



## CERTIFICATE OF ANALYSIS

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**Product Description:** V-PLEX<sup>®</sup> SARS-CoV-2 Panel 2 Kit  
**Kit Catalog Numbers:** K15383-Series; K15384-Series; K15385-Series; K15386-Series;  
 K15475Series; K15476-Series; K15477-Series  
**Kit Lot Number:** K0082016  
**Expiration Date:** 31 DEC 2022

### Kit Components:

| Description                                    | Lot Number       | Storage Temperature | Expiration Date |
|--|------------------|---------------------|-----------------|
| SARS CoV-2 Plate 2                             | Z0056737         | 2-8°C               | 31 DEC 2022     |
| 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                       | A0080301         | 2-8°C               | 31 MAR 2025     |
| SULFO-TAG <sup>™</sup> Anti-Human IgG Antibody | D00V0014         | 2-8°C               | 31 DEC 2024     |
| 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 |            |                   |
| 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 S1 RBD       | ≤ 18%                      | ≤ 10%                  | ≤ 13%              | Pass       | 1,500 – 1,000,000 |

### Coating Confirmation Testing Results:

| Spot | Description             | Result |
|------|-------------------------|--------|
| 1    | SARS CoV-2 Spike        | Pass   |
| 3    | SARS CoV-2 Nucleocapsid | Pass   |
| 10   | SARS CoV-2 S1 RBD       | Pass   |



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### 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%           | < 25%               | ± 25%                              | 0.80 – 1.2              |
| SARS CoV-2 Nucleocapsid | 50 – 200%                          | 70 – 130%           | < 25%               | ± 25%                              | 0.80 – 1.2              |
| SARS CoV-2 S1 RBD       | 50 – 200%                          | 70 – 130%           | < 25%               | ± 25%                              | 0.80 – 1.2              |

### Additional Comments:

Functional testing was executed using SARS CoV-2 Plate 2 (Z0056737), SULFO-TAG Anti-Human IgG Antibody (D00V0002), Reference Standard 1 (A00V0004), and Serology Controls (A00C0731, A00C0732, A00C0733).

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        |
|-----------------|---------------|----------|-----------|-------------|
| Review/Approval | Karen Hamilla | Quality  |           | 28 APR 2022 |