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Supplementary Materials for

Comparing antibody assays as correlates of protection against COVID-19 in the COVE mRNA-1273 vaccine efficacy trial

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Other Supplementary Material for this manuscript includes the following:

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Principal Investigator	Study Team	Institution	Location
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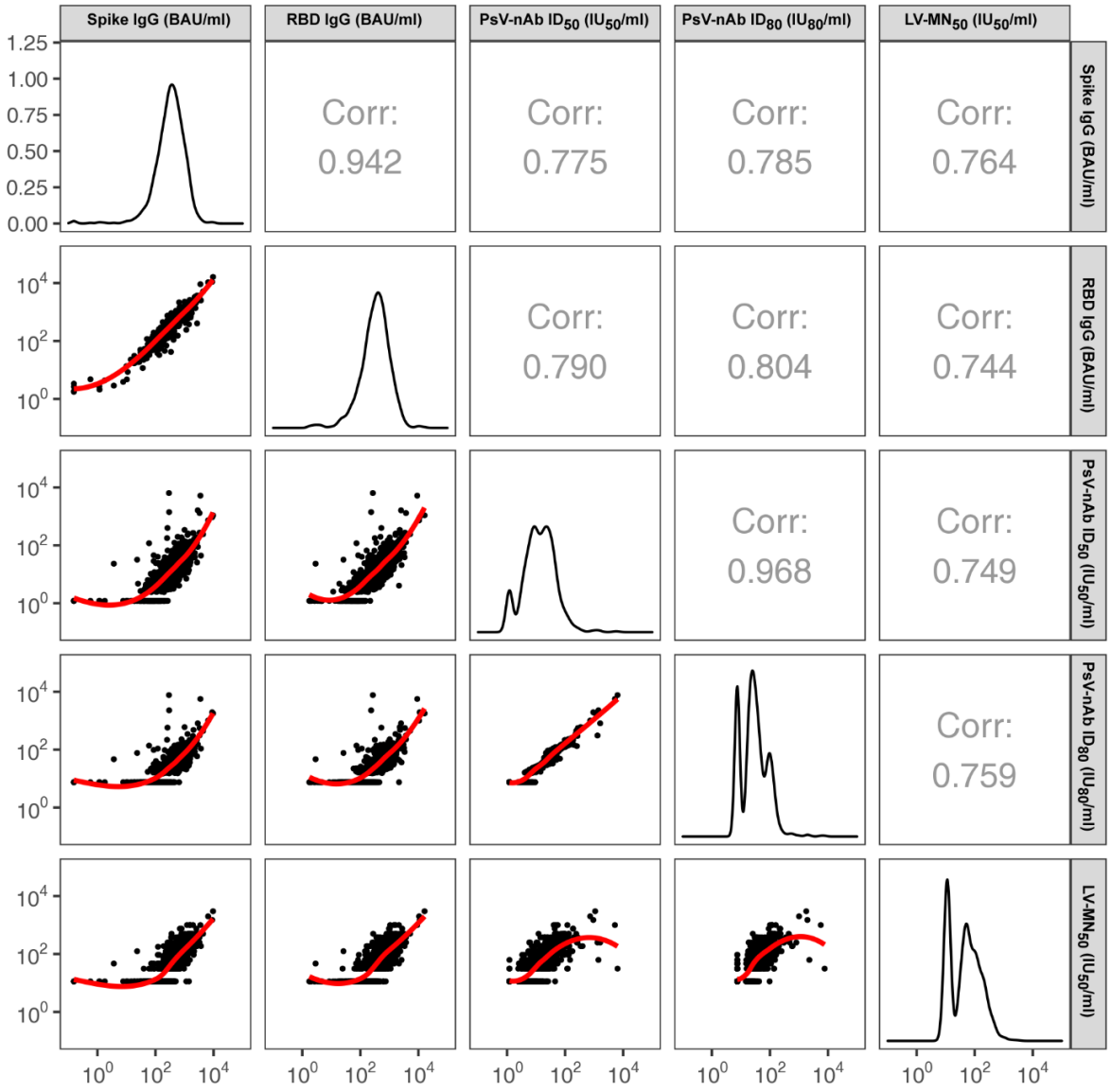


Fig. S1. In baseline SARS-CoV-2 negative per-protocol vaccine recipients in the immunogenicity subcohort, D29 LV-MN$_{50}$ titers are highly correlated with D29 spike IgG concentrations, D29 RBD IgG concentrations, D29 PsV-nAb ID$_{50}$ titers, and D29 PsV-nAb ID$_{80}$ titers.

Corr indicates baseline variable-adjusted Spearman rank correlation. ID$_{50}$, 50% inhibitory dilution; ID$_{80}$, 80% inhibitory dilution; LV, live virus; MN$_{50}$, 50% microneutralization dilution; nAb, neutralizing antibody; PsV, pseudovirus. Correlations of spike IgG, receptor binding domain (RBD) IgG, PsV-nAb ID$_{50}$, and PsV-nAb ID$_{80}$ were reported previously [fig. S5 in (*10*)] and are included here for comparison with LV-MN$_{50}$. Serological assay readouts are expressed in values relative to the World Health Organization (WHO) International Standard for anti-SARS-CoV-2 immunoglobulin (*27*): binding antibody readouts were converted to Binding Antibody Units per ml (BAU/ml) and pseudovirus neutralizing antibody titers as well as microneutralization assay readouts were calibrated to International Units/ml (IU$_{50}$/ml or IU$_{80}$/ml).

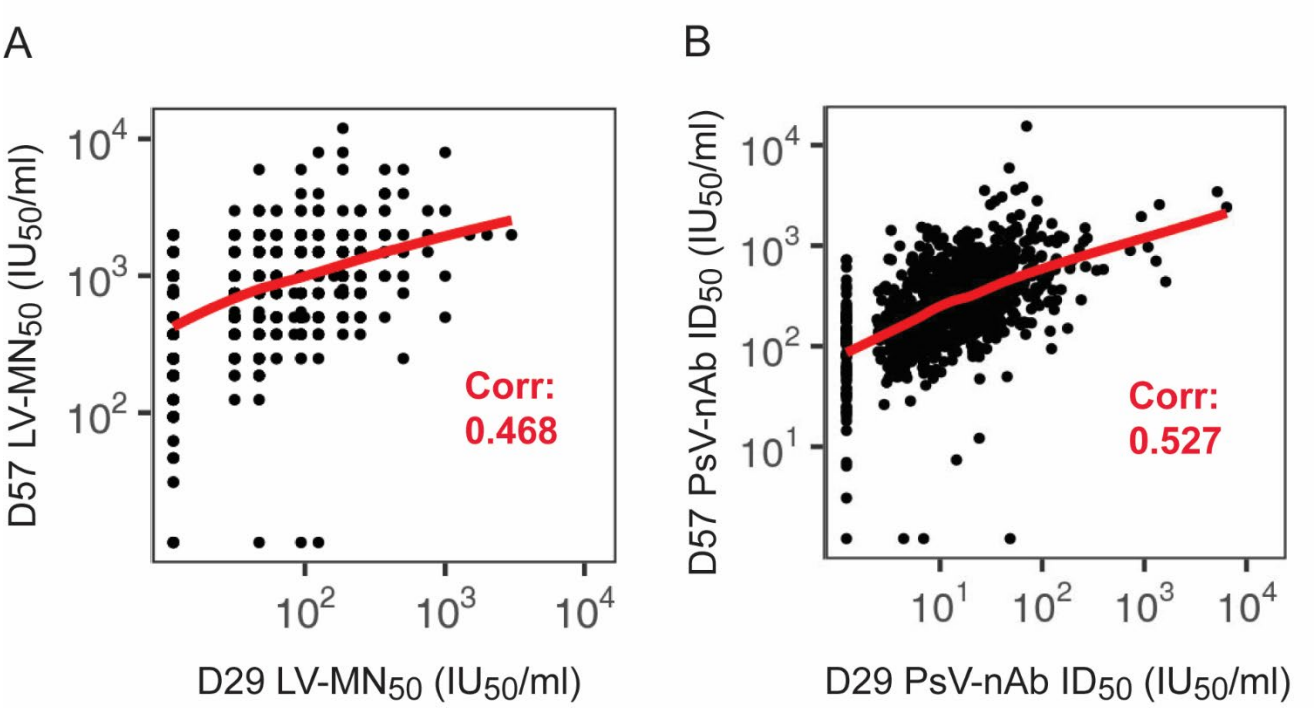


Fig. S2. D29 LV-MN$_{50}$ (PsV-nAb ID$_{50}$) titers correlate moderately with D57 LV-MN$_{50}$ (PsV-nAb ID$_{50}$) titers in baseline SARS-CoV-2 negative per-protocol vaccine recipients in the immunogenicity subcohort.

(A) LV-MN$_{50}$ and **(B)** PsV-nAb ID$_{50}$ values are presented. Corr indicates baseline variable-adjusted Spearman rank correlation. **(B)** was published previously [fig. S4C in (*10*)] and is included here for comparison. Serological assay readouts are expressed in values relative to the WHO International Standard for anti-SARS-CoV-2 immunoglobulin (*28*): binding antibody readouts were converted to BAU/ml and pseudovirus neutralizing antibody titers as well as microneutralization assay readouts were calibrated to IU$_{50}$/ml or IU$_{80}$/ml. ID$_{50}$, 50% inhibitory dilution; IU, international units; LV, live virus; MN$_{50}$, 50% microneutralization dilution; nAb, neutralizing antibody; PsV, pseudovirus.

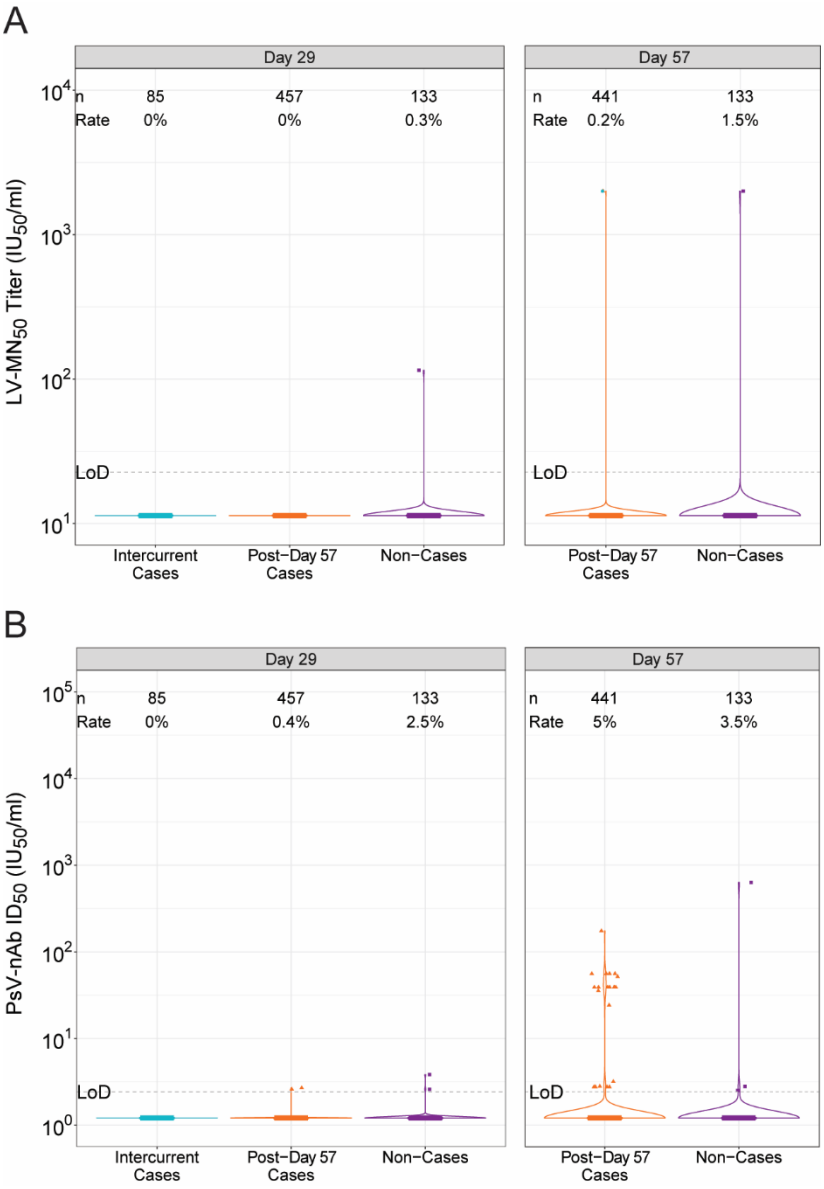


Fig. S3. D29 and D57 LV-MN$_{50}$ and PsV-nAb ID$_{50}$ titers and response rates are zero or near-zero in baseline SARS-CoV-2 negative per-protocol placebo recipients.

(A) LV-MN$_{50}$ and **(B)** PsV-nAb ID$_{50}$ values are presented by COVID-19 outcome status in placebo recipients. Data points are from baseline SARS-CoV-2 negative per-protocol placebo recipients in the D29 marker or D57 marker case-cohort set. Post D57 cases are COVID-19 endpoints starting 7 days post D57 through the end of blinded follow-up (last COVID-19 endpoint 126 days post dose two); Intercurrent cases are COVID-19 endpoints starting 7 days post D29 through 6 days post D57. The violin plots contain interior box plots with upper and lower horizontal edges showing the 25th and 75th percentiles of antibody concentrations and the middle showing line the 50th percentile. Vertical bars show the distance from the 25th (or 75th) percentile and the minimum (or maximum) within the 25th (or 75th) percentile minus (or plus) 1.5 times the interquartile range. Each side shows a rotated probability density (estimated by a kernel density estimator with a default Gaussian kernel) of the data. Positive response for MN$_{50}$ was defined by value > limit of detection (LoD; 22.66 IU$_{50}$/ml). Positive/detectable response for ID$_{50}$

was defined by value > LoD (2.42 IU_{50}/ml). Positive response rates are computed with Inverse Probability Sampling (IPS) weighting. The pseudovirus-nAb ID_{50} values were previously published [fig. S8C in (*10*)] and are included here for comparison. The minor differences in PsV-nAb ID_{50} response rates between those in (*10*) and those here are due to the fact that in (*10*) the lower limit of quantitation (LLOQ) was used to define positive response rate for the pseudovirus neutralization assay (instead of LoD as incorrectly stated), whereas LoD was used to define positive response rate for the pseudovirus neutralization assay in the present work. Serological assay readouts are expressed in values relative to the WHO International Standard for anti-SARS-CoV-2 immunoglobulin (*27*): pseudovirus neutralizing antibody titers and microneutralization assay readouts were calibrated to IU_{50}/ml. LV, live virus; PsV, pseudovirus; nAb, neutralizing antibody; ID_{50}, 50% inhibitory dilution; MN_{50}, 50% microneutralization dilution.

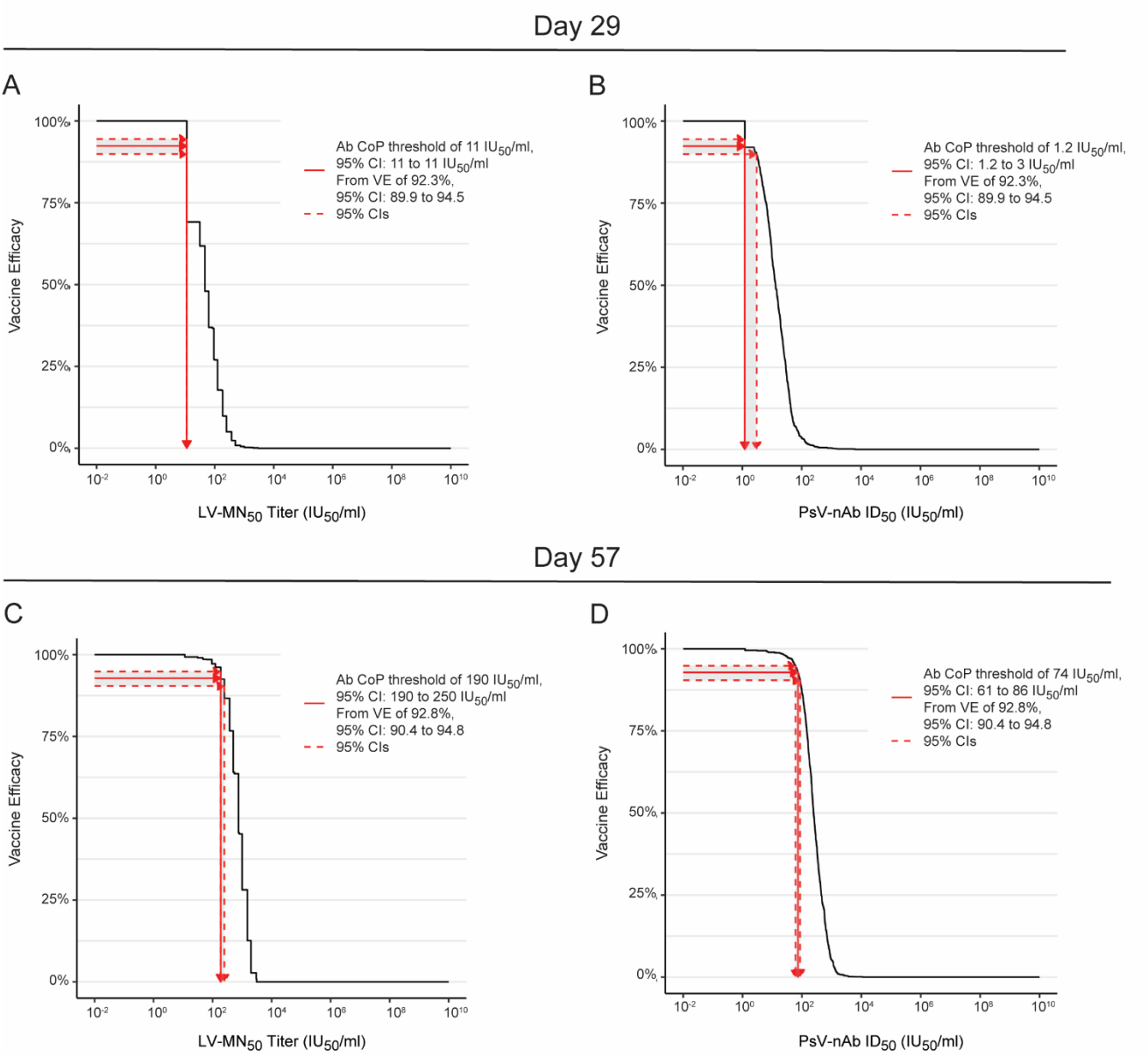


Fig. S4. By applying the Siber method (*35*), a threshold of perfect vs. no protection for each antibody marker is estimated.

Shown are inverse probability sampling (IPS)-weighted empirical reverse cumulative distribution function curves for **(A)** D29 LV-MN_{50}, **(B)** D29 PsV-nAb ID_{50}, **(C)** D57 LV-MN_{50}, and **(D)** D29 PsV-nAb ID_{50}. **(B)** and **(D)** were previously published [fig. S12C and fig. 11C, respectively, in (*10*)] and are included here for comparison. Serological assay readouts are expressed in values relative to the WHO International Standard for anti-SARS-CoV-2 immunoglobulin (*27*): PsV nAb titers and MN assay readouts were calibrated to IU_{50}/ml. Ab, antibody; CoP, correlate of protection; CI, confidence interval; ID_{50}, 50% inhibitory dilution; LV, live virus; MN_{50}, nAb, neutralizing antibody; 50% microneutralization dilution; PsV, pseudovirus; VE, vaccine efficacy.

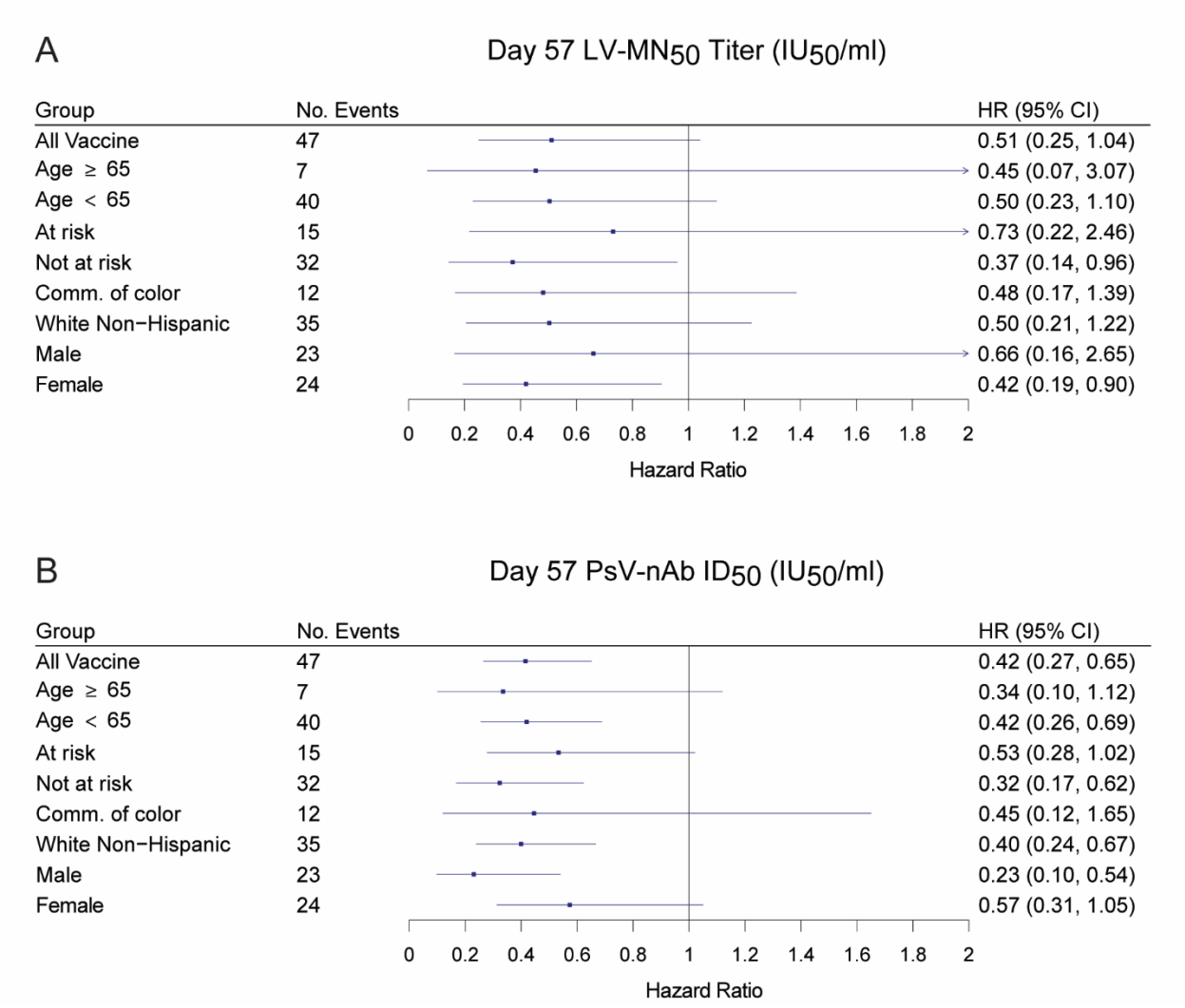
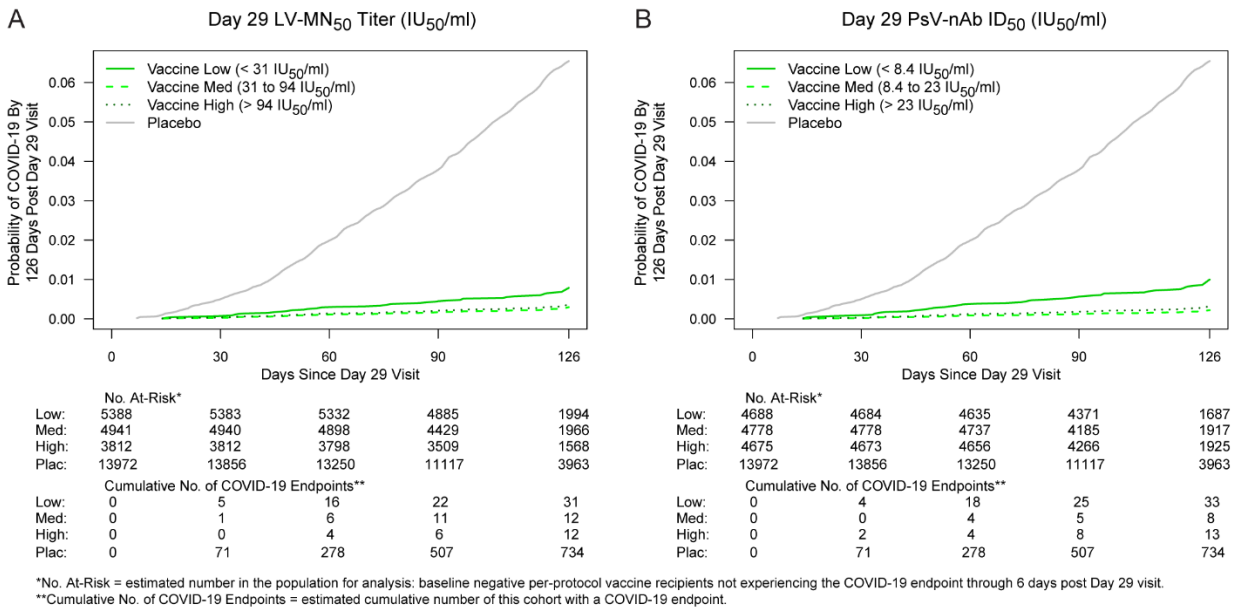


Fig. S5. Hazard ratios (HRs) of COVID-19 in prespecified vaccine recipient subgroups per 10-fold increase in each D57 neutralizing antibody marker are all less than 1, but with most 95% confidence intervals for LV-MN_{50} titer overlapping one.

(A) LV-MN_{50} titer and **(B)** PsV-nAb ID_{50} titer are shown for baseline SARS-CoV-2 negative per-protocol vaccine recipients overall and for individual subgroups. Community (Comm.) of color is the complement of White Non-Hispanic participants (different from Minority because missing values are included in Community of color). **(B)** was published previously as Fig. 3C in (*10*) and is included here for comparison. Baseline covariates adjusted for baseline risk score, at risk status, and community of color status. Serological assay readouts assessed as immune correlates were first expressed in values relative to the WHO International Standard for anti-SARS-CoV-2 immunoglobulin (*27*): pseudovirus neutralizing antibody titers and microneutralization assay readouts were calibrated to IU_{50}/ml. CI, confidence interval; ID_{50}, 50% inhibitory dilution; IU, international units; LV, live virus; MN_{50}, 50% microneutralization dilution; nAb, neutralizing antibody; PsV, pseudovirus.



*No. At-Risk = estimated number in the population for analysis: baseline negative per-protocol vaccine recipients not experiencing the COVID-19 endpoint through 6 days post Day 29 visit.
**Cumulative No. of COVID-19 Endpoints = estimated cumulative number of this cohort with a COVID-19 endpoint.

C

COVE 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	FDR-adjusted P-value	FWER-adjusted P-value
Live Virus-MN_{50} (IU_{50}/ml)	Low	31/5,388	0.0058	1	N/A	N/A	0.025	0.026	0.021
	Medium	12/4,941	0.0024	0.37	(0.17,0.82)	0.014			
	High	12/3,812	0.0031	0.46	(0.21,1.01)	0.053			
Pseudovirus-nAb ID_{50} (IU_{50}/ml)	Low	33/4,688	0.0070	1	N/A	N/A	<0.001	0.001	0.001
	Medium	8/4,778	0.0017	0.22	(0.09,0.53)	<0.001			
	High	13/4,675	0.0028	0.32	(0.15,0.69)	0.003			
Placebo		751/13,972	0.0538						

Fig. S6. Analyses of COVID-19 risk by Low, Medium, and High tertiles show evidence for D29 LV-MN_{50} and D29 PsV-nAb ID_{50} as correlates of risk.

The plots and table show cumulative incidence of COVID-19 by Low, Medium, and High tertiles of **(A)** D29 LV-MN_{50} titer or **(B)** D29 PsV-nAb ID_{50} titer in baseline SARS-CoV-2–negative per-protocol vaccine recipients. **(C)** Estimated hazard ratios of COVID-19 for Medium vs. Low and for High vs. Low tertile of D29 antibody marker titer. The overall p-value is from a generalized Wald test for whether the COVID-19 hazard differed across Low, Medium, and High subgroups. The PsV-nAb ID_{50} results in **(B)** and **(C)** were previously published [fig. S18B and S18C, respectively, in (*10*)] and are included here for comparison. Baseline covariates adjusted for were baseline risk score, at risk status, and community of color status. Serological assay readouts assessed as immune correlates were first expressed in values relative to the WHO International Standard for anti-SARS-CoV-2 immunoglobulin (*27*): pseudovirus neutralizing antibody titers and microneutralization assay readouts were calibrated to IU_{50}/ml. Maximum failure event time 126 days post D29 visit. Tertile values are given in the legends in **(A)** and **(B)**. No. at-risk = estimated number in the population for analysis: baseline negative per-protocol vaccine recipients not experiencing the COVID-19 endpoint through 6 days post D29 visit; No. cases = estimated number of this cohort with an observed COVID-19 endpoint. The total count

(55) across all tertiles for each marker differs from 46 (Fig. 2, Table 1), because the 55 includes all vaccine breakthrough cases including the 9 without D1, D29, D57 antibody marker data. FDR (false discovery rate)-adjusted p-values and FWER (family-wise error rate)-adjusted p-values are computed over the set of p-values both for quantitative markers and categorical markers (Low, Medium, High) using the Westfall and Young permutation method (10,000 replicates). CI, confidence interval; ID_{50}, 50% inhibitory dilution; IU, international units; LV, live virus; MN_{50}, 50% microneutralization dilution; nAb, neutralizing antibody; PsV, pseudovirus; Pt. Est., point estimate.

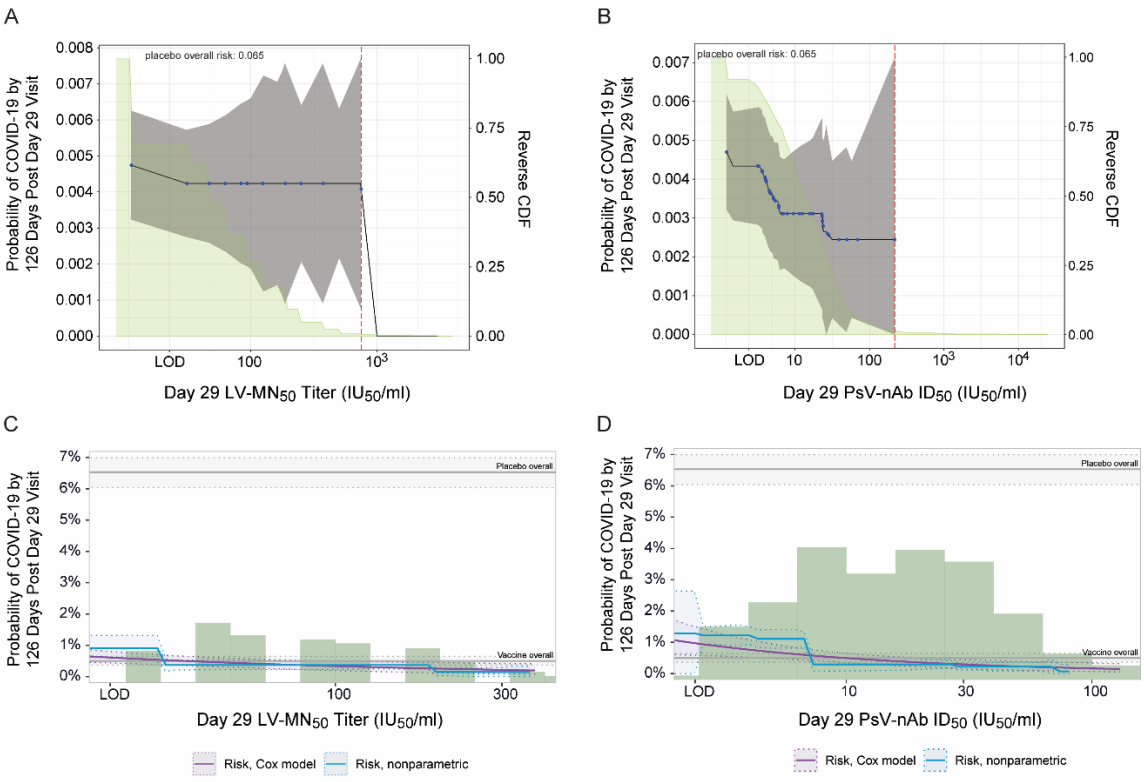
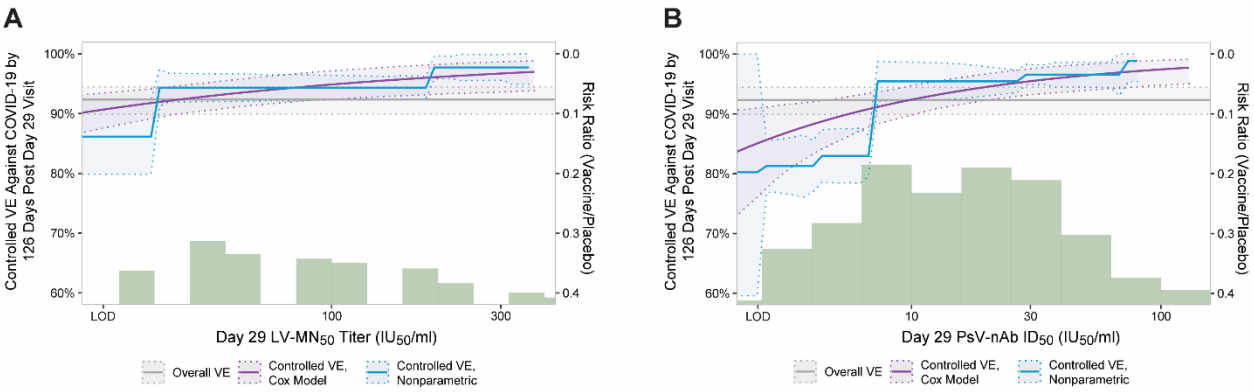


Fig. S7. Further correlate of risk analyses show weaker evidence for D29 LV-MN$_{50}$ compared to D29 PsV-nAb ID$_{50}$ as a correlate of risk.

(A and B) Cumulative incidence of COVID-19 by 126 days after D29 by vaccinated baseline SARS-CoV-2–negative per-protocol subgroups defined by D29 **(A)** LV-MN$_{50}$ or **(B)** ID$_{50}$ titer above a threshold, with reverse cumulative distribution function (CDF) of D29 marker titer overlaid in green. The blue dots correspond to marker values where an event is observed, linearly interpolated by solid black lines. The gray shaded area is pointwise 95% CIs. The upper boundary of the green shaded area is the estimate of the reverse cumulative distribution function (CDF) of the D29 marker value in baseline SARS-CoV-2–negative per-protocol vaccine recipients. The vertical red dashed line is the marker threshold above which no post–D29 COVID-19 endpoints occurred. **(C and D)** Cumulative incidence of COVID-19 by 126 days post D29 is shown by **(C)** D29 LV-MN$_{50}$ titer or **(D)** D29 PsV-nAb titer, estimated using (solid purple line) a Cox model or (solid blue line) a nonparametric model. The purple dotted lines indicate bootstrap pointwise 95% CIs and the blue dotted lines indicate influence-function-based Wald-based 95% CIs. The upper and lower horizontal gray lines are the overall cumulative incidence of COVID-19 from 7 to 126 days post D29 in placebo and vaccine recipients, respectively. **(B)** and **(D)** were previously published [fig. S22A and S22B, respectively, of (*10*) and are shown here for comparison]. The green histograms indicate the frequency distribution of D29 marker among baseline SARS-CoV-2 negative per-protocol vaccine recipients. All analyses adjusted for the following baseline covariates: baseline risk score, at risk status, and community of color status. Serological assay readouts assessed as immune correlates were first expressed in values relative to the WHO International Standard for anti-SARS-CoV-2 immunoglobulin (*27*): pseudovirus neutralizing antibody titers and microneutralization assay readouts were calibrated to IU$_{50}$/ml. CI, confidence interval; ID$_{50}$, 50%

inhibitory dilution; IU, international units; LV, live virus; MN_{50}, 50% microneutralization dilution; nAb, neutralizing antibody; PsV, pseudovirus.



C

	D29 LV-MN$_{50}$		D57 LV-MN$_{50}$	
Controlled VE Pt. Est.	87.7%	97.0%	87.6%	95.5%
Marker Percentile	2.5th	97.5th	2.5th	97.5th
Percentile Value (IU$_{50}$/ml)	11.3	375	93.7	2998

Fig. S8. Correlate of protection analyses show that vaccine efficacy against COVID-19 increases with D29 LV-MN$_{50}$ titer and more strongly with D29 PsV-nAb ID$_{50}$ titer.

(A and B) Vaccine efficacy (solid purple line) by D29 **(A)** LV-MN$_{50}$ titer or **(B)** PsV-nAb ID$_{50}$ titer was estimated using a Cox proportional hazards implementation of (*30*). The dashed gray lines indicate bootstrap point-wise 95% CIs. Vaccine efficacy (solid blue line) by D29 **(A)** PsV-nAb ID$_{50}$ titer or **(B)** LV-MN$_{50}$ titer was estimated using a nonparametric implementation of (*30*). The blue shaded area represents the 95% CIs. The green histograms indicate the frequency distribution of D29 marker among baseline SARS-CoV-2 negative per-protocol vaccine recipients. The horizontal gray line is the overall vaccine efficacy from 7 to 126 days post D29, with the dotted gray lines indicating the 95% CIs. Baseline covariates adjusted for were baseline risk score, at risk status, and community of color status. Serological assay readouts assessed as immune correlates were first expressed in values relative to the WHO International Standard for anti-SARS-CoV-2 immunoglobulin (*27*): pseudovirus neutralizing antibody titers and microneutralization assay readouts were calibrated to IU$_{50}$/ml. **(C)** Comparison of controlled VE point estimates at the 2.5th and 97.5th marker percentiles for D29 LV-MN$_{50}$ (fig. S8A) and D57 LV-MN$_{50}$ (Fig. 2F). CI, confidence interval; ID$_{50}$, 50% inhibitory dilution; IU, international units; LV, live virus; MN$_{50}$, 50% microneutralization dilution; nAb, neutralizing antibody; PsV, pseudovirus.

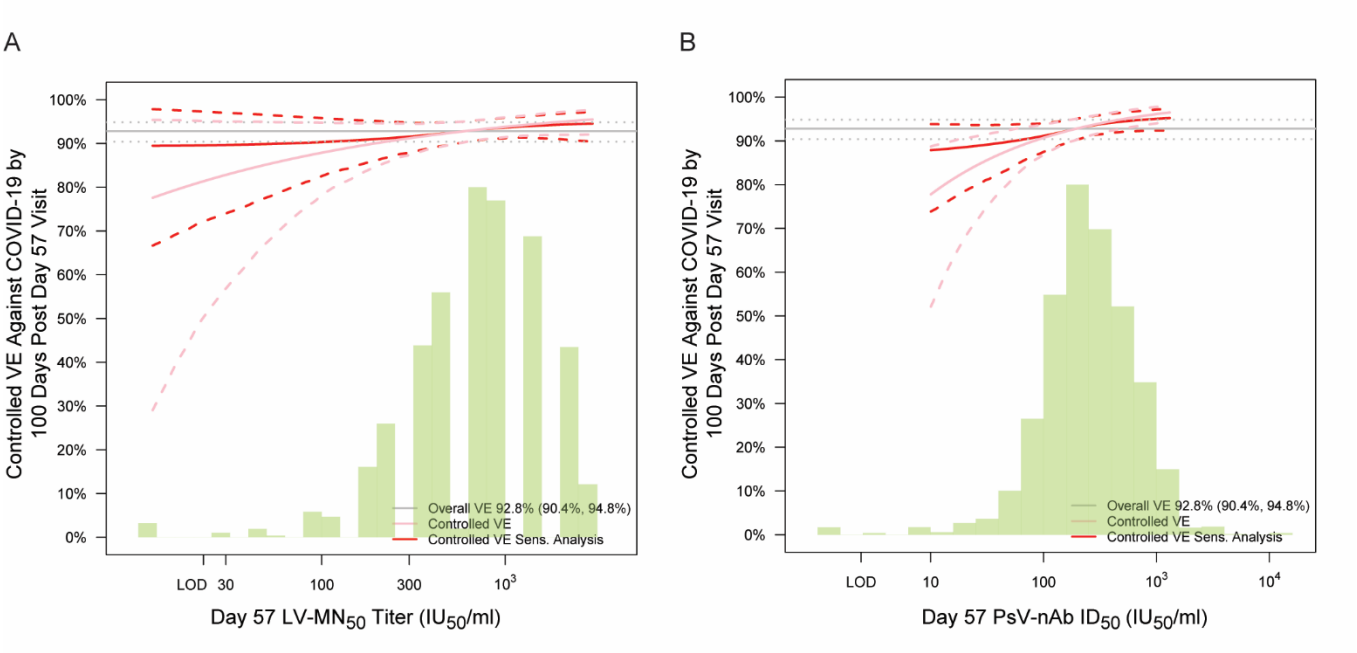


Fig. S9. Estimated vaccine efficacy against COVID-19 still increases, but to a lesser extent, with increasing D57 LV-MN_{50} titer and D57 PsV-nAb ID_{50} titer in a sensitivity analysis.

Vaccine efficacy is shown by D57 **(A)** LV-MN_{50} and **(B)** PsV-nAb ID_{50} titer. Vaccine efficacy estimates were obtained using the method of Gilbert, Fong, and Carone (*30*). The pink solid line represents point estimates assuming no unmeasured confounding; the dashed lines are bootstrap point-wise 95% CIs. The red solid line represents point estimates assuming unmeasured confounding in a sensitivity analysis (dashed lines are bootstrap point-wise 95% CIs). See supplementary text S2 in (*16*) and the Statistical Analysis Plan (Section 12.1.2) for details of the sensitivity analysis. The horizontal gray line is the overall vaccine efficacy from 7 to 100 days post D57, with the dotted gray lines indicating the 95% CIs (this number 92.8% differs from the 94.1% reported in (*16*), which was based on counting COVID-19 endpoints starting 14 days post D29). The green histogram is an estimate of the frequency distribution of D57 marker among baseline SARS-CoV-2 negative per-protocol vaccine recipients. Serological assay readouts assessed as immune correlates were first expressed in values relative to the WHO International Standard for anti-SARS-CoV-2 immunoglobulin (*27*): pseudovirus neutralizing antibody titers and microneutralization assay readouts were calibrated to IU_{50}/ml. CI, confidence interval; ID_{50}, 50% inhibitory dilution; IU, international units; LV, live virus; MN_{50}, 50% microneutralization dilution; nAb, neutralizing antibody; PsV, pseudovirus.

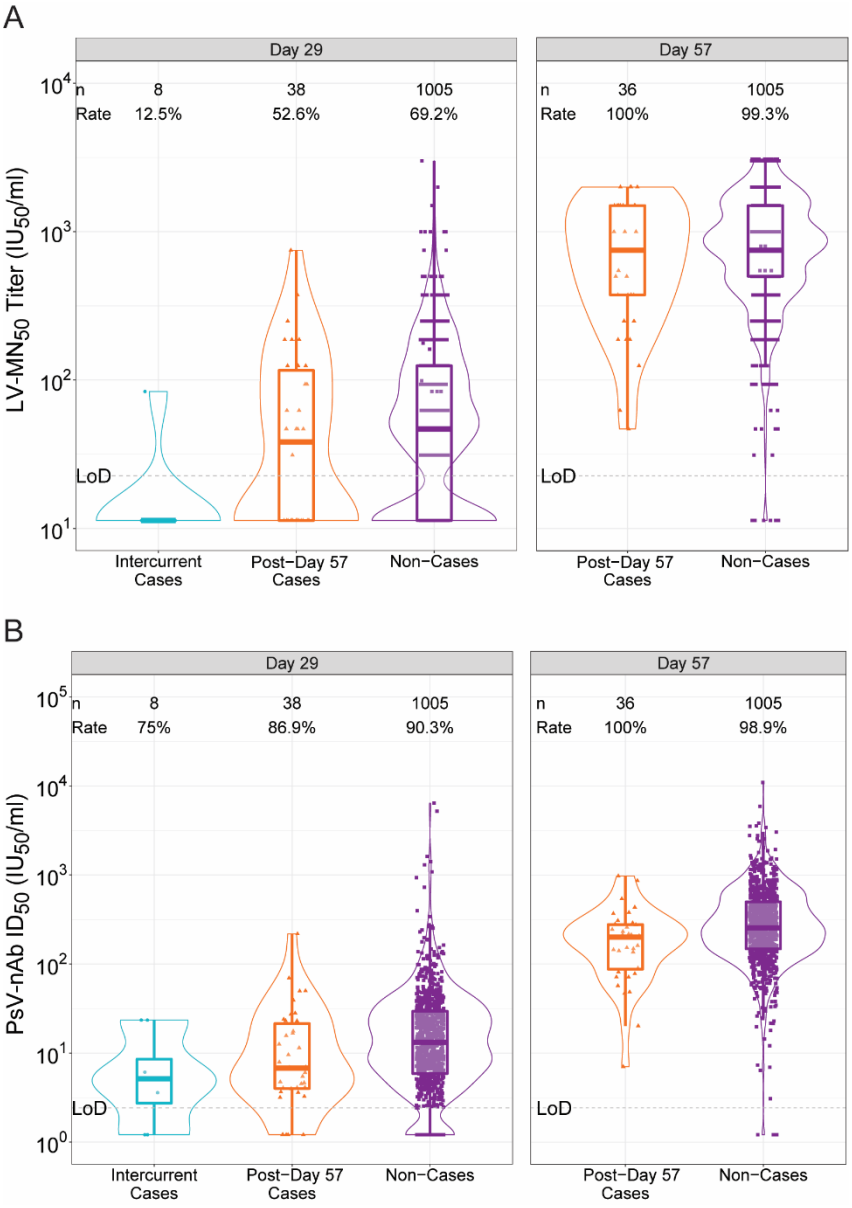
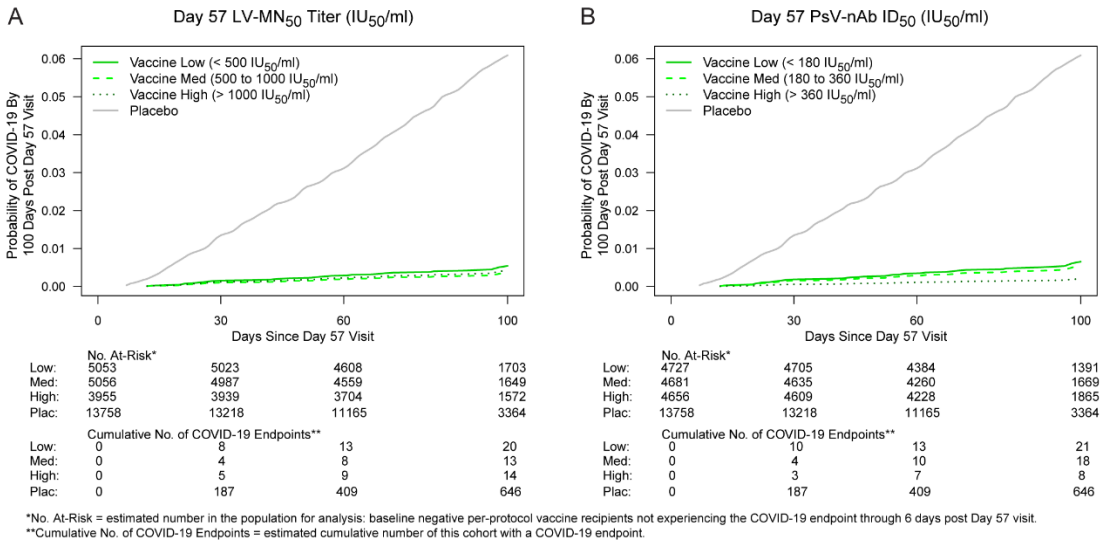


Fig. S10. Response rates and neutralizing antibody titers are higher at D57 than at D29, for both LV-MN$_{50}$ and PsV-nAb ID$_{50}$.

(A) LV-MN$_{50}$ and **(B)** PsV-nAb ID$_{50}$ titers were stratified by COVID-19 outcome status in vaccine recipients. Data points are from baseline negative per-protocol vaccine recipients in the D29 marker or D57 marker case-cohort set. Post D57 cases are COVID-19 endpoints starting 7 days post D57 through the end of blinded follow-up (last COVID-19 endpoint 126 days post dose 2); Intercurrent cases are COVID-19 endpoints starting 7 days post D29 through 6 days post D57. The violin plots contain interior box plots with upper and lower horizontal edges indicating the 25th and 75th percentiles of antibody concentration and middle line the 50th percentile; vertical bars represent the distance from the 25th (or 75th) percentile and the minimum (or maximum) within the 25th (or 75th) percentile minus (or plus) 1.5 times the interquartile range. Each side shows a rotated probability density (estimated by a kernel density estimator with a default Gaussian kernel) of the data. Positive response rates were computed with inverse probability of

sampling weighting. The PsV-nAb ID_{50} results in **(B)** were previously published [Fig. 1B in (*10*)] and are included here for comparison. Positive response for MN_{50} was defined by value > LoD (22.66 IU_{50}/ml). Positive/detectable response for ID_{50} was defined by value > LoD (2.42 IU_{50}/ml). The minor differences in pseudovirus-nAb ID_{50} response rates between those in (*10*) and those here are due to the fact that in (*10*) the lower limit of quantitation (LLOQ) was used to define positive response rate for the pseudovirus neutralization assay (instead of LoD as incorrectly stated), whereas LoD was used to define positive response rate for the pseudovirus neutralization assay in this work. Serological assay readouts are expressed in values relative to the WHO International Standard for anti-SARS-CoV-2 immunoglobulin (*27*): pseudovirus neutralizing antibody titers and microneutralization assay readouts were calibrated to IU_{50}/ml. ID_{50}, 50% inhibitory dilution; IU, international units; LV, live virus; MN_{50}, 50% microneutralization dilution; nAb, neutralizing antibody; PsV, pseudovirus.



*No. At-Risk = estimated number in the population for analysis: baseline negative per-protocol vaccine recipients not experiencing the COVID-19 endpoint through 6 days post Day 57 visit.
**Cumulative No. of COVID-19 Endpoints = estimated cumulative number of this cohort with a COVID-19 endpoint.

C

COVE 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	FDR-adjusted P-value	FWER-adjusted P-value
Live Virus-MN_{50} (IU_{50}/ml)	Low	20/5,053	0.0040	1	N/A	N/A	0.579	0.587	0.571
	Medium	13/5,056	0.0026	0.66	(0.30,1.46)	0.305			
	High	14/3,955	0.0035	0.78	(0.34,1.77)	0.551			
Pseudovirus-nAb ID_{50} (IU_{50}/ml)	Low	21/4,727	0.0044	1	N/A	N/A	0.052	0.067	0.108
	Medium	18/4,681	0.0038	0.82	(0.39, 1.72)	0.599			
	High	8/4,656	0.0017	0.31	(0.12, 0.80)	0.016			
Placebo		659/13,758	0.0479						

Fig. S11. Analyses of COVID-19 risk by Low, Medium, and High tertiles show no evidence for D57 LV-MN_{50} or D57 PsV-nAb ID_{50} as a correlate of risk.

The plots and table show cumulative incidence of COVID-19 by Low, Medium, and High tertiles of **(A)** D57 LV-MN_{50} titer or **(B)** D57 PsV-nAb ID_{50} titer in baseline SARS-CoV-2–negative per-protocol vaccine recipients. **(C)** Estimated hazard ratios of COVID-19 for Medium vs. Low and for High vs. Low tertile of D57 antibody marker titer. The overall p-value is from a generalized Wald test of whether the hazard rate of COVID-19 differed across the Low, Medium, and High subgroups. The PsV-nAb ID_{50} results in **(B)** and **(C)** were previously published [Fig. 2B and 2C, respectively, in (*10*)] and are included here for comparison. Baseline covariates adjusted for were baseline risk score, at risk status, and community of color status. Serological assay readouts assessed as immune correlates were first expressed in values relative to the WHO International Standard for anti-SARS-CoV-2 immunoglobulin (*27*): pseudovirus neutralizing antibody titers and microneutralization assay readouts were calibrated to International Units/ml (IU_{50}/ml). Maximum failure event time 100 days post D57 visit. Tertile values are given in the legends in **(A)** and **(B)**. No. at-risk = estimated number in the population for analysis: baseline negative per-protocol vaccine recipients not experiencing the COVID-19 endpoint through 6 days post D57 visit; No. cases = estimated number of this cohort with an observed COVID-19 endpoint. The total count (47) across all tertiles for each marker differs from 36 (Fig. 2, Table 1), because the 47 includes all vaccine breakthrough cases including the 9 without D1, D29, D57 antibody marker data. FDR (false discovery rate)-adjusted p-values and

FWER (family-wise error rate)-adjusted p-values are computed over the set of p-values both for quantitative markers and categorical markers (Low, Medium, High) using the Westfall and Young permutation method (10,000 replicates). CI, confidence interval; ID_{50}, 50% inhibitory dilution; IU, international units; FDR, false discovery rate; FWER, family-wise error rate; LV, live virus; MN_{50}, 50% microneutralization dilution; nAb, neutralizing antibody; PsV, pseudovirus; Pt. Est., point estimate.

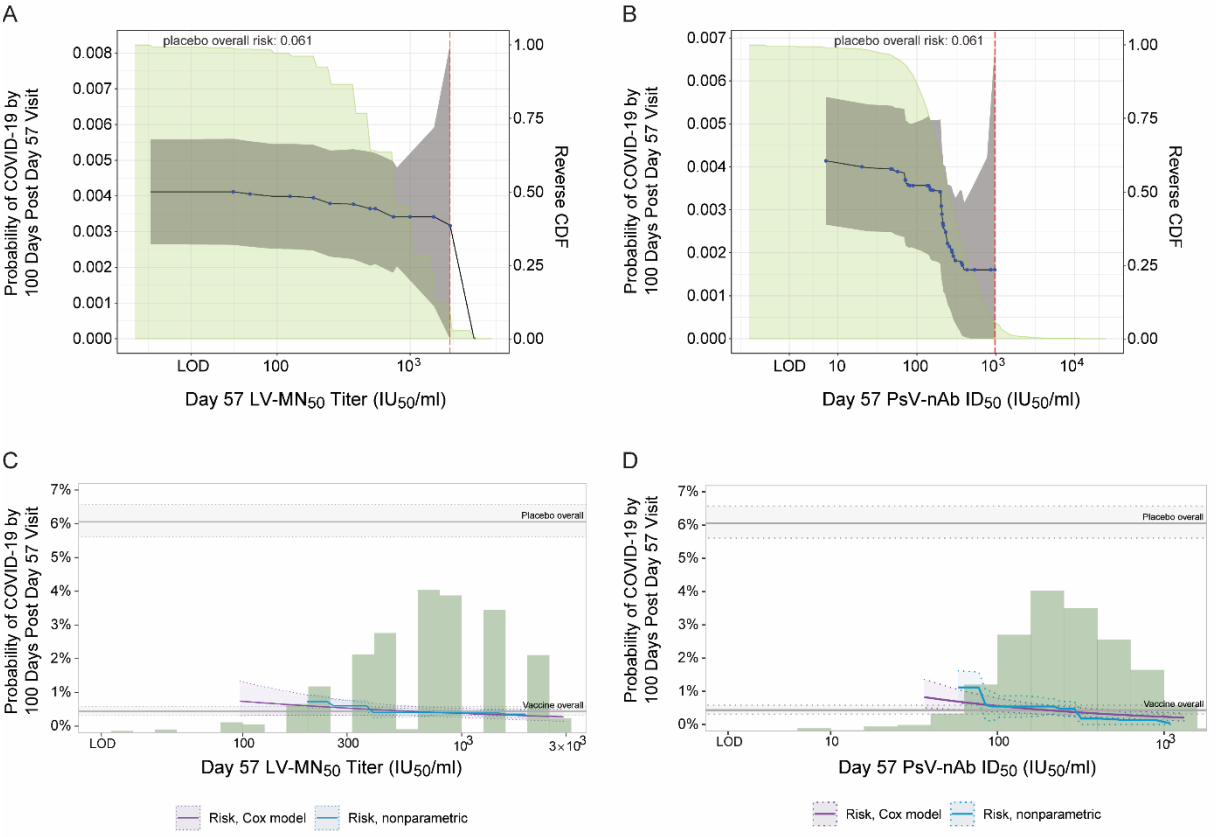


Fig. S12. Correlate of risk analyses show evidence for both D57 LV-MN$_{50}$ and D57 PsV-nAb ID$_{50}$ as correlates of risk, with stronger evidence for D57 PsV-nAb ID$_{50}$.

(A and B) Cumulative incidence of COVID-19 by 100 days after D57 in vaccinated baseline SARS-CoV-2–negative per-protocol subgroups defined by D57 **(A)** LV-MN$_{50}$ or **(B)** PsV-nAb ID$_{50}$ titer above a threshold, with reverse cumulative distribution function (CDF) of D57 marker titer overlaid in green. The blue dots correspond to marker values where an event is observed, linearly interpolated by solid black lines. The gray shaded area is pointwise 95% CIs. The upper boundary of the green shaded area is the estimate of the reverse cumulative distribution function (CDF) of the D57 marker value in baseline SARS-CoV-2–negative per-protocol vaccine recipients. The vertical red dashed line is the marker threshold above which no post–D57 COVID-19 endpoints occurred. **(C and D)** Cumulative incidence of COVID-19 by 100 days post D57 is shown by **(C)** D57 LV-MN$_{50}$ titer or **(D)** D57 PsV-nAb titer, estimated using (solid purple line) a Cox model or (solid blue line) a nonparametric model. The purple dotted lines indicate bootstrap pointwise 95% CIs and the blue dotted lines indicate influence-function-based Wald-based 95% CIs. The upper and lower horizontal gray lines are the overall cumulative incidence of COVID-19 from 7 to 100 days post D57 in placebo and vaccine recipients, respectively. The dotted black lines indicate bootstrap pointwise 95% CIs. **(B)** and **(D)** were previously published [Fig. 4A and 4B, respectively, of (*10*) and are shown here for comparison]. The green histograms indicate the frequency distribution of D29 marker among baseline SARS-CoV-2 negative per-protocol vaccine recipients. All analyses adjusted for the following baseline covariates: baseline risk score, at risk status, and community of color status. Serological assay

readouts assessed as immune correlates were first expressed in values relative to the WHO International Standard for anti-SARS-CoV-2 immunoglobulin (*27*): pseudovirus neutralizing antibody titers and microneutralization assay readouts were calibrated to IU_{50}/ml. CI, confidence interval; ID_{50}, 50% inhibitory dilution; IU, international units; LV, live virus; MN_{50}, 50% microneutralization dilution; nAb, neutralizing antibody; PsV, pseudovirus.

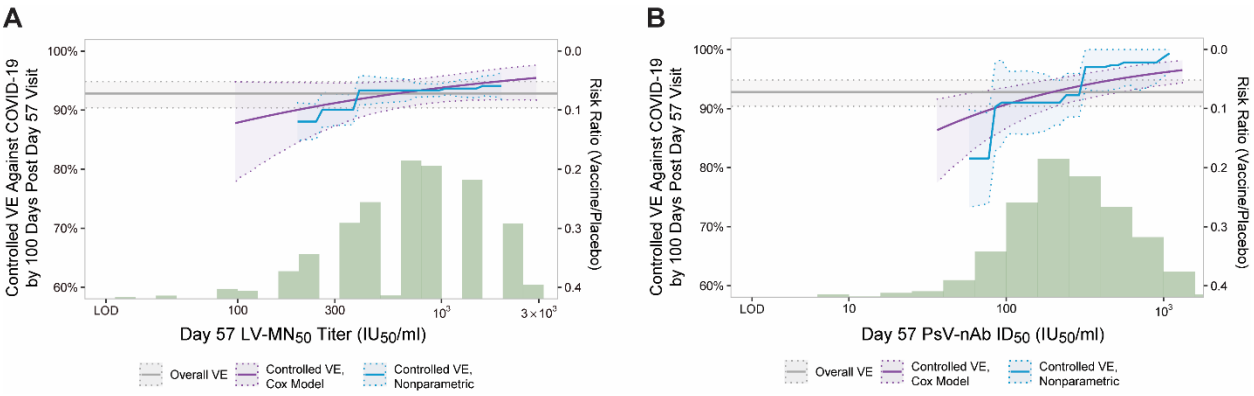


Fig. S13. Correlate of protection analyses of D57 neutralizing antibody concentrations show that vaccine efficacy against COVID-19 increases with D57 LV-MN$_{50}$ titer and more strongly with D57 PsV-nAb ID$_{50}$ titer.

(A and B) Vaccine efficacy (solid purple line) by D57 **(A)** LV-MN$_{50}$ titer or **(B)** PsV-nAb ID$_{50}$ titer was estimated using a Cox proportional hazards implementation of (*30*). The dashed gray lines indicate bootstrap point-wise 95% CIs. Vaccine efficacy (solid blue line) by D57 **(A)** live virus-MN$_{50}$ titer or **(B)** PsV-nAb ID$_{50}$ titer was estimated using a nonparametric implementation of (*30*). The blue shaded area represents the 95% CIs. The green histograms indicate the frequency distribution of D57 marker among baseline SARS-CoV-2 negative per-protocol vaccine recipients. The horizontal gray line is the overall vaccine efficacy from 7 to 100 days post D57, with the dotted gray lines indicating the 95% CIs. Baseline covariates adjusted for were baseline risk score, at risk status, and community of color status. Serological assay readouts assessed as immune correlates were first expressed in values relative to the WHO International Standard for anti-SARS-CoV-2 immunoglobulin (*27*): pseudovirus neutralizing antibody titers and microneutralization assay readouts were calibrated to IU$_{50}$/ml. CI, confidence interval; ID$_{50}$, 50% inhibitory dilution; IU, international units; LV, live virus; MN$_{50}$, 50% microneutralization dilution; nAb, neutralizing antibody; PsV, pseudovirus.

Table S1. Numbers of per-protocol baseline negative participants with antibody markers measured and included in each of the D29 and D57 correlates analyses, for each of the five immunoassays. Cases for D29 marker correlates analyses (Intercurrent cases + Post D57 cases) are baseline SARS-CoV-2 negative per-protocol vaccine recipients with the symptomatic infection COVID-19 primary endpoint diagnosed starting 7 days after D29 through the end of the blinded phase. Cases for D57 marker correlates analyses (Post D57 cases) are baseline SARS-CoV-2 negative per-protocol vaccine recipients with the symptomatic infection COVID-19 primary endpoint diagnosed starting 7 days after D57 through the end of the blinded phase. The last COVID-19 endpoint within the blinded phase occurred 100 days after D57.

	D29 Correlates Analyses		D57 Correlates Analyses	
Antibody Marker	**Cases**	**Non-Cases**	**Cases**	**Non-Cases**
Binding antibody to spike	46	1005	36	1005
Binding antibody to RBD	46	1005	36	1005
PsV-nAb ID_{50} titer	42	1005	32	1005
PsV-nAb ID_{80} titer	42	1005	32	1005
LV-MN_{50}	39	985	31	968

Table S2. Comparison of live virus neutralization MN_{50} titer and pseudovirus neutralization ID_{50} titer response rates and Geometric Mean Titers (GMTs) by COVID-19 outcome status. Analysis based on baseline negative per-protocol vaccine recipients in the D29 marker or D57 marker case-cohort sets. Median (interquartile range) days from dose one to D29 was 28 (28 to 30) and from D29 to D57 was 28 (28 to 30) are shown. [1]Cases for D29 marker correlates analyses (Intercurrent cases + Post D57 cases) are baseline SARS-CoV-2 negative per-protocol vaccine recipients with the symptomatic infection COVID-19 primary endpoint diagnosed starting 7 days after D29 through the end of the blinded phase. Cases for D57 marker correlates analyses (Post D57 cases) are baseline SARS-CoV-2 negative per-protocol vaccine recipients with the symptomatic infection COVID-19 primary endpoint diagnosed starting 7 days after D57 through the end of the blinded phase. The last COVID-19 endpoint within the blinded phase occurred 100 days after D57. [2]N for Cases for D29 marker analyses is the number of vaccine breakthrough cases with D1 and D29 antibody marker data included, and N for Cases for D57 marker analyses is the number of vaccine breakthrough cases with D1, D29, and D57 antibody data included. [3]N for Non-Cases in Immunogenicity Subcohort is the number of participants with D1, D29, and D57 antibody marker data included in both the D29 and D57 marker correlates analyses. [4]Serological assay readouts are expressed in values relative to the WHO International Standard for anti-SARS-CoV-2 immunoglobulin (*28*): pseudovirus neutralizing antibody titers and microneutralization assay readouts were calibrated to IU_{50}/ml. [5]Pseudovirus-nAb ID_{50} GMTs and ratios were previously published *(16)* and are included here for comparison. The pseudovirus-nAb ID_{50} response rates in this table differ from those in Table 1 in (*10*) because here positive response for ID_{50} was defined by value > LoD (2.42 IU_{50}/ml), whereas in *(16)* positive response for ID_{50} was defined by value > LLOQ (4.477 IU_{50}/ml).

		COVID-19 Cases[1]			Non-Cases in Immunogenicity Subcohort			Comparison	
Visit for Marker	Marker	N[2]	Response Rate (95% CI)	GMT (95% CI)	N[3]	Response Rate (95% CI)	GMT (95% CI)	Response Rate Difference (95% CI)	Ratio of GM (Cases/Non-Cases) (95% CI)
D29	LV-MN_{50} (IU_{50}/ml)[4]	46	45.7% (31.6%, 60.4%)	31.4 (22.0, 45.0)	1005	69.2% (65.8%, 72.4%)	48.4 (44.6, 52.6)	-24% (-38, -8.4%)	0.65 (0.45, 0.94)
D29	PsV-nAb ID_{50} (IU_{50}/ml)[5]	46	84.8% (70.9%, 92.7%)	7.6 (5.4, 10.8)	1005	92.0% (89.8%, 93.7%)	13.0 (11.9, 14.1)	-7.2% (-21, 1%)	0.59 (0.41, 0.84)
D57	LV-MN_{50} (IU_{50}/ml)	36	100.0% (100.0%, 100.0%)	594 (433, 816)	1005	99.3% (98.3%, 99.7%)	718 (676, 763)	1% (0, 2%)	0.83 (0.60, 1.14)
D57	PsV-nAb ID_{50} (IU_{50}/ml)	36	100.0% (100.0%, 100.0%)	160 (117, 220)	1005	99.5% (98.6%, 99.8%)	247 (231, 264)	1% (0, 1%)	0.65 (0.47, 0.90)

Table S3. Ranking of antibody marker performance in each of three categories of immune correlate-quality criteria. Baseline covariates were adjusted for baseline risk score, at risk status, and community of color status. Maximum failure event time was 126 days post D29 visit (D29 markers) or 100 days post D57 visit (D57 markers). FWER-adjusted P values were computed over the set of p-values both for quantitative markers and categorical markers (Low, Medium, High) using the Westfall and Young permutation method (10,000 replicates). All serological assay readouts assessed as immune correlates were first expressed in values relative to the WHO International Standard for anti-SARS-CoV-2 immunoglobulin (*27*): binding antibody readouts were converted to BAU/ml and pseudovirus neutralizing antibody titers as well as microneutralization assay readouts were calibrated to IU_{50}/ml or IU_{80}/ml. The shading represents, within each category, the antibody marker (out of all 10 for categories 1 and 2; out of the 3 evaluable ones for category 3) with the best performance.

	Category 1: Correlate of Risk (CoR)									**Category 2: Correlate of Protection (CoP): VE Modification**							**Category 3: CoP: VE Mediation**				
	HR per SD (Cox, quant.)		HR p-value (Cox, quant.)		HR High vs. Low tertile (Cox)		Hazard Ratio p-value tertile (Cox)		**CoR: Median rank**	Range of CVE Pt. Est. (Cox, 5th to 95th perc.)		Range of CVE Pt. Est. (NP, 5th to 95th percentile)		E-value Marg. Risk Ratio 95% UCL		**CoP: VE Mod Median rank**	Proportion Mediated				**CoP: VE Med Median rank**
	Pt. Est. (95% CI)	Rank	FWER	Rank	Pt. Est. (95% CI)	Rank	FWER	Rank		Pt. Est. (95% CI)	Rank	Pt. Est. (95% CI)	Rank	E-value	Rank		Pt. Est.	Rank	95% LCL	Rank	
D29 Spike IgG (BAU/ml)	0.73 (0.62, 0.86)	7	<0.001	1	0.19 (0.08, 0.44)	1	<0.001	1	**1**	6.6	7	16.9	7	4.5	1	**7**	--	--	--	--	--
D57 Spike IgG (BAU/ml)	0.85 (0.76, 0.95)	10	0.020	9	0.23 (0.09, 0.60)	4	0.020	5	**7**	2.7	10	21.9	2	3.1	4	**4**	--	--	--	--	--
D29 RBD IgG (BAU/ml)	0.68 (0.55, 0.83)	5	0.001	2	0.28 (0.13, 0.60)	5	0.005	4	**4.5**	9.3	3	14.9	8	3.0	5	**5**	--	--	--	--	--
D57 RBD IgG (BAU/ml)	0.80 (0.70, 0.92)	9	0.010	7	0.28 (0.12, 0.67)	5	0.021	6	**6.5**	4.0	9	23.9	1	2.6	6	**6**	--	--	--	--	--
D29 PsV-nAb ID_{50} (IU_{50}/ml)	0.55 (0.38, 0.79)	2	0.004	5	0.32 (0.15, 0.69)	8	0.001	2	**3.5**	17.7	1	18.7	3	2.5	7	**3**	69.9 (59.8, 80.0)	1	59.8	1	**1**
D57 PsV-nAb ID_{50} (IU_{50}/ml)	0.69 (0.57, 0.83)	6	0.002	3	0.31 (0.12, 0.80)	7	0.108	9	**6.5**	7.5	6	17.7	6	2.0	8	**6**	--	--	--	--	--
D29 PsV-nAb ID_{80} (IU_{80}/ml)	0.48 (0.30, 0.77)	1	0.006	6	0.22 (0.09, 0.51)	3	0.004	3	**3**	14.7	2	18.2	4	3.7	2	**2**	48.5 (35.0, 62.0)	2	35.0	2	**2**
D57 PsV-nAb ID_{80} (IU_{80}/ml)	0.67 (0.54, 0.83)	4	0.003	4	0.20 (0.07, 0.61)	2	0.025	8	**4**	8.4	5	17.8	5	3.3	3	**5**	--	--	--	--	--
D29 LV-MN_{50} (IU_{50}/ml)	0.62 (0.43, 0.91)	3	0.017	8	0.46 (0.21, 1.01)	9	0.021	6	**7**	9.3	3	11.5	9	1.2	9	**9**	29.2 (17.2, 41.2)	3	17.2	3	**3**
D57 LV-MN_{50} (IU_{50}/ml)	0.78 (0.59, 1.02)	8	0.108	10	0.78 (0.34, 1.77)	10	0.571	10	**10**	5	8	6.0	10	1.0	10	**10**	--	--	--	--	--

Table S4. Ratio of sample sizes required to power a future immunogenicity or immunobridging trial for the column D57 antibody marker compared to the row D57 antibody marker, calculated using the method described by Follmann (*18*). Confidence intervals are based on 10^3 bootstrap replicates.

Ratios					
	D57 Spike IgG	D57 RBD IgG	D57 ID_{50}	D57 ID_{80}	D57 LV-MN_{50}
D57 Spike IgG	-	0.85	0.54	0.58	2.33
D57 RBD IgG	1.18	-	0.64	0.68	2.75
D57 ID_{50}	1.84	1.56	-	1.06	4.29
D57 ID_{80}	1.74	1.47	0.94	-	4.04
D57 LV-MN_{50}	0.43	0.36	0.23	0.25	-
Lower and upper bounds of the ratios					
	D57 Spike IgG	D57 RBD IgG	D57 ID_{50}	D57 ID_{80}	D57 LV-MN_{50}
D57 Spike IgG	-	(0.56, 1.20)	(0.11, 1.82)	(0.13, 1.59)	(0.57, Inf)
D57 RBD IgG	(0.83, 1.79)	-	(0.15, 2.14)	(0.17, 1.80)	(0.69, Inf)
D57 ID_{50}	(0.55, 8.94)	(0.47, 6.77)	-	(0.67, 1.74)	(1.07, Inf)
D57 ID_{80}	(0.63, 7.77)	(0.56, 5.74)	(0.58, 1.49)	-	(1.15, Inf)
D57 LV-MN_{50}	(0.00, 1.76)	(0.00, 1.44)	(0.00, .93)	(0.00, .87)	-

Table S5. Ratio of sample sizes required to power a future immunogenicity or immunobridging trial for the column D29 antibody marker compared to the row D29 antibody marker, calculated using the method described by Follmann (*18*). Confidence intervals are based on 10^3 bootstrap replicates.

Ratios					
	D29 Spike IgG	D29 RBD IgG	D29 ID_{50}	D29 ID_{80}	D29 LV-MN_{50}
D29 Spike IgG	-	1.12	1.41	1.65	2.45
D29 RBD IgG	0.90	-	1.26	1.48	2.19
D29 ID_{50}	0.71	0.79	-	1.17	1.74
D29 ID_{80}	0.61	0.68	0.85	-	1.48
D29 LV-MN_{50}	0.41	0.46	0.58	0.68	-
Lower and upper bounds of the ratios					
	D29 Spike IgG	D29 RBD IgG	D29 ID_{50}	D29 ID_{80}	D29 LV-MN_{50}
D29 Spike IgG	-	(0.74, 2.59)	(0.53, 4.59)	(0.62, 5.10)	(0.89, 17)
D29 RBD IgG	(0.39, 1.35)	-	(0.36, 3.25)	(0.39, 3.68)	(0.59, 12)
D29 ID_{50}	(0.22, 1.88)	(0.31, 2.77)	-	(0.73, 1.70)	(0.55, 11)
D29 ID_{80}	(0.20, 1.62)	(0.27, 2.57)	(0.59, 1.37)	-	(0.51, 10)
D29 LV-MN_{50}	(0.06, 1.12)	(0.08, 1.70)	(0.09, 1.83)	(0.10, 1.95)	-

Table S6. Estimated hazard ratio of COVID-19 per standard deviation (SD) increase in D29 and D57 marker, restricting to post D57 cases, in SARS-CoV-2 baseline negative per-protocol vaccine recipients (exploratory analyses). *Two-phase sampling Cox model was adjusted for baseline risk score, at risk status, and communities of color status. All serological assay readouts assessed as immune correlates were first expressed in values relative to the WHO International Standard for anti-SARS-CoV-2 immunoglobulin (*27*): binding antibody readouts were converted to BAU/ml and pseudovirus neutralizing antibody titers as well as microneutralization assay readouts were calibrated to IU_{50}/ml or IU_{80}/ml. BAU, binding antibody units; CI, confidence interval; ID_{50}, 50% inhibitory dilution; ID_{80}, 80% inhibitory dilution; IU, international units; LV, live virus; MN_{50}, 50% microneutralization dilution; nAb, neutralizing antibody; PsV, pseudovirus; Pt. Est., point estimate; SD, standard deviation.

	Hazard ratio* per SD increase in marker	
Antibody marker	D29 markers Pt. Est. (95% CI)	D57 markers Pt. Est. (95% CI)
Spike IgG (BAU/ml)	0.65 (0.47, 0.89)	0.66 (0.50, 0.88)
RBD IgG (BAU/ml)	0.59 (0.36, 0.96)	0.57 (0.40, 0.82)
PsV-nAb ID_{50} (IU_{50}/ml)	0.45 (0.22, 0.92)	0.42 (0.27, 0.65)
PsV-nAb ID_{80} (IU_{80}/ml)	0.29 (0.09, 0.92)	0.35 (0.20, 0.61)
LV-MN_{50} (IU_{50}/ml)	0.63 (0.30, 1.33)	0.51 (0.25, 1.04)

Table S7. Estimated hazard ratio of COVID-19 per standard deviation (SD) increase in the marker, for antibody marker pairs in SARS-CoV-2 baseline negative per-protocol vaccine recipients (exploratory analyses). *Two-phase sampling Cox model was adjusted for baseline risk score, at risk status, and communities of color status. **P-value from generalized Wald test of null hypothesis that all assay marker variables have null association. All serological assay readouts assessed as immune correlates were first expressed in values relative to the WHO International Standard for anti-SARS-CoV-2 immunoglobulin (*28*): binding antibody readouts were converted to BAU/ml and pseudovirus neutralizing antibody titers as well as microneutralization assay readouts were calibrated to IU_{50}/ml or IU_{80}/ml. BAU, binding antibody units; CI, confidence interval; ID_{50}, 50% inhibitory dilution; ID_{80}, 80% inhibitory dilution; IU, international units; LV, live virus; MN_{50}, 50% microneutralization dilution; nAb, neutralizing antibody; PsV, pseudovirus; SD, standard deviation.

Marker	Estimated Hazard Ratio per SD-Increase in the Marker (95% CI)*		
D29 Markers			
D29 RBD IgG (BAU/ml)	--	0.91 (0.62, 1.34)	0.77 (0.58, 1.04)
D29 PsV-nAb ID_{50} (IU_{50}/ml)	0.60 (0.34, 1.07)	0.60 (0.34, 1.04)	--
D29 LV-MN_{50} (IU_{50}/ml)	0.89 (0.49, 1.60)	--	0.75 (0.47, 1.19)
P-value**	0.005	0.002	0.004
D57 Markers			
D57 RBD IgG (BAU/ml)	--	1.04 (0.70, 1.55)	0.82 (0.65, 1.04)
D57 PsV-nAb ID_{50} (IU_{50}/ml)	0.56 (0.37, 0.86)	0.66 (0.40, 1.08)	--
D57 LV-MN_{50} (IU_{50}/ml)	1.26 (0.78, 2.04)	--	0.95 (0.63, 1.43)
P-value**	<0.001	<0.001	0.008

Table S8. Predictors of symptomatic COVID-19 in baseline negative per-protocol vaccine recipients and their coefficients in the discrete SuperLearner learner (top-performing learner based on cross-validated risk) selected for a representative fold of cross-validation (out of the 5 folds) across all 34 variable sets. Results shown are for the first random seed (out of 10 random seeds). SL.glm_screen_all: generalized linear model fit without screening of variables; SL.glmnet.0_screen_all: Lasso model with alpha = 1 fit without screening of variables; risk score: detailed in supplementary text S1 of (*10*)]; HighRiskInd: Indicator that participant had at least one of the following risk factors: chronic lung disease (e.g., emphysema, chronic bronchitis, idiopathic pulmonary fibrosis, cystic fibrosis, or moderate-to-severe asthma); cardiac disease (e.g., heart failure, congenital coronary artery disease, cardiomyopathies, or pulmonary hypertension); severe obesity (body mass index≥40); diabetes (type 1, type 2, or gestational); liver disease; or HIV infection; MinorityInd: Indicator that subjects are Black or African American, Hispanic or Latino, American Indian or Alaska Native, Native Hawaiian, and other Pacific Islander; Day29bindSpike: IgG Spike concentration at D29; Day57pseudoneutid50: PsV-nAb ID_{50} titer at D57; Day29pseudoneutid80: PsV-nAb ID_{80} titer at D29; Day57pseudoneutid80: PsV-nAb ID_{58} titer at D57; Delta29overBpseudoneutid80_2fold: Indicator that D29 PsV-ID_{80} titer is at least 2 times larger than D1 PsV-nAb ID_{80} titer; Delta29overBpseudoneutid50_4fold: Indicator that D29 PsV-nAb ID_{50} titer is at least 4 times larger than D1 PsV-nAb ID_{50} titer; Day57liveneutmn50: WT LV-MN_{50} titer at D57; Delta57overBliveneutmn50_4fold: Indicator that D57 WT LV-MN_{50} titer is at least 4 times larger than D1 WT LV-MN_{50} titer; comb_nlPCA1_d57_d29: First component of non-linear principal component analysis (PCA) as combination score across all five markers at D29 and D57; Coefficient: log odds ratio in a logistic regression model (glm) or an L1-penalized logistic regression model (glmnet). CI, confidence interval; ID_{50}, 50% inhibitory dilution; ID_{80}, 80% inhibitory dilution; IU, international units; LV, live virus; MN_{50}, 50% microneutralization dilution; nAb, neutralizing antibody; PsV, pseudovirus.

Variable Set	Learner	Predictors/Features	Coefficient	Odds Ratio
1 Baseline Risk Factors	SL.glm_screen_all	(Intercept)	-5.874	0.0028
		risk_score	0.433	1.542
		HighRiskInd	0.328	1.388
		MinorityInd	-0.209	0.811
2 Baseline Risk Factors + IgG Spike, RBD markers at D29, D57	SL.glmnet.0_screen_all	(Intercept)	-5.686	0.0034
		risk_score	0.170	1.185
		HighRiskInd	0.174	1.190
		MinorityInd	-0.031	0.969
		Day57bindSpike	-0.090	0.914
3 Baseline Risk Factors + Pseudovirus neutralization ID_{50}, ID_{80} markers at D29, D57	SL.glm_screen_all	(Intercept)	-6.086	0.0023
		risk_score	0.690	1.993

		HighRiskInd	0.275	1.317
		MinorityInd	-0.071	0.932
		Day57pseudoneutid80	-0.329	0.720
		Day29pseudoneutid80	-0.048	0.953
		Delta29overBpseudoneutid80_2fold	-0.395	0.674
4 Baseline Risk Factors + Wild-Type Live virus neutralization ID_{50}, ID_{80} markers at D29, D57	SL.glmnet.0_screen_all	(Intercept)	-5.991	0.003
		risk_score	0.556	1.744
		HighRiskInd	0.231	1.259
		MinorityInd	-0.17	0.844
		Day57liveneutmn50	-0.334	0.716
		Delta57overBliveneutmn50_4fold	0.202	1.224
5 Baseline Risk Factors + All Markers at D29, D57 _	SL.glmnet.0_screen_all	(Intercept)	-6.038	0.0024
		risk_score	0.547	1.728
		HighRiskInd	0.181	1.198
		MinorityInd	-0.098	0.906
		Day57pseudoneutid50	-0.140	0.870
		Day57pseudoneutid80	-0.086	0.918
		Delta29overBpseudoneutid50_4fold	-0.071	0.932
		Delta29overBpseudoneutid80_2fold	-0.274	0.760
		comb_nlPCA1_d57_d29	0.0398	1.041

Table S9. Immune assay limits. All serological assay readouts assessed as immune correlates were first expressed in values relative to the WHO International Standard for anti-SARS-CoV-2 immunoglobulin (*28*): binding antibody readouts were converted to BAU/ml and pseudovirus neutralizing antibody titers as well as microneutralization assay readouts were calibrated to IU_{50}/ml or IU_{80}/ml. [1]LV-MN_{50} values below the LoD were assigned the value LoD/2. Values between the LoD and the LLOQ were taken as their actual numeric value. Values greater than the ULOQ were assigned the value of the ULOQ. [2] PsV-nAb ID_{50} and PsV-nAb ID_{80} values below the LoD were assigned the value LoD/2. Values between the LoD and the LLOQ were taken as their actual numeric value. For immunogenicity reporting, values greater than the ULOQ were not given a ceiling value of the ULOQ, the actual readouts were used. For the immune correlates analyses, values greater than the ULOQ were assigned the value of the ULOQ. [3] Antibody response was defined by detectable IgG concentration above the antigen-specific positivity cut-off (10.8424 BAU/ml for spike, 14.0858 BAU/ml for RBD). BAU, binding antibody units; CI, confidence interval; ID_{50}, 50% inhibitory dilution; ID_{80}, 80% inhibitory dilution; IU, international units; LoD, limit of detection; LV, live virus; MN_{50}, 50% microneutralization dilution; nAb, neutralizing antibody; PsV, pseudovirus; ULOQ, upper limit of quantitation.

	Live Virus Microneutralization Assay (LV-MN_{50}) (Battelle) (IU_{50}/ml)[1]	Pseudovirus Neutralization Assay (PsV-nAb) (Duke) (IU_{50}/ml)[2]	Pseudovirus Neutralization Assay (PsV-nAb) (Duke) (IU_{80}/ml)[2]	Binding Antibody Assay (VRC) (BAU/ml)[3]	Binding Antibody Assay (VRC) (BAU/ml)[3]
	LV-MN_{50}	PsV-nAb ID_{50}	PsV-nAb ID_{80}	Spike	RBD
Positivity Cutoff	22.66	2.42	15.02	10.8424	14.0858
LoD	22.66	2.42	15.02	0.3076	1.5936
LLOQ	44.1	4.477	21.4786	1.7968	3.43
ULOQ	3083.74	10919	15368	10,155.95	16,269

Table S10. The 13 learner-screen combinations inputted into superlearner.

Learner	Screen
SL.mean	All
SL.glmnet.0	All
SL.glmnet.1	All
SL.xgboost.2.no	All
SL.xgboost.4.no	All
SL.xgboost.2.yes	All
SL.xgboost.4.yes	All
SL.ranger.yes	All
SL.ranger.no	All
SL.glm	All
SL.glm	glmnet
SL.glm	univar_logistic_pval
SL.glm	highcor_random

Table S11. 34 variable sets for fitting superlearner to predict COVID-19 in baseline negative per-protocol vaccine recipients. Baseline risk factors are baseline risk score, at-risk status, and community of color status. bAb, binding antibody; BAU, binding antibody units; ID_{50}, 50% inhibitory dilution; ID_{80}, 80% inhibitory dilution; IU, international units; LoD, limit of detection; LV, live virus; MN_{50}, 50% microneutralization dilution; nAb, neutralizing antibody; PCA, principal components analysis; PsV, pseudovirus; ULOQ, upper limit of quantitation.

Variable Set Name	Variables included in the set
1_baselineRiskFactors	Baseline risk factors only (Reference model)
2_bAbSpike_D57	Baseline risk factors + D57 bAb anti-Spike markers
3_bAbRBD_D57	Baseline risk factors + D57 bAb anti-RBD markers
4_pnabID50_D57	Baseline risk factors + D57 p-nAb ID_{50} markers
5_pnabID80_D57	Baseline risk factors + D57 p-nAb ID_{80} markers
6_lnabMN50_D57	Baseline risk factors + D57 l-nAb MN_{50} markers
7_bAb_pnabID50_D57	Baseline risk factors + D57 bAb markers and p-nAb ID_{50} markers
8_bAb_pnabID80_D57	Baseline risk factors + D57 bAb markers and p-nAb ID_{80} markers
9_bAb_lnabMN50_D57	Baseline risk factors + D57 bAb markers and l-nAb MN_{50} markers
10_bAb_combScores_D57	Baseline risk factors + D57 bAb markers and combination scores across the five markers [PCA1, PCA2, FSDAM1/FSDAM2 (the first two components of nonlinear PCA), and the maximum signal diversity score]
11_allMarkers_D57	Baseline risk factors + all individual D57 marker variables
12_allMarkers_combScores_D57	Baseline risk factors + all individual D57 marker variables and their combination scores (Full model of D57 markers)
13_bAbSpike_D29	Baseline risk factors + D29 bAb anti-Spike markers
14_bAbRBD_D29	Baseline risk factors + D29 bAb anti-RBD markers
15_pnabID50_D29	Baseline risk factors + D29 p-nAb ID_{50} markers
16_pnabID80_D29	Baseline risk factors + D29 p-nAb ID_{80} markers
17_lnabMN50_D29	Baseline risk factors + D29 l-nAb MN_{50} markers
18_bAb_pnabID50_D29	Baseline risk factors + D29 bAb markers and p-nAb ID_{50} markers
19_bAb_pnabID80_D29	Baseline risk factors + D29 bAb markers and p-nAb ID_{80} markers
20_bAb_lnabMN50_D29	Baseline risk factors + D29 bAb markers and l-nAb MN_{50} markers
21_bAb_combScores_D29	Baseline risk factors + D29 bAb markers and combination scores across the five markers [PCA1, PCA2, FSDAM1/FSDAM2 (the first two components of nonlinear PCA), and the maximum signal diversity score]
22_allMarkers_D29	Baseline risk factors + all individual D29 marker variables
23_allMarkers_combScores_D29	Baseline risk factors + all individual D29 marker variables and their combination scores (Full model of D29 markers)
24_bAbSpike_D29_D57	Baseline risk factors + D29 and D57 bAb anti-Spike markers
25_bAbRBD_D29_D57	Baseline risk factors + D29 and D57 bAb anti-RBD markers
26_pnabID50_D29_D57	Baseline risk factors + D29 and D57 p-nAb ID_{50} markers
27_pnabID80_D29_D57	Baseline risk factors + D29 and D57 p-nAb ID_{80} markers
28_lnabMN50_D29_D57	Baseline risk factors + D29 and D57 l-nAb MN_{50} markers
29_bAb_pnabID50_D29_D57	Baseline risk factors + D29 and D57 bAb markers and p-nAb ID_{50} markers

30_bAb_pnabID80_D29_D57	Baseline risk factors + D29 and D57 bAb markers and p-nAb ID_{80} markers
31_bAb_lnabMN50_D29_D57	Baseline risk factors + D29 and D57 bAb markers and l-nAb MN_{50} markers
32_bAb_combScores_D29_D57	Baseline risk factors + D29 and D57 bAb markers and combination scores across the ten markers [PCA1, PCA2, FSDAM1/FSDAM2 (the first two components of nonlinear PCA), and the maximum signal diversity score]
33_allMarkers_D29_D57	Baseline risk factors + all individual D29 and D57 marker variables
34_allMarkers_combScores_D29_D57	Baseline risk factors + all individual D29 and D57 marker variables and their combination scores (Full model of D29 and D57 markers)

Data file S1. Statistical analysis plan.