CoVPN COVID-19 Correlates Analysis

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Chapter 1

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Figure 1.165: (Mock data) violinplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (2 timepoints)

Figure 1.166: (Mock data) violinplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (2 timepoints)

Figure 1.167: (Mock data) violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by sex assigned at birth (2 timepoints)

Figure 1.168: (Mock data) violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by sex assigned at birth (2 timepoints)

Figure 1.169: (Mock data) violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by sex assigned at birth (2 timepoints)

Figure 1.170: (Mock data) violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by sex assigned at birth (2 timepoints)

Figure 1.171: (Mock data) lineplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (3 timepoints)

Figure 1.172: (Mock data) lineplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (3 timepoints)

Figure 1.173: (Mock data) lineplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (3 timepoints)

Figure 1.174: (Mock data) lineplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (3 timepoints)

Figure 1.175: (Mock data) lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by sex assigned at birth (3 timepoints)

Figure 1.176: (Mock data) lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by sex assigned at birth (3 timepoints)

Figure 1.177: (Mock data) lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by sex assigned at birth (3 timepoints)

Figure 1.178: (Mock data) lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by sex assigned at birth (3 timepoints)

Figure 1.179: (Mock data) violinplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (3 timepoints)

Figure 1.180: (Mock data) violinplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (3 timepoints)

Figure 1.181: (Mock data) violinplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (3 timepoints)

Figure 1.182: (Mock data) violinplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (3 timepoints)

Figure 1.183: (Mock data) violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by sex assigned at birth (3 timepoints)

Figure 1.184: (Mock data) violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by sex assigned at birth (3 timepoints)

Figure 1.185: (Mock data) violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by sex assigned at birth (3 timepoints)

Figure 1.186: (Mock data) violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by sex assigned at birth (3 timepoints)

Figure 1.187: (Mock data) lineplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (2 timepoints)

Figure 1.188: (Mock data) lineplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (2 timepoints)

Figure 1.189: (Mock data) lineplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (2 timepoints)

Figure 1.190: (Mock data) lineplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (2 timepoints)

Figure 1.191: (Mock data) lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by race and ethnic group (2 timepoints)

Figure 1.192: (Mock data) lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by race and ethnic group (2 timepoints)

Figure 1.193: (Mock data) lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by race and ethnic group (2 timepoints)

Figure 1.194: (Mock data) lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by race and ethnic group (2 timepoints)

Figure 1.195: (Mock data) violinplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (2 timepoints)

Figure 1.196: (Mock data) violinplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (2 timepoints)

Figure 1.197: (Mock data) violinplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (2 timepoints)

Figure 1.198: (Mock data) violinplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (2 timepoints)

Figure 1.199: (Mock data) violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by race and ethnic group (2 timepoints)

Figure 1.200: (Mock data) violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by race and ethnic group (2 timepoints)

Figure 1.201: (Mock data) violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by race and ethnic group (2 timepoints)

Figure 1.202: (Mock data) violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by race and ethnic group (2 timepoints)

Figure 1.203: (Mock data) lineplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (3 timepoints)

Figure 1.204: (Mock data) lineplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (3 timepoints)

Figure 1.205: (Mock data) lineplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (3 timepoints)

Figure 1.206: (Mock data) lineplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (3 timepoints)

Figure 1.207: (Mock data) lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by race and ethnic group (3 timepoints)

Figure 1.208: (Mock data) lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by race and ethnic group (3 timepoints)

Figure 1.209: (Mock data) lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by race and ethnic group (3 timepoints)

Figure 1.210: (Mock data) lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by race and ethnic group (3 timepoints)

Figure 1.211: (Mock data) violinplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (3 timepoints)

Figure 1.212: (Mock data) violinplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (3 timepoints)

Figure 1.213: (Mock data) violinplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (3 timepoints)

Figure 1.214: (Mock data) violinplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (3 timepoints)

Figure 1.215: (Mock data) violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by race and ethnic group (3 timepoints)

Figure 1.216: (Mock data) violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by race and ethnic group (3 timepoints)

Figure 1.217: (Mock data) violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by race and ethnic group (3 timepoints)

Figure 1.218: (Mock data) violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by race and ethnic group (3 timepoints)

Figure 1.219: (Mock data) lineplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (2 timepoints)

Figure 1.220: (Mock data) lineplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (2 timepoints)

Figure 1.221: (Mock data) lineplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (2 timepoints)

Figure 1.222: (Mock data) lineplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (2 timepoints)

Figure 1.223: (Mock data) lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by dichotomous classification of race and ethnic group (2 timepoints)

Figure 1.224: (Mock data) lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by dichotomous classification of race and ethnic group (2 timepoints)

Figure 1.225: (Mock data) lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by dichotomous classification of race and ethnic group (2 timepoints)

Figure 1.226: (Mock data) lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by dichotomous classification of race and ethnic group (2 timepoints)

Figure 1.227: (Mock data) violinplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (2 timepoints)

Figure 1.228: (Mock data) violinplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (2 timepoints)

Figure 1.229: (Mock data) violinplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (2 timepoints)

Figure 1.230: (Mock data) violinplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (2 timepoints)

Figure 1.231: (Mock data) violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by dichotomous classification of race and ethnic group (2 timepoints)

Figure 1.232: (Mock data) violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by dichotomous classification of race and ethnic group (2 timepoints)

Figure 1.233: (Mock data) violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by dichotomous classification of race and ethnic group (2 timepoints)

Figure 1.234: (Mock data) violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by dichotomous classification of race and ethnic group (2 timepoints)

Figure 1.235: (Mock data) lineplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (3 timepoints)

Figure 1.236: (Mock data) lineplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (3 timepoints)

Figure 1.237: (Mock data) lineplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (3 timepoints)

Figure 1.238: (Mock data) lineplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (3 timepoints)

Figure 1.239: (Mock data) lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by dichotomous classification of race and ethnic group (3 timepoints)

Figure 1.240: (Mock data) lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by dichotomous classification of race and ethnic group (3 timepoints)

Figure 1.241: (Mock data) lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by dichotomous classification of race and ethnic group (3 timepoints)

Figure 1.242: (Mock data) lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by dichotomous classification of race and ethnic group (3 timepoints)

Figure 1.243: (Mock data) violinplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (3 timepoints)

Figure 1.244: (Mock data) violinplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (3 timepoints)

Figure 1.245: (Mock data) violinplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (3 timepoints)

Figure 1.246: (Mock data) violinplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (3 timepoints)

Figure 1.247: (Mock data) violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by dichotomous classification of race and ethnic group (3 timepoints)

Figure 1.248: (Mock data) violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by dichotomous classification of race and ethnic group (3 timepoints)

Figure 1.249: (Mock data) violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by dichotomous classification of race and ethnic group (3 timepoints)

Figure 1.250: (Mock data) violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by dichotomous classification of race and ethnic group (3 timepoints)

Figure 1.251: (Mock data) scatterplots of Binding Antibody to Spike: baseline negative vaccine arm at day 1

Figure 1.252: (Mock data) scatterplots of Binding Antibody to Spike: baseline negative vaccine arm at day 29

Figure 1.253: (Mock data) scatterplots of Binding Antibody to Spike: baseline negative vaccine arm at day 57

Figure 1.254: (Mock data) scatterplots of Binding Antibody to RBD: baseline negative vaccine arm at day 1

Figure 1.255: (Mock data) scatterplots of Binding Antibody to RBD: baseline negative vaccine arm at day 29

Figure 1.256: (Mock data) scatterplots of Binding Antibody to RBD: baseline negative vaccine arm at day 57

Figure 1.257: (Mock data) scatterplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm at day 1

Figure 1.258: (Mock data) scatterplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm at day 29

Figure 1.259: (Mock data) scatterplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm at day 57

Figure 1.260: (Mock data) scatterplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm at day 1

Figure 1.261: (Mock data) scatterplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm at day 29

Figure 1.262: (Mock data) scatterplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm at day 57

Figure 1.263: (Mock data) scatterplots of Binding Antibody to Spike: by arm at day 1

Figure 1.264: (Mock data) scatterplots of Binding Antibody to Spike: by arm at day 29

Figure 1.265: (Mock data) scatterplots of Binding Antibody to Spike: by arm at day 57

Figure 1.266: (Mock data) scatterplots of Binding Antibody to RBD: by arm at day 1

Figure 1.267: (Mock data) scatterplots of Binding Antibody to RBD: by arm at day 29

Figure 1.268: (Mock data) scatterplots of Binding Antibody to RBD: by arm at day 57

Figure 1.269: (Mock data) scatterplots of Pseudovirus Neutralization ID50: by arm at day 1

Figure 1.270: (Mock data) scatterplots of Pseudovirus Neutralization ID50: by arm at day 29

Figure 1.271: (Mock data) scatterplots of Pseudovirus Neutralization ID50: by arm at day 57

Figure 1.272: (Mock data) scatterplots of Pseudovirus Neutralization ID80: by arm at day 1

Figure 1.273: (Mock data) scatterplots of Pseudovirus Neutralization ID80: by arm at day 29

Figure 1.274: (Mock data) scatterplots of Pseudovirus Neutralization ID80: by arm at day 57

Chapter 2

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.

2.1 Hazard ratios

Table 2.1: Inference for Day 57 antibody marker covariate-adjusted correlates of risk of COVID in the vaccine group: Hazard ratios per 10-fold increment in the marker*

Mock Immunologic Marker	No. cases / No. at-risk**	HR per 10-fold incr. Pt. Est.	95% CI	P-value (2-sided)	q-value	FWER
Spike IgG (IU/ml)	72/13,254	0.08	(0.05-0.12)	<0.001	<0.001	<0.001
RBD IgG (IU/ml)	72/13,254	0.17	(0.12-0.25)	<0.001	<0.001	<0.001
PsV-nAb ID50	72/13,254	0.24	(0.18-0.31)	<0.001	<0.001	<0.001
PsV-nAb ID80	72/13,254	0.38	(0.28-0.51)	<0.001	<0.001	<0.001

*Baseline covariates adjusted for: age in years, at risk or not, community of color or not **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.

Table 2.2: Inference for Day 57 antibody marker covariate-adjusted correlates of risk of COVID in the vaccine group: Hazard ratios for Middle vs. Upper tertile vs. Lower tertile*

Mock Immunologic Marker	Tertile	No. cases / No. at-risk**	Attack rate	Haz. Ratio Pt. Est.	Haz. Ratio 95% CI	P-value (2-sided)	Overall P-value***	Overall q-value	Overall FWER
Spike IgG (IU/ml)	Lower	67/4,425	0.0151	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	4/4,403	0.0009	0.04	(0.01-0.11)	<0.001			
	Upper	1/4,426	0.0002	0.00	(0.00-0.03)	<0.001			
RBD IgG (IU/ml)	Lower	45/4,437	0.0101	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	19/4,398	0.0043	0.24	(0.13-0.43)	<0.001			
	Upper	8/4,420	0.0018	0.05	(0.02-0.12)	<0.001			
PsV-nAb ID50	Lower	56/4,443	0.0126	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	9/4,382	0.0021	0.10	(0.05-0.22)	<0.001			
	Upper	6/4,429	0.0014	0.05	(0.02-0.11)	<0.001			
PsV-nAb ID80	Lower	40/4,434	0.0090	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	21/4,400	0.0048	0.43	(0.24-0.79)	0.006			
	Upper	11/4,420	0.0025	0.17	(0.08-0.34)	<0.001			
Placebo		713/13,271	0.0537						

*Baseline covariates adjusted for: age in years, at risk or not, community of color or not . Average follow-up time 172 days, maximum follow-up time 185 days. Cutpoints: Spike IgG (IU/ml) [6.09, 6.7), RBD IgG (IU/ml) [5.68, 6.38), PsV-nAb ID50 [2.8, 3.66), PsV-nAb ID80 [3.08, 3.82) **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 2.1: Forest plots of hazard ratios among baseline seronegative vaccine recipients and subgroups with 95% point-wise confidence intervals.

Figure 2.2: Forest plots of hazard ratios of 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.

Figure 2.3: Forest plots of hazard ratios of Day57binding Ab to RBD markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

Figure 2.4: Forest plots of hazard ratios of 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.

Figure 2.5: Forest plots of hazard ratios of 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.

2.2 Marginalized risk and controlled vaccine efficacy plots

Figure 2.6: Marginalized cumulative risk by Day 172 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 172 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.

Figure 2.7: Marginalized cumulative risk by Day 57 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 172and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.

Figure 2.8: Controlled VE with sensitivity analysis as functions of Day 57 markers (=s) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.

Figure 2.9: 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 3

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.

3.1 Hazard ratios

Table 3.1: Inference for Day 29 antibody marker covariate-adjusted correlates of risk of COVID in the vaccine group: Hazard ratios per 10-fold increment in the marker*

Mock Immunologic Marker	No. cases / No. at-risk**	HR per 10-fold incr. Pt. Est.	95% CI	P-value (2-sided)	q-value	FWER
Spike IgG (IU/ml)	83/13,271	0.09	(0.05-0.16)	<0.001	<0.001	<0.001
RBD IgG (IU/ml)	83/13,271	0.25	(0.16-0.38)	<0.001	<0.001	<0.001
PsV-nAb ID50	83/13,271	0.32	(0.23-0.46)	<0.001	<0.001	<0.001
PsV-nAb ID80	83/13,271	0.57	(0.43-0.75)	<0.001	<0.001	<0.001

*Baseline covariates adjusted for: age in years, at risk or not, community of color or not **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.

Table 3.2: Inference for Day 29 antibody marker covariate-adjusted correlates of risk of COVID in the vaccine group: Hazard ratios for Middle vs. Upper tertile vs. Lower tertile*

Mock Immunologic Marker	Tertile	No. cases / No. at-risk**	Attack rate	Haz. Ratio Pt. Est.	Haz. Ratio 95% CI	P-value (2-sided)	Overall P-value***	Overall q-value	Overall FWER
Spike IgG (IU/ml)	Lower	54/4,422	0.0122	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	24/4,423	0.0054	0.20	(0.11-0.37)	<0.001			
	Upper	5/4,427	0.0011	0.02	(0.01-0.06)	<0.001			
RBD IgG (IU/ml)	Lower	46/4,419	0.0104	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	25/4,428	0.0056	0.30	(0.17-0.55)	<0.001			
	Upper	12/4,424	0.0027	0.08	(0.04-0.17)	<0.001			
PsV-nAb ID50	Lower	47/4,403	0.0107	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	24/4,420	0.0054	0.33	(0.19-0.59)	<0.001			
	Upper	12/4,448	0.0027	0.12	(0.06-0.25)	<0.001			
PsV-nAb ID80	Lower	30/4,416	0.0068	1	N/A	N/A	0.001	<0.001	<0.001
	Middle	36/4,429	0.0081	0.94	(0.55-1.62)	0.834			
	Upper	17/4,426	0.0038	0.33	(0.17-0.64)	0.001			
Placebo		821/13,299	0.0617						

*Baseline covariates adjusted for: age in years, at risk or not, community of color or not . Average follow-up time 200 days, maximum follow-up time 213 days. Cutpoints: Spike IgG (IU/ml) [4.38, 4.94), RBD IgG (IU/ml) [4.11, 4.66), PsV-nAb ID50 [1.67, 2.38), PsV-nAb ID80 [1.97, 2.64) **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 3.1: Forest plots of hazard ratios among baseline seronegative vaccine recipients and subgroups with 95% point-wise confidence intervals.

Figure 3.2: Forest plots of hazard ratios of 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.

Figure 3.3: Forest plots of hazard ratios of Day29binding Ab to RBD markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals.

Figure 3.4: Forest plots of hazard ratios of 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.

Figure 3.5: Forest plots of hazard ratios of 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.

3.2 Marginalized risk and controlled vaccine efficacy plots

Figure 3.6: Marginalized cumulative risk by Day 200 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 200 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: Marginalized cumulative risk by Day 29 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 200and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.

Figure 3.8: Controlled VE with sensitivity analysis as functions of Day 29 markers (=s) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.

Figure 3.9: 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.