COVID-19 Baseline Risk Score Analysis Report

MockCOVE Study

USG COVID-19 Response Biostatistics Team

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Disclaimers

- The data presented in the analysis originated from the Moderna Sponsored mRNA-1273-P301 clinical study and are provided to NIAID in accordance with Clinical Trial Agreement between the parties. The study was funded in part by BARDA under Government Contract No. 75A50120C00034

- The preliminary immunogenicity data presented here do not reflect the Sponsors statistical analysis plan and therefore should not be interpreted as a protocol defined read-out of the clinical study.

- These data are not to be disclosed without written permission of Moderna.

Chapter 2

Baseline Risk Score (Proxy for SARS-CoV-2 Exposure)

Table 2.1: Variables considered for risk score analysis.

Variable.Name	Definition	Total.missing.values	Comments
MinorityInd	Baseline covariate underrepresented minority status (1=minority, 0=non-minority)	0/13336 (0.0%)	NA
EthnicityHispanic	Indicator ethnicity = Hispanic (0 = Non-Hispanic)	0/13336 (0.0%)	NA
EthnicityNotreported	Indicator ethnicity = Not reported (0 = Non-Hispanic)	0/13336 (0.0%)	NA
EthnicityUnknown	Indicator ethnicity = Unknown (0 = Non-Hispanic)	0/13336 (0.0%)	NA
Black	Indicator race = Black (0 = White)	0/13336 (0.0%)	NA
Asian	Indicator race = Asian (0 = White)	0/13336 (0.0%)	NA
NatAmer	Indicator race = American Indian or Alaska Native (0 = White)	0/13336 (0.0%)	NA
PacIsl	Indicator race = Native Hawaiian or Other Pacific Islander (0 = White)	0/13336 (0.0%)	NA
Multiracial	Indicator race = Multiracial (0 = White)	0/13336 (0.0%)	NA
Other	Indicator race = Other (0 = White)	0/13336 (0.0%)	NA
Notreported	Indicator race = Not reported (0 = White)	0/13336 (0.0%)	NA
Unknown	Indicator race = unknown (0 = White)	0/13336 (0.0%)	NA
HighRiskInd	Baseline covariate high risk pre-existing condition (1=yes, 0=no)	0/13336 (0.0%)	NA
Sex	Sex assigned at birth (1=female, 0=male)	0/13336 (0.0%)	NA
Age	Age at enrollment in years, between 18 and 85	0/13336 (0.0%)	NA
BMI	BMI at enrollment (kg/m^2)	0/13336 (0.0%)	NA

Table 2.2: All learner-screen combinations (14 in total) used as input to the Superlearner.

Learner	Screen*
SL.mean	all
SL.glm	all
	glmnet
	univar_logistic_pval
	highcor_random

Note:
*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

SL.glm	all	0.716 [0.700, 0.731]	
SL.glm	highcor_random	0.716 [0.700, 0.731]	
SL.glm	glmnet	0.715 [0.699, 0.731]	
SL	-	0.714 [0.698, 0.730]	
Discrete SL	-	0.714 [0.698, 0.730]	
SL.glm	univar_logistic_pval	0.713 [0.697, 0.730]	
SL.mean	all	0.500 [0.468, 0.532]	

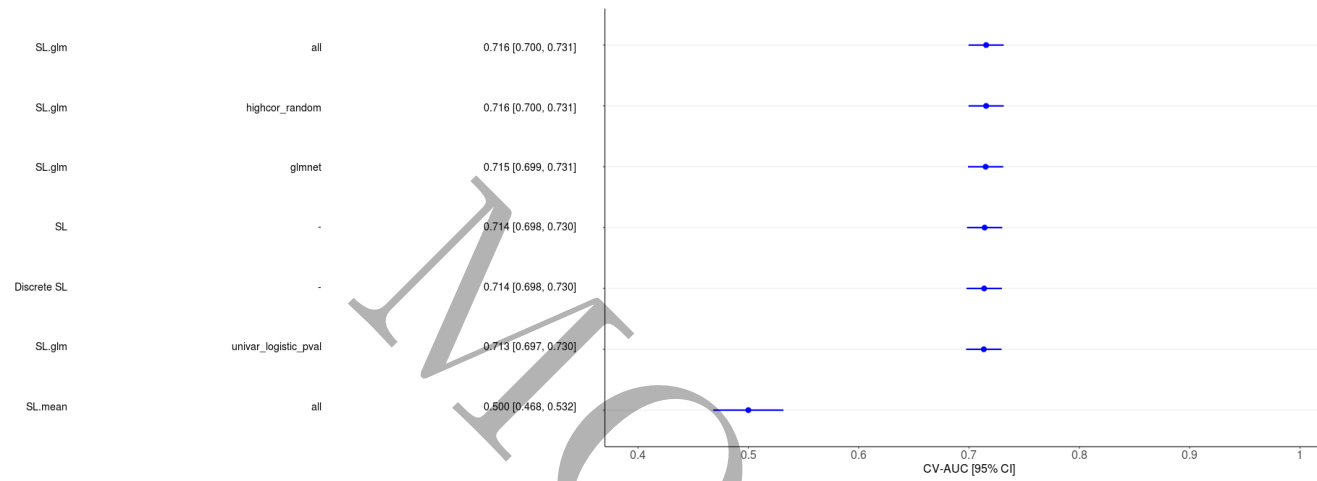Figure 2.1: Cross-validated AUC (95% CI) of algorithms for predicting COVID-19 disease status starting 7 days after Day 57.

Figure 2.2: CV-estimated predicted probabilities of COVID-19 disease 7 days after Day 57 by case/control status for top 2 learners, SuperLearner and Discrete SL.

Figure 2.3: ROC curves based off CV-estimated predicted probabilities for the top 2 learners, Superlearner and Discrete SL.

Table 2.3: Weights assigned by Superlearner.

Learner	Screen	Weight
SL.glm	screen_all	0.590
SL.glm	screen_glmnet	0.376
SL.mean	screen_all	0.034
SL.glm	screen_univariate_logistic_pval	0.000
SL.glm	screen_highcor_random	0.000

Table 2.4: Predictors in learners assigned weight > 0.0 by Superlearner.

Learner	Screen	Weight	Predictors	Coefficient	Odds.Ratio
SL.glm	screen__all	0.59	(Intercept)	-2.767	0.063
SL.glm	screen__all	0.59	MinorityInd	-0.015	0.985
SL.glm	screen__all	0.59	EthnicityHispanic	-0.013	0.987
SL.glm	screen__all	0.59	EthnicityNotreported	0.046	1.048
SL.glm	screen__all	0.59	EthnicityUnknown	-0.072	0.931
SL.glm	screen__all	0.59	Black	-0.024	0.977
SL.glm	screen__all	0.59	Asian	0.057	1.058
SL.glm	screen__all	0.59	NatAmer	0.007	1.007
SL.glm	screen__all	0.59	PacIsl	-0.025	0.975
SL.glm	screen__all	0.59	Multiracial	-0.052	0.95
SL.glm	screen__all	0.59	Other	0.055	1.056
SL.glm	screen__all	0.59	Notreported	0.005	1.005
SL.glm	screen__all	0.59	Unknown	0.01	1.01
SL.glm	screen__all	0.59	HighRiskInd	-0.019	0.981
SL.glm	screen__all	0.59	Sex	-0.006	0.994
SL.glm	screen__all	0.59	Age	0.824	2.279
SL.glm	screen__all	0.59	BMI	-0.045	0.956
SL.glm	screen__glmnet	0.376	(Intercept)	-2.767	0.063
SL.glm	screen__glmnet	0.376	EthnicityNotreported	0.048	1.049
SL.glm	screen__glmnet	0.376	EthnicityUnknown	-0.071	0.932
SL.glm	screen__glmnet	0.376	Black	-0.035	0.966
SL.glm	screen__glmnet	0.376	Asian	0.05	1.051
SL.glm	screen__glmnet	0.376	Multiracial	-0.064	0.938
SL.glm	screen__glmnet	0.376	Other	0.048	1.049
SL.glm	screen__glmnet	0.376	Age	0.824	2.279
SL.glm	screen__glmnet	0.376	BMI	-0.045	0.956

Figure 2.4: Superlearner predicted probabilities of COVID-19 disease in vaccinees 7 days after Day 57 by case/control status.

Figure 2.5: ROC curve based off Superlearner predicted probabilities in vaccinees.

Table 2.5: Cases per treatment arm prior to risk score analysis.

Study-Arm	Non-Cases	Post-Day 57-Cases
Placebo	12307	1029
Vaccine	13201	52

Table 2.6: Cases per treatment arm post risk score analysis.

Study-Arm	Non-Cases	Post-Day 57-Cases
Placebo	12307	1029
Vaccine	13201	52

Chapter 3

Appendix

- This report was built from the `CoVPN/correlates_reporting` repository with commit hash b400af2c05e50f0d638fb3ba48a84b9adcecbb5c. A diff of the changes introduced by that commit may be viewed at https://github.com/CoVPN/correlates_reporting/commit/b400af2c05e50f0d638fb3ba48a84b9adcecbb5c

- The sha256 hash sum of the raw input file, "COVID_VEtrial_practicedata_primarystage1.csv": 83d0f55d1745ffd42be124d8f9ec9a9903abcc13cd22f95e537542a08b41300a

- The sha256 hash sum of the processed file, "moderna_mock_data_processed.csv": b693743f019df4aab6f3e36a230927f153f76610c44c2ca289e00f29d9f25214