COVID-19 Correlates of Risk Analysis Report

mock Study

USG COVID-19 Response Biostatistics Team

March 28, 2021

Contents

1 Summary Tables 29

2 Graphical Descriptions of Antibody Marker Data 35

2.1 Boxplots 35

2.2 Weighted RCDF plots 42

2.3 Weighted RCDF plots of threshold correlate concentration for overall vaccine efficacy 50

2.4 Spaghetti plots 52

2.5 Violin and line plots 53

3 Day 57 Univariate CoR: Cox Models of Risk 179

3.1 Hazard ratios 179

3.2 Marginalized risk and controlled vaccine efficacy plots 184

4 Day 29 Univariate CoR: Cox Models of Risk 189

4.1 Hazard ratios 189

4.2 Marginalized risk and controlled vaccine efficacy plots 194

5 Univariate CoR: Nonparametric Threshold Modeling 199

5.1 Plots and Tables with estimates and pointwise confidence interval for Day 57 200

5.2 Plots and Tables with estimates and pointwise confidence intervals for Day 29 205

5.3 Plots and Tables with estimates and pointwise confidence interval for Day 57 (monotone-corrected) 210

5.4 Plots and Tables with estimates and pointwise confidence intervals for Day 29 (monotone-corrected) 215

5.5 Plots and Tables with estimates and simultaneous confidence bands for Day 57 . . . 220

5.6 Plots and Tables with estimates and simultaneous confidence bands for Day 29 . . . 225

5.7 Plots and Tables with estimates and pointwise confidence interval for Day 57 (monotone-corrected) 230

5.8 Plots and Tables with estimates and pointwise confidence intervals for Day 29 (monotone-corrected) 235

List of Tables

1.1 Table 1. Demographic and Clinical Characteristics at Baseline in the baseline SARS-CoV-2 negative per-protocol cohort . . . 29

1.2 Table 2. Demographic and Clinical Characteristics at Baseline in the baseline SARS-CoV-2 positive per-protocol cohort . . . 31

1.3 Table 3. Antibody levels in the baseline SARS-CoV-2 negative per-protocol cohort (vaccine recipients) . . . 32

1.4 Table 4. Antibody levels in the baseline SARS-CoV-2 positive per-protocol cohort (vaccine recipients) . . . 33

1.5 Table 5. Antibody levels in the baseline SARS-CoV-2 positive per-protocol cohort (placebo recipients) . . . 34

3.1 Inference for Day 57 antibody marker covariate-adjusted correlates of risk of COVID in the vaccine group: Hazard ratios per 10-fold increment in the marker* . . . 179

3.2 Inference for Day 57 antibody marker covariate-adjusted correlates of risk of COVID in the vaccine group: Hazard ratios for Middle vs. Upper tertile vs. Lower tertile* . . . 180

4.1 Inference for Day 29 antibody marker covariate-adjusted correlates of risk of COVID in the vaccine group: Hazard ratios per 10-fold increment in the marker* . . . 189

4.2 Inference for Day 29 antibody marker covariate-adjusted correlates of risk of COVID in the vaccine group: Hazard ratios for Middle vs. Upper tertile vs. Lower tertile* . . . 190

5.1 Table of risk estimates for a range of thresholds of Day 57 Spike protein binding antibody levels with pointwise 95% confidence intervals. . . . 201

5.2 Table of risk estimates for a range of thresholds of Day 57 RBD binding antibody levels with pointwise 95% confidence intervals. . . . 202

5.3 Table of risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. . . . 203

5.4 Table of risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. . . . 204

5.5 Table of risk estimates for a range of thresholds of Day 29 Spike protein antibody levels with pointwise 95% confidence intervals. 206

5.6 Table of risk estimates for a range of thresholds of Day 29 RBD binding antibody levels with pointwise 95% confidence intervals. 207

5.7 Table of risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. 208

5.8 Table of risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. 209

5.9 Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Spike protein binding antibody levels with pointwise 95% confidence intervals. 211

5.10 Table of monotone-corrected risk estimates for a range of thresholds of Day 57 RBD binding antibody levels with pointwise 95% confidence intervals. 212

5.11 Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. 213

5.12 Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. 214

5.13 Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Spike protein antibody levels with pointwise 95% confidence intervals. 216

5.14 Table of monotone-corrected risk estimates for a range of thresholds of Day 29 RBD binding antibody levels with pointwise 95% confidence intervals. 217

5.15 Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. 218

5.16 Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. 219

5.17 Table of risk estimates for a range of thresholds of Day 57 Spike protein binding antibody levels with simultaneous 95% confidence intervals. 221

5.18 Table of risk estimates for a range of thresholds of Day 57 RBD binding antibody levels with simultaneous 95% confidence intervals. 222

5.19 Table of risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. 223

5.20 Table of risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. 224

5.21 Table of risk estimates for a range of thresholds of Day 29 Spike protein antibody levels with simultaneous 95% confidence intervals. 226

5.22 Table of risk estimates for a range of thresholds of Day 29 RBD binding antibody levels with simultaneous 95% confidence intervals. 227

5.23 Table of risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. 228

5.24 Table of risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. 229

5.25 Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Spike protein binding antibody levels with simultaneous 95% confidence intervals. 231

5.26 Table of monotone-corrected risk estimates for a range of thresholds of Day 57 RBD binding antibody levels with simultaneous 95% confidence intervals. 232

5.27 Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. 233

5.28 Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. 234

5.29 Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Spike protein antibody levels with simultaneous 95% confidence intervals. 236

5.30 Table of monotone-corrected risk estimates for a range of thresholds of Day 29 RBD binding antibody levels with simultaneous 95% confidence intervals. 237

5.31 Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. 238

5.32 Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. 239

List of Figures

2.1 Boxplots of D57 Ab markers: baseline negative vaccine arm. 35

2.2 Boxplots of D57 fold-rise over D1 Ab markers: baseline negative vaccine arm. 36

2.3 Boxplots of D29 Ab markers: baseline negative vaccine arm. 37

2.4 Boxplots of D29 fold-rise over D1 Ab markers: baseline negative vaccine arm. 38

2.5 Boxplots of D57 Ab markers: baseline positive vaccine arm. 39

2.6 Boxplots of D57 fold-rise over D1 Ab markers: baseline positive vaccine arm. 40

2.7 Boxplots of D29 Ab markers: baseline positive vaccine arm. 41

2.8 Boxplots of D29 fold-rise over D1 Ab markers: baseline positive vaccine arm. 42

2.9 RCDF plots for D57 Ab markers: baseline negative by treatment arm. 43

2.10 RCDF plots for D57 fold-rise over D1 Ab markers: baseline negative by treatment arm. 44

2.11 RCDF plots for D29 Ab markers: baseline negative by treatment arm. 45

2.12 RCDF plots for D29 fold-rise over D1 Ab markers: baseline negative by treatment arm. 46

2.13 RCDF plots for D57 Ab markers: baseline positive by treatment arm. 47

2.14 RCDF plots for D57 fold-rise over D1 Ab markers: baseline positive by treatment arm. 48

2.15 RCDF plots for D29 Ab markers: baseline positive by treatment arm. 49

2.16 RCDF plots for D29 fold-rise over D1 Ab markers: baseline positive by treatment arm. 50

2.17 Marker RCDF of D57 anti-Spike binding Ab: baseline negative vaccine arm 50

2.18 Marker RCDF of D57 anti-RBD binding Ab: baseline negative vaccine arm 51

2.19 Marker RCDF of D57 PsV-nAb ID50: baseline negative vaccine arm 51

2.20 Marker RCDF of D57 PsV-nAb ID80: baseline negative vaccine arm 51

2.21 Spaghetti Plots of Marker Trajectory: baseline negative vaccine arm 52

2.22 Spaghetti Plots of Marker Trajectory: baseline positive vaccine arm 53
2.23 lineplots of Binding Antibody to Spike: baseline negative placebo arm (2 timepoints) 53
2.24 lineplots of Binding Antibody to Spike: baseline negative vaccine arm (2 timepoints) 54
2.25 lineplots of Binding Antibody to RBD: baseline negative placebo arm (2 timepoints) 54
2.26 lineplots of Binding Antibody to RBD: baseline negative vaccine arm (2 timepoints) 55
2.27 lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm (2 timepoints) 55
2.28 lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm (2 timepoints) 56
2.29 lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm (2 timepoints) 56
2.30 lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm (2 timepoints) 57
2.31 violinplots of Binding Antibody to Spike: baseline negative placebo arm (2 timepoints) 57
2.32 violinplots of Binding Antibody to Spike: baseline negative vaccine arm (2 timepoints) 58
2.33 violinplots of Binding Antibody to RBD: baseline negative placebo arm (2 timepoints) 58
2.34 violinplots of Binding Antibody to RBD: baseline negative vaccine arm (2 timepoints) 59
2.35 violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm (2 timepoints) 59
2.36 violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm (2 timepoints) 60
2.37 violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm (2 timepoints) 60
2.38 violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm (2 timepoints) 61
2.39 lineplots of Binding Antibody to Spike: baseline negative placebo arm (3 timepoints) 61
2.40 lineplots of Binding Antibody to Spike: baseline negative vaccine arm (3 timepoints) 62
2.41 lineplots of Binding Antibody to RBD: baseline negative placebo arm (3 timepoints) 62
2.42 lineplots of Binding Antibody to RBD: baseline negative vaccine arm (3 timepoints) 63
2.43 lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm (3 timepoints) 63
2.44 lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm (3 timepoints) 64
2.45 lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm (3 timepoints) 64

2.46 lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm (3 timepoints) . . . 65
2.47 violinplots of Binding Antibody to Spike: baseline negative placebo arm (3 timepoints) 65
2.48 violinplots of Binding Antibody to Spike: baseline negative vaccine arm (3 timepoints) 66
2.49 violinplots of Binding Antibody to RBD: baseline negative placebo arm (3 timepoints) 66
2.50 violinplots of Binding Antibody to RBD: baseline negative vaccine arm (3 timepoints) 67
2.51 violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm (3 timepoints) . . . 67
2.52 violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm (3 timepoints) . . . 68
2.53 violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm (3 timepoints) . . . 68
2.54 violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm (3 timepoints) . . . 69
2.55 lineplots of Binding Antibody to Spike: baseline negative placebo arm by age (2 timepoints) . . . 69
2.56 lineplots of Binding Antibody to Spike: baseline negative vaccine arm by age (2 timepoints) . . . 70
2.57 lineplots of Binding Antibody to RBD: baseline negative placebo arm by age (2 timepoints) . . . 70
2.58 lineplots of Binding Antibody to RBD: baseline negative vaccine arm by age (2 timepoints) . . . 71
2.59 lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age (2 timepoints) . . . 71
2.60 lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age (2 timepoints) . . . 72
2.61 lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age (2 timepoints) . . . 72
2.62 lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age (2 timepoints) . . . 73
2.63 violinplots of Binding Antibody to Spike: baseline negative placebo arm by age (2 timepoints) . . . 73
2.64 violinplots of Binding Antibody to Spike: baseline negative vaccine arm by age (2 timepoints) . . . 74
2.65 violinplots of Binding Antibody to RBD: baseline negative placebo arm by age (2 timepoints) . . . 74

2.66 violinplots of Binding Antibody to RBD: baseline negative vaccine arm by age (2 timepoints) . . . 75
2.67 violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age (2 timepoints) . . . 75
2.68 violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age (2 timepoints) . . . 76
2.69 violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age (2 timepoints) . . . 76
2.70 violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age (2 timepoints) . . . 77
2.71 lineplots of Binding Antibody to Spike: baseline negative placebo arm by age (3 timepoints) . . . 77
2.72 lineplots of Binding Antibody to Spike: baseline negative vaccine arm by age (3 timepoints) . . . 78
2.73 lineplots of Binding Antibody to RBD: baseline negative placebo arm by age (3 timepoints) . . . 78
2.74 lineplots of Binding Antibody to RBD: baseline negative vaccine arm by age (3 timepoints) . . . 79
2.75 lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age (3 timepoints) . . . 79
2.76 lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age (3 timepoints) . . . 80
2.77 lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age (3 timepoints) . . . 80
2.78 lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age (3 timepoints) . . . 81
2.79 violinplots of Binding Antibody to Spike: baseline negative placebo arm by age (3 timepoints) . . . 81
2.80 violinplots of Binding Antibody to Spike: baseline negative vaccine arm by age (3 timepoints) . . . 82
2.81 violinplots of Binding Antibody to RBD: baseline negative placebo arm by age (3 timepoints) . . . 82
2.82 violinplots of Binding Antibody to RBD: baseline negative vaccine arm by age (3 timepoints) . . . 83
2.83 violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age (3 timepoints) . . . 83
2.84 violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age (3 timepoints) . . . 84

2.85 violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age (3 timepoints) . . . 84
2.86 violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age (3 timepoints) . . . 85
2.87 lineplots of Binding Antibody to Spike: baseline negative placebo arm by risk condition (2 timepoints) . . . 85
2.88 lineplots of Binding Antibody to Spike: baseline negative vaccine arm by risk condition (2 timepoints) . . . 86
2.89 lineplots of Binding Antibody to RBD: baseline negative placebo arm by risk condition (2 timepoints) . . . 86
2.90 lineplots of Binding Antibody to RBD: baseline negative vaccine arm by risk condition (2 timepoints) . . . 87
2.91 lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by risk condition (2 timepoints) . . . 87
2.92 lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by risk condition (2 timepoints) . . . 88
2.93 lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by risk condition (2 timepoints) . . . 88
2.94 lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by risk condition (2 timepoints) . . . 89
2.95 violinplots of Binding Antibody to Spike: baseline negative placebo arm by risk condition (2 timepoints) . . . 89
2.96 violinplots of Binding Antibody to Spike: baseline negative vaccine arm by risk condition (2 timepoints) . . . 90
2.97 violinplots of Binding Antibody to RBD: baseline negative placebo arm by risk condition (2 timepoints) . . . 90
2.98 violinplots of Binding Antibody to RBD: baseline negative vaccine arm by risk condition (2 timepoints) . . . 91
2.99 violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by risk condition (2 timepoints) . . . 91
2.100 violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by risk condition (2 timepoints) . . . 92
2.101 violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by risk condition (2 timepoints) . . . 92
2.102 violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by risk condition (2 timepoints) . . . 93
2.103 lineplots of Binding Antibody to Spike: baseline negative placebo arm by risk condition (3 timepoints) . . . 93

2.104 lineplots of Binding Antibody to Spike: baseline negative vaccine arm by risk condition (3 timepoints) . . . 94
2.105 lineplots of Binding Antibody to RBD: baseline negative placebo arm by risk condition (3 timepoints) . . . 94
2.106 lineplots of Binding Antibody to RBD: baseline negative vaccine arm by risk condition (3 timepoints) . . . 95
2.107 lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by risk condition (3 timepoints) . . . 95
2.108 lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by risk condition (3 timepoints) . . . 96
2.109 lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by risk condition (3 timepoints) . . . 96
2.110 lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by risk condition (3 timepoints) . . . 97
2.111 violinplots of Binding Antibody to Spike: baseline negative placebo arm by risk condition (3 timepoints) . . . 97
2.112 violinplots of Binding Antibody to Spike: baseline negative vaccine arm by risk condition (3 timepoints) . . . 98
2.113 violinplots of Binding Antibody to RBD: baseline negative placebo arm by risk condition (3 timepoints) . . . 98
2.114 violinplots of Binding Antibody to RBD: baseline negative vaccine arm by risk condition (3 timepoints) . . . 99
2.115 violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by risk condition (3 timepoints) . . . 99
2.116 violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by risk condition (3 timepoints) . . . 100
2.117 violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by risk condition (3 timepoints) . . . 100
2.118 violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by risk condition (3 timepoints) . . . 101
2.119 lineplots of Binding Antibody to Spike: baseline negative placebo arm by age and risk condition (2 timepoints) . . . 101
2.120 lineplots of Binding Antibody to Spike: baseline negative vaccine arm by age and risk condition (2 timepoints) . . . 102
2.121 lineplots of Binding Antibody to RBD: baseline negative placebo arm by age and risk condition (2 timepoints) . . . 102
2.122 lineplots of Binding Antibody to RBD: baseline negative vaccine arm by age and risk condition (2 timepoints) . . . 103

2.123 lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age and risk condition (2 timepoints) . . . 103
2.124 lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age and risk condition (2 timepoints) . . . 104
2.125 lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age and risk condition (2 timepoints) . . . 104
2.126 lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age and risk condition (2 timepoints) . . . 105
2.127 violinplots of Binding Antibody to Spike: baseline negative placebo arm by age and risk condition (2 timepoints) . . . 105
2.128 violinplots of Binding Antibody to Spike: baseline negative vaccine arm by age and risk condition (2 timepoints) . . . 106
2.129 violinplots of Binding Antibody to RBD: baseline negative placebo arm by age and risk condition (2 timepoints) . . . 106
2.130 violinplots of Binding Antibody to RBD: baseline negative vaccine arm by age and risk condition (2 timepoints) . . . 107
2.131 violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age and risk condition (2 timepoints) . . . 107
2.132 violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age and risk condition (2 timepoints) . . . 108
2.133 violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age and risk condition (2 timepoints) . . . 108
2.134 violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age and risk condition (2 timepoints) . . . 109
2.135 lineplots of Binding Antibody to Spike: baseline negative placebo arm by age and risk condition (3 timepoints) . . . 109
2.136 lineplots of Binding Antibody to Spike: baseline negative vaccine arm by age and risk condition (3 timepoints) . . . 110
2.137 lineplots of Binding Antibody to RBD: baseline negative placebo arm by age and risk condition (3 timepoints) . . . 110
2.138 lineplots of Binding Antibody to RBD: baseline negative vaccine arm by age and risk condition (3 timepoints) . . . 111
2.139 lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age and risk condition (3 timepoints) . . . 111
2.140 lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age and risk condition (3 timepoints) . . . 112
2.141 lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age and risk condition (3 timepoints) . . . 112

2.142 lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age and risk condition (3 timepoints) . . . 113
2.143 violinplots of Binding Antibody to Spike: baseline negative placebo arm by age and risk condition (3 timepoints) . . . 113
2.144 violinplots of Binding Antibody to Spike: baseline negative vaccine arm by age and risk condition (3 timepoints) . . . 114
2.145 violinplots of Binding Antibody to RBD: baseline negative placebo arm by age and risk condition (3 timepoints) . . . 114
2.146 violinplots of Binding Antibody to RBD: baseline negative vaccine arm by age and risk condition (3 timepoints) . . . 115
2.147 violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by age and risk condition (3 timepoints) . . . 115
2.148 violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by age and risk condition (3 timepoints) . . . 116
2.149 violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by age and risk condition (3 timepoints) . . . 116
2.150 violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by age and risk condition (3 timepoints) . . . 117
2.151 lineplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (2 timepoints) . . . 117
2.152 lineplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (2 timepoints) . . . 118
2.153 lineplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (2 timepoints) . . . 118
2.154 lineplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (2 timepoints) . . . 119
2.155 lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by sex assigned at birth (2 timepoints) . . . 119
2.156 lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by sex assigned at birth (2 timepoints) . . . 120
2.157 lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by sex assigned at birth (2 timepoints) . . . 120
2.158 lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by sex assigned at birth (2 timepoints) . . . 121
2.159 violinplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (2 timepoints) . . . 121
2.160 violinplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (2 timepoints) . . . 122

2.161 violinplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (2 timepoints) . . . 122
2.162 violinplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (2 timepoints) . . . 123
2.163 violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by sex assigned at birth (2 timepoints) . . . 123
2.164 violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by sex assigned at birth (2 timepoints) . . . 124
2.165 violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by sex assigned at birth (2 timepoints) . . . 124
2.166 violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by sex assigned at birth (2 timepoints) . . . 125
2.167 lineplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (3 timepoints) . . . 125
2.168 lineplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (3 timepoints) . . . 126
2.169 lineplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (3 timepoints) . . . 126
2.170 lineplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (3 timepoints) . . . 127
2.171 lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by sex assigned at birth (3 timepoints) . . . 127
2.172 lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by sex assigned at birth (3 timepoints) . . . 128
2.173 lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by sex assigned at birth (3 timepoints) . . . 128
2.174 lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by sex assigned at birth (3 timepoints) . . . 129
2.175 violinplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (3 timepoints) . . . 129
2.176 violinplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (3 timepoints) . . . 130
2.177 violinplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (3 timepoints) . . . 130
2.178 violinplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (3 timepoints) . . . 131
2.179 violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by sex assigned at birth (3 timepoints) . . . 131

2.180 violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by sex assigned at birth (3 timepoints) . . . 132
2.181 violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by sex assigned at birth (3 timepoints) . . . 132
2.182 violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by sex assigned at birth (3 timepoints) . . . 133
2.183 lineplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (2 timepoints) . . . 133
2.184 lineplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (2 timepoints) . . . 134
2.185 lineplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (2 timepoints) . . . 134
2.186 lineplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (2 timepoints) . . . 135
2.187 lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by race and ethnic group (2 timepoints) . . . 135
2.188 lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by race and ethnic group (2 timepoints) . . . 136
2.189 lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by race and ethnic group (2 timepoints) . . . 136
2.190 lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by race and ethnic group (2 timepoints) . . . 137
2.191 violinplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (2 timepoints) . . . 137
2.192 violinplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (2 timepoints) . . . 138
2.193 violinplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (2 timepoints) . . . 138
2.194 violinplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (2 timepoints) . . . 139
2.195 violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by race and ethnic group (2 timepoints) . . . 139
2.196 violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by race and ethnic group (2 timepoints) . . . 140
2.197 violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by race and ethnic group (2 timepoints) . . . 140
2.198 violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by race and ethnic group (2 timepoints) . . . 141

2.199 lineplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (3 timepoints) . . . 141
2.200 lineplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (3 timepoints) . . . 142
2.201 lineplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (3 timepoints) . . . 142
2.202 lineplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (3 timepoints) . . . 143
2.203 lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by race and ethnic group (3 timepoints) . . . 143
2.204 lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by race and ethnic group (3 timepoints) . . . 144
2.205 lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by race and ethnic group (3 timepoints) . . . 144
2.206 lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by race and ethnic group (3 timepoints) . . . 145
2.207 violinplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (3 timepoints) . . . 145
2.208 violinplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (3 timepoints) . . . 146
2.209 violinplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (3 timepoints) . . . 146
2.210 violinplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (3 timepoints) . . . 147
2.211 violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by race and ethnic group (3 timepoints) . . . 147
2.212 violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by race and ethnic group (3 timepoints) . . . 148
2.213 violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by race and ethnic group (3 timepoints) . . . 148
2.214 violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by race and ethnic group (3 timepoints) . . . 149
2.215 lineplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (2 timepoints) . . . 149
2.216 lineplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (2 timepoints) . . . 150
2.217 lineplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (2 timepoints) . . . 150

2.218 lineplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (2 timepoints) 151
2.219 lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by dichotomous classification of race and ethnic group (2 timepoints) 151
2.220 lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by dichotomous classification of race and ethnic group (2 timepoints) 152
2.221 lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by dichotomous classification of race and ethnic group (2 timepoints) 152
2.222 lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by dichotomous classification of race and ethnic group (2 timepoints) 153
2.223 violinplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (2 timepoints) 153
2.224 violinplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (2 timepoints) 154
2.225 violinplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (2 timepoints) 154
2.226 violinplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (2 timepoints) 155
2.227 violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by dichotomous classification of race and ethnic group (2 timepoints) 155
2.228 violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by dichotomous classification of race and ethnic group (2 timepoints) 156
2.229 violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by dichotomous classification of race and ethnic group (2 timepoints) 156
2.230 violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by dichotomous classification of race and ethnic group (2 timepoints) 157
2.231 lineplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (3 timepoints) 157
2.232 lineplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (3 timepoints) 158
2.233 lineplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (3 timepoints) 158
2.234 lineplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (3 timepoints) 159
2.235 lineplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by dichotomous classification of race and ethnic group (3 timepoints) 159
2.236 lineplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by dichotomous classification of race and ethnic group (3 timepoints) 160

2.237 lineplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by dichotomous classification of race and ethnic group (3 timepoints) . . . 160

2.238 lineplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by dichotomous classification of race and ethnic group (3 timepoints) . . . 161

2.239 violinplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (3 timepoints) . . . 161

2.240 violinplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (3 timepoints) . . . 162

2.241 violinplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (3 timepoints) . . . 162

2.242 violinplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (3 timepoints) . . . 163

2.243 violinplots of Pseudovirus Neutralization ID50: baseline negative placebo arm by dichotomous classification of race and ethnic group (3 timepoints) . . . 163

2.244 violinplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm by dichotomous classification of race and ethnic group (3 timepoints) . . . 164

2.245 violinplots of Pseudovirus Neutralization ID80: baseline negative placebo arm by dichotomous classification of race and ethnic group (3 timepoints) . . . 164

2.246 violinplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm by dichotomous classification of race and ethnic group (3 timepoints) . . . 165

2.247 scatterplots of Binding Antibody to Spike: baseline negative vaccine arm at day 1 . 165

2.248 scatterplots of Binding Antibody to Spike: baseline negative vaccine arm at day 29 . 166

2.249 scatterplots of Binding Antibody to Spike: baseline negative vaccine arm at day 57 . 166

2.250 scatterplots of Binding Antibody to RBD: baseline negative vaccine arm at day 1 . . 167

2.251 scatterplots of Binding Antibody to RBD: baseline negative vaccine arm at day 29 . 167

2.252 scatterplots of Binding Antibody to RBD: baseline negative vaccine arm at day 57 . 168

2.253 scatterplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm at day 1 . . . 168

2.254 scatterplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm at day 29 . . . 169

2.255 scatterplots of Pseudovirus Neutralization ID50: baseline negative vaccine arm at day 57 . . . 169

2.256 scatterplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm at day 1 . . . 170

2.257 scatterplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm at day 29 . . . 170

2.258 scatterplots of Pseudovirus Neutralization ID80: baseline negative vaccine arm at day 57 . . . 171
2.259 scatterplots of Binding Antibody to Spike: by arm at day 1 . . . 171
2.260 scatterplots of Binding Antibody to Spike: by arm at day 29 . . . 172
2.261 scatterplots of Binding Antibody to Spike: by arm at day 57 . . . 172
2.262 scatterplots of Binding Antibody to RBD: by arm at day 1 . . . 173
2.263 scatterplots of Binding Antibody to RBD: by arm at day 29 . . . 173
2.264 scatterplots of Binding Antibody to RBD: by arm at day 57 . . . 174
2.265 scatterplots of Pseudovirus Neutralization ID50: by arm at day 1 . . . 174
2.266 scatterplots of Pseudovirus Neutralization ID50: by arm at day 29 . . . 175
2.267 scatterplots of Pseudovirus Neutralization ID50: by arm at day 57 . . . 175
2.268 scatterplots of Pseudovirus Neutralization ID80: by arm at day 1 . . . 176
2.269 scatterplots of Pseudovirus Neutralization ID80: by arm at day 29 . . . 176
2.270 scatterplots of Pseudovirus Neutralization ID80: by arm at day 57 . . . 177

3.1 Forest plots of hazard ratios per 10-fold increase in the marker among baseline seronegative vaccine recipients and subgroups with 95% point-wise confidence intervals. . . . 181
3.2 Forest plots of hazard ratios per 10-fold increase in the Day 57 binding Ab to spike markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals. . . . 182
3.3 Forest plots of hazard ratios per 10-fold increase in the Day 57 binding Ab to RBD markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals. . . . 182
3.4 Forest plots of hazard ratios per 10-fold increase in the Day 57 pseudo neut ID50 markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals. . . . 182
3.5 Forest plots of hazard ratios per 10-fold increase in the Day 57 pseudo neut ID80 markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals. . . . 183
3.6 Marginalized cumulative risk by Day 174 as functions of Day 57 markers (=s) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. The horizontal lines indicate the overall cumulative risk of the placebo and vaccine arms by Day 174 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection. . . . 184

3.7 Marginalized cumulative risk by Day 174 as functions of Day 57 markers above a threshold ($\geq s$) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands (at least 5 cases are required). The horizontal lines indicate the overall cumulative risk of the vaccine arm by Day 174 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection. 185

3.8 Controlled VE with sensitivity analysis as functions of Day 57 markers (=s) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection. 186

3.9 Marginalized cumulative incidence rate curves for trichotomized Day 57 markers among baseline seronegative vaccine recipients. The gray line is the overall cumulative incidence rate curve in the placebo arm. 187

4.1 Forest plots of hazard ratios per 10-fold increase in the marker among baseline seronegative vaccine recipients and subgroups with 95% point-wise confidence intervals. 191

4.2 Forest plots of hazard ratios per 10-fold increase in the Day 29 binding Ab to spike markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals. 192

4.3 Forest plots of hazard ratios per 10-fold increase in the Day 29 binding Ab to RBD markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals. 192

4.4 Forest plots of hazard ratios per 10-fold increase in the Day 29 pseudo neut ID50 markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals. 192

4.5 Forest plots of hazard ratios per 10-fold increase in the Day 29 pseudo neut ID80 markers among baseline seronegative vaccine recipients (top row) and eight subpopulations (row 2-9) with 95% point-wise confidence intervals. 193

4.6 Marginalized cumulative risk by Day 202 as functions of Day 29 markers (=s) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. The horizontal lines indicate the overall cumulative risk of the placebo and vaccine arms by Day 202 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection. 194

4.7 Marginalized cumulative risk by Day 202 as functions of Day 29 markers above a threshold ($\geq s$) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands (at least 5 cases are required). The horizontal lines indicate the overall cumulative risk of the vaccine arm by Day 202 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection. 195

4.8 Controlled VE with sensitivity analysis as functions of Day 29 markers (=s) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection. 196

4.9 Marginalized cumulative incidence rate curves for trichotomized Day 29 markers among baseline seronegative vaccine recipients. The gray line is the overall cumulative incidence rate curve in the placebo arm. 197

5.1 Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. . . . 201

5.2 Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. 202

5.3 Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. 203

5.4 Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. 204

5.5 Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. 206

5.6 Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. 207

5.7 Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. 208

5.8 Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. 209

5.9 Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing. 211

5.10 Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing. 212

5.11 Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing. 213

5.12 Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing. 214

5.13 Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing. 216

5.14 Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing. 217

5.15 Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing. 218

5.16 Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing. 219

5.17 Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. 221

5.18 Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. 222

5.19 Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. 223

5.20 Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. 224

5.21 Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. 226

5.22 Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. 227

5.23 Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. 228

5.24 Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. 229

5.25 Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing. 231

5.26 Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing. 232

5.27 Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing. 233

5.28 Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing. 234

5.29 Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing. 236

5.30 Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing. 237

5.31 Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing. 238

5.32 Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing. 239

MOCK

MOCK

Chapter 1

Summary Tables

MOCK

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

Characteristics	Vaccine (N = 914)	Placebo (N = 163)	Total (N = 1077)
Age			
Age < 65	432 (47.3%)	80 (49.1%)	512 (47.5%)
Age ≥ 65	482 (52.7%)	83 (50.9%)	565 (52.5%)
Mean (Range)	58.6 (18.0, 85.0)	59.0 (18.0, 85.0)	58.7 (18.0, 85.0)
BMI			
Mean ± SD	30.1 ± 7.0	29.6 ± 7.2	30.0 ± 7.0
Sex			
Female	519 (56.8%)	87 (53.4%)	606 (56.3%)
Male	395 (43.2%)	76 (46.6%)	471 (43.7%)
Race			
White Non-Hispanic	362 (43.8%)	67 (44.7%)	429 (43.9%)
Black or African American	195 (23.6%)	39 (26.0%)	234 (24.0%)
Asian	67 (8.1%)	12 (8.0%)	79 (8.1%)
American Indian or Alaska Native	13 (1.6%)	5 (3.3%)	18 (1.8%)
Native Hawaiian or Other Pacific Islander	17 (2.1%)	1 (0.7%)	18 (1.8%)
Multiracial	52 (6.3%)	8 (5.3%)	60 (6.1%)
Other	34 (4.1%)	4 (2.7%)	38 (3.9%)
Not reported and unknown	87 (10.5%)	14 (9.3%)	101 (10.3%)
Communities of Color	420 (53.7%)	73 (52.1%)	493 (53.5%)
Hispanic or Latino ethnicity			
Hispanic or Latino	136 (14.9%)	20 (12.3%)	156 (14.5%)
Not Hispanic or Latino	690 (75.5%)	130 (79.8%)	820 (76.1%)
Not reported and unknown	88 (9.6%)	13 (8.0%)	101 (9.4%)

(continued)

Characteristics	Vaccine (N = 914)	Placebo (N = 163)	Total (N = 1077)
Risk for Severe Covid-19			
At-risk	469 (51.3%)	84 (51.5%)	553 (51.3%)
Not at-risk	445 (48.7%)	79 (48.5%)	524 (48.7%)
Age, Risk for Severe Covid-19			
Age $<$ 65 At-risk	214 (23.4%)	40 (24.5%)	254 (23.6%)
Age $<$ 65 Not at-risk	218 (23.9%)	40 (24.5%)	258 (24.0%)
Age $\geq$ 65	482 (52.7%)	83 (50.9%)	565 (52.5%)

This table summarises the random subcohort, which was randomly sampled from the per-protocol individuals without a COVID failure event $<$ 7 days post Day 57. The sampling was stratified by the key baseline covariates: assigned treatment arm, baseline SARS-CoV-2 status (defined by serostatus and possibly also NAAT and/or RNA PCR testing), any additional important demographic factors such as the randomization strata (e.g., defined by age and/or co-morbidities).

MOCK

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

Characteristics	Vaccine (N = 274)	Placebo (N = 270)	Total (N = 544)
Age			
Age < 65	146 (53.3%)	147 (54.4%)	293 (53.9%)
Age ≥ 65	128 (46.7%)	123 (45.6%)	251 (46.1%)
Mean (Range)	56.0 (18.0, 85.0)	55.8 (18.0, 85.0)	55.9 (18.0, 85.0)
BMI			
Mean ± SD	30.7 ± 6.8	30.1 ± 7.2	30.4 ± 7.0
Sex			
Female	153 (55.8%)	155 (57.4%)	308 (56.6%)
Male	121 (44.2%)	115 (42.6%)	236 (43.4%)
Race			
White Non-Hispanic	125 (49.8%)	121 (49.0%)	246 (49.4%)
Black or African American	52 (20.7%)	60 (24.3%)	112 (22.5%)
Asian	24 (9.6%)	13 (5.3%)	37 (7.4%)
American Indian or Alaska Native	6 (2.4%)	4 (1.6%)	10 (2.0%)
Native Hawaiian or Other Pacific Islander	5 (2.0%)	1 (0.4%)	6 (1.2%)
Multiracial	12 (4.8%)	19 (7.7%)	31 (6.2%)
Other	7 (2.8%)	5 (2.0%)	12 (2.4%)
Not reported and unknown	20 (8.0%)	24 (9.7%)	44 (8.8%)
Communities of Color	120 (49.0%)	111 (47.8%)	231 (48.4%)
Hispanic or Latino ethnicity			
Hispanic or Latino	35 (12.8%)	38 (14.1%)	73 (13.4%)
Not Hispanic or Latino	217 (79.2%)	214 (79.3%)	431 (79.2%)
Not reported and unknown	22 (8.0%)	18 (6.7%)	40 (7.4%)
Risk for Severe Covid-19			
At-risk	125 (45.6%)	123 (45.6%)	248 (45.6%)
Not at-risk	149 (54.4%)	147 (54.4%)	296 (54.4%)
Age, Risk for Severe Covid-19			
Age < 65 At-risk	73 (26.6%)	75 (27.8%)	148 (27.2%)
Age < 65 Not at-risk	73 (26.6%)	72 (26.7%)	145 (26.7%)
Age ≥ 65	128 (46.7%)	123 (45.6%)	251 (46.1%)

This table summarises the random subcohort, which was randomly sampled from the per-protocol individuals without a COVID failure event < 7 days post Day 57. The sampling was stratified by the key baseline covariates: assigned treatment arm, baseline SARS-CoV-2 status (defined by serostatus and possibly also NAAT and/or RNA PCR testing), any additional important demographic factors such as the randomization strata (e.g., defined by age and/or co-morbidities).

MOCK

Table 3. Antibody levels in the baseline SARS-CoV-2 negative per-protocol cohort (vaccine recipients)

		Baseline SARS-CoV-2 Negative Vaccine Recipients							
		Cases*			Non-Cases/Control			Comparison	
Visit	Marker	N	Resp rate	GMT/GMC	N	Resp rate	GMT/GMC	Resp Rate Difference	GMTR/GMCR
Day 29	Anti N IgG (IU/ml)	11	64.1/64.1 = 100.0% (100.0%, 100.0%)	9163 (3359, 24998)	903	13230.9/13230.9 = 100.0% (100.0%, 100.0%)	23718 (20083, 28010)	0% (0%, 0%)	0.39 (0.14, 1.07)
Day 29	Anti RBD IgG (IU/ml)	11	64.1/64.1 = 100.0% (100.0%, 100.0%)	9820 (4734, 20366)	903	13230.9/13230.9 = 100.0% (100.0%, 100.0%)	23105 (20011, 26677)	0% (0%, 0%)	0.43 (0.20, 0.89)
Day 29	Anti Spike IgG (IU/ml)	11	64.1/64.1 = 100.0% (100.0%, 100.0%)	12852 (7097, 23271)	903	13230.9/13230.9 = 100.0% (100.0%, 100.0%)	41328 (37060, 46086)	0% (0%, 0%)	0.31 (0.17, 0.57)
Day 29	Pseudovirus-nAb ID50	11	56.7/64.1 = 90.9% (46.3%, 99.1%)	37 (16, 86)	903	11676.4/13230.9 = 88.3% (84.8%, 91.1%)	107 (91, 126)	2.6% (-42.1%, 11.6%)	0.35 (0.15, 0.82)
Day 29	Pseudovirus-nAb ID80	11	56.1/64.1 = 81.8% (42.0%, 96.5%)	103 (30, 351)	903	12465.5/13230.9 = 94.2% (91.6%, 96.1%)	190 (161, 223)	-12.4% (-52.3%, 2.6%)	0.54 (0.16, 1.87)
Day 57	Anti N IgG (IU/ml)	11	64.1/64.1 = 100.0% (100.0%, 100.0%)	110124 (35353, 343038)	903	13230.9/13230.9 = 100.0% (100.0%, 100.0%)	327744 (269226, 398981)	0% (0%, 0%)	0.34 (0.11, 1.06)
Day 57	Anti RBD IgG (IU/ml)	11	64.1/64.1 = 100.0% (100.0%, 100.0%)	334195 (161041, 693528)	903	13230.9/13230.9 = 100.0% (100.0%, 100.0%)	974227 (829937, 1143602)	0% (0%, 0%)	0.34 (0.16, 0.72)
Day 57	Anti Spike IgG (IU/ml)	11	64.1/64.1 = 100.0% (100.0%, 100.0%)	240794 (105801, 548023)	903	13230.9/13230.9 = 100.0% (100.0%, 100.0%)	2116905 (1856215, 2414208)	0% (0%, 0%)	0.11 (0.05, 0.26)
Day 57	Pseudovirus-nAb ID50	11	64.1/64.1 = 100.0% (100.0%, 100.0%)	188 (73, 487)	903	13095.3/13230.9 = 99.0% (98.0%, 99.5%)	1517 (1244, 1850)	1% (0.5%, 2%)	0.12 (0.05, 0.33)
Day 57	Pseudovirus-nAb ID80	11	64.1/64.1 = 100.0% (100.0%, 100.0%)	350 (165, 740)	903	13110.7/13230.9 = 99.1% (97.1%, 99.7%)	2249 (1829, 2766)	0.9% (0.3%, 2.9%)	0.16 (0.07, 0.34)

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

MOCK

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

		Baseline SARS-CoV-2 Positive Vaccine Recipients							
		Cases*			Non-Cases/Control			Comparison	
Visit	Marker	N	Resp rate	GMT/GMC	N	Resp rate	GMT/GMC	Resp Rate Difference	GMTR/GMCR
Day 29	Anti N IgG (IU/ml)	2	17.2/17.2 = 100.0%	130813 (3444, 4969160)	272	1414.8/1414.8 = 100.0% (100.0%, 100.0%)	43029 (32995, 56114)	0%	3.04 (0.08, 116.61)
Day 29	Anti RBD IgG (IU/ml)	2	17.2/17.2 = 100.0%	153444 (6865, 3429945)	272	1414.8/1414.8 = 100.0% (100.0%, 100.0%)	35885 (27859, 46223)	0%	4.28 (0.19, 96.57)
Day 29	Anti Spike IgG (IU/ml)	2	17.2/17.2 = 100.0%	104737 (14230, 770889)	272	1414.8/1414.8 = 100.0% (100.0%, 100.0%)	80297 (65042, 99128)	0%	1.30 (0.18, 9.71)
Day 29	Pseudovirus-nAb ID50	2	17.2/17.2 = 100.0%	323 (71, 1472)	272	1365.9/1414.8 = 96.5% (91.4%, 98.6%)	185 (141, 244)	3.5%	1.74 (0.37, 8.13)
Day 29	Pseudovirus-nAb ID80	2	17.2/17.2 = 100.0%	481 (4, 60966)	272	1390.1/1414.8 = 98.2% (93.6%, 99.5%)	428 (320, 573)	1.8%	1.12 (0.01, 143.66)
Day 57	Anti N IgG (IU/ml)	2	17.2/17.2 = 100.0%	2440779 (43120, 138159231)	272	1414.8/1414.8 = 100.0% (100.0%, 100.0%)	985914 (697182, 1394221)	0%	2.48 (0.04, 142.23)
Day 57	Anti RBD IgG (IU/ml)	2	17.2/17.2 = 100.0%	2749023 (61314, 123253076)	272	1414.8/1414.8 = 100.0% (100.0%, 100.0%)	2328268 (1802226, 3007855)	0%	1.18 (0.03, 53.40)
Day 57	Anti Spike IgG (IU/ml)	2	17.2/17.2 = 100.0%	3627856 (538606, 24435925)	272	1414.8/1414.8 = 100.0% (100.0%, 100.0%)	5409865 (4378235, 6684574)	0%	0.67 (0.10, 4.57)
Day 57	Pseudovirus-nAb ID50	2	17.2/17.2 = 100.0%	1829 (160, 20945)	272	1414.8/1414.8 = 100.0% (100.0%, 100.0%)	5816 (3934, 8599)	0%	0.31 (0.03, 3.72)
Day 57	Pseudovirus-nAb ID80	2	17.2/17.2 = 100.0%	5772 (290, 114704)	272	1414.8/1414.8 = 100.0% (100.0%, 100.0%)	7960 (5601, 11311)	0%	0.73 (0.04, 14.71)

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

MOCK

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

		Baseline SARS-CoV-2 Positive Placebo Recipients							
		Cases*			Non-Cases/Control			Comparison	
Visit	Marker	N	Resp rate	GMT/GMC	N	Resp rate	GMT/GMC	Resp Rate Difference	GMTR/GMCR
Day 29	Anti N IgG (IU/ml)	2	4/4 = 100.0%	44658 (376, 5310188)	268	1353/1353 = 100.0% (100.0%, 100.0%)	12485 (9430, 16531)	0%	3.58 (0.03, 428.83)
Day 29	Anti RBD IgG (IU/ml)	2	4/4 = 100.0%	42959 (6946, 265696)	268	1353/1353 = 100.0% (100.0%, 100.0%)	12824 (10117, 16255)	0%	3.35 (0.53, 21.04)
Day 29	Anti Spike IgG (IU/ml)	2	4/4 = 100.0%	37021 (6048, 226609)	268	1353/1353 = 100.0% (100.0%, 100.0%)	18162 (15129, 21803)	0%	2.04 (0.33, 12.59)
Day 29	Pseudovirus-nAb ID50	2	1.6/4 = 50.0%	93 (0, 28176)	268	1138.2/1353 = 84.1% (76.9%, 89.4%)	51 (40, 66)	-34.1%	1.80 (0.01, 550.47)
Day 29	Pseudovirus-nAb ID80	2	4/4 = 100.0%	372 (107, 1290)	268	1254.5/1353 = 92.7% (86.8%, 96.1%)	129 (98, 169)	7.3%	2.89 (0.81, 10.32)
Day 57	Anti N IgG (IU/ml)	2	4/4 = 100.0%	652604 (78974, 5392810)	268	1353/1353 = 100.0% (100.0%, 100.0%)	129537 (92255, 181885)	0%	5.04 (0.59, 42.78)
Day 57	Anti RBD IgG (IU/ml)	2	4/4 = 100.0%	2348281 (194513, 28349939)	268	1353/1353 = 100.0% (100.0%, 100.0%)	380897 (298347, 486288)	0%	6.17 (0.50, 75.32)
Day 57	Anti Spike IgG (IU/ml)	2	4/4 = 100.0%	767715 (603034, 977368)	268	1353/1353 = 100.0% (100.0%, 100.0%)	676673 (530979, 862343)	0%	1.13 (0.81, 1.60)
Day 57	Pseudovirus-nAb ID50	2	4/4 = 100.0%	1515 (18, 129242)	268	1297.7/1353 = 95.9% (90.6%, 98.3%)	565 (408, 782)	4.1%	2.68 (0.03, 231.59)
Day 57	Pseudovirus-nAb ID80	2	4/4 = 100.0%	6066 (474, 77675)	268	1326.1/1353 = 98.0% (93.2%, 99.4%)	1319 (934, 1864)	2%	4.60 (0.35, 60.26)

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

MOCK

Chapter 2

Graphical Descriptions of Antibody Marker Data

MOCK

2.1 Boxplots

2.1.1 Baseline seronegative

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

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

MOCK

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

MOCK

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

MOCK

2.1.2 Baseline seropositive

MOCK

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

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

MOCK

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

MOCK

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

MOCK

2.2 Weighted RCDF plots

2.2.1 Baseline seronegative

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

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

MOCK

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

MOCK

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

MOCK

2.2.2 Baseline seropositive

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

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

MOCK

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

MOCK

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

MOCK

2.3 Weighted RCDF plots of threshold correlate concentration for overall vaccine efficacy

2.3.1 Baseline seronegative

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

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

MOCK

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

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

2.4 Spaghetti plots

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

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

2.5 Violin and line plots

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

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

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

MOCK

MOCK

Chapter 3

Day 57 Univariate CoR: Cox Models of Risk

MOCK

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

3.1 Hazard ratios

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

Mock Immunologic Marker	No. cases / No. at-risk**	HR per 10-fold incr. Pt. Est.	95% CI	P-value (2-sided)	q-value	FWER
Anti Spike IgG (IU/ml)	70/13,295	0.10	(0.06-0.15)	<0.001	<0.001	<0.001
Anti RBD IgG (IU/ml)	70/13,295	0.27	(0.20-0.37)	<0.001	<0.001	<0.001
Pseudovirus-nAb ID50	70/13,295	0.30	(0.23-0.40)	<0.001	<0.001	<0.001
Pseudovirus-nAb ID80	70/13,295	0.49	(0.37-0.63)	<0.001	<0.001	<0.001

*Baseline covariates adjusted for: age in years, at risk or not, community of color or not . Average follow-up time 172 days, maximum follow-up time 185 days.
**No. at-risk = number of per-protocol baseline negative vaccine recipients at-risk for COVID; no. cases = number of this cohort with an observed COVID endpoints starting 7 days post Day 57 visit.

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

Mock Immunologic Marker	Tertile	No. cases / No. at-risk**	Attack rate	Haz. Ratio Pt. Est.	Haz. Ratio 95% CI	P-value (2-sided)	Overall P-value***	Overall q-value	Overall FWER
Anti Spike IgG (IU/ml)	Lower	58/4,434	0.0131	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	11/4,436	0.0025	0.10	(0.05-0.19)	<0.001			
	Upper	1/4,424	0.0002	0.00	(0.00-0.03)	<0.001			
Anti RBD IgG (IU/ml)	Lower	38/4,459	0.0085	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	27/4,397	0.0061	0.40	(0.23-0.69)	0.001			
	Upper	5/4,439	0.0011	0.05	(0.02-0.12)	<0.001			
Pseudovirus-nAb ID50	Lower	45/4,457	0.0101	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	21/4,364	0.0048	0.31	(0.17-0.56)	<0.001			
	Upper	5/4,475	0.0011	0.05	(0.02-0.12)	<0.001			
Pseudovirus-nAb ID80	Lower	35/4,443	0.0079	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	25/4,419	0.0057	0.46	(0.26-0.83)	0.010			
	Upper	10/4,433	0.0023	0.15	(0.07-0.33)	<0.001			
Placebo		719/13,359	0.0538						

*Baseline covariates adjusted for: age in years, at risk or not, community of color or not . Average follow-up time 172 days, maximum follow-up time 185 days. Cutpoints: Anti Spike IgG (IU/ml) [6.03, 6.67), Anti RBD IgG (IU/ml) [5.65, 6.39), Pseudovirus-nAb ID50 [2.74, 3.56), Pseudovirus-nAb ID80 [2.9, 3.83).
**No. at-risk = number of per-protocol baseline negative vaccine recipients at-risk for COVID at 7 days post Day 57 visit; no. cases = number of this cohort with an observed COVID endpoints.
***Generalized Wald-test p-value of the null hypothesis that the hazard rate is constant across the Lower, Middle, and Upper tertile groups.

MOCK

MOCK

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

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

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

MOCK

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

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

MOCK

3.2 Marginalized risk and controlled vaccine efficacy plots

Figure 3.6: Marginalized cumulative risk by Day 174 as functions of Day 57 markers (=s) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. The horizontal lines indicate the overall cumulative risk of the placebo and vaccine arms by Day 174 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.

MOCK

Figure 3.7: Marginalized cumulative risk by Day 174 as functions of Day 57 markers above a threshold ($\geq s$) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands (at least 5 cases are required). The horizontal lines indicate the overall cumulative risk of the vaccine arm by Day 174 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.

MOCK

Figure 3.8: Controlled VE with sensitivity analysis as functions of Day 57 markers (=s) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.

MOCK

Figure 3.9: Marginalized cumulative incidence rate curves for trichotomized Day 57 markers among baseline seronegative vaccine recipients. The gray line is the overall cumulative incidence rate curve in the placebo arm.

MOCK

Chapter 4

Day 29 Univariate CoR: Cox Models of Risk

MOCK

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

4.1 Hazard ratios

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

Mock Immunologic Marker	No. cases / No. at-risk**	HR per 10-fold incr. Pt. Est.	95% CI	P-value (2-sided)	q-value	FWER
Anti Spike IgG (IU/ml)	81/13,315	0.09	(0.05-0.16)	<0.001	<0.001	<0.001
Anti RBD IgG (IU/ml)	81/13,315	0.29	(0.20-0.42)	<0.001	<0.001	<0.001
Pseudovirus-nAb ID50	81/13,315	0.38	(0.28-0.51)	<0.001	<0.001	<0.001
Pseudovirus-nAb ID80	81/13,315	0.59	(0.43-0.81)	0.001	<0.001	<0.001

*Baseline covariates adjusted for: age in years, at risk or not, community of color or not . Average follow-up time 200 days, maximum follow-up time 213 days.
**No. at-risk = number of per-protocol baseline negative vaccine recipients at-risk for COVID; no. cases = number of this cohort with an observed COVID endpoints starting 7 days post Day 29 visit.

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

Mock Immunologic Marker	Tertile	No. cases / No. at-risk**	Attack rate	Haz. Ratio Pt. Est.	Haz. Ratio 95% CI	P-value (2-sided)	Overall P-value***	Overall q-value	Overall FWER
Anti Spike IgG (IU/ml)	Lower	49/4,460	0.0110	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	21/4,406	0.0048	0.24	(0.13-0.43)	<0.001			
	Upper	11/4,449	0.0025	0.06	(0.03-0.14)	<0.001			
Anti RBD IgG (IU/ml)	Lower	40/4,461	0.0090	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	21/4,412	0.0048	0.38	(0.22-0.68)	0.001			
	Upper	20/4,442	0.0045	0.19	(0.10-0.35)	<0.001			
Pseudovirus-nAb ID50	Lower	40/4,441	0.0090	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	30/4,429	0.0068	0.54	(0.32-0.92)	0.022			
	Upper	10/4,445	0.0022	0.14	(0.07-0.29)	<0.001			
Pseudovirus-nAb ID80	Lower	29/4,440	0.0065	1	N/A	N/A	0.075		
	Middle	28/4,434	0.0063	0.76	(0.43-1.35)	0.349			
	Upper	24/4,441	0.0054	0.50	(0.27-0.91)	0.023			
Placebo		828/13,380	0.0619						

*Baseline covariates adjusted for: age in years, at risk or not, community of color or not . Average follow-up time 200 days, maximum follow-up time 213 days. Cutpoints: Anti Spike IgG (IU/ml) [4.35, 4.87), Anti RBD IgG (IU/ml) [4.05, 4.64), Pseudovirus-nAb ID50 [1.67, 2.39), Pseudovirus-nAb ID80 [1.92, 2.61).
**No. at-risk = number of per-protocol baseline negative vaccine recipients at-risk for COVID at 7 days post Day 29 visit; no. cases = number of this cohort with an observed COVID endpoints.
***Generalized Wald-test p-value of the null hypothesis that the hazard rate is constant across the Lower, Middle, and Upper tertile groups.

MOCK

MOCK

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

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

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

MOCK

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

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

MOCK

4.2 Marginalized risk and controlled vaccine efficacy plots

MOCK

Figure 4.6: Marginalized cumulative risk by Day 202 as functions of Day 29 markers (=s) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. The horizontal lines indicate the overall cumulative risk of the placebo and vaccine arms by Day 202 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.

MOCK

Figure 4.7: Marginalized cumulative risk by Day 202 as functions of Day 29 markers above a threshold ($\geq s$) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands (at least 5 cases are required). The horizontal lines indicate the overall cumulative risk of the vaccine arm by Day 202 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.

MOCK

Figure 4.8: Controlled VE with sensitivity analysis as functions of Day 29 markers (=s) among baseline seronegative vaccine recipients with 95% bootstrap point-wise confidence bands. Histograms of the immunological markers in the vaccine arm are overlaid. lod: lower limit of detection.

MOCK

Figure 4.9: Marginalized cumulative incidence rate curves for trichotomized Day 29 markers among baseline seronegative vaccine recipients. The gray line is the overall cumulative incidence rate curve in the placebo arm.

MOCK

Chapter 5

Univariate CoR: Nonparametric Threshold Modeling

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

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

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

MOCK

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

MOCK

5.1.1 Day 57 Spike protein binding antibody

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

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

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
4.536	$3.44 * 10^4$	0.00480	0.00353	0.00608
5.413	$2.59 * 10^5$	0.00271	0.00173	0.00369
5.797	$6.27 * 10^5$	0.00172	0.00090	0.00255
6.165	$1.46 * 10^6$	0.00115	0.00040	0.00191
6.405	$2.54 * 10^6$	0.00079	0.00008	0.00150
6.622	$4.19 * 10^6$	0.00021	0.00000	0.00064
6.820	$6.61 * 10^6$	0.00028	0.00000	0.00087
7.127	$1.34 * 10^7$	0.00000	0.00000	NA
7.409	$2.56 * 10^7$	0.00000	0.00000	NA
8.244	$1.75 * 10^8$	0.00000	0.00000	NA

MOCK

5.1.2 Day 57 RBD binding antibody

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

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

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
4.062	$1.15 * 10^4$	0.00490	0.00360	0.00619
5.085	$1.22 * 10^5$	0.00405	0.00282	0.00529
5.507	$3.21 * 10^5$	0.00377	0.00247	0.00507
5.839	$6.90 * 10^5$	0.00288	0.00163	0.00414
6.048	$1.12 * 10^6$	0.00238	0.00113	0.00364
6.257	$1.81 * 10^6$	0.00159	0.00043	0.00275
6.499	$3.16 * 10^6$	0.00131	0.00007	0.00255
6.847	$7.03 * 10^6$	0.00043	0.00000	0.00134
7.181	$1.52 * 10^7$	0.00087	0.00000	0.00279
8.239	$1.73 * 10^8$	0.00000	0.00000	NA

MOCK

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

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

Table of risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.699	$5.00 * 10^0$	0.00508	0.00376	0.00639
2.033	$1.08 * 10^2$	0.00390	0.00268	0.00512
2.447	$2.80 * 10^2$	0.00347	0.00223	0.00471
2.913	$8.18 * 10^2$	0.00265	0.00145	0.00385
3.196	$1.57 * 10^3$	0.00235	0.00112	0.00358
3.464	$2.91 * 10^3$	0.00115	0.00016	0.00215
3.736	$5.45 * 10^3$	0.00134	0.00013	0.00255
4.123	$1.33 * 10^4$	0.00000	0.00000	NA
4.629	$4.26 * 10^4$	0.00000	0.00000	NA
5.730	$5.37 * 10^5$	0.00000	0.00000	NA

MOCK

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

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

Table of risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
1.289	$1.95 * 10^1$	0.00514	0.00381	0.00647
2.368	$2.33 * 10^2$	0.00469	0.00334	0.00605
2.755	$5.69 * 10^2$	0.00428	0.00290	0.00565
3.104	$1.27 * 10^3$	0.00343	0.00203	0.00482
3.373	$2.36 * 10^3$	0.00310	0.00169	0.00452
3.624	$4.21 * 10^3$	0.00284	0.00130	0.00438
3.909	$8.11 * 10^3$	0.00244	0.00085	0.00404
4.259	$1.82 * 10^4$	0.00206	0.00013	0.00400
4.676	$4.74 * 10^4$	0.00256	0.00000	0.00567
5.796	$6.25 * 10^5$	0.00000	0.00000	NA

MOCK

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

MOCK

5.2.1 Day 29 Spike protein antibody

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

Table of risk estimates for a range of thresholds of Day 29 Spike protein antibody levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
3.202	$1.59 * 10^3$	0.00567	0.00427	0.00707
3.926	$8.43 * 10^3$	0.00476	0.00341	0.00611
4.187	$1.54 * 10^4$	0.00460	0.00318	0.00602
4.478	$3.01 * 10^4$	0.00355	0.00215	0.00494
4.658	$4.55 * 10^4$	0.00278	0.00138	0.00419
4.841	$6.93 * 10^4$	0.00230	0.00083	0.00377
5.022	$1.05 * 10^5$	0.00182	0.00031	0.00332
5.310	$2.04 * 10^5$	0.00147	0.00000	0.00353
5.523	$3.33 * 10^5$	0.00132	0.00000	0.00393
6.259	$1.82 * 10^6$	0.00000	0.00000	NA

MOCK

5.2.2 Day 29 RBD binding antibody

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

Table of risk estimates for a range of thresholds of Day 29 RBD binding antibody levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
2.882	$7.62 * 10^2$	0.00576	0.00435	0.00718
3.628	$4.25 * 10^3$	0.00523	0.00379	0.00666
3.889	$7.74 * 10^3$	0.00459	0.00316	0.00602
4.180	$1.51 * 10^4$	0.00434	0.00278	0.00589
4.395	$2.48 * 10^4$	0.00486	0.00298	0.00674
4.603	$4.01 * 10^4$	0.00414	0.00217	0.00611
4.826	$6.70 * 10^4$	0.00365	0.00148	0.00583
5.105	$1.27 * 10^5$	0.00104	0.00000	0.00253
5.422	$2.64 * 10^5$	0.00097	0.00000	0.00298
6.197	$1.57 * 10^6$	0.00000	0.00000	NA

MOCK

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

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

Table of risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.699	$5.00 * 10^0$	0.00585	0.00442	0.00727
1.363	$2.31 * 10^1$	0.00470	0.00331	0.00609
1.628	$4.25 * 10^1$	0.00469	0.00318	0.00619
1.848	$7.05 * 10^1$	0.00451	0.00290	0.00611
2.078	$1.20 * 10^2$	0.00399	0.00237	0.00561
2.293	$1.96 * 10^2$	0.00343	0.00175	0.00511
2.537	$3.44 * 10^2$	0.00143	0.00016	0.00270
2.791	$6.18 * 10^2$	0.00091	0.00000	0.00217
3.109	$1.29 * 10^3$	0.00199	0.00000	0.00481
4.080	$1.20 * 10^4$	0.00000	0.00000	NA

MOCK

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

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

Table of risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.699	$5.00 * 10^0$	0.00585	0.00442	0.00727
1.525	$3.35 * 10^1$	0.00535	0.00387	0.00682
1.840	$6.92 * 10^1$	0.00580	0.00412	0.00748
2.049	$1.12 * 10^2$	0.00554	0.00379	0.00730
2.276	$1.89 * 10^2$	0.00542	0.00350	0.00733
2.583	$3.83 * 10^2$	0.00479	0.00269	0.00690
2.785	$6.10 * 10^2$	0.00559	0.00288	0.00830
3.039	$1.09 * 10^3$	0.00342	0.00095	0.00589
3.351	$2.24 * 10^3$	0.00161	0.00000	0.00398
4.285	$1.93 * 10^4$	0.00000	0.00000	NA

MOCK

5.3 Plots and Tables with estimates and pointwise confidence interval for Day 57 (monotone-corrected)

MOCK

5.3.1 Day 57 Spike protein binding antibody

Figure 5.9: Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

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

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
4.536	$3.44 * 10^4$	0.00480	0.00353	0.00608
5.413	$2.59 * 10^5$	0.00271	0.00173	0.00369
5.797	$6.27 * 10^5$	0.00172	0.00090	0.00255
6.165	$1.46 * 10^6$	0.00115	0.00040	0.00191
6.405	$2.54 * 10^6$	0.00083	0.00012	0.00153
6.622	$4.19 * 10^6$	0.00024	0.00000	0.00067
6.820	$6.61 * 10^6$	0.00024	0.00000	0.00083
7.127	$1.34 * 10^7$	0.00000	0.00000	NA
7.409	$2.56 * 10^7$	0.00000	0.00000	NA
8.244	$1.75 * 10^8$	0.00000	0.00000	NA

MOCK

5.3.2 Day 57 RBD binding antibody

Figure 5.10: Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table of monotone-corrected risk estimates for a range of thresholds of Day 57 RBD binding antibody levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
4.062	$1.15 * 10^4$	0.00490	0.00360	0.00619
5.085	$1.22 * 10^5$	0.00407	0.00283	0.00531
5.507	$3.21 * 10^5$	0.00377	0.00247	0.00507
5.839	$6.90 * 10^5$	0.00288	0.00163	0.00414
6.048	$1.12 * 10^6$	0.00238	0.00113	0.00364
6.257	$1.81 * 10^6$	0.00159	0.00043	0.00275
6.499	$3.16 * 10^6$	0.00124	0.00001	0.00248
6.847	$7.03 * 10^6$	0.00064	0.00000	0.00155
7.181	$1.52 * 10^7$	0.00064	0.00000	0.00255
8.239	$1.73 * 10^8$	0.00000	0.00000	NA

MOCK

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

Figure 5.11: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.699	$5.00 * 10^0$	0.00508	0.00376	0.00639
2.033	$1.08 * 10^2$	0.00390	0.00268	0.00512
2.447	$2.80 * 10^2$	0.00347	0.00223	0.00471
2.913	$8.18 * 10^2$	0.00272	0.00152	0.00392
3.196	$1.57 * 10^3$	0.00235	0.00112	0.00358
3.464	$2.91 * 10^3$	0.00126	0.00027	0.00225
3.736	$5.45 * 10^3$	0.00126	0.00005	0.00247
4.123	$1.33 * 10^4$	0.00000	0.00000	NA
4.629	$4.26 * 10^4$	0.00000	0.00000	NA
5.730	$5.37 * 10^5$	0.00000	0.00000	NA

MOCK

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

Figure 5.12: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
1.289	$1.95 * 10^1$	0.00514	0.00381	0.00647
2.368	$2.33 * 10^2$	0.00469	0.00334	0.00605
2.755	$5.69 * 10^2$	0.00428	0.00290	0.00565
3.104	$1.27 * 10^3$	0.00343	0.00203	0.00482
3.373	$2.36 * 10^3$	0.00312	0.00171	0.00454
3.624	$4.21 * 10^3$	0.00284	0.00130	0.00438
3.909	$8.11 * 10^3$	0.00243	0.00083	0.00402
4.259	$1.82 * 10^4$	0.00208	0.00015	0.00402
4.676	$4.74 * 10^4$	0.00208	0.00000	0.00520
5.796	$6.25 * 10^5$	0.00000	0.00000	NA

MOCK

5.4 Plots and Tables with estimates and pointwise confidence intervals for Day 29 (monotone-corrected)

MOCK

5.4.1 Day 29 Spike protein antibody

Figure 5.13: Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Spike protein antibody levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
3.202	$1.59 * 10^3$	0.00567	0.00427	0.00707
3.926	$8.43 * 10^3$	0.00476	0.00341	0.00611
4.187	$1.54 * 10^4$	0.00459	0.00317	0.00601
4.478	$3.01 * 10^4$	0.00355	0.00215	0.00494
4.658	$4.55 * 10^4$	0.00278	0.00138	0.00419
4.841	$6.93 * 10^4$	0.00230	0.00083	0.00377
5.022	$1.05 * 10^5$	0.00182	0.00031	0.00332
5.310	$2.04 * 10^5$	0.00172	0.00000	0.00379
5.523	$3.33 * 10^5$	0.00172	0.00000	0.00434
6.259	$1.82 * 10^6$	0.00000	0.00000	NA

MOCK

5.4.2 Day 29 RBD binding antibody

Figure 5.14: Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table of monotone-corrected risk estimates for a range of thresholds of Day 29 RBD binding antibody levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
2.882	$7.62 * 10^2$	0.00576	0.00435	0.00718
3.628	$4.25 * 10^3$	0.00523	0.00379	0.00666
3.889	$7.74 * 10^3$	0.00459	0.00316	0.00602
4.180	$1.51 * 10^4$	0.00452	0.00297	0.00607
4.395	$2.48 * 10^4$	0.00452	0.00264	0.00640
4.603	$4.01 * 10^4$	0.00414	0.00217	0.00611
4.826	$6.70 * 10^4$	0.00365	0.00148	0.00583
5.105	$1.27 * 10^5$	0.00112	0.00000	0.00261
5.422	$2.64 * 10^5$	0.00112	0.00000	0.00314
6.197	$1.57 * 10^6$	0.00000	0.00000	NA

MOCK

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

Figure 5.15: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.699	$5.00 * 10^0$	0.00585	0.00442	0.00727
1.363	$2.31 * 10^1$	0.00470	0.00331	0.00610
1.628	$4.25 * 10^1$	0.00468	0.00318	0.00619
1.848	$7.05 * 10^1$	0.00445	0.00284	0.00606
2.078	$1.20 * 10^2$	0.00411	0.00249	0.00573
2.293	$1.96 * 10^2$	0.00343	0.00175	0.00511
2.537	$3.44 * 10^2$	0.00164	0.00037	0.00291
2.791	$6.18 * 10^2$	0.00164	0.00039	0.00290
3.109	$1.29 * 10^3$	0.00164	0.00000	0.00446
4.080	$1.20 * 10^4$	0.00000	0.00000	NA

MOCK

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

Figure 5.16: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.699	$5.00 * 10^0$	0.00585	0.00442	0.00727
1.525	$3.35 * 10^1$	0.00554	0.00406	0.00701
1.840	$6.92 * 10^1$	0.00554	0.00386	0.00721
2.049	$1.12 * 10^2$	0.00545	0.00369	0.00721
2.276	$1.89 * 10^2$	0.00534	0.00343	0.00726
2.583	$3.83 * 10^2$	0.00515	0.00304	0.00726
2.785	$6.10 * 10^2$	0.00515	0.00244	0.00786
3.039	$1.09 * 10^3$	0.00349	0.00102	0.00596
3.351	$2.24 * 10^3$	0.00242	0.00005	0.00480
4.285	$1.93 * 10^4$	0.00000	0.00000	NA

MOCK

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

MOCK

5.5.1 Day 57 Spike protein binding antibody

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

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

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
4.536	$3.44 * 10^4$	0.00480	0.00289	0.00671
5.413	$2.59 * 10^5$	0.00271	0.00125	0.00418
5.797	$6.27 * 10^5$	0.00172	0.00049	0.00296
6.165	$1.46 * 10^6$	0.00115	0.00002	0.00228
6.405	$2.54 * 10^6$	0.00079	0.00000	0.00185
6.622	$4.19 * 10^6$	0.00021	0.00000	0.00085
6.820	$6.61 * 10^6$	0.00028	0.00000	0.00116
7.127	$1.34 * 10^7$	0.00000	0.00000	NA
7.409	$2.56 * 10^7$	0.00000	0.00000	NA
8.244	$1.75 * 10^8$	0.00000	0.00000	NA

MOCK

5.5.2 Day 57 RBD binding antibody

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

Table of risk estimates for a range of thresholds of Day 57 RBD binding antibody levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
4.062	$1.15 * 10^4$	0.00490	0.00302	0.00677
5.085	$1.22 * 10^5$	0.00405	0.00226	0.00585
5.507	$3.21 * 10^5$	0.00377	0.00188	0.00565
5.839	$6.90 * 10^5$	0.00288	0.00106	0.00470
6.048	$1.12 * 10^6$	0.00238	0.00056	0.00420
6.257	$1.81 * 10^6$	0.00159	0.00000	0.00327
6.499	$3.16 * 10^6$	0.00131	0.00000	0.00310
6.847	$7.03 * 10^6$	0.00043	0.00000	0.00176
7.181	$1.52 * 10^7$	0.00087	0.00000	0.00365
8.239	$1.73 * 10^8$	0.00000	0.00000	NA

MOCK

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

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

Table of risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.699	$5.00 * 10^0$	0.00508	0.00314	0.00701
2.033	$1.08 * 10^2$	0.00390	0.00211	0.00570
2.447	$2.80 * 10^2$	0.00347	0.00165	0.00529
2.913	$8.18 * 10^2$	0.00265	0.00089	0.00442
3.196	$1.57 * 10^3$	0.00235	0.00055	0.00416
3.464	$2.91 * 10^3$	0.00115	0.00000	0.00261
3.736	$5.45 * 10^3$	0.00134	0.00000	0.00312
4.123	$1.33 * 10^4$	0.00000	0.00000	NA
4.629	$4.26 * 10^4$	0.00000	0.00000	NA
5.730	$5.37 * 10^5$	0.00000	0.00000	NA

MOCK

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

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

Table of risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
1.289	$1.95 * 10^1$	0.00514	0.00323	0.00706
2.368	$2.33 * 10^2$	0.00469	0.00274	0.00665
2.755	$5.69 * 10^2$	0.00428	0.00229	0.00626
3.104	$1.27 * 10^3$	0.00343	0.00141	0.00544
3.373	$2.36 * 10^3$	0.00310	0.00107	0.00514
3.624	$4.21 * 10^3$	0.00284	0.00061	0.00506
3.909	$8.11 * 10^3$	0.00244	0.00015	0.00474
4.259	$1.82 * 10^4$	0.00206	0.00000	0.00485
4.676	$4.74 * 10^4$	0.00256	0.00000	0.00705
5.796	$6.25 * 10^5$	0.00000	0.00000	NA

MOCK

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

MOCK

5.6.1 Day 29 Spike protein antibody

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

Table of risk estimates for a range of thresholds of Day 29 Spike protein antibody levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
3.202	$1.59 * 10^3$	0.00567	0.00364	0.00770
3.926	$8.43 * 10^3$	0.00476	0.00280	0.00672
4.187	$1.54 * 10^4$	0.00460	0.00254	0.00666
4.478	$3.01 * 10^4$	0.00355	0.00153	0.00557
4.658	$4.55 * 10^4$	0.00278	0.00076	0.00481
4.841	$6.93 * 10^4$	0.00230	0.00017	0.00443
5.022	$1.05 * 10^5$	0.00182	0.00000	0.00400
5.310	$2.04 * 10^5$	0.00147	0.00000	0.00446
5.523	$3.33 * 10^5$	0.00132	0.00000	0.00511
6.259	$1.82 * 10^6$	0.00000	0.00000	NA

MOCK

5.6.2 Day 29 RBD binding antibody

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

Table of risk estimates for a range of thresholds of Day 29 RBD binding antibody levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
2.882	$7.62 * 10^2$	0.00576	0.00374	0.00779
3.628	$4.25 * 10^3$	0.00523	0.00318	0.00728
3.889	$7.74 * 10^3$	0.00459	0.00255	0.00663
4.180	$1.51 * 10^4$	0.00434	0.00211	0.00656
4.395	$2.48 * 10^4$	0.00486	0.00217	0.00755
4.603	$4.01 * 10^4$	0.00414	0.00132	0.00696
4.826	$6.70 * 10^4$	0.00365	0.00054	0.00676
5.105	$1.27 * 10^5$	0.00104	0.00000	0.00317
5.422	$2.64 * 10^5$	0.00097	0.00000	0.00385
6.197	$1.57 * 10^6$	0.00000	0.00000	NA

MOCK

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

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

Table of risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.699	$5.00 * 10^0$	0.00585	0.00382	0.00788
1.363	$2.31 * 10^1$	0.00470	0.00271	0.00668
1.628	$4.25 * 10^1$	0.00469	0.00254	0.00683
1.848	$7.05 * 10^1$	0.00451	0.00222	0.00680
2.078	$1.20 * 10^2$	0.00399	0.00168	0.00630
2.293	$1.96 * 10^2$	0.00343	0.00104	0.00582
2.537	$3.44 * 10^2$	0.00143	0.00000	0.00323
2.791	$6.18 * 10^2$	0.00091	0.00000	0.00270
3.109	$1.29 * 10^3$	0.00199	0.00000	0.00601
4.080	$1.20 * 10^4$	0.00000	0.00000	NA

MOCK

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

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

Table of risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.699	$5.00 * 10^0$	0.00585	0.00382	0.00788
1.525	$3.35 * 10^1$	0.00535	0.00324	0.00745
1.840	$6.92 * 10^1$	0.00580	0.00341	0.00819
2.049	$1.12 * 10^2$	0.00554	0.00304	0.00805
2.276	$1.89 * 10^2$	0.00542	0.00269	0.00814
2.583	$3.83 * 10^2$	0.00479	0.00179	0.00780
2.785	$6.10 * 10^2$	0.00559	0.00172	0.00945
3.039	$1.09 * 10^3$	0.00342	0.00000	0.00694
3.351	$2.24 * 10^3$	0.00161	0.00000	0.00499
4.285	$1.93 * 10^4$	0.00000	0.00000	NA

MOCK

5.7 Plots and Tables with estimates and pointwise confidence interval for Day 57 (monotone-corrected)

MOCK

5.7.1 Day 57 Spike protein binding antibody

Figure 5.25: Adjusted threshold-response function for a range of thresholds of the Day 57 Spike protein binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

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

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
4.536	$3.44 * 10^4$	0.00480	0.00289	0.00671
5.413	$2.59 * 10^5$	0.00271	0.00125	0.00418
5.797	$6.27 * 10^5$	0.00172	0.00049	0.00296
6.165	$1.46 * 10^6$	0.00115	0.00002	0.00228
6.405	$2.54 * 10^6$	0.00083	0.00000	0.00189
6.622	$4.19 * 10^6$	0.00024	0.00000	0.00089
6.820	$6.61 * 10^6$	0.00024	0.00000	0.00112
7.127	$1.34 * 10^7$	0.00000	0.00000	NA
7.409	$2.56 * 10^7$	0.00000	0.00000	NA
8.244	$1.75 * 10^8$	0.00000	0.00000	NA

MOCK

5.7.2 Day 57 RBD binding antibody

Figure 5.26: Adjusted threshold-response function for a range of thresholds of the Day 57 RBD binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table of monotone-corrected risk estimates for a range of thresholds of Day 57 RBD binding antibody levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
4.062	$1.15 * 10^4$	0.00490	0.00302	0.00677
5.085	$1.22 * 10^5$	0.00407	0.00228	0.00586
5.507	$3.21 * 10^5$	0.00377	0.00188	0.00565
5.839	$6.90 * 10^5$	0.00288	0.00106	0.00470
6.048	$1.12 * 10^6$	0.00238	0.00056	0.00420
6.257	$1.81 * 10^6$	0.00159	0.00000	0.00327
6.499	$3.16 * 10^6$	0.00124	0.00000	0.00304
6.847	$7.03 * 10^6$	0.00064	0.00000	0.00196
7.181	$1.52 * 10^7$	0.00064	0.00000	0.00341
8.239	$1.73 * 10^8$	0.00000	0.00000	NA

MOCK

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

Figure 5.27: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.699	$5.00 * 10^0$	0.00508	0.00314	0.00701
2.033	$1.08 * 10^2$	0.00390	0.00211	0.00570
2.447	$2.80 * 10^2$	0.00347	0.00165	0.00529
2.913	$8.18 * 10^2$	0.00272	0.00095	0.00448
3.196	$1.57 * 10^3$	0.00235	0.00055	0.00416
3.464	$2.91 * 10^3$	0.00126	0.00000	0.00272
3.736	$5.45 * 10^3$	0.00126	0.00000	0.00304
4.123	$1.33 * 10^4$	0.00000	0.00000	NA
4.629	$4.26 * 10^4$	0.00000	0.00000	NA
5.730	$5.37 * 10^5$	0.00000	0.00000	NA

MOCK

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

Figure 5.28: Adjusted threshold-response function for a range of thresholds of the Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
1.289	$1.95 * 10^1$	0.00514	0.00323	0.00706
2.368	$2.33 * 10^2$	0.00469	0.00274	0.00665
2.755	$5.69 * 10^2$	0.00428	0.00229	0.00626
3.104	$1.27 * 10^3$	0.00343	0.00141	0.00544
3.373	$2.36 * 10^3$	0.00312	0.00108	0.00516
3.624	$4.21 * 10^3$	0.00284	0.00061	0.00506
3.909	$8.11 * 10^3$	0.00243	0.00013	0.00473
4.259	$1.82 * 10^4$	0.00208	0.00000	0.00487
4.676	$4.74 * 10^4$	0.00208	0.00000	0.00657
5.796	$6.25 * 10^5$	0.00000	0.00000	NA

MOCK

5.8 Plots and Tables with estimates and pointwise confidence intervals for Day 29 (monotone-corrected)

MOCK

5.8.1 Day 29 Spike protein antibody

Figure 5.29: Adjusted threshold-response function for a range of thresholds of the Day 29 Spike protein antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Spike protein antibody levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
3.202	$1.59 * 10^3$	0.00567	0.00364	0.00770
3.926	$8.43 * 10^3$	0.00476	0.00280	0.00672
4.187	$1.54 * 10^4$	0.00459	0.00253	0.00665
4.478	$3.01 * 10^4$	0.00355	0.00153	0.00557
4.658	$4.55 * 10^4$	0.00278	0.00076	0.00481
4.841	$6.93 * 10^4$	0.00230	0.00017	0.00443
5.022	$1.05 * 10^5$	0.00182	0.00000	0.00400
5.310	$2.04 * 10^5$	0.00172	0.00000	0.00472
5.523	$3.33 * 10^5$	0.00172	0.00000	0.00551
6.259	$1.82 * 10^6$	0.00000	0.00000	NA

MOCK

5.8.2 Day 29 RBD binding antibody

Figure 5.30: Adjusted threshold-response function for a range of thresholds of the Day 29 RBD binding antibody levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table of monotone-corrected risk estimates for a range of thresholds of Day 29 RBD binding antibody levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
2.882	$7.62 * 10^2$	0.00576	0.00374	0.00779
3.628	$4.25 * 10^3$	0.00523	0.00318	0.00728
3.889	$7.74 * 10^3$	0.00459	0.00255	0.00663
4.180	$1.51 * 10^4$	0.00452	0.00230	0.00674
4.395	$2.48 * 10^4$	0.00452	0.00183	0.00721
4.603	$4.01 * 10^4$	0.00414	0.00132	0.00696
4.826	$6.70 * 10^4$	0.00365	0.00054	0.00676
5.105	$1.27 * 10^5$	0.00112	0.00000	0.00325
5.422	$2.64 * 10^5$	0.00112	0.00000	0.00400
6.197	$1.57 * 10^6$	0.00000	0.00000	NA

MOCK

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

Figure 5.31: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (50% titer) levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.699	$5.00 * 10^0$	0.00585	0.00382	0.00788
1.363	$2.31 * 10^1$	0.00470	0.00272	0.00669
1.628	$4.25 * 10^1$	0.00468	0.00254	0.00683
1.848	$7.05 * 10^1$	0.00445	0.00216	0.00674
2.078	$1.20 * 10^2$	0.00411	0.00180	0.00642
2.293	$1.96 * 10^2$	0.00343	0.00104	0.00582
2.537	$3.44 * 10^2$	0.00164	0.00000	0.00345
2.791	$6.18 * 10^2$	0.00164	0.00000	0.00343
3.109	$1.29 * 10^3$	0.00164	0.00000	0.00565
4.080	$1.20 * 10^4$	0.00000	0.00000	NA

MOCK

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

Figure 5.32: Adjusted threshold-response function for a range of thresholds of the Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Pseudo virus-neutralizing antibody (80% titer) levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.699	$5.00 * 10^0$	0.00585	0.00382	0.00788
1.525	$3.35 * 10^1$	0.00554	0.00343	0.00764
1.840	$6.92 * 10^1$	0.00554	0.00314	0.00793
2.049	$1.12 * 10^2$	0.00545	0.00294	0.00796
2.276	$1.89 * 10^2$	0.00534	0.00262	0.00807
2.583	$3.83 * 10^2$	0.00515	0.00215	0.00816
2.785	$6.10 * 10^2$	0.00515	0.00129	0.00902
3.039	$1.09 * 10^3$	0.00349	0.00000	0.00701
3.351	$2.24 * 10^3$	0.00242	0.00000	0.00581
4.285	$1.93 * 10^4$	0.00000	0.00000	NA

MOCK

MOCK

Bibliography

Donovan, K., Hudgens, M., and Gilbert, P. B. (2019). Nonparametric inference for immune response thresholds of risk in vaccine studies. Annals of Applied Statistics, 13(2):1147–1165. PMCID: PMC6613658 [Delayed release (embargo): Available on 2020-06-01].

MOCK