6.977	9.48×10^6	0.00000	0.00000	NA
7.282	1.91×10^7	0.00000	0.00000	NA

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

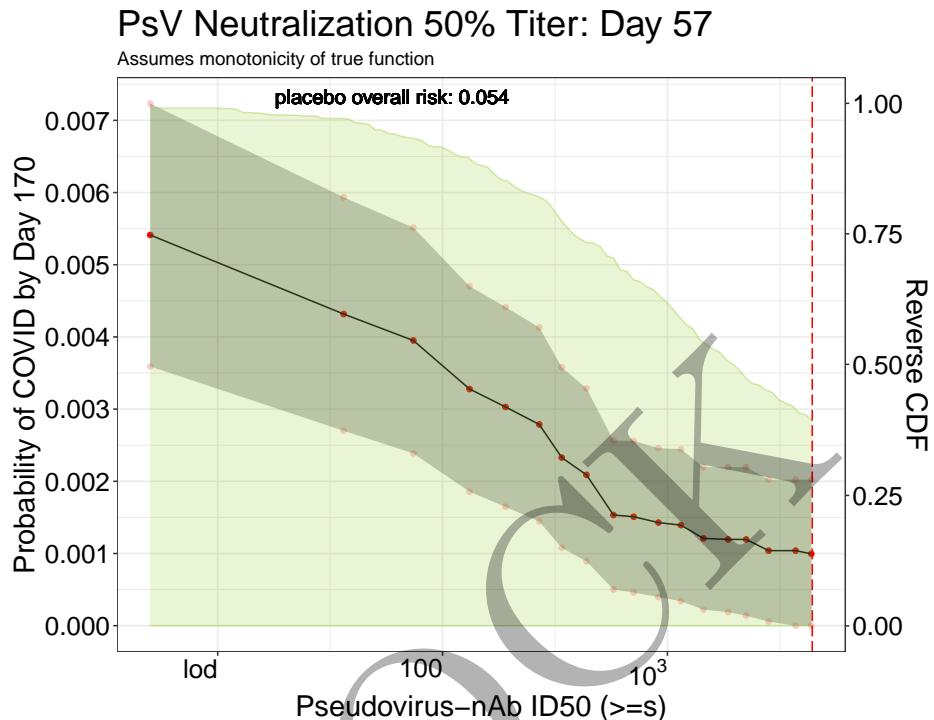


Figure 5.27: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence 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
0.699	$5.00 * 10^0$	0.00541	0.00359	0.00723
1.872	$7.45 * 10^1$	0.00395	0.00239	0.00551
2.277	$1.89 * 10^2$	0.00303	0.00165	0.00441
2.533	$3.41 * 10^2$	0.00233	0.00108	0.00358
2.764	$5.81 * 10^2$	0.00153	0.00050	0.00257
2.853	$7.13 * 10^2$	0.00151	0.00046	0.00256
3.061	$1.15 * 10^3$	0.00139	0.00034	0.00245
3.266	$1.85 * 10^3$	0.00120	0.00019	0.00220
3.453	$2.84 * 10^3$	0.00104	0.00006	0.00202
3.644	$4.41 * 10^3$	0.00100	0.00000	0.00206

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

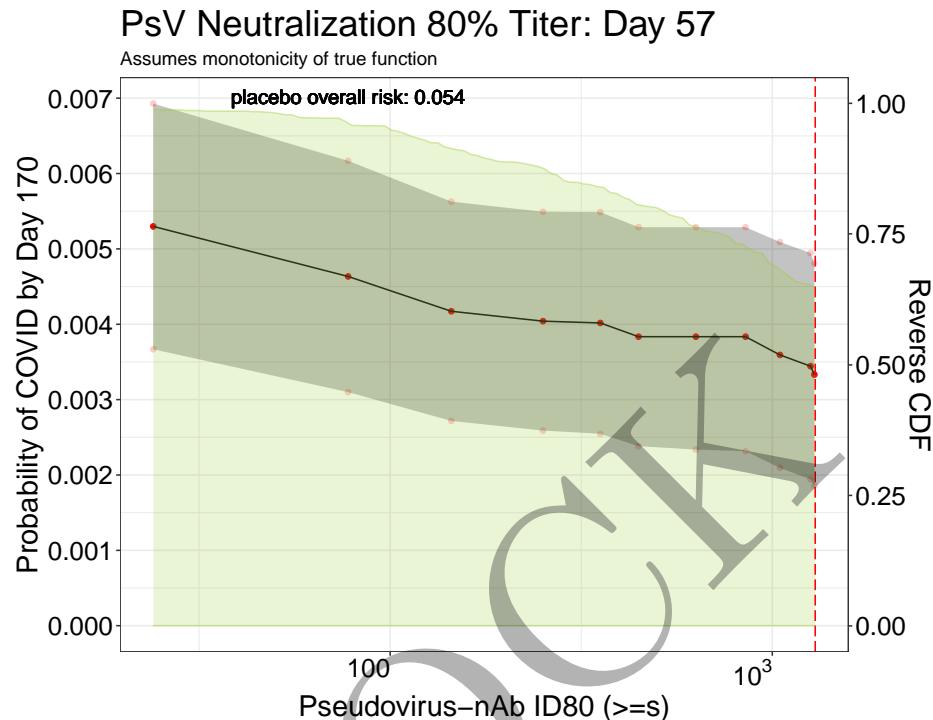


Figure 5.28: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence 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
1.378	2.39×10^1	0.00530	0.00367	0.00693
1.889	7.74×10^1	0.00463	0.00310	0.00617
2.161	1.45×10^2	0.00417	0.00272	0.00563
2.396	2.49×10^2	0.00404	0.00259	0.00549
2.547	3.52×10^2	0.00402	0.00255	0.00549
2.802	6.34×10^2	0.00384	0.00234	0.00533
2.935	8.61×10^2	0.00384	0.00232	0.00535
3.016	1.04×10^3	0.00359	0.00209	0.00509
3.100	1.26×10^3	0.00344	0.00194	0.00495
3.112	1.29×10^3	0.00333	0.00186	0.00481

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

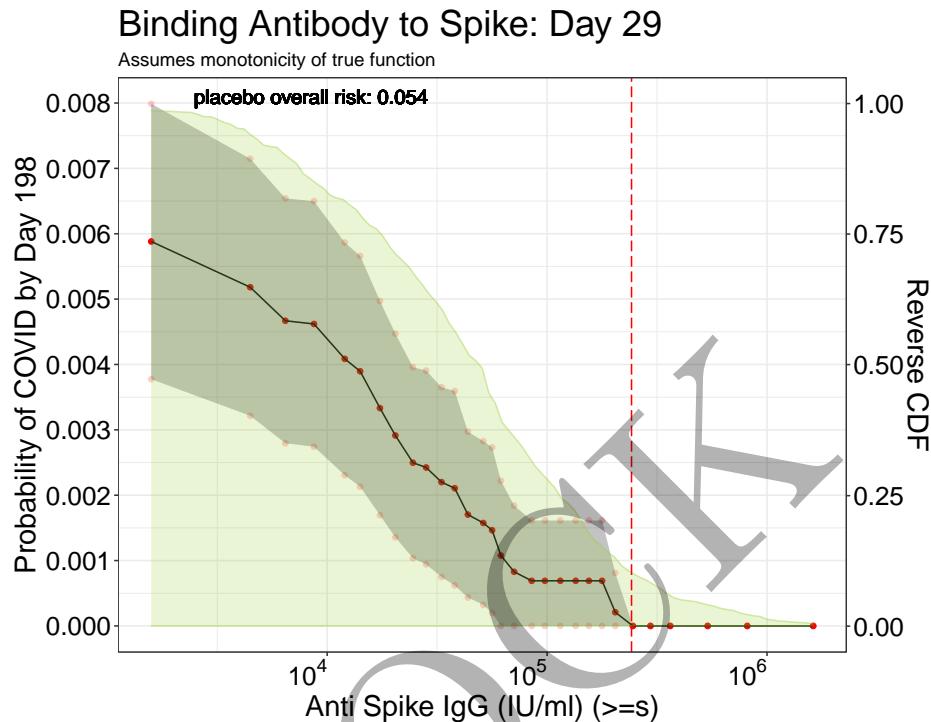


Figure 5.29: Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted 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
3.196	1.57×10^3	0.00588	0.00378	0.00799
3.938	8.67×10^3	0.00462	0.00274	0.00650
4.236	1.72×10^4	0.00333	0.00169	0.00497
4.516	3.28×10^4	0.00220	0.00075	0.00365
4.711	5.14×10^4	0.00157	0.00032	0.00283
4.852	7.11×10^4	0.00083	0.00000	0.00184
5.064	1.16×10^5	0.00069	0.00000	0.00176
5.312	2.05×10^5	0.00021	0.00000	0.00081
5.560	3.63×10^5	0.00000	0.00000	NA
6.214	1.64×10^6	0.00000	0.00000	NA

5.8.2 Day 29 RBD binding antibody

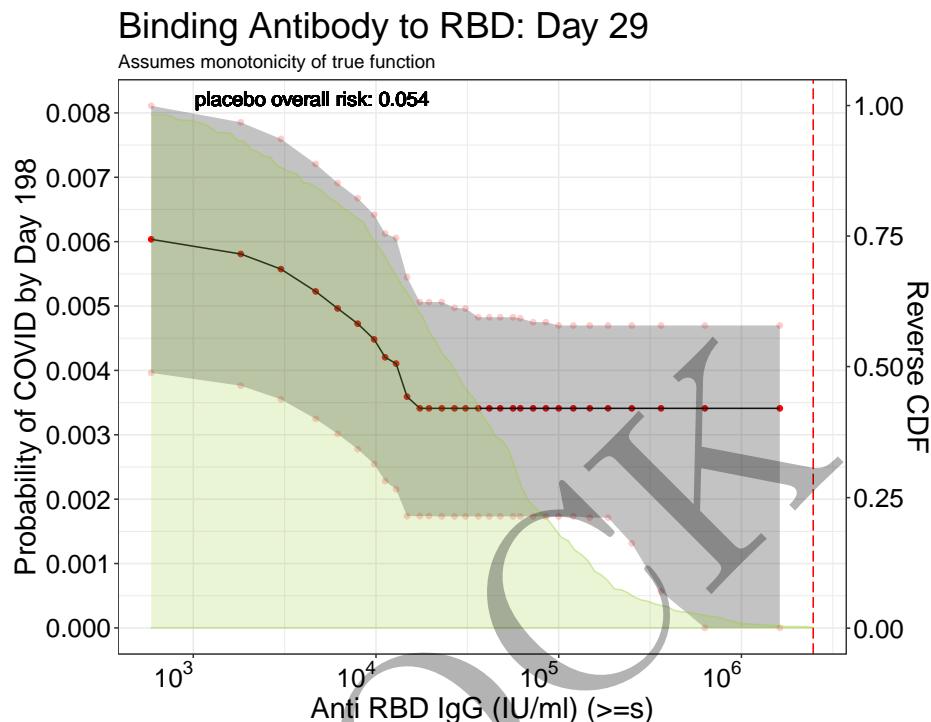


Figure 5.30: Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted 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
2.774	5.94×10^2	0.00604	0.00396	0.00811
3.669	4.67×10^3	0.00523	0.00325	0.00721
3.986	9.68×10^3	0.00448	0.00255	0.00642
4.236	1.72×10^4	0.00341	0.00176	0.00506
4.428	2.68×10^4	0.00341	0.00185	0.00497
4.619	4.16×10^4	0.00341	0.00196	0.00486
4.793	6.21×10^4	0.00341	0.00201	0.00481
5.076	1.19×10^5	0.00341	0.00188	0.00494
5.403	2.53×10^5	0.00341	0.00131	0.00551
6.212	1.63×10^6	0.00341	0.00000	0.01670

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

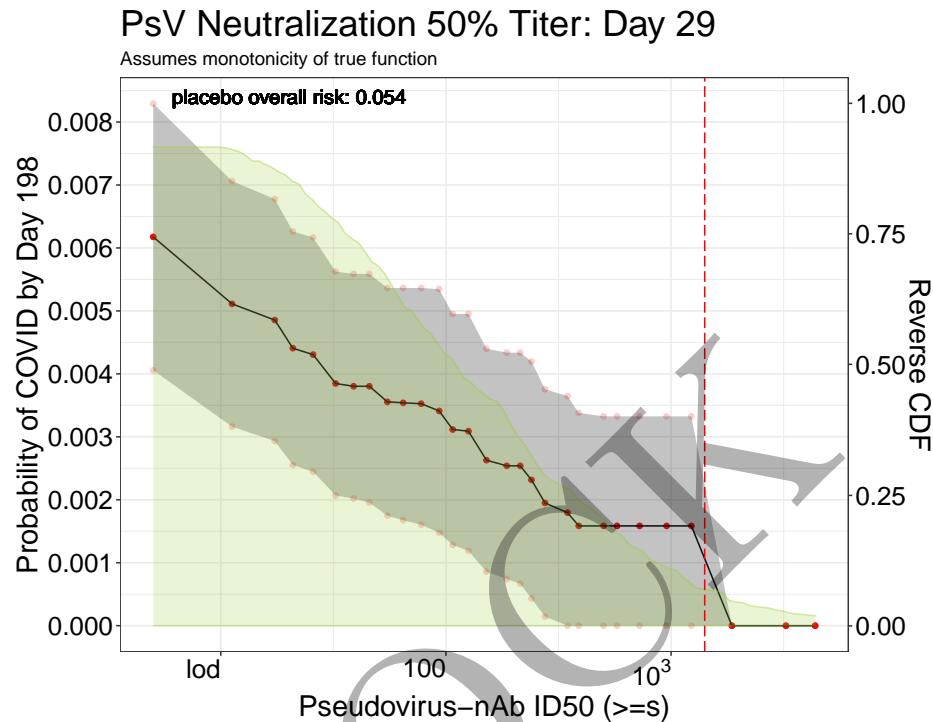


Figure 5.31: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence 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
0.699	$5.00 * 10^0$	0.00618	0.00406	0.00829
1.323	$2.10 * 10^1$	0.00441	0.00255	0.00626
1.589	$3.88 * 10^1$	0.00380	0.00202	0.00559
1.808	$6.43 * 10^1$	0.00354	0.00168	0.00541
2.031	$1.07 * 10^2$	0.00312	0.00128	0.00495
2.327	$2.12 * 10^2$	0.00254	0.00067	0.00441
2.540	$3.47 * 10^2$	0.00179	0.00000	0.00365
2.759	$5.74 * 10^2$	0.00158	0.00000	0.00363
3.089	$1.23 * 10^3$	0.00158	0.00000	0.00614
3.644	$4.41 * 10^3$	0.00000	0.00000	NA

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

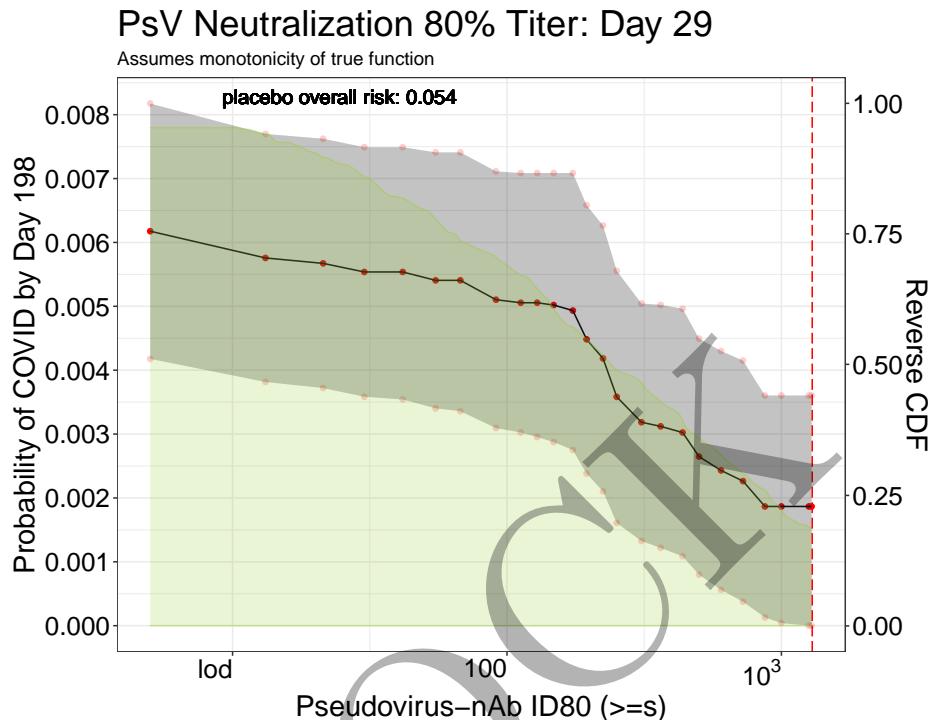


Figure 5.32: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence 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	$5.00 * 10^0$	0.00618	0.00418	0.00817
1.482	$3.03 * 10^1$	0.00554	0.00358	0.00749
1.744	$5.55 * 10^1$	0.00541	0.00340	0.00741
2.046	$1.11 * 10^2$	0.00506	0.00302	0.00709
2.238	$1.73 * 10^2$	0.00493	0.00275	0.00712
2.348	$2.23 * 10^2$	0.00418	0.00210	0.00626
2.564	$3.66 * 10^2$	0.00312	0.00122	0.00502
2.779	$6.01 * 10^2$	0.00243	0.00056	0.00430
2.938	$8.67 * 10^2$	0.00187	0.00013	0.00360
3.112	$1.29 * 10^3$	0.00187	0.00000	0.00404