



## CERTIFICATE OF ANALYSIS

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**Product Description:** V-PLEX® SARS-CoV-2 Panel 2 Kit  
**Kit Catalog Numbers:** K15383-Series; K15384-Series; K15385-Series; K15386-Series; K15475-Series; K15476-Series; K15477-Series  
**Kit Lot Number:** K0082330  
**Expiration Date:** 31 JAN 2024

### Kit Components:

| Description                        | Lot Number       | Storage Temperature | Expiration Date |
|------------------------------------|------------------|---------------------|-----------------|
| SARS-CoV-2 Plate 2                 | Z0057389         | 2-8°C               | 31 DEC 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™ Human ACE2 Protein      | D0081760         | 2-8°C               | 31 JAN 2024     |
| ACE2 Calibration Reagent           | A0080309         | 2-8°C               | 30 APR 2025     |
| SULFO-TAG™ Anti-Human IgG Antibody | D00V0029         | 2-8°C               | 31 JUL 2026     |
| SULFO-TAG™ Anti-Human IgM Antibody | Not Kit Specific | 2-8°C               | See Label       |
| SULFO-TAG™ Anti-Human IgA Antibody | Not Kit Specific | 2-8°C               | See Label       |
| SULFO-TAG™ Anti-Mouse IgG Antibody | Not Kit Specific | 2-8°C               | See Label       |
| SULFO-TAG™ Anti-Mouse IgM Antibody | Not Kit Specific | 2-8°C               | See Label       |
| SULFO-TAG™ 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 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%           | < 20%               | ± 25%                              | 0.80 – 1.2              |
| SARS CoV-2 Nucleocapsid | 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 2 (Z0057389), SULFO-TAG Anti-Human IgG Antibody (D00V0029), Reference Standard 1 (A0080286), and Serology Controls (A00C0825, 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        |
|-----------------|---------------|----------|-----------|-------------|
| Review/Approval | Karen Hamilla | Quality  |           | 15 AUG 2023 |