

Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

Supplement to: Gilbert PB, Montefiori DC, McDermott A, et al. Immune Correlates Analysis of the mRNA-1273 COVID-19 Vaccine Efficacy Trial

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Principal Investigator	Study Team	Institution	Location
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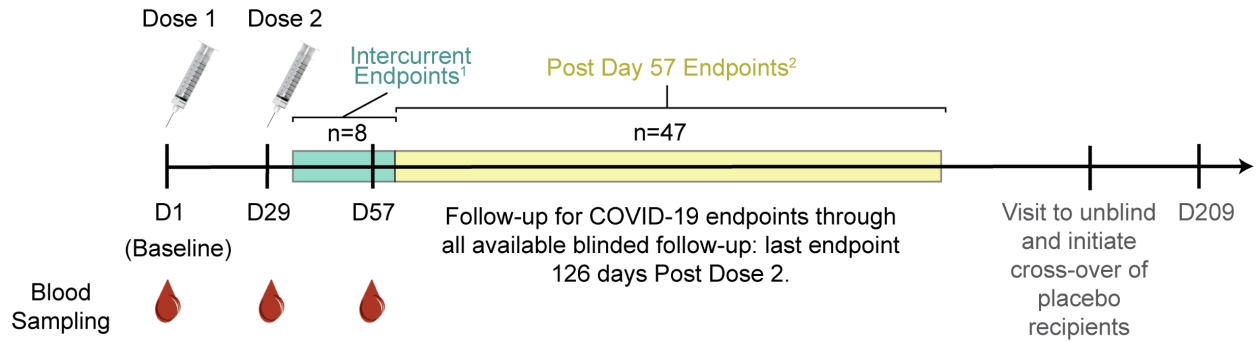
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Figure S1. Timing of mRNA-1273 doses, blood sampling, and the two time periods for diagnosis of COVID-19 endpoints (“Intercurrent” and “Post Day 57”). The schematic applies to baseline SARS-CoV-2 negative per-protocol recipients of two doses of mRNA-1273.

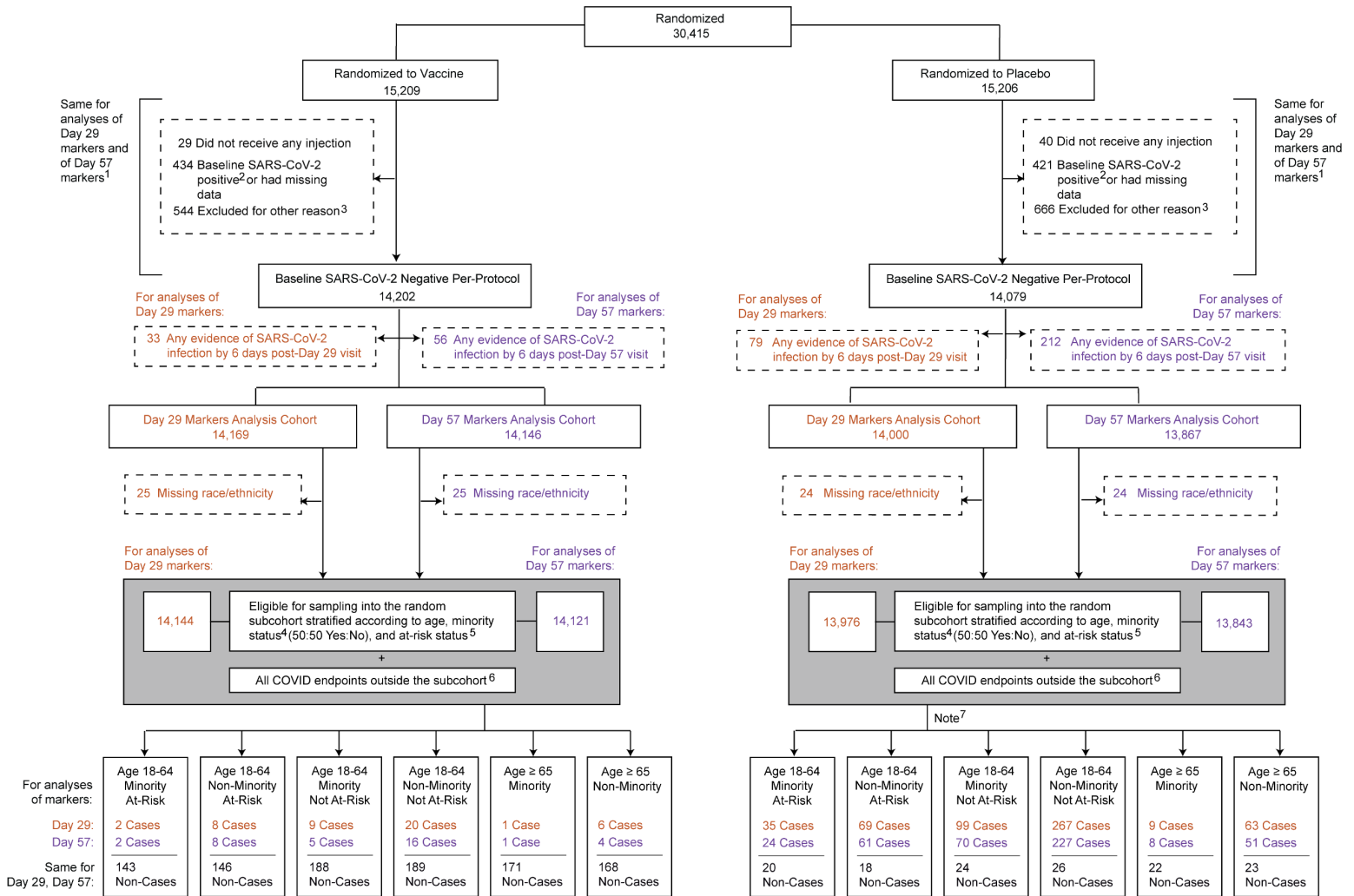
For Baseline Negative Per-Protocol recipients of two doses of mRNA-1273:



¹Intercurrent Endpoints: ≥ 7 days post Dose 2 through 6 days post Day 57; used in Day 29 marker correlates analyses only

²Post Day 57 Endpoints: ≥ 7 days post Day 57; used in Day 29 and in Day 57 marker correlates analyses

Figure S2. Flowchart of study participants from enrollment to the case-cohort set of baseline SARS-CoV-2 negative per-protocol participants.



1 If a participant had multiple reasons for exclusion from the Per-Protocol Set, they were only counted in the earliest-listed reason.
 2 Baseline SARS-CoV-2 positive is defined as immunologic or virologic evidence of prior COVID-19 (i.e. a positive nasopharyngeal swab and/or binding antibodies against SARS-CoV-2 nucleocapsid above the limit of detection or above the lower limit of quantification) at Day 1 before the first dose of investigational product (same definition as in Baden et al. 2021).
 3 The other reasons for exclusion were: did not receive second dose; received incorrect vaccine; received dose 2 out of window; other major protocol deviations; were living with HIV; adjudicated COVID-19 cases up to Day 29 visit (dose 2 date).
 4 Minority includes Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders. Non-Minority includes all other races with observed race (Asian, Multiracial, White, Other) and observed ethnicity Not Hispanic or Latino.
 5 Participants 18-64 were categorized as "At-Risk" (of severe COVID-19 illness) if they 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 (BMI ≥40); diabetes (type 1, type 2, or gestational); liver disease; or HIV infection (same as in Baden et al. 2021).
 6 Correlates analyses of Day 29 markers start counting COVID-19 endpoints at 7 days post Day 29 visit, and correlates analyses of Day 57 markers start counting COVID-19 endpoints at 7 days post Day 57 visit.
 7 Almost all of the antibody levels for placebo recipients were negative, as expected given restriction to participants without evidence of prior SARS-CoV-2 infection. These antibody data were not included in correlates analyses as they do not contribute value except for verifying low false positive rates of the assays.

Supplementary Text 1: Additional details on the immunoassays

Solid-phase electrochemiluminescence S-binding IgG immunoassay (ECLIA)

MSD SECTOR® plates were precoated by MSD with SARS-CoV-2 spike (S-2P), receptor binding domain (RBD) protein, Nucleocapsid (N) protein and a Bovine Serum Albumin (BSA) control in each well in a specific spot-designation for each antigen. The assay was performed with a Beckman Coulter Biomek based automation integration platform including the Biotek 405TS Plate Washer. Serum samples were heat-inactivated for 30 minutes at 56°C prior to assay. Plates were blocked for 60 minutes at room temperature (RT) with MSD blocker A solution without shaking. Plates were washed and MSD reference standard (calibrator), QC test sample (pool of COVID-19 convalescent sera) and human serum test samples were added to the precoated wells in duplicates in an 8-point dilution series. Reference standard was added in triplicates. MSD Control sera (low, medium and high) were added undiluted in triplicates as per validated assay format. Additional assay controls might be added in triplicates. Samples were incubated at RT for 4 hours with shaking on a Titramax Plate shaker (Heidolph) at 1500 rpm. SARS-CoV-2 specific antibodies present in the sera or controls bound to the coated antigens. Plates were washed to remove unbound antibodies. Antibodies bound to the SARS-CoV-2 viral proteins were detected using an MSD SULFO-TAG™ anti-human IgG detection antibody incubated for 60 minutes at RT and with shaking. Plates were washed and a read solution (MSD GOLD™ read buffer) containing electrochemiluminescence (ECL) substrate was applied to the wells, and the plate was entered into the MSD MESO Sector S 600 detection system. An electric current was applied to the plates and areas of well surface which form antigen-anti human IgG antibody SULFO-TAG™ complex emitted light in the presence of the ECL substrate.

The MSD MESO Sector S 600 detection system quantitates the amount of light emitted and reports the ECL unit response as a result for each test sample, control sample and reference standard of each plate. Analysis was performed with the MSD Discovery Workbench software, Version 4.0. Calculated ECLIA parameters to measure binding antibody activities include interpolated concentrations or assigned arbitrary units (AU/mL) read from the standard curve. Recently the arbitrary units were bridged to the WHO International Standard and a conversion factor was calculated and confirmed. Parallelism was established for all three antigens between the MSD provided reference standard and the WHO provided international standard. Concentration assignments were performed and then confirmed both at MSD and as part of a multi-site confirmation study. Sample results reported here have been converted to international units (IU/mL).

Neutralization assay

The neutralization assay was performed as detailed in Shen et al.¹ Briefly, spike-pseudotyped virus was prepared by transfection in 293T cells using a lentivirus backbone vector, a spike-expression plasmid, a TMPRSS2 expression plasmid and a firefly Luc reporter plasmid. A pre-titrated dose of pseudovirus was incubated with eight serial 5-fold dilutions of serum samples (1:10 start dilution) in duplicate in 96-well flat-bottom poly-L-lysine-coated culture plates for 1 hr at 37° C prior to adding 293T/ACE2 cells. One set of eight wells received cells + virus (virus control) and another set of eight wells received cells only (background control). Luminescence was measured after 66-72 hr of incubation using Promega 1X lysis buffer and Bright-Glo luciferase reagent. Neutralization titers are the inhibitory dilution of serum samples at which relative luminescence units (RLUs) were reduced by either 50% (ID50) or 80% (ID80) compared to virus control wells after subtraction of background RLUs. Serum samples were heat-inactivated for 30 min at 56°C prior to assay.

Calibrated neutralization titers (cID50 and cID80)

Results from the neutralization assay are reported as calibrated ID50 (cID50) and calibrated ID80 (cID80) titers. The calibration was conducted for the First WHO International Standard for Anti-SARS-CoV-2 Immunoglobulin (20/136) in the SARS-CoV-2 spike-pseudotyped virus neutralization assay in 293T/ACE2 cells. The reagent is intended to be used in part to normalize neutralization titers across multiple SARS-CoV-2 neutralization assays (SOP CFAR02-A0026 “Measuring Neutralizing Antibodies Against SARS-CoV2 Using Pseudotyped Virus and 293T/ACE2 Cells” from the Duke Montefiori lab). The calibration work was performed by the “Neutralizing Antibody Core” Laboratory in the Surgical Oncology Research Facility, under the GCLP oversight of the Quality Assurance for Duke Vaccine Immunogenicity Programs (QADVIP).

Reagent description. In December 2020, the WHO released a well-characterized international standard for the purpose of improving comparability of results among different assays in different laboratories and reducing interlaboratory variability of anti-SARS-CoV-2 antibody assays.² As described in the user instructions provided by the National Institute for Biological Standards and Controls (NIBSC): “The First WHO International Standard for anti-SARS-CoV-2 immunoglobulin is the freeze-dried equivalent of 0.25 mL of pooled plasma obtained from eleven individuals recovered from SARS-CoV-2 infection. The preparation was evaluated in a WHO International Collaborative study. The intended use of the International Standard is for the calibration and harmonization of serological assays detecting anti-SARS-CoV-2 neutralizing antibodies. The preparation can also be used as an internal reference reagent for the harmonization of binding antibody assays. The preparation has been solvent-detergent treated to minimize the risk of the presence of enveloped viruses”.³

Reagent preparation and storage. The reagent was shipped as a lyophilized powder by the NIBSC on December 23, 2020 and was received at Duke on January 4, 2021. A second shipment of the lyophilized reagent was received from the NIBSC on March 15, 2021. The reagent was stored at -80°C upon arrival. Each vial of lyophilized reagent was reconstituted with 0.25 mL of sterile distilled water (Invitrogen, Cat No. 10977015, Ultra-pure DNase, RNase free, Lot 2186762, Exp 30-Aug-2022) as described in the instruction packet³ and stored at 4°C until use (no longer than 4 weeks).

Protocol and assay results. Neutralization assays were conducted in accordance with SOP CFAR02-A0026 “Measuring Neutralizing Antibodies Against SARS-CoV2 Using Pseudotyped Virus and 293T/ACE2 Cells” using the spike pseudotyped virus CoV-2 VRC7480.D614G.1[CMVΔR8.2]/293T/17. The assays were performed between January 5, 2021 and April 16, 2021 by four operators. All assays used either a 1:20 or 1:30 start dilution and a 5-fold dilution series for a total of 8 dilutions. One vial of the standard was reconstituted on January 5 and assayed once on each of 10 plates in a single setting by a single operator (EY) on January 5, 2021; the plates were read on January 8, 2021 (Exp ID EY18-134 in Table 1). These 10 assay results were described in Duke-02-MVR-COVID0001.2. In response to FDA/CBER recommendations (MF 026862, comments dated March 1, 2021), additional assays were performed over different operators and days to yield more precise estimates of the calibration factors. Additional vials of the reagent were reconstituted on March 20, 2021 and assayed in quadruplicate by two operators on two days. A third operator assayed the reconstituted standard in quadruplicate on 3 days. All assays were set up within 24 days of reconstitution. The WHO assigned an arbitrary unitage of 250 IU/ampoule (1000 IU/mL) for neutralizing activity. For calibration purposes, ID50 and ID80 titers may be converted to IUs by dividing 1000 IU/mL by either the mean, median or geometric mean ID50 and ID80 titer as a dilution factor. Thus, the calibration factor for mean ID50 is $1000 \div 4135 = 0.242$. The calibration factor for mean ID80 is $1000 \div 666 = 1.502$. The calibration factor for median ID50 is $1000 \div 2422 = 0.413$. The calibration factor for median ID80 is $1000 \div 489 = 2.045$. The calibration factor for geometric mean ID50 is $1000 \div 3047 = 0.328$. The calibration factor for geometric mean ID80 is $1000 \div 567 = 1.764$. The calibration factors are summarized in the following table:

SUMMARY VALUES FOR WHO ANTI-SARS-COV-2 IgG (20/136)		
Virus: SARS-CoV-2 D614G Variant		Calibration Factor
Arithmetic mean ID50	4135	0.242
Arithmetic mean ID80	666	1.502
Median ID50	2422	0.413
Median ID80	489	2.045
Geometric Mean ID50	3047	0.328
Geometric Mean ID80	567	1.764

The three types of calibration factors (based on arithmetic mean, median, and geometric mean) were compared head-to-head on validation data from Day 29 and Day 57 ID50 and ID80 values from 30 recipients of the mRNA-1273 vaccine, with the common samples conducted by both the Duke Montefiori neutralization assay used for the COVE trial immune correlates study and the Monogram PhenoSense neutralization assays. The results showed that using arithmetic mean of the WHO IS sample for calibration yielded the highest agreement between the calibrated vaccine responses from the two labs, based on the concordance correlation coefficient (manuscript in preparation). Based on this validation experiment, the arithmetic mean calibration factors were selected for use in reporting results in terms of cID50 and cID80 titers.

Calibration of ID50 and ID80 titers between the Duke neutralization assay on COVE trial samples and the Monogram PhenoSense neutralization assay performed on AZD12222⁴ samples

Using the WHO First Anti-SARS CoV-2 Immunoglobulin International Standard (20/136): 1000 IU/mL, PhenoSense SARS CoV-2 nAb titers can be converted to IU/ml by multiplying the nAb titer (ID50 or ID80) by the appropriate conversion factor, where conversion factors were estimated both for the D614 pseudovirus vaccine strain and for the D614G pseudovirus mutation strain. For each strain, conversion factors were calculated using the mean, geometric mean and median based on 24 replicate tests of the 20/136 standard (6 replicates per day x 4 days). Based on the validation data noted above the arithmetic mean conversion factor was used. For the D614 strain, the conversion factors for ID50 and ID80 were 0.1428 and 0.4585, respectively. For the D614G strain, the conversion factors for ID50 and ID80 were 0.0653 and 0.2281, respectively. In the main article, these conversion factors were first applied as follows: the ID50 values reported in Table 2 of Feng et al.⁴ corresponding to 70% and 90% estimated vaccine efficacy were multiplied by 0.1428, where the D614 strain factor was used because the AZD12222 performed the Monogram PhenoSense pseudovirus neutralization assay on participant samples using the D614 strain. Specifically, the ID50 values 57, 183, 982, 303 reported in Table 2 of Feng et al. were each multiplied by 0.1428 to obtain cID50 values 8, 26, 140, 43, respectively; these values are reported in the Discussion in the main article.

In addition, because the Duke neutralization assay performed on COVE samples used the D614G strain, the main article also reports a sensitivity analysis which assumes that D614G is more sensitive to neutralization by vaccine recipient sera than D614. The multiplicative factor defining more sensitive was taken to be $(0.1428/0.0653) = 2.19$, the ratio of conversion factors (D614 vs. D614G) calculated in the Monogram study that defined the conversion factors. This factor was applied to each cID50 value from the AZD12222 study, which means that each AZD12222 ID50 value on its original scale was multiplied by $0.1428 * 2.19 = 0.31$. Therefore, in this sensitivity analysis, the ID50 values 57, 183, 982, 303 reported in Table 2 of Feng et al. were each multiplied by 0.31 to obtain the cID50 values 18, 57, 307, 95, respectively.

Table S1. Meso-Discovery (MSD) and pseudovirus neutralization assay limits of the four antibody markers evaluated as immune correlates.

Reported units	MSD Binding Assay (VRC)			PsV nAb (Duke)	
	IU/ml*			Calibrated titers**	
	Spike	RBD	N	cID50	cID80
Positivity Cutoff	10.8424	14.0858	23.5	2.42	15.02
LOD	0.3076	1.5936	0.09	2.42	15.02
LLOQ	1.7968	3.43	4.49	4.477	21.4786
ULOQ	10,155.95	16,269	575	10919	15368

*AU/ml units converted to IU/ml units for all data analysis.

**Original titers calibrated to the WHO anti-SARS-CoV-2 immunoglobulin International Standard (NIBSC code: 20/136) for all data analyses.^{2,3} cID50 = calibrated ID50 titer; cID80 = calibrated ID80 titer.

Supplementary Text 2: Baseline covariates adjusted for in immune correlates analyses, including the baseline COVID-19 risk score

In addition to adjusting for the at-risk indicator (a stratification factor used in the COVE trial randomization) and the indicator of membership in community of color, all correlates analyses adjust for a baseline COVID-19 risk score that was developed through machine learning of the baseline SARS-CoV-2 negative per-protocol placebo arm data in the COVE trial. This supplementary text summarizes the COVID-19 risk score, with the Statistical Analysis Plan providing additional details.

Table S2 lists the input variables that were included in the machine learning to build a model predicting the COVID-19 endpoint, where cases are COVID-19 endpoints starting 7 days post Day 57 visit and non-cases are participants with follow-up beyond 7 days post Day 57 visit and that never registered a COVID-19 endpoint. The risk score is defined as the logit of the predicted COVID-19 outcome probability from the predictive regression model, estimated using the ensemble algorithm superlearner (i.e. stacking), where this logit predicted outcome is scaled to have empirical mean zero and empirical standard deviation one.

Table S2. Individual baseline variables input into the Superlearner model for predicting occurrence of COVID-19 in baseline SARS-CoV-2 negative per-protocol placebo recipients.¹

Variable Name	Definition	Total missing values
MinorityInd	Baseline covariate underrepresented minority status	0/14079 (0.0%)
EthnicityHispanic	(1=minority, 0=non-minority)	0/14079 (0.0%)
EthnicityNotreported	Indicator ethnicity = Hispanic (0 = Non-Hispanic)	0/14079 (0.0%)
EthnicityUnknown	Indicator ethnicity = Not reported (0 = Non-Hispanic)	0/14079 (0.0%)
Black	Indicator ethnicity = Unknown (0 = Non-Hispanic)	0/14079 (0.0%)
Asian	Indicator race = Black (0 = White)	0/14079 (0.0%)
NatAmer	Indicator race = Asian (0 = White)	0/14079 (0.0%)
PacIsl	Indicator race = American Indian or Alaska Native (0 = White)	0/14079 (0.0%)
Multiracial	White)	0/14079 (0.0%)
Other	Indicator race = Native Hawaiian or Other Pacific Islander (0 = White)	0/14079 (0.0%)
Notreported	Indicator race = Multiracial (0 = White)	0/14079 (0.0%)
Unknown	Indicator race = Other (0 = White)	0/14079 (0.0%)
HighRiskInd	Indicator race = Not reported (0 = White)	0/14079 (0.0%)
Sex	Indicator race = unknown (0 = White)	0/14079 (0.0%)
Age	Baseline covariate high risk pre-existing condition	0/14079 (0.0%)
BMI	(1=yes, 0=no)	0/14079 (0.0%)
	Sex assigned at birth (1=female, 0=male)	
	Age at enrollment in years, between 18 and 85	0/14079 (0.0%)
	BMI at enrollment (kg/m ²)	79/14079 (0.6%)

¹The per-protocol group for immune correlates analysis is slightly different than that for the primary vaccine efficacy analysis,⁵ due in part to a data cutoff for the primary vaccine efficacy analysis of November 25, 2020⁵ vs a data cutoff for the immune correlates analysis of March 26, 2021, and also in part due to the inclusion of participants

with HIV in the per-protocol set for vaccine efficacy analysis⁵ vs. the exclusion of participants with HIV from the per-protocol set for the immune correlates analysis

The following details were used in the implementation of superlearner of the baseline SARS-CoV-2 negative per-protocol placebo arm:

- All of the selected learners (i.e., regression methods for classifying whether a participant has a COVID-19 outcome or not) were coded into the SuperLearner R package available on CRAN, and the analysis was done using this R package.
- Each quantitative and ordinal variable was pre-scaled to have empirical mean 0 and standard deviation 1.
- 5-fold cross-validation was used with no more than $\max(20, \text{floor}(np/20))$ input variables included in each model, where np is the number of evaluable placebo arm cases.
- High-correlation variable screening was used, not allowing any pair of input variables to have Spearman rank correlation $r > 0.9$.
- Two levels of cross-validation (CV) were used. The outer level computed CV-AUC over 5-fold cross-validation, and the inner level used 5-fold CV.
- Results for comparing classification accuracy of different models were based on point and 95% confidence interval estimates of cross-validated area under the ROC curve (CV-AUC).^{6,7} Results are presented as forest plots of point and 95% confidence interval estimates similar to those used in Figure 3B of Neidich et al.⁸ and in Figure 2 of Magaret, Benkeser, and Williamson et al.⁹ CV-AUC was estimated using the *vimp* R package¹⁰ available on CRAN.

Table S3 lists the learning algorithms that were applied to estimate the conditional probability of the COVID-19 outcome based on the input variables listed in **Table S2**. Some of the algorithms are non-data-adaptive type learning algorithms, such as parametric regression models (e.g., generalized linear models [glms]), which are simple and stable. Data-adaptive type algorithms are also included, for increasing flexibility of modeling and reducing the risk of model misspecification: SL.randomForest, SL.gam, SL.polymars, and SL.xgboost. All of the selected learners are coded into the SuperLearner R package.

Table S3. Learning algorithm-screen combinations (14 in total) used as input to the Superlearner model in baseline negative per-protocol placebo recipients.

Learner	Screen*
SL.mean	all
SL.glm	all
	glmnet
	univar_logistic_pval
	highcor_random
SL.glm.interaction	glmnet
	univar_logistic_pval
	highcor_random
SL.glmnet	all
SL.gam	glmnet
	univar_logistic_pval
	highcor_random
SL.xgboost	all
SL.ranger.imp	all

*Screen details:

all: includes all variables

glmnet: includes variables with non-zero coefficients in the standard implementation of SL.glmnet that optimizes the lasso tuning parameter via cross-validation

univar_logistic_pval: Wald test 2-sided p-value in a logistic regression model < 0.10

highcor_random: if pairs of quantitative variables with Spearman rank correlation > 0.90, select one of the variables at random

Table S4 shows the weights that the Superlearner ensemble model applied to each of the individual prediction algorithms in the modeling of the placebo arm.

Table S4. Weights assigned by Superlearner to each individual learner in the modeling of the placebo arm

Learner	Screen	Weight
SL.gam	screen_highcor_random	0.369
SL.gam	screen_univariate_logistic_pval	0.291
SL.ranger.imp	screen_all	0.165
SL.mean	screen_all	0.112
SL.xgboost	screen_all	0.062
SL.glm	screen_all	0.000
SL.glmnet	screen_all	0.000
SL.glm	screen_glmnet	0.000
SL.glm	screen_univariate_logistic_pval	0.000
SL.glm	screen_highcor_random	0.000
SL.glm.interaction	screen_glmnet	0.000
SL.glm.interaction	screen_univariate_logistic_pval	0.000
SL.glm.interaction	screen_highcor_random	0.000
SL.gam	screen_glmnet	0.000

To inform about which individual input variables were most important for the risk score, **Table S5** shows the predictors used in the learners that were assigned positive weight by the Superlearner model, with multiple metrics reported that can be used for ranking variable importance. BMI and age were ranked as the two most important variables for predicting COVID-19.

Table S5. Predictors in learners assigned positive weight by Superlearner in the modeling of the placebo arm.

Learner	Screen	Weight	Predictors	Coefficient	Odds		Importance	Feature	Gain	Cover	Frequency
					Ratio						
SL.gam	screen_highcor_random	0.369	(Intercept)	-3.109	0.045		NA	NA	NA	NA	NA
SL.gam	screen_highcor_random	0.369	s(Age,2)	-0.280	0.756		NA	NA	NA	NA	NA
SL.gam	screen_highcor_random	0.369	s(BMI,2)	0.174	1.190		NA	NA	NA	NA	NA
SL.gam	screen_highcor_random	0.369	MinorityInd	-0.042	0.959		NA	NA	NA	NA	NA
SL.gam	screen_highcor_random	0.369	EthnicityHispanic	0.027	1.028		NA	NA	NA	NA	NA
SL.gam	screen_highcor_random	0.369	EthnicityNotreported	-0.046	0.955		NA	NA	NA	NA	NA
SL.gam	screen_highcor_random	0.369	EthnicityUnknown	-0.056	0.945		NA	NA	NA	NA	NA
SL.gam	screen_highcor_random	0.369	Black	-0.250	0.779		NA	NA	NA	NA	NA
SL.gam	screen_highcor_random	0.369	Asian	-0.047	0.954		NA	NA	NA	NA	NA
SL.gam	screen_highcor_random	0.369	NatAmer	-0.059	0.943		NA	NA	NA	NA	NA
SL.gam	screen_highcor_random	0.369	PacIsl	-0.442	0.643		NA	NA	NA	NA	NA
SL.gam	screen_highcor_random	0.369	Multiracial	-0.143	0.866		NA	NA	NA	NA	NA
SL.gam	screen_highcor_random	0.369	Other	0.018	1.018		NA	NA	NA	NA	NA
SL.gam	screen_highcor_random	0.369	Notreported	0.033	1.034		NA	NA	NA	NA	NA
SL.gam	screen_highcor_random	0.369	Unknown	0.029	1.030		NA	NA	NA	NA	NA
SL.gam	screen_highcor_random	0.369	HighRiskInd	0.007	1.007		NA	NA	NA	NA	NA
SL.gam	screen_highcor_random	0.369	Sex	0.054	1.056		NA	NA	NA	NA	NA
SL.gam	screen_univariate_logistic_pval	0.291	(Intercept)	-3.084	0.046		NA	NA	NA	NA	NA
SL.gam	screen_univariate_logistic_pval	0.291	s(Age,2)	-0.274	0.761		NA	NA	NA	NA	NA
SL.gam	screen_univariate_logistic_pval	0.291	s(BMI,2)	0.183	1.201		NA	NA	NA	NA	NA
SL.gam	screen_univariate_logistic_pval	0.291	EthnicityHispanic	0.010	1.010		NA	NA	NA	NA	NA
SL.gam	screen_univariate_logistic_pval	0.291	Black	-0.268	0.765		NA	NA	NA	NA	NA
SL.gam	screen_univariate_logistic_pval	0.291	Multiracial	-0.150	0.861		NA	NA	NA	NA	NA
SL.ranger.imp	screen_all	0.165	MinorityInd	NA	NA	3.296	NA	NA	NA	NA	NA
SL.ranger.imp	screen_all	0.165	EthnicityHispanic	NA	NA	3.844	NA	NA	NA	NA	NA
SL.ranger.imp	screen_all	0.165	EthnicityNotreported	NA	NA	1.069	NA	NA	NA	NA	NA
SL.ranger.imp	screen_all	0.165	EthnicityUnknown	NA	NA	0.433	NA	NA	NA	NA	NA
SL.ranger.imp	screen_all	0.165	Black	NA	NA	2.608	NA	NA	NA	NA	NA
SL.ranger.imp	screen_all	0.165	Asian	NA	NA	2.318	NA	NA	NA	NA	NA
SL.ranger.imp	screen_all	0.165	NatAmer	NA	NA	0.971	NA	NA	NA	NA	NA
SL.ranger.imp	screen_all	0.165	PacIsl	NA	NA	0.133	NA	NA	NA	NA	NA
SL.ranger.imp	screen_all	0.165	Multiracial	NA	NA	1.394	NA	NA	NA	NA	NA
SL.ranger.imp	screen_all	0.165	Other	NA	NA	2.155	NA	NA	NA	NA	NA

SL.ranger.imp	screen_all	0.165	Notreported	NA	NA	1.390	NA	NA	NA	NA
SL.ranger.imp	screen_all	0.165	Unknown	NA	NA	1.682	NA	NA	NA	NA
SL.ranger.imp	screen_all	0.165	HighRiskInd	NA	NA	4.380	NA	NA	NA	NA
SL.ranger.imp	screen_all	0.165	Sex	NA	NA	6.329	NA	NA	NA	NA
SL.ranger.imp	screen_all	0.165	Age	NA	NA	50.511	NA	NA	NA	NA
SL.ranger.imp	screen_all	0.165	BMI	NA	NA	109.263	NA	NA	NA	NA
SL.xgboost	screen_all	0.062	NA	NA	NA	NA	BMI	0.664	0.796	0.75
SL.xgboost	screen_all	0.062	NA	NA	NA	NA	Age	0.238	0.153	0.17
SL.xgboost	screen_all	0.062	NA	NA	NA	NA	Sex	0.025	0.006	0.01
SL.xgboost	screen_all	0.062	NA	NA	NA	NA	Black	0.022	0.018	0.01
SL.xgboost	screen_all	0.062	NA	NA	NA	NA	MinorityInd	0.018	0.009	0.01
SL.xgboost	screen_all	0.062	NA	NA	NA	NA	HighRiskInd	0.014	0.006	0.01
SL.xgboost	screen_all	0.062	NA	NA	NA	NA	EthnicityHispanic	0.011	0.004	0.00
SL.xgboost	screen_all	0.062	NA	NA	NA	NA	Multiracial	0.007	0.004	0.00
SL.xgboost	screen_all	0.062	NA	NA	NA	NA	Asian	0.001	0.003	0.00
SL.xgboost	screen_all	0.062	NA	NA	NA	NA	Other	0.000	0.001	0.00

Figure S3 Panel A shows the cross-validated receiver operating characteristic curve for the 2 top-performing learners, Superlearner, and the Discrete Superlearner models classifying COVID-19 outcome status in baseline SARS-CoV-2 negative per-protocol placebo recipients, with predictive performance summarized by cross-validated area under the receiver operating characteristic curve (CV-AUC). The point estimate of CV-AUC for the Superlearner was 0.612 with 95% CI 0.591, 0.633.

Figure S3 Panel B shows the receiver operating characteristic curve for the Superlearner model built from baseline SARS-CoV-2 negative per-protocol placebo recipients applied to baseline SARS-CoV-2 negative per-protocol vaccine recipients, for which the point estimate of AUC for classifying COVID-19 outcome status was 0.614.

Figure S3. (A) Cross-validated receiver operating characteristic curve for the 2 top-performing learners, Superlearner, and the Discrete Superlearner models classifying COVID-19 outcome occurrence in baseline SARS-CoV-2 negative per-protocol placebo recipients, with cross-validated area under the curve (CV-AUC) summarizing classification performance. (B) Receiver operating characteristic curve for the Superlearner upon applying the model built from placebo recipients to baseline SARS-CoV-2 negative per-protocol vaccine recipients, with AUC in parentheses summarizing classification performance.

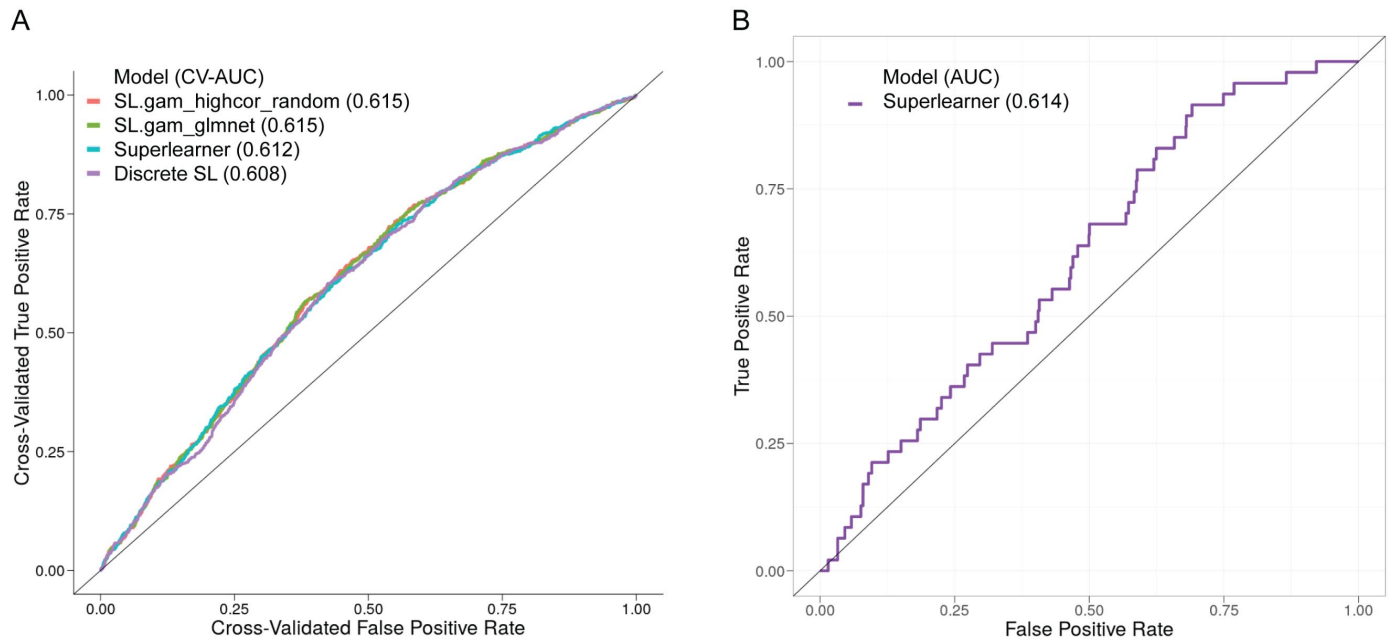


Figure S4 shows Superlearner model predicted probabilities of the COVID-19 endpoint starting 7 days post Day 57 visit by case vs. non-case status, for baseline SARS-CoV-2 negative per-protocol vaccine recipients in the case-cohort set.

Figure S4. Superlearner model predicted probabilities of the COVID-19 endpoint starting 7 days post Day 57 visit by case vs. non-case (i.e., control) status, for baseline SARS-CoV-2 negative per-protocol vaccine recipients in the case-cohort set.

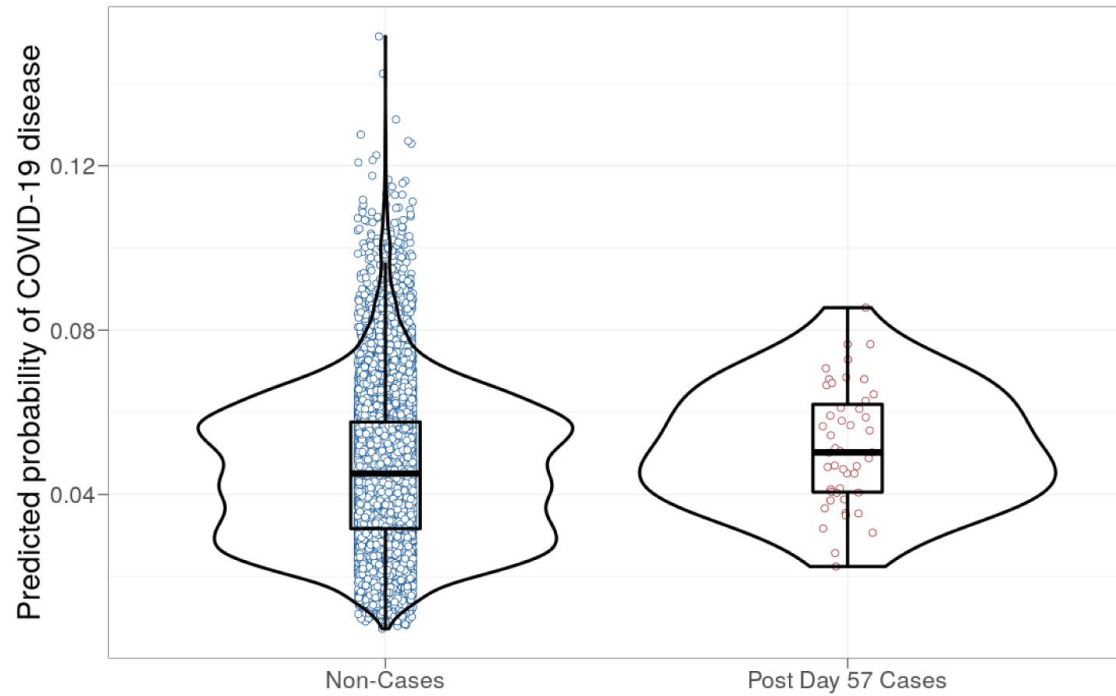


Table S6. Numbers of participants in the case-cohort set by baseline sampling strata. Case-cohort set = baseline SARS-CoV-2 negative per-protocol participants sampled into the immunogenicity subcohort or acquired the COVID-19 primary endpoint: all such participants have Day 1, 29, 57 antibody data, except for Day 29 marker correlates analyses intercurrent cases may not have Day 57 antibody data and Day 57 antibody data are not used.

Baseline Sampling Strata of SARS-CoV-2 Negative Participants							
	1	2	3	4	5	6	Total
Vaccine							
Day 29 Cases	1	6	2	8	9	20	46
Day 57 Cases	1	4	2	8	5	16	36
Non-Cases	171	168	143	146	188	189	1005
Placebo							
Day 29 Cases	9	63	35	69	99	267	542
Day 57 Cases	8	51	24	61	70	227	441
Non-Cases	22	23	20	18	24	26	133

Demographic covariate strata:

1. Age \geq 65 Minority
2. Age \geq 65 Non-Minority
3. Age < 65 At-risk Minority
4. Age < 65 At-risk Non-Minority
5. Age < 65 Not At-risk Minority
6. Age < 65 Not At-risk Non-Minority

Minority includes Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders.

Non-Minority includes all other races with observed race (Asian, Multiracial, White, Other) and observed ethnicity Not Hispanic or Latino.

Unknown includes unknown, unreported race or ethnicity.

Cases for Day 29 marker correlates analyses are baseline SARS-CoV-2 negative per-protocol vaccine recipients with the symptomatic infection COVID-19 primary endpoint diagnosed starting 7 days after the Day 29 study visit. Cases for Day 57 marker correlates analyses are baseline SARS-CoV-2 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 are baseline SARS-CoV-2 negative per-protocol participants sampled into the immunogenicity subcohort with no COVID-19 primary endpoint up to the time of data cut and no evidence of SARS-CoV-2 infection up to six days post Day 57 visit.

Table S7. Demographics and clinical characteristics of baseline SARS-CoV-2 negative per-protocol trial participants in the immunogenicity subcohort and thus have Day 1, 29, 57 antibody marker data.

Characteristics	Vaccine (N = 1010)	Placebo (N = 137)	Total (N = 1147)
Age			
Age < 65	670 (66.3%)	91 (66.4%)	761 (66.3%)
Age ≥ 65	340 (33.7%)	46 (33.6%)	386 (33.7%)
Mean (Range)	54.6 (18.0, 87.0)	53.4 (19.0, 85.0)	54.4 (18.0, 87.0)
BMI			
Mean ± SD	30.9 ± 7.6	31.3 ± 9.0	30.9 ± 7.8
Risk for Severe COVID-19			
At-risk	396 (39.2%)	57 (41.6%)	453 (39.5%)
Not at-risk	614 (60.8%)	80 (58.4%)	694 (60.5%)
Age, Risk for Severe COVID-19			
Age < 65 At-risk	291 (28.8%)	40 (29.2%)	331 (28.9%)
Age < 65 Not at-risk	379 (37.5%)	51 (37.2%)	430 (37.5%)
Age ≥ 65	340 (33.7%)	46 (33.6%)	386 (33.7%)
Sex Assigned at Birth			
Female	476 (47.1%)	63 (46.0%)	539 (47.0%)
Male	534 (52.9%)	74 (54.0%)	608 (53.0%)
Hispanic or Latino Ethnicity			
Hispanic or Latino	322 (31.9%)	44 (32.1%)	366 (31.9%)
Not Hispanic or Latino	685 (67.8%)	93 (67.9%)	778 (67.8%)
Not reported and unknown	3 (0.3%)	0 (0.0%)	3 (0.3%)
Race			
White	735 (72.8%)	99 (72.3%)	834 (72.7%)
Black or African American	182 (18.0%)	24 (17.5%)	206 (18.0%)
Asian	25 (2.5%)	6 (4.4%)	31 (2.7%)
American Indian or Alaska Native	17 (1.7%)	2 (1.5%)	19 (1.7%)
Native Hawaiian or Other Pacific Islander	5 (0.5%)	0 (0.0%)	5 (0.4%)
Multiracial	12 (1.2%)	4 (2.9%)	16 (1.4%)
Other	25 (2.5%)	2 (1.5%)	27 (2.4%)
Not reported and unknown	9 (0.9%)	0 (0.0%)	9 (0.8%)
White Non-Hispanic	468 (46.3%)	61 (44.5%)	529 (46.1%)
Communities of Color	542 (53.7%)	76 (55.5%)	618 (53.9%)

This table summarizes the baseline SARS-CoV-2 negative per-protocol immunogenicity subcohort, which was randomly sampled within 12 strata defined by enrollment characteristics: Assigned treatment arm × Baseline SARS-CoV-2 naïve vs. non-naïve status (defined by serostatus and NAAT testing) × Randomization strata (Age < 65 and at-risk, Age < 65 and not at-risk, Age ≥ 65) × Community of color (Yes/No) defined by White Non-Hispanic vs. all others (same as in Baden et al.⁵).

Figure S5. For each antibody marker, correlations of Day 29 levels with Day 57 levels in baseline SARS-CoV-2 negative per-protocol vaccine recipients in the immunogenicity subcohort. Corr = baseline variable adjusted Spearman rank correlation.

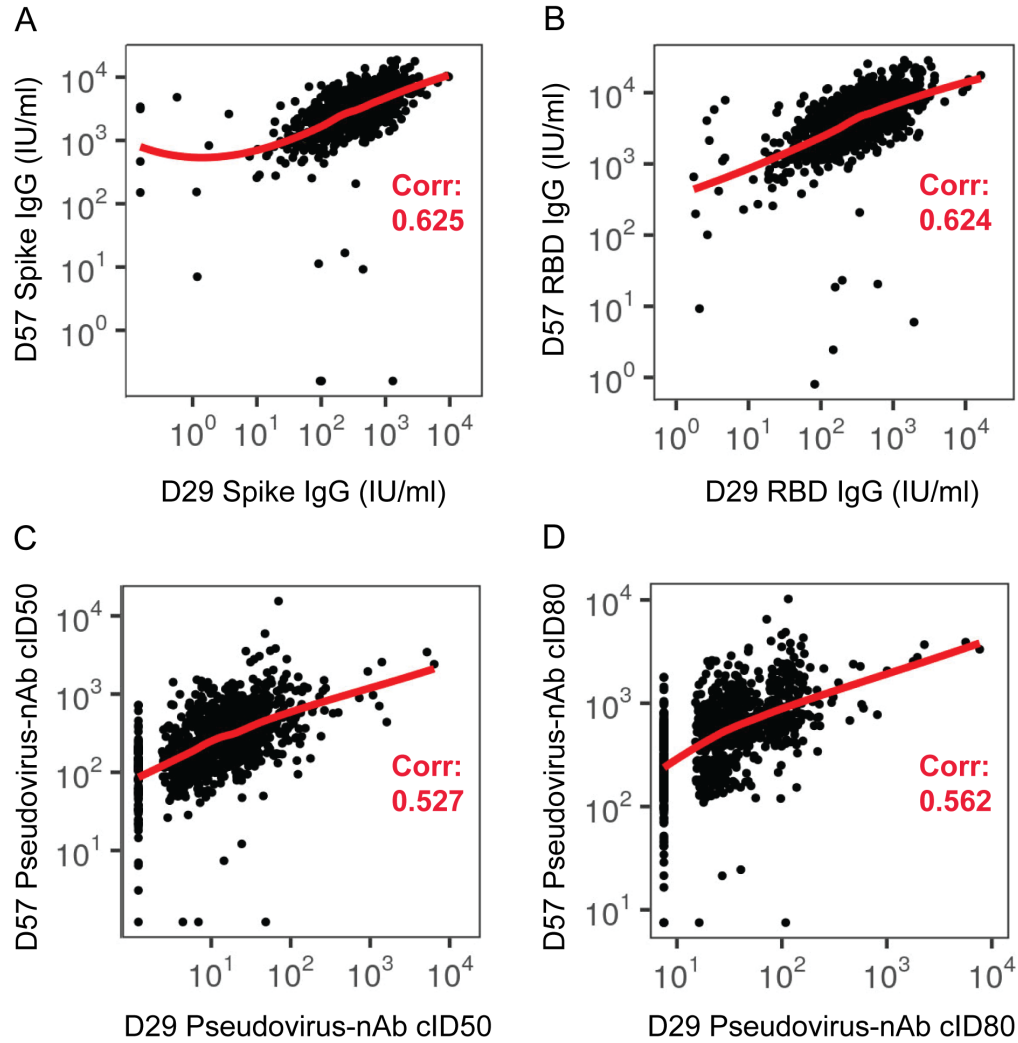


Figure S6. Correlations of Day 29 antibody markers in baseline SARS-CoV-2 negative per-protocol vaccine recipients in the immunogenicity subcohort. cID50, cID80: calibrated ID50, ID80 titer. Corr = baseline variable adjusted Spearman rank correlation.

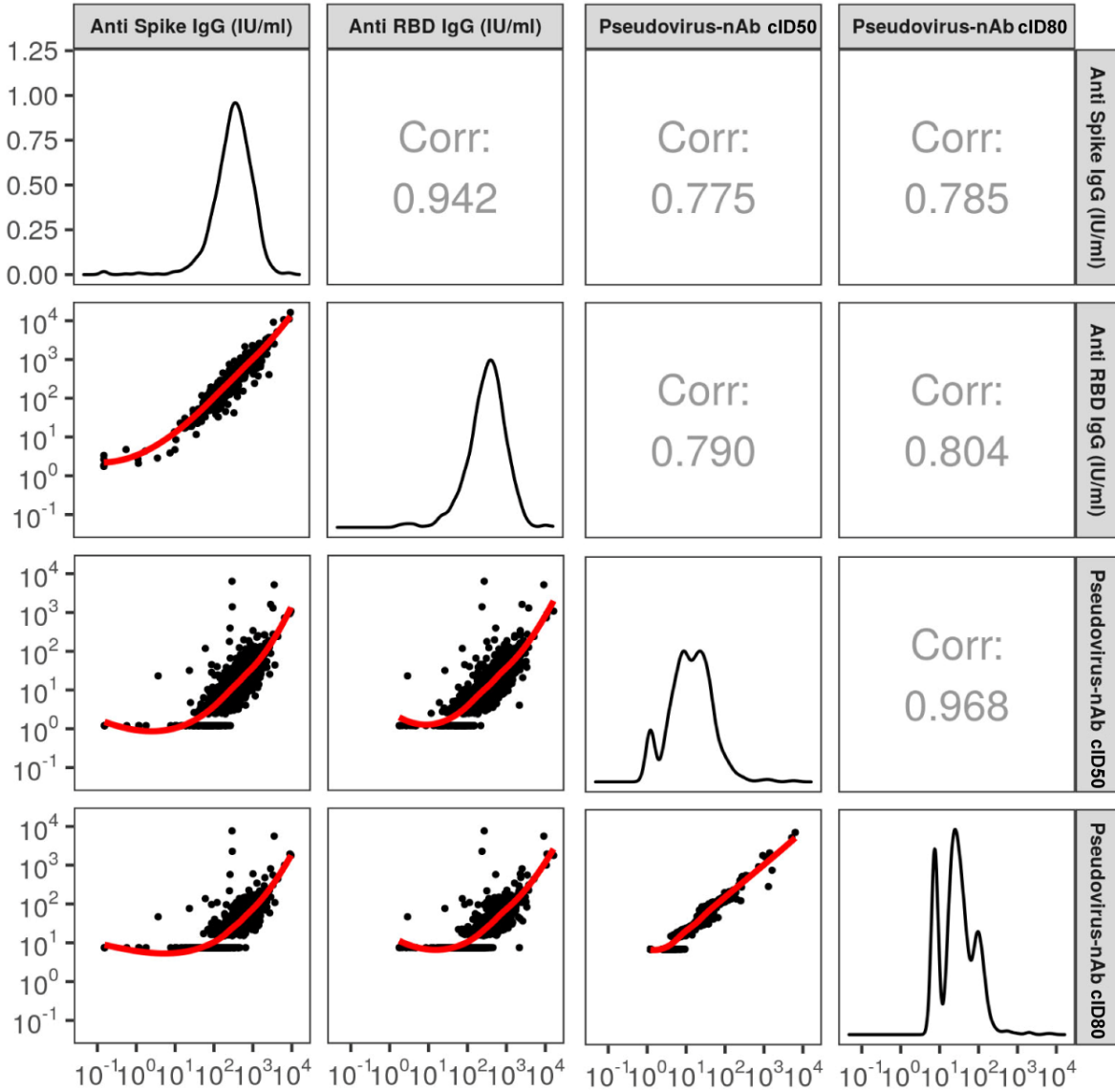


Figure S7. Correlations of Day 57 antibody markers in baseline SARS-CoV-2 negative per-protocol vaccine recipients in the immunogenicity subcohort. cID50, cID80: calibrated ID50, ID80 titer. Corr = baseline variable adjusted Spearman rank correlation.

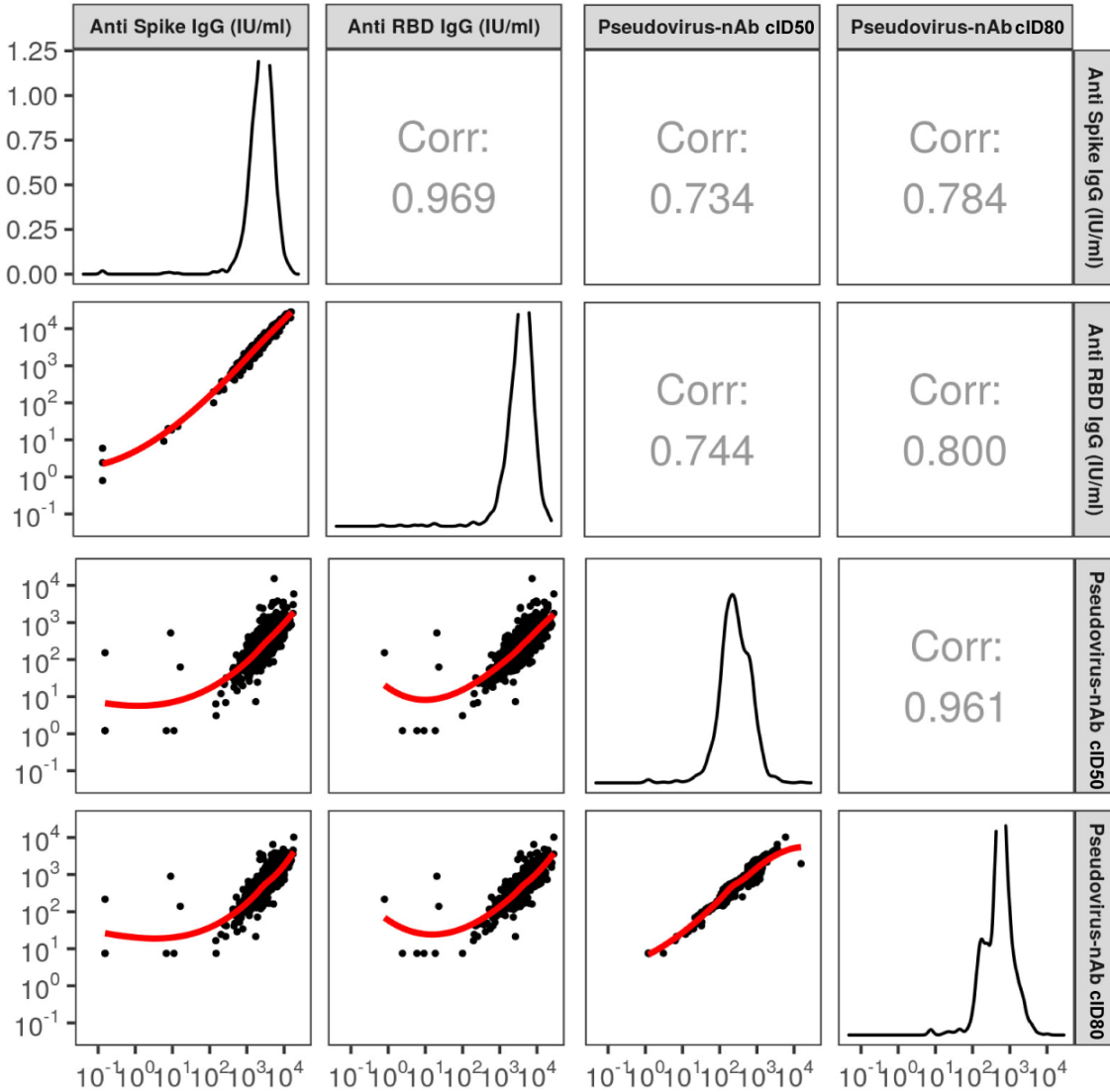


Figure S8. A) Anti-RBD IgG concentration and B) pseudovirus neutralization cID80 titer by COVID-19 outcome status. Data points are from baseline SARS-CoV-2 negative per-protocol vaccine recipients selected into the case-cohort set. Pos.Cut, Positivity cut-off. LoD, limit of detection. ULoQ, upper limit of quantitation; ULOQ = 15,368 for cID80 (above all data points). Post Day 57 cases are COVID endpoints starting 7 days post Day 57 visit; Intercurrent cases are COVID endpoints starting 7 days post Day 29 visit through 6 days post Day 57 visit.

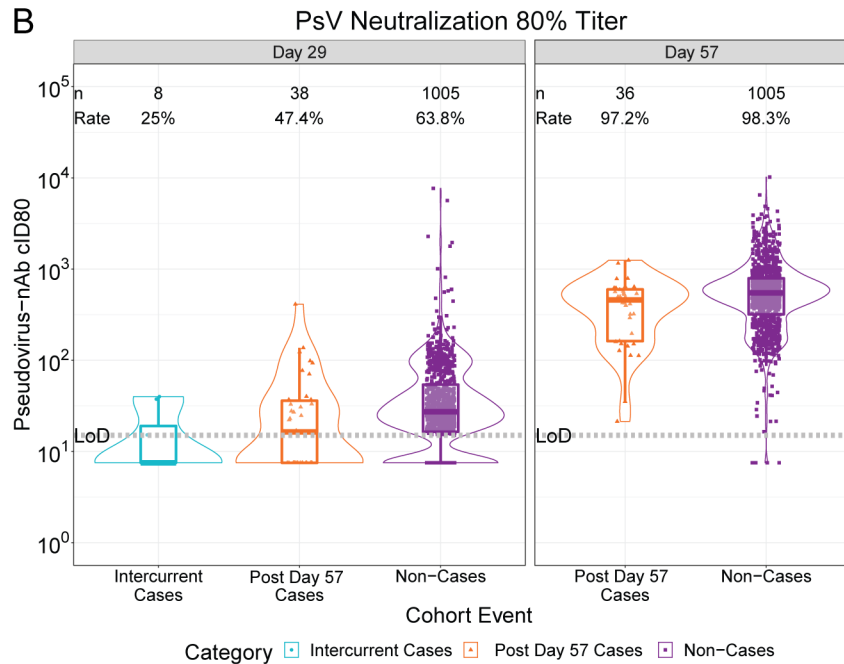
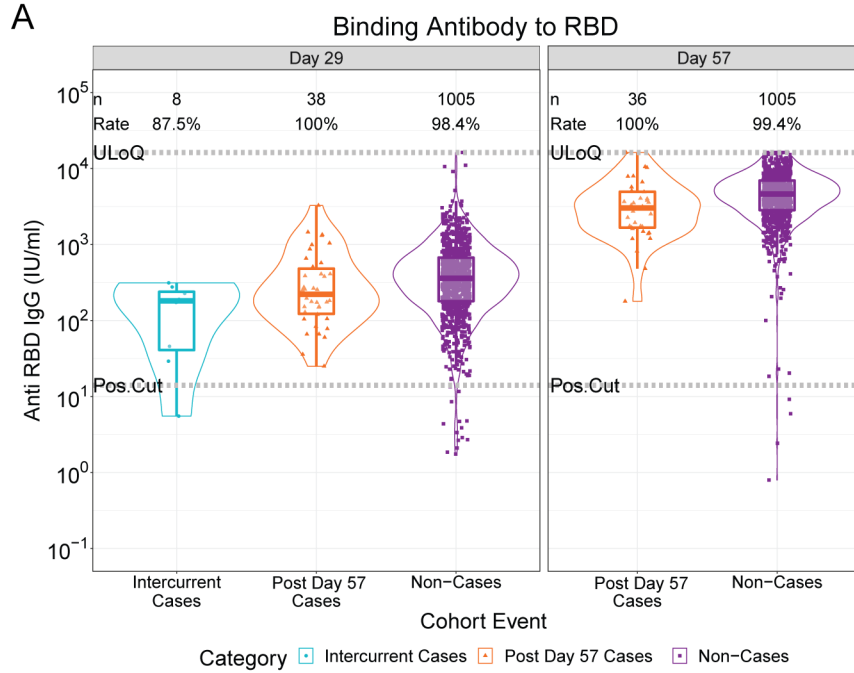


Figure S9. Marker values (Spike IgG, RBD IgG, cID50, cID80) by COVID-19 outcome status in placebo recipients. Data points are from baseline SARS-CoV-2 negative per-protocol placebo recipients selected into the case-cohort set. Positive response rates are computed with Inverse Probability Sampling (IPS) weighting. Pos.Cut, Positivity cut-off. LoD, limit of detection. ULoQ, upper limit of quantitation.

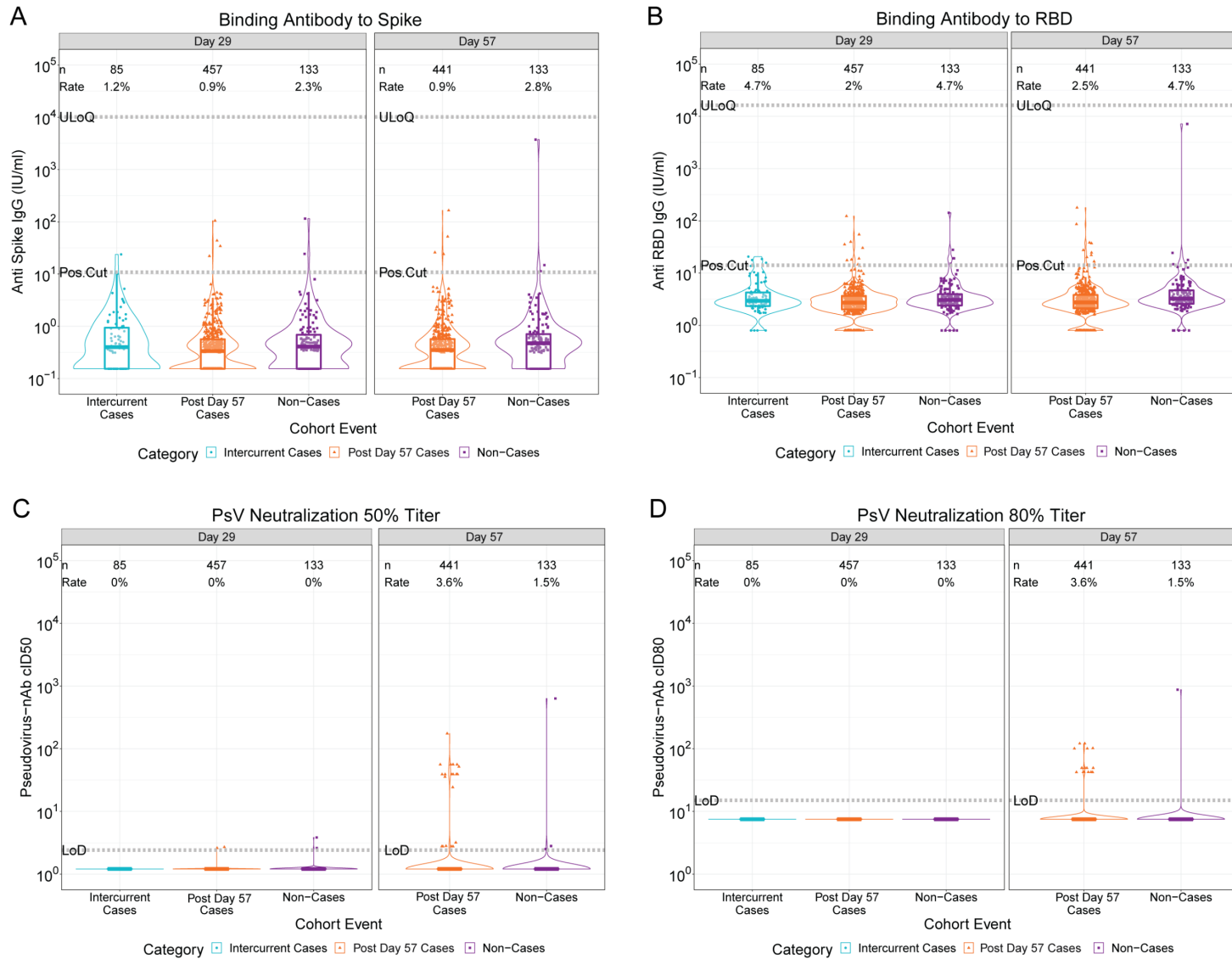


Figure S10. Day 29 marker data points from baseline SARS-CoV-2 negative per-protocol vaccine recipients selected into the case-cohort set. Non-cases are represented by orange dots, intercurrent cases by large blue circles, and post Day 57 cases by large purple squares.

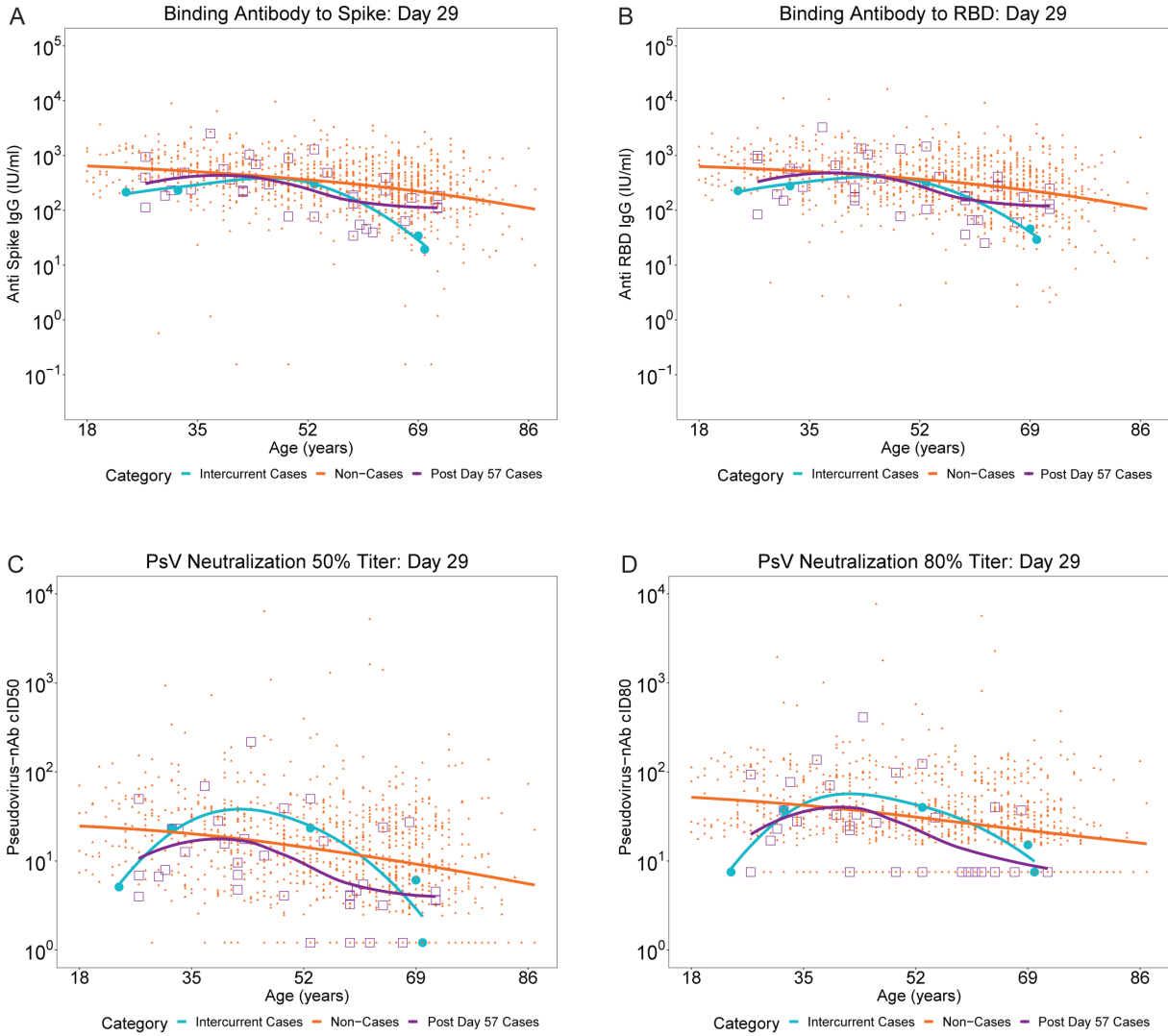


Figure S11. Day 57 marker data points from baseline SARS-CoV-2 negative per-protocol vaccine recipients selected into the case-cohort set. Non-cases are represented by orange dots, intercurrent cases by large blue circles, and post Day 57 cases by large purple squares.

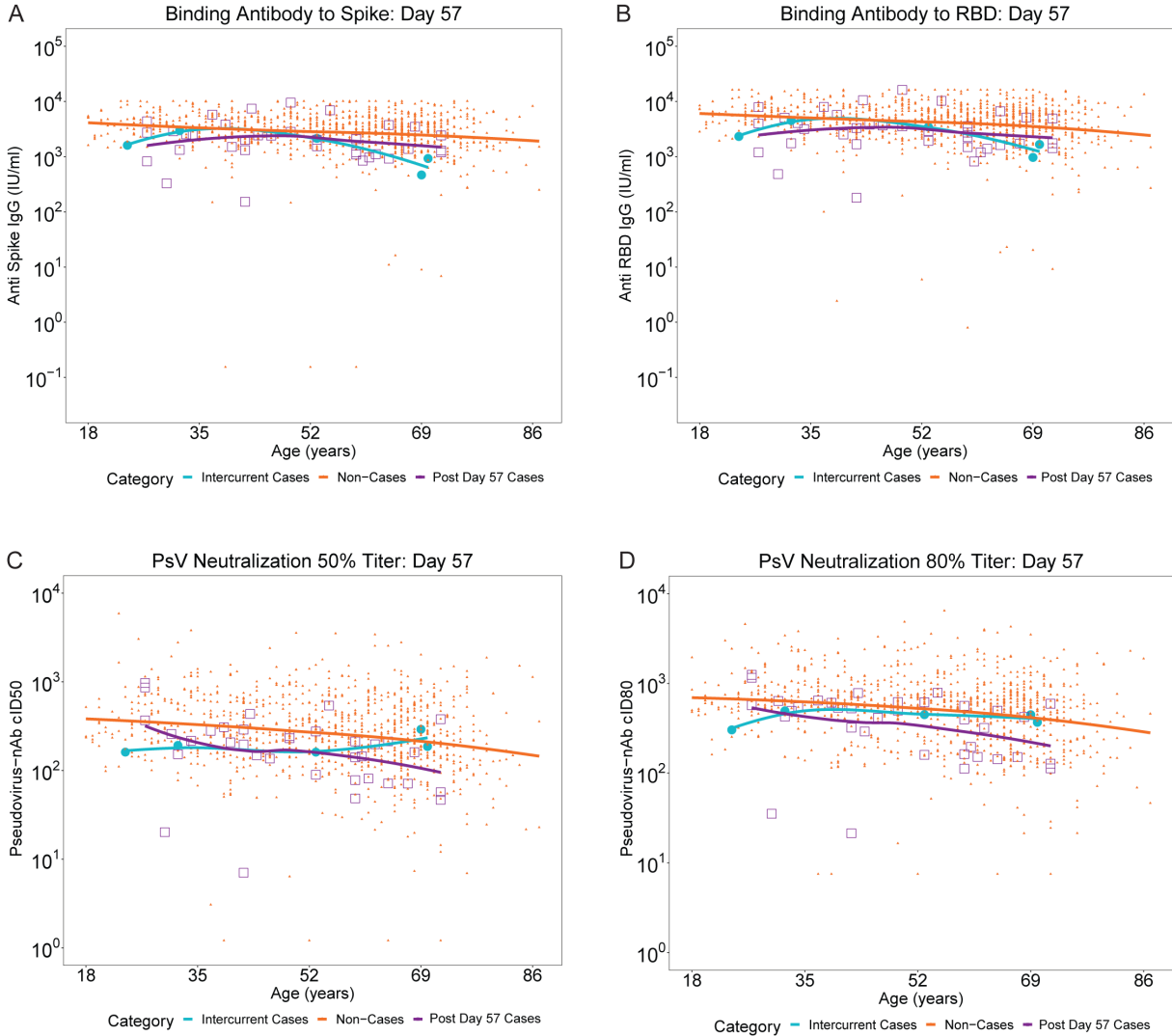


Figure S12. Inverse probability sampling (IPS)-weighted empirical reverse cumulative distribution function curves for each Day 57 marker (Spike IgG, RBD IgG, cID50, cID80) and application of the Siber (2007) method¹¹ for estimating a threshold of perfect vs. no protection. cID50, cID80: calibrated ID50, ID80 titer.

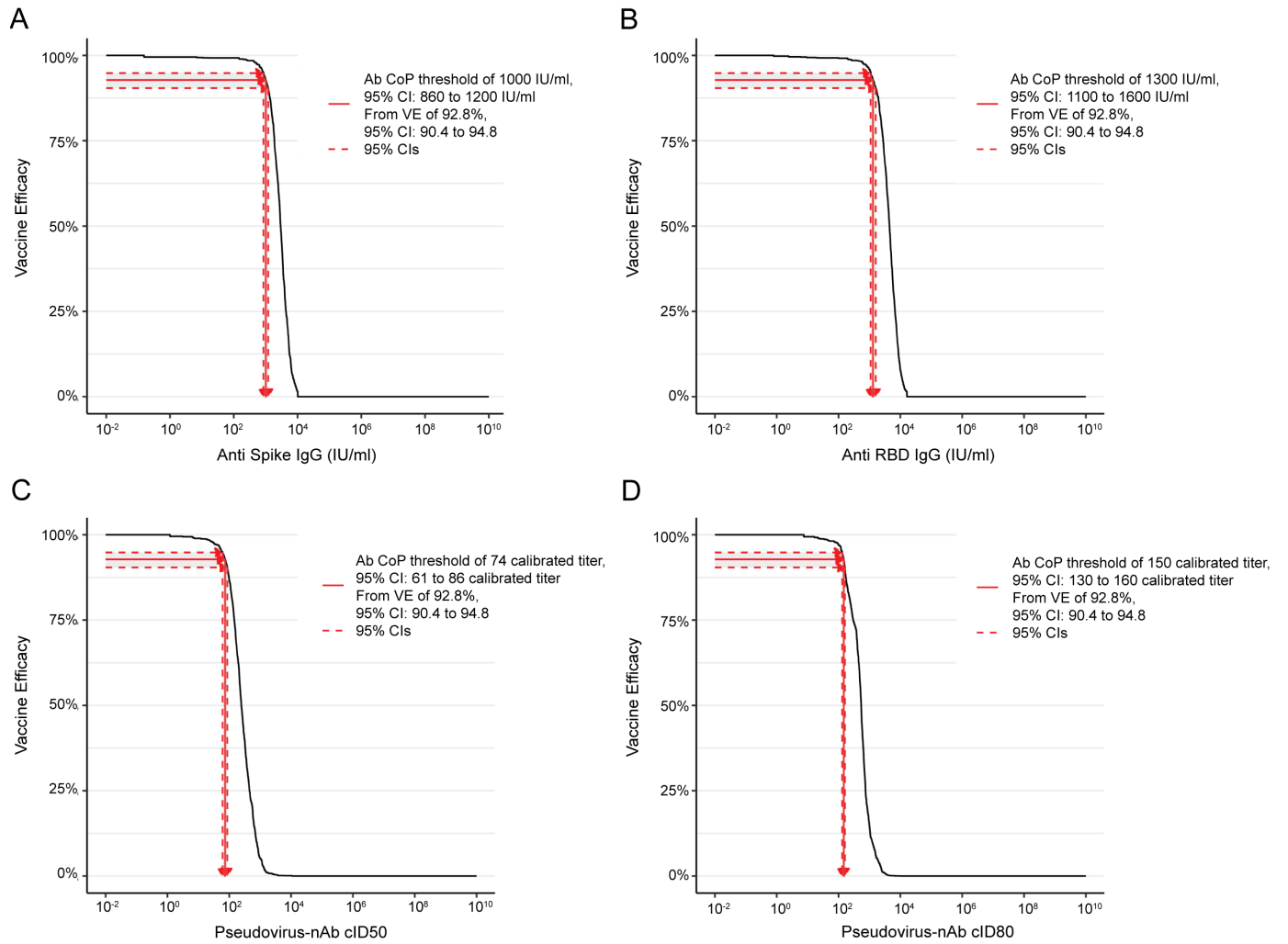


Figure S13. Inverse probability sampling (IPS)-weighted empirical reverse cumulative distribution function curves for each Day 29 marker (Spike IgG, RBD IgG, cID50, cID80) and application of the Siber (2007) method¹¹ for estimating a threshold of perfect vs. no protection. cID50, cID80: calibrated ID50, ID80 titer.

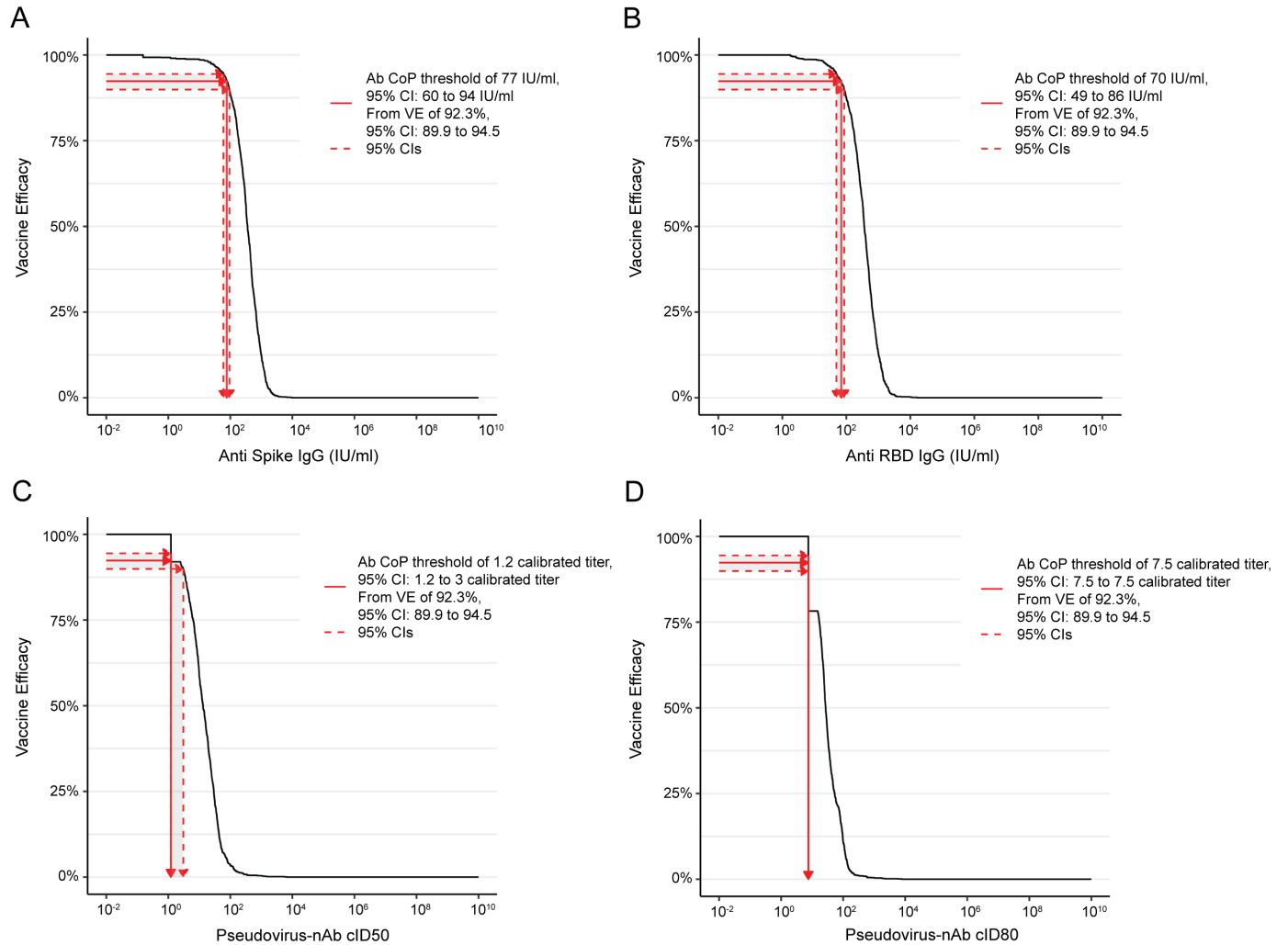


Figure S14. Day 29 and Day 57 antibody markers (Spike IgG, RBD IgG, cID50, cID80) vs. number of days from Day 29 visit until COVID-19 primary endpoint diagnosis for per-protocol baseline SARS-CoV-2 negative vaccine recipient breakthrough cases. Blue circles are Day 29 marker values for Intercurrent Cases. Orange triangles are Day 29, Day 57 marker values for Post Day 57 cases, with paired marker values from the same participant joined by a vertical line segment, with Day 57 marker value always the top triangle. cID50, cID80: calibrated ID50, ID80 titer.

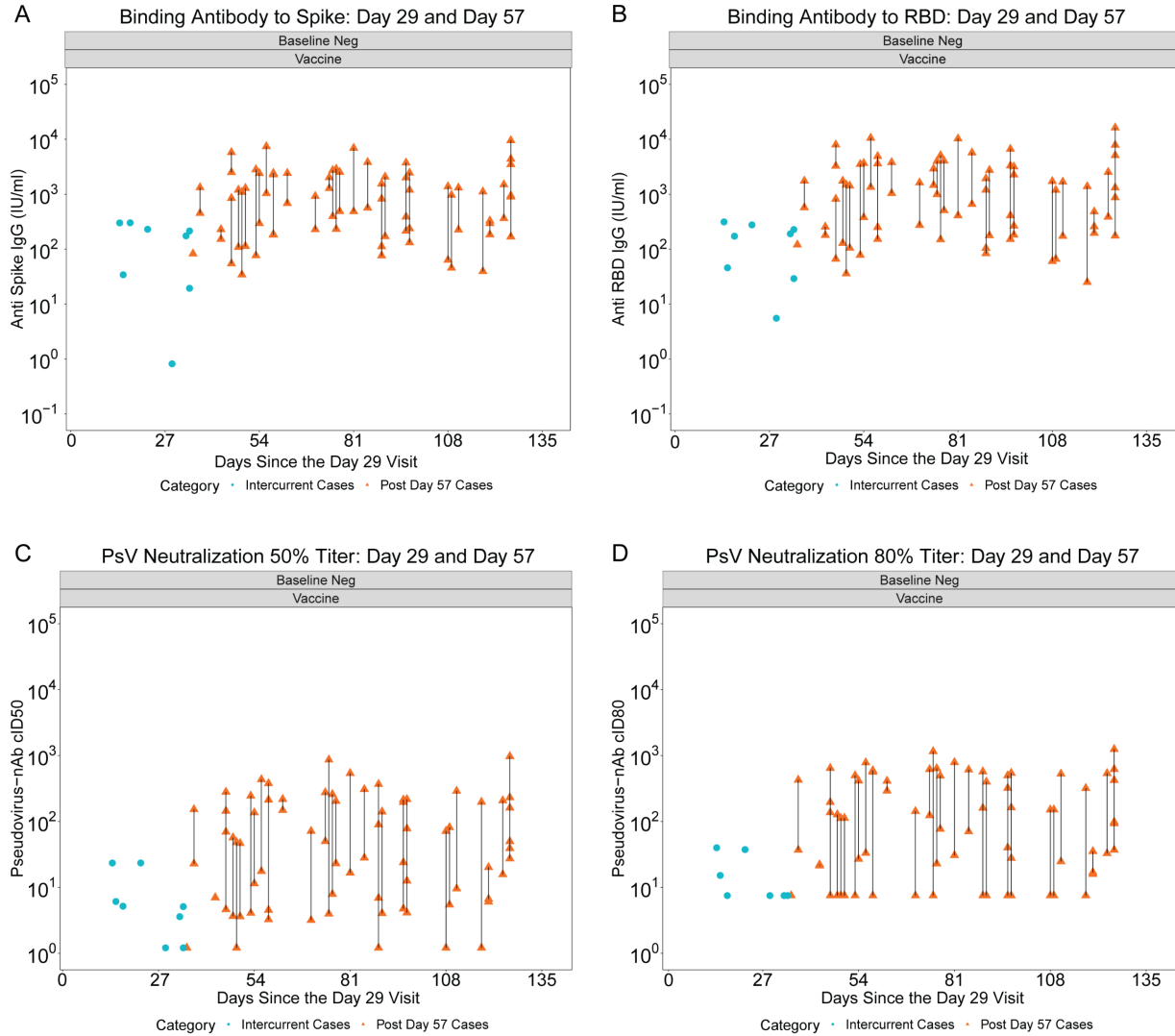
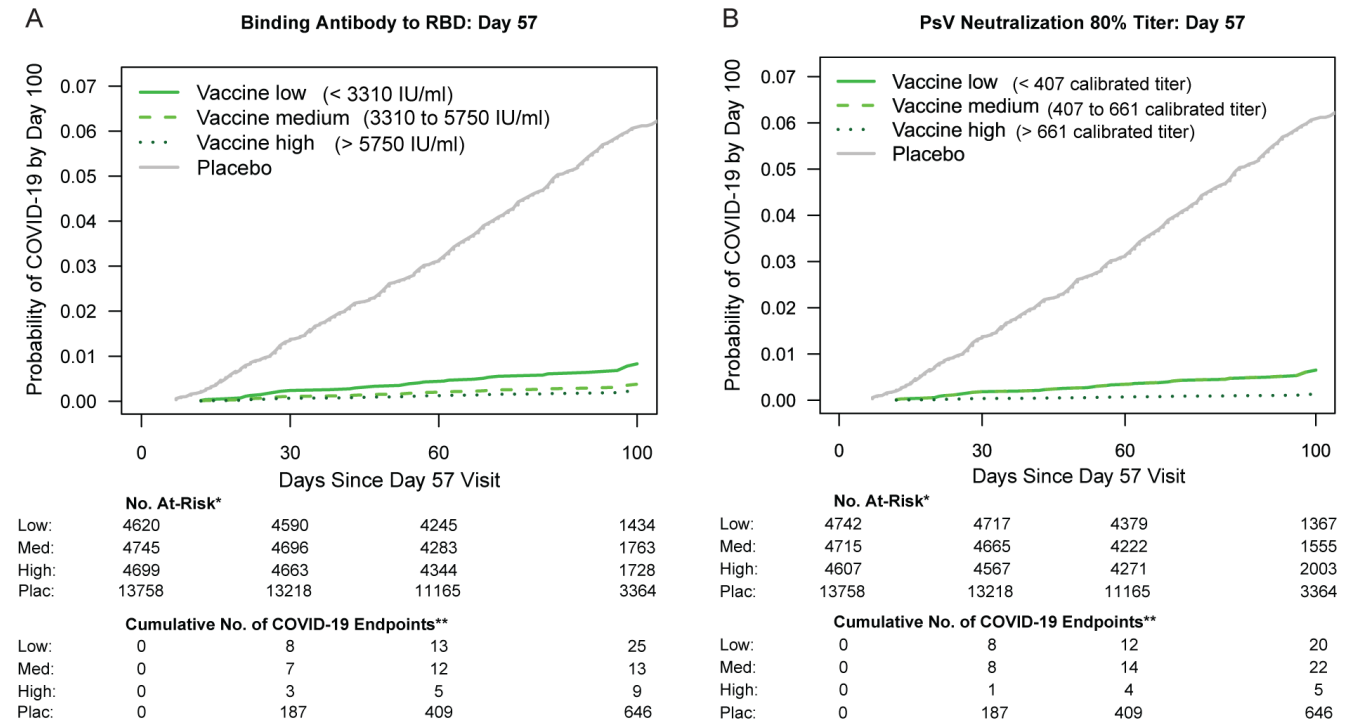
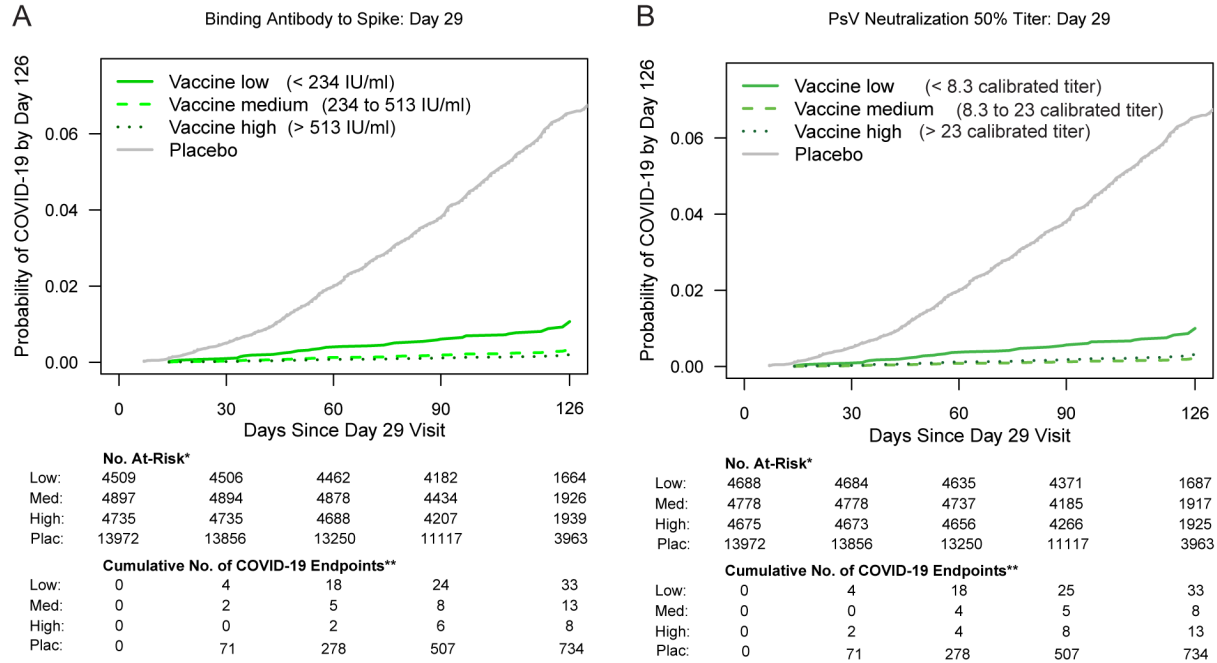


Figure S15: Covariate-adjusted cumulative incidence of COVID-19 by Low, Medium, High tertile of Day 57 IgG concentration or pseudovirus neutralization titer. (A) Anti-RBD IgG concentration; (B) cID80 titer.



*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.

Figure S16. Covariate-adjusted cumulative incidence of COVID-19 by Low, Medium, High tertile of Day 29 IgG concentration or pseudovirus neutralization titer. (A) Anti-Spike IgG concentration; (B) cID50 titer; (C) IgG (Spike, RBD) and (cID50, cID80). The overall p-value is from a generalized Wald test for whether the COVID-19 hazard differed across Low, Medium, and High subgroups.



*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.	95% CI	P-value (2-sided)	Overall P-value	Overall q-value [†]	Overall FWER
Anti Spike IgG (IU/ml)	Low	33/4,509	0.0073	1	N/A	N/A	<0.001	<0.001	<0.001
	Medium	13/4,897	0.0027	0.31	(0.15,0.65)	0.002			
	High	8/4,735	0.0017	0.19	(0.08,0.44)	<0.001			
Anti RBD IgG (IU/ml)	Low	30/4,559	0.0066	1	N/A	N/A	0.002	0.004	0.003
	Medium	14/4,803	0.0029	0.40	(0.19,0.84)	0.016			
	High	11/4,779	0.0023	0.28	(0.13,0.60)	0.001			
Pseudovirus-nAb cID50	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			
Pseudovirus-nAb cID80	Low	31/4,709	0.0066	1	N/A	N/A	0.001	0.003	0.002
	Medium	16/4,827	0.0033	0.44	(0.21,0.90)	0.025			
	High	8/4,604	0.0017	0.22	(0.09,0.51)	<0.001			
Placebo		734/13,972	0.0525						

Baseline covariates adjusted for: baseline risk score, at risk or not, community of color or not. Maximum failure event time 126 days post Day 29 visit.

[†]Tertiles:

Spike IgG: Low is < 234 IU/ml, Medium is 234 to 513 IU/ml, High is > 513 IU/ml.

RBD IgG: Low is < 234 IU/ml, Medium is 234 to 537 IU/ml, High is > 537 IU/ml.

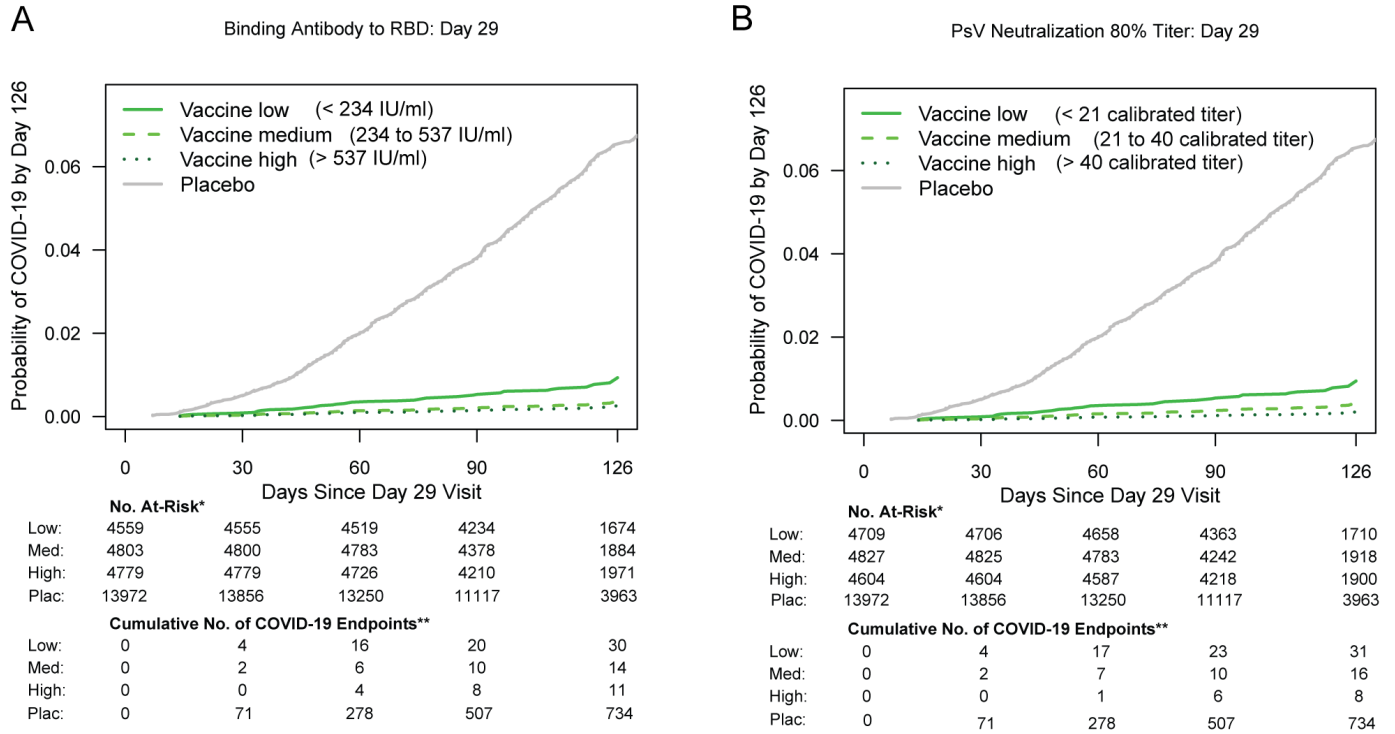
ID50: Low is < 8.3, Medium is 8.3 to 23, High is > 23 (all in calibrated titer).

ID80: Low is < 21, Medium is 21 to 40, High is > 40 (all in calibrated titer).

[§]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; No. cases = estimated number of this cohort with an observed COVID-19 endpoint.

[†]q-value and FWER (family-wide error rate) are computed over the set of p-values both for quantitative markers and categorical markers using the Westfall and Young permutation method (10000 replicates).

Figure S17: Covariate-adjusted cumulative incidence of COVID-19 by Low, Medium, High tertile of Day 29 IgG concentration or pseudovirus neutralization titer. (A) Anti-RBD IgG concentration; (B) cID80 titer.



*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.

Figure S18. Covariate-adjusted hazard ratios of COVID-19 per 10-fold increase in each Day 29 antibody marker in baseline SARS-CoV-2 negative per-protocol vaccine recipients overall and in subgroups. (A) Inferences for IgG (Spike, RBD) and (cID50, cID80); (B) Forest plots for anti-Spike IgG concentration; (C) Forest plots for cID50.

A

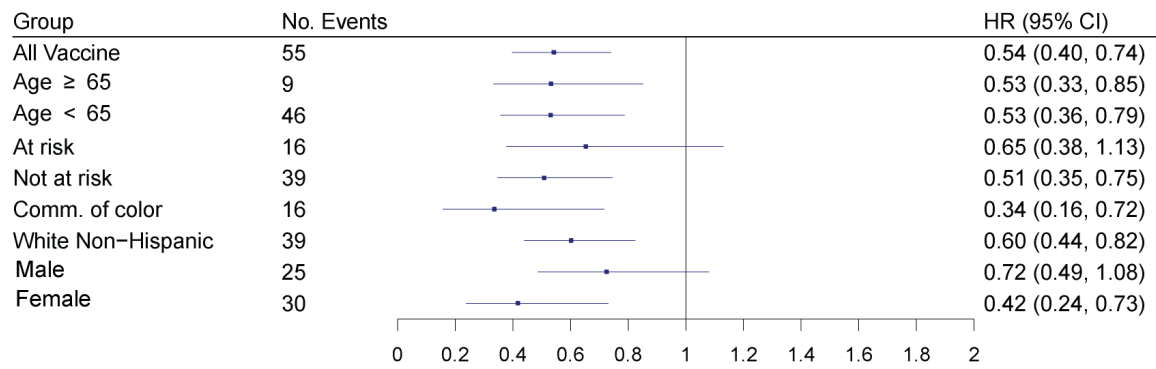
COVE Immunologic Marker	No. cases / No. at-risk*	HR per 10-fold incr. Pt. Est.	95% CI	P-value (2-sided)	q-value **	FWER
Anti Spike IgG (IU/ml)	55/14,141	0.54	(0.40,0.74)	<0.001	<0.001	<0.001
Anti RBD IgG (IU/ml)	55/14,141	0.46	(0.30,0.70)	<0.001	0.001	0.001
Pseudovirus-nAb cID50	55/14,141	0.33	(0.17,0.65)	0.001	0.003	0.002
Pseudovirus-nAb cID80	55/14,141	0.19	(0.07,0.56)	0.003	0.004	0.003

*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; No. cases = estimated number of this cohort with an observed COVID-19 endpoint starting 7 days post Day 29 visit.

** q-value and FWER (family-wide error rate) are computed over the set of p-values both for quantitative markers and categorical markers using the Westfall and Young permutation method (10000 replicates).

B

Binding Antibody to Spike: Day 29



C

PsV Neutralization 50% Titer: Day 29

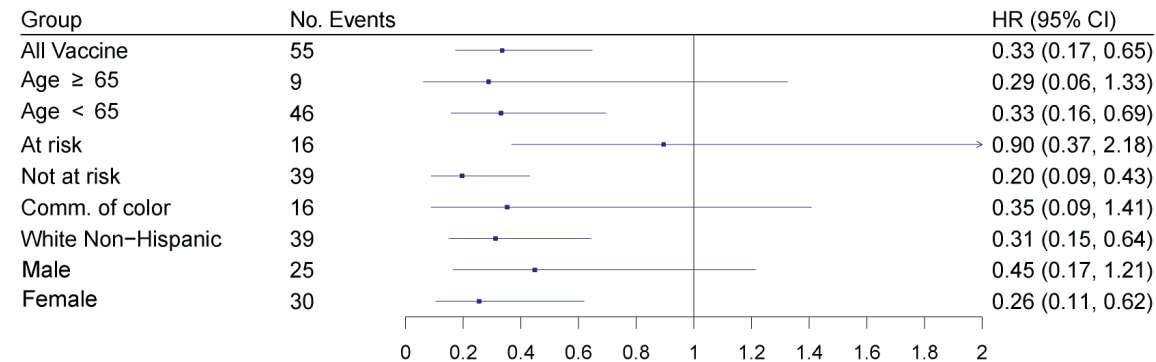


Figure S19. Covariate-adjusted risk of COVID-19 by the level of each Day 57 marker (Spike IgG, RBD IgG, cID50, cID80), estimated with a generalized additive model.

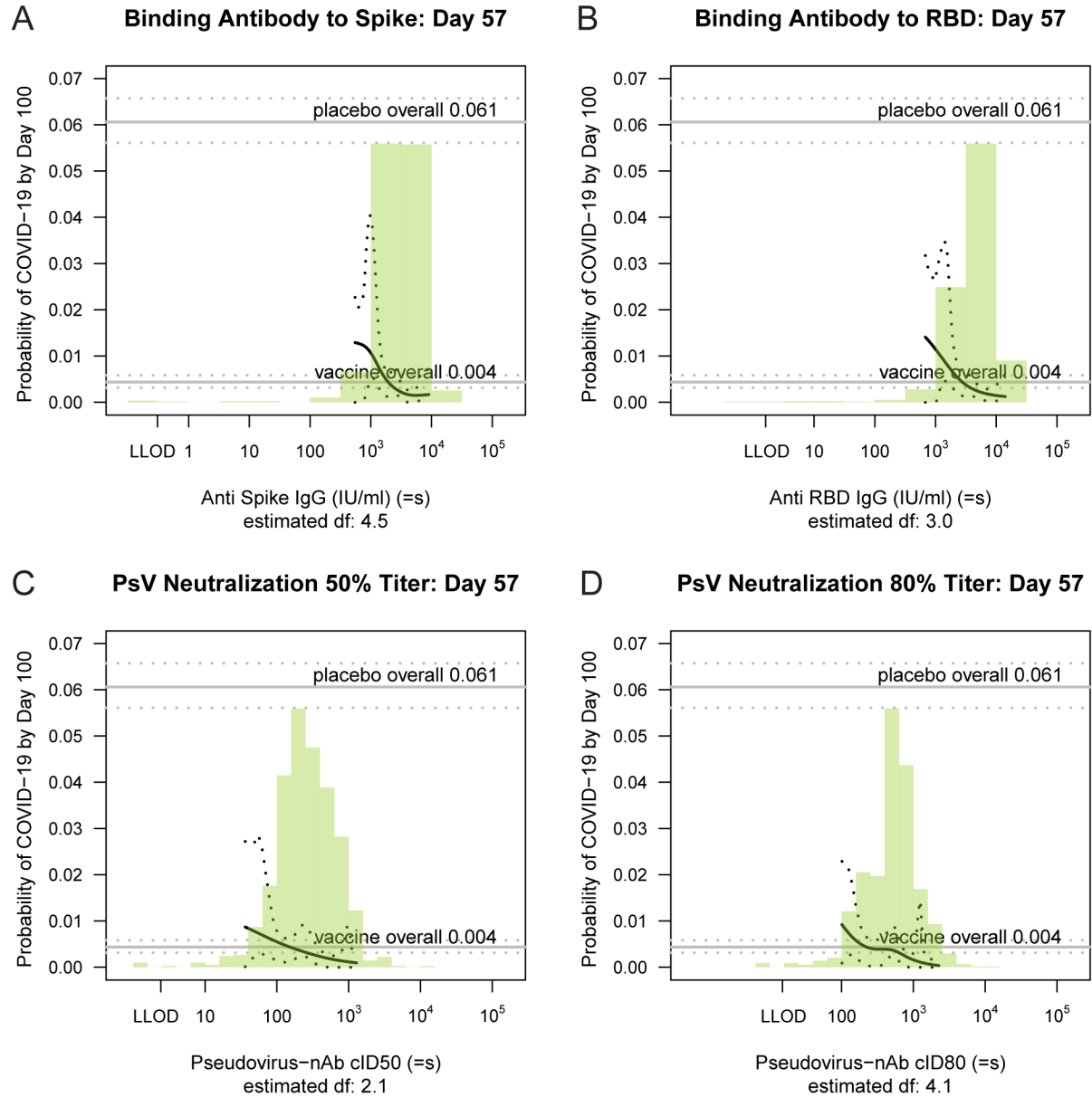


Figure S20. Covariate-adjusted risk of COVID-19 by the level of each Day 29 marker (Spike IgG, RBD IgG, cID50, cID80), estimated with a generalized additive model.

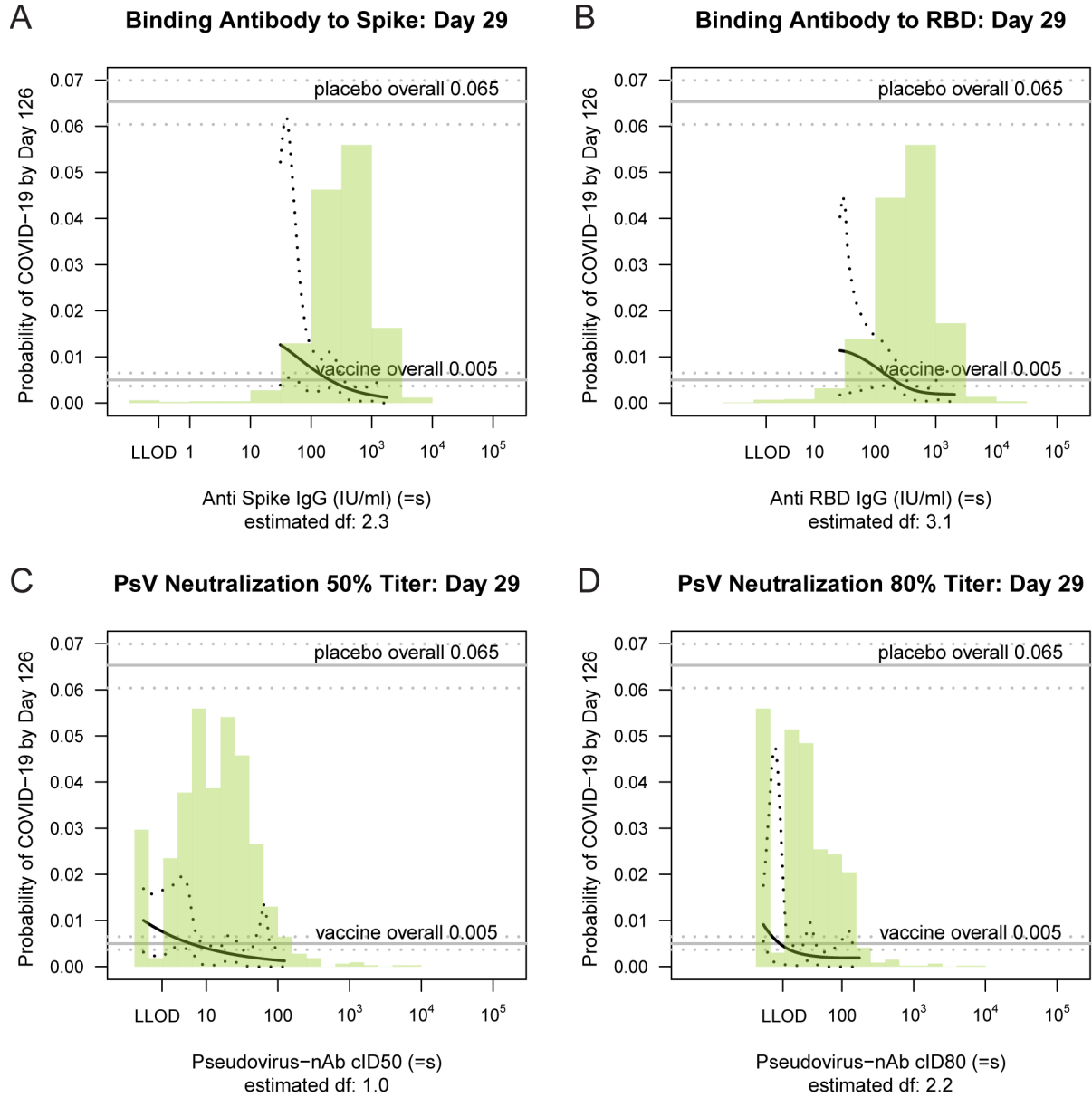
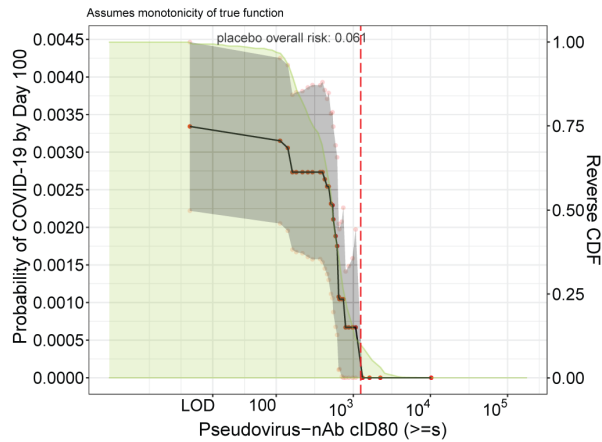
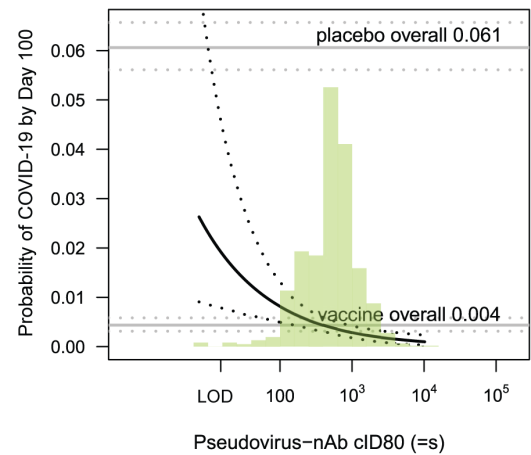


Figure S21. (A) Covariate-adjusted risk of COVID-19 by subgroups defined by Day 57 cID80 level above a threshold, with reverse cumulative distribution function of Day 57 cID80 level overlaid in green; (B) Covariate-adjusted cumulative incidence of COVID-19 by 100 days post Day 57 by Day 57 cID80 level; (C) Vaccine efficacy by Day 57 cID80 level. In (A), the gray shaded area is pointwise 95% confidence intervals (CIs). The upper boundary of the green shaded area is the estimate of the reverse cumulative distribution function of the marker in baseline SARS-CoV-2 negative per-protocol vaccine recipients. In (B), the dotted lines indicate bootstrap point-wise 95% CIs. In (C), vaccine efficacy estimates were obtained using the method of Gilbert, Fong, and Carone.¹² In (B) and (C), the green histograms are an estimate of the density of marker level in baseline negative per-protocol vaccine recipients. LOD, limit of detection. cID80: ID80 nAb titer calibrated to the WHO International Standard.

A PsV Neutralization 80% Titer: Day 57



B PsV Neutralization 80% Titer: Day 57



C PsV Neutralization 80% Titer: Day 57

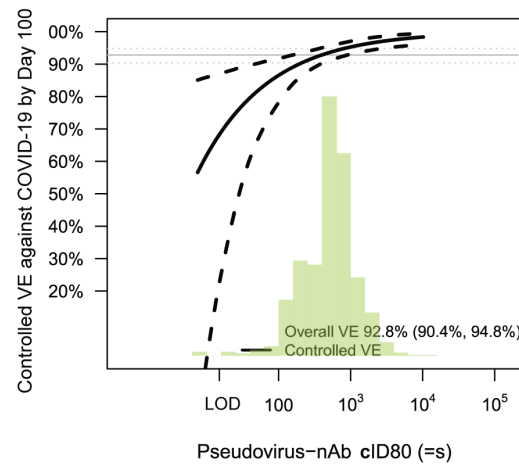


Figure S22. (A) Covariate-adjusted risk of COVID-19 by subgroups defined by Day 57 Anti-Spike IgG level above a threshold, with reverse cumulative distribution function of Day 57 Anti-Spike IgG level overlaid in green; (B) Covariate-adjusted cumulative incidence of COVID-19 by 100 days post Day 57 by Day 57 Anti-Spike IgG level; (C) Controlled vaccine efficacy by Day 57 Anti-Spike IgG level. In (A), the gray shaded area is pointwise 95% confidence intervals (CIs). The upper boundary of the green shaded area is the estimate of the reverse cumulative distribution function of the marker in baseline SARS-CoV-2 negative per-protocol vaccine recipients. In (B), the dotted lines indicate bootstrap point-wise 95% CIs. In (C), vaccine efficacy estimates were obtained using the method of Gilbert, Fong, and Carone.¹² In (B) and (C), the green histograms are an estimate of the density of marker level in baseline negative per-protocol vaccine recipients. LOD, limit of detection.

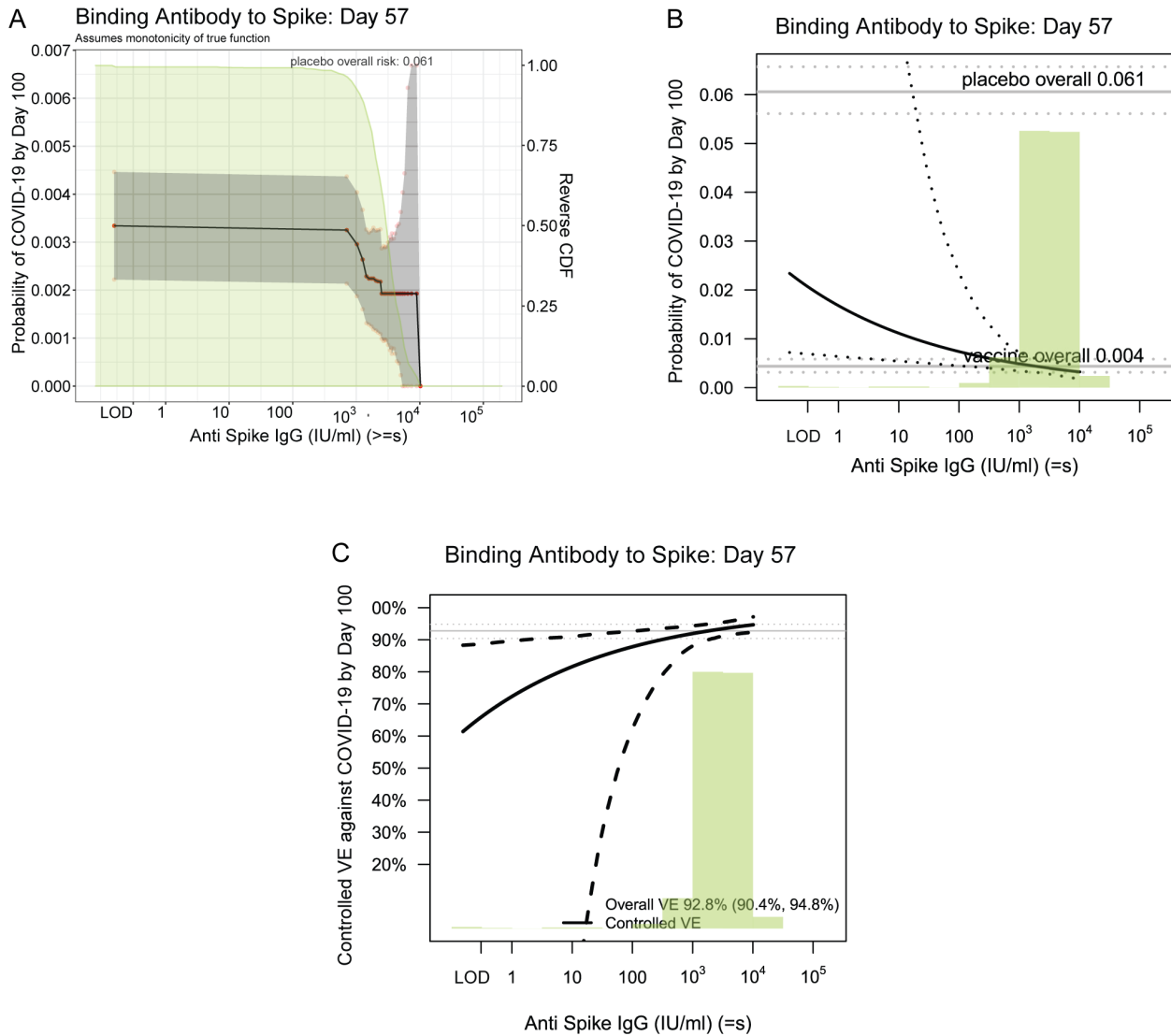


Figure S23. (A) Covariate-adjusted risk of COVID-19 by subgroups defined by Day 57 Anti-RBD IgG level above a threshold, with reverse cumulative distribution function of Day 57 Anti-RBD IgG level overlaid in green; (B) Covariate-adjusted cumulative incidence of COVID-19 by 100 days post Day 57 by Day 57 Anti-RBD IgG level; (C) Controlled vaccine efficacy by Day 57 Anti-RBD IgG level. In (A), the gray shaded area is pointwise 95% confidence intervals (CIs). The upper boundary of the green shaded area is the estimate of the reverse cumulative distribution function of the marker in baseline SARS-CoV-2 negative per-protocol vaccine recipients. In (B), the dotted lines indicate bootstrap point-wise 95% CIs. In (C), vaccine efficacy estimates were obtained using the method of Gilbert, Fong, and Carone.¹² In (B) and (C), the green histograms are an estimate of the density of marker level in baseline negative per-protocol vaccine recipients. LOD, limit of detection.

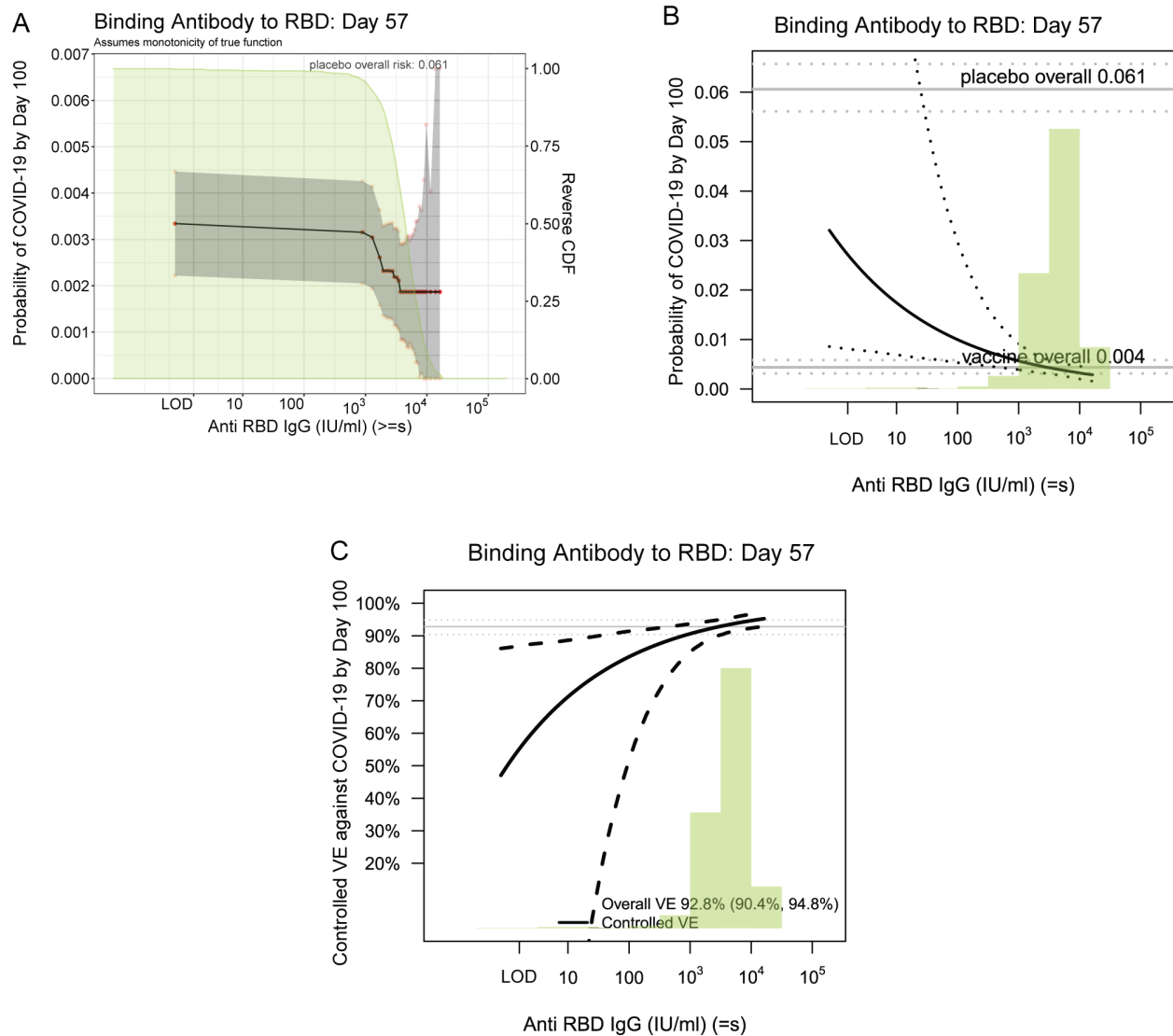


Figure S24. (A) Covariate-adjusted risk of COVID-19 by subgroups defined by Day 29 cID50 level above a threshold, with reverse cumulative distribution function of Day 29 cID50 level overlaid in green; (B) Covariate-adjusted cumulative incidence of COVID-19 by 126 days post Day 29 by Day 29 cID50 level; (C) Controlled vaccine efficacy by Day 29 cID50 level. In (A), the gray shaded area is pointwise 95% confidence intervals (CIs). The upper boundary of the green shaded area is the estimate of the reverse cumulative distribution function of the marker in baseline SARS-CoV-2 negative per-protocol vaccine recipients. In (B), the dotted lines indicate bootstrap point-wise 95% CIs. In (C), vaccine efficacy estimates were obtained using the method of Gilbert, Fong, and Carone.¹² In (B) and (C), the green histograms are an estimate of the density of marker level in baseline negative per-protocol vaccine recipients. LOD, limit of detection. cID50: ID50 nAb titer calibrated to the WHO International Standard.

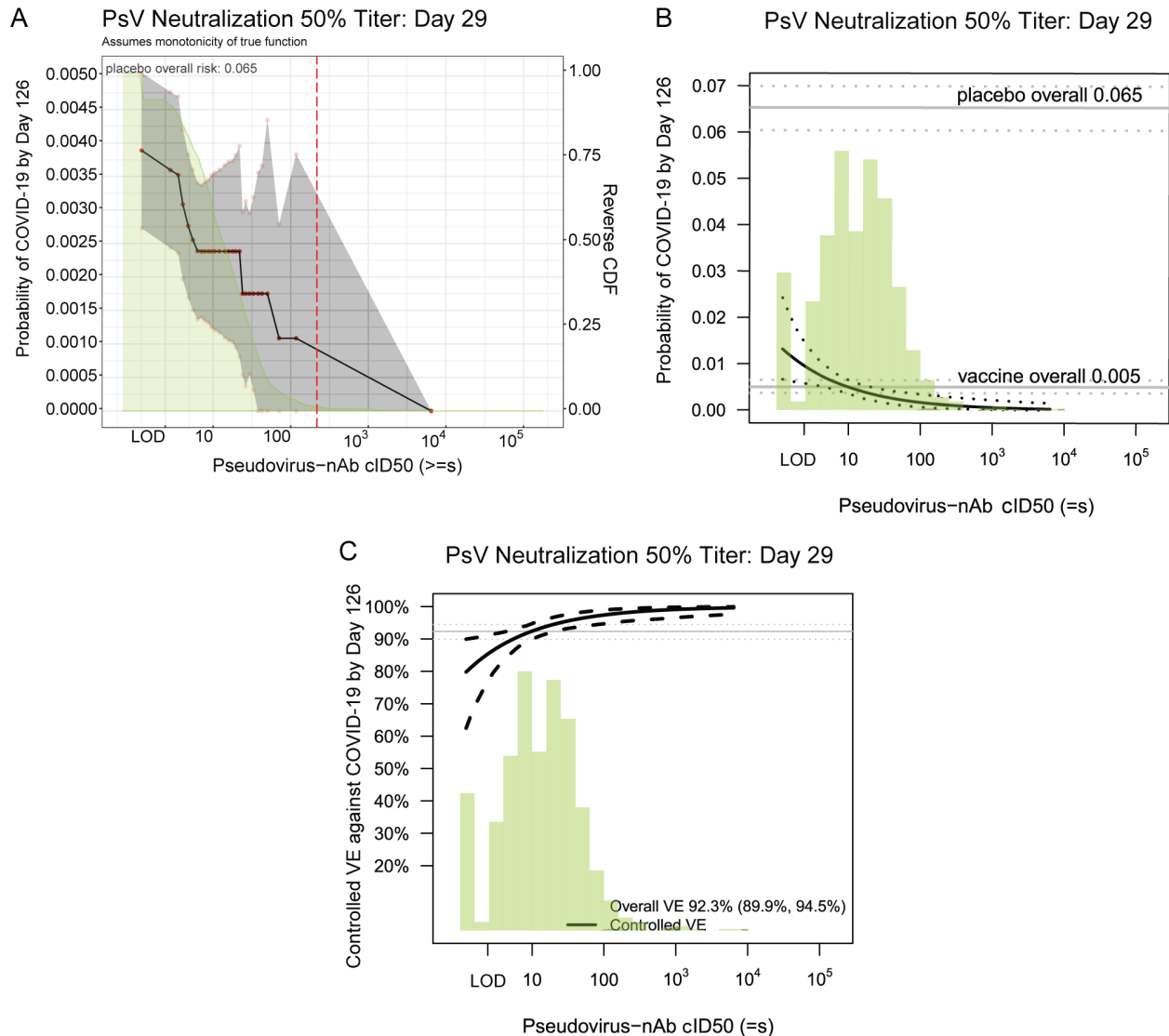


Figure S25. (A) Covariate-adjusted risk of COVID-19 by subgroups defined by Day 29 cID80 level above a threshold, with reverse cumulative distribution function of Day 29 cID80 level overlaid in green; (B) Covariate-adjusted cumulative incidence of COVID-19 by 126 days post Day 29 by Day 29 cID80 level; (C) Controlled vaccine efficacy by Day 29 cID80 level. In (A), the gray shaded area is pointwise 95% confidence intervals (CIs). The upper boundary of the green shaded area is the estimate of the reverse cumulative distribution function of the marker in baseline SARS-CoV-2 negative per-protocol vaccine recipients. In (B), the dotted lines indicate bootstrap point-wise 95% CIs. In (C), vaccine efficacy estimates were obtained using the method of Gilbert, Fong, and Carone.¹² In (B) and (C), the green histograms are an estimate of the density of marker level in baseline negative per-protocol vaccine recipients. LOD, limit of detection. cID80: ID80 nAb titer calibrated to the WHO International Standard.

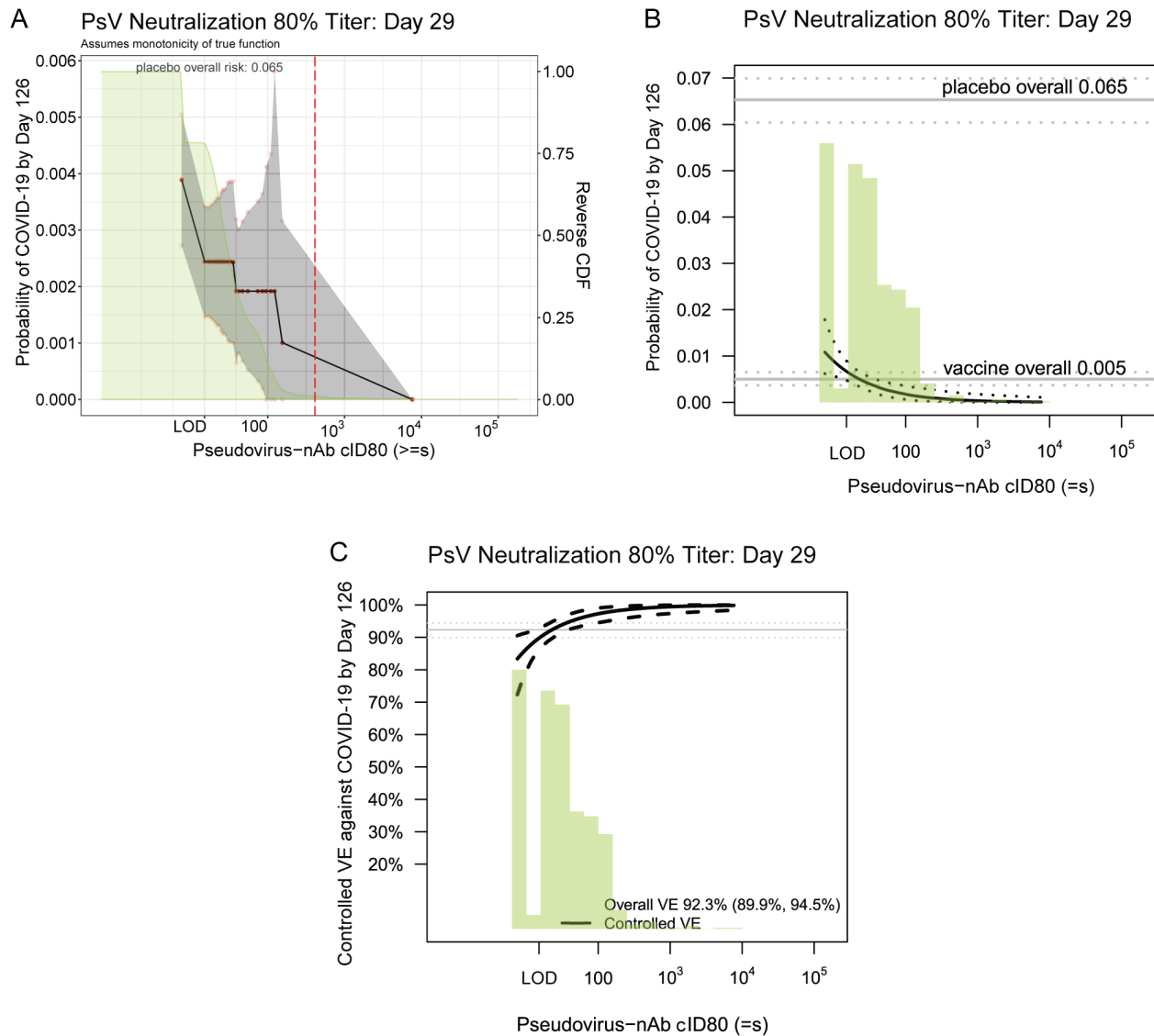


Figure S26. (A) Covariate-adjusted risk of COVID-19 by subgroups defined by Day 29 Anti-Spike IgG level above a threshold, with reverse cumulative distribution function of Day 29 Anti-Spike IgG level overlaid in green; (B) Covariate-adjusted cumulative incidence of COVID-19 by 126 days post Day 29 by Day 29 Anti-Spike IgG level; (C) Controlled vaccine efficacy by Day 29 Anti-Spike IgG level. In (A), the gray shaded area is pointwise 95% confidence intervals (CIs). The upper boundary of the green shaded area is the estimate of the reverse cumulative distribution function of the marker in baseline SARS-CoV-2 negative per-protocol vaccine recipients. In (B), the dotted lines indicate bootstrap point-wise 95% CIs. In (C), vaccine efficacy estimates were obtained using the method of Gilbert, Fong, and Carone.¹² In (B) and (C), the green histograms are an estimate of the density of marker level in baseline negative per-protocol vaccine recipients. LOD, limit of detection.

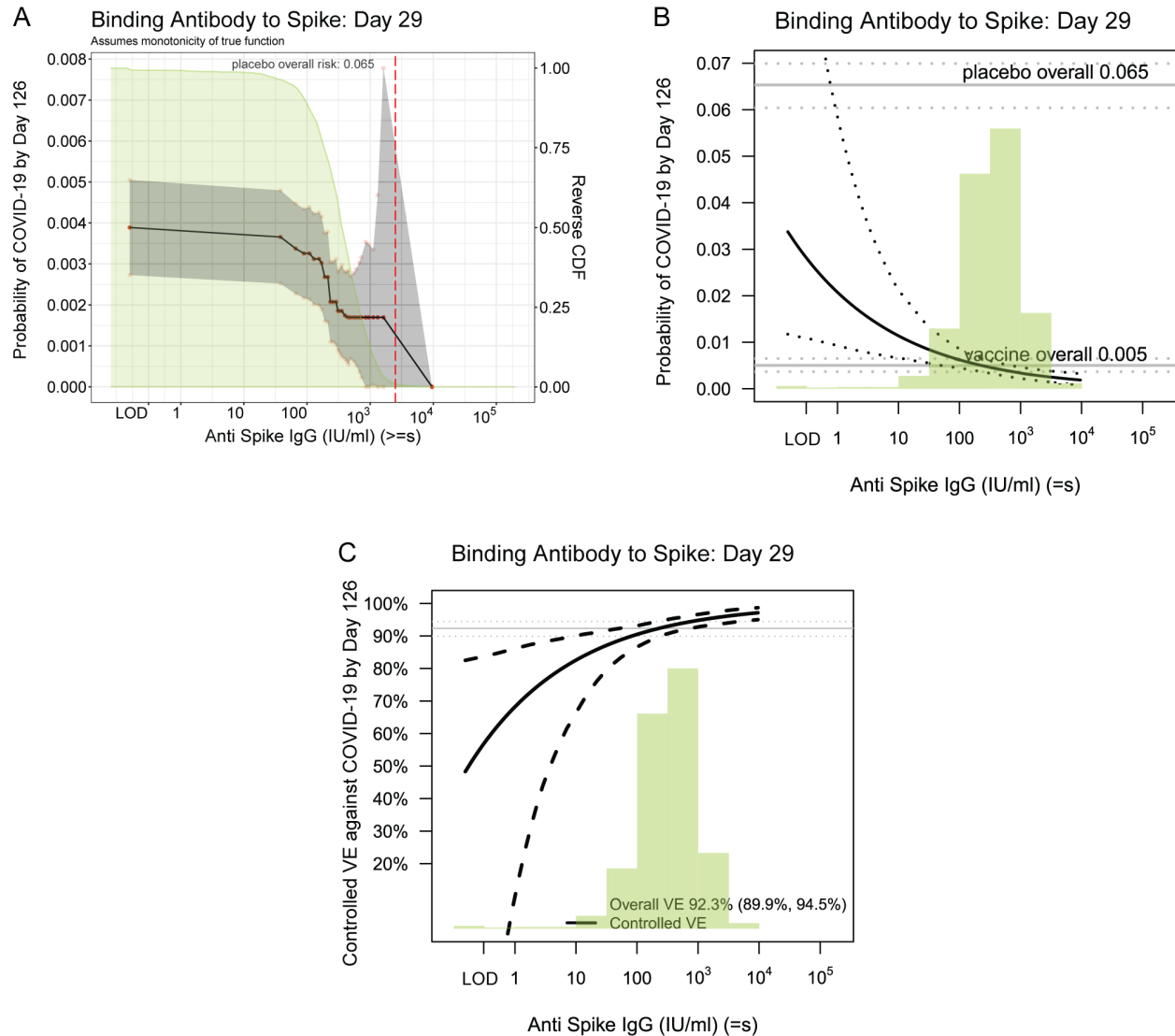
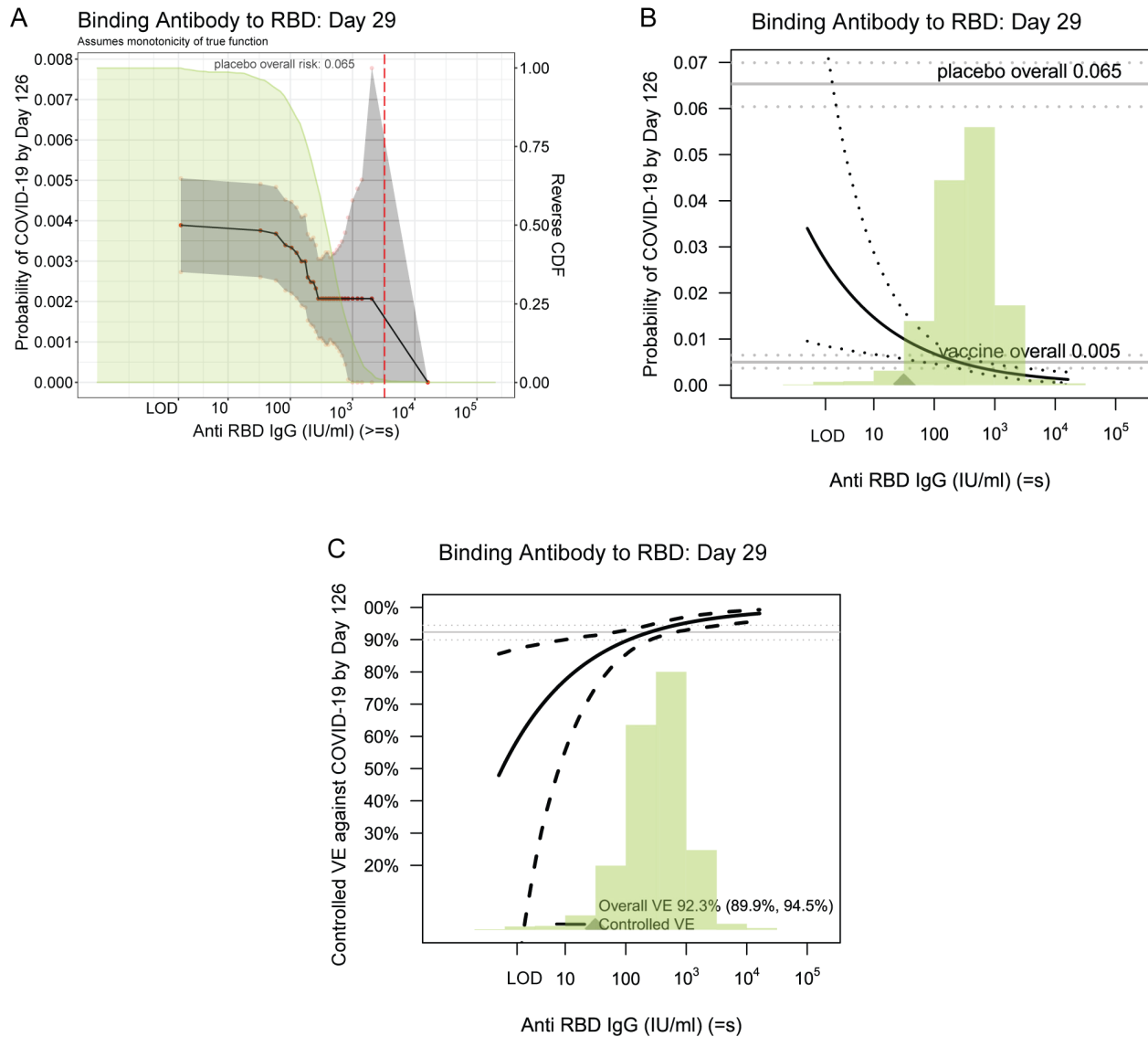


Figure S27. (A) Covariate-adjusted risk of COVID-19 by subgroups defined by Day 29 Anti-RBD IgG level above a threshold, with reverse cumulative distribution function of Day 29 Anti-RBD IgG level overlaid in green; (B) Covariate-adjusted cumulative incidence of COVID-19 by 126 days post Day 29 by Day 29 Anti-RBD IgG level; (C) Controlled vaccine efficacy by Day 29 Anti-RBD IgG level. In (A), the gray shaded area is pointwise 95% confidence intervals (CIs). The upper boundary of the green shaded area is the estimate of the reverse cumulative distribution function of the marker in baseline SARS-CoV-2 negative per-protocol vaccine recipients. In (B), the dotted lines indicate bootstrap point-wise 95% CIs. In (C), vaccine efficacy estimates were obtained using the method of Gilbert, Fong, and Carone.¹² In (B) and (C), the green histograms are an estimate of the density of marker level in baseline negative per-protocol vaccine recipients. LOD, limit of detection.



Supplementary Text 3: Controlled vaccine efficacy sensitivity analysis to assess robustness of the effect of antibody marker on preventing COVID-19 to unmeasured confounding

Figure 2 reports results for estimation and inference for baseline covariate-marginalized COVID-19 risk ratios comparing vaccine recipients with Day 57 antibody marker in the third tertile vs. in the first tertile; denote this marginalized risk ratio by $RR_M(0,1)$, where 1 indicates the third tertile and 0 indicates the first tertile. As described in the SAP and Gilbert, Fong, and Carone,¹² under the assumption of no unmeasured confounding of the effect of the antibody marker on COVID-19, the COVID-19 risk ratio $RR_M(0,1)$ equals a causal effect parameter $RR_C(0,1)$, the controlled effects risk ratio, which in turn equals $(1 - CVE(1))/(1 - CVE(0))$, where $CVE(1)$ is controlled vaccine efficacy for vaccine recipients with third tertile marker level and $CVE(0)$ is controlled vaccine efficacy for vaccine recipients with first tertile marker level. In sensitivity analysis, we allow for some unmeasured confounding that makes $RR_M(0,1) < RR_C(0,1)$. In particular, as specified in the SAP the first part of the sensitivity analysis reports E-values, both for the point estimate of $RR_C(0,1)$ and for the upper 95% confidence limit of $RR_C(0,1)$. The E-value is the minimum strength of association, on the risk ratio scale, that an unmeasured confounder would need to have with both the antibody marker (exposure) and the COVID-19 outcome in order to fully explain away a specific observed exposure-outcome association, conditional on the measured covariates.¹³ Here ‘fully explain away’ means that $RR_C(0,1) = 1$, or equivalently $CVE(0) = CVE(1)$, i.e., controlled vaccine efficacy does not differ by upper vs. lower tertile, which means no correlate of protection. Many epidemiologists recommend that E-values are always reported (or alternative sensitivity metrics) for causal inferences, given that it is not possible to guarantee that all confounders are controlled for in the analysis; thus by using E-values we are implementing best practice.

In addition, we apply the sensitivity analysis technique developed by Ding and Vanderweele (2016),¹⁴ as implemented in the SAP and in Gilbert, Fong, and Carone¹² for the COVE trial correlates application, to estimate $RR_C(0,1) = (1 - CVE(1))/(1 - CVE(0))$ under a specified scenario of unmeasured confounding that makes it harder to conclude a correlate of protection. This sensitivity analysis specifies an amount of unmeasured confounding defined by $RR_{UD}(0,1) = RR_{EU}(0,1) = 2$, where these parameters are defined in Ding and Vanderweele (2016)¹⁴ and in our SAP and Gilbert et al. If the 95% confidence interval for $RR_C(0,1) = (1 - CVE(1))/(1 - CVE(0))$ is less than 1 after accounting for this confounding that pushes the confidence interval upwards, it provides evidence for a correlate of protection with a degree of robustness to possible unmeasured confounding.

Table S8 shows results for the eight Day 57 and Day 29 antibody markers categorized by upper vs. lower tertile that were assessed as correlates. For example, the E-value of 9.3 for the Day 57 cID80 marker means that a marginalized risk ratio $RR_M(0,1)$ at the observed value 0.20 could be explained away (i.e., $RR_C(0,1) = 1.0$) by an unmeasured confounder associated with both the exposure and the outcome by a marginalized risk ratio of 9.3-fold each, after accounting for the measured potential confounders (risk score, at-risk status, community of color indicator), but that weaker confounding could not do so. In addition, the E-value of 3.3 for the upper confidence limit UL indicates the strength of unmeasured confounding at which statistical significance of the inference that $CVE(1) > CVE(0)$ would be lost.

Table S8. Sensitivity analysis to assess Day 57 and Day 29 antibody markers categorized as upper vs. lower tertiles as controlled vaccine efficacy CoPs against COVID-19

Antibody Marker	Marginalized Risk Ratio $RR_M(0,1)$		Controlled Risk Ratio = $(1-CVE(1))/(1-CVE(0))^1$		E-values ²	
	Point Est.	95% CI	Point Est.	95% CI	For Point Est.	For 95% CI UL
Day 57 Spike IgG	0.24	0.06, 0.56	0.32	0.09, 0.75	7.9	3.0
Day 57 RBD IgG	0.28	0.08, 0.62	0.38	0.11, 0.83	6.5	2.6
Day 57 PsV cID50	0.31	0.08, 0.72	0.42	0.11, 0.96	5.9	2.1
Day 57 PsV cID80	0.20	0.03, 0.51	0.27	0.05, 0.68	9.3	3.3
Day 29 Spike IgG	0.19	0.06, 0.40	0.26	0.08, 0.53	9.8	4.5
Day 29 RBD IgG	0.29	0.10, 0.59	0.38	0.13, 0.79	6.5	2.8
Day 29 PsV cID50	0.33	0.13, 0.65	0.44	0.17, 0.86	5.5	2.5
Day 29 PsV cID80	0.22	0.07, 0.46	0.30	0.10, 0.61	8.5	3.8

¹Conservative (upper bound) estimate assuming unmeasured confounding at level $RR_{UD}(0, 1) = RR_{EU}(0, 1) = 2$ and thus $B(0, 1) = 4/3$.

²E-values are computed for upper tertile ($s = 1$) vs. lower tertile ($s = 0$) biomarker subgroups after controlling for baseline risk score, at risk or not, community of color or not; UL = upper limit.

A second sensitivity analysis was conducted to assess robustness of findings on correlates of vaccine efficacy as a function of the quantitative antibody marker level varying over its whole range as studied in **Figure 4C** for cID50 titer and in **Figures S21-S27** for the other seven antibody markers. With details in the SAP and Gilbert, Fong, and Carone,¹² the sensitivity analysis was done similar to the analysis above for categorized markers, except now instead of specifying $RR_{UD}(0,1)$ and $RR_{EU}(0,1)$ for third tertile vs. first tertile, we specified $RR_{UD}(s^{15}, s^{85}) = 2$ and $RR_{EU}(s^{15}, s^{85}) = 2$ for s^{15} the 15th percentile of the antibody marker and s^{85} the 85th percentile of the antibody marker. We then specified unmeasured confounding across the whole range of antibody marker levels through the model

$$\log(RR_{UD}(s_1, s_2)) = [(s_2 - s_1) / (s^{85} - s^{15})] \log(RR_{UD}(s^{15}, s^{85})) \text{ for all } s_1 \leq s_2,$$

with the same model used for $RR_{EU}(s_1, s_2)$. The result of the sensitivity analysis is point estimates of controlled vaccine efficacy $CVE(s)$ over the range s of antibody marker levels, with 95% bootstrap pointwise confidence intervals, which build in robustness to unmeasured confounding by supposing bias that makes the estimate of the curve $CVE(s)$ flatter.

Figures S28 and S29 show the results for the eight antibody markers.

Figure S28. Vaccine efficacy with sensitivity analysis by Day 57 (A) Anti-Spike IgG level, (B) Anti-RBD IgG level, (C) cID50 level, or (D) cID80 level. Vaccine efficacy estimates were obtained using the method of Gilbert, Fong, and Carone.¹² The upper boundary of the green shaded area is the estimate of the reverse cumulative distribution function of the marker in baseline SARS-CoV-2 negative per-protocol vaccine recipients. The pink solid line is point estimates assuming no unmeasured confounding; the dashed lines are bootstrap point-wise 95% CIs. The red solid line is point estimates assuming unmeasured confounding in a sensitivity analysis (dashed lines are bootstrap point-wise 95% CIs); see Supplementary Text 3 for details of the sensitivity analysis. LOD, limit of detection.

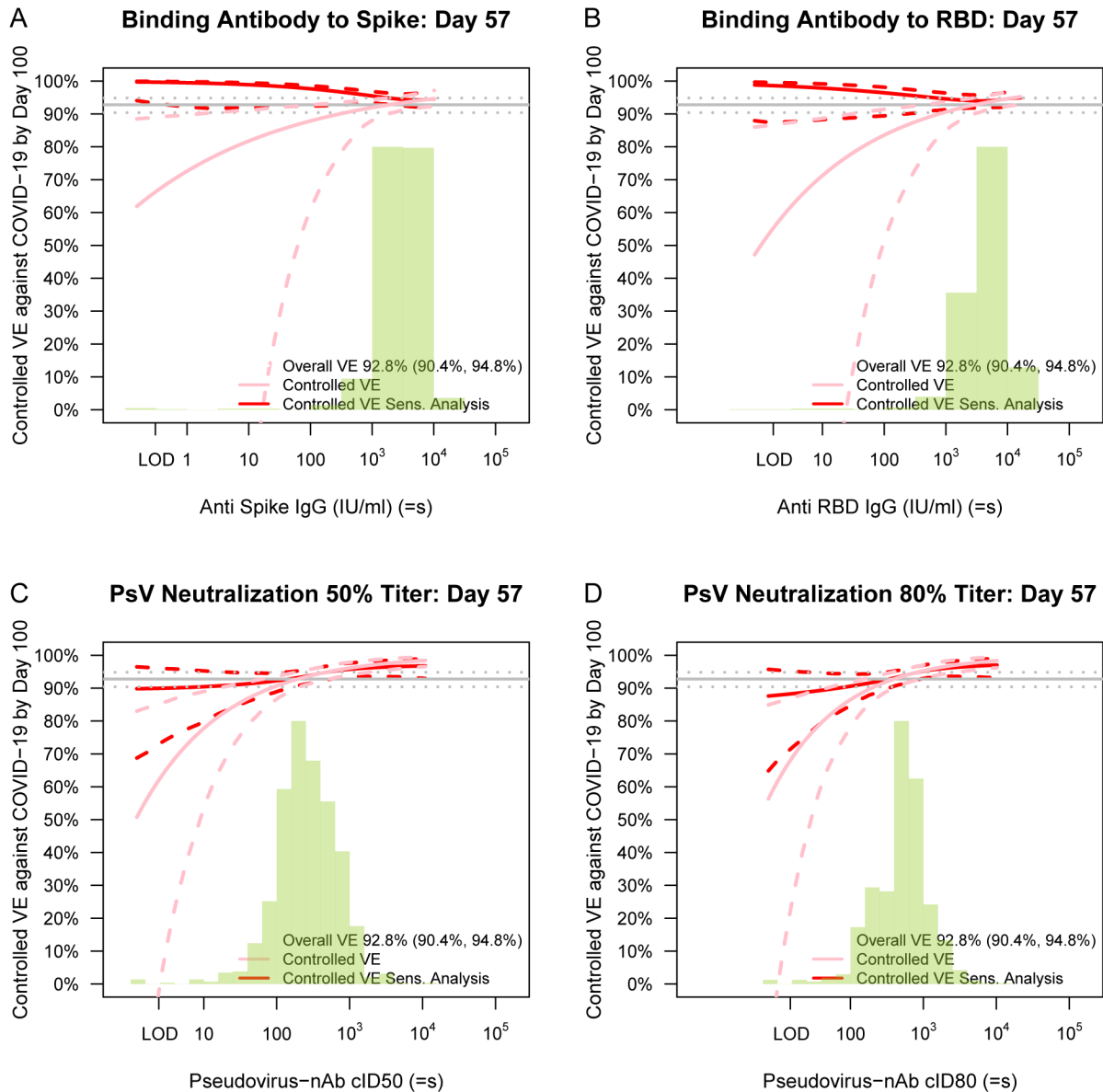


Figure S29. Vaccine efficacy with sensitivity analysis by Day 29 (A) Anti-Spike IgG level, (B) Anti-RBD IgG level, (C) cID50 level, or (D) cID80 level. Vaccine efficacy estimates were obtained using the method of Gilbert, Fong, and Carone.¹² The upper boundary of the green shaded area is the estimate of the reverse cumulative distribution function of the marker in baseline SARS-CoV-2 negative per-protocol vaccine recipients. The pink solid line is point estimates assuming no unmeasured confounding; the dashed lines are bootstrap point-wise 95% CIs. The red solid line is point estimates assuming unmeasured confounding in a sensitivity analysis (dashed lines are bootstrap point-wise 95% CIs); see Supplementary Text 3 for details of the sensitivity analysis. LOD, limit of detection.

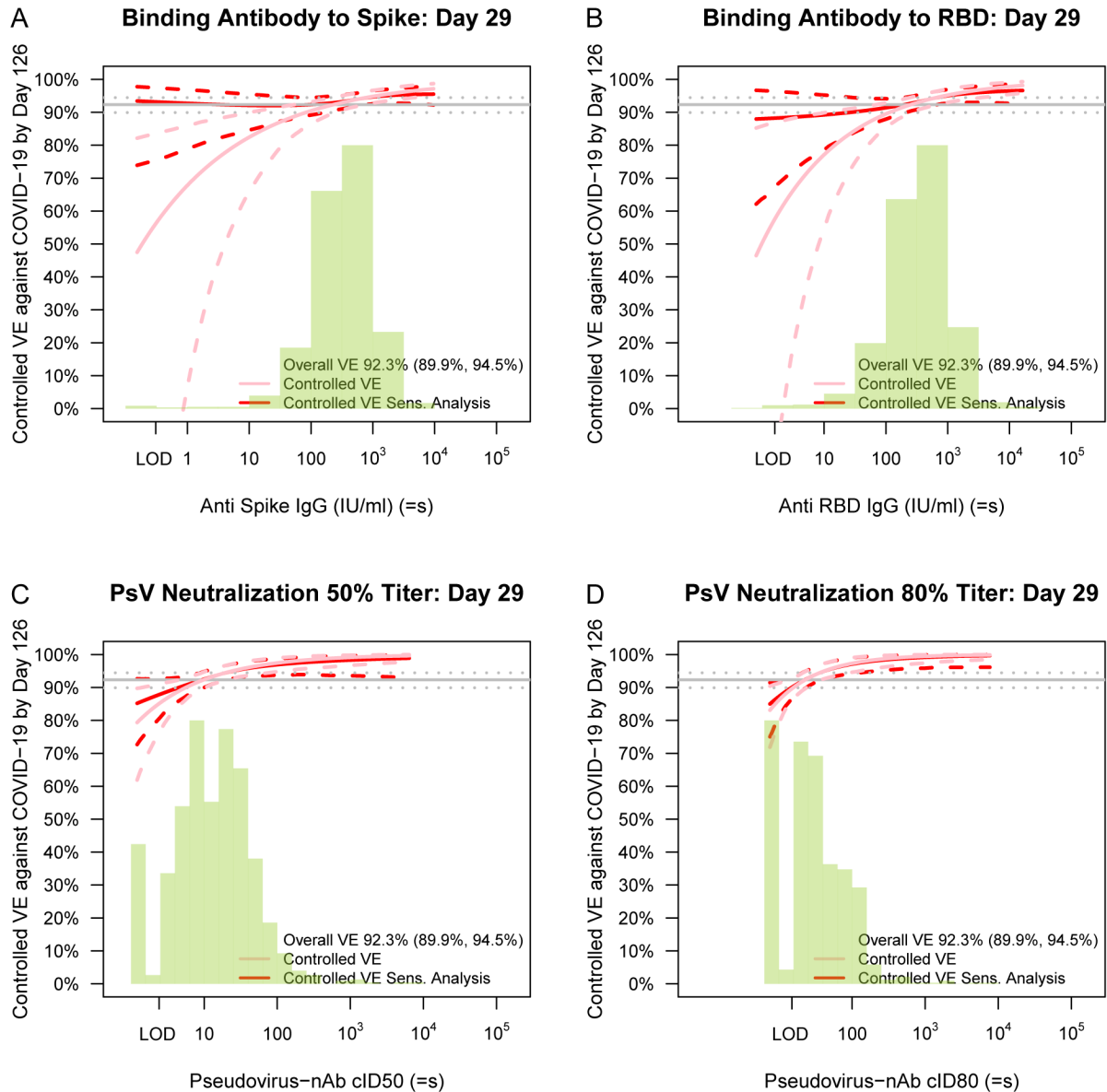


Table S9. Table of mediation effect estimates for quantitative markers with 95% confidence intervals.

Direct VE = VE comparing vaccine vs. placebo with marker set to distribution in placebo.

Indirect VE = VE in vaccinated comparing observed marker vs. hypothetical marker under placebo.

Prop. mediated = fraction of total risk reduction from vaccine attributed to antibody response.

Time	Assay	Direct VE	Indirect VE	Prop. mediated
Day 29	PsV Neutralization 50% Titer (Calibrated, cID50)	0.560 (0.422, 0.665)	0.832 (0.769, 0.878)	0.685 (0.585, 0.784)
Day 29	PsV Neutralization 80% Titer (Calibrated, cID80)	0.739 (0.601, 0.829)	0.717 (0.597, 0.801)	0.485 (0.345, 0.624)

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