



## CERTIFICATE OF ANALYSIS

Page 1 of 2

**Product Description:** V-PLEX<sup>®</sup> SARS-CoV-2 Panel 31 Kit  
**Kit Catalog Numbers:** K15642-Series; K15643-Series; K15645-Series; K15644-Series; K15646-Series; K15647-Series; K15648-Series  
**Kit Lot Number:** K0082177  
**Expiration Date:** 31 JAN 2024

### Kit Components:

| Description                                    | Lot Number       | Storage Temperature | Expiration Date |
|--|------------------|---------------------|-----------------|
| SARS-CoV-2 Plate 31                            | Z0057293         | 2-8°C               | 30 APR 2025     |
| Reference Standard 1                           | A0080286         | ≤ -70°C             | 28 FEB 2026     |
| Serology Control 1.1                           | A00C0825         | ≤ -70°C             | 31 MAR 2027     |
| Serology Control 1.2                           | A00C0826         | ≤ -70°C             | 31 MAR 2027     |
| Serology Control 1.3                           | A00C0827         | ≤ -70°C             | 31 MAR 2027     |
| SULFO-TAG <sup>™</sup> Human ACE2 Protein      | D0081760         | 2-8°C               | 31 JAN 2024     |
| ACE2 Calibration Reagent                       | A0080327         | 2-8°C               | 31 OCT 2025     |
| SULFO-TAG <sup>™</sup> Anti-Human IgG Antibody | D00V0027         | 2-8°C               | 30 NOV 2025     |
| SULFO-TAG <sup>™</sup> Anti-Human IgM Antibody | Not Kit Specific | 2-8°C               | See Label       |
| SULFO-TAG <sup>™</sup> Anti-Human IgA Antibody | Not Kit Specific | 2-8°C               | See Label       |
| SULFO-TAG <sup>™</sup> Anti-Mouse IgG Antibody | Not Kit Specific | 2-8°C               | See Label       |
| SULFO-TAG <sup>™</sup> Anti-Mouse IgM Antibody | Not Kit Specific | 2-8°C               | See Label       |
| SULFO-TAG <sup>™</sup> Anti-Mouse IgA Antibody | Not Kit Specific | 2-8°C               | See Label       |
| Diluent 100                                    | Not Kit Specific | 2-8°C               | See Label       |
| MSD Blocker A Kit                              | Not Kit Specific | Room Temperature    | See Label       |
| MSD GOLD Read Buffer B                         | Not Kit Specific | Room Temperature    | See Label       |

See product insert regarding which components are provided with each IgG, IgA, IgM, or ACE2 kit.

### Plate Uniformity Testing Results:

| Parameter               | Precision                  |                        |                    | Uniformity                | Signal            |
|-------------------------|----------------------------|------------------------|--------------------|---------------------------|-------------------|
|                         | CV of Intra-plate Averages | Average Intra-plate CV | Max Intra-plate CV | Average Uniformity Metric | Average Signal    |
| SARS-CoV-2 Spike        | ≤ 18%                      | ≤ 10%                  | ≤ 13%              | Pass                      | 1,500 – 1,000,000 |
| SARS-CoV-2 Nucleocapsid | ≤ 18%                      | ≤ 10%                  | ≤ 13%              | Pass                      | 1,500 – 1,000,000 |
| SARS-CoV-2 Spike (BA.5) | ≤ 18%                      | ≤ 10%                  | ≤ 13%              | Pass                      | 1,500 – 1,000,000 |
| RBD (BA.4; BA.5)        | ≤ 18%                      | ≤ 10%                  | ≤ 13%              | Pass                      | 1,500 – 1,000,000 |
| SARS-CoV-2 S1 RBD       | ≤ 18%                      | ≤ 10%                  | ≤ 13%              | Pass                      | 1,500 – 1,000,000 |



## CERTIFICATE OF ANALYSIS

Page 2 of 2

### Coating Confirmation Testing Results:

| Spot | Description             | Result |
|------|-------------------------|--------|
| 1    | SARS-CoV-2 Spike        | Pass   |
| 3    | SARS-CoV-2 Nucleocapsid | Pass   |
| 8    | SARS-CoV-2 Spike (BA.5) | Pass   |
| 9    | RBD (BA.4; BA.5)        | Pass   |
| 10   | SARS-CoV-2 S1 RBD       | Pass   |

**RBD** indicates SARS-CoV-2 Receptor Binding Domain with mutation(s) listed.

### Functional Testing Results:

| Sample Type             | Calibrator                         | Controls            |                     | Samples                            |                         |
|-------------------------|------------------------------------|---------------------|---------------------|------------------------------------|-------------------------|
| Metric                  | Avg Signal Ratio<br>Test:Reference | Control<br>Recovery | Control<br>Conc. CV | Avg % Difference<br>Test:Reference | Slope<br>Test:Reference |
| SARS-CoV-2 Spike        | 50 – 200%                          | 70 – 130%           | < 20%               | ± 25%                              | 0.80 – 1.2              |
| SARS-CoV-2 Nucleocapsid | 50 – 200%                          | 70 – 130%           | < 20%               | ± 25%                              | 0.80 – 1.2              |
| SARS-CoV-2 Spike (BA.5) | 50 – 200%                          | 70 – 130%           | < 20%               | ± 25%                              | 0.80 – 1.2              |
| RBD (BA.4; BA.5)        | 50 – 200%                          | 70 – 130%           | < 20%               | ± 25%                              | 0.80 – 1.2              |
| SARS-CoV-2 S1 RBD       | 50 – 200%                          | 70 – 130%           | < 20%               | ± 25%                              | 0.80 – 1.2              |

### Additional Comments:

Functional testing was executed using SARS-CoV-2 Plate 31 (Z0057293), SULFO-TAG Anti-Human IgG Antibody (D00V0027), Reference Standard 1 (A0080286), and Serology Controls (A00C825, A00C0826, A00C0827).

All kit components were manufactured and tested according to MSD documents. The lots listed in the Kit Components table meet MSD's specifications.

### Statement:

The above product is intended for Research Use Only. Not for use in Diagnostic Procedures.

|                        | Name          | Function | Signature | Date        |
|------------------------|---------------|----------|-----------|-------------|
| <b>Review/Approval</b> | Karen Hamilla | Quality  |           | 06 DEC 2022 |