

ADIS where PPSIFL='Y' and PARCAT1='Serum SARS-CoV-2 Binding Antibodies' and  
PARAMCD contains "S2PIGG" and ADT<=EFFCODT and ANL01FL='Y' and APERIOD=1.  
BigN: ADSL where PPSIFL='Y'.

by Baseline SARS-CoV-2 Status

Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative

Antibody: SARSCOV2S2P IgG Antibody

SCOV2BL

PARAM that doesn't contain 'LOG10', ISLLOQ, ISULOQ

(28438.87)

Timepoint

Data Category

Statistic

Baseline (Day 1)

n [1]

GM Level

95% CI [2]

Median

Min, Max

Day 29

n [1]

GM Level

95% CI [2]

Median

Min, Max

N1

GM Fold-Rise

95% CI [2]

Seroresponse [3]

n (%) [4]

95% CI [5]

&gt;= 2-fold Increase

n (%) [4]

95% CI [5]

&gt;= 3-fold Increase

n (%) [4]

95% CI [5]

&gt;= 4-fold Increase

n (%) [4]

95% CI [5]

AVISIT

n[1]: the number of unique subjects with non-missing AVAL where PARAM doesn't contain 'LOG10' at each AVISIT.

For median, min, max, use AVAL where PARAM doesn't contain 'LOG10'.

For GM level, use AVAL where PARAM is LOG10(PARAM) (i.e., PARAM contains 'LOG10') to calculate mean, then transfer back ( $10^{\text{mean}}$ ).

N1: the number of unique subjects with non-missing AVAL where PARAM doesn't contain 'LOG10' at both baseline and the post-baseline AVISIT.

GMFR: use CHG where PARAM contains 'LOG10' to calculate mean, then transfer back ( $10^{\text{mean}}$ ).

Seroresponse: # of subjects with CRIT6FL=Y where PARAM doesn't contain 'LOG10'

Main side: Use macro mclopperis.SAS. CALL %clopper2(lib=ADB, datain=ADIS, trt=TRT01P, cohort=SCOV2BL, subset=PPSIFL='Y' and parcat1='Serum SARS-CoV-2 Binding Antibodies' and index(PARAMCD,'S2PIGG')>0 and ANL01FL='Y' and substr(param,1,5)^='LOG10' and ADT<=EFFCODT and APERIOD=1, crit=CRIT6FL, dataout=summary2, grvar=);

Output: summary2.lowercl and summary2.uppercl

&gt;=2: # of subjects with CRIT1FL=Y where PARAM doesn't contain 'LOG10'. Replace CRIT4FL with CRIT1FL in macro call.

&gt;=3: # of subjects with CRIT2FL=Y where PARAM doesn't contain 'LOG10'. Replace CRIT4FL with CRIT2FL in macro call.

&gt;=4: # of subjects with CRIT3FL=Y where PARAM doesn't contain 'LOG10'. Replace CRIT4FL with CRIT3FL in macro call.

datain=ADIS, subset=PPSIFL='Y'  
ex(PARAMCD,'S2PIGG')>0 and  
FCODT and APERIOD=1,

summary1.UPPERGMT.  
summary1.UPPERGMR

greater than for AVAL.

(xx.xx, xx.xx)

Note: Footnotes are

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Table 14.2.4.1.1.3.1

Summary of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status  
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative

Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)

Timepoint	Placebo (N=142)	mRNA-1273 (N=1055)
Data Category		
Statistic		
Day 57		
n [1]	xx	xx
GM Level	xx.x	xx.x
95% CI [2]	(xx.xx, xx.xx)	(xx.xx, xx.xx)
Median	xx.x	xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x
N1	xx	xx
GM Fold-Rise	xx.xx	xx.xx
95% CI [2]	(xx.xx, xx.xx)	(xx.xx, xx.xx)
Seroresponse [3]		
n (%) [4]	xx (xx.x)	xx (xx.x)
95% CI [5]	(xx.xx, xx.xx)	(xx.xx, xx.xx)
>= 2-fold Increase from Baseline [6]		
n (%) [4]	xx (xx.x)	xx (xx.x)
95% CI [5]	(xx.xx, xx.xx)	(xx.xx, xx.xx)
>= 3-fold Increase from Baseline [6]		
n (%) [4]	xx (xx.x)	xx (xx.x)
95% CI [5]	(xx.xx, xx.xx)	(xx.xx, xx.xx)
>= 4-fold Increase from Baseline [6]		
n (%) [4]	xx (xx.x)	xx (xx.x)
95% CI [5]	(xx.xx, xx.xx)	(xx.xx, xx.xx)

Note: Footnotes are listed on last page.

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Table 14.2.4.1.1.1.3.1

Summary of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status  
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive

Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: xx.x, ULOQ: xx.x)

Timepoint Data Category Statistic	Placebo (N=xx)	mRNA-1273 (N=xx)
Baseline (Day 1)		
n [1]	xx	xx
GM Level	xx.x	xx.x
95% CI [2]	(xx.xx, xx.xx)	(xx.xx, xx.xx)
Median	xx.x	xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x
Day 29		
n [1]	xx	xx
GM Level	xx.x	xx.x
95% CI [2]	(xx.xx, xx.xx)	(xx.xx, xx.xx)
Median	xx.x	xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x
N1	xx	xx
GM Fold-Rise	xx.xx	xx.xx
95% CI [2]	(xx.xx, xx.xx)	(xx.xx, xx.xx)
Seroresponse [3]		
n (%) [4]	xx (xx.x)	xx (xx.x)
95% CI [5]	(xx.xx, xx.xx)	(xx.xx, xx.xx)
>= 2-fold Increase from Baseline [6]		
n (%) [4]	xx (xx.x)	xx (xx.x)
95% CI [5]	(xx.xx, xx.xx)	(xx.xx, xx.xx)
>= 3-fold Increase from Baseline [6]		
n (%) [4]	xx (xx.x)	xx (xx.x)
95% CI [5]	(xx.xx, xx.xx)	(xx.xx, xx.xx)
>= 4-fold Increase from Baseline [6]		
n (%) [4]	xx (xx.x)	xx (xx.x)
95% CI [5]	(xx.xx, xx.xx)	(xx.xx, xx.xx)

Note: Footnotes are listed on last page.

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Table 14.2.4.1.1.3.1

Summary of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status  
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive

Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)

Timepoint	Placebo	mRNA-1273
Data Category	(N=xx)	(N=xx)
Statistic		
Day 57		
n [1]	xx	xx
GM Level	xx.x	xx.x
95% CI [2]	(xx.xx, xx.xx)	(xx.xx, xx.xx)
Median	xx.x	xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x
N1	xx	xx
GM Fold-Rise	xx.xx	xx.xx
95% CI [2]	(xx.xx, xx.xx)	(xx.xx, xx.xx)
Seroresponse [3]		
n (%) [4]	xx (xx.x)	xx (xx.x)
95% CI [5]	(xx.xx, xx.xx)	(xx.xx, xx.xx)
>= 2-fold Increase from Baseline [6]		
n (%) [4]	xx (xx.x)	xx (xx.x)
95% CI [5]	(xx.xx, xx.xx)	(xx.xx, xx.xx)
>= 3-fold Increase from Baseline [6]		
n (%) [4]	xx (xx.x)	xx (xx.x)
95% CI [5]	(xx.xx, xx.xx)	(xx.xx, xx.xx)
>= 4-fold Increase from Baseline [6]		
n (%) [4]	xx (xx.x)	xx (xx.x)
95% CI [5]	(xx.xx, xx.xx)	(xx.xx, xx.xx)

Note: Footnotes are listed on last page.

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Table 14.2.4.1.1.1.3.1  
Summary of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status  
Per-Protocol Random Subcohort for Immunogenicity

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CI = confidence interval, GM = geometric mean, MSD = meso scale discovery.  
N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.  
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.

- [1] Number of subjects with non-missing data at the corresponding timepoint.
- [2] 95% CI is calculated based on the t-distribution of the log-transformed values or the difference in the log-transformed values for GM value and GM fold-rise, respectively, then back transformed to the original scale for presentation.
- [3] Seroresponse at a subject level is defined as a change from below the LLOQ to equal or above the LLOQ, or at least a 1.9-fold rise if baseline is equal to or above the LLOQ.
- [4] Number of subjects meeting the criterion at the time point. Percentages are based on N1.
- [5] 95% CI is calculated using the Clopper-Pearson method.
- [6]  $\geq z$ -fold increase from baseline at participant level is defined as a  $\geq z \times \text{LLOQ}$  for participants with baseline antibody level below the LLOQ, or a  $z$ -times or higher level ratio in participants with baseline antibody level equal to or above the LLOQ.