COVID-19 Correlates of Risk Analysis Report

MockCOVE Study

USG COVID-19 Response Biostatistics Team

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Chapter 1

Disclaimers

The data presented in the analysis are provided to NIAID in accordance with Clinical Trial Agreement between the parties. The study was funded in part by BARDA under Government Contract No. 75A50120C00034.

Statistical Analysis Plan

The SAP is available at https://doi.org/10.6084/m9.figshare.13198595

Reproducibility Notice

This project integrates the virtual environments framework provided by the `renv` package for computational reproducibility. By taking this approach, all results are generated using a consistent versioning of both R and several R packages. This version of the report was built with R version 4.0.4 (2021-02-15), pandoc version 2.2, and the following R packages:

package	version	source
bookdown	0.21.7	Github (rstudio/bookdown@0cec2fd)
bslib	0.2.4.9002	Github (rstudio/bslib@c7835c2)
data.table	1.14.0	CRAN (R 4.0.4)
delayed	0.4.0	Github (tlverse/delayed@f415340)
devtools	2.3.2	CRAN (R 4.0.4)
dplyr	1.0.5	CRAN (R 4.0.4)
ggplot2	3.3.3	CRAN (R 4.0.4)
hal9001	0.4.0	Github (tlverse/hal9001@b41ed5d)
haldensify	0.1.5	Github (nhejazi/haldensify@16350cc)
here	1.0.1	CRAN (R 4.0.4)
kableExtra	1.3.4	CRAN (R 4.0.4)
knitr	1.31	CRAN (R 4.0.4)
latex2exp	0.5.0	CRAN (R 4.0.4)
mvtnorm	1.1-1	CRAN (R 4.0.4)
origami	1.0.3	CRAN (R 4.0.4)
readr	1.4.0	CRAN (R 4.0.4)
rmarkdown	2.7.4	Github (rstudio/rmarkdown@a11240d)
skimr	2.1.3	CRAN (R 4.0.4)
sl3	1.4.3	Github (tlverse/sl3@982f4d6)
stringr	1.4.0	CRAN (R 4.0.4)
SuperLearner	2.0-28	CRAN (R 4.0.4)
svyVGAM	1.0	CRAN (R 4.0.4)
tibble	3.1.1	CRAN (R 4.0.4)

package	version	source
tidyr	1.1.3	CRAN (R 4.0.4)
txshift	0.3.6	Github (nhejazi/txshift@c0f572a)
VGAM	1.1-5	CRAN (R 4.0.4)
xtable	1.8-4	CRAN (R 4.0.4)

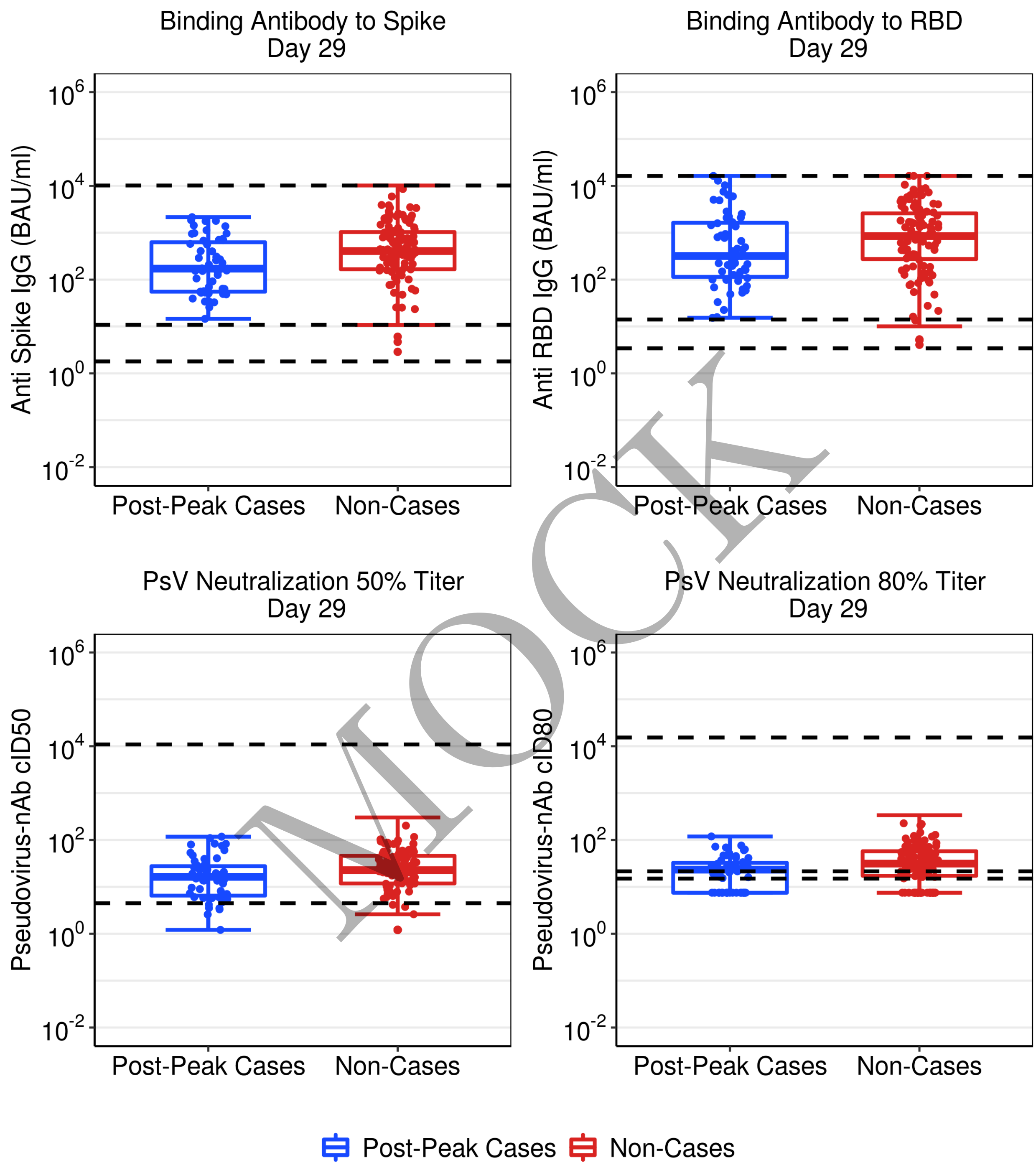
To get started with using this project and its `renv` package library, we first recommend briefly reviewing the `renv` collaboration guide.

Chapter 2

Graphical Descriptions of Antibody Marker Data

2.1 Boxplots

\begin{figure}[H]

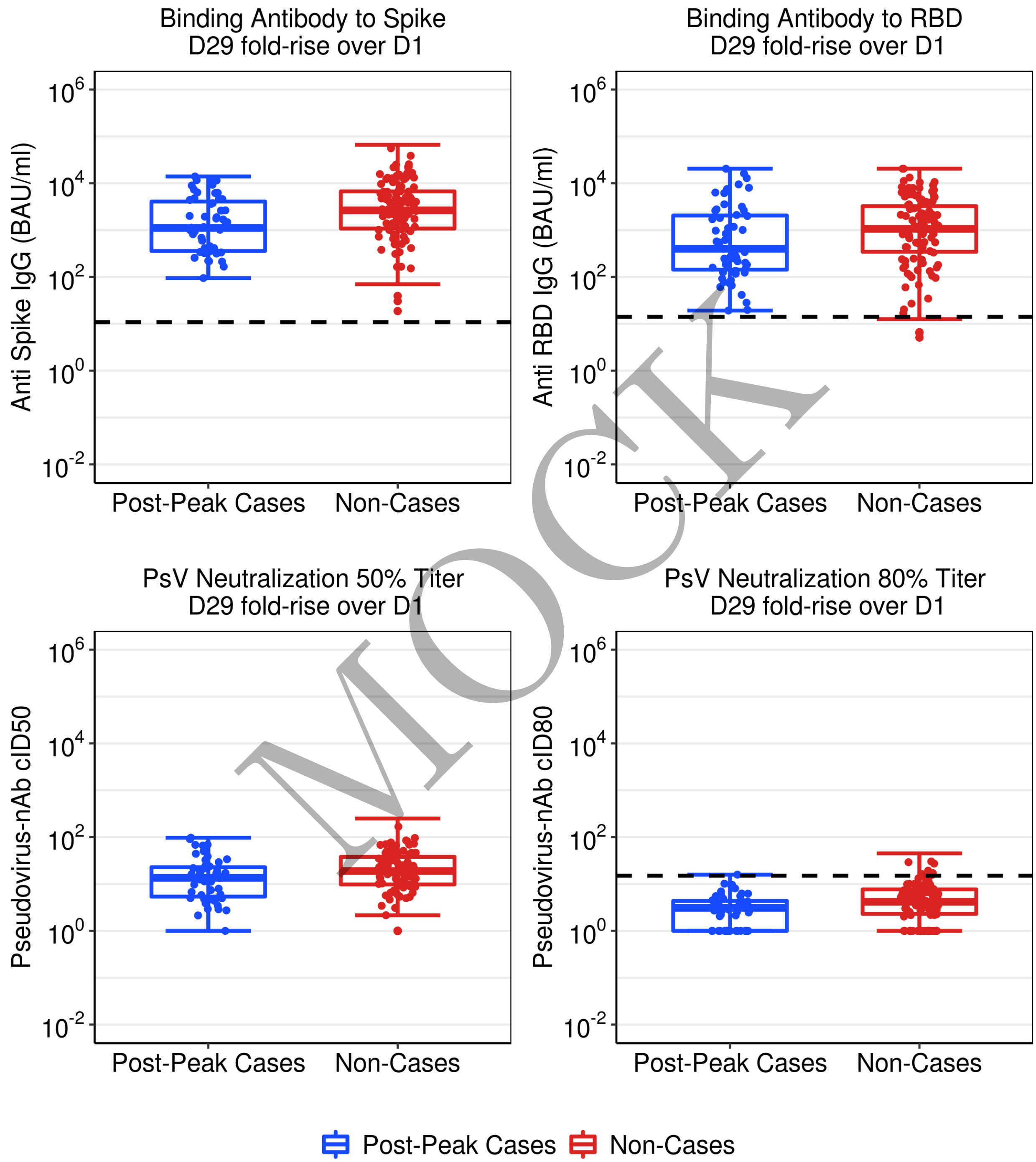


\caption{

Figure 3.1: Boxplots of Day 29 Ab markers: vaccine arm. The three dashed lines in each figure are ULOQ, LLOQ, and LLOD, from top to bottom respectively.

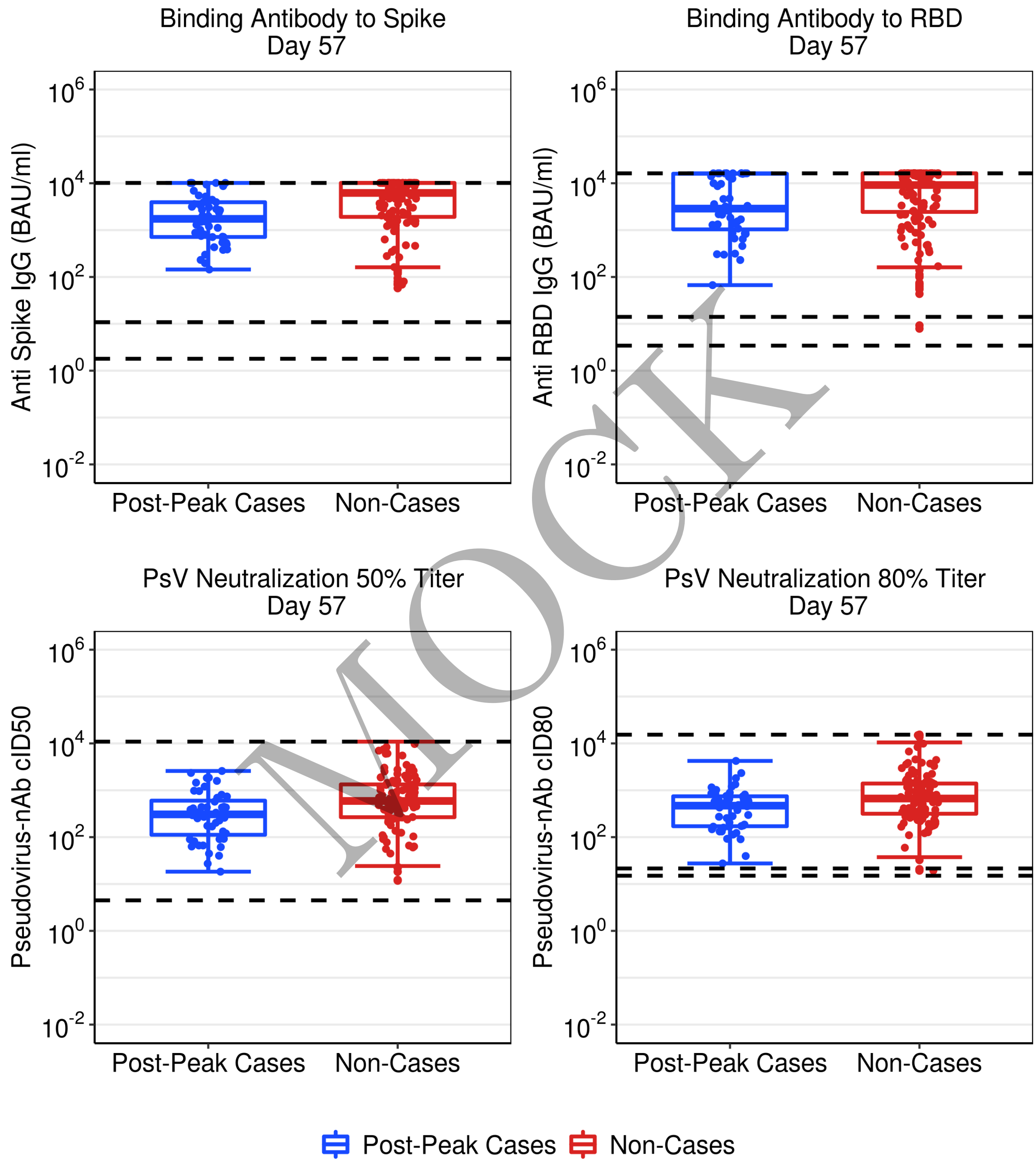
} \end{figure}

\begin{figure}[H]



\caption{
Figure 3.2: Boxplots of D29 fold-rise over D1 Ab markers: vaccine arm.
} \end{figure}

\begin{figure}[H]

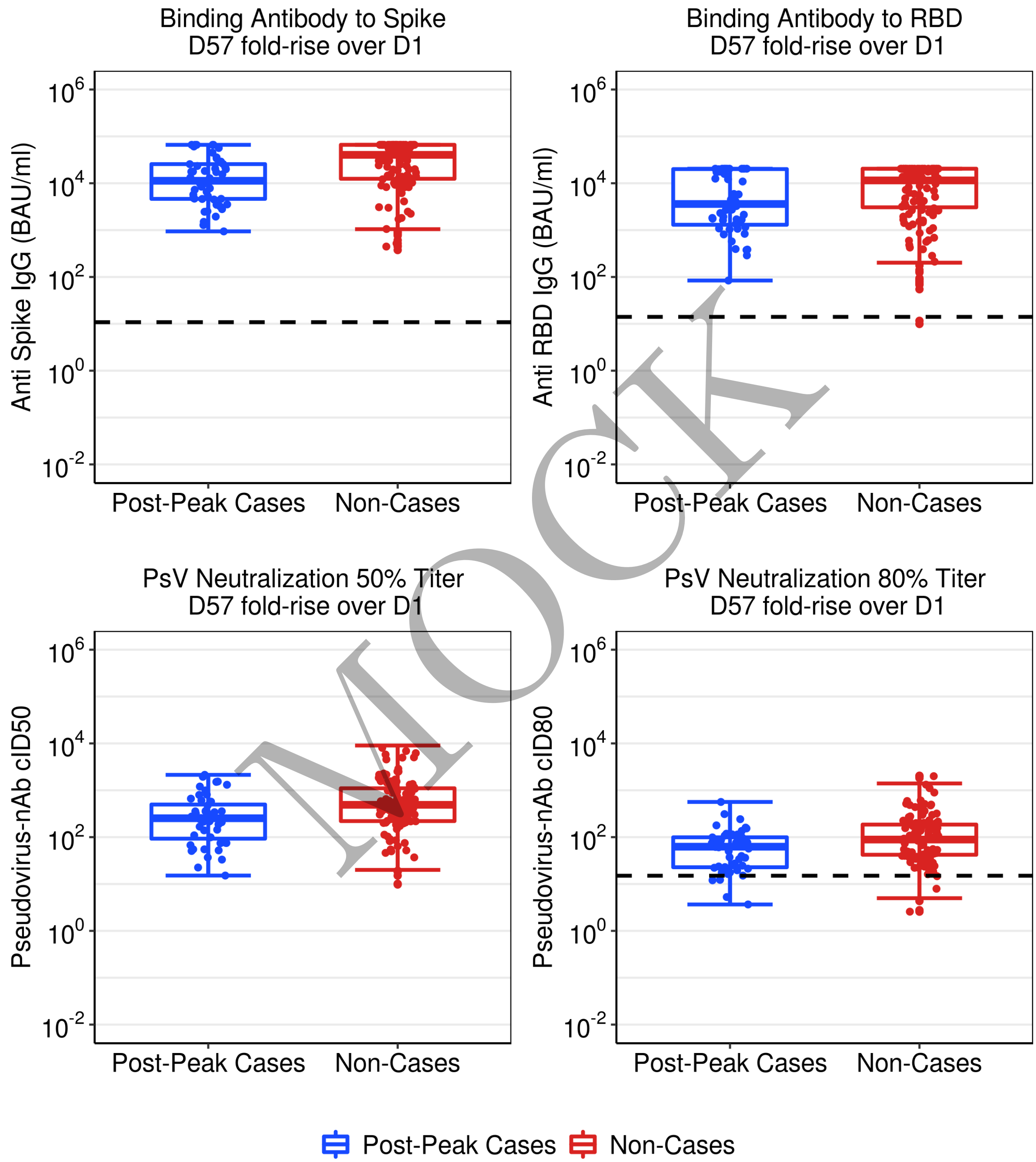


\caption{

Figure 3.3: Boxplots of Day 57 Ab markers: vaccine arm. The three dashed lines in each figure are ULOQ, LLOQ, and LLOD, from top to bottom respectively.

} \end{figure}

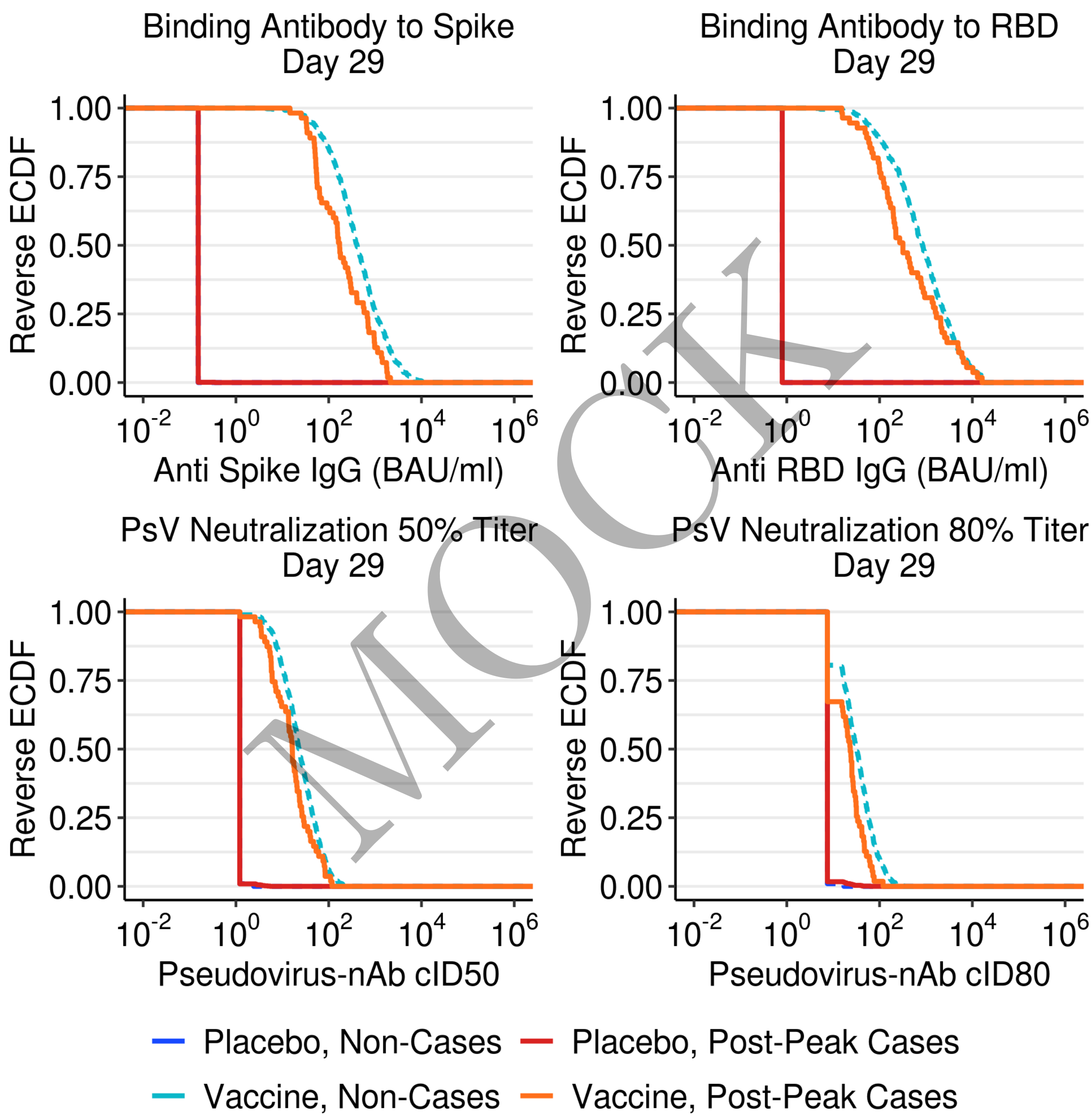
\begin{figure}[H]



\caption{
Figure 3.4: Boxplots of D57 fold-rise over D1 Ab markers: vaccine arm.
} \end{figure}

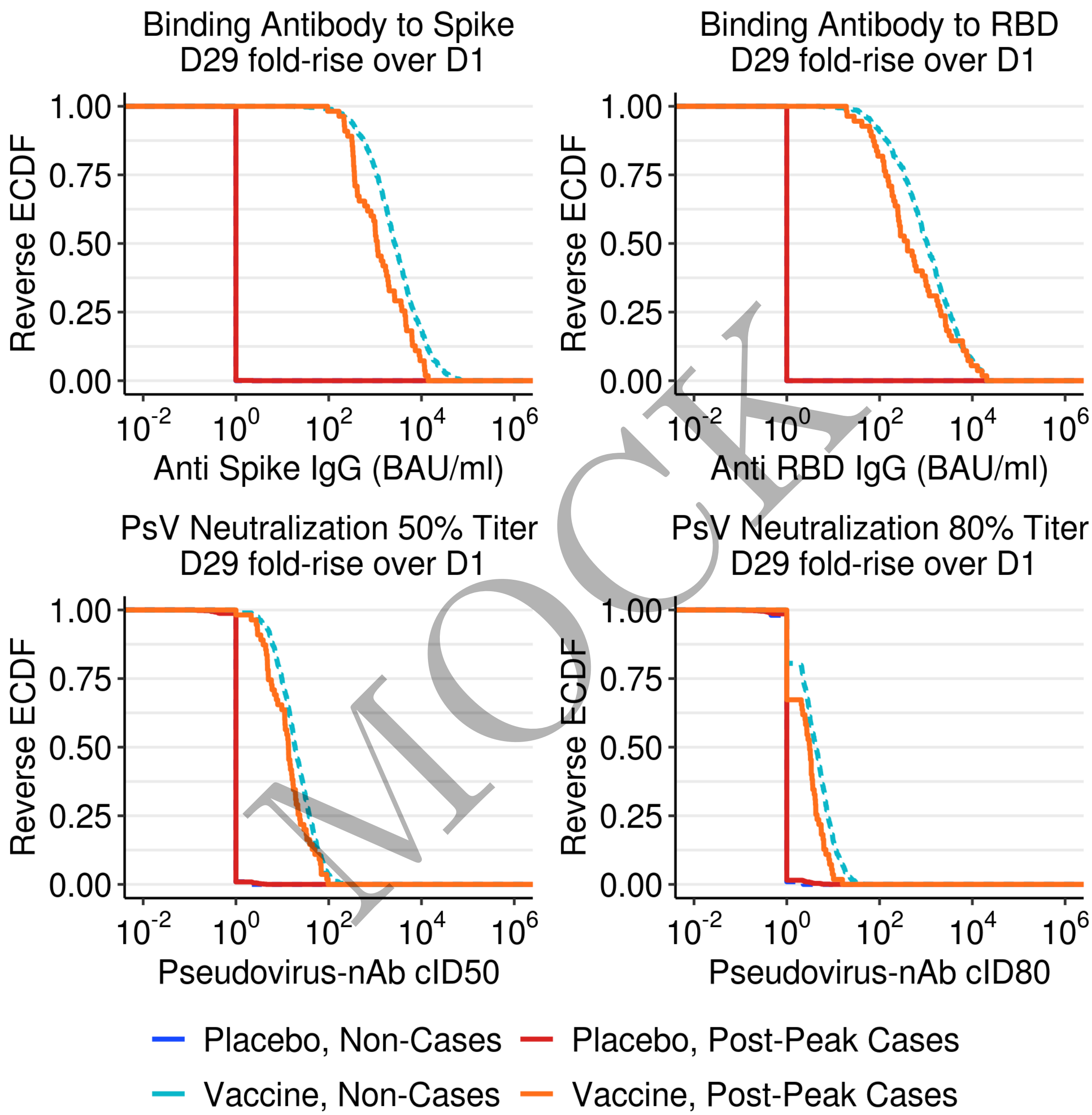
2.2 Weighted RCDF plots

\begin{figure}[H]



\caption{
Figure 3.5: RCDF plots for Day 29 Ab markers by treatment arm.
} \end{figure}

\begin{figure}[H]

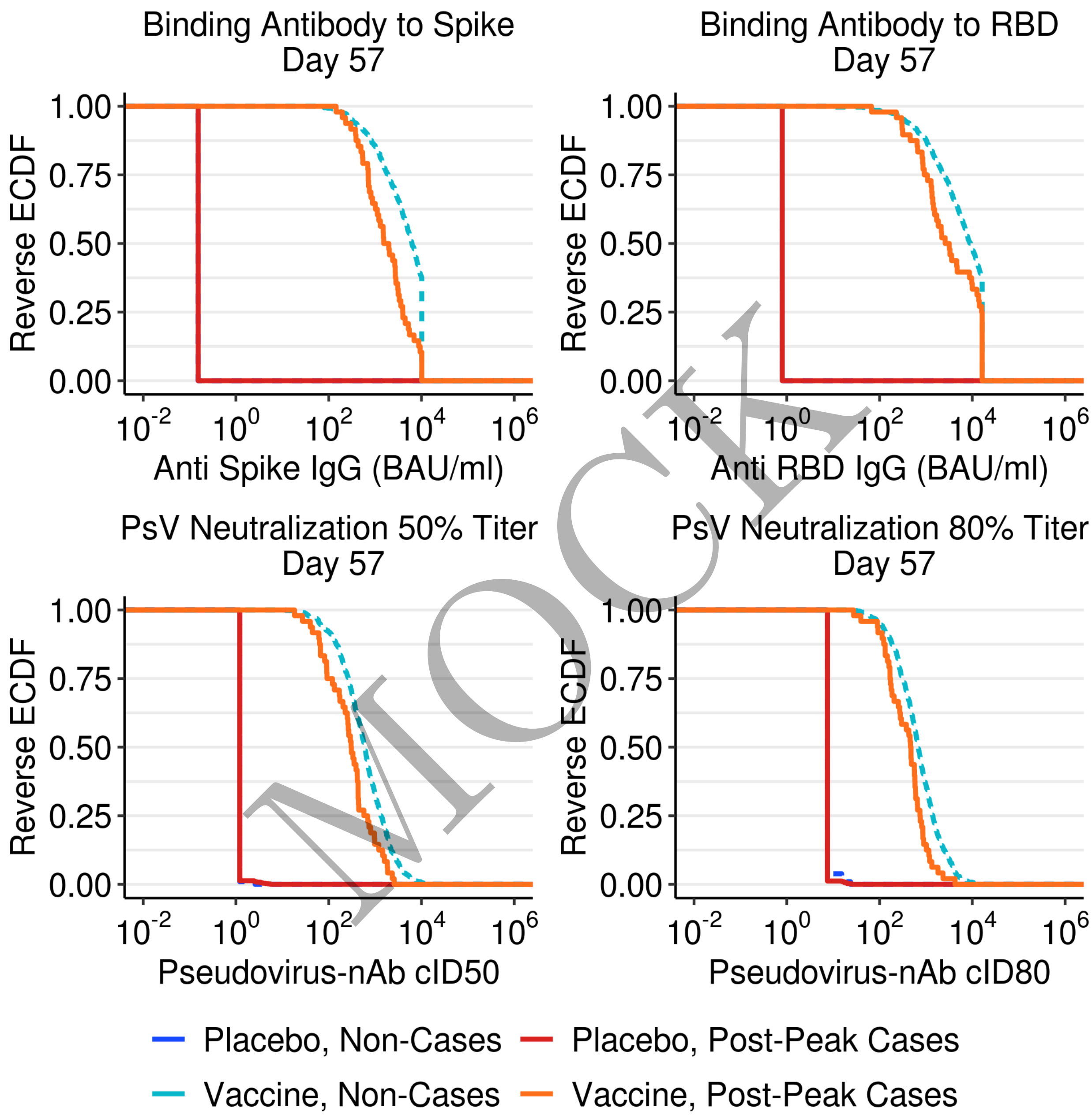


\caption{

Figure 3.6: RCDF plots for D29 fold-rise over D1 Ab markers by treatment arm.

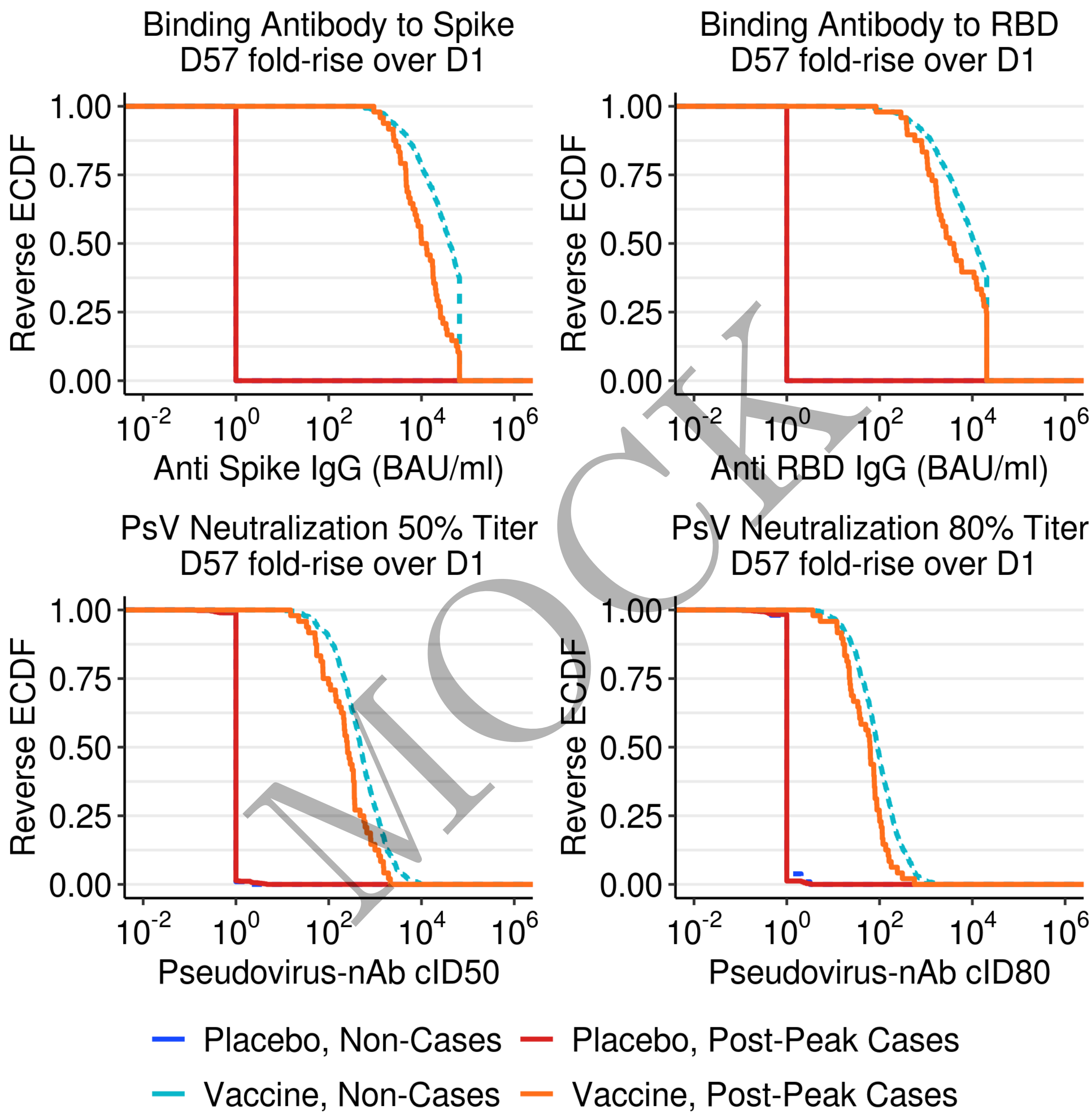
} \end{figure}

\begin{figure}[H]



\caption{
Figure 3.7: RCDF plots for Day 57 Ab markers by treatment arm.
} \end{figure}

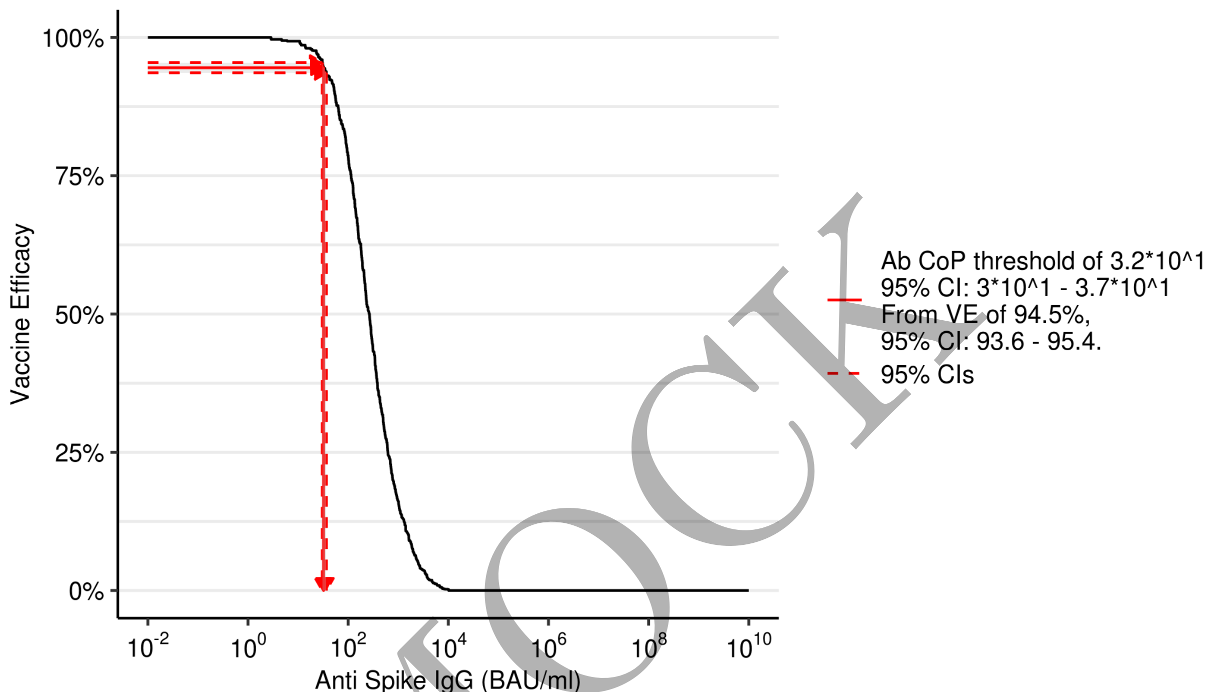
\begin{figure}[H]



\caption{
Figure 3.8: RCDF plots for D57 fold-rise over D1 Ab markers by treatment arm.
} \end{figure}

2.3 Weighted RCDF plots of threshold correlate concentration for vaccine efficacy

\begin{figure}[H]

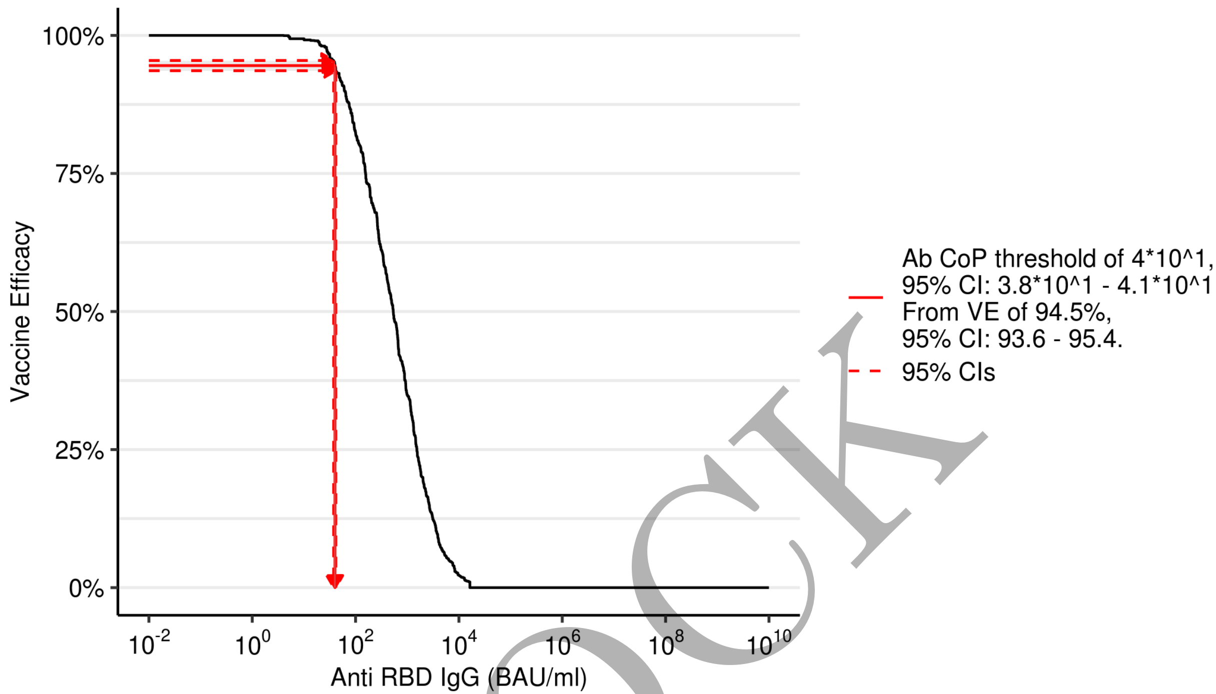


\caption{

Figure 3.9: Marker RCDF of Day 29 anti-Spike binding Ab: vaccine arm.

} \end{figure}

\begin{figure}[H]

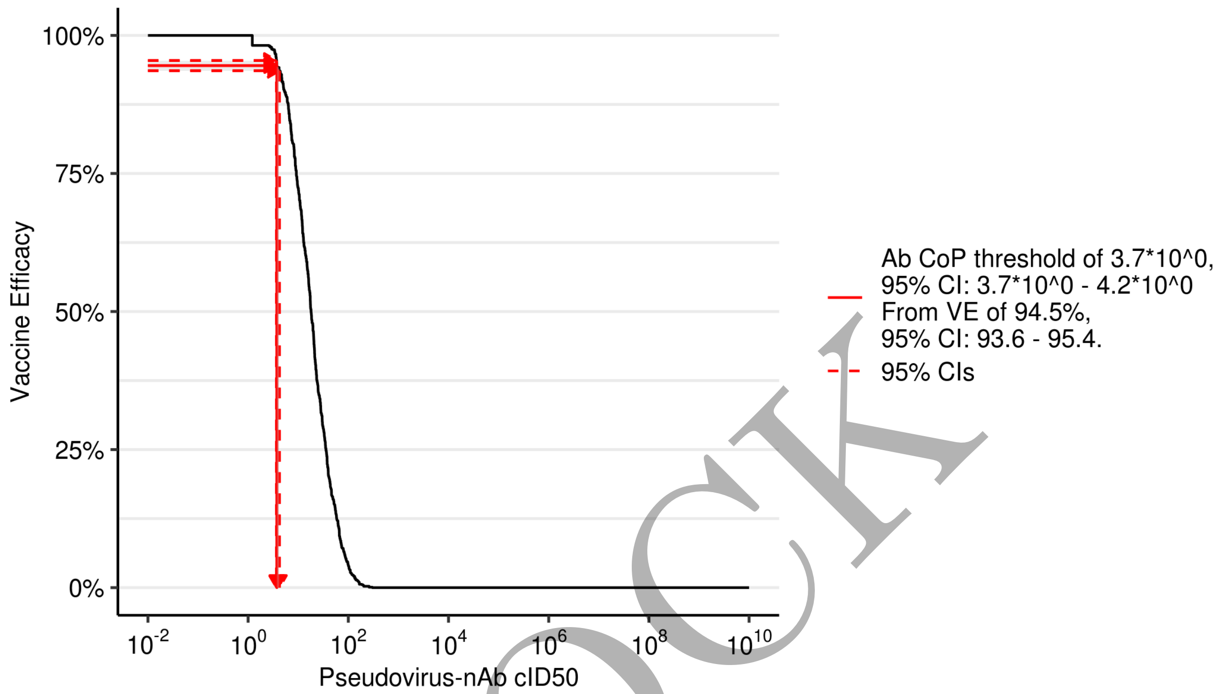


\caption{

Figure 3.10: Marker RCDF of Day 29 anti-RBD binding Ab: vaccine arm.

} \end{figure}

\begin{figure}[H]

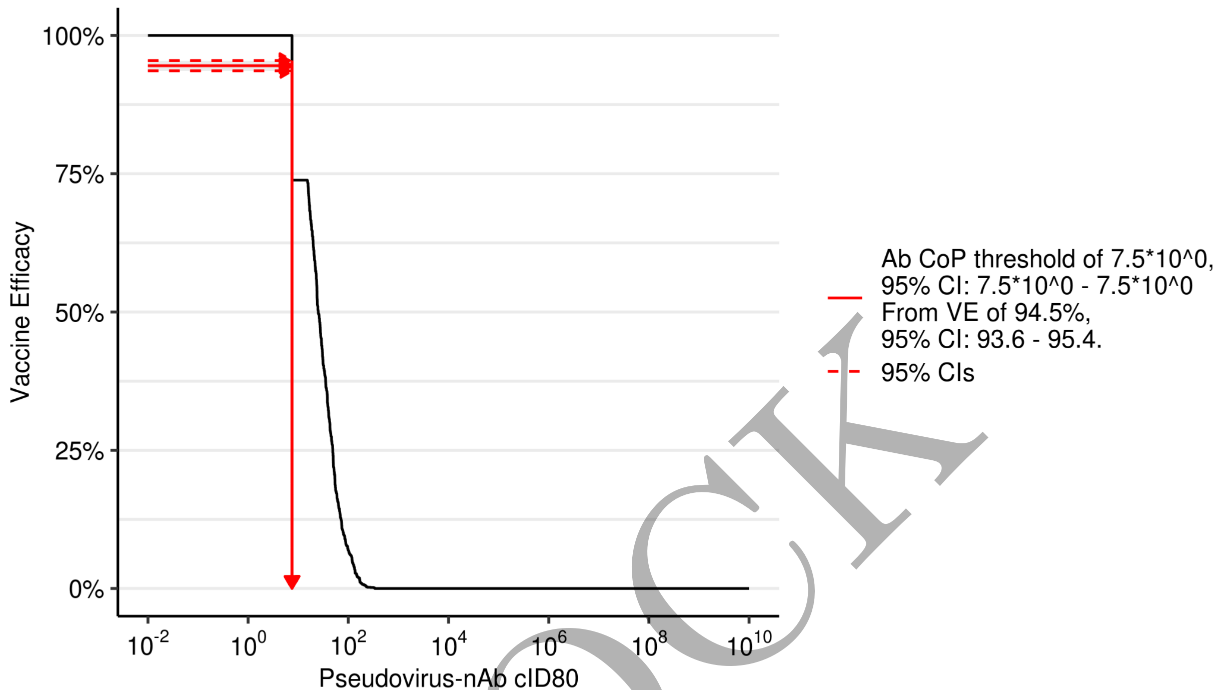


\caption{

Figure 3.11: Marker RCDF of Day 29 PsV-nAb ID50: vaccine arm.

} \end{figure}

\begin{figure}[H]

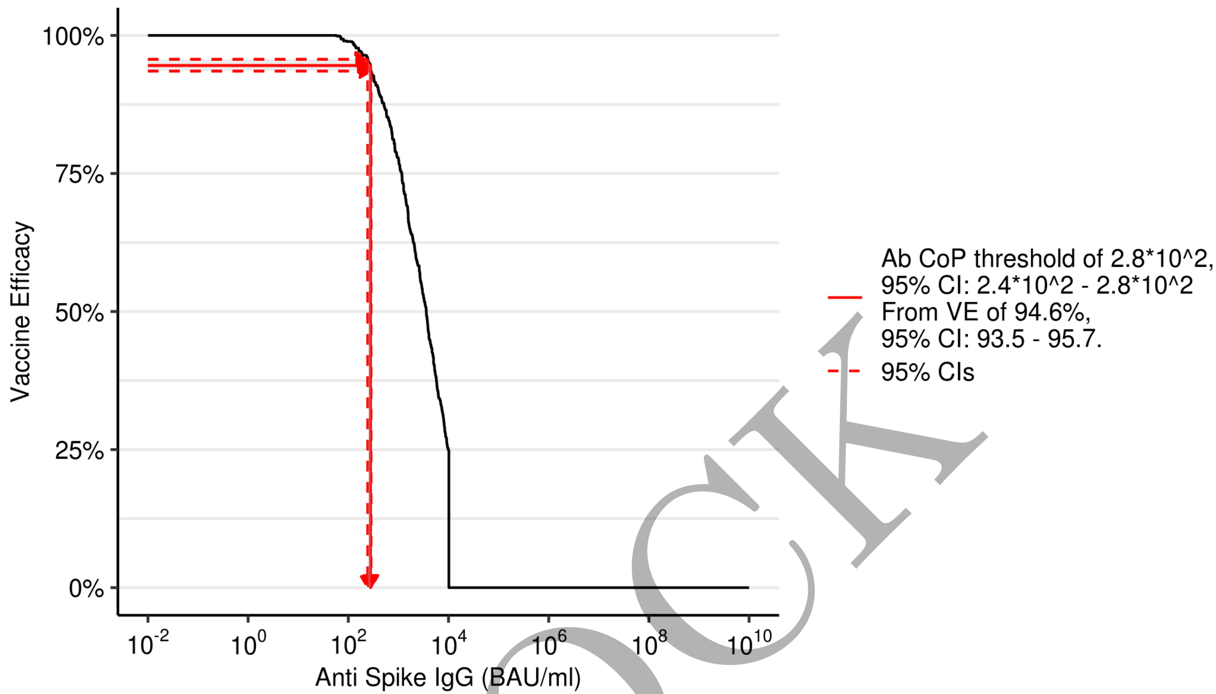


\caption{

Figure 3.12: Marker RCDF of Day 29 PsV-nAb ID80: vaccine arm.

} \end{figure}

\begin{figure}[H]

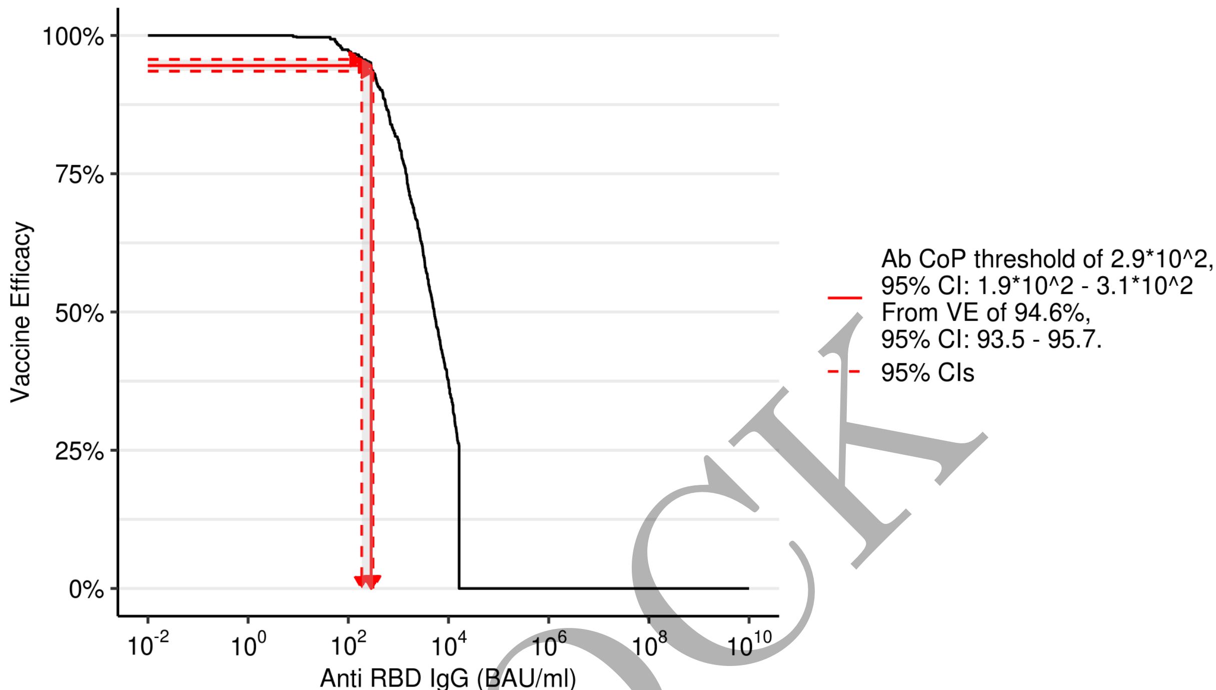


\caption{

Figure 3.13: Marker RCDF of Day 57 anti-Spike binding Ab: vaccine arm.

} \end{figure}

\begin{figure}[H]

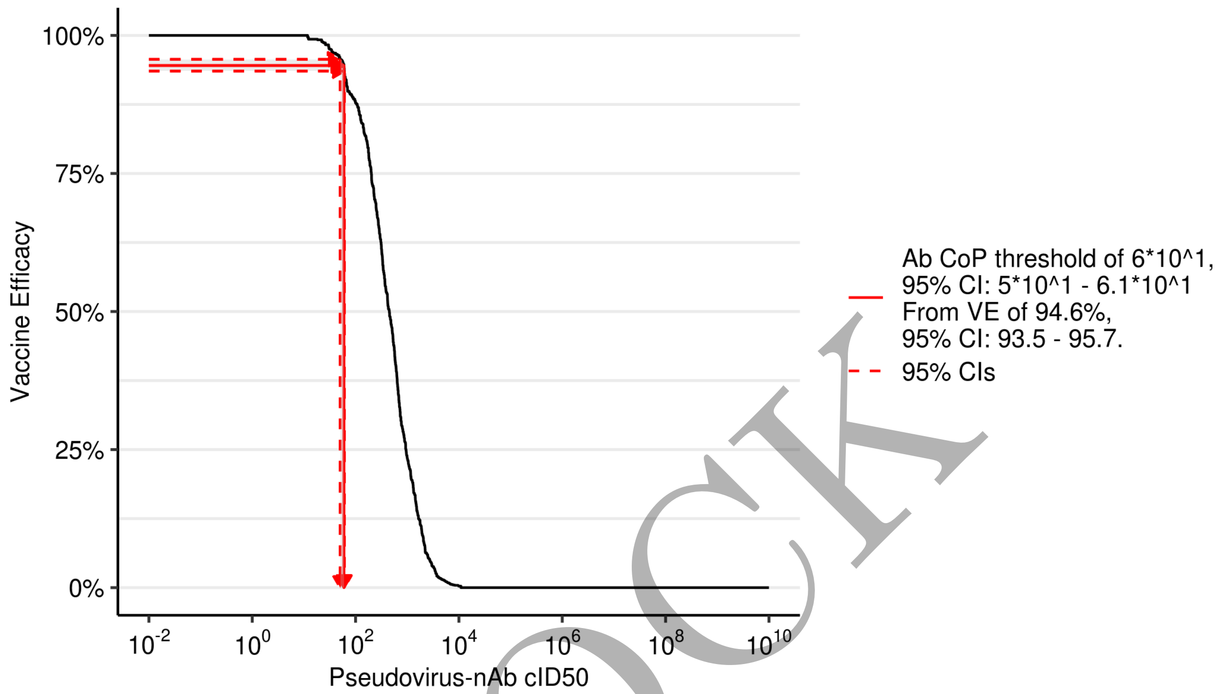


\caption{

Figure 3.14: Marker RCDF of Day 57 anti-RBD binding Ab: vaccine arm.

} \end{figure}

\begin{figure}[H]

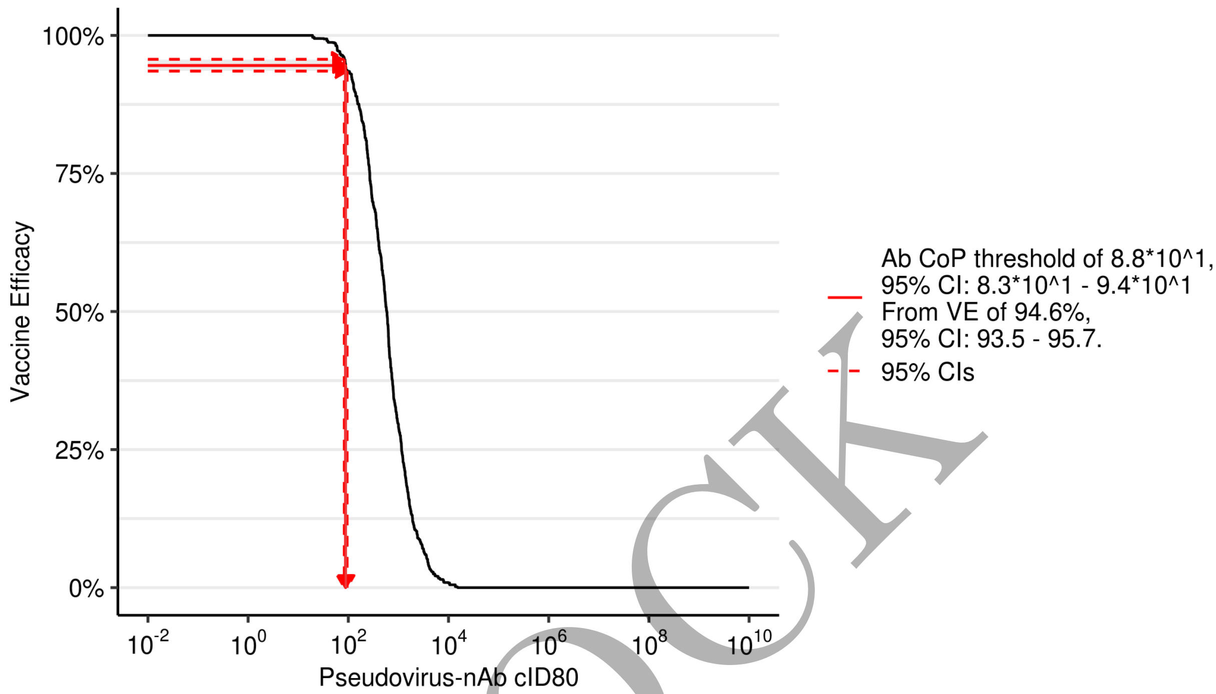


\caption{

Figure 3.15: Marker RCDF of Day 57 PsV-nAb ID50: vaccine arm.

} \end{figure}

\begin{figure}[H]



\caption{

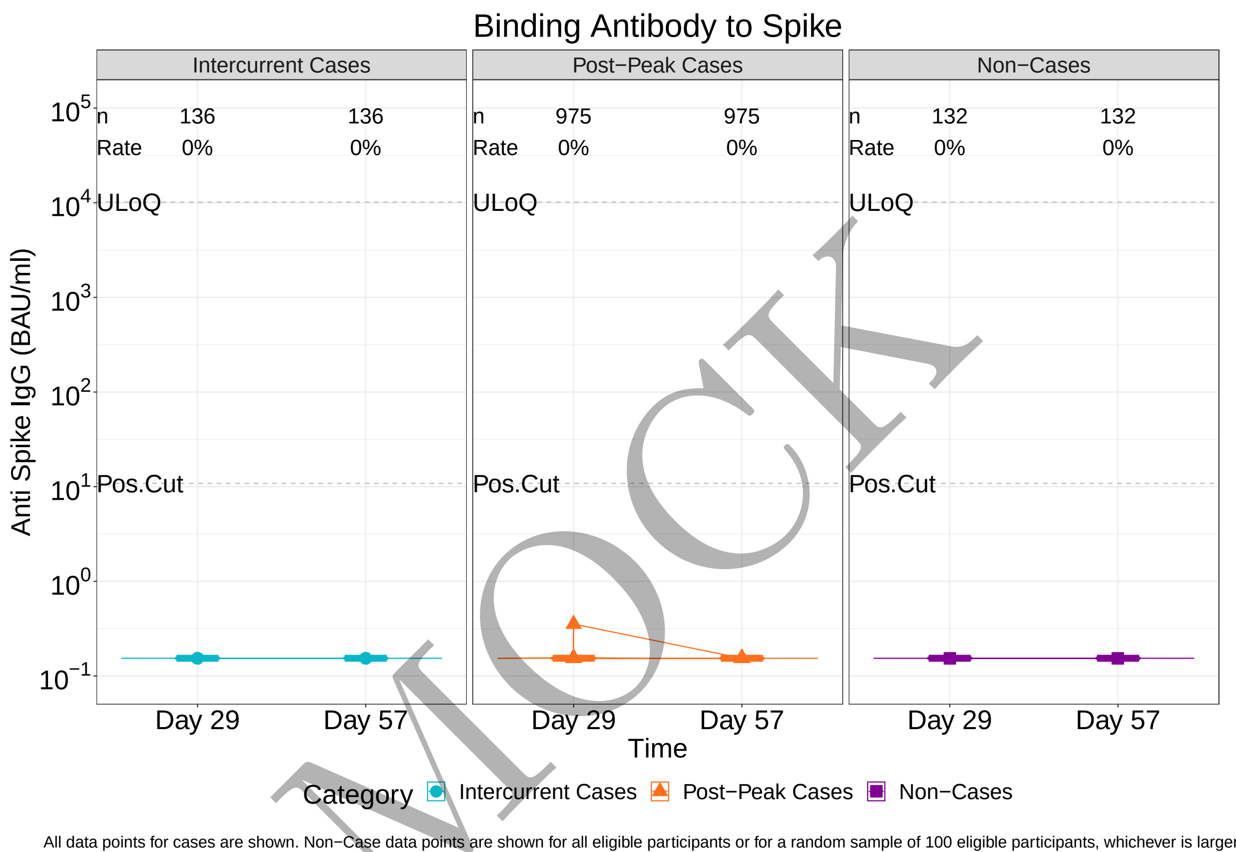
Figure 3.16: Marker RCDF of Day 57 PsV-nAb ID80: vaccine arm.

} \end{figure}

2.4 Violin and line plots

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



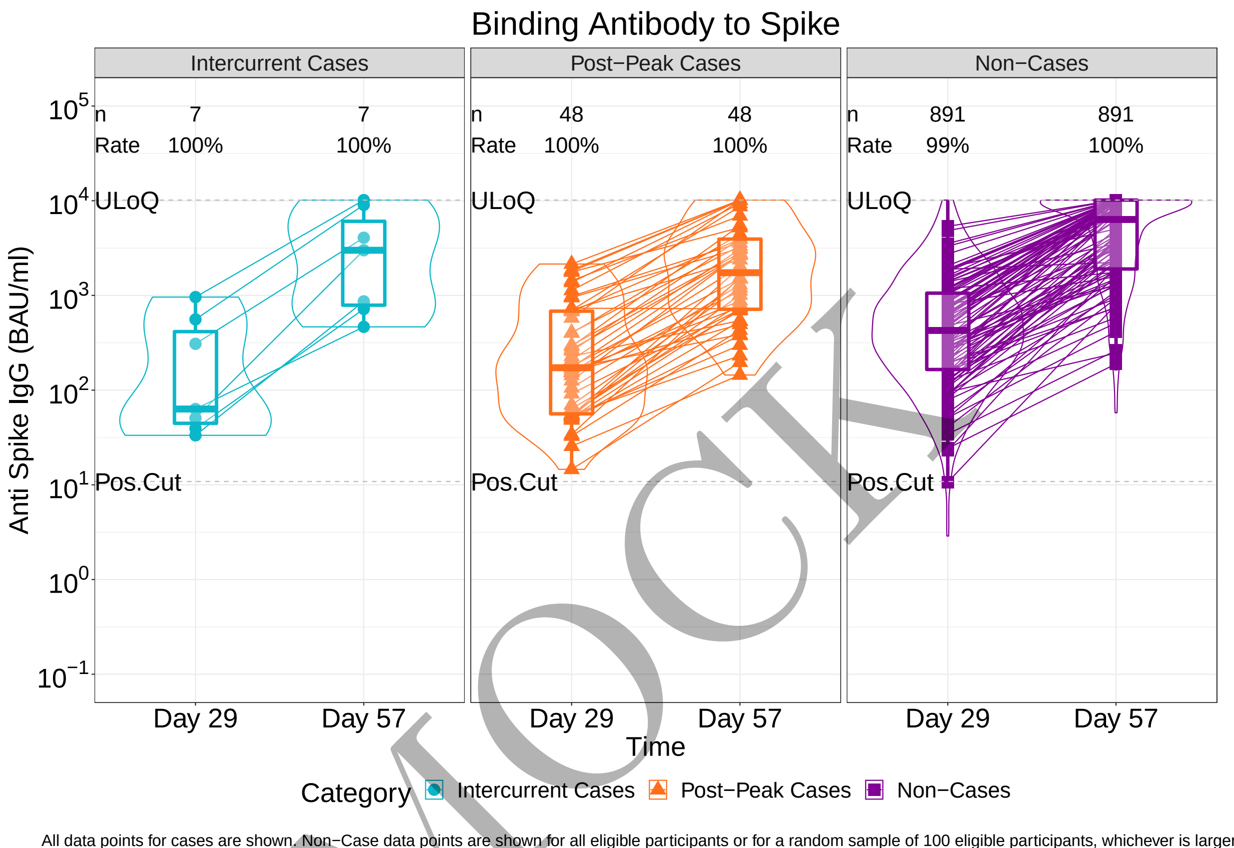
\caption{

Figure 2.5.1: lineplots of Binding Antibody to Spike: baseline negative placebo arm (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



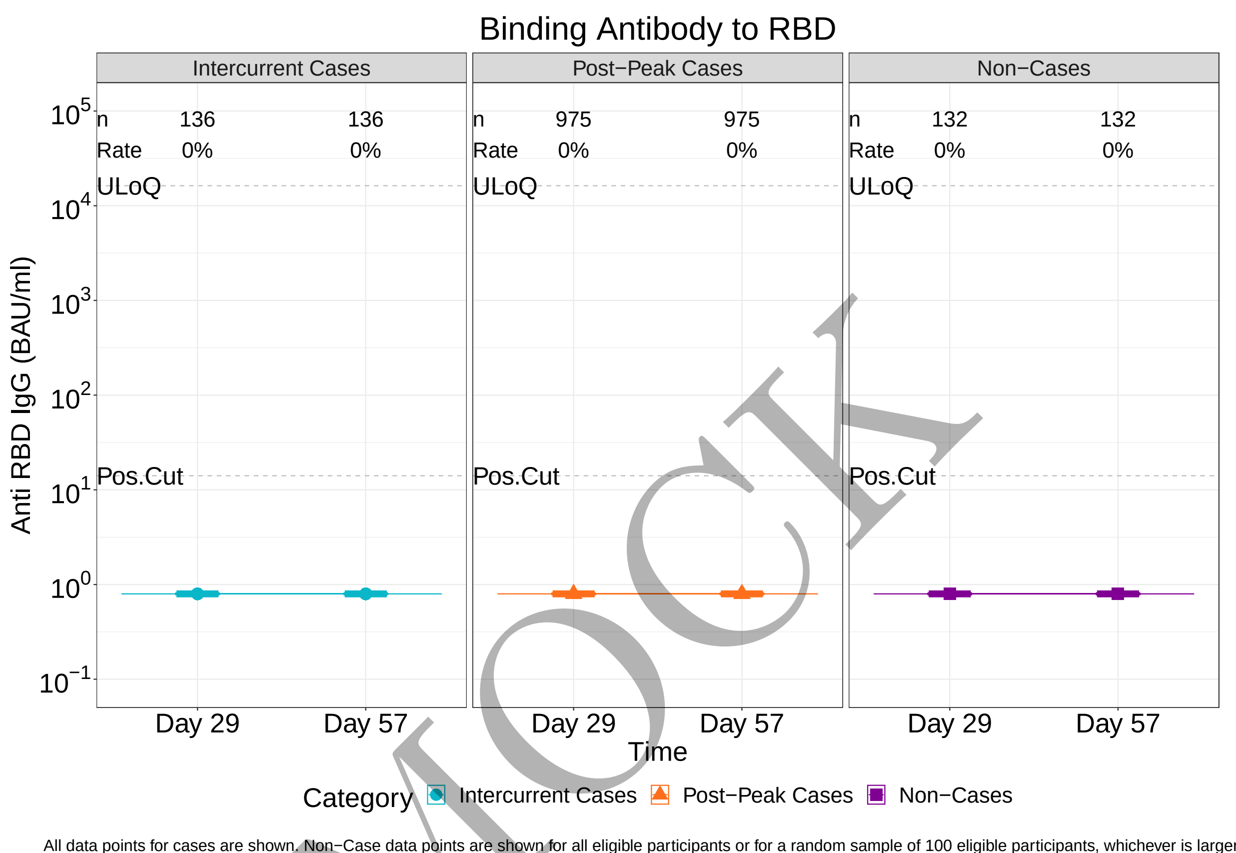
\caption{

Figure 2.5.2: lineplots of Binding Antibody to Spike: baseline negative vaccine arm (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



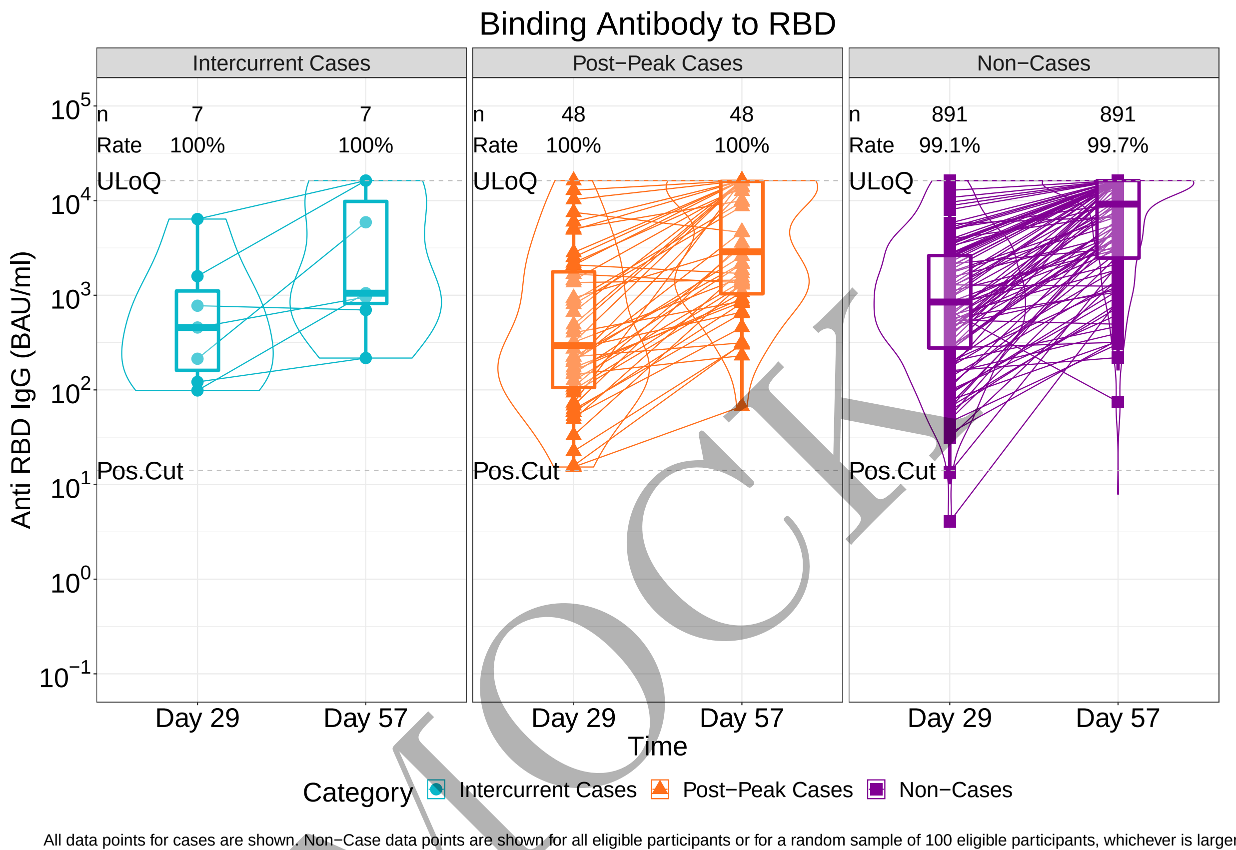
\caption{

Figure 2.5.3: lineplots of Binding Antibody to RBD: baseline negative placebo arm (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



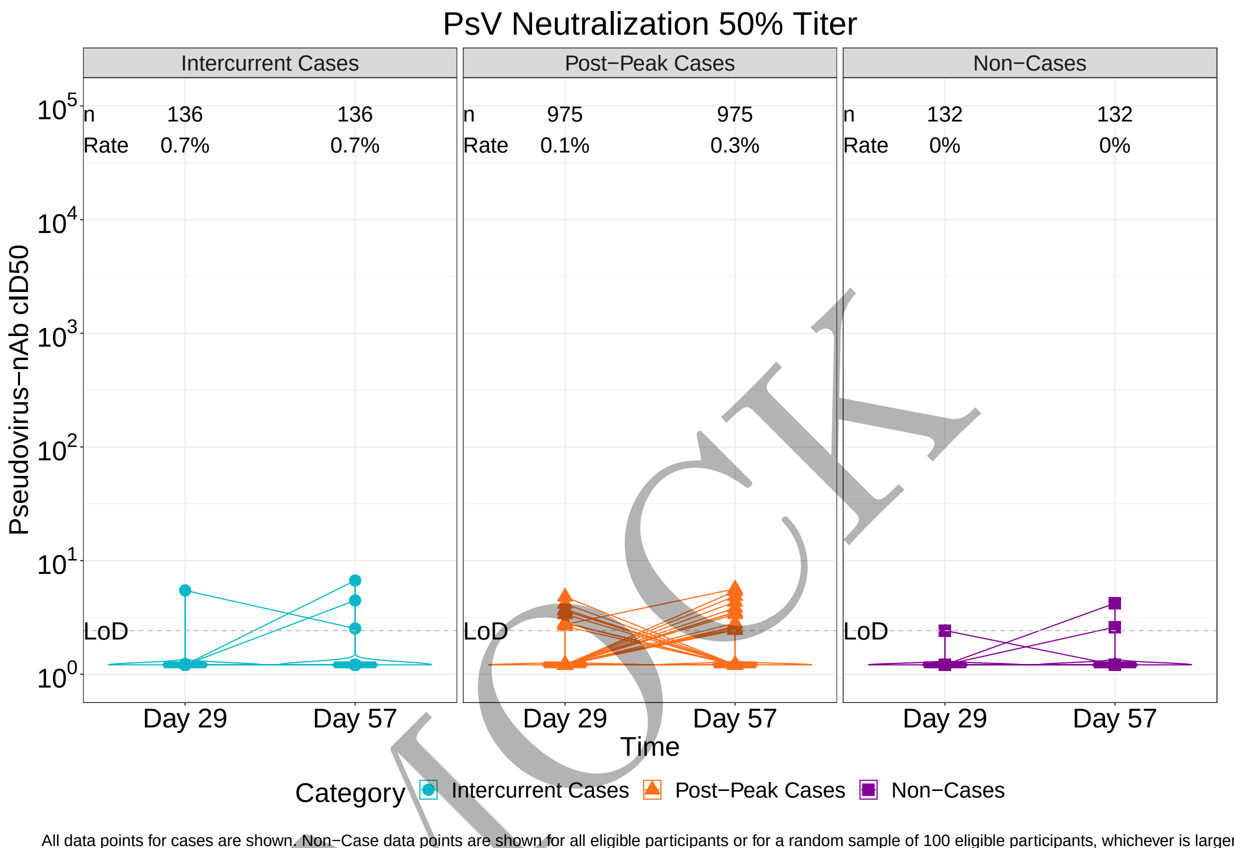
\caption{

Figure 2.5.4: lineplots of Binding Antibody to RBD: baseline negative vaccine arm (version 1)

} \end{figure}

```
r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")
```

\begin{figure}



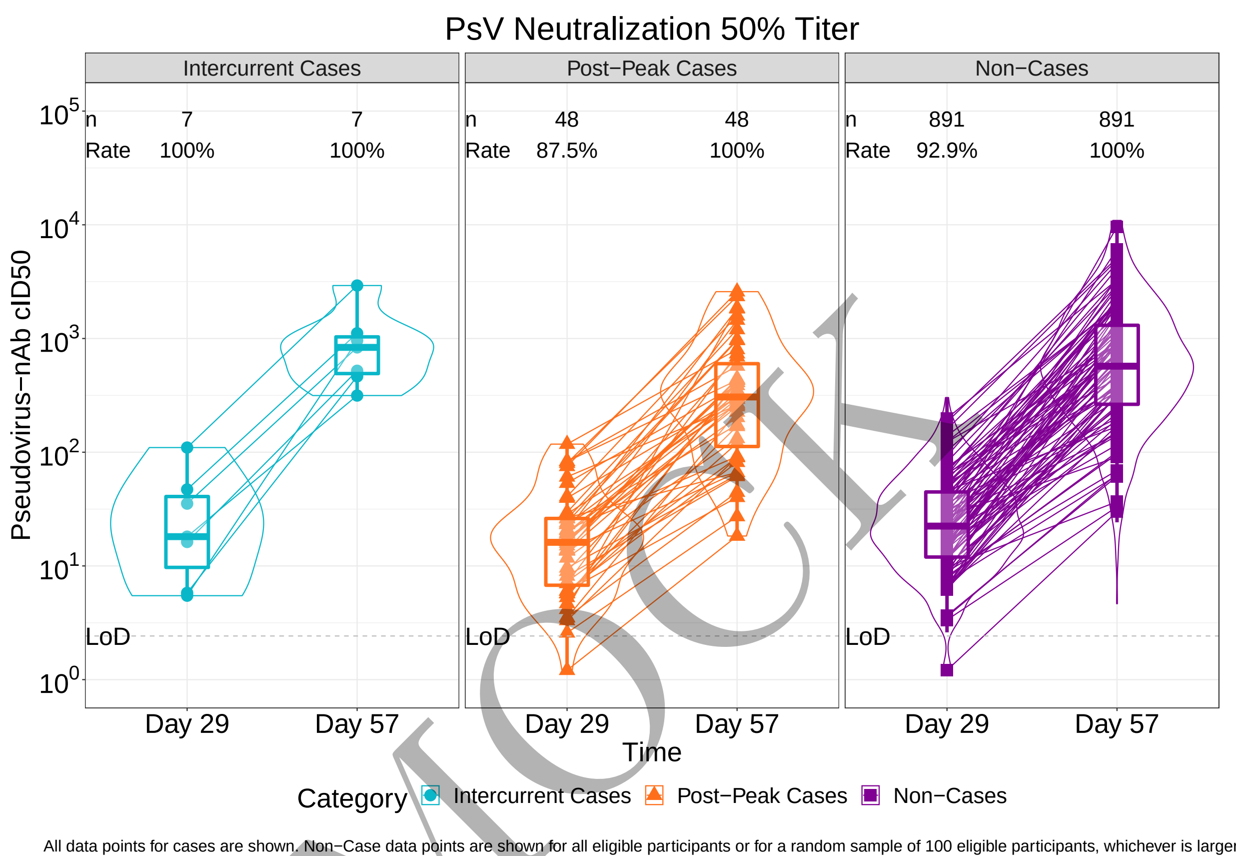
\caption{

Figure 2.5.5: lineplots of PsV Neutralization 50% Titer: baseline negative placebo arm (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



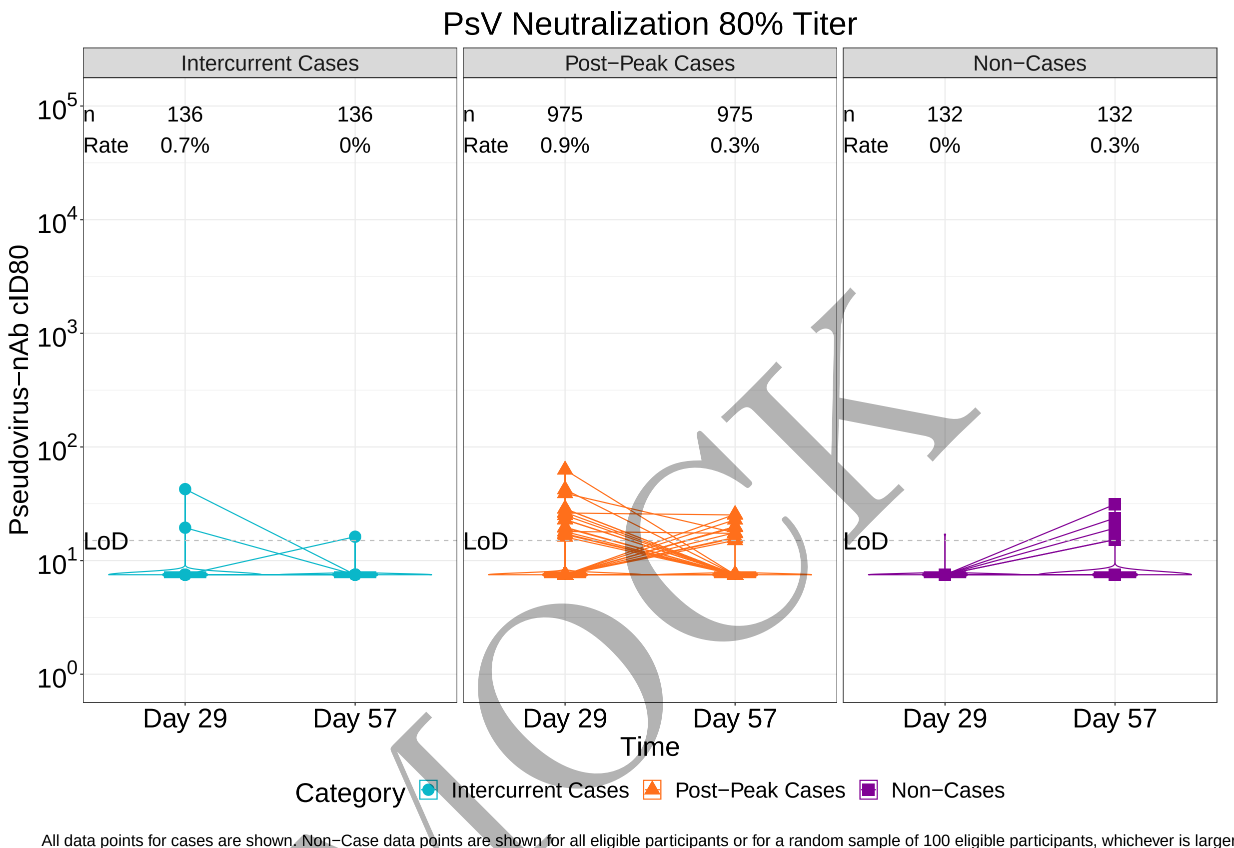
\caption{

Figure 2.5.6: lineplots of PsV Neutralization 50% Titer: baseline negative vaccine arm (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



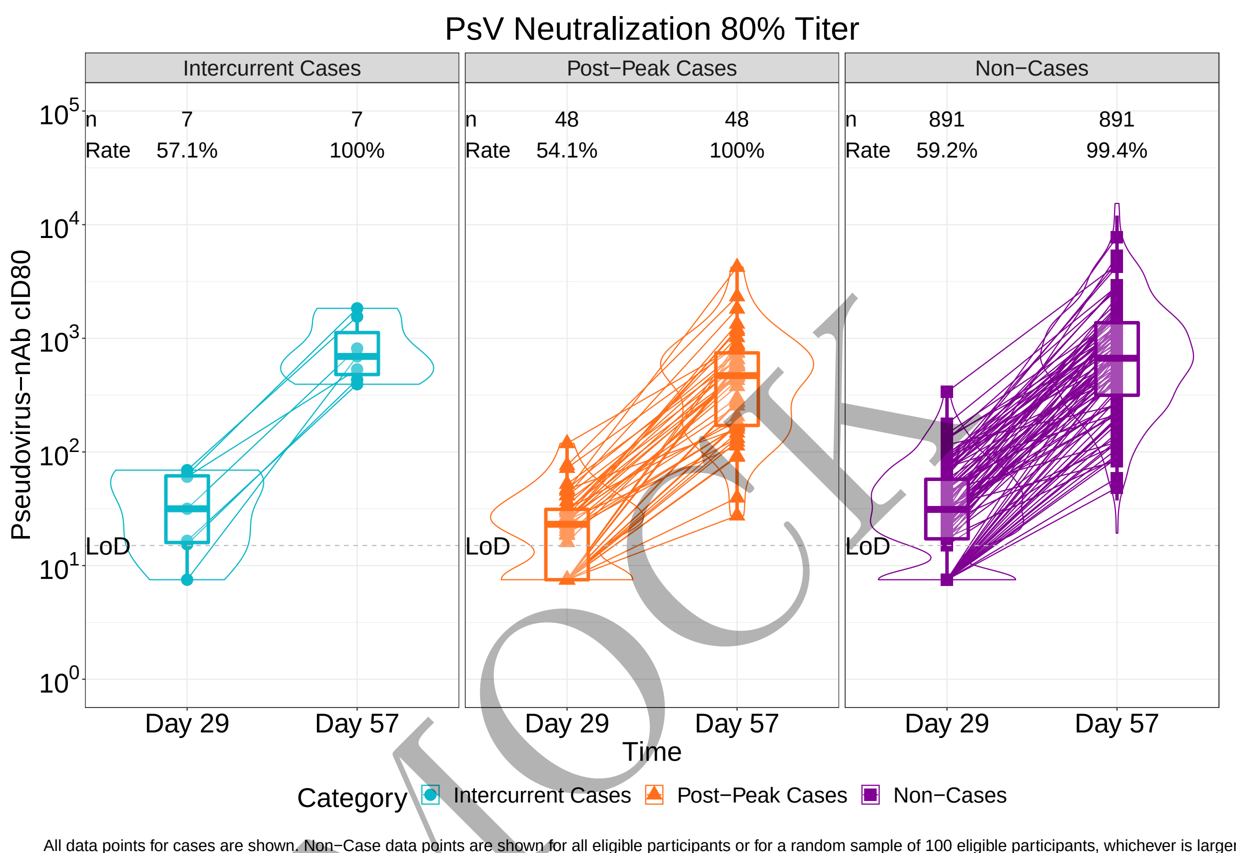
\caption{

Figure 2.5.7: lineplots of PsV Neutralization 80% Titer: baseline negative placebo arm (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



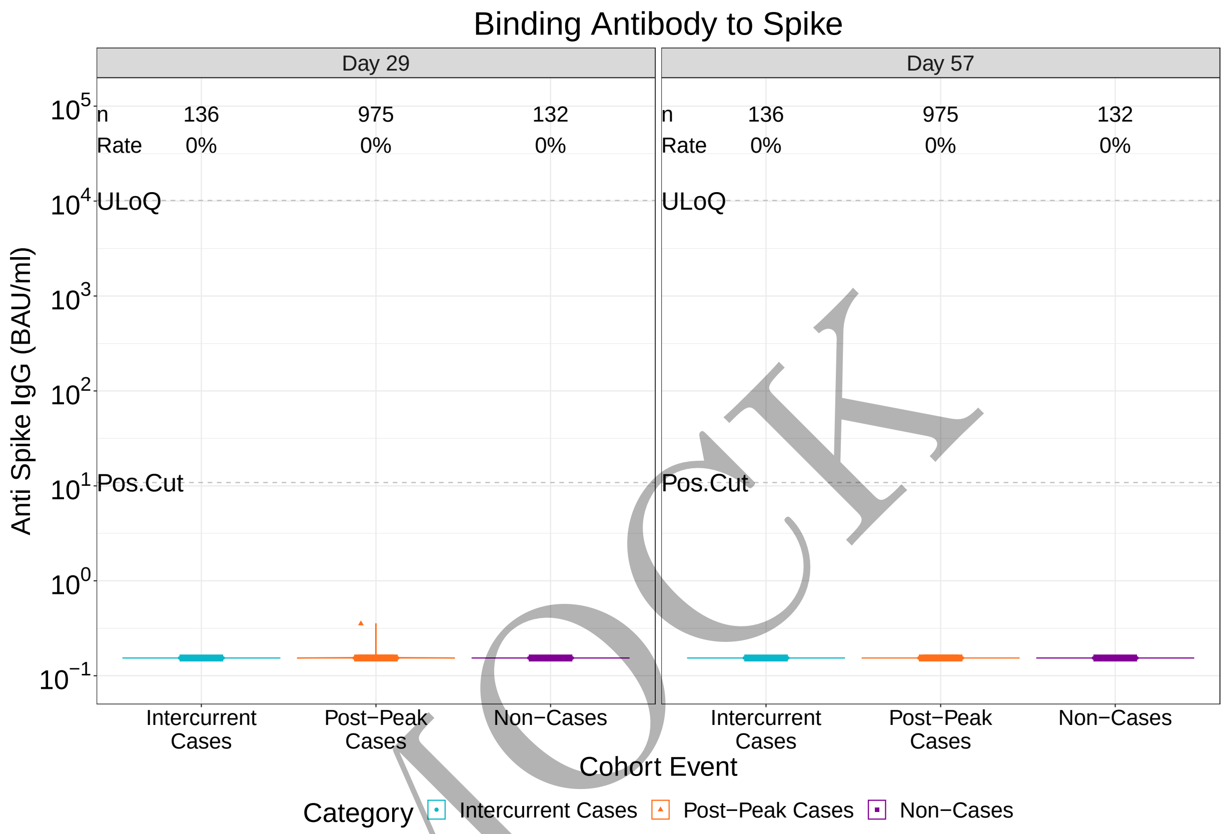
\caption{

Figure 2.5.8: lineplots of PsV Neutralization 80% Titer: baseline negative vaccine arm (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



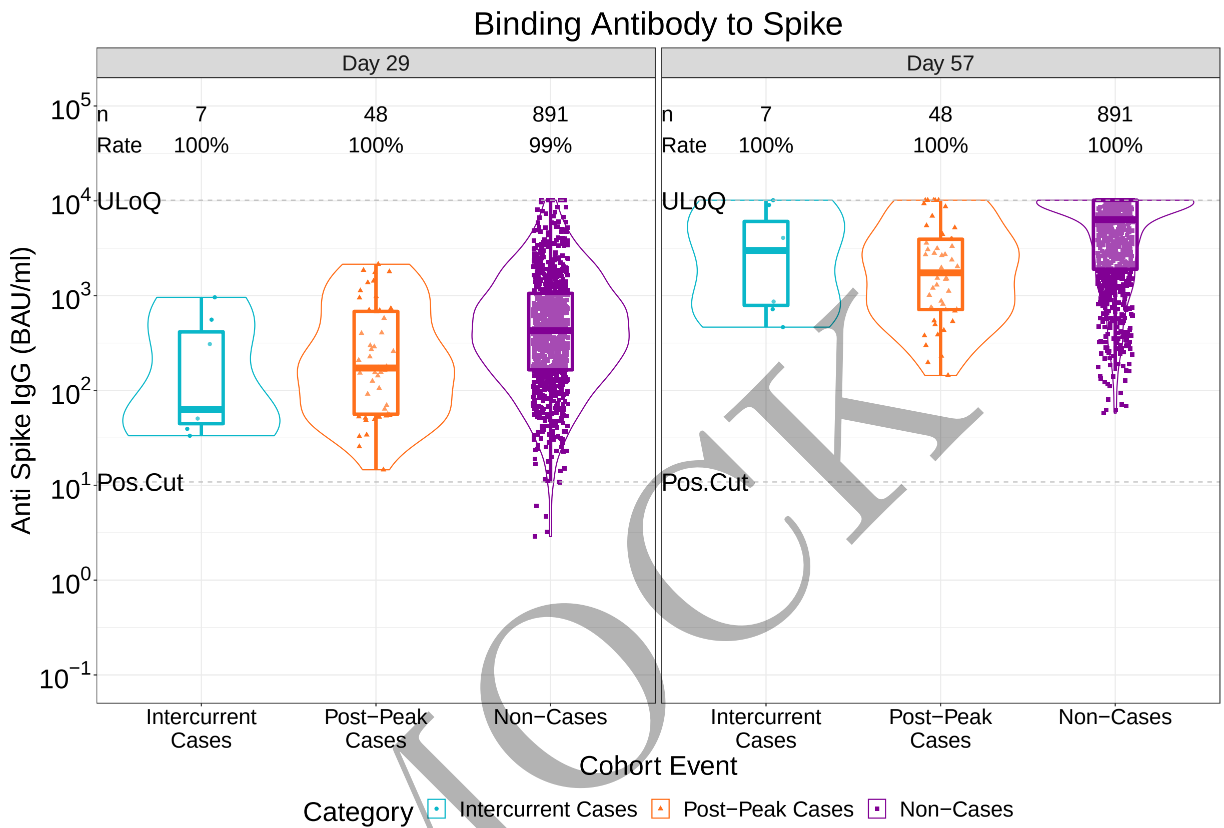
\caption{

Figure 2.5.9: violinplots of Binding Antibody to Spike: baseline negative placebo arm (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

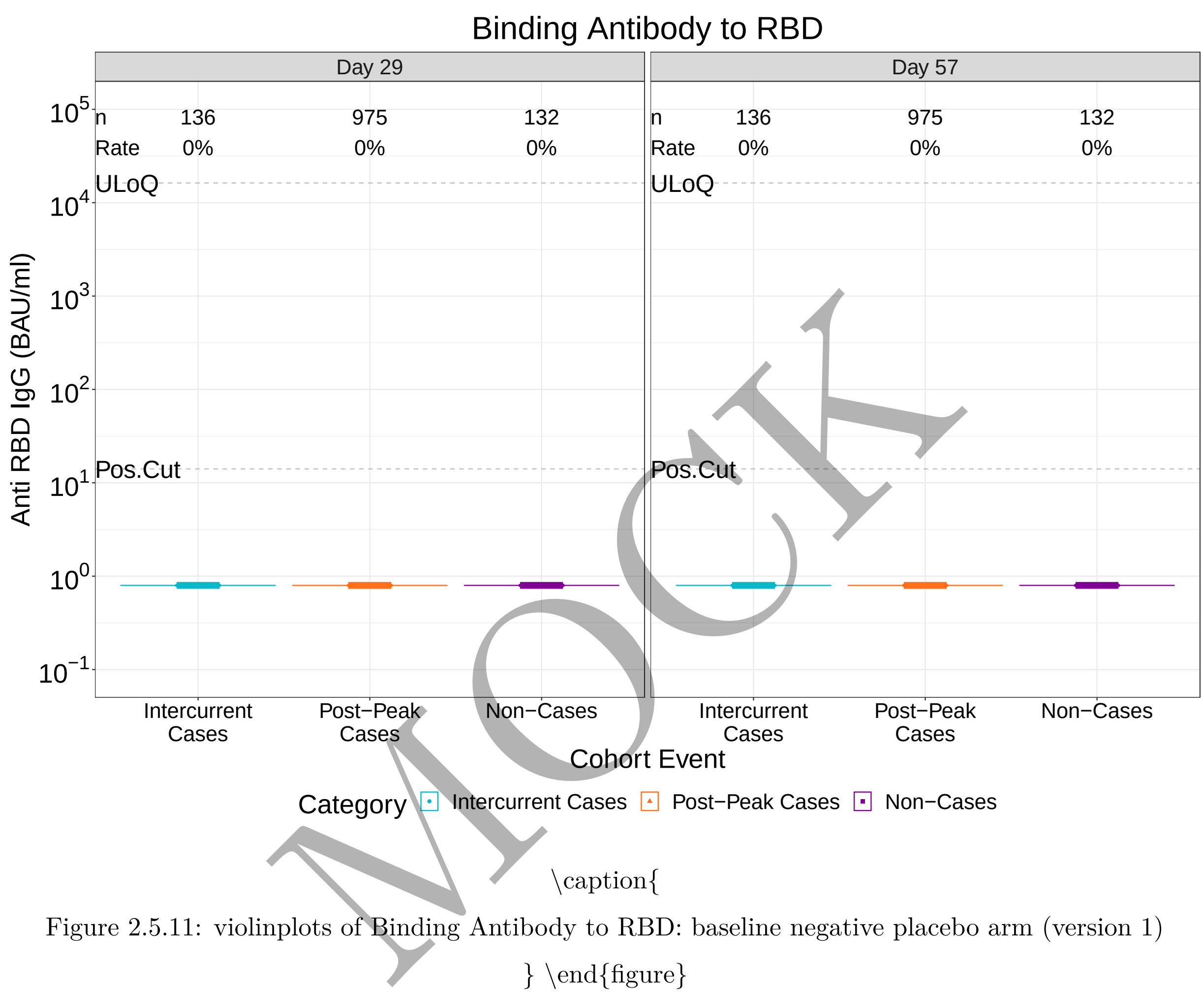
\begin{figure}



\caption{
Figure 2.5.10: violinplots of Binding Antibody to Spike: baseline negative vaccine arm (version 1)
} \end{figure}

`r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")`

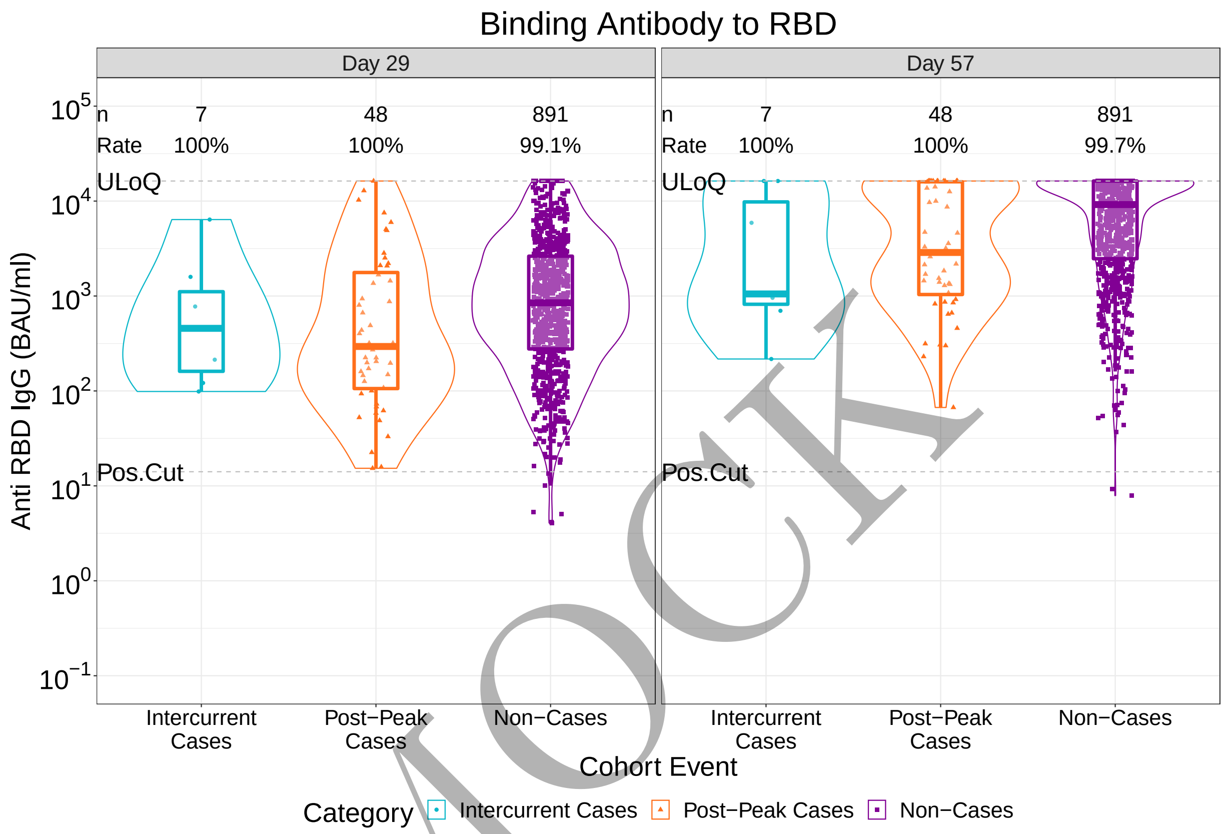
\begin{figure}



\caption{
Figure 2.5.11: violinplots of Binding Antibody to RBD: baseline negative placebo arm (version 1)
} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



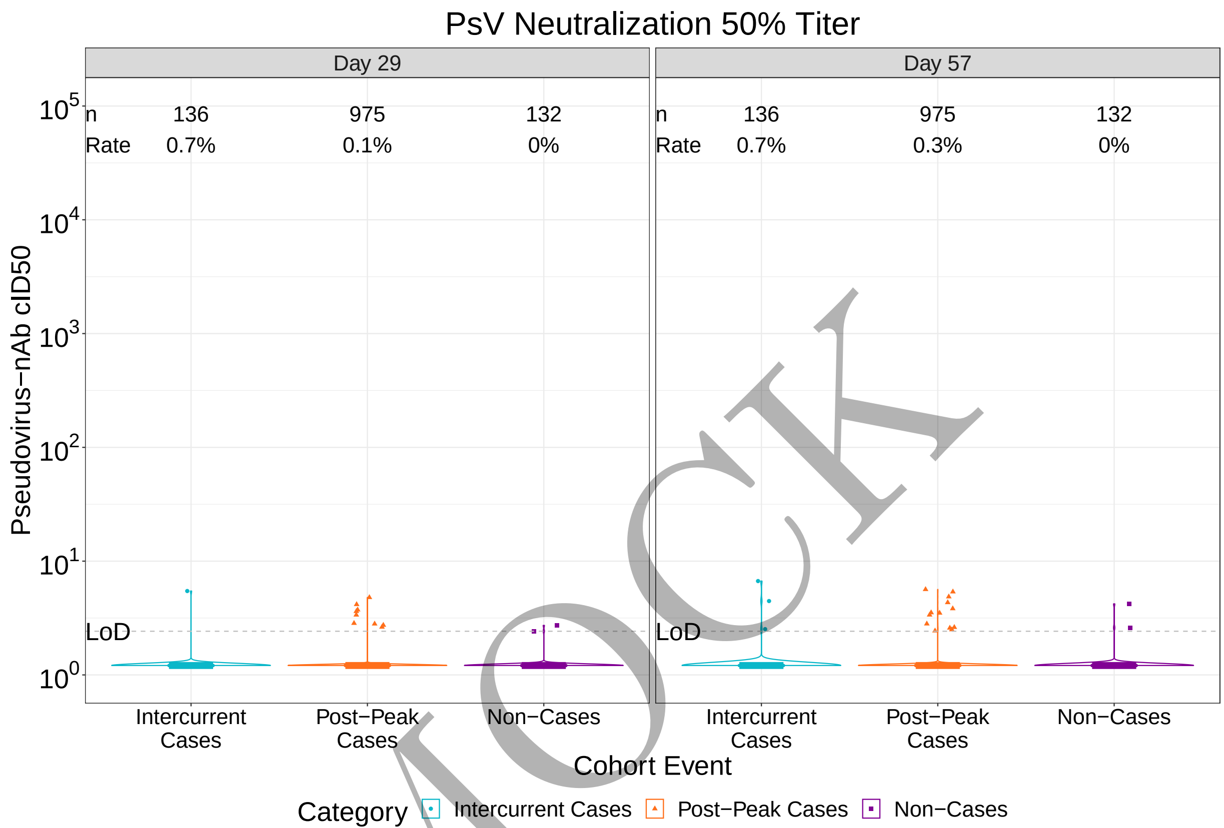
\caption{

Figure 2.5.12: violinplots of Binding Antibody to RBD: baseline negative vaccine arm (version 1)

} \end{figure}

`r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")`

\begin{figure}



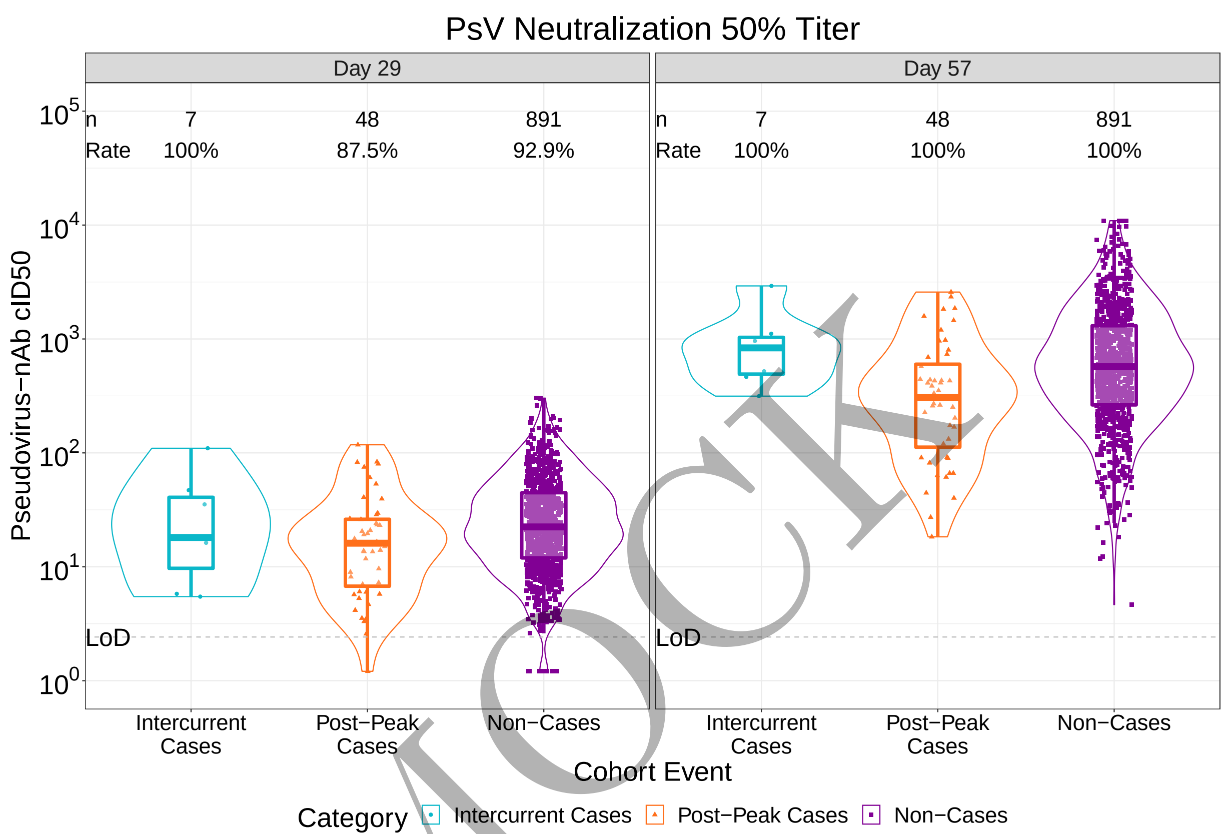
\caption{

Figure 2.5.13: violinplots of PsV Neutralization 50% Titer: baseline negative placebo arm (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

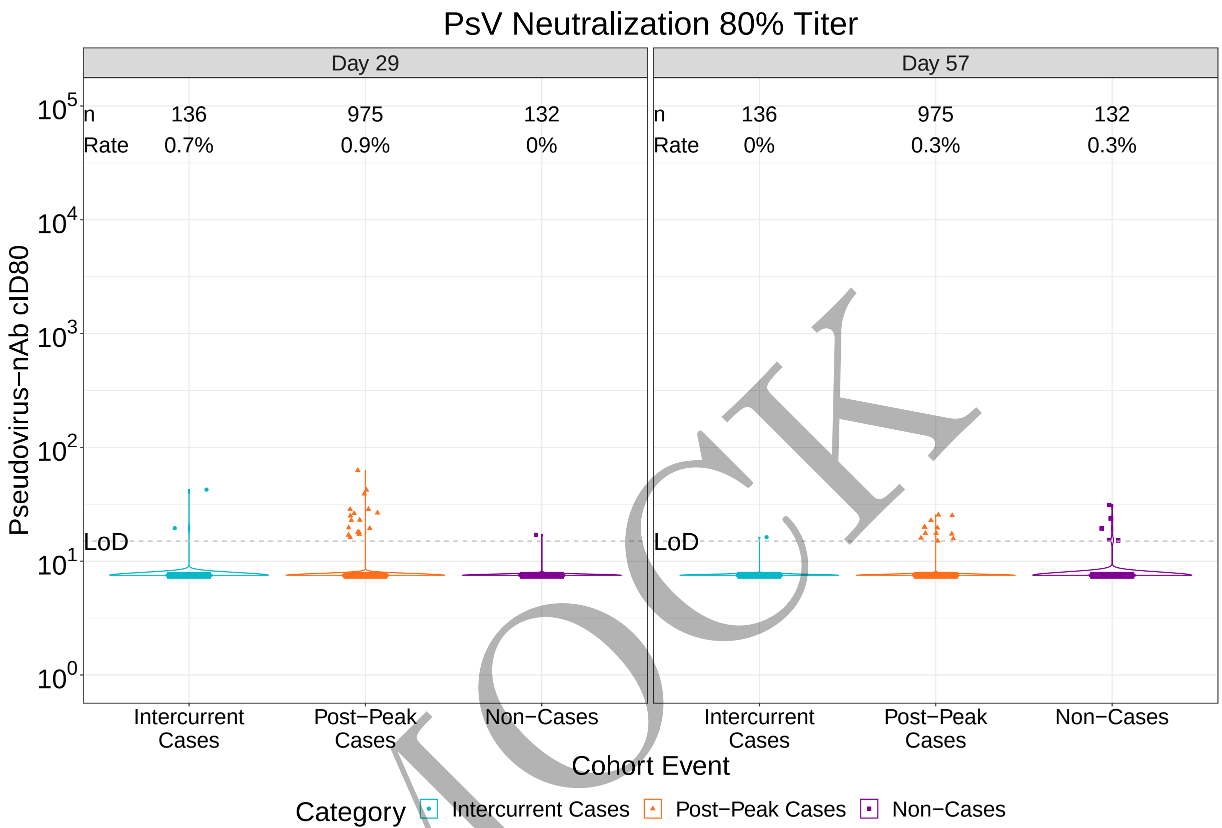
\begin{figure}



\caption{
Figure 2.5.14: violinplots of PsV Neutralization 50% Titer: baseline negative vaccine arm (version 1)
} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



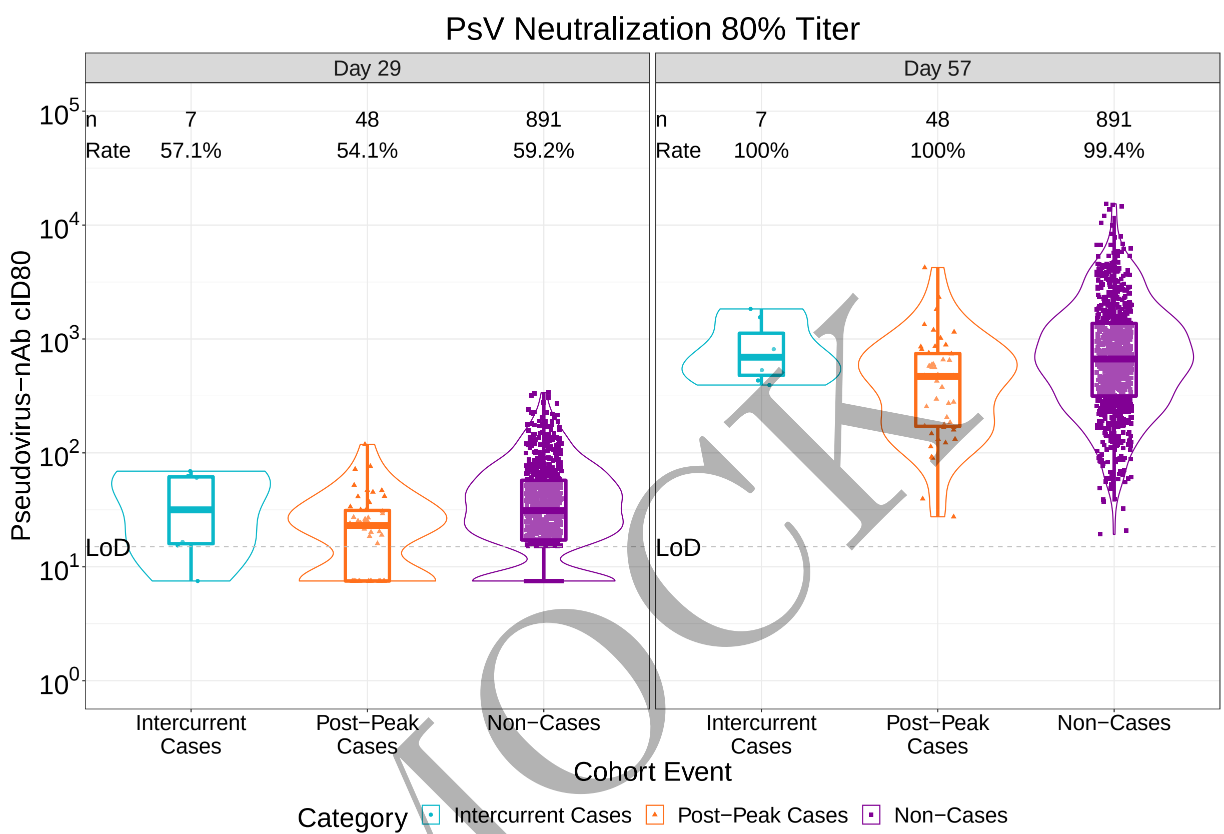
\caption{

Figure 2.5.15: violinplots of PsV Neutralization 80% Titer: baseline negative placebo arm (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

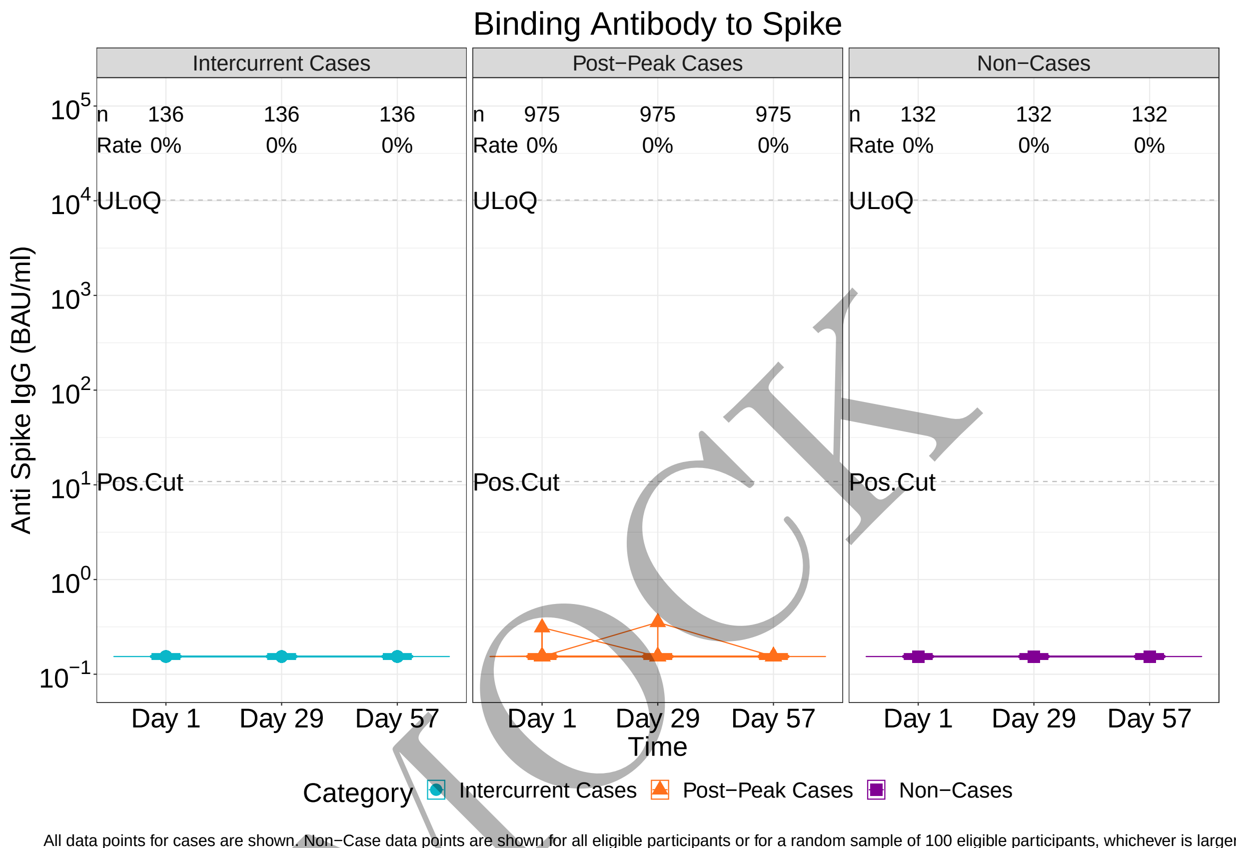
\begin{figure}



\caption{
Figure 2.5.16: violinplots of PsV Neutralization 80% Titer: baseline negative vaccine arm (version 1)
} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



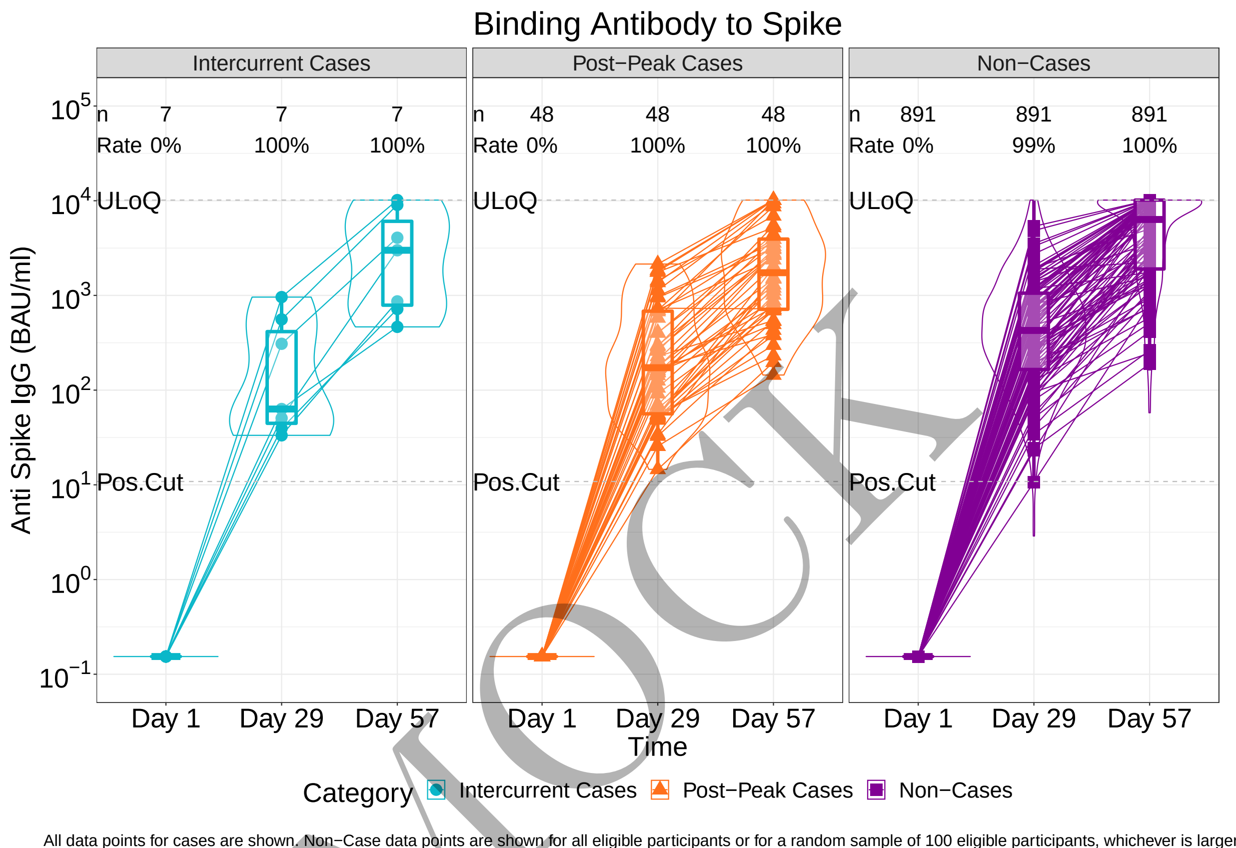
\caption{

Figure 2.5.17: lineplots of Binding Antibody to Spike: baseline negative placebo arm (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

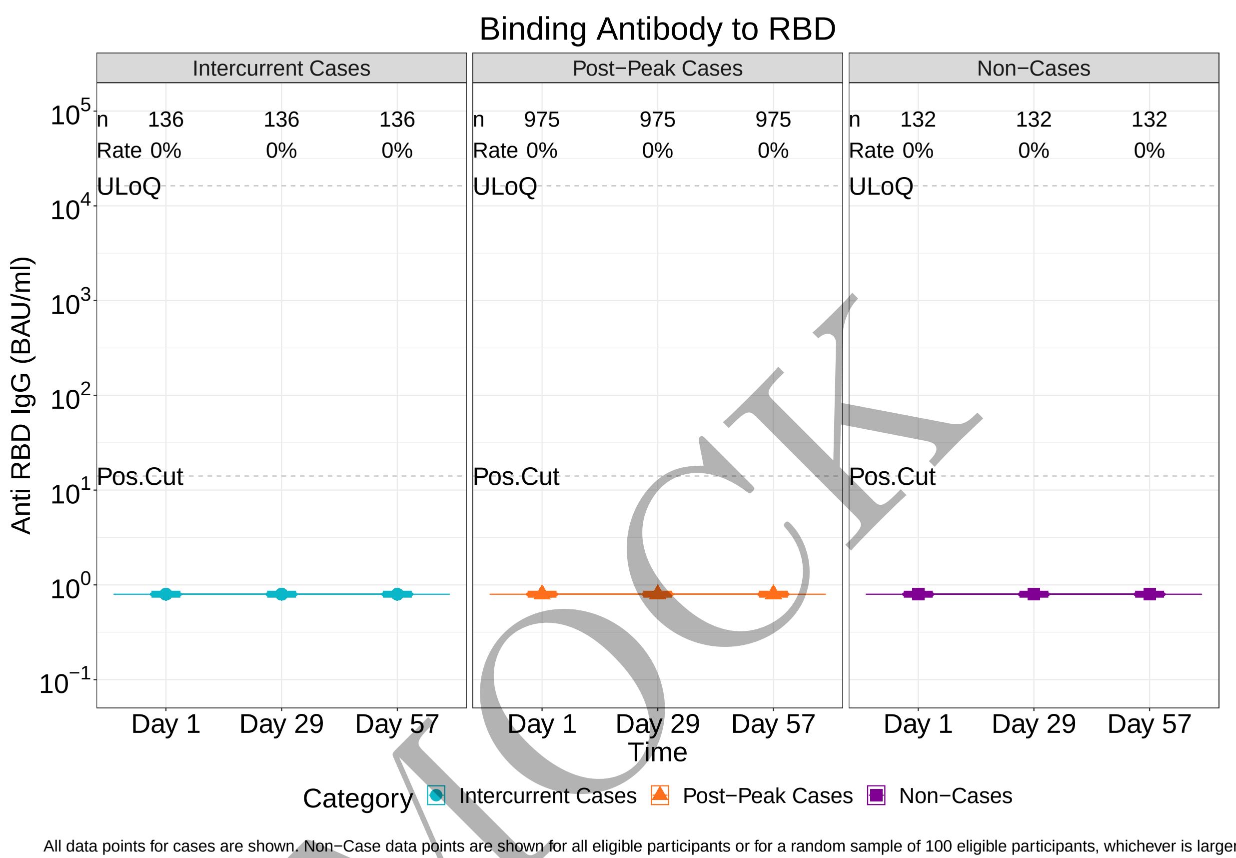
\begin{figure}



\caption{
Figure 2.5.18: lineplots of Binding Antibody to Spike: baseline negative vaccine arm (version 2)
} \end{figure}

`r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")`

\begin{figure}



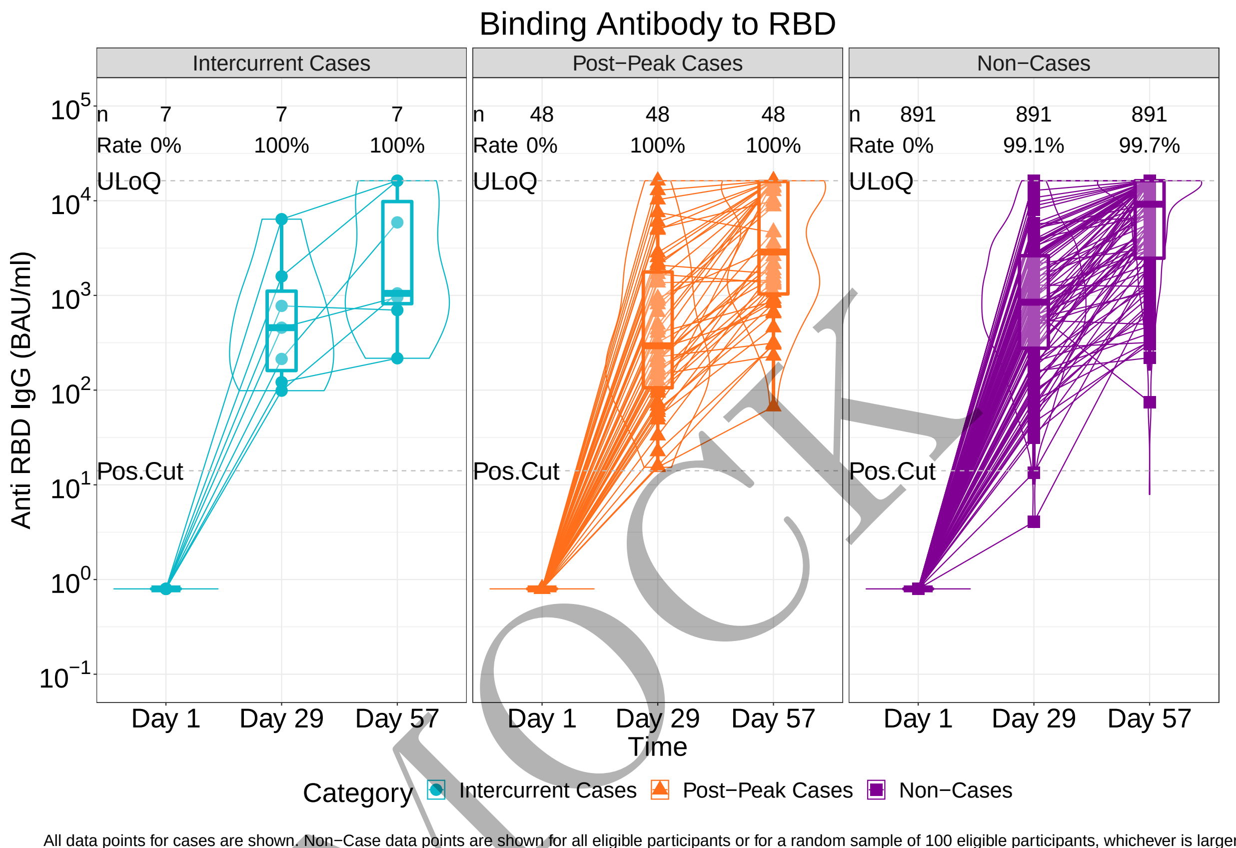
\caption{

Figure 2.5.19: lineplots of Binding Antibody to RBD: baseline negative placebo arm (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



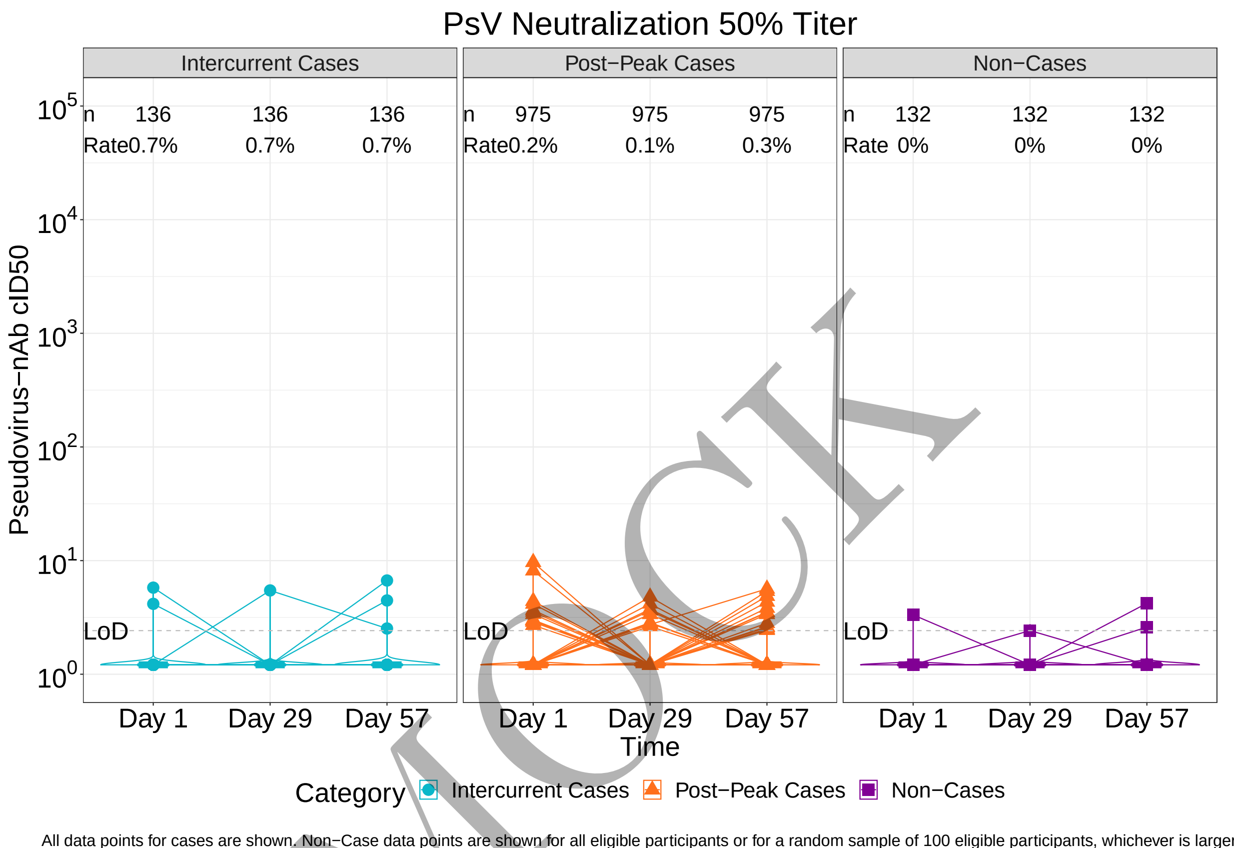
\caption{

Figure 2.5.20: lineplots of Binding Antibody to RBD: baseline negative vaccine arm (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



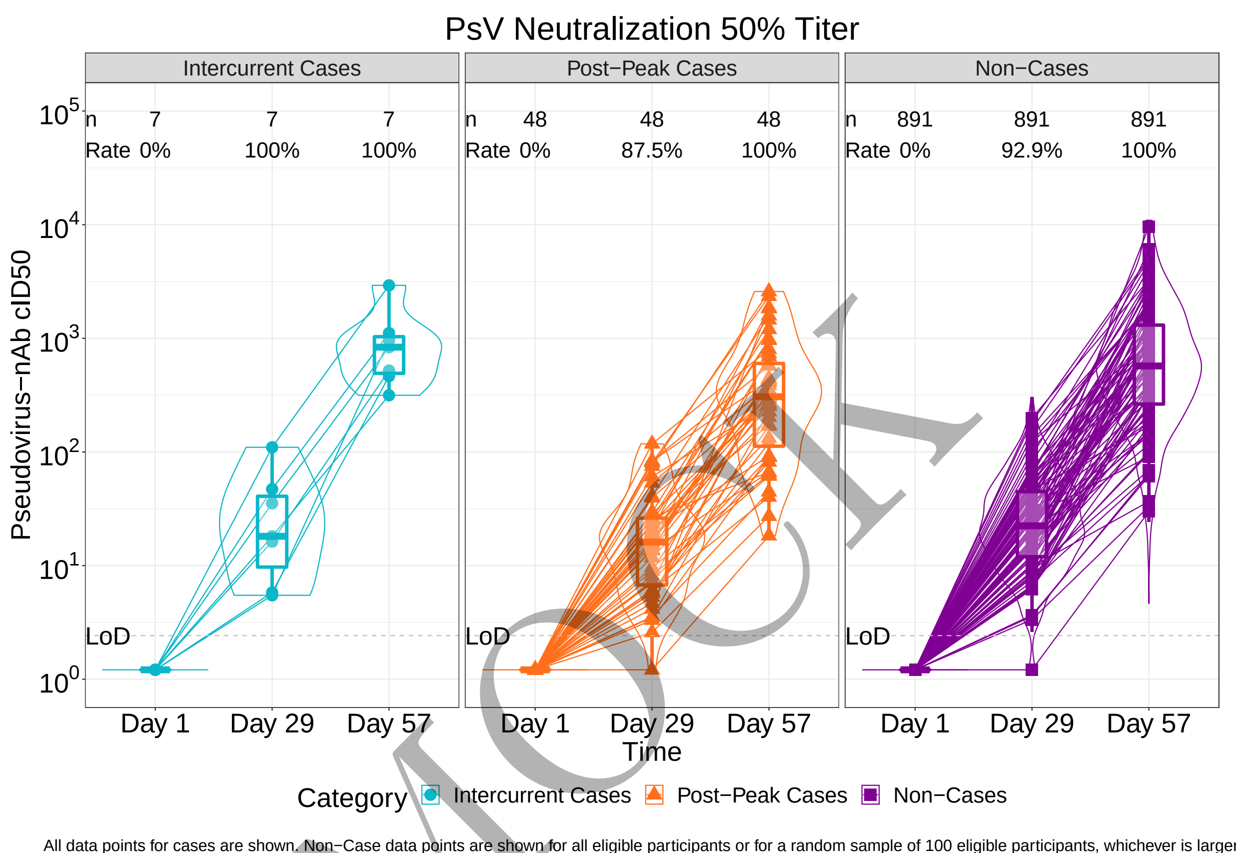
\caption{

Figure 2.5.21: lineplots of PsV Neutralization 50% Titer: baseline negative placebo arm (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



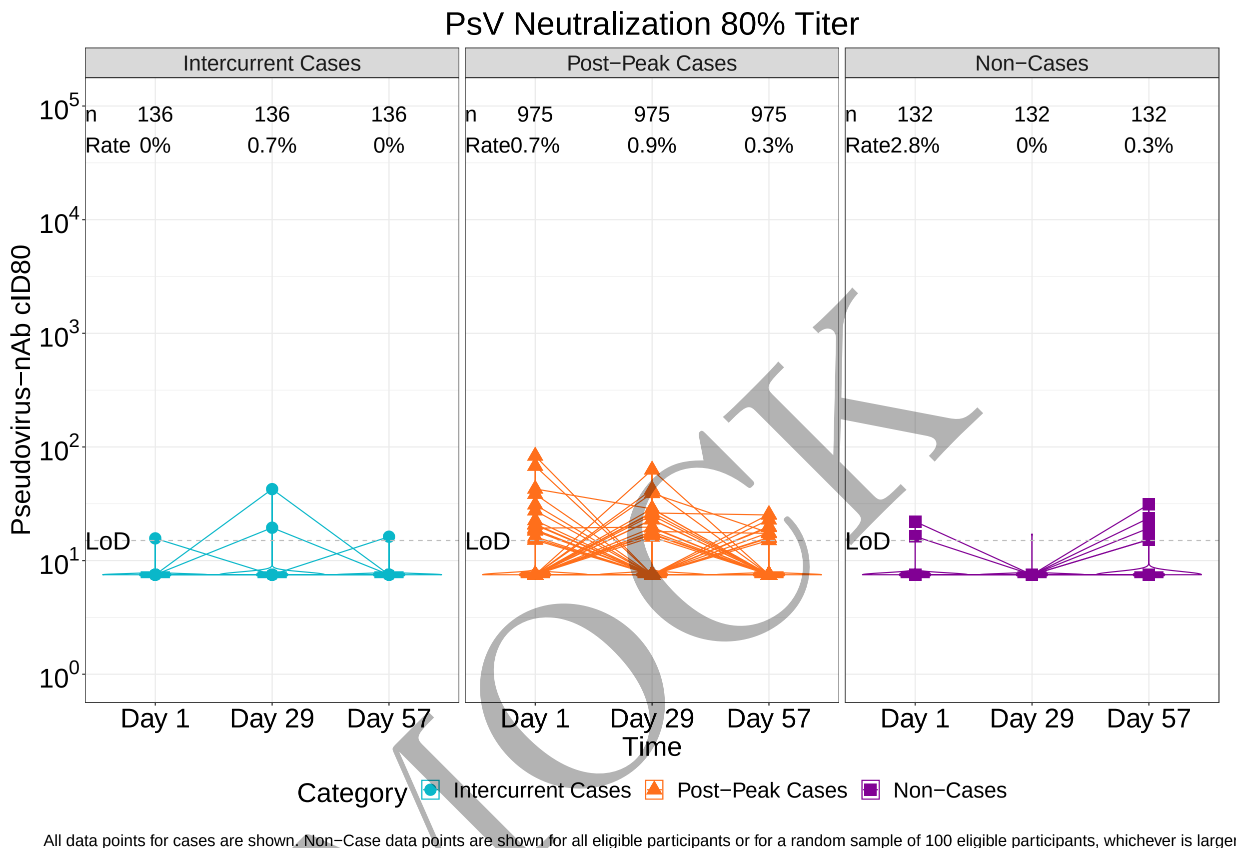
\caption{

Figure 2.5.22: lineplots of PsV Neutralization 50% Titer: baseline negative vaccine arm (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



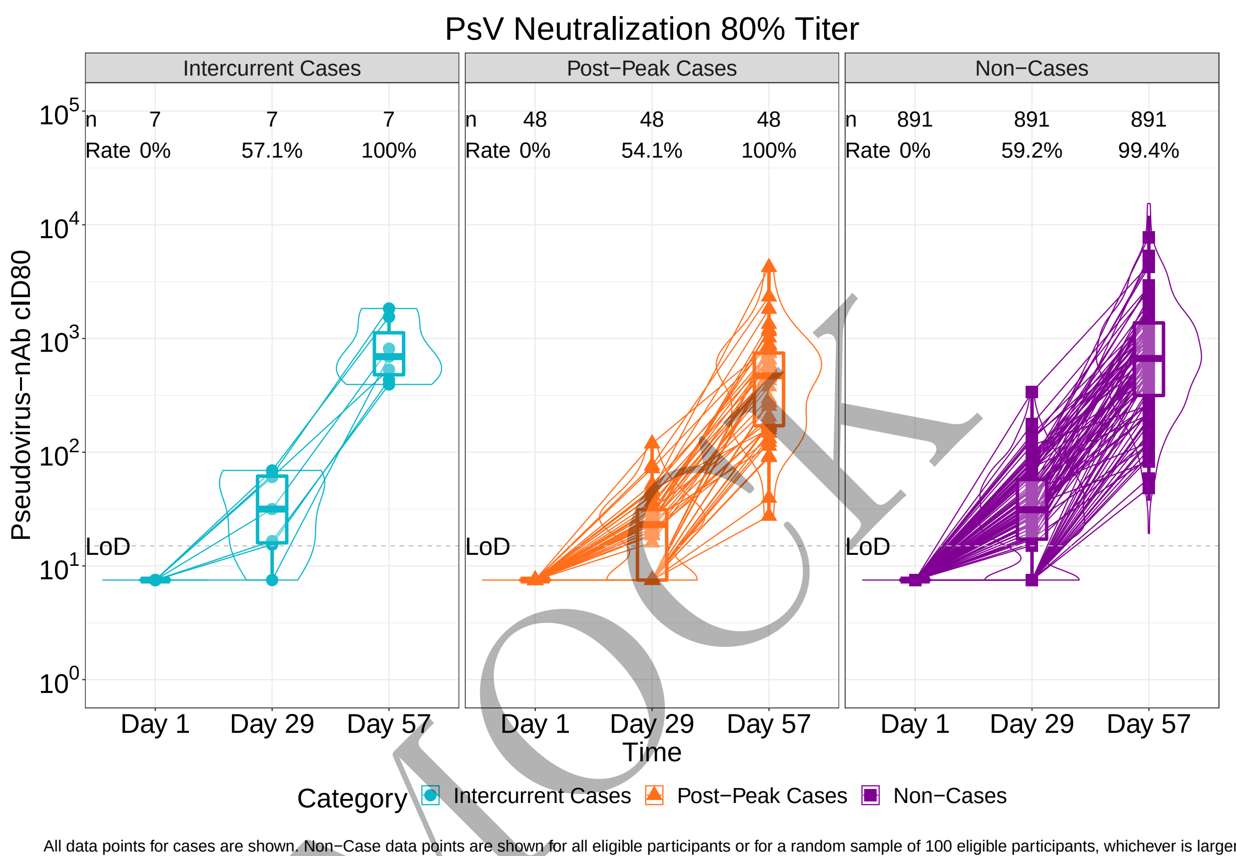
\caption{

Figure 2.5.23: lineplots of PsV Neutralization 80% Titer: baseline negative placebo arm (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



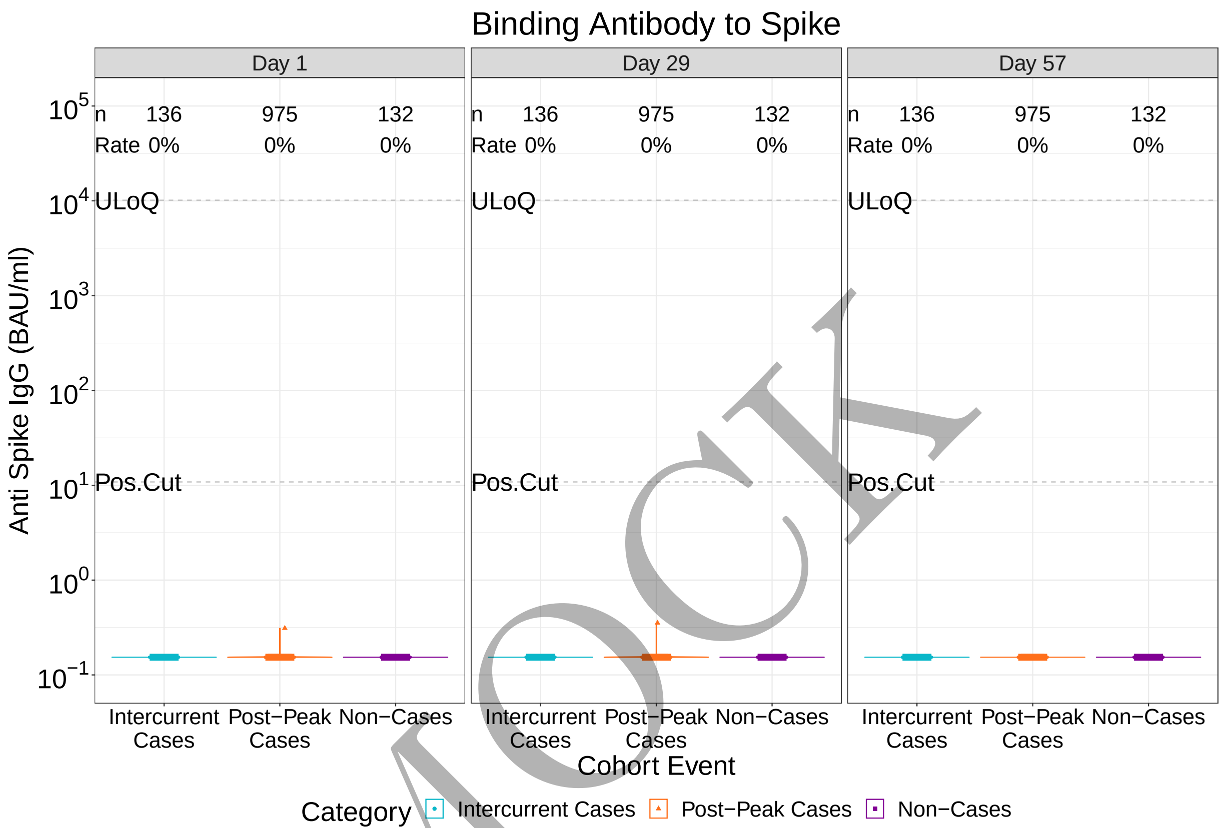
\caption{

Figure 2.5.24: lineplots of PsV Neutralization 80% Titer: baseline negative vaccine arm (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



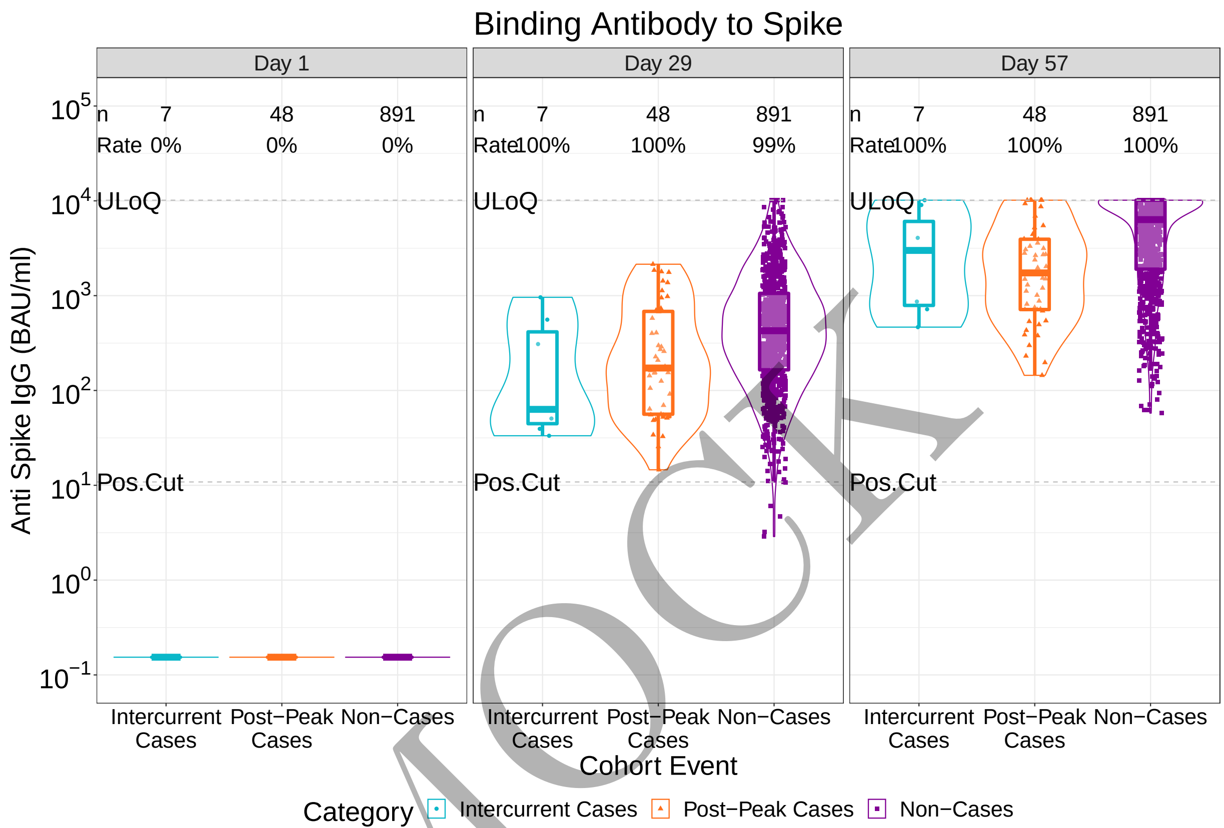
\caption{

Figure 2.5.25: violinplots of Binding Antibody to Spike: baseline negative placebo arm (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

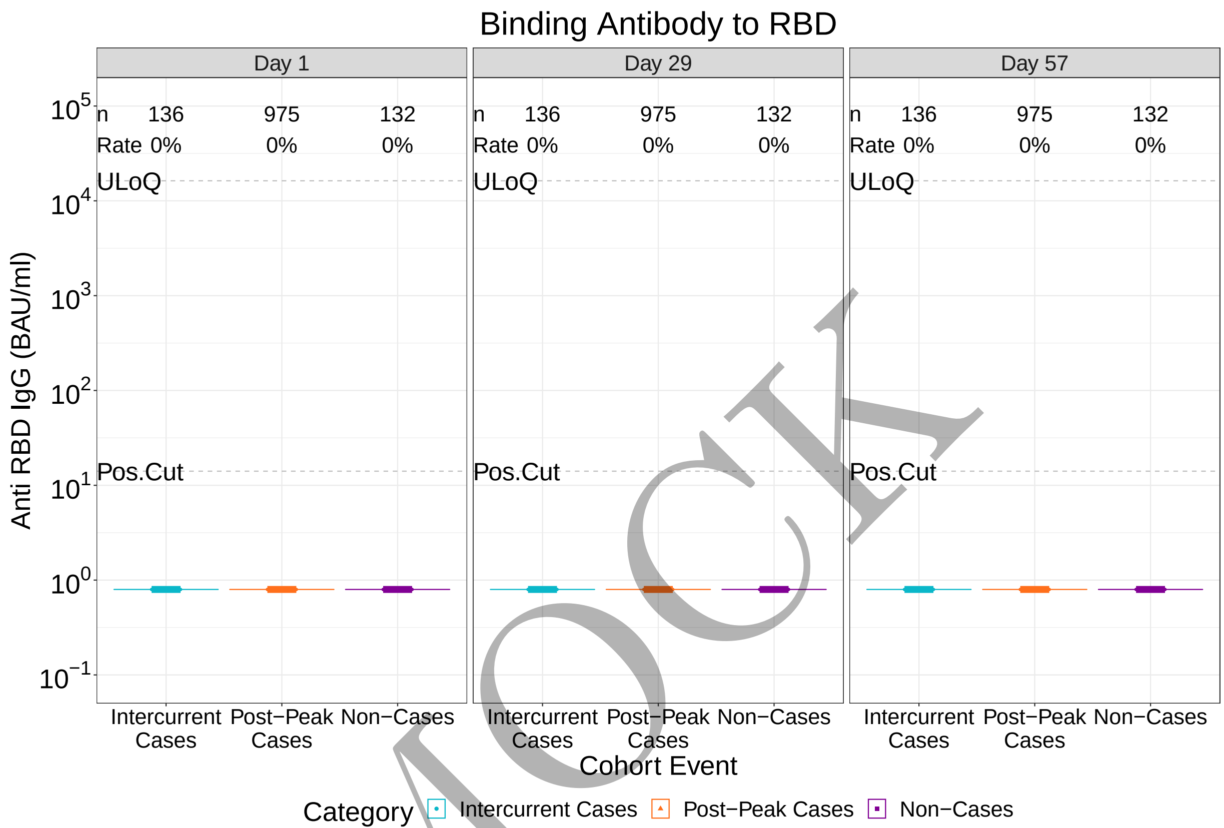
\begin{figure}



\caption{
Figure 2.5.26: violinplots of Binding Antibody to Spike: baseline negative vaccine arm (version 2)
} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



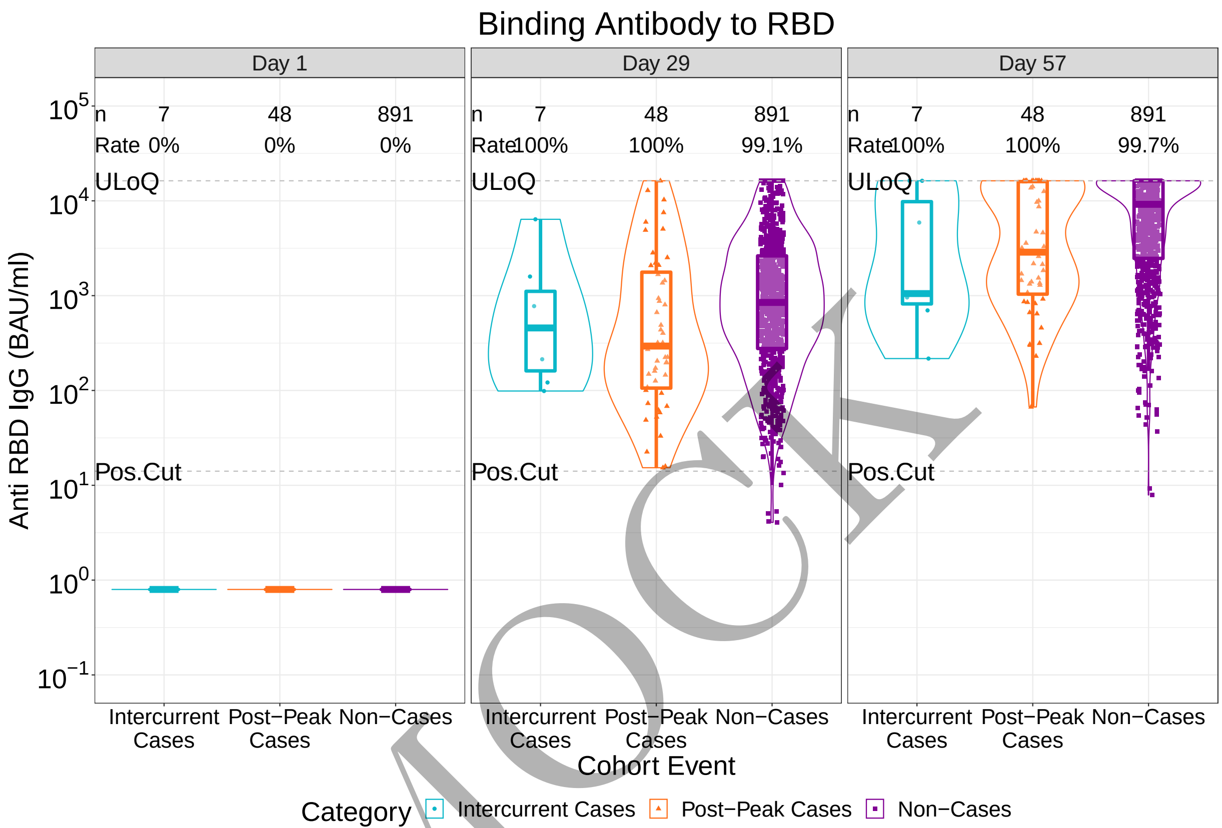
\caption{

Figure 2.5.27: violinplots of Binding Antibody to RBD: baseline negative placebo arm (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



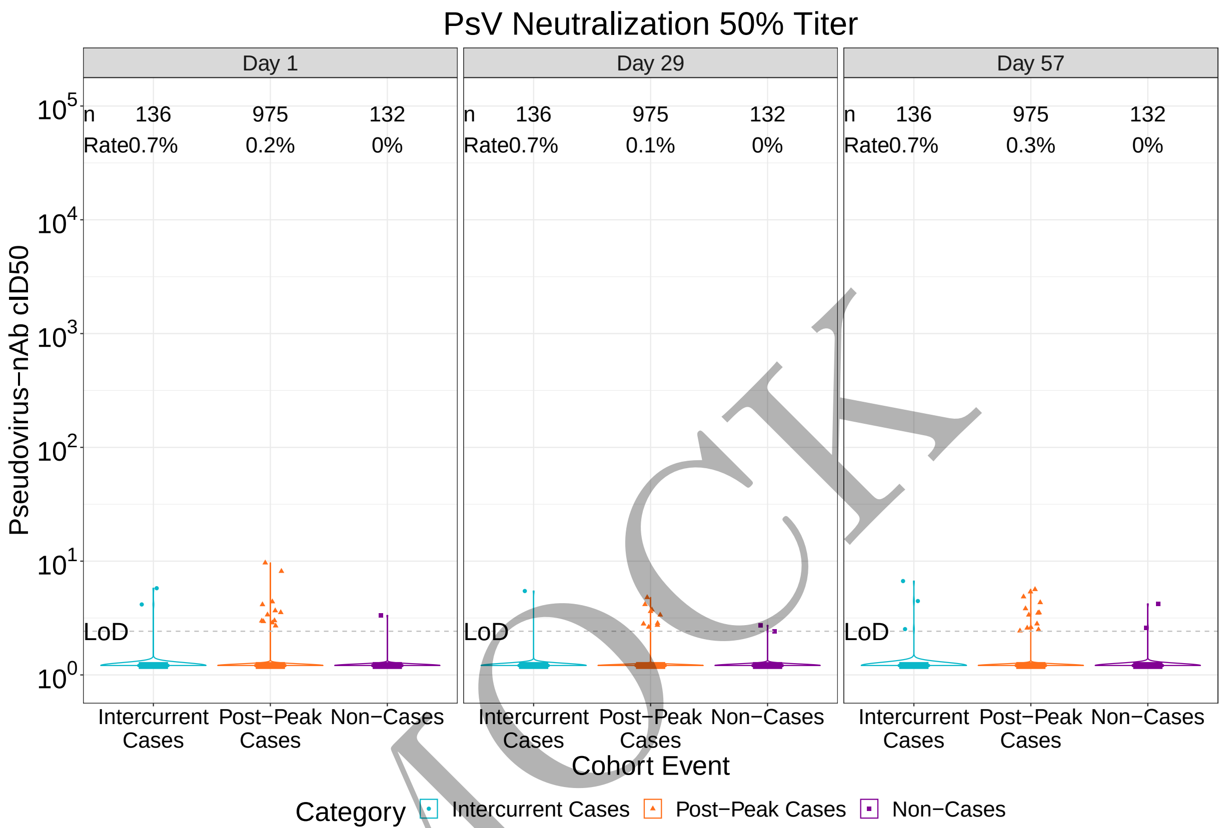
\caption{

Figure 2.5.28: violinplots of Binding Antibody to RBD: baseline negative vaccine arm (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



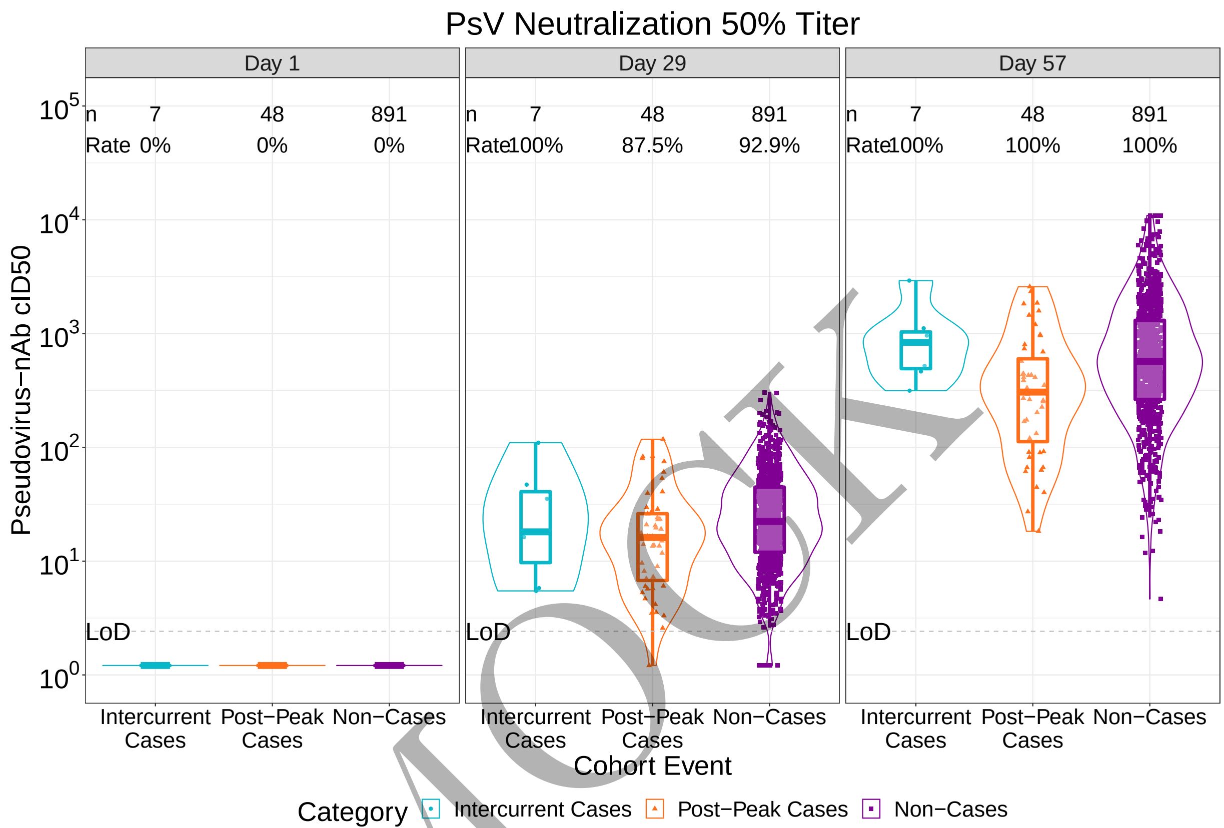
\caption{

Figure 2.5.29: violinplots of PsV Neutralization 50% Titer: baseline negative placebo arm (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



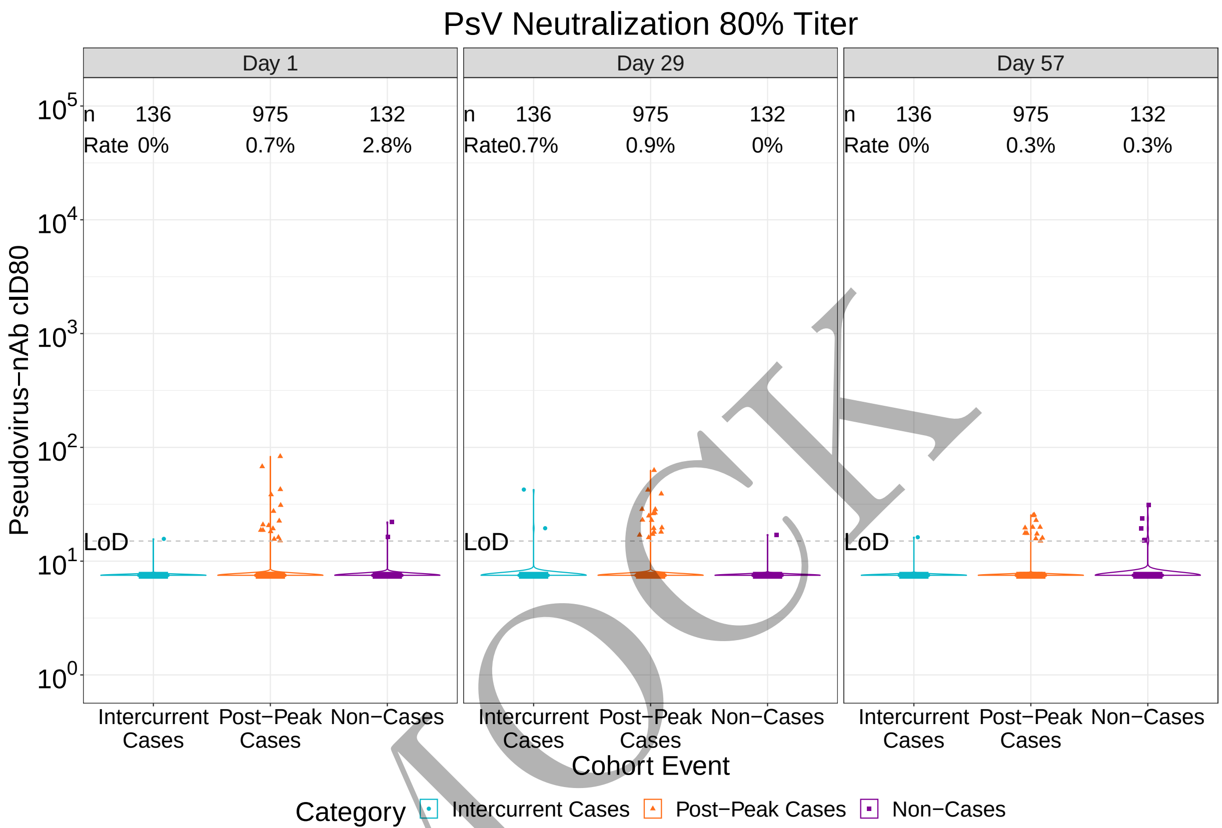
\caption{

Figure 2.5.30: violinplots of PsV Neutralization 50% Titer: baseline negative vaccine arm (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



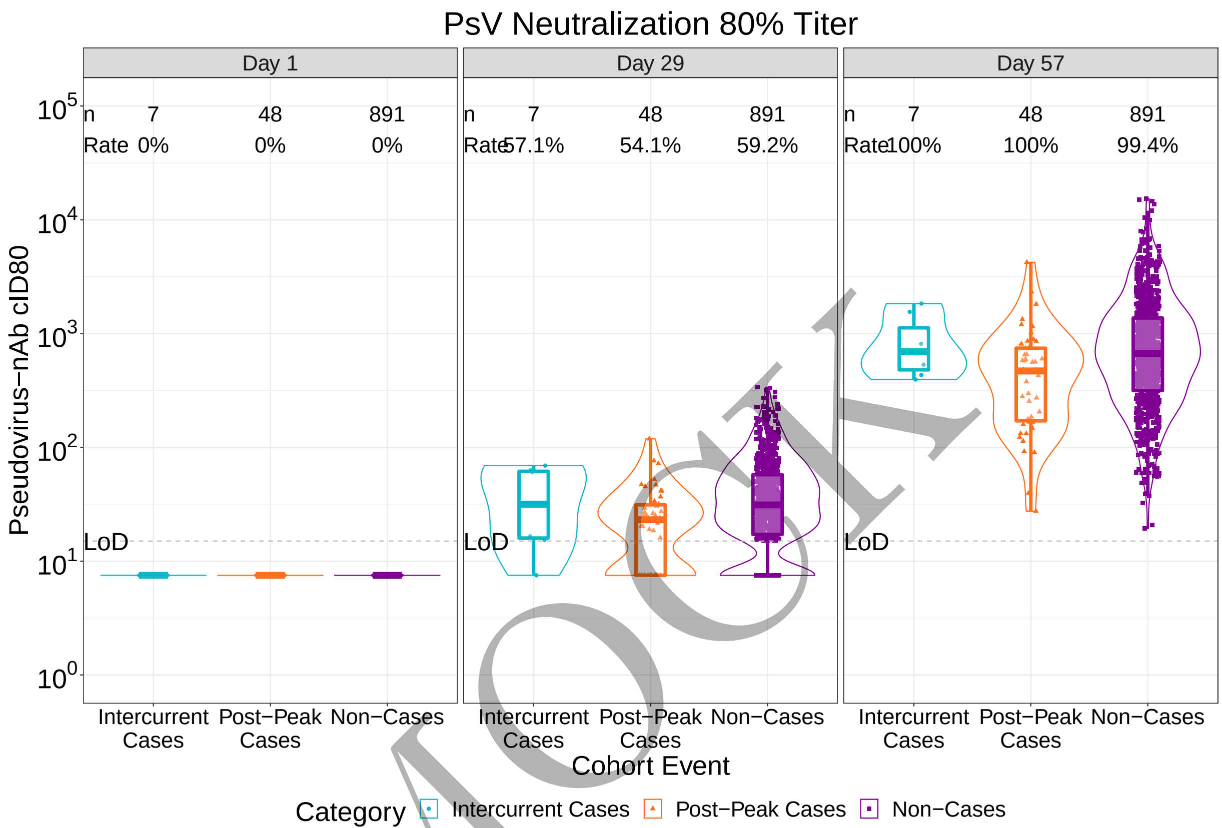
\caption{

Figure 2.5.31: violinplots of PsV Neutralization 80% Titer: baseline negative placebo arm (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

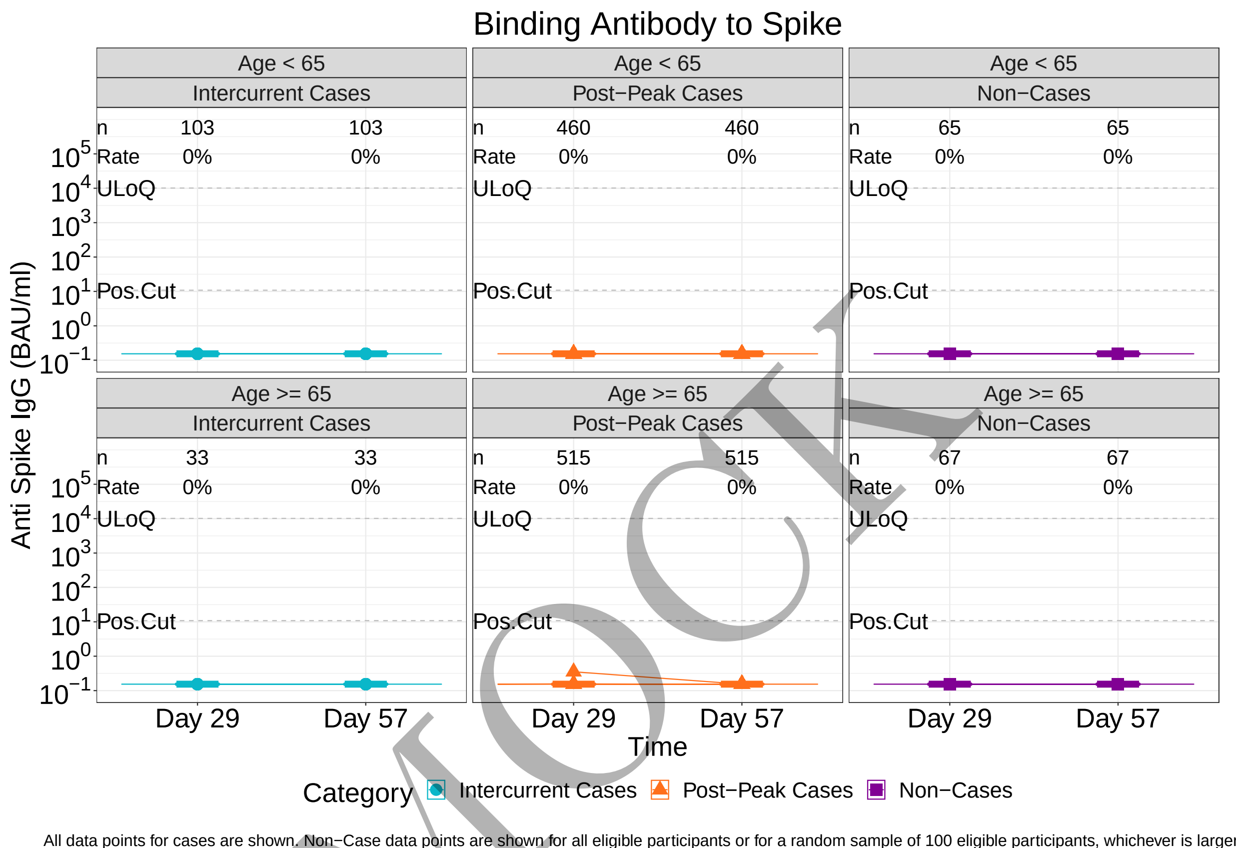
\begin{figure}



\caption{
Figure 2.5.32: violinplots of PsV Neutralization 80% Titer: baseline negative vaccine arm (version 2)
} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



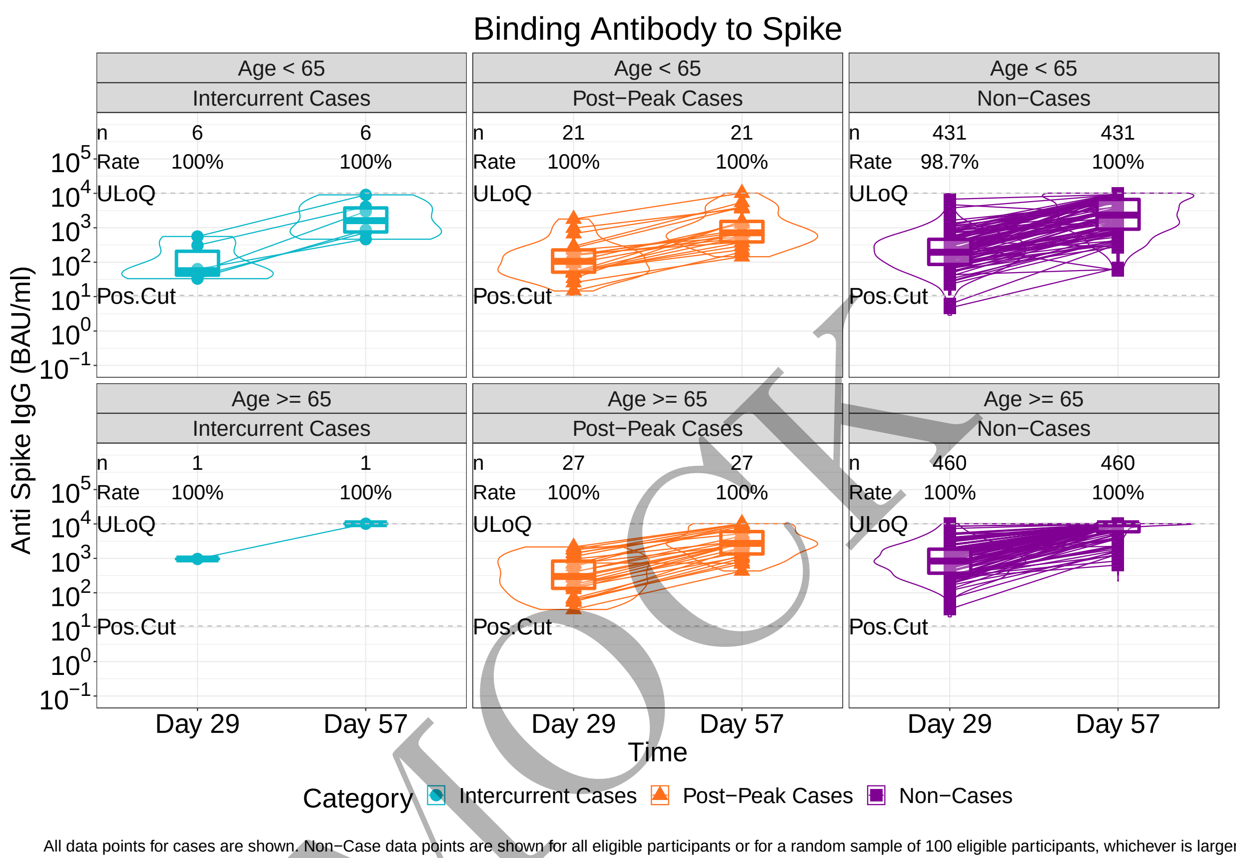
\caption{

Figure 2.5.33: lineplots of Binding Antibody to Spike: baseline negative placebo arm by age (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



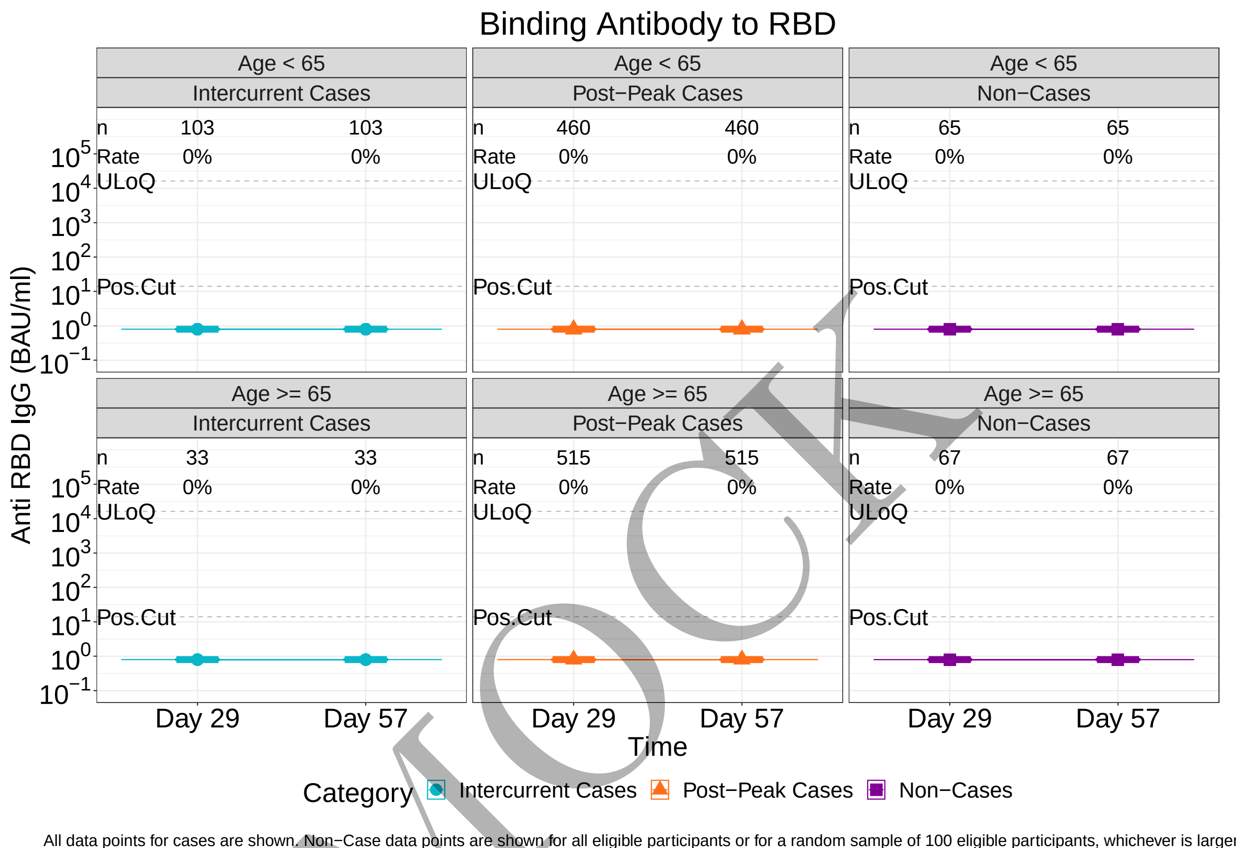
\caption{

Figure 2.5.34: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by age (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



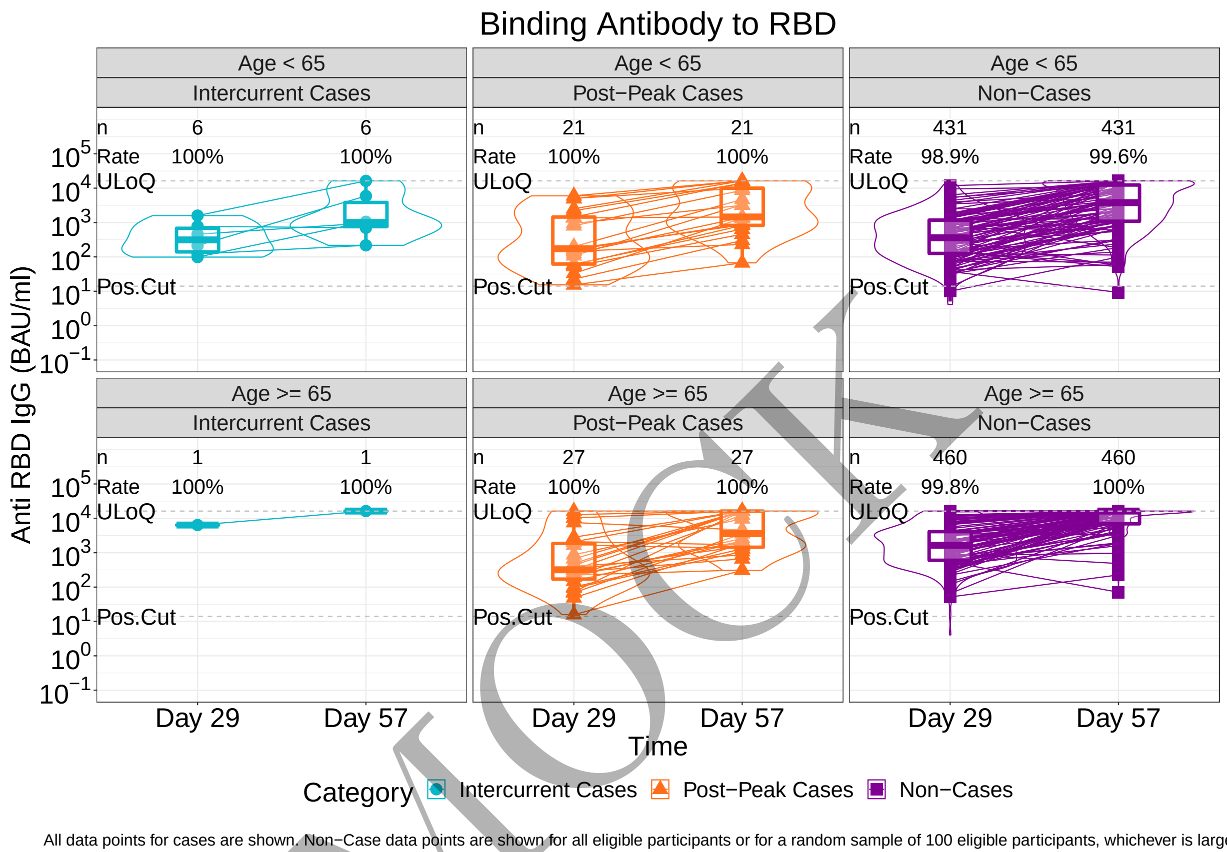
\caption{

Figure 2.5.35: lineplots of Binding Antibody to RBD: baseline negative placebo arm by age (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



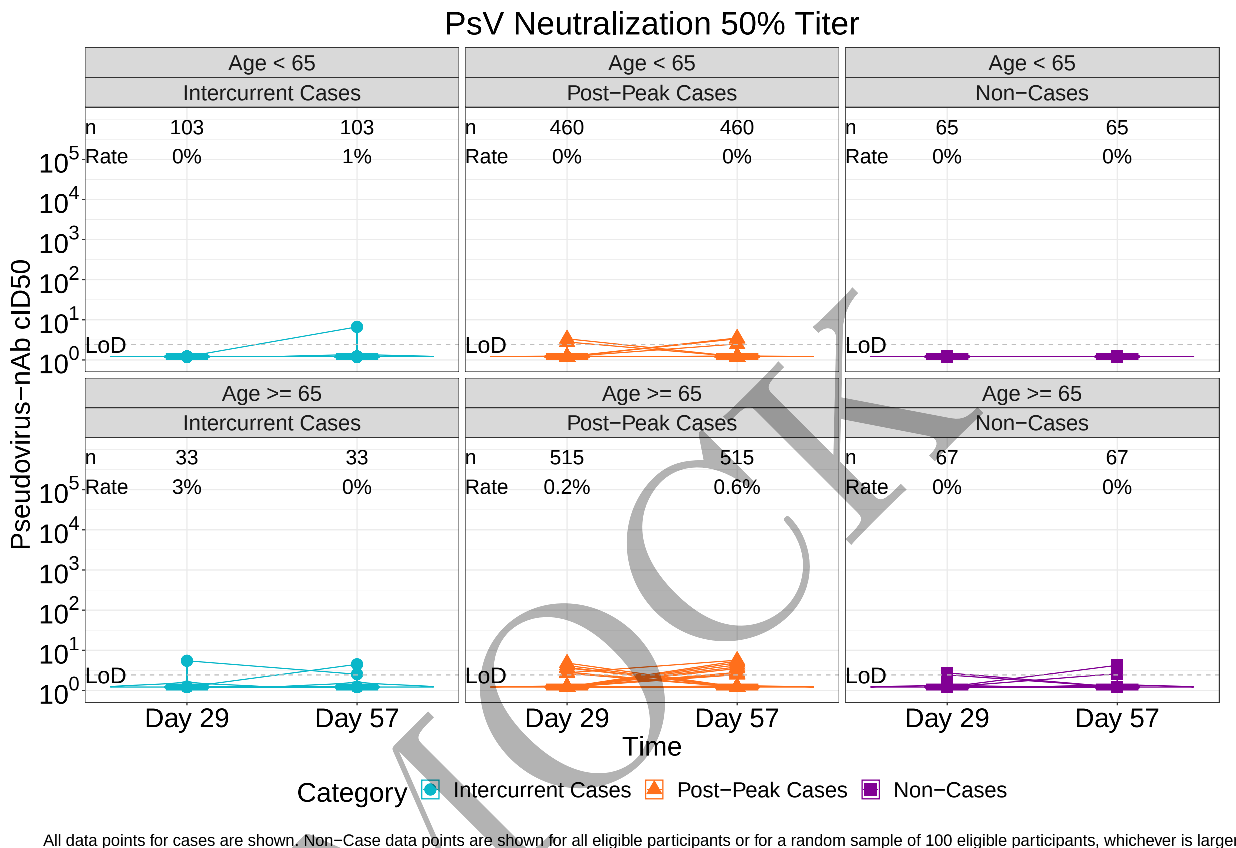
\caption{

Figure 2.5.36: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by age (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}

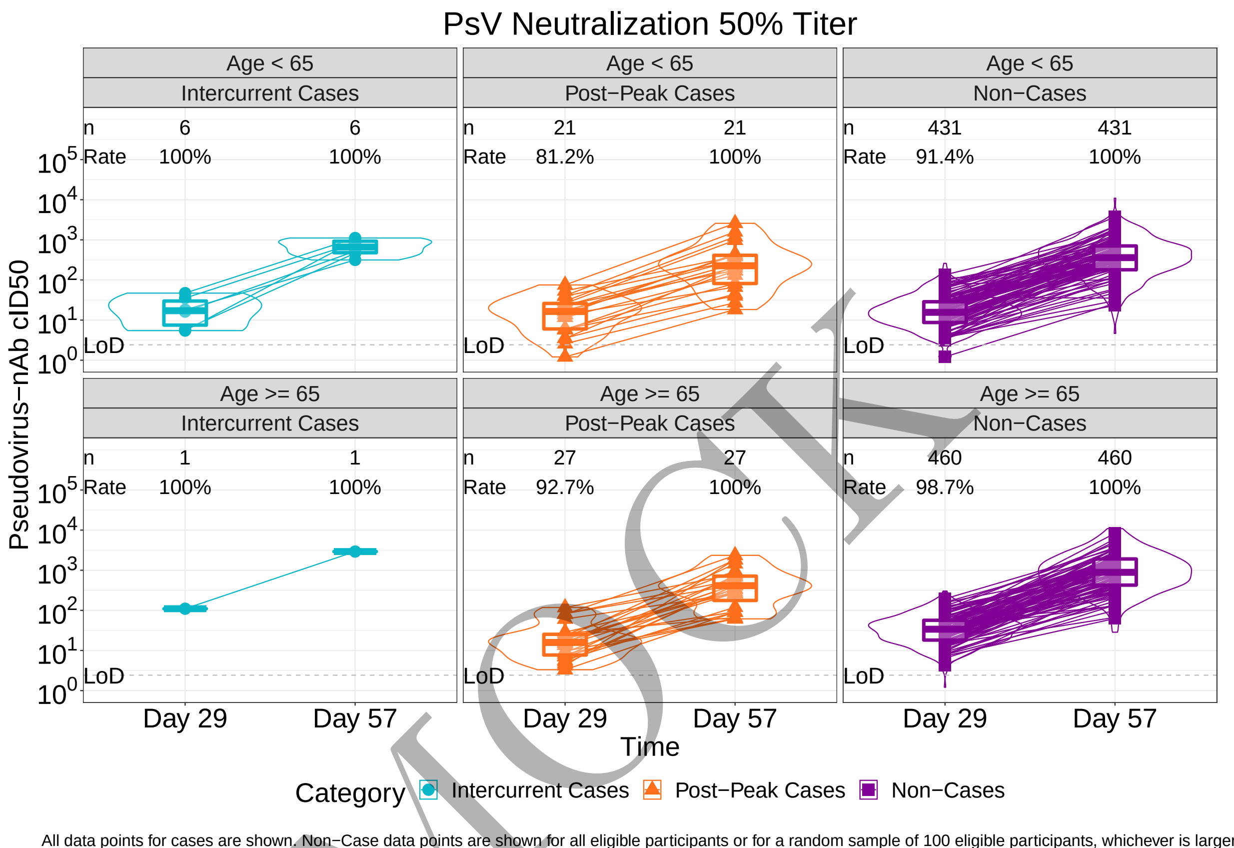


\caption{

Figure 2.5.37: lineplots of PsV Neutralization 50% Titer: baseline negative placebo arm by age (version 1)

} \end{figure}

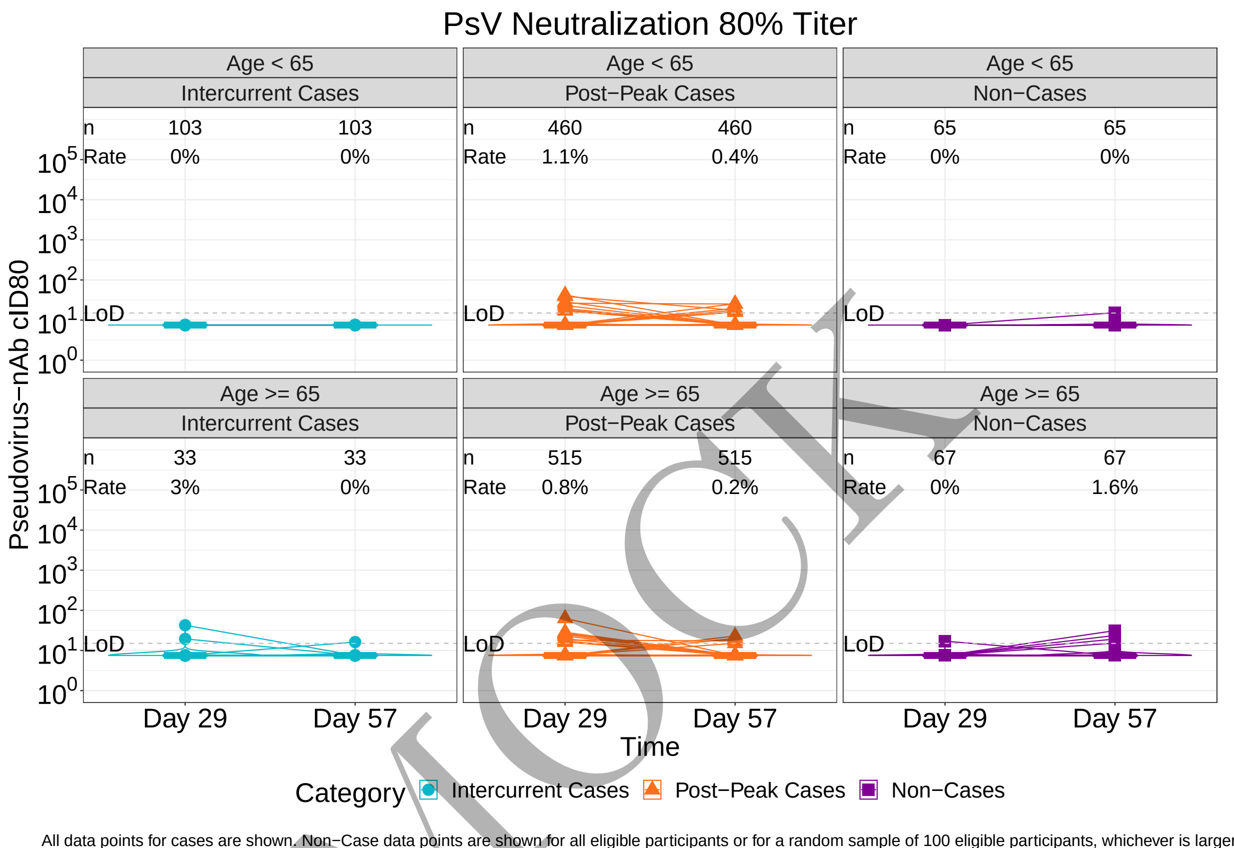
r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")
\begin{figure}



\caption{
Figure 2.5.38: lineplots of PsV Neutralization 50% Titer: baseline negative vaccine arm by age (version 1)
} \end{figure}

r `COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")`

\begin{figure}



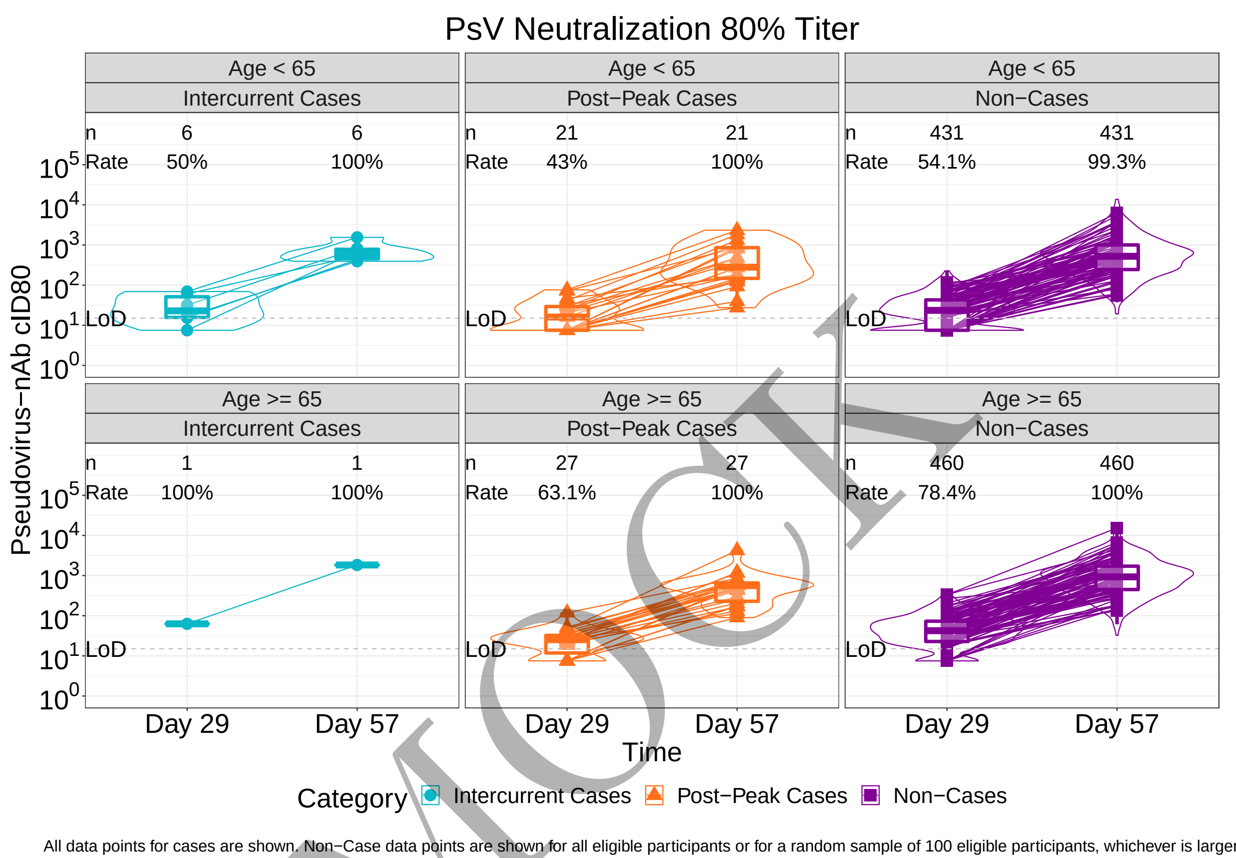
\caption{

Figure 2.5.39: lineplots of PsV Neutralization 80% Titer: baseline negative placebo arm by age (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

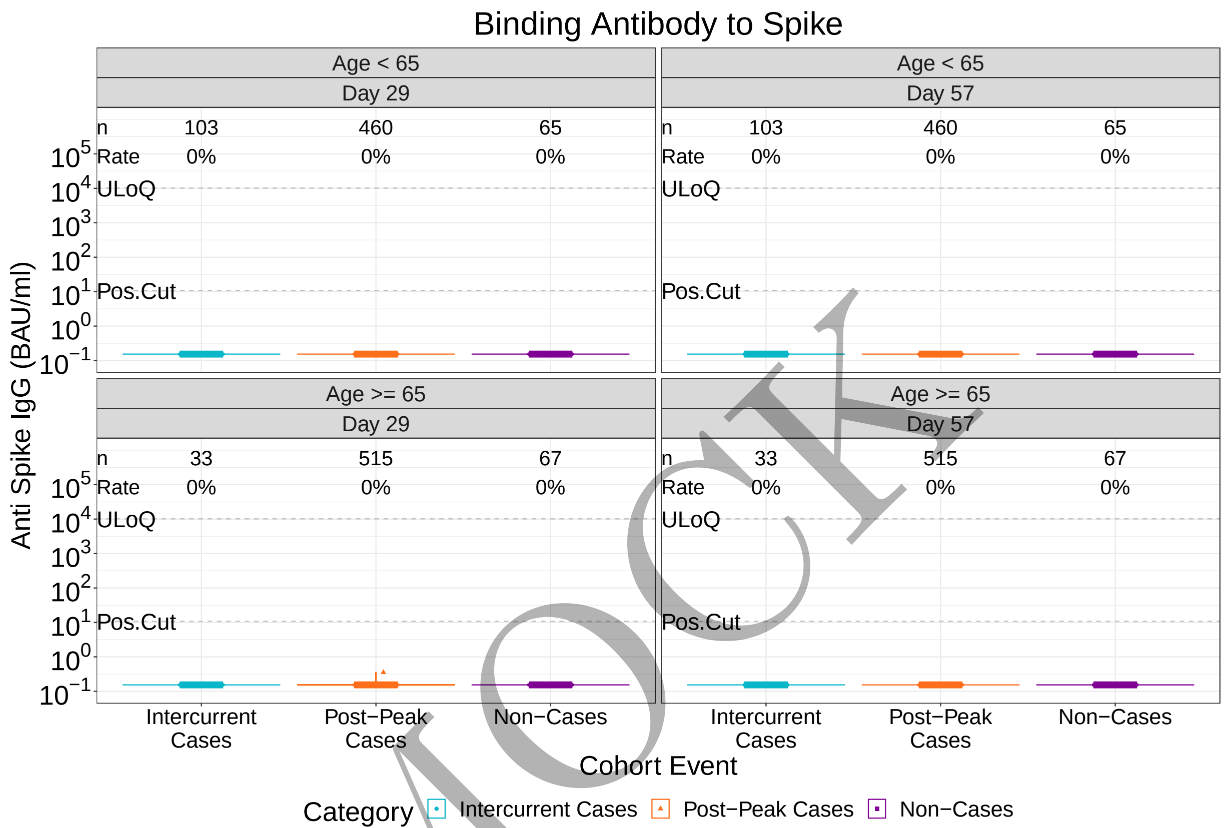
\begin{figure}



\caption{
Figure 2.5.40: lineplots of PsV Neutralization 80% Titer: baseline negative vaccine arm by age (version 1)
} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



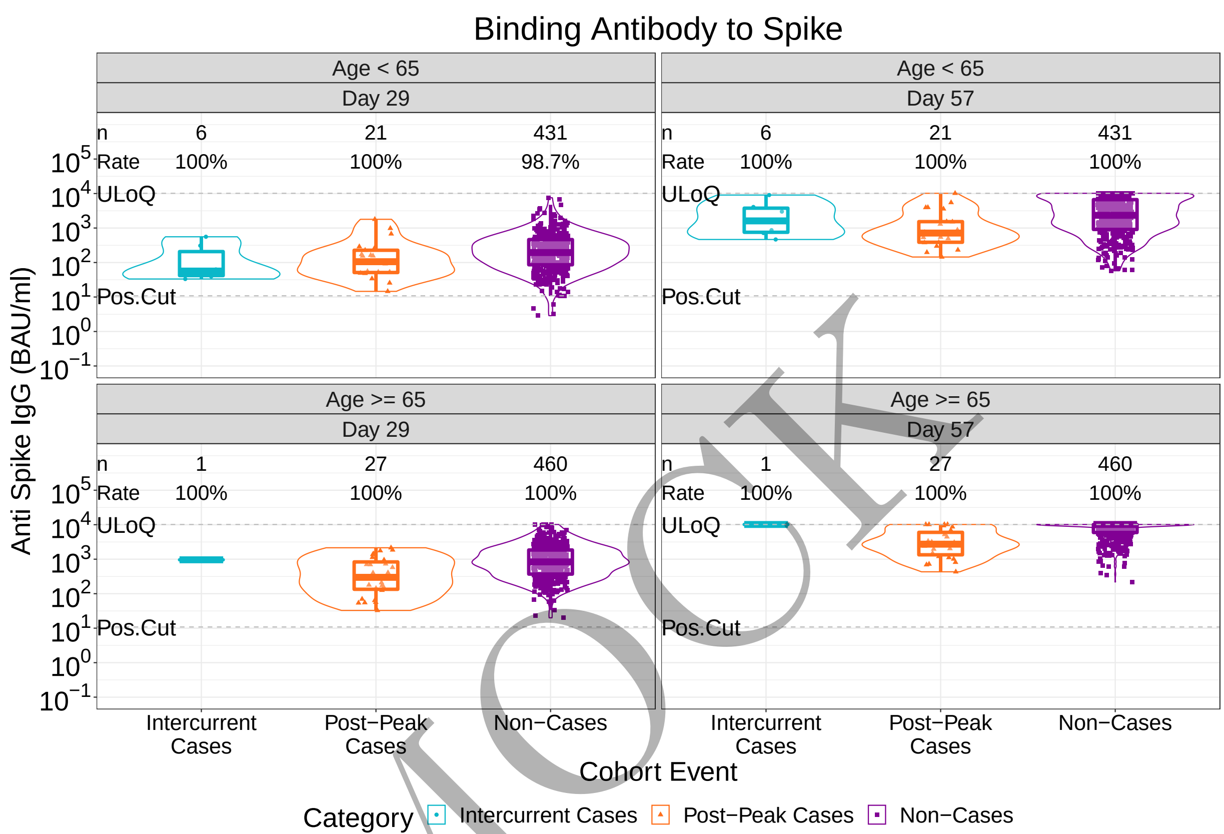
\caption{

Figure 2.5.41: violinplots of Binding Antibody to Spike: baseline negative placebo arm by age (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

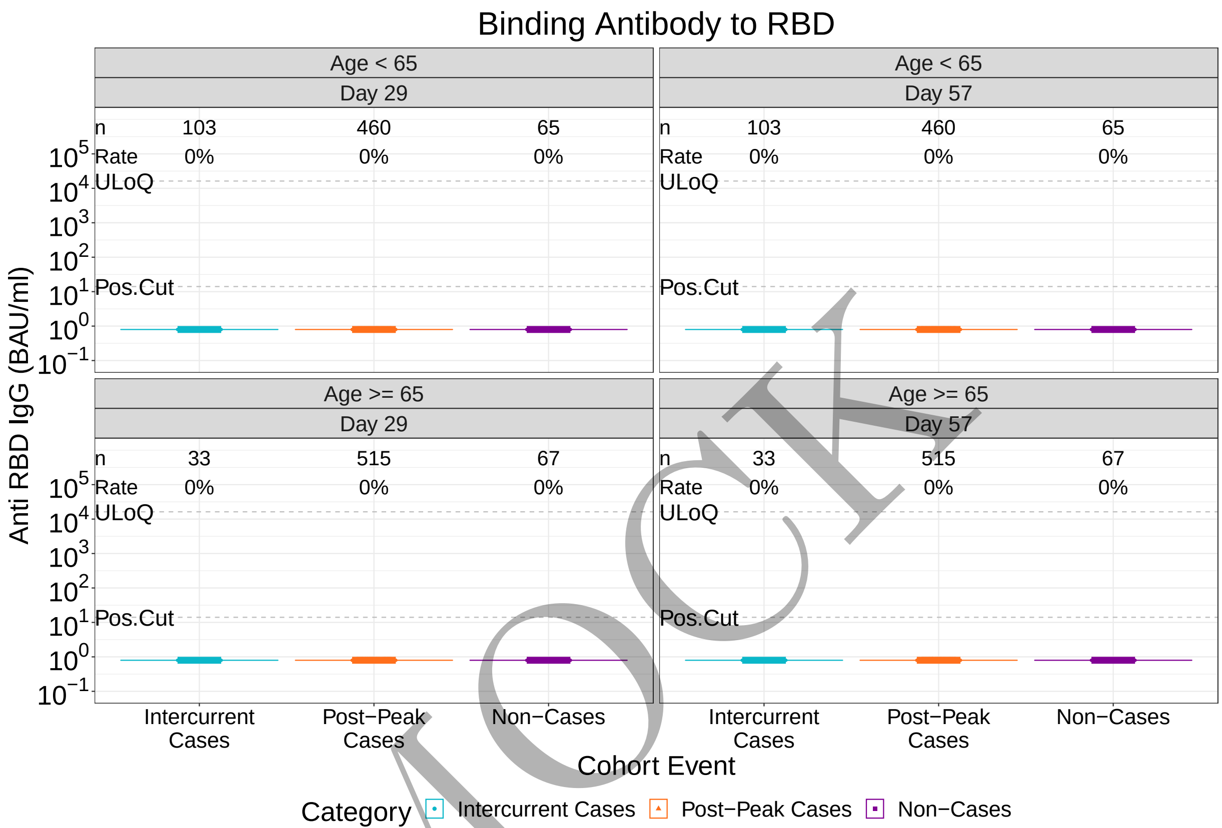
\begin{figure}



\caption{
Figure 2.5.42: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by age (version 1)
} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



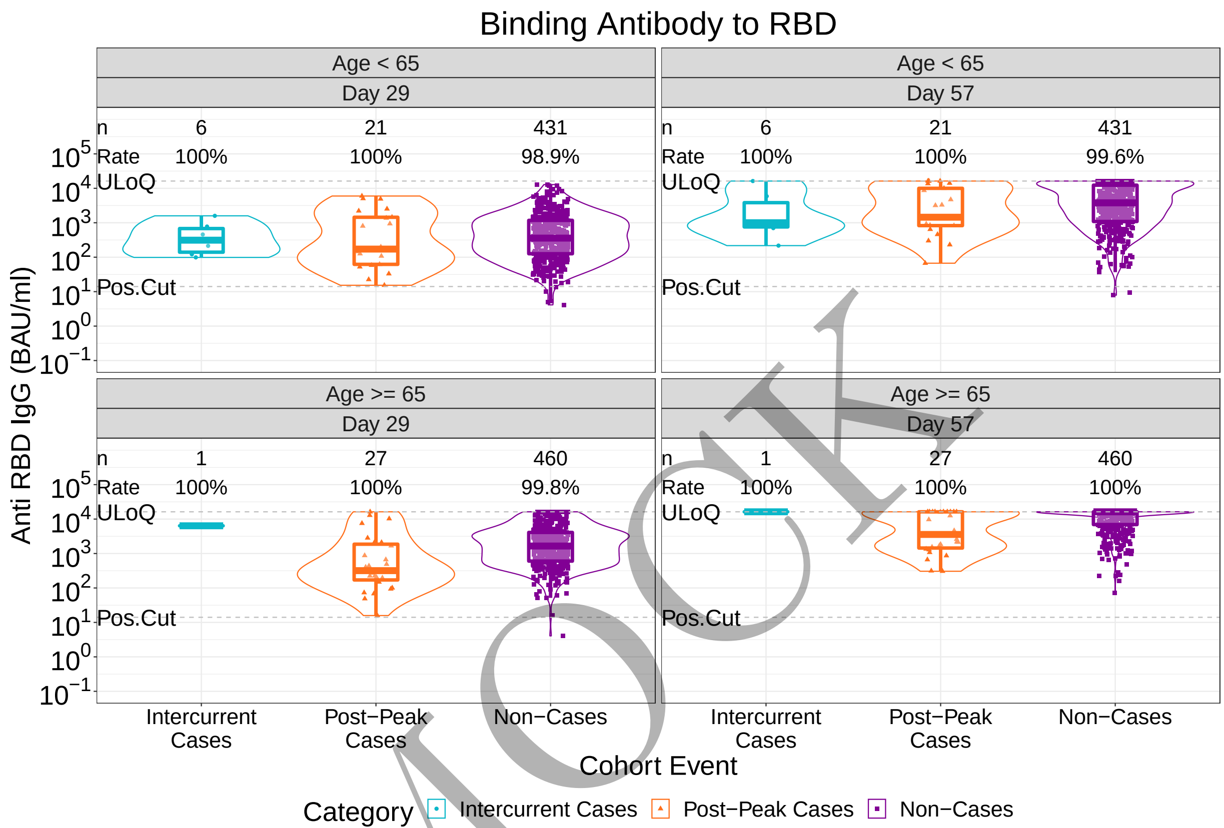
\caption{

Figure 2.5.43: violinplots of Binding Antibody to RBD: baseline negative placebo arm by age (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



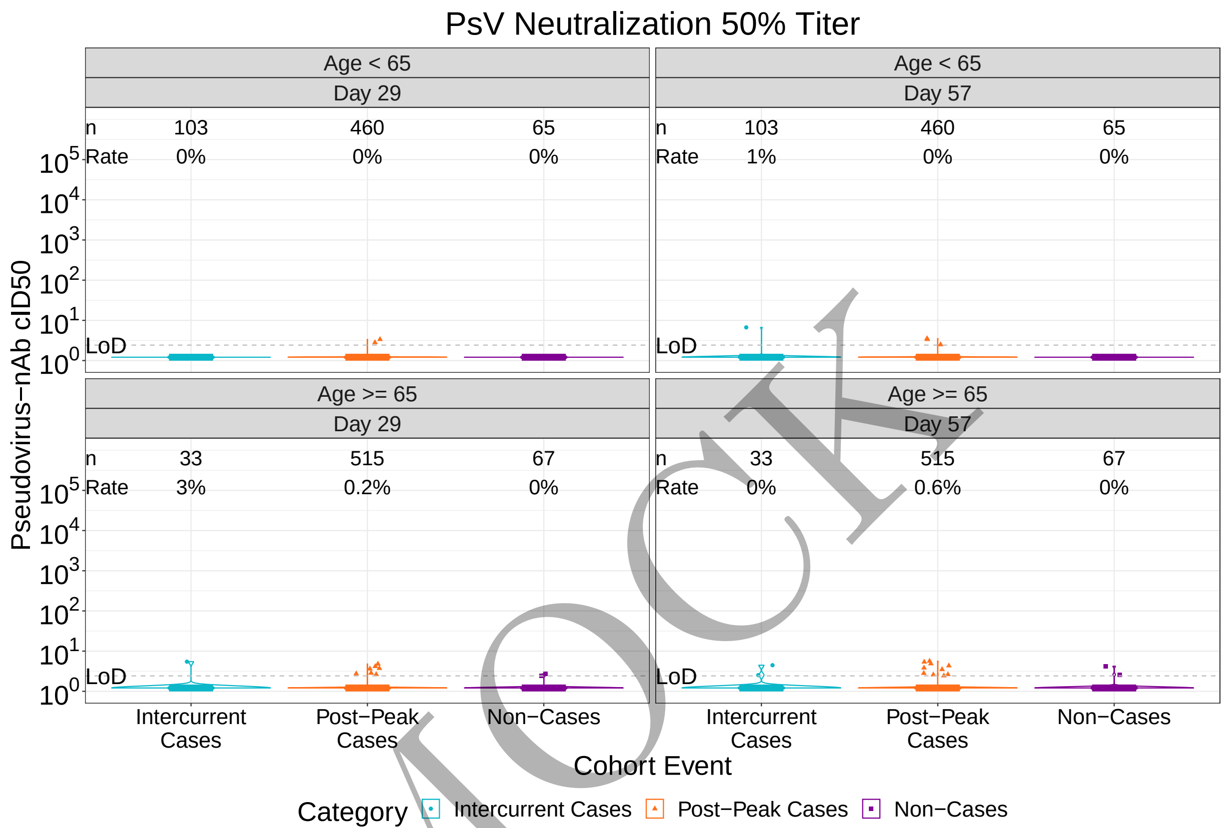
\caption{

Figure 2.5.44: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by age (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



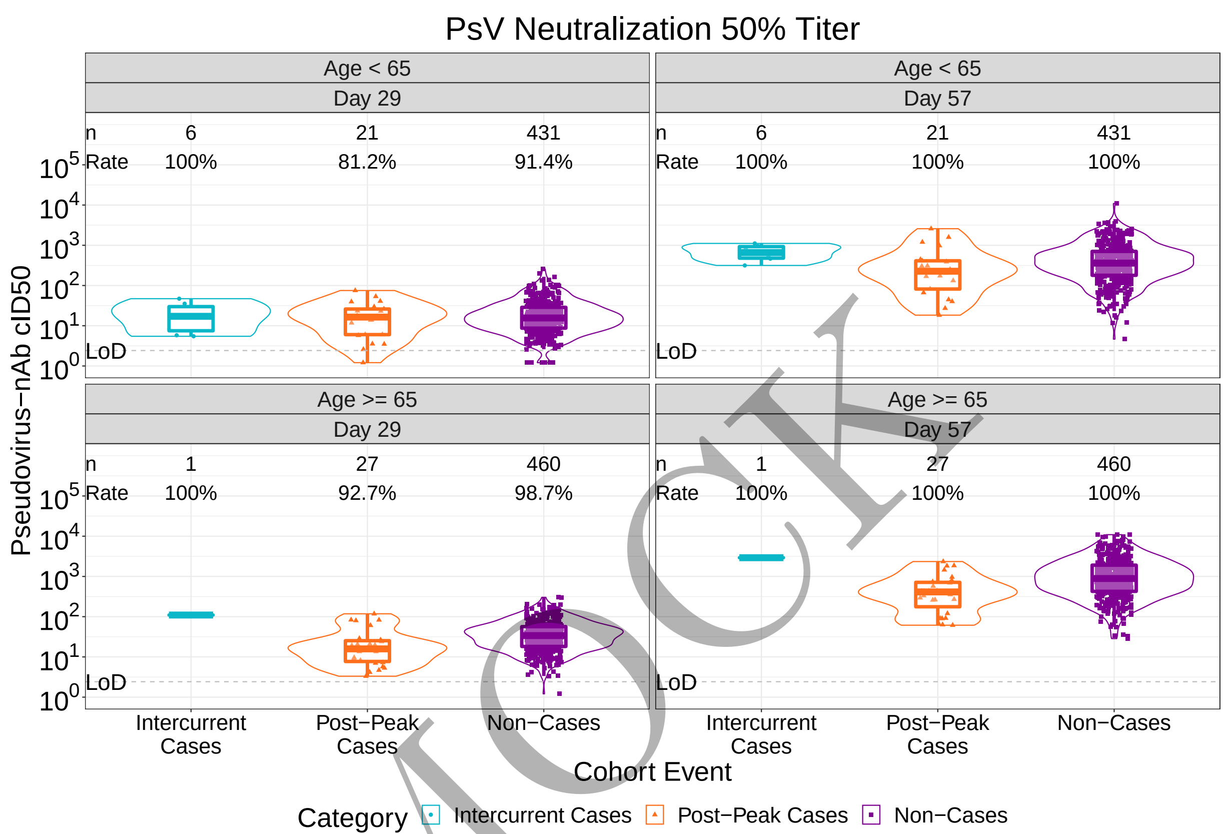
\caption{

Figure 2.5.45: violinplots of PsV Neutralization 50% Titer: baseline negative placebo arm by age (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

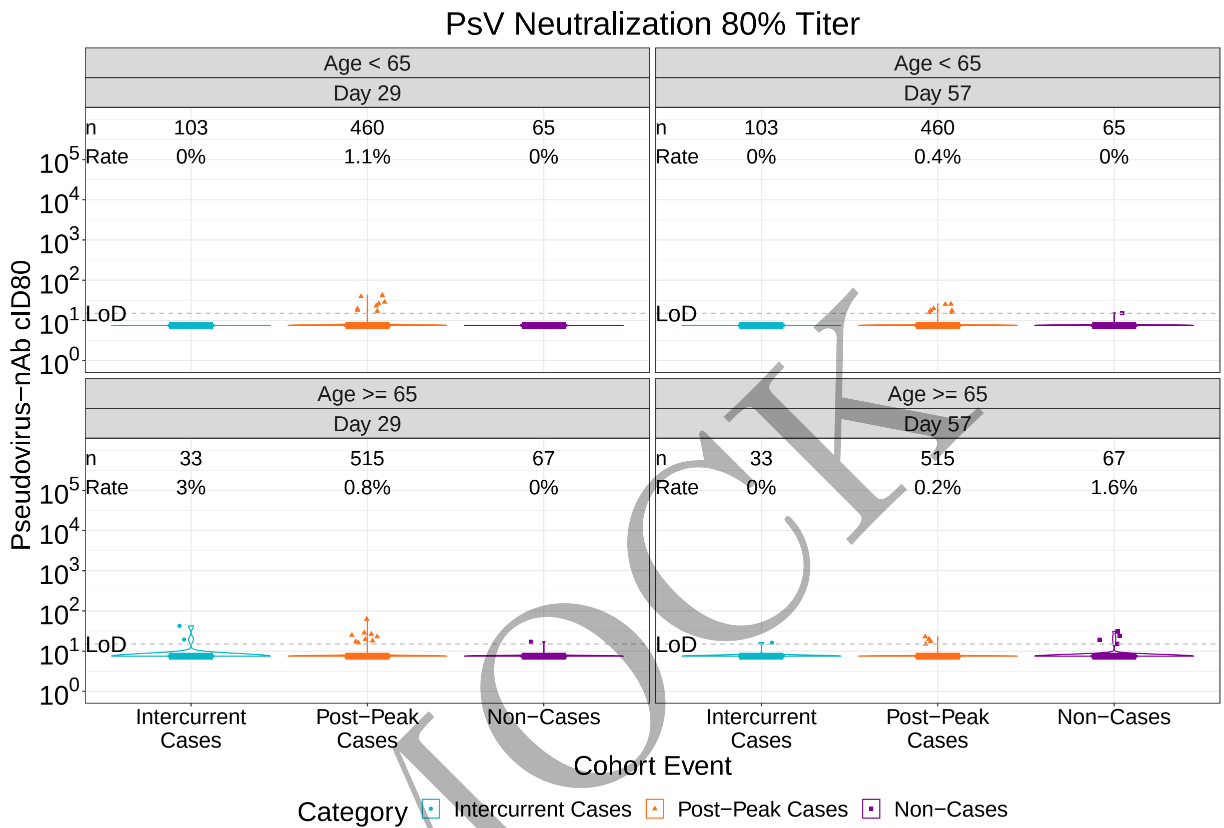
\begin{figure}



\caption{
Figure 2.5.46: violinplots of PsV Neutralization 50% Titer: baseline negative vaccine arm by age (version 1)
} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



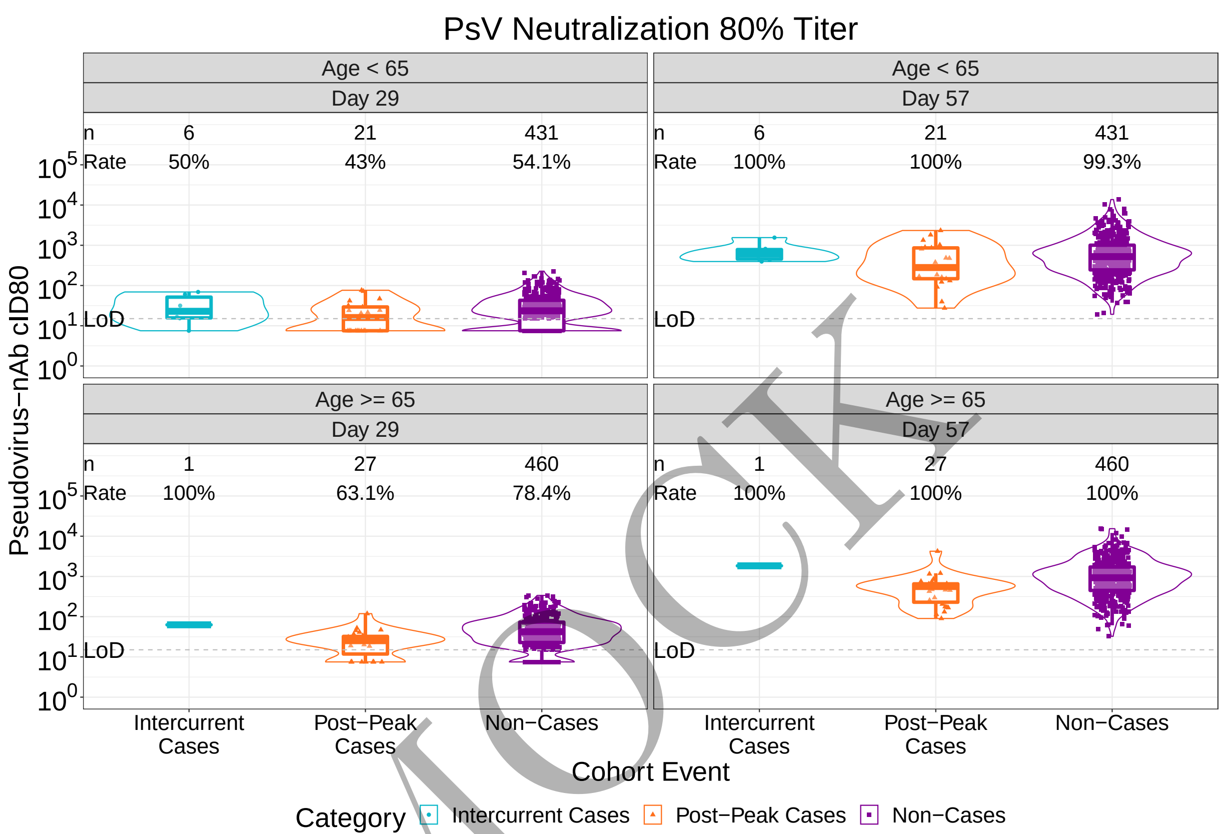
\caption{

Figure 2.5.47: violinplots of PsV Neutralization 80% Titer: baseline negative placebo arm by age (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



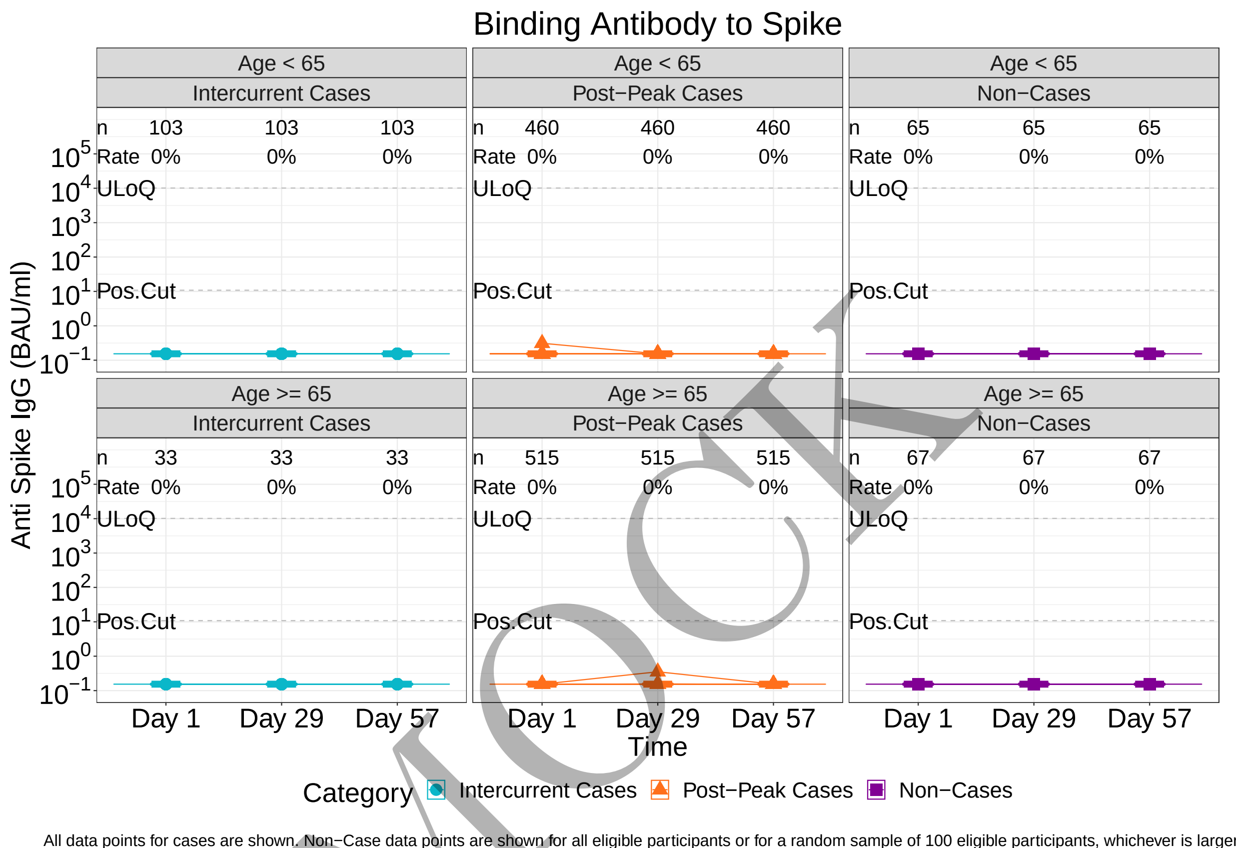
\caption{

Figure 2.5.48: violinplots of PsV Neutralization 80% Titer: baseline negative vaccine arm by age (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



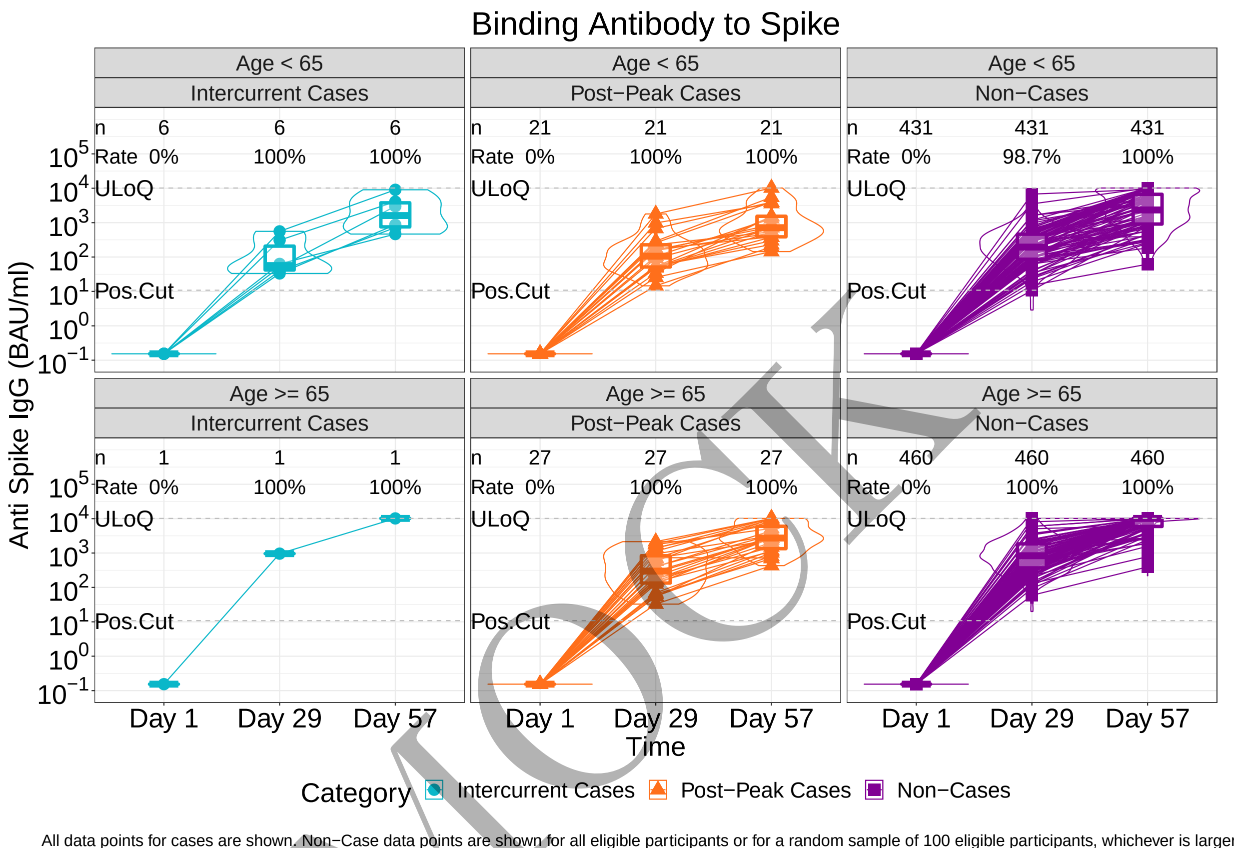
\caption{

Figure 2.5.49: lineplots of Binding Antibody to Spike: baseline negative placebo arm by age (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



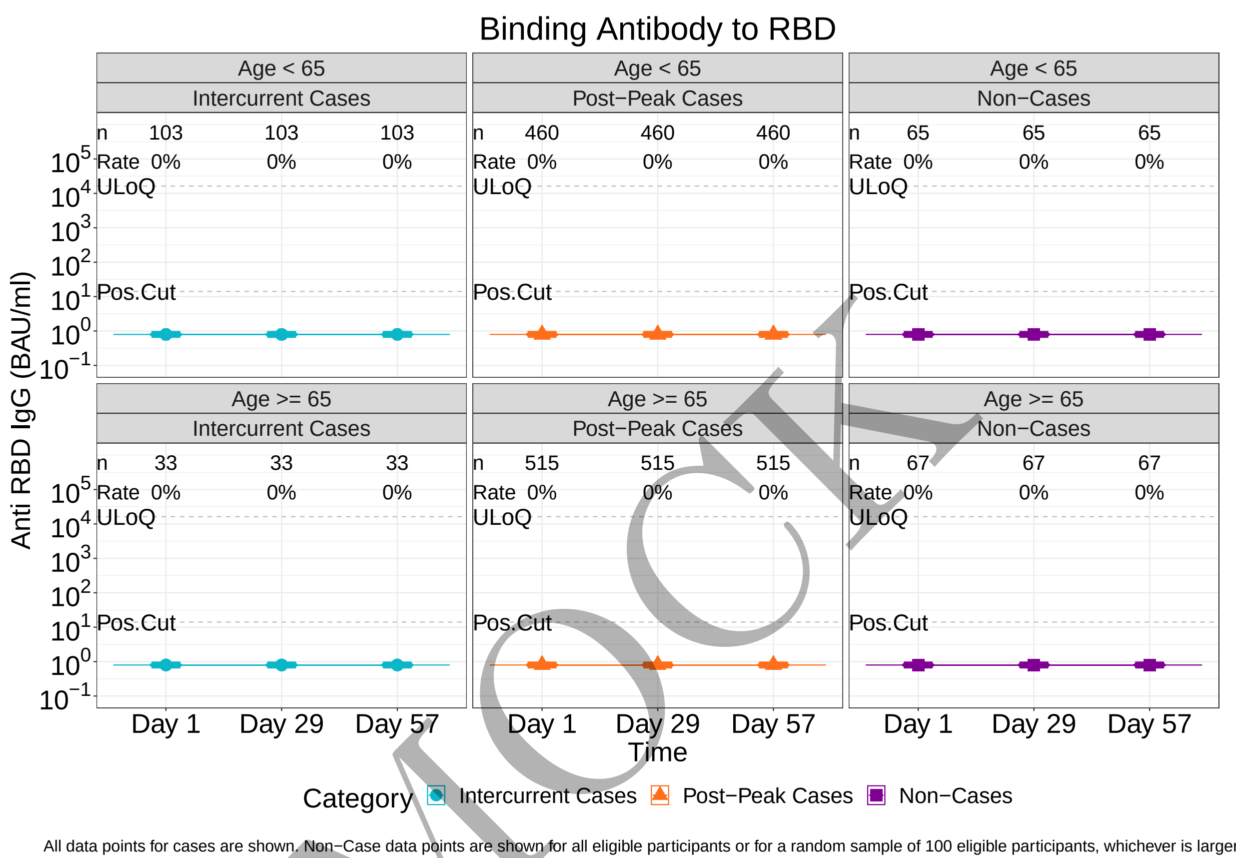
\caption{

Figure 2.5.50: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by age (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

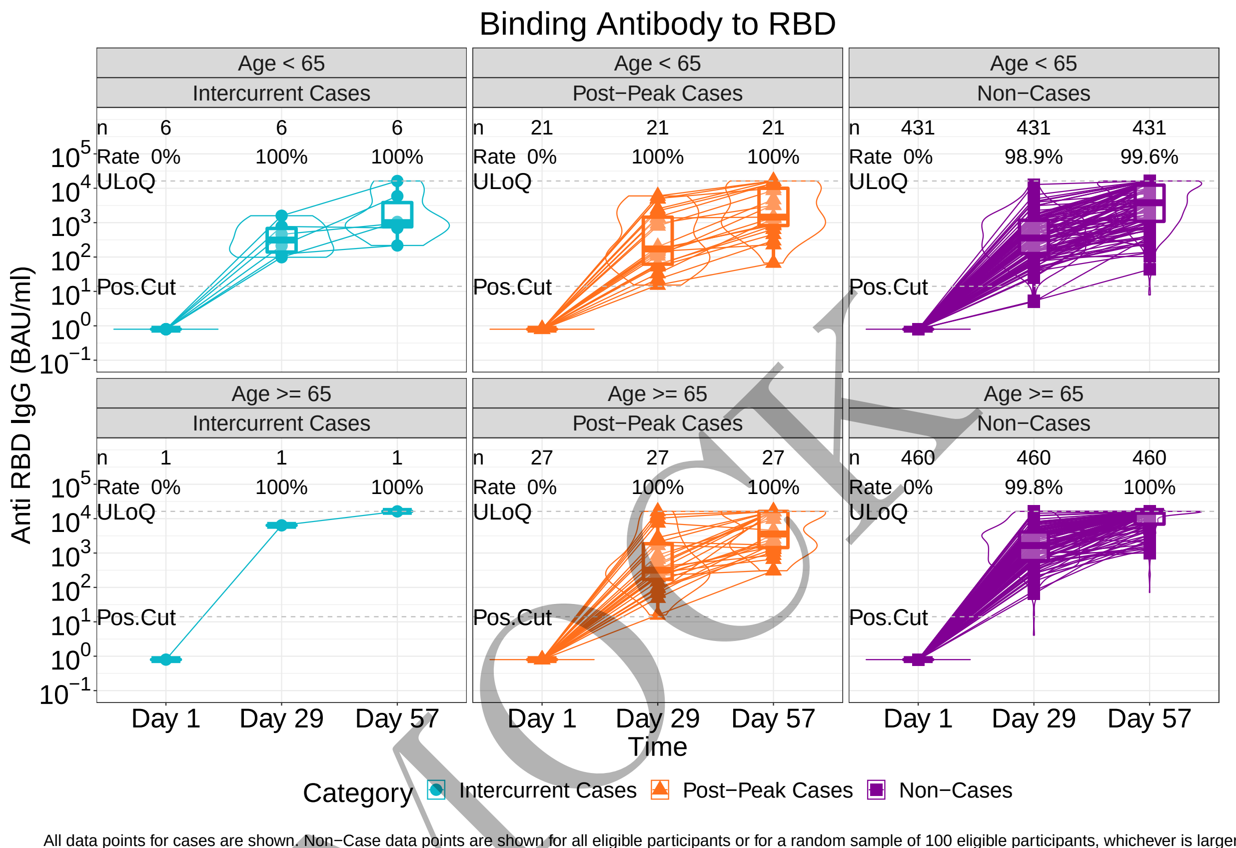
\begin{figure}



\caption{
Figure 2.5.51: lineplots of Binding Antibody to RBD: baseline negative placebo arm by age (version 2)
} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



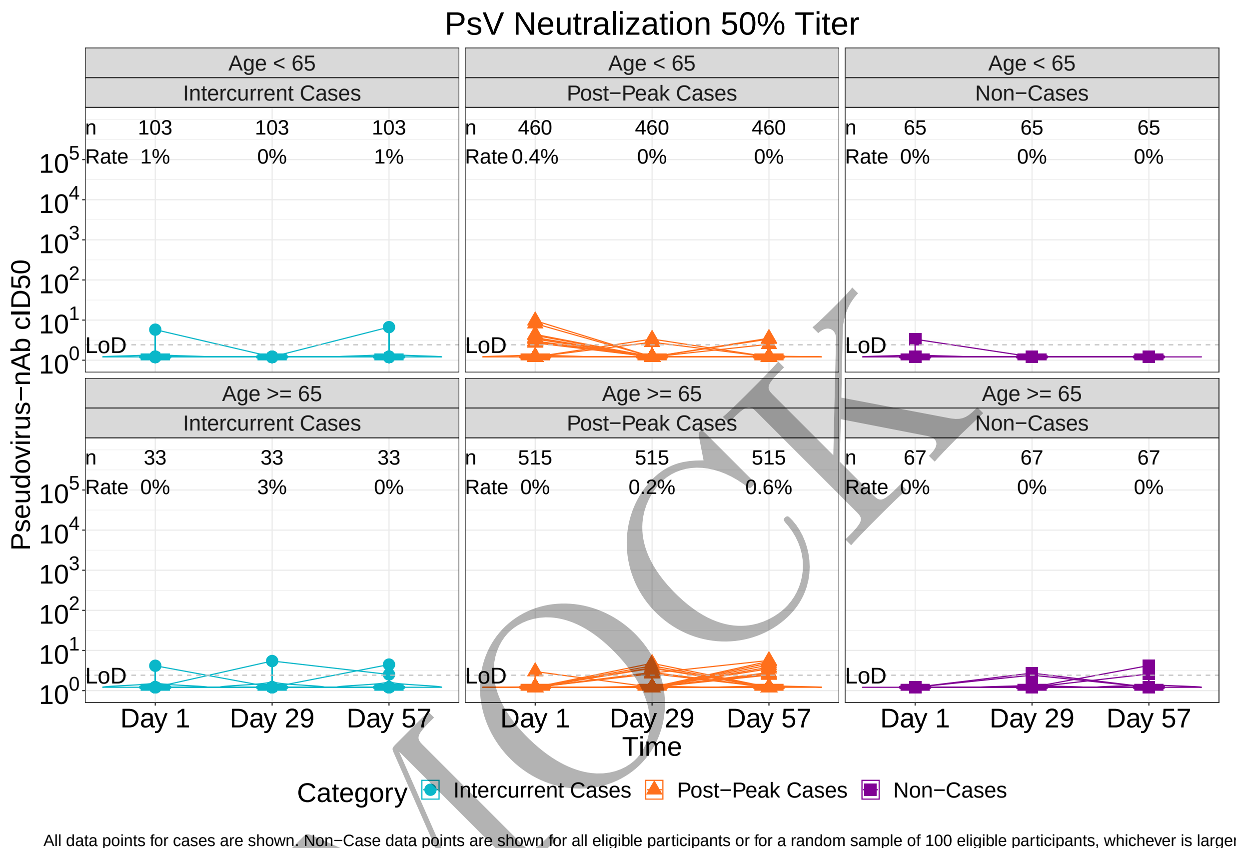
\caption{

Figure 2.5.52: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by age (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

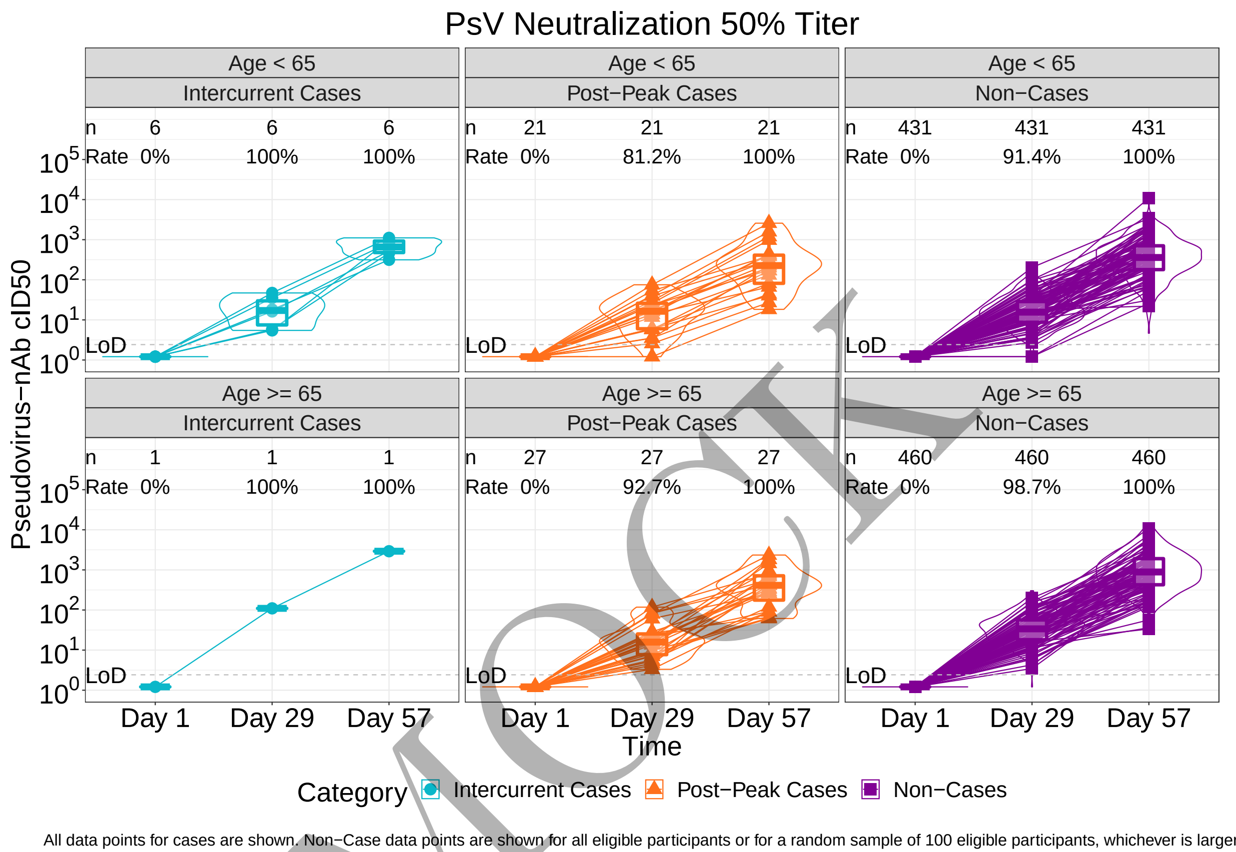
\begin{figure}



\caption{
Figure 2.5.53: lineplots of PsV Neutralization 50% Titer: baseline negative placebo arm by age (version 2)
} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



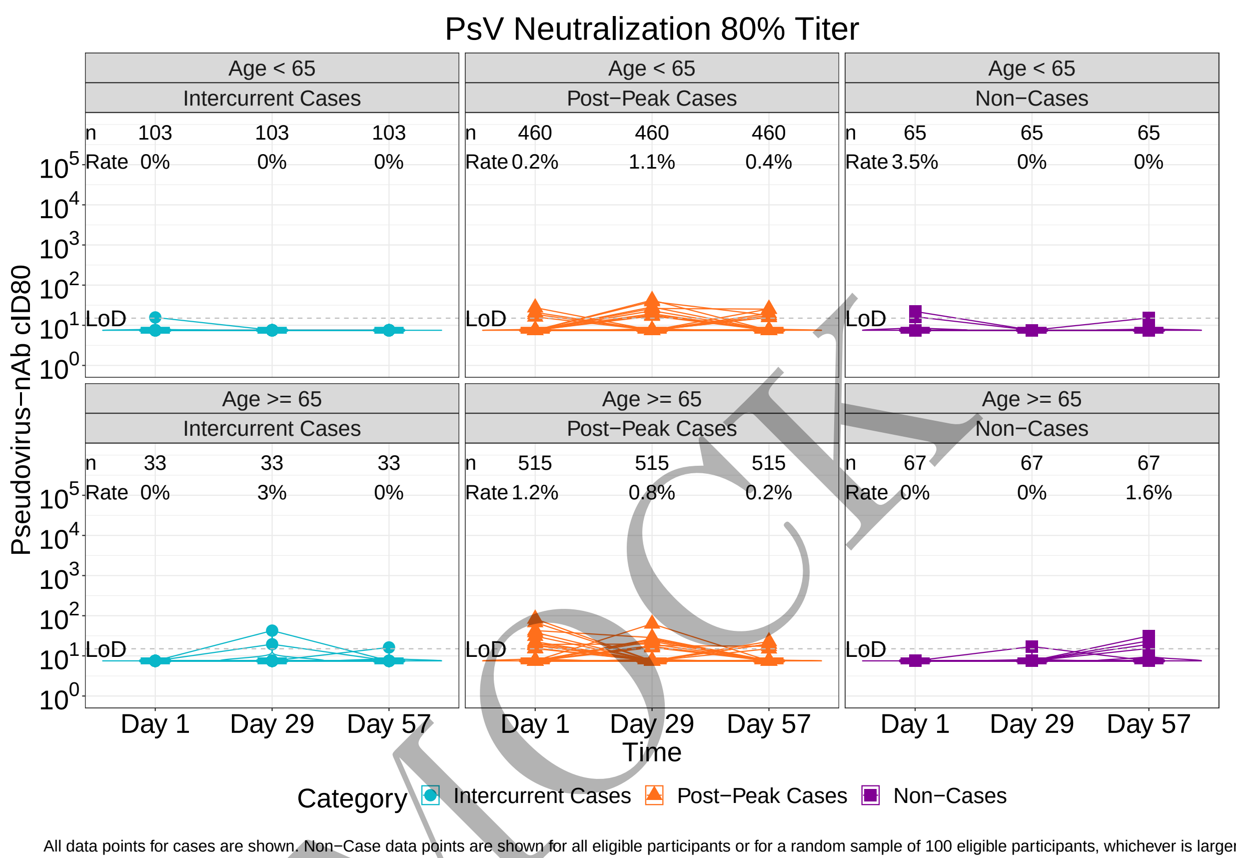
\caption{

Figure 2.5.54: lineplots of PsV Neutralization 50% Titer: baseline negative vaccine arm by age (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



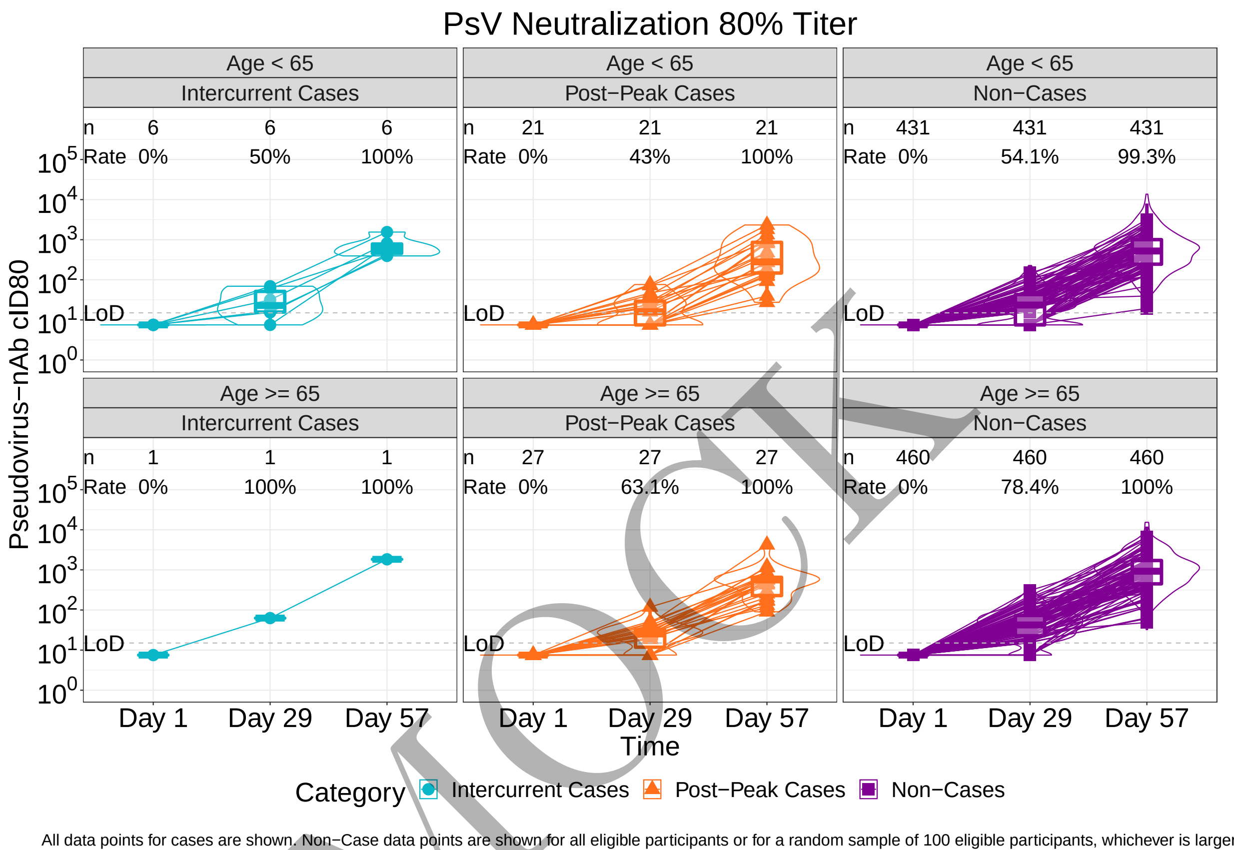
\caption{

Figure 2.5.55: lineplots of PsV Neutralization 80% Titer: baseline negative placebo arm by age (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



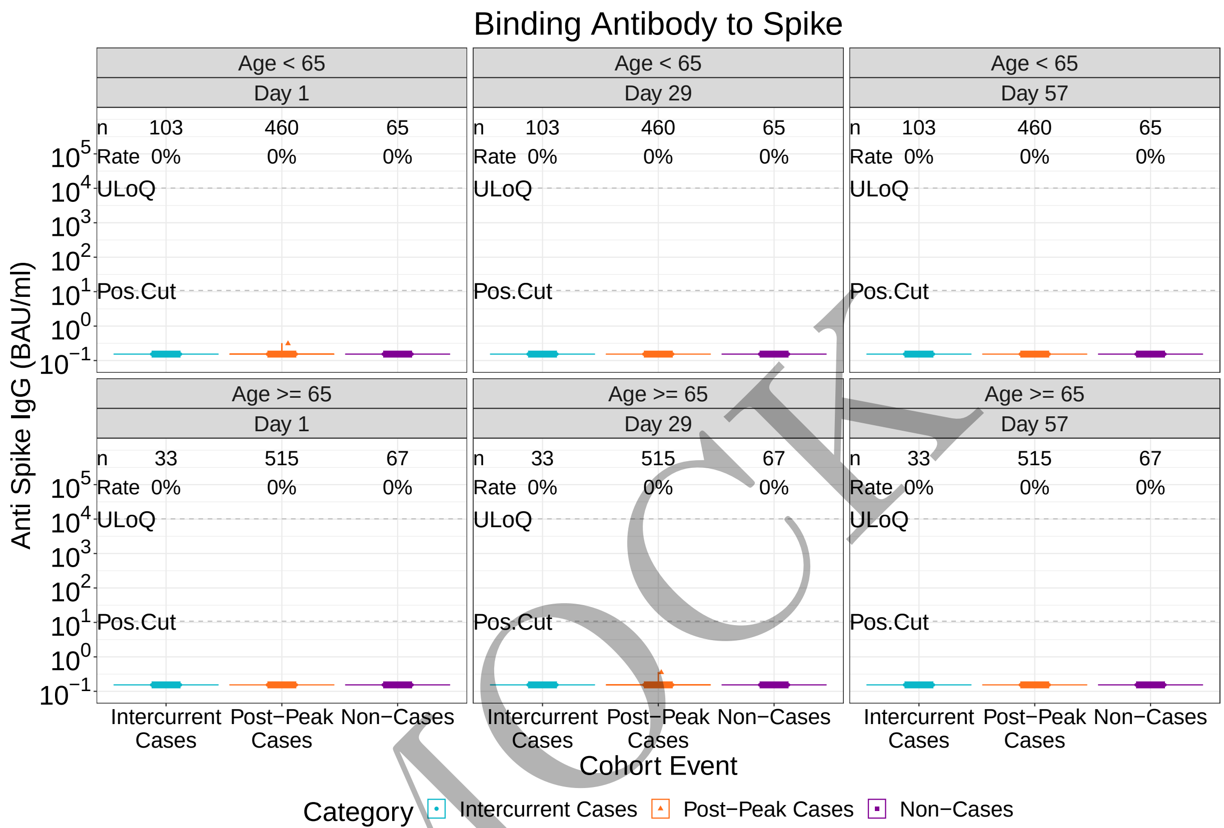
\caption{

Figure 2.5.56: lineplots of PsV Neutralization 80% Titer: baseline negative vaccine arm by age (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



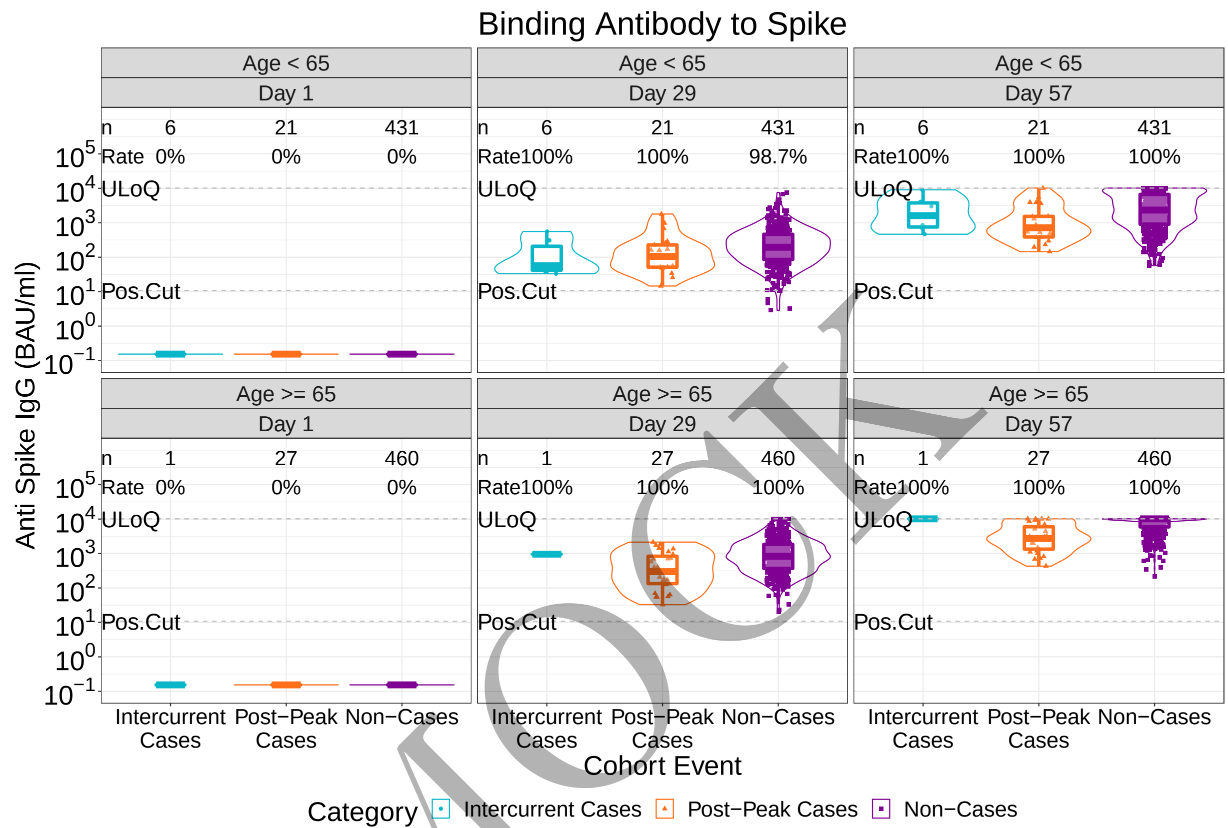
\caption{

Figure 2.5.57: violinplots of Binding Antibody to Spike: baseline negative placebo arm by age (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

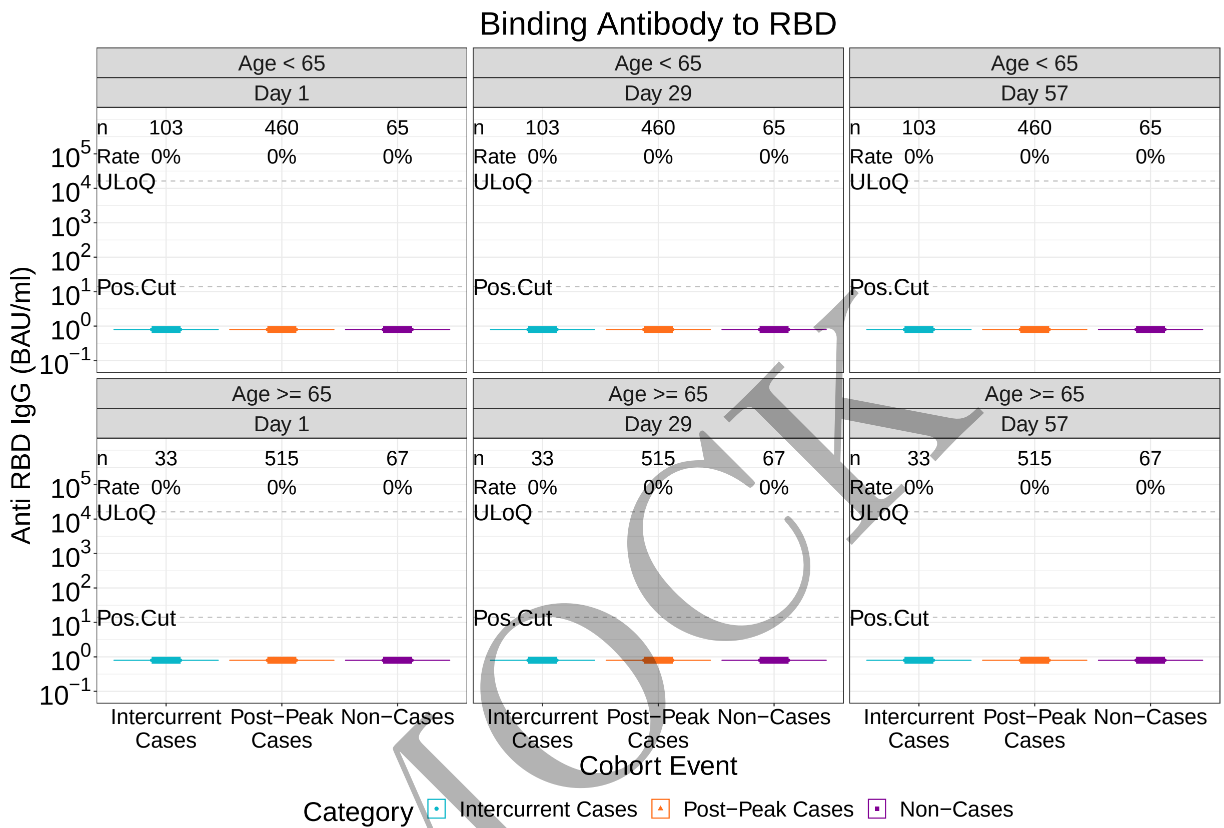
\begin{figure}



\caption{
Figure 2.5.58: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by age (version 2)
} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

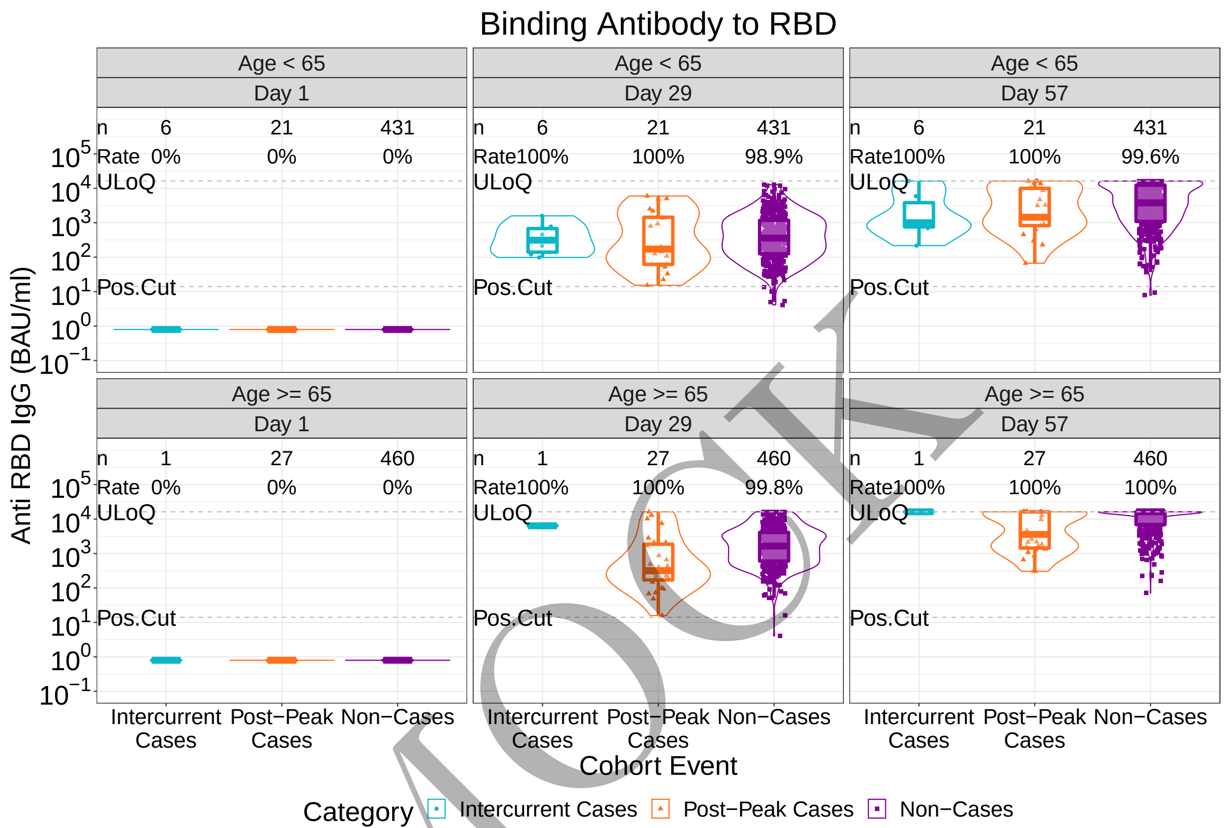
\begin{figure}



\caption{
Figure 2.5.59: violinplots of Binding Antibody to RBD: baseline negative placebo arm by age (version 2)
} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



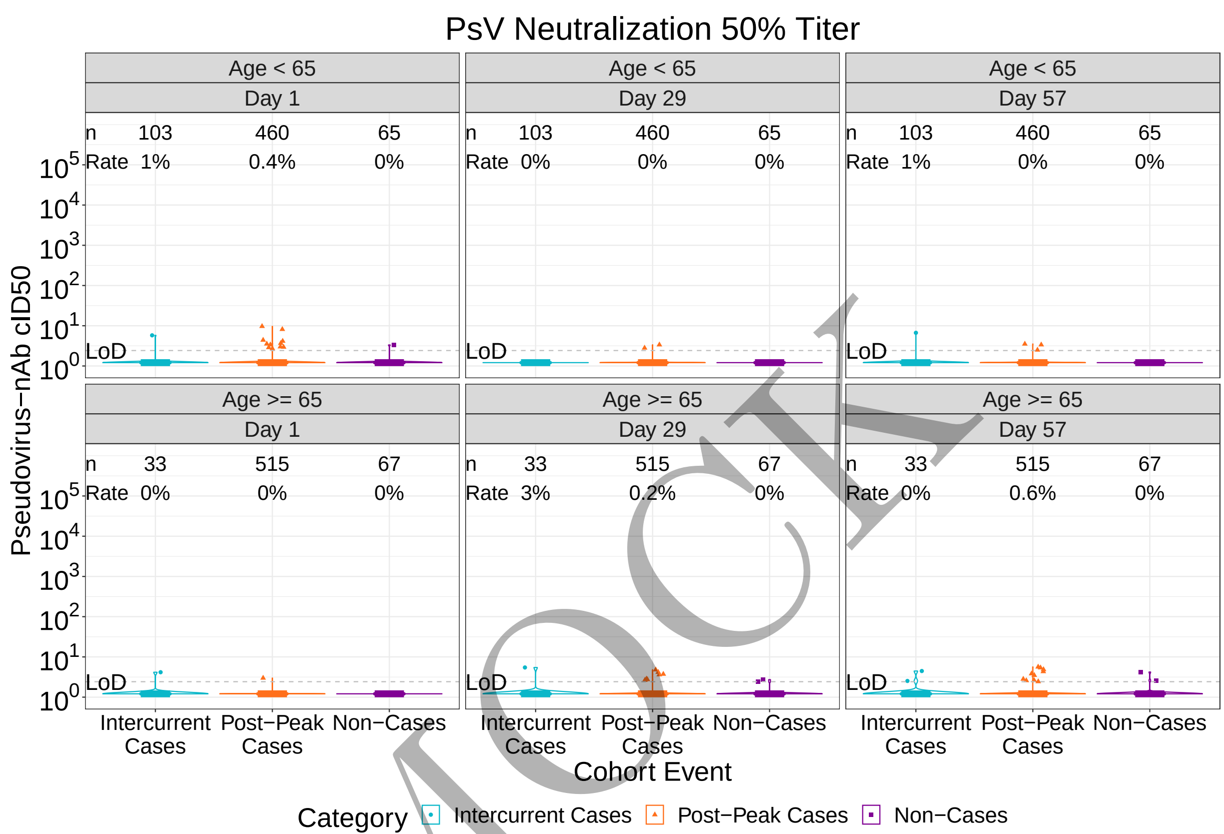
\caption{

Figure 2.5.60: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by age (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



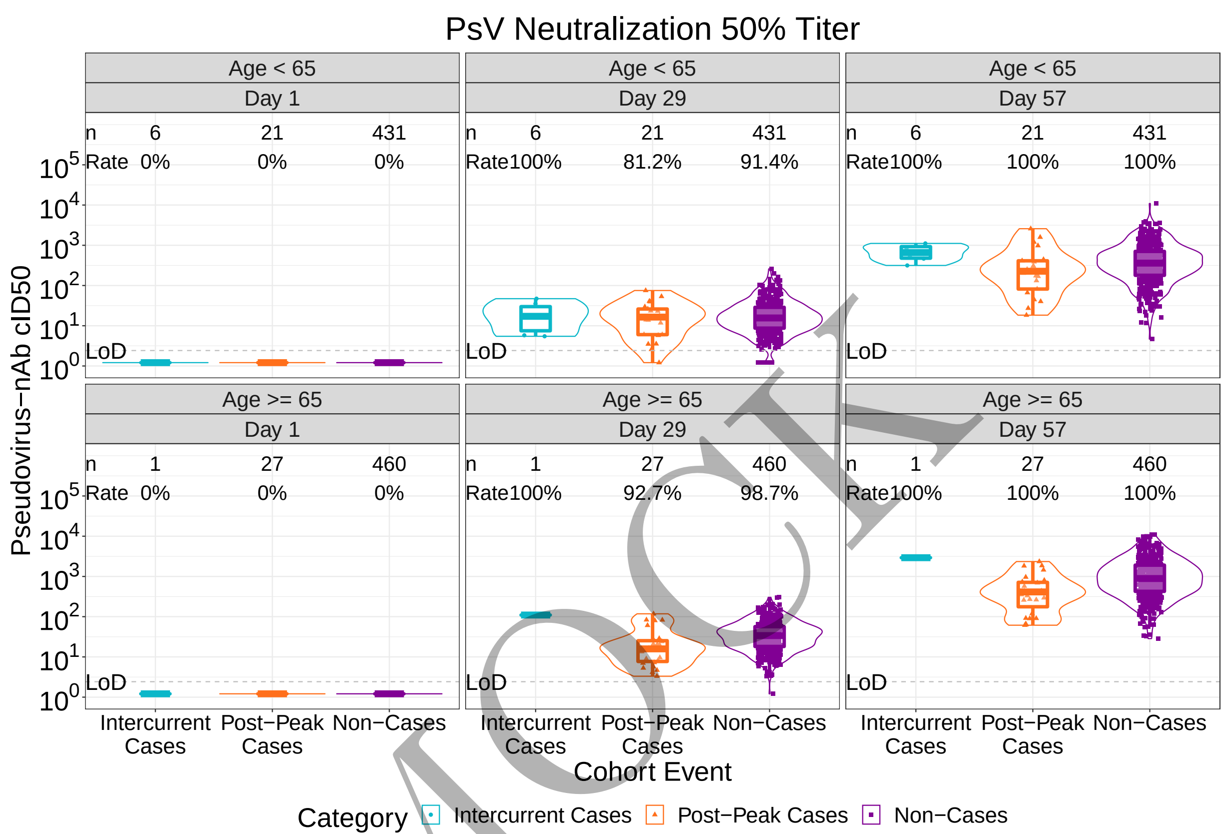
\caption{

Figure 2.5.61: violinplots of PsV Neutralization 50% Titer: baseline negative placebo arm by age (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



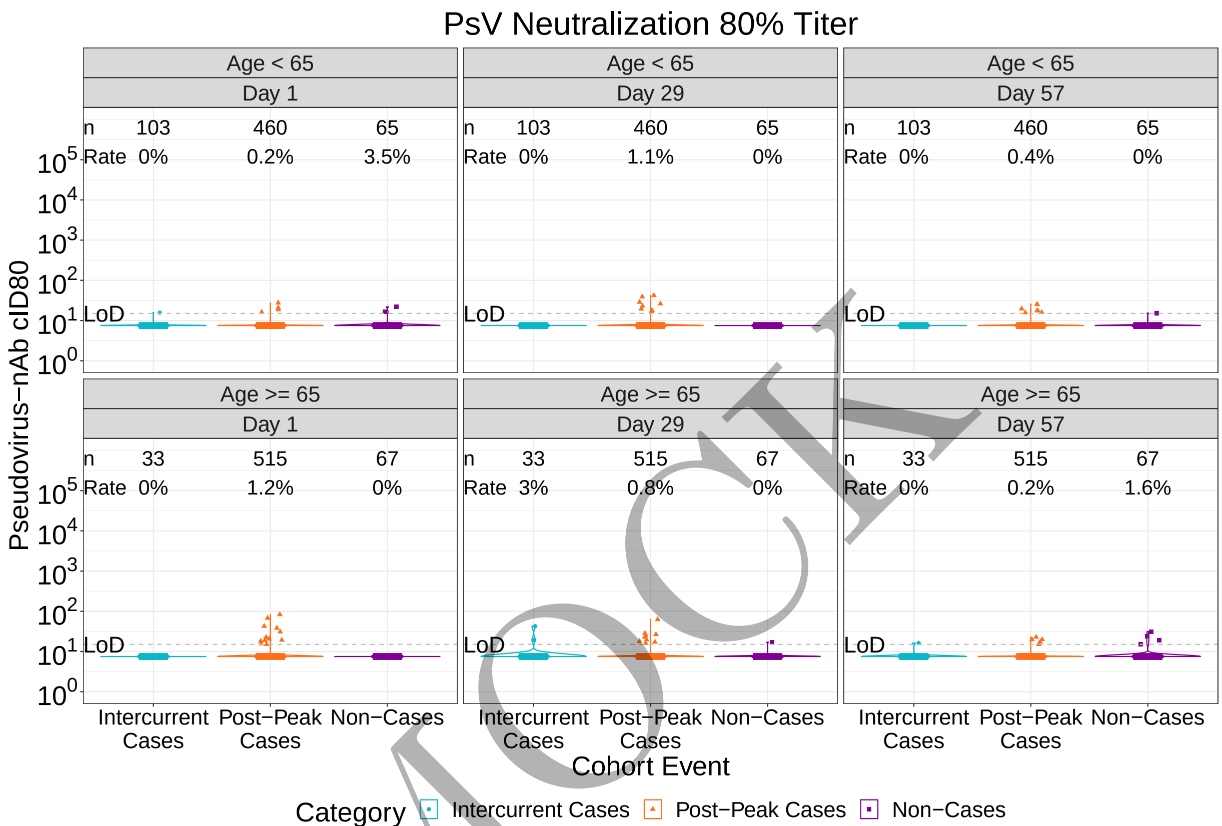
\caption{

Figure 2.5.62: violinplots of PsV Neutralization 50% Titer: baseline negative vaccine arm by age (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



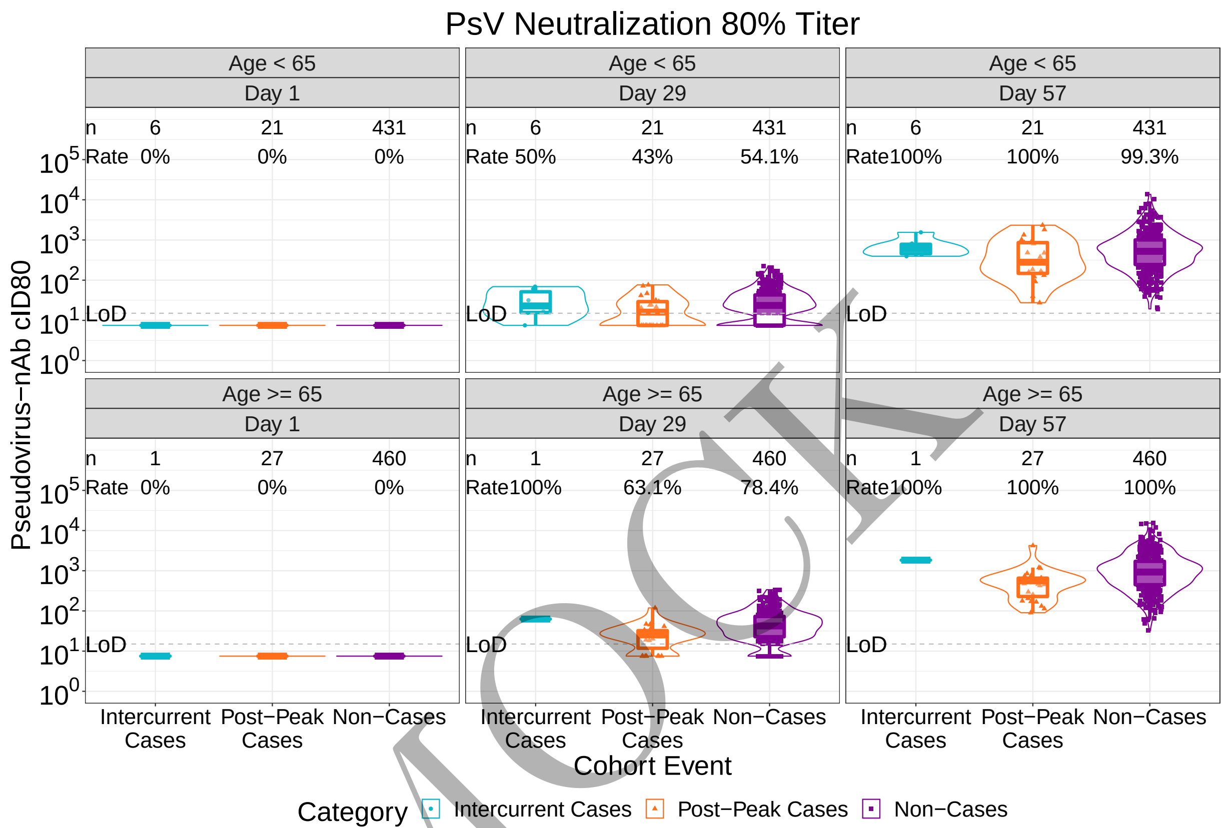
\caption{

Figure 2.5.63: violinplots of PsV Neutralization 80% Titer: baseline negative placebo arm by age (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



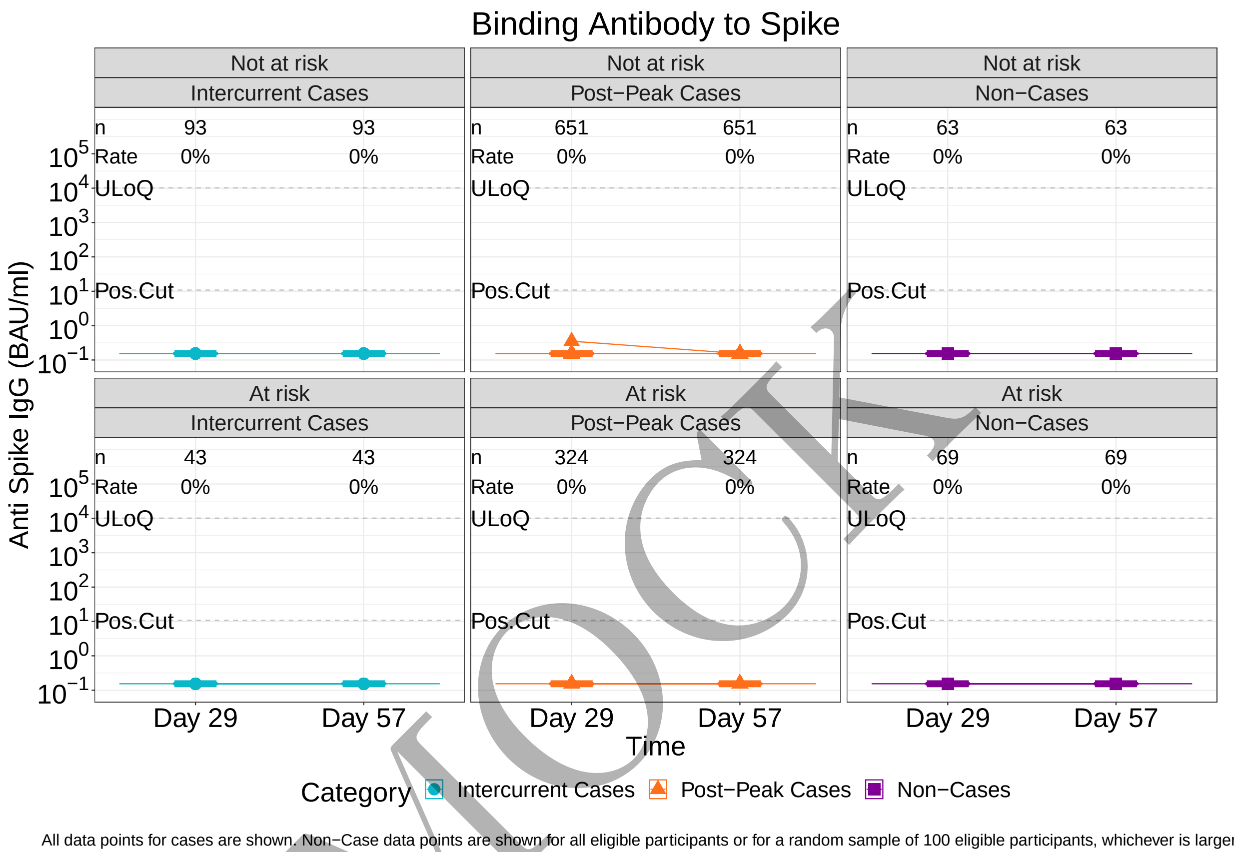
\caption{

Figure 2.5.64: violinplots of PsV Neutralization 80% Titer: baseline negative vaccine arm by age (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



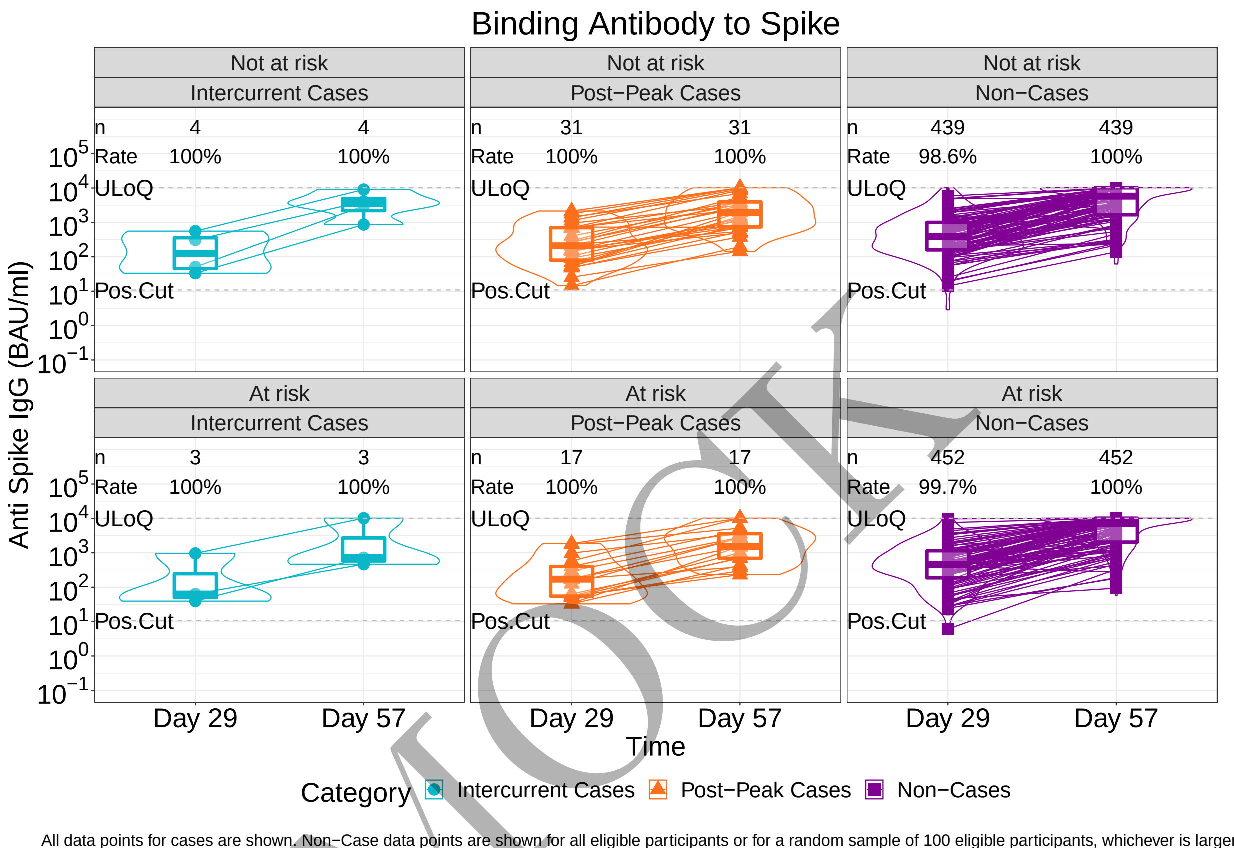
\caption{

Figure 2.5.65: lineplots of Binding Antibody to Spike: baseline negative placebo arm by risk condition (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



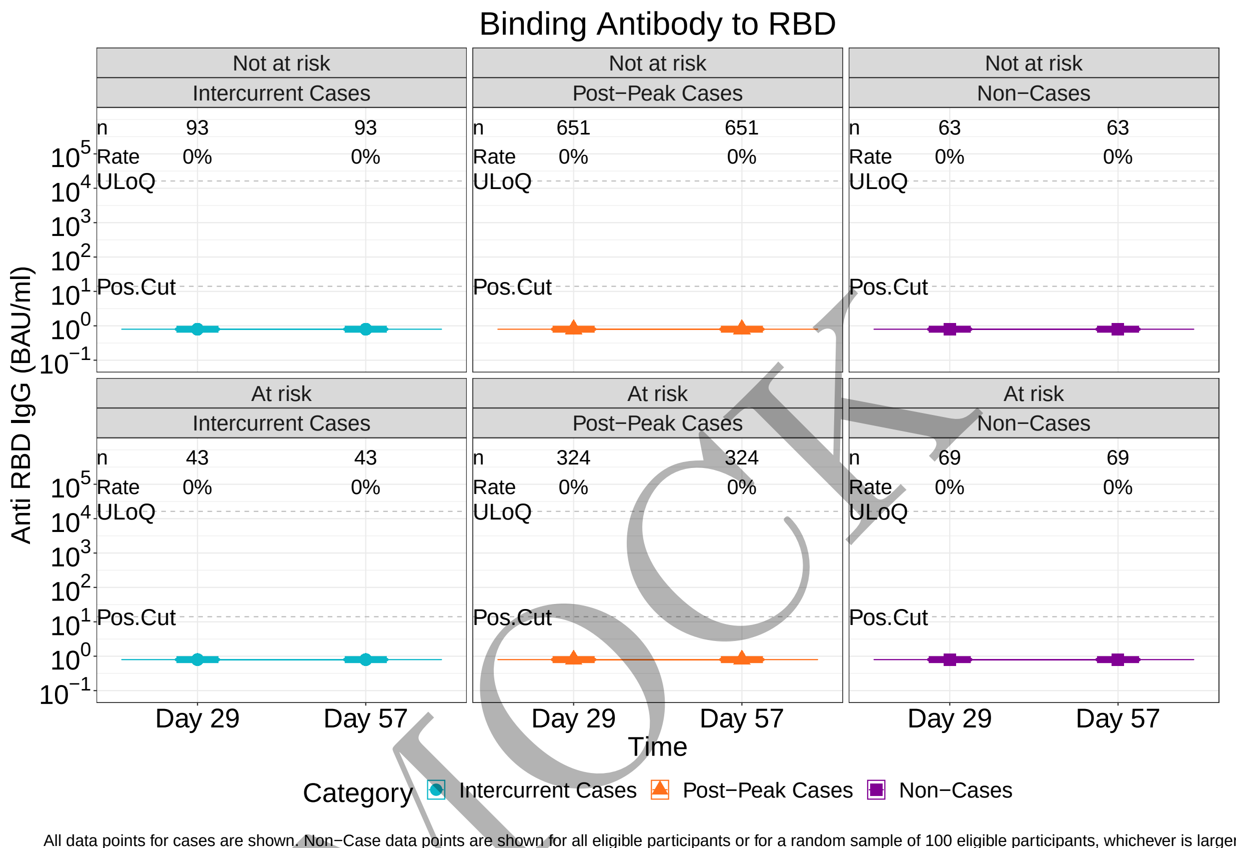
\caption{

Figure 2.5.66: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by risk condition (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



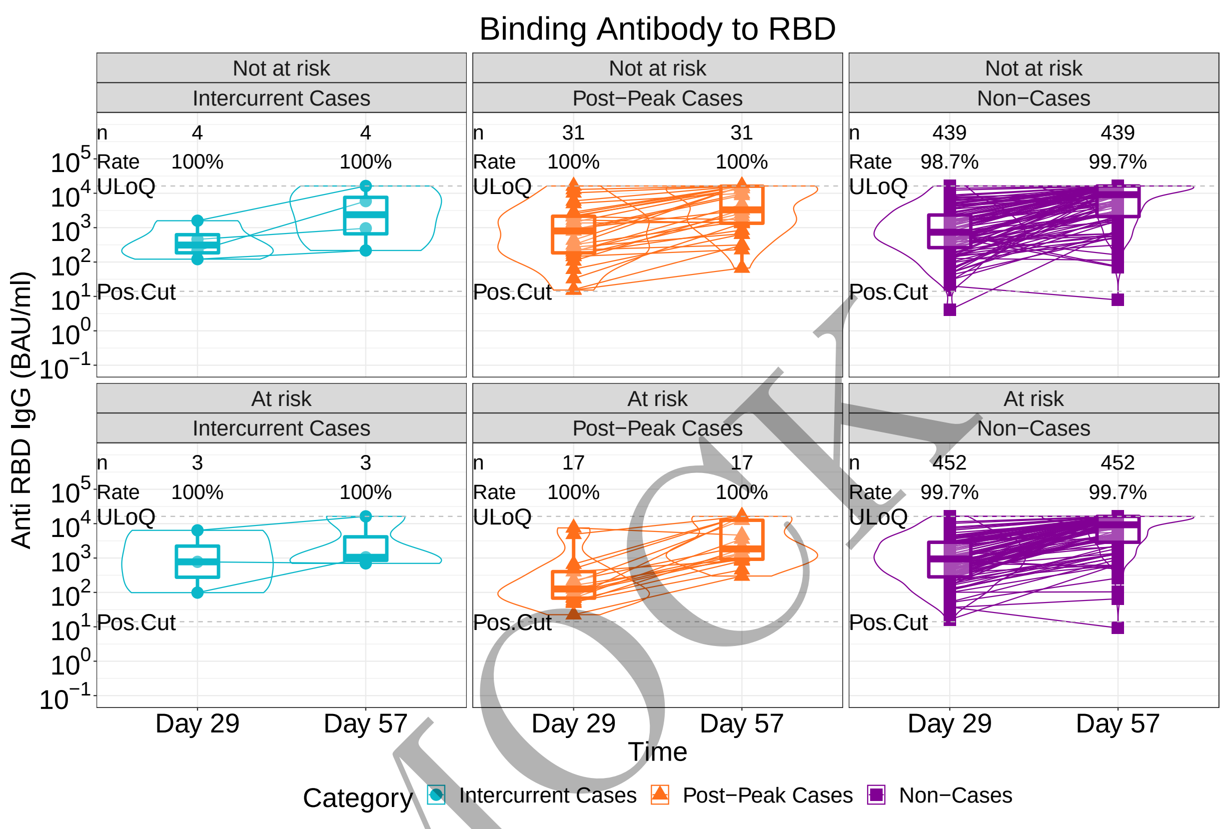
\caption{

Figure 2.5.67: lineplots of Binding Antibody to RBD: baseline negative placebo arm by risk condition (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



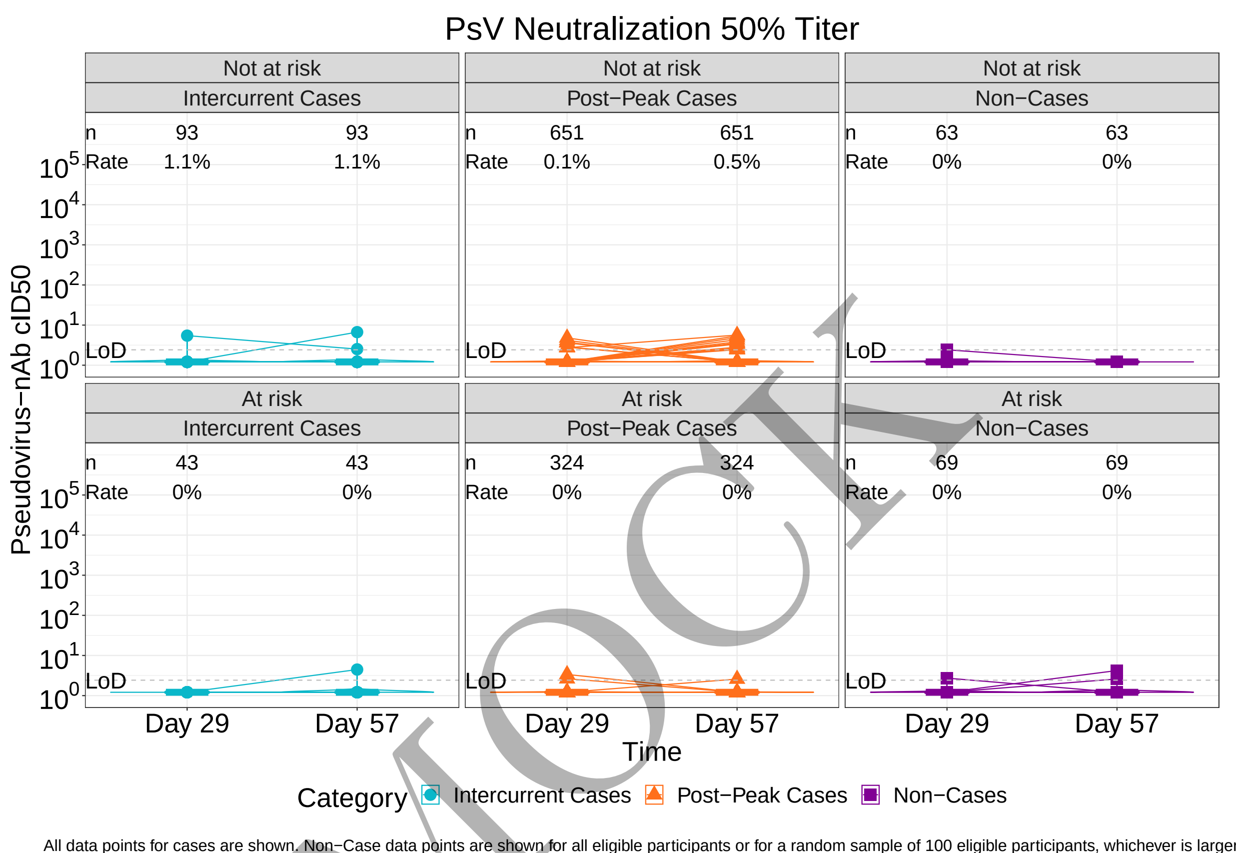
\caption{

Figure 2.5.68: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by risk condition (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



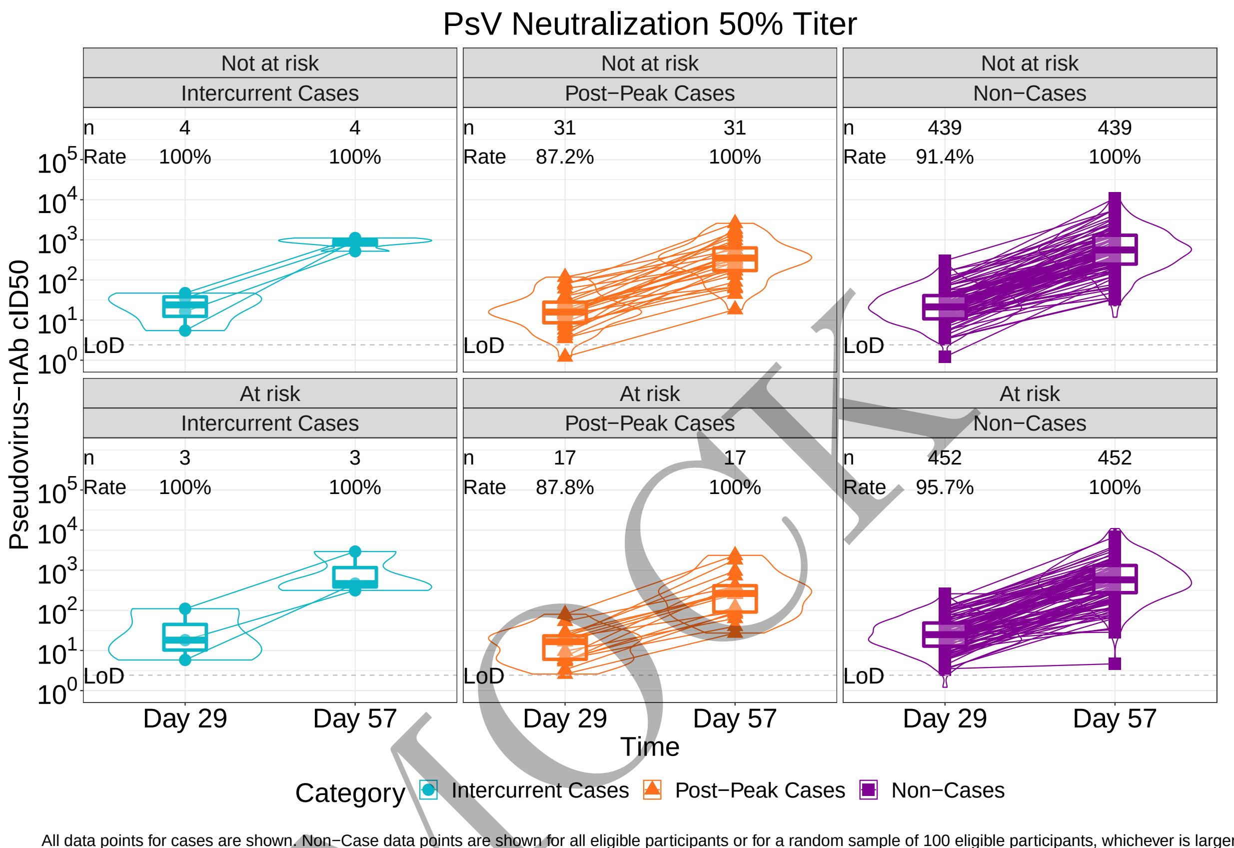
\caption{

Figure 2.5.69: lineplots of PsV Neutralization 50% Titer: baseline negative placebo arm by risk condition (version 1)

} \end{figure}

`r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")`

\begin{figure}



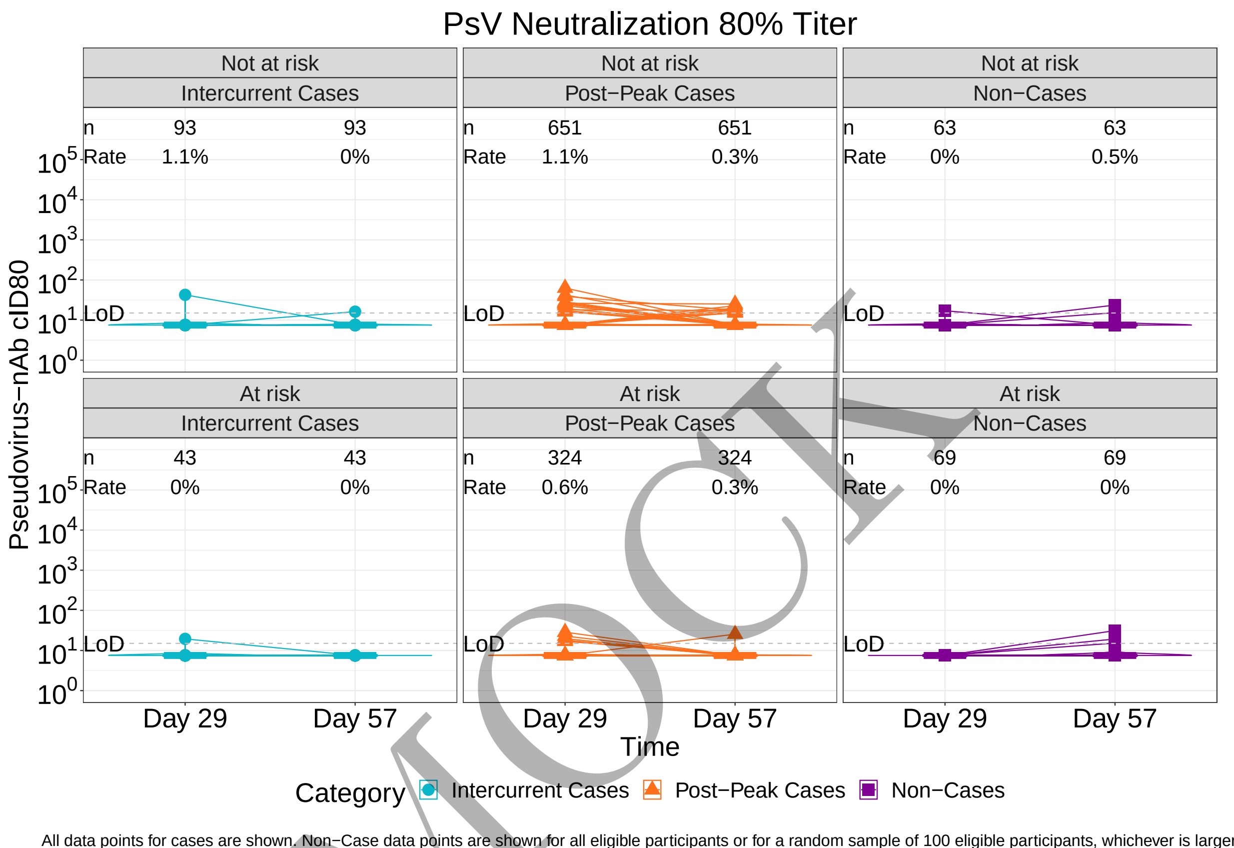
\caption{

Figure 2.5.70: lineplots of PsV Neutralization 50% Titer: baseline negative vaccine arm by risk condition (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



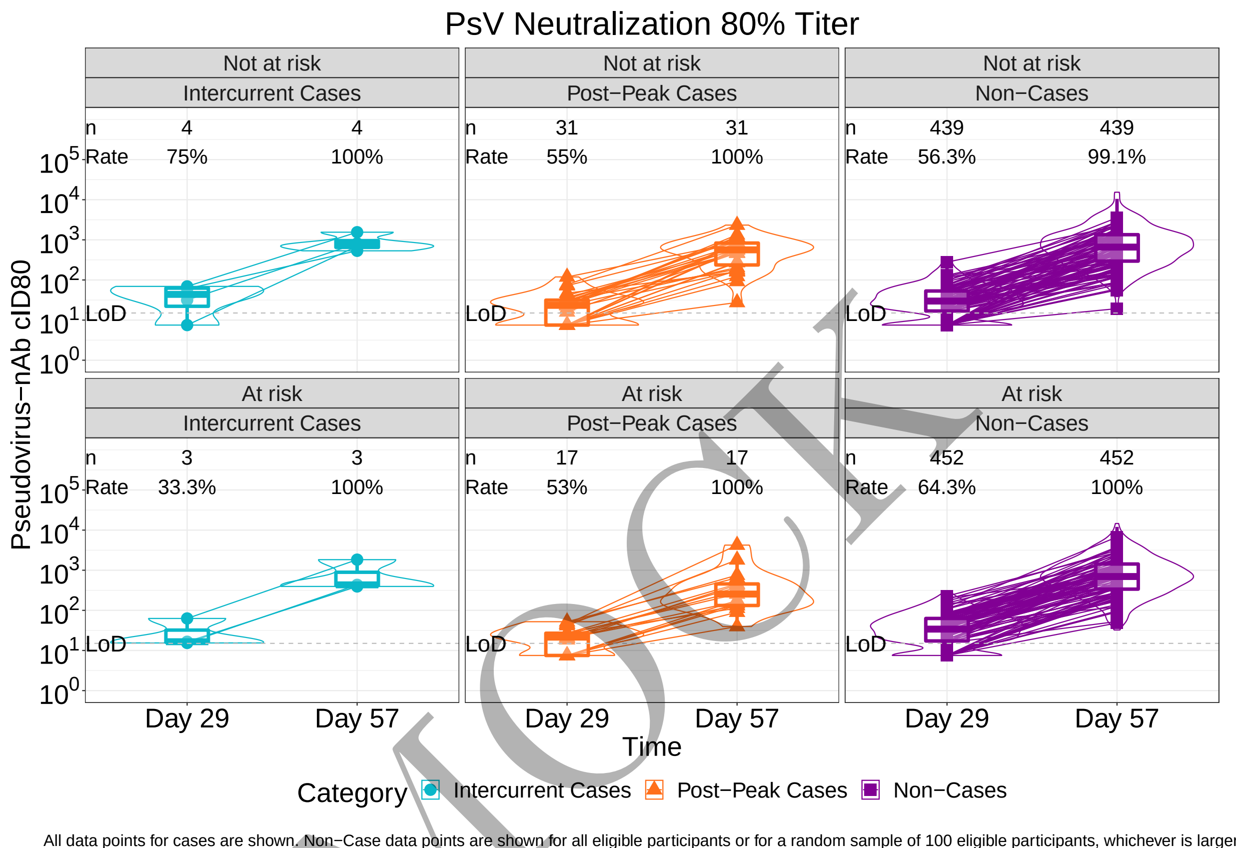
\caption{

Figure 2.5.71: lineplots of PsV Neutralization 80% Titer: baseline negative placebo arm by risk condition (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

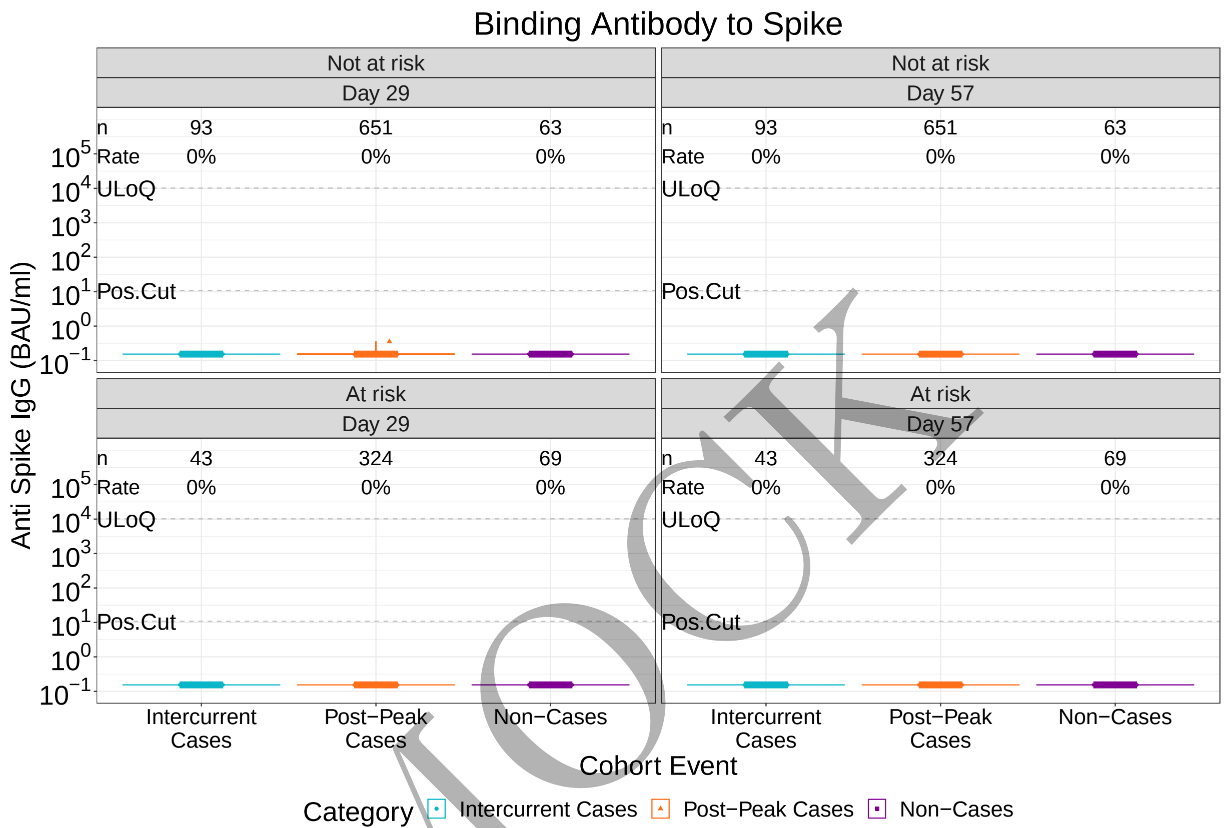
\begin{figure}



\caption{
Figure 2.5.72: lineplots of PsV Neutralization 80% Titer: baseline negative vaccine arm by risk condition (version 1)
} \end{figure}

`r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")`

\begin{figure}



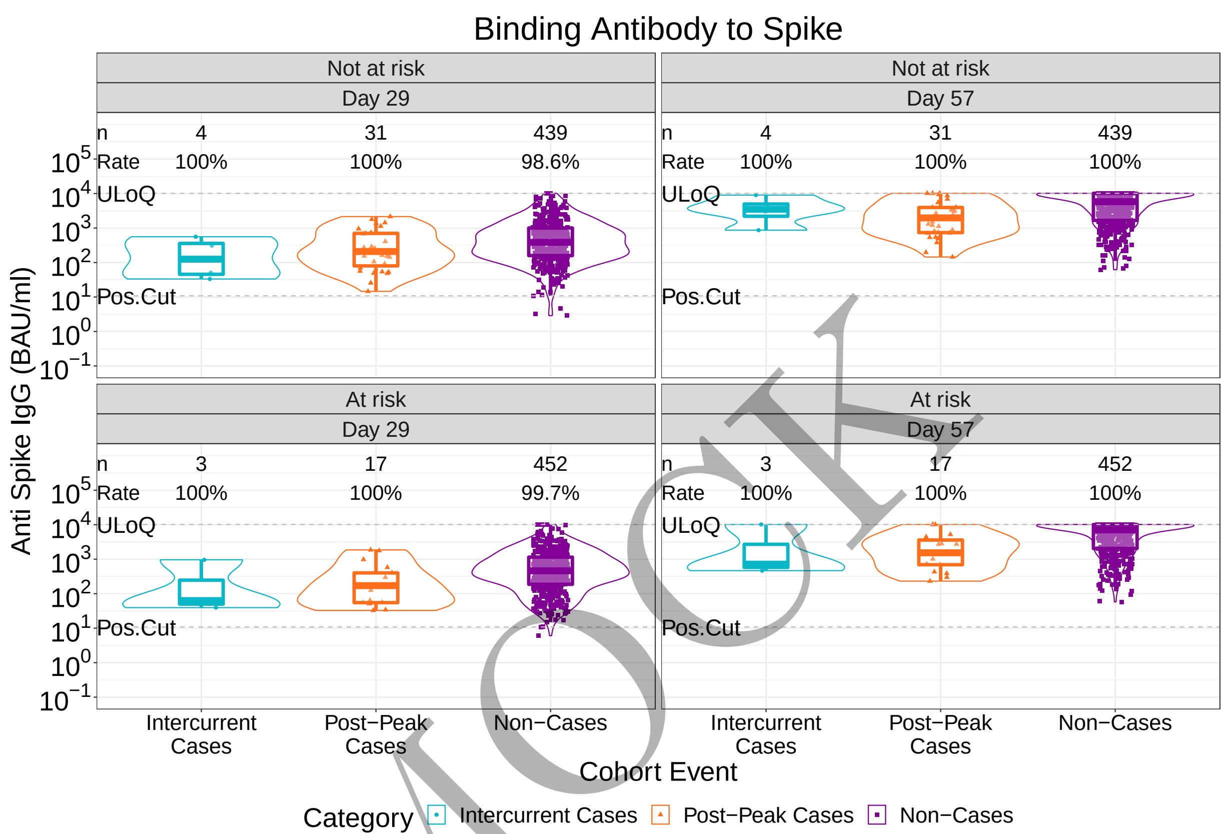
\caption{

Figure 2.5.73: violinplots of Binding Antibody to Spike: baseline negative placebo arm by risk condition (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



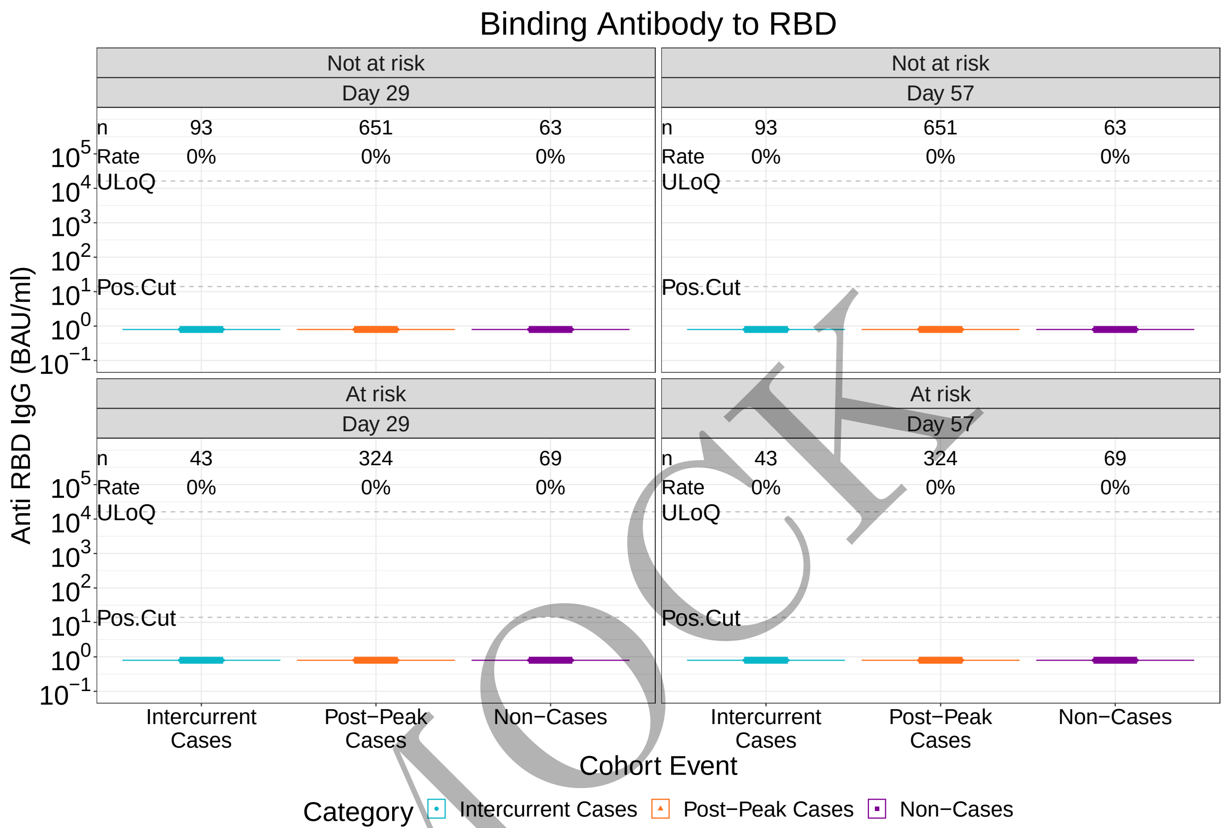
\caption{

Figure 2.5.74: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by risk condition (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



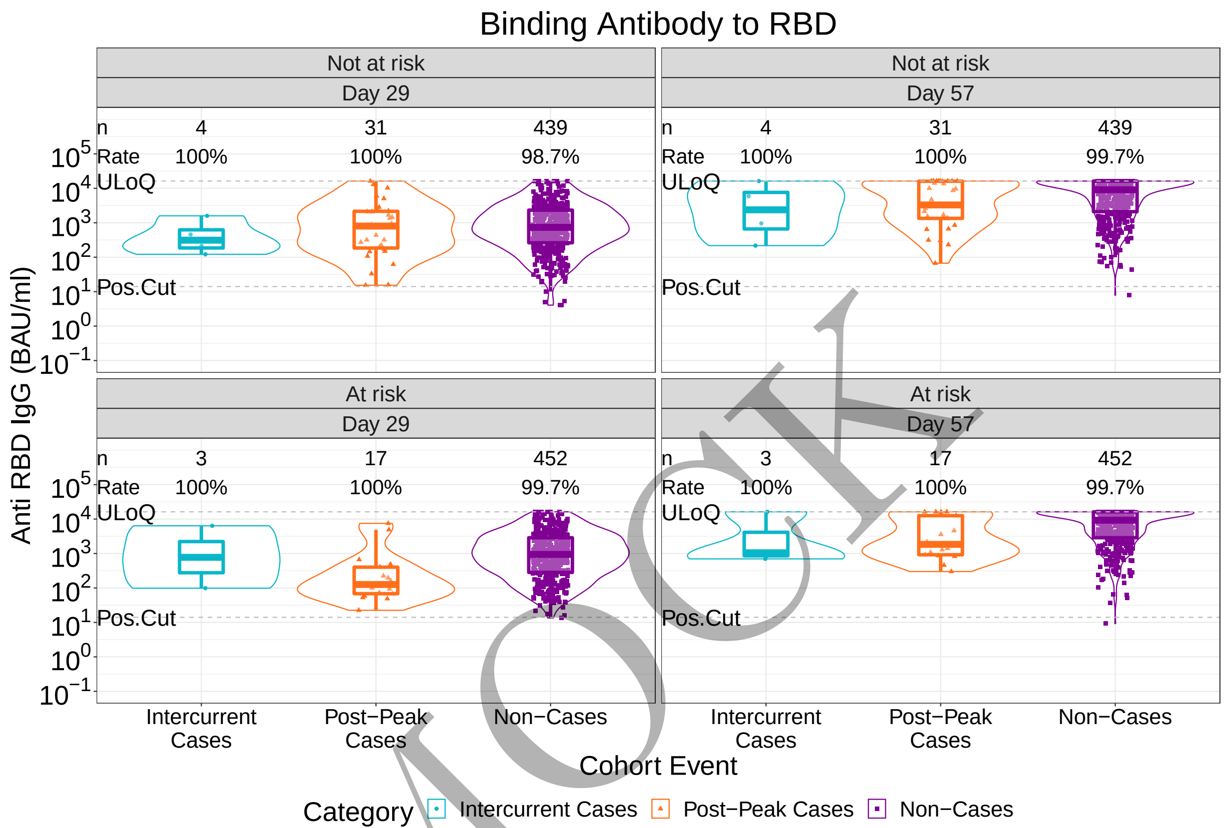
\caption{

Figure 2.5.75: violinplots of Binding Antibody to RBD: baseline negative placebo arm by risk condition (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



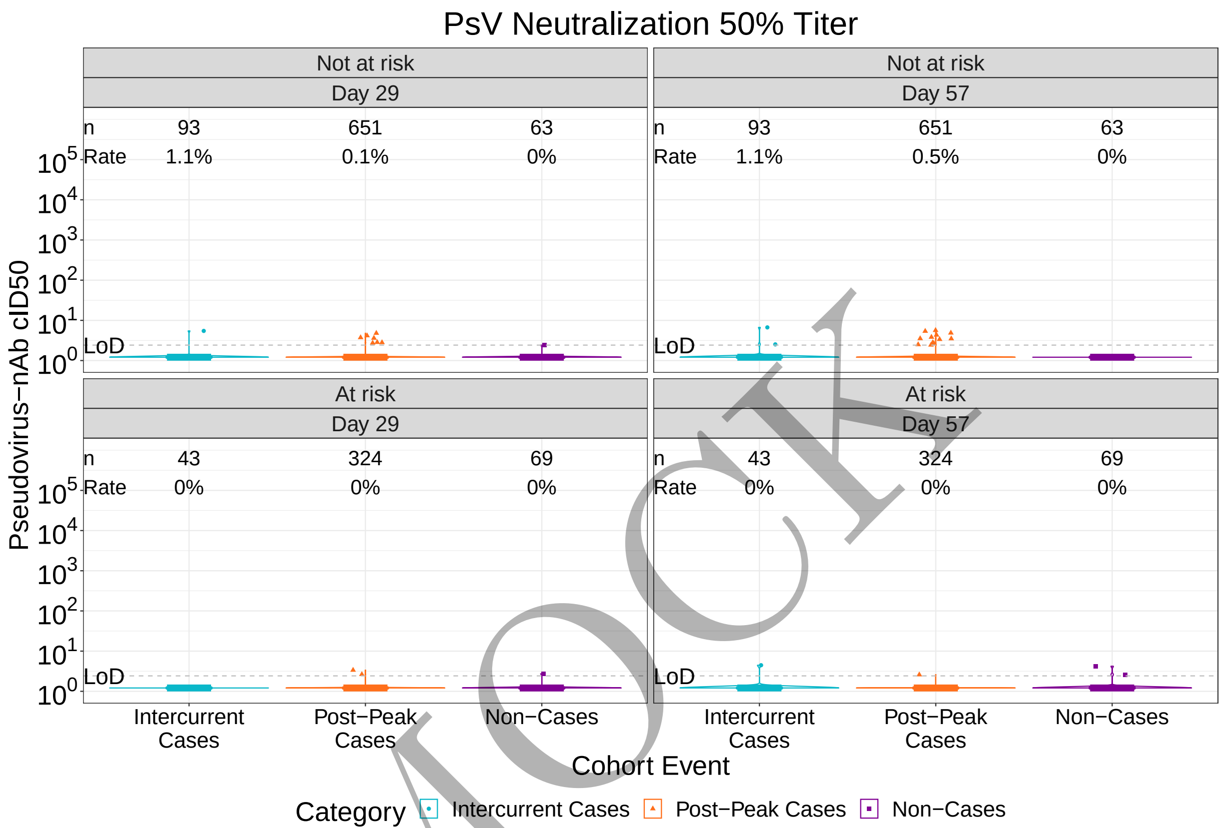
\caption{

Figure 2.5.76: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by risk condition (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



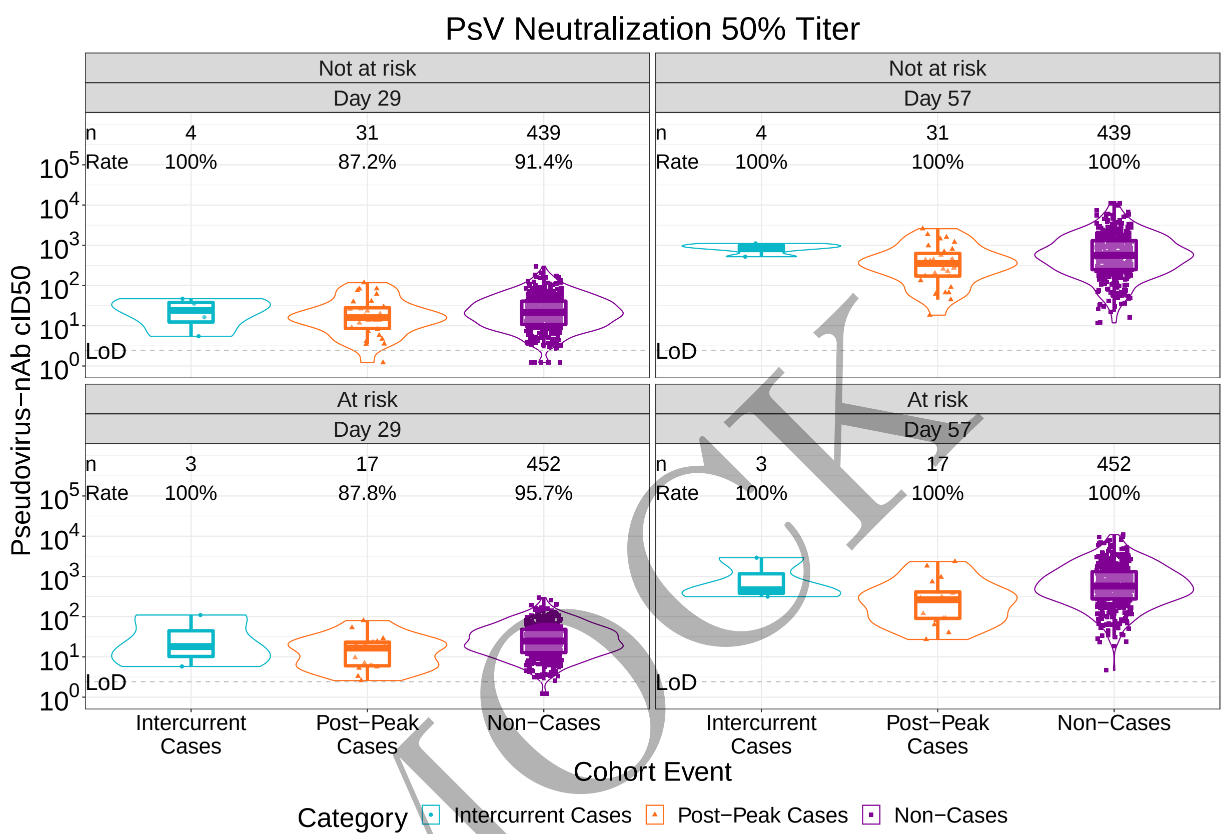
\caption{

Figure 2.5.77: violinplots of PsV Neutralization 50% Titer: baseline negative placebo arm by risk condition (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



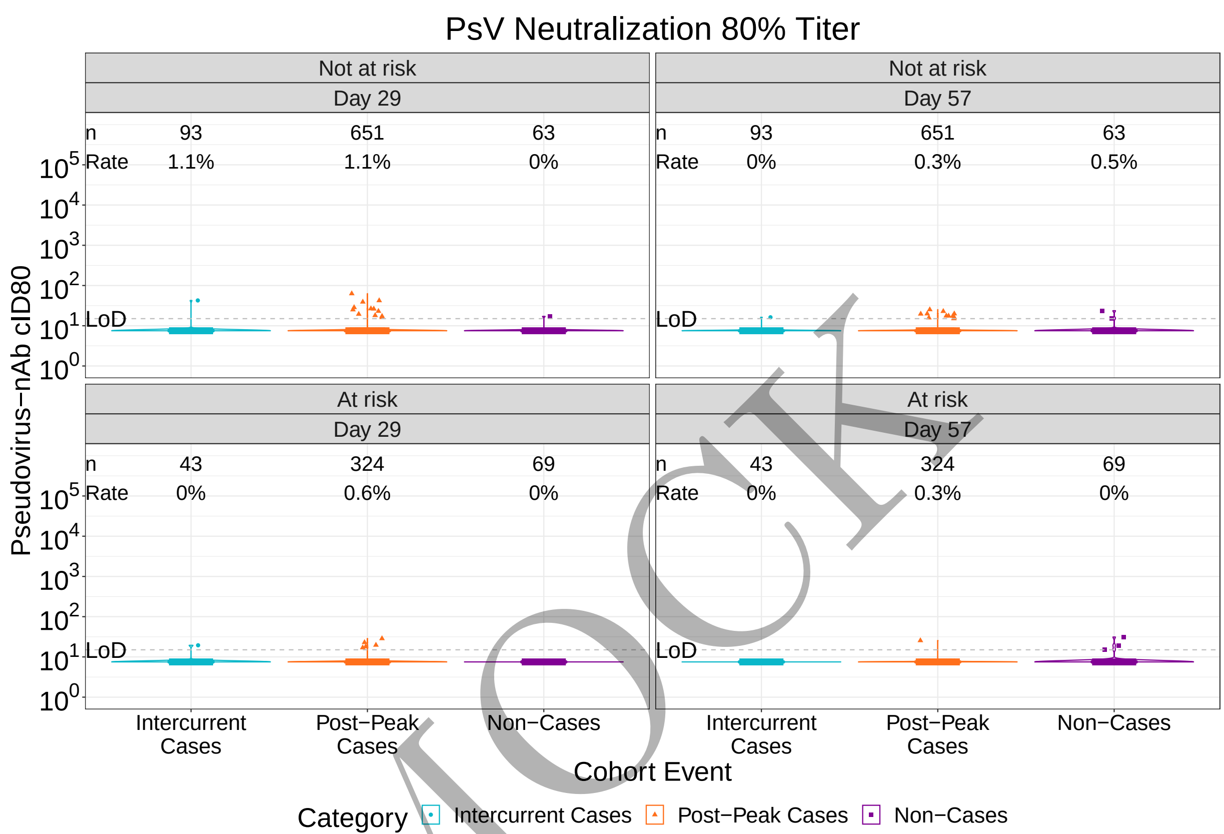
\caption{

Figure 2.5.78: violinplots of PsV Neutralization 50% Titer: baseline negative vaccine arm by risk condition (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



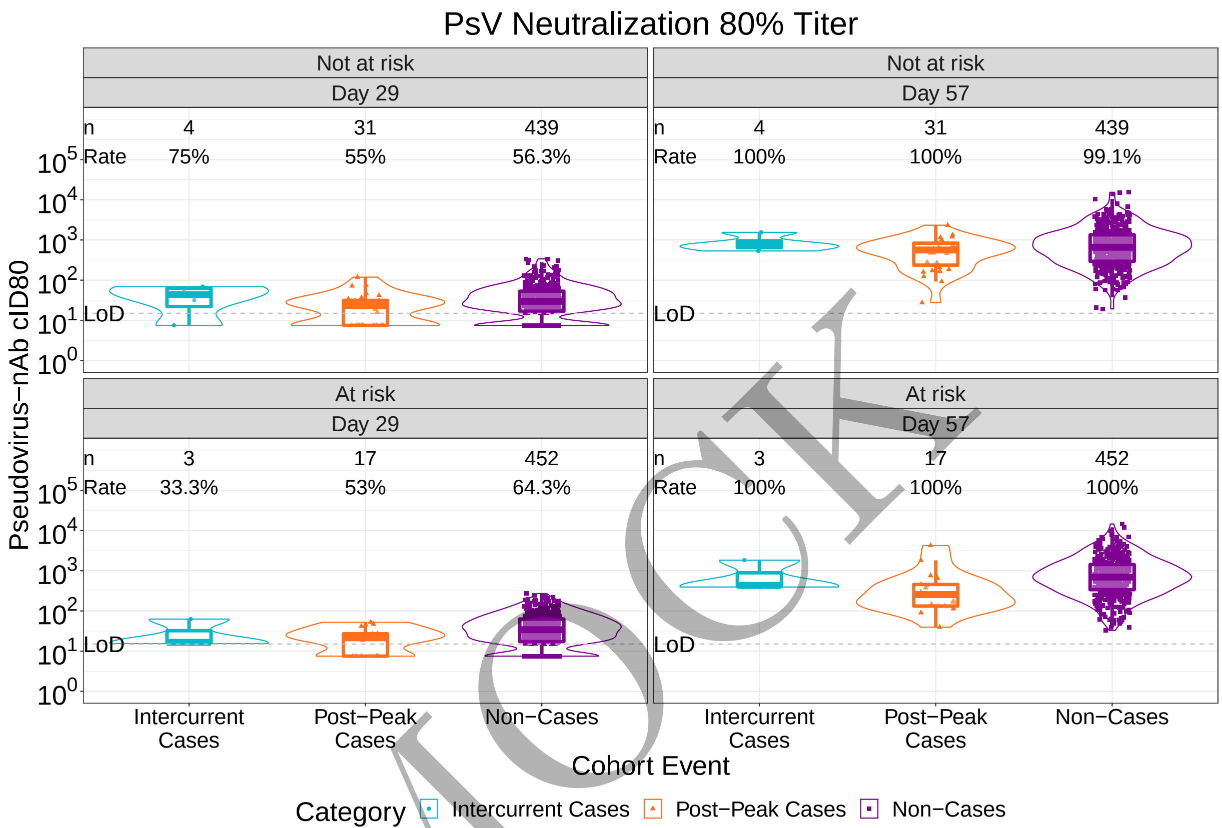
\caption{

Figure 2.5.79: violinplots of PsV Neutralization 80% Titer: baseline negative placebo arm by risk condition (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



\caption{

Figure 2.5.80: violinplots of PsV Neutralization 80% Titer: baseline negative vaccine arm by risk condition (version 1)

} \end{figure}

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r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")
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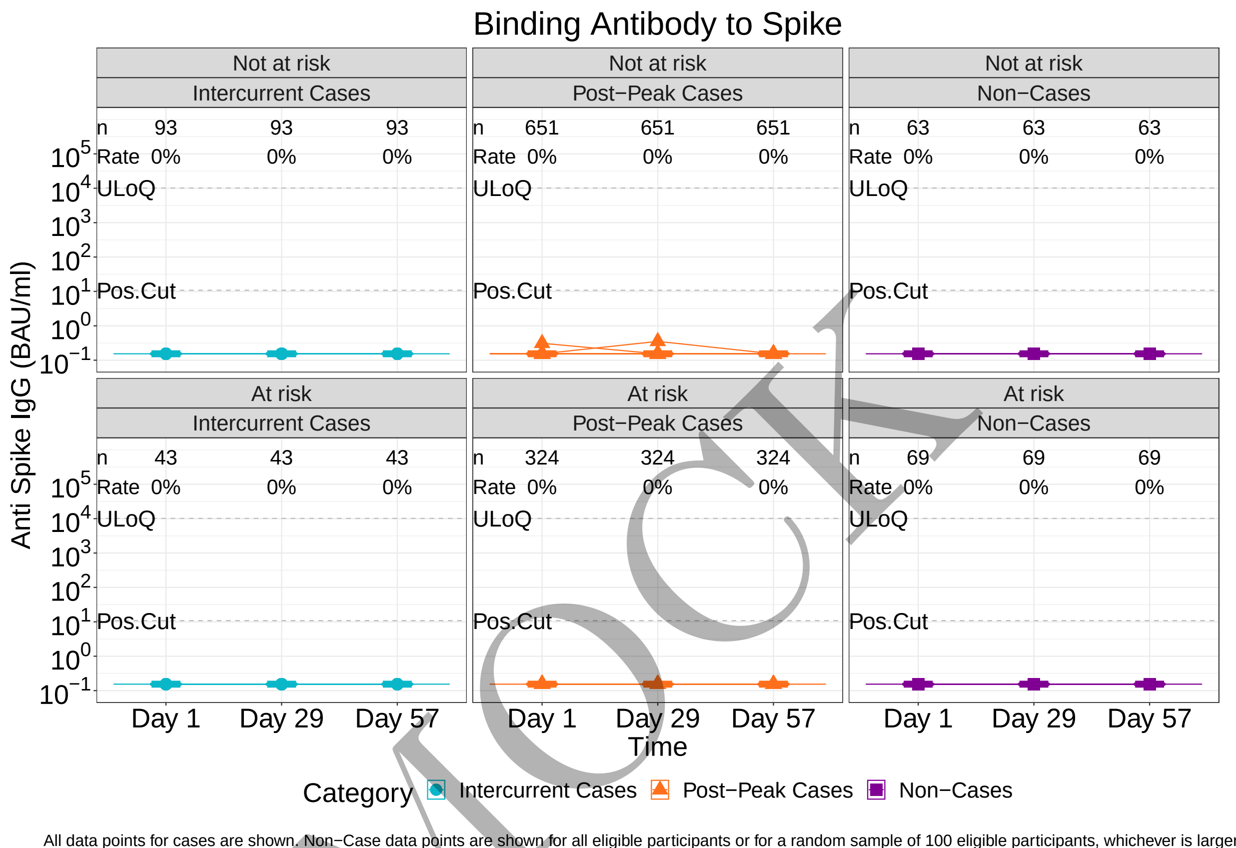
\begin{figure}



\caption{

Figure 2.5.81: lineplots of Binding Antibody to Spike: baseline negative placebo arm by risk condition (version 2)

} \end{figure}

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r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")
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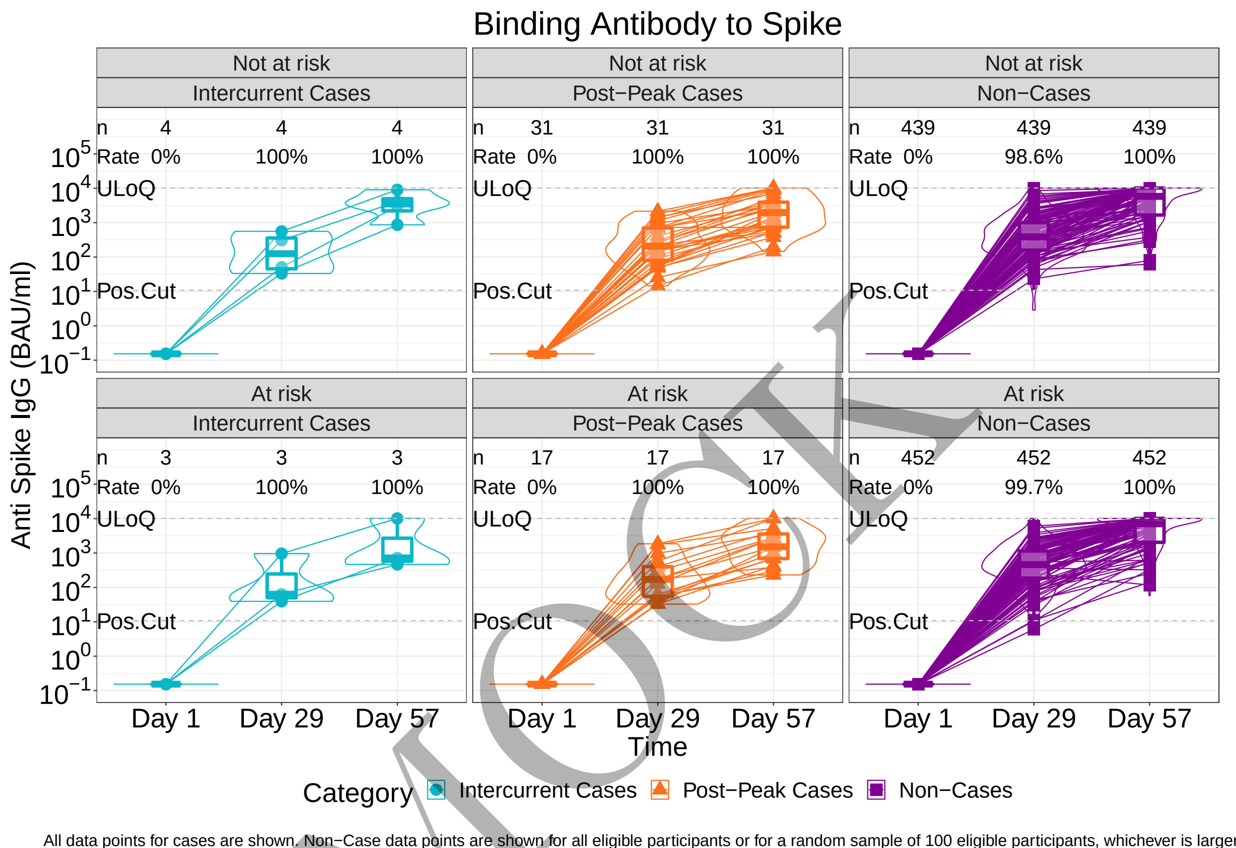
\begin{figure}



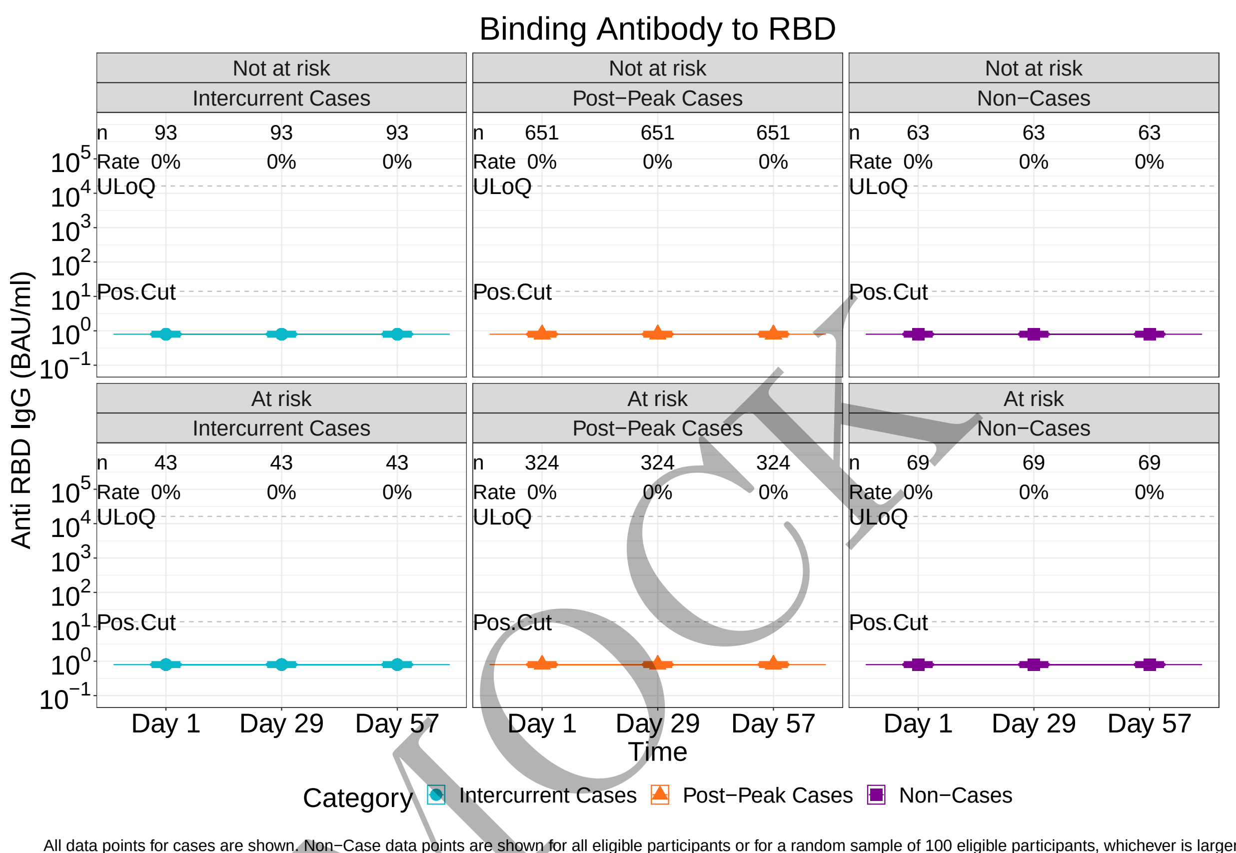
\caption{

Figure 2.5.82: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by risk condition (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



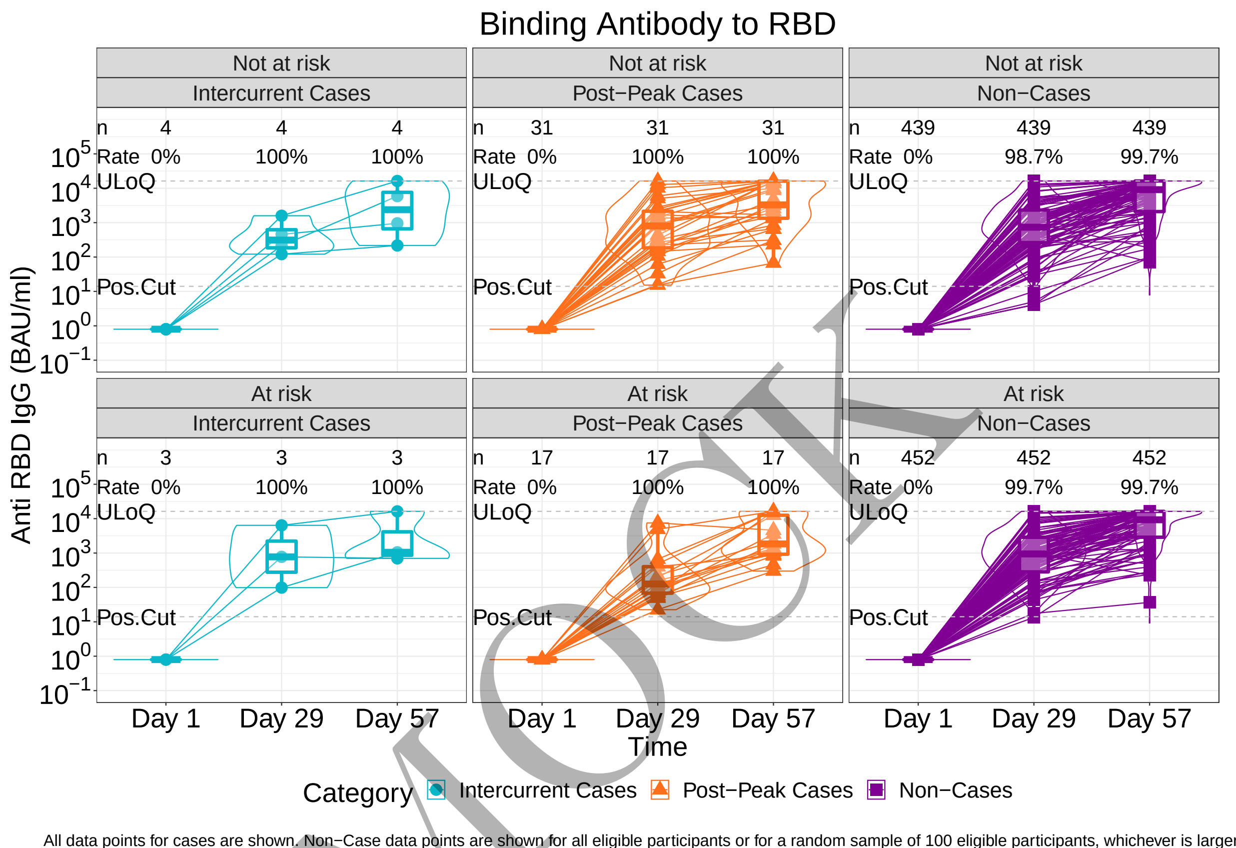
\caption{

Figure 2.5.83: lineplots of Binding Antibody to RBD: baseline negative placebo arm by risk condition (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



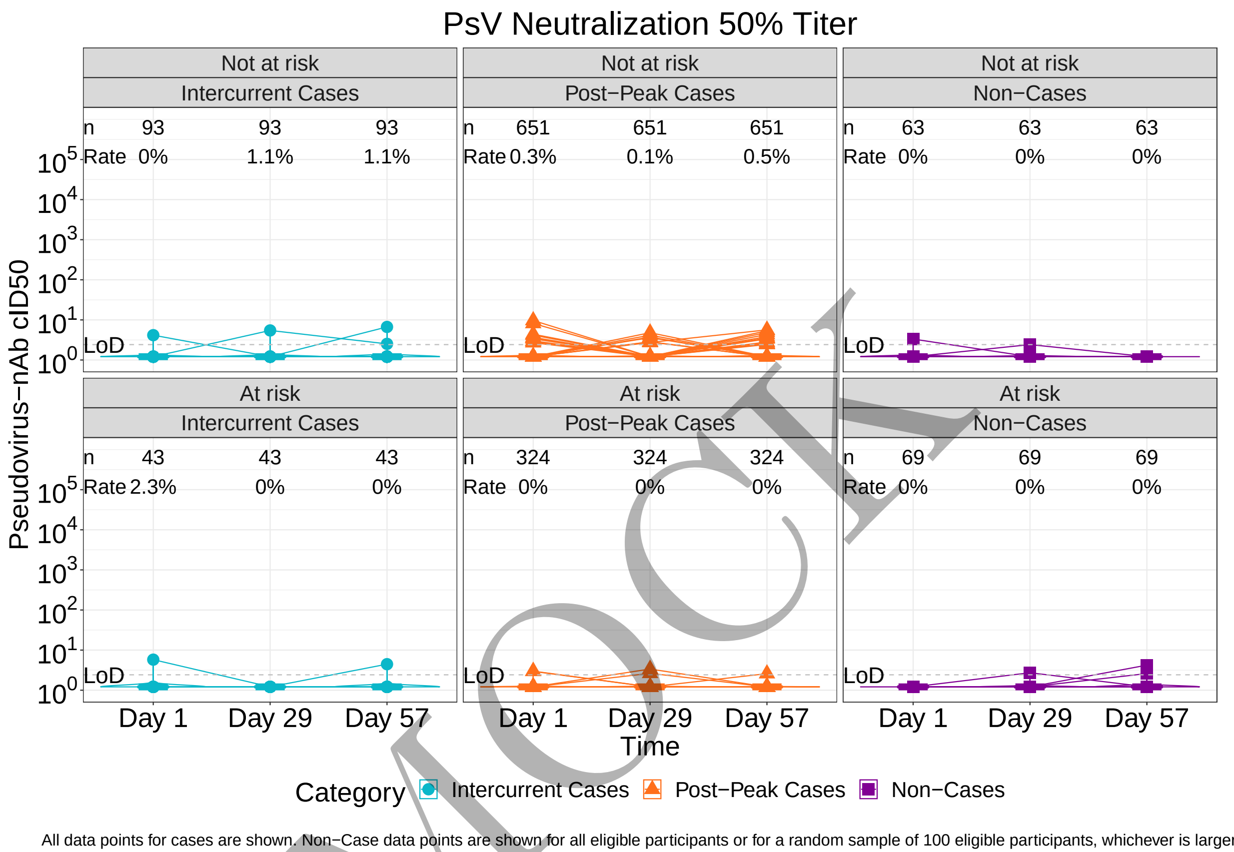
\caption{

Figure 2.5.84: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by risk condition (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



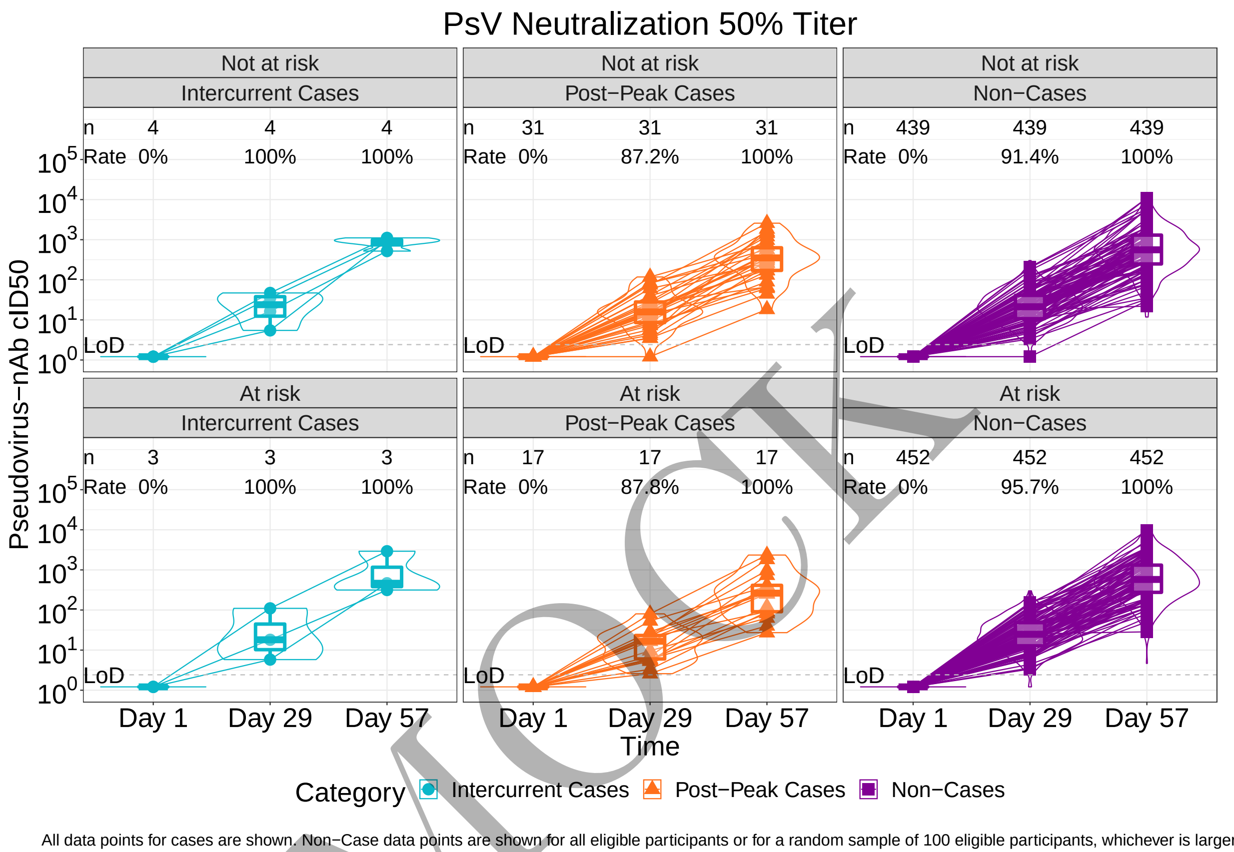
\caption{

Figure 2.5.85: lineplots of PsV Neutralization 50% Titer: baseline negative placebo arm by risk condition (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



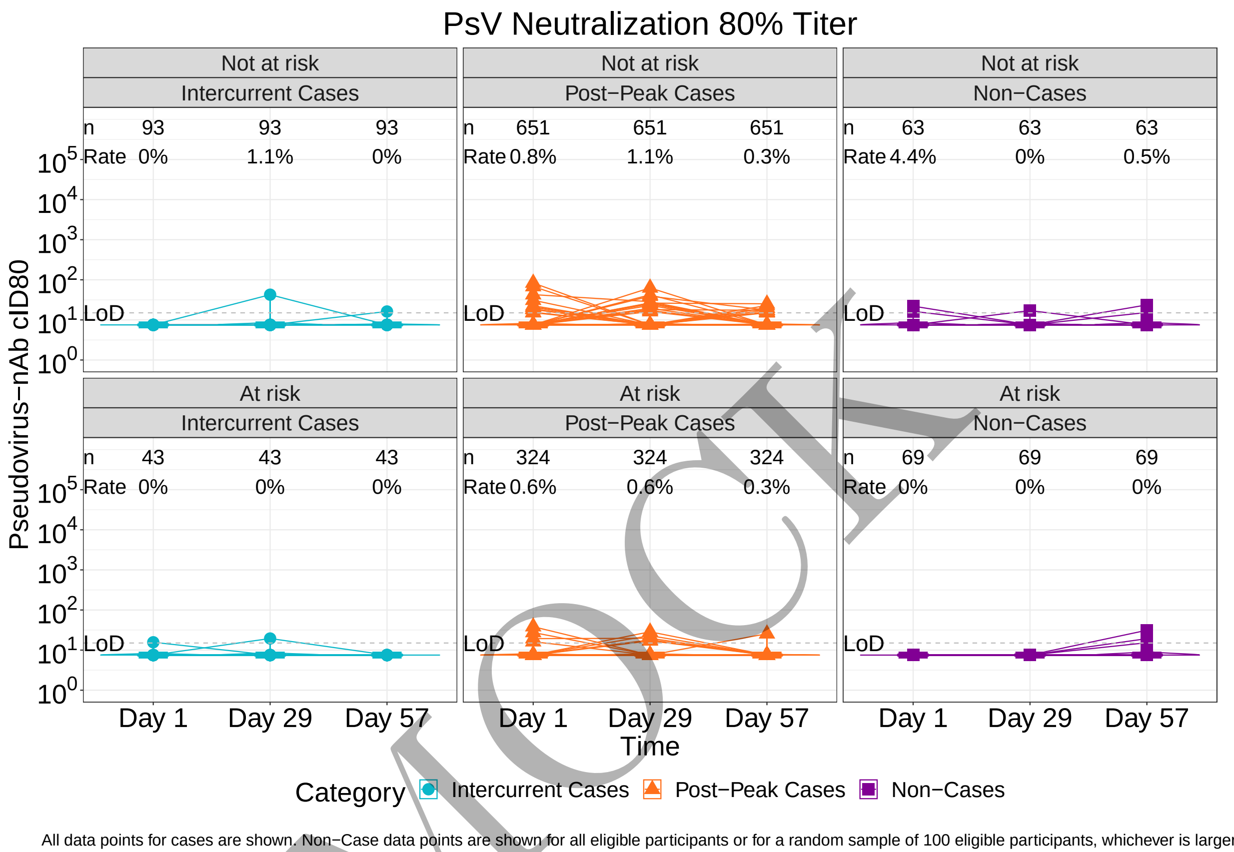
\caption{

Figure 2.5.86: lineplots of PsV Neutralization 50% Titer: baseline negative vaccine arm by risk condition (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



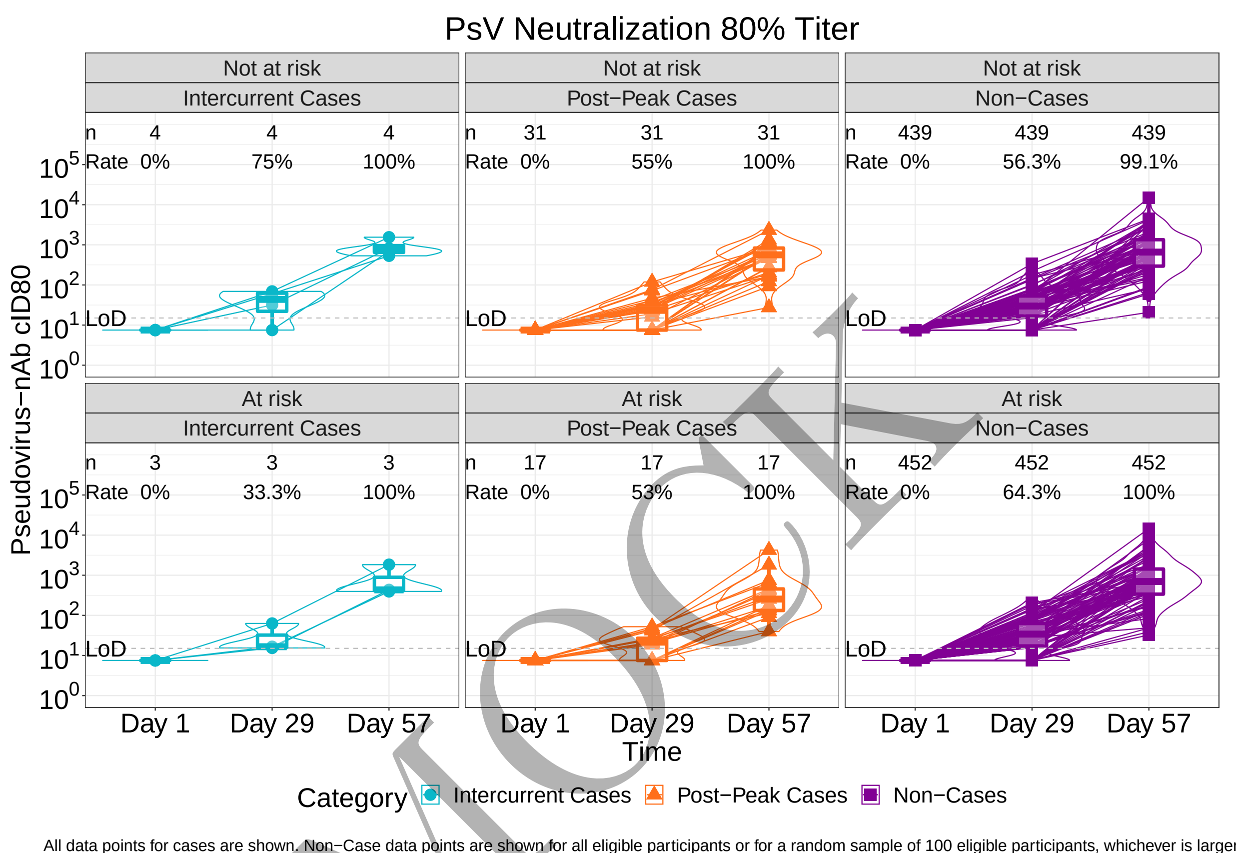
\caption{

Figure 2.5.87: lineplots of PsV Neutralization 80% Titer: baseline negative placebo arm by risk condition (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



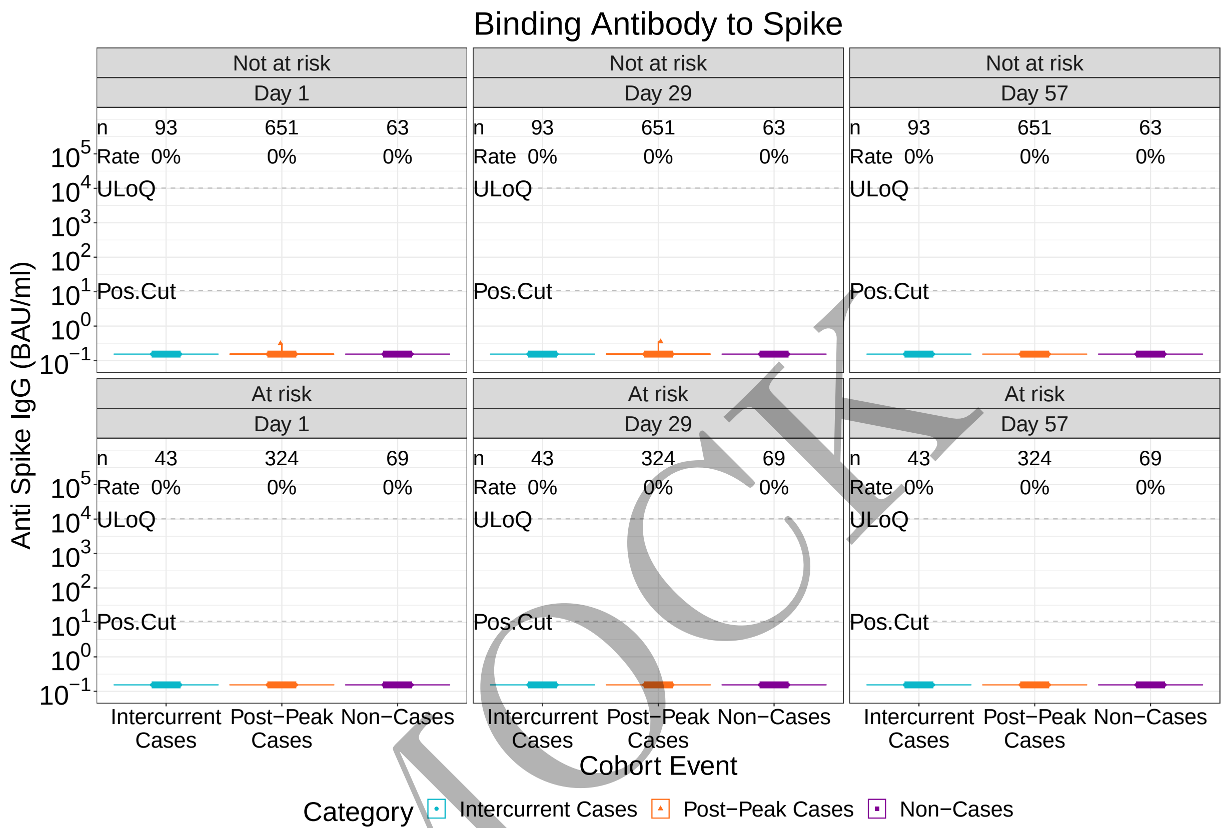
\caption{

Figure 2.5.88: lineplots of PsV Neutralization 80% Titer: baseline negative vaccine arm by risk condition (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



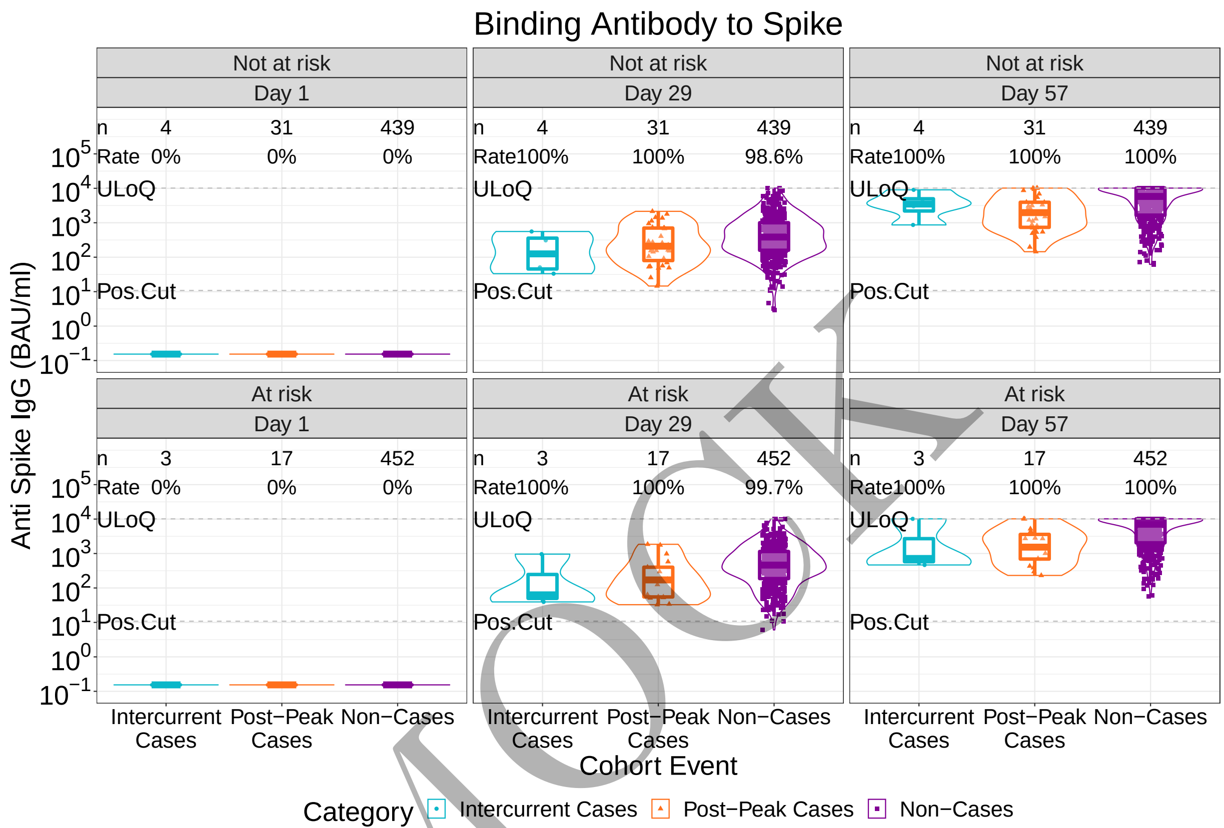
\caption{

Figure 2.5.89: violinplots of Binding Antibody to Spike: baseline negative placebo arm by risk condition (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



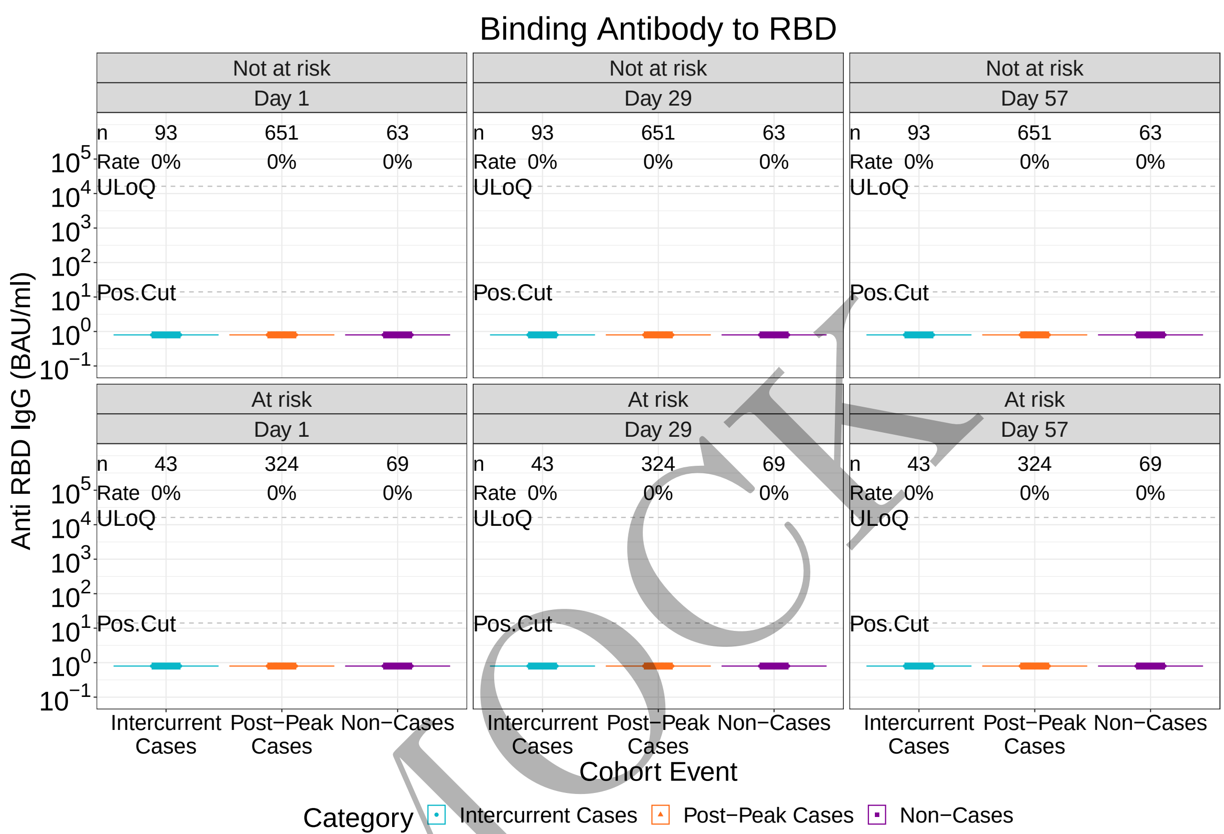
\caption{

Figure 2.5.90: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by risk condition (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



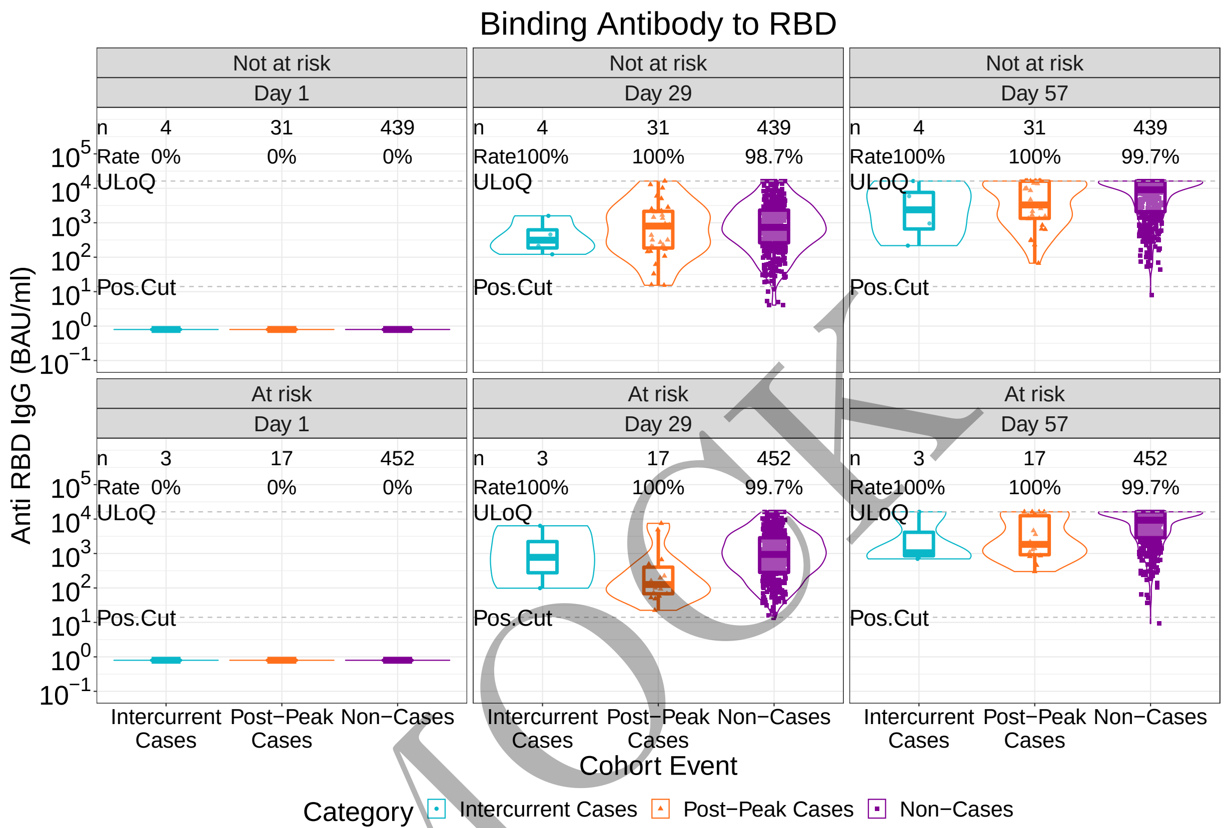
\caption{

Figure 2.5.91: violinplots of Binding Antibody to RBD: baseline negative placebo arm by risk condition (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



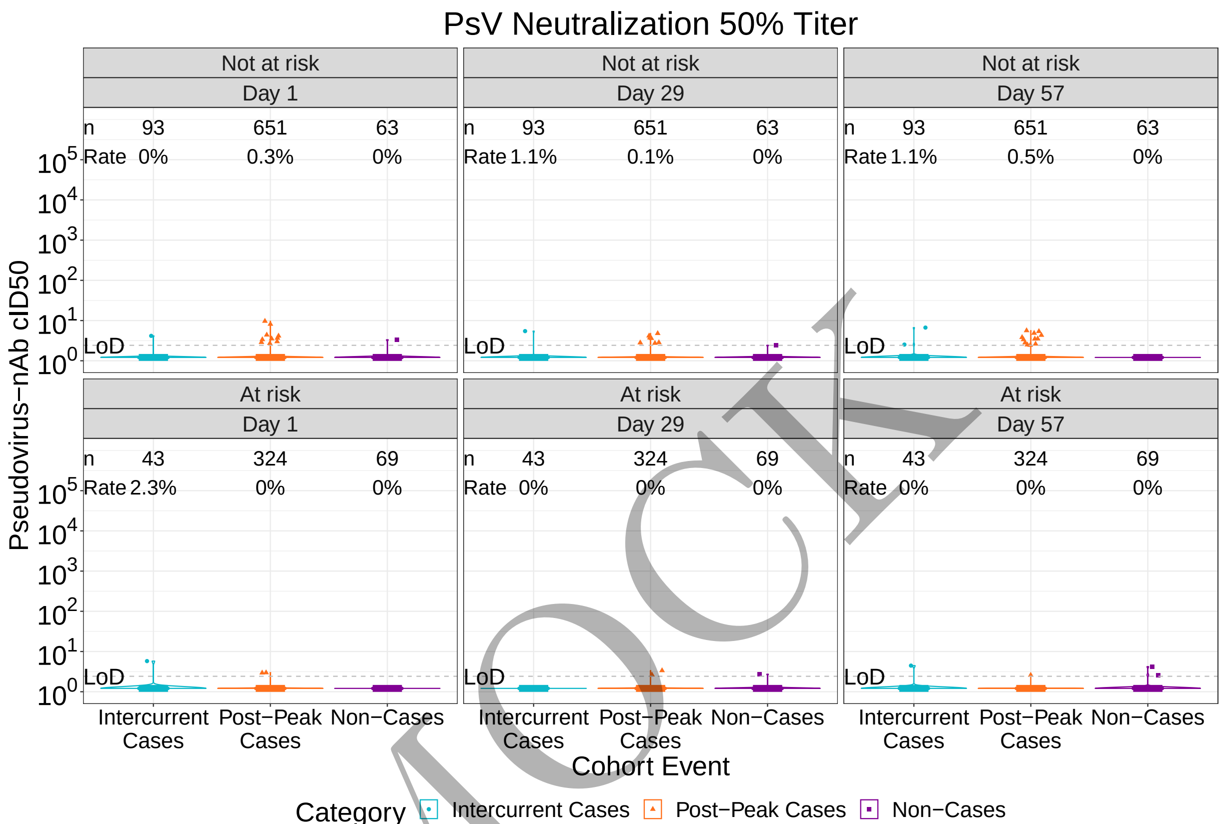
\caption{

Figure 2.5.92: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by risk condition (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



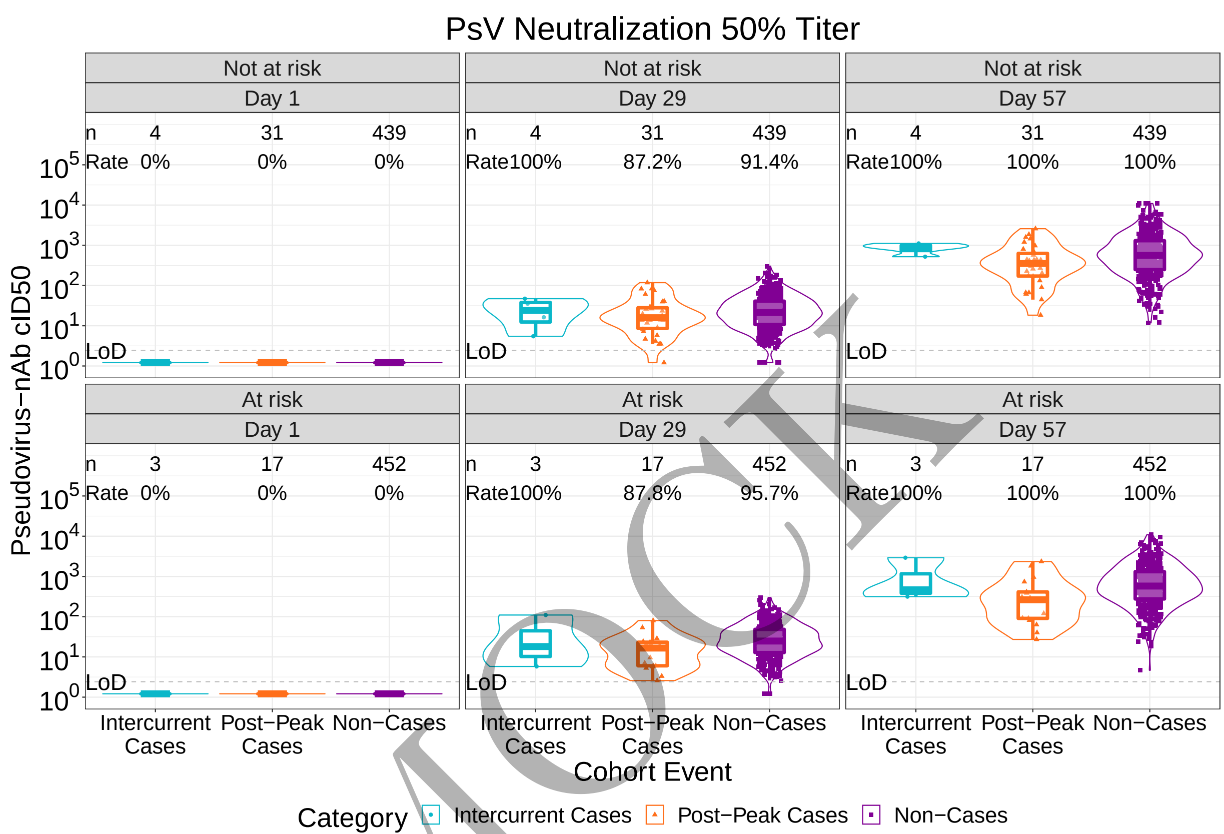
\caption{

Figure 2.5.93: violinplots of PsV Neutralization 50% Titer: baseline negative placebo arm by risk condition (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



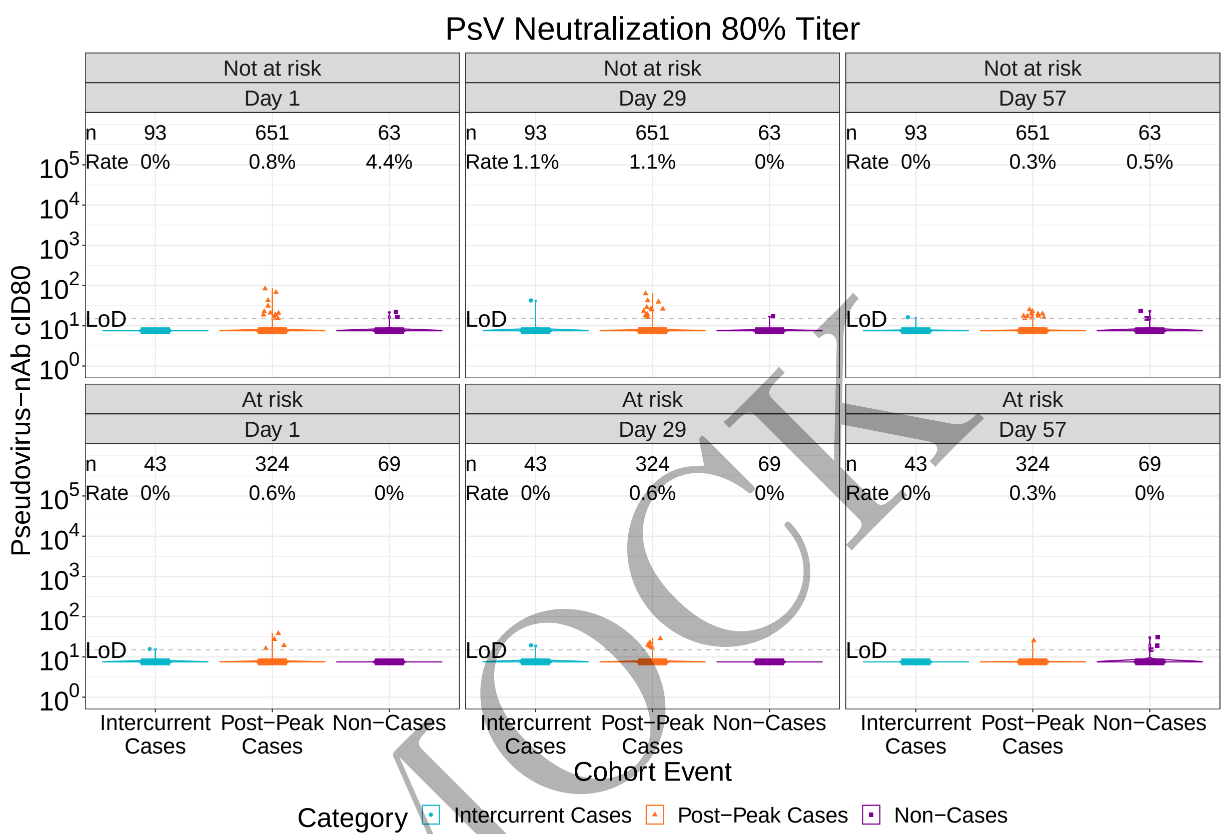
\caption{

Figure 2.5.94: violinplots of PsV Neutralization 50% Titer: baseline negative vaccine arm by risk condition (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



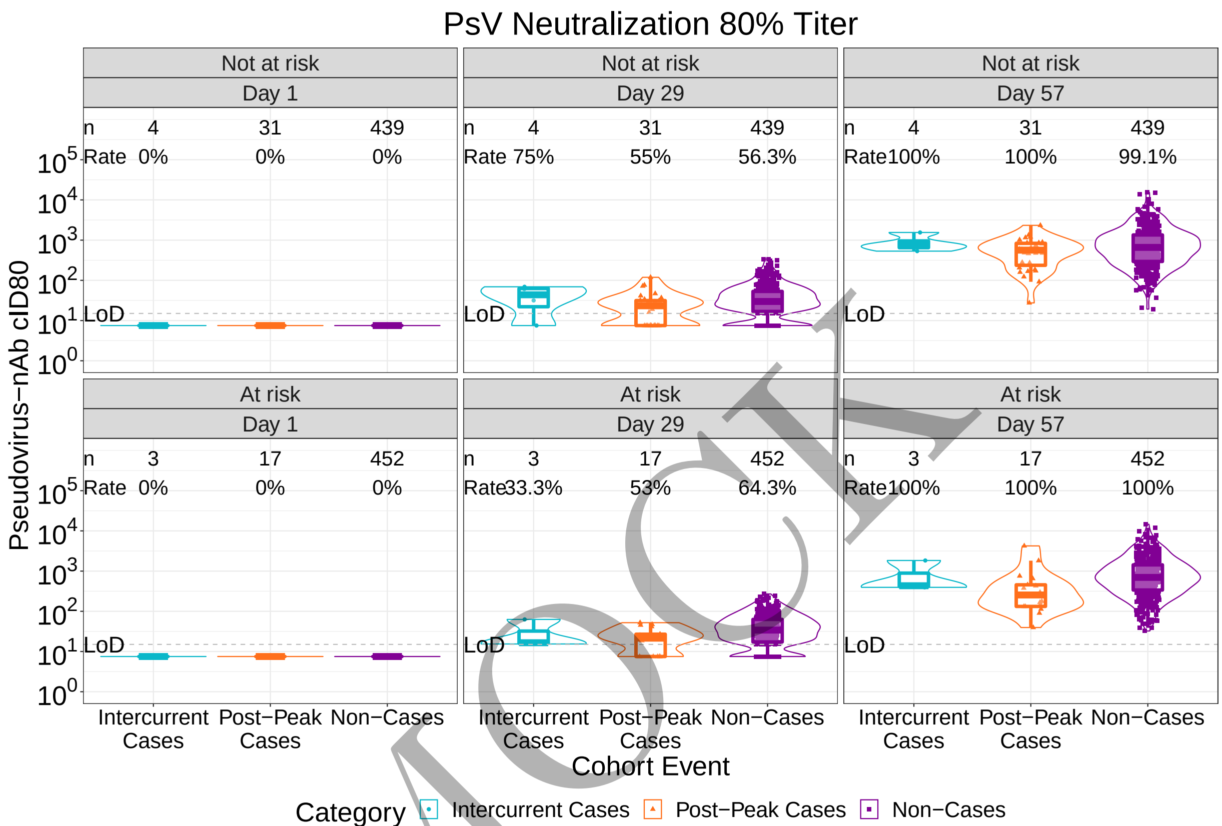
\caption{

Figure 2.5.95: violinplots of PsV Neutralization 80% Titer: baseline negative placebo arm by risk condition (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

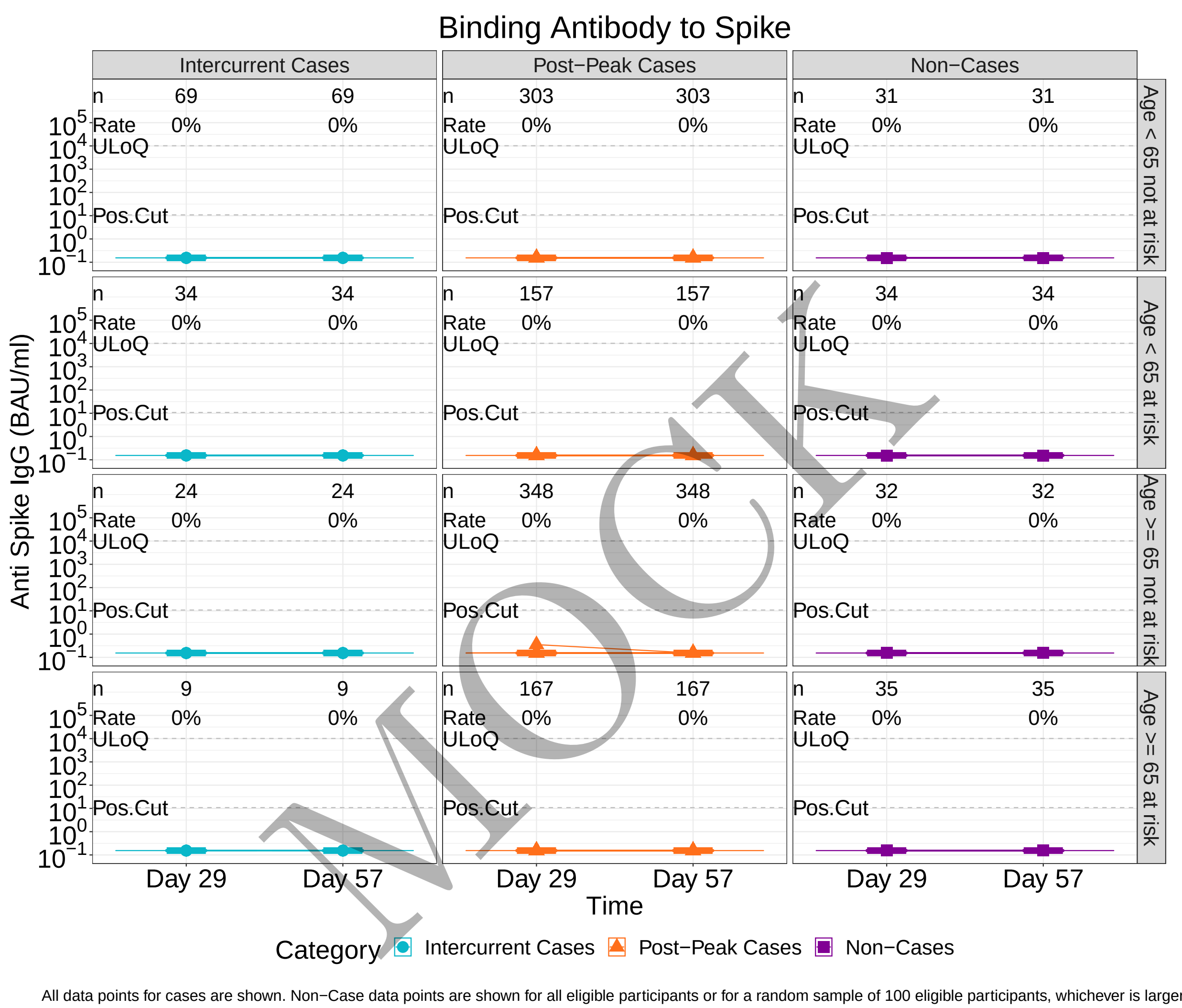
\begin{figure}



\caption{
Figure 2.5.96: violinplots of PsV Neutralization 80% Titer: baseline negative vaccine arm by risk condition (version 2)
} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



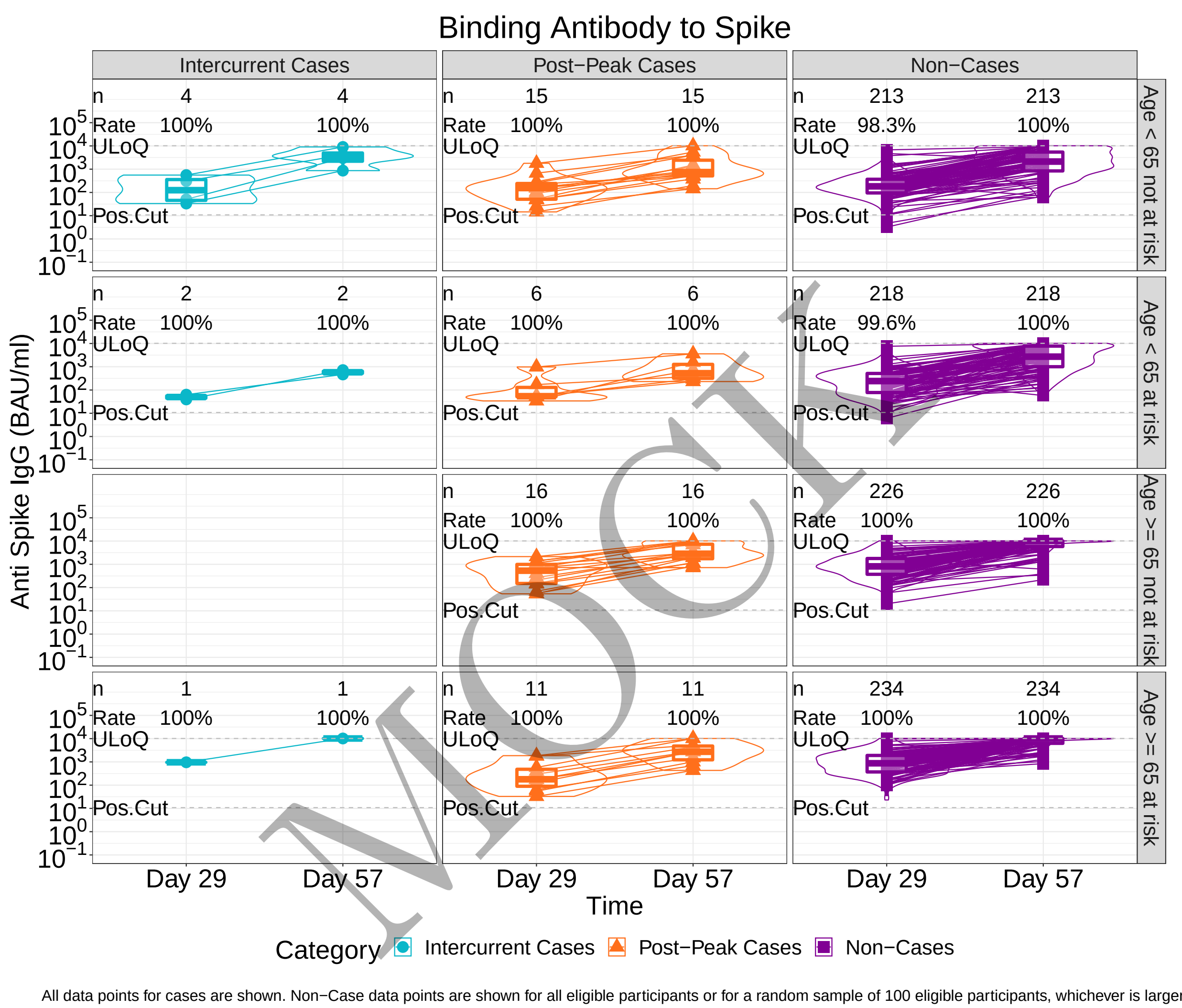
\caption{

Figure 2.5.97: lineplots of Binding Antibody to Spike: baseline negative placebo arm by age and risk condition (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



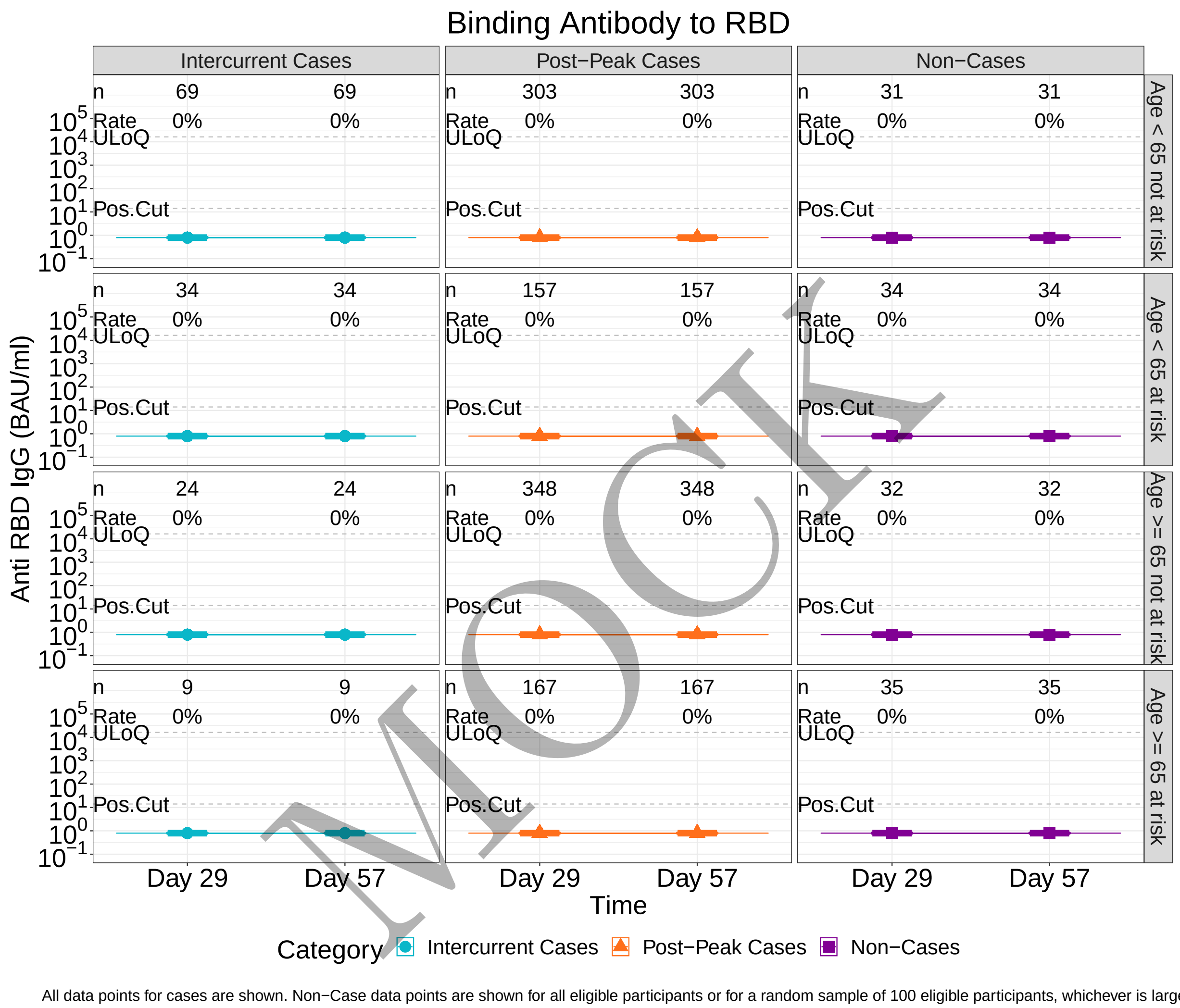
\caption{

Figure 2.5.98: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by age and risk condition (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



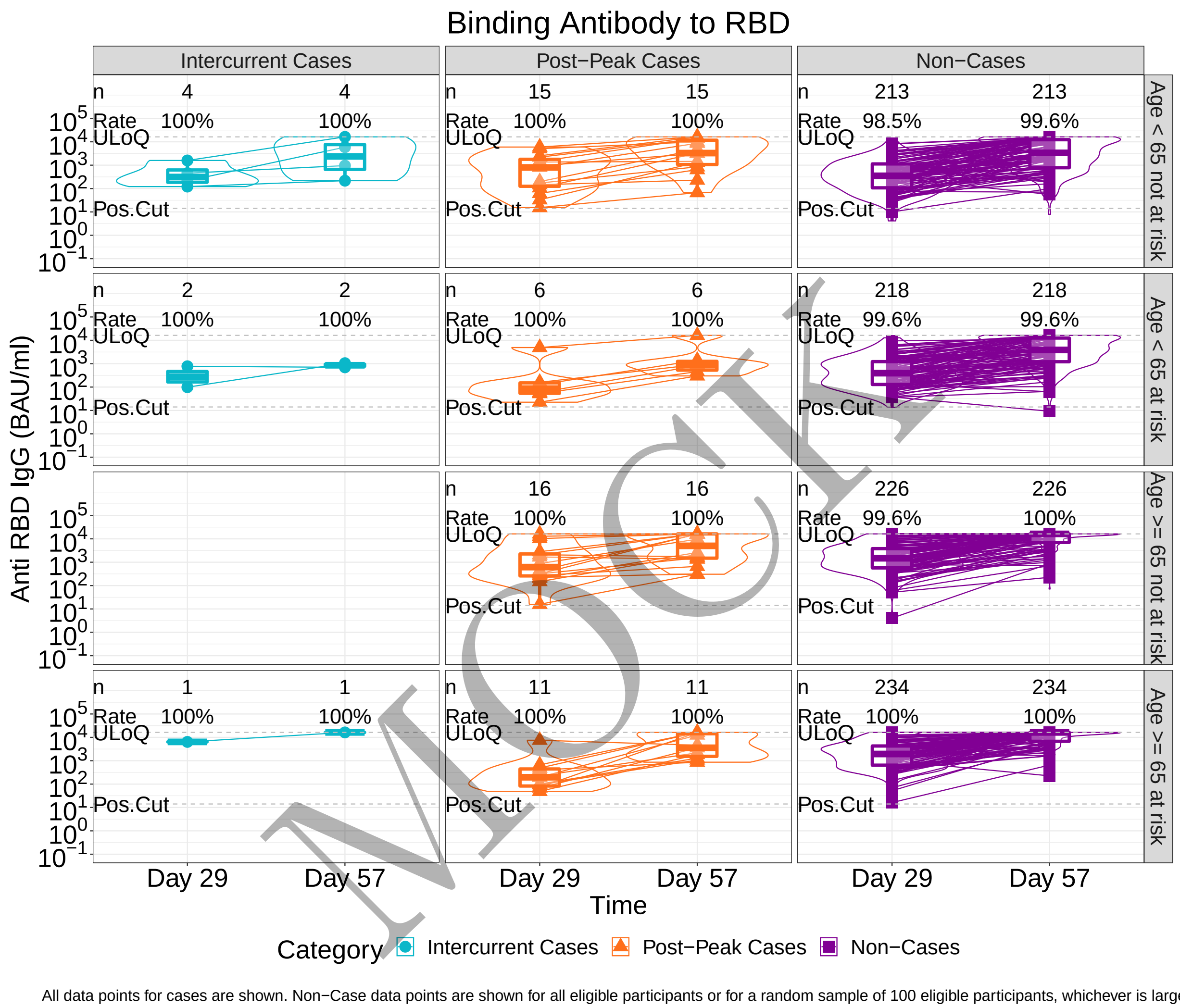
\caption{

Figure 2.5.99: lineplots of Binding Antibody to RBD: baseline negative placebo arm by age and risk condition (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



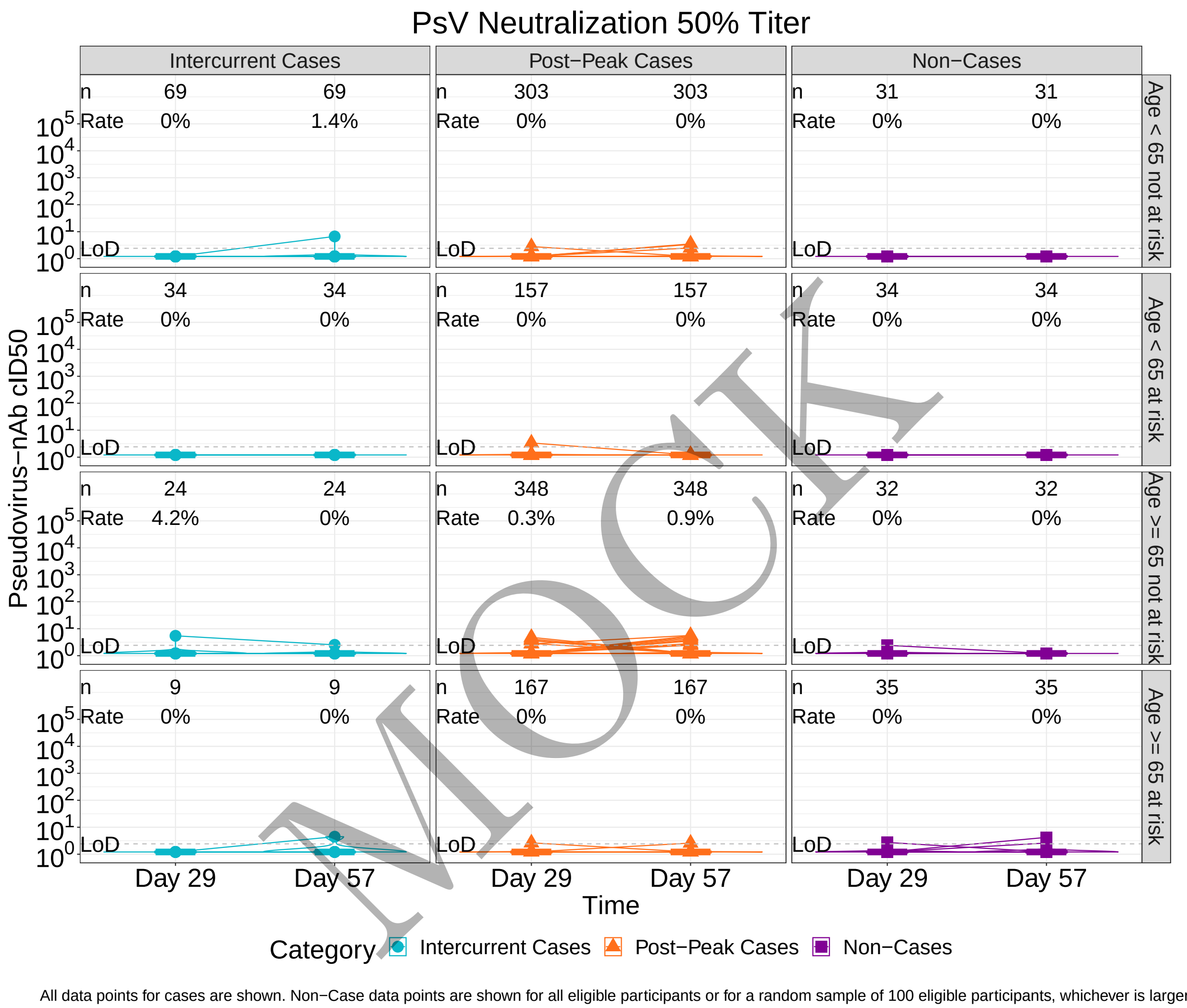
\caption{

Figure 2.5.100: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by age and risk condition (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



\caption{

Figure 2.5.101: lineplots of PsV Neutralization 50% Titer: baseline negative placebo arm by age and risk condition (version 1)

} \end{figure}

```
r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")
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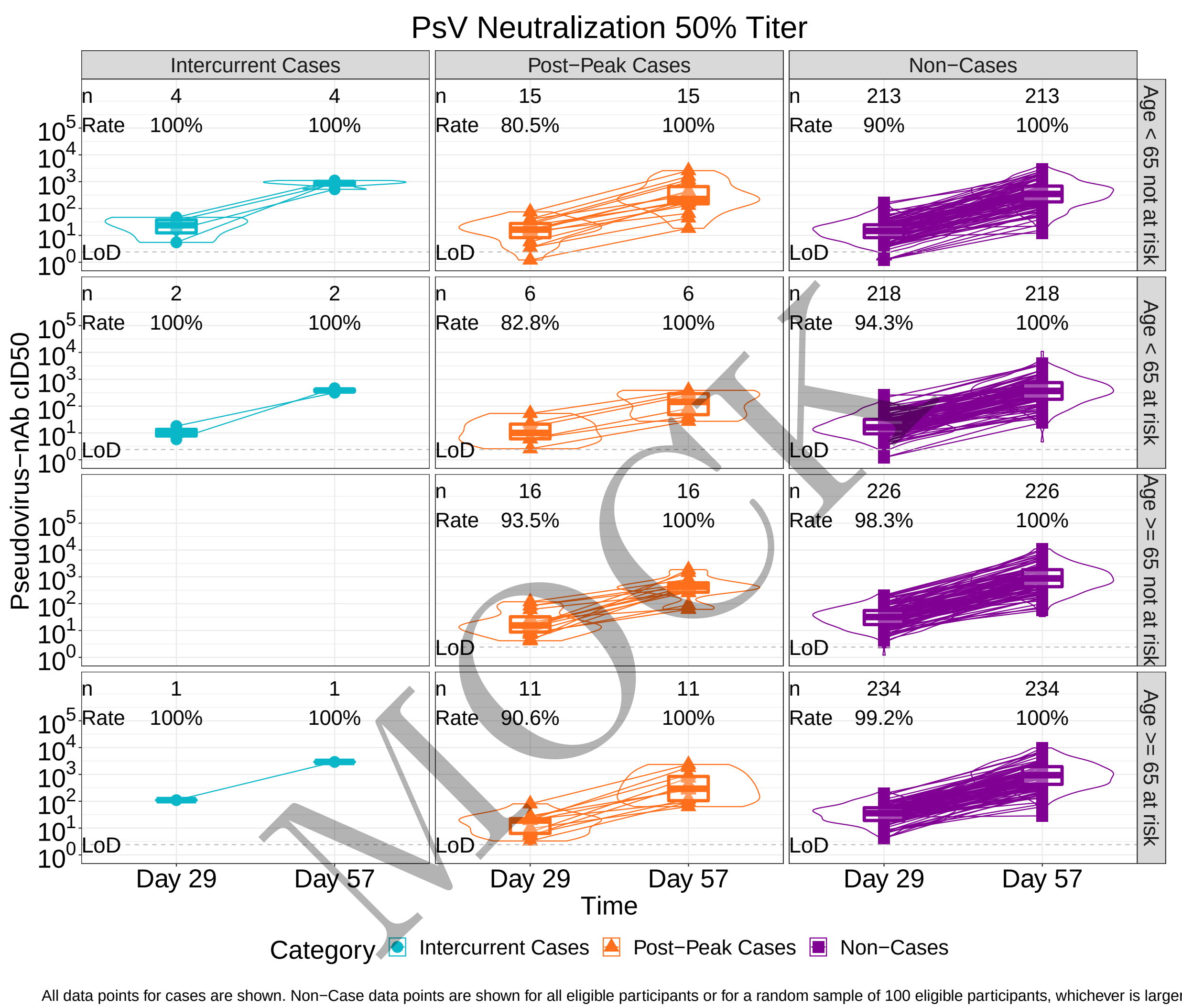
\begin{figure}



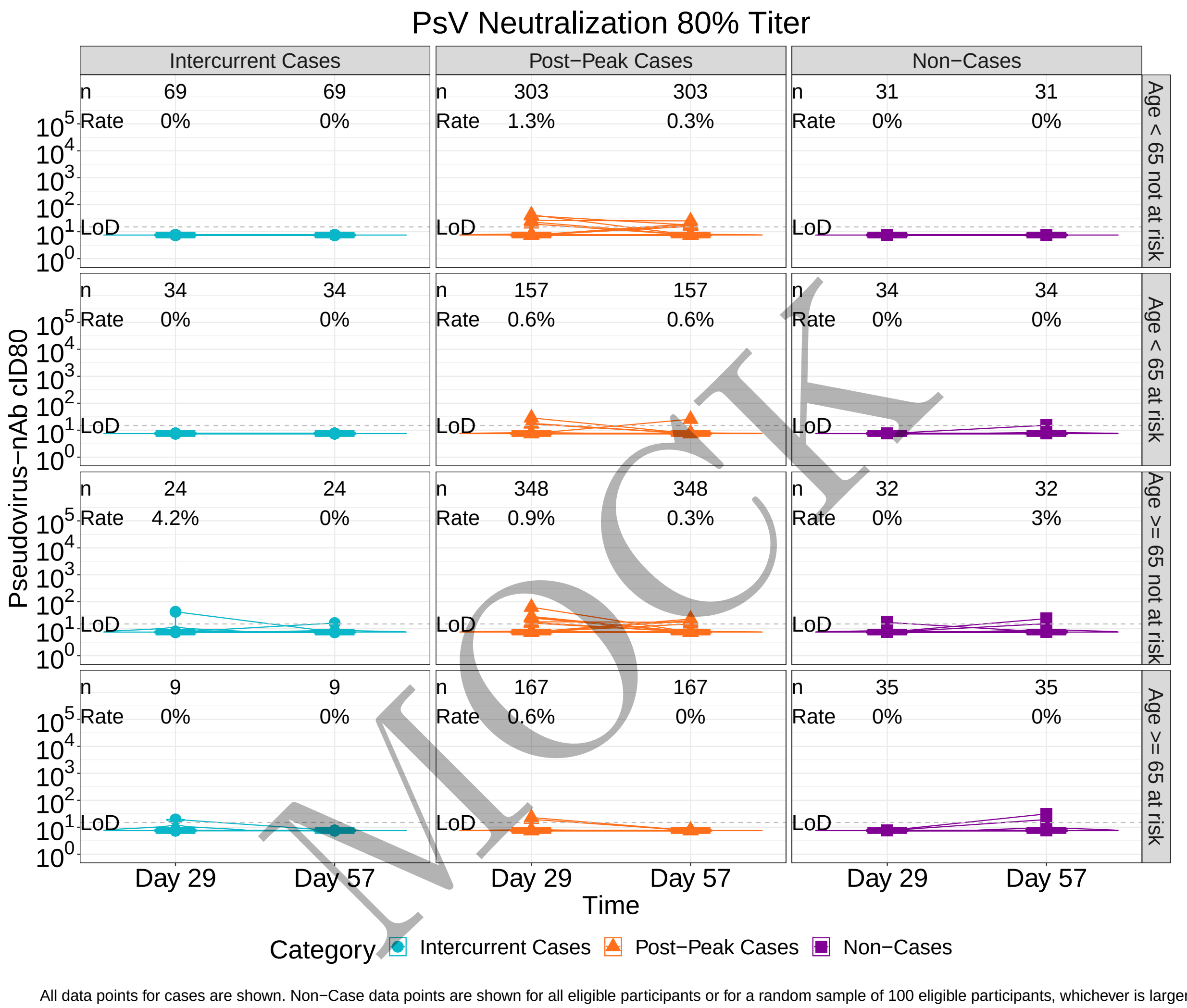
\caption{

Figure 2.5.102: lineplots of PsV Neutralization 50% Titer: baseline negative vaccine arm by age and risk condition (version 1)

} \end{figure}

`r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")`

\begin{figure}



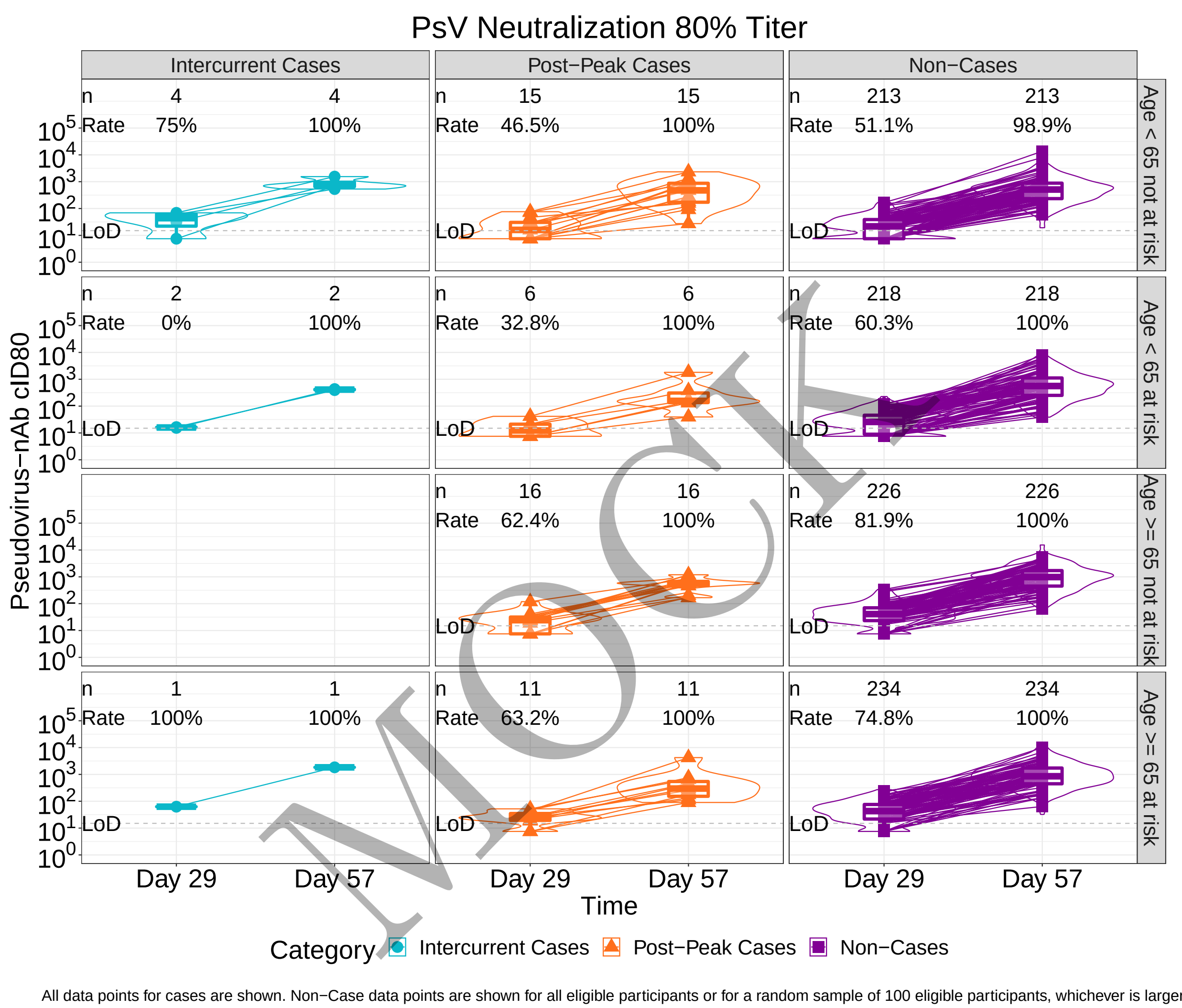
\caption{

Figure 2.5.103: lineplots of PsV Neutralization 80% Titer: baseline negative placebo arm by age and risk condition (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



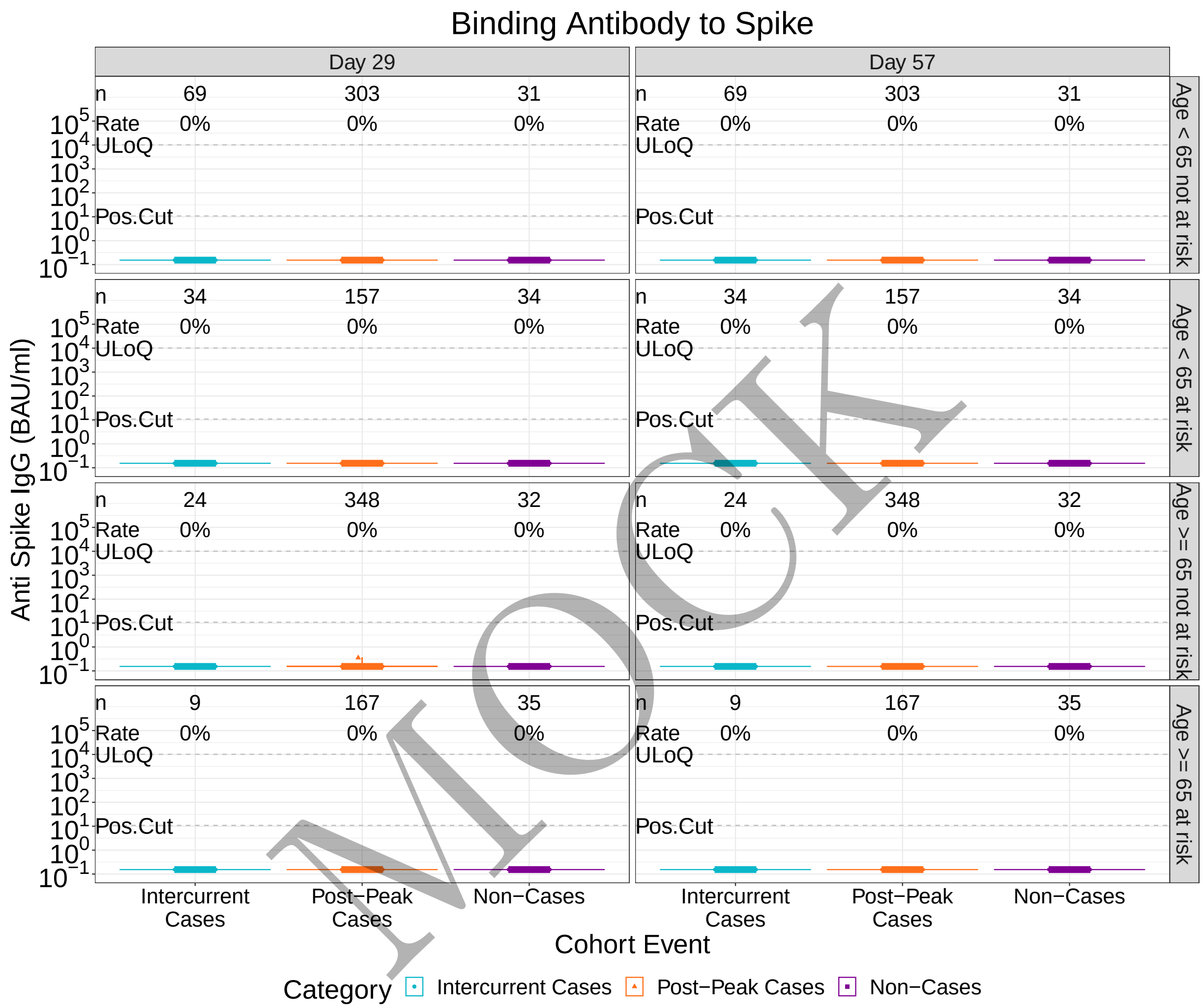
\caption{

Figure 2.5.104: lineplots of PsV Neutralization 80% Titer: baseline negative vaccine arm by age and risk condition (version 1)

} \end{figure}

`r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")`

\begin{figure}



\caption{

Figure 2.5.105: violinplots of Binding Antibody to Spike: baseline negative placebo arm by age and risk condition (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

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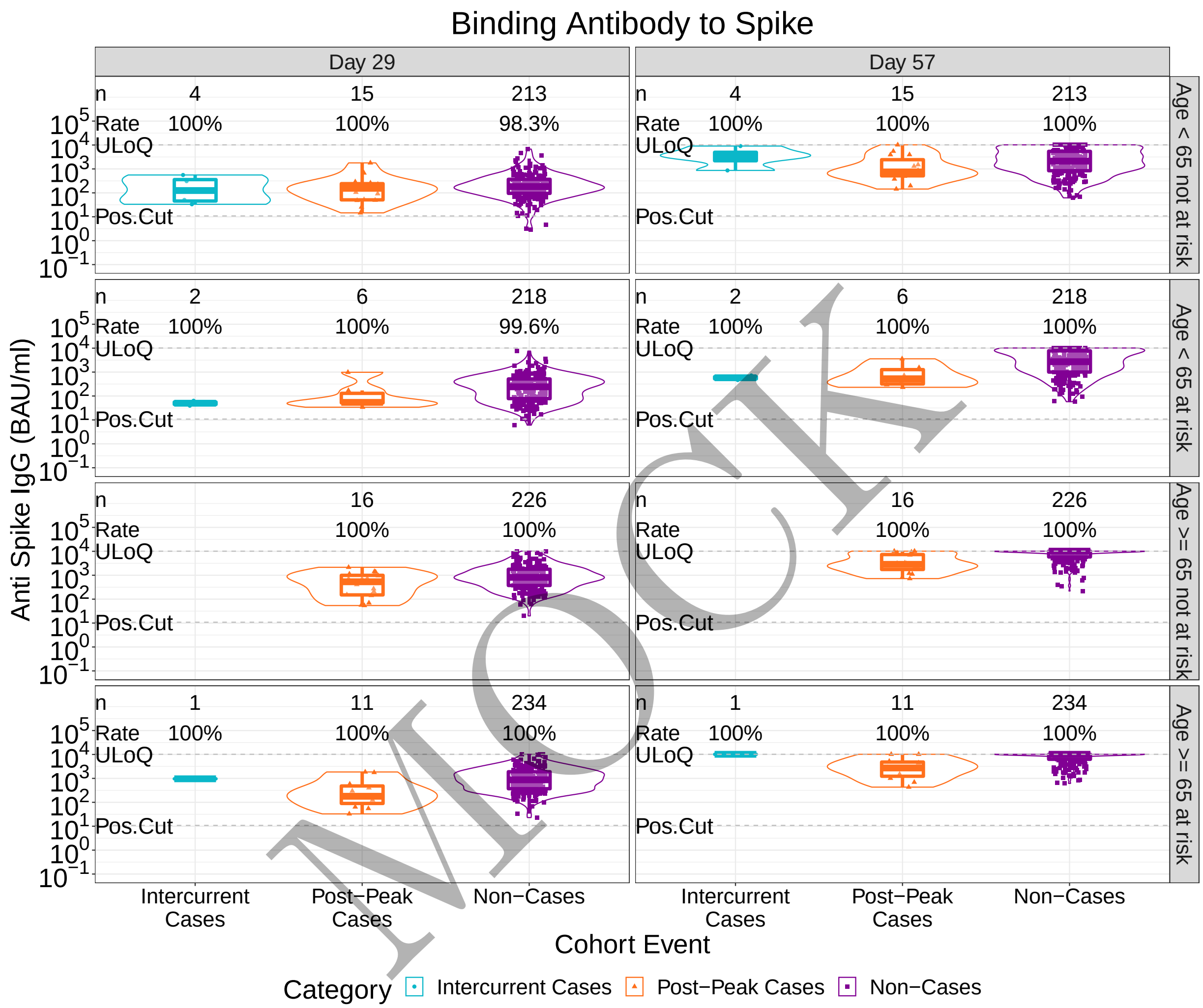


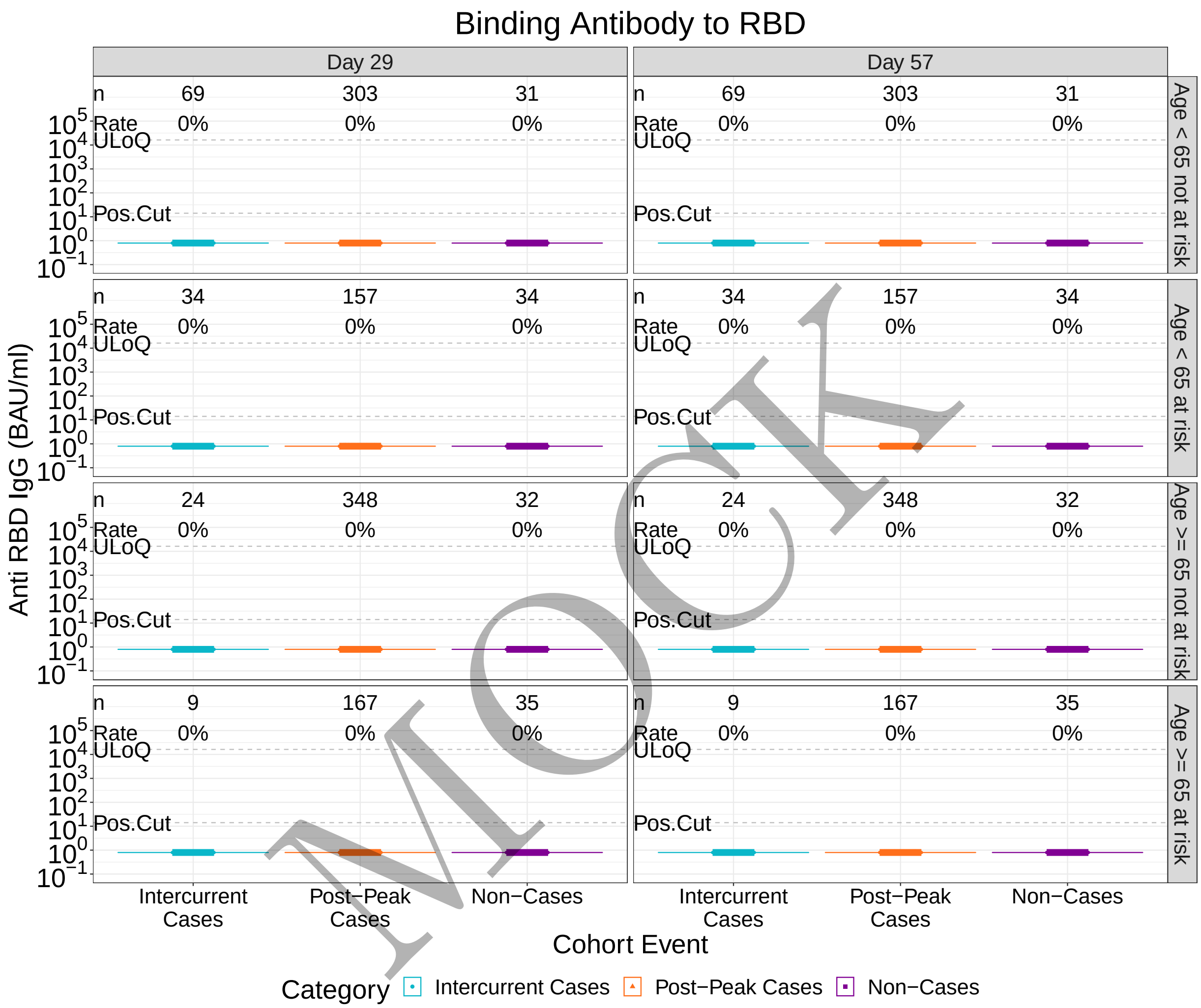
\caption{

Figure 2.5.106: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by age and risk condition (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



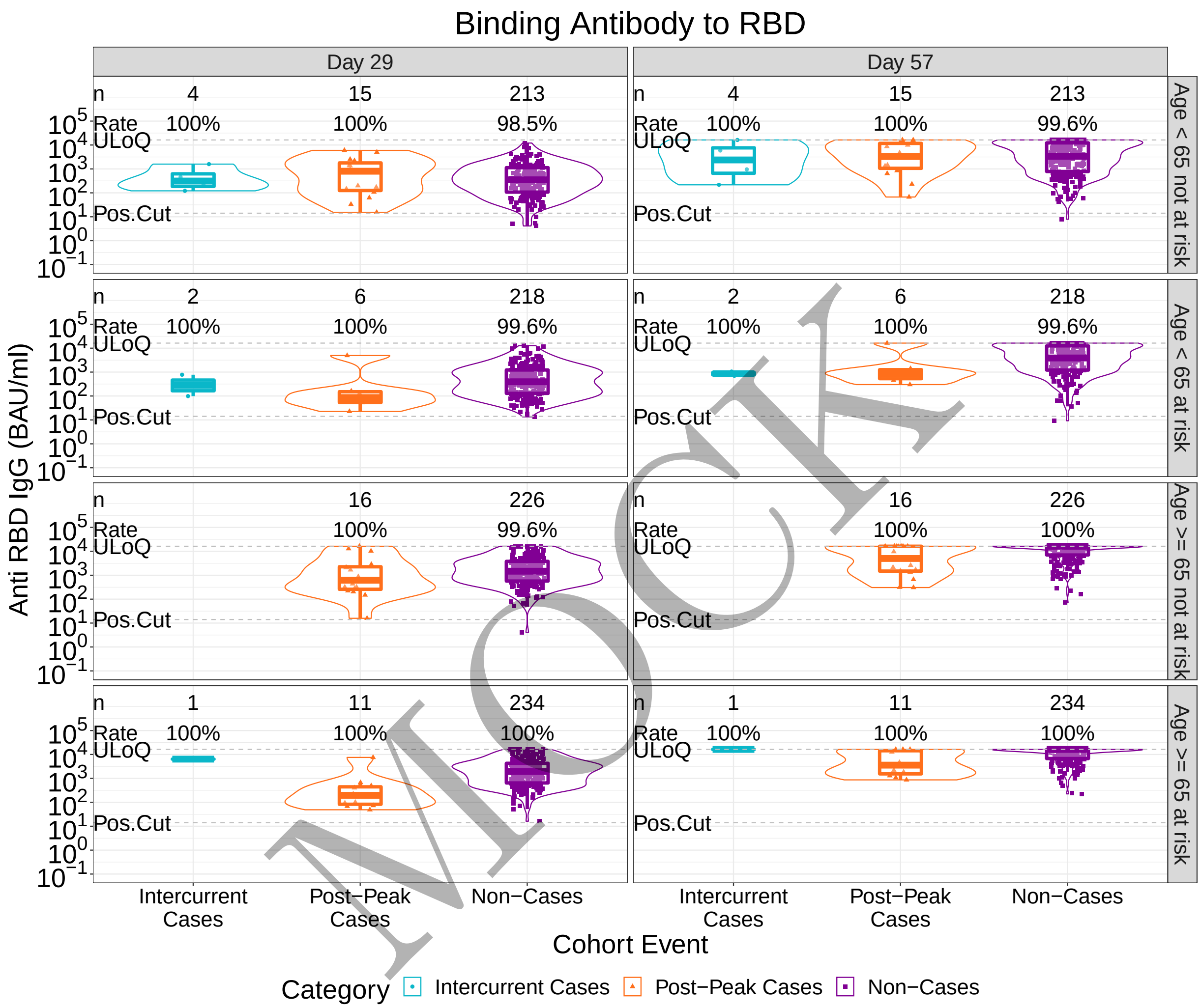
\caption{

Figure 2.5.107: violinplots of Binding Antibody to RBD: baseline negative placebo arm by age and risk condition (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



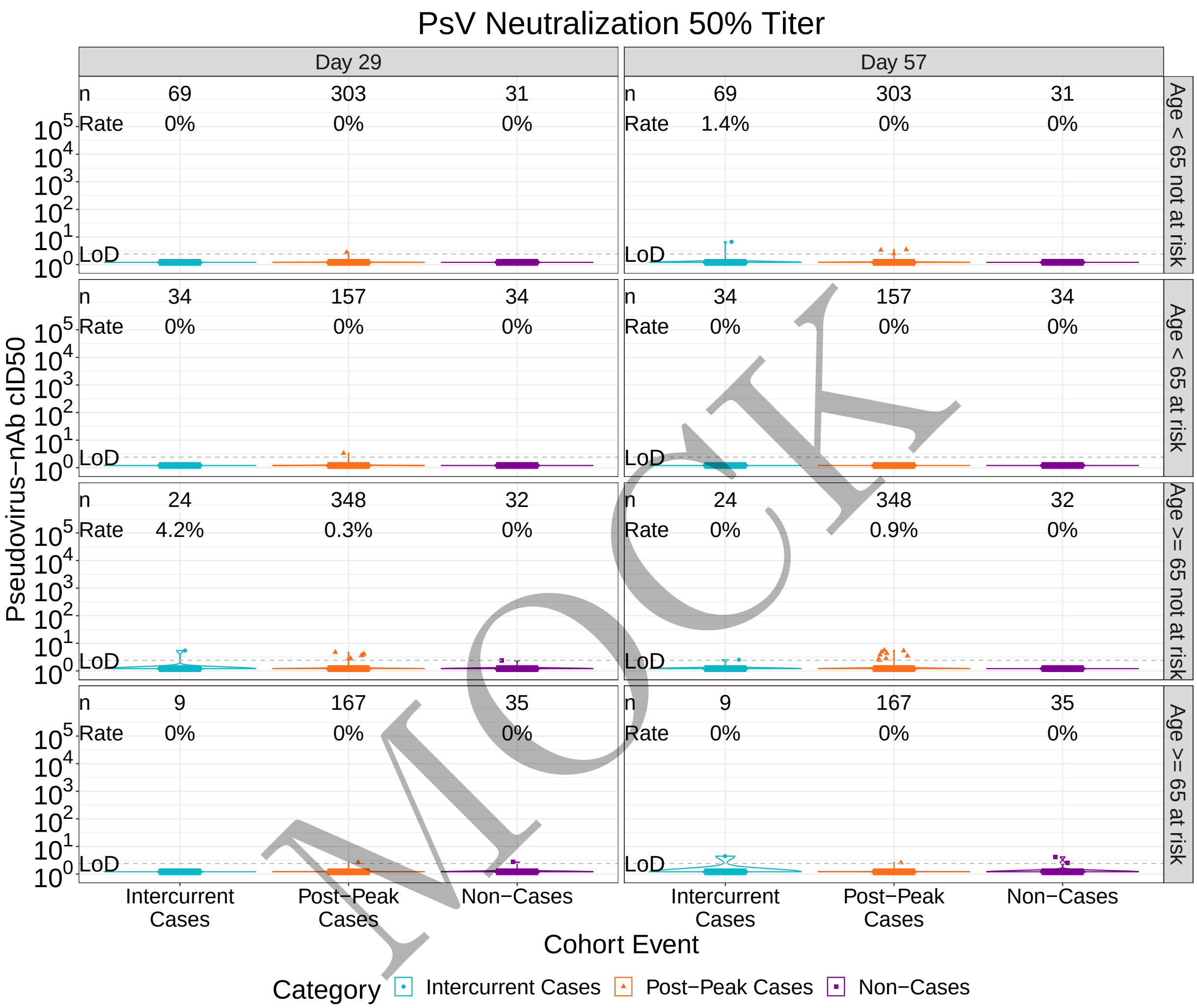
\caption{

Figure 2.5.108: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by age and risk condition (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



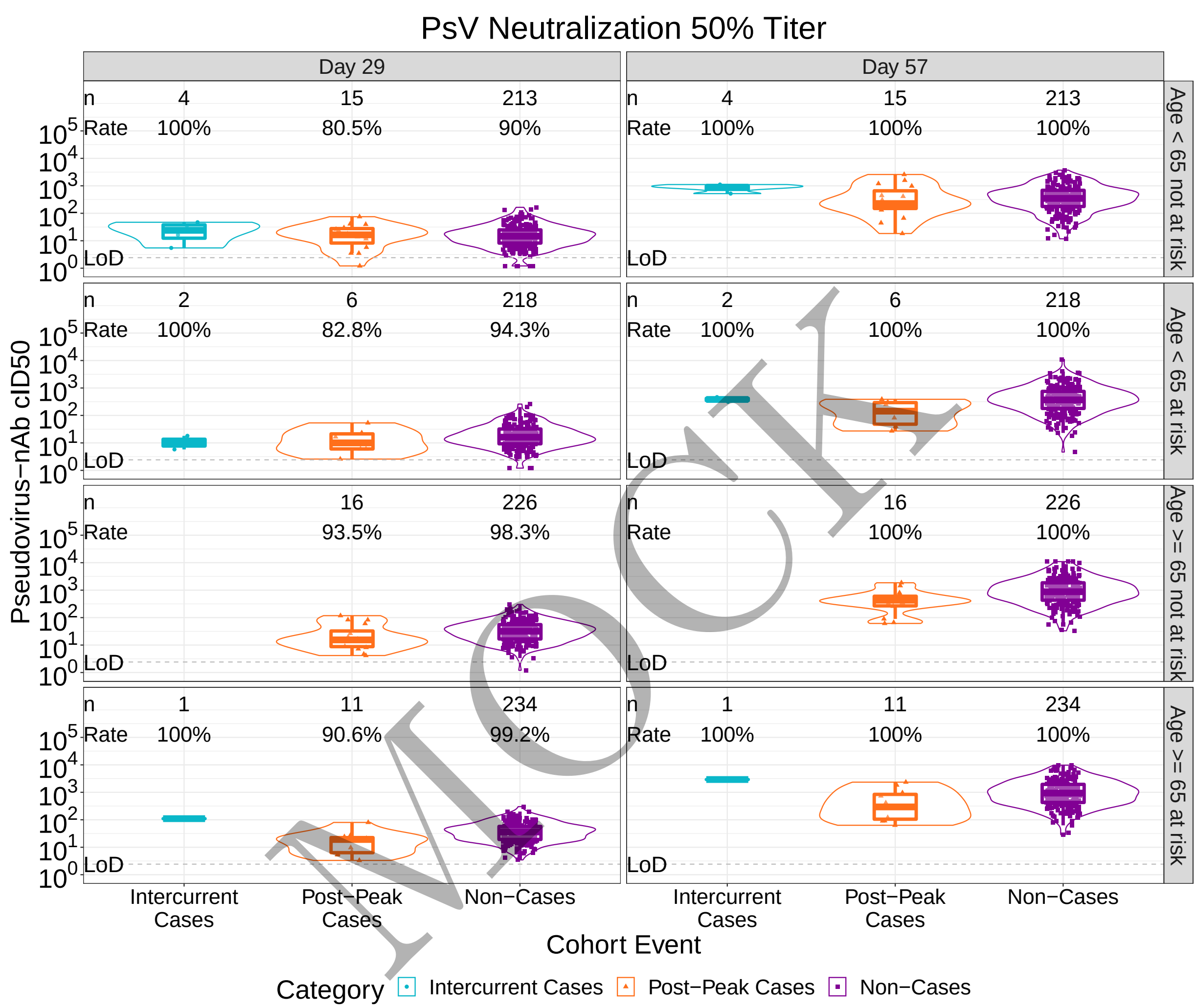
\caption{

Figure 2.5.109: violinplots of PsV Neutralization 50% Titer: baseline negative placebo arm by age and risk condition (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



\caption{

Figure 2.5.110: violinplots of PsV Neutralization 50% Titer: baseline negative vaccine arm by age and risk condition (version 1)

} \end{figure}

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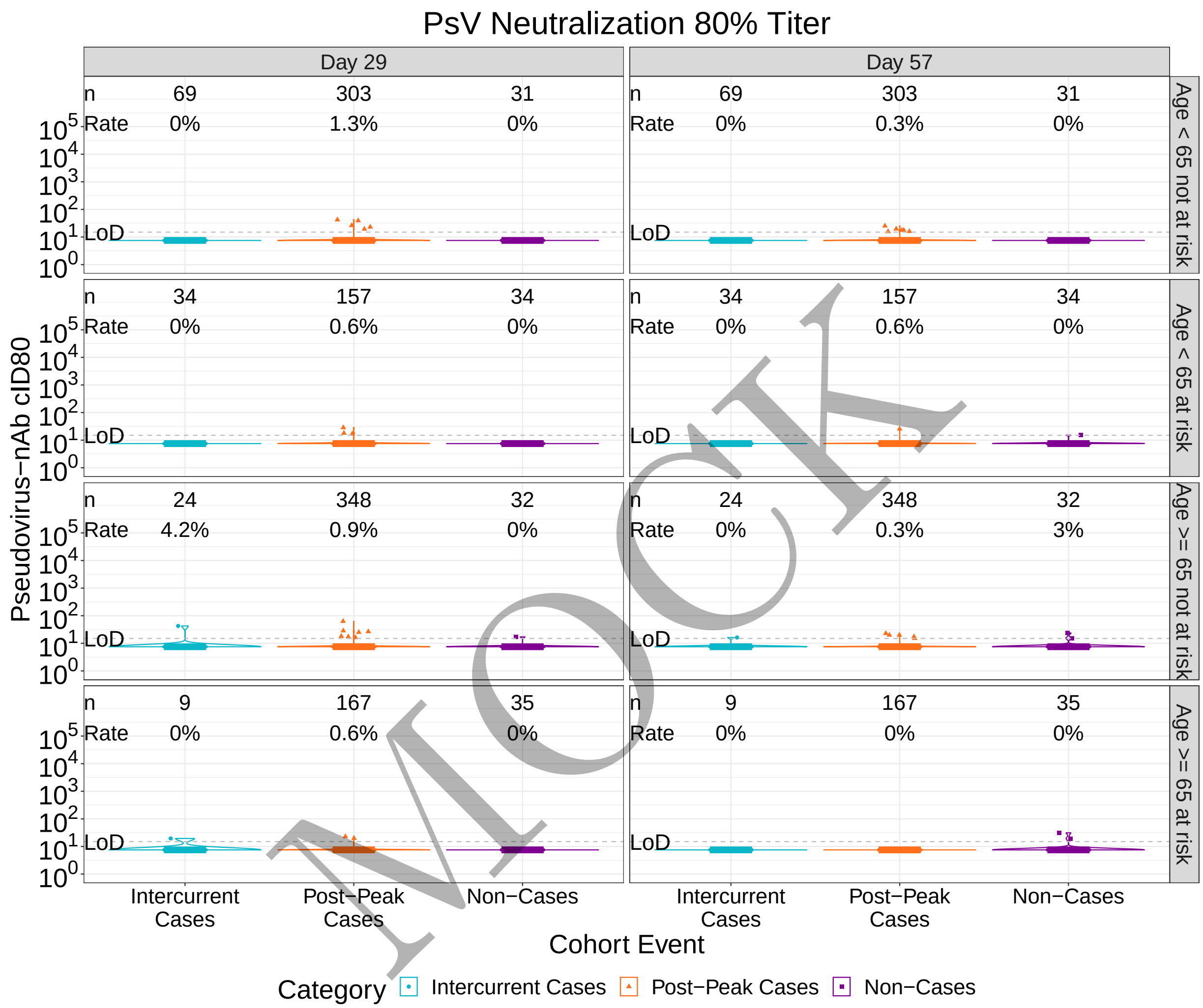
\begin{figure}



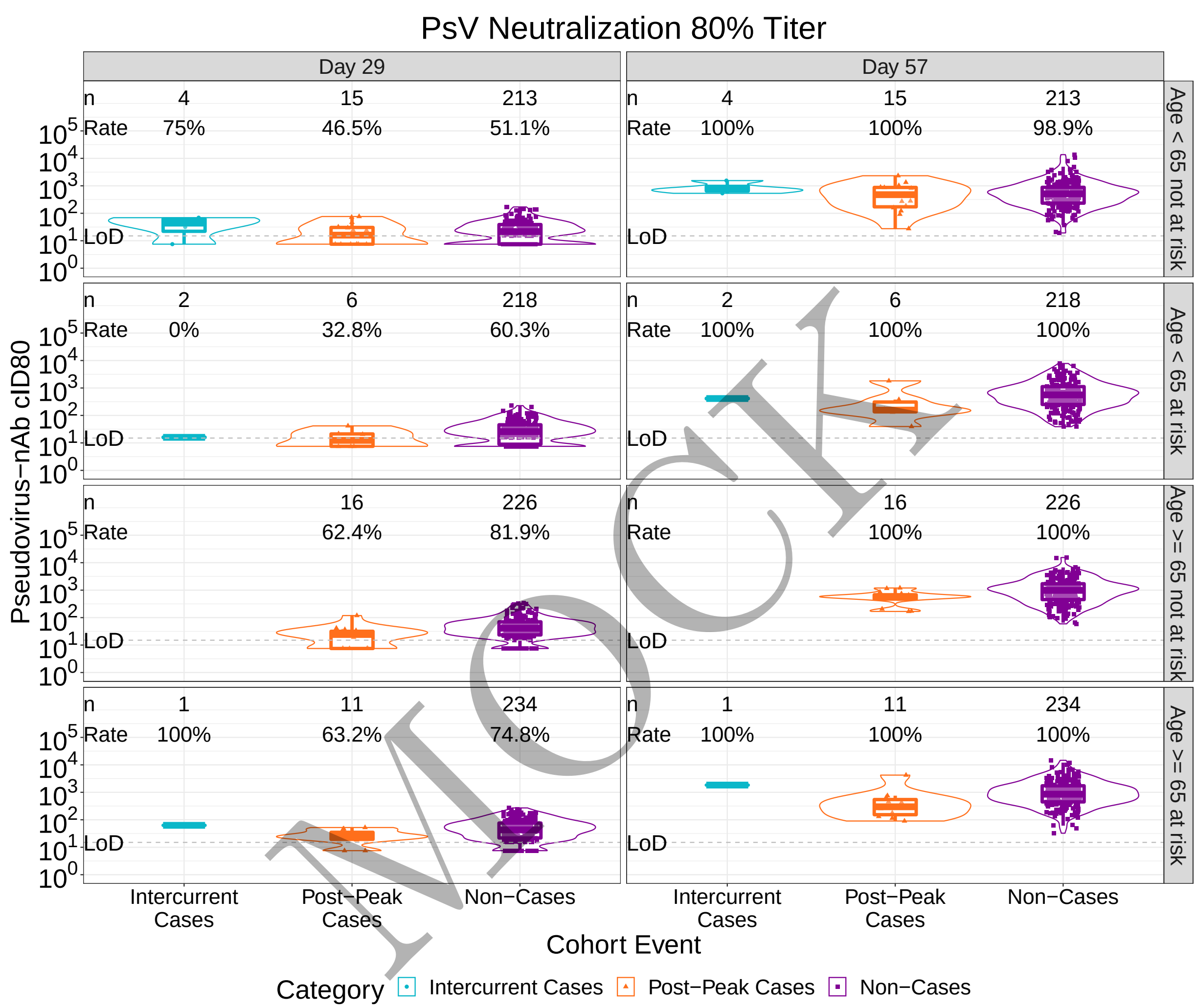
\caption{

Figure 2.5.111: violinplots of PsV Neutralization 80% Titer: baseline negative placebo arm by age and risk condition (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



\caption{

Figure 2.5.112: violinplots of PsV Neutralization 80% Titer: baseline negative vaccine arm by age and risk condition (version 1)

} \end{figure}

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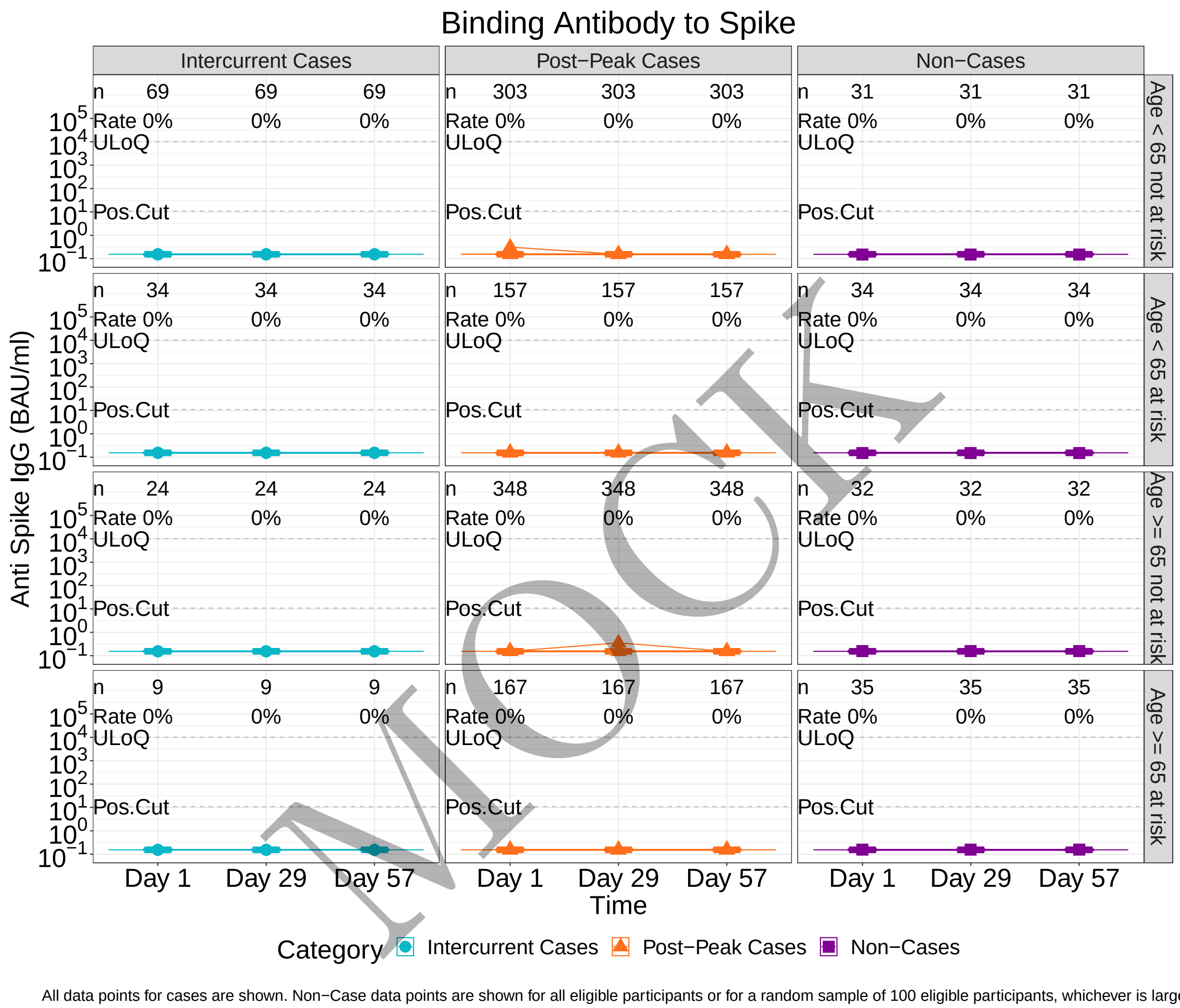
\begin{figure}



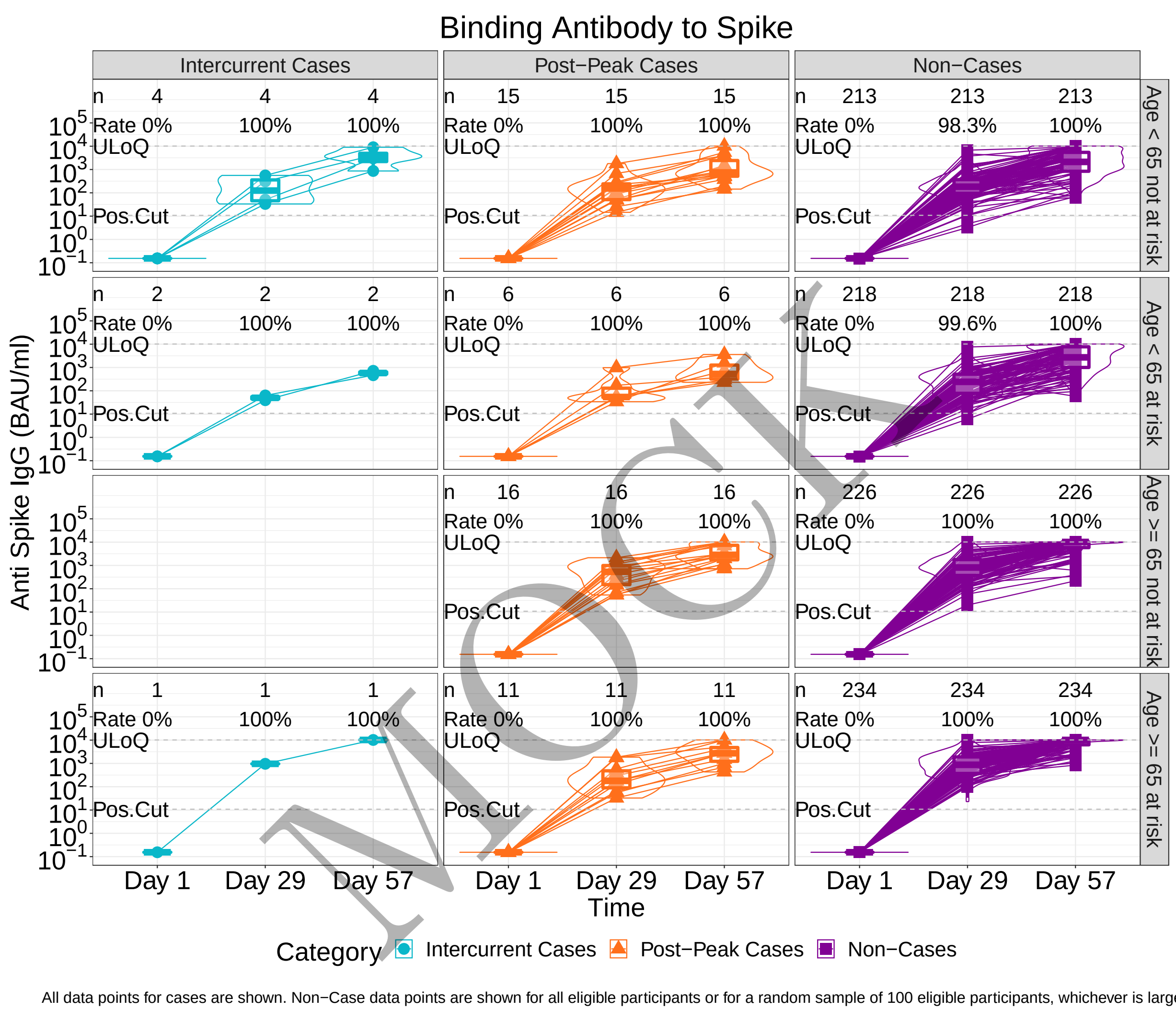
\caption{

Figure 2.5.113: lineplots of Binding Antibody to Spike: baseline negative placebo arm by age and risk condition (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



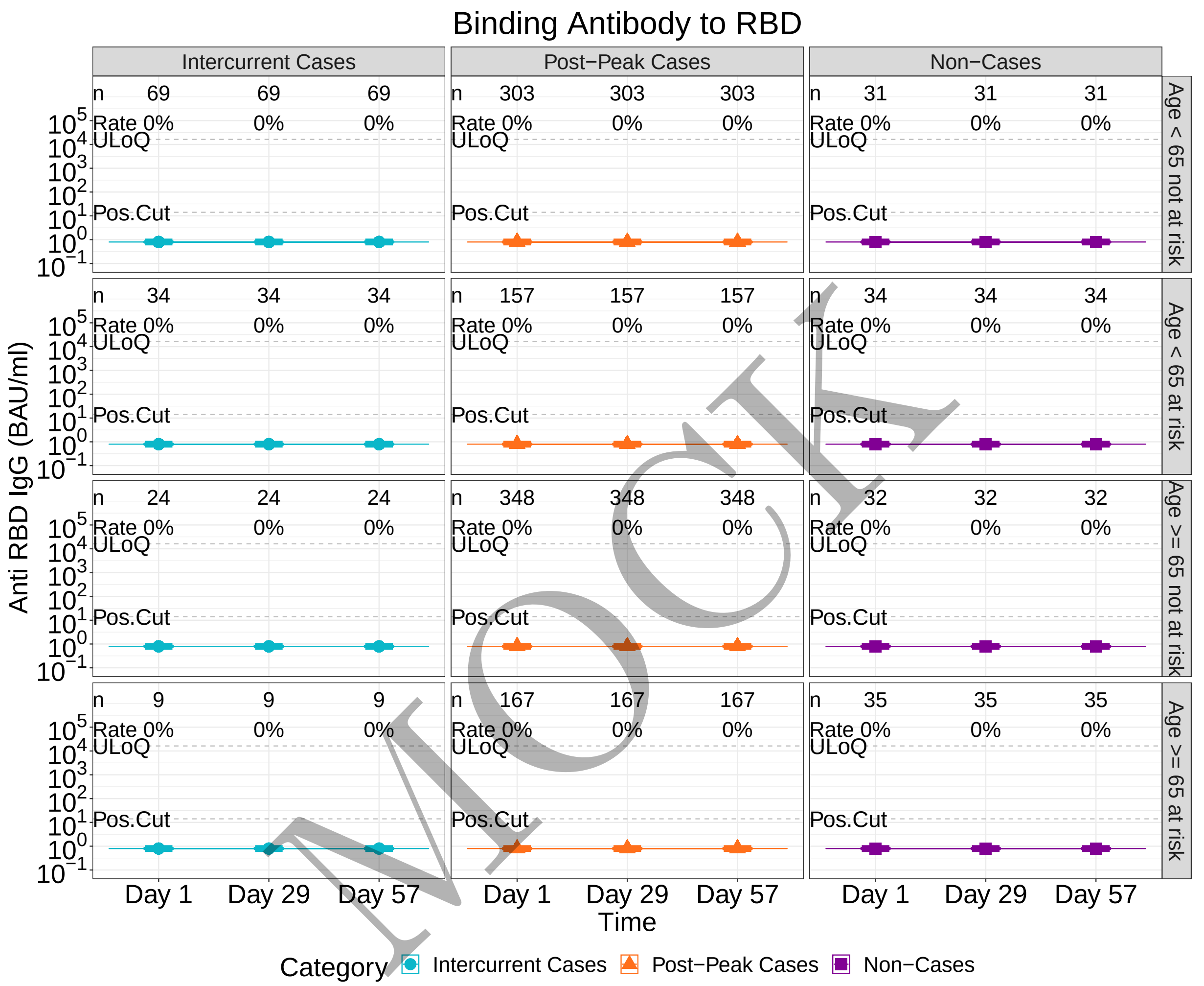
\caption{

Figure 2.5.114: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by age and risk condition (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



All data points for cases are shown. Non−Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger

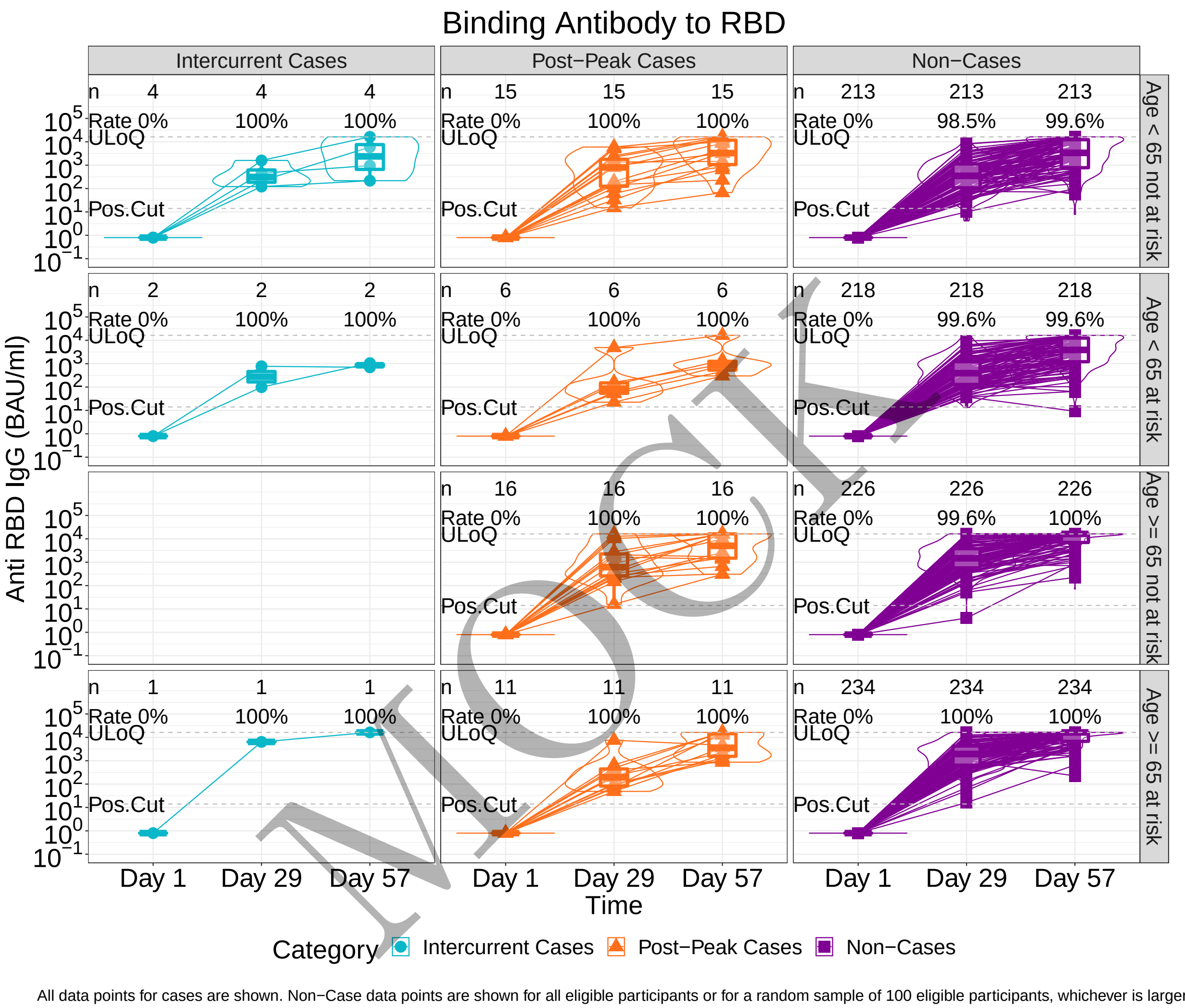
\caption{

Figure 2.5.115: lineplots of Binding Antibody to RBD: baseline negative placebo arm by age and risk condition (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



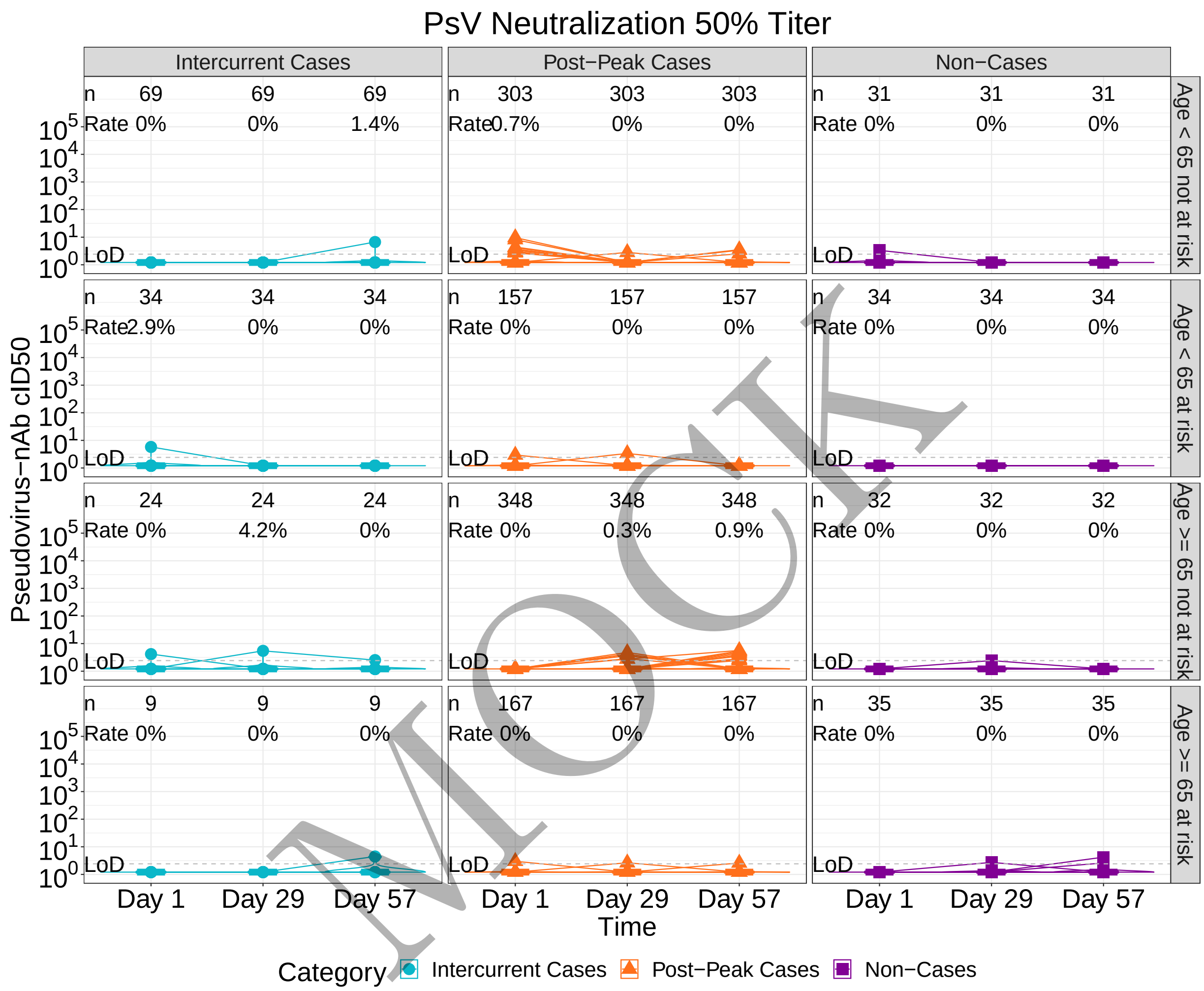
\caption{

Figure 2.5.116: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by age and risk condition (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



All data points for cases are shown. Non−Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger

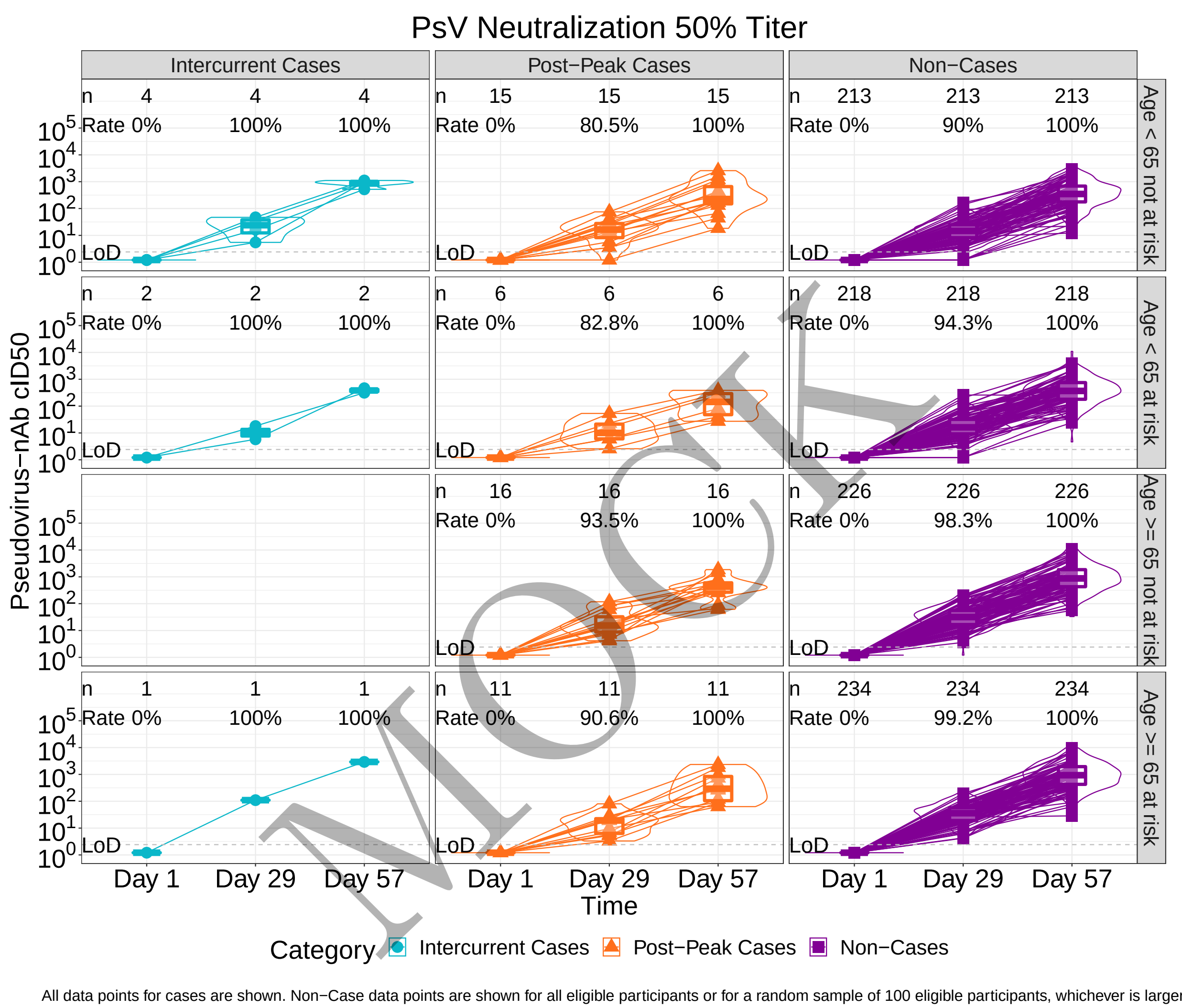
\caption{

Figure 2.5.117: lineplots of PsV Neutralization 50% Titer: baseline negative placebo arm by age and risk condition (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



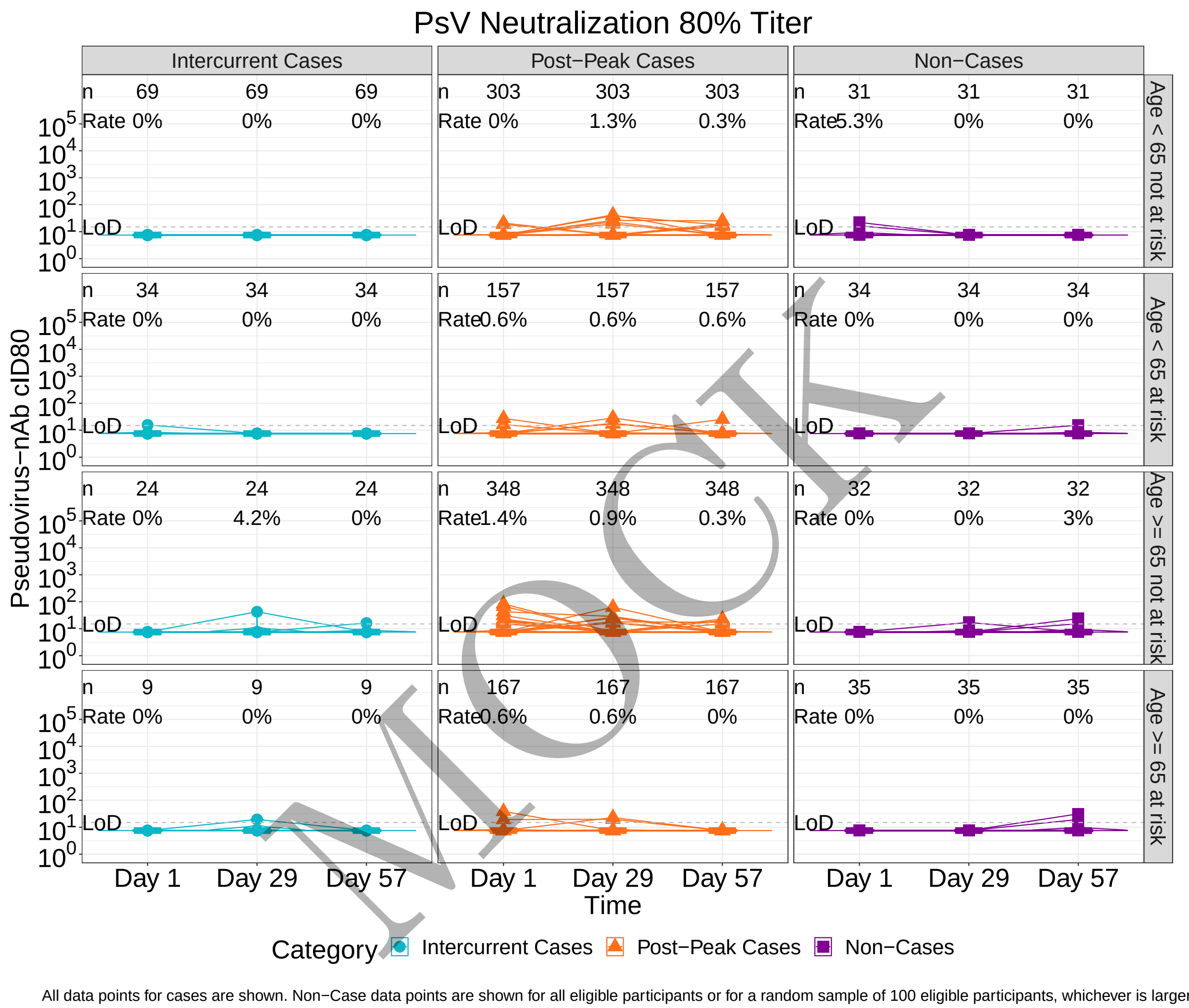
\caption{

Figure 2.5.118: lineplots of PsV Neutralization 50% Titer: baseline negative vaccine arm by age and risk condition (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



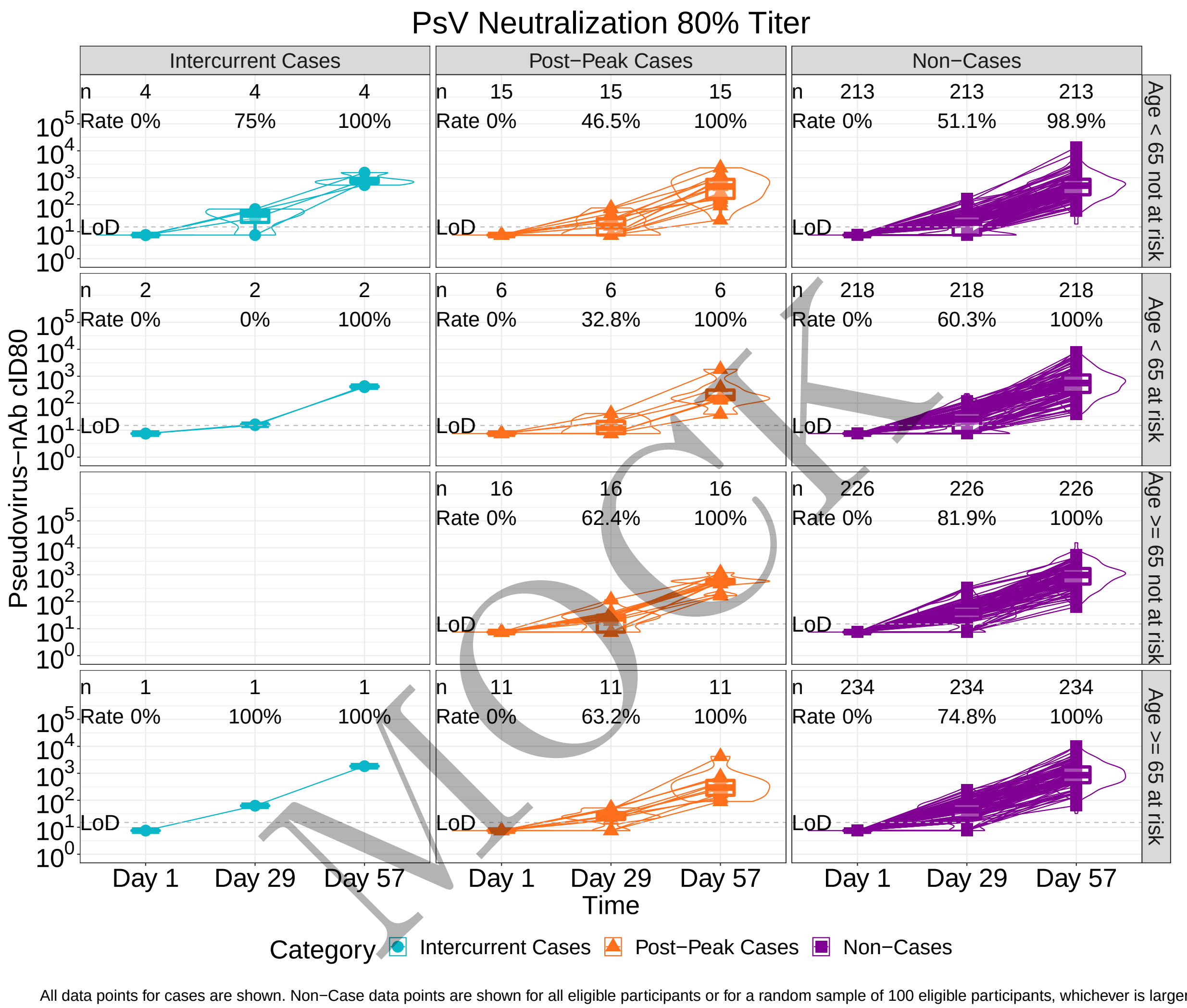
\caption{

Figure 2.5.119: lineplots of PsV Neutralization 80% Titer: baseline negative placebo arm by age and risk condition (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



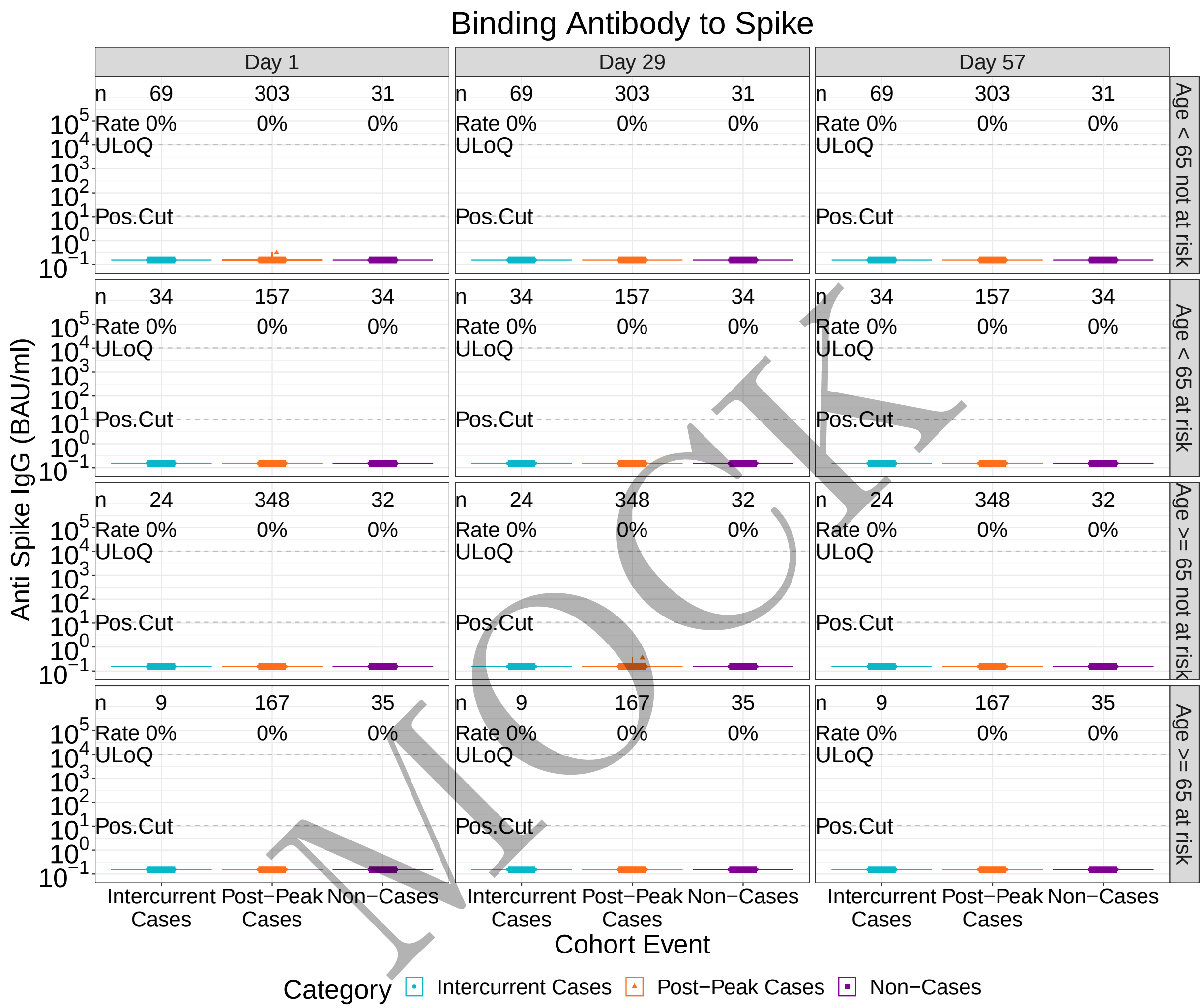
\caption{

Figure 2.5.120: lineplots of PsV Neutralization 80% Titer: baseline negative vaccine arm by age and risk condition (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



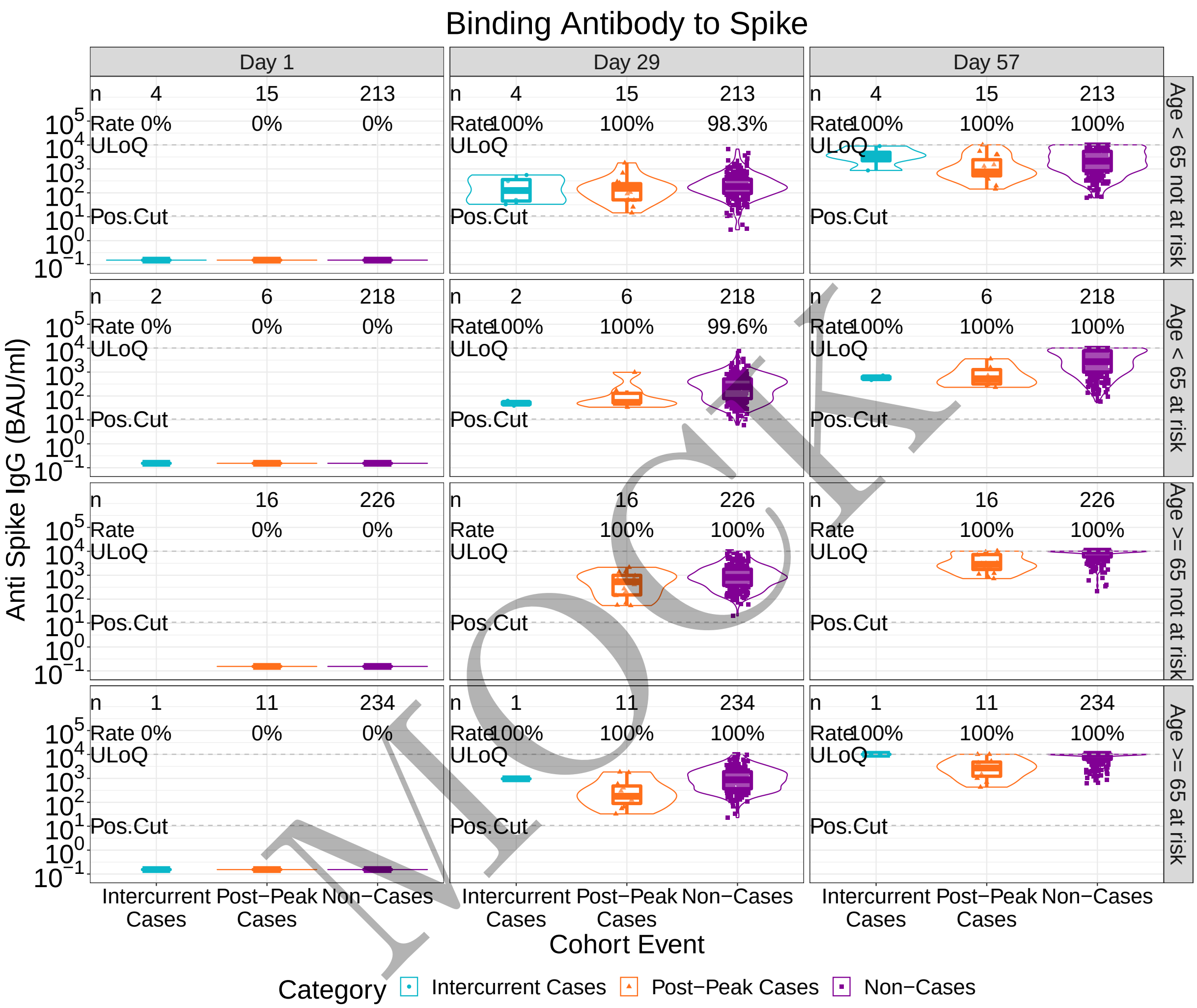
\caption{

Figure 2.5.121: violinplots of Binding Antibody to Spike: baseline negative placebo arm by age and risk condition (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



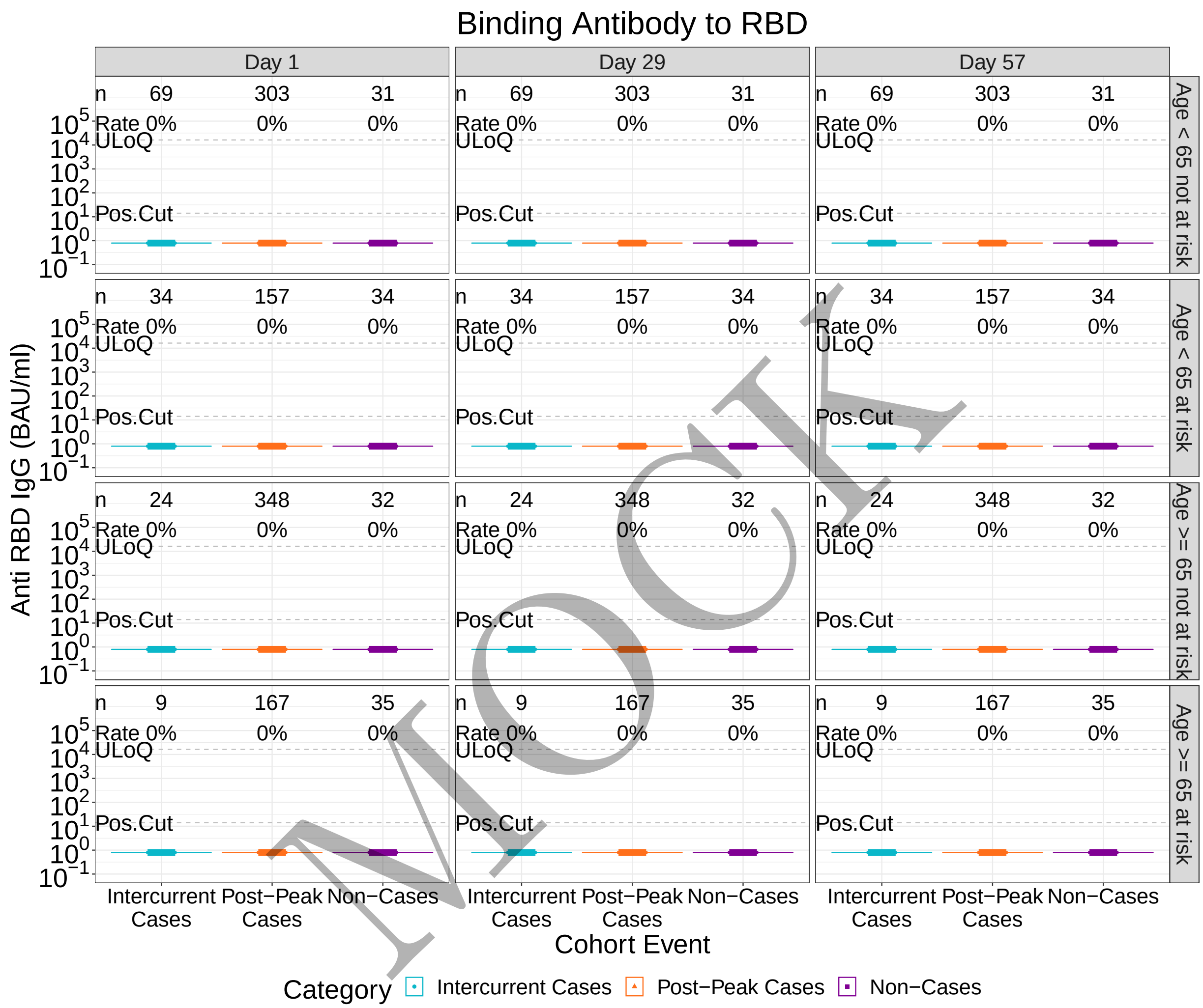
\caption{

Figure 2.5.122: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by age and risk condition (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



\caption{

Figure 2.5.123: violinplots of Binding Antibody to RBD: baseline negative placebo arm by age and risk condition (version 2)

} \end{figure}

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r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")
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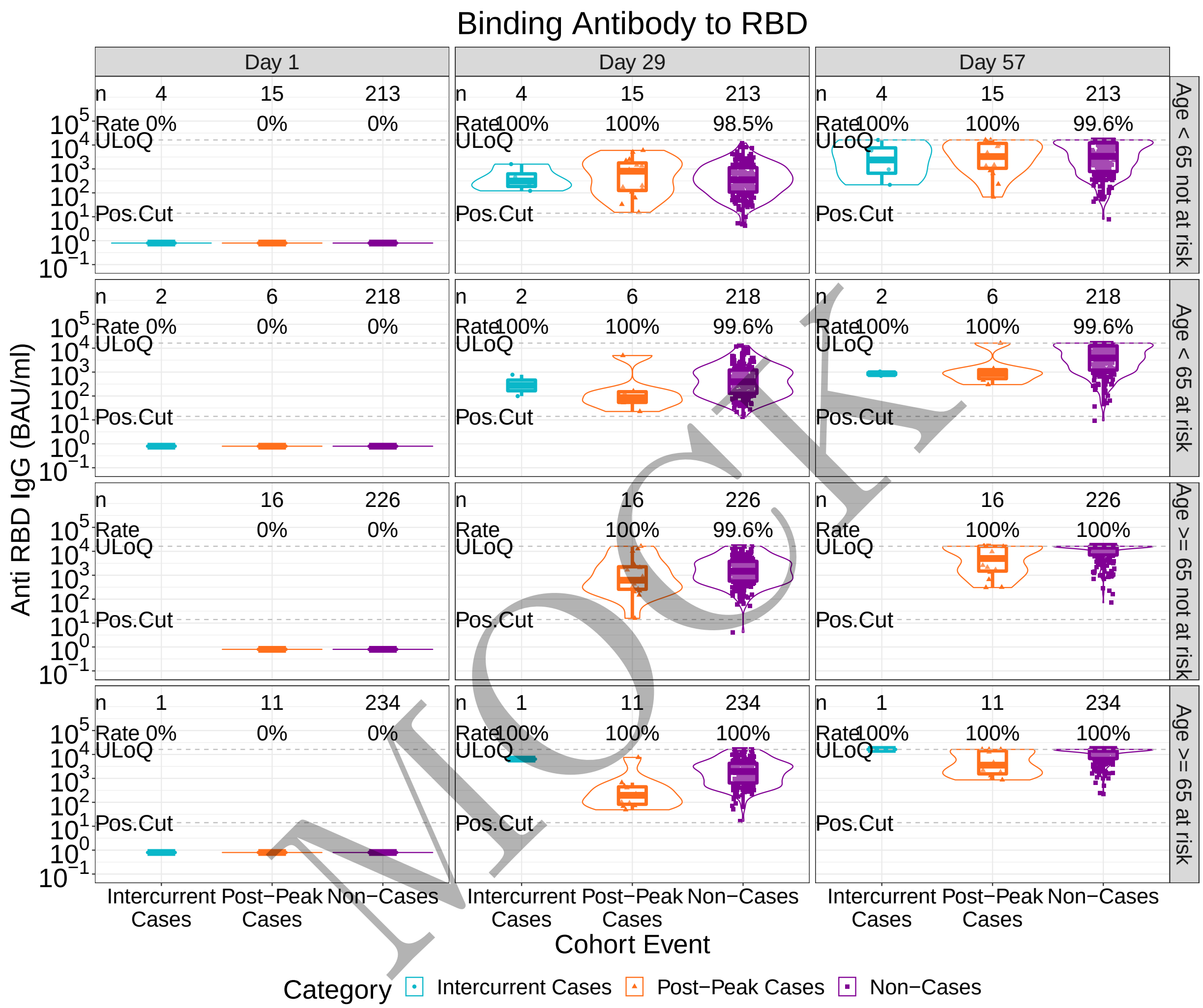
\begin{figure}



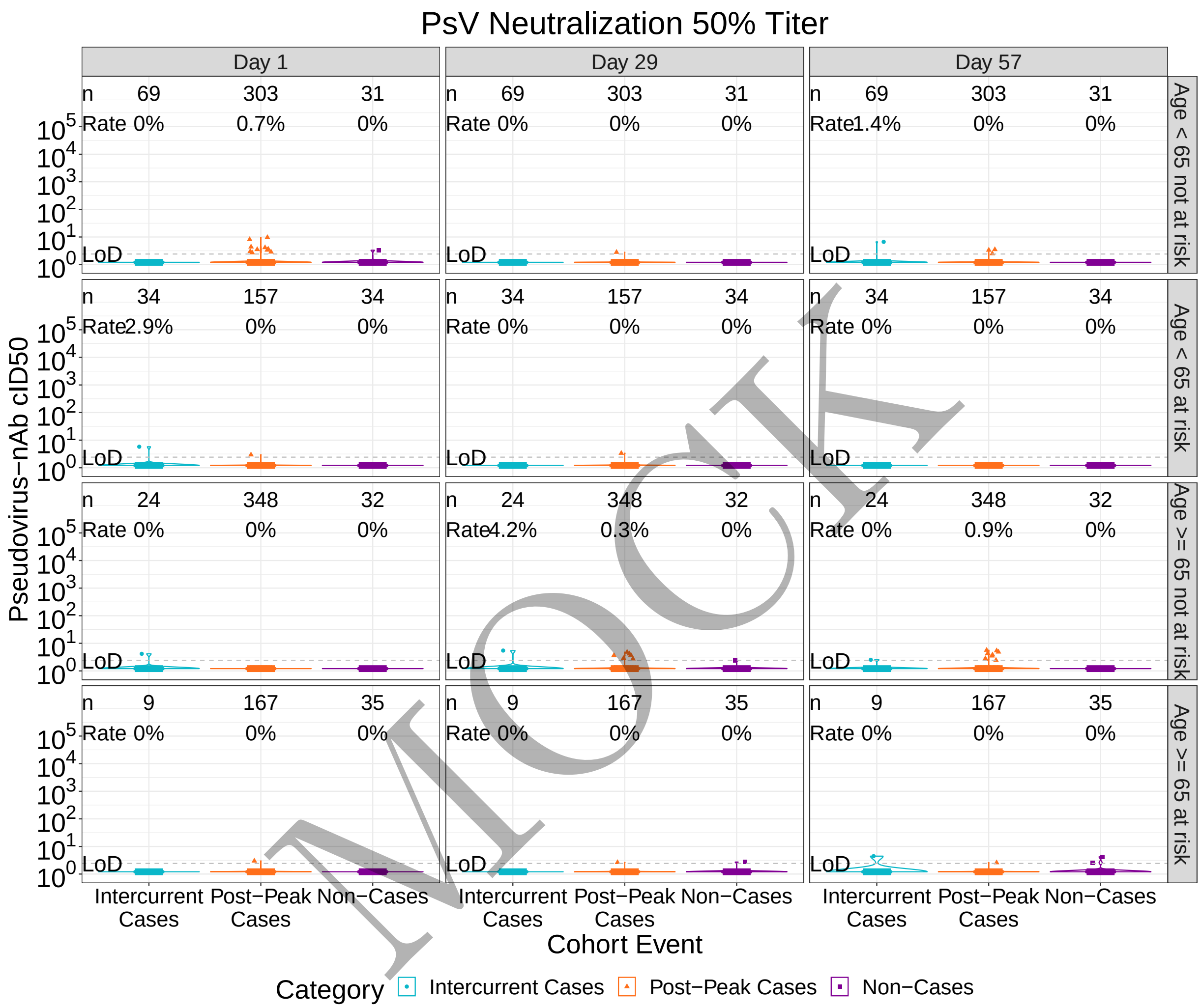
\caption{

Figure 2.5.124: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by age and risk condition (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



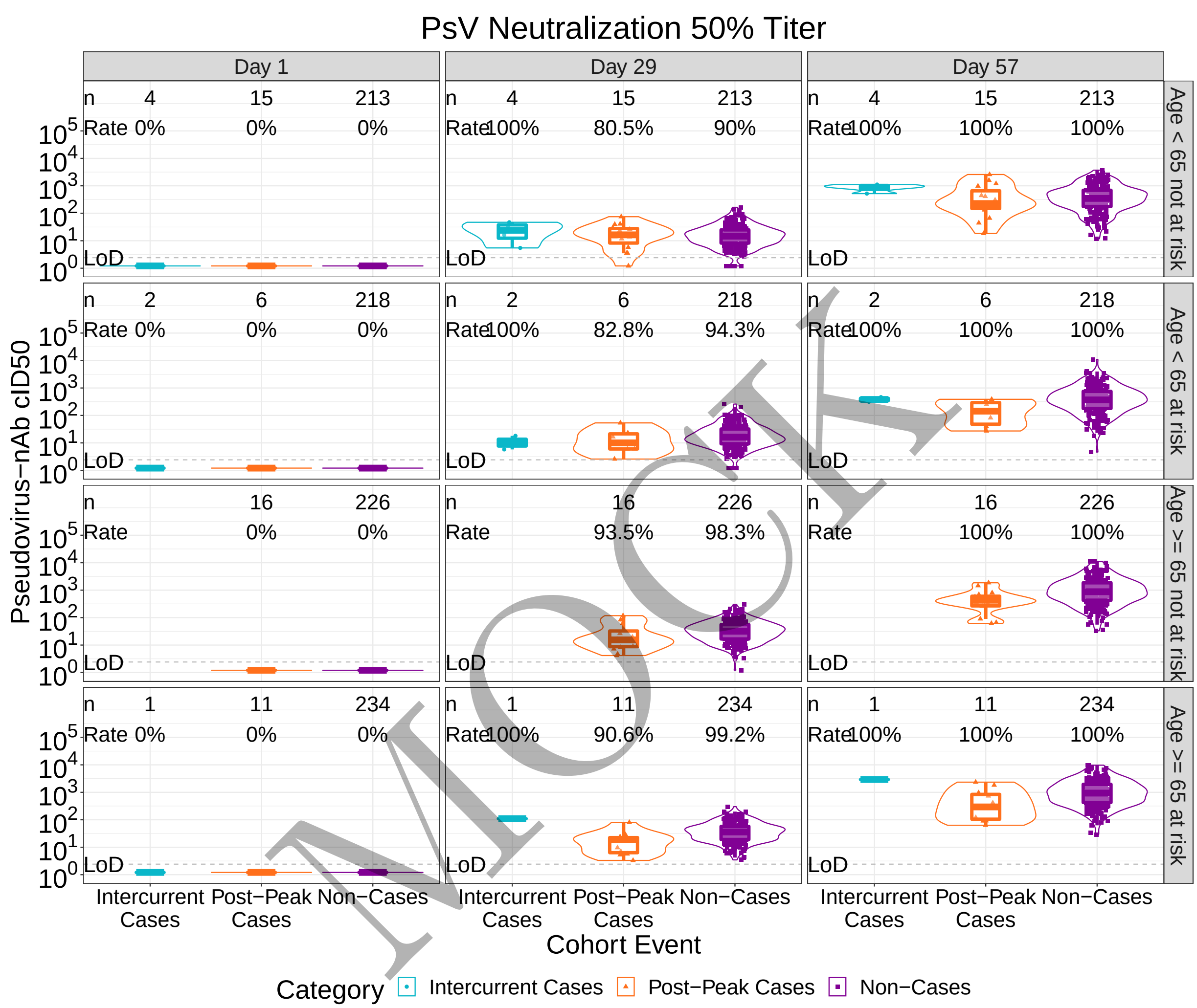
\caption{

Figure 2.5.125: violinplots of PsV Neutralization 50% Titer: baseline negative placebo arm by age and risk condition (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



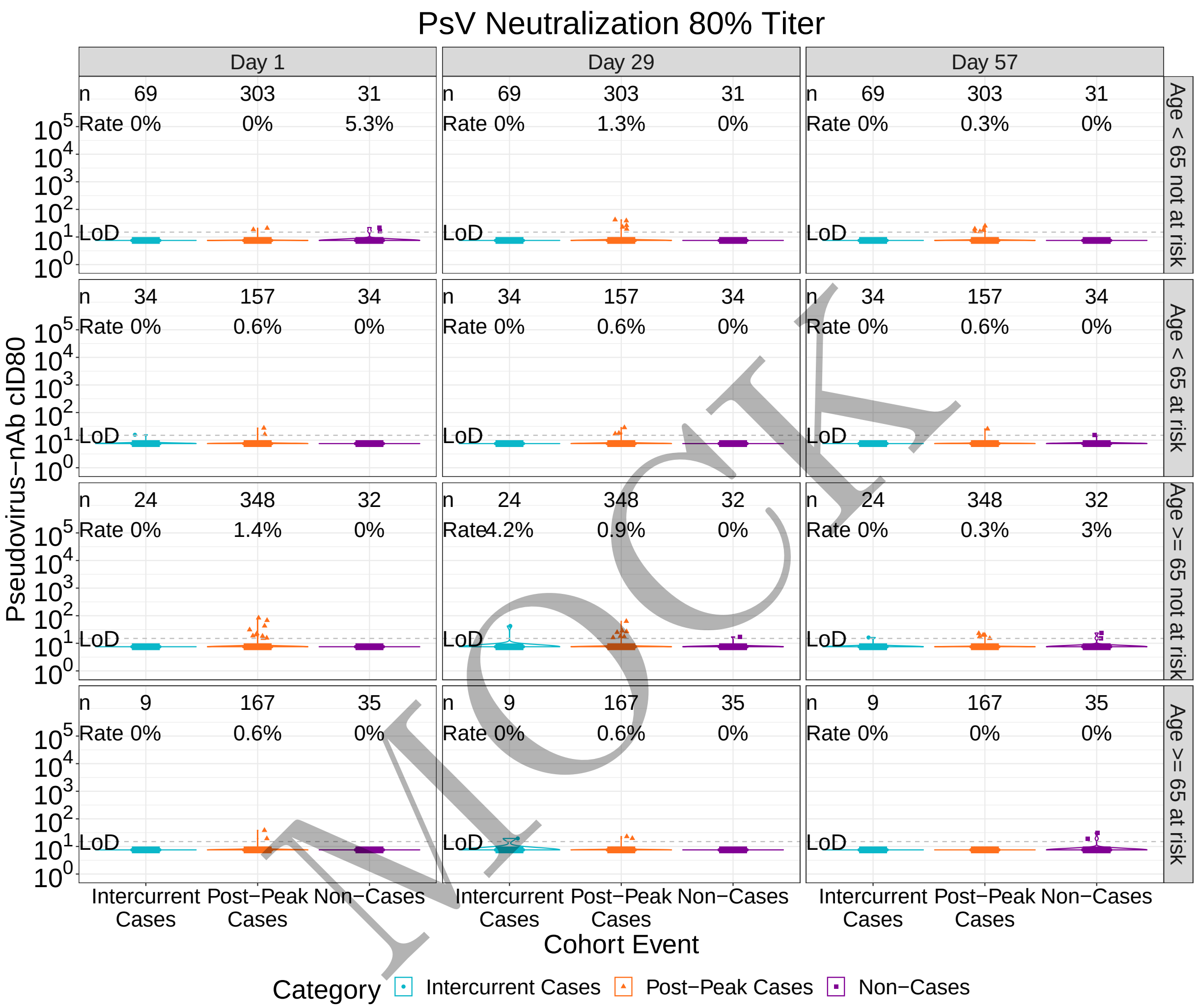
\caption{

Figure 2.5.126: violinplots of PsV Neutralization 50% Titer: baseline negative vaccine arm by age and risk condition (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



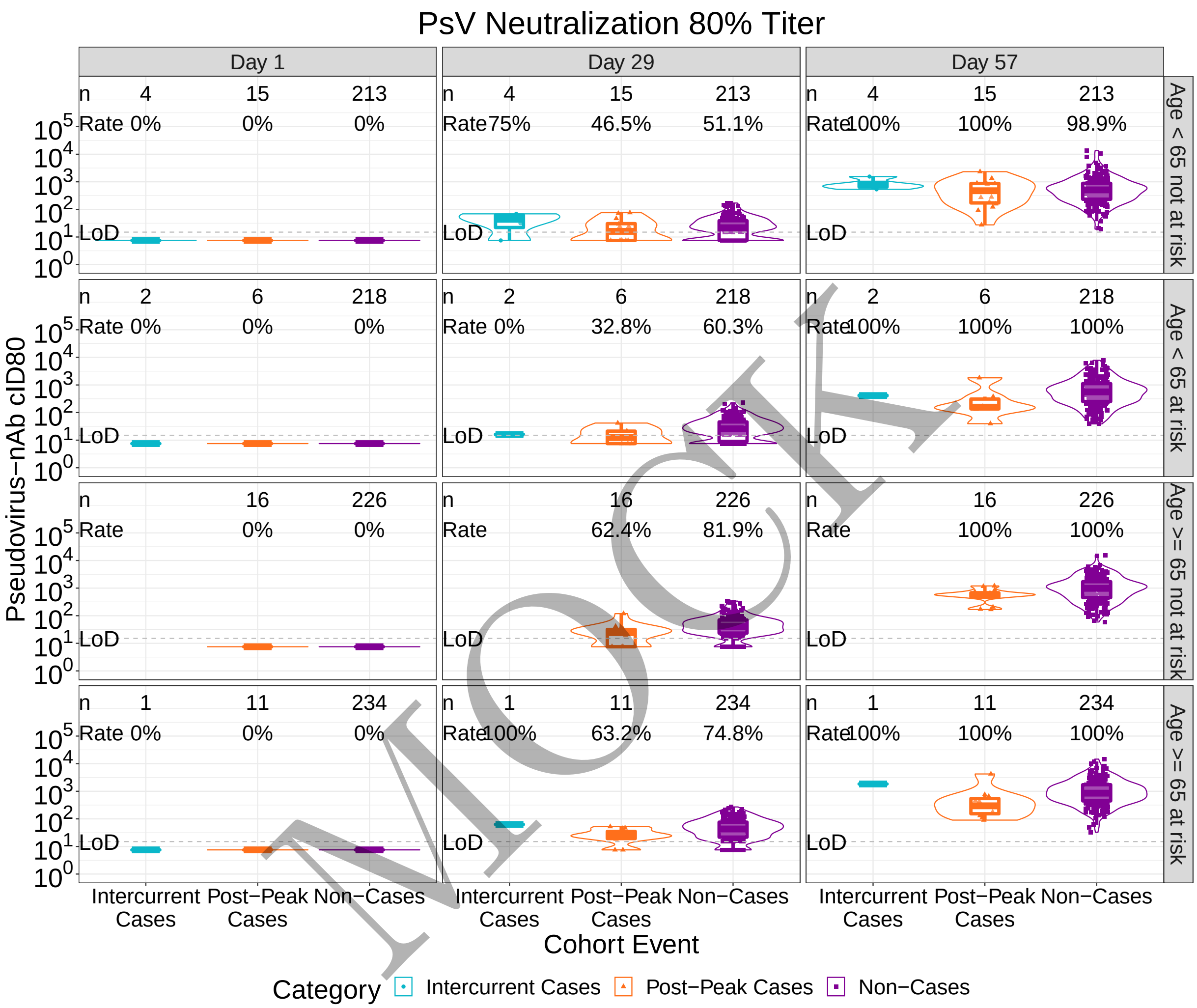
\caption{

Figure 2.5.127: violinplots of PsV Neutralization 80% Titer: baseline negative placebo arm by age and risk condition (version 2)

} \end{figure}

`r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")`

\begin{figure}



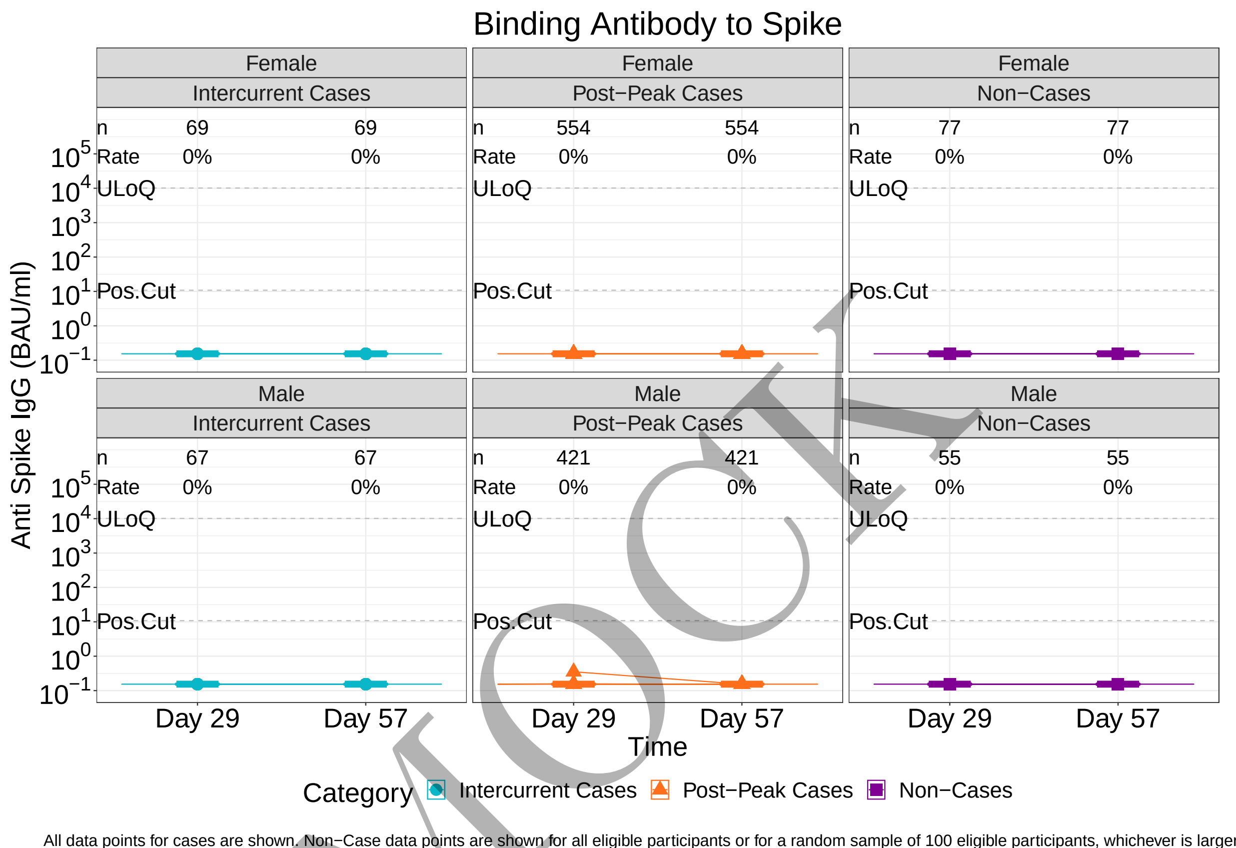
\caption{

Figure 2.5.128: violinplots of PsV Neutralization 80% Titer: baseline negative vaccine arm by age and risk condition (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



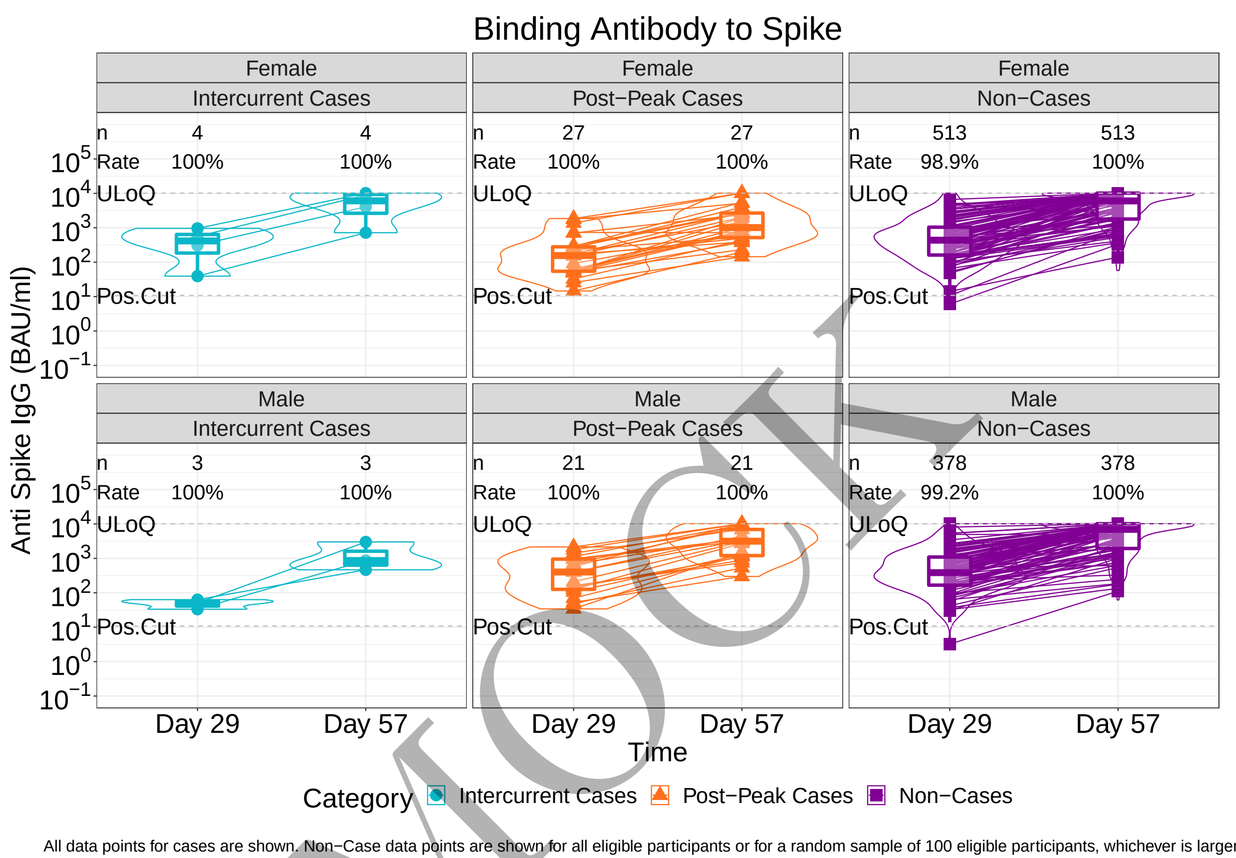
\caption{

Figure 2.5.129: lineplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



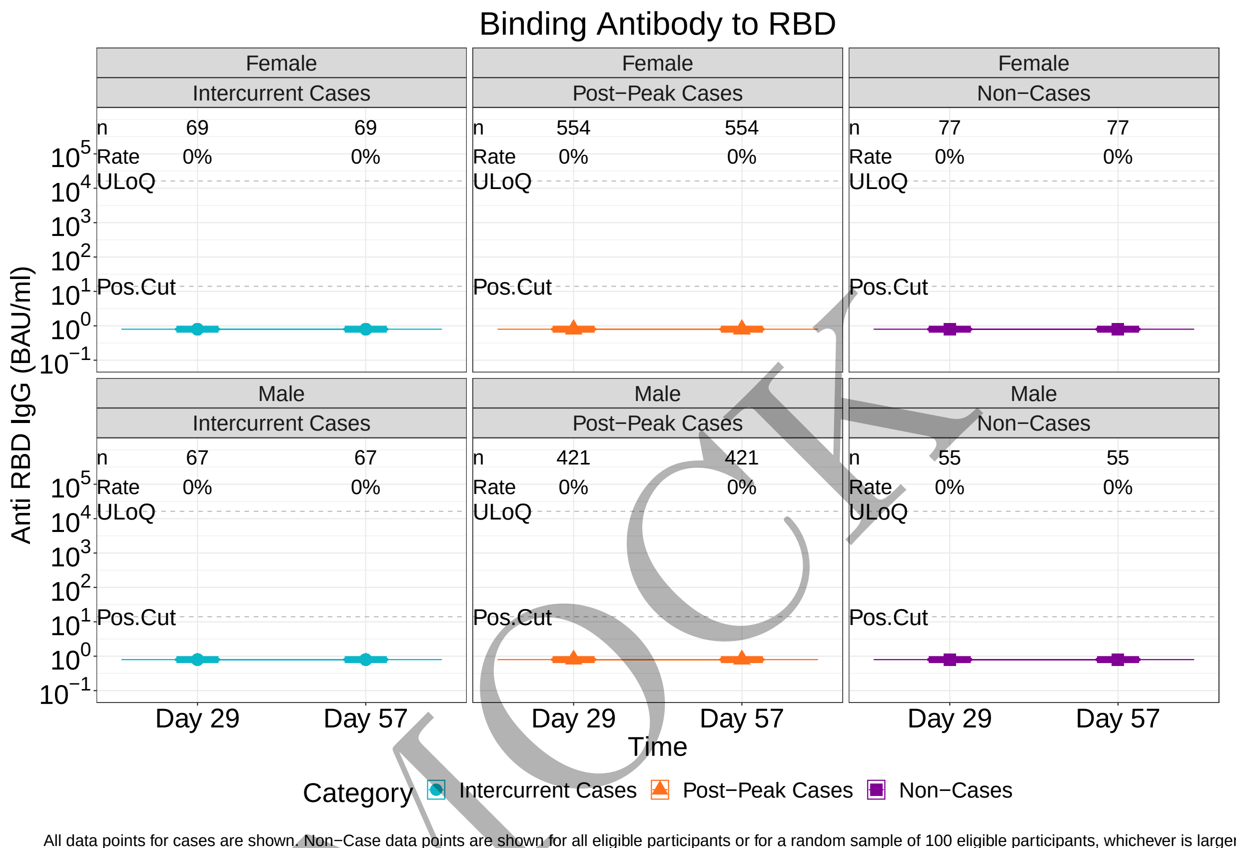
\caption{

Figure 2.5.130: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



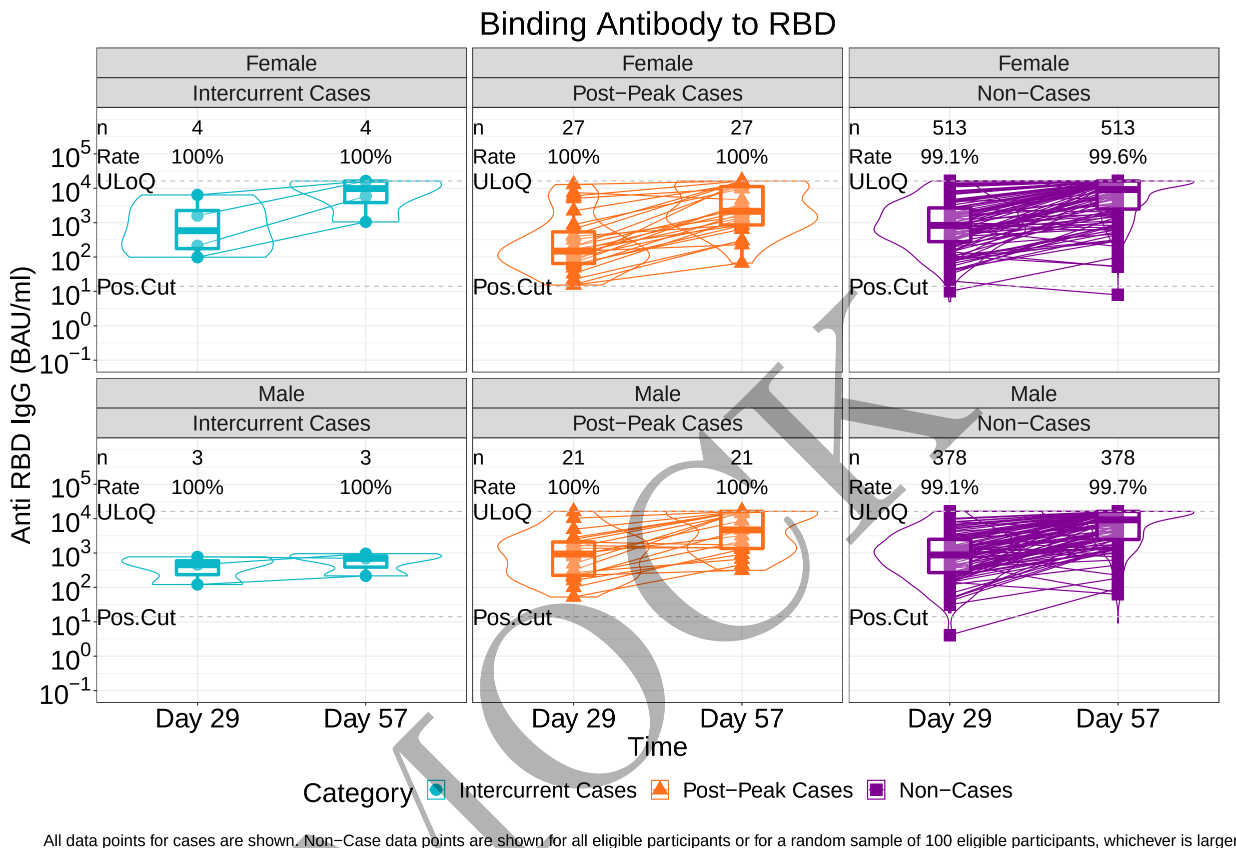
\caption{

Figure 2.5.131: lineplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



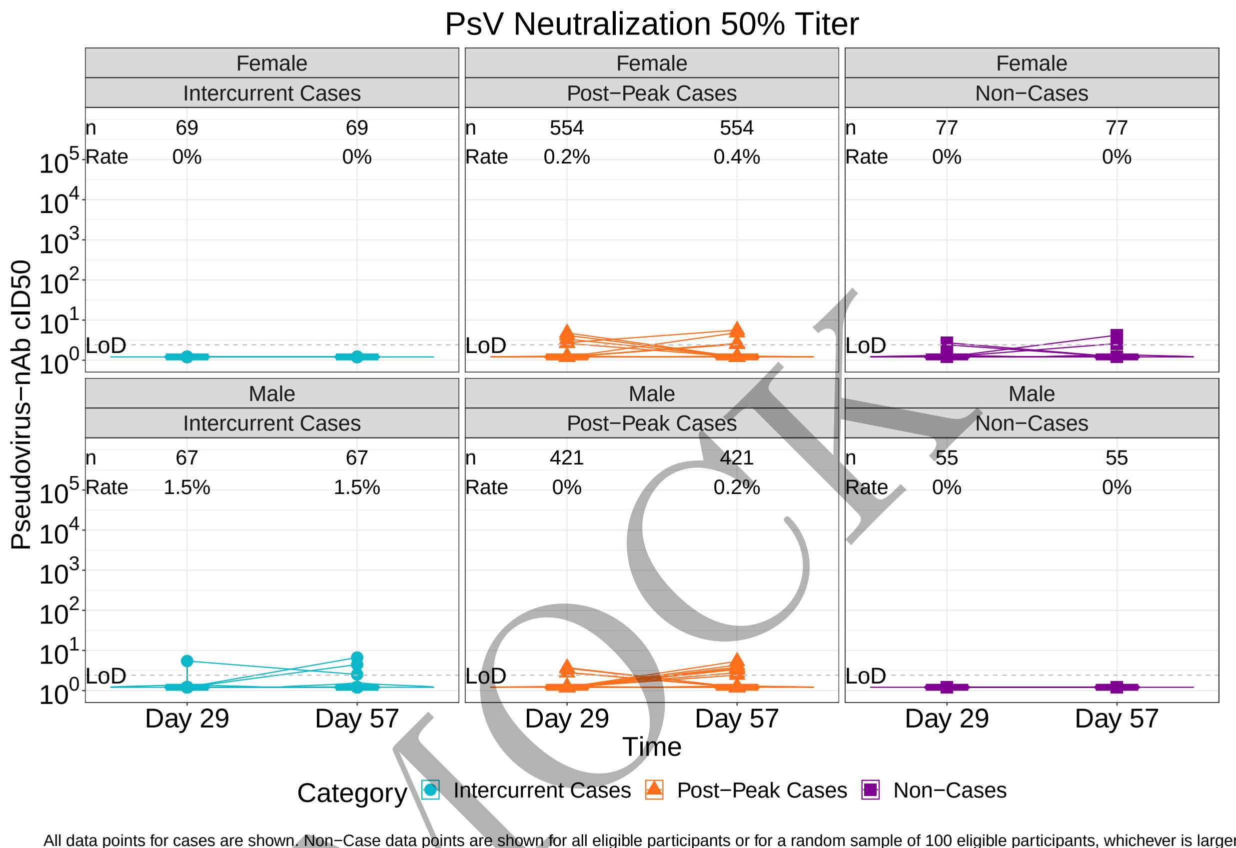
\caption{

Figure 2.5.132: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



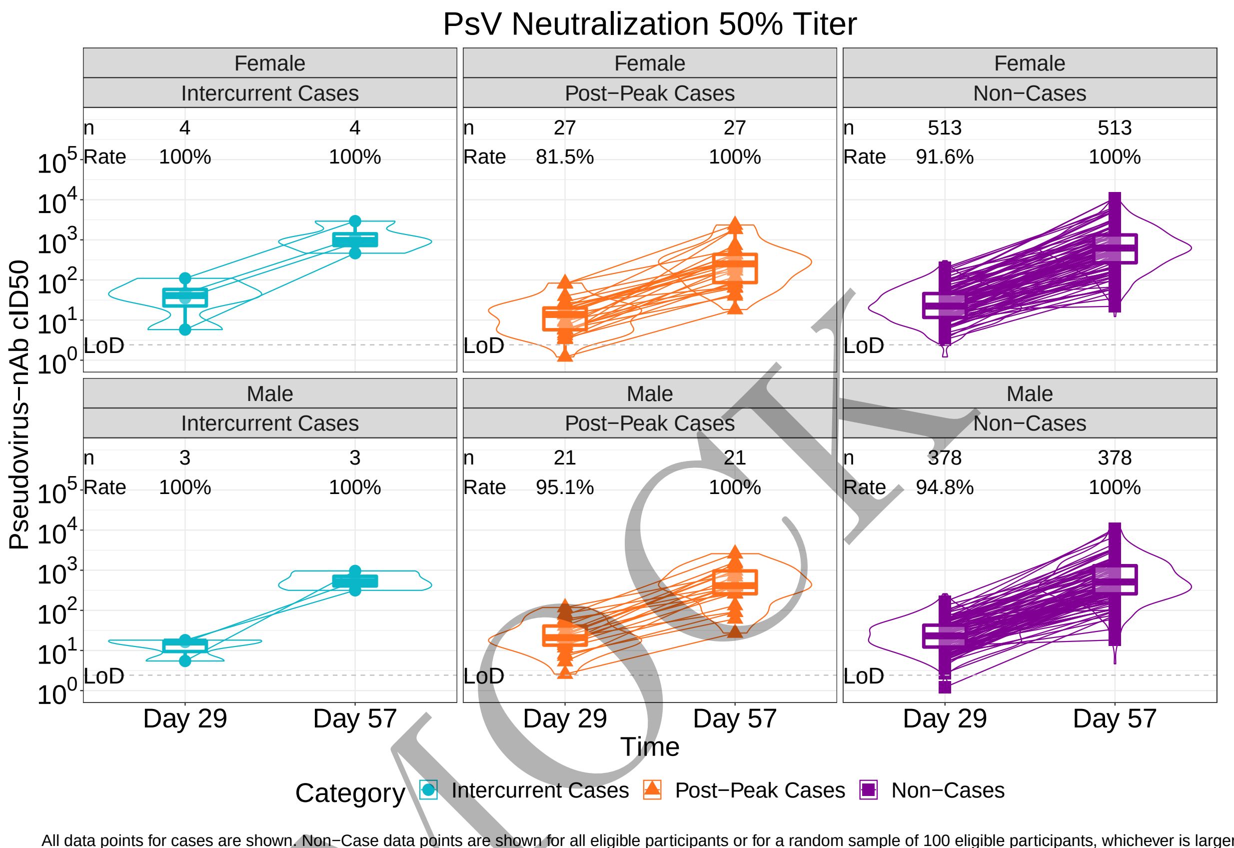
\caption{

Figure 2.5.133: lineplots of PsV Neutralization 50% Titer: baseline negative placebo arm by sex assigned at birth (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



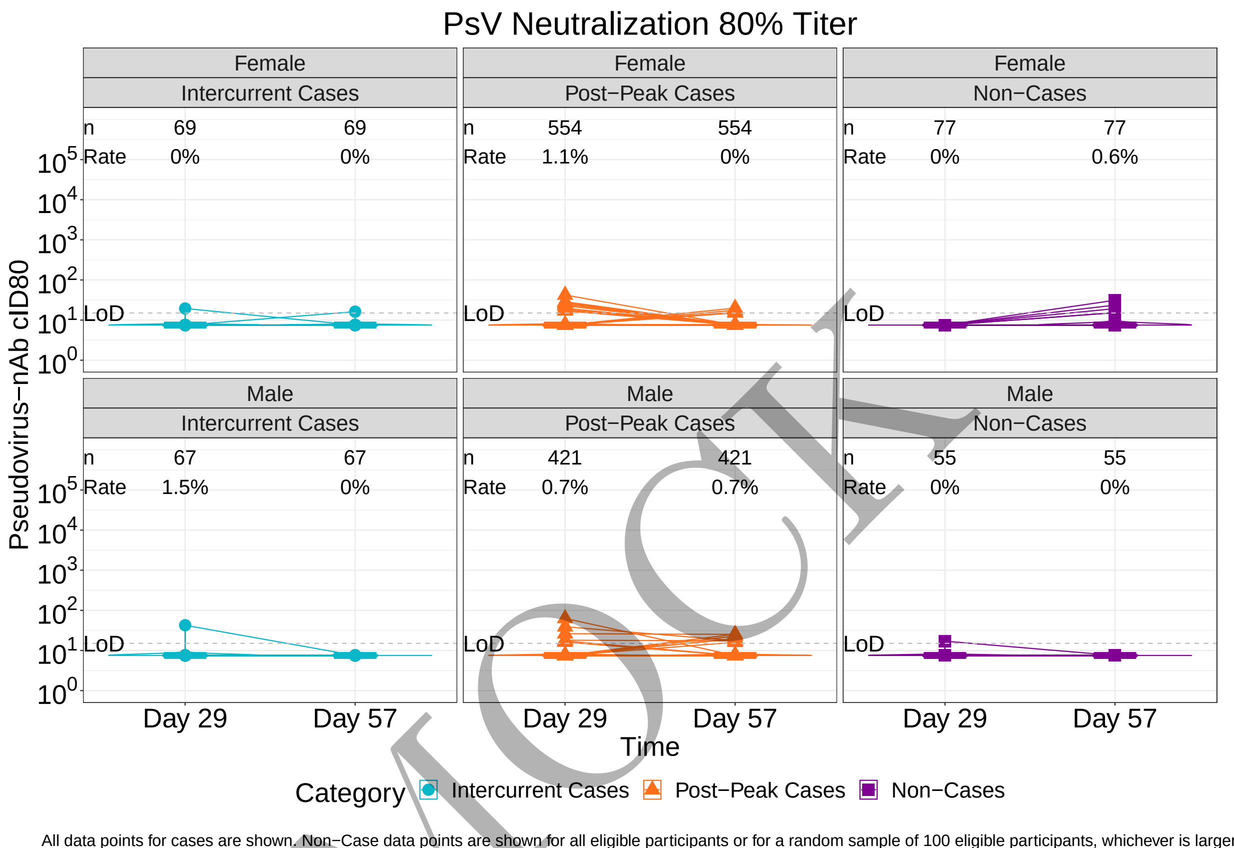
\caption{

Figure 2.5.134: lineplots of PsV Neutralization 50% Titer: baseline negative vaccine arm by sex assigned at birth (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



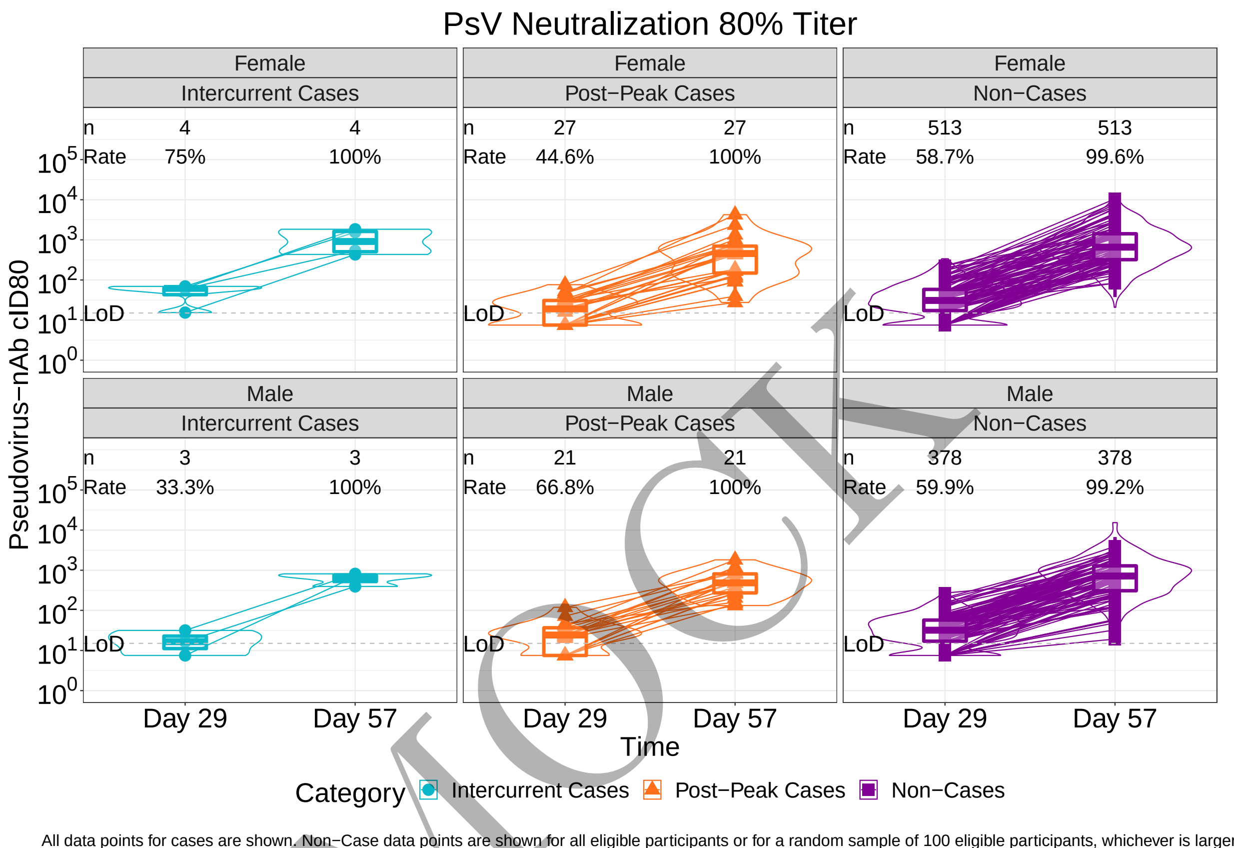
\caption{

Figure 2.5.135: lineplots of PsV Neutralization 80% Titer: baseline negative placebo arm by sex assigned at birth (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



\caption{

Figure 2.5.136: lineplots of PsV Neutralization 80% Titer: baseline negative vaccine arm by sex assigned at birth (version 1)

} \end{figure}

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r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")
```
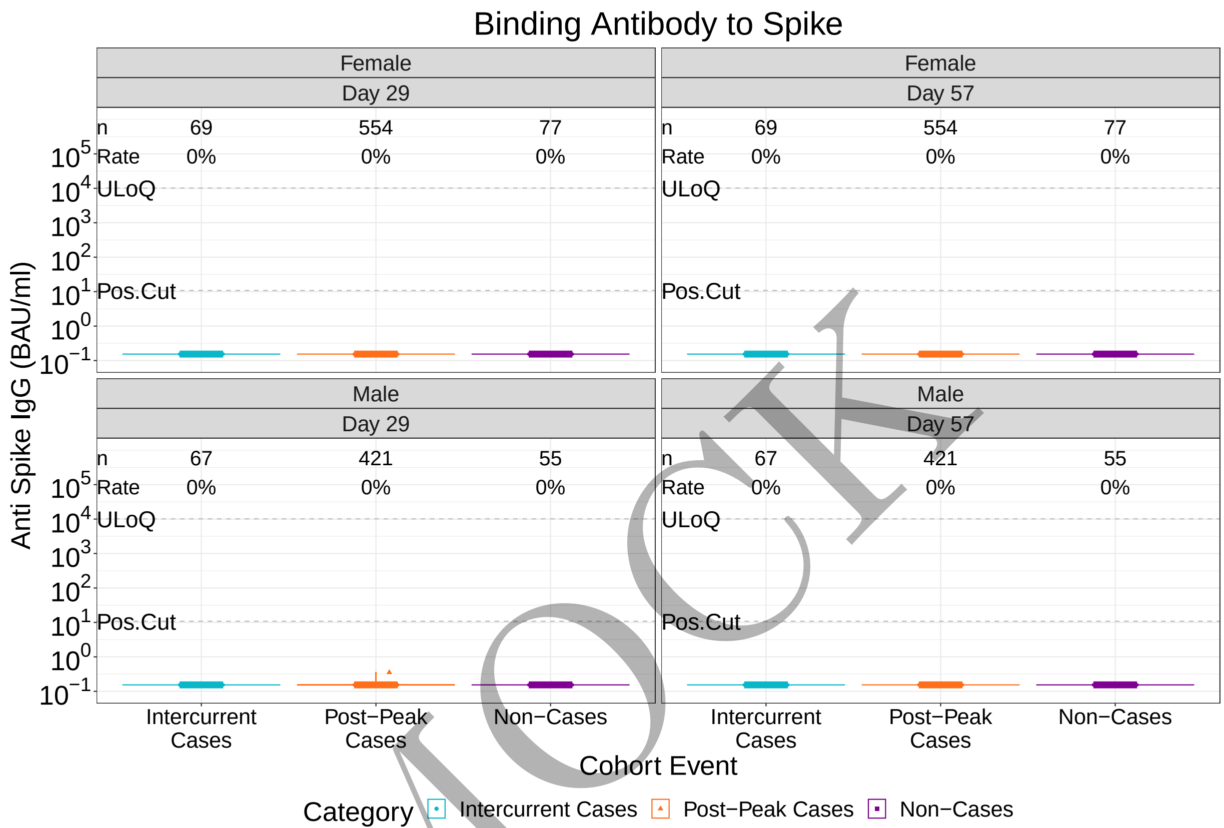

\begin{figure}



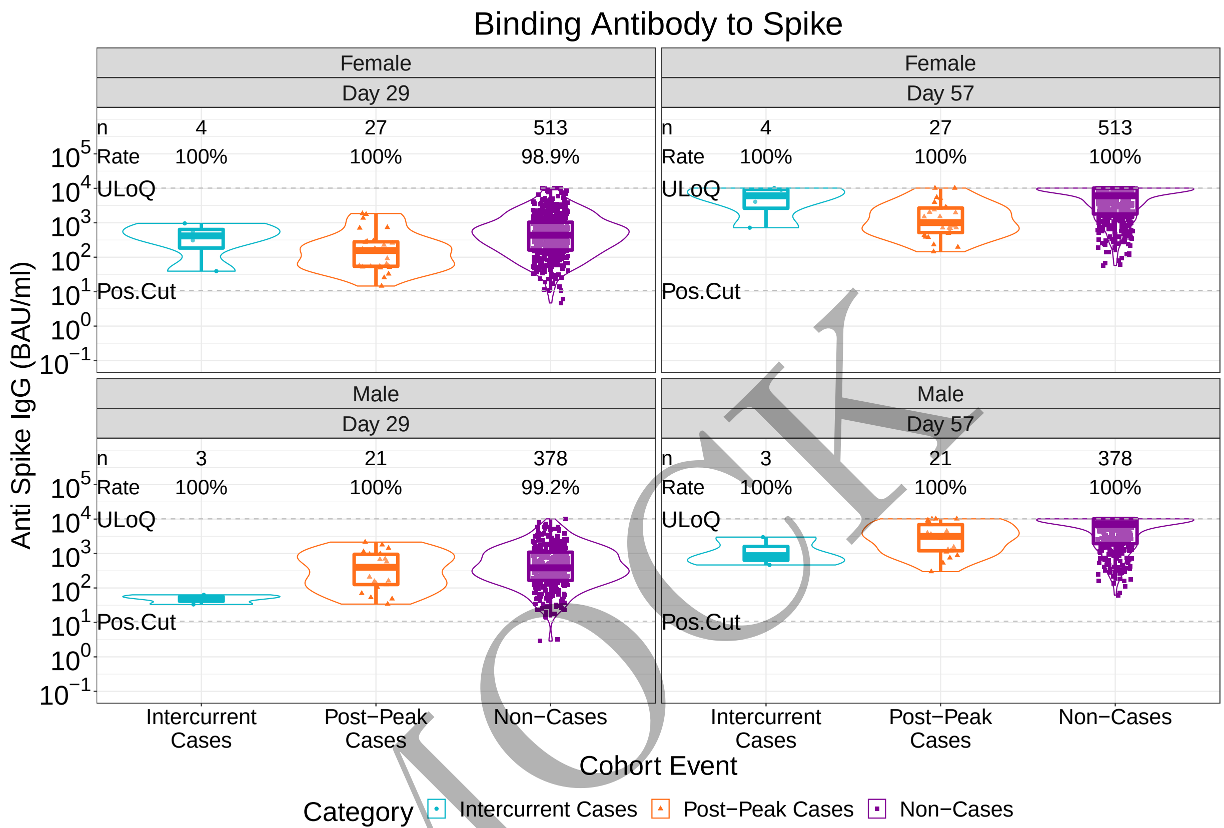
\caption{

Figure 2.5.137: violinplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



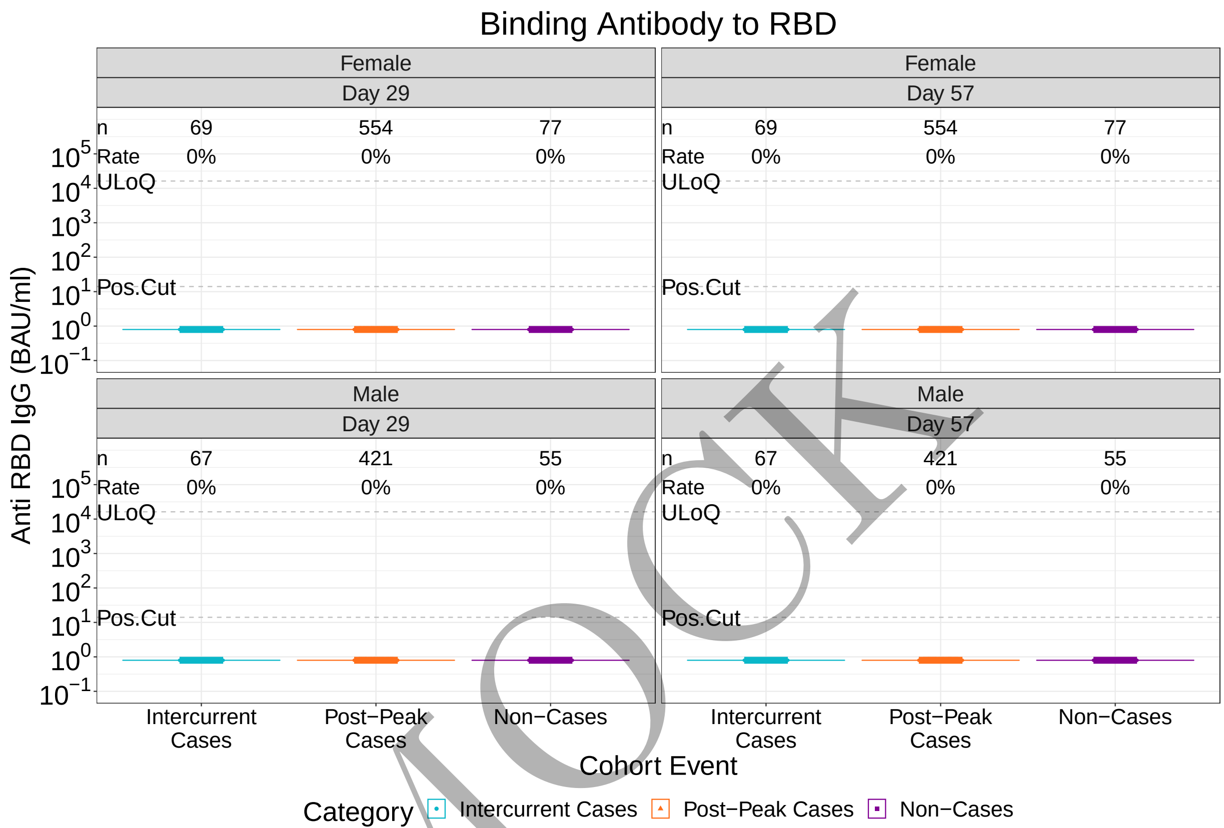
\caption{

Figure 2.5.138: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



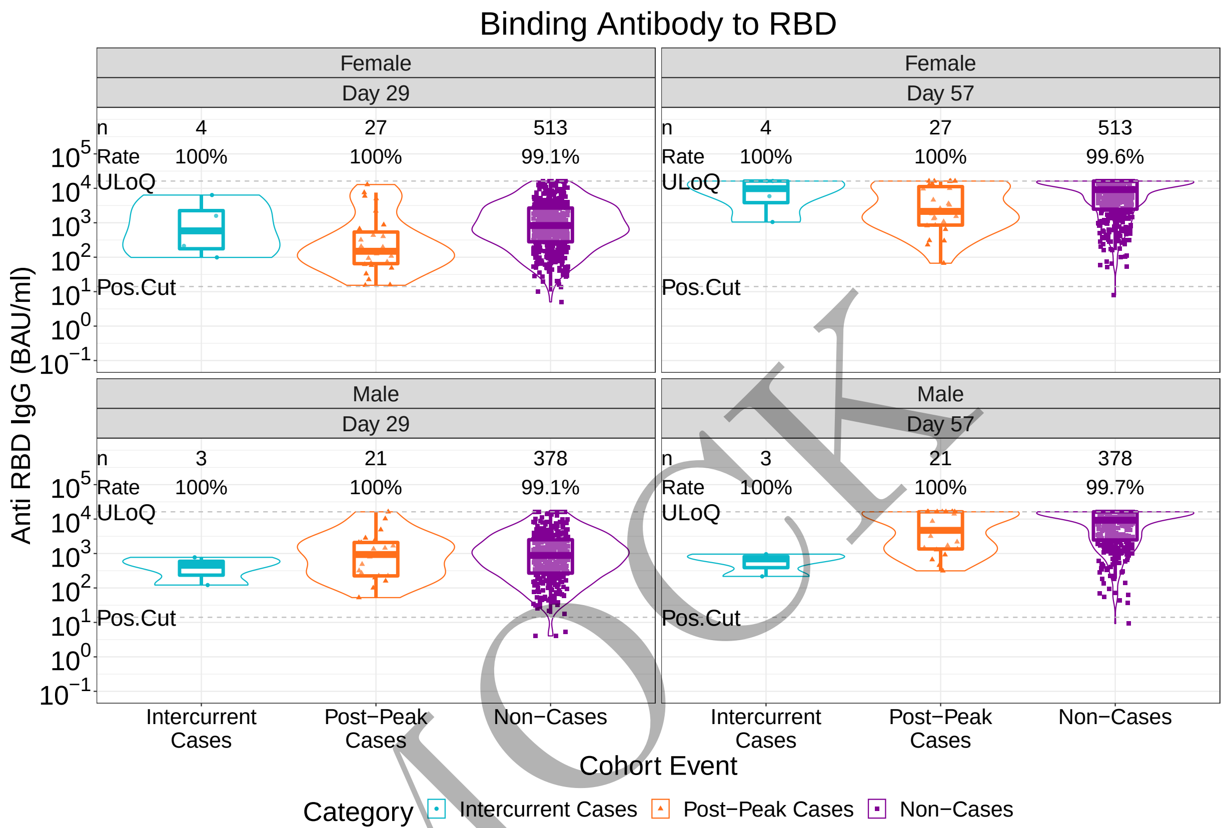
\caption{

Figure 2.5.139: violinplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



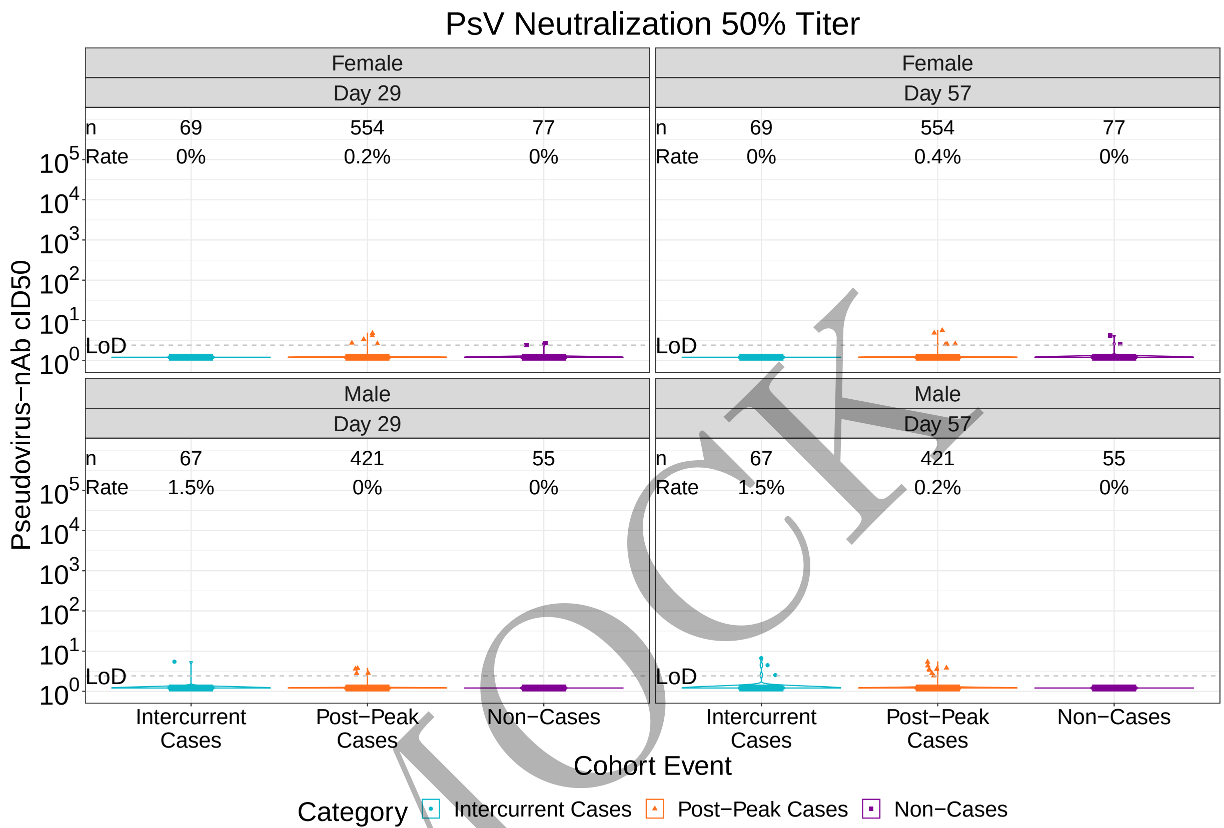
\caption{

Figure 2.5.140: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



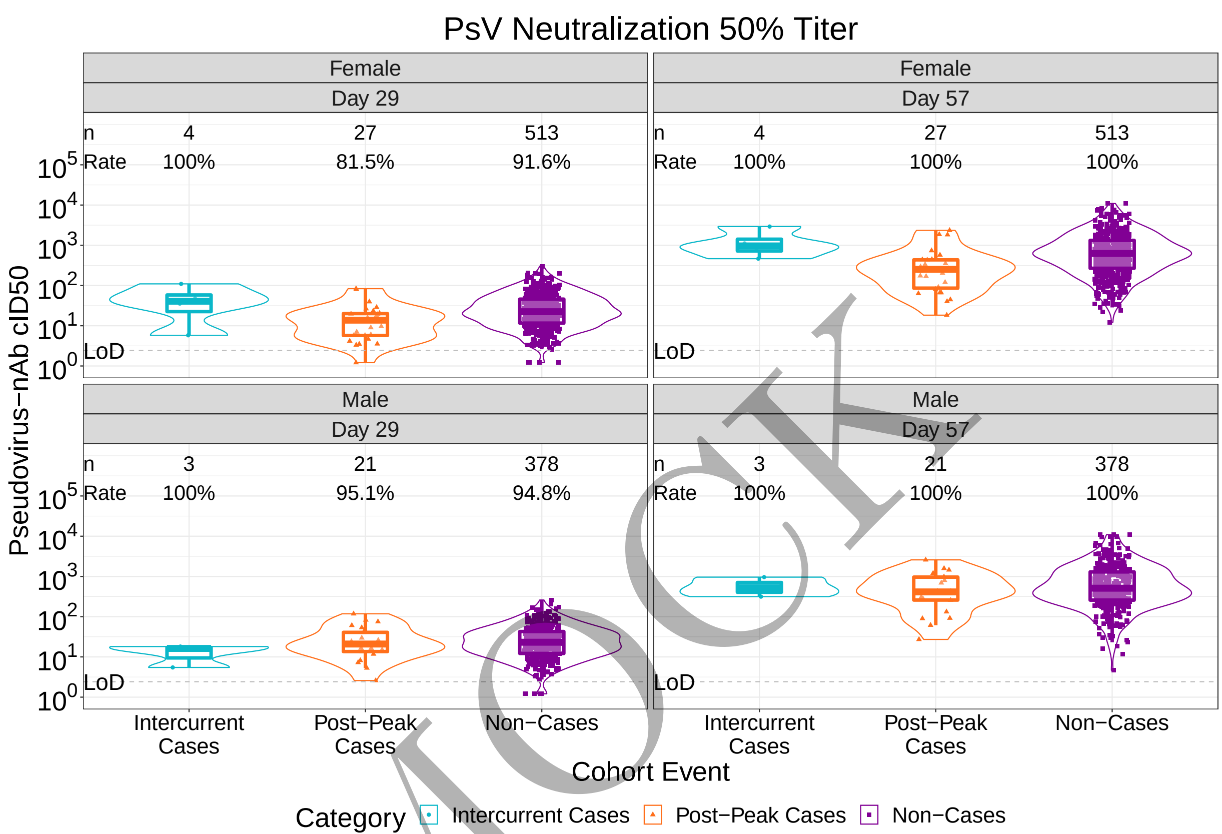
\caption{

Figure 2.5.141: violinplots of PsV Neutralization 50% Titer: baseline negative placebo arm by sex assigned at birth (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



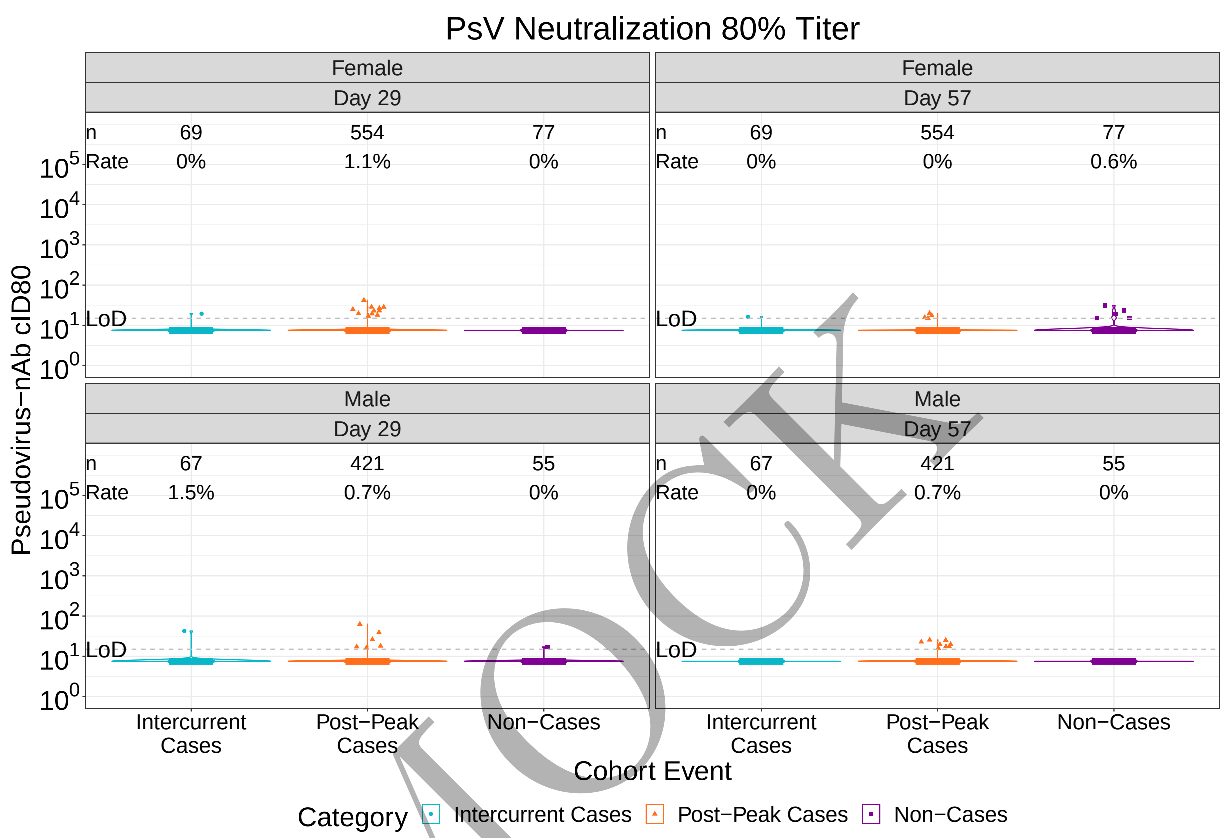
\caption{

Figure 2.5.142: violinplots of PsV Neutralization 50% Titer: baseline negative vaccine arm by sex assigned at birth (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



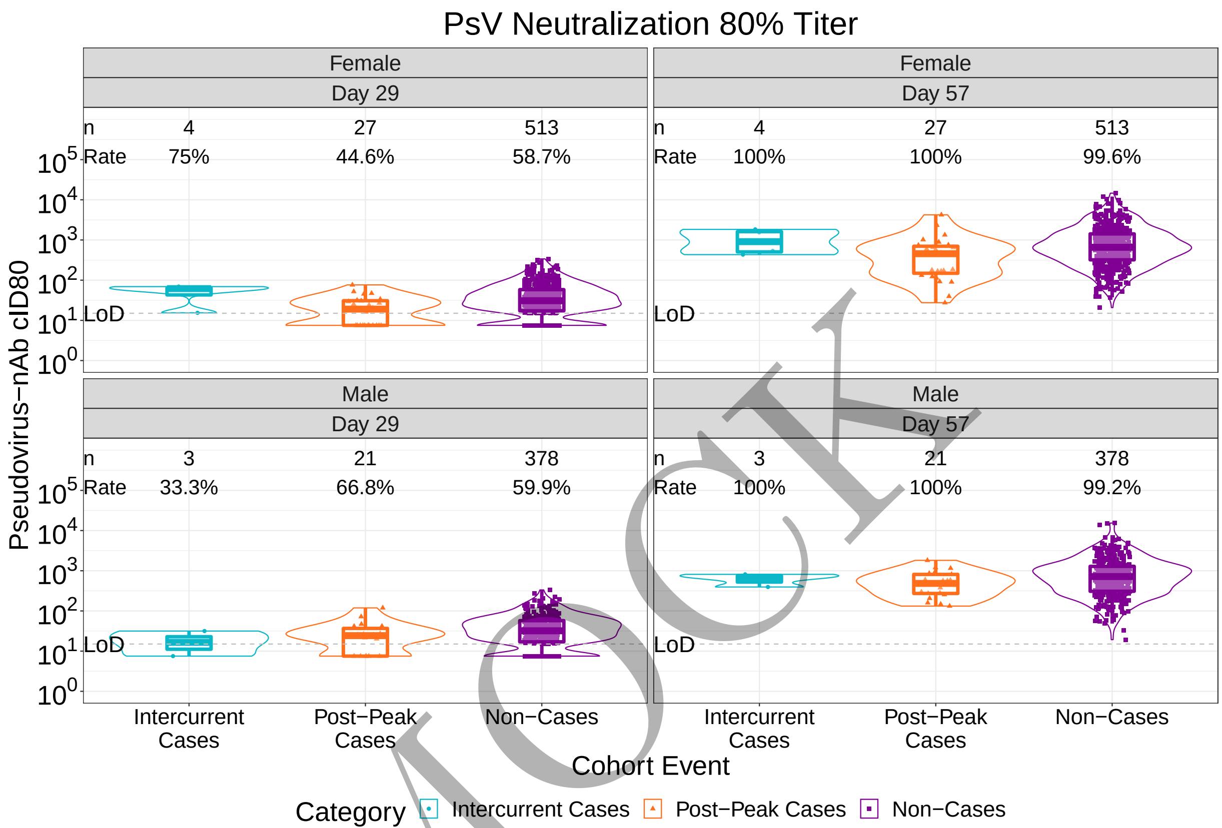
\caption{

Figure 2.5.143: violinplots of PsV Neutralization 80% Titer: baseline negative placebo arm by sex assigned at birth (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



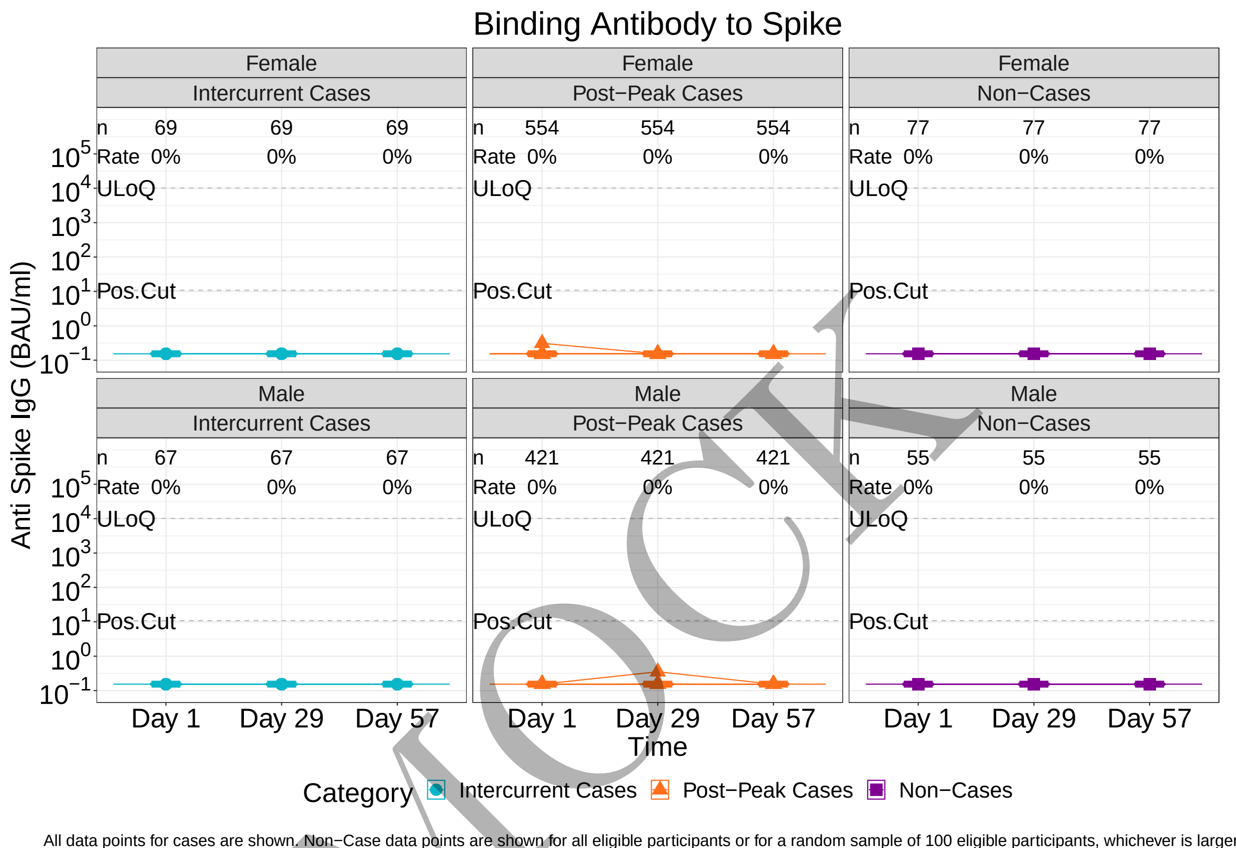
\caption{

Figure 2.5.144: violinplots of PsV Neutralization 80% Titer: baseline negative vaccine arm by sex assigned at birth (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



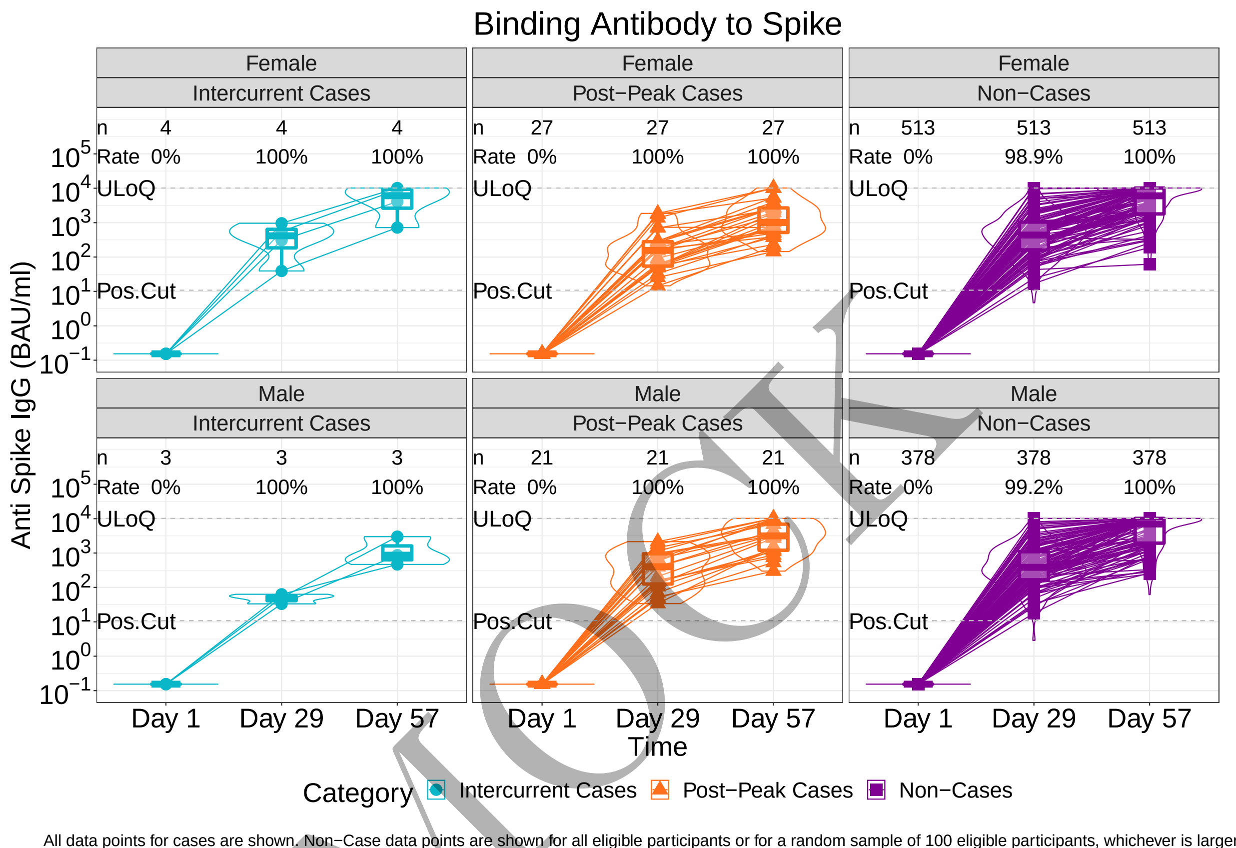
\caption{

Figure 2.5.145: lineplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



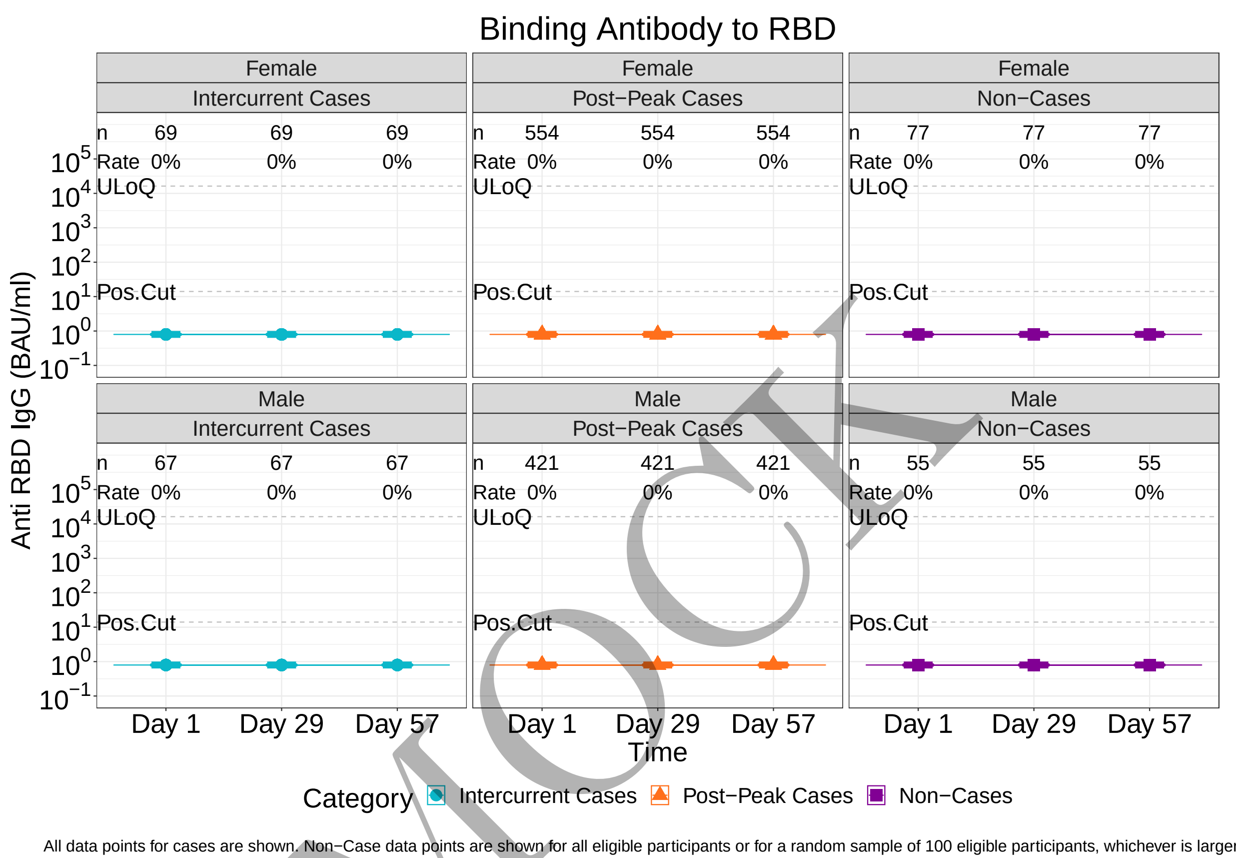
\caption{

Figure 2.5.146: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



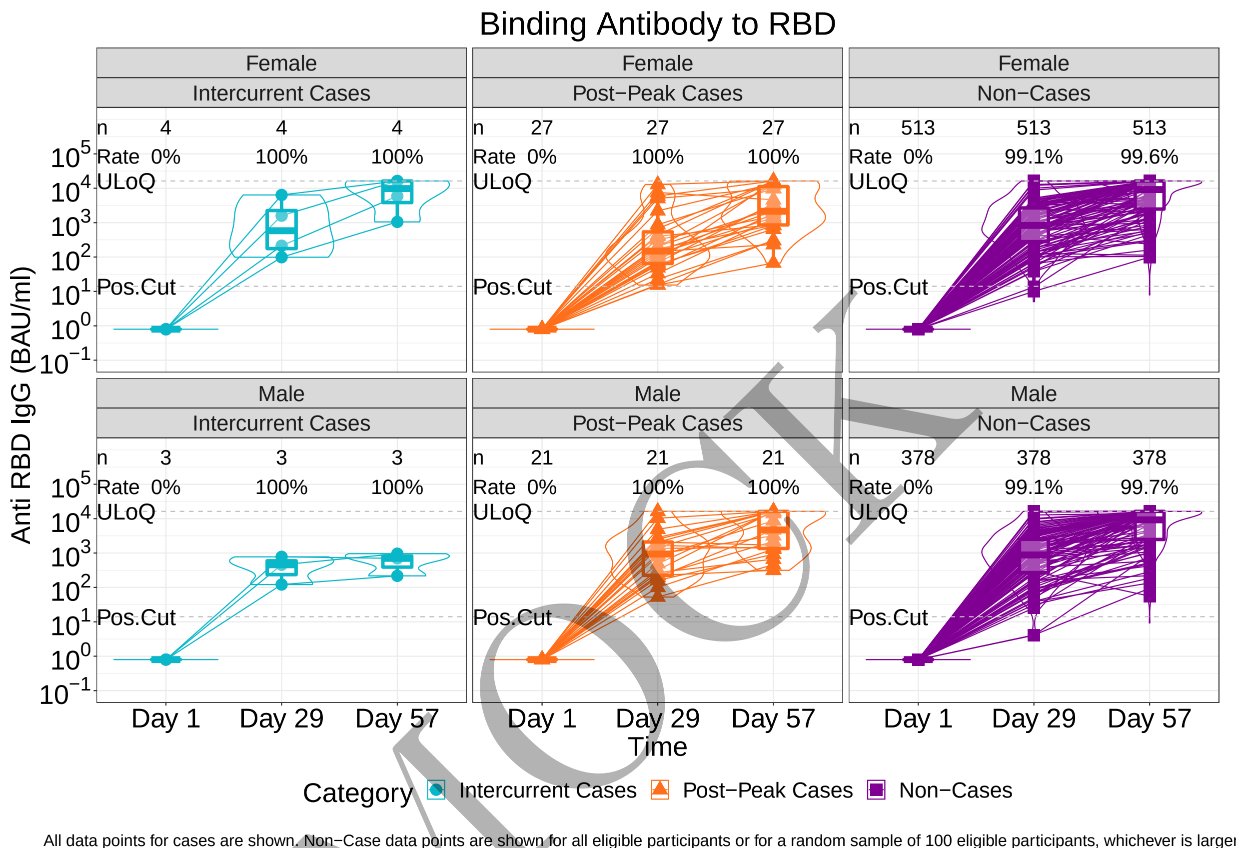
\caption{

Figure 2.5.147: lineplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



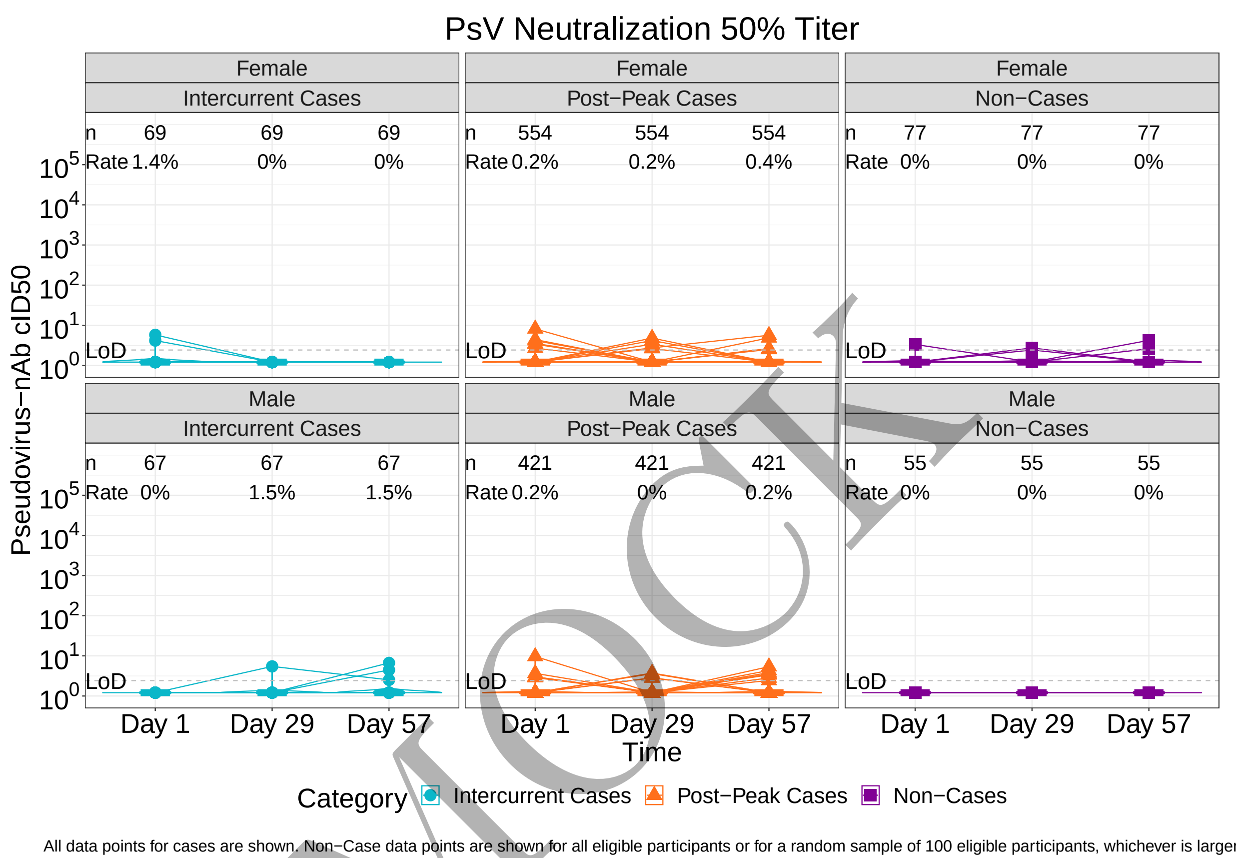
\caption{

Figure 2.5.148: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



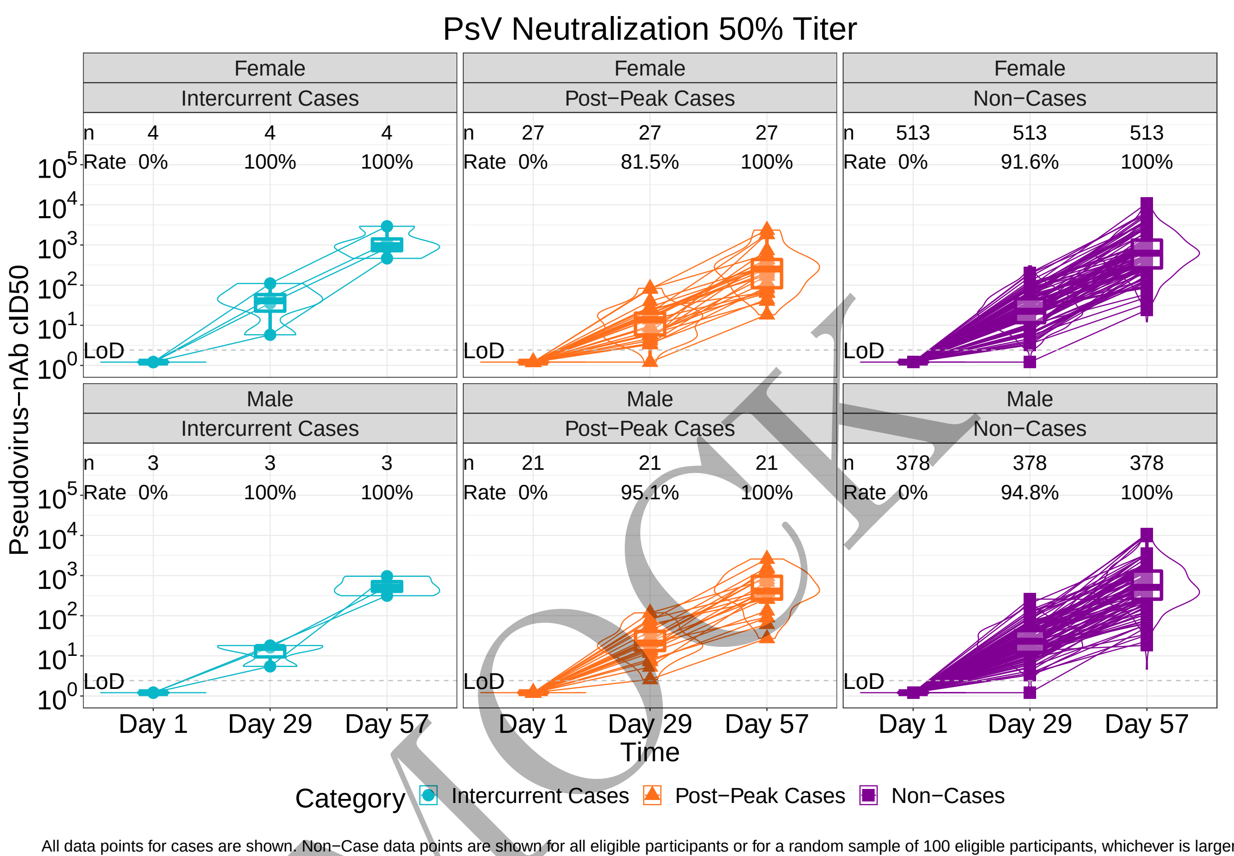
\caption{

Figure 2.5.149: lineplots of PsV Neutralization 50% Titer: baseline negative placebo arm by sex assigned at birth (version 2)

} \end{figure}

`r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")`

\begin{figure}



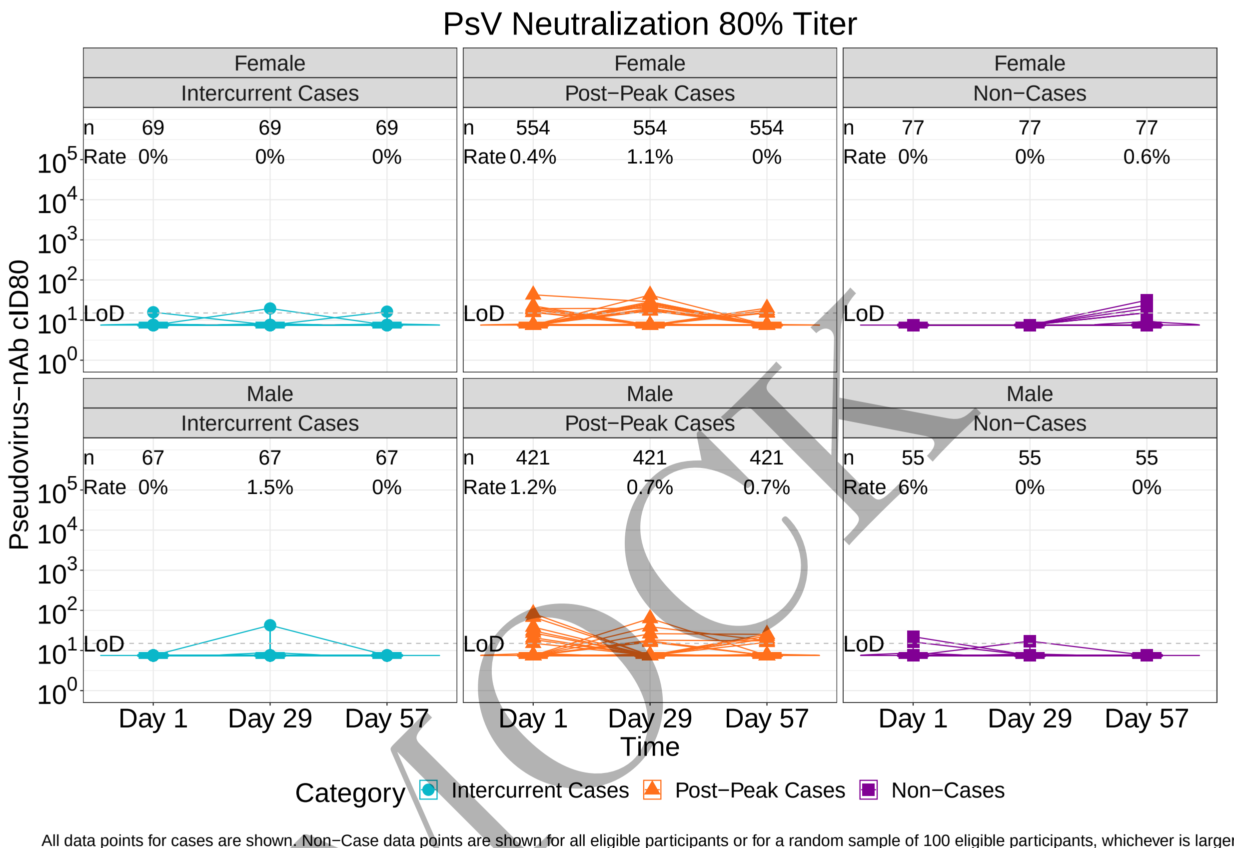
\caption{

Figure 2.5.150: lineplots of PsV Neutralization 50% Titer: baseline negative vaccine arm by sex assigned at birth (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



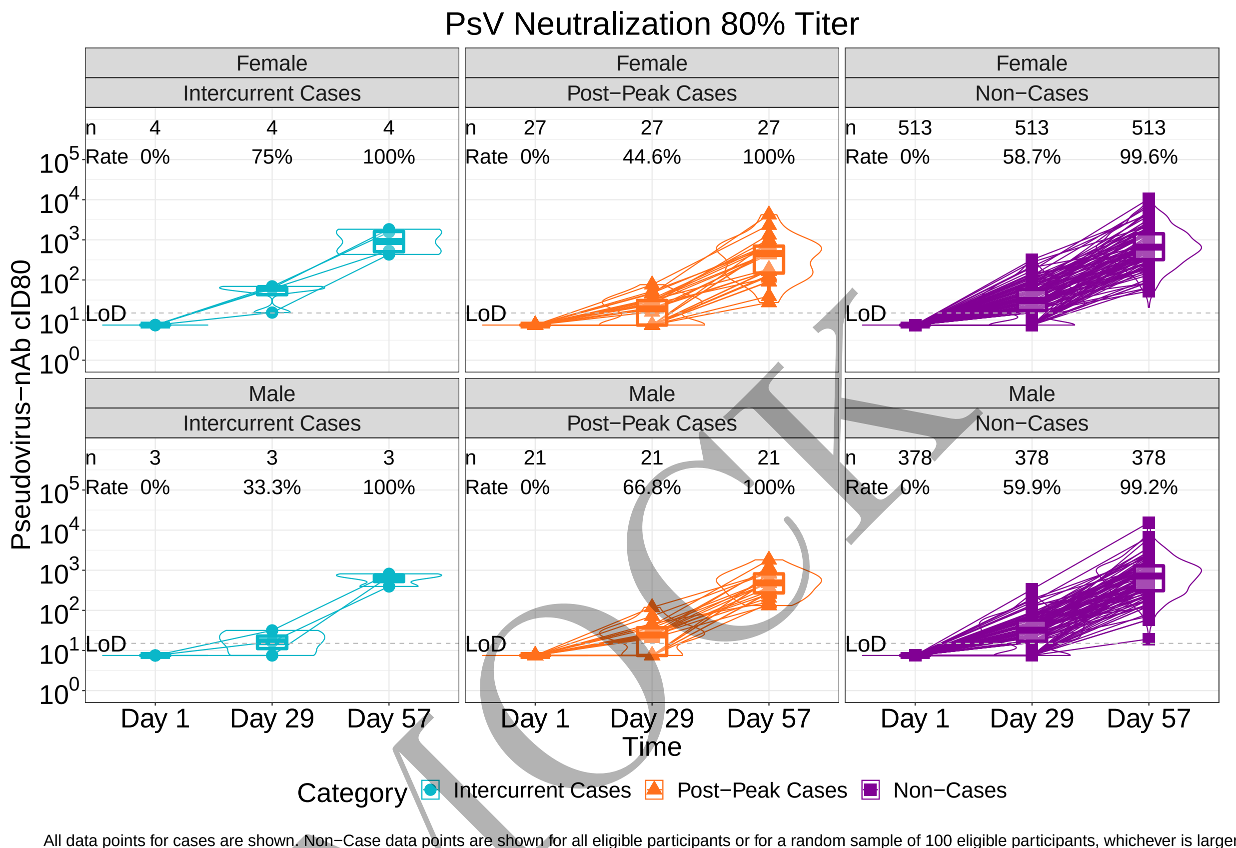
\caption{

Figure 2.5.151: lineplots of PsV Neutralization 80% Titer: baseline negative placebo arm by sex assigned at birth (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



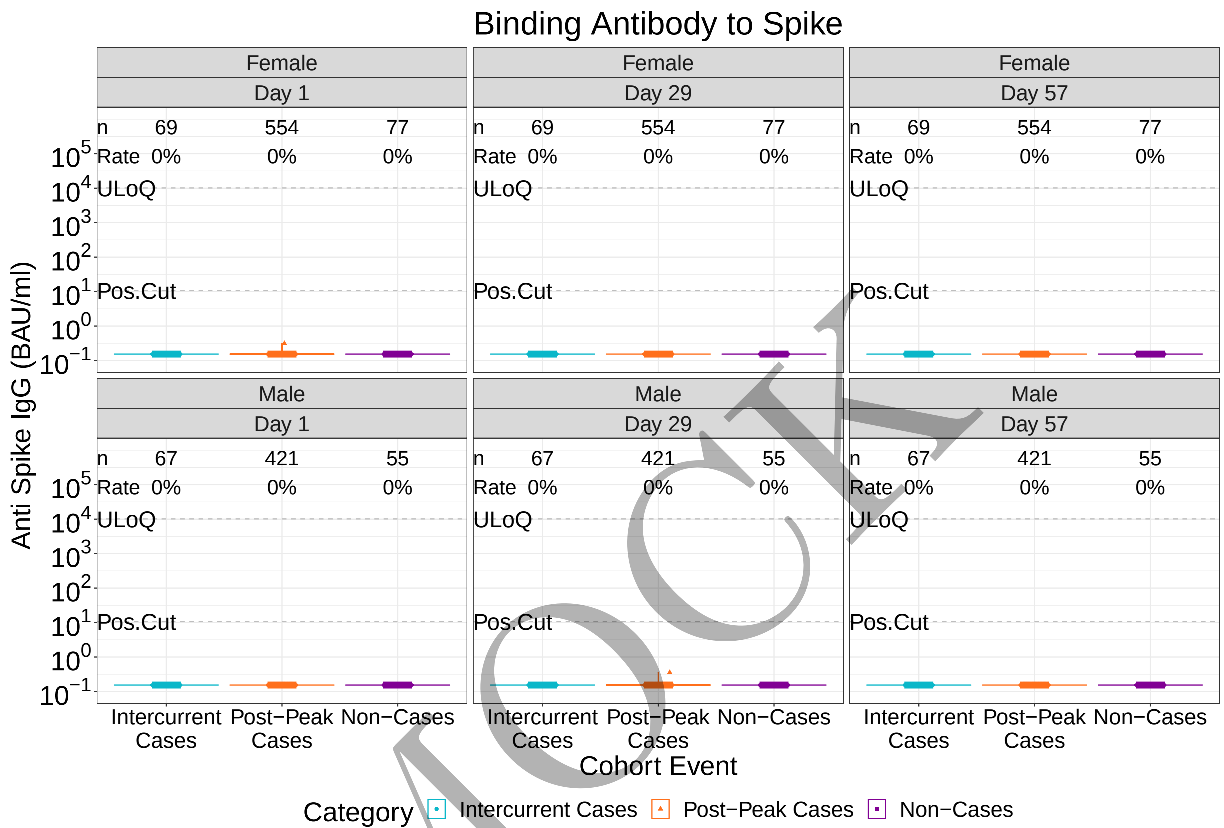
\caption{

Figure 2.5.152: lineplots of PsV Neutralization 80% Titer: baseline negative vaccine arm by sex assigned at birth (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



\caption{

Figure 2.5.153: violinplots of Binding Antibody to Spike: baseline negative placebo arm by sex assigned at birth (version 2)

} \end{figure}

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r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")
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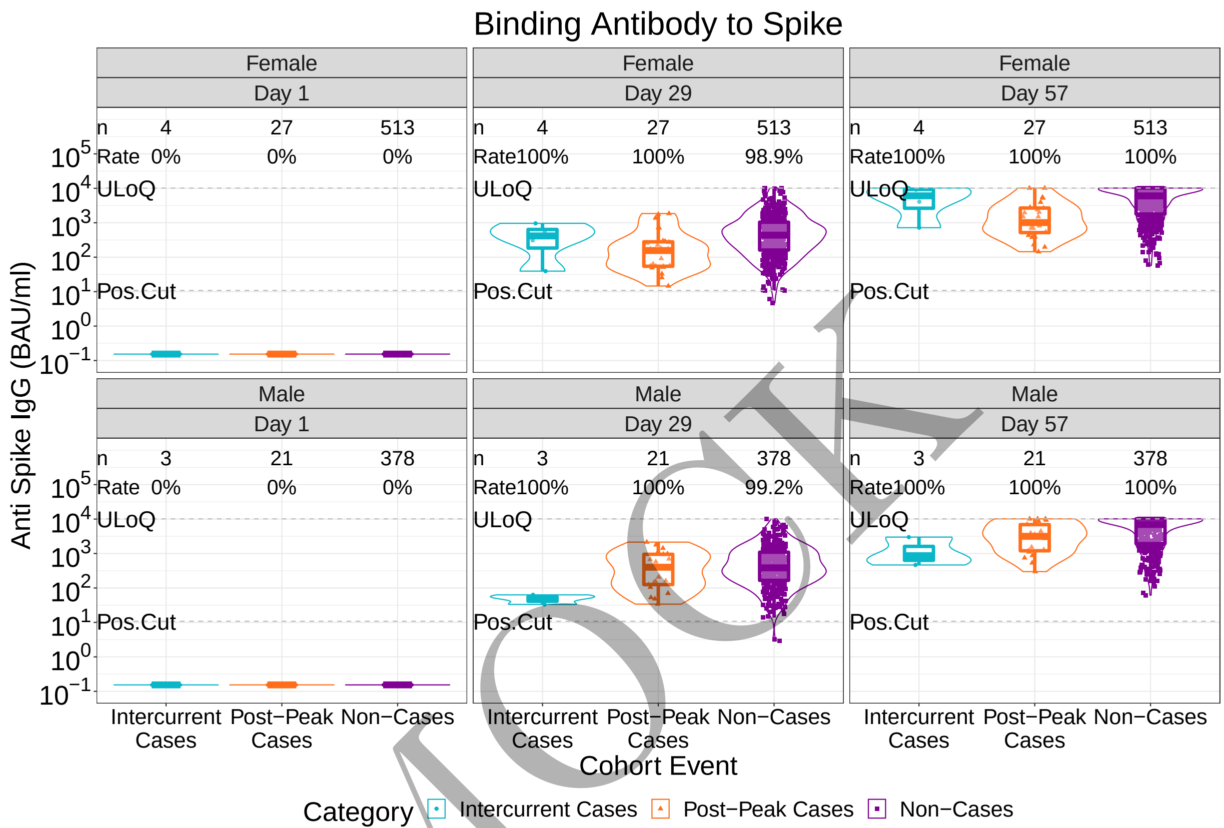
\begin{figure}



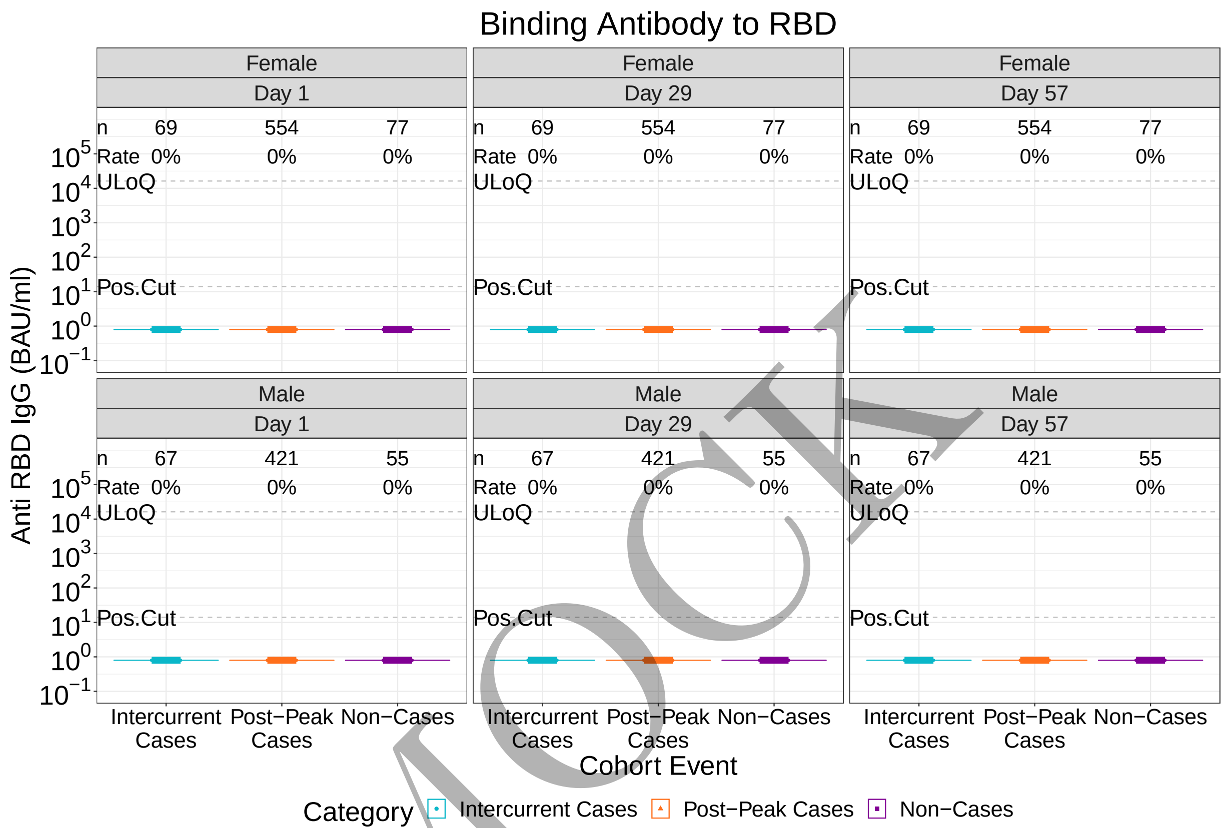
\caption{

Figure 2.5.154: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by sex assigned at birth (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



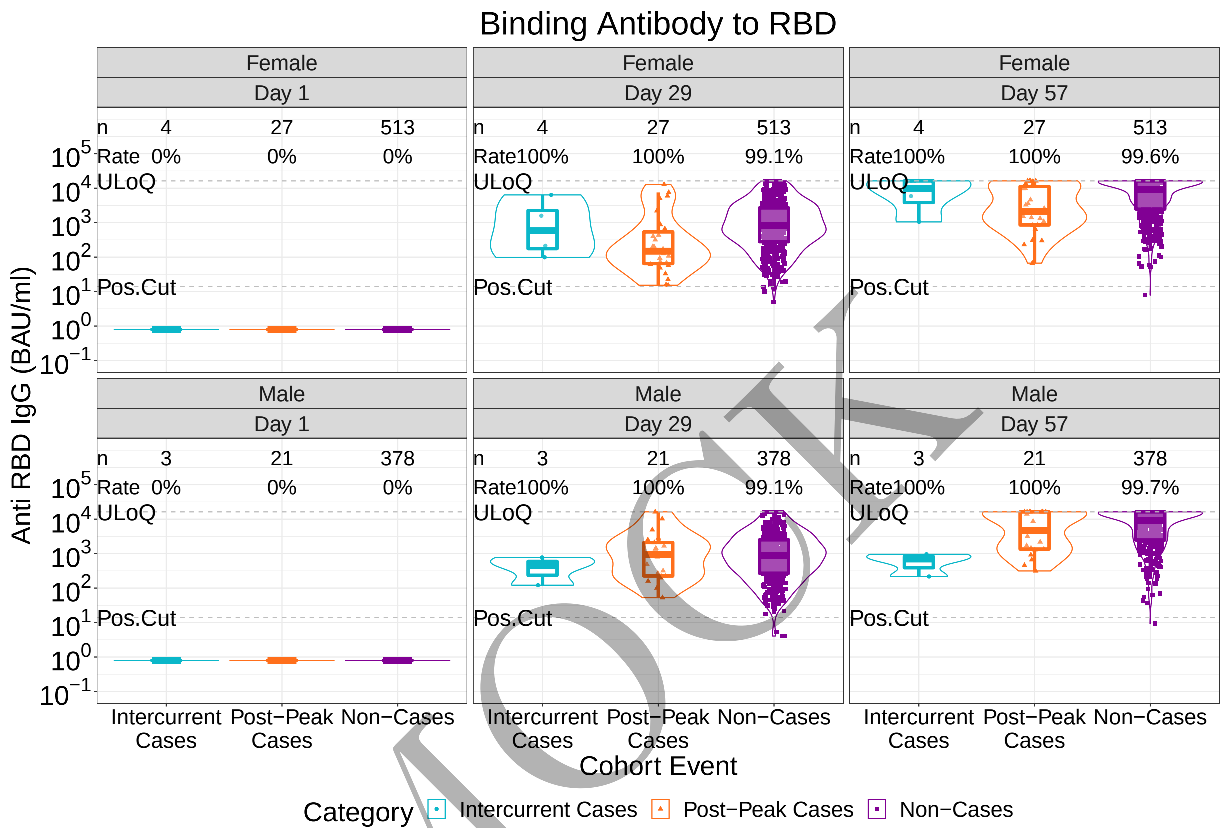
\caption{

Figure 2.5.155: violinplots of Binding Antibody to RBD: baseline negative placebo arm by sex assigned at birth (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



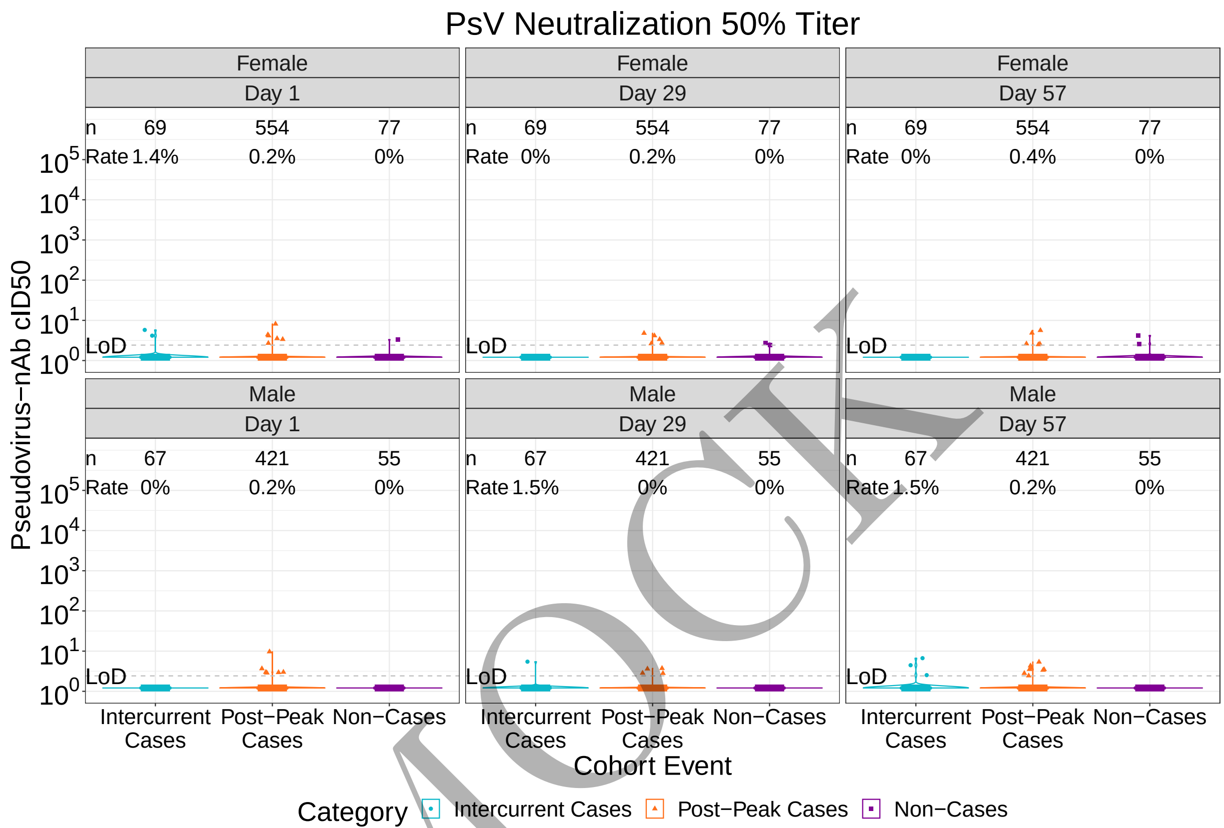
\caption{

Figure 2.5.156: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by sex assigned at birth (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



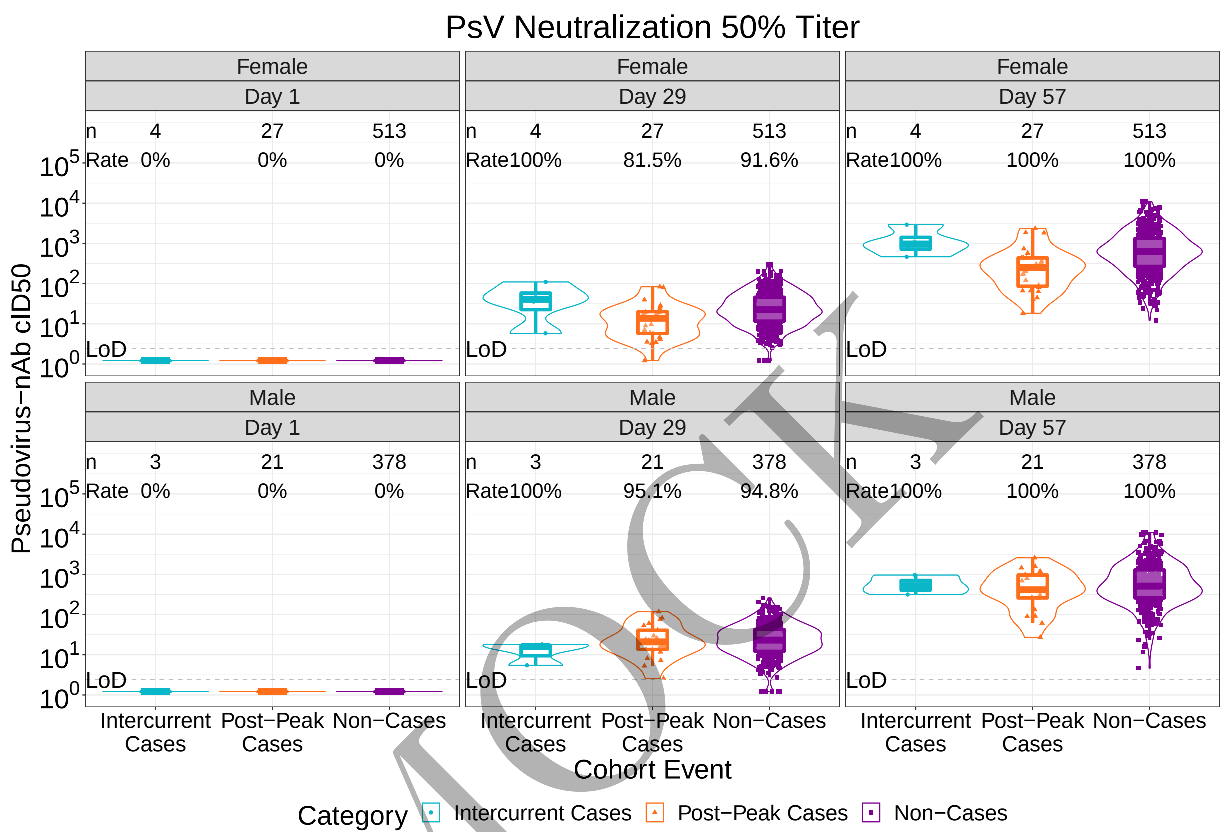
\caption{

Figure 2.5.157: violinplots of PsV Neutralization 50% Titer: baseline negative placebo arm by sex assigned at birth (version 2)

} \end{figure}

`r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")`

\begin{figure}



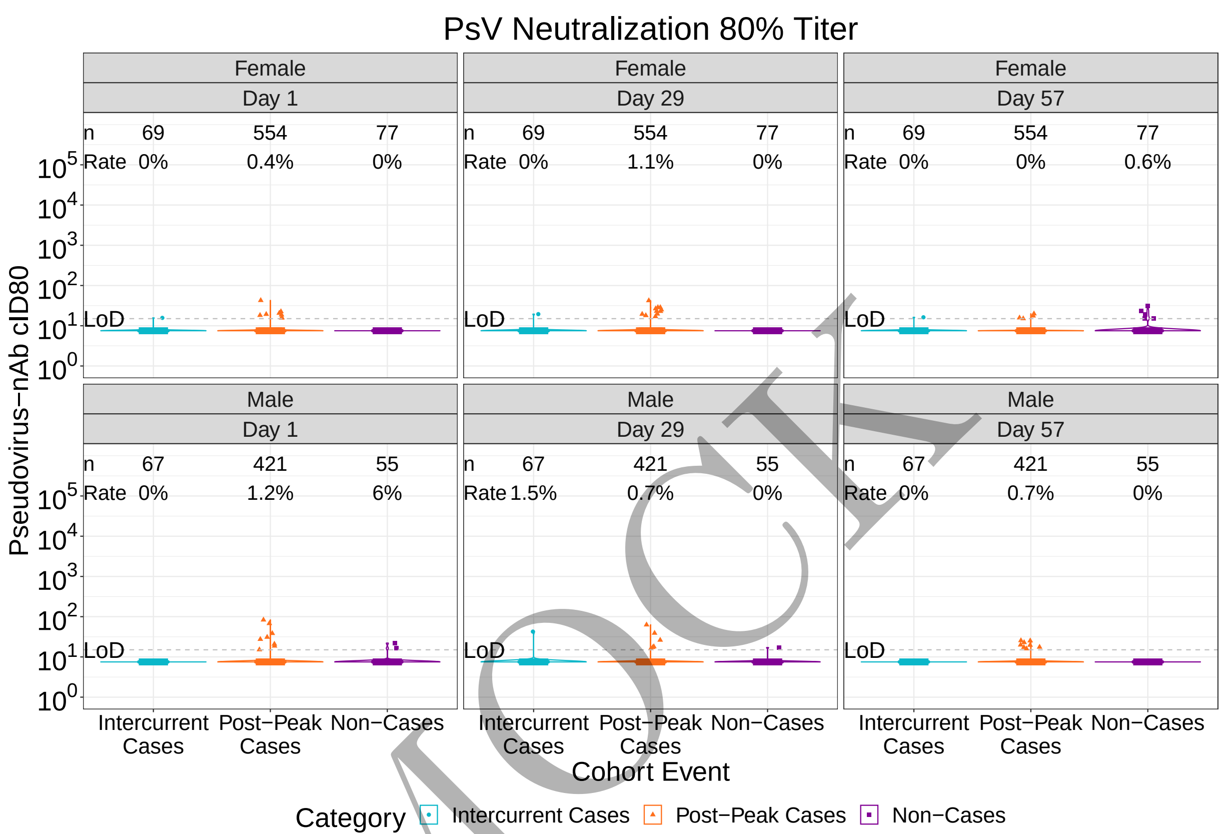
\caption{

Figure 2.5.158: violinplots of PsV Neutralization 50% Titer: baseline negative vaccine arm by sex assigned at birth (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



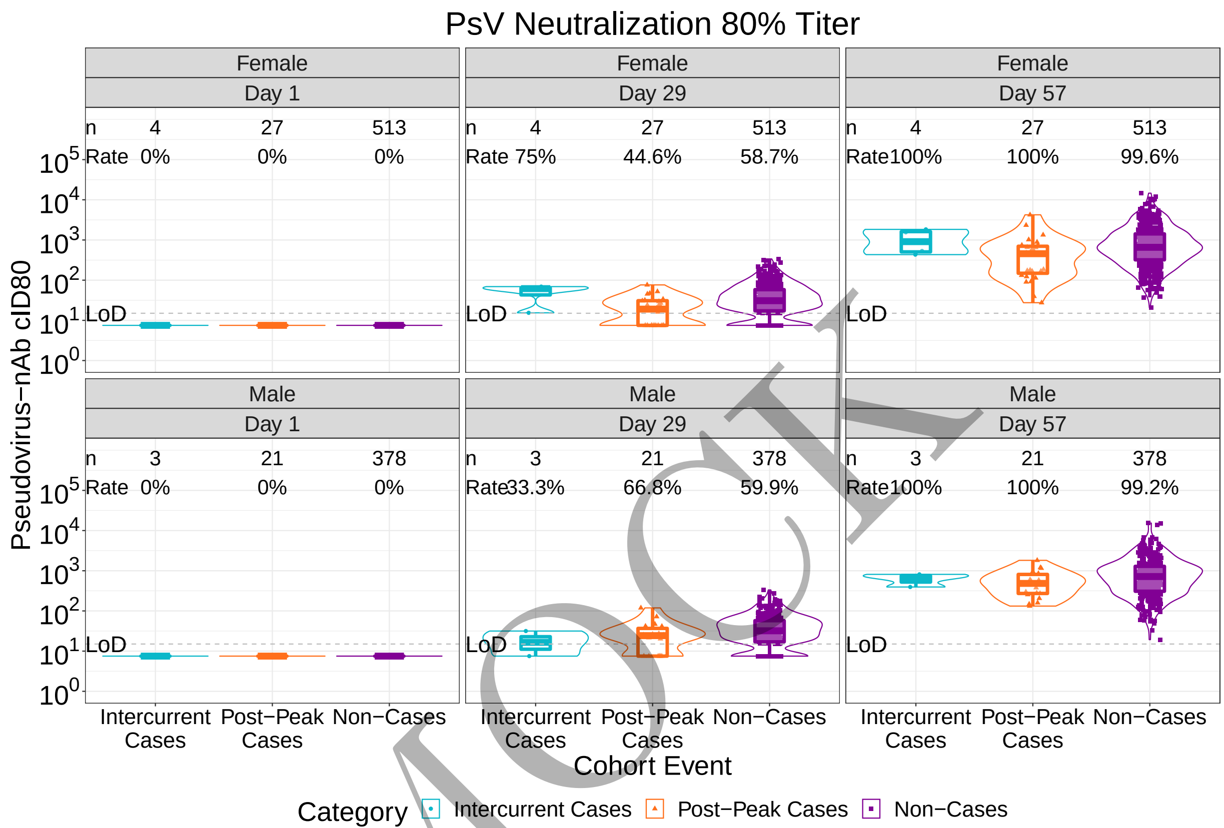
\caption{

Figure 2.5.159: violinplots of PsV Neutralization 80% Titer: baseline negative placebo arm by sex assigned at birth (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



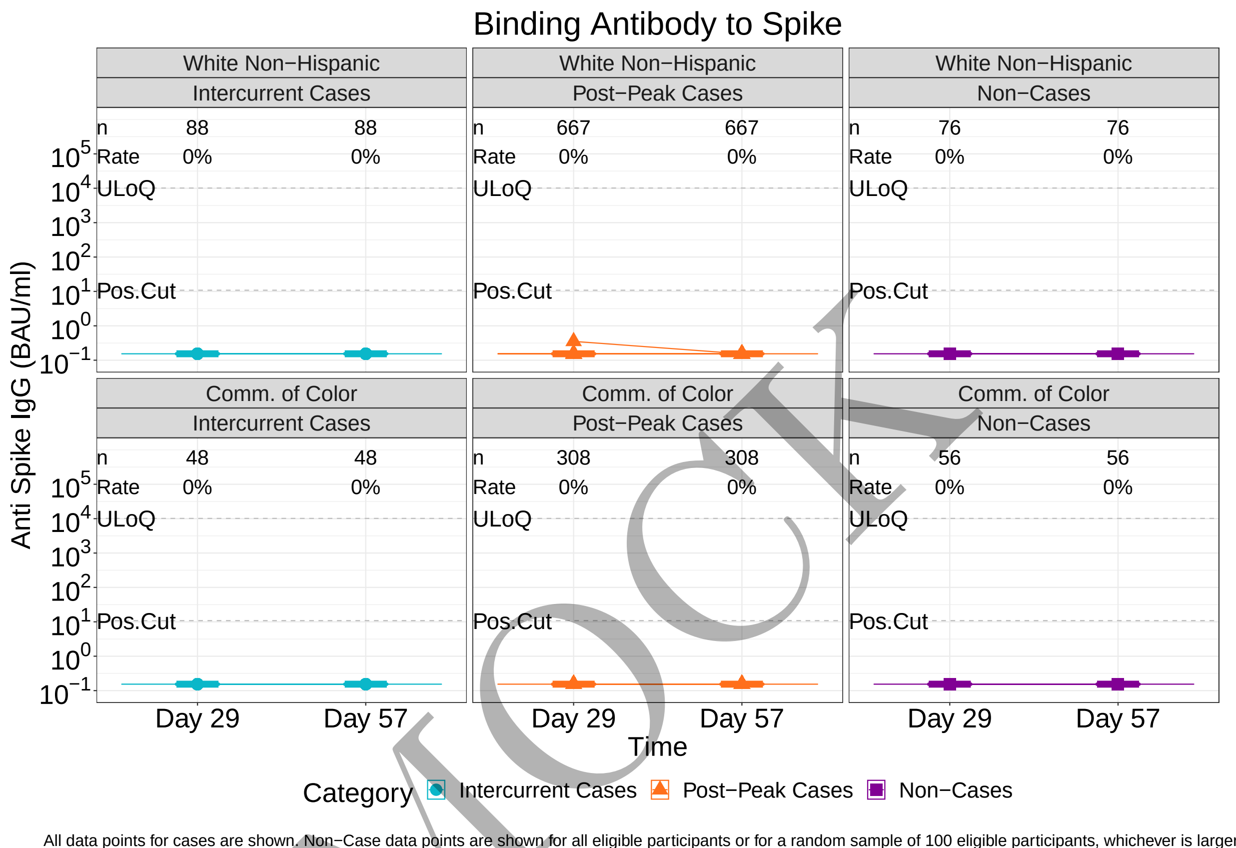
\caption{

Figure 2.5.160: violinplots of PsV Neutralization 80% Titer: baseline negative vaccine arm by sex assigned at birth (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



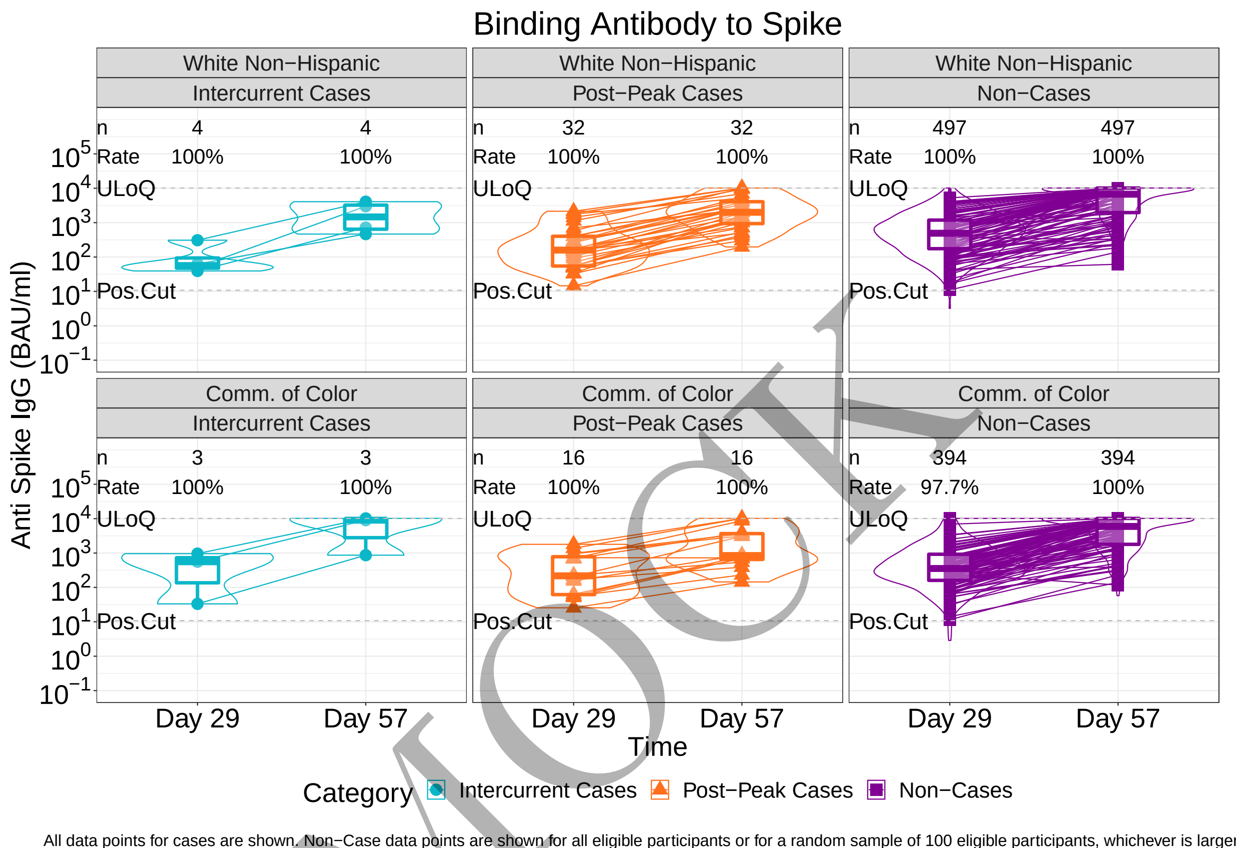
\caption{

Figure 2.5.161: lineplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



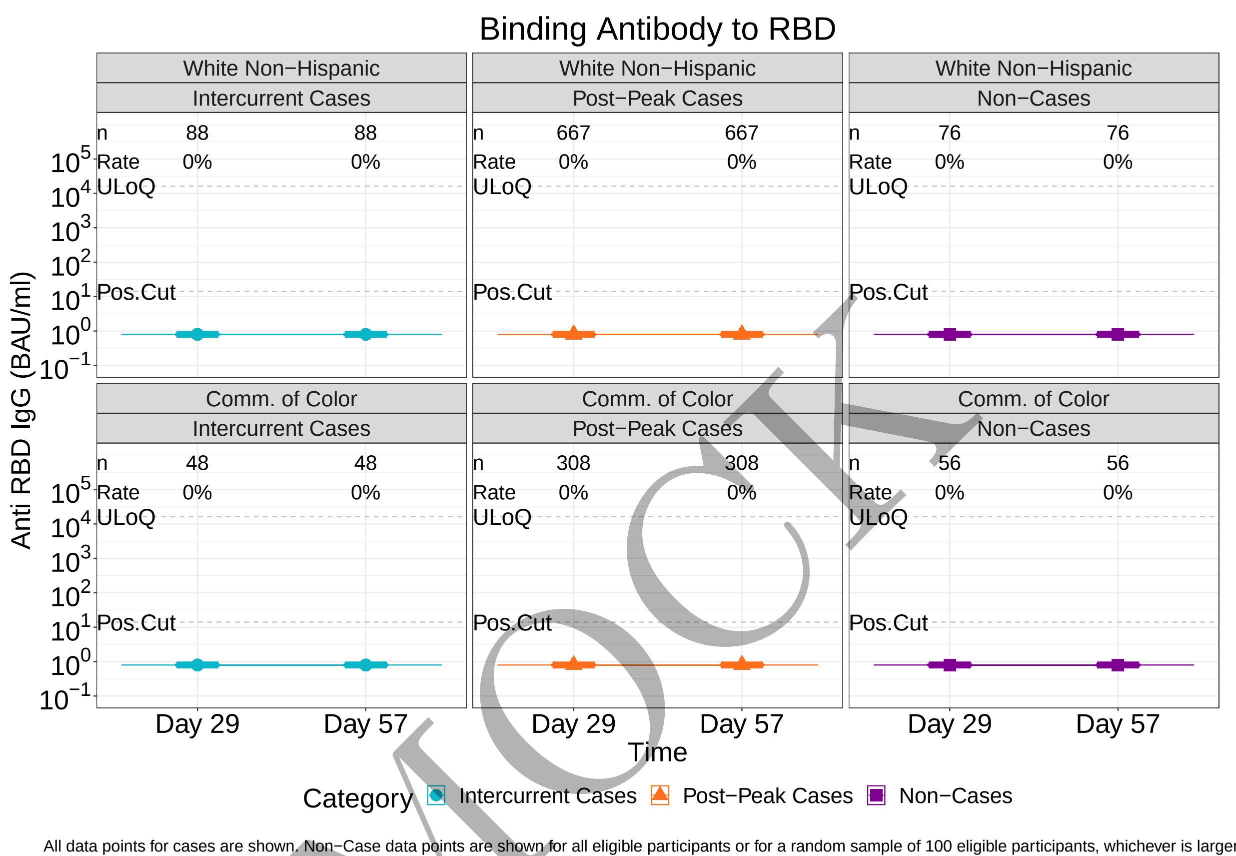
\caption{

Figure 2.5.162: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



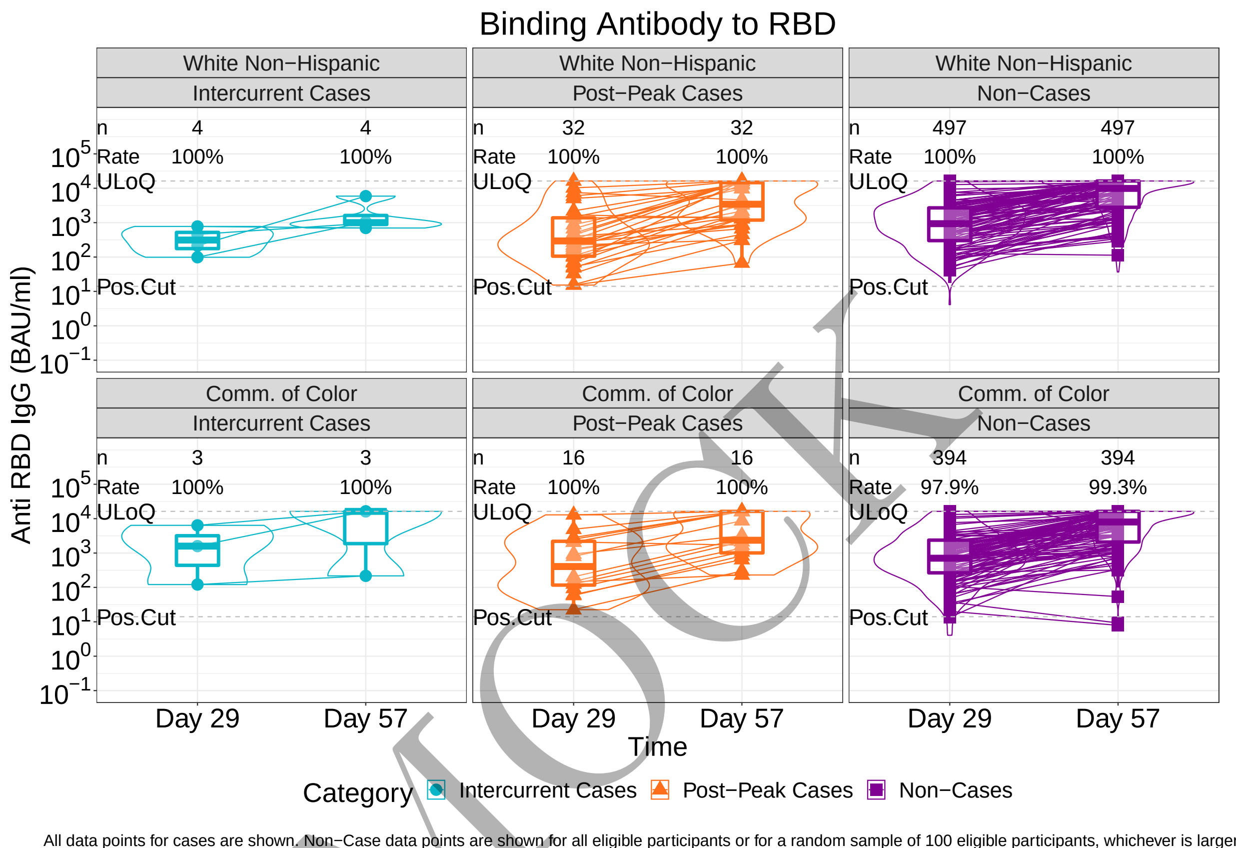
\caption{

Figure 2.5.163: lineplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



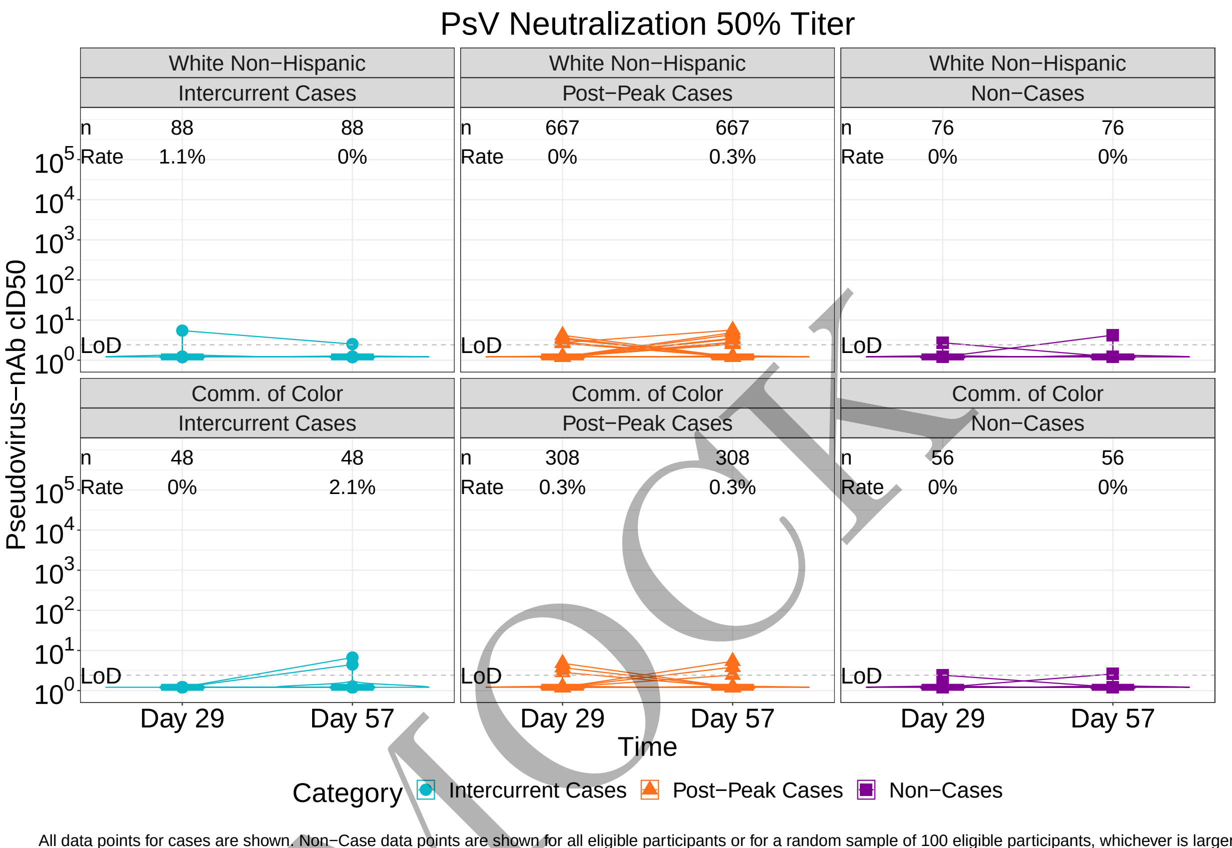
\caption{

Figure 2.5.164: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



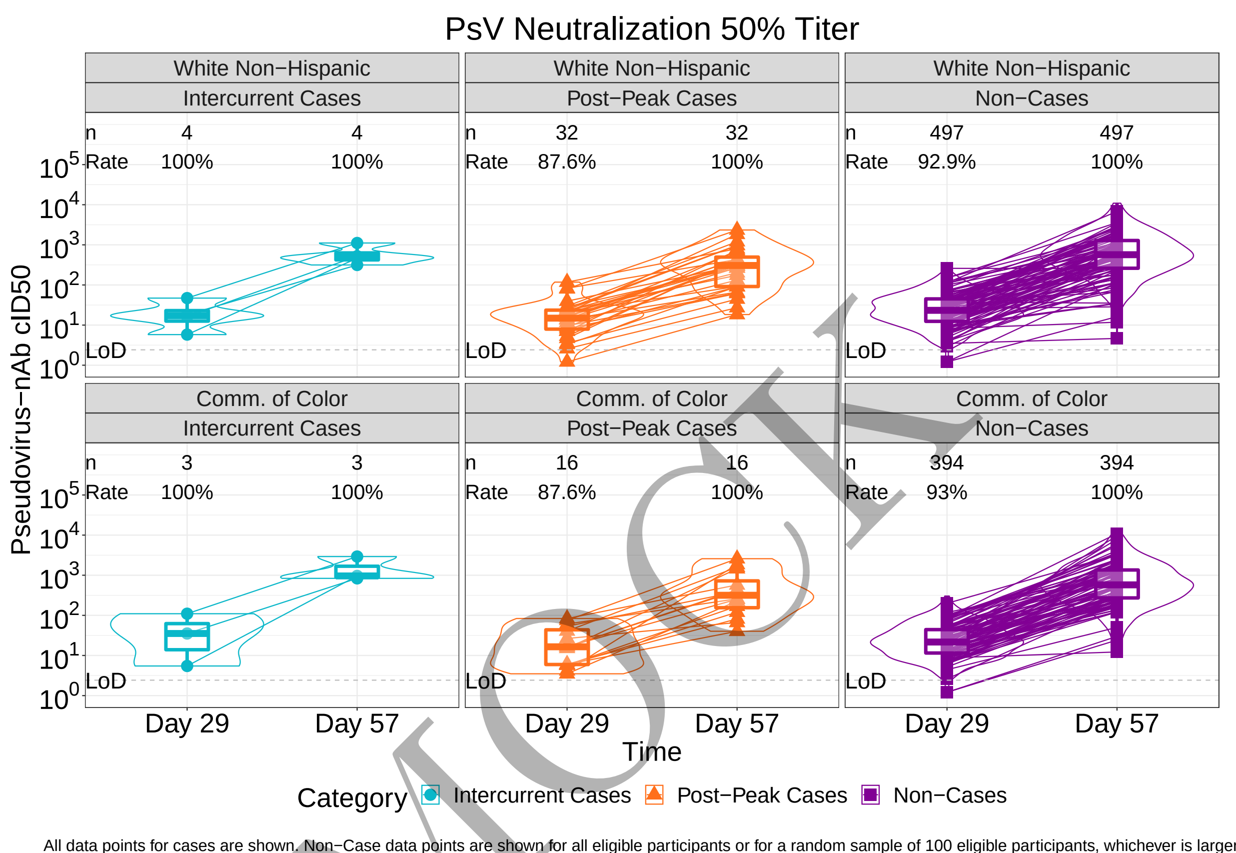
\caption{

Figure 2.5.165: lineplots of PsV Neutralization 50% Titer: baseline negative placebo arm by race and ethnic group (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



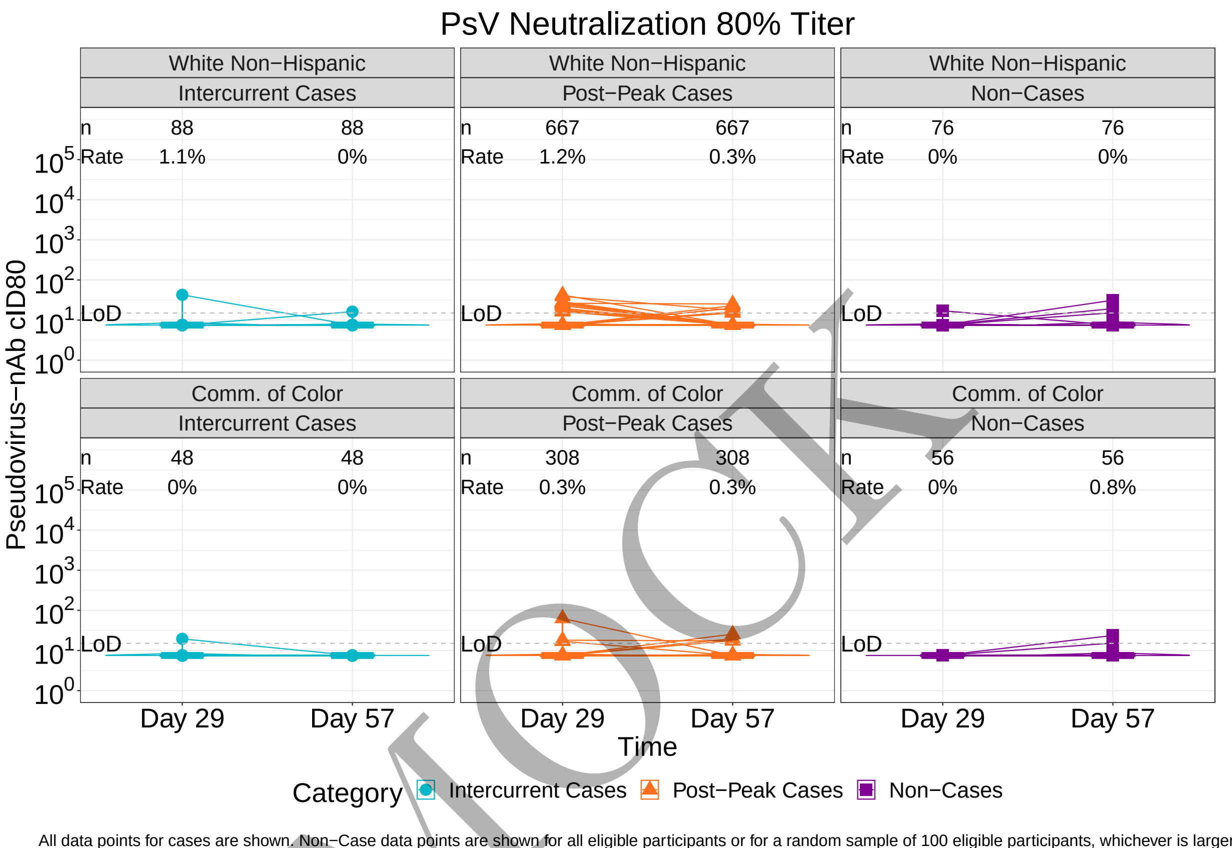
\caption{

Figure 2.5.166: lineplots of PsV Neutralization 50% Titer: baseline negative vaccine arm by race and ethnic group (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



\caption{

Figure 2.5.167: lineplots of PsV Neutralization 80% Titer: baseline negative placebo arm by race and ethnic group (version 1)

} \end{figure}

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r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")
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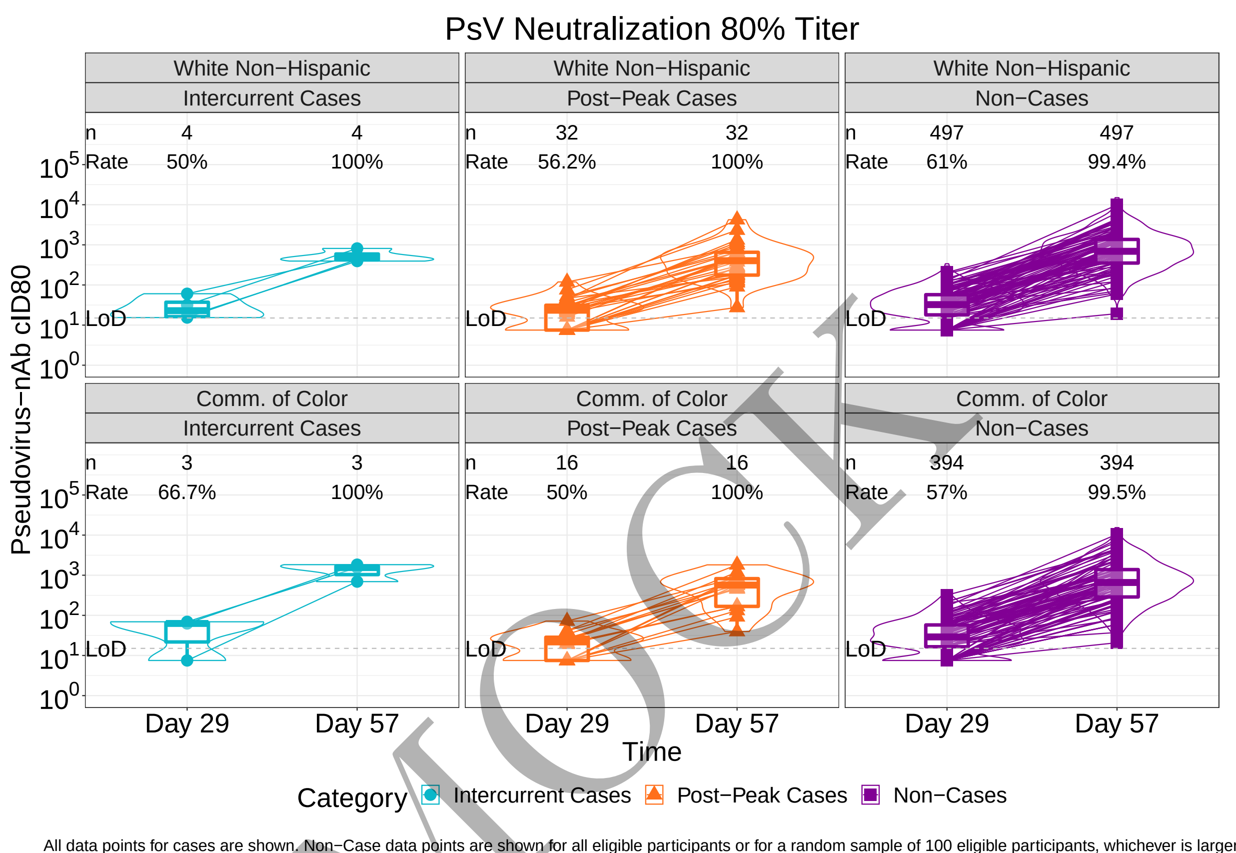


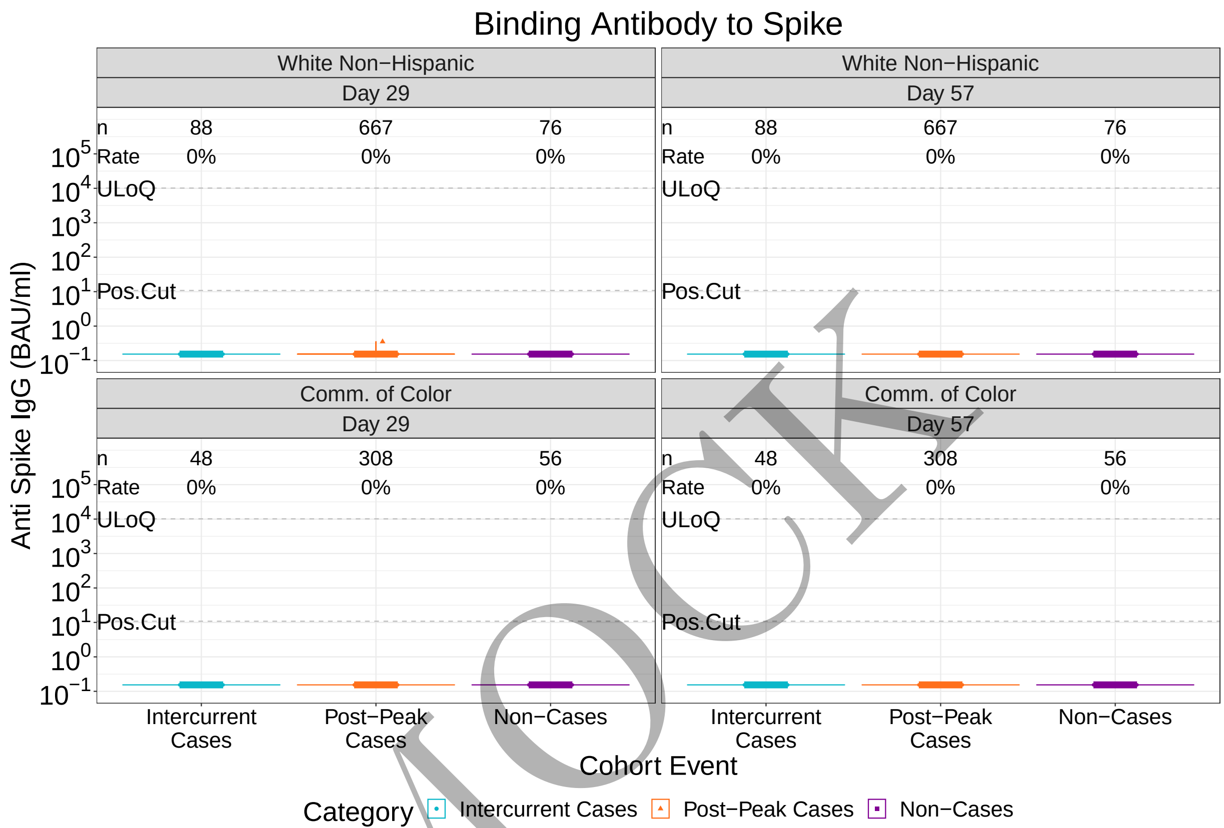
\caption{

Figure 2.5.168: lineplots of PsV Neutralization 80% Titer: baseline negative vaccine arm by race and ethnic group (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



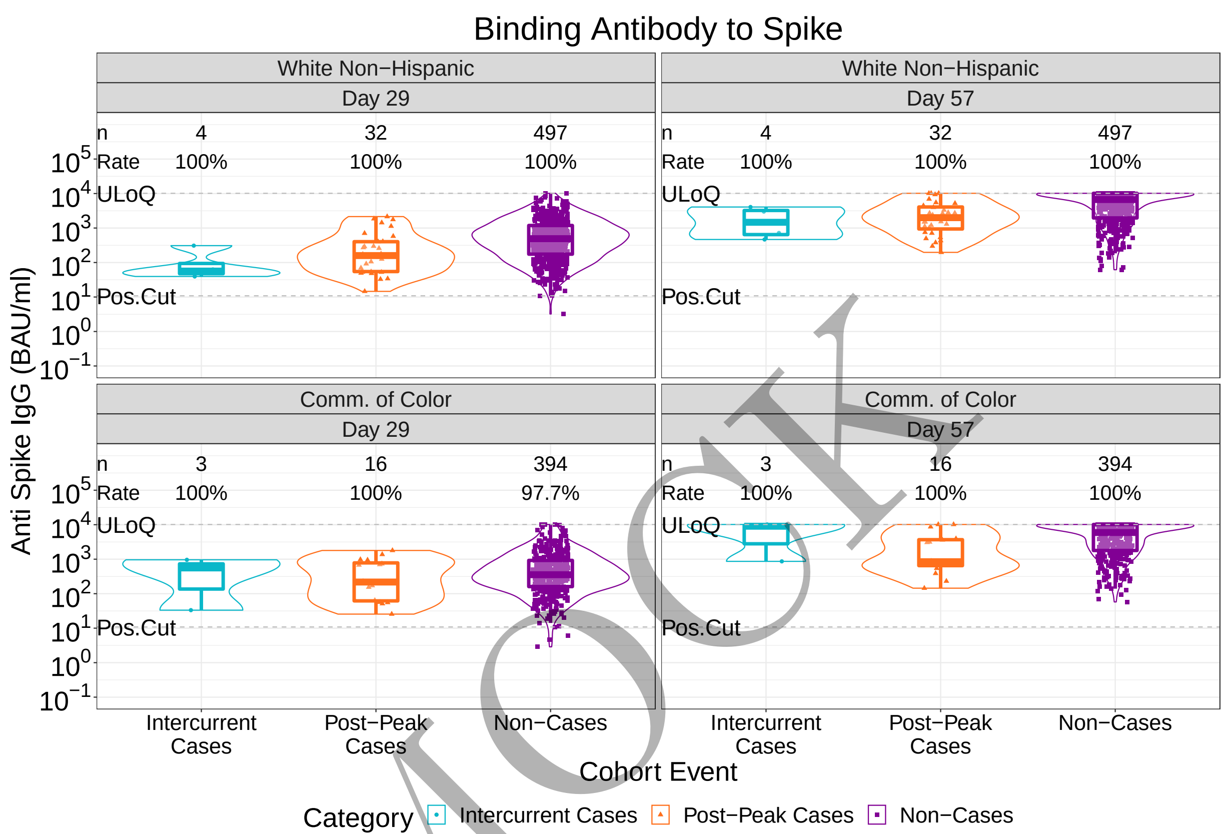
\caption{

Figure 2.5.169: violinplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



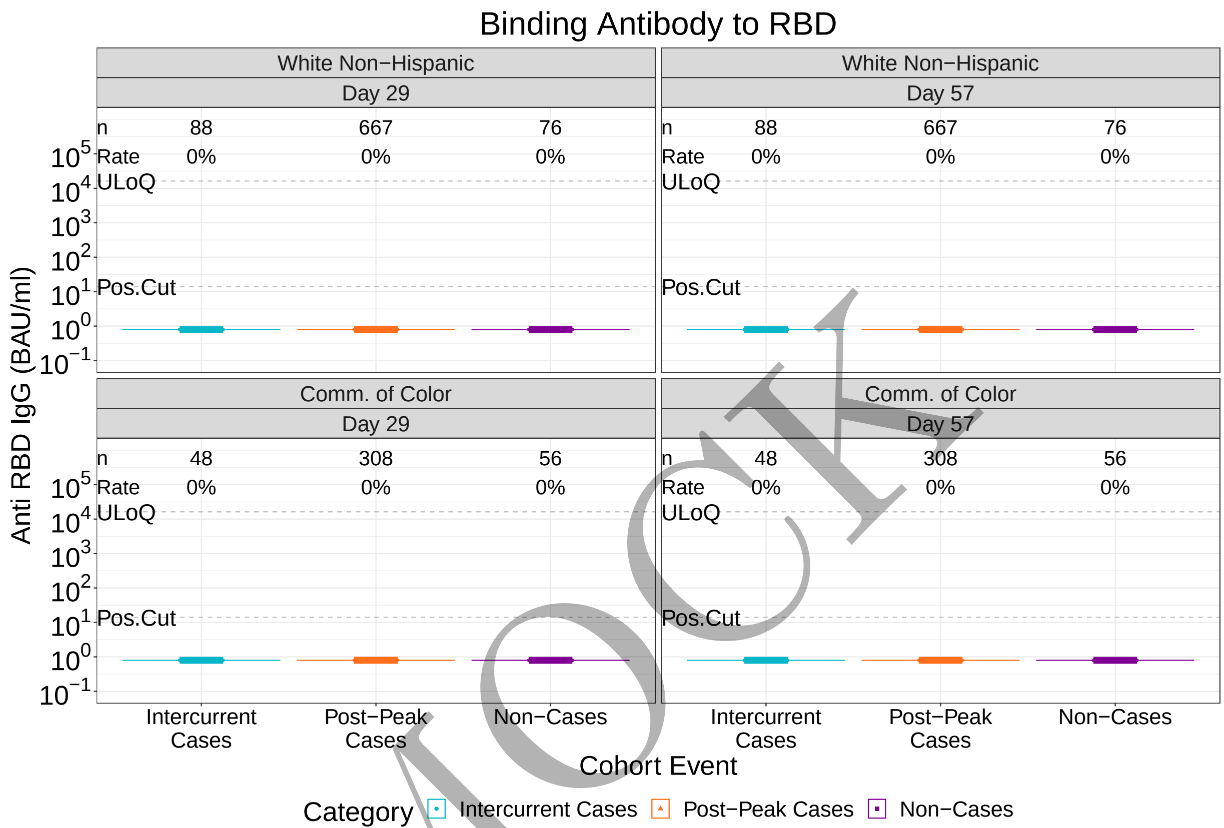
\caption{

Figure 2.5.170: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



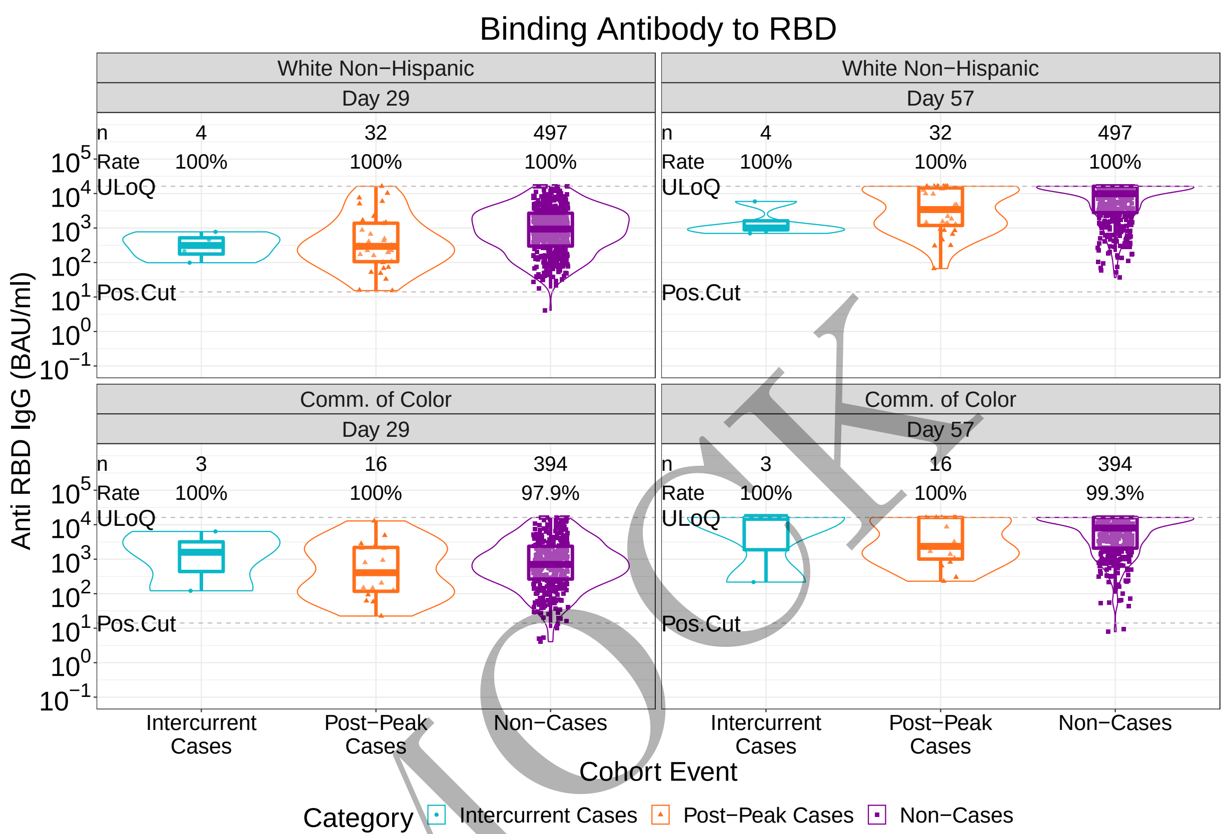
\caption{

Figure 2.5.171: violinplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



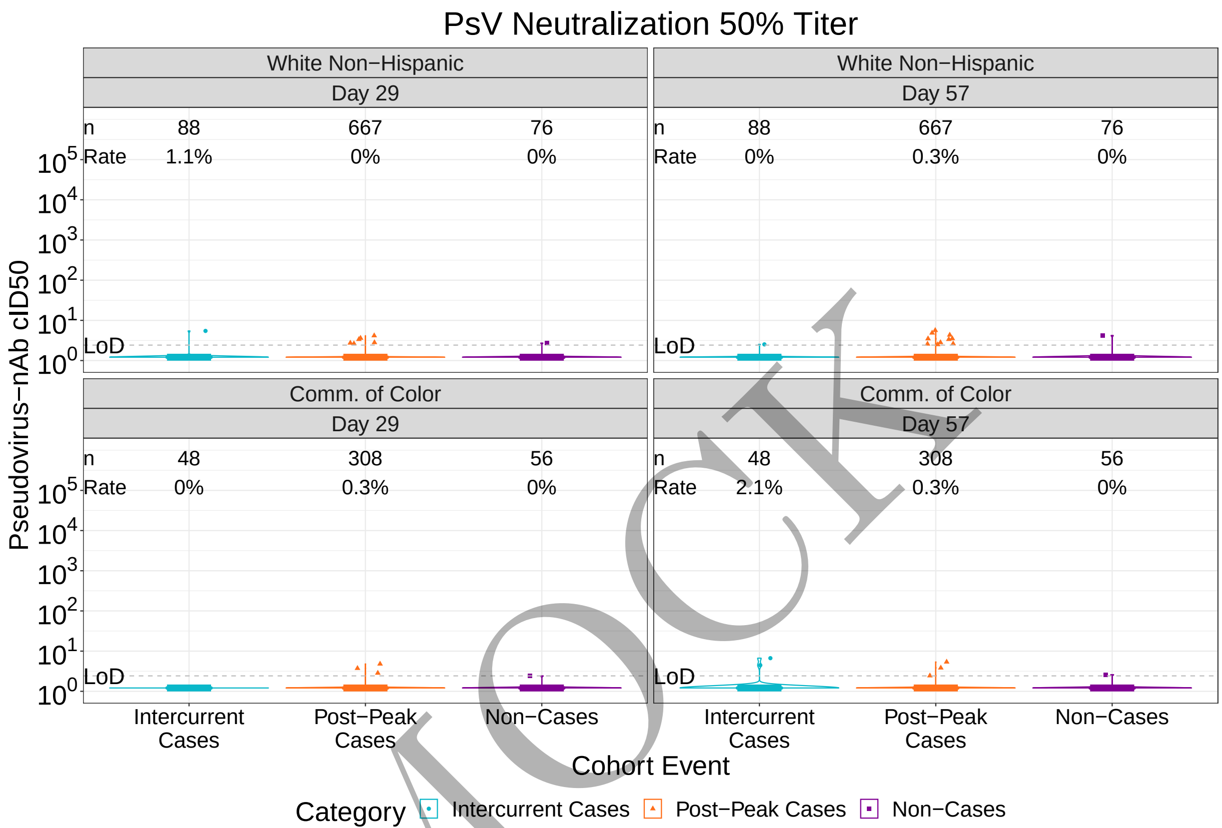
\caption{

Figure 2.5.172: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



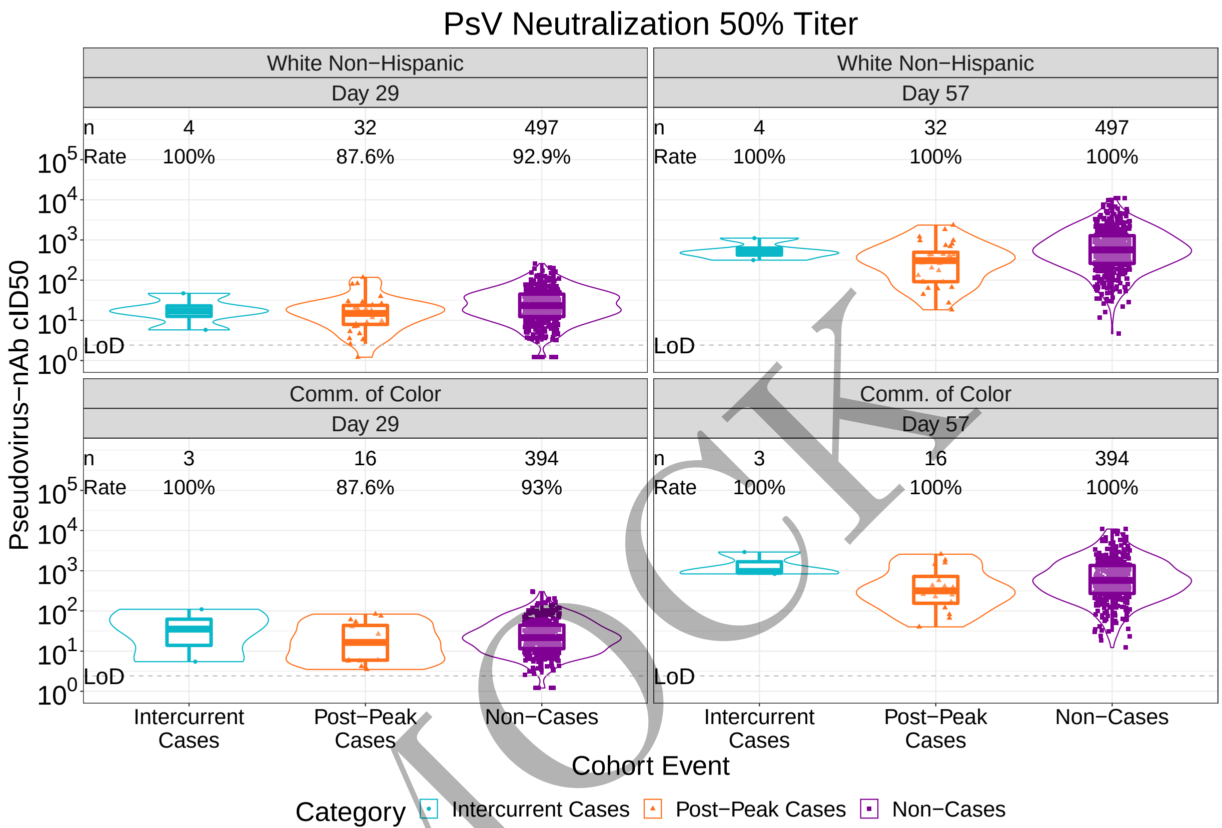
\caption{

Figure 2.5.173: violinplots of PsV Neutralization 50% Titer: baseline negative placebo arm by race and ethnic group (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



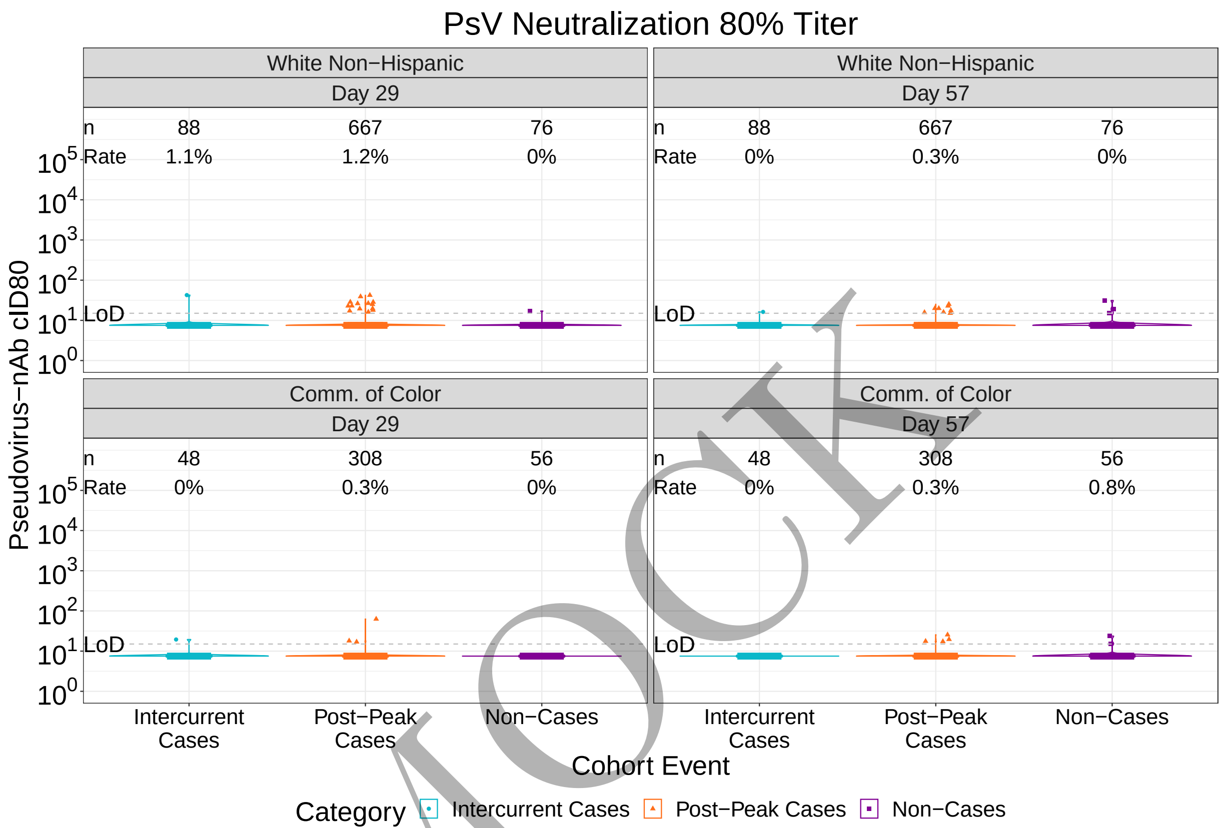
\caption{

Figure 2.5.174: violinplots of PsV Neutralization 50% Titer: baseline negative vaccine arm by race and ethnic group (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



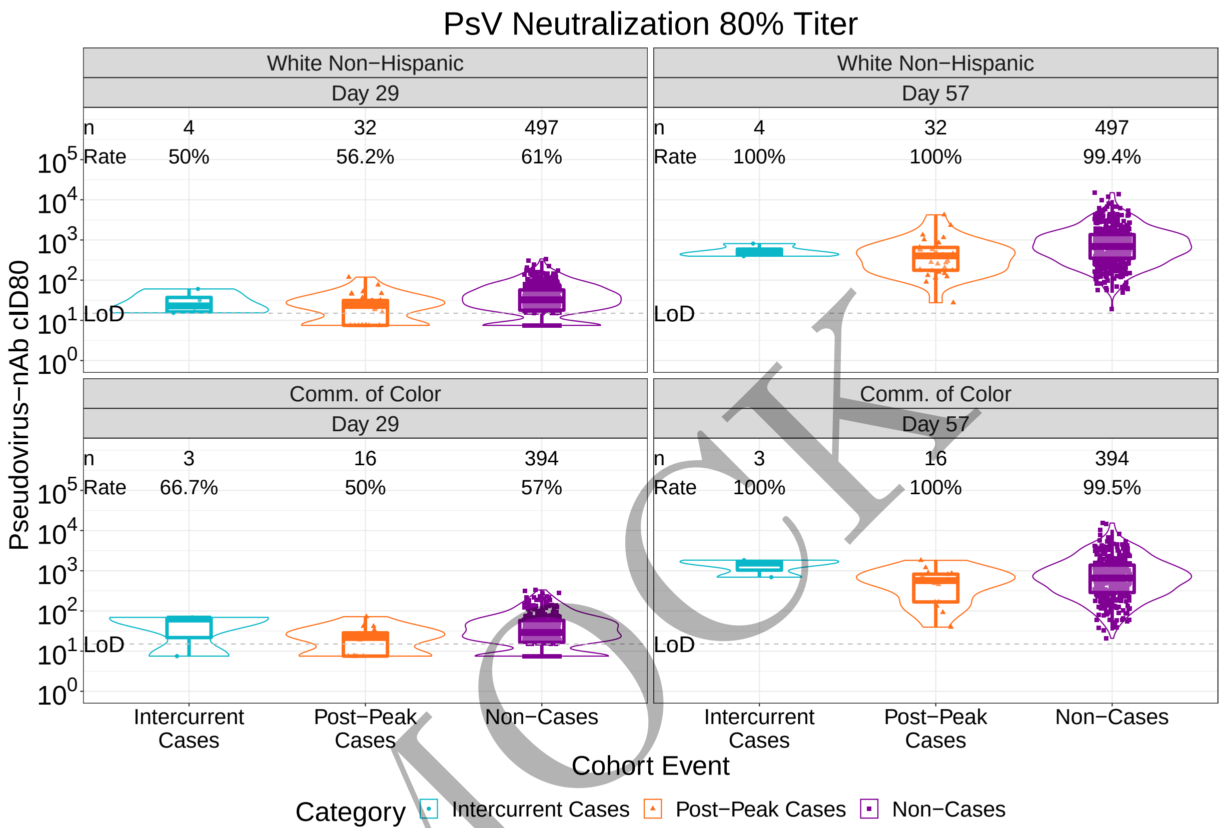
\caption{

Figure 2.5.175: violinplots of PsV Neutralization 80% Titer: baseline negative placebo arm by race and ethnic group (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



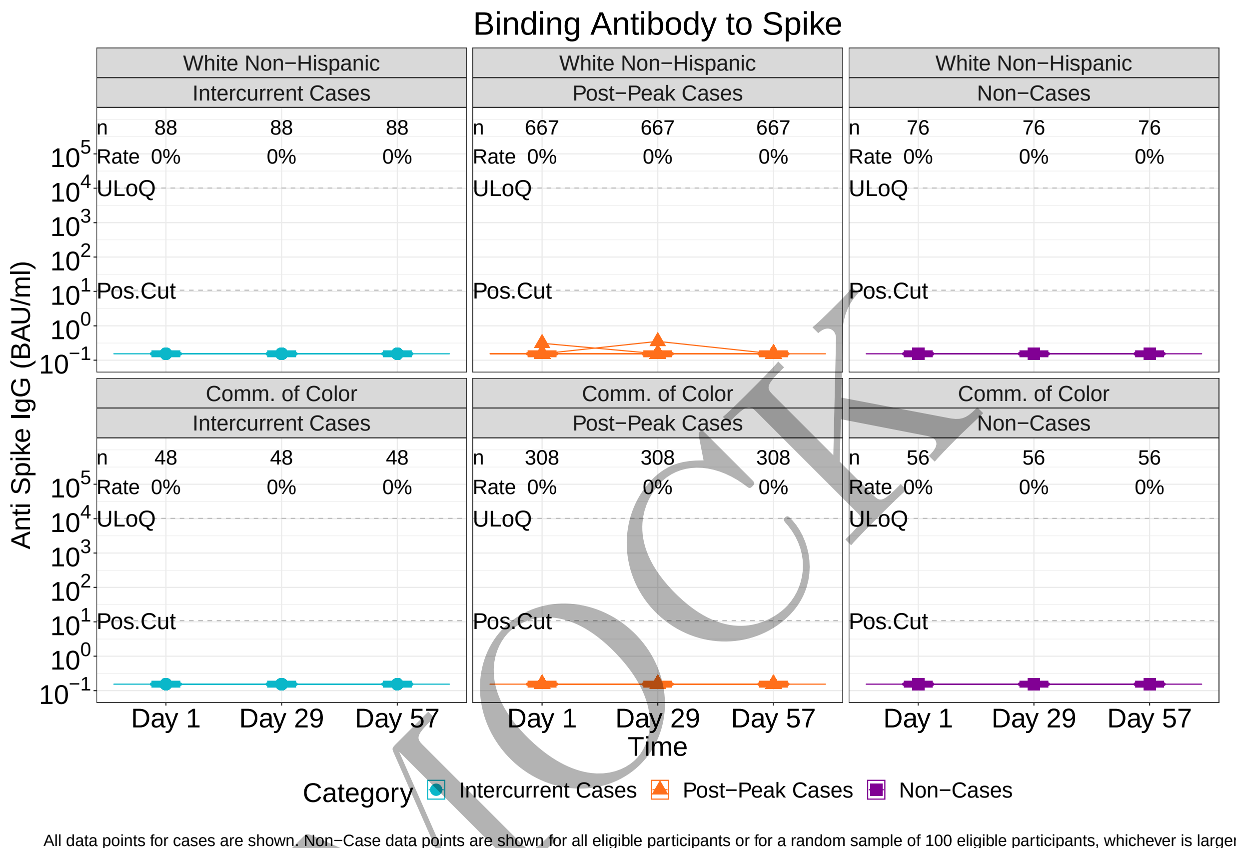
\caption{

Figure 2.5.176: violinplots of PsV Neutralization 80% Titer: baseline negative vaccine arm by race and ethnic group (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



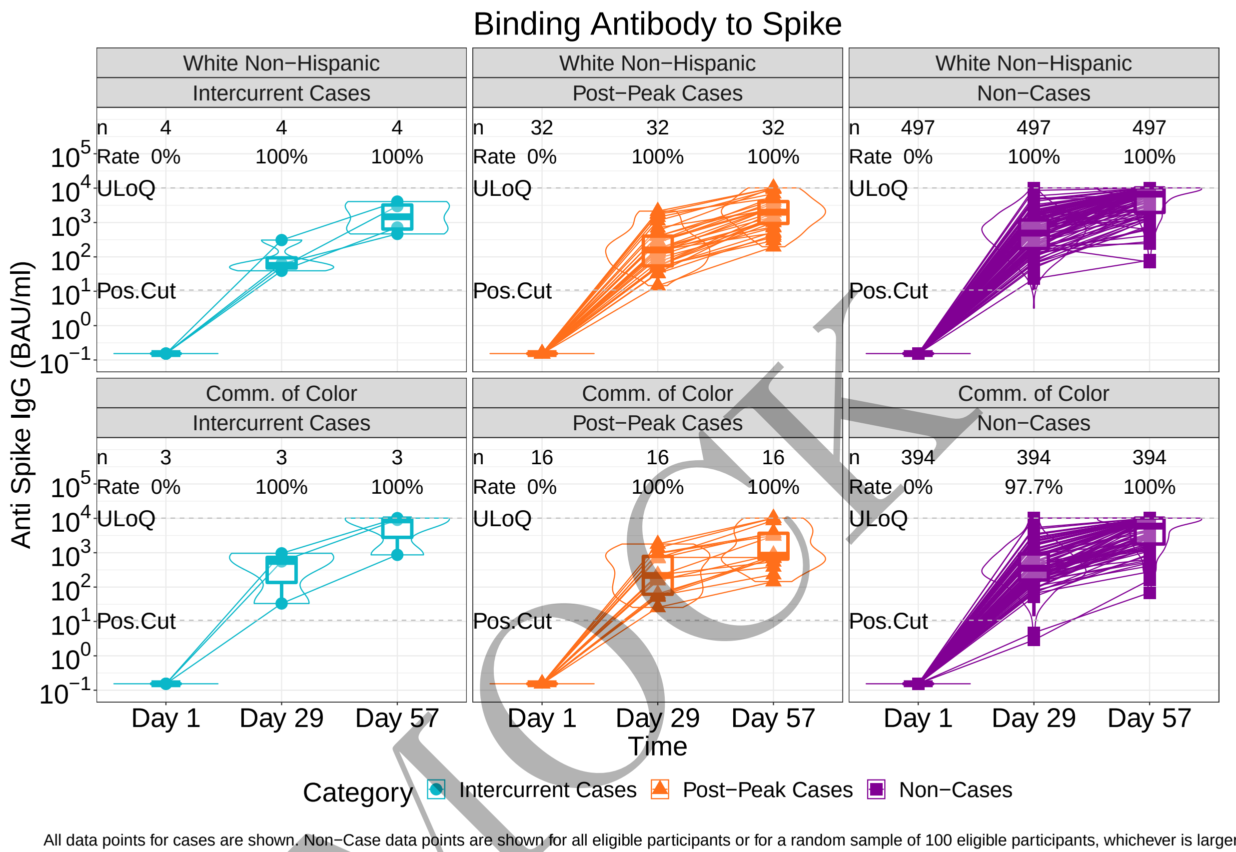
\caption{

Figure 2.5.177: lineplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



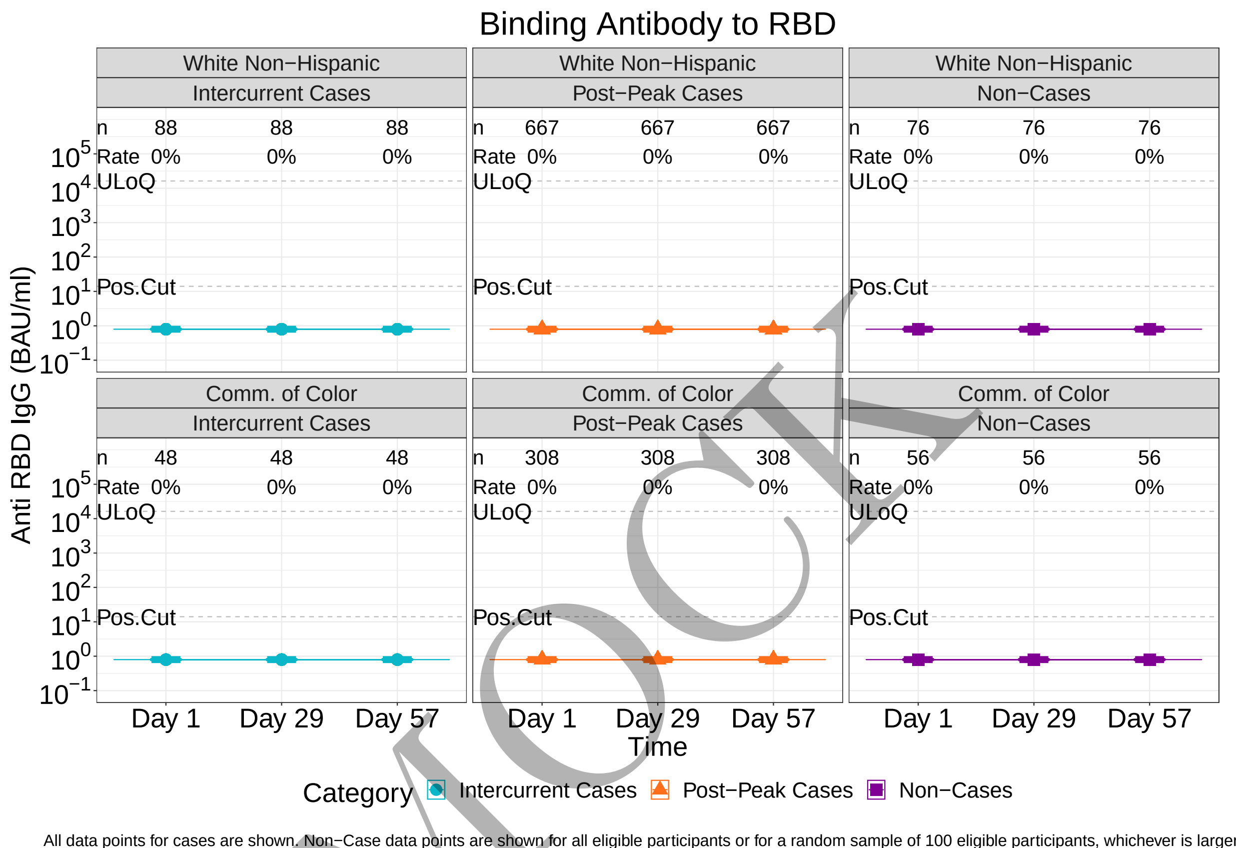
\caption{

Figure 2.5.178: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



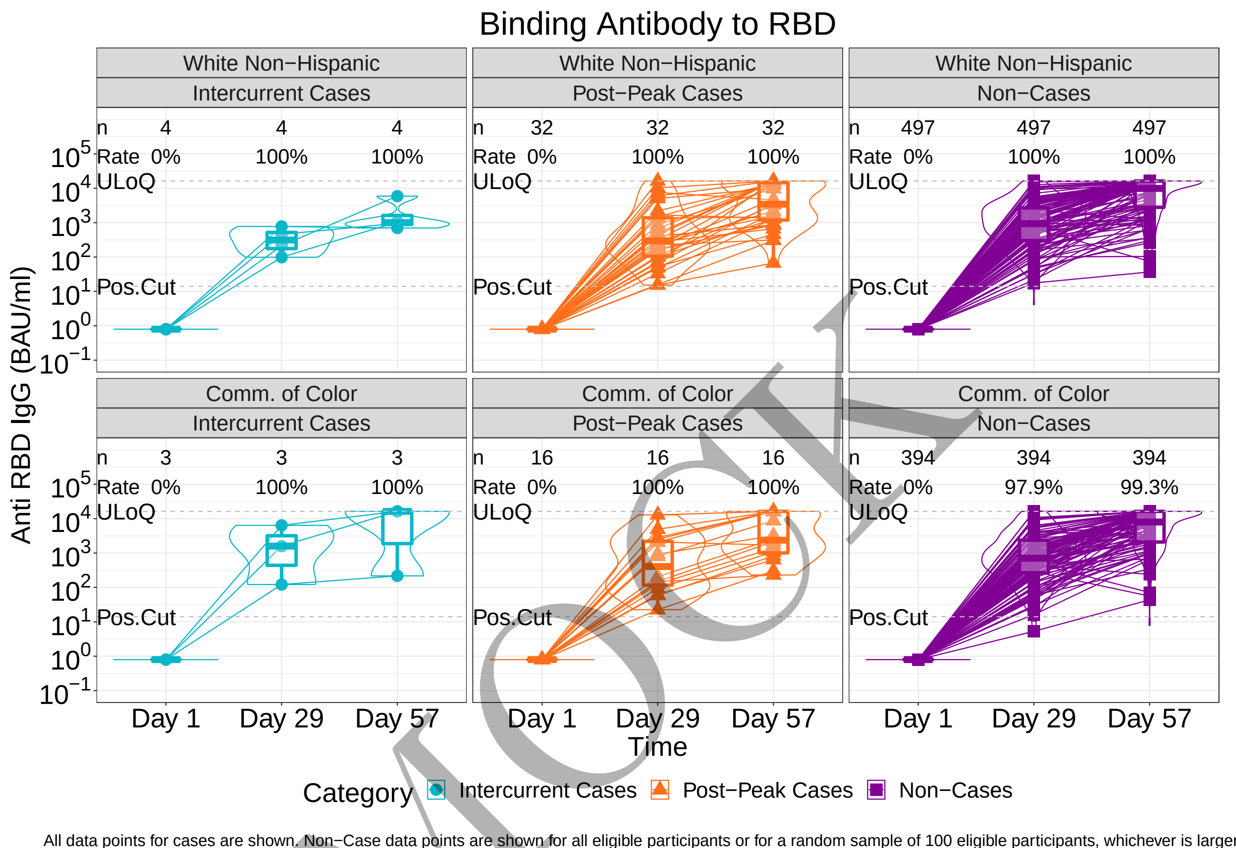
\caption{

Figure 2.5.179: lineplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



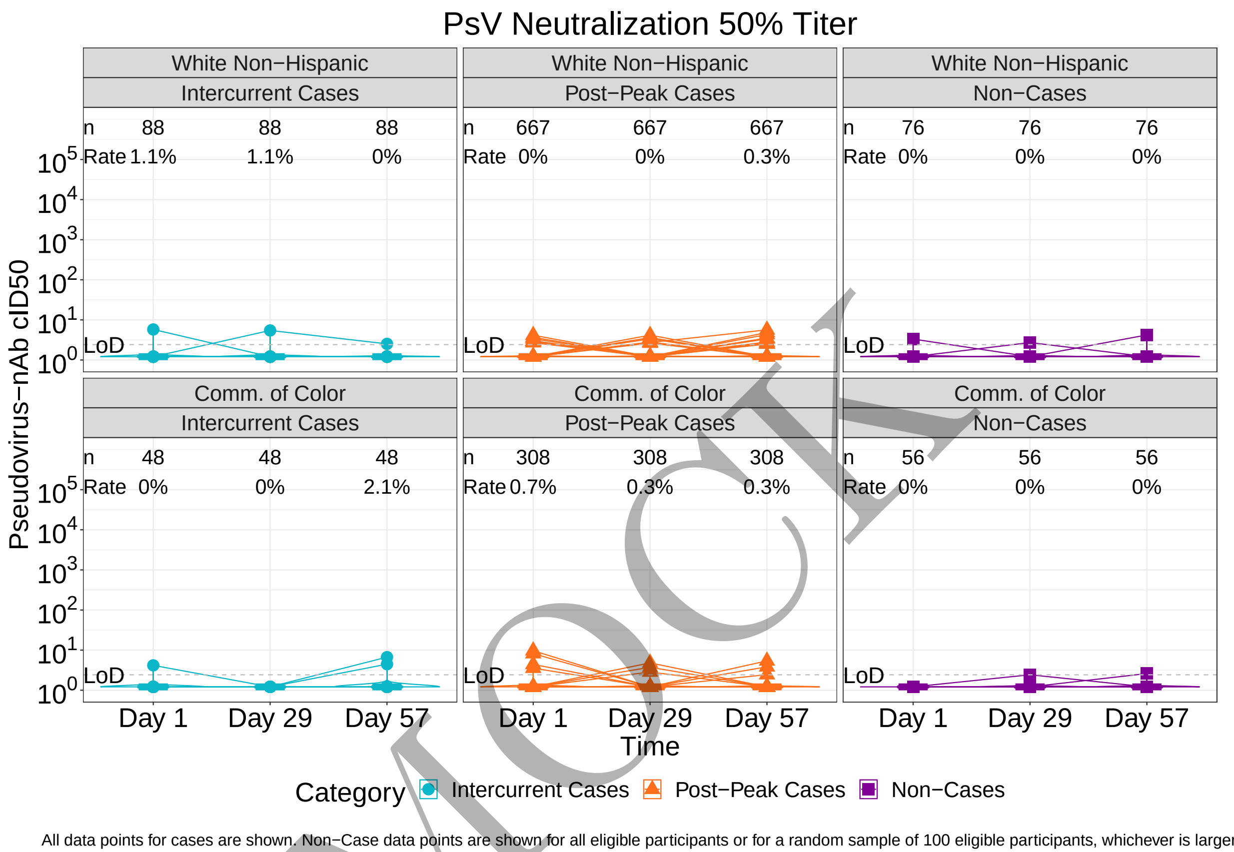
\caption{

Figure 2.5.180: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



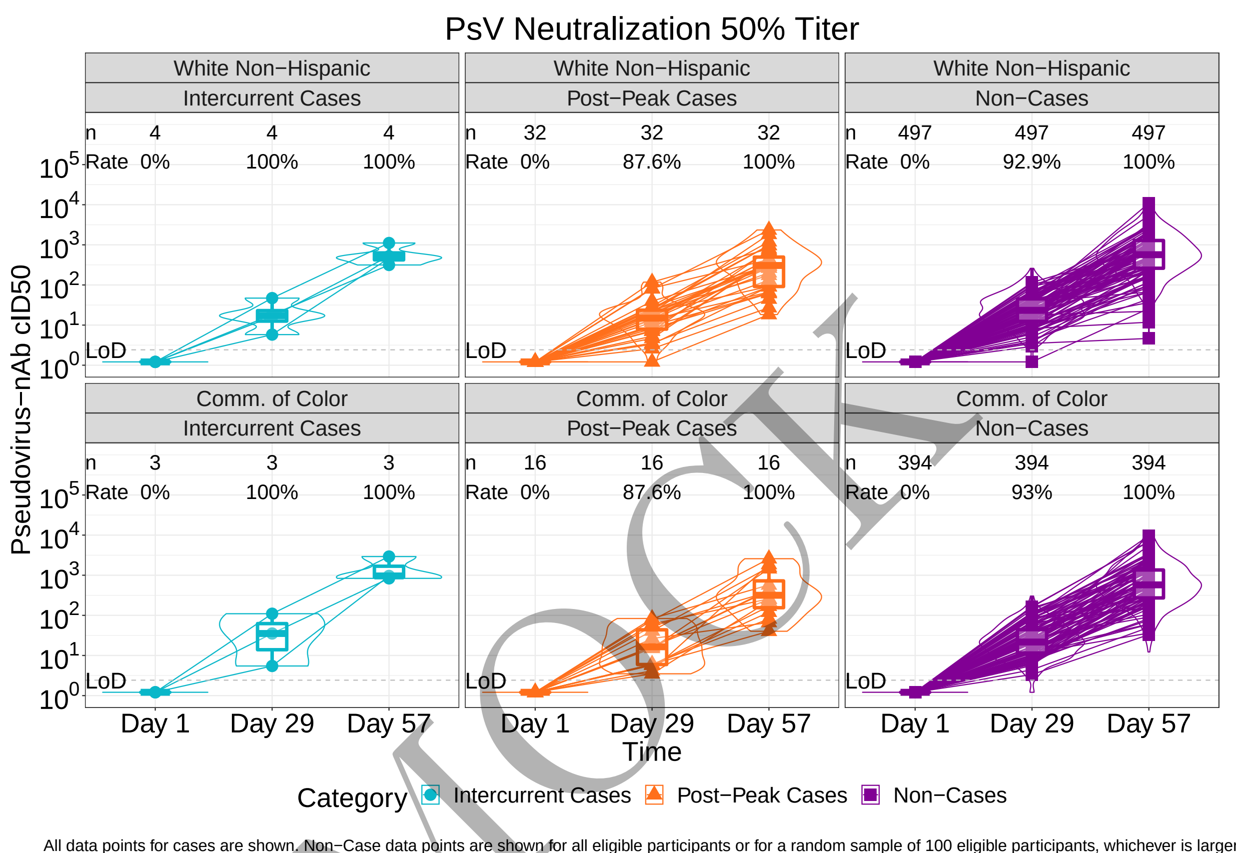
\caption{

Figure 2.5.181: lineplots of PsV Neutralization 50% Titer: baseline negative placebo arm by race and ethnic group (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



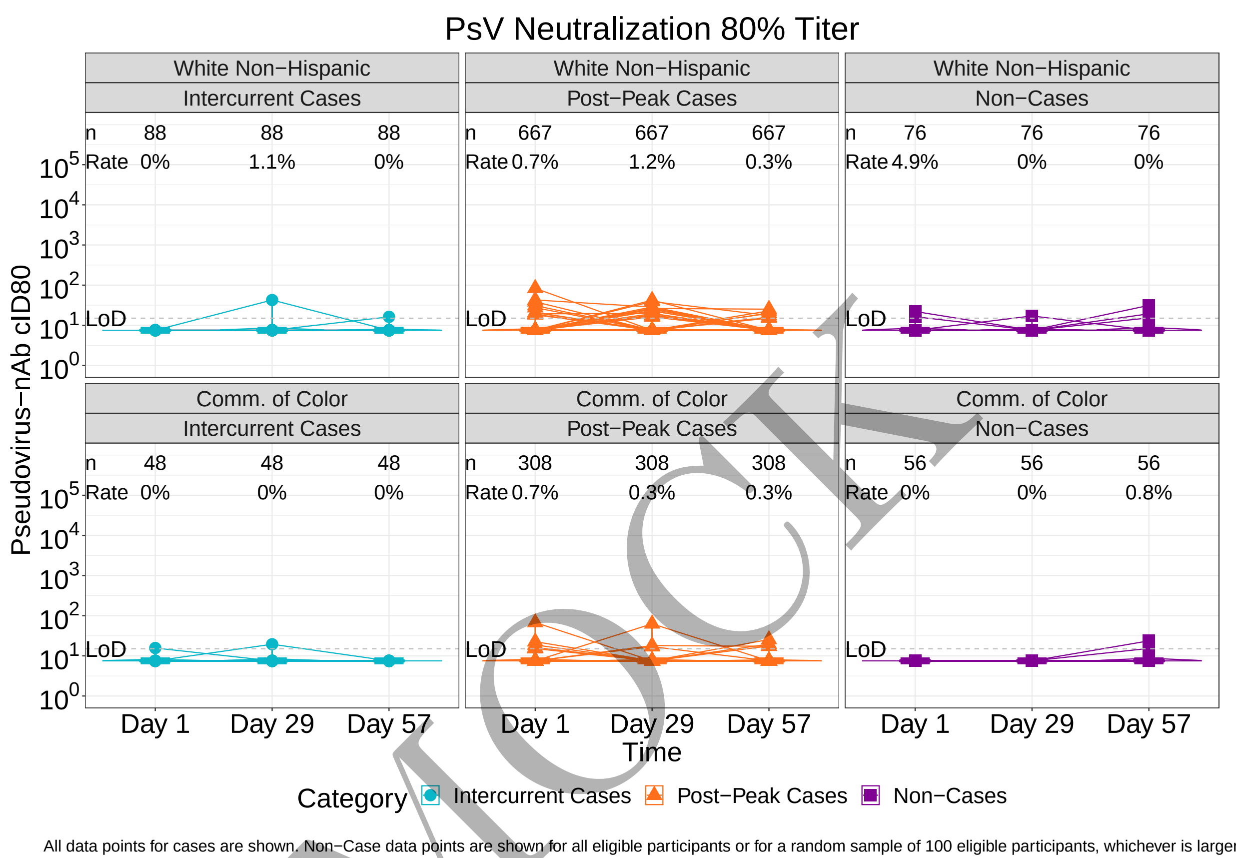
\caption{

Figure 2.5.182: lineplots of PsV Neutralization 50% Titer: baseline negative vaccine arm by race and ethnic group (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



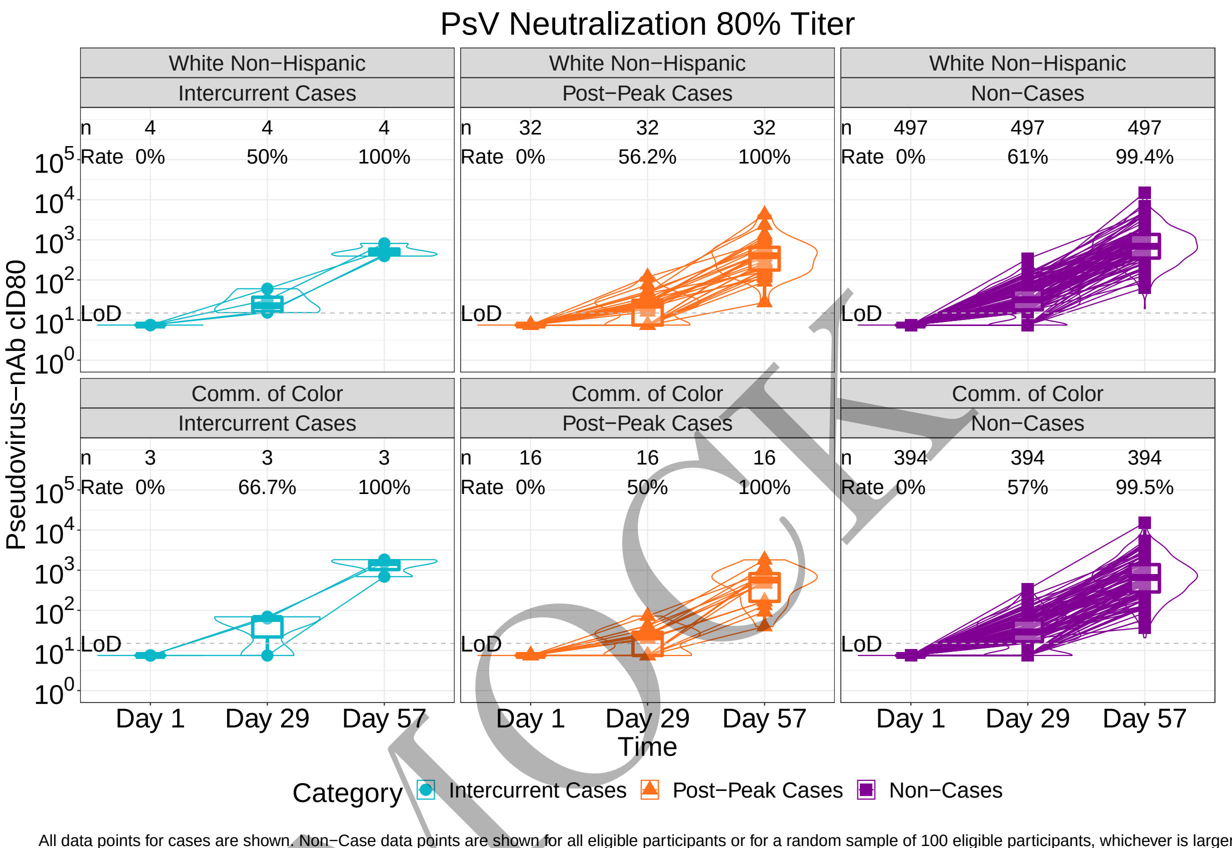
\caption{

Figure 2.5.183: lineplots of PsV Neutralization 80% Titer: baseline negative placebo arm by race and ethnic group (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



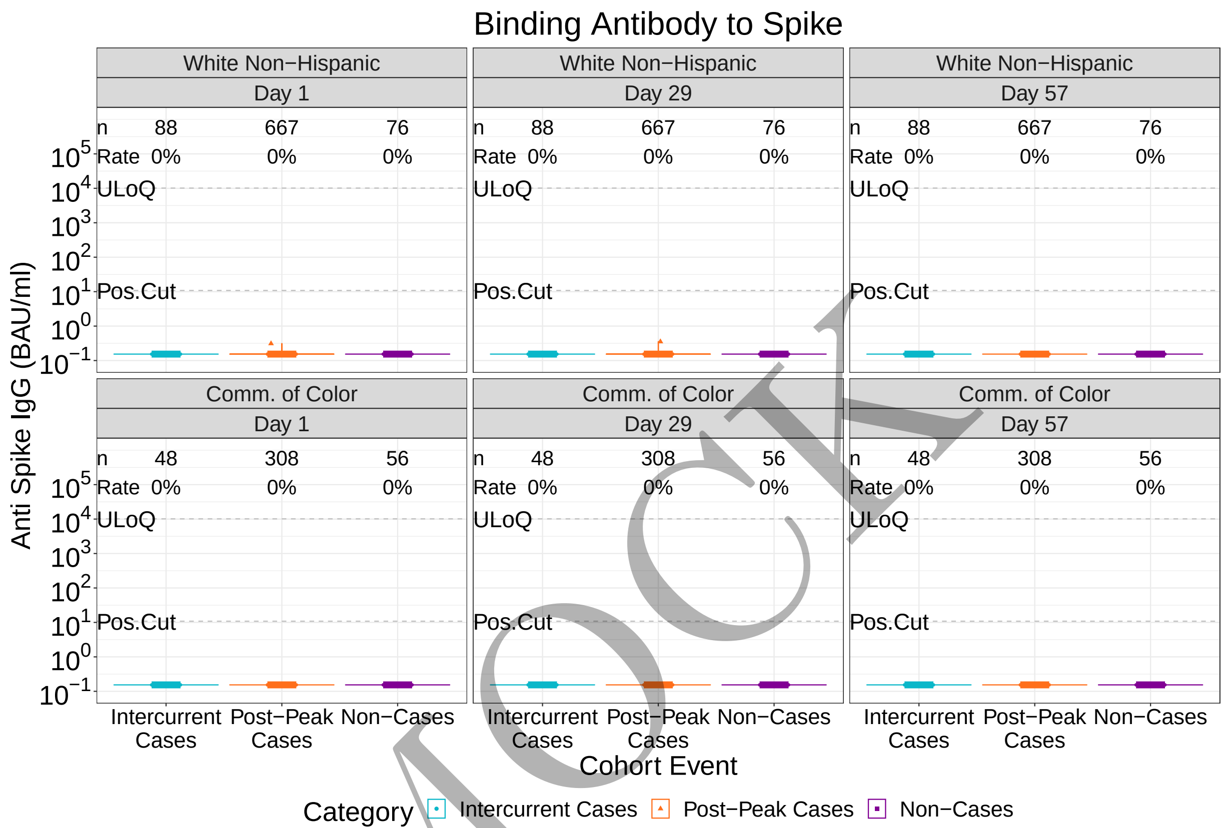
\caption{

Figure 2.5.184: lineplots of PsV Neutralization 80% Titer: baseline negative vaccine arm by race and ethnic group (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



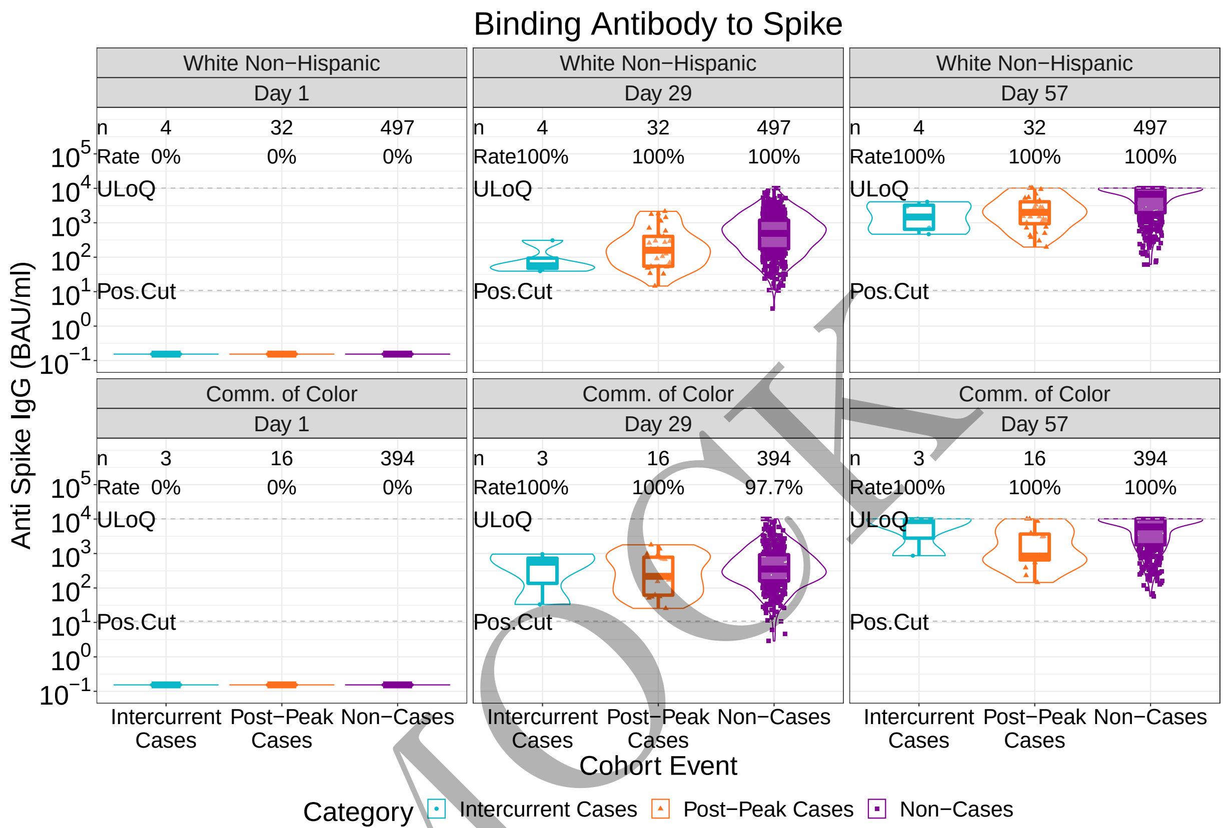
\caption{

Figure 2.5.185: violinplots of Binding Antibody to Spike: baseline negative placebo arm by race and ethnic group (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



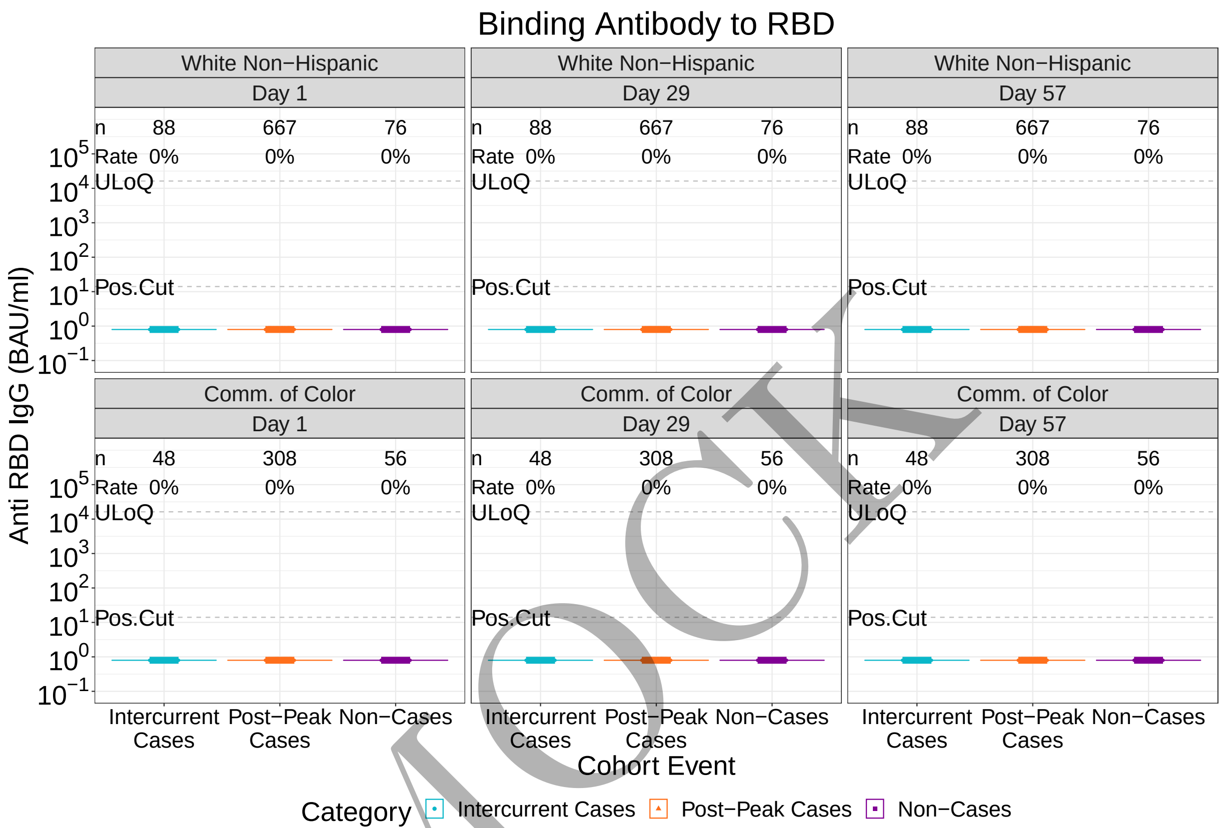
\caption{

Figure 2.5.186: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by race and ethnic group (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



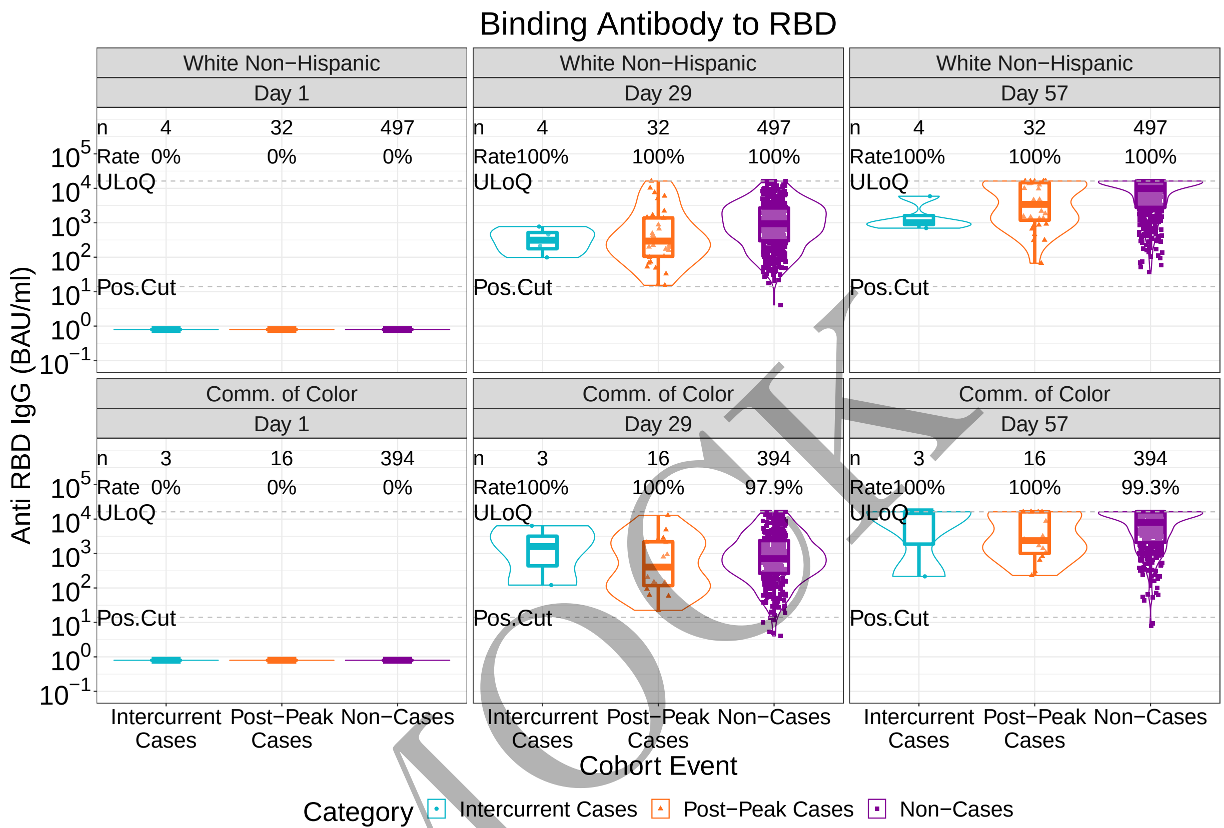
\caption{

Figure 2.5.187: violinplots of Binding Antibody to RBD: baseline negative placebo arm by race and ethnic group (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



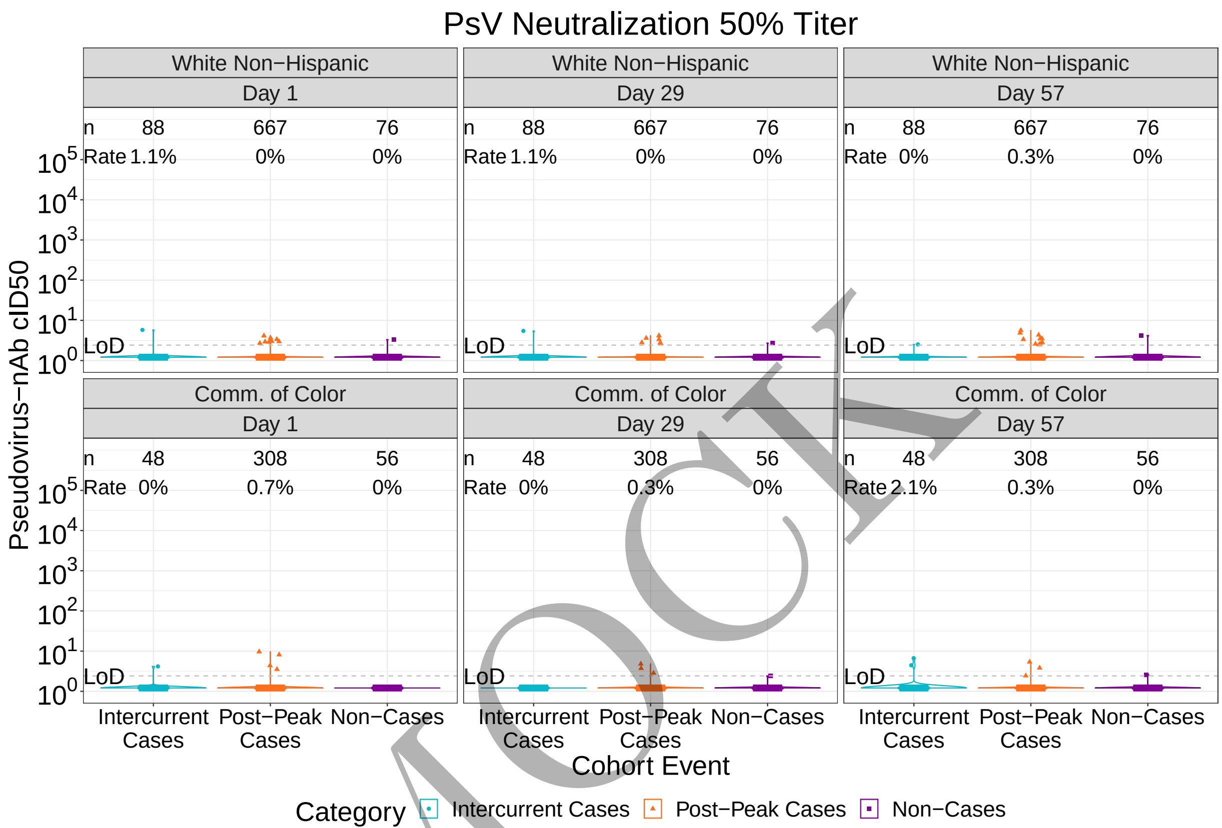
\caption{

Figure 2.5.188: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by race and ethnic group (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



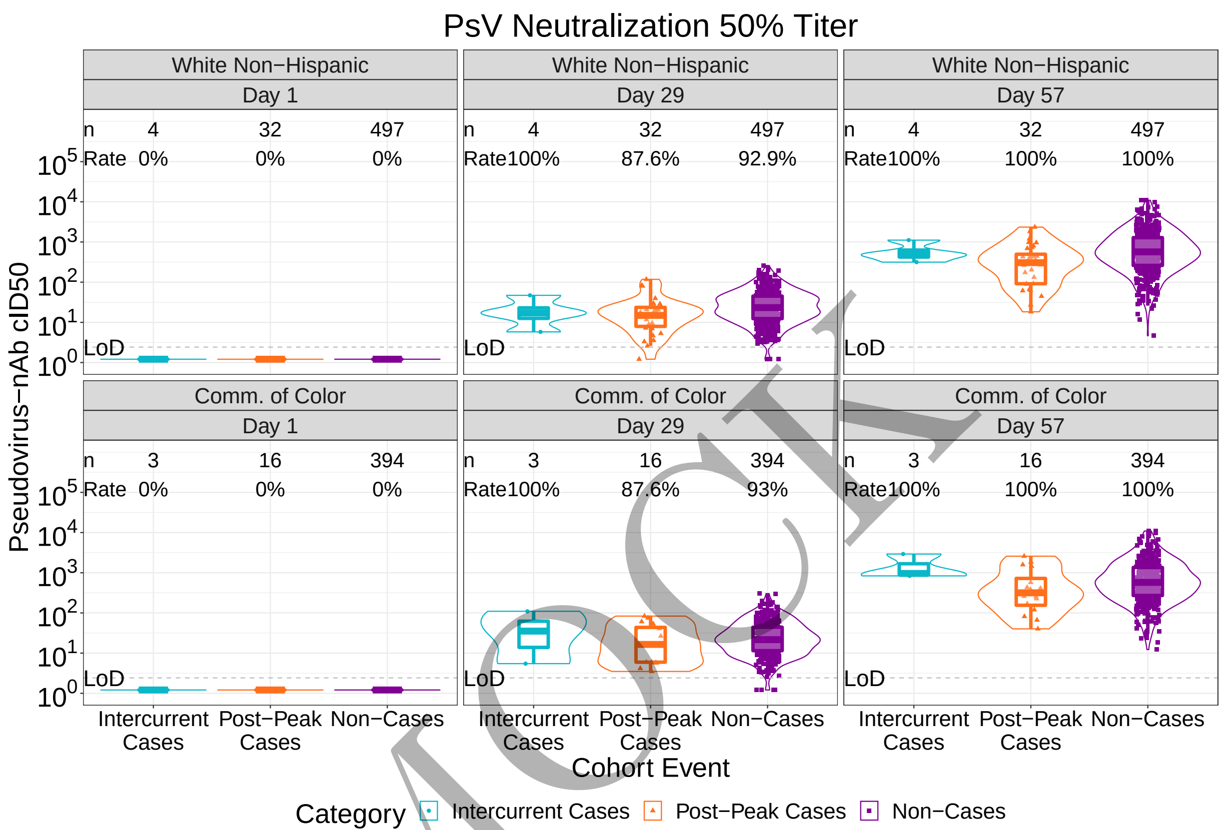
\caption{

Figure 2.5.189: violinplots of PsV Neutralization 50% Titer: baseline negative placebo arm by race and ethnic group (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



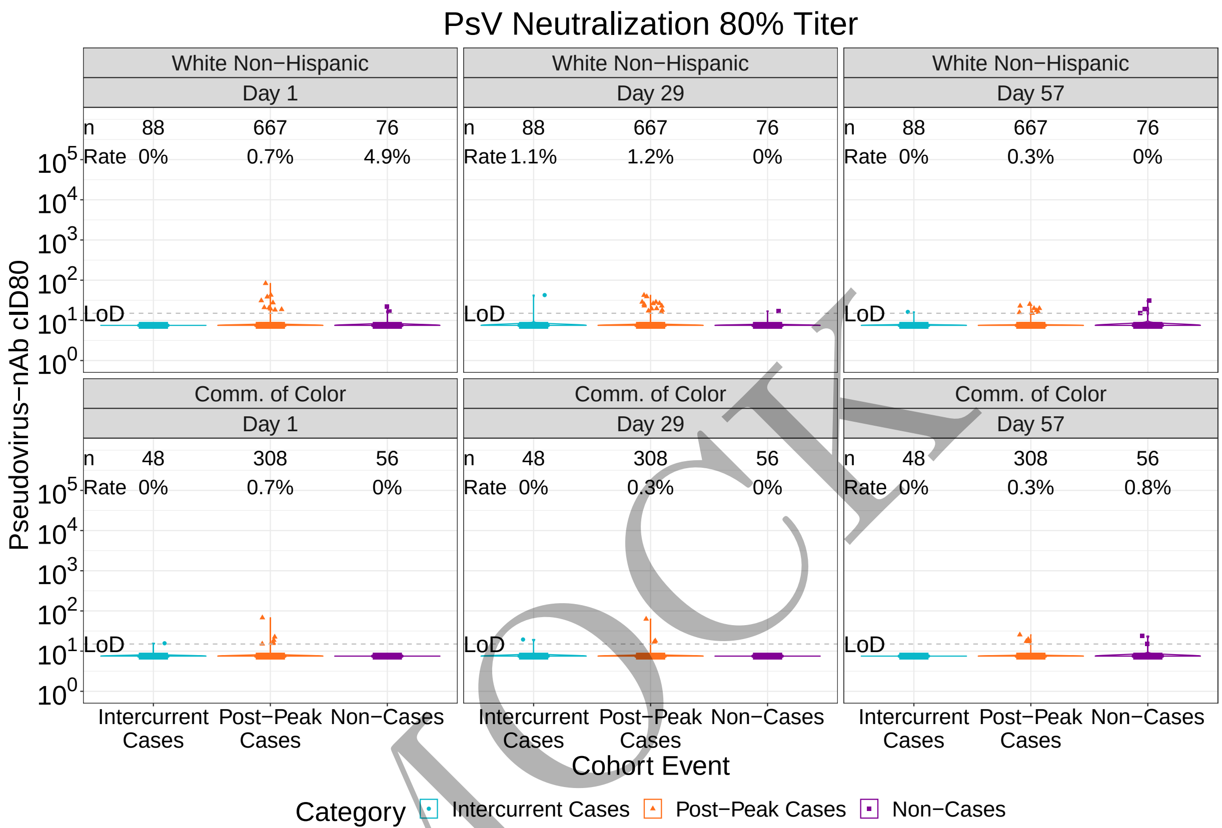
\caption{

Figure 2.5.190: violinplots of PsV Neutralization 50% Titer: baseline negative vaccine arm by race and ethnic group (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



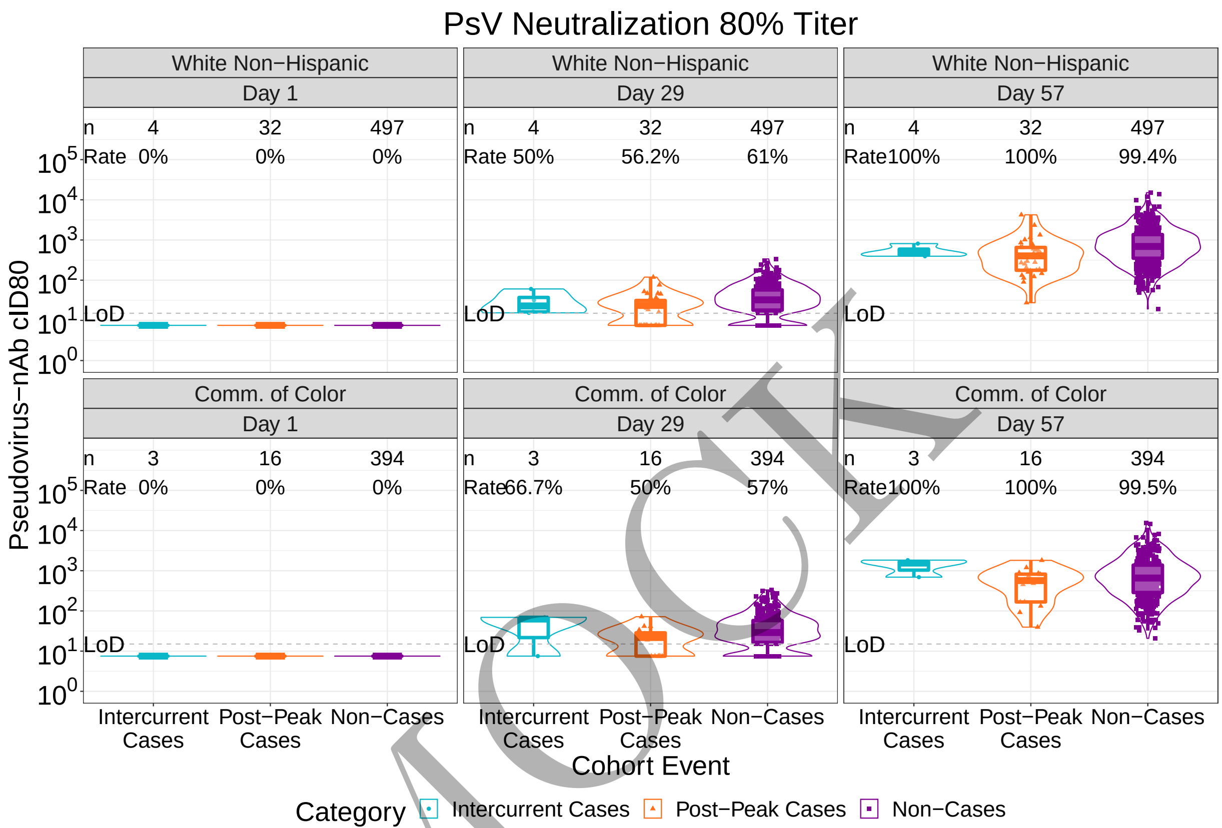
\caption{

Figure 2.5.191: violinplots of PsV Neutralization 80% Titer: baseline negative placebo arm by race and ethnic group (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



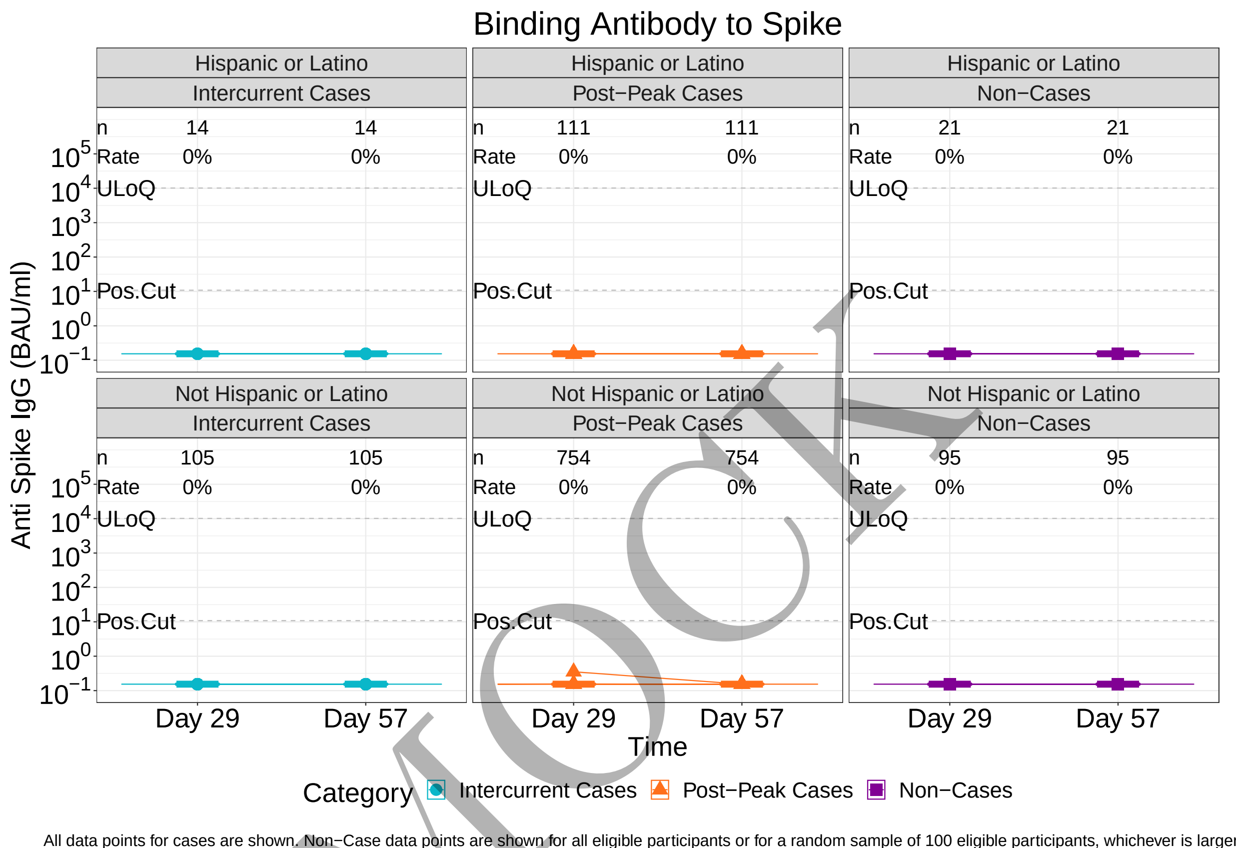
\caption{

Figure 2.5.192: violinplots of PsV Neutralization 80% Titer: baseline negative vaccine arm by race and ethnic group (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



\caption{

Figure 2.5.193: lineplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)

} \end{figure}

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r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")
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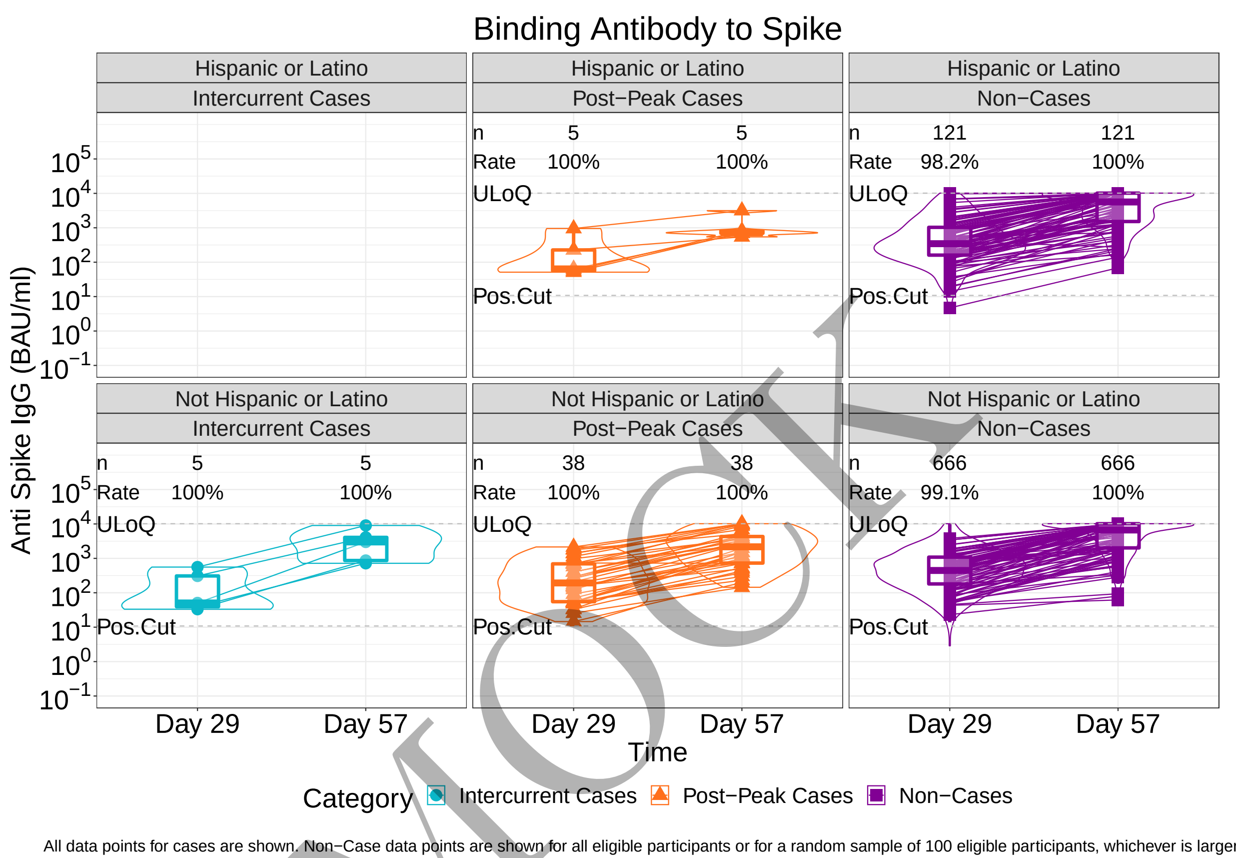
\begin{figure}



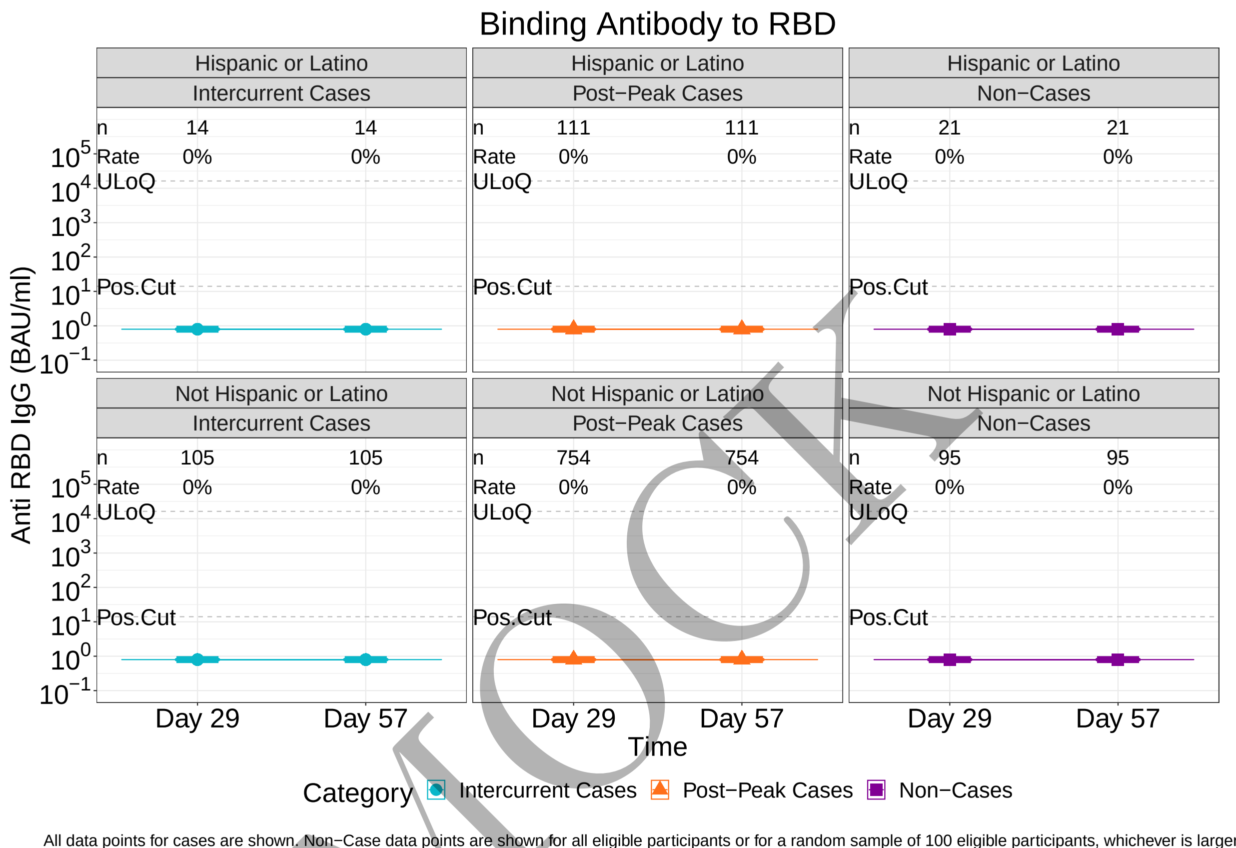
\caption{

Figure 2.5.194: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



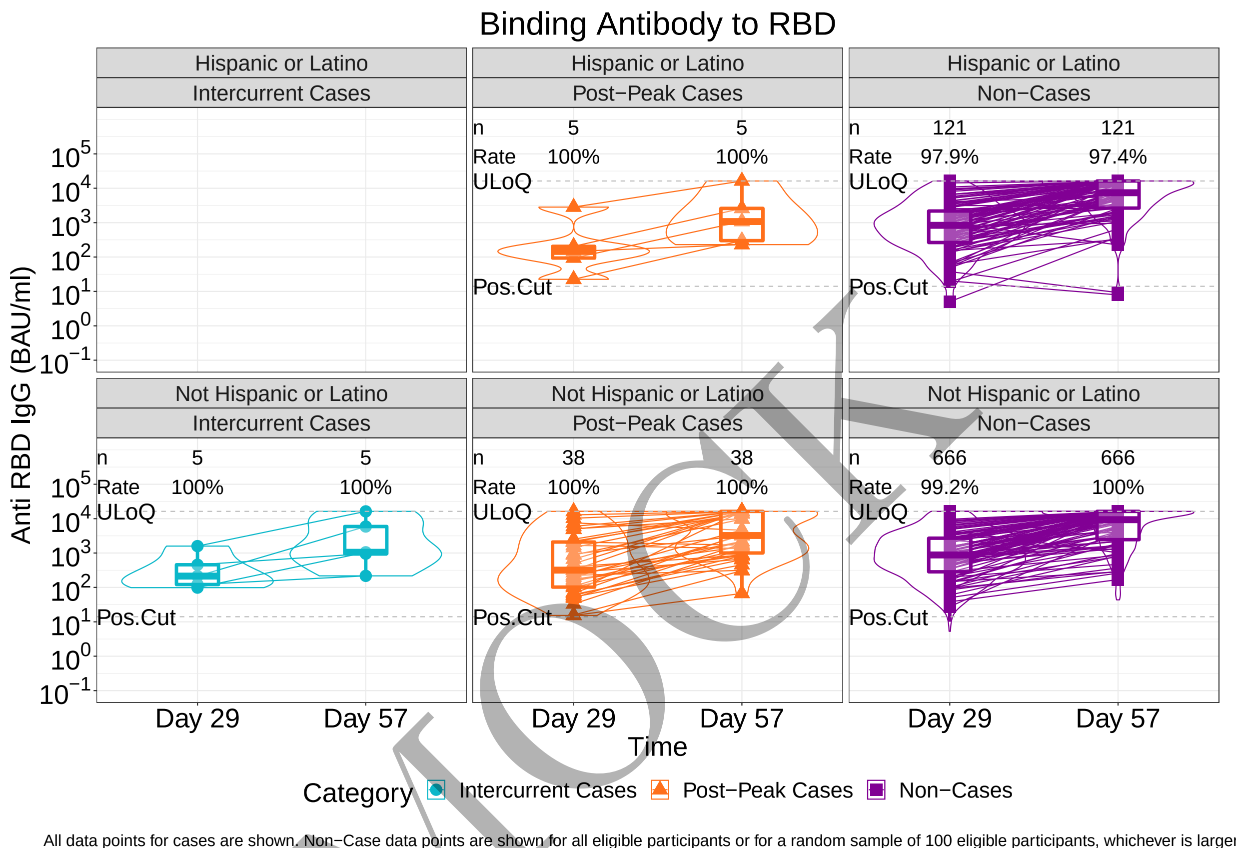
\caption{

Figure 2.5.195: lineplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



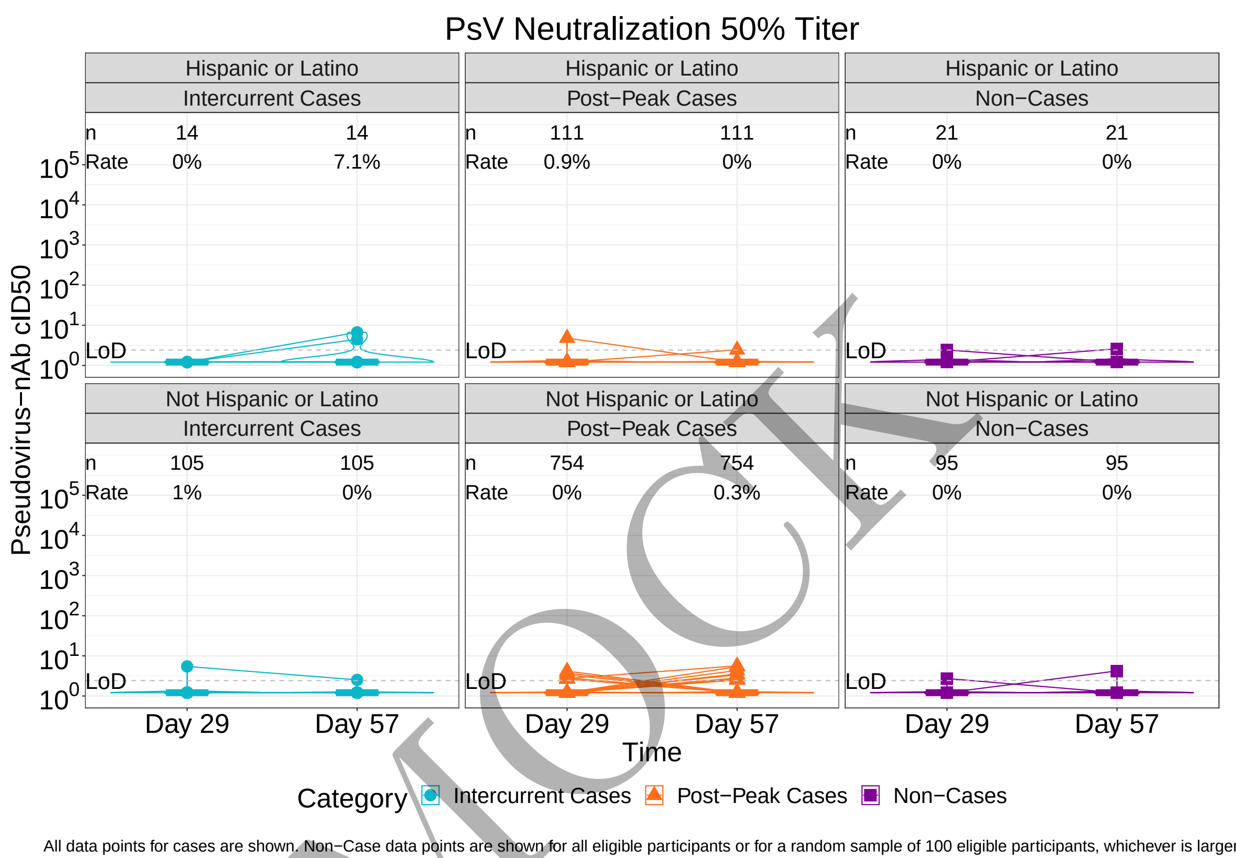
\caption{

Figure 2.5.196: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



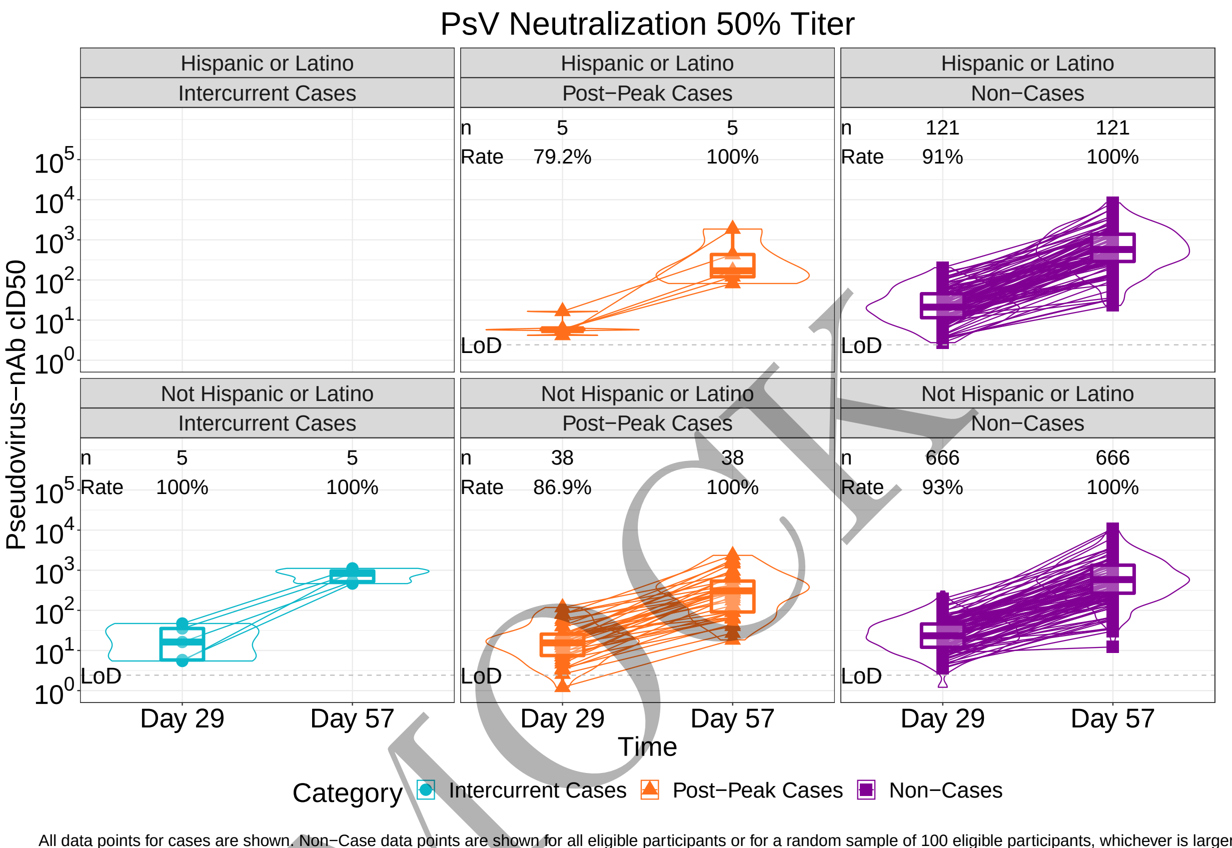
\caption{

Figure 2.5.197: lineplots of PsV Neutralization 50% Titer: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



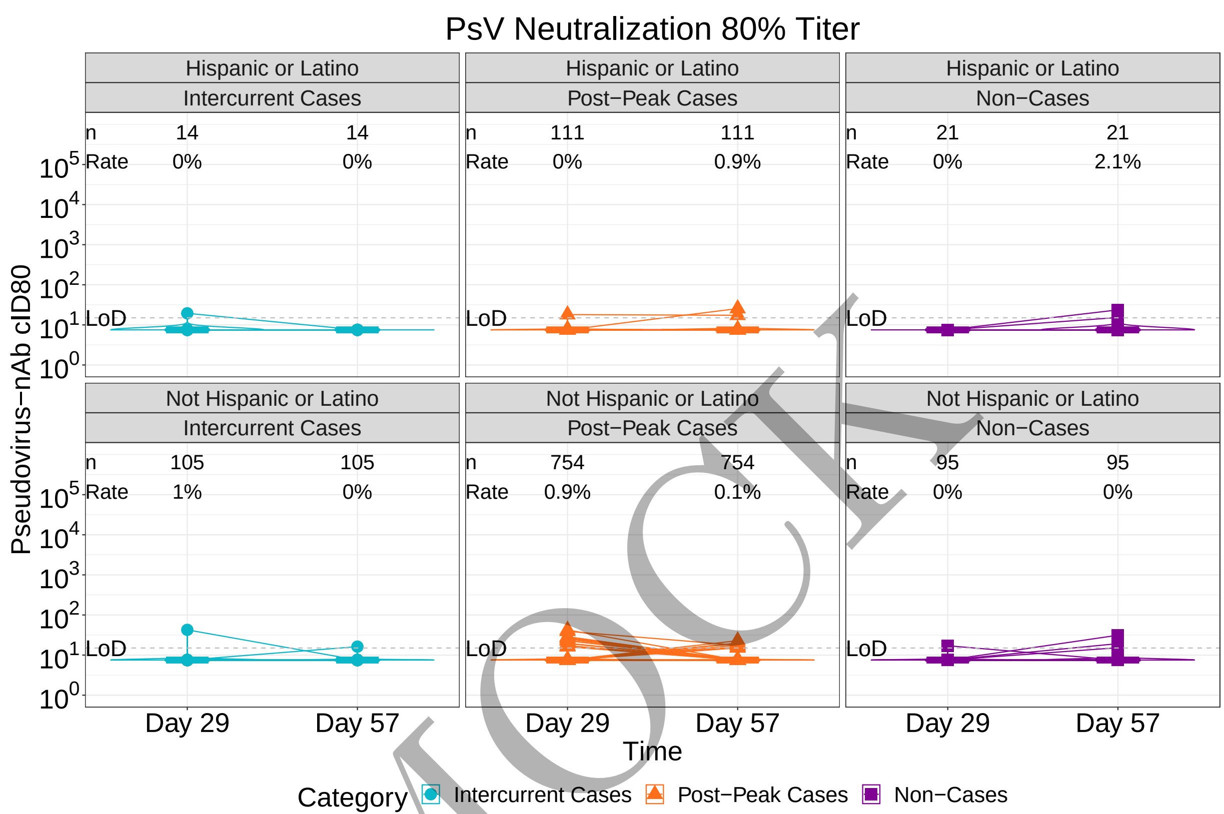
\caption{

Figure 2.5.198: lineplots of PsV Neutralization 50% Titer: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



All data points for cases are shown. Non−Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger

\caption{

Figure 2.5.199: lineplots of PsV Neutralization 80% Titer: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

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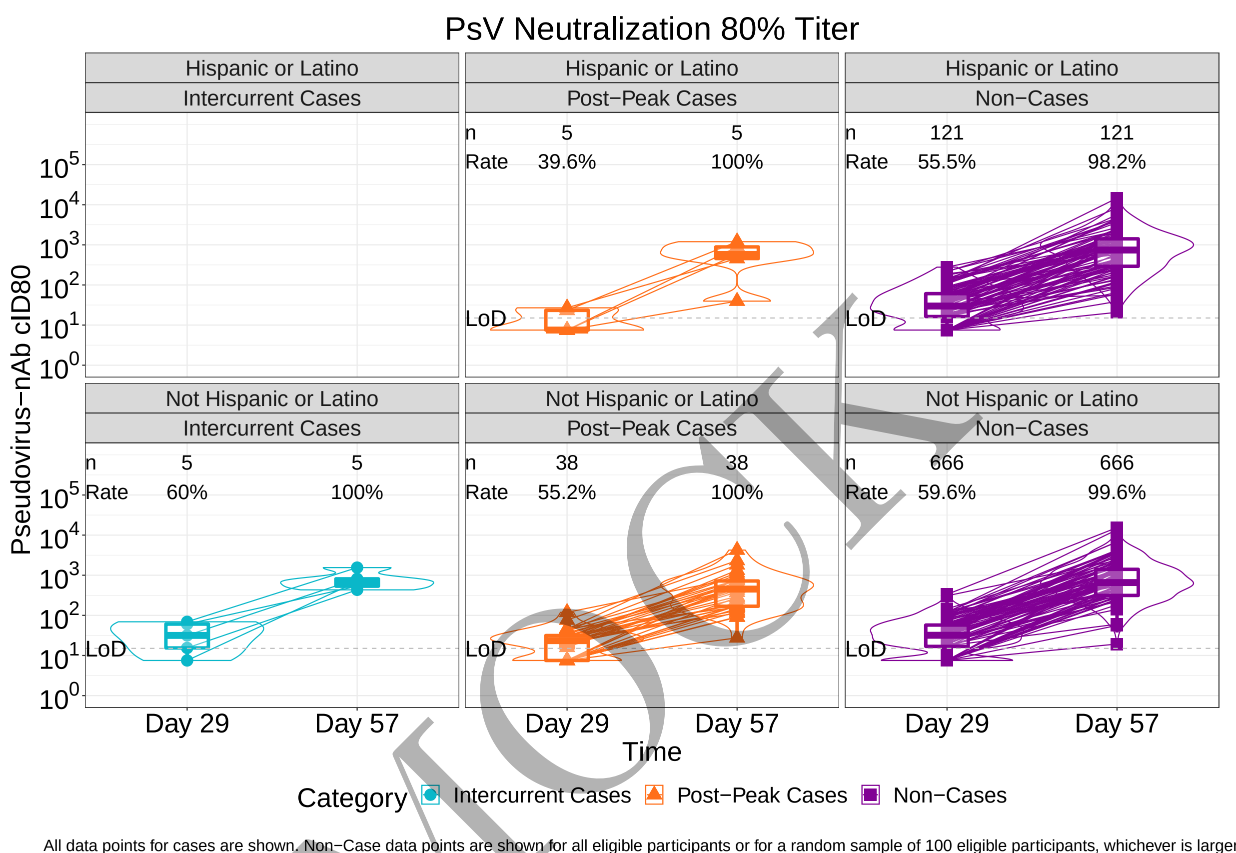

\caption{

Figure 2.5.200: lineplots of PsV Neutralization 80% Titer: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)

} \end{figure}

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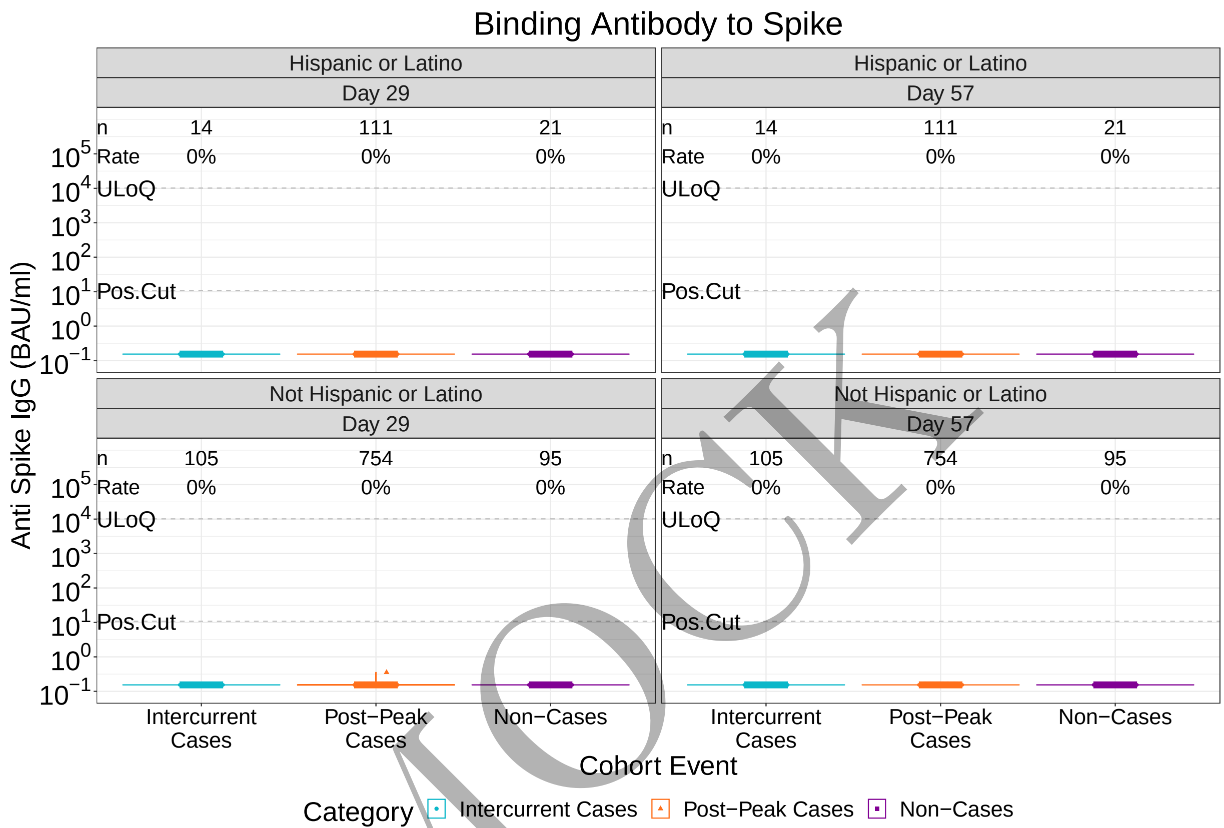

\caption{

Figure 2.5.201: violinplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)

} \end{figure}

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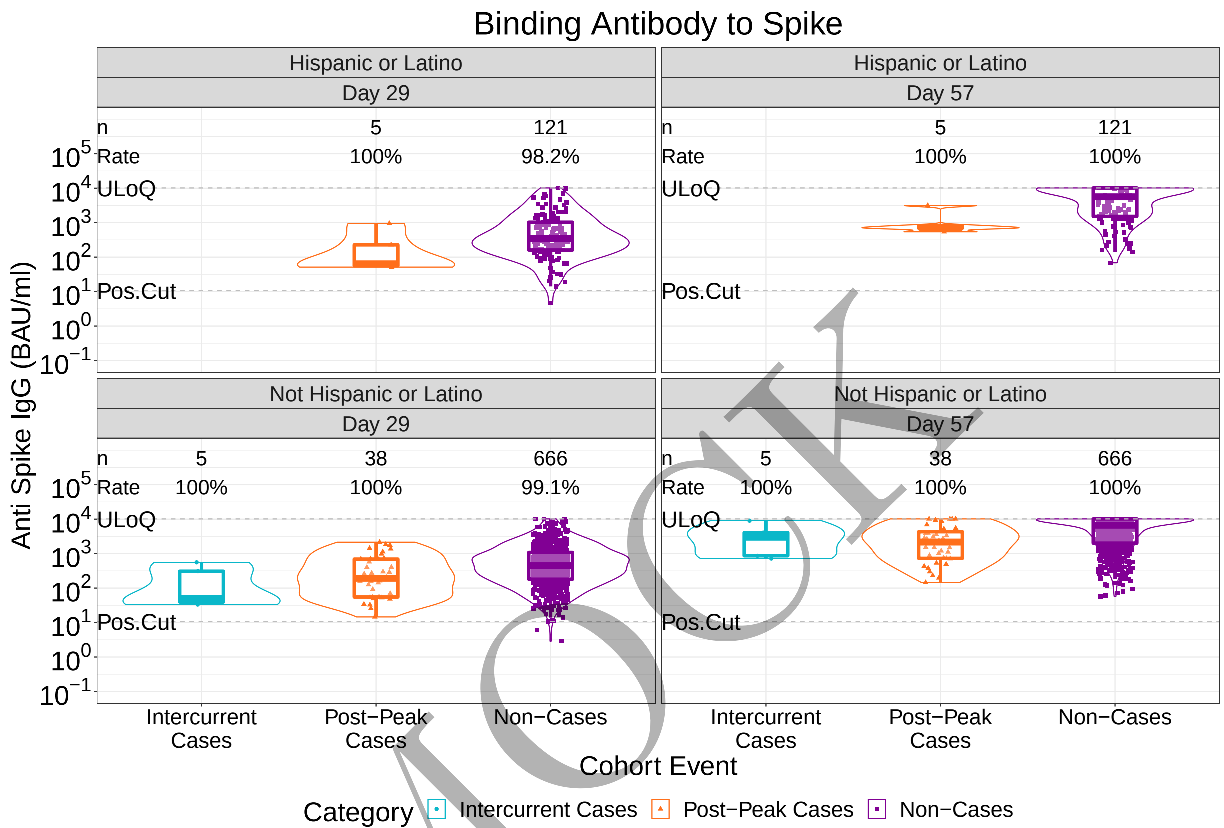
\begin{figure}



\caption{

Figure 2.5.202: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)

} \end{figure}

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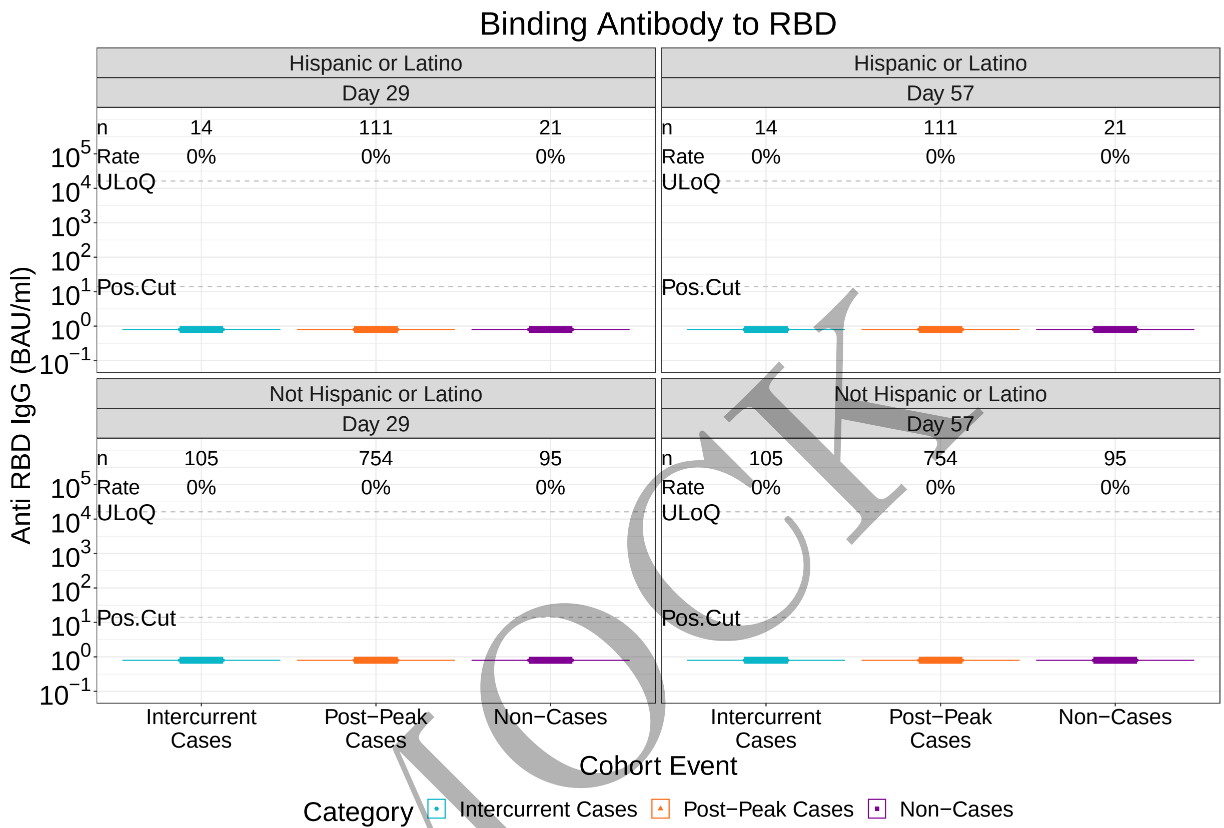


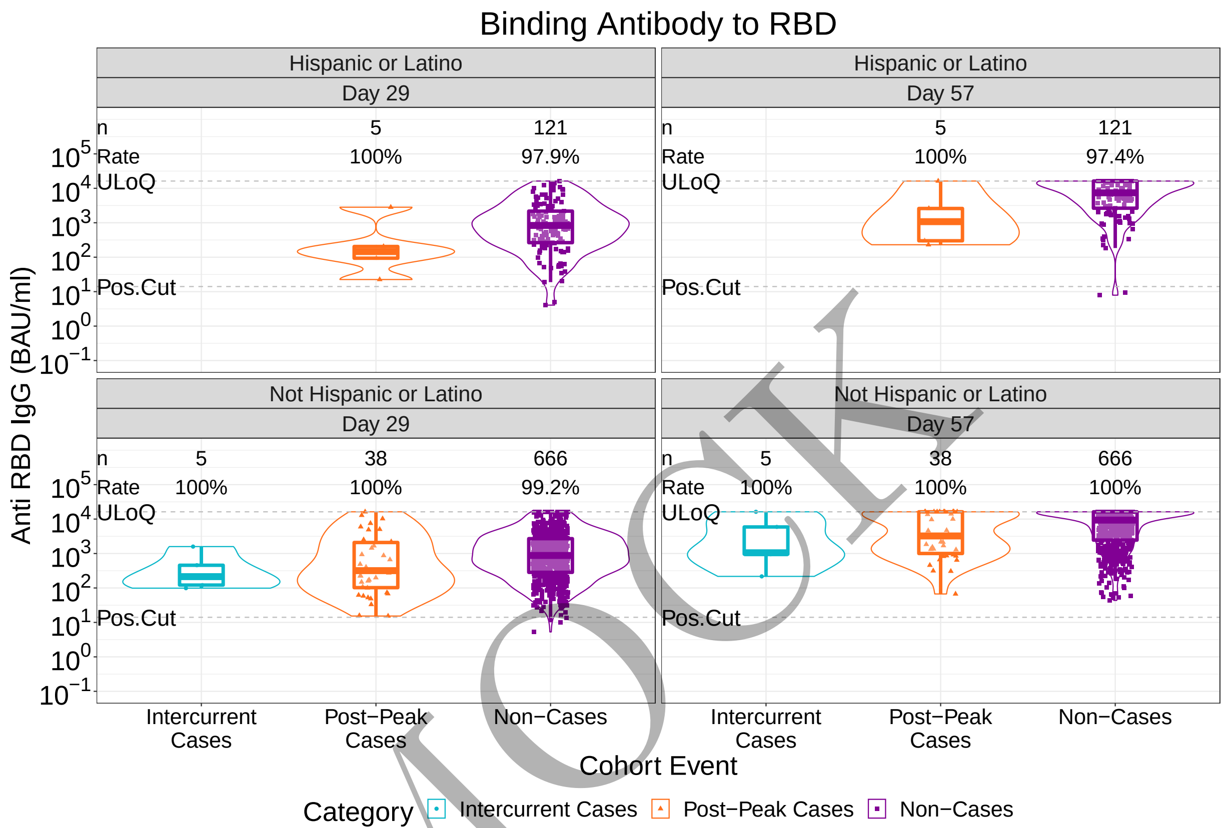
\caption{

Figure 2.5.203: violinplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



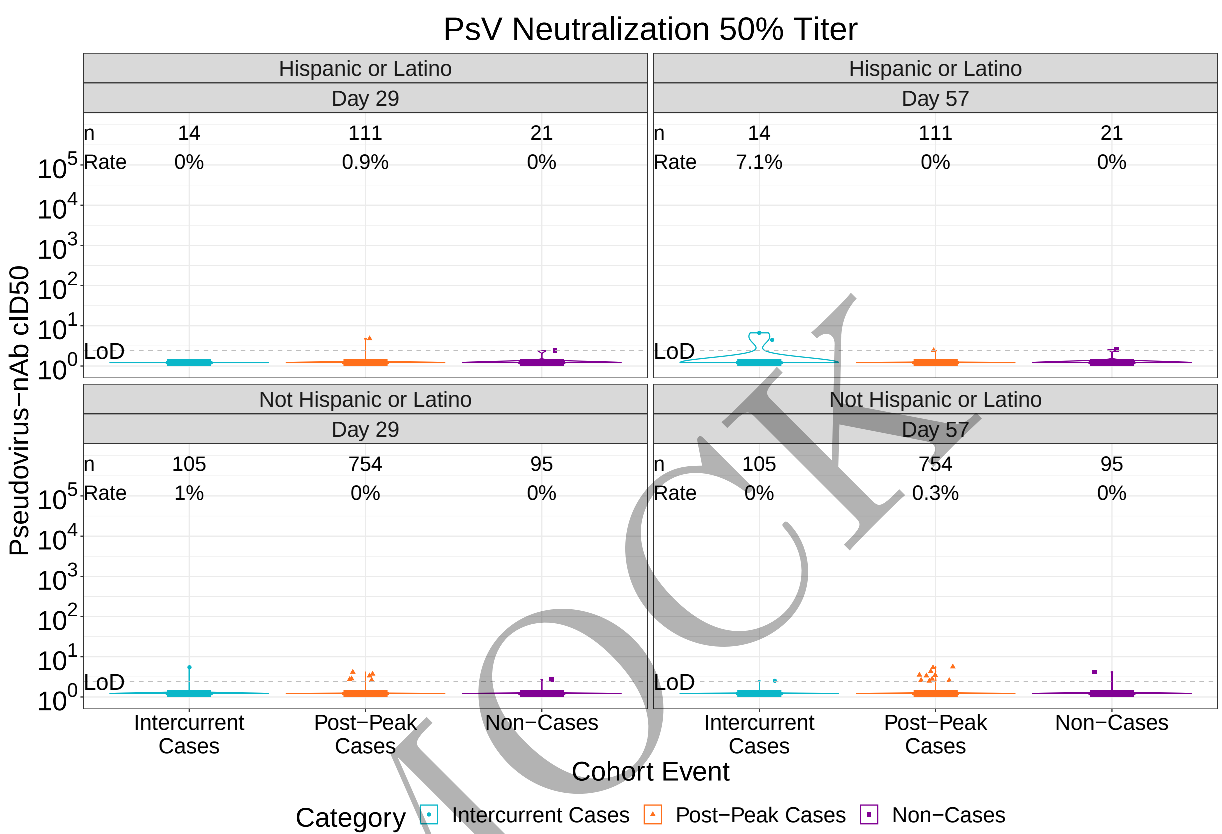
\caption{

Figure 2.5.204: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



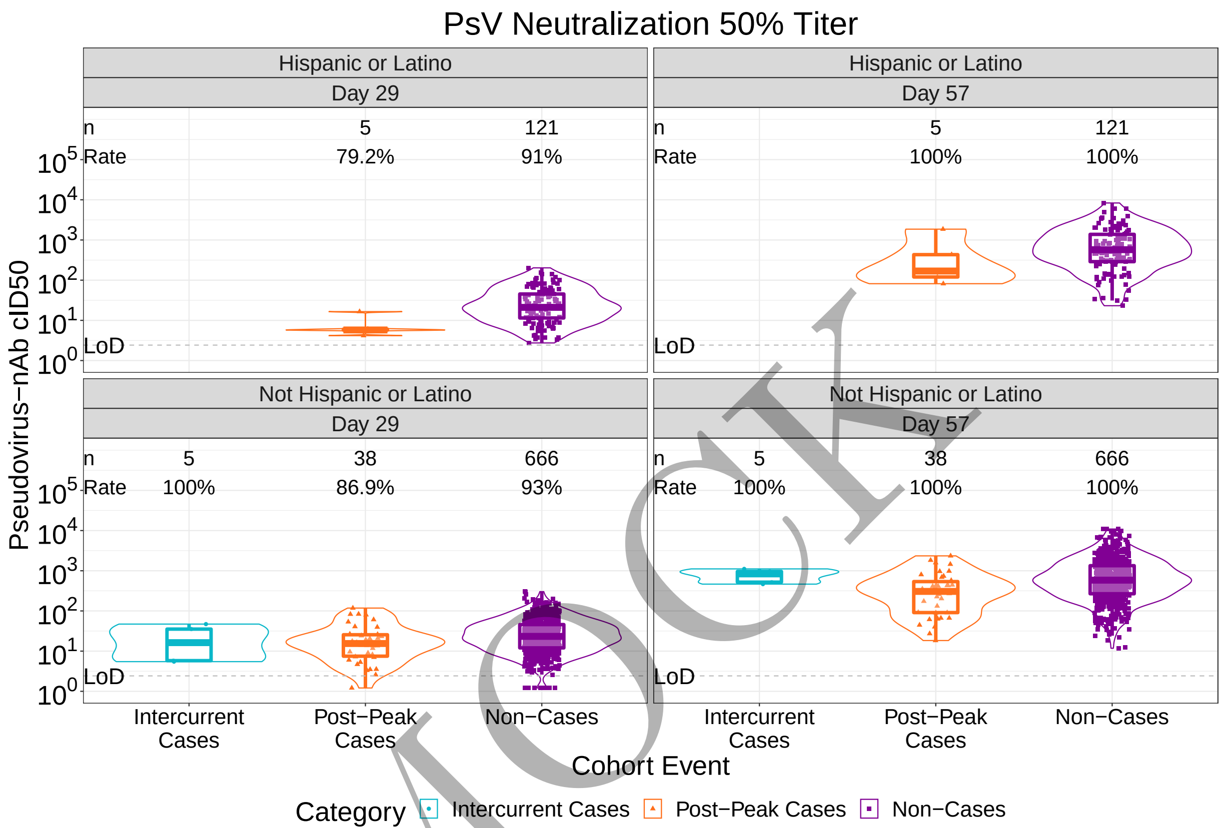
\caption{

Figure 2.5.205: violinplots of PsV Neutralization 50% Titer: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



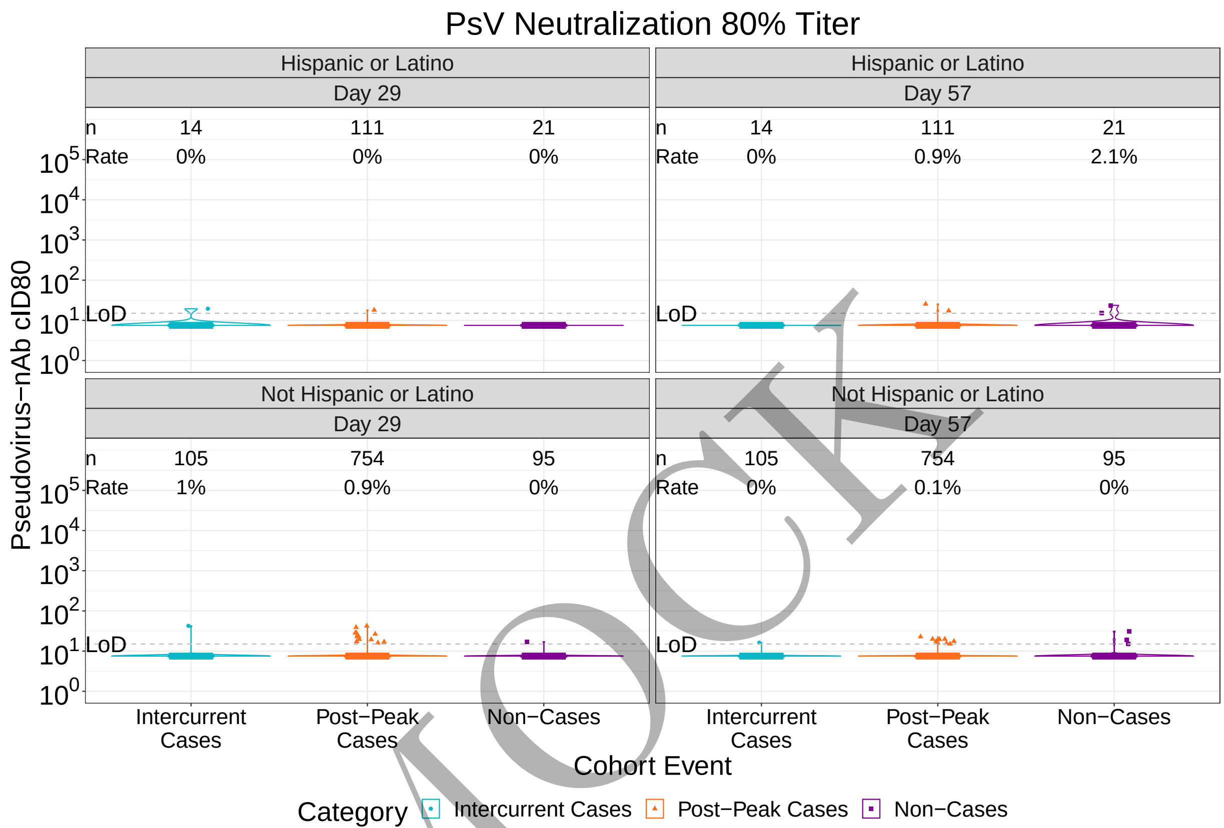
\caption{

Figure 2.5.206: violinplots of PsV Neutralization 50% Titer: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



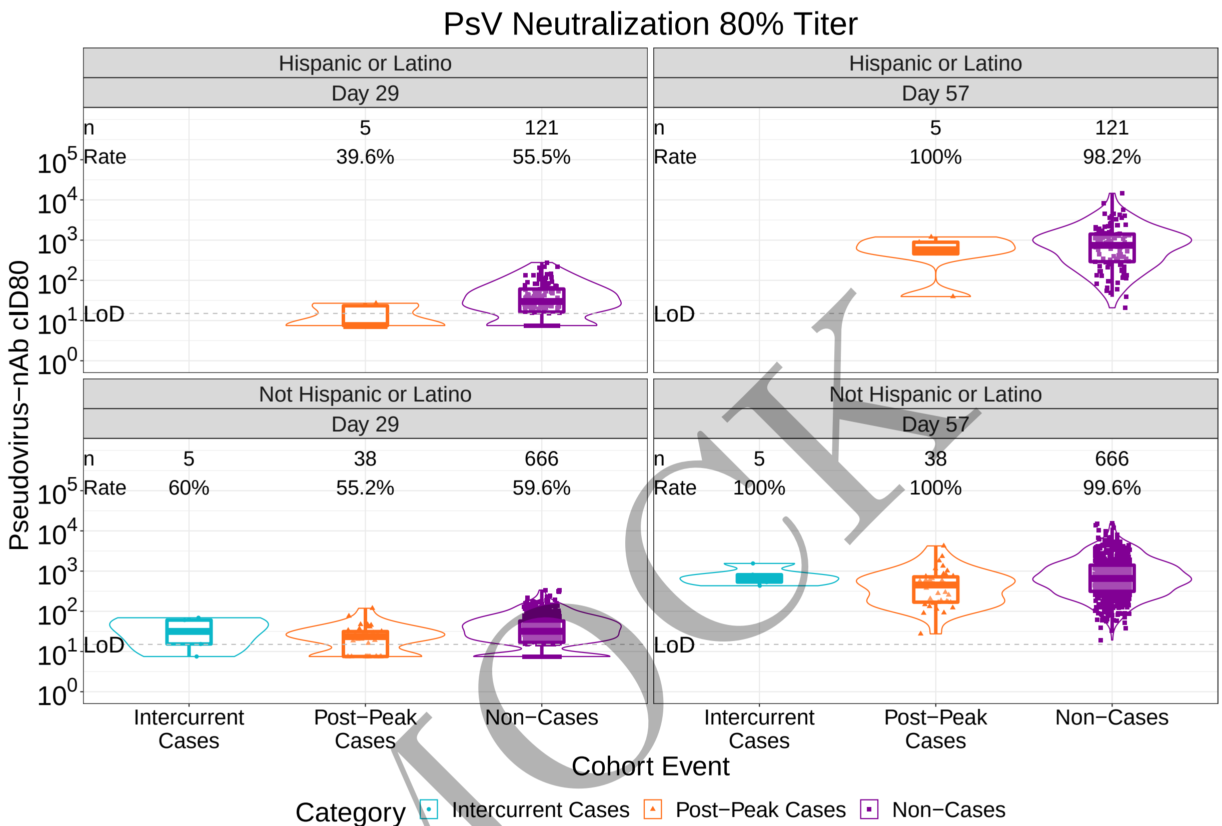
\caption{

Figure 2.5.207: violinplots of PsV Neutralization 80% Titer: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



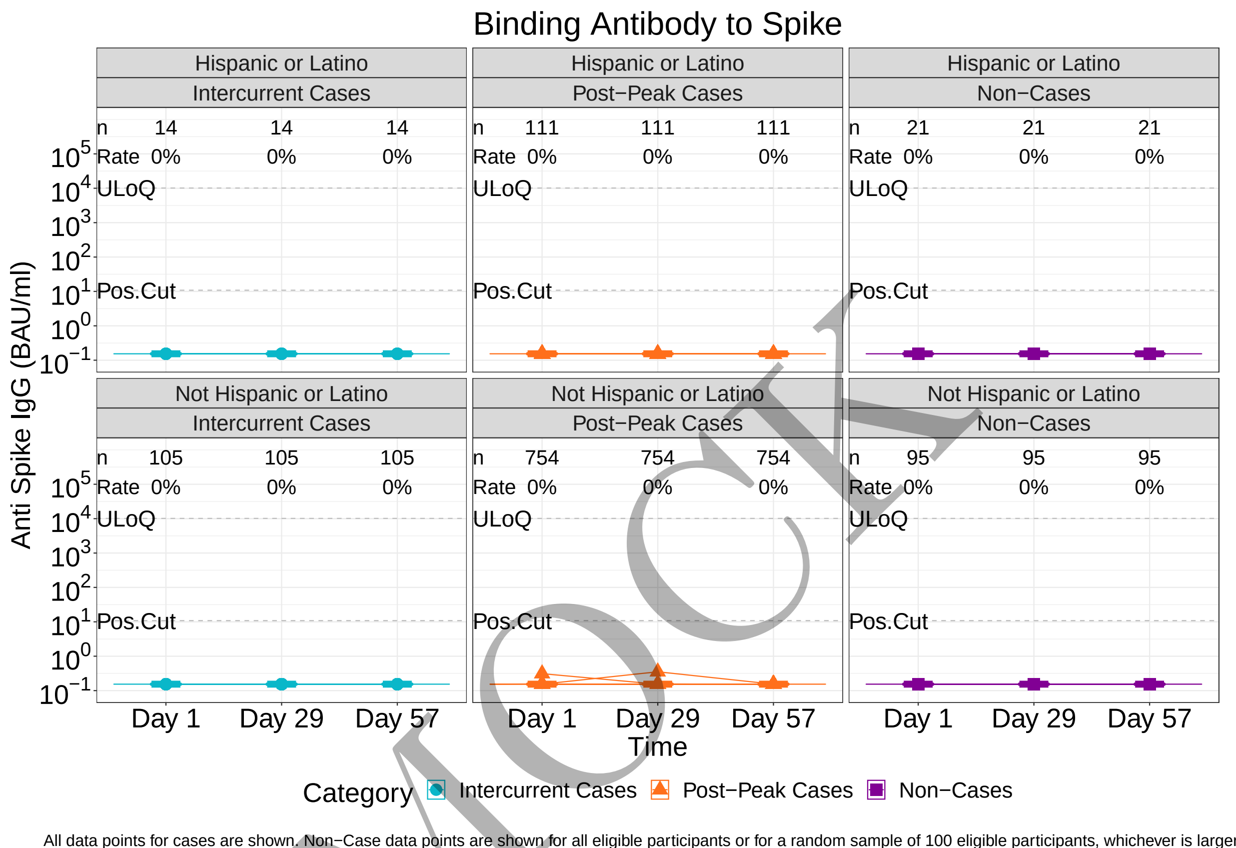
\caption{

Figure 2.5.208: violinplots of PsV Neutralization 80% Titer: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 1)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



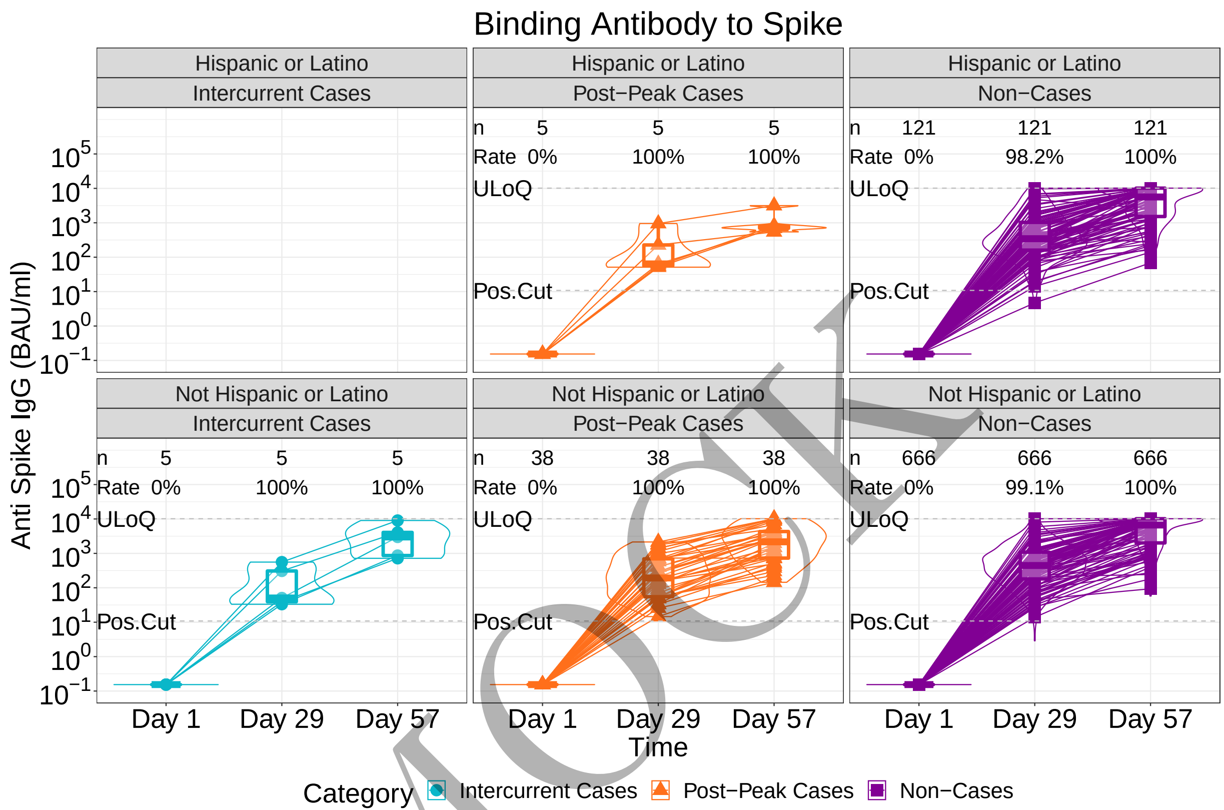
\caption{

Figure 2.5.209: lineplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



All data points for cases are shown. Non−Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger

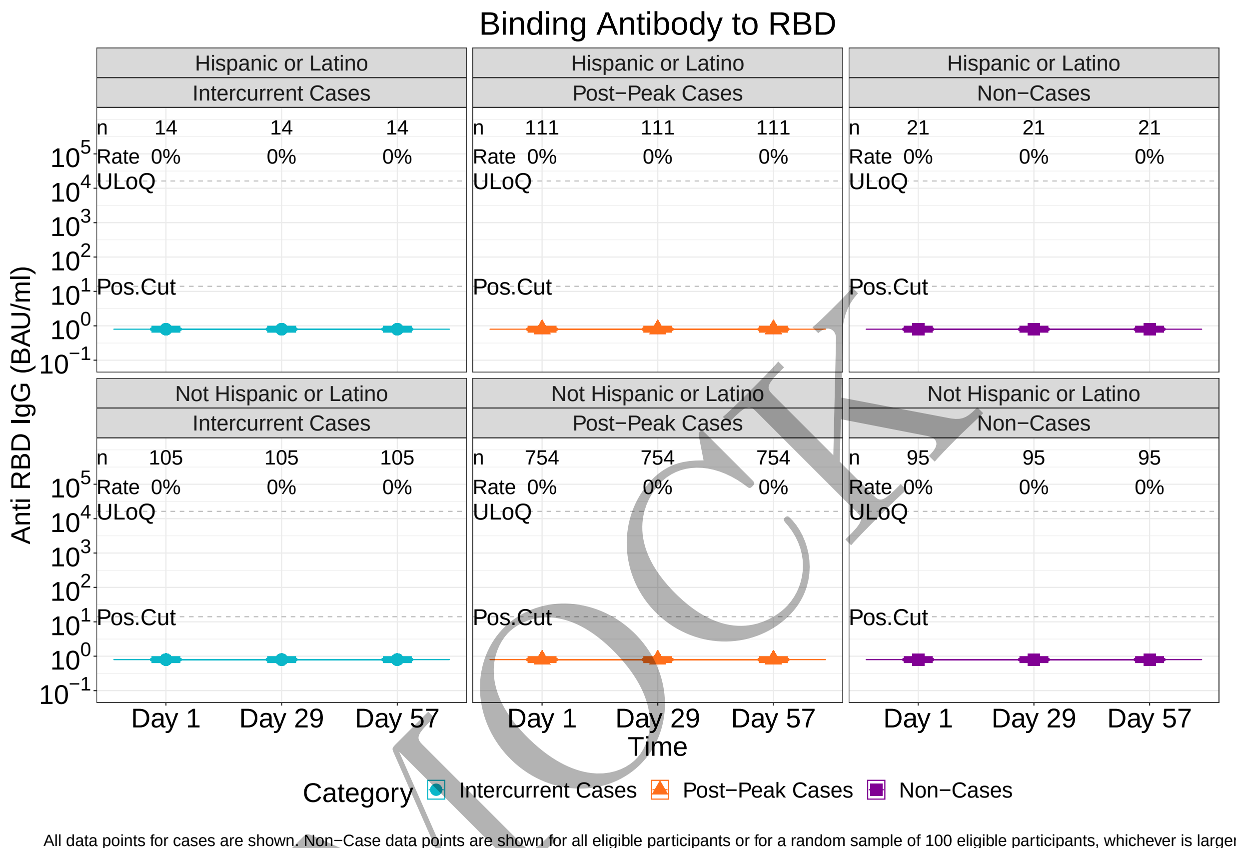
\caption{

Figure 2.5.210: lineplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



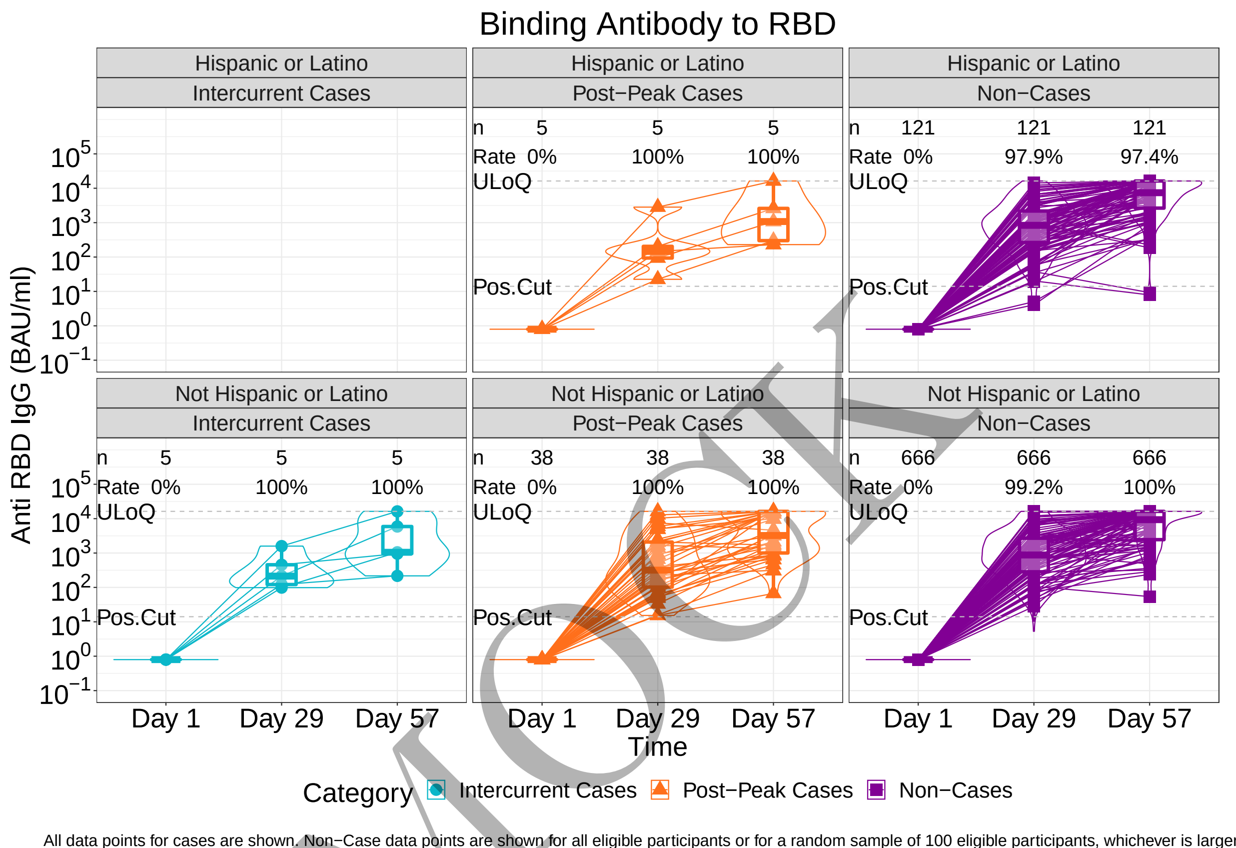
\caption{

Figure 2.5.211: lineplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



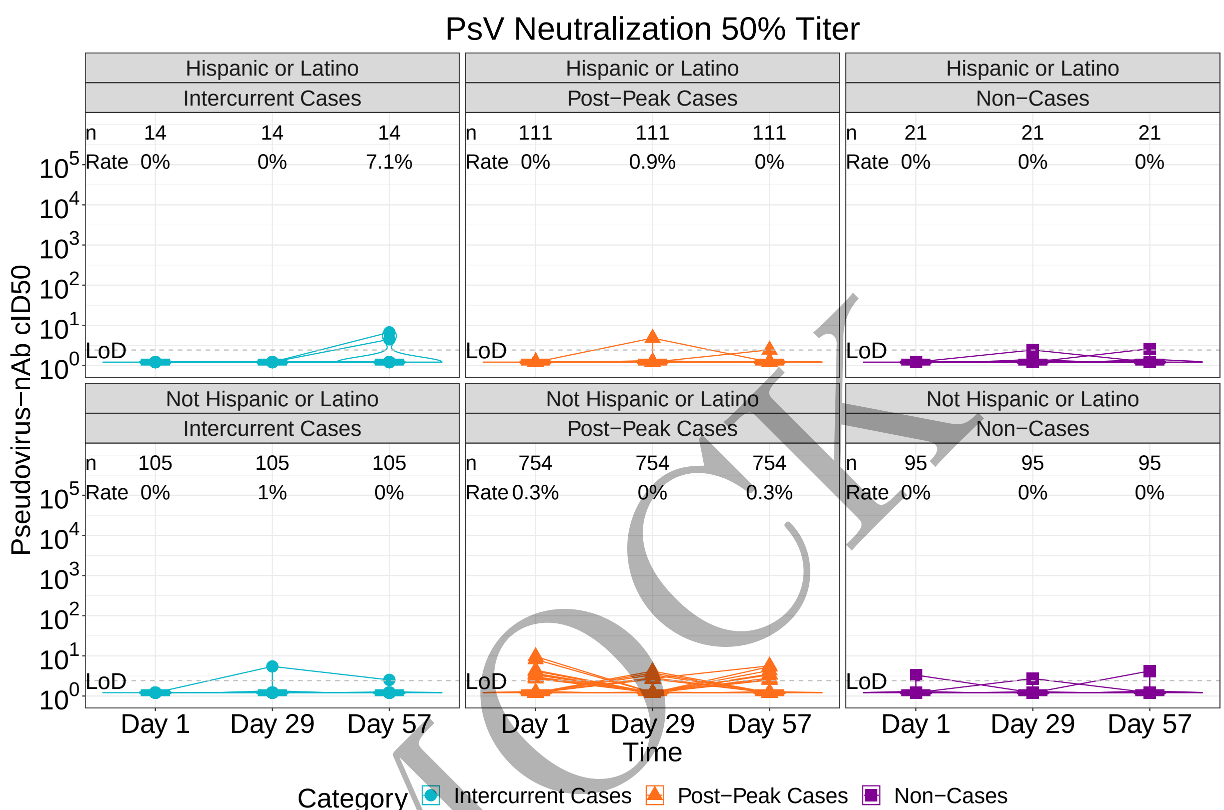
\caption{

Figure 2.5.212: lineplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



All data points for cases are shown. Non−Case data points are shown for all eligible participants or for a random sample of 100 eligible participants, whichever is larger

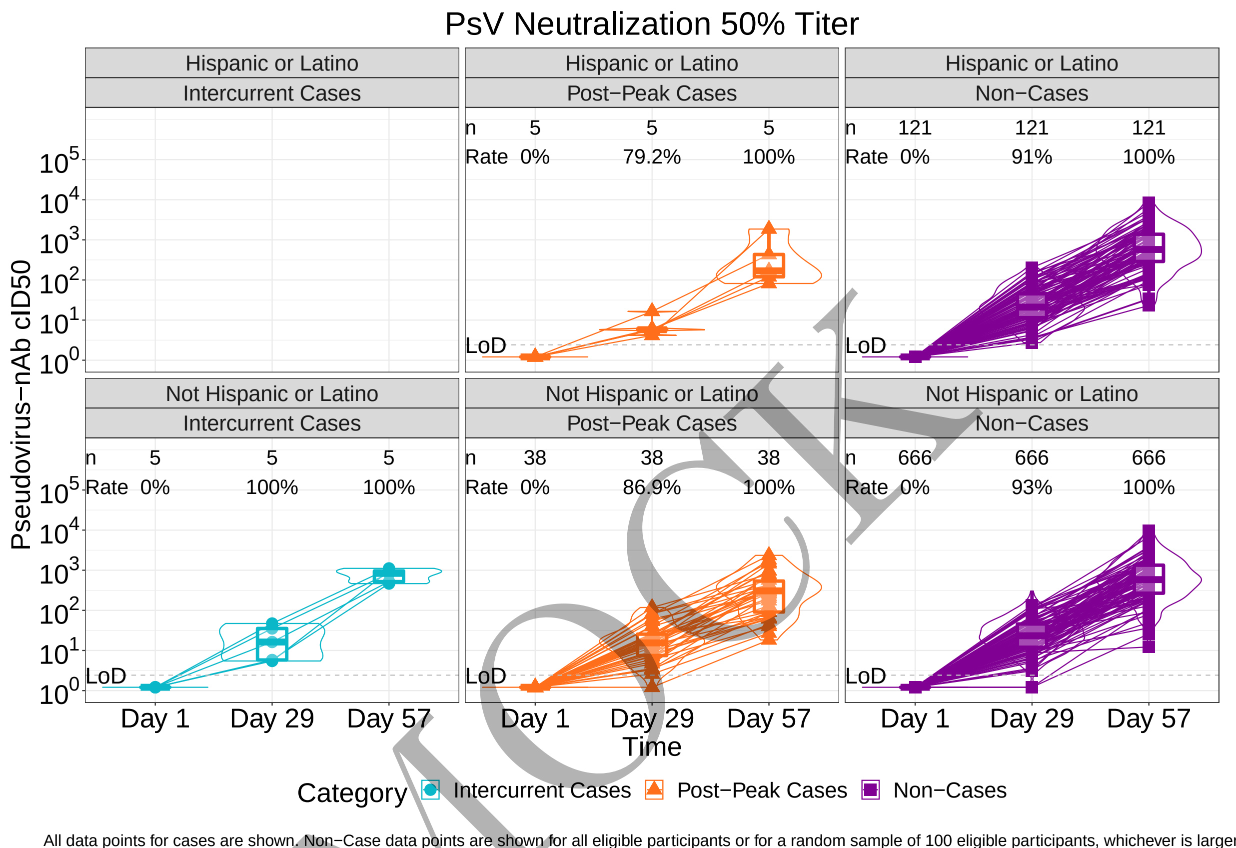
\caption{

Figure 2.5.213: lineplots of PsV Neutralization 50% Titer: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



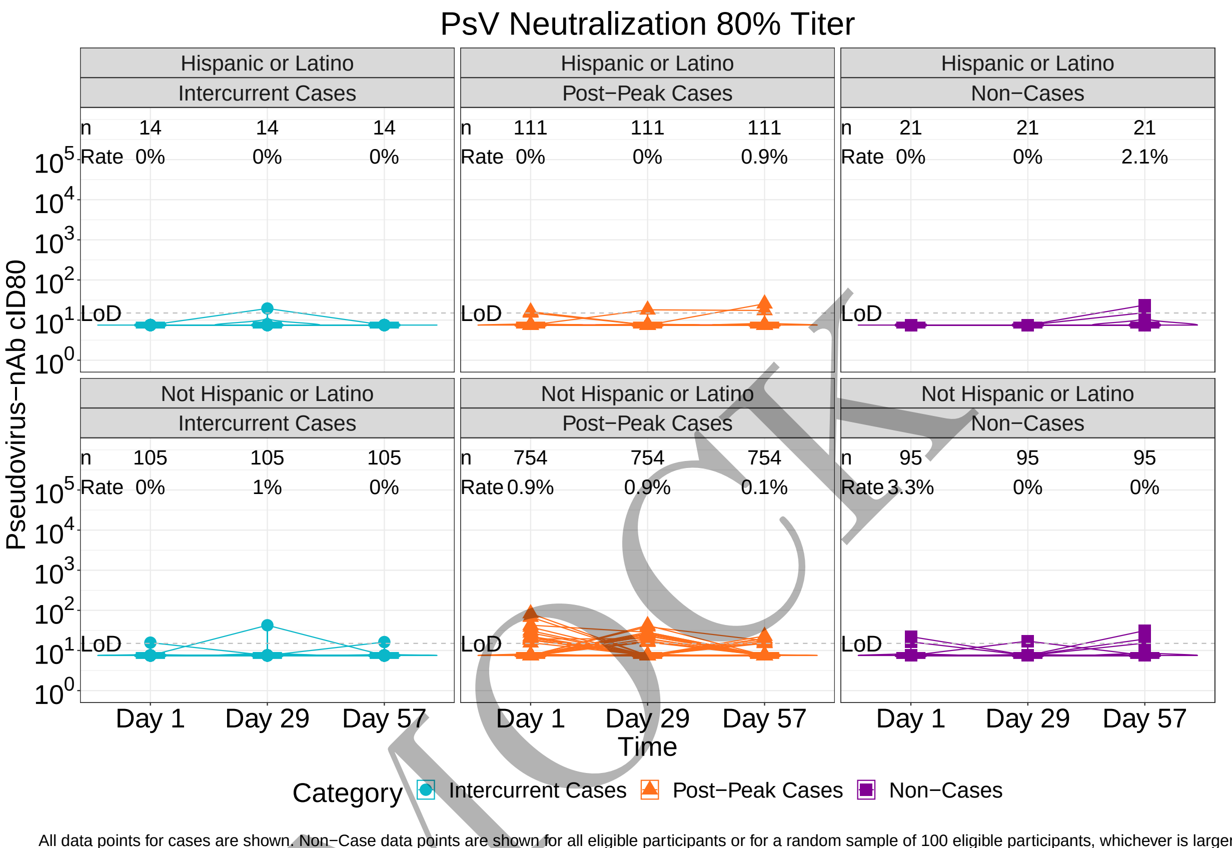
\caption{

Figure 2.5.214: lineplots of PsV Neutralization 50% Titer: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



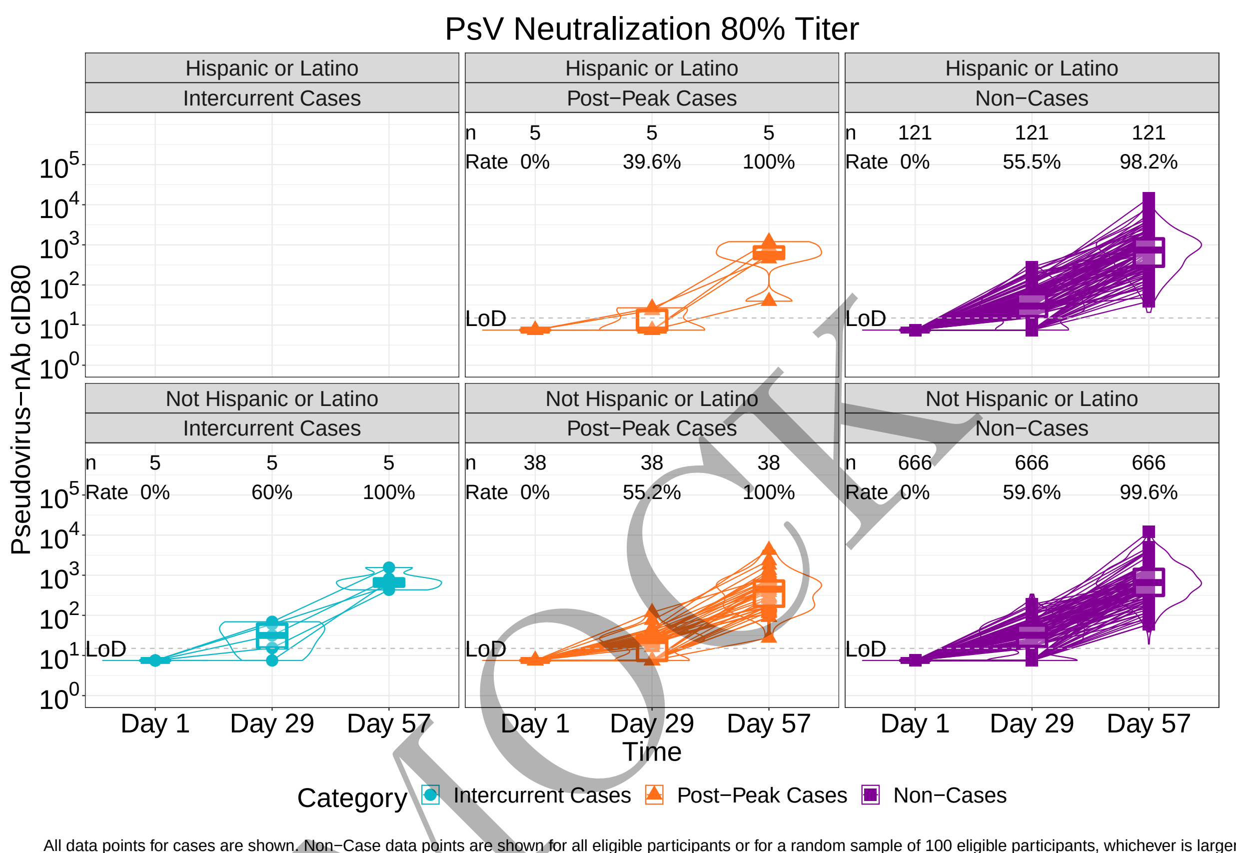
\caption{

Figure 2.5.215: lineplots of PsV Neutralization 80% Titer: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



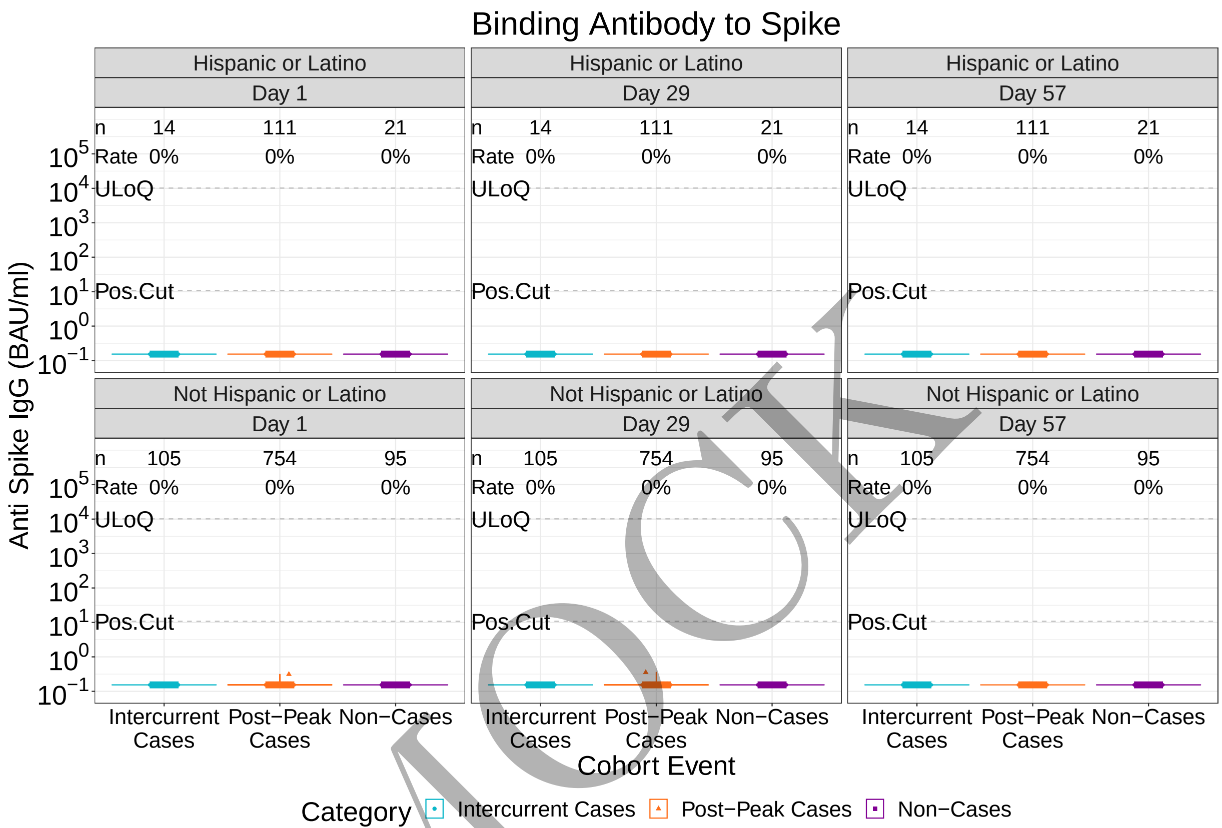
\caption{

Figure 2.5.216: lineplots of PsV Neutralization 80% Titer: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



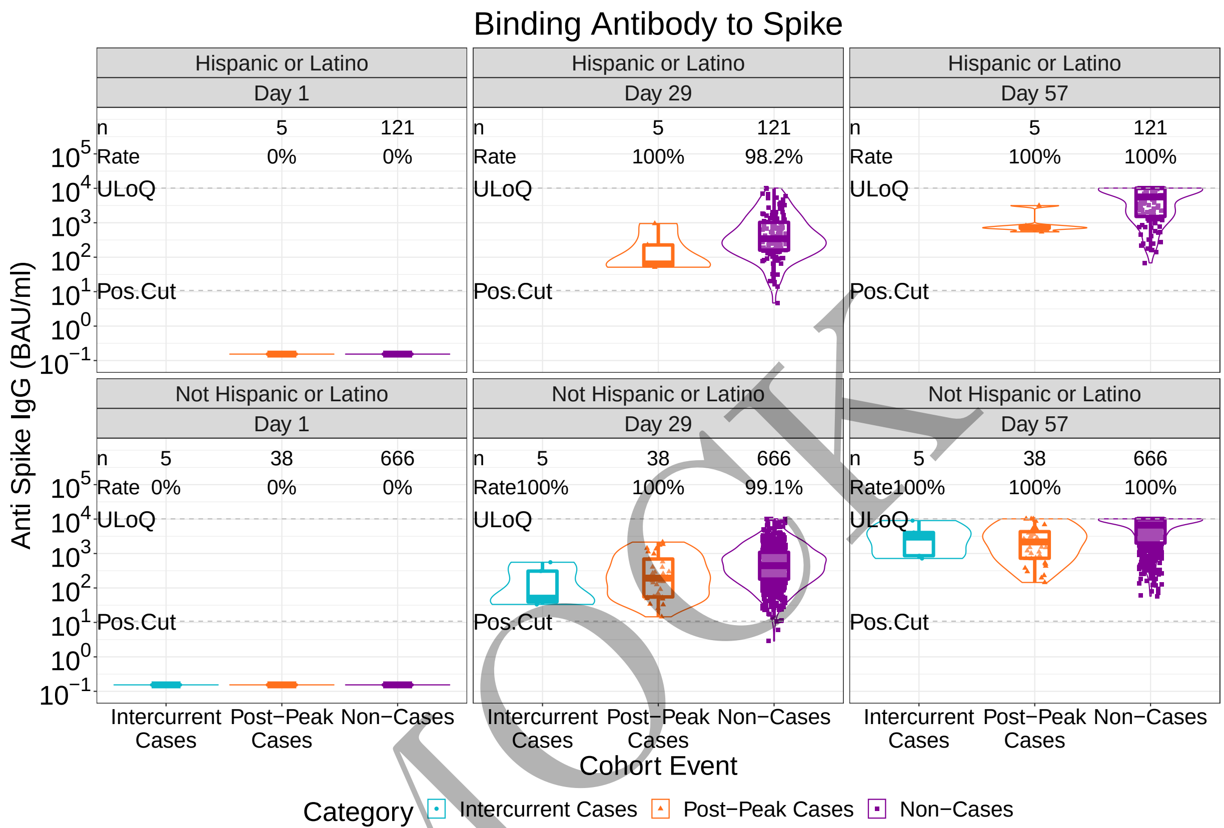
\caption{

Figure 2.5.217: violinplots of Binding Antibody to Spike: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



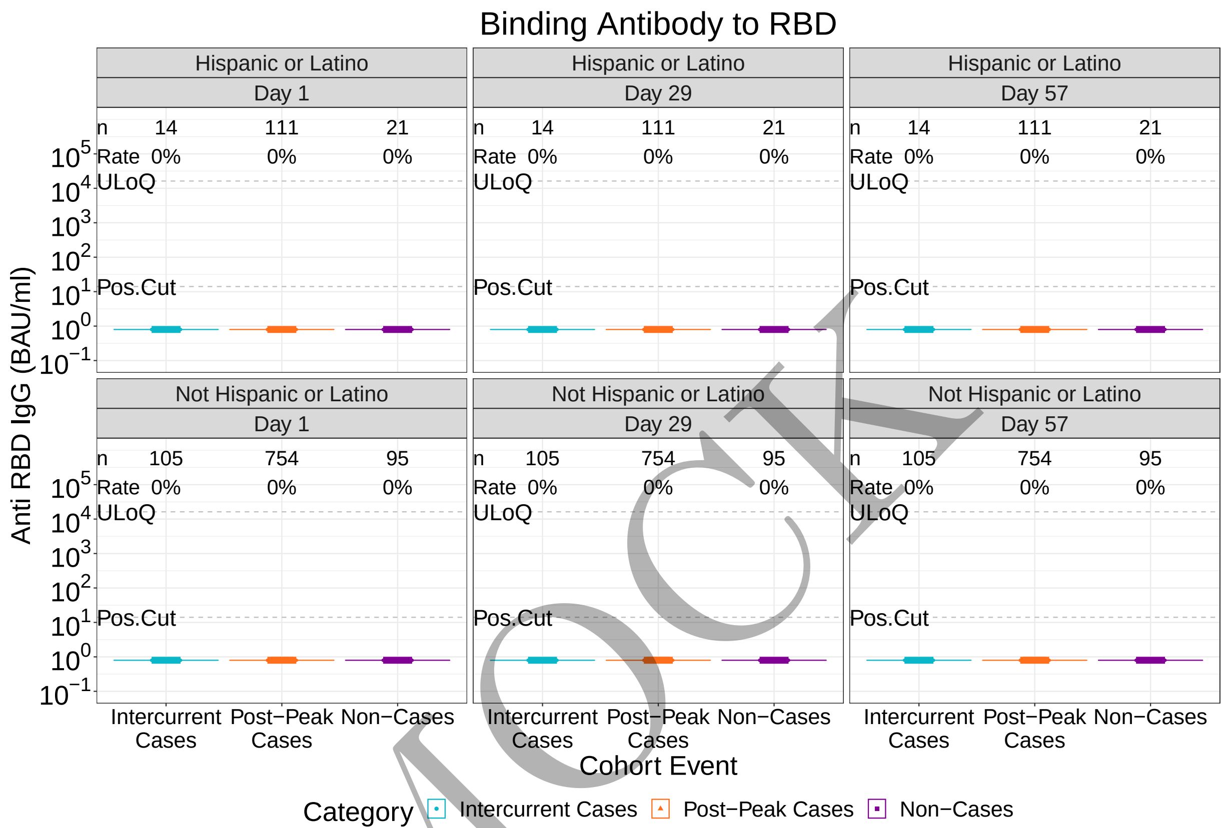
\caption{

Figure 2.5.218: violinplots of Binding Antibody to Spike: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



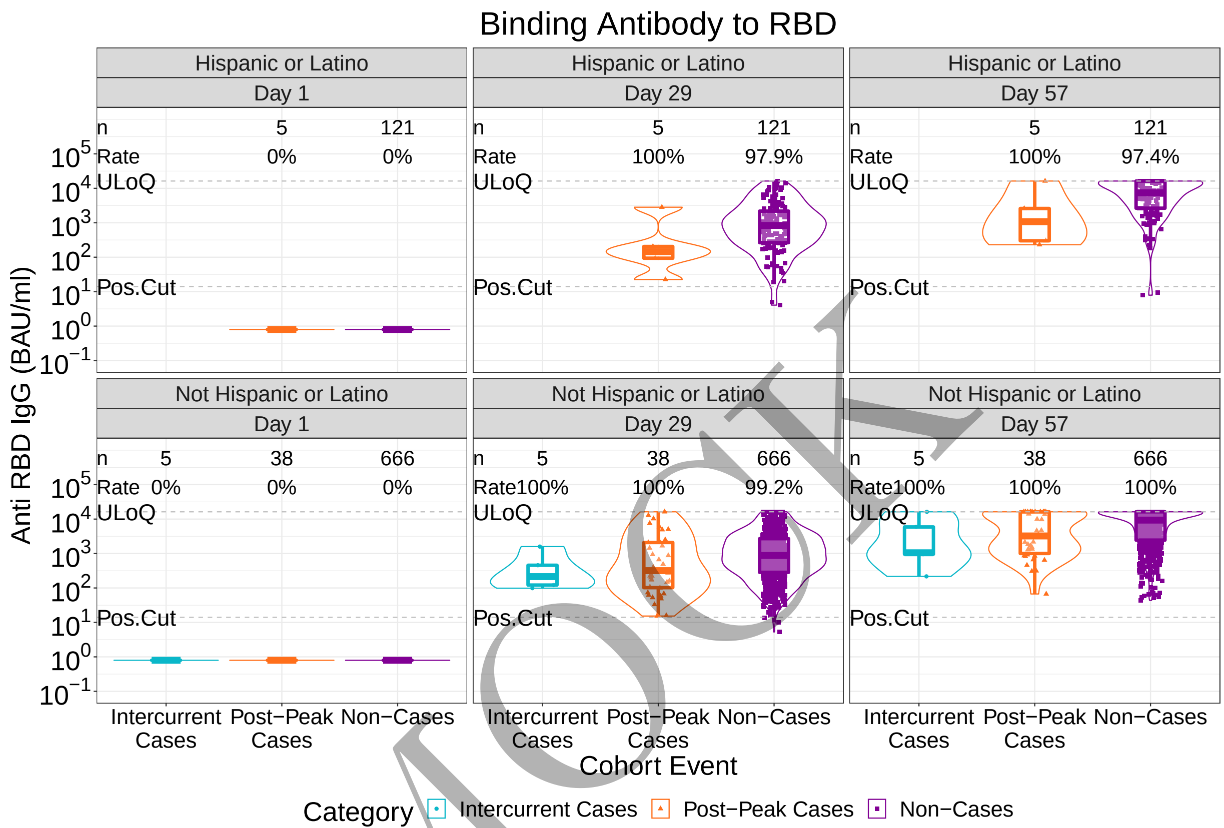
\caption{

Figure 2.5.219: violinplots of Binding Antibody to RBD: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



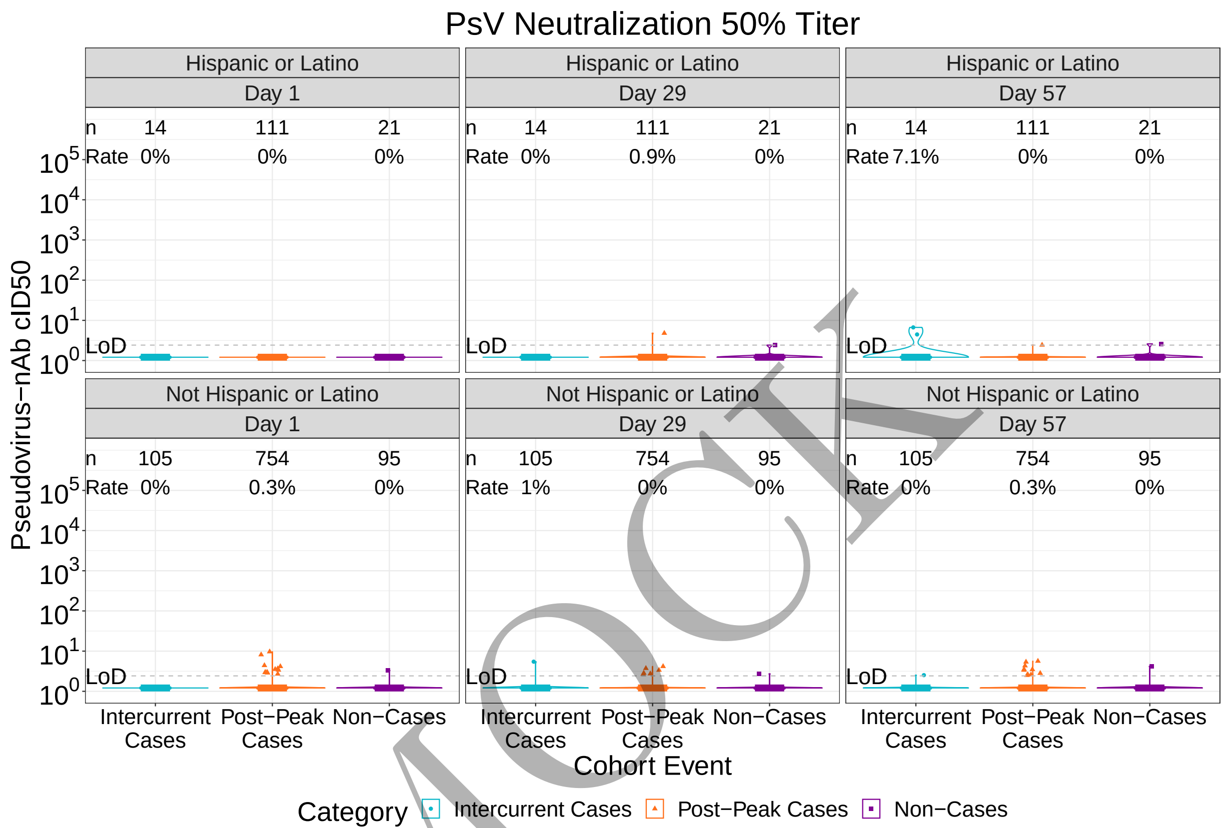
\caption{

Figure 2.5.220: violinplots of Binding Antibody to RBD: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



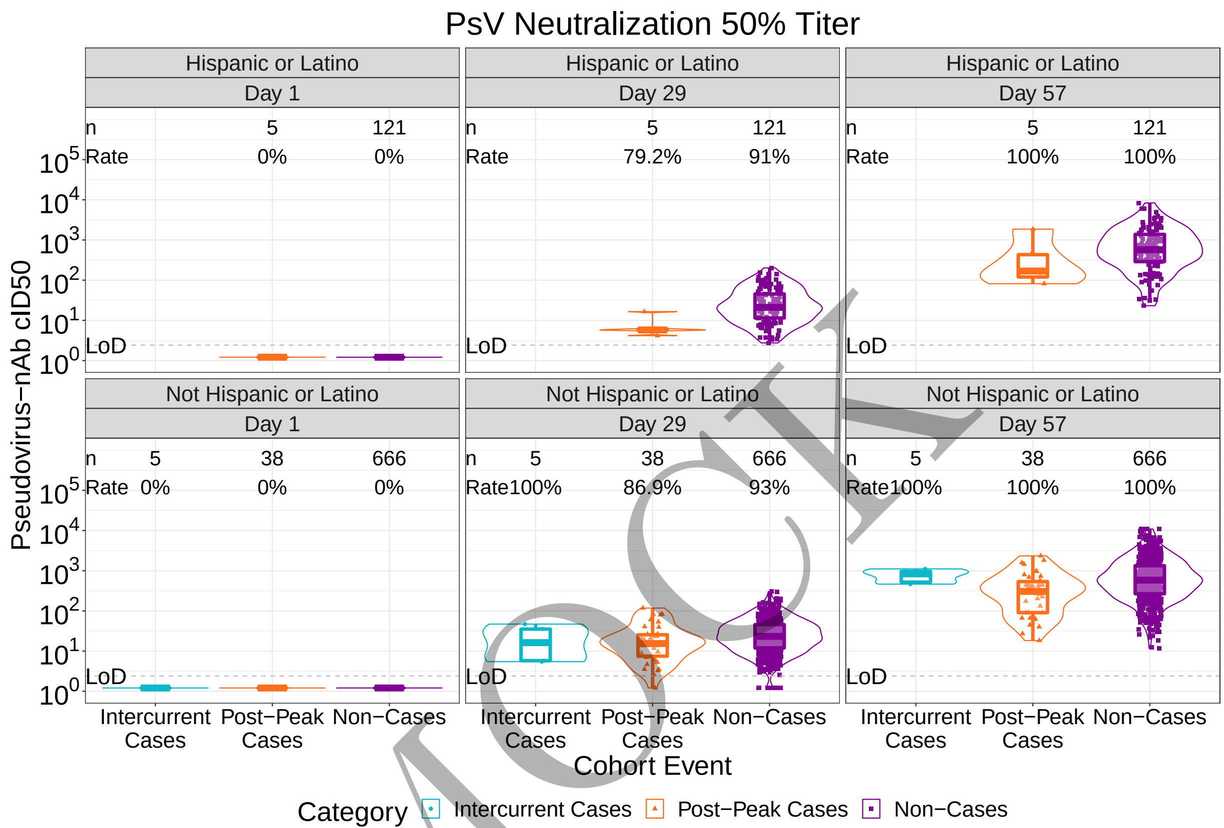
\caption{

Figure 2.5.221: violinplots of PsV Neutralization 50% Titer: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



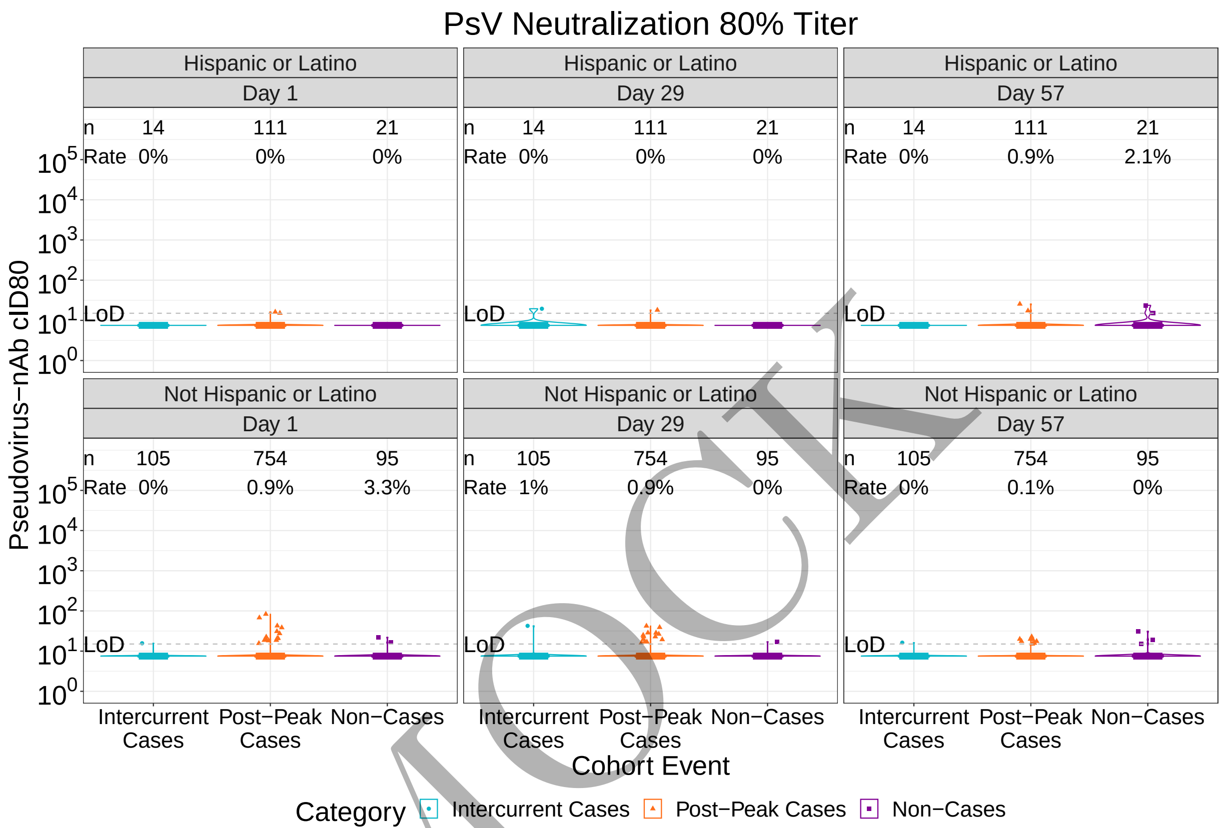
\caption{

Figure 2.5.222: violinplots of PsV Neutralization 50% Titer: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



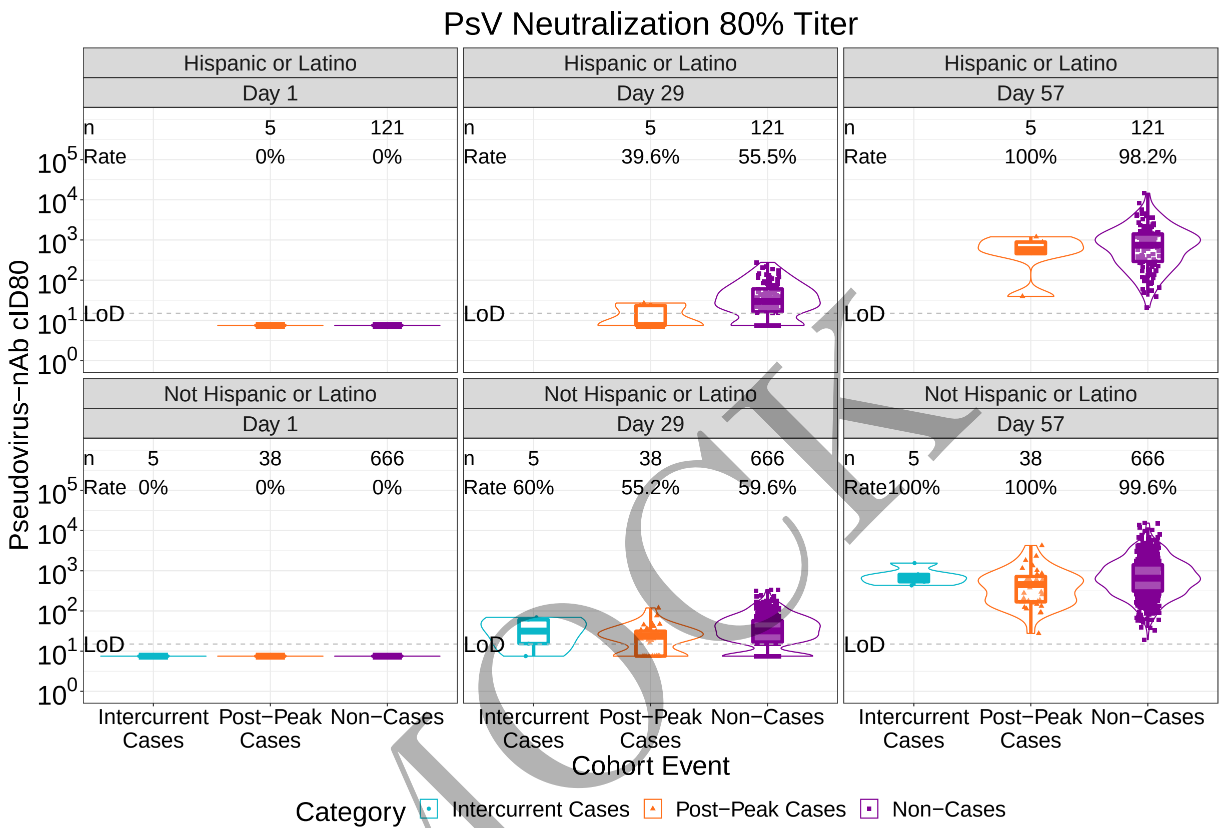
\caption{

Figure 2.5.223: violinplots of PsV Neutralization 80% Titer: baseline negative placebo arm by dichotomous classification of race and ethnic group (version 2)

} \end{figure}

r COR=ifelse(grepl("ENSEMBLE", study_name), "D29", "D29D57")

\begin{figure}



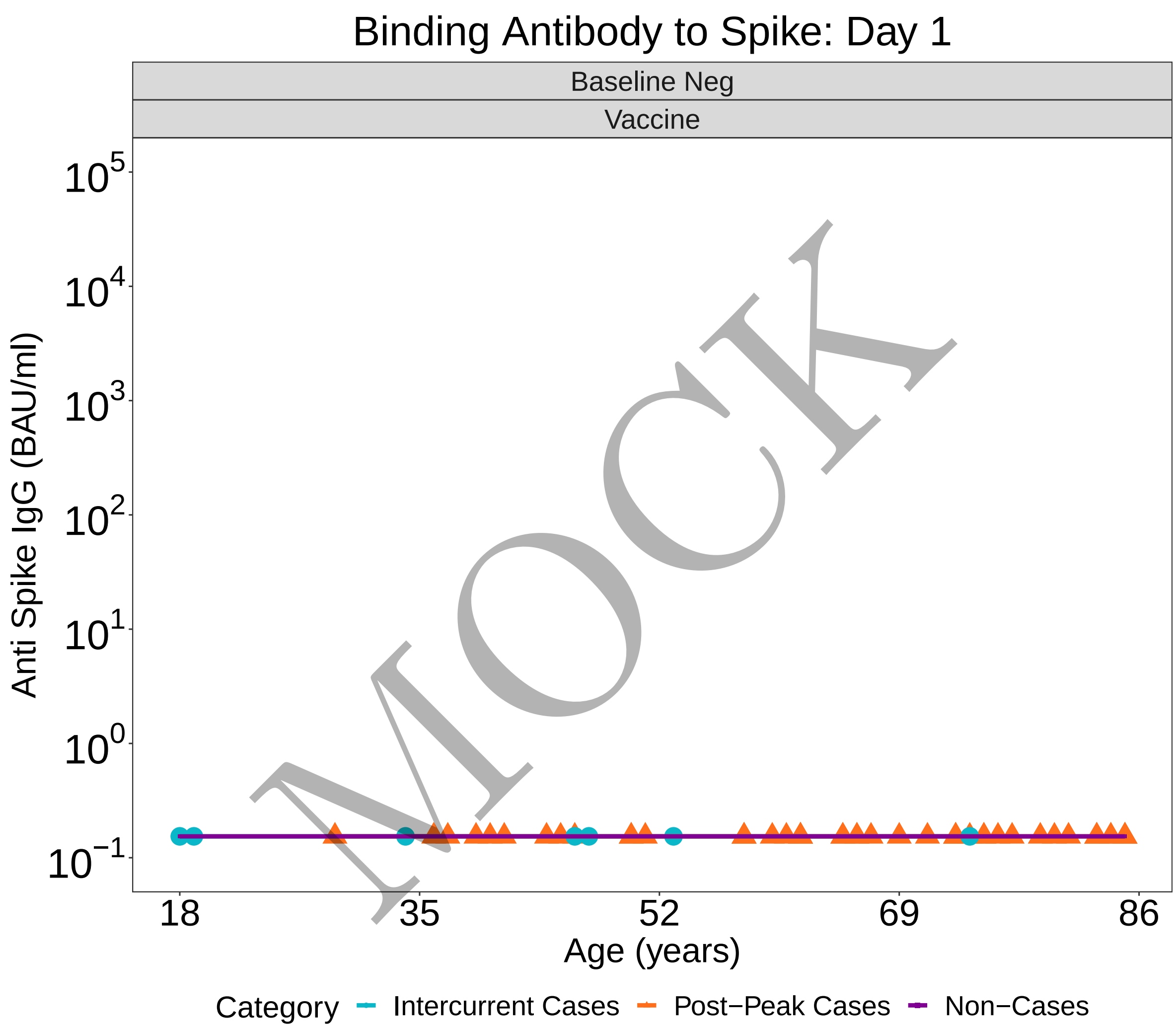
\caption{

Figure 2.5.224: violinplots of PsV Neutralization 80% Titer: baseline negative vaccine arm by dichotomous classification of race and ethnic group (version 2)

} \end{figure}

2.5 Scatter plots

\begin{figure}[H]

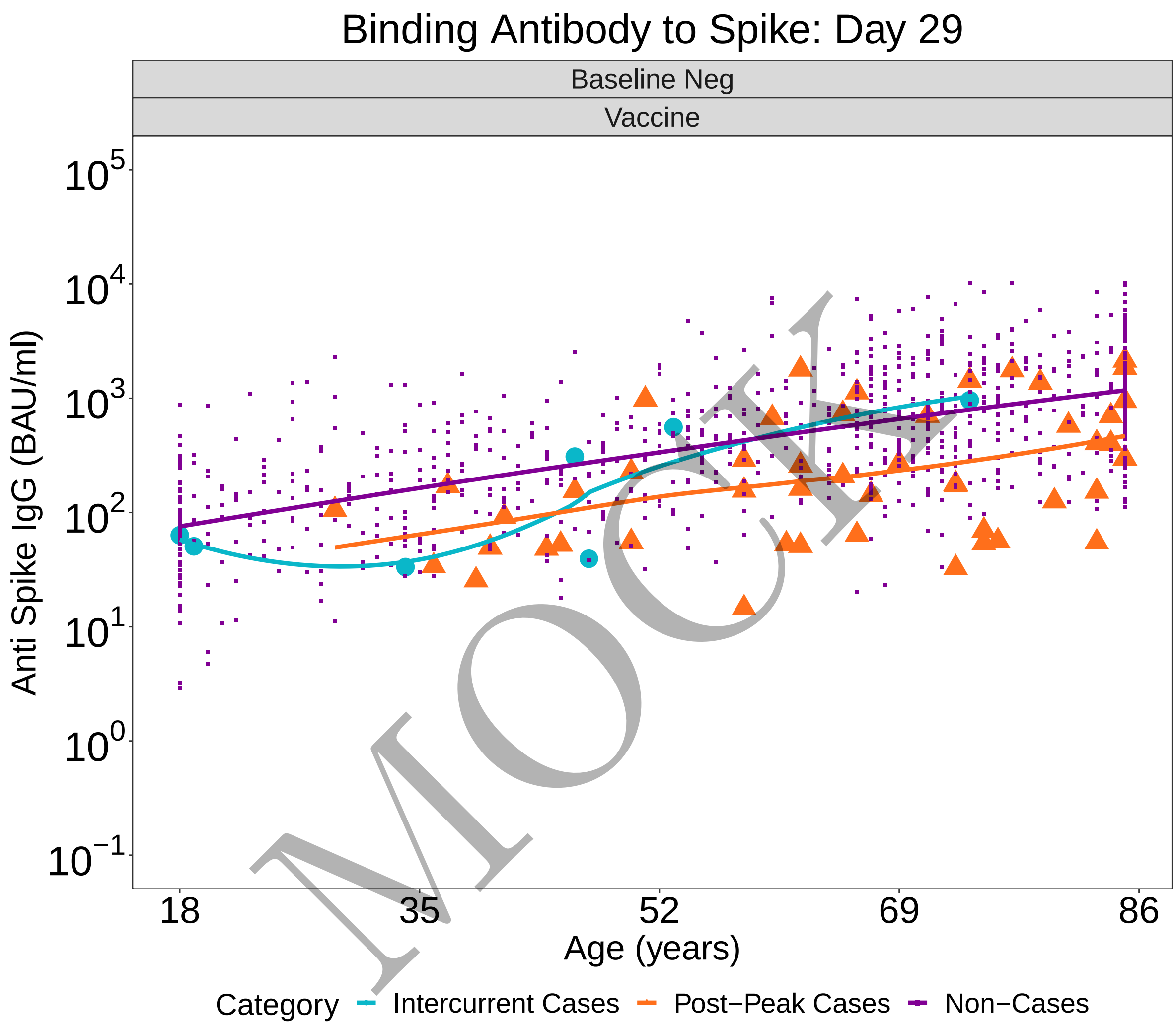


\caption{

Figure 2.6.1: scatterplots of Binding Antibody to Spike vs Age: baseline negative vaccine arm at day 1

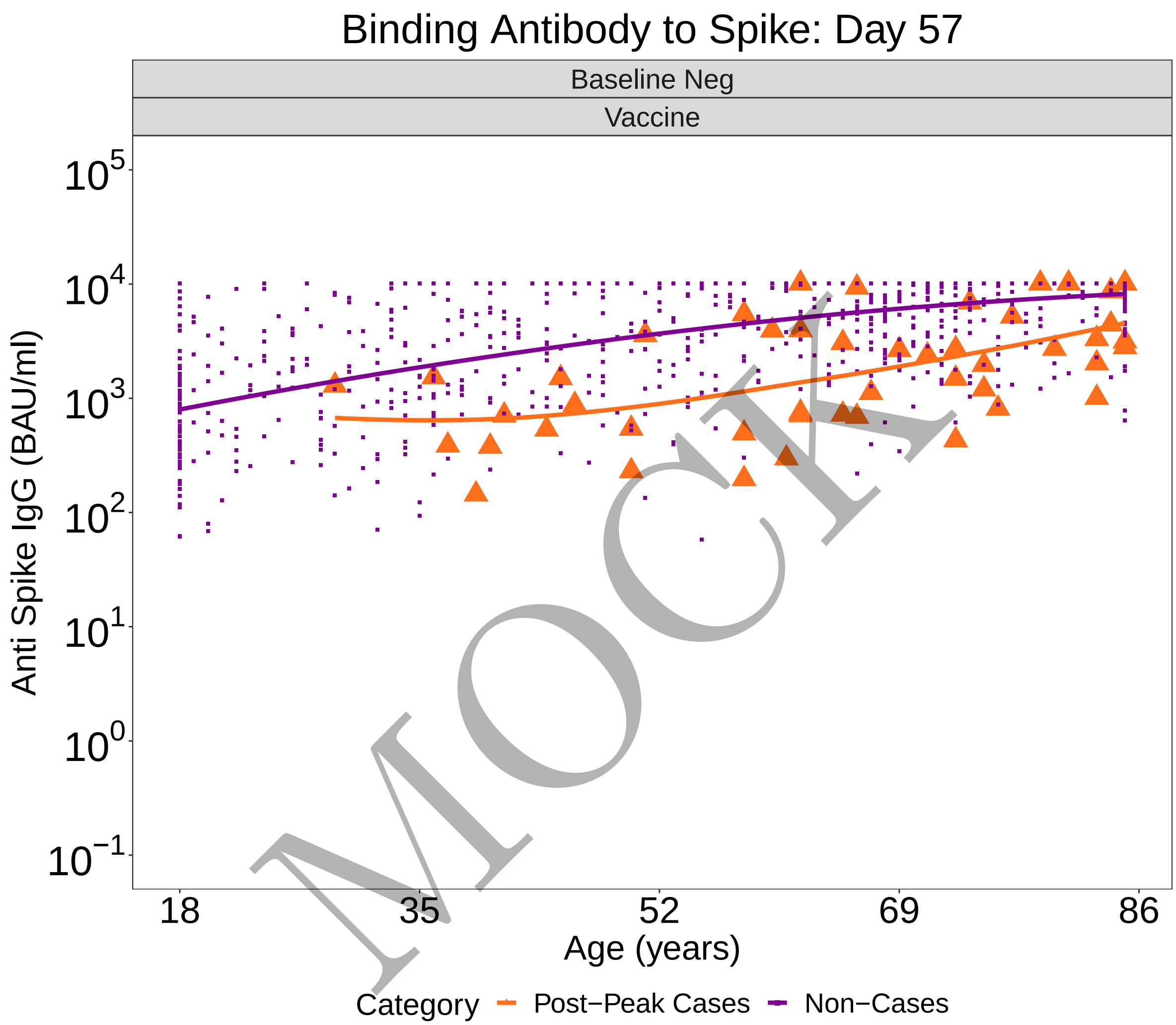
} \end{figure}

\begin{figure}[H]



\caption{
Figure 2.6.2: scatterplots of Binding Antibody to Spike vs Age: baseline negative vaccine arm at day 29
} \end{figure}

\begin{figure}[H]

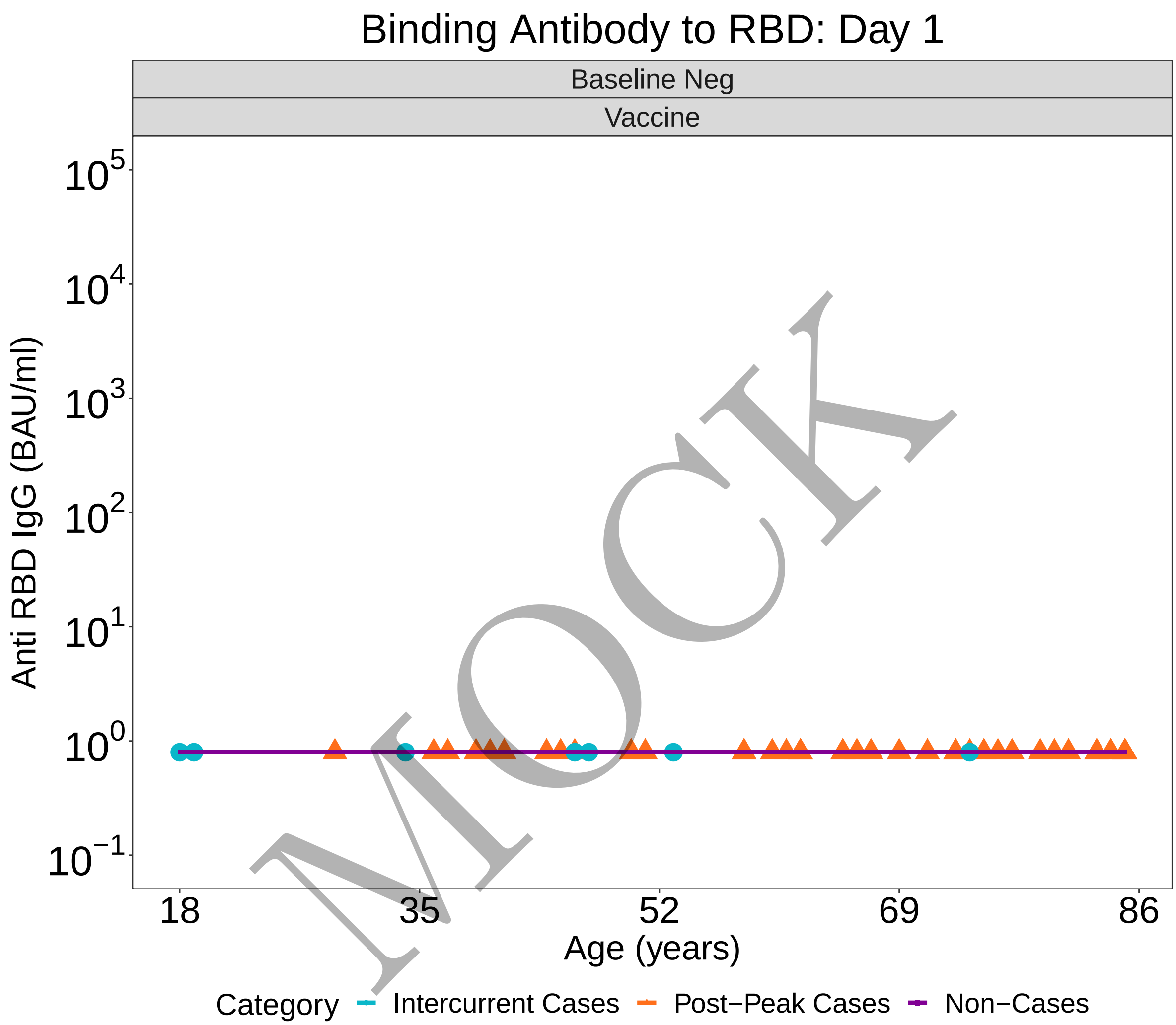


\caption{

Figure 2.6.3: scatterplots of Binding Antibody to Spike vs Age: baseline negative vaccine arm at day 57

} \end{figure}

\begin{figure}[H]

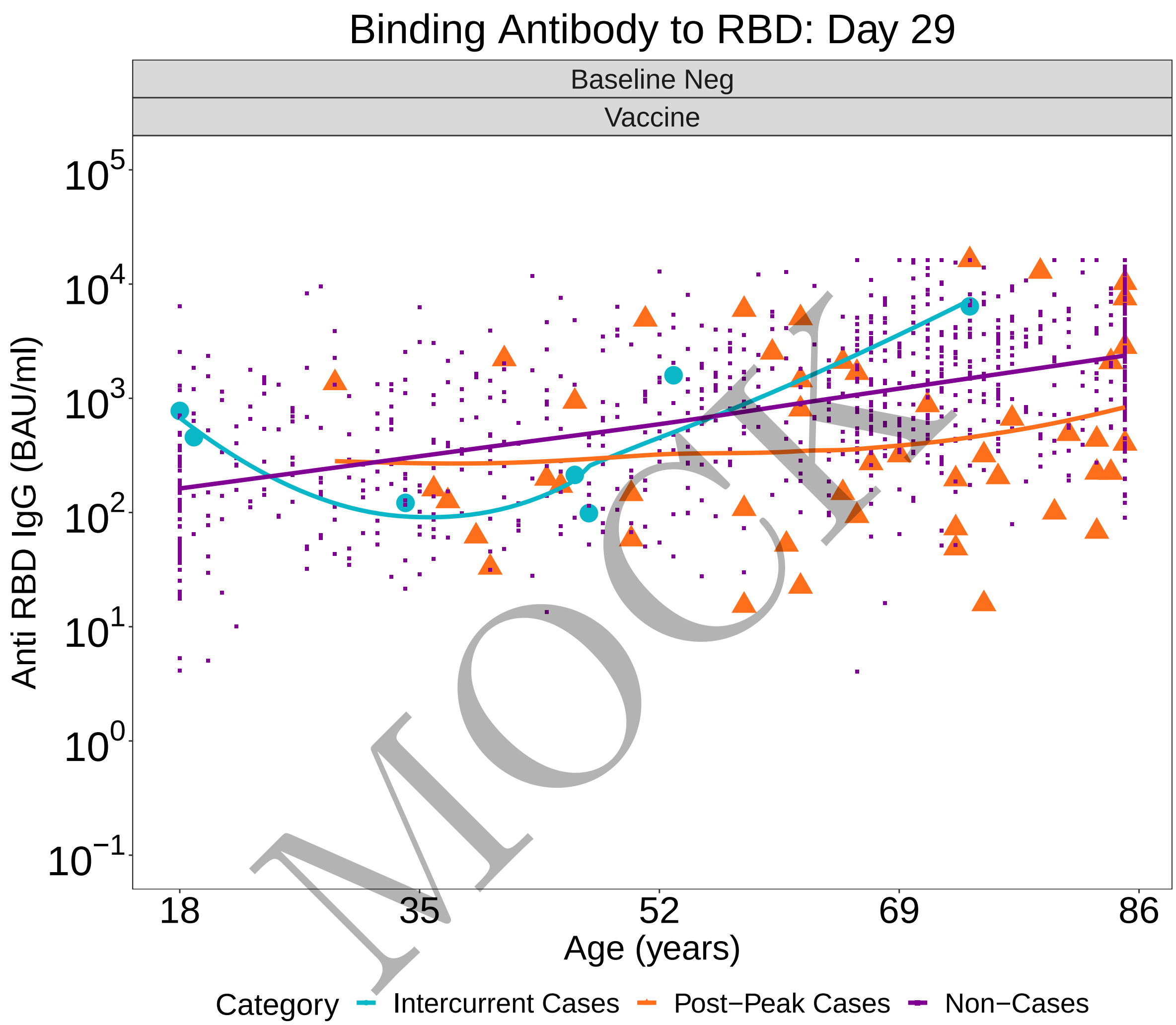


\caption{

Figure 2.6.4: scatterplots of Binding Antibody to RBD vs Age: baseline negative vaccine arm at day 1

} \end{figure}

\begin{figure}[H]

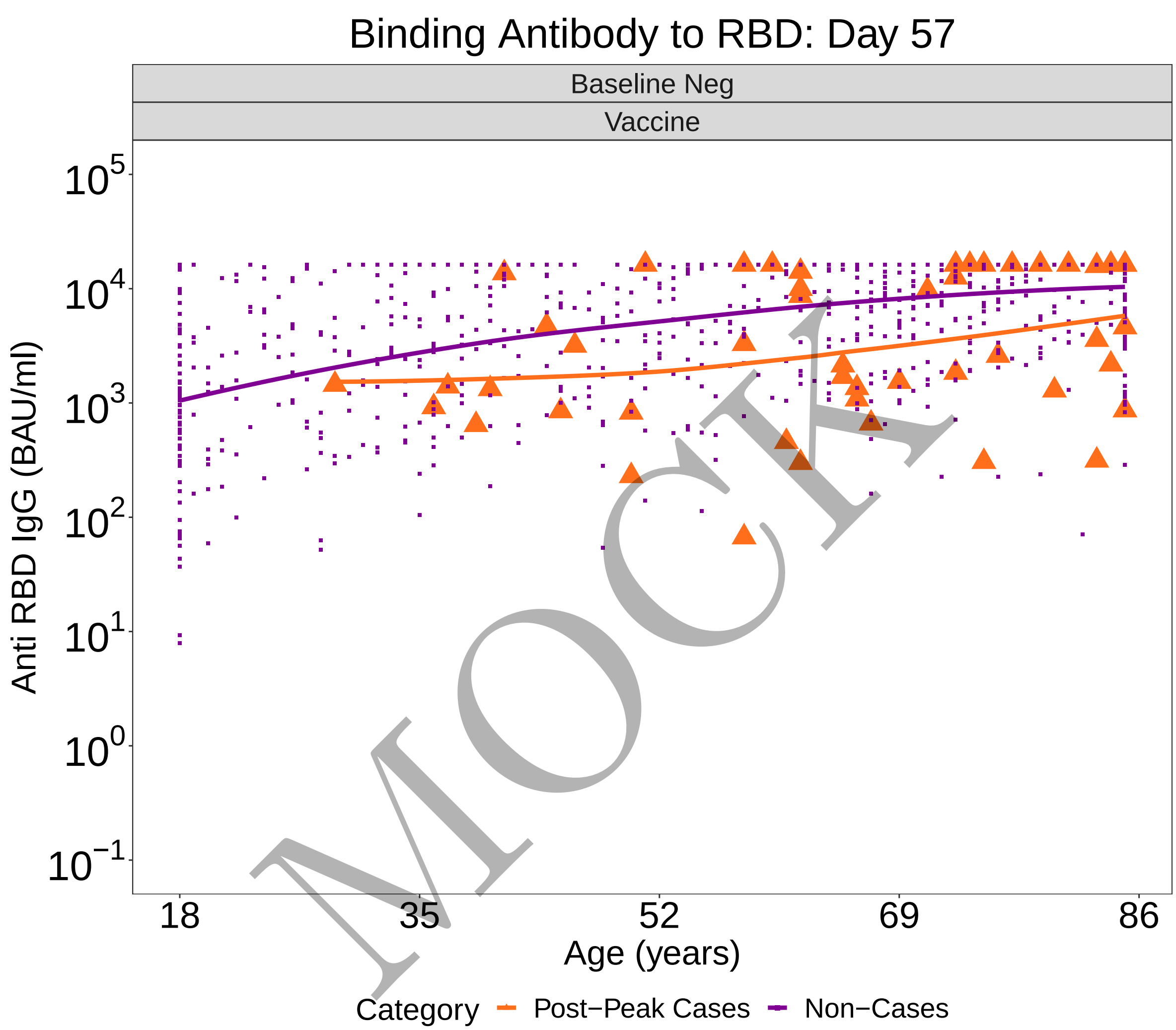


\caption{

Figure 2.6.5: scatterplots of Binding Antibody to RBD vs Age: baseline negative vaccine arm at day 29

} \end{figure}

\begin{figure}[H]

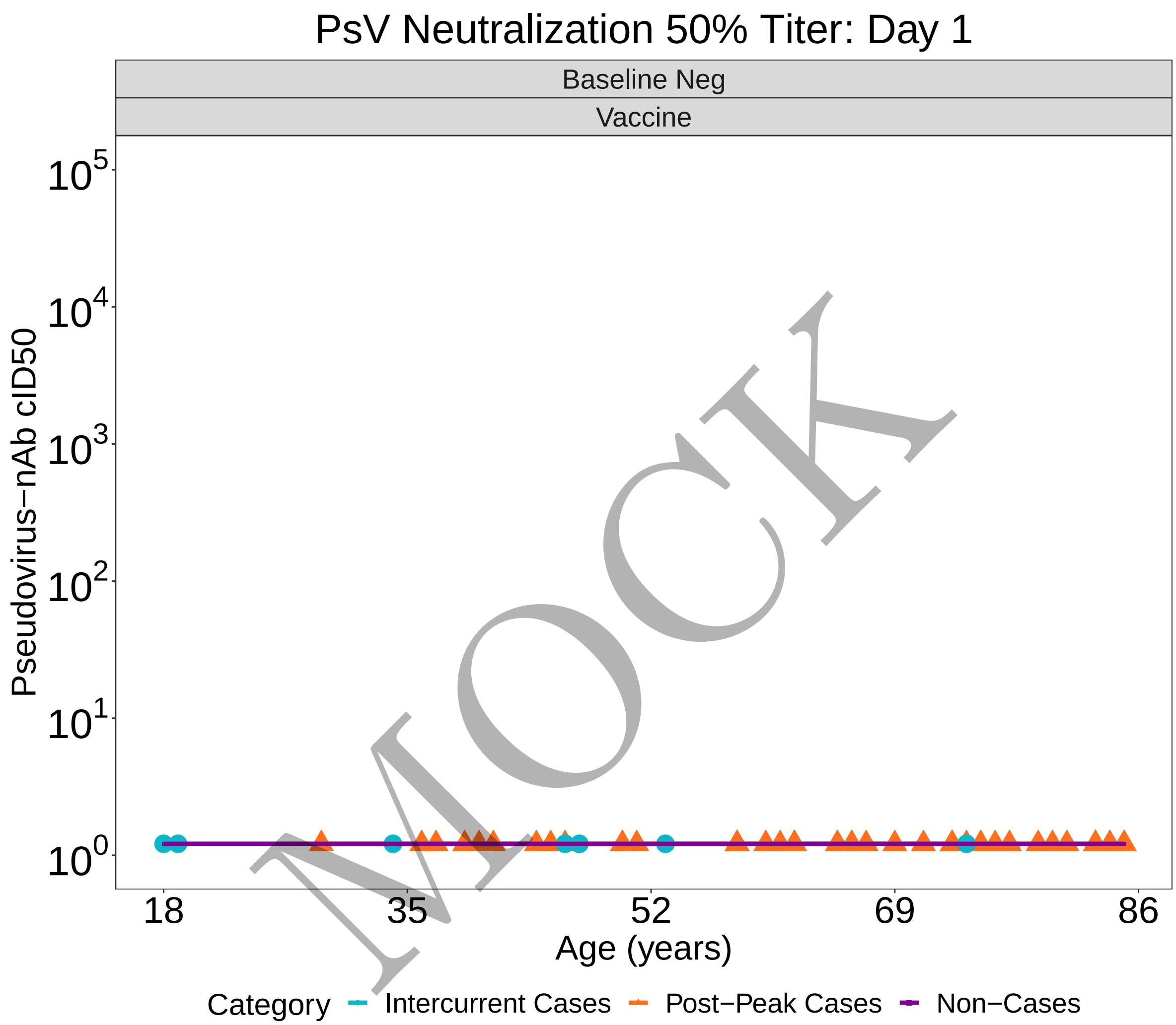


\caption{

Figure 2.6.6: scatterplots of Binding Antibody to RBD vs Age: baseline negative vaccine arm at day 57

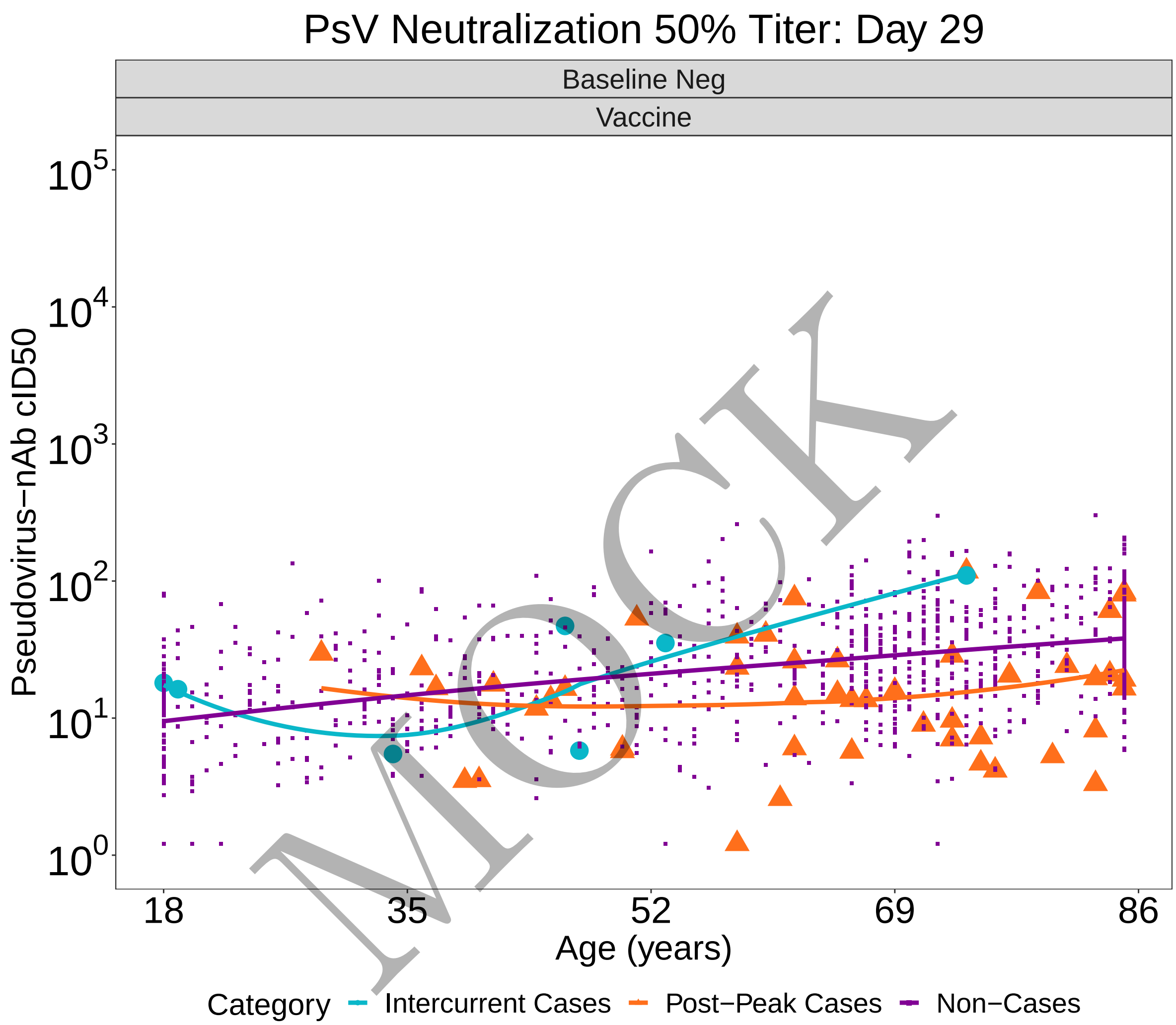
} \end{figure}

\begin{figure}[H]



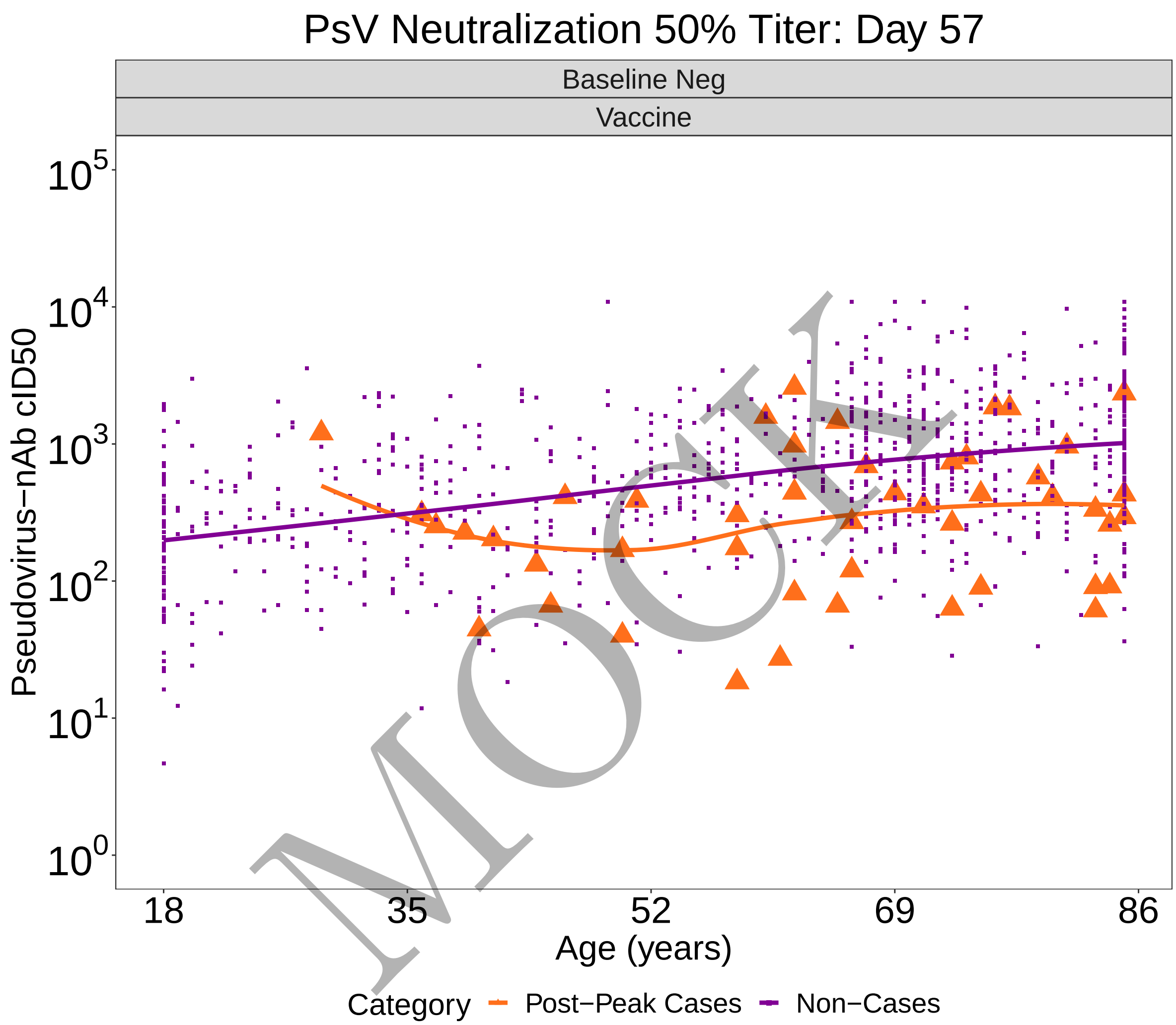
\caption{
Figure 2.6.7: scatterplots of PsV Neutralization 50% Titer vs Age: baseline negative vaccine arm at day 1
} \end{figure}

\begin{figure}[H]



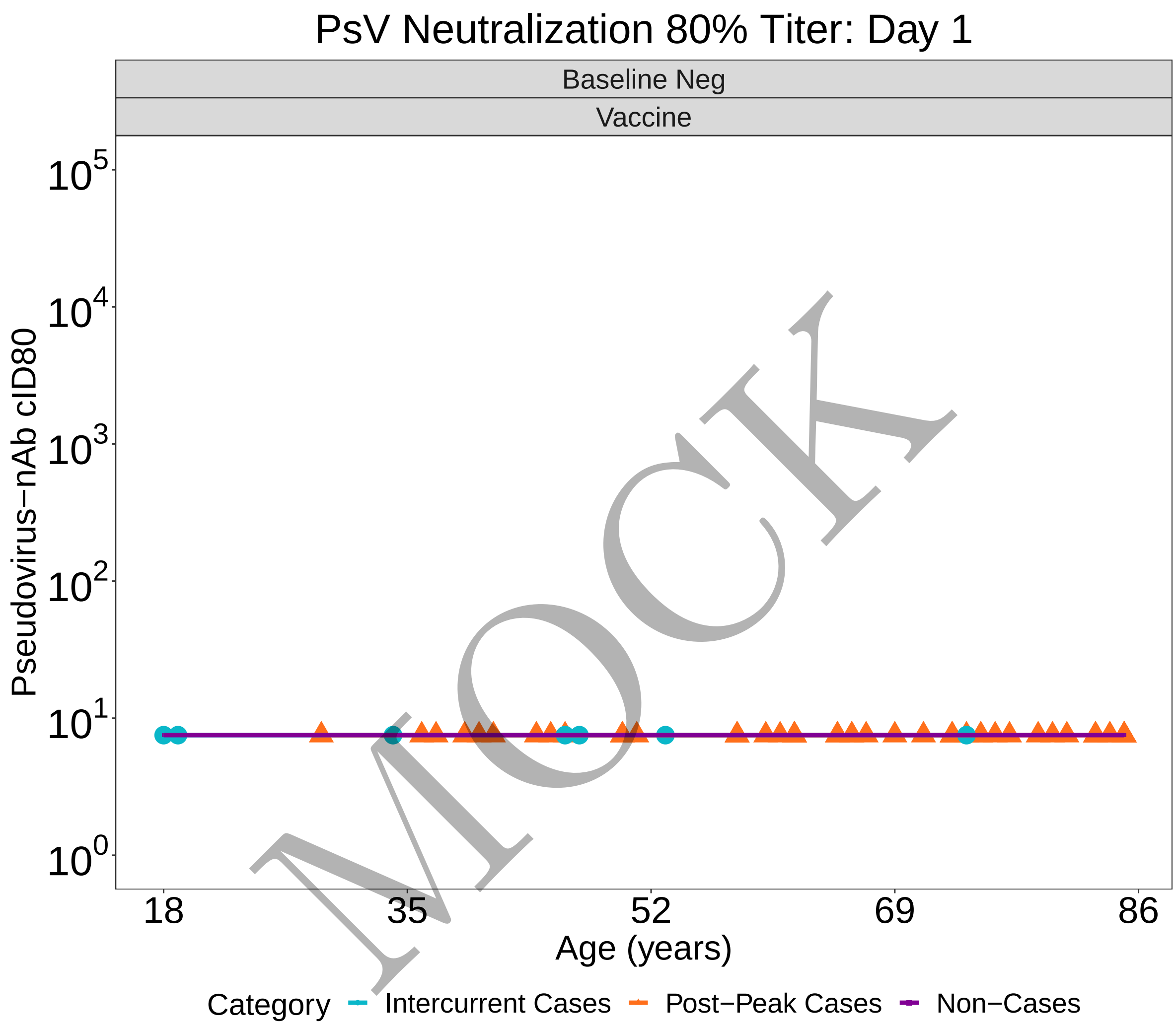
\caption{
Figure 2.6.8: scatterplots of PsV Neutralization 50% Titer vs Age: baseline negative vaccine arm at day 29
} \end{figure}

\begin{figure}[H]



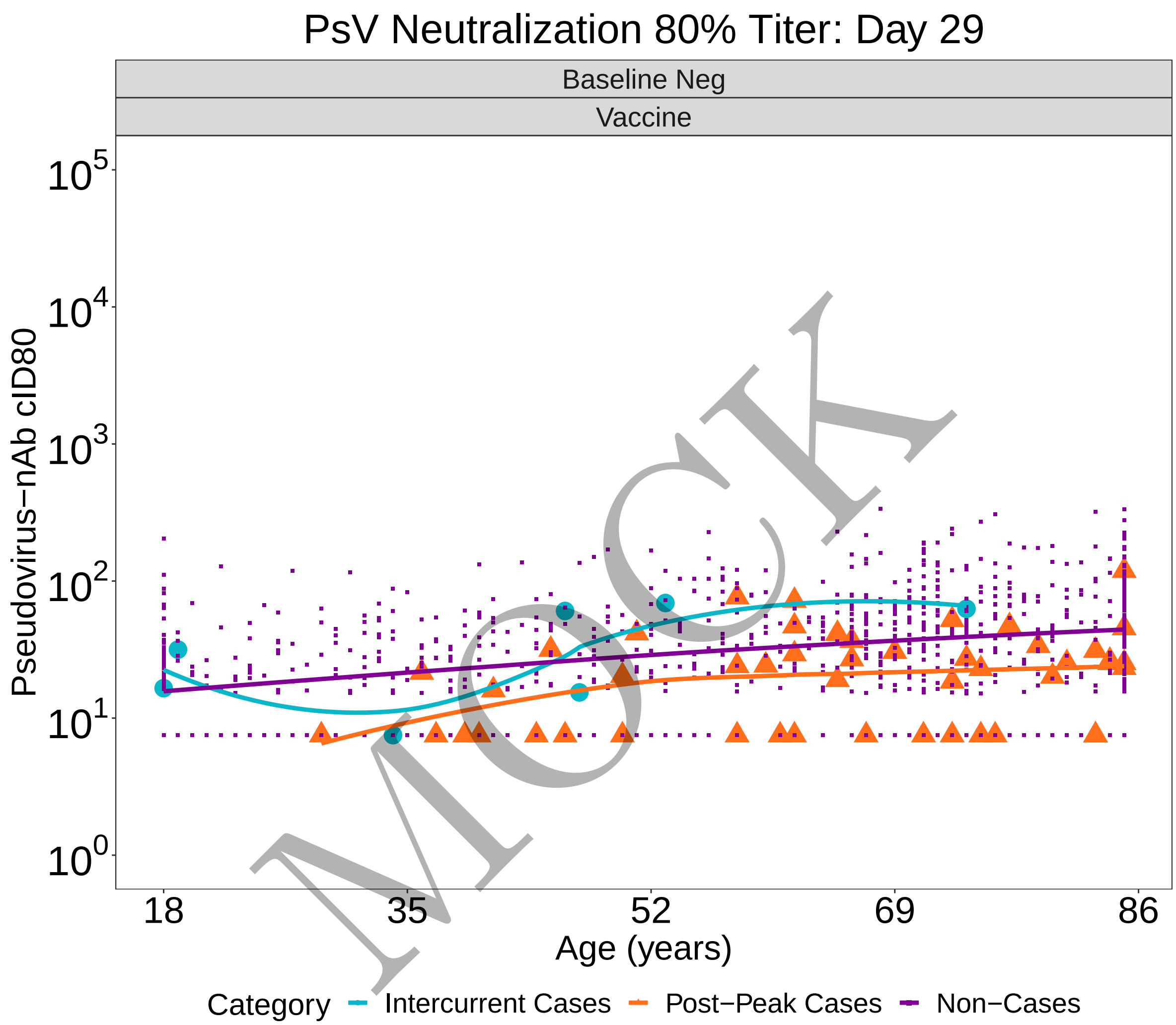
\caption{
Figure 2.6.9: scatterplots of PsV Neutralization 50% Titer vs Age: baseline negative vaccine arm at day 57
} \end{figure}

\begin{figure}[H]



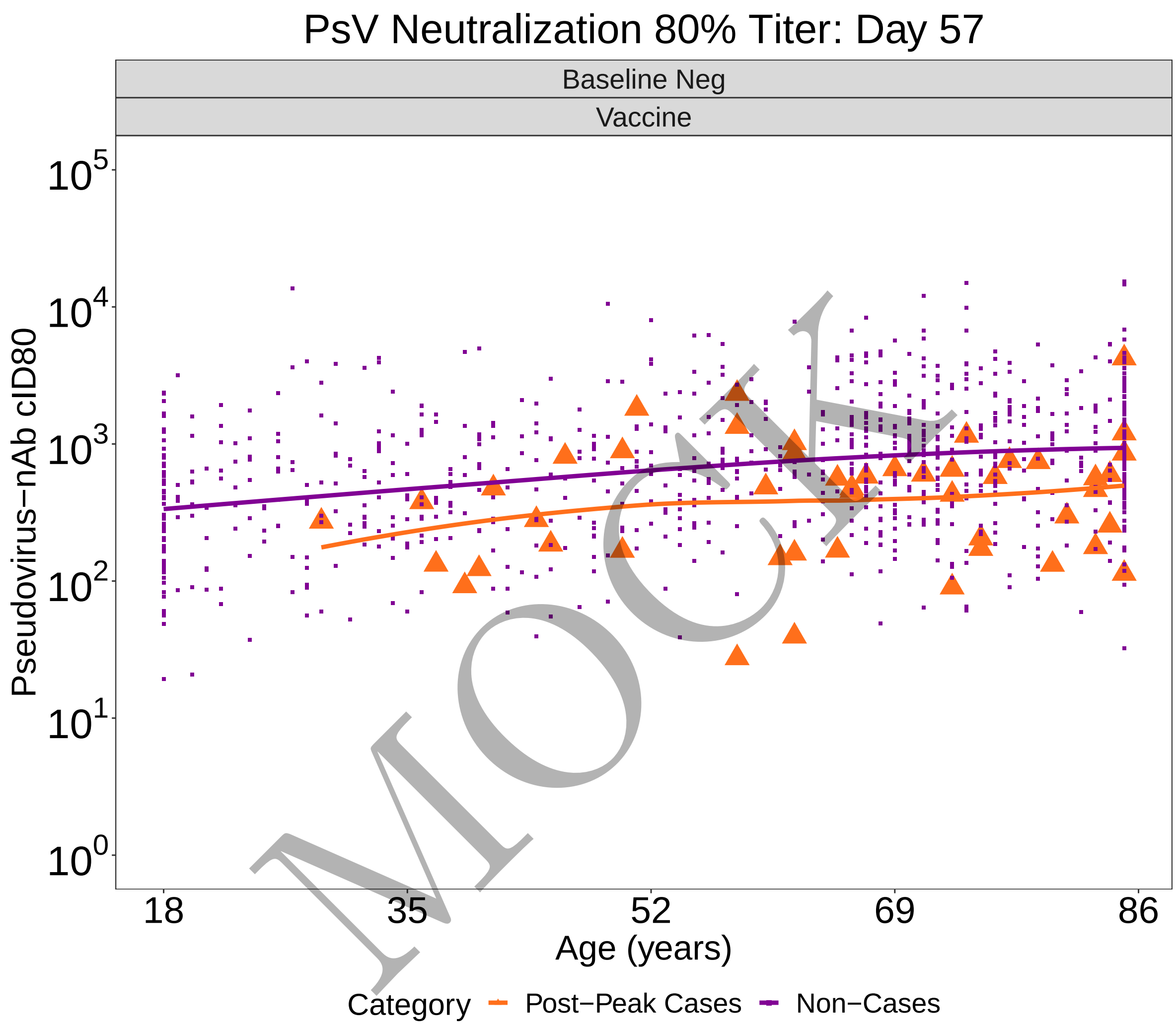
\caption{
Figure 2.6.10: scatterplots of PsV Neutralization 80% Titer vs Age: baseline negative vaccine arm at day 1
} \end{figure}

\begin{figure}[H]



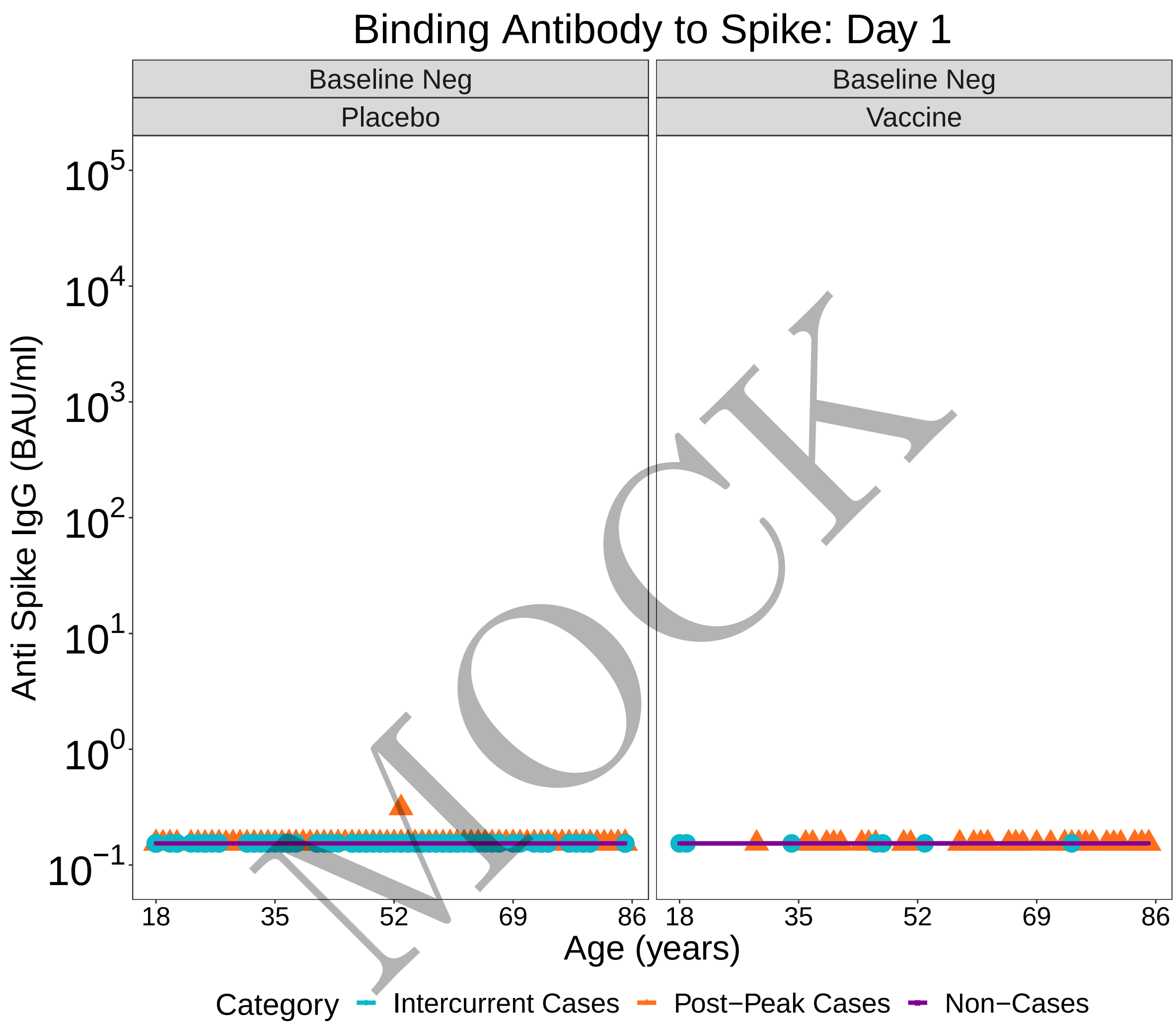
\caption{
Figure 2.6.11: scatterplots of PsV Neutralization 80% Titer vs Age: baseline negative vaccine arm at day 29
} \end{figure}

\begin{figure}[H]



\caption{
Figure 2.6.12: scatterplots of PsV Neutralization 80% Titer vs Age: baseline negative vaccine arm at day 57
} \end{figure}

\begin{figure}[H]

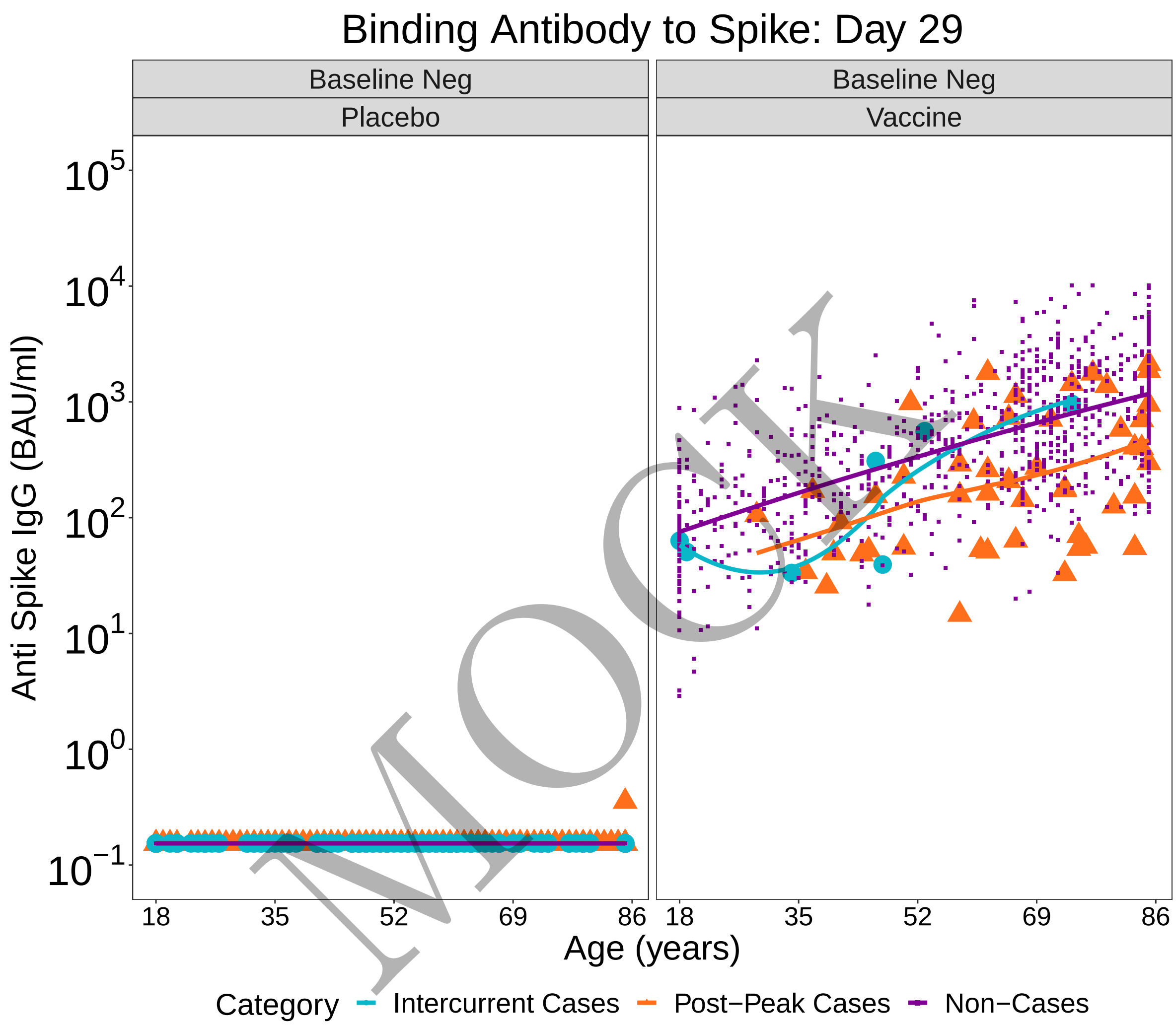


\caption{

Figure 2.6.13: scatterplots of Binding Antibody to Spike vs Age: by arm at day 1

} \end{figure}

\begin{figure}[H]

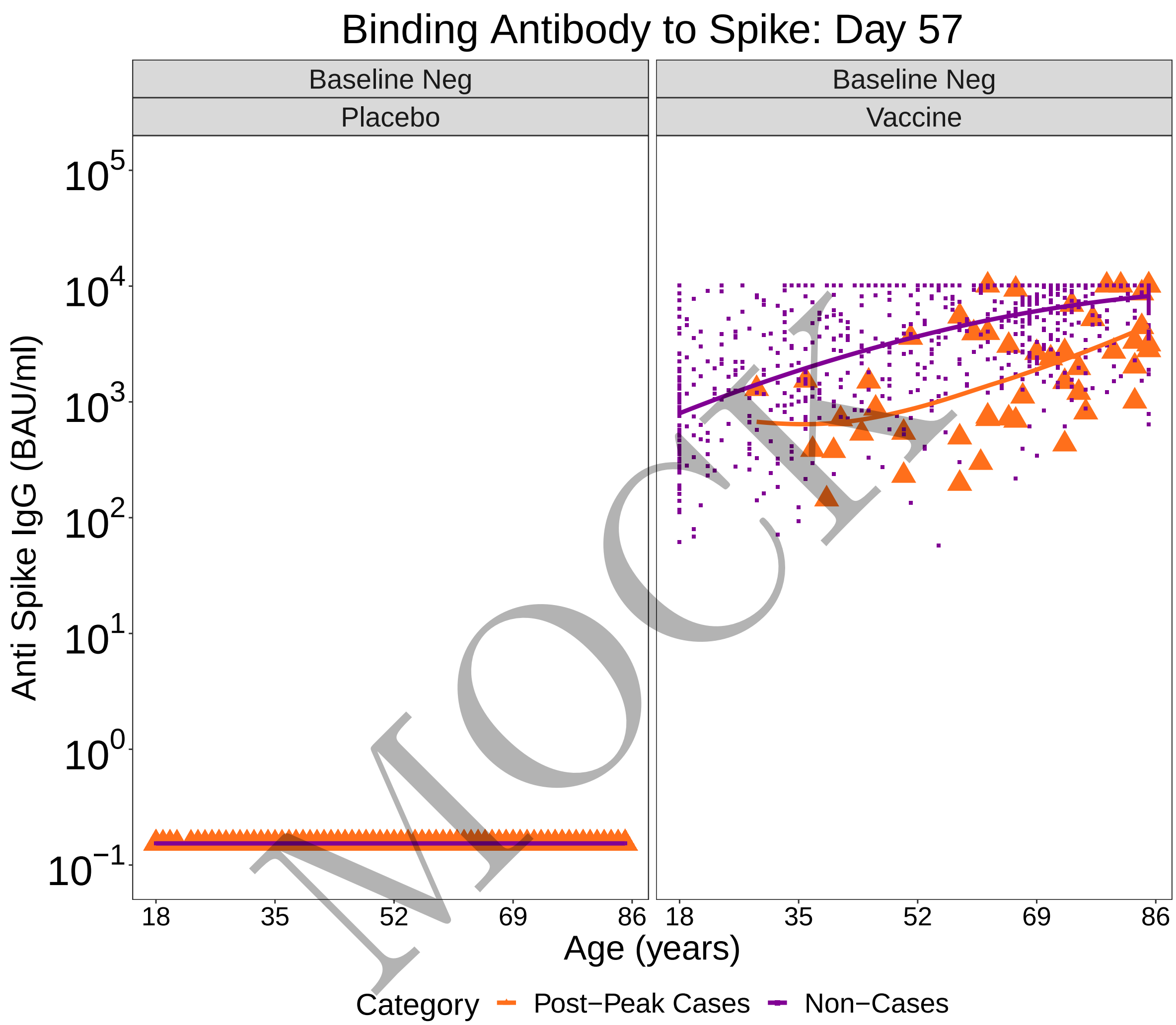


\caption{

Figure 2.6.14: scatterplots of Binding Antibody to Spike vs Age: by arm at day 29

} \end{figure}

\begin{figure}[H]

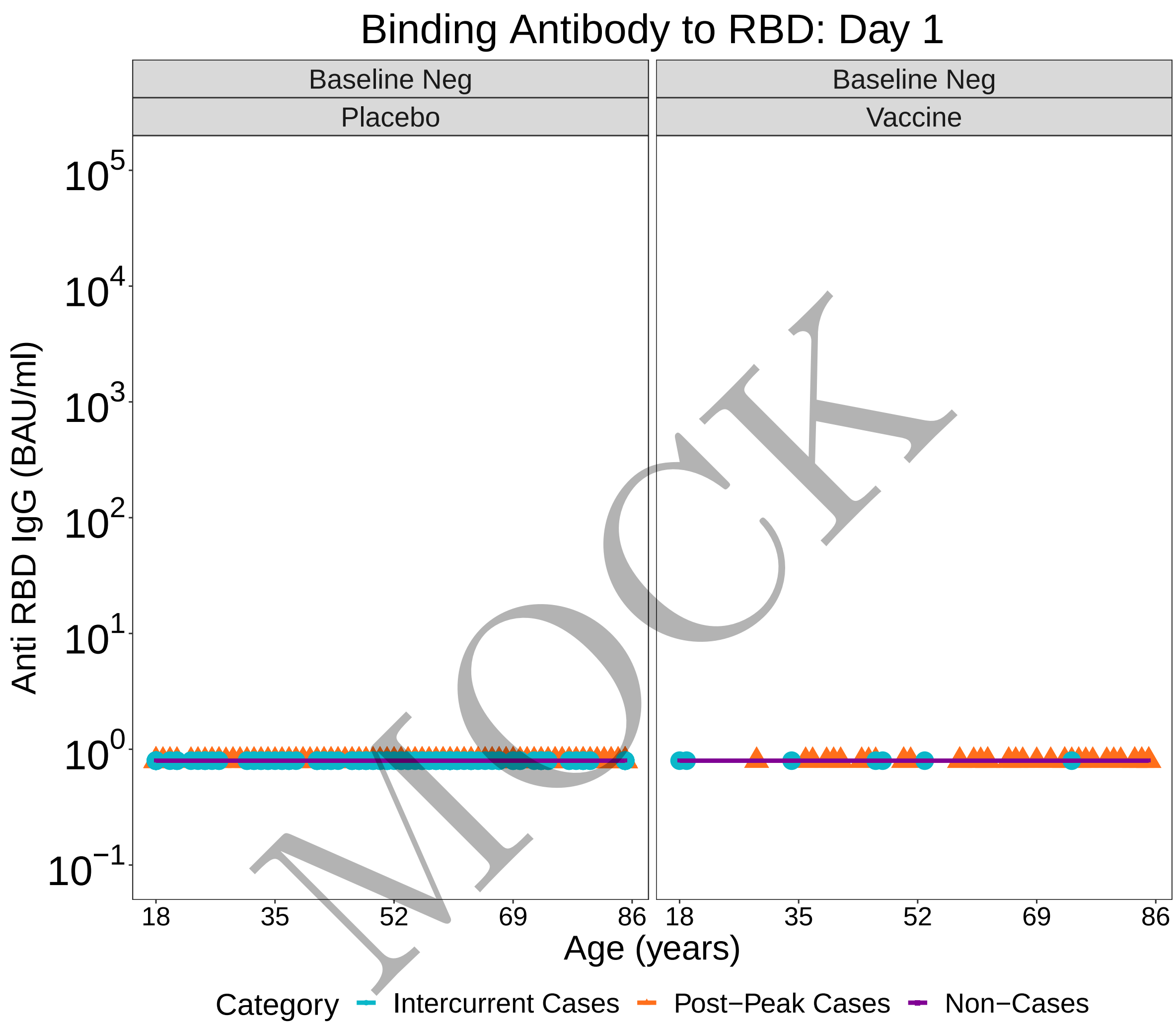


\caption{

Figure 2.6.15: scatterplots of Binding Antibody to Spike vs Age: by arm at day 57

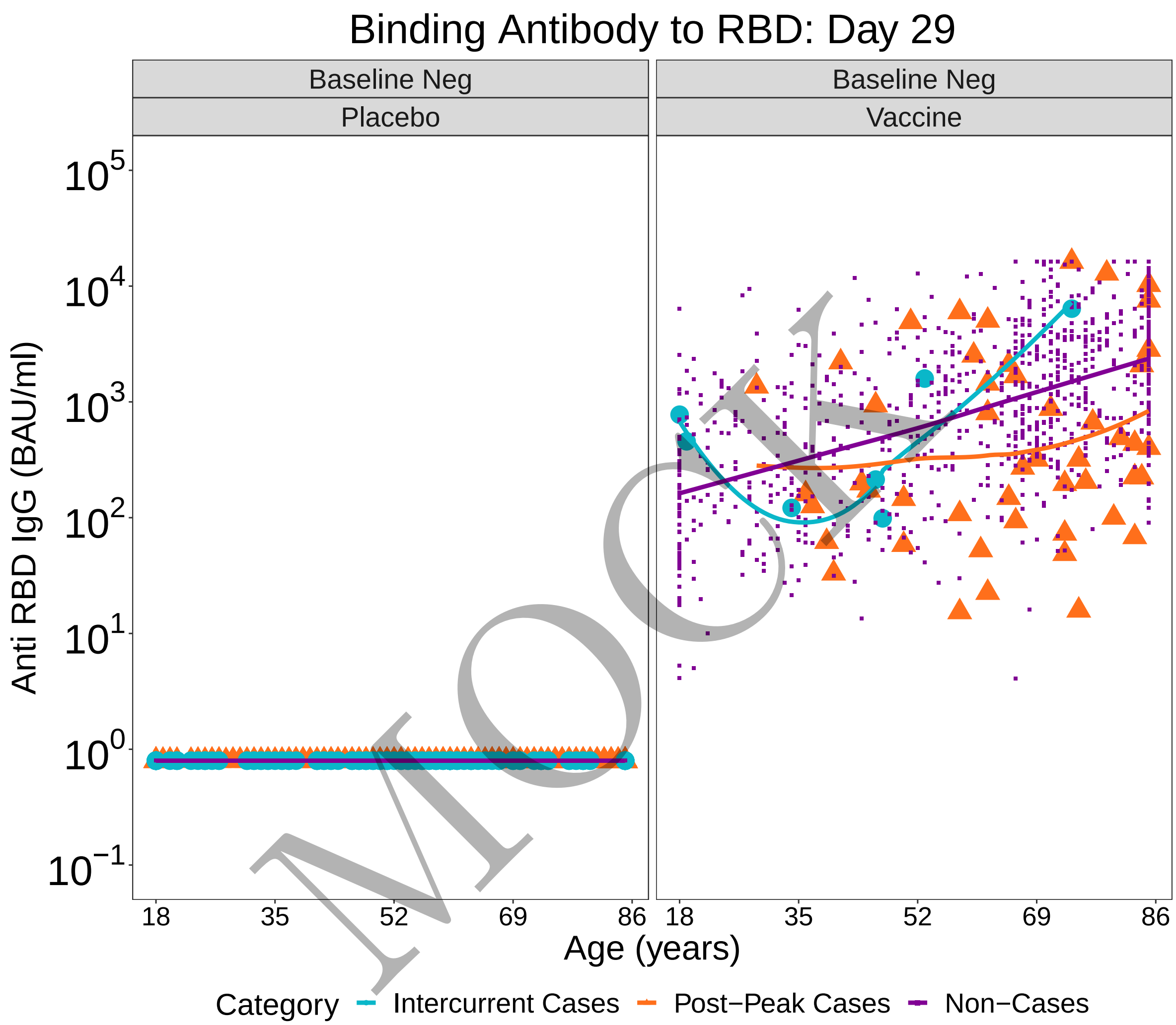
} \end{figure}

\begin{figure}[H]



\caption{
Figure 2.6.16: scatterplots of Binding Antibody to RBD vs Age: by arm at day 1
} \end{figure}

\begin{figure}[H]

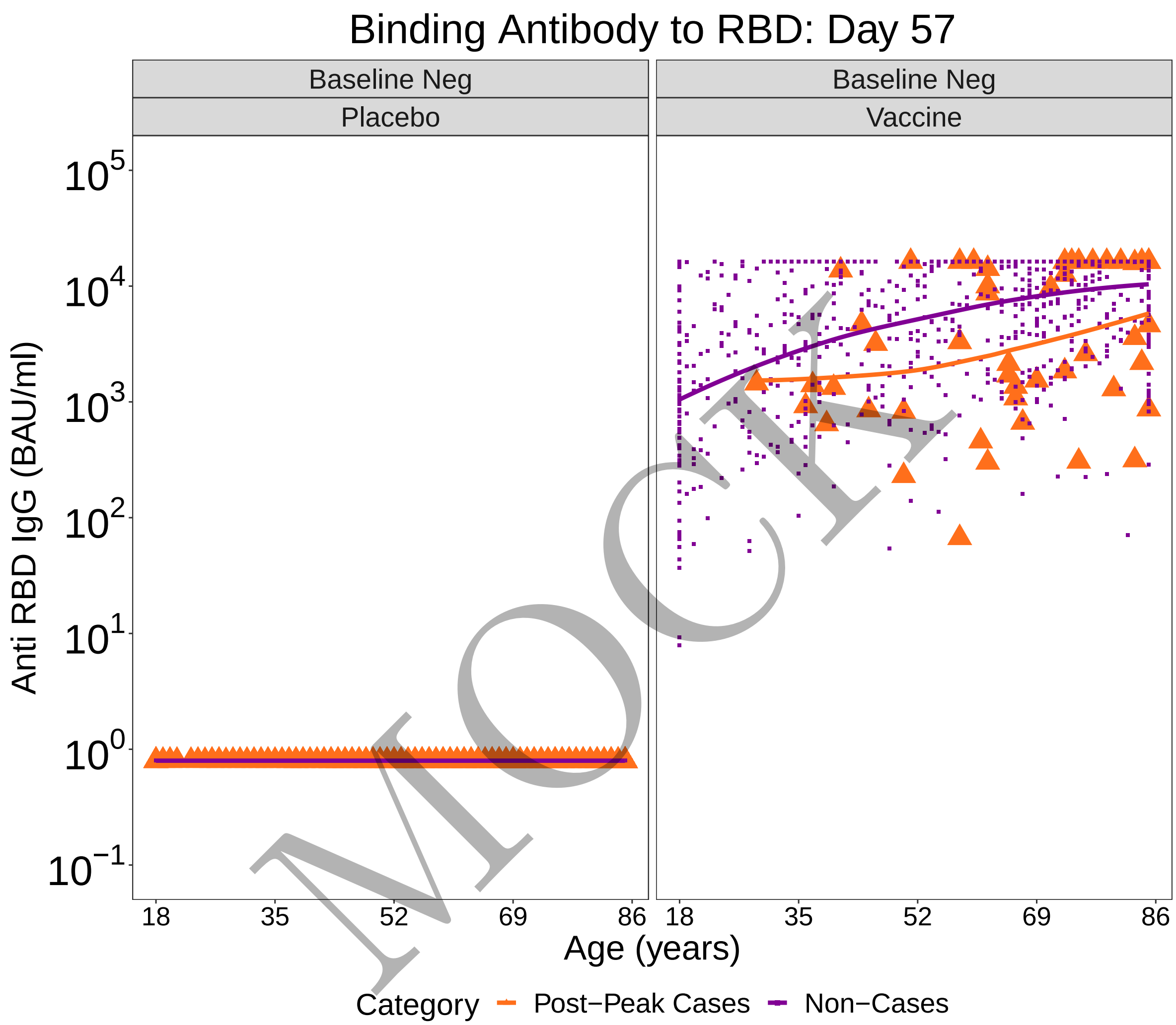


\caption{

Figure 2.6.17: scatterplots of Binding Antibody to RBD vs Age: by arm at day 29

} \end{figure}

\begin{figure}[H]

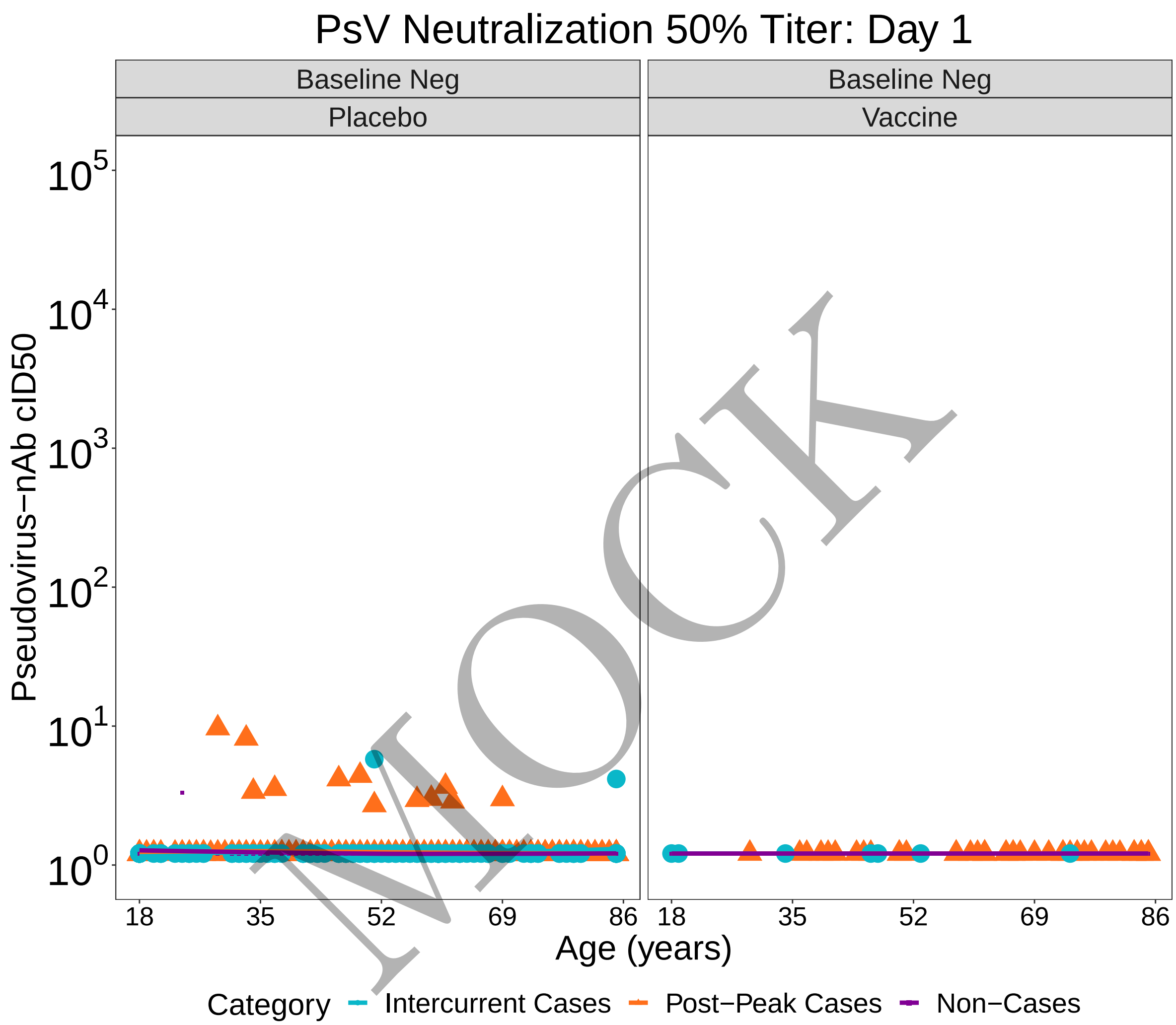


\caption{

Figure 2.6.18: scatterplots of Binding Antibody to RBD vs Age: by arm at day 57

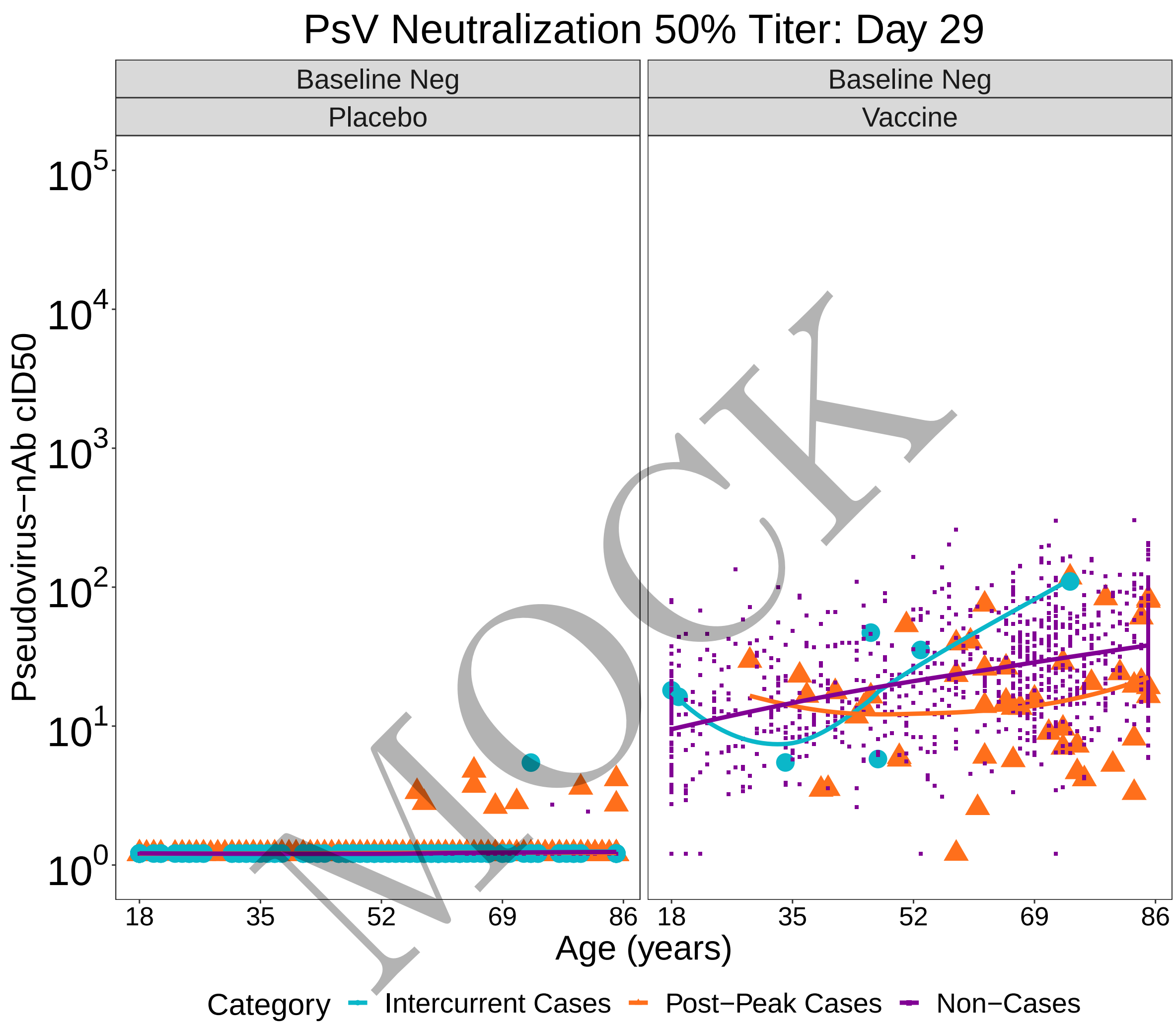
} \end{figure}

\begin{figure}[H]



\caption{
Figure 2.6.19: scatterplots of PsV Neutralization 50% Titer vs Age: by arm at day 1
} \end{figure}

\begin{figure}[H]

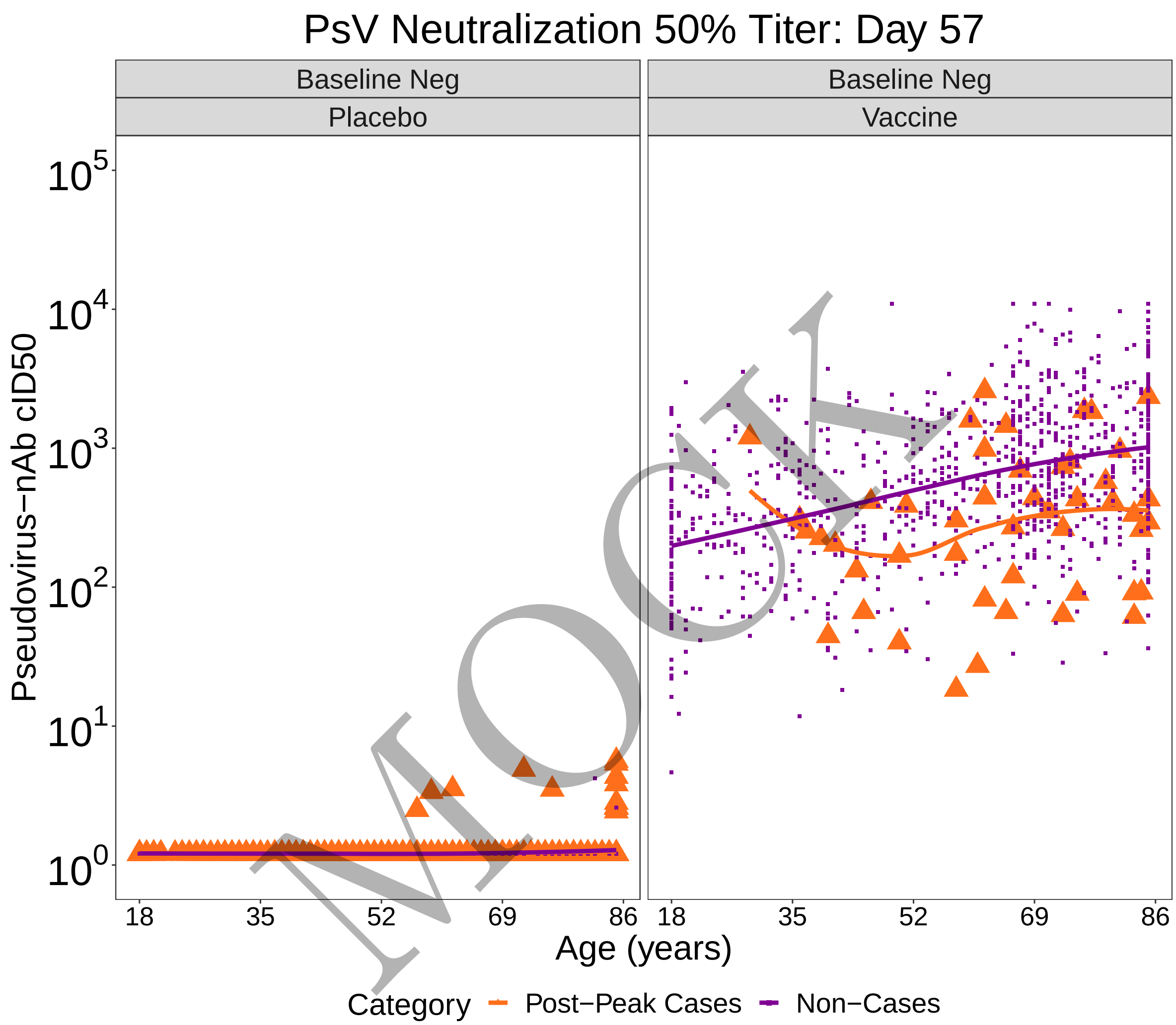


\caption{

Figure 2.6.20: scatterplots of PsV Neutralization 50% Titer vs Age: by arm at day 29

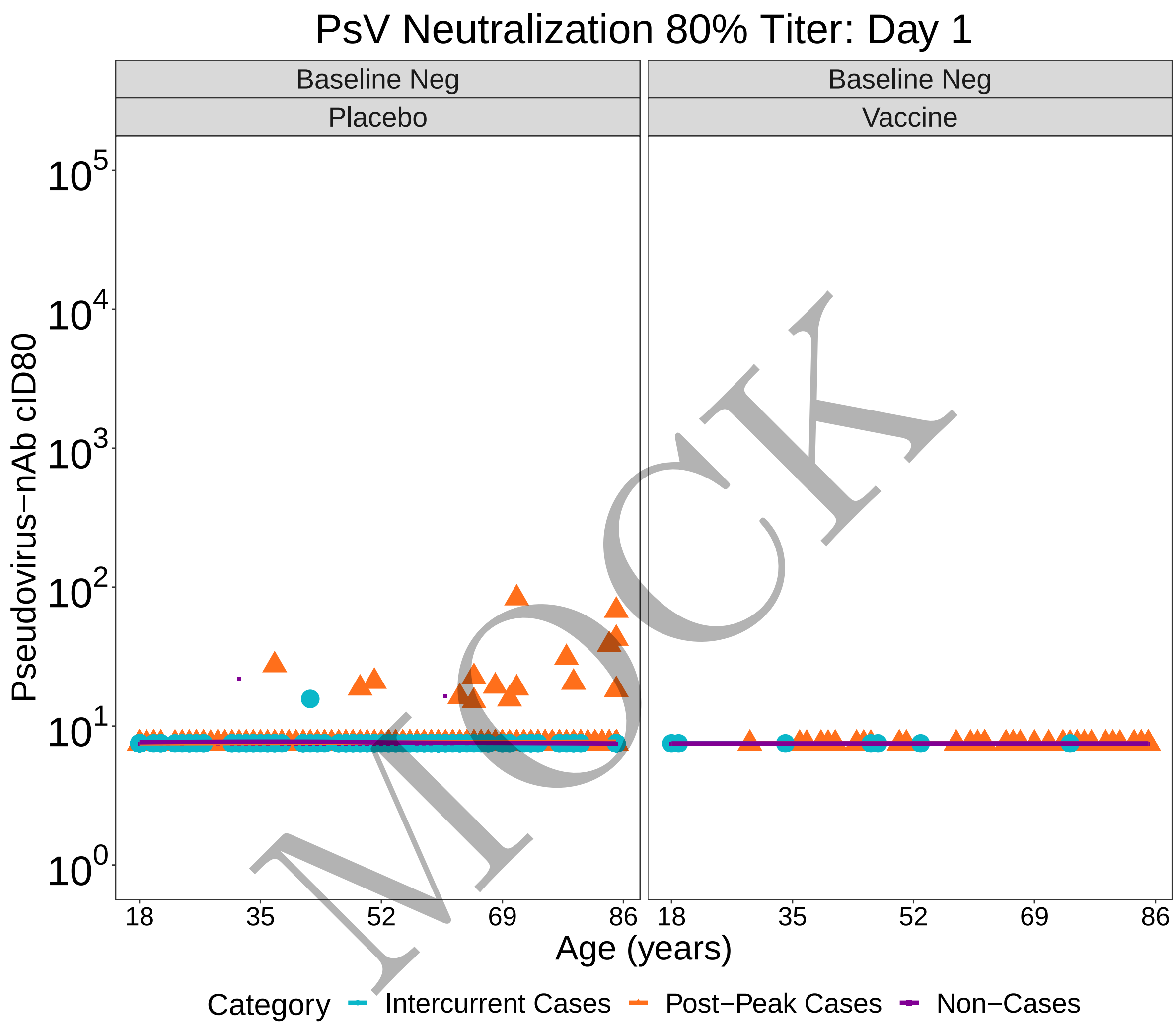
} \end{figure}

\begin{figure}[H]



\caption{
Figure 2.6.21: scatterplots of PsV Neutralization 50% Titer vs Age: by arm at day 57
} \end{figure}

\begin{figure}[H]

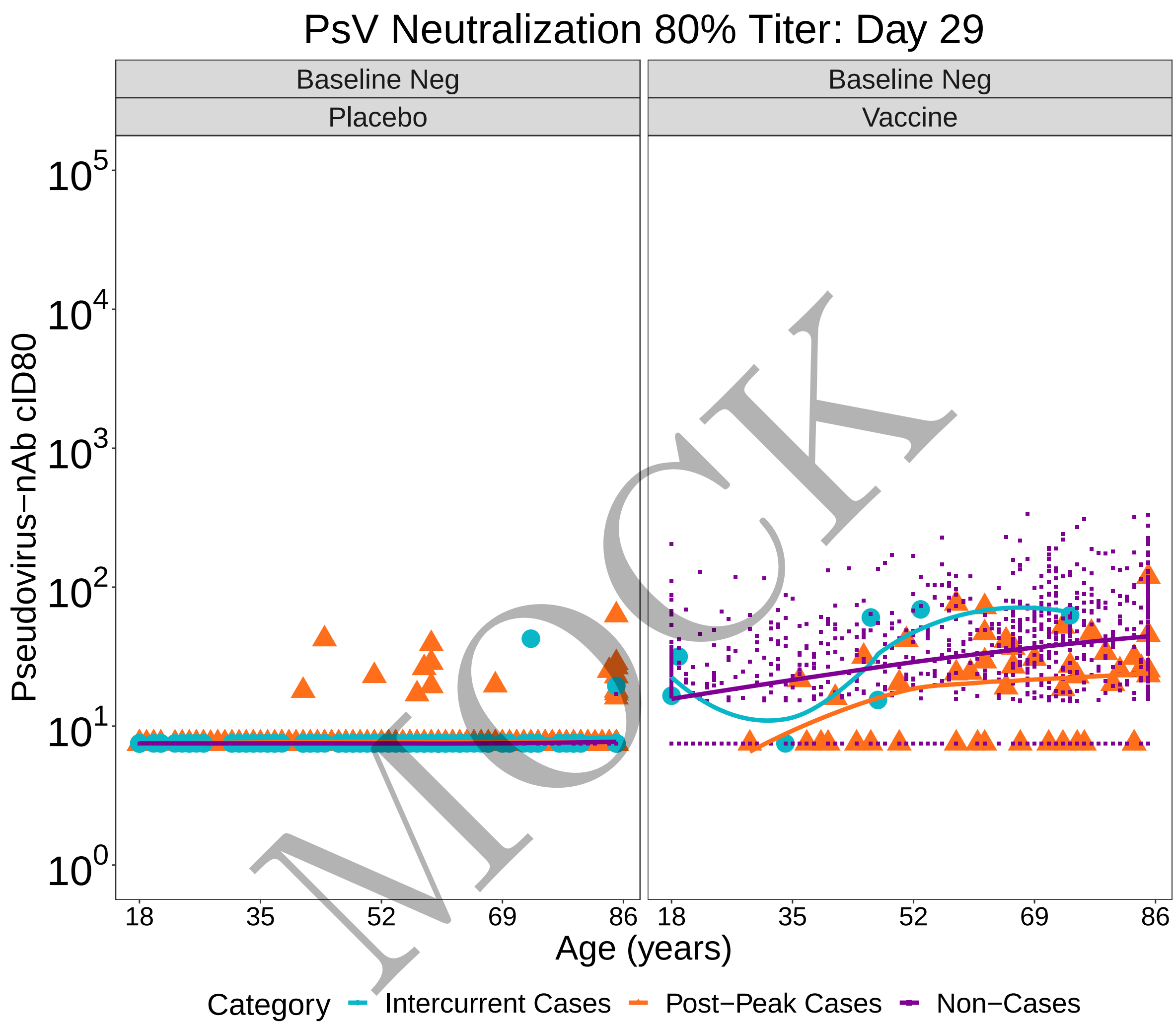


\caption{

Figure 2.6.22: scatterplots of PsV Neutralization 80% Titer vs Age: by arm at day 1

} \end{figure}

\begin{figure}[H]

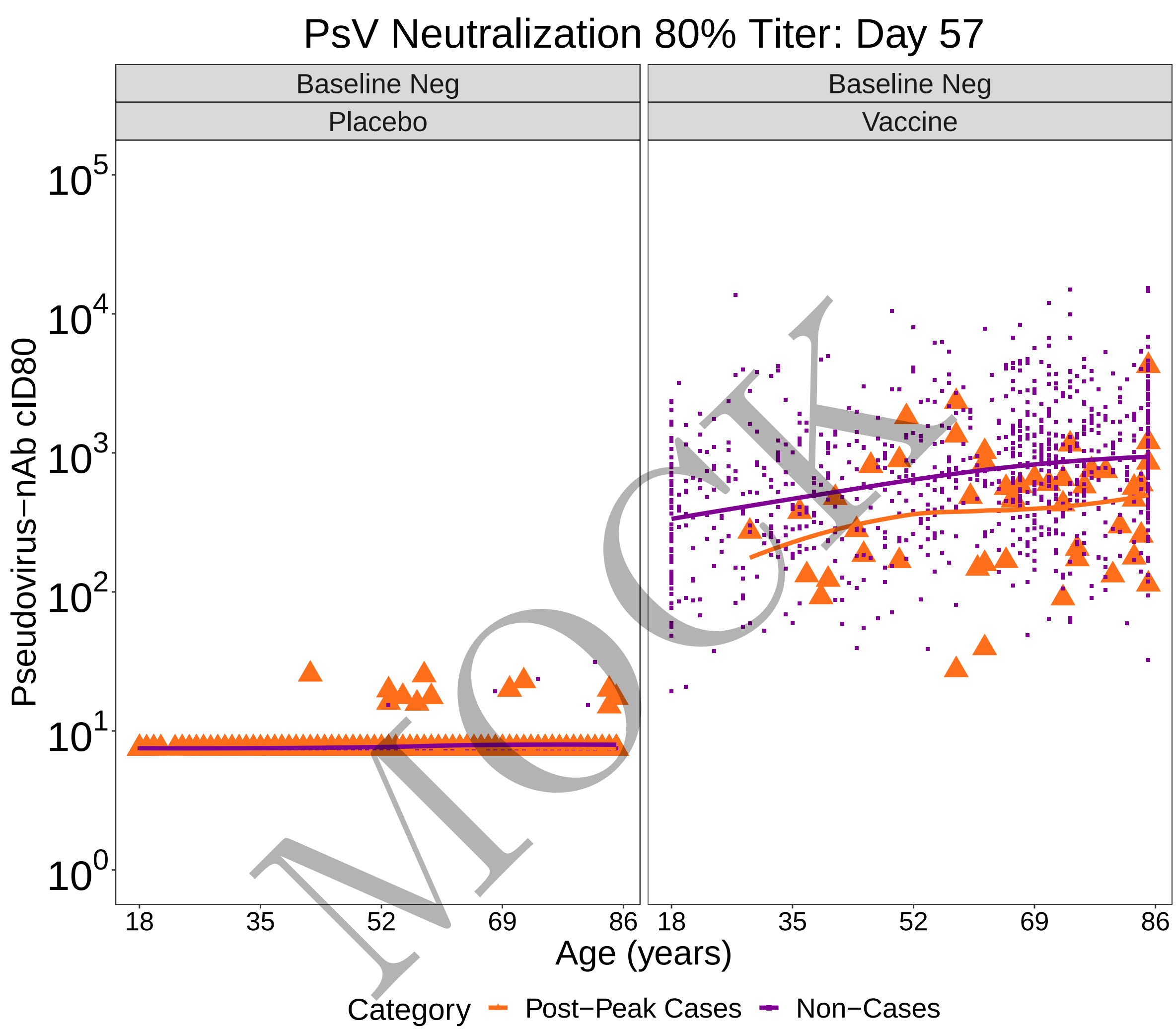


\caption{

Figure 2.6.23: scatterplots of PsV Neutralization 80% Titer vs Age: by arm at day 29

} \end{figure}

\begin{figure}[H]

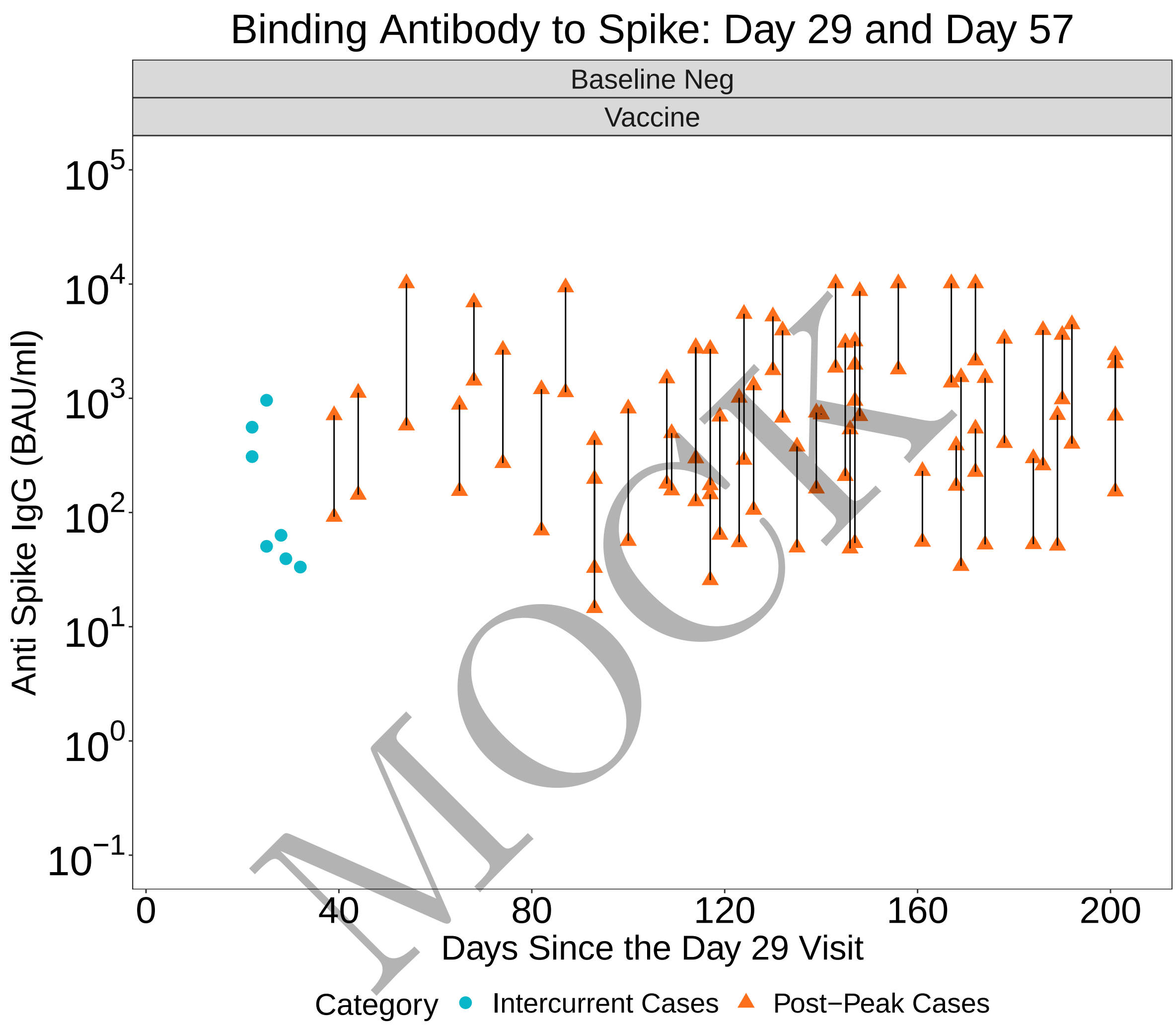


\caption{

Figure 2.6.24: scatterplots of PsV Neutralization 80% Titer vs Age: by arm at day 57

} \end{figure}

\begin{figure}[H]

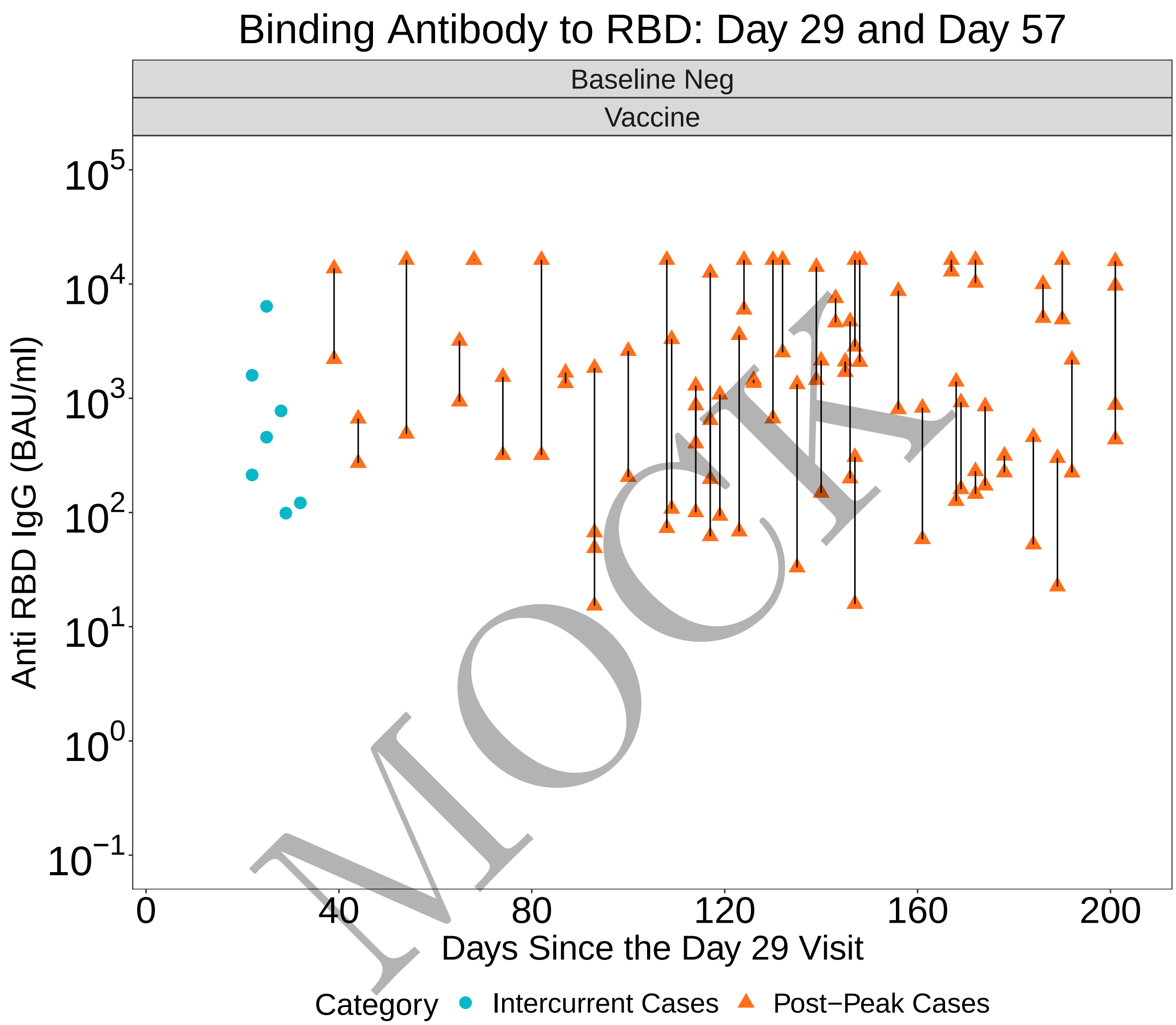


\caption{

Figure 2.6.25: scatterplots of Binding Antibody to Spike vs Days Since the Day 29 Visit: baseline negative vaccine arm at Day 29 and Day 57

} \end{figure}

\begin{figure}[H]

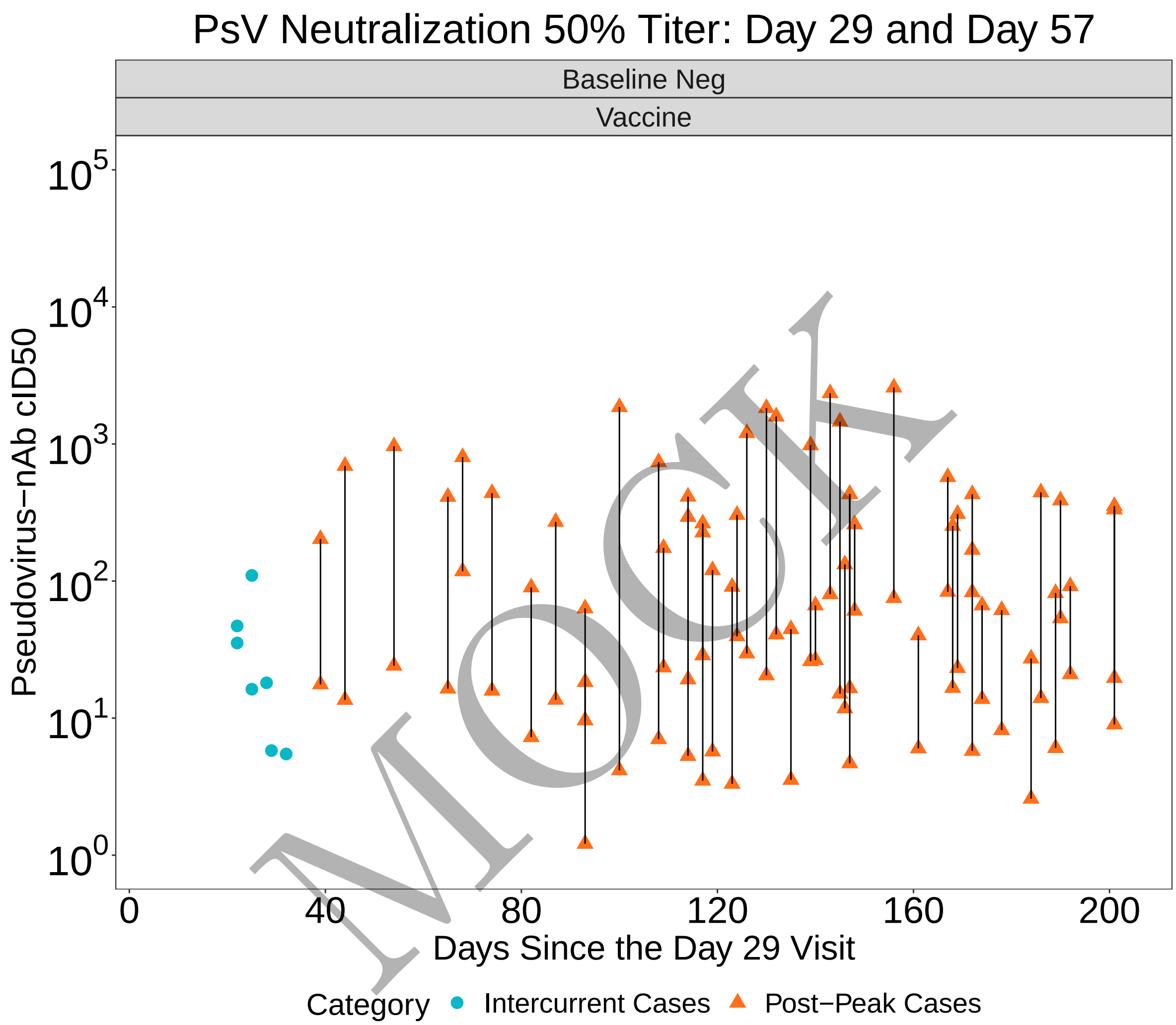


\caption{

Figure 2.6.26: scatterplots of Binding Antibody to RBD vs Days Since the Day 29 Visit: baseline negative vaccine arm at Day 29 and Day 57

} \end{figure}

\begin{figure}[H]

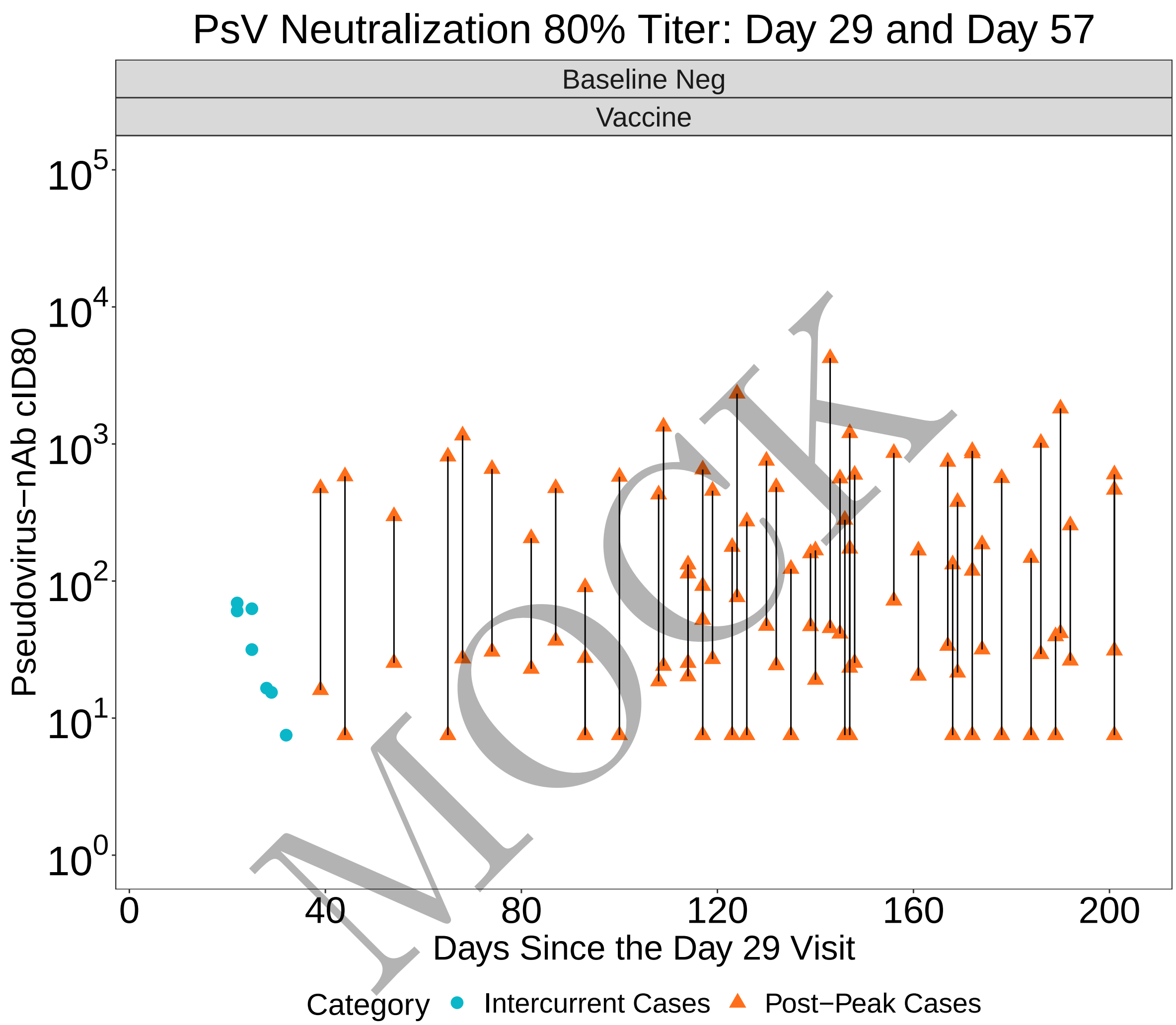


\caption{

Figure 2.6.27: scatterplots of PsV Neutralization 50% Titer vs Days Since the Day 29 Visit: baseline negative vaccine arm at Day 29 and Day 57

} \end{figure}

\begin{figure}[H]

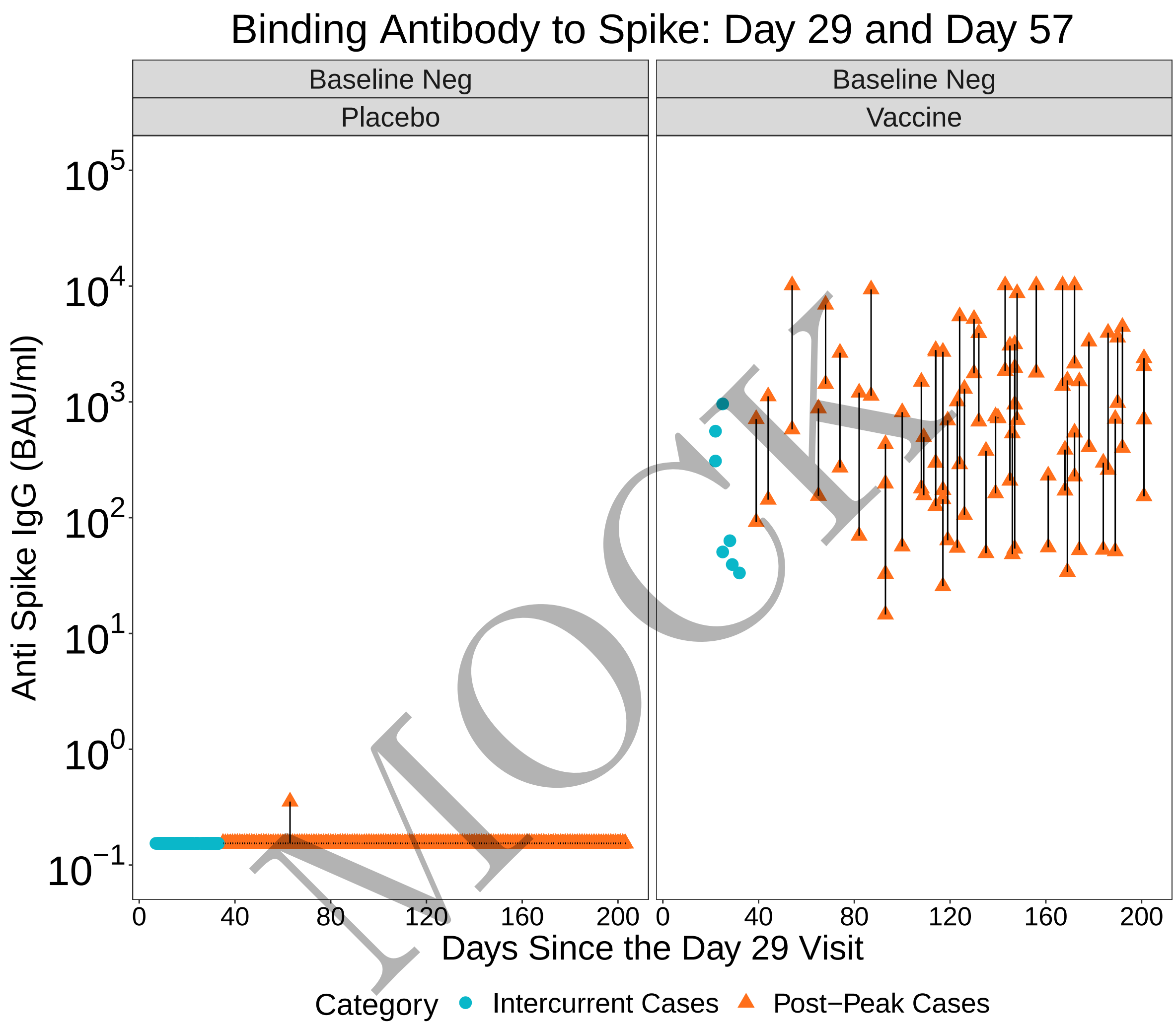


\caption{

Figure 2.6.28: scatterplots of PsV Neutralization 80% Titer vs Days Since the Day 29 Visit: baseline negative vaccine arm at Day 29 and Day 57

} \end{figure}

\begin{figure}[H]

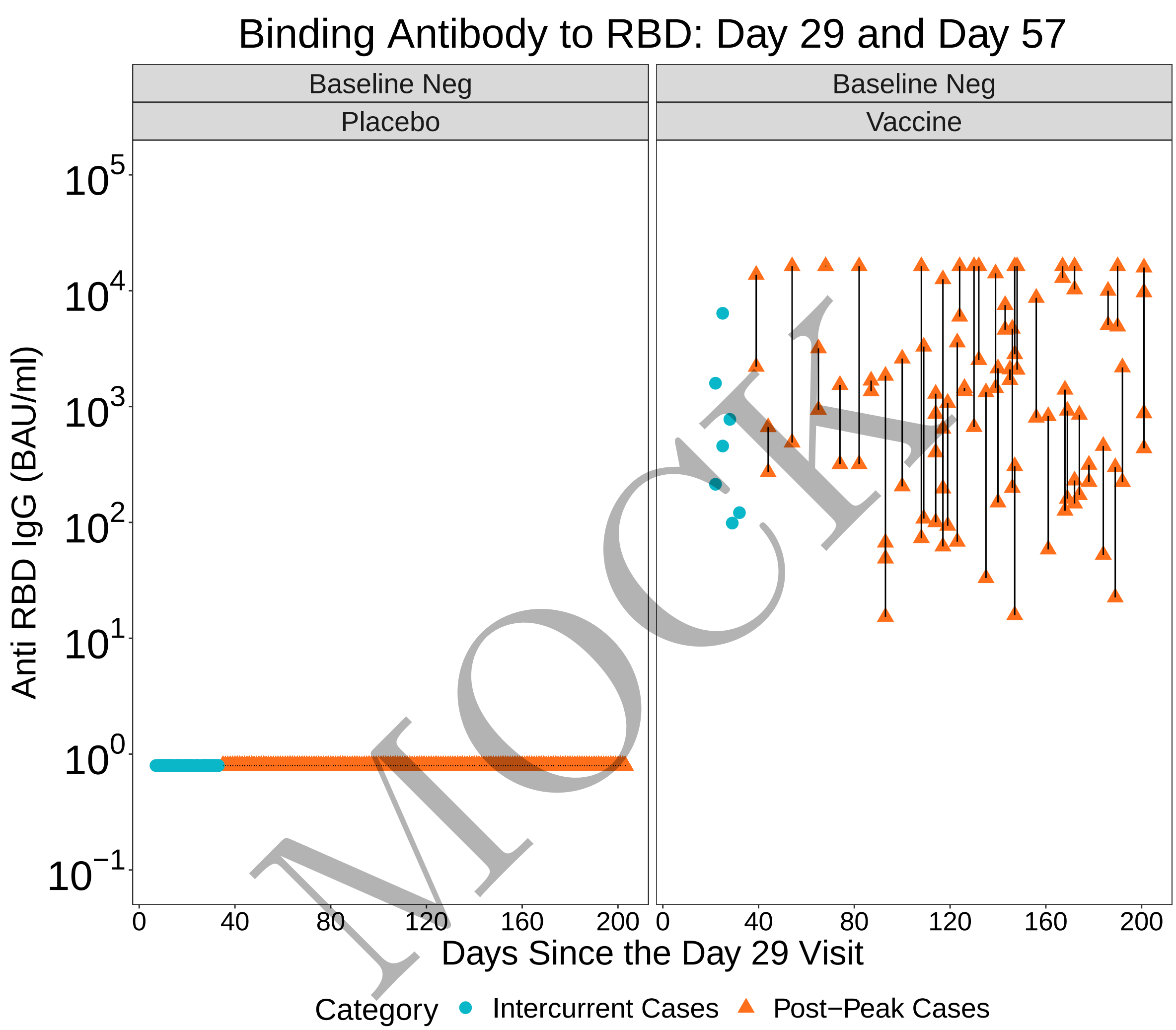


\caption{

Figure 2.6.29: scatterplots of Binding Antibody to Spike vs Days Since the Day 29 Visit: by arm at Day 29 and Day 57

} \end{figure}

\begin{figure}[H]

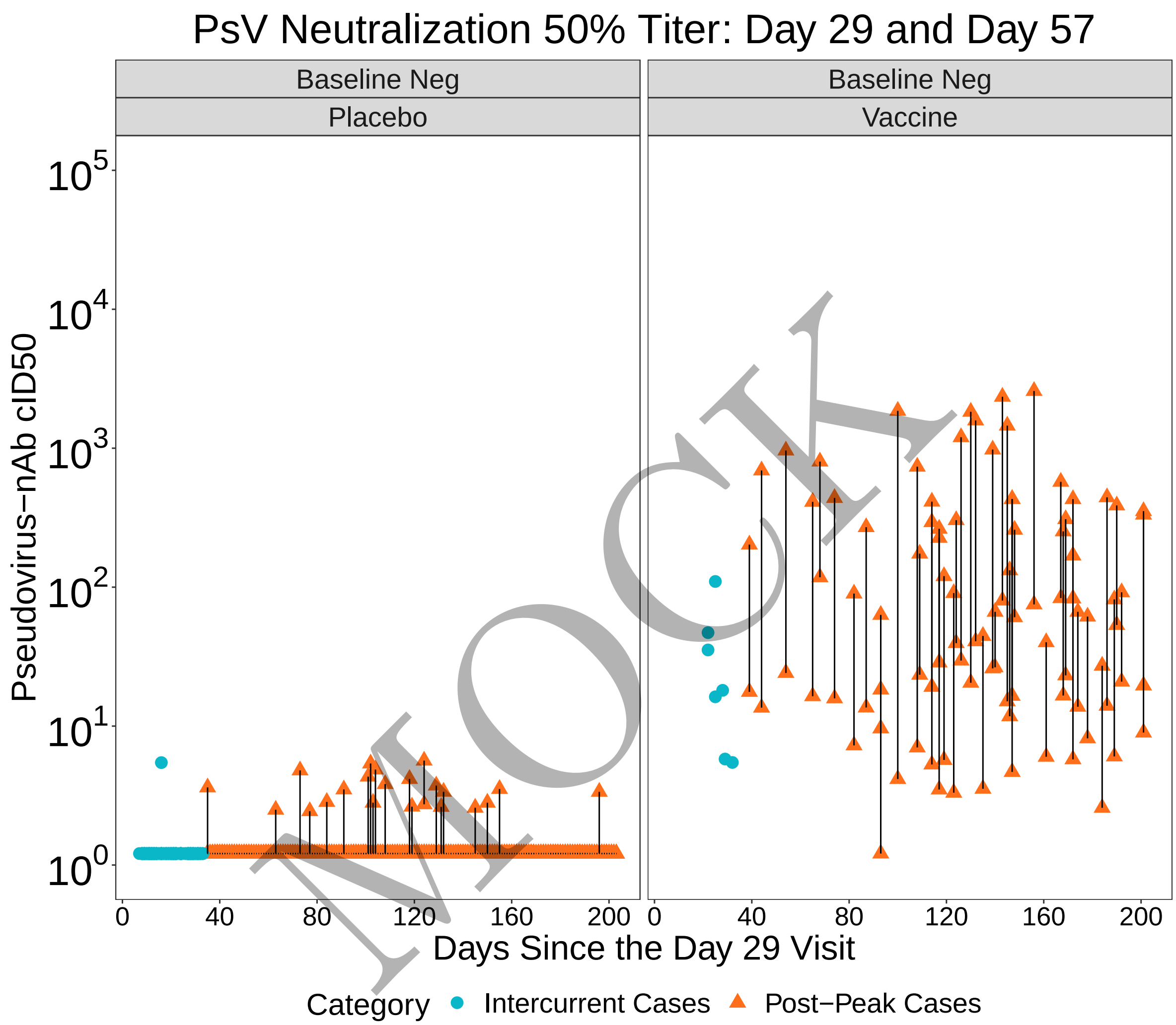


\caption{

Figure 2.6.30: scatterplots of Binding Antibody to RBD vs Days Since the Day 29 Visit: by arm at Day 29 and Day 57

} \end{figure}

\begin{figure}[H]

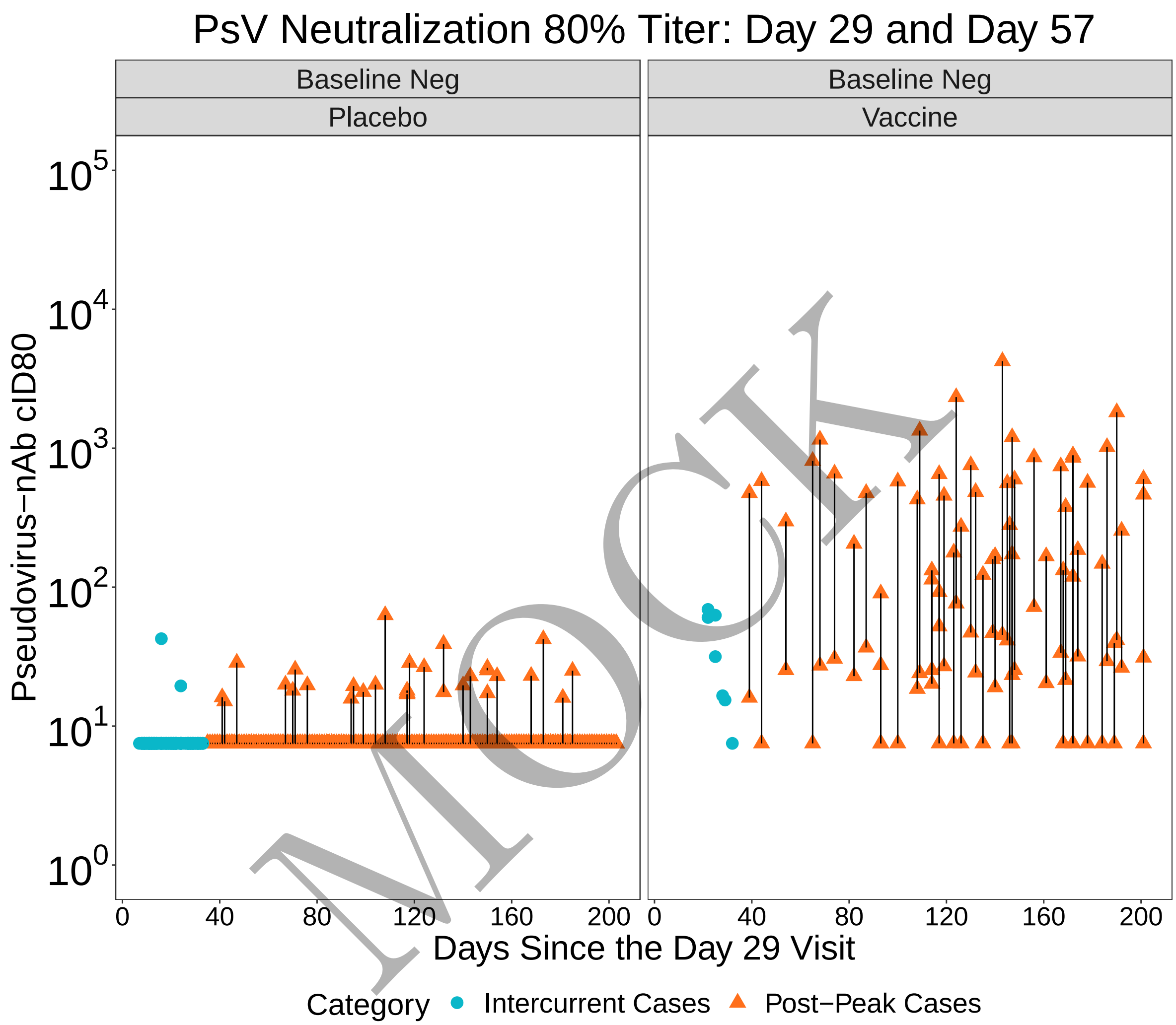


\caption{

Figure 2.6.31: scatterplots of PsV Neutralization 50% Titer vs Days Since the Day 29 Visit: by arm at Day 29 and Day 57

} \end{figure}

\begin{figure}[H]



\caption{

Figure 2.6.32: scatterplots of PsV Neutralization 80% Titer vs Days Since the Day 29 Visit: by arm at Day 29 and Day 57

} \end{figure}

Chapter 3

Graphical Descriptions of Time to Event Data

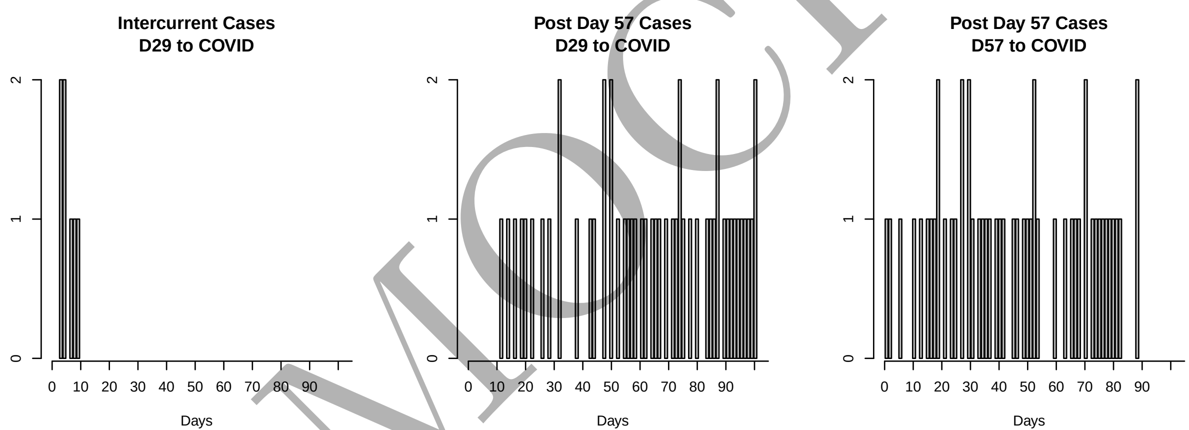


Figure 3.1: Distribution of the number of days to COVID endpoints, vaccine arm, baseline negative.

Chapter 4

Day D29 Univariate CoR: Cox Models of Risk

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

4.1 Hazard ratios

Table 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*

MockCOVE 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 (BAU/ml)	58/11,204	0.11	(0.05-0.24)	<0.001	<0.001	<0.001
Anti RBD IgG (BAU/ml)	58/11,204	0.37	(0.19-0.70)	0.002	<0.001	<0.001
Pseudovirus-nAb cID50	58/11,204	0.25	(0.11-0.60)	0.002	<0.001	<0.001
Pseudovirus-nAb cID80	58/11,204	0.24	(0.11-0.49)	<0.001	<0.001	<0.001

*Baseline covariates adjusted for: MinorityInd + HighRiskInd + Age. Maximum failure event time 201 days.
**No. at-risk = estimated number in the population for analysis, i.e. baseline negative per-protocol vaccine recipients not experiencing the COVID endpoint or infected through 6 days post Day 29 visit; no. cases = number of this cohort with an observed COVID endpoint.
***q-value and FWER (family-wide error rate) are computed over the set of p-values both for quantitative markers and categorical markers using the Westfall and Young permutation method (10 replicates).

Table 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*

MockCOVE 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 (BAU/ml)	Lower	24/3,752	0.0064	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	17/3,729	0.0046	0.27	(0.13-0.57)	<0.001			
	Upper	17/3,723	0.0046	0.12	(0.05-0.29)	<0.001			
Anti RBD IgG (BAU/ml)	Lower	27/3,745	0.0072	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	13/3,747	0.0035	0.25	(0.11-0.56)	<0.001			
	Upper	18/3,712	0.0048	0.21	(0.09-0.49)	<0.001			
Pseudovirus-nAb cID50	Lower	21/3,741	0.0056	1	N/A	N/A	0.013	0.100	0.062
	Middle	22/3,729	0.0059	0.68	(0.33-1.41)	0.301			
	Upper	15/3,734	0.0040	0.29	(0.12-0.68)	0.004			
Pseudovirus-nAb cID80	Lower	22/3,739	0.0059	1	N/A	N/A	0.007	<0.001	0.043
	Middle	23/3,736	0.0062	0.78	(0.41-1.47)	0.442			
	Upper	13/3,729	0.0035	0.30	(0.14-0.64)	0.002			
Placebo		1166/11,505	0.1013						

*Baseline covariates adjusted for: MinorityInd + HighRiskInd + Age. Maximum failure event time 201 days. Cutpoints: Anti Spike IgG (BAU/ml) [2.18, 2.65), Anti RBD IgG (BAU/ml) [2.42, 3.06), Pseudovirus-nAb cID50 [1.08, 1.44), Pseudovirus-nAb cID80 [1.25, 1.59), all on the log10 scale.
**No. at-risk = estimated number in the population for analysis, i.e. baseline negative per-protocol vaccine recipients not experiencing the COVID endpoint or infected through 6 days post Day 29 visit; no. cases = number of this cohort with an observed COVID endpoint.
***Generalized Wald-test p-value of the null hypothesis that the hazard rate is constant across the Lower, Middle, and Upper tertile groups.
† q-value and FWER (family-wide error rate) are computed over the set of p-values both for quantitative markers and categorical markers using the Westfall and Young permutation method (10 replicates).

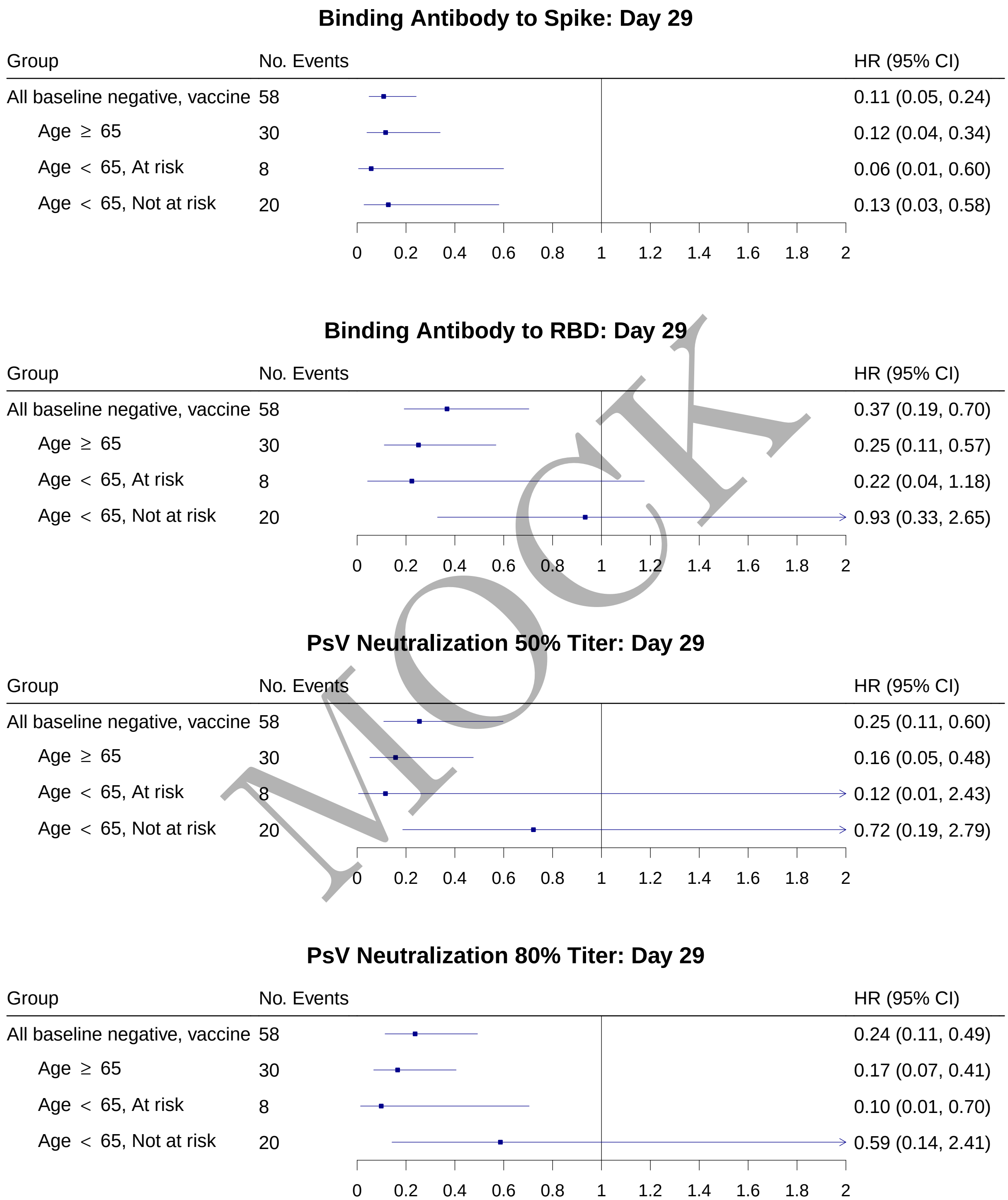


Figure 4.1: Forest plots of hazard ratios per 10-fold increase in the marker among baseline negative vaccine recipients and subgroups with 95% point-wise confidence intervals.

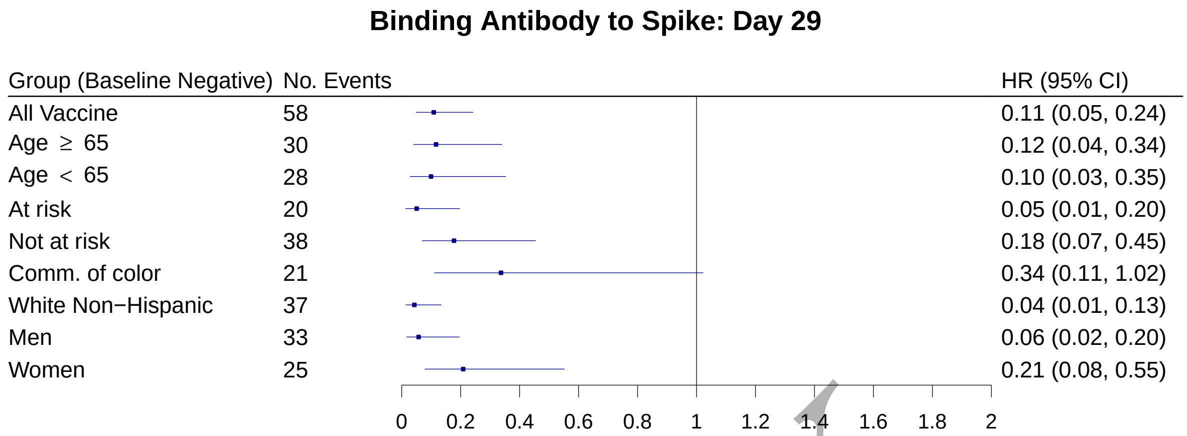


Figure 4.2: Forest plots of hazard ratios per 10-fold increase in the Day 29 binding Ab to spike markers among baseline negative vaccine recipients (top row) and different subpopulations with 95% point-wise confidence intervals.

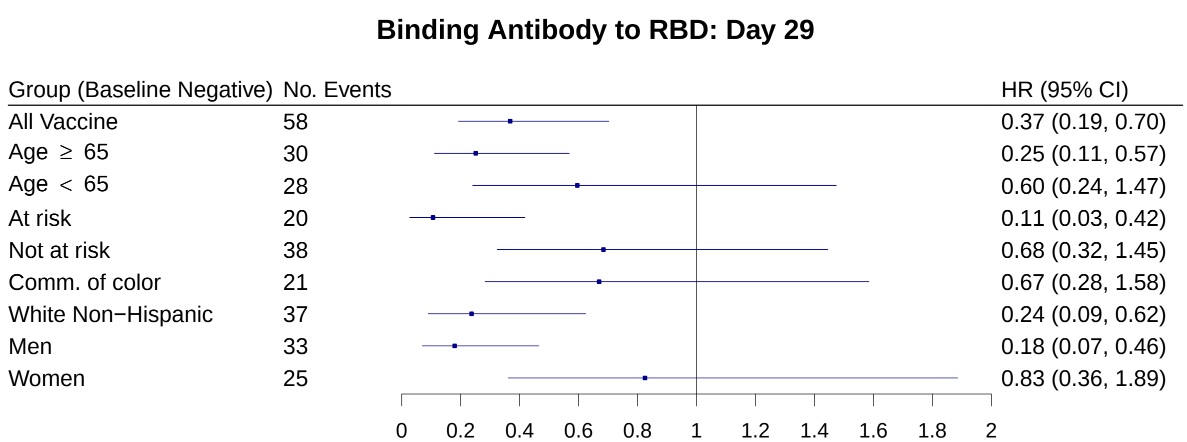


Figure 4.3: Forest plots of hazard ratios per 10-fold increase in the Day 29 binding Ab to RBD markers among baseline negative vaccine recipients (top row) and different subpopulations with 95% point-wise confidence intervals.

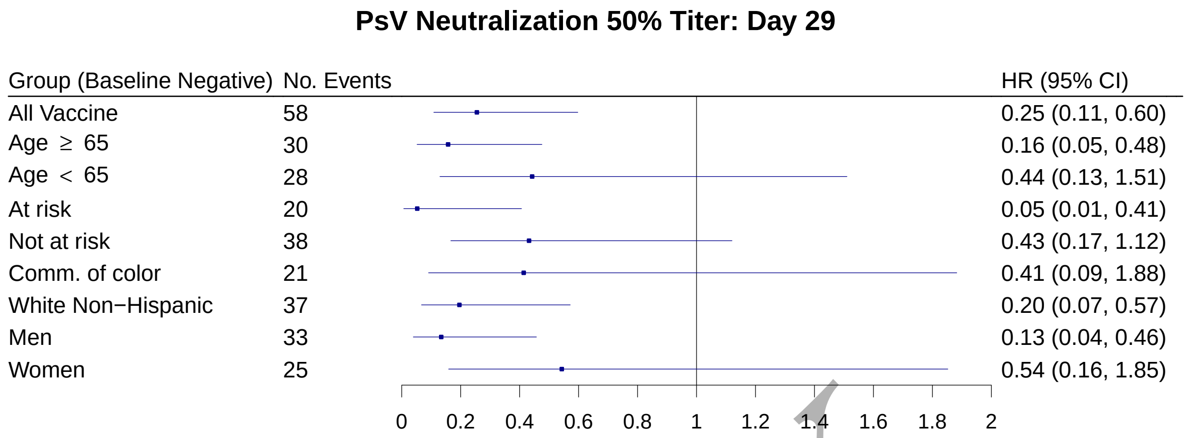


Figure 4.4: Forest plots of hazard ratios per 10-fold increase in the Day 29 pseudo neut ID50 markers among baseline negative vaccine recipients (top row) and different subpopulations with 95% point-wise confidence intervals.

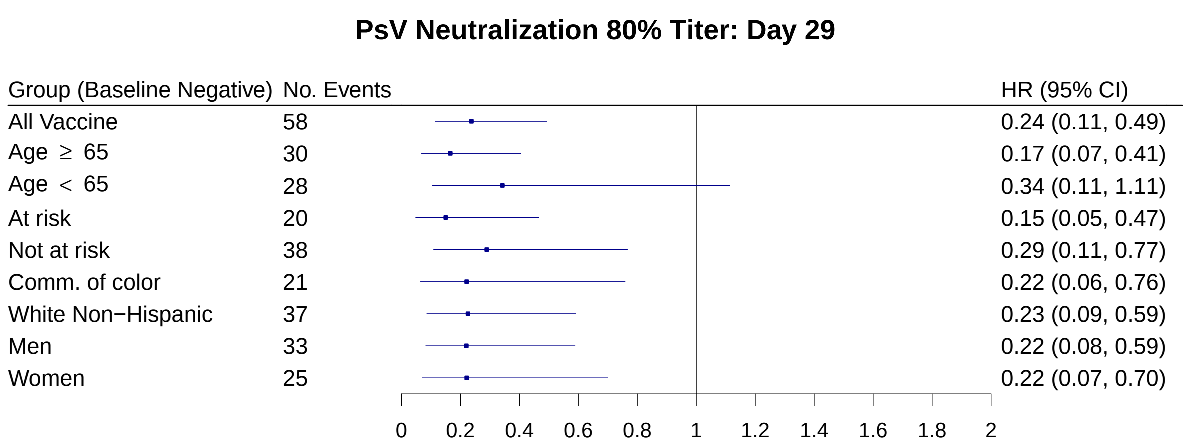


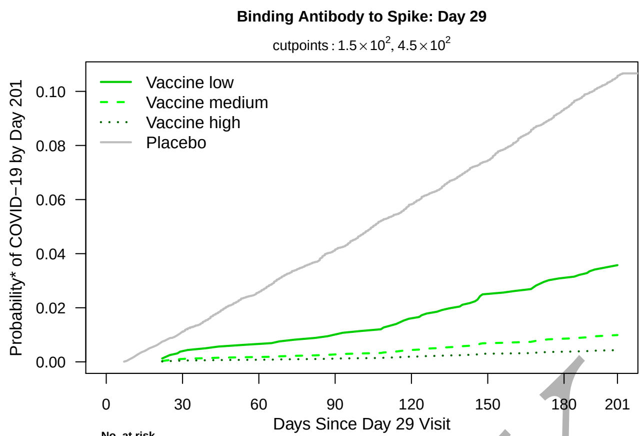
Figure 4.5: Forest plots of hazard ratios per 10-fold increase in the Day 29 pseudo neut ID80 markers among baseline negative vaccine recipients (top row) and different subpopulations with 95% point-wise confidence intervals.

4.2 Marginalized risk and controlled vaccine efficacy plots

Table 4.3: Analysis of Day 29 markers (upper vs. lower tertile) as a CoR and a controlled risk CoP.

	marginalized risk ratio $RR_M(0,1)$		controlled risk ratio $RR_C(0,1)$[1]		e(0,1)[2]	
	Point Est.	95% CI	Point Est.	95% CI	Point Est.	95% CI UL
Anti Spike IgG (BAU/ml)	0.12	0.06–0.21	0.16	0.08–0.29	16.1	8.8
Anti RBD IgG (BAU/ml)	0.21	0.11–0.38	0.28	0.14–0.51	9.0	4.7
Pseudovirus-nAb cID50	0.29	0.24–0.37	0.38	0.32–0.50	6.4	4.8
Pseudovirus-nAb cID80	0.30	0.21–0.49	0.40	0.28–0.65	6.1	3.5

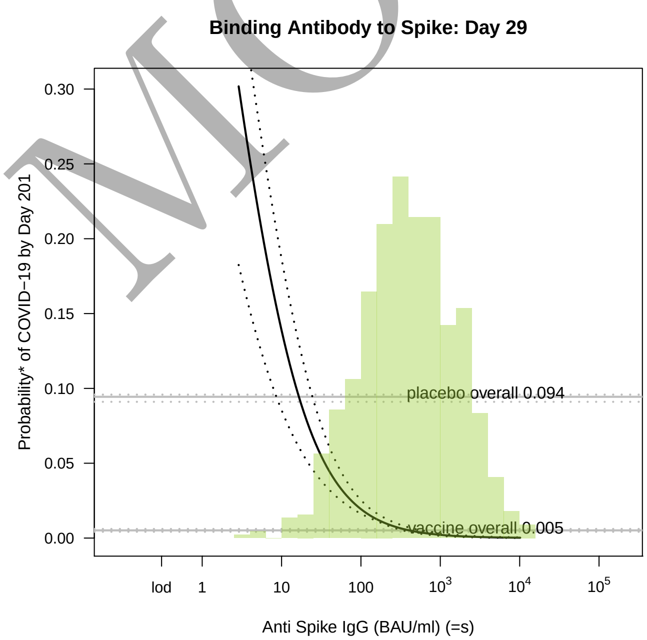
[1]Conservative (upper bound) estimate assuming unmeasured confounding at level $RR_{UD}(0,1) = RR_{EU}(0,1) = 2$ and thus $B(0,1) = 4/3$.
[2]E-values are computed for upper tertile ($s = 1$) vs. lower tertile ($s = 0$) biomarker subgroups after controlling for MinorityInd + HighRiskInd + Age; UL = upper limit.



No. at risk	0	30	60	90	120	150	180	201
Low:	3752	3749	3691	3671	3588	3583	3548	2828
Med:	3729	3728	3680	3650	3638	3561	3483	2688
High:	3723	3721	3690	3623	3614	3585	3518	2903
Plac:	11505	11381	11061	10703	10350	10021	9639	7830

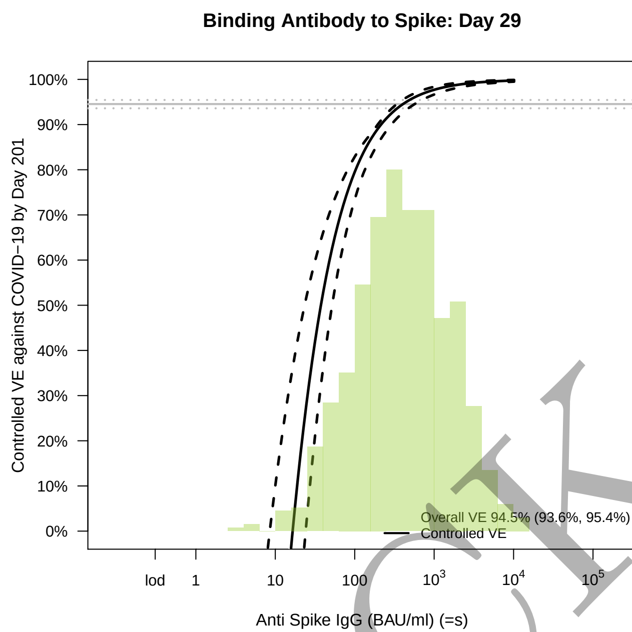
Cumulative No. of COVID−19 Endpoints								
Low:	0	3	6	7	14	19	22	24
Med:	0	1	1	3	7	11	14	17
High:	0	2	3	5	5	12	15	17
Plac:	0	129	296	473	658	835	1039	1166

(a) Marginalized cumulative incidence rate curves for trichotomized Day 29 markers among vaccine recipients. The gray line is the overall cumulative incidence rate curve in the placebo arm.

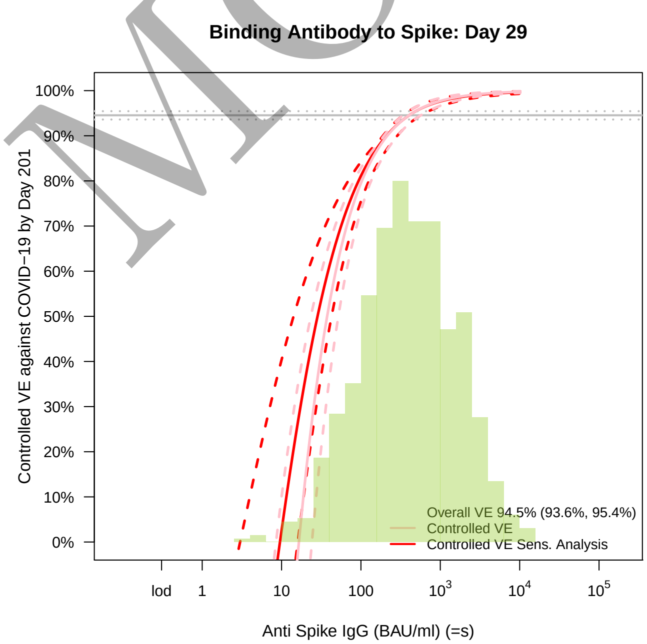


(b) Marginalized cumulative risk by Day 201 as functions of Day 29 markers (=s) among vaccine recipients with 95% bootstrap point-wise confidence bands (10 replicates). The horizontal lines indicate the overall cumulative risk of the placebo and vaccine arms by Day 201 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod =0.3.

Figure 4.6: Marginalized cumulative risk curves (=s).

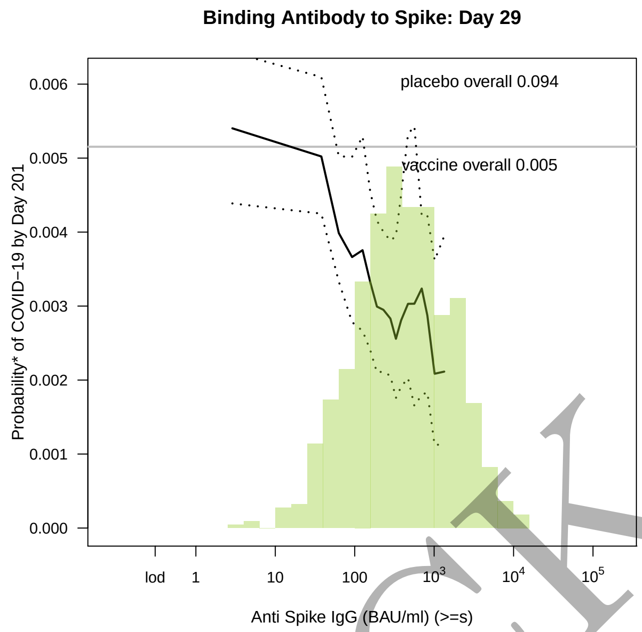


(a) Controlled VE with sensitivity analysis as functions of Day 29 markers (=s) among vaccine recipients with 95% bootstrap pointwise confidence bands (10 replicates). Histograms of the immunological markers in the vaccine arm are overlaid. lod =0.3.

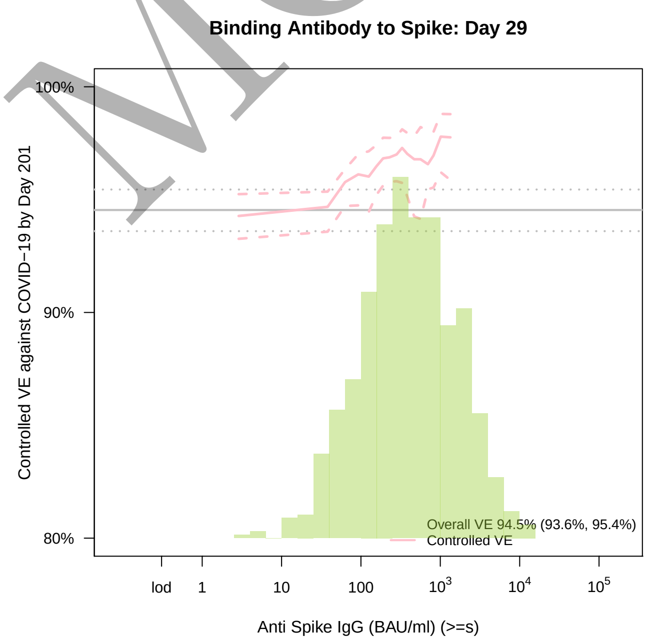


(b) Controlled VE with sensitivity analysis as functions of Day 29 markers (=s) among vaccine recipients with 95% bootstrap pointwise confidence bands (10 replicates). Histograms of the immunological markers in the vaccine arm are overlaid. lod =0.3.

Figure 4.7: Controlled VE curves (=s).



(a) Marginalized cumulative risk by Day 201 post Day 29 visit as functions of Day 29 markers above a threshold ($\geq s$) among vaccine recipients with 95% bootstrap point-wise confidence bands (at least 5 cases are required, 10 replicates). The horizontal lines indicate the overall cumulative risk of the vaccine arm by Day 201 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod =0.3.



(b) Controlled VE as functions of Day 29 markers (>=s) among vaccine recipients with 95% bootstrap point-wise confidence bands (10 replicates). Histograms of the immunological markers in the vaccine arm are overlaid. lod =0.3.

Figure 4.8: Marginalized cumulative risk curves and controlled VE curves (>=s).

Table 4.4: Marginalized cumulative risk by Day 201 as functions of Day 29 Anti Spike IgG (BAU/ml) (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence intervals (10 replicates).

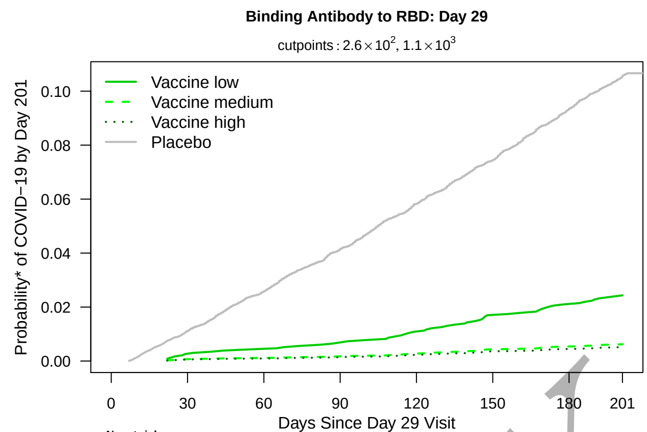
s	Estimate	s	Estimate	s	Estimate	s	Estimate
2.9	.3018 (.1825,.3740)	29	.0590 (.0407,.0814)	227	.0089 (.0079,.0119)	1294	.0017 (.0011,.0025)
3	.2890 (.1744,.3594)	32	.0550 (.0383,.0756)	228	.0089 (.0079,.0119)	1402	.0016 (.0010,.0024)
3	.2764 (.1665,.3453)	34	.0511 (.0361,.0702)	248	.0082 (.0072,.0110)	1523	.0014 (.0009,.0022)
4	.2641 (.1589,.3314)	37	.0476 (.0340,.0651)	269	.0076 (.0066,.0102)	1654	.0013 (.0009,.0021)
4	.2520 (.1515,.3177)	40	.0442 (.0320,.0604)	292	.0070 (.0060,.0095)	1779	.0012 (.0008,.0019)
4	.2403 (.1443,.3046)	44	.0411 (.0301,.0559)	318	.0065 (.0055,.0088)	1796	.0012 (.0008,.0019)
5	.2288 (.1374,.2918)	48	.0382 (.0283,.0517)	329	.0063 (.0053,.0085)	1950	.0011 (.0007,.0018)
5	.2175 (.1307,.2792)	52	.0354 (.0267,.0478)	345	.0060 (.0050,.0081)	2118	.0011 (.0007,.0017)
6	.2066 (.1243,.2668)	56	.0329 (.0251,.0443)	375	.0056 (.0046,.0075)	2238	.0010 (.0006,.0016)
6	.1960 (.1181,.2546)	61	.0305 (.0236,.0410)	407	.0051 (.0042,.0070)	2300	.0010 (.0006,.0015)
7	.1858 (.1122,.2428)	64	.0293 (.0228,.0392)	442	.0047 (.0038,.0065)	2498	.0009 (.0005,.0014)
7	.1758 (.1064,.2311)	66	.0283 (.0222,.0379)	474	.0044 (.0035,.0061)	2713	.0008 (.0005,.0013)
8	.1662 (.1010,.2198)	72	.0262 (.0208,.0350)	480	.0044 (.0035,.0060)	2946	.0008 (.0005,.0012)
8	.1570 (.0957,.2087)	78	.0243 (.0196,.0323)	500	.0042 (.0033,.0058)	3200	.0007 (.0004,.0012)
9	.1480 (.0907,.1980)	85	.0225 (.0184,.0299)	521	.0041 (.0032,.0056)	3475	.0007 (.0004,.0011)
10	.1395 (.0859,.1875)	92	.0209 (.0173,.0276)	566	.0037 (.0029,.0052)	3774	.0006 (.0003,.0010)
11	.1313 (.0813,.1773)	93	.0208 (.0172,.0274)	614	.0035 (.0026,.0049)	4098	.0006 (.0003,.0009)
12	.1234 (.0769,.1675)	100	.0193 (.0163,.0254)	667	.0032 (.0024,.0045)	4451	.0005 (.0003,.0009)
13	.1159 (.0727,.1580)	109	.0179 (.0153,.0234)	708	.0030 (.0022,.0043)	4833	.0005 (.0003,.0008)
14	.1088 (.0687,.1488)	118	.0166 (.0144,.0216)	725	.0030 (.0022,.0042)	5249	.0004 (.0002,.0008)
15	.1020 (.0649,.1399)	128	.0153 (.0135,.0200)	787	.0027 (.0020,.0039)	5700	.0004 (.0002,.0007)
16	.0955 (.0613,.1314)	130	.0151 (.0133,.0197)	855	.0025 (.0018,.0037)	6191	.0004 (.0002,.0007)
18	.0893 (.0579,.1232)	139	.0142 (.0127,.0185)	928	.0023 (.0017,.0034)	6723	.0003 (.0002,.0006)
19	.0835 (.0546,.1154)	151	.0131 (.0119,.0172)	1000	.0022 (.0015,.0032)	7301	.0003 (.0002,.0006)
21	.0780 (.0515,.1079)	164	.0122 (.0111,.0160)	1008	.0022 (.0015,.0032)	7929	.0003 (.0001,.0006)
23	.0729 (.0486,.1007)	178	.0112 (.0102,.0148)	1095	.0020 (.0014,.0029)	8611	.0003 (.0001,.0005)
25	.0680 (.0458,.0939)	194	.0104 (.0094,.0138)	1189	.0018 (.0013,.0027)	9352	.0003 (.0001,.0005)
27	.0634 (.0432,.0875)	210	.0096 (.0086,.0128)	1291	.0017 (.0011,.0026)	10156	.0002 (.0001,.0005)

Table 4.5: Controlled VE as functions of Day 29 Anti Spike IgG (BAU/ml) (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence intervals (10 replicates).Overall cumulative incidence from 7 to 201 days post Day 29 was 0.005 in vaccine recipients compared to 0.094 in placebo recipients, with cumulative vaccine efficacy 94.5% (95% CI 93.6 to 95.4%).

s	Estimate	s	Estimate	s	Estimate	s	Estimate
2.9	-2.1976 (-2.9975,-0.9216)	32	0.4177 (0.2075, 0.5965)	248	0.9128 (0.8851, 0.9227)	1654	0.9858 (0.9784, 0.9907)
3	-2.0619 (-2.8347,-0.8363)	34	0.4581 (0.2638, 0.6200)	269	0.9194 (0.8934, 0.9294)	1779	0.9868 (0.9797, 0.9915)
3	-1.9287 (-2.6741,-0.7534)	37	0.4960 (0.3168, 0.6422)	292	0.9255 (0.9012, 0.9356)	1796	0.9869 (0.9799, 0.9916)
4	-1.7982 (-2.5158,-0.6731)	40	0.5314 (0.3666, 0.6632)	318	0.9311 (0.9083, 0.9413)	1950	0.9879 (0.9813, 0.9923)
4	-1.6704 (-2.3601,-0.5952)	44	0.5646 (0.4134, 0.6830)	329	0.9335 (0.9114, 0.9436)	2118	0.9888 (0.9826, 0.9930)
4	-1.5455 (-2.2078,-0.5199)	48	0.5956 (0.4571, 0.7017)	345	0.9363 (0.9150, 0.9464)	2238	0.9894 (0.9834, 0.9934)
5	-1.4236 (-2.0604,-0.4471)	52	0.6245 (0.4981, 0.7194)	375	0.9411 (0.9212, 0.9511)	2300	0.9897 (0.9838, 0.9936)
5	-1.3048 (-1.9249,-0.3768)	56	0.6515 (0.5363, 0.7361)	407	0.9456 (0.9269, 0.9554)	2498	0.9905 (0.9849, 0.9942)
6	-1.1893 (-1.7935,-0.3091)	61	0.6767 (0.5717, 0.7518)	442	0.9497 (0.9321, 0.9593)	2713	0.9912 (0.9859, 0.9947)
6	-1.0770 (-1.6662,-0.2439)	64	0.6900 (0.5899, 0.7601)	474	0.9530 (0.9361, 0.9624)	2946	0.9919 (0.9869, 0.9952)
7	-0.9682 (-1.5417,-0.1812)	66	0.7002 (0.6039, 0.7666)	480	0.9535 (0.9368, 0.9629)	3200	0.9925 (0.9878, 0.9956)
7	-0.8629 (-1.4201,-0.1209)	72	0.7220 (0.6338, 0.7806)	500	0.9553 (0.9390, 0.9646)	3475	0.9931 (0.9886, 0.9960)
8	-0.7611 (-1.3013,-0.0632)	78	0.7423 (0.6618, 0.7937)	521	0.9571 (0.9411, 0.9662)	3774	0.9936 (0.9893, 0.9963)
8	-0.6630 (-1.1854,-0.0078)	85	0.7612 (0.6877, 0.8061)	566	0.9603 (0.9452, 0.9692)	4098	0.9941 (0.9900, 0.9967)
9	-0.5685 (-1.0727, 0.0452)	92	0.7788 (0.7118, 0.8178)	614	0.9633 (0.9490, 0.9719)	4451	0.9945 (0.9906, 0.9970)
10	-0.4778 (-0.9630, 0.0959)	93	0.7800 (0.7134, 0.8186)	667	0.9661 (0.9525, 0.9744)	4833	0.9950 (0.9912, 0.9972)
11	-0.3909 (-0.8566, 0.1443)	100	0.7951 (0.7341, 0.8288)	708	0.9680 (0.9548, 0.9760)	5249	0.9953 (0.9918, 0.9975)
12	-0.3076 (-0.7535, 0.1905)	109	0.8103 (0.7549, 0.8391)	725	0.9687 (0.9558, 0.9766)	5700	0.9957 (0.9923, 0.9977)
13	-0.2281 (-0.6538, 0.2346)	118	0.8243 (0.7741, 0.8488)	787	0.9711 (0.9588, 0.9787)	6191	0.9960 (0.9928, 0.9979)
14	-0.1523 (-0.5574, 0.2765)	128	0.8374 (0.7914, 0.8580)	855	0.9733 (0.9617, 0.9806)	6723	0.9963 (0.9932, 0.9981)
15	-0.0802 (-0.4646, 0.3165)	130	0.8397 (0.7943, 0.8597)	928	0.9753 (0.9643, 0.9823)	7301	0.9966 (0.9936, 0.9983)
16	-0.0116 (-0.3754, 0.3545)	139	0.8495 (0.8063, 0.8666)	1000	0.9770 (0.9665, 0.9837)	7929	0.9969 (0.9940, 0.9984)
18	0.0534 (-0.2897, 0.3906)	151	0.8607 (0.8201, 0.8747)	1008	0.9772 (0.9668, 0.9839)	8611	0.9971 (0.9944, 0.9986)
19	0.1149 (-0.2077, 0.4250)	164	0.8712 (0.8330, 0.8827)	1095	0.9789 (0.9691, 0.9853)	9352	0.9973 (0.9947, 0.9987)
21	0.1731 (-0.1294, 0.4575)	178	0.8808 (0.8450, 0.8906)	1189	0.9805 (0.9712, 0.9866)	10156	0.9975 (0.9951, 0.9988)
23	0.2281 (-0.0547, 0.4884)	194	0.8898 (0.8561, 0.8995)	1291	0.9820 (0.9732, 0.9878)	56.2	.6515 (.5363,.7361)
25	0.2799 (0.0164, 0.5177)	210	0.8980 (0.8665, 0.9077)	1294	0.9821 (0.9732, 0.9878)	210	.8980 (.8665,.9077)
27	0.3287 (0.0838, 0.5454)	227	0.9052 (0.8755, 0.9148)	1402	0.9834 (0.9750, 0.9889)	442	.9497 (.9321,.9593)
29	0.3746 (0.1477, 0.5717)	228	0.9057 (0.8761, 0.9153)	1523	0.9847 (0.9768, 0.9898)		

Table 4.6: Controlled VE with sensitivity analysis as functions of Day 29 Anti Spike IgG (BAU/ml) (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence intervals (10 replicates).

s	Estimate	s	Estimate	s	Estimate	s	Estimate
2.9	-0.6890 (-1.1114,-0.0150)	32	0.5362 (0.3688, 0.6786)	248	0.9139 (0.8865, 0.9236)	1654	0.9846 (0.9765, 0.9900)
3	-0.6429 (-1.0575, 0.0147)	34	0.5632 (0.4066, 0.6937)	269	0.9201 (0.8943, 0.9300)	1779	0.9856 (0.9778, 0.9907)
3	-0.5962 (-1.0024, 0.0443)	37	0.5889 (0.4429, 0.7082)	292	0.9259 (0.9017, 0.9360)	1796	0.9857 (0.9780, 0.9908)
4	-0.5489 (-0.9462, 0.0739)	40	0.6134 (0.4775, 0.7221)	318	0.9313 (0.9086, 0.9415)	1950	0.9866 (0.9793, 0.9915)
4	-0.5012 (-0.8890, 0.1032)	44	0.6367 (0.5105, 0.7355)	329	0.9336 (0.9116, 0.9437)	2118	0.9876 (0.9806, 0.9922)
4	-0.4532 (-0.8313, 0.1323)	48	0.6588 (0.5420, 0.7484)	345	0.9364 (0.9151, 0.9465)	2238	0.9881 (0.9814, 0.9926)
5	-0.4049 (-0.7740, 0.1612)	52	0.6798 (0.5719, 0.7607)	375	0.9412 (0.9212, 0.9511)	2300	0.9884 (0.9817, 0.9928)
5	-0.3565 (-0.7214, 0.1897)	56	0.6996 (0.6003, 0.7725)	407	0.9456 (0.9269, 0.9554)	2498	0.9892 (0.9828, 0.9934)
6	-0.3080 (-0.6691, 0.2179)	61	0.7184 (0.6270, 0.7838)	442	0.9497 (0.9321, 0.9593)	2713	0.9899 (0.9839, 0.9939)
6	-0.2597 (-0.6170, 0.2456)	64	0.7285 (0.6408, 0.7899)	474	0.9529 (0.9360, 0.9623)	2946	0.9906 (0.9848, 0.9944)
7	-0.2116 (-0.5646, 0.2729)	66	0.7362 (0.6515, 0.7947)	480	0.9535 (0.9367, 0.9629)	3200	0.9912 (0.9857, 0.9948)
7	-0.1638 (-0.5119, 0.2997)	72	0.7530 (0.6747, 0.8050)	500	0.9552 (0.9389, 0.9645)	3475	0.9918 (0.9865, 0.9952)
8	-0.1164 (-0.4589, 0.3260)	78	0.7689 (0.6966, 0.8150)	521	0.9569 (0.9410, 0.9661)	3774	0.9923 (0.9872, 0.9956)
8	-0.0697 (-0.4057, 0.3518)	85	0.7838 (0.7173, 0.8245)	566	0.9601 (0.9449, 0.9690)	4098	0.9928 (0.9879, 0.9960)
9	-0.0236 (-0.3525, 0.3769)	92	0.7979 (0.7367, 0.8335)	614	0.9630 (0.9485, 0.9716)	4451	0.9933 (0.9885, 0.9963)
10	0.0217 (-0.2994, 0.4015)	93	0.7989 (0.7380, 0.8342)	667	0.9657 (0.9519, 0.9741)	4833	0.9937 (0.9891, 0.9966)
11	0.0662 (-0.2465, 0.4255)	100	0.8112 (0.7550, 0.8422)	708	0.9675 (0.9542, 0.9756)	5249	0.9941 (0.9897, 0.9968)
12	0.1097 (-0.1939, 0.4488)	109	0.8237 (0.7722, 0.8505)	725	0.9682 (0.9550, 0.9762)	5700	0.9945 (0.9902, 0.9971)
13	0.1521 (-0.1418, 0.4715)	118	0.8355 (0.7884, 0.8584)	787	0.9705 (0.9579, 0.9782)	6191	0.9949 (0.9907, 0.9973)
14	0.1934 (-0.0902, 0.4936)	128	0.8466 (0.8032, 0.8660)	855	0.9726 (0.9606, 0.9801)	6723	0.9952 (0.9911, 0.9975)
15	0.2335 (-0.0393, 0.5150)	130	0.8486 (0.8056, 0.8674)	928	0.9745 (0.9632, 0.9817)	7301	0.9955 (0.9916, 0.9977)
16	0.2724 (0.0108, 0.5357)	139	0.8570 (0.8159, 0.8732)	1000	0.9762 (0.9653, 0.9831)	7929	0.9958 (0.9920, 0.9979)
18	0.3100 (0.0599, 0.5559)	151	0.8667 (0.8278, 0.8801)	1008	0.9763 (0.9655, 0.9832)	8611	0.9961 (0.9924, 0.9980)
19	0.3463 (0.1080, 0.5753)	164	0.8759 (0.8391, 0.8870)	1095	0.9780 (0.9677, 0.9846)	9352	0.9963 (0.9928, 0.9982)
21	0.3813 (0.1550, 0.5941)	178	0.8845 (0.8498, 0.8940)	1189	0.9795 (0.9697, 0.9859)	10156	0.9966 (0.9931, 0.9983)
23	0.4150 (0.2007, 0.6123)	194	0.8926 (0.8598, 0.9021)	1291	0.9809 (0.9716, 0.9870)	56.2	.6515 (.5363,.7361)
25	0.4473 (0.2450, 0.6298)	210	0.9001 (0.8692, 0.9096)	1294	0.9810 (0.9716, 0.9871)	210	.8980 (.8665,.9077)
27	0.4782 (0.2879, 0.6467)	227	0.9067 (0.8775, 0.9161)	1402	0.9823 (0.9734, 0.9881)	442	.9497 (.9321,.9593)
29	0.5079 (0.3294, 0.6630)	228	0.9072 (0.8781, 0.9167)	1523	0.9835 (0.9750, 0.9891)		



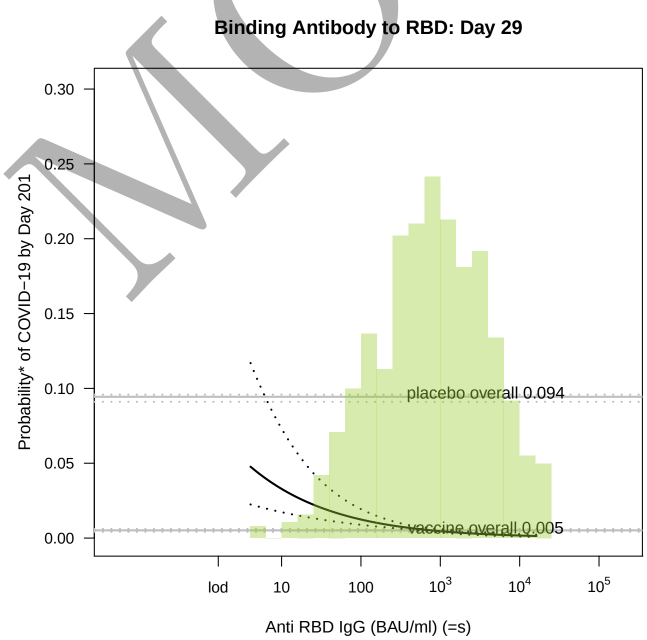
No. at risk

Low:	3745	3743	3730	3711	3625	3620	3550	2785
Med:	3747	3745	3691	3602	3596	3517	3449	2846
High:	3712	3710	3641	3631	3619	3591	3550	2788
Plac:	11505	11381	11061	10703	10350	10021	9639	7830

Cumulative No. of COVID−19 Endpoints

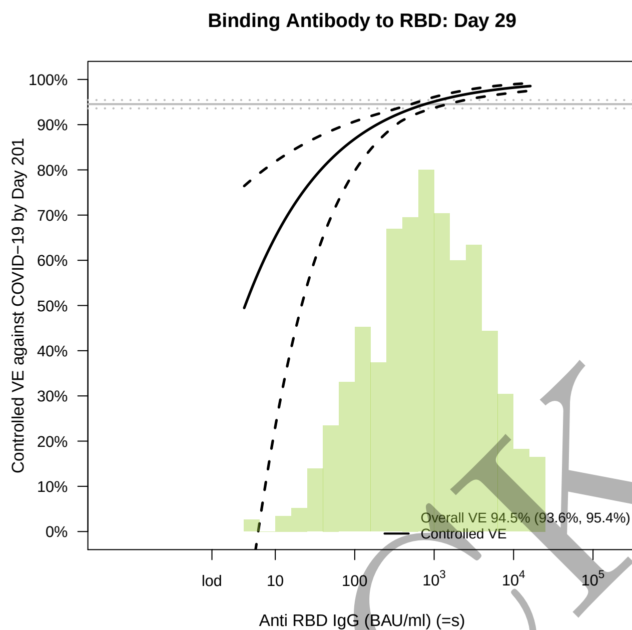
Low:	0	2	3	3	13	18	24	27
Med:	0	2	4	7	8	9	11	13
High:	0	2	3	5	5	14	16	18
Plac:	0	129	296	473	658	835	1039	1166

(a) Marginalized cumulative incidence rate curves for trichotomized Day 29 markers among vaccine recipients. The gray line is the overall cumulative incidence rate curve in the placebo arm.

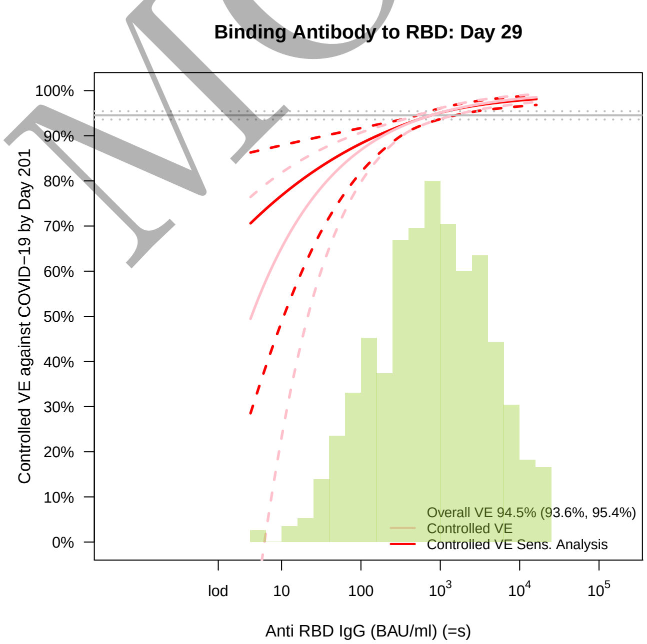


(b) Marginalized cumulative risk by Day 201 as functions of Day 29 markers (=s) among vaccine recipients with 95% bootstrap point-wise confidence bands (10 replicates). The horizontal lines indicate the overall cumulative risk of the placebo and vaccine arms by Day 201 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod =1.6.

Figure 4.9: Marginalized cumulative risk curves (=s).

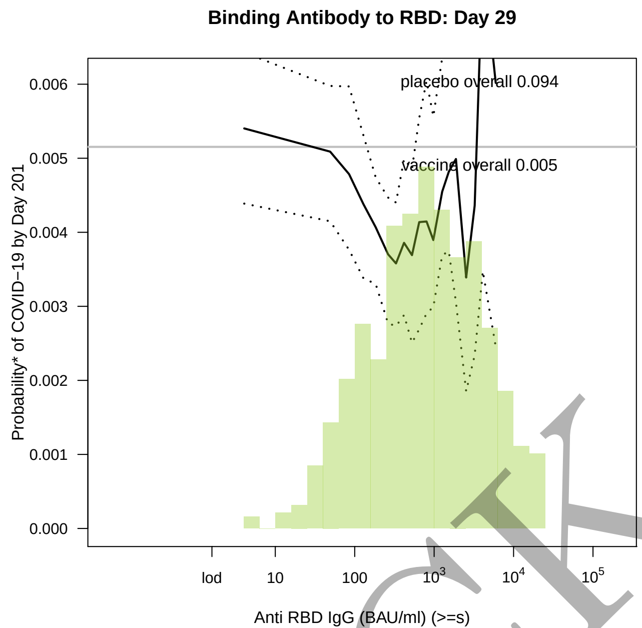


(a) Controlled VE with sensitivity analysis as functions of Day 29 markers (=s) among vaccine recipients with 95% bootstrap pointwise confidence bands (10 replicates). Histograms of the immunological markers in the vaccine arm are overlaid. lod =1.6.

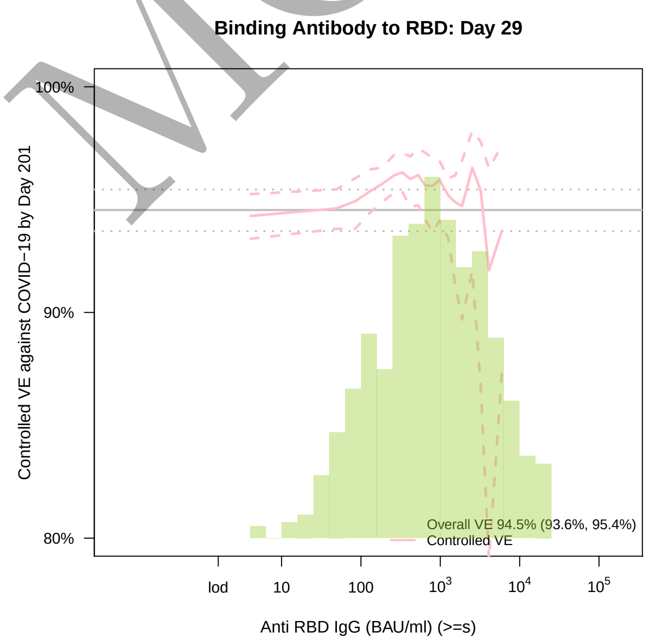


(b) Controlled VE with sensitivity analysis as functions of Day 29 markers (=s) among vaccine recipients with 95% bootstrap pointwise confidence bands (10 replicates). Histograms of the immunological markers in the vaccine arm are overlaid. lod =1.6.

Figure 4.10: Controlled VE curves (=s).



(a) Marginalized cumulative risk by Day 201 post Day 29 visit as functions of Day 29 markers above a threshold ($\geq s$) among vaccine recipients with 95% bootstrap point-wise confidence bands (at least 5 cases are required, 10 replicates). The horizontal lines indicate the overall cumulative risk of the vaccine arm by Day 201 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod =1.6.



(b) Controlled VE as functions of Day 29 markers (>=s) among vaccine recipients with 95% bootstrap point-wise confidence bands (10 replicates). Histograms of the immunological markers in the vaccine arm are overlaid. lod =1.6.

Figure 4.11: Marginalized cumulative risk curves and controlled VE curves (>=s).

Table 4.7: Marginalized cumulative risk by Day 201 as functions of Day 29 Anti RBD IgG (BAU/ml) (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence intervals (10 replicates).

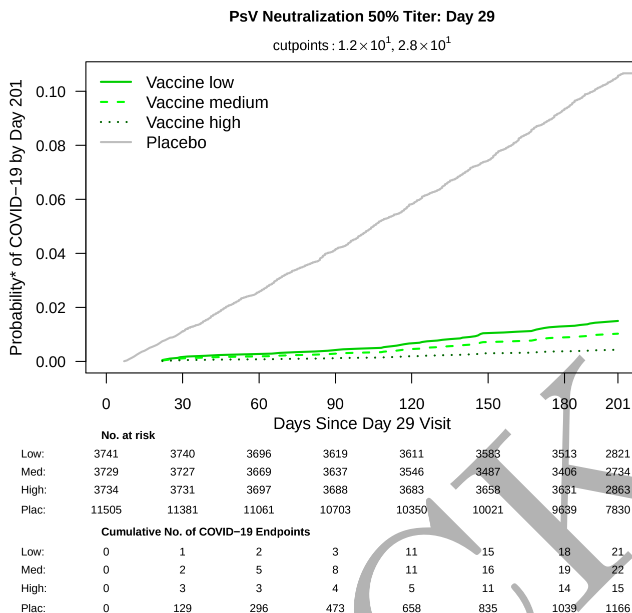
s	Estimate	s	Estimate	s	Estimate	s	Estimate
4.1	.0477 (.0225,.1169)	42	.0179 (.0114,.0320)	345	.0073 (.0060,.0094)	2178	.0033 (.0024,.0045)
4	.0461 (.0219,.1122)	46	.0173 (.0111,.0305)	375	.0070 (.0059,.0089)	2368	.0032 (.0023,.0044)
5	.0445 (.0214,.1076)	50	.0166 (.0108,.0291)	407	.0068 (.0057,.0086)	2575	.0031 (.0022,.0042)
5	.0430 (.0209,.1031)	55	.0161 (.0106,.0277)	408	.0068 (.0057,.0086)	2800	.0030 (.0021,.0041)
6	.0416 (.0204,.0987)	59	.0155 (.0103,.0263)	443	.0065 (.0055,.0083)	3045	.0028 (.0020,.0040)
6	.0401 (.0199,.0945)	65	.0150 (.0101,.0251)	482	.0063 (.0053,.0080)	3085	.0028 (.0020,.0040)
7	.0388 (.0194,.0905)	70	.0144 (.0098,.0238)	500	.0062 (.0052,.0079)	3311	.0027 (.0019,.0039)
7	.0375 (.0190,.0866)	76	.0139 (.0096,.0227)	524	.0061 (.0051,.0077)	3601	.0026 (.0018,.0038)
8	.0362 (.0185,.0828)	83	.0134 (.0094,.0216)	570	.0059 (.0048,.0074)	3915	.0026 (.0017,.0036)
9	.0349 (.0181,.0792)	87	.0132 (.0092,.0210)	620	.0057 (.0046,.0072)	4099	.0025 (.0017,.0036)
9	.0337 (.0176,.0757)	90	.0130 (.0091,.0206)	648	.0056 (.0045,.0070)	4258	.0025 (.0016,.0035)
10	.0326 (.0172,.0723)	98	.0125 (.0089,.0196)	674	.0055 (.0044,.0069)	4630	.0024 (.0015,.0034)
11	.0315 (.0168,.0690)	107	.0121 (.0087,.0186)	733	.0053 (.0042,.0067)	5034	.0023 (.0015,.0033)
12	.0304 (.0164,.0659)	116	.0116 (.0085,.0177)	797	.0051 (.0040,.0065)	5474	.0022 (.0014,.0033)
13	.0293 (.0160,.0629)	126	.0112 (.0083,.0169)	867	.0049 (.0039,.0063)	5736	.0022 (.0014,.0032)
14	.0283 (.0156,.0600)	129	.0111 (.0082,.0167)	942	.0047 (.0037,.0061)	5953	.0021 (.0013,.0032)
16	.0273 (.0152,.0572)	137	.0108 (.0081,.0161)	980	.0046 (.0036,.0060)	6473	.0021 (.0013,.0031)
17	.0264 (.0149,.0546)	149	.0105 (.0079,.0153)	1000	.0046 (.0036,.0060)	7039	.0020 (.0012,.0030)
18	.0255 (.0145,.0520)	162	.0101 (.0077,.0146)	1025	.0046 (.0035,.0059)	7654	.0019 (.0012,.0029)
20	.0246 (.0142,.0496)	176	.0097 (.0075,.0139)	1114	.0044 (.0034,.0057)	8323	.0018 (.0011,.0029)
22	.0237 (.0138,.0472)	191	.0094 (.0073,.0133)	1212	.0042 (.0032,.0056)	9050	.0018 (.0010,.0028)
24	.0229 (.0135,.0450)	192	.0094 (.0073,.0132)	1317	.0041 (.0031,.0054)	9841	.0017 (.0010,.0027)
26	.0221 (.0132,.0428)	209	.0091 (.0071,.0126)	1433	.0039 (.0030,.0052)	10701	.0017 (.0009,.0026)
28	.0214 (.0129,.0408)	227	.0087 (.0070,.0120)	1557	.0038 (.0028,.0051)	11636	.0016 (.0009,.0026)
30	.0206 (.0125,.0389)	247	.0084 (.0068,.0114)	1558	.0038 (.0028,.0051)	12653	.0015 (.0009,.0025)
33	.0199 (.0122,.0371)	268	.0081 (.0066,.0109)	1694	.0037 (.0027,.0049)	13759	.0015 (.0008,.0024)
36	.0192 (.0119,.0353)	292	.0078 (.0064,.0103)	1842	.0035 (.0026,.0048)	14962	.0014 (.0008,.0024)
39	.0185 (.0117,.0336)	317	.0076 (.0062,.0098)	2003	.0034 (.0025,.0046)	16269	.0014 (.0007,.0023)

Table 4.8: Controlled VE as functions of Day 29 Anti RBD IgG (BAU/ml) (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence intervals (10 replicates).Overall cumulative incidence from 7 to 201 days post Day 29 was 0.005 in vaccine recipients compared to 0.094 in placebo recipients, with cumulative vaccine efficacy 94.5% (95% CI 93.6 to 95.4%).

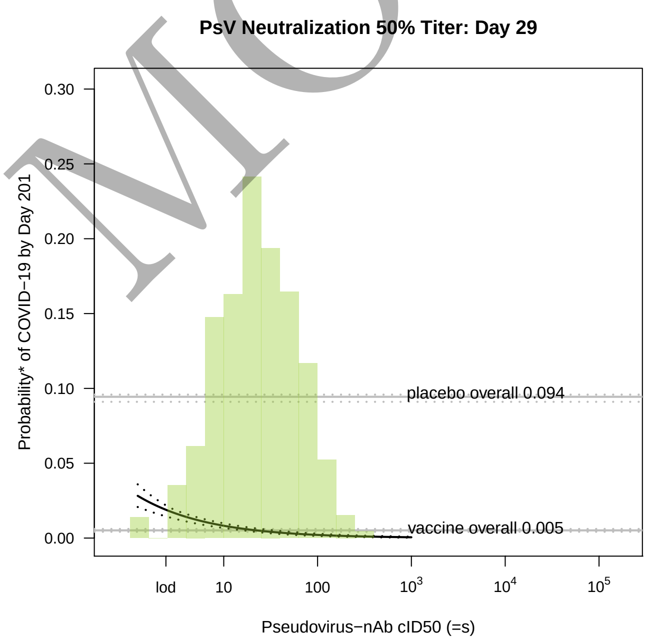
s	Estimate	s	Estimate	s	Estimate	s	Estimate
4.1	.4947 (-0.2286,.7644)	46	.8172 (0.6801,.8835)	407	.9281 (0.9102,.9398)	2800	.9687 (0.9567,.9778)
4	.5117 (-0.1785,.7700)	50	.8236 (0.6954,.8864)	408	.9281 (0.9103,.9399)	3045	.9698 (0.9579,.9789)
5	.5282 (-0.1300,.7755)	55	.8298 (0.7100,.8891)	443	.9307 (0.9135,.9416)	3085	.9700 (0.9581,.9790)
5	.5442 (-0.0829,.7808)	59	.8358 (0.7240,.8918)	482	.9331 (0.9166,.9434)	3311	.9709 (0.9590,.9799)
6	.5597 (-0.0374,.7860)	65	.8415 (0.7373,.8944)	500	.9342 (0.9179,.9444)	3601	.9720 (0.9601,.9808)
6	.5746 (0.0066,.7911)	70	.8471 (0.7500,.8970)	524	.9355 (0.9196,.9457)	3915	.9730 (0.9611,.9818)
7	.5891 (0.0492,.7961)	76	.8525 (0.7621,.8995)	570	.9378 (0.9224,.9479)	4099	.9735 (0.9616,.9822)
7	.6031 (0.0903,.8010)	83	.8577 (0.7736,.9019)	620	.9400 (0.9250,.9500)	4258	.9739 (0.9621,.9826)
8	.6167 (0.1300,.8058)	87	.8606 (0.7800,.9033)	648	.9411 (0.9263,.9511)	4630	.9749 (0.9631,.9834)
9	.6298 (0.1682,.8104)	90	.8627 (0.7846,.9043)	674	.9421 (0.9274,.9520)	5034	.9757 (0.9640,.9842)
9	.6425 (0.2051,.8150)	98	.8675 (0.7951,.9066)	733	.9442 (0.9297,.9541)	5474	.9766 (0.9650,.9850)
10	.6548 (0.2406,.8194)	107	.8722 (0.8051,.9089)	797	.9462 (0.9318,.9561)	5736	.9771 (0.9655,.9854)
11	.6666 (0.2747,.8237)	116	.8767 (0.8144,.9111)	867	.9481 (0.9338,.9580)	5953	.9774 (0.9659,.9857)
12	.6781 (0.3076,.8280)	126	.8810 (0.8233,.9132)	942	.9499 (0.9358,.9599)	6473	.9782 (0.9668,.9864)
13	.6892 (0.3392,.8321)	129	.8821 (0.8255,.9137)	980	.9508 (0.9367,.9607)	7039	.9790 (0.9676,.9870)
14	.6999 (0.3696,.8361)	137	.8852 (0.8318,.9153)	1000	.9512 (0.9372,.9611)	7654	.9798 (0.9684,.9876)
16	.7103 (0.3987,.8401)	149	.8893 (0.8398,.9174)	1025	.9517 (0.9377,.9616)	8323	.9805 (0.9693,.9882)
17	.7203 (0.4267,.8439)	162	.8932 (0.8475,.9194)	1114	.9534 (0.9396,.9633)	9050	.9812 (0.9701,.9888)
18	.7300 (0.4535,.8477)	176	.8969 (0.8548,.9213)	1212	.9551 (0.9414,.9649)	9841	.9819 (0.9708,.9893)
20	.7394 (0.4792,.8513)	191	.9004 (0.8614,.9232)	1317	.9567 (0.9431,.9665)	10701	.9825 (0.9716,.9898)
22	.7484 (0.5038,.8549)	192	.9006 (0.8618,.9233)	1433	.9582 (0.9448,.9679)	11636	.9831 (0.9723,.9903)
24	.7572 (0.5273,.8584)	209	.9041 (0.8684,.9251)	1557	.9597 (0.9464,.9693)	12653	.9837 (0.9730,.9908)
26	.7656 (0.5499,.8618)	227	.9075 (0.8747,.9269)	1558	.9597 (0.9465,.9693)	13759	.9843 (0.9737,.9912)
28	.7738 (0.5715,.8652)	247	.9108 (0.8807,.9287)	1694	.9611 (0.9481,.9707)	14962	.9849 (0.9744,.9916)
30	.7817 (0.5921,.8684)	268	.9139 (0.8864,.9304)	1842	.9625 (0.9496,.9720)	16269	.9854 (0.9751,.9920)
33	.7893 (0.6113,.8716)	292	.9170 (0.8919,.9323)	2003	.9639 (0.9511,.9732)	10.2	.6548 (.2406,.8194)
36	.7966 (0.6297,.8747)	317	.9199 (0.8970,.9343)	2178	.9651 (0.9526,.9744)	191	.9004 (.8614,.9232)
39	.8037 (0.6473,.8777)	345	.9227 (0.9019,.9362)	2368	.9664 (0.9540,.9756)	942	.9499 (.9358,.9599)
42	.8106 (0.6641,.8807)	375	.9255 (0.9066,.9381)	2575	.9676 (0.9553,.9767)		

Table 4.9: Controlled VE with sensitivity analysis as functions of Day 29 Anti RBD IgG (BAU/ml) (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence intervals (10 replicates).

s	Estimate	s	Estimate	s	Estimate	s	Estimate
4.1	.7060 (.2853,.8629)	46	.8503 (.7380,.9046)	407	.9290 (.9113,.9406)	2800	.9669 (.9541,.9765)
4	.7122 (.3054,.8644)	50	.8541 (.7480,.9060)	408	.9290 (.9114,.9406)	3045	.9679 (.9551,.9775)
5	.7183 (.3252,.8659)	55	.8578 (.7577,.9074)	443	.9313 (.9143,.9421)	3085	.9680 (.9553,.9776)
5	.7243 (.3449,.8674)	59	.8615 (.7672,.9087)	482	.9336 (.9171,.9437)	3311	.9688 (.9560,.9784)
6	.7302 (.3643,.8689)	65	.8651 (.7763,.9101)	500	.9345 (.9184,.9447)	3601	.9697 (.9568,.9793)
6	.7360 (.3834,.8704)	70	.8686 (.7851,.9115)	524	.9358 (.9199,.9459)	3915	.9706 (.9576,.9801)
7	.7417 (.4022,.8718)	76	.8721 (.7937,.9128)	570	.9379 (.9226,.9480)	4099	.9710 (.9581,.9806)
7	.7473 (.4208,.8733)	83	.8755 (.8019,.9142)	620	.9401 (.9251,.9500)	4258	.9714 (.9584,.9809)
8	.7529 (.4390,.8748)	87	.8774 (.8066,.9149)	648	.9412 (.9263,.9511)	4630	.9722 (.9592,.9817)
9	.7583 (.4569,.8762)	90	.8788 (.8099,.9155)	674	.9421 (.9275,.9520)	5034	.9730 (.9599,.9824)
9	.7637 (.4745,.8777)	98	.8821 (.8176,.9169)	733	.9442 (.9297,.9541)	5474	.9737 (.9606,.9831)
10	.7690 (.4918,.8791)	107	.8853 (.8251,.9182)	797	.9462 (.9318,.9561)	5736	.9741 (.9610,.9835)
11	.7742 (.5087,.8806)	116	.8884 (.8321,.9195)	867	.9480 (.9337,.9580)	5953	.9744 (.9613,.9838)
12	.7793 (.5252,.8820)	126	.8915 (.8389,.9209)	942	.9498 (.9356,.9598)	6473	.9751 (.9620,.9844)
13	.7843 (.5414,.8835)	129	.8923 (.8406,.9212)	980	.9506 (.9365,.9606)	7039	.9758 (.9627,.9850)
14	.7893 (.5573,.8849)	137	.8945 (.8455,.9222)	1000	.9510 (.9369,.9610)	7654	.9765 (.9633,.9856)
16	.7941 (.5727,.8863)	149	.8975 (.8518,.9235)	1025	.9515 (.9374,.9615)	8323	.9771 (.9639,.9862)
17	.7989 (.5878,.8878)	162	.9004 (.8579,.9249)	1114	.9531 (.9392,.9631)	9050	.9777 (.9645,.9867)
18	.8036 (.6025,.8892)	176	.9033 (.8638,.9262)	1212	.9547 (.9408,.9646)	9841	.9783 (.9651,.9872)
20	.8083 (.6168,.8906)	191	.9060 (.8691,.9274)	1317	.9561 (.9424,.9660)	10701	.9789 (.9657,.9877)
22	.8128 (.6308,.8920)	192	.9061 (.8694,.9275)	1433	.9575 (.9439,.9674)	11636	.9794 (.9662,.9882)
24	.8173 (.6443,.8935)	209	.9089 (.8749,.9288)	1557	.9589 (.9454,.9687)	12653	.9799 (.9667,.9886)
26	.8217 (.6575,.8949)	227	.9116 (.8802,.9301)	1558	.9589 (.9454,.9687)	13759	.9805 (.9673,.9891)
28	.8260 (.6704,.8963)	247	.9142 (.8853,.9315)	1694	.9602 (.9468,.9700)	14962	.9810 (.9678,.9895)
30	.8302 (.6828,.8977)	268	.9168 (.8902,.9328)	1842	.9614 (.9481,.9711)	16269	.9814 (.9683,.9899)
33	.8344 (.6945,.8991)	292	.9193 (.8949,.9342)	2003	.9626 (.9494,.9723)	10.2	.6548 (.2406,.8194)
36	.8385 (.7059,.9005)	317	.9218 (.8995,.9358)	2178	.9637 (.9507,.9733)	191	.9004 (.8614,.9232)
39	.8425 (.7169,.9018)	345	.9243 (.9039,.9374)	2368	.9648 (.9519,.9744)	942	.9499 (.9358,.9599)
42	.8464 (.7276,.9032)	375	.9267 (.9081,.9390)	2575	.9659 (.9530,.9755)		

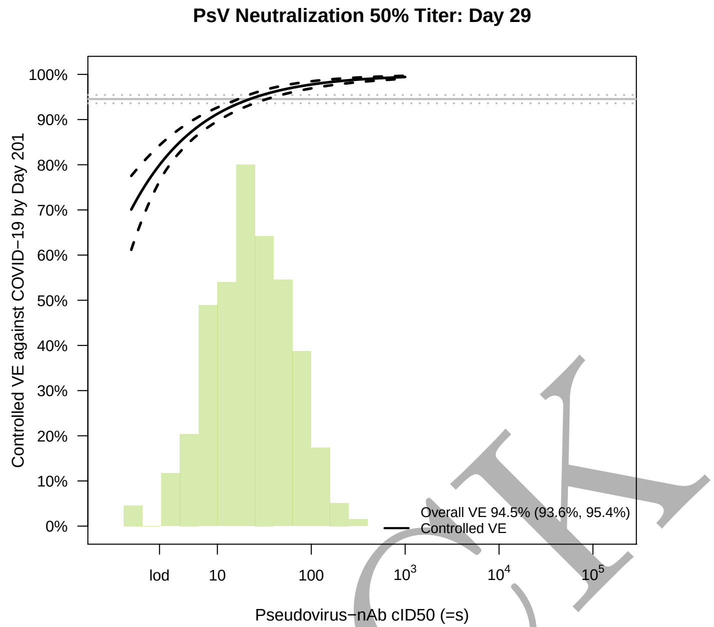


(a) Marginalized cumulative incidence rate curves for trichotomized Day 29 markers among vaccine recipients. The gray line is the overall cumulative incidence rate curve in the placebo arm.

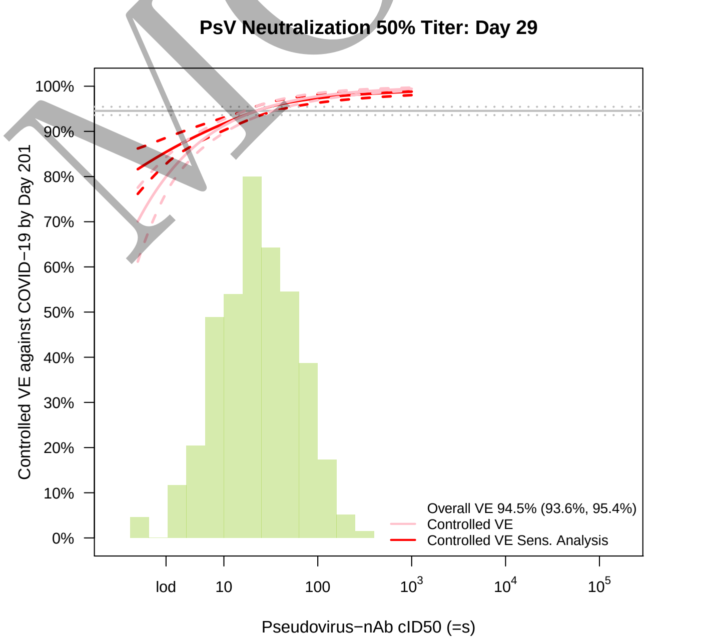


(b) Marginalized cumulative risk by Day 201 as functions of Day 29 markers (=s) among vaccine recipients with 95% bootstrap point-wise confidence bands (10 replicates). The horizontal lines indicate the overall cumulative risk of the placebo and vaccine arms by Day 201 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod =2.4.

Figure 4.12: Marginalized cumulative risk curves (=s).

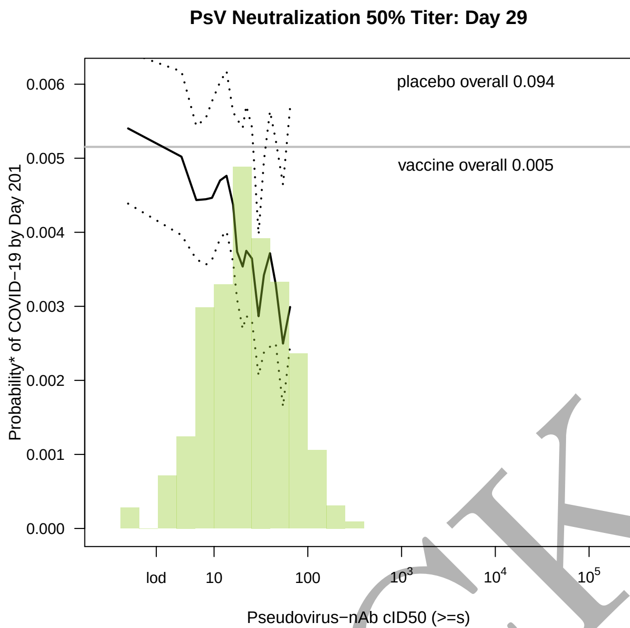


(a) Controlled VE with sensitivity analysis as functions of Day 29 markers (=s) among vaccine recipients with 95% bootstrap point-wise confidence bands (10 replicates). Histograms of the immunological markers in the vaccine arm are overlaid. lod =2.4.

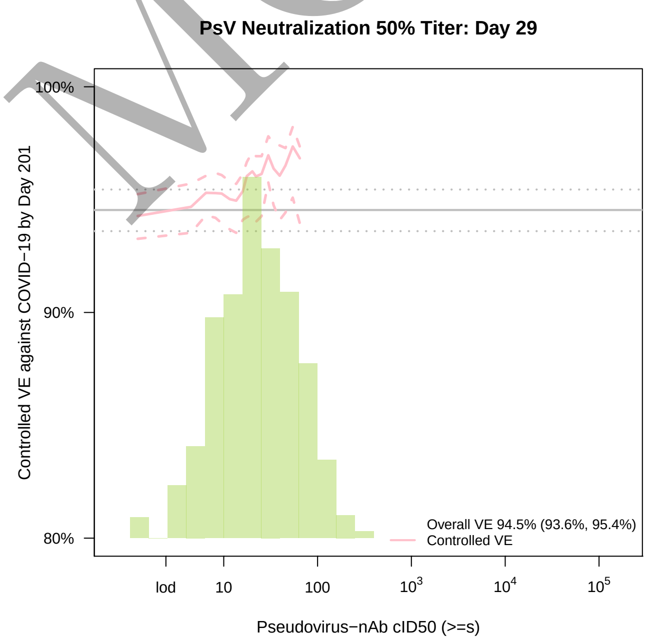


(b) Controlled VE with sensitivity analysis as functions of Day 29 markers (=s) among vaccine recipients with 95% bootstrap point-wise confidence bands (10 replicates). Histograms of the immunological markers in the vaccine arm are overlaid. lod =2.4.

Figure 4.13: Controlled VE curves (=s).



(a) Marginalized cumulative risk by Day 201 post Day 29 visit as functions of Day 29 markers above a threshold ($\geq s$) among vaccine recipients with 95% bootstrap point-wise confidence bands (at least 5 cases are required, 10 replicates). The horizontal lines indicate the overall cumulative risk of the vaccine arm by Day 201 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod =2.4.



(b) Controlled VE as functions of Day 29 markers (>=s) among vaccine recipients with 95% bootstrap point-wise confidence bands (10 replicates). Histograms of the immunological markers in the vaccine arm are overlaid. lod =2.4.

Figure 4.14: Marginalized cumulative risk curves and controlled VE curves (>=s).

Table 4.10: Marginalized cumulative risk by Day 201 as functions of Day 29 Pseudovirus-nAb cID50 (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence intervals (10 replicates).

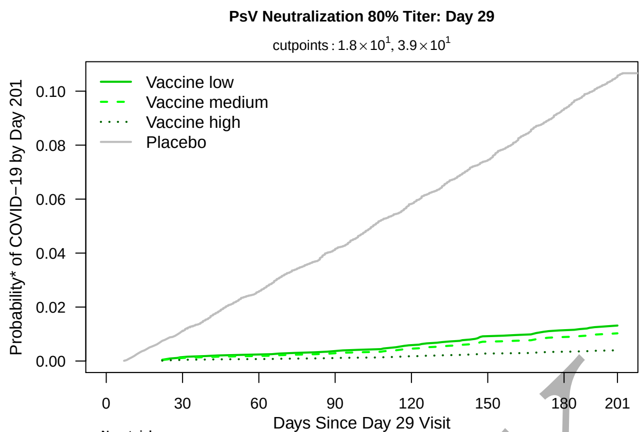
s	Estimate	s	Estimate	s	Estimate	s	Estimate
1.2	.0282 (.0208,.0359)	6	.0114 (.0091,.0132)	21	.0054 (.0043,.0067)	79	.0024 (.0017,.0033)
1	.0273 (.0202,.0345)	6	.0110 (.0088,.0128)	22	.0052 (.0041,.0065)	80	.0024 (.0016,.0033)
1	.0265 (.0197,.0332)	6	.0107 (.0085,.0124)	23	.0050 (.0040,.0063)	84	.0023 (.0016,.0032)
1	.0256 (.0191,.0319)	7	.0106 (.0085,.0124)	25	.0048 (.0038,.0061)	89	.0023 (.0015,.0031)
2	.0248 (.0186,.0306)	7	.0103 (.0083,.0121)	25	.0048 (.0037,.0060)	94	.0022 (.0015,.0031)
2	.0240 (.0180,.0295)	7	.0100 (.0080,.0117)	26	.0047 (.0037,.0060)	99	.0021 (.0014,.0030)
2	.0233 (.0175,.0283)	8	.0097 (.0078,.0114)	27	.0045 (.0035,.0058)	105	.0021 (.0014,.0029)
2	.0225 (.0170,.0272)	8	.0094 (.0076,.0110)	29	.0044 (.0034,.0056)	111	.0020 (.0013,.0028)
2	.0218 (.0165,.0261)	8	.0093 (.0075,.0109)	31	.0043 (.0032,.0055)	117	.0019 (.0013,.0027)
2	.0211 (.0160,.0251)	9	.0091 (.0073,.0107)	32	.0041 (.0031,.0053)	124	.0019 (.0012,.0026)
2	.0205 (.0156,.0241)	9	.0088 (.0071,.0104)	34	.0040 (.0030,.0052)	131	.0018 (.0012,.0026)
2	.0198 (.0151,.0232)	10	.0085 (.0069,.0101)	34	.0040 (.0030,.0051)	139	.0017 (.0011,.0025)
2	.0192 (.0147,.0223)	10	.0084 (.0069,.0100)	36	.0038 (.0029,.0050)	146	.0017 (.0011,.0024)
2	.0186 (.0143,.0214)	10	.0082 (.0067,.0098)	38	.0037 (.0028,.0049)	155	.0016 (.0010,.0024)
3	.0180 (.0138,.0205)	11	.0079 (.0065,.0095)	41	.0036 (.0027,.0047)	164	.0016 (.0010,.0023)
3	.0174 (.0134,.0197)	11	.0077 (.0063,.0092)	43	.0035 (.0026,.0046)	173	.0015 (.0010,.0022)
3	.0168 (.0130,.0190)	12	.0074 (.0061,.0089)	45	.0034 (.0025,.0045)	183	.0015 (.0009,.0022)
3	.0163 (.0126,.0184)	13	.0072 (.0059,.0087)	48	.0033 (.0024,.0043)	194	.0014 (.0009,.0021)
3	.0158 (.0123,.0178)	13	.0070 (.0058,.0084)	51	.0032 (.0023,.0042)	205	.0014 (.0008,.0020)
3	.0153 (.0119,.0172)	14	.0067 (.0056,.0082)	54	.0031 (.0022,.0041)	216	.0013 (.0008,.0020)
4	.0148 (.0116,.0167)	15	.0065 (.0054,.0080)	54	.0031 (.0022,.0041)	229	.0013 (.0008,.0019)
4	.0143 (.0112,.0162)	16	.0063 (.0052,.0077)	57	.0030 (.0021,.0040)	242	.0013 (.0008,.0019)
4	.0138 (.0109,.0157)	16	.0063 (.0052,.0077)	60	.0029 (.0020,.0039)	256	.0012 (.0007,.0018)
4	.0134 (.0106,.0153)	17	.0061 (.0050,.0075)	63	.0028 (.0019,.0037)	271	.0012 (.0007,.0018)
5	.0130 (.0102,.0148)	18	.0059 (.0048,.0073)	65	.0027 (.0019,.0037)	286	.0011 (.0007,.0017)
5	.0126 (.0099,.0144)	19	.0057 (.0047,.0071)	67	.0027 (.0019,.0036)	302	.0011 (.0006,.0017)
5	.0122 (.0096,.0140)	20	.0055 (.0045,.0069)	71	.0026 (.0018,.0035)	500	.0008 (.0005,.0013)
5	.0118 (.0093,.0136)	20	.0055 (.0044,.0068)	75	.0025 (.0017,.0034)	1000	.0005 (.0003,.0009)

Table 4.11: Controlled VE as functions of Day 29 Pseudovirus-nAb cID50 (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence intervals (10 replicates).Overall cumulative incidence from 7 to 201 days post Day 29 was 0.005 in vaccine recipients compared to 0.094 in placebo recipients, with cumulative vaccine efficacy 94.5% (95% CI 93.6 to 95.4%).

s	Estimate	s	Estimate	s	Estimate	s	Estimate
1.2	.7008 (.6117,.7754)	6	.8833 (.8652,.9043)	23	.9469 (.9339,.9570)	89	.9759 (.9671,.9834)
1	.7103 (.6268,.7815)	6	.8870 (.8692,.9071)	25	.9486 (.9357,.9587)	94	.9767 (.9680,.9841)
1	.7194 (.6413,.7873)	7	.8877 (.8699,.9076)	25	.9496 (.9368,.9596)	99	.9775 (.9689,.9847)
1	.7283 (.6553,.7931)	7	.8907 (.8730,.9099)	26	.9503 (.9376,.9603)	105	.9782 (.9698,.9853)
2	.7369 (.6687,.7990)	7	.8942 (.8768,.9125)	27	.9519 (.9394,.9619)	111	.9789 (.9707,.9858)
2	.7453 (.6816,.8047)	8	.8976 (.8804,.9151)	29	.9535 (.9411,.9633)	117	.9796 (.9715,.9864)
2	.7534 (.6941,.8103)	8	.9009 (.8839,.9176)	31	.9550 (.9428,.9648)	124	.9803 (.9723,.9869)
2	.7612 (.7060,.8157)	8	.9016 (.8847,.9182)	32	.9564 (.9444,.9662)	131	.9809 (.9731,.9874)
2	.7688 (.7175,.8209)	9	.9041 (.8873,.9201)	34	.9578 (.9460,.9675)	139	.9815 (.9739,.9879)
2	.7761 (.7286,.8261)	9	.9072 (.8906,.9224)	34	.9579 (.9461,.9675)	146	.9821 (.9746,.9884)
2	.7833 (.7393,.8312)	10	.9102 (.8938,.9248)	36	.9592 (.9476,.9687)	155	.9827 (.9753,.9888)
2	.7902 (.7495,.8362)	10	.9109 (.8946,.9253)	38	.9605 (.9491,.9700)	164	.9833 (.9760,.9892)
2	.7969 (.7593,.8410)	10	.9131 (.8970,.9270)	41	.9618 (.9505,.9711)	173	.9838 (.9767,.9896)
2	.8034 (.7688,.8456)	11	.9159 (.9000,.9292)	43	.9631 (.9519,.9723)	183	.9843 (.9774,.9900)
3	.8096 (.7779,.8502)	11	.9186 (.9029,.9313)	45	.9643 (.9533,.9733)	194	.9849 (.9780,.9904)
3	.8157 (.7860,.8546)	12	.9212 (.9058,.9334)	48	.9654 (.9546,.9744)	205	.9853 (.9786,.9908)
3	.8216 (.7934,.8588)	13	.9238 (.9086,.9354)	51	.9665 (.9559,.9754)	216	.9858 (.9792,.9911)
3	.8273 (.8006,.8630)	13	.9262 (.9113,.9373)	54	.9676 (.9572,.9763)	229	.9863 (.9798,.9915)
3	.8328 (.8075,.8670)	14	.9286 (.9139,.9392)	54	.9676 (.9572,.9763)	242	.9867 (.9804,.9918)
3	.8382 (.8142,.8709)	15	.9309 (.9164,.9410)	57	.9687 (.9584,.9773)	256	.9872 (.9809,.9921)
4	.8434 (.8202,.8747)	16	.9332 (.9189,.9431)	60	.9697 (.9596,.9781)	271	.9876 (.9815,.9924)
4	.8484 (.8260,.8784)	16	.9334 (.9191,.9433)	63	.9707 (.9608,.9790)	286	.9880 (.9820,.9927)
4	.8533 (.8315,.8820)	17	.9353 (.9213,.9453)	65	.9710 (.9612,.9793)	302	.9884 (.9825,.9930)
4	.8580 (.8369,.8855)	18	.9374 (.9236,.9475)	67	.9716 (.9619,.9798)	500	.9914 (.9865,.9950)
5	.8625 (.8421,.8888)	19	.9394 (.9257,.9495)	71	.9725 (.9630,.9806)	1000	.9943 (.9905,.9969)
5	.8669 (.8471,.8921)	20	.9414 (.9279,.9515)	75	.9734 (.9641,.9813)		(,)
5	.8712 (.8520,.8953)	20	.9422 (.9287,.9523)	79	.9743 (.9651,.9821)	8	.9009 (.8839,.9176)
5	.8754 (.8568,.8984)	21	.9433 (.9299,.9534)	80	.9745 (.9653,.9822)	26	.9503 (.9376,.9603)
6	.8794 (.8612,.9014)	22	.9451 (.9319,.9552)	84	.9751 (.9661,.9828)		

Table 4.12: Controlled VE with sensitivity analysis as functions of Day 29 Pseudovirus-nAb cID50 (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence intervals (10 replicates).

s	Estimate	s	Estimate	s	Estimate	s	Estimate
1.2	.8163 (.7616,.8621)	6	.8975 (.8817,.9160)	23	.9469 (.9338,.9570)	89	.9721 (.9617,.9807)
1	.8196 (.7676,.8639)	6	.8998 (.8840,.9177)	25	.9486 (.9357,.9586)	94	.9727 (.9625,.9813)
1	.8228 (.7734,.8657)	7	.9002 (.8844,.9180)	25	.9495 (.9366,.9595)	99	.9733 (.9632,.9818)
1	.8260 (.7792,.8675)	7	.9022 (.8864,.9194)	26	.9501 (.9374,.9602)	105	.9739 (.9638,.9823)
2	.8291 (.7848,.8694)	7	.9045 (.8887,.9210)	27	.9517 (.9391,.9617)	111	.9745 (.9645,.9828)
2	.8322 (.7903,.8714)	8	.9067 (.8910,.9227)	29	.9531 (.9406,.9631)	117	.9750 (.9651,.9833)
2	.8353 (.7957,.8733)	8	.9090 (.8934,.9243)	31	.9545 (.9421,.9644)	124	.9755 (.9657,.9838)
2	.8384 (.8010,.8753)	8	.9095 (.8939,.9247)	32	.9558 (.9436,.9656)	131	.9761 (.9663,.9842)
2	.8414 (.8062,.8772)	9	.9112 (.8956,.9260)	34	.9570 (.9450,.9668)	139	.9766 (.9669,.9846)
2	.8444 (.8113,.8791)	9	.9134 (.8979,.9276)	34	.9571 (.9450,.9669)	146	.9771 (.9674,.9850)
2	.8473 (.8163,.8811)	10	.9155 (.9002,.9292)	36	.9582 (.9463,.9680)	155	.9775 (.9680,.9854)
2	.8502 (.8212,.8831)	10	.9161 (.9007,.9296)	38	.9594 (.9475,.9691)	164	.9780 (.9685,.9858)
2	.8531 (.8260,.8850)	10	.9177 (.9024,.9309)	41	.9604 (.9488,.9701)	173	.9785 (.9690,.9862)
2	.8560 (.8307,.8869)	11	.9198 (.9046,.9325)	43	.9615 (.9499,.9711)	183	.9789 (.9695,.9866)
3	.8588 (.8352,.8889)	11	.9219 (.9068,.9341)	45	.9625 (.9510,.9720)	194	.9793 (.9700,.9869)
3	.8616 (.8393,.8908)	12	.9239 (.9090,.9357)	48	.9635 (.9521,.9729)	205	.9797 (.9704,.9873)
3	.8643 (.8429,.8926)	13	.9260 (.9112,.9372)	51	.9644 (.9532,.9738)	216	.9801 (.9709,.9876)
3	.8671 (.8465,.8945)	13	.9280 (.9134,.9388)	54	.9653 (.9541,.9746)	229	.9805 (.9714,.9879)
3	.8698 (.8501,.8964)	14	.9300 (.9155,.9403)	54	.9653 (.9542,.9746)	242	.9809 (.9718,.9882)
3	.8724 (.8535,.8982)	15	.9320 (.9177,.9419)	57	.9662 (.9551,.9754)	256	.9813 (.9722,.9885)
4	.8751 (.8566,.9001)	16	.9339 (.9198,.9437)	60	.9670 (.9560,.9762)	271	.9816 (.9726,.9888)
4	.8777 (.8596,.9019)	16	.9341 (.9200,.9439)	63	.9678 (.9569,.9769)	286	.9820 (.9731,.9891)
4	.8803 (.8625,.9037)	17	.9358 (.9219,.9457)	65	.9681 (.9573,.9772)	302	.9823 (.9735,.9893)
4	.8828 (.8654,.9055)	18	.9377 (.9239,.9477)	67	.9686 (.9578,.9776)	500	.9851 (.9767,.9914)
5	.8853 (.8683,.9073)	19	.9396 (.9260,.9497)	71	.9693 (.9587,.9783)	1000	.9881 (.9803,.9936)
5	.8878 (.8711,.9090)	20	.9415 (.9279,.9516)	75	.9700 (.9595,.9789)		(,)
5	.8903 (.8739,.9108)	20	.9422 (.9287,.9523)	79	.9707 (.9603,.9796)	8	.9009 (.8839,.9176)
5	.8927 (.8767,.9125)	21	.9433 (.9299,.9534)	80	.9709 (.9604,.9797)	26	.9503 (.9376,.9603)
6	.8951 (.8793,.9143)	22	.9451 (.9319,.9552)	84	.9714 (.9610,.9802)		



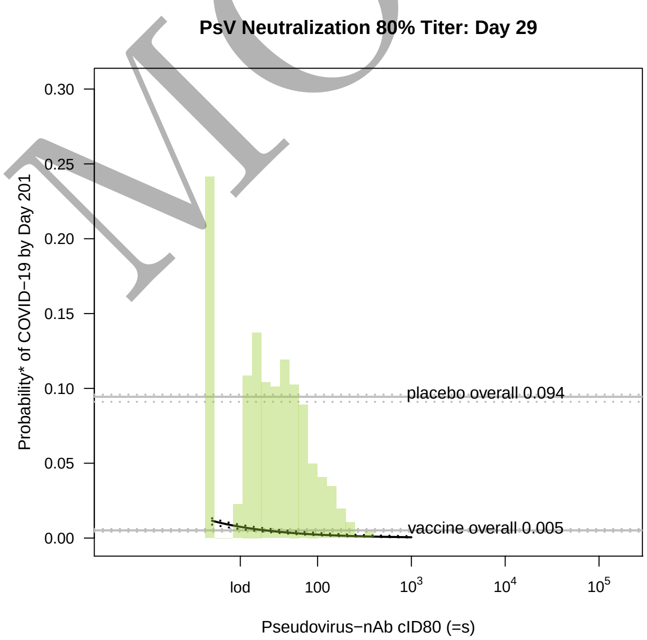
No. at risk

	0	30	60	90	120	150	180	201
Low:	3739	3737	3652	3570	3523	3494	3435	2845
Med:	3736	3735	3708	3704	3680	3660	3572	2565
High:	3729	3726	3701	3670	3637	3574	3543	3008
Plac:	11505	11381	11061	10703	10350	10021	9639	7830

Cumulative No. of COVID−19 Endpoints

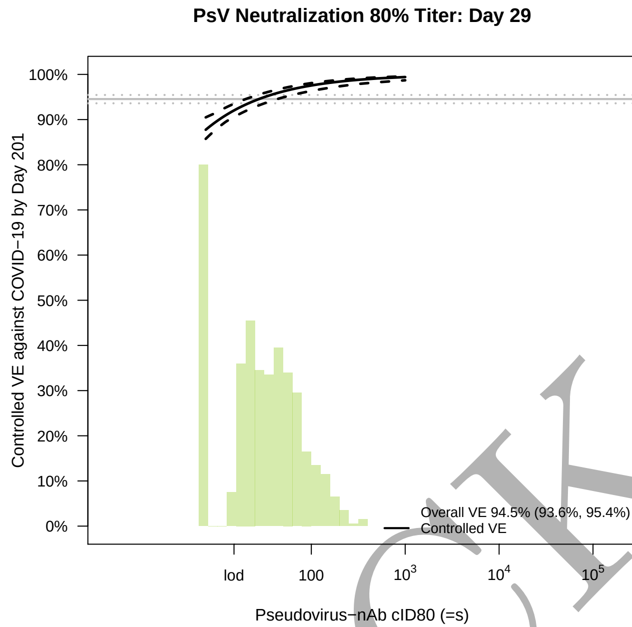
	0	30	60	90	120	150	180	201
Low:	0	2	5	6	11	16	19	22
Med:	0	1	2	6	12	16	20	23
High:	0	3	3	3	4	9	12	13
Plac:	0	129	296	473	658	835	1039	1166

(a) Marginalized cumulative incidence rate curves for trichotomized Day 29 markers among vaccine recipients. The gray line is the overall cumulative incidence rate curve in the placebo arm.

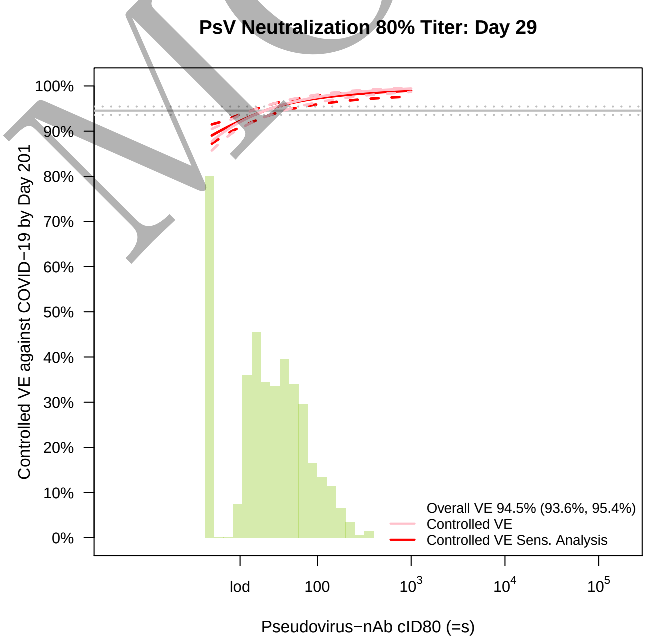


(b) Marginalized cumulative risk by Day 201 as functions of Day 29 markers (=s) among vaccine recipients with 95% bootstrap point-wise confidence bands (10 replicates). The horizontal lines indicate the overall cumulative risk of the placebo and vaccine arms by Day 201 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod =15.

Figure 4.15: Marginalized cumulative risk curves (=s).

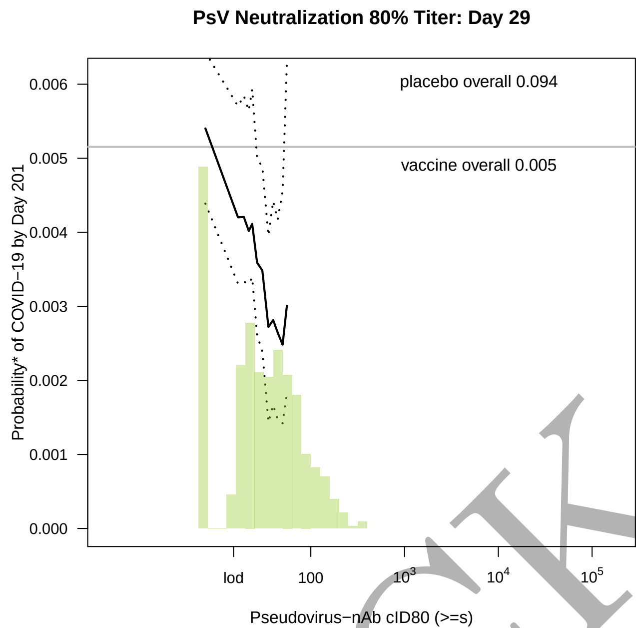


(a) Controlled VE with sensitivity analysis as functions of Day 29 markers (=s) among vaccine recipients with 95% bootstrap point-wise confidence bands (10 replicates). Histograms of the immunological markers in the vaccine arm are overlaid. lod =15.

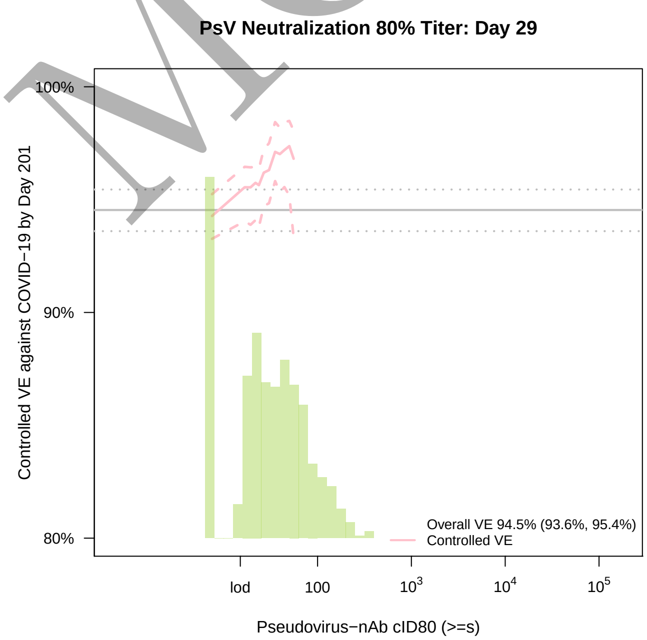


(b) Controlled VE with sensitivity analysis as functions of Day 29 markers (=s) among vaccine recipients with 95% bootstrap point-wise confidence bands (10 replicates). Histograms of the immunological markers in the vaccine arm are overlaid. lod =15.

Figure 4.16: Controlled VE curves (=s).



(a) Marginalized cumulative risk by Day 201 post Day 29 visit as functions of Day 29 markers above a threshold ($\geq s$) among vaccine recipients with 95% bootstrap point-wise confidence bands (at least 5 cases are required, 10 replicates). The horizontal lines indicate the overall cumulative risk of the vaccine arm by Day 201 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod =15.



(b) Controlled VE as functions of Day 29 markers (>=s) among vaccine recipients with 95% bootstrap point-wise confidence bands (10 replicates). Histograms of the immunological markers in the vaccine arm are overlaid. lod =15.

Figure 4.17: Marginalized cumulative risk curves and controlled VE curves (>=s).

Table 4.13: Marginalized cumulative risk by Day 201 as functions of Day 29 Pseudovirus-nAb cID80 (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence intervals (10 replicates).

s	Estimate	s	Estimate	s	Estimate	s	Estimate
7.5	.0116 (.0090,.0132)	20	.0064 (.0051,.0078)	49	.0036 (.0029,.0049)	129	.0020 (.0015,.0031)
8	.0116 (.0090,.0132)	20	.0062 (.0050,.0076)	51	.0035 (.0028,.0048)	134	.0019 (.0015,.0030)
8	.0116 (.0090,.0132)	21	.0061 (.0049,.0075)	53	.0034 (.0028,.0047)	139	.0019 (.0015,.0030)
8	.0113 (.0088,.0129)	22	.0060 (.0048,.0074)	55	.0033 (.0027,.0046)	145	.0018 (.0014,.0029)
8	.0110 (.0086,.0126)	22	.0059 (.0047,.0073)	58	.0033 (.0026,.0045)	151	.0018 (.0014,.0029)
8	.0108 (.0084,.0123)	23	.0058 (.0046,.0072)	60	.0032 (.0026,.0045)	157	.0018 (.0014,.0028)
9	.0105 (.0083,.0120)	24	.0057 (.0045,.0071)	62	.0031 (.0025,.0044)	163	.0017 (.0013,.0028)
9	.0103 (.0081,.0117)	25	.0055 (.0044,.0069)	64	.0031 (.0025,.0043)	169	.0017 (.0013,.0027)
9	.0100 (.0079,.0115)	26	.0054 (.0043,.0068)	65	.0030 (.0024,.0043)	176	.0016 (.0013,.0027)
10	.0098 (.0077,.0112)	27	.0053 (.0042,.0067)	67	.0030 (.0024,.0042)	183	.0016 (.0012,.0026)
10	.0096 (.0075,.0110)	27	.0053 (.0042,.0067)	70	.0029 (.0023,.0042)	190	.0016 (.0012,.0026)
11	.0093 (.0074,.0107)	28	.0051 (.0041,.0065)	73	.0028 (.0023,.0041)	197	.0015 (.0012,.0025)
11	.0091 (.0072,.0105)	29	.0050 (.0040,.0064)	75	.0028 (.0022,.0040)	205	.0015 (.0011,.0025)
11	.0089 (.0071,.0103)	30	.0049 (.0039,.0063)	75	.0028 (.0022,.0040)	213	.0014 (.0011,.0024)
12	.0087 (.0069,.0101)	31	.0048 (.0038,.0062)	78	.0027 (.0021,.0039)	221	.0014 (.0011,.0024)
12	.0085 (.0067,.0099)	32	.0047 (.0038,.0060)	81	.0026 (.0021,.0039)	230	.0014 (.0010,.0024)
13	.0083 (.0066,.0097)	34	.0046 (.0037,.0059)	85	.0026 (.0020,.0038)	239	.0013 (.0010,.0023)
13	.0081 (.0064,.0095)	35	.0045 (.0036,.0058)	88	.0025 (.0020,.0037)	248	.0013 (.0010,.0023)
14	.0079 (.0063,.0093)	35	.0044 (.0036,.0058)	91	.0024 (.0019,.0037)	258	.0013 (.0010,.0022)
14	.0077 (.0061,.0091)	36	.0044 (.0035,.0057)	92	.0024 (.0019,.0037)	268	.0013 (.0009,.0022)
15	.0075 (.0060,.0090)	38	.0042 (.0034,.0056)	95	.0024 (.0019,.0036)	279	.0012 (.0009,.0022)
15	.0074 (.0059,.0089)	39	.0041 (.0033,.0055)	99	.0023 (.0018,.0035)	290	.0012 (.0009,.0021)
16	.0074 (.0059,.0088)	41	.0040 (.0033,.0054)	103	.0023 (.0018,.0035)	301	.0012 (.0009,.0021)
16	.0072 (.0057,.0086)	42	.0040 (.0032,.0053)	107	.0022 (.0017,.0034)	313	.0011 (.0009,.0020)
17	.0070 (.0056,.0084)	44	.0039 (.0031,.0052)	111	.0022 (.0017,.0033)	325	.0011 (.0008,.0020)
17	.0069 (.0055,.0083)	45	.0038 (.0031,.0051)	115	.0021 (.0017,.0033)	338	.0011 (.0008,.0020)
18	.0067 (.0053,.0081)	46	.0038 (.0030,.0051)	120	.0021 (.0016,.0032)	500	.0008 (.0006,.0017)
19	.0065 (.0052,.0079)	48	.0037 (.0030,.0050)	124	.0020 (.0016,.0032)	1000	.0006 (.0004,.0012)

Table 4.14: Controlled VE as functions of Day 29 Pseudovirus-nAb cID80 (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence intervals (10 replicates).Overall cumulative incidence from 7 to 201 days post Day 29 was 0.005 in vaccine recipients compared to 0.094 in placebo recipients, with cumulative vaccine efficacy 94.5% (95% CI 93.6 to 95.4%).

s	Estimate	s	Estimate	s	Estimate	s	Estimate
7.5	.8775 (.8573,.9049)	20	.9340 (.9198,.9460)	53	.9637 (.9507,.9707)	145	.9805 (.9693,.9850)
8	.8775 (.8573,.9049)	21	.9356 (.9214,.9473)	55	.9646 (.9516,.9714)	151	.9810 (.9698,.9853)
8	.8775 (.8573,.9049)	22	.9363 (.9221,.9478)	58	.9654 (.9525,.9721)	157	.9814 (.9704,.9857)
8	.8803 (.8607,.9065)	22	.9371 (.9230,.9485)	60	.9662 (.9533,.9728)	163	.9819 (.9709,.9861)
8	.8831 (.8640,.9081)	23	.9386 (.9245,.9497)	62	.9670 (.9542,.9735)	169	.9823 (.9714,.9864)
8	.8859 (.8673,.9096)	24	.9400 (.9261,.9508)	64	.9676 (.9548,.9740)	176	.9827 (.9720,.9868)
9	.8886 (.8704,.9112)	25	.9415 (.9275,.9520)	65	.9678 (.9550,.9742)	183	.9831 (.9725,.9871)
9	.8912 (.8735,.9127)	26	.9428 (.9289,.9532)	67	.9686 (.9558,.9749)	190	.9835 (.9730,.9874)
9	.8937 (.8765,.9143)	27	.9441 (.9301,.9542)	70	.9693 (.9566,.9755)	197	.9839 (.9735,.9878)
10	.8962 (.8795,.9161)	27	.9442 (.9303,.9543)	73	.9700 (.9574,.9761)	205	.9843 (.9739,.9881)
10	.8987 (.8823,.9180)	28	.9455 (.9316,.9554)	75	.9707 (.9581,.9767)	213	.9847 (.9744,.9884)
11	.9011 (.8851,.9198)	29	.9468 (.9329,.9565)	75	.9707 (.9582,.9767)	221	.9850 (.9749,.9887)
11	.9034 (.8879,.9217)	30	.9480 (.9342,.9575)	78	.9714 (.9589,.9773)	230	.9854 (.9753,.9889)
11	.9057 (.8905,.9235)	31	.9493 (.9354,.9585)	81	.9721 (.9597,.9779)	239	.9857 (.9758,.9892)
12	.9079 (.8931,.9252)	32	.9505 (.9367,.9595)	85	.9728 (.9604,.9785)	248	.9861 (.9762,.9895)
12	.9101 (.8956,.9270)	34	.9516 (.9379,.9605)	88	.9734 (.9611,.9790)	258	.9864 (.9766,.9898)
13	.9122 (.8977,.9286)	35	.9528 (.9391,.9614)	91	.9740 (.9618,.9795)	268	.9867 (.9770,.9900)
13	.9142 (.8998,.9303)	35	.9531 (.9394,.9617)	92	.9741 (.9618,.9796)	279	.9871 (.9775,.9903)
14	.9163 (.9018,.9319)	36	.9539 (.9403,.9623)	95	.9747 (.9625,.9800)	290	.9874 (.9779,.9905)
14	.9182 (.9038,.9335)	38	.9550 (.9414,.9632)	99	.9753 (.9632,.9806)	301	.9877 (.9783,.9908)
15	.9202 (.9057,.9350)	39	.9561 (.9425,.9641)	103	.9758 (.9638,.9810)	313	.9880 (.9787,.9910)
15	.9212 (.9067,.9358)	41	.9571 (.9436,.9650)	107	.9764 (.9645,.9815)	325	.9882 (.9790,.9912)
16	.9220 (.9076,.9365)	42	.9581 (.9447,.9658)	111	.9770 (.9651,.9820)	338	.9885 (.9794,.9915)
16	.9239 (.9095,.9379)	44	.9591 (.9458,.9667)	115	.9775 (.9658,.9825)	500	.9910 (.9825,.9934)
17	.9257 (.9113,.9394)	45	.9596 (.9463,.9671)	120	.9781 (.9664,.9829)	1000	.9942 (.9869,.9959)
17	.9274 (.9131,.9408)	46	.9601 (.9468,.9675)	124	.9786 (.9670,.9833)		(,)
18	.9291 (.9148,.9421)	48	.9610 (.9478,.9683)	129	.9791 (.9676,.9838)	11	.9011 (.8851,.9198)
19	.9308 (.9165,.9435)	49	.9619 (.9488,.9691)	134	.9796 (.9682,.9842)	32	.9505 (.9367,.9595)
20	.9324 (.9182,.9448)	51	.9628 (.9498,.9699)	139	.9801 (.9687,.9846)		

Table 4.15: Controlled VE with sensitivity analysis as functions of Day 29 Pseudovirus-nAb cID80 (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence intervals (10 replicates).

s	Estimate	s	Estimate	s	Estimate	s	Estimate
7.5	.8904 (.8724,.9149)	20	.9345 (.9204,.9465)	53	.9625 (.9491,.9697)	145	.9770 (.9637,.9822)
8	.8904 (.8724,.9149)	21	.9360 (.9219,.9476)	55	.9633 (.9498,.9704)	151	.9774 (.9641,.9826)
8	.8904 (.8724,.9149)	22	.9366 (.9225,.9481)	58	.9640 (.9506,.9710)	157	.9778 (.9646,.9829)
8	.8924 (.8747,.9159)	22	.9374 (.9233,.9487)	60	.9647 (.9513,.9716)	163	.9782 (.9650,.9832)
8	.8943 (.8770,.9169)	23	.9388 (.9248,.9498)	62	.9654 (.9520,.9722)	169	.9785 (.9654,.9835)
8	.8962 (.8793,.9178)	24	.9402 (.9262,.9510)	64	.9659 (.9524,.9727)	176	.9789 (.9657,.9838)
9	.8981 (.8815,.9188)	25	.9415 (.9276,.9521)	65	.9661 (.9526,.9728)	183	.9793 (.9661,.9841)
9	.9000 (.8838,.9198)	26	.9429 (.9289,.9532)	67	.9668 (.9533,.9734)	190	.9796 (.9665,.9844)
9	.9019 (.8860,.9208)	27	.9441 (.9302,.9542)	70	.9674 (.9539,.9740)	197	.9800 (.9669,.9847)
10	.9037 (.8881,.9221)	27	.9442 (.9303,.9543)	73	.9680 (.9545,.9745)	205	.9803 (.9672,.9850)
10	.9055 (.8903,.9235)	28	.9455 (.9316,.9554)	75	.9686 (.9551,.9750)	213	.9806 (.9676,.9853)
11	.9073 (.8924,.9249)	29	.9468 (.9329,.9564)	75	.9686 (.9551,.9750)	221	.9809 (.9679,.9855)
11	.9091 (.8944,.9263)	30	.9480 (.9342,.9575)	78	.9692 (.9557,.9756)	230	.9813 (.9683,.9858)
11	.9108 (.8965,.9277)	31	.9492 (.9354,.9585)	81	.9698 (.9563,.9761)	239	.9816 (.9686,.9861)
12	.9125 (.8985,.9290)	32	.9504 (.9366,.9594)	85	.9704 (.9569,.9765)	248	.9819 (.9690,.9863)
12	.9142 (.9005,.9304)	34	.9515 (.9377,.9603)	88	.9709 (.9575,.9770)	258	.9822 (.9693,.9866)
13	.9159 (.9021,.9317)	35	.9526 (.9388,.9612)	91	.9715 (.9580,.9775)	268	.9824 (.9696,.9868)
13	.9176 (.9037,.9330)	35	.9529 (.9391,.9615)	92	.9715 (.9580,.9775)	279	.9827 (.9699,.9870)
14	.9192 (.9053,.9343)	36	.9536 (.9399,.9621)	95	.9720 (.9585,.9779)	290	.9830 (.9702,.9873)
14	.9208 (.9068,.9356)	38	.9546 (.9409,.9630)	99	.9725 (.9591,.9784)	301	.9833 (.9705,.9875)
15	.9224 (.9084,.9368)	39	.9556 (.9420,.9638)	103	.9730 (.9596,.9788)	313	.9835 (.9709,.9877)
15	.9233 (.9092,.9375)	41	.9566 (.9429,.9646)	107	.9735 (.9601,.9792)	325	.9838 (.9711,.9879)
16	.9240 (.9099,.9381)	42	.9575 (.9439,.9653)	111	.9740 (.9606,.9796)	338	.9841 (.9714,.9881)
16	.9256 (.9115,.9393)	44	.9584 (.9448,.9661)	115	.9744 (.9610,.9800)	500	.9864 (.9736,.9901)
17	.9271 (.9130,.9406)	45	.9588 (.9453,.9665)	120	.9749 (.9615,.9804)	1000	.9897 (.9769,.9927)
17	.9286 (.9145,.9418)	46	.9593 (.9457,.9669)	124	.9753 (.9620,.9808)		(,)
18	.9301 (.9160,.9430)	48	.9601 (.9466,.9676)	129	.9758 (.9624,.9812)	11	.9011 (.8851,.9198)
19	.9316 (.9175,.9441)	49	.9609 (.9475,.9683)	134	.9762 (.9629,.9815)	32	.9505 (.9367,.9595)
20	.9331 (.9190,.9453)	51	.9617 (.9483,.9690)	139	.9766 (.9633,.9819)		

Chapter 5

Day D57 Univariate CoR: Cox Models of Risk

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

5.1 Hazard ratios

Table 5.1: 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*

MockCOVE	No. cases /	HR per 10-fold incr.		P-value	q-value	FWER
Immunologic Marker	No. at-risk**	Pt. Est.	95% CI	(2-sided)	***	
Anti Spike IgG (BAU/ml)	51/11,163	0.07	(0.04-0.14)	<0.001	<0.001	<0.001
Anti RBD IgG (BAU/ml)	51/11,163	0.35	(0.21-0.58)	<0.001	<0.001	<0.001
Pseudovirus-nAb cID50	51/11,163	0.19	(0.10-0.38)	<0.001	<0.001	<0.001
Pseudovirus-nAb cID80	51/11,163	0.21	(0.10-0.41)	<0.001	<0.001	<0.001

*Baseline covariates adjusted for: MinorityInd + HighRiskInd + Age. Maximum failure event time 173 days.
**No. at-risk = estimated number in the population for analysis, i.e. baseline negative per-protocol vaccine recipients not experiencing the COVID endpoint or infected through 6 days post Day 57 visit; no. cases = number of this cohort with an observed COVID endpoint.
***q-value and FWER (family-wide error rate) are computed over the set of p-values both for quantitative markers and categorical markers using the Westfall and Young permutation method (10 replicates).

Table 5.2: 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*

MockCOVE 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 (BAU/ml)	Lower	28/4,218	0.0066	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	18/4,193	0.0043	0.20	(0.10-0.41)	<0.001			
	Upper	5/2,752	0.0018	0.04	(0.01-0.11)	<0.001			
Anti RBD IgG (BAU/ml)	Lower	26/4,145	0.0063	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	13/4,137	0.0031	0.27	(0.12-0.59)	0.001			
	Upper	13/2,881	0.0045	0.18	(0.08-0.42)	<0.001			
Pseudovirus-nAb cID50	Lower	23/3,724	0.0062	1	N/A	N/A	<0.001	<0.001	<0.001
	Middle	16/3,726	0.0043	0.40	(0.20-0.82)	0.013			
	Upper	12/3,712	0.0032	0.18	(0.08-0.41)	<0.001			
Pseudovirus-nAb cID80	Lower	21/3,722	0.0056	1	N/A	N/A	0.003	<0.001	0.013
	Middle	19/3,720	0.0051	0.58	(0.29-1.17)	0.128			
	Upper	11/3,721	0.0030	0.24	(0.10-0.54)	<0.001			
Placebo		1010/11,301	0.0894						

*Baseline covariates adjusted for: MinorityInd + HighRiskInd + Age. Maximum failure event time 173 days. Cutpoints: Anti Spike IgG (BAU/ml) [3.31, 4.01), Anti RBD IgG (BAU/ml) [3.44, 4.21), Pseudovirus-nAb cID50 [2.43, 2.85), Pseudovirus-nAb cID80 [2.55, 2.93), all on the log10 scale.
**No. at-risk = estimated number in the population for analysis, i.e. baseline negative per-protocol vaccine recipients not experiencing the COVID endpoint or infected through 6 days post Day 57 visit; no. cases = number of this cohort with an observed COVID endpoint.
***Generalized Wald-test p-value of the null hypothesis that the hazard rate is constant across the Lower, Middle, and Upper tertile groups.
† q-value and FWER (family-wide error rate) are computed over the set of p-values both for quantitative markers and categorical markers using the Westfall and Young permutation method (10 replicates).

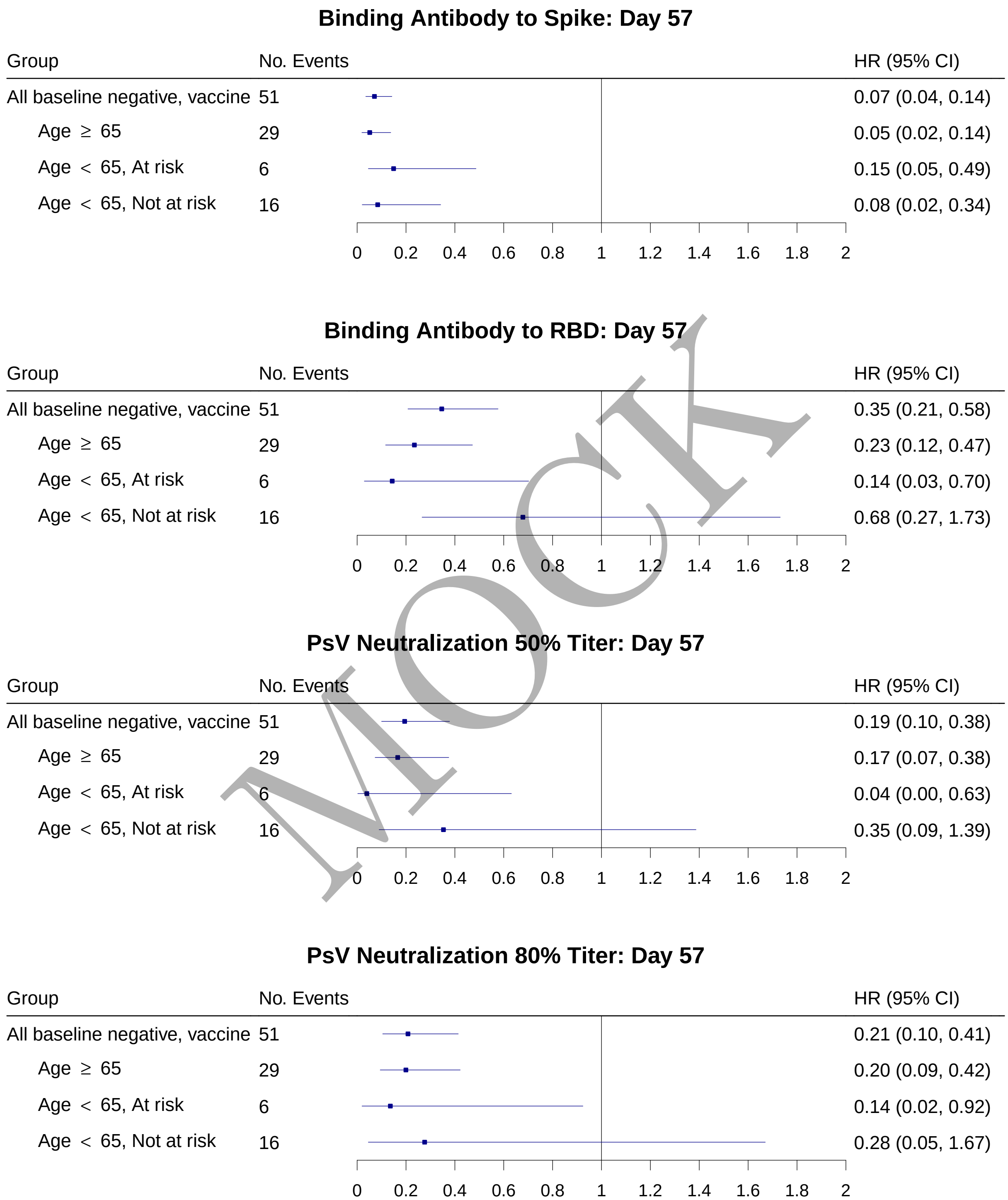


Figure 5.1: Forest plots of hazard ratios per 10-fold increase in the marker among baseline negative vaccine recipients and subgroups with 95% point-wise confidence intervals.

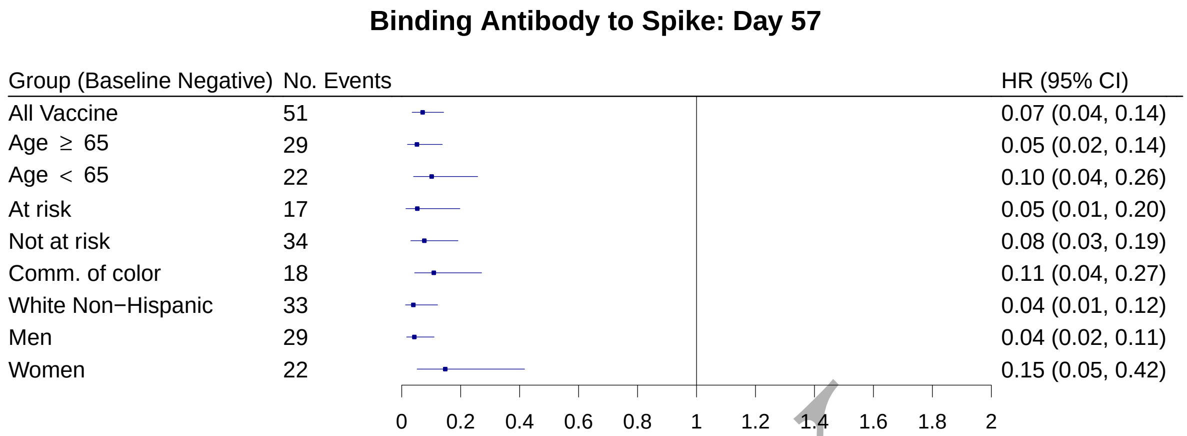


Figure 5.2: Forest plots of hazard ratios per 10-fold increase in the Day 57 binding Ab to spike markers among baseline negative vaccine recipients (top row) and different subpopulations with 95% point-wise confidence intervals.

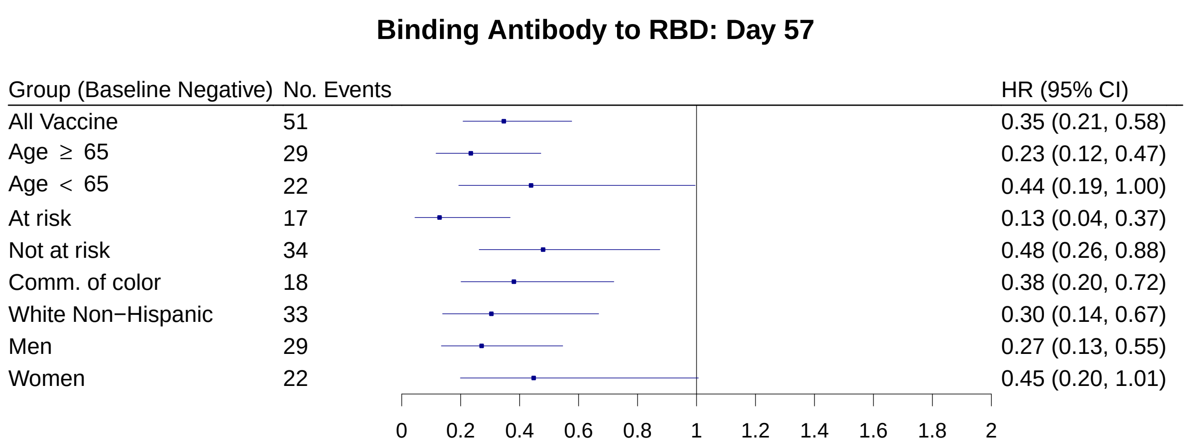


Figure 5.3: Forest plots of hazard ratios per 10-fold increase in the Day 57 binding Ab to RBD markers among baseline negative vaccine recipients (top row) and different subpopulations with 95% point-wise confidence intervals.

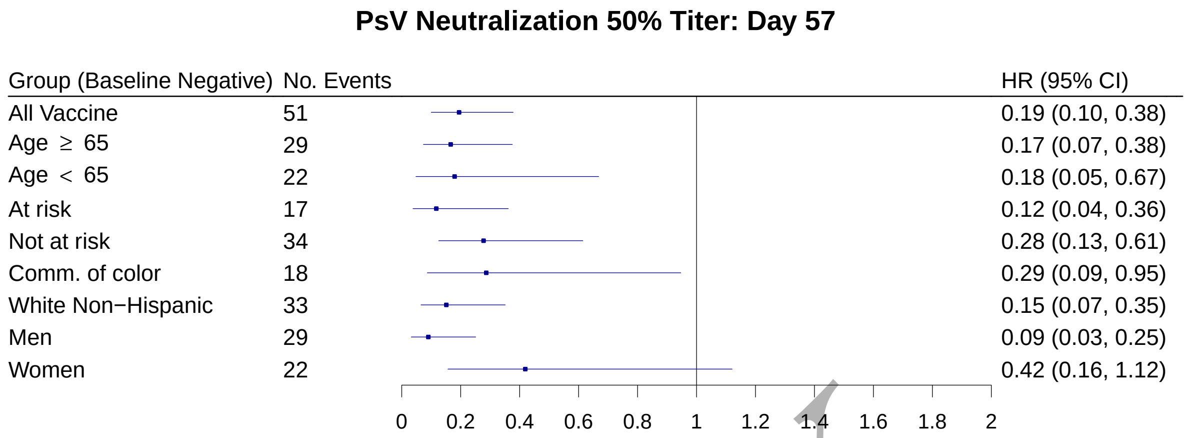


Figure 5.4: Forest plots of hazard ratios per 10-fold increase in the Day 57 pseudo neut ID50 markers among baseline negative vaccine recipients (top row) and different subpopulations with 95% point-wise confidence intervals.

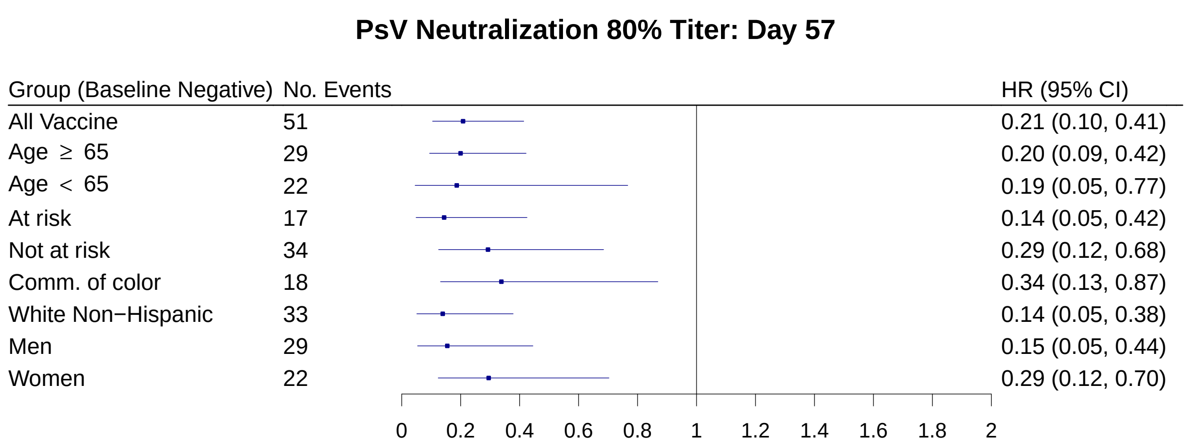


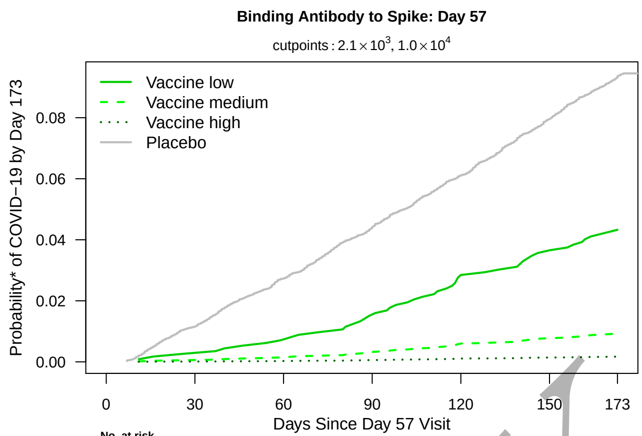
Figure 5.5: Forest plots of hazard ratios per 10-fold increase in the Day 57 pseudo neut ID80 markers among baseline negative vaccine recipients (top row) and different subpopulations with 95% point-wise confidence intervals.

5.2 Marginalized risk and controlled vaccine efficacy plots

Table 5.3: Analysis of Day 57 markers (upper vs. lower tertile) as a CoR and a controlled risk CoP.

	marginalized risk ratio $RR_M(0,1)$		controlled risk ratio $RR_C(0,1)^1$		e(0,1)[2]	
	Point Est.	95% CI	Point Est.	95% CI	Point Est.	95% CI UL
Anti Spike IgG (BAU/ml)	0.04	0.03–0.06	0.05	0.03–0.08	50.9	34.9
Anti RBD IgG (BAU/ml)	0.18	0.08–0.38	0.25	0.11–0.50	10.3	4.8
Pseudovirus-nAb cID50	0.18	0.12–0.31	0.24	0.16–0.41	10.5	6.0
Pseudovirus-nAb cID80	0.24	0.10–0.46	0.32	0.14–0.62	7.9	3.7

[1]Conservative (upper bound) estimate assuming unmeasured confounding at level $RR_{UD}(0,1) = RR_{EU}(0,1) = 2$ and thus $B(0,1) = 4/3$.
[2]E-values are computed for upper tertile ($s = 1$) vs. lower tertile ($s = 0$) biomarker subgroups after controlling for MinorityInd + HighRiskInd + Age; UL = upper limit.



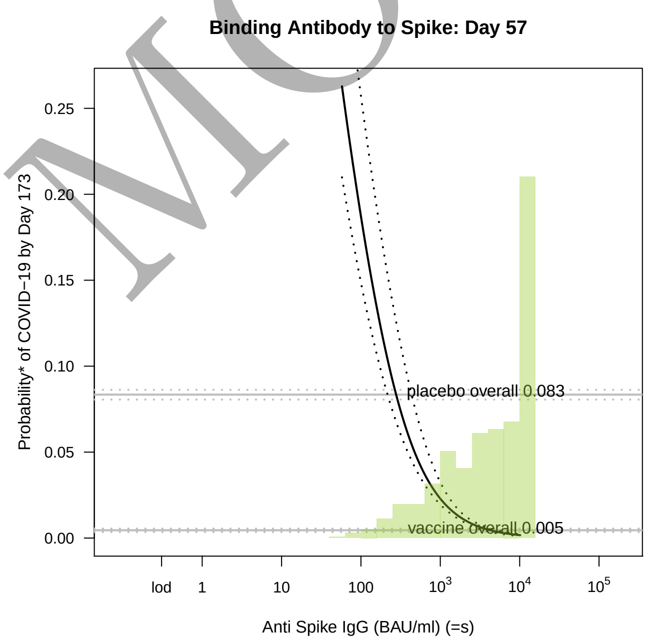
No. at risk

	0	30	60	90	120	150	173
Low:	4218	4123	4059	3991	3950	3856	3071
Med:	4193	4176	4130	4107	4064	4013	3151
High:	2752	2739	2731	2719	2691	2656	2170
Plac:	11301	11054	10708	10369	10023	9635	7815

Cumulative No. of COVID−19 Endpoints

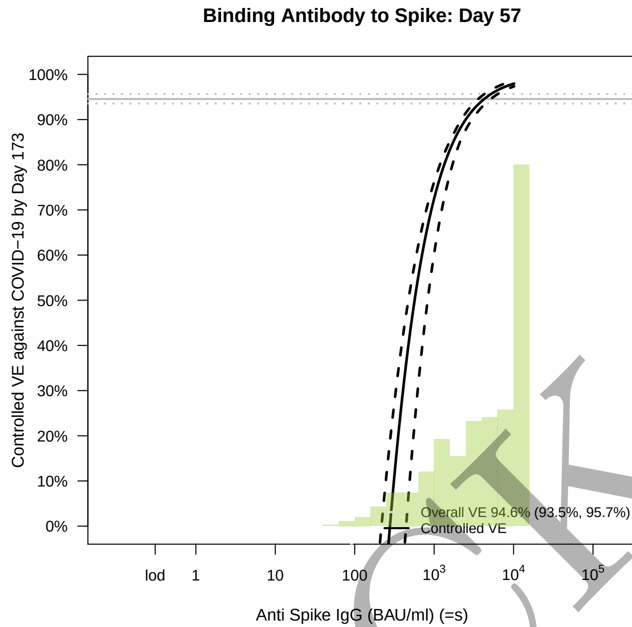
	0	30	60	90	120	150	173
Low:	0	2	4	11	19	24	28
Med:	0	0	3	6	13	14	18
High:	0	1	1	1	2	5	5
Plac:	0	131	305	489	672	869	1010

(a) Marginalized cumulative incidence rate curves for trichotomized Day 57 markers among vaccine recipients. The gray line is the overall cumulative incidence rate curve in the placebo arm.

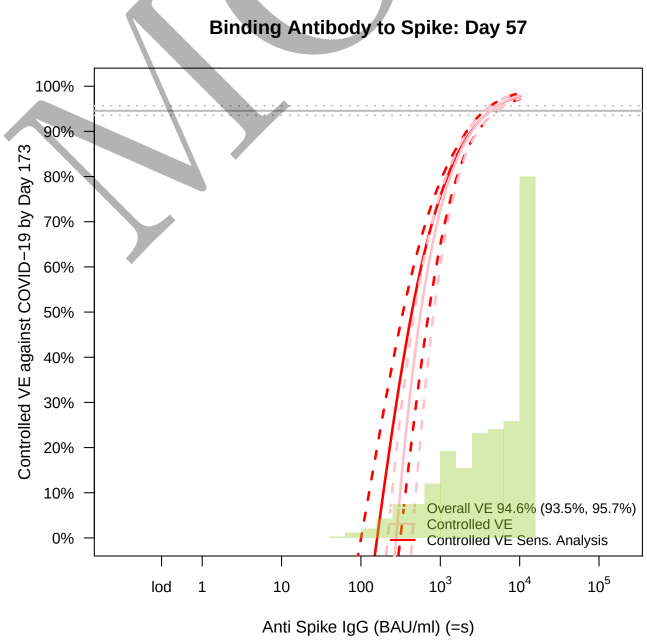


(b) Marginalized cumulative risk by Day 173 as functions of Day 57 markers (=s) among vaccine recipients with 95% bootstrap point-wise confidence bands (10 replicates). The horizontal lines indicate the overall cumulative risk of the placebo and vaccine arms by Day 173 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod =0.3.

Figure 5.6: Marginalized cumulative risk curves (=s).

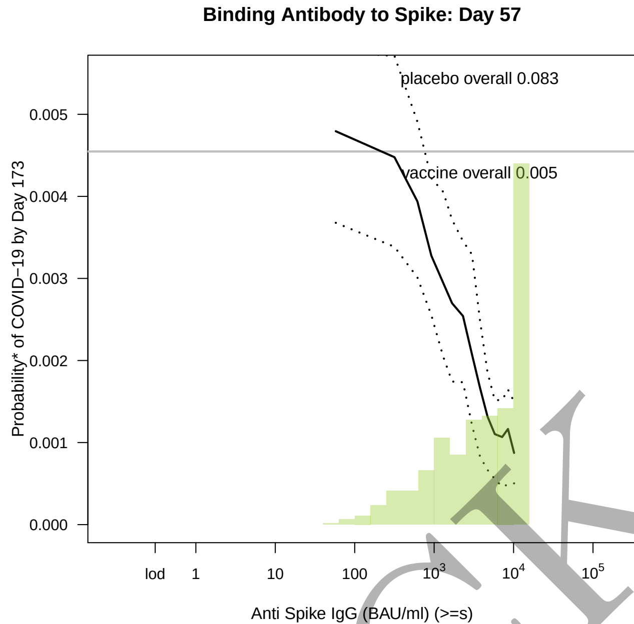


(a) Controlled VE with sensitivity analysis as functions of Day 57 markers (=s) among vaccine recipients with 95% bootstrap pointwise confidence bands (10 replicates). Histograms of the immunological markers in the vaccine arm are overlaid. lod =0.3.

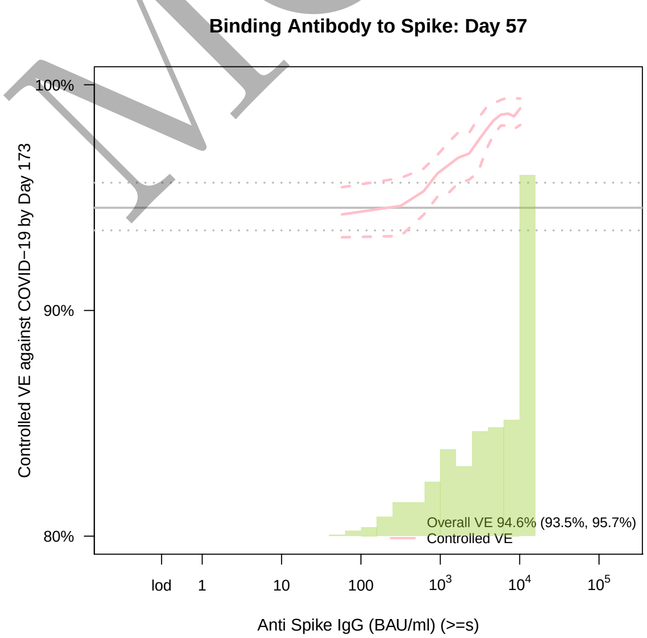


(b) Controlled VE with sensitivity analysis as functions of Day 57 markers (=s) among vaccine recipients with 95% bootstrap pointwise confidence bands (10 replicates). Histograms of the immunological markers in the vaccine arm are overlaid. lod =0.3.

Figure 5.7: Controlled VE curves (=s).



(a) Marginalized cumulative risk by Day 173 post Day 57 visit as functions of Day 57 markers above a threshold ($\geq s$) among vaccine recipients with 95% bootstrap point-wise confidence bands (at least 5 cases are required, 10 replicates). The horizontal lines indicate the overall cumulative risk of the vaccine arm by Day 173 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod =0.3.



(b) Controlled VE as functions of Day 57 markers (>=s) among vaccine recipients with 95% bootstrap point-wise confidence bands (10 replicates). Histograms of the immunological markers in the vaccine arm are overlaid. lod =0.3.

Figure 5.8: Marginalized cumulative risk curves and controlled VE curves (>=s).

Table 5.4: Marginalized cumulative risk by Day 173 as functions of Day 57 Anti Spike IgG (BAU/ml) (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence intervals (10 replicates).

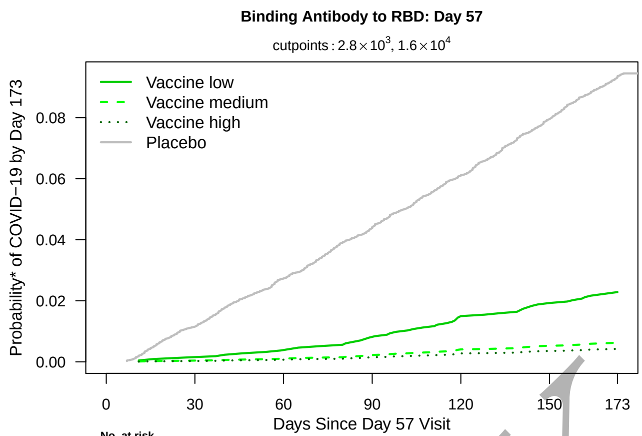
s	Estimate	s	Estimate	s	Estimate	s	Estimate
57.7	.2628 (.2099,.3457)	249	.0920 (.0743,.1374)	922	.0250 (.0212,.0359)	3392	.0059 (.0047,.0072)
61	.2551 (.2035,.3369)	262	.0878 (.0710,.1318)	968	.0237 (.0202,.0338)	3573	.0056 (.0044,.0067)
64	.2475 (.1973,.3281)	276	.0838 (.0679,.1262)	1000	.0229 (.0195,.0325)	3765	.0052 (.0042,.0064)
67	.2400 (.1912,.3194)	291	.0799 (.0649,.1208)	1020	.0224 (.0191,.0317)	3967	.0049 (.0039,.0060)
71	.2326 (.1852,.3109)	307	.0761 (.0620,.1155)	1075	.0212 (.0181,.0297)	4180	.0047 (.0036,.0057)
75	.2253 (.1793,.3024)	323	.0725 (.0592,.1103)	1133	.0200 (.0171,.0278)	4404	.0044 (.0034,.0054)
79	.2182 (.1735,.2940)	341	.0690 (.0565,.1052)	1193	.0189 (.0162,.0260)	4640	.0041 (.0032,.0051)
83	.2111 (.1678,.2857)	359	.0657 (.0539,.1003)	1257	.0179 (.0153,.0243)	4685	.0041 (.0032,.0051)
88	.2042 (.1622,.2775)	378	.0625 (.0513,.0955)	1325	.0169 (.0145,.0227)	4889	.0039 (.0030,.0048)
92	.1974 (.1567,.2694)	399	.0594 (.0489,.0909)	1359	.0164 (.0141,.0220)	5151	.0037 (.0028,.0046)
97	.1907 (.1514,.2614)	420	.0564 (.0466,.0864)	1396	.0159 (.0137,.0212)	5427	.0035 (.0026,.0043)
103	.1841 (.1461,.2535)	442	.0536 (.0444,.0820)	1471	.0150 (.0130,.0198)	5718	.0033 (.0025,.0041)
108	.1776 (.1410,.2458)	466	.0509 (.0422,.0778)	1549	.0142 (.0122,.0185)	6024	.0031 (.0023,.0039)
114	.1713 (.1360,.2381)	491	.0483 (.0401,.0737)	1633	.0134 (.0115,.0173)	6347	.0029 (.0022,.0037)
120	.1651 (.1311,.2305)	500	.0474 (.0395,.0723)	1720	.0126 (.0109,.0161)	6688	.0027 (.0020,.0035)
126	.1590 (.1263,.2231)	517	.0458 (.0381,.0698)	1812	.0119 (.0102,.0150)	7046	.0026 (.0019,.0033)
133	.1530 (.1216,.2157)	545	.0434 (.0362,.0660)	1909	.0113 (.0097,.0141)	7245	.0025 (.0018,.0032)
140	.1472 (.1171,.2085)	574	.0412 (.0344,.0623)	2012	.0106 (.0091,.0132)	7424	.0024 (.0017,.0031)
148	.1415 (.1126,.2014)	605	.0390 (.0327,.0588)	2120	.0100 (.0085,.0124)	7822	.0023 (.0016,.0030)
156	.1359 (.1083,.1944)	638	.0370 (.0310,.0555)	2233	.0094 (.0080,.0117)	8241	.0021 (.0015,.0028)
164	.1305 (.1040,.1875)	643	.0366 (.0307,.0550)	2353	.0089 (.0075,.0110)	8683	.0020 (.0014,.0027)
173	.1252 (.0999,.1808)	672	.0350 (.0294,.0523)	2479	.0084 (.0070,.0103)	9149	.0019 (.0013,.0025)
182	.1200 (.0959,.1741)	708	.0332 (.0279,.0492)	2612	.0079 (.0066,.0097)	9639	.0018 (.0012,.0024)
192	.1150 (.0920,.1676)	746	.0314 (.0264,.0463)	2752	.0075 (.0061,.0091)	10156	.0017 (.0011,.0022)
202	.1101 (.0883,.1613)	786	.0297 (.0251,.0436)	2876	.0071 (.0058,.0087)	10156	.0017 (.0011,.0022)
213	.1054 (.0846,.1552)	828	.0281 (.0237,.0409)	2900	.0070 (.0058,.0086)	10156	.0017 (.0011,.0022)
224	.1008 (.0811,.1491)	872	.0266 (.0225,.0384)	3055	.0066 (.0054,.0081)	10156	.0017 (.0011,.0022)
236	.0963 (.0776,.1432)	919	.0251 (.0213,.0360)	3219	.0063 (.0051,.0076)	10156	.0017 (.0011,.0022)

Table 5.5: Controlled VE as functions of Day 57 Anti Spike IgG (BAU/ml) (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence intervals (10 replicates).Overall cumulative incidence from 7 to 173 days post Day 57 was 0.005 in vaccine recipients compared to 0.083 in placebo recipients, with cumulative vaccine efficacy 94.6% (95% CI 93.5 to 95.7%).

s	Estimate	s	Estimate	s	Estimate	s	Estimate
57.7	-2.1493 (-3.2079,-1.4888)	262	-0.0523 (-0.6113, 0.1465)	1000	0.7251 (0.6032, 0.7623)	3967	0.9408 (0.9273, 0.9520)
61	-2.0570 (-3.1003,-1.4155)	276	-0.0040 (-0.5434, 0.1841)	1020	0.7311 (0.6131, 0.7671)	4180	0.9442 (0.9315, 0.9550)
64	-1.9659 (-2.9937,-1.3432)	291	0.0427 (-0.4770, 0.2203)	1075	0.7459 (0.6376, 0.7794)	4404	0.9474 (0.9354, 0.9579)
67	-1.8761 (-2.8883,-1.2720)	307	0.0876 (-0.4121, 0.2553)	1133	0.7599 (0.6608, 0.7910)	4640	0.9504 (0.9390, 0.9605)
71	-1.7876 (-2.7840,-1.2020)	323	0.1310 (-0.3488, 0.2891)	1193	0.7732 (0.6827, 0.8020)	4685	0.9510 (0.9396, 0.9610)
75	-1.7004 (-2.6809,-1.1332)	341	0.1727 (-0.2870, 0.3216)	1257	0.7858 (0.7033, 0.8125)	4889	0.9533 (0.9424, 0.9630)
79	-1.6146 (-2.5789,-1.0656)	359	0.2128 (-0.2268, 0.3530)	1325	0.7977 (0.7226, 0.8225)	5151	0.9560 (0.9456, 0.9654)
83	-1.5301 (-2.4781,-0.9992)	378	0.2513 (-0.1683, 0.3832)	1359	0.8034 (0.7318, 0.8272)	5427	0.9585 (0.9486, 0.9676)
88	-1.4469 (-2.3785,-0.9341)	399	0.2882 (-0.1114, 0.4122)	1396	0.8090 (0.7409, 0.8320)	5718	0.9609 (0.9515, 0.9696)
92	-1.3652 (-2.2801,-0.8701)	420	0.3237 (-0.0562, 0.4401)	1471	0.8197 (0.7580, 0.8410)	6024	0.9632 (0.9542, 0.9716)
97	-1.2849 (-2.1830,-0.8075)	442	0.3576 (-0.0028, 0.4668)	1549	0.8298 (0.7740, 0.8495)	6347	0.9653 (0.9567, 0.9735)
103	-1.2060 (-2.0871,-0.7461)	466	0.3902 (0.0489, 0.4925)	1633	0.8394 (0.7891, 0.8576)	6688	0.9673 (0.9591, 0.9753)
108	-1.1285 (-1.9925,-0.6860)	491	0.4213 (0.0988, 0.5172)	1720	0.8484 (0.8032, 0.8654)	7046	0.9692 (0.9613, 0.9770)
114	-1.0525 (-1.8993,-0.6271)	500	0.4316 (0.1155, 0.5254)	1812	0.8570 (0.8164, 0.8729)	7245	0.9702 (0.9624, 0.9778)
120	-0.9780 (-1.8073,-0.5695)	517	0.4510 (0.1470, 0.5408)	1909	0.8651 (0.8288, 0.8807)	7424	0.9710 (0.9633, 0.9786)
126	-0.9051 (-1.7166,-0.5132)	545	0.4794 (0.1933, 0.5634)	2012	0.8727 (0.8404, 0.8882)	7822	0.9727 (0.9653, 0.9800)
133	-0.8336 (-1.6274,-0.4582)	574	0.5065 (0.2378, 0.5850)	2120	0.8799 (0.8512, 0.8952)	8241	0.9743 (0.9671, 0.9814)
140	-0.7637 (-1.5395,-0.4045)	605	0.5323 (0.2806, 0.6057)	2233	0.8868 (0.8604, 0.9017)	8683	0.9758 (0.9689, 0.9826)
148	-0.6953 (-1.4530,-0.3520)	638	0.5569 (0.3215, 0.6255)	2353	0.8932 (0.8686, 0.9079)	9149	0.9772 (0.9705, 0.9838)
156	-0.6286 (-1.3683,-0.3008)	643	0.5608 (0.3279, 0.6286)	2479	0.8993 (0.8763, 0.9137)	9639	0.9785 (0.9721, 0.9849)
164	-0.5635 (-1.2864,-0.2501)	672	0.5804 (0.3606, 0.6444)	2612	0.9050 (0.8836, 0.9191)	10156	0.9797 (0.9736, 0.9859)
173	-0.5000 (-1.2059,-0.2007)	708	0.6027 (0.3980, 0.6624)	2752	0.9105 (0.8902, 0.9242)	10156	0.9797 (0.9736, 0.9859)
182	-0.4381 (-1.1268,-0.1526)	746	0.6240 (0.4337, 0.6796)	2876	0.9148 (0.8955, 0.9282)	10156	0.9797 (0.9736, 0.9859)
192	-0.3779 (-1.0489,-0.1059)	786	0.6442 (0.4676, 0.6960)	2900	0.9156 (0.8965, 0.9290)	10156	0.9797 (0.9736, 0.9859)
202	-0.3194 (-0.9725,-0.0605)	828	0.6634 (0.4999, 0.7117)	3055	0.9204 (0.9024, 0.9334)	10156	0.9797 (0.9736, 0.9859)
213	-0.2626 (-0.8974,-0.0165)	872	0.6817 (0.5305, 0.7266)	3219	0.9250 (0.9080, 0.9376)	785.8	.6442 (.4676,.6960)
224	-0.2075 (-0.8238, 0.0262)	919	0.6990 (0.5595, 0.7408)	3392	0.9293 (0.9132, 0.9416)	2479	.8993 (.8763,.9137)
236	-0.1541 (-0.7515, 0.0676)	922	0.7000 (0.5613, 0.7416)	3573	0.9333 (0.9182, 0.9453)	4640	.9504 (.9390,.9605)
249	-0.1023 (-0.6807, 0.1077)	968	0.7155 (0.5870, 0.7543)	3765	0.9372 (0.9229, 0.9487)		

Table 5.6: Controlled VE with sensitivity analysis as functions of Day 57 Anti Spike IgG (BAU/ml) (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence intervals (10 replicates).

s	Estimate	s	Estimate	s	Estimate	s	Estimate
57.7	-0.5625 (-1.0878,-0.2348)	262	0.2666 (-0.1230, 0.4052)	1000	0.7566 (0.6487, 0.7895)	3967	0.9408 (0.9273, 0.9520)
61	-0.5358 (-1.0600,-0.2135)	276	0.2928 (-0.0872, 0.4253)	1020	0.7612 (0.6564, 0.7932)	4180	0.9442 (0.9315, 0.9550)
64	-0.5087 (-1.0316,-0.1919)	291	0.3185 (-0.0515, 0.4450)	1075	0.7726 (0.6758, 0.8026)	4404	0.9474 (0.9354, 0.9579)
67	-0.4813 (-1.0027,-0.1702)	307	0.3437 (-0.0159, 0.4643)	1133	0.7836 (0.6943, 0.8116)	4640	0.9504 (0.9389, 0.9605)
71	-0.4536 (-0.9732,-0.1483)	323	0.3683 (0.0196, 0.4832)	1193	0.7941 (0.7120, 0.8203)	4685	0.9509 (0.9395, 0.9610)
75	-0.4256 (-0.9432,-0.1262)	341	0.3924 (0.0548, 0.5018)	1257	0.8042 (0.7288, 0.8286)	4889	0.9532 (0.9422, 0.9630)
79	-0.3973 (-0.9127,-0.1039)	359	0.4159 (0.0897, 0.5199)	1325	0.8139 (0.7448, 0.8367)	5151	0.9558 (0.9454, 0.9653)
83	-0.3688 (-0.8816,-0.0816)	378	0.4388 (0.1243, 0.5377)	1359	0.8185 (0.7524, 0.8405)	5427	0.9583 (0.9483, 0.9674)
88	-0.3400 (-0.8501,-0.0591)	399	0.4611 (0.1586, 0.5550)	1396	0.8231 (0.7600, 0.8444)	5718	0.9606 (0.9511, 0.9694)
92	-0.3110 (-0.8181,-0.0366)	420	0.4829 (0.1924, 0.5719)	1471	0.8319 (0.7744, 0.8517)	6024	0.9628 (0.9537, 0.9713)
97	-0.2818 (-0.7857,-0.0140)	442	0.5040 (0.2257, 0.5883)	1549	0.8404 (0.7881, 0.8588)	6347	0.9649 (0.9562, 0.9732)
103	-0.2525 (-0.7528, 0.0086)	466	0.5245 (0.2585, 0.6043)	1633	0.8485 (0.8010, 0.8657)	6688	0.9668 (0.9584, 0.9749)
108	-0.2231 (-0.7195, 0.0312)	491	0.5444 (0.2906, 0.6199)	1720	0.8562 (0.8133, 0.8723)	7046	0.9686 (0.9605, 0.9765)
114	-0.1935 (-0.6858, 0.0539)	500	0.5511 (0.3015, 0.6252)	1812	0.8636 (0.8249, 0.8788)	7245	0.9695 (0.9616, 0.9774)
120	-0.1639 (-0.6518, 0.0765)	517	0.5637 (0.3221, 0.6351)	1909	0.8706 (0.8358, 0.8856)	7424	0.9703 (0.9625, 0.9781)
126	-0.1342 (-0.6173, 0.0991)	545	0.5824 (0.3529, 0.6498)	2012	0.8773 (0.8462, 0.8922)	7822	0.9719 (0.9643, 0.9795)
133	-0.1045 (-0.5826, 0.1216)	574	0.6004 (0.3830, 0.6640)	2120	0.8838 (0.8560, 0.8985)	8241	0.9734 (0.9661, 0.9808)
140	-0.0748 (-0.5476, 0.1441)	605	0.6179 (0.4122, 0.6779)	2233	0.8899 (0.8643, 0.9044)	8683	0.9748 (0.9677, 0.9820)
148	-0.0452 (-0.5123, 0.1665)	638	0.6348 (0.4407, 0.6913)	2353	0.8957 (0.8717, 0.9100)	9149	0.9762 (0.9693, 0.9831)
156	-0.0157 (-0.4769, 0.1887)	643	0.6374 (0.4452, 0.6934)	2479	0.9013 (0.8788, 0.9154)	9639	0.9774 (0.9708, 0.9842)
164	0.0137 (-0.4423, 0.2114)	672	0.6510 (0.4683, 0.7042)	2612	0.9066 (0.8855, 0.9204)	10156	0.9786 (0.9722, 0.9852)
173	0.0430 (-0.4074, 0.2339)	708	0.6667 (0.4950, 0.7168)	2752	0.9116 (0.8916, 0.9252)	10156	0.9786 (0.9722, 0.9852)
182	0.0720 (-0.3723, 0.2562)	746	0.6818 (0.5208, 0.7289)	2876	0.9157 (0.8966, 0.9290)	10156	0.9786 (0.9722, 0.9852)
192	0.1008 (-0.3371, 0.2783)	786	0.6964 (0.5457, 0.7406)	2900	0.9164 (0.8975, 0.9297)	10156	0.9786 (0.9722, 0.9852)
202	0.1293 (-0.3016, 0.3002)	828	0.7104 (0.5697, 0.7519)	3055	0.9210 (0.9031, 0.9339)	10156	0.9786 (0.9722, 0.9852)
213	0.1575 (-0.2660, 0.3218)	872	0.7239 (0.5927, 0.7628)	3219	0.9254 (0.9084, 0.9380)	785.8	.6442 (.4676,.6960)
224	0.1854 (-0.2303, 0.3431)	919	0.7368 (0.6149, 0.7733)	3392	0.9295 (0.9135, 0.9418)	2479	.8993 (.8763,.9137)
236	0.2129 (-0.1946, 0.3641)	922	0.7376 (0.6162, 0.7740)	3573	0.9335 (0.9184, 0.9454)	4640	.9504 (.9390,.9605)
249	0.2400 (-0.1588, 0.3848)	968	0.7492 (0.6361, 0.7834)	3765	0.9372 (0.9230, 0.9488)		



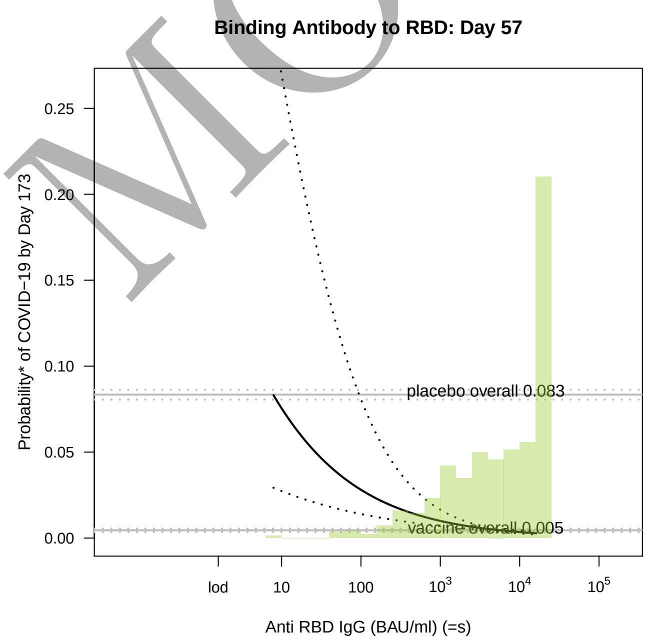
No. at risk

	0	30	60	90	120	150	173
Low:	4145	4089	4005	3961	3955	3872	3040
Med:	4137	4093	4061	4016	3930	3859	2983
High:	2881	2855	2853	2840	2820	2794	2369
Plac:	11301	11054	10708	10369	10023	9635	7815

Cumulative No. of COVID−19 Endpoints

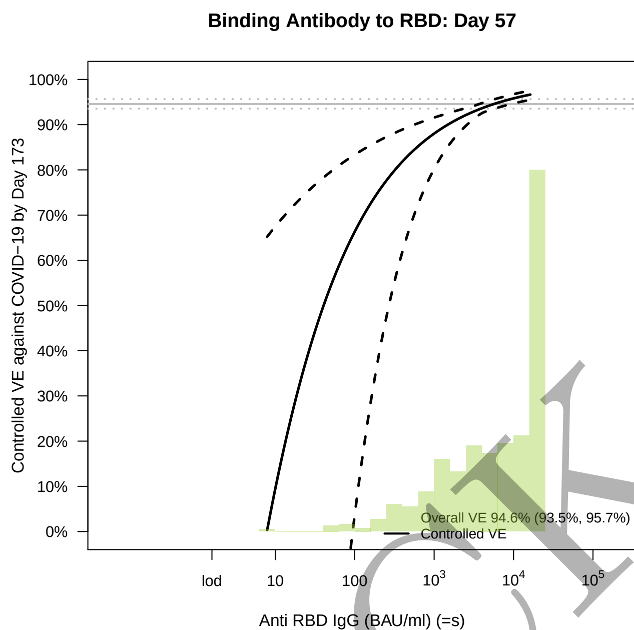
	0	30	60	90	120	150	173
Low:	0	1	3	10	16	22	26
Med:	0	1	2	4	8	10	13
High:	0	1	3	4	10	12	13
Plac:	0	131	305	489	672	869	1010

(a) Marginalized cumulative incidence rate curves for trichotomized Day 57 markers among vaccine recipients. The gray line is the overall cumulative incidence rate curve in the placebo arm.

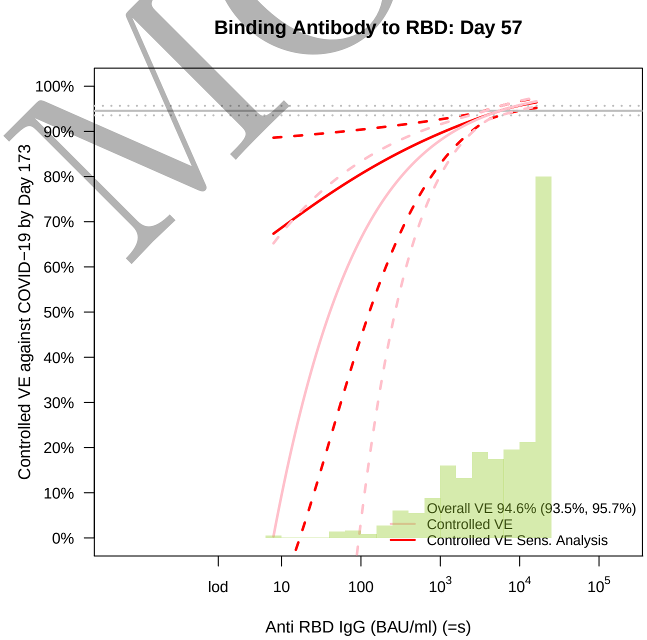


(b) Marginalized cumulative risk by Day 173 as functions of Day 57 markers (=s) among vaccine recipients with 95% bootstrap point-wise confidence bands (10 replicates). The horizontal lines indicate the overall cumulative risk of the placebo and vaccine arms by Day 173 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod =1.6.

Figure 5.9: Marginalized cumulative risk curves (=s).

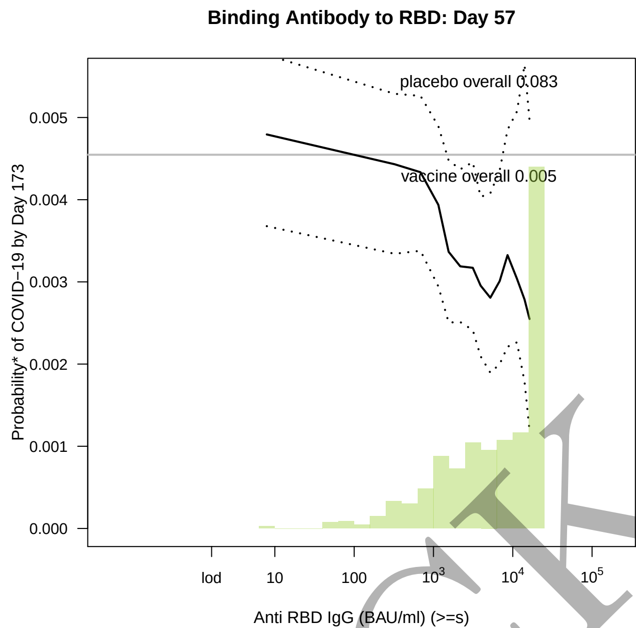


(a) Controlled VE with sensitivity analysis as functions of Day 57 markers (=s) among vaccine recipients with 95% bootstrap point-wise confidence bands (10 replicates). Histograms of the immunological markers in the vaccine arm are overlaid. lod =1.6.

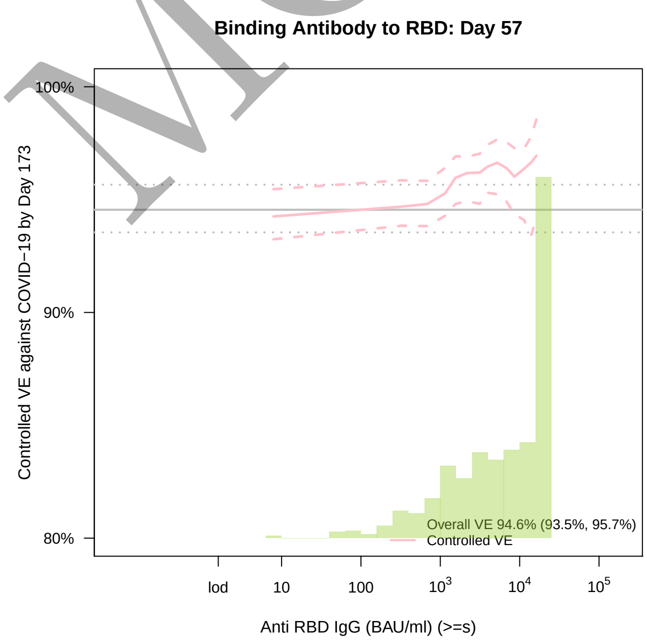


(b) Controlled VE with sensitivity analysis as functions of Day 57 markers (=s) among vaccine recipients with 95% bootstrap point-wise confidence bands (10 replicates). Histograms of the immunological markers in the vaccine arm are overlaid. lod =1.6.

Figure 5.10: Controlled VE curves (=s).



(a) Marginalized cumulative risk by Day 173 post Day 57 visit as functions of Day 57 markers above a threshold ($\geq s$) among vaccine recipients with 95% bootstrap point-wise confidence bands (at least 5 cases are required, 10 replicates). The horizontal lines indicate the overall cumulative risk of the vaccine arm by Day 173 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod =1.6.



(b) Controlled VE as functions of Day 57 markers (>=s) among vaccine recipients with 95% bootstrap point-wise confidence bands (10 replicates). Histograms of the immunological markers in the vaccine arm are overlaid. lod =1.6.

Figure 5.11: Marginalized cumulative risk curves and controlled VE curves (>=s).

Table 5.7: Marginalized cumulative risk by Day 173 as functions of Day 57 Anti RBD IgG (BAU/ml) (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence intervals (10 replicates).

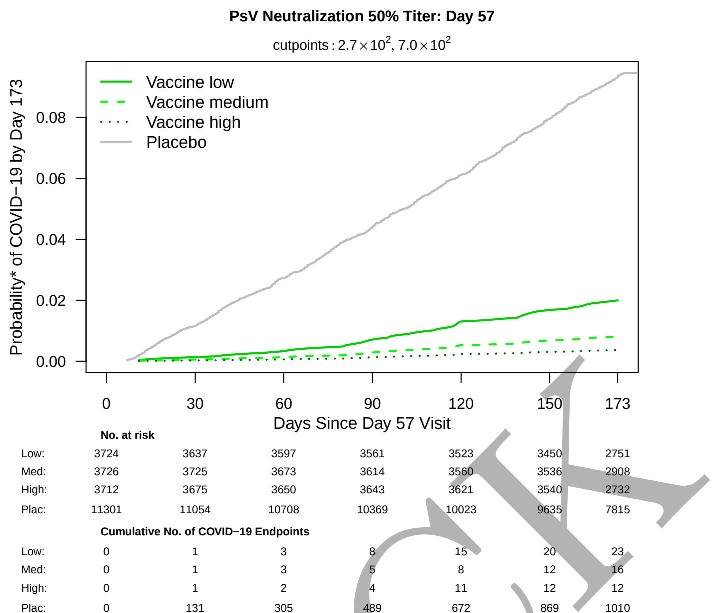
s	Estimate	s	Estimate	s	Estimate	s	Estimate
7.9	.0832 (.0293,.2959)	68	.0332 (.0156,.1021)	548	.0131 (.0085,.0255)	3483	.0057 (.0046,.0069)
9	.0806 (.0286,.2872)	74	.0321 (.0153,.0974)	592	.0127 (.0083,.0241)	3762	.0055 (.0044,.0066)
9	.0781 (.0280,.2785)	80	.0310 (.0150,.0929)	639	.0122 (.0081,.0228)	3798	.0054 (.0044,.0065)
10	.0757 (.0274,.2700)	86	.0300 (.0146,.0886)	690	.0118 (.0079,.0216)	4064	.0053 (.0042,.0063)
11	.0733 (.0268,.2616)	93	.0290 (.0143,.0845)	743	.0114 (.0077,.0205)	4389	.0051 (.0041,.0061)
12	.0710 (.0262,.2533)	101	.0280 (.0140,.0805)	746	.0114 (.0077,.0204)	4741	.0049 (.0039,.0059)
13	.0687 (.0256,.2451)	109	.0271 (.0137,.0766)	806	.0110 (.0075,.0193)	5121	.0047 (.0038,.0058)
14	.0666 (.0251,.2370)	117	.0262 (.0134,.0730)	870	.0106 (.0074,.0183)	5531	.0046 (.0036,.0056)
15	.0645 (.0245,.2291)	127	.0253 (.0131,.0694)	940	.0103 (.0072,.0173)	5974	.0044 (.0035,.0054)
16	.0624 (.0240,.2213)	137	.0244 (.0128,.0660)	1000	.0100 (.0070,.0166)	6453	.0043 (.0033,.0053)
17	.0604 (.0234,.2137)	148	.0236 (.0125,.0628)	1015	.0099 (.0070,.0164)	6791	.0042 (.0033,.0052)
18	.0585 (.0229,.2061)	160	.0228 (.0122,.0597)	1096	.0096 (.0068,.0155)	6970	.0041 (.0032,.0051)
20	.0566 (.0224,.1988)	172	.0221 (.0119,.0567)	1152	.0094 (.0067,.0149)	7528	.0040 (.0031,.0050)
22	.0548 (.0219,.1915)	186	.0213 (.0117,.0538)	1184	.0092 (.0067,.0146)	8131	.0038 (.0030,.0049)
23	.0530 (.0214,.1844)	201	.0206 (.0114,.0511)	1279	.0089 (.0065,.0138)	8782	.0037 (.0028,.0047)
25	.0513 (.0210,.1775)	217	.0199 (.0111,.0485)	1382	.0086 (.0064,.0131)	9486	.0036 (.0027,.0046)
27	.0496 (.0205,.1707)	235	.0192 (.0109,.0460)	1492	.0083 (.0062,.0124)	10246	.0035 (.0026,.0045)
29	.0480 (.0200,.1641)	254	.0186 (.0106,.0437)	1612	.0080 (.0061,.0117)	11067	.0033 (.0025,.0044)
32	.0465 (.0196,.1576)	274	.0179 (.0104,.0414)	1625	.0080 (.0060,.0117)	11504	.0033 (.0024,.0043)
34	.0449 (.0192,.1513)	296	.0173 (.0102,.0393)	1741	.0078 (.0059,.0111)	11953	.0032 (.0024,.0043)
37	.0435 (.0187,.1452)	319	.0167 (.0099,.0372)	1880	.0075 (.0058,.0105)	12911	.0031 (.0023,.0042)
40	.0420 (.0183,.1392)	345	.0162 (.0097,.0353)	2031	.0072 (.0056,.0099)	13945	.0030 (.0022,.0041)
43	.0407 (.0179,.1334)	373	.0156 (.0095,.0335)	2194	.0070 (.0055,.0094)	15063	.0029 (.0021,.0040)
47	.0393 (.0175,.1278)	403	.0151 (.0093,.0317)	2369	.0067 (.0054,.0089)	16269	.0028 (.0020,.0039)
50	.0380 (.0171,.1223)	435	.0146 (.0091,.0300)	2559	.0065 (.0052,.0085)	16269	.0028 (.0020,.0039)
54	.0368 (.0167,.1170)	470	.0141 (.0089,.0284)	2764	.0063 (.0051,.0080)	16269	.0028 (.0020,.0039)
59	.0355 (.0164,.1118)	500	.0137 (.0087,.0272)	2986	.0061 (.0049,.0076)	16269	.0028 (.0020,.0039)
63	.0344 (.0160,.1069)	507	.0136 (.0087,.0269)	3225	.0059 (.0047,.0073)	16269	.0028 (.0020,.0039)

Table 5.8: Controlled VE as functions of Day 57 Anti RBD IgG (BAU/ml) (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence intervals (10 replicates).Overall cumulative incidence from 7 to 173 days post Day 57 was 0.005 in vaccine recipients compared to 0.083 in placebo recipients, with cumulative vaccine efficacy 94.6% (95% CI 93.5 to 95.7%).

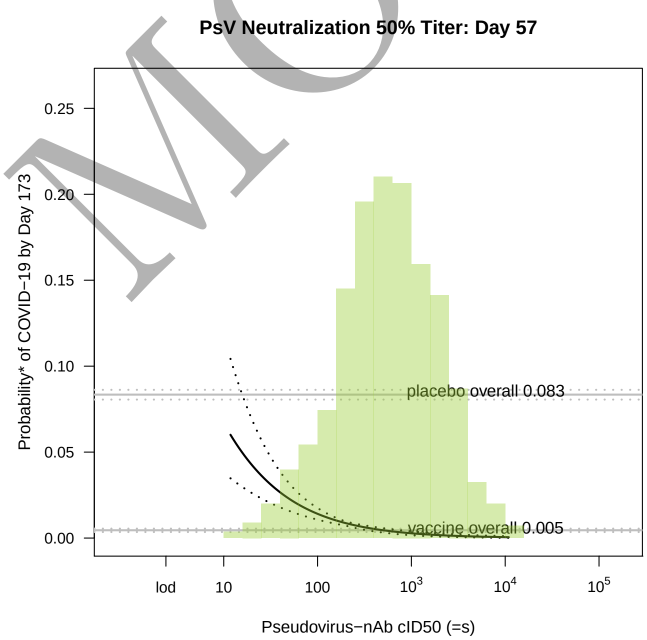
s	Estimate	s	Estimate	s	Estimate	s	Estimate
7.9	.0034 (-2.5294,.6522)	74	.6152 (-0.1619,.8181)	639	.8534 (0.7274,.9037)	4064	.9368 (0.9263,.9481)
9	.0342 (-2.4250,.6598)	80	.6280 (-0.1085,.8222)	690	.8584 (0.7420,.9059)	4389	.9390 (0.9286,.9500)
9	.0642 (-2.3219,.6672)	86	.6404 (-0.0571,.8261)	743	.8631 (0.7553,.9079)	4741	.9411 (0.9308,.9518)
10	.0934 (-2.2201,.6745)	93	.6525 (-0.0076,.8300)	746	.8633 (0.7559,.9080)	5121	.9432 (0.9327,.9537)
11	.1218 (-2.1196,.6816)	101	.6641 (0.0400,.8338)	806	.8680 (0.7690,.9101)	5531	.9451 (0.9345,.9554)
12	.1494 (-2.0206,.6886)	109	.6754 (0.0858,.8375)	870	.8725 (0.7815,.9121)	5974	.9470 (0.9363,.9571)
13	.1762 (-1.9230,.6954)	117	.6863 (0.1298,.8412)	940	.8769 (0.7933,.9141)	6453	.9489 (0.9381,.9587)
14	.2022 (-1.8270,.7021)	127	.6968 (0.1719,.8447)	1000	.8803 (0.8024,.9157)	6791	.9501 (0.9392,.9598)
15	.2275 (-1.7324,.7087)	137	.7070 (0.2124,.8482)	1015	.8811 (0.8045,.9161)	6970	.9506 (0.9398,.9603)
16	.2521 (-1.6395,.7151)	148	.7169 (0.2511,.8516)	1096	.8852 (0.8151,.9180)	7528	.9524 (0.9414,.9619)
17	.2760 (-1.5481,.7214)	160	.7265 (0.2882,.8550)	1152	.8878 (0.8216,.9192)	8131	.9540 (0.9430,.9635)
18	.2992 (-1.4584,.7275)	172	.7357 (0.3237,.8582)	1184	.8892 (0.8251,.9198)	8782	.9556 (0.9446,.9650)
20	.3217 (-1.3704,.7335)	186	.7447 (0.3576,.8614)	1279	.8930 (0.8346,.9216)	9486	.9571 (0.9461,.9665)
22	.3435 (-1.2842,.7394)	201	.7533 (0.3901,.8645)	1382	.8967 (0.8436,.9235)	10246	.9586 (0.9476,.9679)
23	.3647 (-1.1997,.7452)	217	.7617 (0.4210,.8675)	1492	.9002 (0.8520,.9253)	11067	.9601 (0.9489,.9693)
25	.3853 (-1.1170,.7508)	235	.7698 (0.4505,.8705)	1612	.9037 (0.8599,.9271)	11504	.9608 (0.9496,.9700)
27	.4052 (-1.0361,.7563)	254	.7776 (0.4787,.8734)	1625	.9040 (0.8607,.9273)	11953	.9615 (0.9502,.9706)
29	.4246 (-0.9571,.7617)	274	.7851 (0.5056,.8763)	1741	.9070 (0.8673,.9289)	12911	.9628 (0.9514,.9719)
32	.4433 (-0.8800,.7670)	296	.7924 (0.5312,.8791)	1880	.9102 (0.8744,.9306)	13945	.9641 (0.9526,.9731)
34	.4615 (-0.8048,.7722)	319	.7995 (0.5555,.8818)	2031	.9133 (0.8810,.9322)	15063	.9653 (0.9538,.9743)
37	.4792 (-0.7315,.7772)	345	.8063 (0.5787,.8845)	2194	.9163 (0.8873,.9338)	16269	.9665 (0.9549,.9755)
40	.4962 (-0.6603,.7822)	373	.8130 (0.6008,.8871)	2369	.9192 (0.8933,.9354)	16269	.9665 (0.9549,.9755)
43	.5128 (-0.5910,.7870)	403	.8193 (0.6218,.8896)	2559	.9220 (0.8990,.9370)	16269	.9665 (0.9549,.9755)
47	.5289 (-0.5237,.7918)	435	.8255 (0.6417,.8921)	2764	.9247 (0.9043,.9387)	16269	.9665 (0.9549,.9755)
50	.5444 (-0.4584,.7964)	470	.8315 (0.6607,.8945)	2986	.9273 (0.9094,.9403)	16269	.9665 (0.9549,.9755)
54	.5595 (-0.3951,.8009)	500	.8362 (0.6753,.8965)	3225	.9298 (0.9142,.9420)	93.1	.6525 (-0.0076,.8300)
59	.5741 (-0.3338,.8054)	507	.8372 (0.6787,.8969)	3483	.9322 (0.9186,.9441)	1492	.9002 (0.8520,.9253)
63	.5882 (-0.2745,.8097)	548	.8428 (0.6958,.8992)	3762	.9346 (0.9227,.9461)	6791	.9501 (0.9392,.9598)
68	.6019 (-0.2172,.8139)	592	.8482 (0.7120,.9015)	3798	.9348 (0.9232,.9464)		

Table 5.9: Controlled VE with sensitivity analysis as functions of Day 57 Anti RBD IgG (BAU/ml) (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence intervals (10 replicates).

s	Estimate	s	Estimate	s	Estimate	s	Estimate
7.9	.6735 (-0.1561,.8861)	74	.7915 (0.3705,.9014)	639	.8807 (0.7782,.9217)	4064	.9372 (0.9267,.9484)
9	.6779 (-0.1424,.8865)	80	.7952 (0.3896,.9021)	690	.8834 (0.7875,.9225)	4389	.9392 (0.9289,.9501)
9	.6822 (-0.1283,.8870)	86	.7988 (0.4084,.9027)	743	.8859 (0.7962,.9233)	4741	.9412 (0.9309,.9519)
10	.6865 (-0.1136,.8874)	93	.8024 (0.4270,.9033)	746	.8861 (0.7966,.9233)	5121	.9432 (0.9327,.9537)
11	.6907 (-0.0985,.8879)	101	.8059 (0.4453,.9040)	806	.8887 (0.8053,.9242)	5531	.9451 (0.9345,.9554)
12	.6950 (-0.0829,.8884)	109	.8094 (0.4633,.9046)	870	.8913 (0.8137,.9251)	5974	.9470 (0.9363,.9571)
13	.6993 (-0.0669,.8888)	117	.8129 (0.4810,.9053)	940	.8939 (0.8218,.9260)	6453	.9488 (0.9380,.9587)
14	.7036 (-0.0505,.8893)	127	.8164 (0.4984,.9060)	1000	.8959 (0.8281,.9267)	6791	.9499 (0.9390,.9597)
15	.7078 (-0.0336,.8898)	137	.8198 (0.5155,.9066)	1015	.8964 (0.8296,.9268)	6970	.9505 (0.9396,.9601)
16	.7120 (-0.0163,.8903)	148	.8231 (0.5322,.9073)	1096	.8989 (0.8371,.9277)	7528	.9521 (0.9411,.9617)
17	.7162 (0.0013,.8908)	160	.8265 (0.5485,.9080)	1152	.9005 (0.8419,.9283)	8131	.9536 (0.9425,.9632)
18	.7204 (0.0193,.8913)	172	.8298 (0.5644,.9087)	1184	.9014 (0.8444,.9287)	8782	.9550 (0.9439,.9646)
20	.7246 (0.0376,.8918)	186	.8331 (0.5800,.9094)	1279	.9038 (0.8514,.9296)	9486	.9564 (0.9452,.9659)
22	.7288 (0.0563,.8923)	201	.8363 (0.5953,.9101)	1382	.9063 (0.8581,.9306)	10246	.9577 (0.9464,.9672)
23	.7329 (0.0752,.8929)	217	.8395 (0.6101,.9108)	1492	.9086 (0.8645,.9316)	11067	.9589 (0.9475,.9684)
25	.7370 (0.0943,.8934)	235	.8427 (0.6245,.9115)	1612	.9110 (0.8706,.9327)	11504	.9595 (0.9480,.9690)
27	.7411 (0.1137,.8939)	254	.8458 (0.6386,.9123)	1625	.9112 (0.8712,.9328)	11953	.9601 (0.9485,.9696)
29	.7451 (0.1332,.8945)	274	.8489 (0.6523,.9130)	1741	.9133 (0.8764,.9337)	12911	.9613 (0.9494,.9707)
32	.7492 (0.1529,.8950)	296	.8520 (0.6656,.9137)	1880	.9156 (0.8820,.9348)	13945	.9623 (0.9503,.9718)
34	.7532 (0.1727,.8956)	319	.8550 (0.6785,.9145)	2031	.9179 (0.8873,.9358)	15063	.9634 (0.9512,.9729)
37	.7571 (0.1926,.8961)	345	.8580 (0.6910,.9153)	2194	.9202 (0.8925,.9369)	16269	.9644 (0.9520,.9739)
40	.7611 (0.2126,.8967)	373	.8609 (0.7032,.9160)	2369	.9224 (0.8975,.9380)	16269	.9644 (0.9520,.9739)
43	.7650 (0.2326,.8973)	403	.8639 (0.7150,.9168)	2559	.9246 (0.9023,.9391)	16269	.9644 (0.9520,.9739)
47	.7689 (0.2526,.8978)	435	.8667 (0.7264,.9176)	2764	.9268 (0.9070,.9404)	16269	.9644 (0.9520,.9739)
50	.7727 (0.2725,.8984)	470	.8696 (0.7374,.9184)	2986	.9289 (0.9114,.9416)	16269	.9644 (0.9520,.9739)
54	.7766 (0.2924,.8990)	500	.8719 (0.7462,.9190)	3225	.9310 (0.9157,.9430)	93.1	.6525 (-0.0076,.8300)
59	.7803 (0.3121,.8996)	507	.8724 (0.7481,.9192)	3483	.9331 (0.9197,.9448)	1492	.9002 (0.8520,.9253)
63	.7841 (0.3318,.9002)	548	.8752 (0.7585,.9200)	3762	.9352 (0.9234,.9466)	6791	.9501 (0.9392,.9598)
68	.7878 (0.3512,.9008)	592	.8780 (0.7685,.9208)	3798	.9354 (0.9238,.9469)		

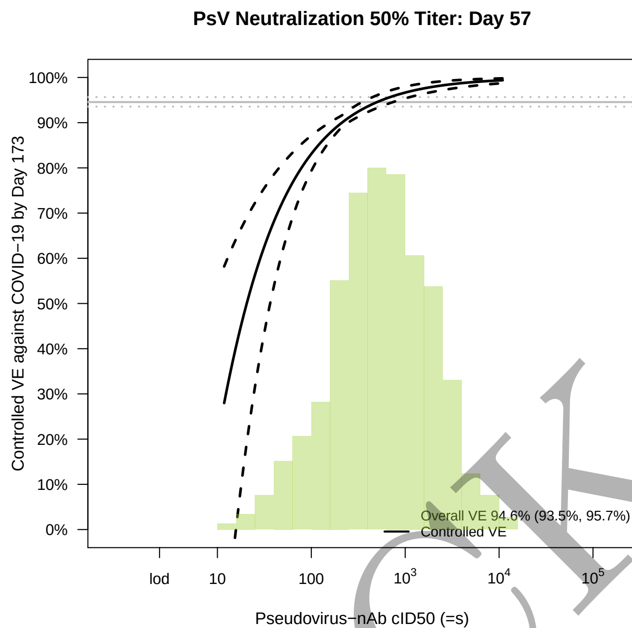


(a) Marginalized cumulative incidence rate curves for trichotomized Day 57 markers among vaccine recipients. The gray line is the overall cumulative incidence rate curve in the placebo arm.

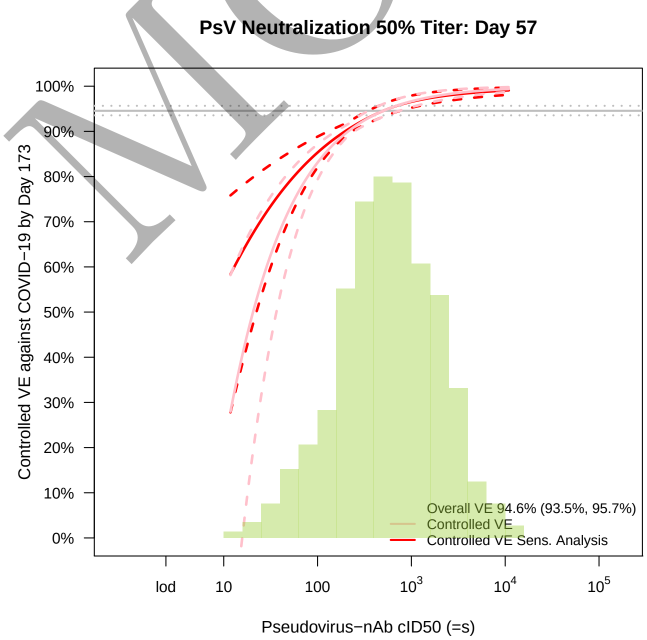


(b) Marginalized cumulative risk by Day 173 as functions of Day 57 markers (=s) among vaccine recipients with 95% bootstrap point-wise confidence bands (10 replicates). The horizontal lines indicate the overall cumulative risk of the placebo and vaccine arms by Day 173 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod =2.4.

Figure 5.12: Marginalized cumulative risk curves (=s).

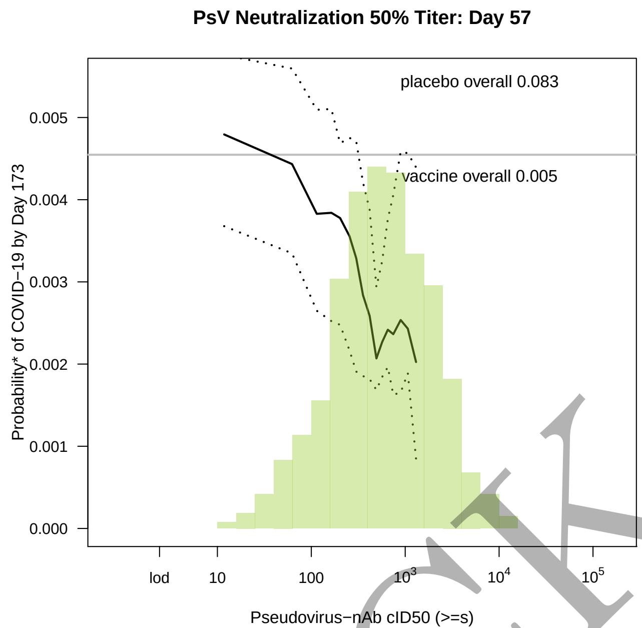


(a) Controlled VE with sensitivity analysis as functions of Day 57 markers (=s) among vaccine recipients with 95% bootstrap point-wise confidence bands (10 replicates). Histograms of the immunological markers in the vaccine arm are overlaid. lod =2.4.

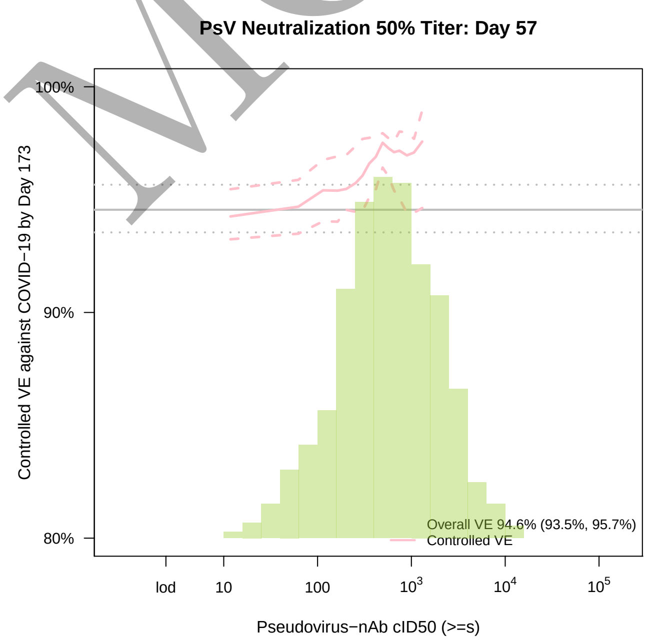


(b) Controlled VE with sensitivity analysis as functions of Day 57 markers (=s) among vaccine recipients with 95% bootstrap point-wise confidence bands (10 replicates). Histograms of the immunological markers in the vaccine arm are overlaid. lod =2.4.

Figure 5.13: Controlled VE curves (=s).



(a) Marginalized cumulative risk by Day 173 post Day 57 visit as functions of Day 57 markers above a threshold ($\geq s$) among vaccine recipients with 95% bootstrap point-wise confidence bands (at least 5 cases are required, 10 replicates). The horizontal lines indicate the overall cumulative risk of the vaccine arm by Day 173 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod =2.4.



(b) Controlled VE as functions of Day 57 markers (>=s) among vaccine recipients with 95% bootstrap point-wise confidence bands (10 replicates). Histograms of the immunological markers in the vaccine arm are overlaid. lod =2.4.

Figure 5.14: Marginalized cumulative risk curves and controlled VE curves (>=s).

Table 5.10: Marginalized cumulative risk by Day 173 as functions of Day 57 Pseudovirus-nAb cID50 (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence intervals (10 replicates).

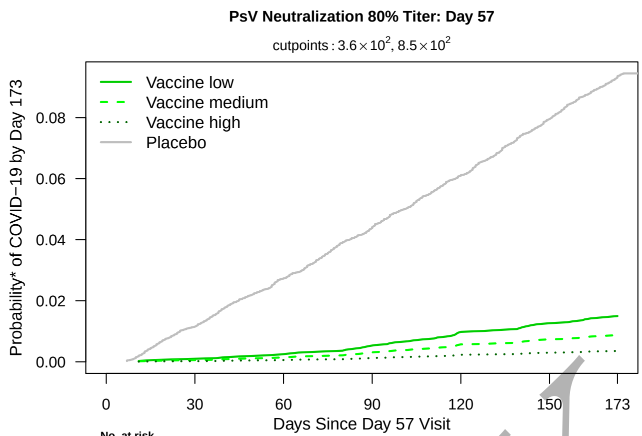
s	Estimate	s	Estimate	s	Estimate	s	Estimate
11.8	.0601 (.0348,.1043)	81	.0163 (.0120,.0208)	427	.0051 (.0037,.0063)	1946	.0017 (.0009,.0027)
13	.0575 (.0335,.0989)	87	.0155 (.0115,.0196)	457	.0049 (.0035,.0060)	1948	.0017 (.0009,.0027)
14	.0549 (.0323,.0939)	93	.0148 (.0111,.0185)	489	.0046 (.0033,.0058)	2085	.0017 (.0008,.0026)
15	.0525 (.0311,.0890)	100	.0141 (.0107,.0174)	490	.0046 (.0033,.0058)	2234	.0016 (.0008,.0025)
16	.0502 (.0300,.0843)	107	.0134 (.0103,.0164)	500	.0046 (.0032,.0058)	2393	.0015 (.0007,.0024)
17	.0479 (.0289,.0798)	115	.0128 (.0099,.0155)	525	.0044 (.0031,.0056)	2519	.0014 (.0007,.0024)
18	.0458 (.0278,.0756)	118	.0126 (.0098,.0152)	562	.0042 (.0029,.0054)	2564	.0014 (.0007,.0024)
19	.0437 (.0268,.0715)	123	.0122 (.0095,.0146)	602	.0040 (.0027,.0052)	2747	.0014 (.0006,.0023)
20	.0418 (.0258,.0676)	132	.0116 (.0091,.0137)	645	.0038 (.0025,.0050)	2944	.0013 (.0006,.0022)
22	.0399 (.0248,.0639)	141	.0111 (.0088,.0129)	655	.0038 (.0025,.0050)	3154	.0012 (.0005,.0021)
24	.0381 (.0239,.0604)	152	.0106 (.0085,.0122)	691	.0036 (.0024,.0048)	3379	.0012 (.0005,.0020)
25	.0364 (.0230,.0570)	162	.0101 (.0081,.0115)	741	.0035 (.0022,.0046)	3621	.0011 (.0005,.0020)
27	.0347 (.0222,.0538)	164	.0100 (.0081,.0114)	794	.0033 (.0021,.0045)	3879	.0011 (.0004,.0019)
29	.0331 (.0214,.0508)	174	.0096 (.0078,.0108)	850	.0031 (.0019,.0043)	4156	.0010 (.0004,.0018)
31	.0316 (.0206,.0479)	186	.0091 (.0075,.0102)	911	.0030 (.0018,.0041)	4453	.0010 (.0004,.0017)
33	.0302 (.0198,.0452)	200	.0087 (.0072,.0097)	927	.0029 (.0018,.0041)	4771	.0009 (.0004,.0017)
36	.0288 (.0190,.0426)	205	.0085 (.0071,.0095)	976	.0028 (.0017,.0040)	5112	.0009 (.0003,.0016)
38	.0274 (.0183,.0401)	214	.0083 (.0068,.0092)	1000	.0028 (.0017,.0039)	5477	.0008 (.0003,.0016)
41	.0262 (.0176,.0378)	229	.0079 (.0064,.0088)	1046	.0027 (.0016,.0038)	5868	.0008 (.0003,.0015)
44	.0250 (.0170,.0356)	246	.0075 (.0060,.0085)	1121	.0026 (.0015,.0037)	6288	.0008 (.0003,.0015)
47	.0238 (.0163,.0336)	263	.0072 (.0057,.0082)	1201	.0025 (.0014,.0036)	6737	.0007 (.0003,.0014)
50	.0227 (.0157,.0316)	282	.0068 (.0053,.0079)	1286	.0023 (.0013,.0034)	7218	.0007 (.0002,.0014)
54	.0217 (.0151,.0297)	302	.0065 (.0050,.0076)	1378	.0022 (.0012,.0033)	7733	.0007 (.0002,.0013)
58	.0207 (.0146,.0280)	324	.0062 (.0047,.0073)	1477	.0021 (.0011,.0032)	8286	.0006 (.0002,.0013)
62	.0197 (.0140,.0264)	345	.0059 (.0044,.0071)	1569	.0020 (.0011,.0031)	8878	.0006 (.0002,.0012)
66	.0188 (.0135,.0249)	347	.0059 (.0044,.0070)	1582	.0020 (.0011,.0031)	9512	.0006 (.0002,.0012)
71	.0179 (.0130,.0234)	372	.0056 (.0042,.0068)	1695	.0019 (.0010,.0030)	10191	.0005 (.0002,.0011)
76	.0171 (.0125,.0221)	398	.0054 (.0039,.0065)	1816	.0018 (.0009,.0028)	10919	.0005 (.0002,.0011)

Table 5.11: Controlled VE as functions of Day 57 Pseudovirus-nAb cID50 (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence intervals (10 replicates).Overall cumulative incidence from 7 to 173 days post Day 57 was 0.005 in vaccine recipients compared to 0.083 in placebo recipients, with cumulative vaccine efficacy 94.6% (95% CI 93.5 to 95.7%).

s	Estimate	s	Estimate	s	Estimate	s	Estimate
11.8	.2798 (-0.2486,.5819)	87	.8141 (0.7674,.8612)	489	.9446 (0.9316,.9598)	2234	.9811 (0.9703,.9908)
13	.3114 (-0.1849,.5971)	93	.8228 (0.7808,.8665)	490	.9446 (0.9316,.9598)	2393	.9820 (0.9714,.9914)
14	.3418 (-0.1239,.6118)	100	.8311 (0.7935,.8716)	500	.9454 (0.9324,.9606)	2519	.9826 (0.9721,.9918)
15	.3709 (-0.0654,.6260)	107	.8391 (0.8054,.8765)	525	.9472 (0.9342,.9624)	2564	.9828 (0.9724,.9919)
16	.3988 (-0.0094,.6397)	115	.8466 (0.8166,.8812)	562	.9497 (0.9366,.9648)	2747	.9837 (0.9734,.9924)
17	.4256 (0.0442,.6529)	118	.8490 (0.8201,.8827)	602	.9521 (0.9390,.9671)	2944	.9844 (0.9744,.9929)
18	.4513 (0.0954,.6657)	123	.8538 (0.8272,.8857)	645	.9544 (0.9412,.9692)	3154	.9852 (0.9754,.9934)
19	.4759 (0.1442,.6780)	132	.8607 (0.8369,.8901)	655	.9549 (0.9417,.9697)	3379	.9859 (0.9763,.9938)
20	.4995 (0.1908,.6899)	141	.8673 (0.8460,.8943)	691	.9566 (0.9434,.9712)	3621	.9866 (0.9772,.9942)
22	.5221 (0.2352,.7014)	152	.8735 (0.8547,.8983)	741	.9587 (0.9455,.9731)	3879	.9872 (0.9780,.9946)
24	.5437 (0.2775,.7124)	162	.8795 (0.8629,.9022)	794	.9606 (0.9475,.9748)	4156	.9878 (0.9788,.9949)
25	.5644 (0.3176,.7231)	164	.8802 (0.8637,.9027)	850	.9625 (0.9495,.9764)	4453	.9884 (0.9796,.9953)
27	.5842 (0.3558,.7334)	174	.8852 (0.8706,.9060)	911	.9643 (0.9514,.9780)	4771	.9890 (0.9804,.9956)
29	.6031 (0.3921,.7434)	186	.8906 (0.8779,.9096)	927	.9647 (0.9518,.9783)	5112	.9895 (0.9811,.9959)
31	.6213 (0.4265,.7529)	200	.8958 (0.8847,.9130)	976	.9660 (0.9532,.9794)	5477	.9900 (0.9818,.9961)
33	.6386 (0.4592,.7622)	205	.8979 (0.8875,.9146)	1000	.9666 (0.9538,.9799)	5868	.9905 (0.9825,.9964)
36	.6552 (0.4902,.7711)	214	.9007 (0.8906,.9168)	1046	.9676 (0.9549,.9807)	6288	.9909 (0.9831,.9966)
38	.6710 (0.5195,.7797)	229	.9054 (0.8955,.9215)	1121	.9692 (0.9566,.9820)	6737	.9914 (0.9837,.9968)
41	.6862 (0.5472,.7879)	246	.9099 (0.8998,.9262)	1201	.9706 (0.9582,.9831)	7218	.9918 (0.9843,.9970)
44	.7007 (0.5735,.7959)	263	.9142 (0.9039,.9305)	1286	.9720 (0.9598,.9842)	7733	.9922 (0.9849,.9972)
47	.7145 (0.5984,.8036)	282	.9182 (0.9075,.9346)	1378	.9734 (0.9612,.9852)	8286	.9925 (0.9854,.9974)
50	.7277 (0.6219,.8110)	302	.9221 (0.9109,.9385)	1477	.9746 (0.9627,.9862)	8878	.9929 (0.9859,.9976)
54	.7404 (0.6440,.8181)	324	.9258 (0.9142,.9421)	1569	.9757 (0.9639,.9870)	9512	.9932 (0.9864,.9977)
58	.7524 (0.6650,.8250)	345	.9291 (0.9172,.9453)	1582	.9758 (0.9641,.9871)	10191	.9936 (0.9869,.9979)
62	.7639 (0.6848,.8316)	347	.9293 (0.9174,.9455)	1695	.9770 (0.9654,.9879)	10919	.9939 (0.9874,.9980)
66	.7749 (0.7035,.8380)	372	.9327 (0.9205,.9487)	1816	.9781 (0.9667,.9887)	35.6	.6552 (.4902,.7711)
71	.7854 (0.7211,.8441)	398	.9359 (0.9234,.9517)	1946	.9791 (0.9679,.9894)	214	.9007 (.8906,.9168)
76	.7954 (0.7377,.8501)	427	.9389 (0.9263,.9545)	1948	.9792 (0.9679,.9894)	562	.9497 (.9366,.9648)
81	.8050 (0.7533,.8558)	457	.9418 (0.9290,.9572)	2085	.9801 (0.9691,.9901)		

Table 5.12: Controlled VE with sensitivity analysis as functions of Day 57 Pseudovirus-nAb cID50 (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence intervals (10 replicates).

s	Estimate	s	Estimate	s	Estimate	s	Estimate
11.8	.5836 (.2781,.7583)	87	.8419 (.8022,.8820)	489	.9446 (.9316,.9598)	2234	.9786 (.9663,.9895)
13	.5958 (.3044,.7635)	93	.8477 (.8116,.8852)	490	.9446 (.9316,.9598)	2393	.9794 (.9672,.9901)
14	.6077 (.3303,.7687)	100	.8533 (.8206,.8885)	500	.9454 (.9324,.9606)	2519	.9800 (.9679,.9905)
15	.6195 (.3556,.7738)	107	.8588 (.8292,.8916)	525	.9472 (.9342,.9624)	2564	.9802 (.9681,.9906)
16	.6309 (.3803,.7788)	115	.8641 (.8375,.8947)	562	.9497 (.9366,.9648)	2747	.9809 (.9690,.9912)
17	.6421 (.4045,.7837)	118	.8657 (.8401,.8957)	602	.9520 (.9388,.9670)	2944	.9816 (.9698,.9916)
18	.6531 (.4281,.7886)	123	.8692 (.8454,.8978)	645	.9542 (.9410,.9691)	3154	.9823 (.9706,.9921)
19	.6638 (.4510,.7934)	132	.8742 (.8527,.9007)	655	.9547 (.9414,.9695)	3379	.9830 (.9714,.9925)
20	.6743 (.4734,.7982)	141	.8790 (.8597,.9037)	691	.9563 (.9430,.9710)	3621	.9836 (.9721,.9929)
22	.6845 (.4951,.8029)	152	.8837 (.8664,.9065)	741	.9582 (.9449,.9728)	3879	.9842 (.9728,.9933)
24	.6945 (.5162,.8075)	162	.8883 (.8729,.9094)	794	.9600 (.9468,.9744)	4156	.9848 (.9735,.9937)
25	.7042 (.5367,.8120)	164	.8888 (.8736,.9097)	850	.9618 (.9485,.9760)	4453	.9853 (.9742,.9940)
27	.7137 (.5565,.8165)	174	.8927 (.8790,.9121)	911	.9634 (.9502,.9774)	4771	.9859 (.9749,.9943)
29	.7230 (.5757,.8208)	186	.8970 (.8850,.9148)	927	.9638 (.9506,.9778)	5112	.9864 (.9755,.9946)
31	.7320 (.5942,.8252)	200	.9011 (.8906,.9175)	976	.9650 (.9518,.9788)	5477	.9869 (.9761,.9949)
33	.7408 (.6121,.8294)	205	.9028 (.8929,.9187)	1000	.9655 (.9523,.9792)	5868	.9873 (.9767,.9952)
36	.7494 (.6294,.8336)	214	.9052 (.8955,.9205)	1046	.9664 (.9533,.9800)	6288	.9878 (.9772,.9954)
38	.7577 (.6461,.8377)	229	.9090 (.8995,.9245)	1121	.9678 (.9547,.9812)	6737	.9882 (.9778,.9957)
41	.7659 (.6622,.8418)	246	.9128 (.9031,.9286)	1201	.9692 (.9561,.9823)	7218	.9886 (.9783,.9959)
44	.7738 (.6777,.8458)	263	.9165 (.9065,.9324)	1286	.9704 (.9575,.9833)	7733	.9890 (.9788,.9961)
47	.7815 (.6926,.8497)	282	.9200 (.9095,.9361)	1378	.9716 (.9587,.9843)	8286	.9894 (.9793,.9963)
50	.7890 (.7069,.8535)	302	.9235 (.9125,.9395)	1477	.9728 (.9599,.9852)	8878	.9898 (.9797,.9965)
54	.7963 (.7207,.8573)	324	.9268 (.9154,.9429)	1569	.9737 (.9610,.9859)	9512	.9901 (.9802,.9967)
58	.8033 (.7339,.8610)	345	.9298 (.9180,.9458)	1582	.9739 (.9611,.9860)	10191	.9905 (.9806,.9968)
62	.8102 (.7466,.8647)	347	.9300 (.9182,.9460)	1695	.9749 (.9622,.9868)	10919	.9908 (.9811,.9970)
66	.8169 (.7588,.8682)	372	.9331 (.9210,.9490)	1816	.9759 (.9633,.9876)	35.6	.6552 (.4902,.7711)
71	.8234 (.7705,.8718)	398	.9361 (.9237,.9519)	1946	.9768 (.9644,.9883)	214	.9007 (.8906,.9168)
76	.8298 (.7817,.8752)	427	.9390 (.9264,.9546)	1948	.9768 (.9644,.9883)	562	.9497 (.9366,.9648)
81	.8359 (.7924,.8786)	457	.9419 (.9291,.9572)	2085	.9777 (.9653,.9889)		



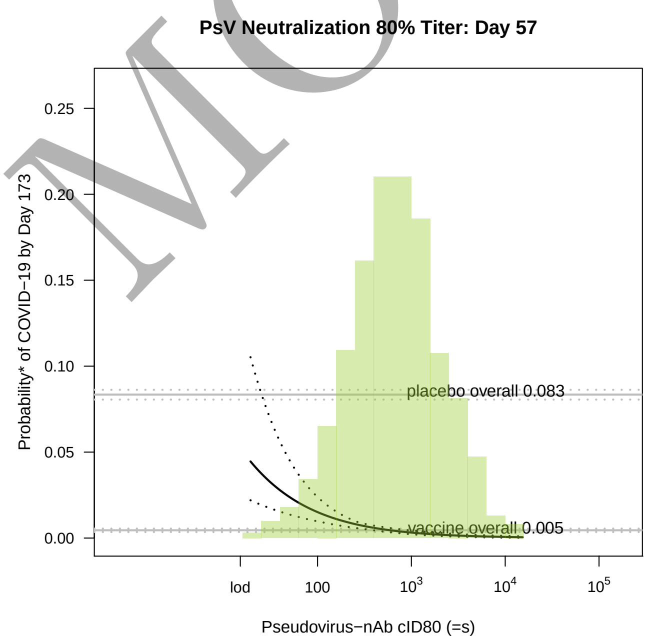
No. at risk

	0	30	60	90	120	150	173
Low:	3722	3619	3532	3489	3411	3342	2815
Med:	3720	3703	3680	3634	3630	3571	2812
High:	3721	3716	3707	3694	3664	3611	2765
Plac:	11301	11054	10708	10369	10023	9635	7815

Cumulative No. of COVID−19 Endpoints

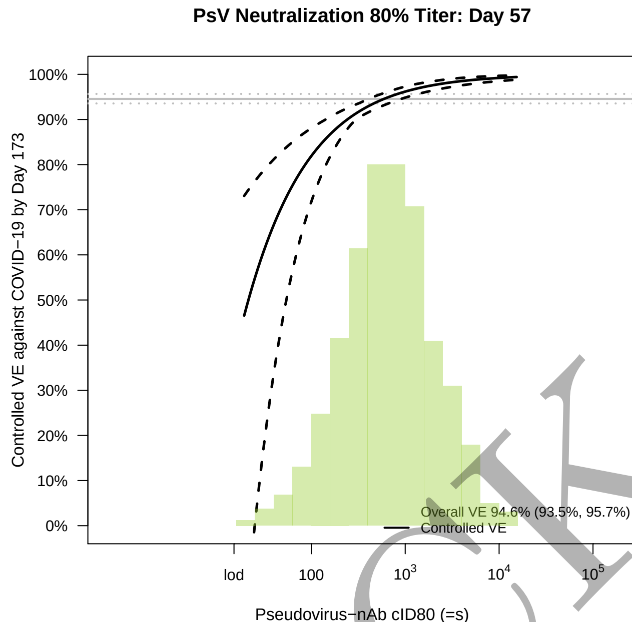
	0	30	60	90	120	150	173
Low:	0	1	2	7	15	18	21
Med:	0	2	5	8	14	17	19
High:	0	0	1	2	5	8	11
Plac:	0	131	305	489	672	869	1010

(a) Marginalized cumulative incidence rate curves for trichotomized Day 57 markers among vaccine recipients. The gray line is the overall cumulative incidence rate curve in the placebo arm.

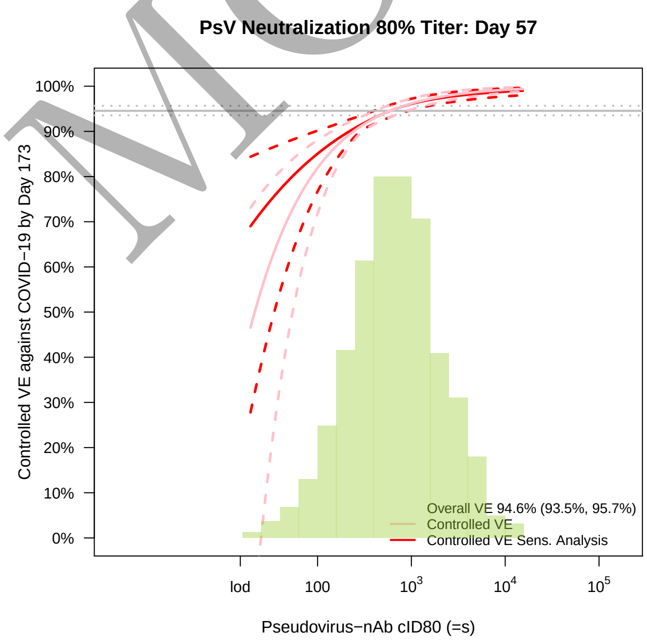


(b) Marginalized cumulative risk by Day 173 as functions of Day 57 markers (=s) among vaccine recipients with 95% bootstrap point-wise confidence bands (10 replicates). The horizontal lines indicate the overall cumulative risk of the placebo and vaccine arms by Day 173 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod =15.

Figure 5.15: Marginalized cumulative risk curves (=s).

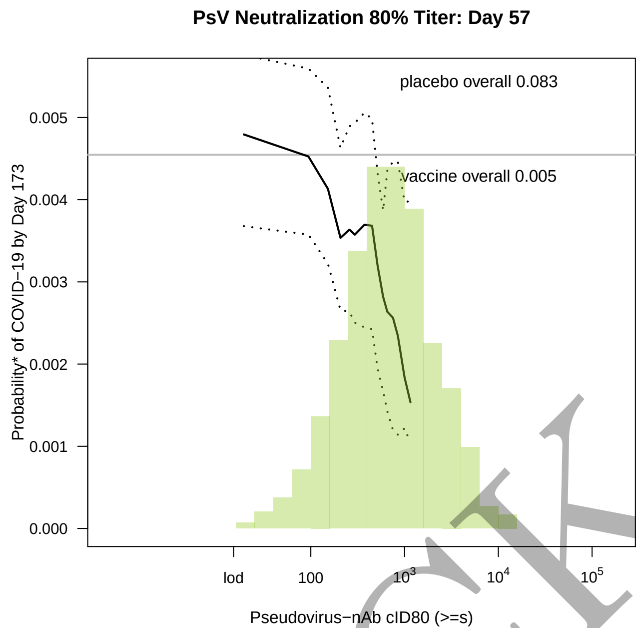


(a) Controlled VE with sensitivity analysis as functions of Day 57 markers (=s) among vaccine recipients with 95% bootstrap pointwise confidence bands (10 replicates). Histograms of the immunological markers in the vaccine arm are overlaid. lod =15.

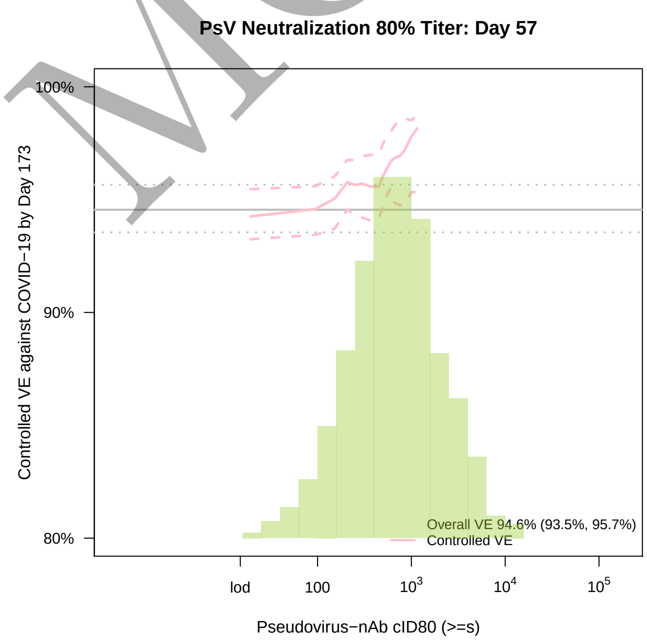


(b) Controlled VE with sensitivity analysis as functions of Day 57 markers (=s) among vaccine recipients with 95% bootstrap pointwise confidence bands (10 replicates). Histograms of the immunological markers in the vaccine arm are overlaid. lod =15.

Figure 5.16: Controlled VE curves (=s).



(a) Marginalized cumulative risk by Day 173 post Day 57 visit as functions of Day 57 markers above a threshold ($\geq s$) among vaccine recipients with 95% bootstrap point-wise confidence bands (at least 5 cases are required, 10 replicates). The horizontal lines indicate the overall cumulative risk of the vaccine arm by Day 173 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod =15.



(b) Controlled VE as functions of Day 57 markers (>=s) among vaccine recipients with 95% bootstrap point-wise confidence bands (10 replicates). Histograms of the immunological markers in the vaccine arm are overlaid. lod =15.

Figure 5.17: Marginalized cumulative risk curves and controlled VE curves (>=s).

Table 5.13: Marginalized cumulative risk by Day 173 as functions of Day 57 Pseudovirus-nAb cID80 (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence intervals (10 replicates).

s	Estimate	s	Estimate	s	Estimate	s	Estimate
19.3	.0446 (.0220,.1052)	128	.0128 (.0086,.0189)	584	.0046 (.0034,.0059)	2659	.0016 (.0010,.0026)
21	.0427 (.0213,.0994)	137	.0123 (.0083,.0178)	602	.0045 (.0033,.0058)	2787	.0016 (.0009,.0025)
22	.0409 (.0206,.0939)	146	.0117 (.0080,.0167)	644	.0043 (.0032,.0056)	2844	.0016 (.0009,.0025)
24	.0391 (.0199,.0887)	156	.0112 (.0077,.0156)	689	.0041 (.0030,.0054)	3043	.0015 (.0008,.0024)
25	.0375 (.0193,.0837)	160	.0110 (.0076,.0153)	738	.0039 (.0029,.0052)	3255	.0014 (.0008,.0023)
27	.0359 (.0186,.0789)	167	.0107 (.0074,.0146)	756	.0039 (.0028,.0051)	3482	.0014 (.0007,.0022)
29	.0343 (.0180,.0744)	179	.0102 (.0071,.0137)	789	.0037 (.0027,.0050)	3725	.0013 (.0007,.0022)
31	.0328 (.0174,.0701)	191	.0098 (.0069,.0129)	844	.0036 (.0026,.0048)	3986	.0012 (.0007,.0021)
33	.0314 (.0168,.0661)	205	.0093 (.0066,.0121)	903	.0034 (.0024,.0046)	4264	.0012 (.0006,.0020)
35	.0301 (.0163,.0622)	207	.0093 (.0066,.0119)	966	.0033 (.0023,.0045)	4561	.0011 (.0006,.0019)
38	.0288 (.0158,.0586)	219	.0089 (.0064,.0113)	1000	.0032 (.0022,.0044)	4880	.0011 (.0005,.0019)
41	.0275 (.0152,.0551)	234	.0085 (.0061,.0106)	1014	.0032 (.0022,.0044)	5221	.0010 (.0005,.0018)
43	.0263 (.0147,.0519)	251	.0081 (.0059,.0099)	1034	.0031 (.0022,.0043)	5585	.0010 (.0005,.0017)
46	.0252 (.0142,.0488)	262	.0079 (.0058,.0095)	1106	.0030 (.0020,.0042)	5975	.0009 (.0004,.0017)
50	.0241 (.0138,.0459)	268	.0078 (.0057,.0093)	1183	.0028 (.0019,.0040)	6392	.0009 (.0004,.0016)
53	.0230 (.0133,.0431)	287	.0074 (.0055,.0088)	1266	.0027 (.0018,.0039)	6838	.0009 (.0004,.0015)
57	.0220 (.0129,.0405)	307	.0071 (.0053,.0085)	1354	.0026 (.0017,.0037)	7316	.0008 (.0004,.0015)
61	.0210 (.0125,.0381)	328	.0068 (.0051,.0081)	1448	.0025 (.0016,.0036)	7826	.0008 (.0003,.0014)
65	.0201 (.0120,.0358)	351	.0065 (.0049,.0078)	1550	.0024 (.0015,.0035)	8373	.0008 (.0003,.0014)
70	.0192 (.0117,.0336)	376	.0062 (.0047,.0075)	1570	.0023 (.0015,.0034)	8957	.0007 (.0003,.0013)
74	.0184 (.0113,.0315)	402	.0059 (.0044,.0072)	1658	.0023 (.0014,.0033)	9582	.0007 (.0003,.0013)
80	.0176 (.0109,.0296)	430	.0057 (.0042,.0069)	1773	.0022 (.0014,.0032)	10251	.0007 (.0003,.0013)
85	.0168 (.0105,.0278)	445	.0055 (.0041,.0068)	1897	.0021 (.0013,.0031)	10967	.0006 (.0003,.0012)
91	.0161 (.0102,.0261)	460	.0054 (.0040,.0067)	1993	.0020 (.0012,.0030)	11733	.0006 (.0002,.0012)
97	.0154 (.0098,.0245)	492	.0052 (.0038,.0065)	2030	.0020 (.0012,.0030)	12552	.0006 (.0002,.0011)
104	.0147 (.0095,.0230)	500	.0051 (.0038,.0064)	2171	.0019 (.0012,.0029)	13428	.0005 (.0002,.0011)
111	.0140 (.0092,.0215)	526	.0049 (.0037,.0062)	2323	.0018 (.0011,.0028)	14365	.0005 (.0002,.0011)
119	.0134 (.0089,.0202)	563	.0047 (.0035,.0060)	2485	.0017 (.0010,.0027)	15368	.0005 (.0002,.0010)

Table 5.14: Controlled VE as functions of Day 57 Pseudovirus-nAb cID80 (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence intervals (10 replicates).Overall cumulative incidence from 7 to 173 days post Day 57 was 0.005 in vaccine recipients compared to 0.083 in placebo recipients, with cumulative vaccine efficacy 94.6% (95% CI 93.5 to 95.7%).

s	Estimate	s	Estimate	s	Estimate	s	Estimate
19.3	.4656 (-0.2449,.7308)	137	.8531 (0.7900,.8979)	644	.9485 (0.9346,.9608)	3043	.9821 (0.9718,.9898)
21	.4883 (-0.1765,.7395)	146	.8596 (0.8031,.9013)	689	.9508 (0.9369,.9629)	3255	.9829 (0.9728,.9905)
22	.5101 (-0.1113,.7480)	156	.8658 (0.8154,.9050)	738	.9530 (0.9392,.9650)	3482	.9836 (0.9738,.9911)
24	.5310 (-0.0491,.7563)	160	.8679 (0.8194,.9062)	756	.9538 (0.9400,.9657)	3725	.9844 (0.9748,.9916)
25	.5511 (0.0100,.7642)	167	.8718 (0.8269,.9084)	789	.9551 (0.9414,.9669)	3986	.9851 (0.9757,.9921)
27	.5704 (0.0662,.7719)	179	.8775 (0.8378,.9118)	844	.9571 (0.9435,.9687)	4264	.9857 (0.9766,.9926)
29	.5888 (0.1196,.7794)	191	.8829 (0.8480,.9150)	903	.9590 (0.9455,.9705)	4561	.9864 (0.9774,.9931)
31	.6066 (0.1703,.7866)	205	.8881 (0.8575,.9181)	966	.9609 (0.9475,.9721)	4880	.9870 (0.9782,.9935)
33	.6235 (0.2184,.7936)	207	.8890 (0.8592,.9186)	1000	.9618 (0.9484,.9729)	5221	.9876 (0.9790,.9939)
35	.6398 (0.2639,.8004)	219	.8931 (0.8665,.9210)	1014	.9621 (0.9488,.9732)	5585	.9881 (0.9798,.9943)
38	.6554 (0.3071,.8070)	234	.8978 (0.8749,.9239)	1034	.9626 (0.9494,.9737)	5975	.9887 (0.9805,.9946)
41	.6704 (0.3479,.8133)	251	.9024 (0.8827,.9266)	1106	.9643 (0.9512,.9751)	6392	.9892 (0.9812,.9950)
43	.6847 (0.3865,.8194)	262	.9053 (0.8877,.9284)	1183	.9659 (0.9529,.9765)	6838	.9897 (0.9818,.9953)
46	.6984 (0.4230,.8254)	268	.9067 (0.8900,.9293)	1266	.9674 (0.9546,.9778)	7316	.9901 (0.9825,.9956)
50	.7116 (0.4575,.8311)	287	.9109 (0.8964,.9318)	1354	.9689 (0.9563,.9790)	7826	.9906 (0.9831,.9959)
53	.7241 (0.4901,.8367)	307	.9149 (0.9015,.9342)	1448	.9703 (0.9578,.9802)	8373	.9910 (0.9837,.9961)
57	.7362 (0.5208,.8420)	328	.9187 (0.9056,.9366)	1550	.9716 (0.9594,.9813)	8957	.9914 (0.9842,.9964)
61	.7477 (0.5498,.8472)	351	.9223 (0.9091,.9395)	1570	.9719 (0.9596,.9815)	9582	.9918 (0.9848,.9966)
65	.7588 (0.5771,.8523)	376	.9257 (0.9124,.9424)	1658	.9729 (0.9608,.9823)	10251	.9922 (0.9853,.9968)
70	.7694 (0.6029,.8571)	402	.9291 (0.9155,.9451)	1773	.9741 (0.9622,.9833)	10967	.9925 (0.9858,.9970)
74	.7795 (0.6271,.8619)	430	.9322 (0.9185,.9477)	1897	.9753 (0.9636,.9842)	11733	.9928 (0.9863,.9972)
80	.7892 (0.6499,.8664)	445	.9338 (0.9200,.9490)	1993	.9761 (0.9645,.9849)	12552	.9932 (0.9868,.9974)
85	.7985 (0.6714,.8708)	460	.9353 (0.9215,.9502)	2030	.9764 (0.9649,.9851)	13428	.9935 (0.9872,.9976)
91	.8073 (0.6917,.8751)	492	.9381 (0.9243,.9525)	2171	.9774 (0.9662,.9860)	14365	.9938 (0.9877,.9977)
97	.8158 (0.7107,.8792)	500	.9388 (0.9249,.9530)	2323	.9784 (0.9674,.9869)	15368	.9940 (0.9881,.9979)
104	.8240 (0.7286,.8832)	526	.9409 (0.9270,.9547)	2485	.9794 (0.9686,.9877)	37.9	.6554 (.3071,.8070)
111	.8317 (0.7454,.8870)	563	.9436 (0.9296,.9569)	2659	.9803 (0.9697,.9885)	234	.8978 (.8749,.9239)
119	.8392 (0.7612,.8908)	584	.9449 (0.9310,.9579)	2787	.9810 (0.9705,.9890)	689	.9508 (.9369,.9629)
128	.8463 (0.7760,.8944)	602	.9461 (0.9321,.9589)	2844	.9812 (0.9708,.9892)		

Table 5.15: Controlled VE with sensitivity analysis as functions of Day 57 Pseudovirus-nAb cID80 (=s) among baseline negative vaccine recipients with 95% bootstrap point-wise confidence intervals (10 replicates).

s	Estimate	s	Estimate	s	Estimate	s	Estimate
19.3	.6900 (.2779,.8438)	137	.8720 (.8171,.9110)	644	.9484 (.9345,.9608)	3043	.9787 (.9666,.9879)
21	.6984 (.3065,.8465)	146	.8764 (.8266,.9131)	689	.9507 (.9368,.9628)	3255	.9794 (.9674,.9886)
22	.7065 (.3343,.8491)	156	.8806 (.8358,.9154)	738	.9528 (.9389,.9648)	3482	.9801 (.9682,.9891)
24	.7145 (.3614,.8516)	160	.8820 (.8388,.9162)	756	.9535 (.9396,.9655)	3725	.9808 (.9689,.9897)
25	.7224 (.3877,.8542)	167	.8848 (.8445,.9177)	789	.9547 (.9409,.9666)	3986	.9814 (.9697,.9902)
27	.7301 (.4134,.8567)	179	.8888 (.8528,.9199)	844	.9566 (.9428,.9684)	4264	.9820 (.9704,.9907)
29	.7376 (.4382,.8592)	191	.8927 (.8607,.9221)	903	.9584 (.9447,.9700)	4561	.9826 (.9711,.9911)
31	.7450 (.4623,.8617)	205	.8965 (.8682,.9242)	966	.9600 (.9464,.9715)	4880	.9831 (.9718,.9916)
33	.7523 (.4857,.8642)	207	.8972 (.8696,.9246)	1000	.9609 (.9472,.9723)	5221	.9837 (.9724,.9920)
35	.7594 (.5082,.8666)	219	.9003 (.8754,.9263)	1014	.9612 (.9476,.9726)	5585	.9842 (.9730,.9924)
38	.7663 (.5300,.8691)	234	.9039 (.8823,.9284)	1034	.9616 (.9480,.9730)	5975	.9847 (.9736,.9928)
41	.7731 (.5511,.8715)	251	.9075 (.8888,.9304)	1106	.9631 (.9496,.9743)	6392	.9852 (.9742,.9931)
43	.7797 (.5714,.8739)	262	.9098 (.8930,.9318)	1183	.9645 (.9511,.9756)	6838	.9856 (.9748,.9934)
46	.7862 (.5910,.8762)	268	.9109 (.8949,.9324)	1266	.9659 (.9525,.9768)	7316	.9861 (.9753,.9938)
50	.7926 (.6099,.8785)	287	.9143 (.9003,.9344)	1354	.9672 (.9539,.9779)	7826	.9865 (.9758,.9941)
53	.7988 (.6280,.8809)	307	.9176 (.9046,.9363)	1448	.9684 (.9552,.9790)	8373	.9869 (.9763,.9944)
57	.8049 (.6455,.8832)	328	.9208 (.9080,.9383)	1550	.9696 (.9565,.9800)	8957	.9873 (.9768,.9947)
61	.8108 (.6623,.8854)	351	.9239 (.9110,.9408)	1570	.9698 (.9567,.9801)	9582	.9877 (.9772,.9949)
65	.8166 (.6784,.8877)	376	.9269 (.9138,.9433)	1658	.9707 (.9577,.9809)	10251	.9881 (.9777,.9952)
70	.8222 (.6939,.8899)	402	.9299 (.9165,.9457)	1773	.9717 (.9588,.9818)	10967	.9884 (.9781,.9954)
74	.8278 (.7088,.8921)	430	.9328 (.9192,.9481)	1897	.9728 (.9599,.9826)	11733	.9888 (.9785,.9956)
80	.8332 (.7230,.8943)	445	.9342 (.9205,.9493)	1993	.9735 (.9607,.9832)	12552	.9891 (.9790,.9958)
85	.8385 (.7366,.8965)	460	.9356 (.9218,.9504)	2030	.9737 (.9610,.9834)	13428	.9895 (.9794,.9960)
91	.8436 (.7497,.8986)	492	.9383 (.9245,.9526)	2171	.9746 (.9620,.9843)	14365	.9898 (.9798,.9962)
97	.8486 (.7622,.9007)	500	.9389 (.9251,.9531)	2323	.9755 (.9630,.9851)	15368	.9901 (.9801,.9964)
104	.8536 (.7742,.9028)	526	.9410 (.9271,.9548)	2485	.9764 (.9639,.9859)	37.9	.6554 (.3071,.8070)
111	.8583 (.7857,.9049)	563	.9436 (.9296,.9569)	2659	.9772 (.9648,.9866)	234	.8978 (.8749,.9239)
119	.8630 (.7966,.9070)	584	.9449 (.9310,.9579)	2787	.9777 (.9655,.9871)	689	.9508 (.9369,.9629)
128	.8676 (.8071,.9090)	602	.9461 (.9321,.9589)	2844	.9780 (.9657,.9873)		

Chapter 6

Univariate CoR: Nonparametric Threshold Modeling (>=s)

An extension of the unadjusted nonparametric threshold-searching approach developed in Donovan, Hudgens, and Gilbert (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 $E_X[E[Y \mid S \geq s, X, A = 1] \mid A = 1]$ 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 $P(Y = 1 \mid S \geq s, A = 1)$. 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 restrictive but flexible specification of the Highly Adaptive Lasso estimator 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.

The blue dots on the plots represent the risk predictions at marker values where there was an observed COVID-19 case.

6.1 Plots and Tables with estimates and pointwise confidence intervals for Day 57

6.1.1 Day 57 bindSpike

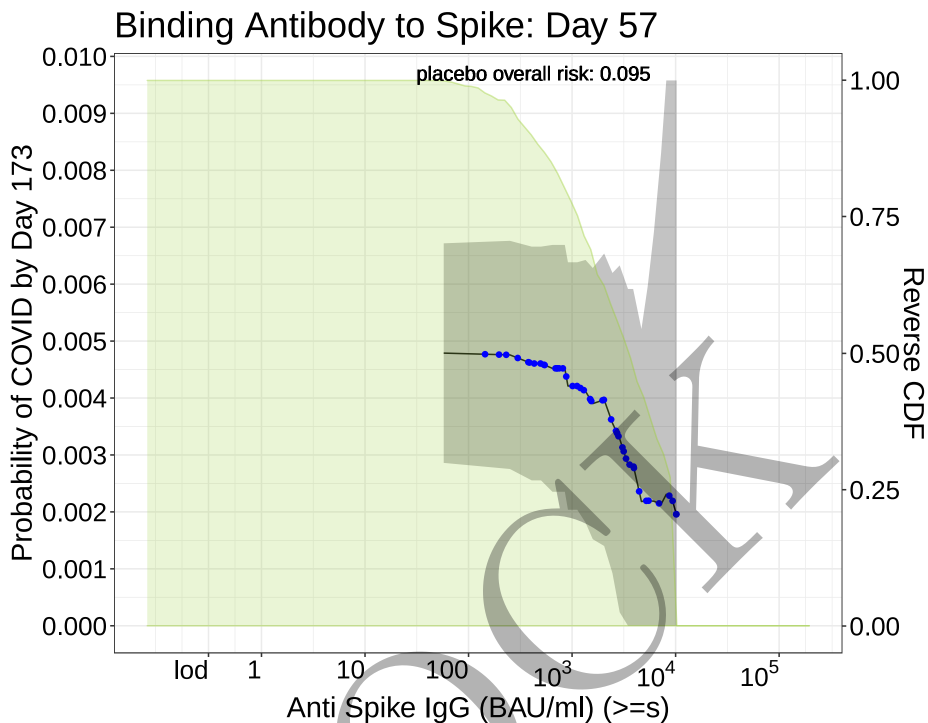


Figure 6.1: Adjusted threshold-response function for a range of thresholds of the Day 57 Day57bindSpike levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table 6.1: Table of risk estimates for a range of thresholds of Day 57 Day57bindSpike levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
1.761	$5.77 * 10^1$	0.00479	0.00286	0.00672
2.699	$5.00 * 10^2$	0.00461	0.00255	0.00666
2.808	$6.43 * 10^2$	0.00452	0.00235	0.00669
2.965	$9.23 * 10^2$	0.00421	0.00204	0.00638
3.000	$1.00 * 10^3$	0.00421	0.00204	0.00638
3.133	$1.36 * 10^3$	0.00412	0.00181	0.00643
3.459	$2.88 * 10^3$	0.00328	0.00024	0.00633
3.671	$4.69 * 10^3$	0.00218	0.00000	0.00521
3.860	$7.24 * 10^3$	0.00213	0.00000	0.00831
4.007	$1.02 * 10^4$	0.00194	0.00000	0.02958
4.007	$1.02 * 10^4$	0.00194	0.00000	0.02958
4.007	$1.02 * 10^4$	0.00194	0.00000	0.02958
4.007	$1.02 * 10^4$	0.00194	0.00000	0.02958
4.007	$1.02 * 10^4$	0.00194	0.00000	0.02958

6.1.2 Day 57 bindRBD

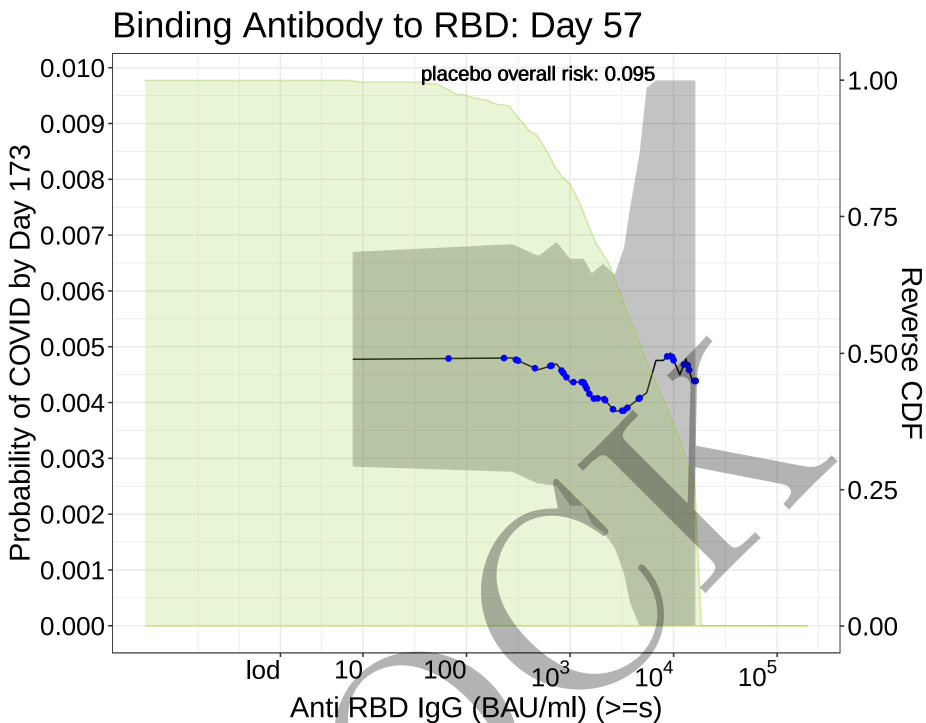


Figure 6.2: Adjusted threshold-response function for a range of thresholds of the Day 57 Day57bindRBD levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table 6.2: Table of risk estimates for a range of thresholds of Day 57 Day57bindRBD levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.898	$7.91 * 10^0$	0.00478	0.00285	0.00670
2.699	$5.00 * 10^2$	0.00459	0.00255	0.00663
2.871	$7.43 * 10^2$	0.00469	0.00251	0.00688
3.000	$1.00 * 10^3$	0.00437	0.00215	0.00658
3.062	$1.15 * 10^3$	0.00437	0.00215	0.00658
3.211	$1.63 * 10^3$	0.00407	0.00182	0.00632
3.580	$3.80 * 10^3$	0.00395	0.00040	0.00749
3.832	$6.79 * 10^3$	0.00475	0.00000	0.01193
4.061	$1.15 * 10^4$	0.00450	0.00000	0.01635
4.211	$1.63 * 10^4$	0.00439	0.00000	0.03856
4.211	$1.63 * 10^4$	0.00439	0.00000	0.03856
4.211	$1.63 * 10^4$	0.00439	0.00000	0.03856
4.211	$1.63 * 10^4$	0.00439	0.00000	0.03856
4.211	$1.63 * 10^4$	0.00439	0.00000	0.03856

6.1.3 Day 57 pseudoneutid50

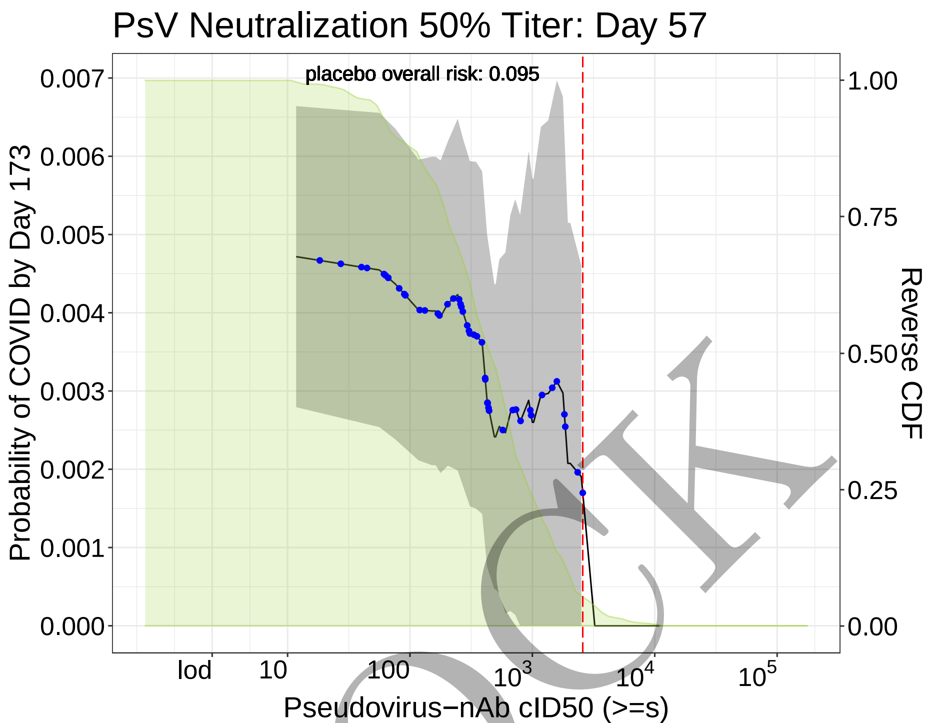


Figure 6.3: Adjusted threshold-response function for a range of thresholds of the Day 57 Day57pseudoneutid50 levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table 6.3: Table of risk estimates for a range of thresholds of Day 57 Day57pseudoneutid50 levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
1.072	$1.18 * 10^1$	0.00472	0.00279	0.00664
2.070	$1.17 * 10^2$	0.00404	0.00211	0.00596
2.214	$1.64 * 10^2$	0.00402	0.00205	0.00599
2.313	$2.06 * 10^2$	0.00412	0.00205	0.00619
2.538	$3.45 * 10^2$	0.00371	0.00150	0.00593
2.690	$4.90 * 10^2$	0.00241	0.00047	0.00436
2.699	$5.00 * 10^2$	0.00241	0.00047	0.00436
2.817	$6.56 * 10^2$	0.00272	0.00019	0.00525
2.967	$9.27 * 10^2$	0.00288	0.00000	0.00607
3.000	$1.00 * 10^3$	0.00260	0.00000	0.00571
3.196	$1.57 * 10^3$	0.00312	0.00000	0.00697
3.290	$1.95 * 10^3$	0.00208	0.00000	0.00515
3.401	$2.52 * 10^3$	0.00191	0.00000	0.00460
4.038	$1.09 * 10^4$	0.00000	NA	NA

6.1.4 Day 57 pseudoneutid80

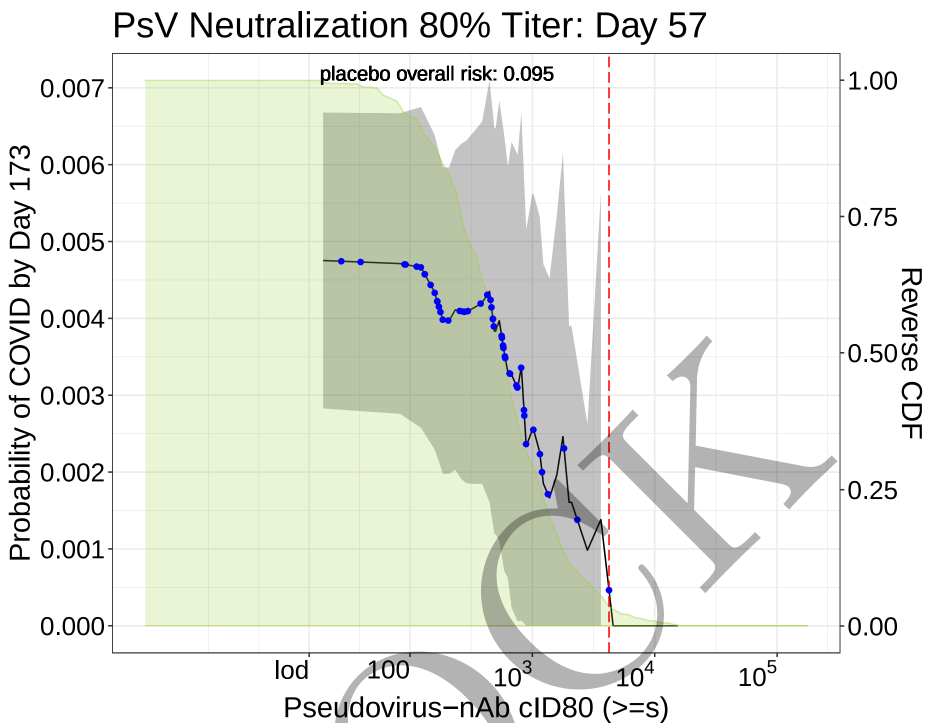


Figure 6.4: Adjusted threshold-response function for a range of thresholds of the Day 57 Day57pseudoneutid80 levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed.

Table 6.4: Table of risk estimates for a range of thresholds of Day 57 Day57pseudoneutid80 levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
1.285	$1.93 * 10^1$	0.00475	0.00283	0.00668
2.204	$1.60 * 10^2$	0.00434	0.00230	0.00639
2.316	$2.07 * 10^2$	0.00397	0.00198	0.00596
2.418	$2.62 * 10^2$	0.00409	0.00191	0.00627
2.648	$4.45 * 10^2$	0.00435	0.00161	0.00710
2.699	$5.00 * 10^2$	0.00383	0.00119	0.00647
2.766	$5.83 * 10^2$	0.00355	0.00072	0.00639
2.878	$7.55 * 10^2$	0.00309	0.00006	0.00613
3.000	$1.00 * 10^3$	0.00255	0.00000	0.00562
3.006	$1.01 * 10^3$	0.00255	0.00000	0.00562
3.196	$1.57 * 10^3$	0.00196	0.00000	0.00535
3.299	$1.99 * 10^3$	0.00161	0.00000	0.00390
3.445	$2.79 * 10^3$	0.00098	0.00000	0.00263
4.187	$1.54 * 10^4$	0.00000	NA	NA

6.2 Plots and Tables with estimates and pointwise confidence intervals for Day 57 (monotone-corrected)

6.2.1 Day 57 bindSpike

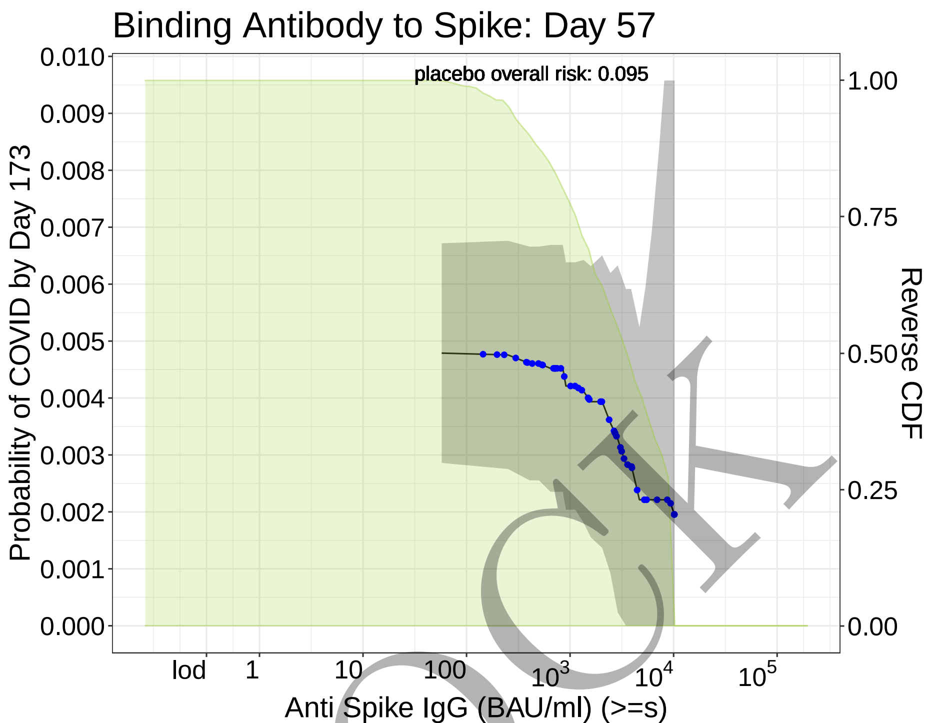


Figure 6.5: Adjusted threshold-response function for a range of thresholds of the Day 57 Day57bindSpike levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.5: Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Day57bindSpike levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
1.761	$5.77 * 10^1$	0.00479	0.00286	0.00672
2.699	$5.00 * 10^2$	0.00461	0.00255	0.00666
2.808	$6.43 * 10^2$	0.00452	0.00235	0.00669
2.965	$9.23 * 10^2$	0.00421	0.00204	0.00638
3.000	$1.00 * 10^3$	0.00421	0.00204	0.00638
3.133	$1.36 * 10^3$	0.00412	0.00181	0.00643
3.459	$2.88 * 10^3$	0.00328	0.00024	0.00633
3.671	$4.69 * 10^3$	0.00221	0.00000	0.00524
3.860	$7.24 * 10^3$	0.00221	0.00000	0.00839
4.007	$1.02 * 10^4$	0.00194	0.00000	0.02958
4.007	$1.02 * 10^4$	0.00194	0.00000	0.02958
4.007	$1.02 * 10^4$	0.00194	0.00000	0.02958
4.007	$1.02 * 10^4$	0.00194	0.00000	0.02958
4.007	$1.02 * 10^4$	0.00194	0.00000	0.02958

6.2.2 Day 57 bindRBD

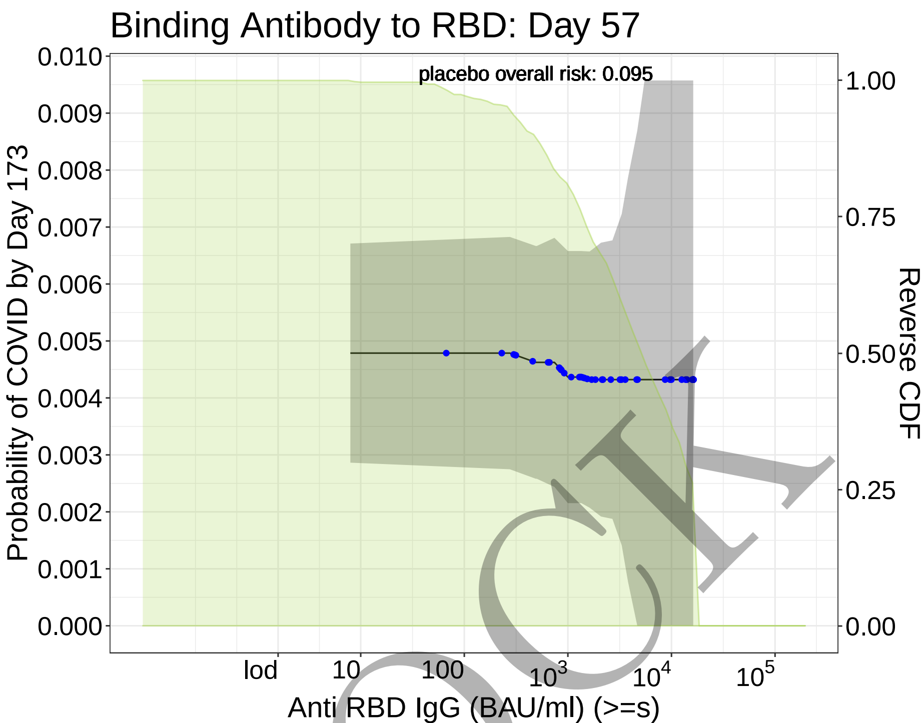


Figure 6.6: Adjusted threshold-response function for a range of thresholds of the Day 57 Day57bindRBD levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.6: Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Day57bindRBD levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.898	$7.91 * 10^0$	0.00479	0.00286	0.00671
2.699	$5.00 * 10^2$	0.00462	0.00258	0.00667
2.871	$7.43 * 10^2$	0.00462	0.00244	0.00681
3.000	$1.00 * 10^3$	0.00437	0.00215	0.00658
3.062	$1.15 * 10^3$	0.00437	0.00215	0.00658
3.211	$1.63 * 10^3$	0.00432	0.00207	0.00657
3.580	$3.80 * 10^3$	0.00432	0.00078	0.00786
3.832	$6.79 * 10^3$	0.00432	0.00000	0.01150
4.061	$1.15 * 10^4$	0.00432	0.00000	0.01617
4.211	$1.63 * 10^4$	0.00432	0.00000	0.03849
4.211	$1.63 * 10^4$	0.00432	0.00000	0.03849
4.211	$1.63 * 10^4$	0.00432	0.00000	0.03849
4.211	$1.63 * 10^4$	0.00432	0.00000	0.03849
4.211	$1.63 * 10^4$	0.00432	0.00000	0.03849

6.2.3 Day 57 pseudoneutid50

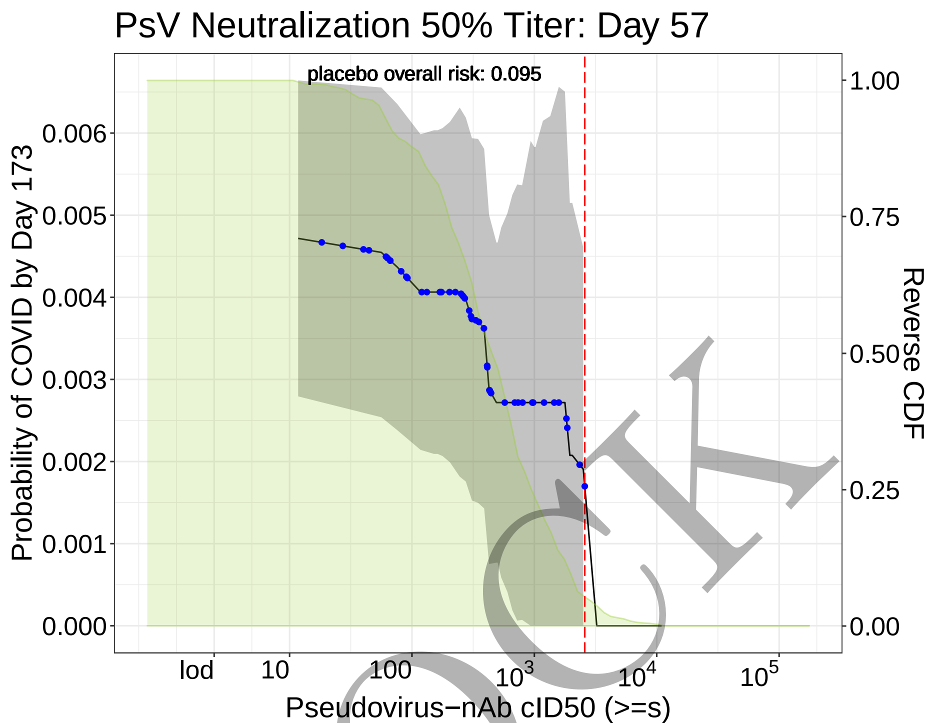


Figure 6.7: Adjusted threshold-response function for a range of thresholds of the Day 57 Day57pseudoneutid50 levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.7: Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Day57pseudoneutid50 levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
1.072	$1.18 * 10^1$	0.00472	0.00279	0.00664
2.070	$1.17 * 10^2$	0.00406	0.00214	0.00599
2.214	$1.64 * 10^2$	0.00406	0.00209	0.00603
2.313	$2.06 * 10^2$	0.00406	0.00199	0.00614
2.538	$3.45 * 10^2$	0.00371	0.00150	0.00593
2.690	$4.90 * 10^2$	0.00272	0.00077	0.00467
2.699	$5.00 * 10^2$	0.00272	0.00077	0.00467
2.817	$6.56 * 10^2$	0.00272	0.00019	0.00525
2.967	$9.27 * 10^2$	0.00272	0.00000	0.00590
3.000	$1.00 * 10^3$	0.00272	0.00000	0.00583
3.196	$1.57 * 10^3$	0.00272	0.00000	0.00656
3.290	$1.95 * 10^3$	0.00208	0.00000	0.00515
3.401	$2.52 * 10^3$	0.00191	0.00000	0.00460
4.038	$1.09 * 10^4$	0.00000	NA	NA

6.2.4 Day 57 pseudoneutid80

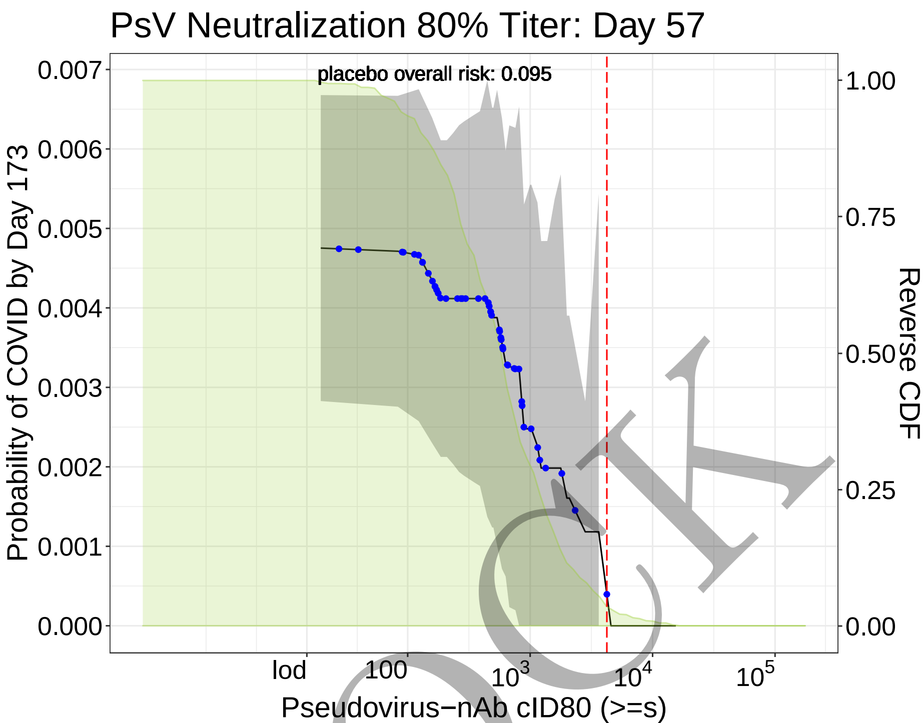


Figure 6.8: Adjusted threshold-response function for a range of thresholds of the Day 57 Day57pseudoneutid80 levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.8: Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Day57pseudoneutid80 levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
1.285	$1.93 * 10^1$	0.00475	0.00283	0.00668
2.204	$1.60 * 10^2$	0.00434	0.00230	0.00639
2.316	$2.07 * 10^2$	0.00412	0.00212	0.00611
2.418	$2.62 * 10^2$	0.00412	0.00194	0.00630
2.648	$4.45 * 10^2$	0.00412	0.00137	0.00686
2.699	$5.00 * 10^2$	0.00388	0.00124	0.00652
2.766	$5.83 * 10^2$	0.00355	0.00072	0.00639
2.878	$7.55 * 10^2$	0.00323	0.00020	0.00627
3.000	$1.00 * 10^3$	0.00248	0.00000	0.00555
3.006	$1.01 * 10^3$	0.00248	0.00000	0.00555
3.196	$1.57 * 10^3$	0.00198	0.00000	0.00537
3.299	$1.99 * 10^3$	0.00161	0.00000	0.00390
3.445	$2.79 * 10^3$	0.00118	0.00000	0.00282
4.187	$1.54 * 10^4$	0.00000	NA	NA

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

6.3.1 Day 29 bindSpike

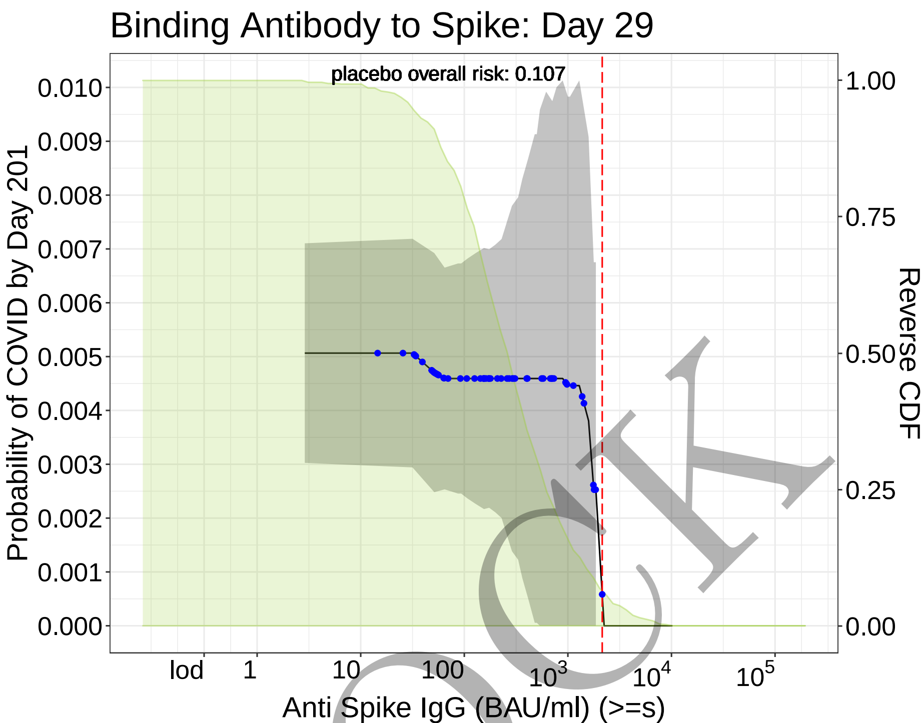


Figure 6.9: Adjusted threshold-response function for a range of thresholds of the Day 29 Day29bindSpike levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.9: Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Day29bindSpike levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.459	$2.88 * 10^0$	0.00507	0.00303	0.00710
1.805	$6.38 * 10^1$	0.00459	0.00253	0.00665
1.967	$9.27 * 10^1$	0.00459	0.00246	0.00673
2.114	$1.30 * 10^2$	0.00459	0.00226	0.00692
2.356	$2.27 * 10^2$	0.00459	0.00200	0.00718
2.518	$3.30 * 10^2$	0.00459	0.00123	0.00796
2.675	$4.73 * 10^2$	0.00459	0.00005	0.00913
2.699	$5.00 * 10^2$	0.00459	0.00005	0.00913
2.850	$7.08 * 10^2$	0.00459	0.00000	0.00975
3.000	$1.00 * 10^3$	0.00446	0.00000	0.00983
3.112	$1.29 * 10^3$	0.00446	0.00000	0.01072
3.250	$1.78 * 10^3$	0.00253	0.00000	0.00675
3.350	$2.24 * 10^3$	0.00000	NA	NA
4.007	$1.02 * 10^4$	0.00000	NA	NA

6.3.2 Day 29 bindRBD

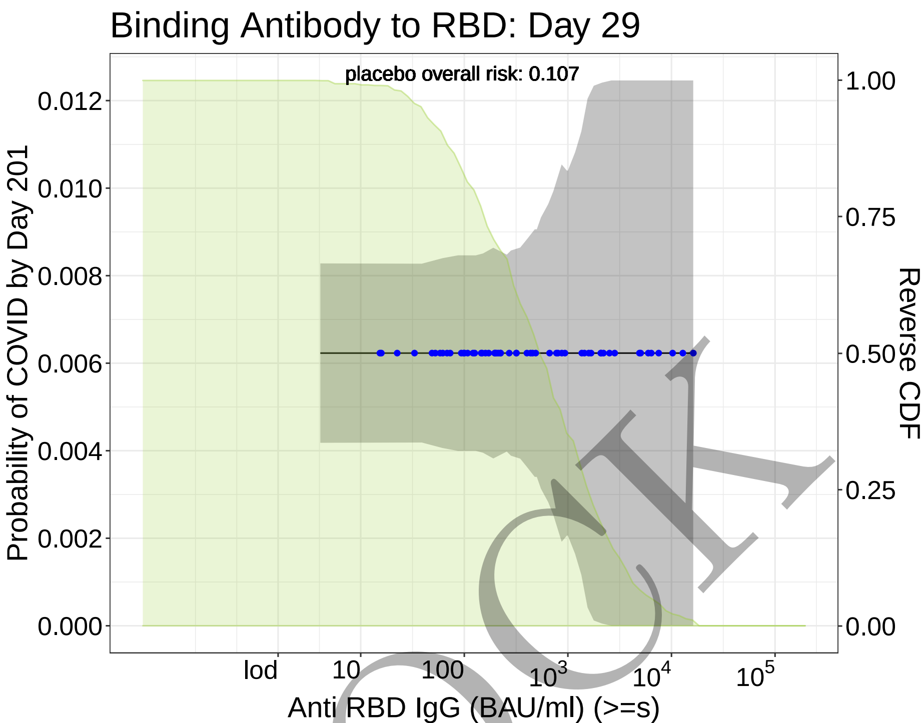


Figure 6.10: Adjusted threshold-response function for a range of thresholds of the Day 29 Day29bindRBD levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.10: Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Day29bindRBD levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.609	$4.06 * 10^0$	0.00623	0.00418	0.00828
1.940	$8.71 * 10^1$	0.00623	0.00400	0.00846
2.110	$1.29 * 10^2$	0.00623	0.00400	0.00846
2.281	$1.91 * 10^2$	0.00623	0.00382	0.00864
2.610	$4.07 * 10^2$	0.00623	0.00361	0.00885
2.699	$5.00 * 10^2$	0.00623	0.00340	0.00906
2.811	$6.47 * 10^2$	0.00623	0.00283	0.00964
2.991	$9.79 * 10^2$	0.00623	0.00206	0.01040
3.000	$1.00 * 10^3$	0.00623	0.00206	0.01040
3.192	$1.56 * 10^3$	0.00623	0.00042	0.01204
3.489	$3.08 * 10^3$	0.00623	0.00000	0.01356
3.613	$4.10 * 10^3$	0.00623	0.00000	0.01532
3.759	$5.74 * 10^3$	0.00623	0.00000	0.01393
4.211	$1.63 * 10^4$	0.00623	0.00000	0.03897

6.3.3 Day 29 pseudoneutid50

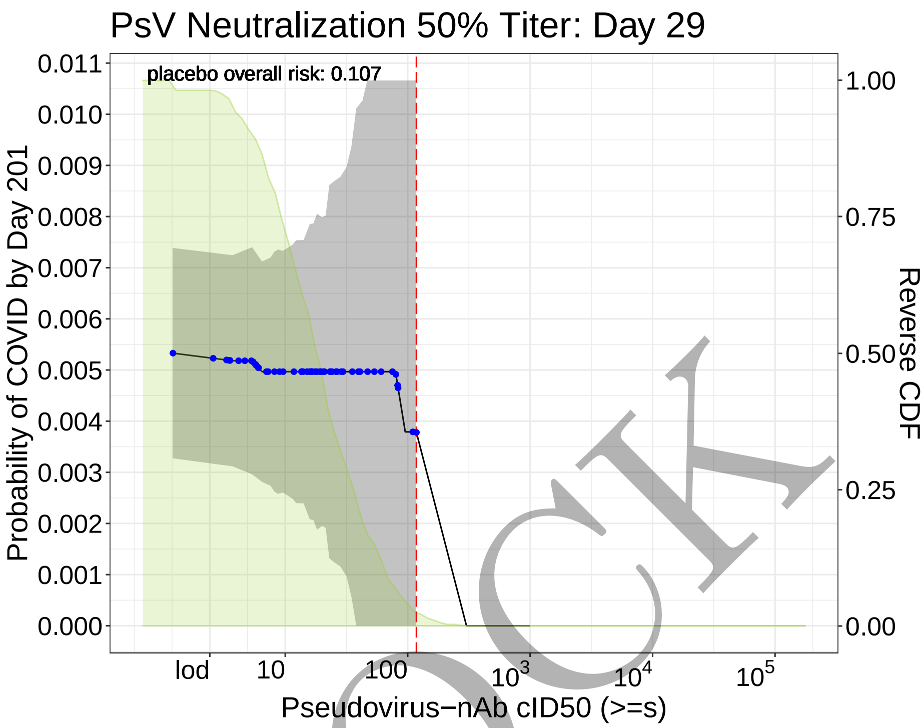


Figure 6.11: Adjusted threshold-response function for a range of thresholds of the Day 29 Day29pseudoneutid50 levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.11: Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Day29pseudoneutid50 levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.083	$1.21 * 10^0$	0.00533	0.00327	0.00739
0.814	$6.52 * 10^0$	0.00497	0.00281	0.00712
0.912	$8.17 * 10^0$	0.00497	0.00263	0.00731
0.985	$9.66 * 10^0$	0.00497	0.00261	0.00733
1.200	$1.58 * 10^1$	0.00497	0.00208	0.00785
1.304	$2.01 * 10^1$	0.00497	0.00195	0.00798
1.404	$2.54 * 10^1$	0.00497	0.00124	0.00869
1.537	$3.44 * 10^1$	0.00497	0.00057	0.00936
1.730	$5.37 * 10^1$	0.00497	0.00000	0.01112
1.811	$6.47 * 10^1$	0.00497	0.00000	0.01205
1.905	$8.04 * 10^1$	0.00497	0.00000	0.01161
2.481	$3.03 * 10^2$	0.00000	NA	NA
2.699	$5.00 * 10^2$	0.00000	NA	NA
3.000	$1.00 * 10^3$	0.00000	NA	NA

6.3.4 Day 29 pseudoneutid80

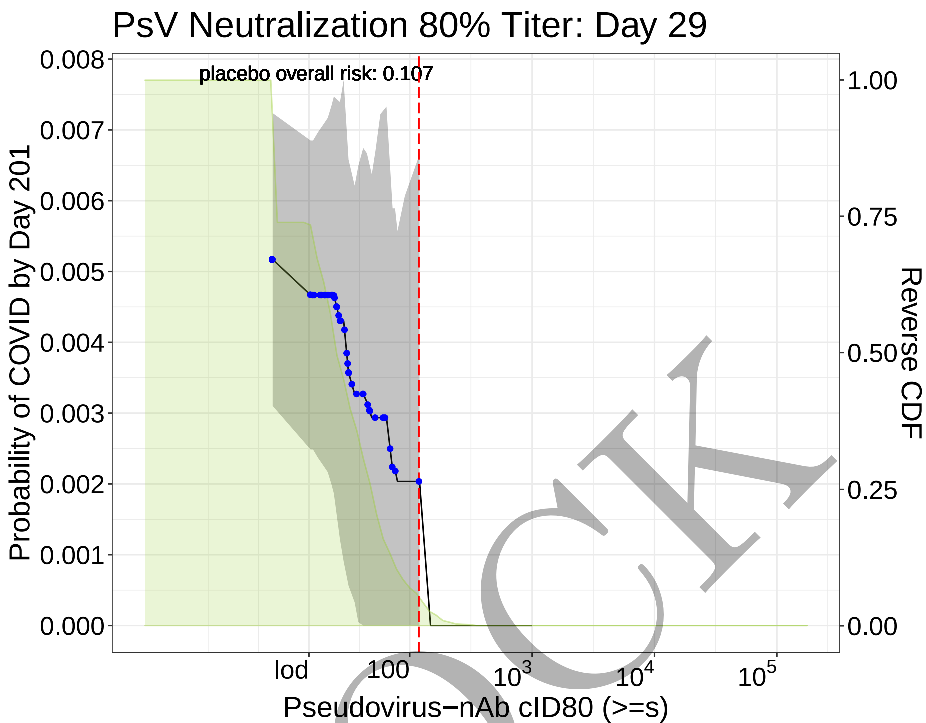


Figure 6.12: Adjusted threshold-response function for a range of thresholds of the Day 29 Day29pseudoneutid80 levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.12: Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Day29pseudoneutid80 levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.876	$7.52 * 10^0$	0.00517	0.00310	0.00724
0.876	$7.52 * 10^0$	0.00517	0.00310	0.00724
0.876	$7.52 * 10^0$	0.00517	0.00310	0.00724
1.185	$1.53 * 10^1$	0.00467	0.00249	0.00685
1.334	$2.16 * 10^1$	0.00467	0.00217	0.00717
1.425	$2.66 * 10^1$	0.00430	0.00121	0.00739
1.548	$3.53 * 10^1$	0.00327	0.00033	0.00621
1.652	$4.49 * 10^1$	0.00316	0.00000	0.00667
1.806	$6.40 * 10^1$	0.00294	0.00000	0.00733
1.877	$7.53 * 10^1$	0.00220	0.00000	0.00589
1.962	$9.16 * 10^1$	0.00203	0.00000	0.00607
2.529	$3.38 * 10^2$	0.00000	NA	NA
2.699	$5.00 * 10^2$	0.00000	NA	NA
3.000	$1.00 * 10^3$	0.00000	NA	NA

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

6.4.1 Day 29 bindSpike

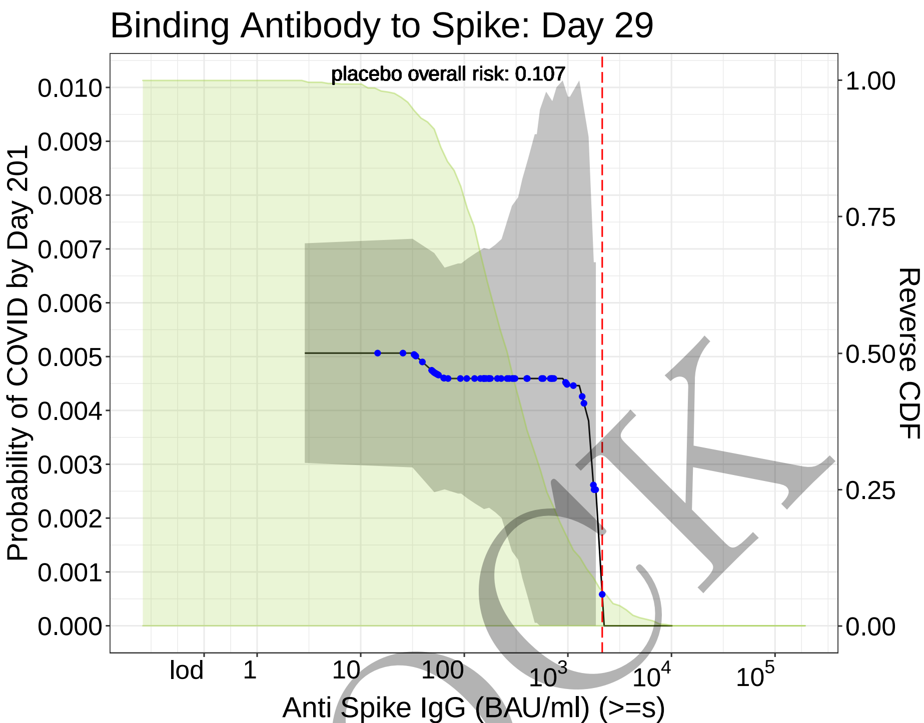


Figure 6.13: Adjusted threshold-response function for a range of thresholds of the Day 29 Day29bindSpike levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.13: Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Day29bindSpike levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.459	$2.88 * 10^0$	0.00507	0.00303	0.00710
1.805	$6.38 * 10^1$	0.00459	0.00253	0.00665
1.967	$9.27 * 10^1$	0.00459	0.00246	0.00673
2.114	$1.30 * 10^2$	0.00459	0.00226	0.00692
2.356	$2.27 * 10^2$	0.00459	0.00200	0.00718
2.518	$3.30 * 10^2$	0.00459	0.00123	0.00796
2.675	$4.73 * 10^2$	0.00459	0.00005	0.00913
2.699	$5.00 * 10^2$	0.00459	0.00005	0.00913
2.850	$7.08 * 10^2$	0.00459	0.00000	0.00975
3.000	$1.00 * 10^3$	0.00446	0.00000	0.00983
3.112	$1.29 * 10^3$	0.00446	0.00000	0.01072
3.250	$1.78 * 10^3$	0.00253	0.00000	0.00675
3.350	$2.24 * 10^3$	0.00000	NA	NA
4.007	$1.02 * 10^4$	0.00000	NA	NA

6.4.2 Day 29 bindRBD

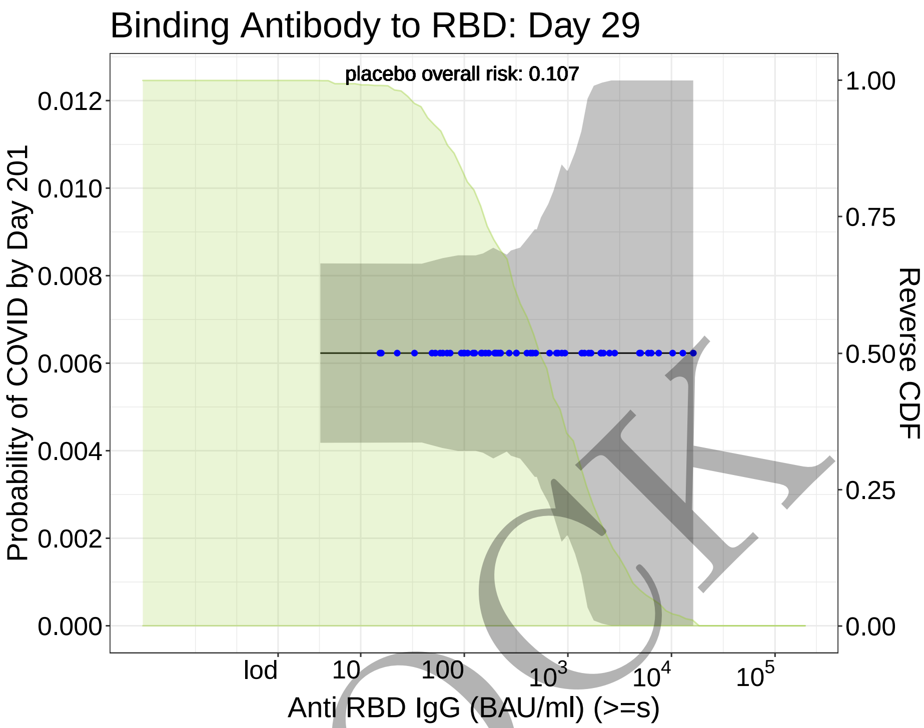


Figure 6.14: Adjusted threshold-response function for a range of thresholds of the Day 29 Day29bindRBD levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.14: Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Day29bindRBD levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.609	$4.06 * 10^0$	0.00623	0.00418	0.00828
1.940	$8.71 * 10^1$	0.00623	0.00400	0.00846
2.110	$1.29 * 10^2$	0.00623	0.00400	0.00846
2.281	$1.91 * 10^2$	0.00623	0.00382	0.00864
2.610	$4.07 * 10^2$	0.00623	0.00361	0.00885
2.699	$5.00 * 10^2$	0.00623	0.00340	0.00906
2.811	$6.47 * 10^2$	0.00623	0.00283	0.00964
2.991	$9.79 * 10^2$	0.00623	0.00206	0.01040
3.000	$1.00 * 10^3$	0.00623	0.00206	0.01040
3.192	$1.56 * 10^3$	0.00623	0.00042	0.01204
3.489	$3.08 * 10^3$	0.00623	0.00000	0.01356
3.613	$4.10 * 10^3$	0.00623	0.00000	0.01532
3.759	$5.74 * 10^3$	0.00623	0.00000	0.01393
4.211	$1.63 * 10^4$	0.00623	0.00000	0.03897

6.4.3 Day 29 pseudoneutid50

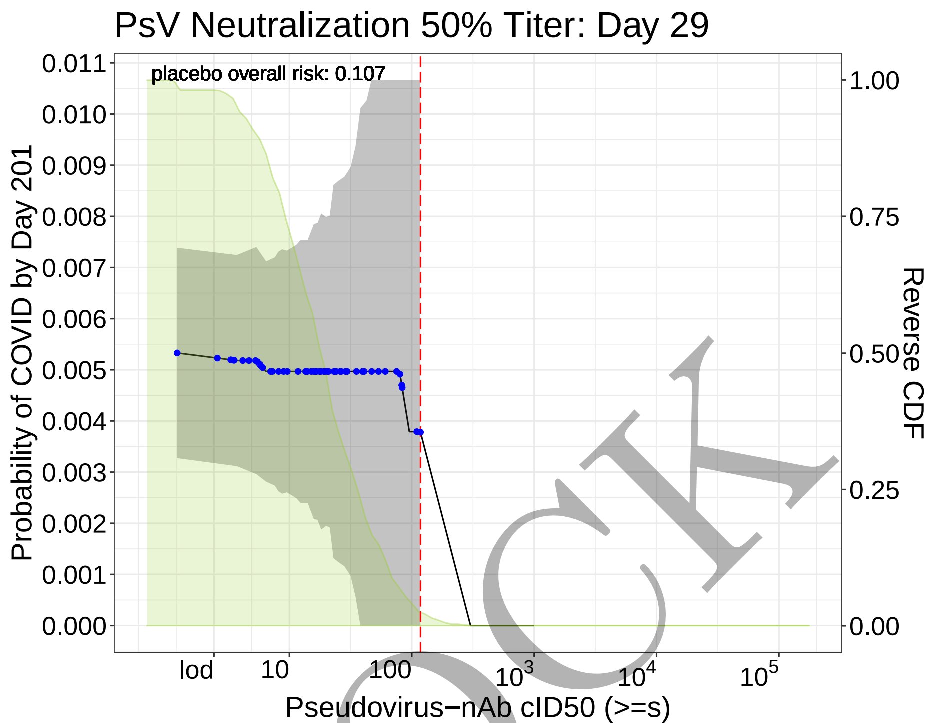


Figure 6.15: Adjusted threshold-response function for a range of thresholds of the Day 29 Day29pseudoneutid50 levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.15: Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Day29pseudoneutid50 levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.083	$1.21 * 10^0$	0.00533	0.00327	0.00739
0.814	$6.52 * 10^0$	0.00497	0.00281	0.00712
0.912	$8.17 * 10^0$	0.00497	0.00263	0.00731
0.985	$9.66 * 10^0$	0.00497	0.00261	0.00733
1.200	$1.58 * 10^1$	0.00497	0.00208	0.00785
1.304	$2.01 * 10^1$	0.00497	0.00195	0.00798
1.404	$2.54 * 10^1$	0.00497	0.00124	0.00869
1.537	$3.44 * 10^1$	0.00497	0.00057	0.00936
1.730	$5.37 * 10^1$	0.00497	0.00000	0.01112
1.811	$6.47 * 10^1$	0.00497	0.00000	0.01205
1.905	$8.04 * 10^1$	0.00497	0.00000	0.01161
2.481	$3.03 * 10^2$	0.00000	NA	NA
2.699	$5.00 * 10^2$	0.00000	NA	NA
3.000	$1.00 * 10^3$	0.00000	NA	NA

6.4.4 Day 29 pseudoneutid80

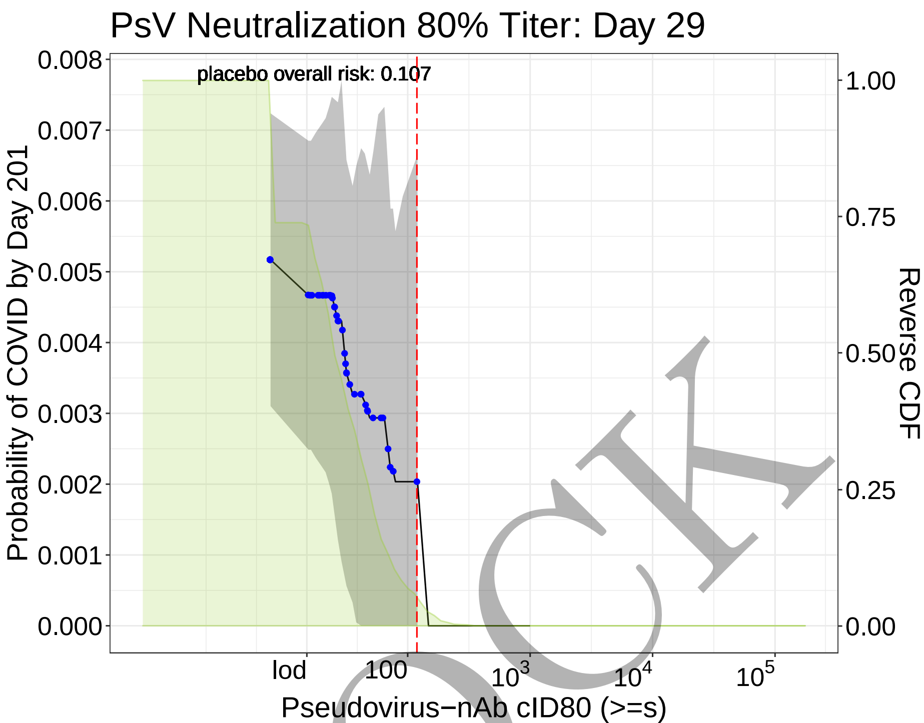


Figure 6.16: Adjusted threshold-response function for a range of thresholds of the Day 29 Day29pseudoneutid80 levels with pointwise 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.16: Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Day29pseudoneutid80 levels with pointwise 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.876	$7.52 * 10^0$	0.00517	0.00310	0.00724
0.876	$7.52 * 10^0$	0.00517	0.00310	0.00724
0.876	$7.52 * 10^0$	0.00517	0.00310	0.00724
1.185	$1.53 * 10^1$	0.00467	0.00249	0.00685
1.334	$2.16 * 10^1$	0.00467	0.00217	0.00717
1.425	$2.66 * 10^1$	0.00430	0.00121	0.00739
1.548	$3.53 * 10^1$	0.00327	0.00033	0.00621
1.652	$4.49 * 10^1$	0.00316	0.00000	0.00667
1.806	$6.40 * 10^1$	0.00294	0.00000	0.00733
1.877	$7.53 * 10^1$	0.00220	0.00000	0.00589
1.962	$9.16 * 10^1$	0.00203	0.00000	0.00607
2.529	$3.38 * 10^2$	0.00000	NA	NA
2.699	$5.00 * 10^2$	0.00000	NA	NA
3.000	$1.00 * 10^3$	0.00000	NA	NA

6.5 Plots and Tables with estimates and simultaneous confidence intervals for Day 57 (monotone-corrected)

6.5.1 Day 57 bindSpike

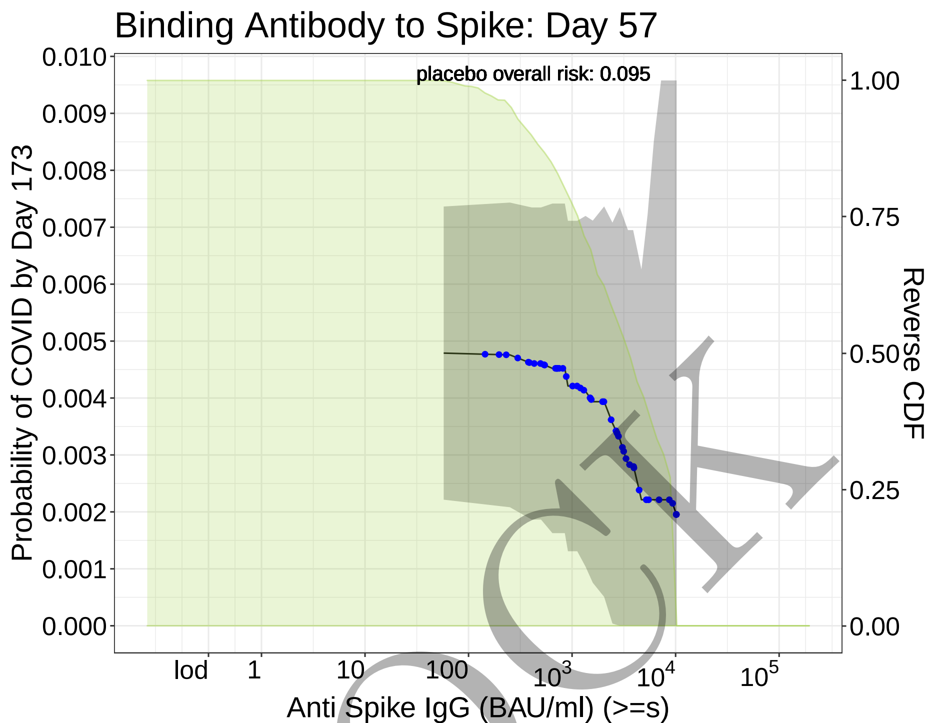


Figure 6.17: Adjusted threshold-response function for a range of thresholds of the Day 57 Day57bindSpike levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.17: Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Day57bindSpike levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
1.761	$5.77 * 10^1$	0.00479	0.00221	0.00736
2.699	$5.00 * 10^2$	0.00461	0.00187	0.00735
2.808	$6.43 * 10^2$	0.00452	0.00163	0.00742
2.965	$9.23 * 10^2$	0.00421	0.00131	0.00711
3.000	$1.00 * 10^3$	0.00421	0.00131	0.00711
3.133	$1.36 * 10^3$	0.00412	0.00104	0.00720
3.459	$2.88 * 10^3$	0.00328	0.00000	0.00735
3.671	$4.69 * 10^3$	0.00221	0.00000	0.00626
3.860	$7.24 * 10^3$	0.00221	0.00000	0.01045
4.007	$1.02 * 10^4$	0.00194	0.00000	0.03884
4.007	$1.02 * 10^4$	0.00194	0.00000	0.03884
4.007	$1.02 * 10^4$	0.00194	0.00000	0.03884
4.007	$1.02 * 10^4$	0.00194	0.00000	0.03884
4.007	$1.02 * 10^4$	0.00194	0.00000	0.03884

6.5.2 Day 57 bindRBD

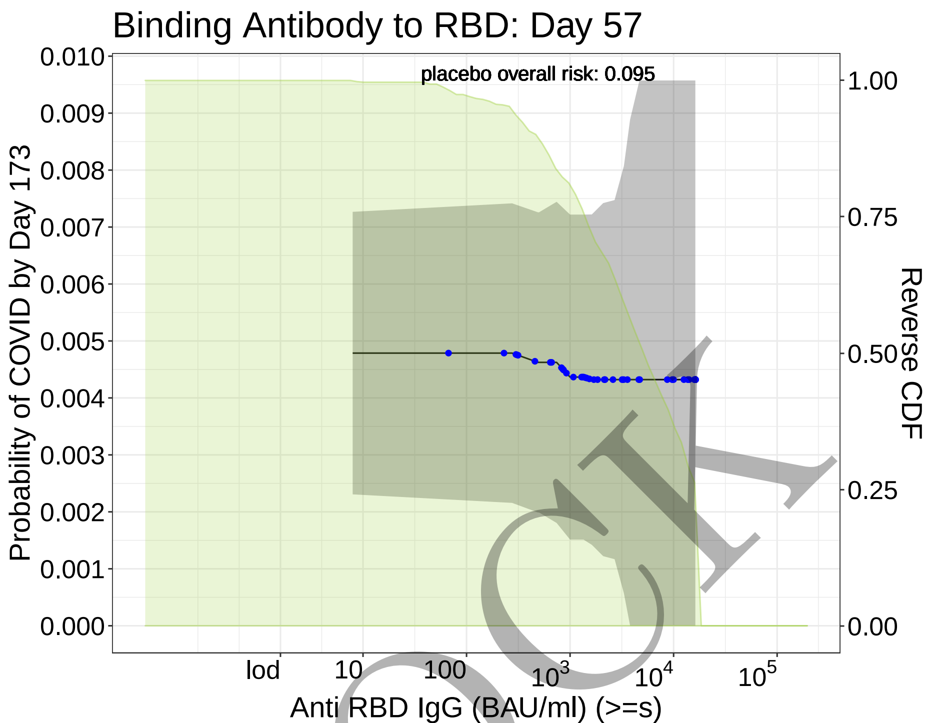


Figure 6.18: Adjusted threshold-response function for a range of thresholds of the Day 57 Day57bindRBD levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.18: Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Day57bindRBD levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.898	$7.91 * 10^0$	0.00479	0.00231	0.00727
2.699	$5.00 * 10^2$	0.00462	0.00199	0.00726
2.871	$7.43 * 10^2$	0.00462	0.00181	0.00744
3.000	$1.00 * 10^3$	0.00437	0.00151	0.00722
3.062	$1.15 * 10^3$	0.00437	0.00151	0.00722
3.211	$1.63 * 10^3$	0.00432	0.00142	0.00722
3.580	$3.80 * 10^3$	0.00432	0.00000	0.00889
3.832	$6.79 * 10^3$	0.00432	0.00000	0.01357
4.061	$1.15 * 10^4$	0.00432	0.00000	0.01960
4.211	$1.63 * 10^4$	0.00432	0.00000	0.04838
4.211	$1.63 * 10^4$	0.00432	0.00000	0.04838
4.211	$1.63 * 10^4$	0.00432	0.00000	0.04838
4.211	$1.63 * 10^4$	0.00432	0.00000	0.04838
4.211	$1.63 * 10^4$	0.00432	0.00000	0.04838

6.5.3 Day 57 pseudoneutid50

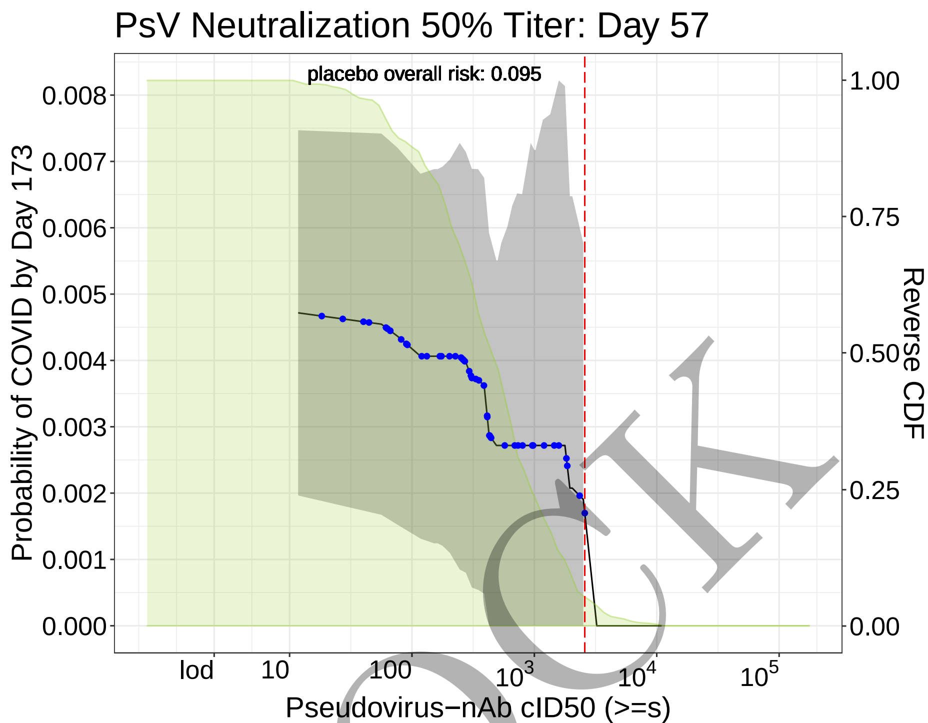


Figure 6.19: Adjusted threshold-response function for a range of thresholds of the Day 57 Day57pseudoneutid50 levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.19: Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Day57pseudoneutid50 levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
1.072	$1.18 * 10^1$	0.00472	0.00196	0.00747
2.070	$1.17 * 10^2$	0.00406	0.00131	0.00681
2.214	$1.64 * 10^2$	0.00406	0.00124	0.00688
2.313	$2.06 * 10^2$	0.00406	0.00110	0.00703
2.538	$3.45 * 10^2$	0.00371	0.00054	0.00688
2.690	$4.90 * 10^2$	0.00272	0.00000	0.00551
2.699	$5.00 * 10^2$	0.00272	0.00000	0.00551
2.817	$6.56 * 10^2$	0.00272	0.00000	0.00634
2.967	$9.27 * 10^2$	0.00272	0.00000	0.00728
3.000	$1.00 * 10^3$	0.00272	0.00000	0.00717
3.196	$1.57 * 10^3$	0.00272	0.00000	0.00822
3.290	$1.95 * 10^3$	0.00208	0.00000	0.00648
3.401	$2.52 * 10^3$	0.00191	0.00000	0.00577
4.038	$1.09 * 10^4$	0.00000	NA	NA

6.5.4 Day 57 pseudoneutid80

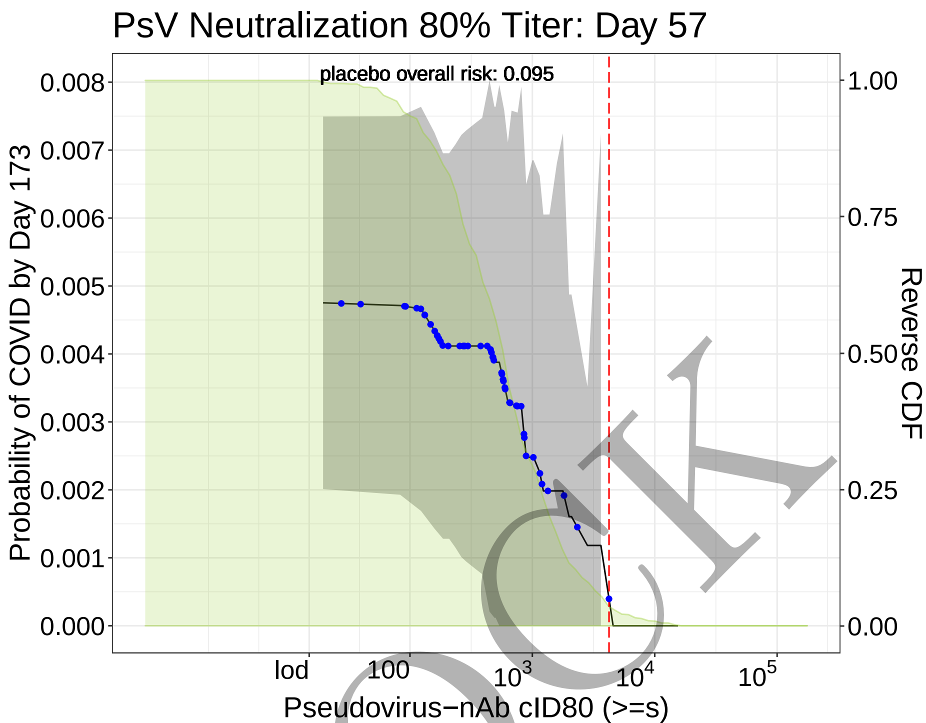


Figure 6.20: Adjusted threshold-response function for a range of thresholds of the Day 57 Day57pseudoneutid80 levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.20: Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Day57pseudoneutid80 levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
1.285	$1.93 * 10^1$	0.00475	0.00201	0.00749
2.204	$1.60 * 10^2$	0.00434	0.00143	0.00726
2.316	$2.07 * 10^2$	0.00412	0.00128	0.00695
2.418	$2.62 * 10^2$	0.00412	0.00101	0.00722
2.648	$4.45 * 10^2$	0.00412	0.00021	0.00803
2.699	$5.00 * 10^2$	0.00388	0.00012	0.00764
2.766	$5.83 * 10^2$	0.00355	0.00000	0.00759
2.878	$7.55 * 10^2$	0.00323	0.00000	0.00755
3.000	$1.00 * 10^3$	0.00248	0.00000	0.00685
3.006	$1.01 * 10^3$	0.00248	0.00000	0.00685
3.196	$1.57 * 10^3$	0.00198	0.00000	0.00680
3.299	$1.99 * 10^3$	0.00161	0.00000	0.00488
3.445	$2.79 * 10^3$	0.00118	0.00000	0.00352
4.187	$1.54 * 10^4$	0.00000	NA	NA

6.6 Plots and Tables with estimates and simultaneous confidence intervals for Day 57 (monotone-corrected)

6.6.1 Day 57 bindSpike

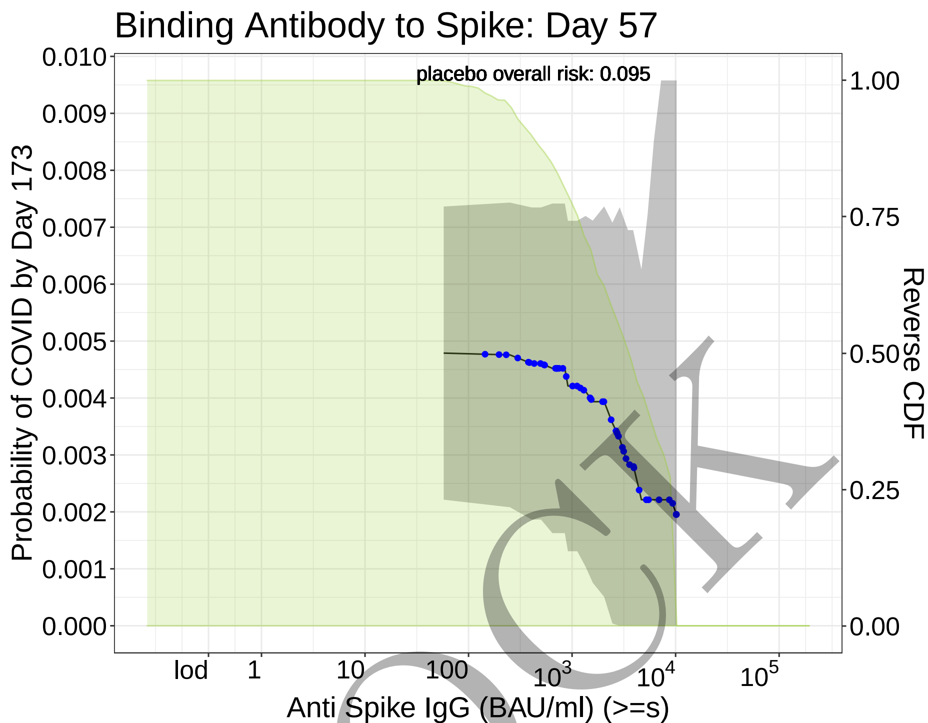


Figure 6.21: Adjusted threshold-response function for a range of thresholds of the Day 57 Day57bindSpike levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.21: Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Day57bindSpike levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
1.761	$5.77 * 10^1$	0.00479	0.00221	0.00736
2.699	$5.00 * 10^2$	0.00461	0.00187	0.00735
2.808	$6.43 * 10^2$	0.00452	0.00163	0.00742
2.965	$9.23 * 10^2$	0.00421	0.00131	0.00711
3.000	$1.00 * 10^3$	0.00421	0.00131	0.00711
3.133	$1.36 * 10^3$	0.00412	0.00104	0.00720
3.459	$2.88 * 10^3$	0.00328	0.00000	0.00735
3.671	$4.69 * 10^3$	0.00221	0.00000	0.00626
3.860	$7.24 * 10^3$	0.00221	0.00000	0.01045
4.007	$1.02 * 10^4$	0.00194	0.00000	0.03884
4.007	$1.02 * 10^4$	0.00194	0.00000	0.03884
4.007	$1.02 * 10^4$	0.00194	0.00000	0.03884
4.007	$1.02 * 10^4$	0.00194	0.00000	0.03884
4.007	$1.02 * 10^4$	0.00194	0.00000	0.03884

6.6.2 Day 57 bindRBD

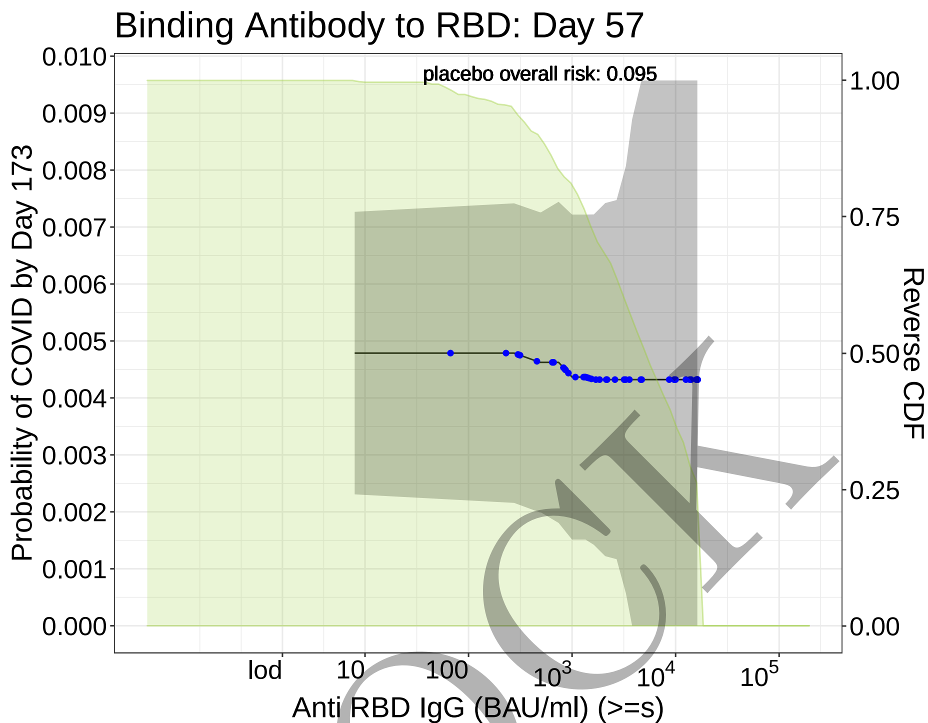


Figure 6.22: Adjusted threshold-response function for a range of thresholds of the Day 57 Day57bindRBD levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.22: Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Day57bindRBD levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.898	$7.91 * 10^0$	0.00479	0.00231	0.00727
2.699	$5.00 * 10^2$	0.00462	0.00199	0.00726
2.871	$7.43 * 10^2$	0.00462	0.00181	0.00744
3.000	$1.00 * 10^3$	0.00437	0.00151	0.00722
3.062	$1.15 * 10^3$	0.00437	0.00151	0.00722
3.211	$1.63 * 10^3$	0.00432	0.00142	0.00722
3.580	$3.80 * 10^3$	0.00432	0.00000	0.00889
3.832	$6.79 * 10^3$	0.00432	0.00000	0.01357
4.061	$1.15 * 10^4$	0.00432	0.00000	0.01960
4.211	$1.63 * 10^4$	0.00432	0.00000	0.04838
4.211	$1.63 * 10^4$	0.00432	0.00000	0.04838
4.211	$1.63 * 10^4$	0.00432	0.00000	0.04838
4.211	$1.63 * 10^4$	0.00432	0.00000	0.04838
4.211	$1.63 * 10^4$	0.00432	0.00000	0.04838

6.6.3 Day 57 pseudoneutid50

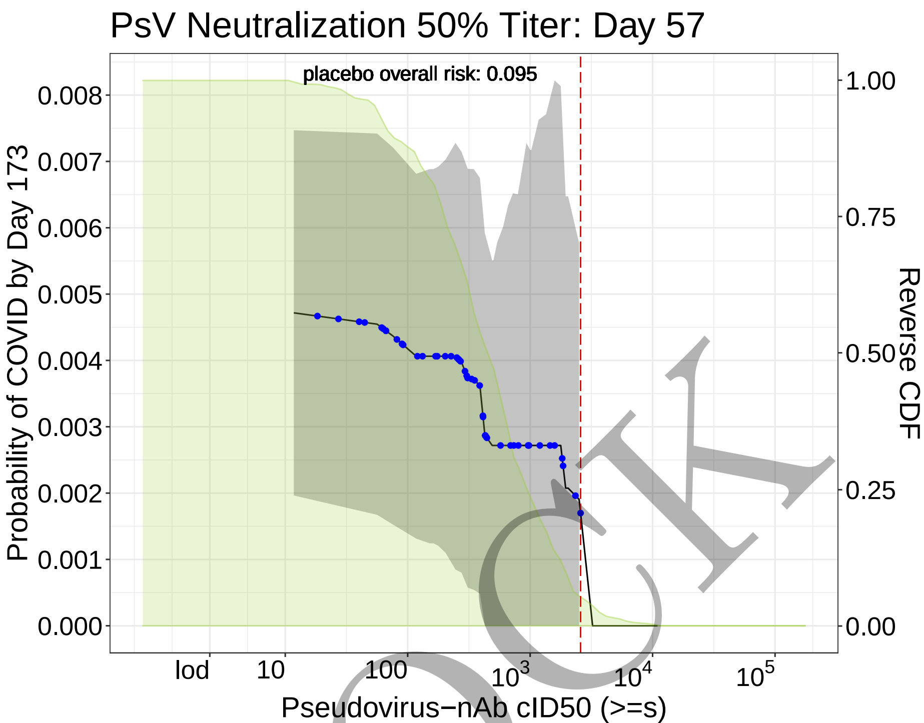


Figure 6.23: Adjusted threshold-response function for a range of thresholds of the Day 57 Day57pseudoneutid50 levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.23: Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Day57pseudoneutid50 levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
1.072	$1.18 * 10^1$	0.00472	0.00196	0.00747
2.070	$1.17 * 10^2$	0.00406	0.00131	0.00681
2.214	$1.64 * 10^2$	0.00406	0.00124	0.00688
2.313	$2.06 * 10^2$	0.00406	0.00110	0.00703
2.538	$3.45 * 10^2$	0.00371	0.00054	0.00688
2.690	$4.90 * 10^2$	0.00272	0.00000	0.00551
2.699	$5.00 * 10^2$	0.00272	0.00000	0.00551
2.817	$6.56 * 10^2$	0.00272	0.00000	0.00634
2.967	$9.27 * 10^2$	0.00272	0.00000	0.00728
3.000	$1.00 * 10^3$	0.00272	0.00000	0.00717
3.196	$1.57 * 10^3$	0.00272	0.00000	0.00822
3.290	$1.95 * 10^3$	0.00208	0.00000	0.00648
3.401	$2.52 * 10^3$	0.00191	0.00000	0.00577
4.038	$1.09 * 10^4$	0.00000	NA	NA

6.6.4 Day 57 pseudoneutid80

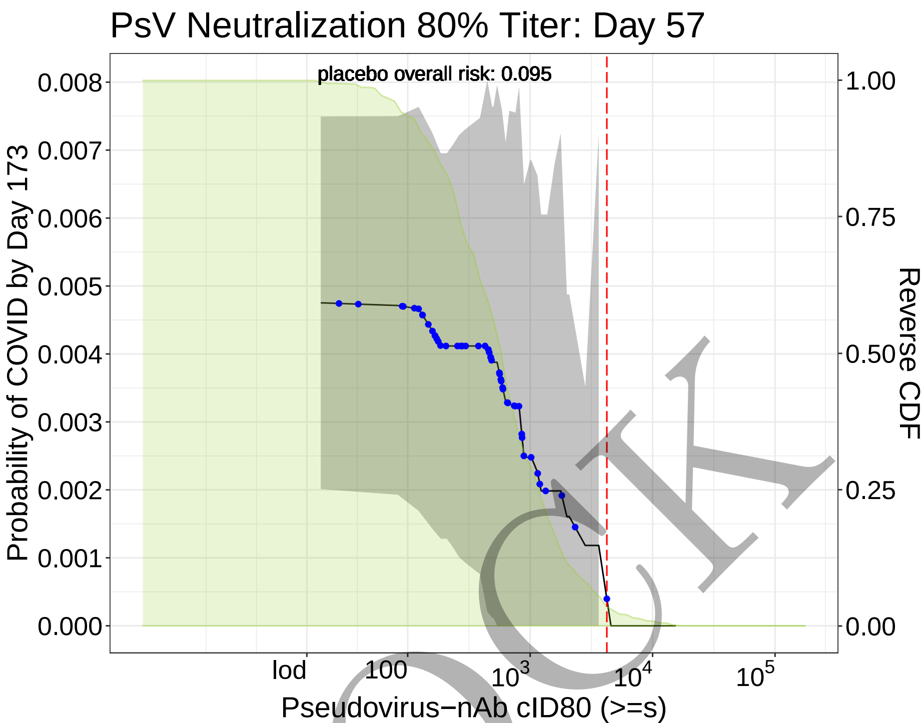


Figure 6.24: Adjusted threshold-response function for a range of thresholds of the Day 57 Day57pseudoneutid80 levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.24: Table of monotone-corrected risk estimates for a range of thresholds of Day 57 Day57pseudoneutid80 levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
1.285	$1.93 * 10^1$	0.00475	0.00201	0.00749
2.204	$1.60 * 10^2$	0.00434	0.00143	0.00726
2.316	$2.07 * 10^2$	0.00412	0.00128	0.00695
2.418	$2.62 * 10^2$	0.00412	0.00101	0.00722
2.648	$4.45 * 10^2$	0.00412	0.00021	0.00803
2.699	$5.00 * 10^2$	0.00388	0.00012	0.00764
2.766	$5.83 * 10^2$	0.00355	0.00000	0.00759
2.878	$7.55 * 10^2$	0.00323	0.00000	0.00755
3.000	$1.00 * 10^3$	0.00248	0.00000	0.00685
3.006	$1.01 * 10^3$	0.00248	0.00000	0.00685
3.196	$1.57 * 10^3$	0.00198	0.00000	0.00680
3.299	$1.99 * 10^3$	0.00161	0.00000	0.00488
3.445	$2.79 * 10^3$	0.00118	0.00000	0.00352
4.187	$1.54 * 10^4$	0.00000	NA	NA

6.7 Plots and Tables with estimates and simultaneous confidence intervals for Day 29 (monotone-corrected)

6.7.1 Day 29 bindSpike

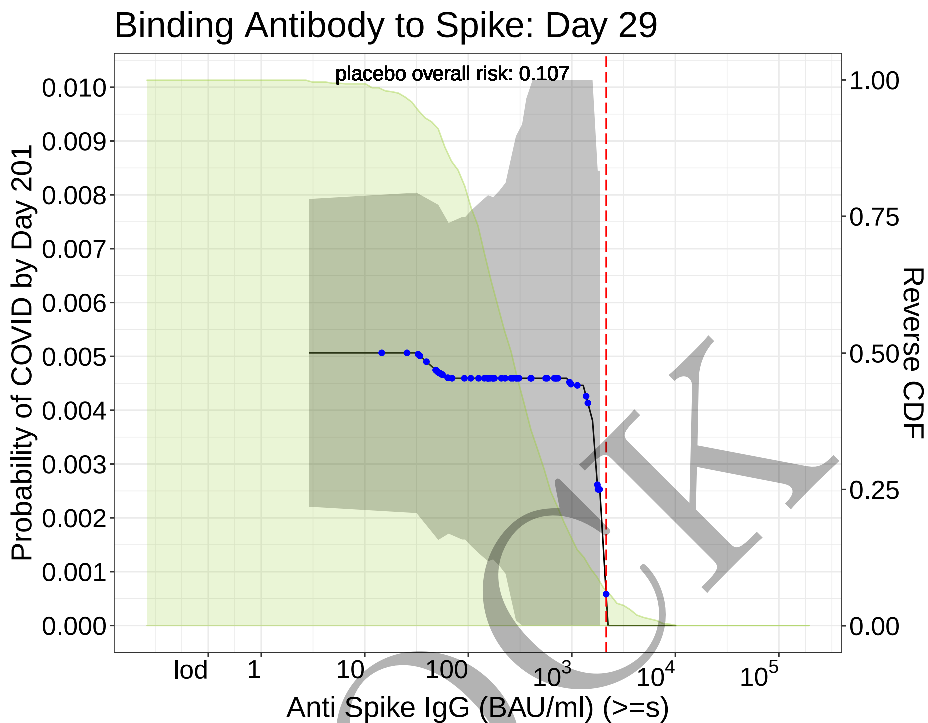


Figure 6.25: Adjusted threshold-response function for a range of thresholds of the Day 29 Day29bindSpike levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.25: Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Day29bindSpike levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.459	$2.88 * 10^0$	0.00507	0.00221	0.00792
1.805	$6.38 * 10^1$	0.00459	0.00171	0.00748
1.967	$9.27 * 10^1$	0.00459	0.00160	0.00759
2.114	$1.30 * 10^2$	0.00459	0.00133	0.00786
2.356	$2.27 * 10^2$	0.00459	0.00096	0.00822
2.518	$3.30 * 10^2$	0.00459	0.00000	0.00931
2.675	$4.73 * 10^2$	0.00459	0.00000	0.01095
2.699	$5.00 * 10^2$	0.00459	0.00000	0.01095
2.850	$7.08 * 10^2$	0.00459	0.00000	0.01181
3.000	$1.00 * 10^3$	0.00446	0.00000	0.01198
3.112	$1.29 * 10^3$	0.00446	0.00000	0.01323
3.250	$1.78 * 10^3$	0.00253	0.00000	0.00845
3.350	$2.24 * 10^3$	0.00000	NA	NA
4.007	$1.02 * 10^4$	0.00000	NA	NA

6.7.2 Day 29 bindRBD

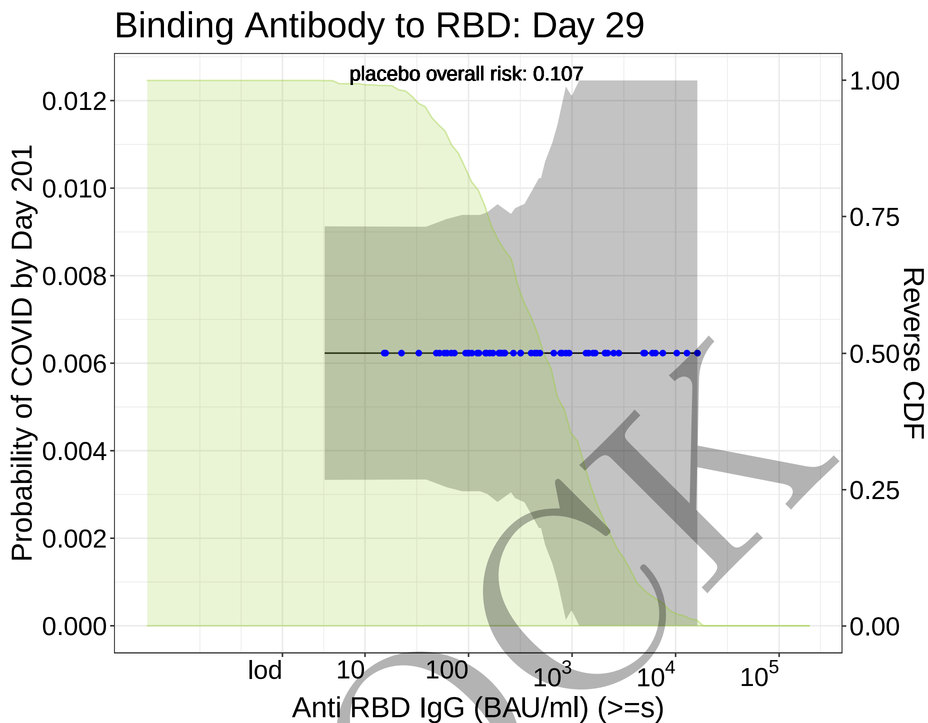


Figure 6.26: Adjusted threshold-response function for a range of thresholds of the Day 29 Day29bindRBD levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.26: Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Day29bindRBD levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.609	$4.06 * 10^0$	0.00623	0.00333	0.00913
1.940	$8.71 * 10^1$	0.00623	0.00307	0.00939
2.110	$1.29 * 10^2$	0.00623	0.00307	0.00939
2.281	$1.91 * 10^2$	0.00623	0.00283	0.00963
2.610	$4.07 * 10^2$	0.00623	0.00253	0.00993
2.699	$5.00 * 10^2$	0.00623	0.00223	0.01023
2.811	$6.47 * 10^2$	0.00623	0.00142	0.01104
2.991	$9.79 * 10^2$	0.00623	0.00034	0.01212
3.000	$1.00 * 10^3$	0.00623	0.00034	0.01212
3.192	$1.56 * 10^3$	0.00623	0.00000	0.01445
3.489	$3.08 * 10^3$	0.00623	0.00000	0.01659
3.613	$4.10 * 10^3$	0.00623	0.00000	0.01908
3.759	$5.74 * 10^3$	0.00623	0.00000	0.01711
4.211	$1.63 * 10^4$	0.00623	0.00000	0.05251

6.7.3 Day 29 pseudoneutid50

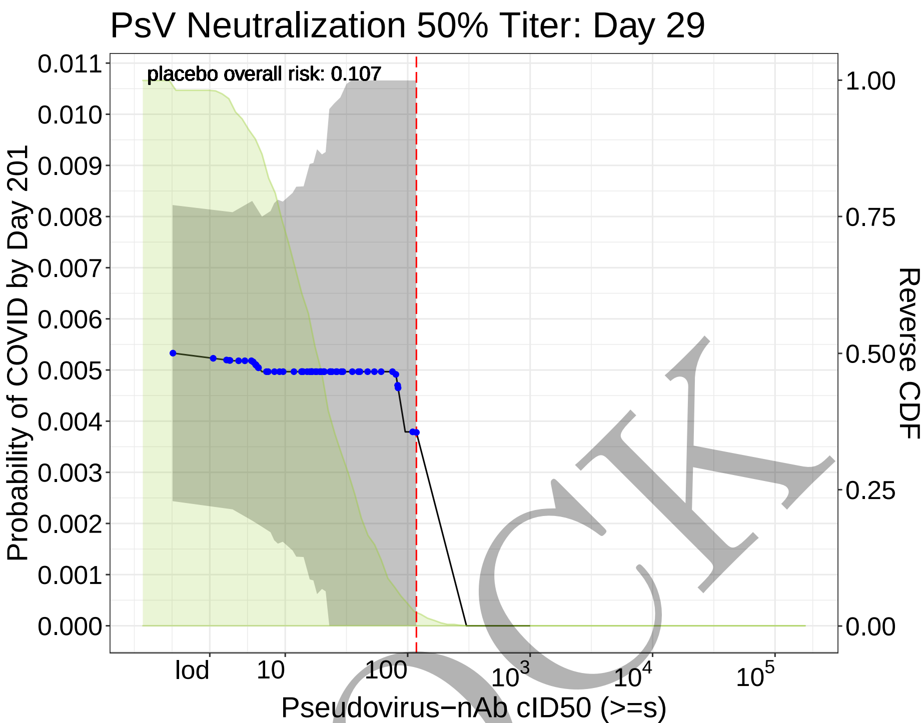


Figure 6.27: Adjusted threshold-response function for a range of thresholds of the Day 29 Day29pseudoneutid50 levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.27: Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Day29pseudoneutid50 levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.083	$1.21 * 10^0$	0.00533	0.00244	0.00822
0.814	$6.52 * 10^0$	0.00497	0.00194	0.00800
0.912	$8.17 * 10^0$	0.00497	0.00167	0.00826
0.985	$9.66 * 10^0$	0.00497	0.00164	0.00829
1.200	$1.58 * 10^1$	0.00497	0.00091	0.00903
1.304	$2.01 * 10^1$	0.00497	0.00072	0.00921
1.404	$2.54 * 10^1$	0.00497	0.00000	0.01021
1.537	$3.44 * 10^1$	0.00497	0.00000	0.01116
1.730	$5.37 * 10^1$	0.00497	0.00000	0.01362
1.811	$6.47 * 10^1$	0.00497	0.00000	0.01494
1.905	$8.04 * 10^1$	0.00497	0.00000	0.01431
2.481	$3.03 * 10^2$	0.00000	NA	NA
2.699	$5.00 * 10^2$	0.00000	NA	NA
3.000	$1.00 * 10^3$	0.00000	NA	NA

6.7.4 Day 29 pseudoneutid80

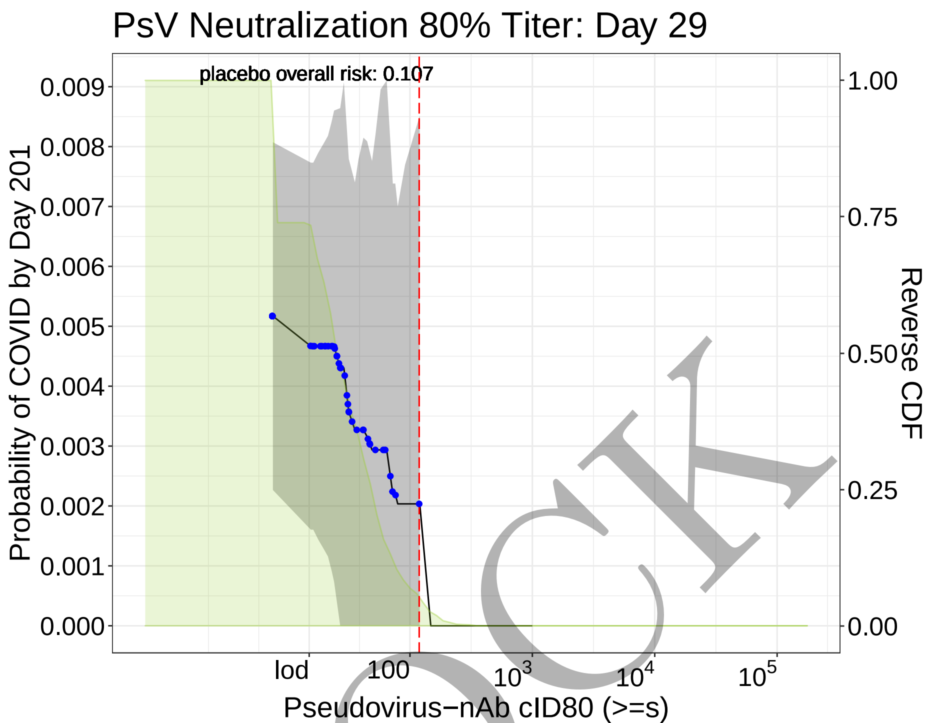


Figure 6.28: Adjusted threshold-response function for a range of thresholds of the Day 29 Day29pseudoneutid80 levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.28: Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Day29pseudoneutid80 levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.876	$7.52 * 10^0$	0.00517	0.00227	0.00807
0.876	$7.52 * 10^0$	0.00517	0.00227	0.00807
0.876	$7.52 * 10^0$	0.00517	0.00227	0.00807
1.185	$1.53 * 10^1$	0.00467	0.00160	0.00773
1.334	$2.16 * 10^1$	0.00467	0.00116	0.00818
1.425	$2.66 * 10^1$	0.00430	0.00000	0.00864
1.548	$3.53 * 10^1$	0.00327	0.00000	0.00740
1.652	$4.49 * 10^1$	0.00316	0.00000	0.00809
1.806	$6.40 * 10^1$	0.00294	0.00000	0.00910
1.877	$7.53 * 10^1$	0.00220	0.00000	0.00738
1.962	$9.16 * 10^1$	0.00203	0.00000	0.00770
2.529	$3.38 * 10^2$	0.00000	NA	NA
2.699	$5.00 * 10^2$	0.00000	NA	NA
3.000	$1.00 * 10^3$	0.00000	NA	NA

6.8 Plots and Tables with estimates and simultaneous confidence intervals for Day 29 (monotone-corrected)

6.8.1 Day 29 bindSpike

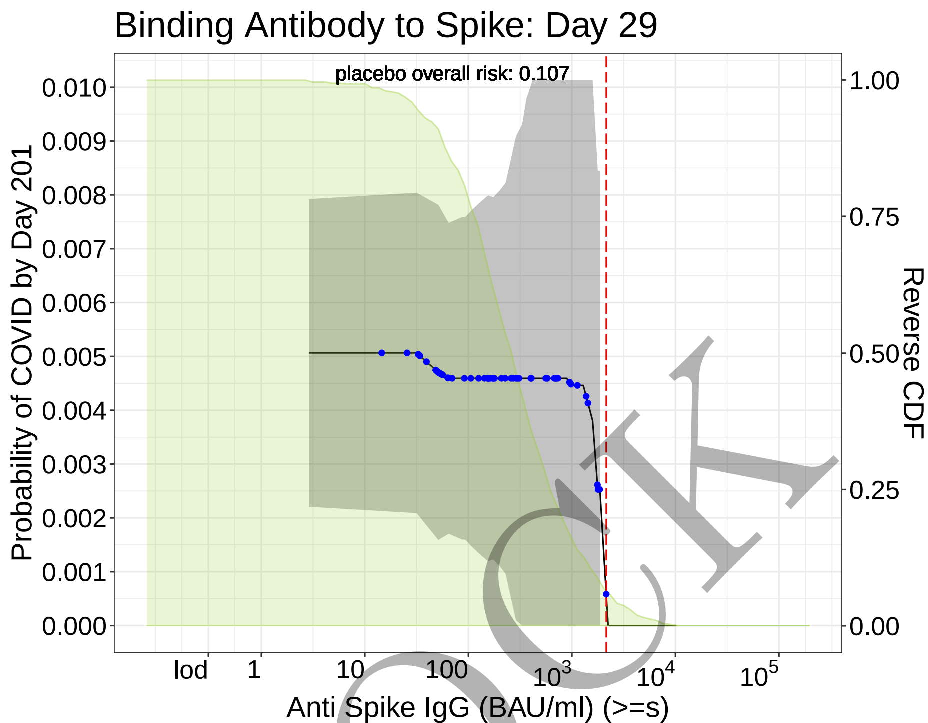


Figure 6.29: Adjusted threshold-response function for a range of thresholds of the Day 29 Day29bindSpike levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.29: Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Day29bindSpike levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.459	$2.88 * 10^0$	0.00507	0.00221	0.00792
1.805	$6.38 * 10^1$	0.00459	0.00171	0.00748
1.967	$9.27 * 10^1$	0.00459	0.00160	0.00759
2.114	$1.30 * 10^2$	0.00459	0.00133	0.00786
2.356	$2.27 * 10^2$	0.00459	0.00096	0.00822
2.518	$3.30 * 10^2$	0.00459	0.00000	0.00931
2.675	$4.73 * 10^2$	0.00459	0.00000	0.01095
2.699	$5.00 * 10^2$	0.00459	0.00000	0.01095
2.850	$7.08 * 10^2$	0.00459	0.00000	0.01181
3.000	$1.00 * 10^3$	0.00446	0.00000	0.01198
3.112	$1.29 * 10^3$	0.00446	0.00000	0.01323
3.250	$1.78 * 10^3$	0.00253	0.00000	0.00845
3.350	$2.24 * 10^3$	0.00000	NA	NA
4.007	$1.02 * 10^4$	0.00000	NA	NA

6.8.2 Day 29 bindRBD

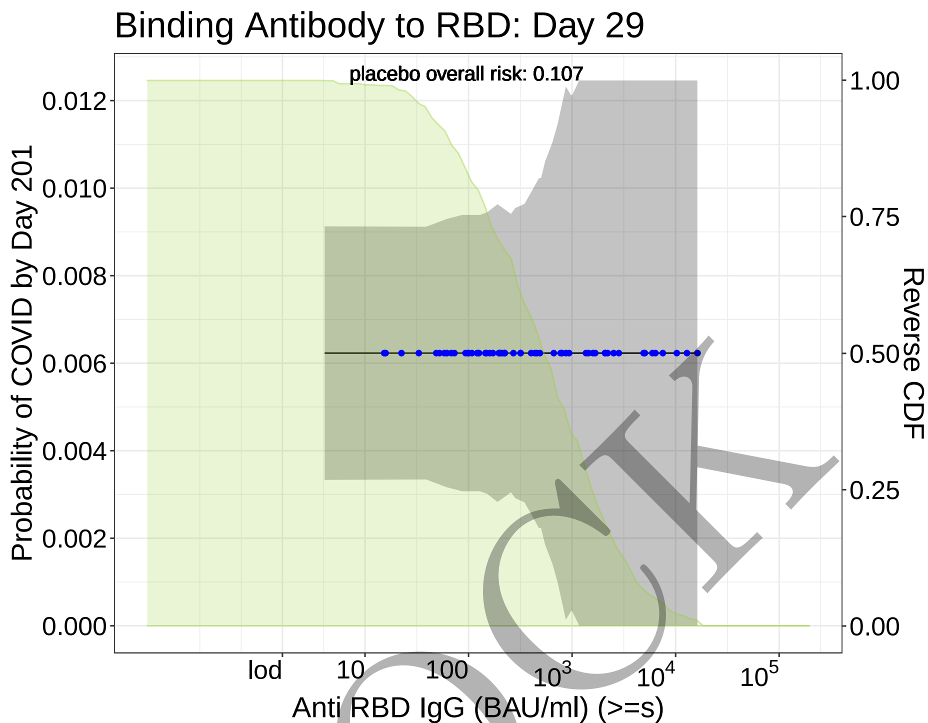


Figure 6.30: Adjusted threshold-response function for a range of thresholds of the Day 29 Day29bindRBD levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.30: Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Day29bindRBD levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.609	$4.06 * 10^0$	0.00623	0.00333	0.00913
1.940	$8.71 * 10^1$	0.00623	0.00307	0.00939
2.110	$1.29 * 10^2$	0.00623	0.00307	0.00939
2.281	$1.91 * 10^2$	0.00623	0.00283	0.00963
2.610	$4.07 * 10^2$	0.00623	0.00253	0.00993
2.699	$5.00 * 10^2$	0.00623	0.00223	0.01023
2.811	$6.47 * 10^2$	0.00623	0.00142	0.01104
2.991	$9.79 * 10^2$	0.00623	0.00034	0.01212
3.000	$1.00 * 10^3$	0.00623	0.00034	0.01212
3.192	$1.56 * 10^3$	0.00623	0.00000	0.01445
3.489	$3.08 * 10^3$	0.00623	0.00000	0.01659
3.613	$4.10 * 10^3$	0.00623	0.00000	0.01908
3.759	$5.74 * 10^3$	0.00623	0.00000	0.01711
4.211	$1.63 * 10^4$	0.00623	0.00000	0.05251

6.8.3 Day 29 pseudoneutid50

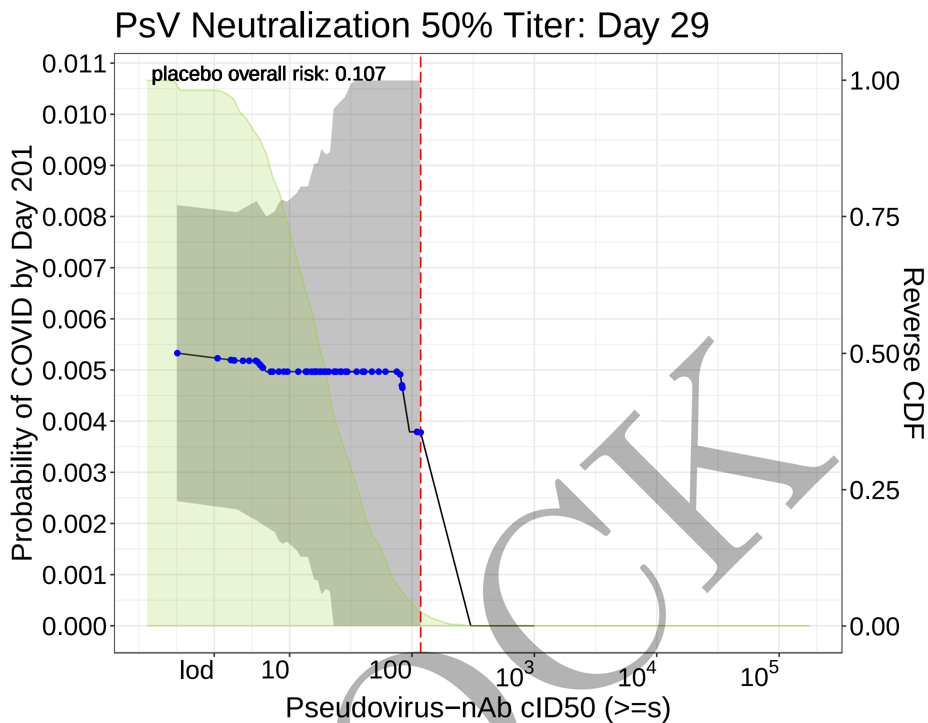


Figure 6.31: Adjusted threshold-response function for a range of thresholds of the Day 29 Day29pseudoneutid50 levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.31: Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Day29pseudoneutid50 levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.083	$1.21 * 10^0$	0.00533	0.00244	0.00822
0.814	$6.52 * 10^0$	0.00497	0.00194	0.00800
0.912	$8.17 * 10^0$	0.00497	0.00167	0.00826
0.985	$9.66 * 10^0$	0.00497	0.00164	0.00829
1.200	$1.58 * 10^1$	0.00497	0.00091	0.00903
1.304	$2.01 * 10^1$	0.00497	0.00072	0.00921
1.404	$2.54 * 10^1$	0.00497	0.00000	0.01021
1.537	$3.44 * 10^1$	0.00497	0.00000	0.01116
1.730	$5.37 * 10^1$	0.00497	0.00000	0.01362
1.811	$6.47 * 10^1$	0.00497	0.00000	0.01494
1.905	$8.04 * 10^1$	0.00497	0.00000	0.01431
2.481	$3.03 * 10^2$	0.00000	NA	NA
2.699	$5.00 * 10^2$	0.00000	NA	NA
3.000	$1.00 * 10^3$	0.00000	NA	NA

6.8.4 Day 29 pseudoneutid80

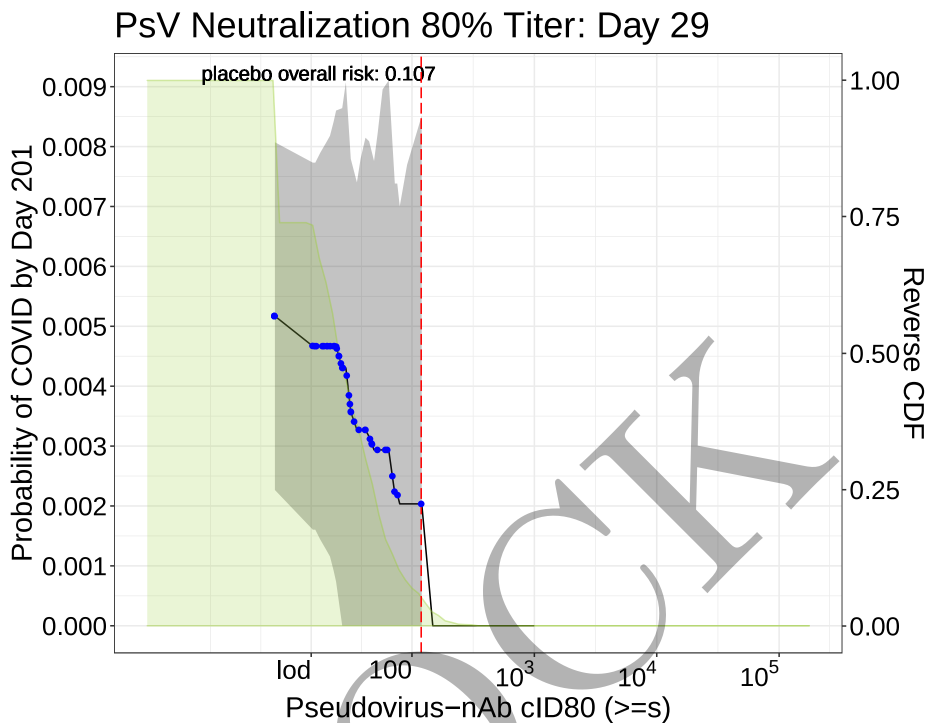


Figure 6.32: Adjusted threshold-response function for a range of thresholds of the Day 29 Day29pseudoneutid80 levels with simultaneous 95% confidence intervals. The dashed red line marks the threshold after which no more COVID events are observed. The estimates and confidence intervals are adjusted using the assumption that the true threshold-response is nonincreasing.

Table 6.32: Table of monotone-corrected risk estimates for a range of thresholds of Day 29 Day29pseudoneutid80 levels with simultaneous 95% confidence intervals.

$\log_{10}$-Threshold	Threshold	Risk estimate	CI left	CI right
0.876	$7.52 * 10^0$	0.00517	0.00227	0.00807
0.876	$7.52 * 10^0$	0.00517	0.00227	0.00807
0.876	$7.52 * 10^0$	0.00517	0.00227	0.00807
1.185	$1.53 * 10^1$	0.00467	0.00160	0.00773
1.334	$2.16 * 10^1$	0.00467	0.00116	0.00818
1.425	$2.66 * 10^1$	0.00430	0.00000	0.00864
1.548	$3.53 * 10^1$	0.00327	0.00000	0.00740
1.652	$4.49 * 10^1$	0.00316	0.00000	0.00809
1.806	$6.40 * 10^1$	0.00294	0.00000	0.00910
1.877	$7.53 * 10^1$	0.00220	0.00000	0.00738
1.962	$9.16 * 10^1$	0.00203	0.00000	0.00770
2.529	$3.38 * 10^2$	0.00000	NA	NA
2.699	$5.00 * 10^2$	0.00000	NA	NA
3.000	$1.00 * 10^3$	0.00000	NA	NA

Chapter 7

Univariate CoR: Nonparametric Threshold Modeling (<=s)

The same methodology as the previous section is apply to estimate the “below” threshold-response function $E_W E[Y = 1|A = 1, X, S \leq s]$.

Chapter 8

Day D29 Univariate CoR: Nonlinear modeling

To explore nonlinear association and threshold modeling, we fit smoothing spline models with degrees of freedom selected by cross-validation using the mgcv R package.

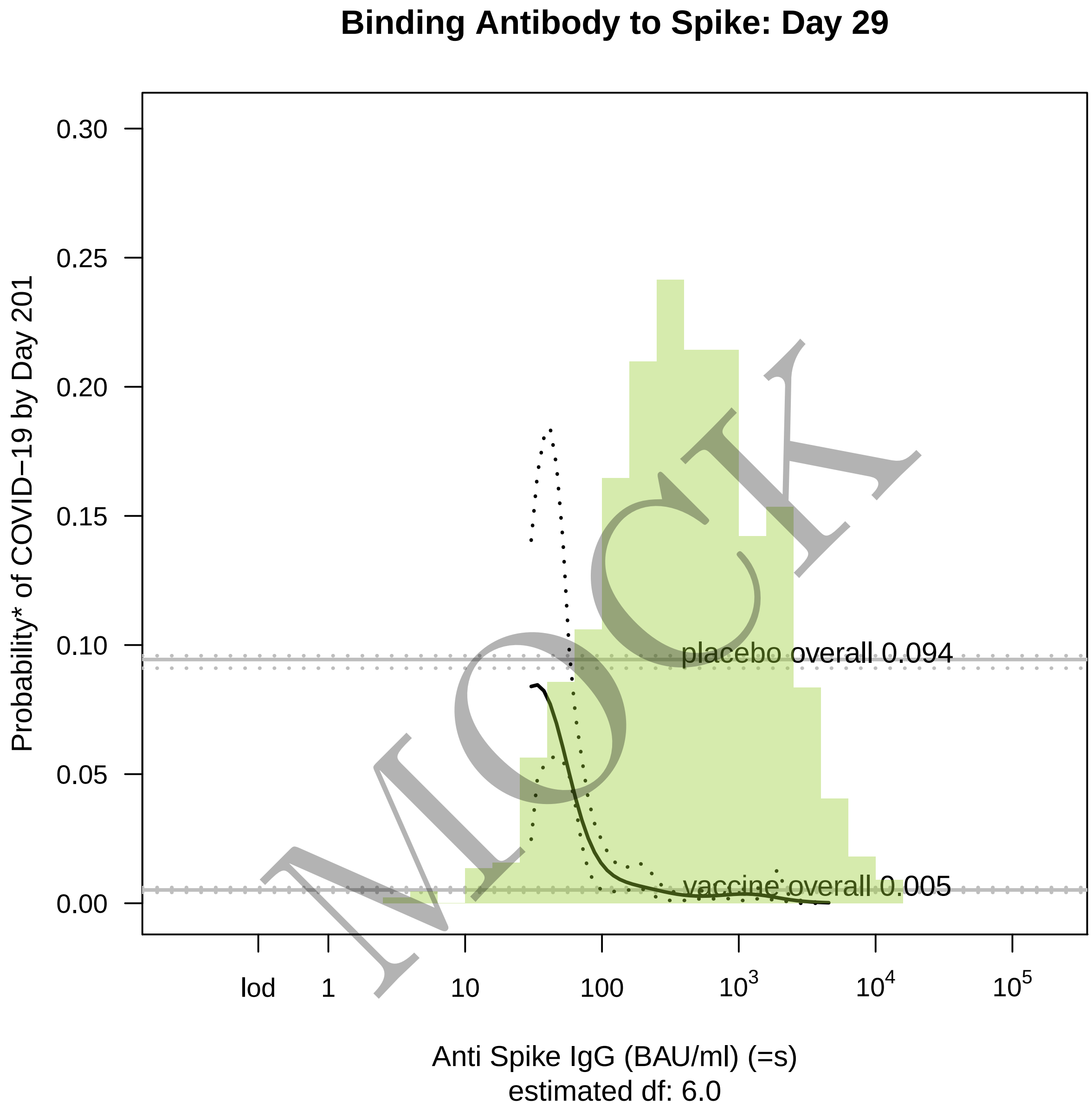


Figure 8.1: Marginalized risk as functions of Day 29 markers (=s) among vaccine recipients with 95% bootstrap point-wise confidence bands (10 replicates) as modeled by GAM with automatic smoothness estimation. Baseline covariates adjusted for: MinorityInd + HighRiskInd + Age. The horizontal lines indicate the overall cumulative risk of the vaccine and placebo arms by Day 201 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod = 0.3.

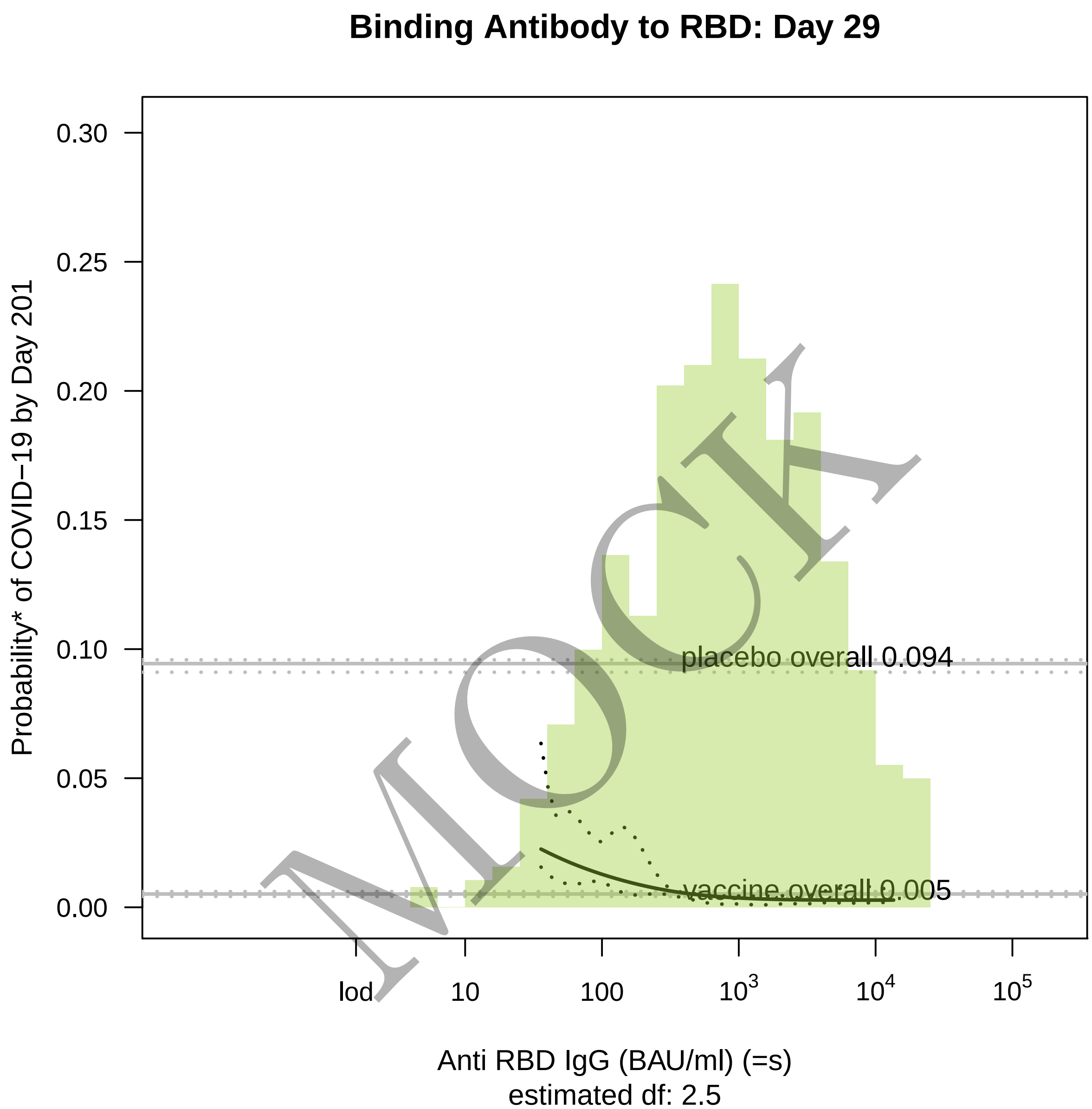


Figure 8.2: Marginalized risk as functions of Day 29 markers (=s) among vaccine recipients with 95% bootstrap point-wise confidence bands (10 replicates) as modeled by GAM with automatic smoothness estimation. Baseline covariates adjusted for: MinorityInd + HighRiskInd + Age. The horizontal lines indicate the overall cumulative risk of the vaccine and placebo arms by Day 201 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod = 1.6.

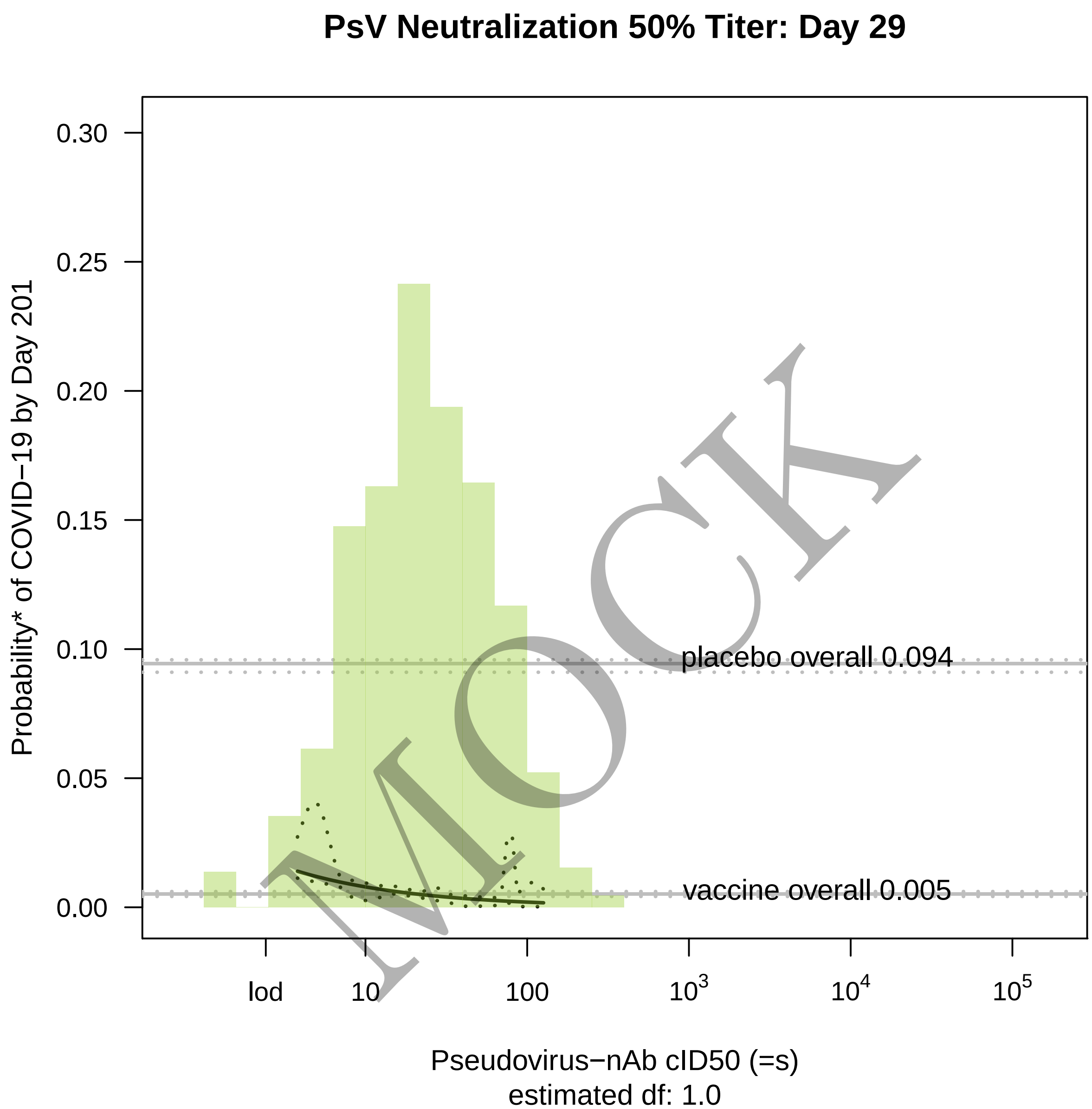


Figure 8.3: Marginalized risk as functions of Day 29 markers (=s) among vaccine recipients with 95% bootstrap point-wise confidence bands (10 replicates) as modeled by GAM with automatic smoothness estimation. Baseline covariates adjusted for: MinorityInd + HighRiskInd + Age. The horizontal lines indicate the overall cumulative risk of the vaccine and placebo arms by Day 201 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod = 2.4.

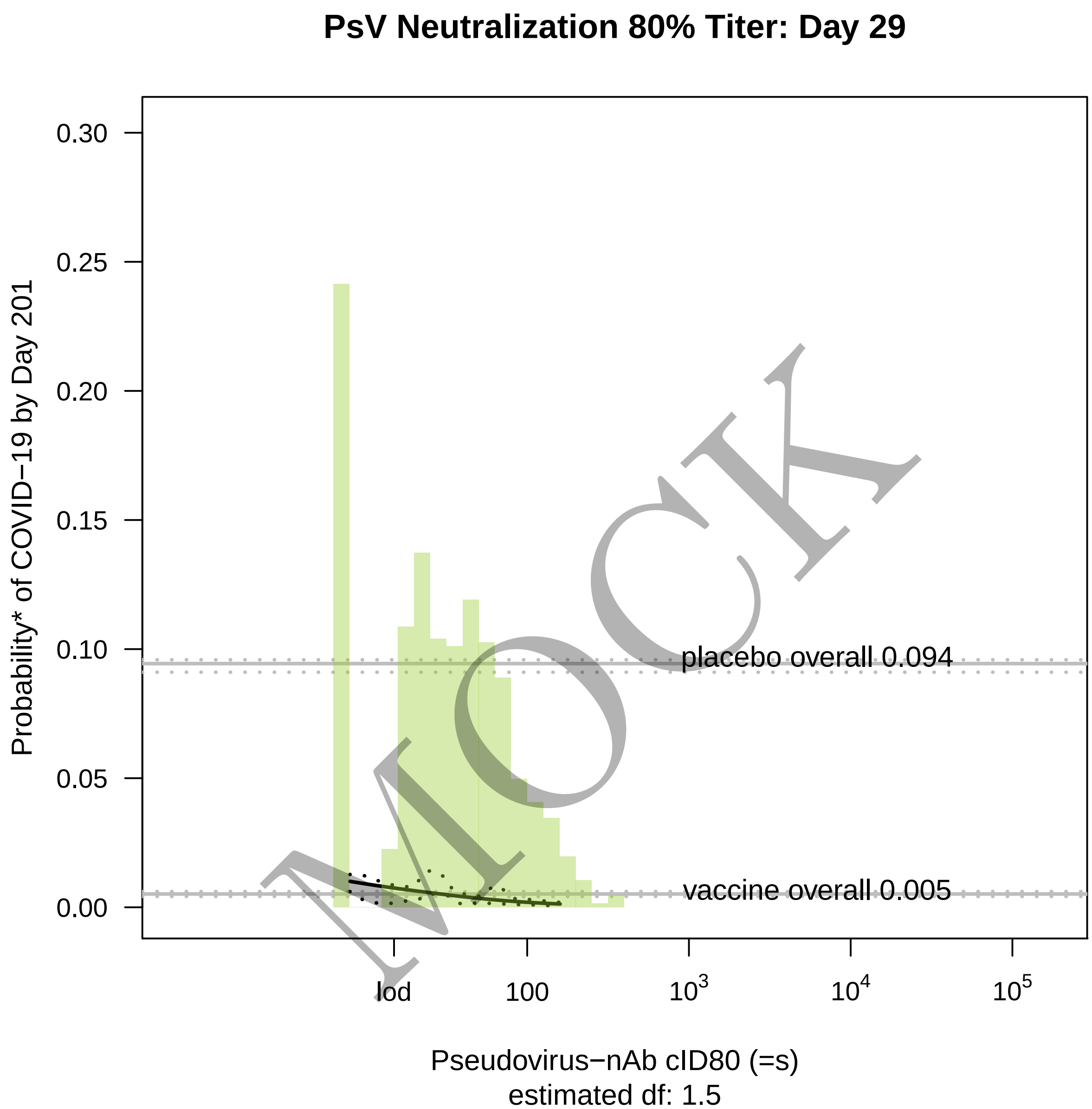


Figure 8.4: Marginalized risk as functions of Day 29 markers (=s) among vaccine recipients with 95% bootstrap point-wise confidence bands (10 replicates) as modeled by GAM with automatic smoothness estimation. Baseline covariates adjusted for: MinorityInd + HighRiskInd + Age. The horizontal lines indicate the overall cumulative risk of the vaccine and placebo arms by Day 201 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod = 15.

Chapter 9

Day D57 Univariate CoR: Nonlinear modeling

To explore nonlinear association and threshold modeling, we fit smoothing spline models with degrees of freedom selected by cross-validation using the mgcv R package.

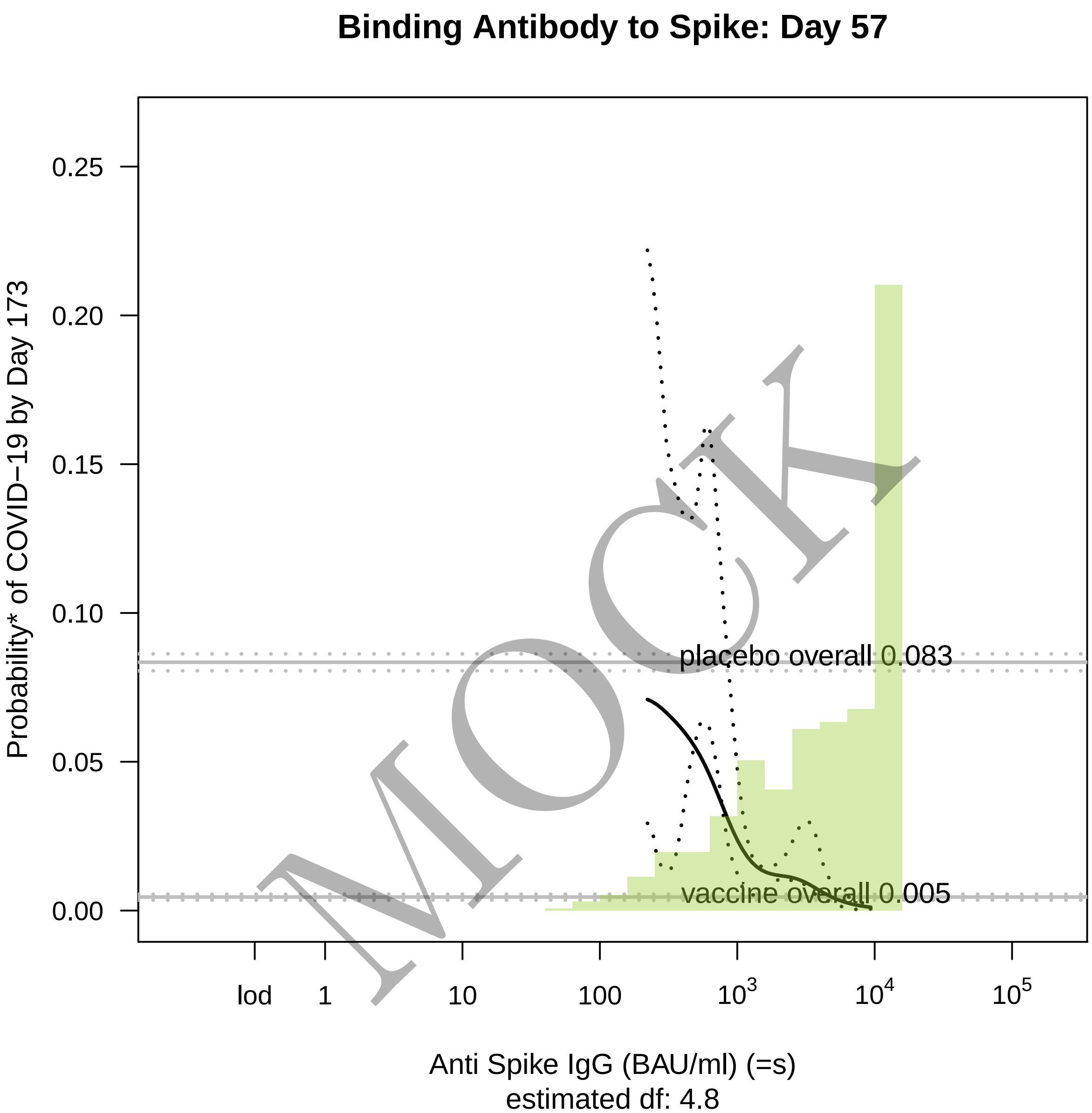


Figure 9.1: Marginalized risk as functions of Day 57 markers (=s) among vaccine recipients with 95% bootstrap point-wise confidence bands (10 replicates) as modeled by GAM with automatic smoothness estimation. Baseline covariates adjusted for: MinorityInd + HighRiskInd + Age. The horizontal lines indicate the overall cumulative risk of the vaccine and placebo arms by Day 173 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod = 0.3.

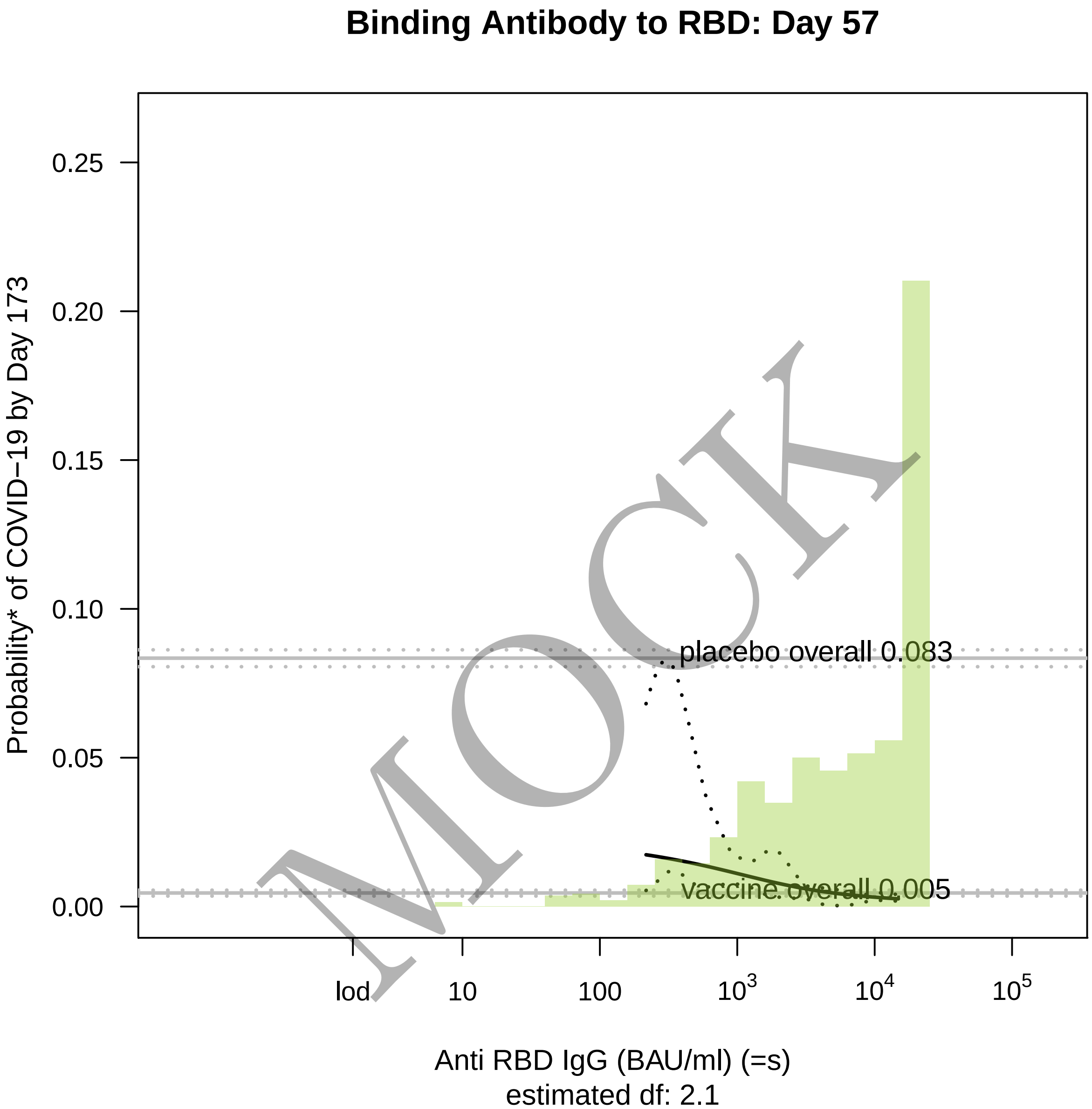


Figure 9.2: Marginalized risk as functions of Day 57 markers (=s) among vaccine recipients with 95% bootstrap point-wise confidence bands (10 replicates) as modeled by GAM with automatic smoothness estimation. Baseline covariates adjusted for: MinorityInd + HighRiskInd + Age. The horizontal lines indicate the overall cumulative risk of the vaccine and placebo arms by Day 173 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod = 1.6.

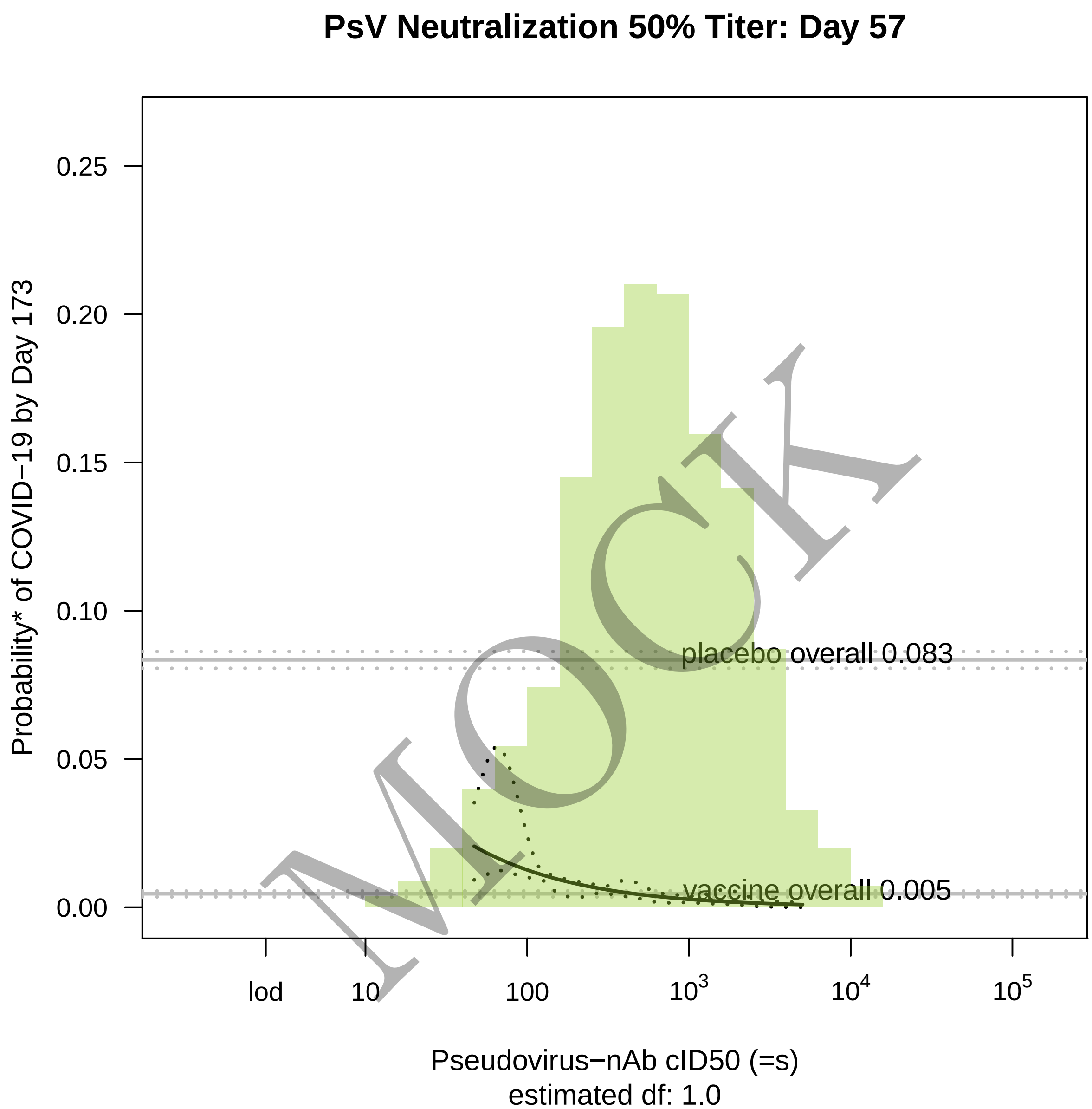


Figure 9.3: Marginalized risk as functions of Day 57 markers (=s) among vaccine recipients with 95% bootstrap point-wise confidence bands (10 replicates) as modeled by GAM with automatic smoothness estimation. Baseline covariates adjusted for: MinorityInd + HighRiskInd + Age. The horizontal lines indicate the overall cumulative risk of the vaccine and placebo arms by Day 173 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod = 2.4.

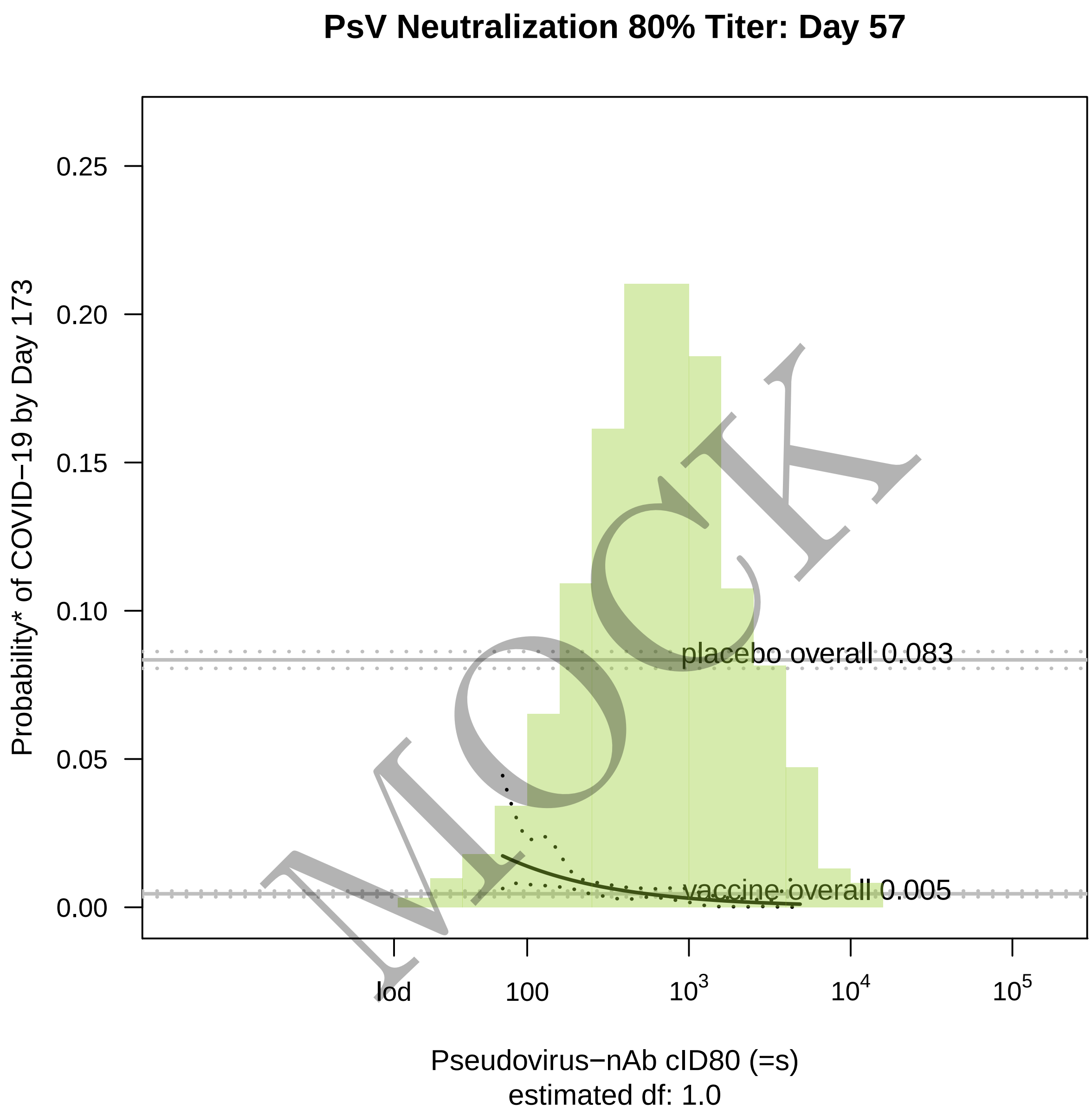


Figure 9.4: Marginalized risk as functions of Day 57 markers (=s) among vaccine recipients with 95% bootstrap point-wise confidence bands (10 replicates) as modeled by GAM with automatic smoothness estimation. Baseline covariates adjusted for: MinorityInd + HighRiskInd + Age. The horizontal lines indicate the overall cumulative risk of the vaccine and placebo arms by Day 173 and its 95% point-wise confidence interval. Histograms of the immunological markers in the vaccine arm are overlaid. lod = 15.

Chapter 10

Appendix

```
#> [1] "reading data from moderna_mock_data_processed_with_riskscore.csv"
```

- This report was built from the `CoVPN/correlates_reporting` repository with commit hash 4687f2af4a13f5cb2de75f432c422c0cc60ba2c7. A diff of the changes introduced by that commit may be viewed at https://github.com/CoVPN/correlates_reporting/commit/4687f2af4a13f5cb2de75f432c422c0cc60ba2c7
- The sha256 hash sum of the processed file, "moderna_mock_data_processed_with_riskscore.csv": c29963d581d8d6b7c13fecc9ca9b60a505a187b34fae117ebc0ad747cff1b26a