



## CERTIFICATE OF ANALYSIS

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**Product Description:** V-PLEX<sup>®</sup> COVID-19 Coronavirus Panel 2 Kit  
**Kit Catalog Numbers:** K15369-Series; K15370-Series; K15371-Series; K15378-Series  
**Kit Lot Number:** K0081593  
**Expiration Date:** 25 JUN 2022

### Kit Components:

| Description                                    | Lot Number       | Storage Temperature | Expiration Date |
|--|------------------|---------------------|-----------------|
| Coronavirus Plate 2                            | Z0056815         | 2-8°C               | 30 APR 2023     |
| SULFO-TAG <sup>™</sup> Anti-Human IgG Antibody | D00V0005         | 2-8°C               | 29 FEB 2024     |
| SULFO-TAG <sup>™</sup> Anti-Human IgM Antibody | D0014233         | 2-8°C               | 31 OCT 2023     |
| SULFO-TAG <sup>™</sup> Anti-Human IgA Antibody | D0014234         | 2-8°C               | 31 OCT 2023     |
| Reference Standard 1                           | A00V0004         | ≤ -70°C             | 30 JUN 2025     |
| Serology Control 1.1                           | A00C0731         | ≤ -70°C             | 30 JUN 2025     |
| Serology Control 1.2                           | A00C0732         | ≤ -70°C             | 30 JUN 2025     |
| Serology Control 1.3                           | A00C0733         | ≤ -70°C             | 30 JUN 2025     |
| SULFO-TAG <sup>™</sup> Human ACE2 Protein      | D00V0001         | 2-8°C               | 25 JUN 2022     |
| ACE2 Calibration Reagent                       | A00V0001         | 2-8°C               | 31 DEC 2023     |
| MSD Blocker A Kit                              | Not Kit Specific | Room Temperature    | See Label       |
| Diluent 100                                    | Not Kit Specific | 2-8°C               | 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, IgM, IgA, and ACE2 kit.

### Plate Uniformity Testing Results:

| Parameter   | Precision                  |                        |                    | Uniformity | Signal            |
|-------------|----------------------------|------------------------|--------------------|------------|-------------------|
|             | CV of Intra-plate Averages | Average Intra-plate CV | Max Intra-plate CV |            |                   |
| CoV-2 Spike | ≤ 18%                      | ≤ 10%                  | ≤ 13%              | Pass       | 1,500 – 1,000,000 |
| NL63 Spike  | ≤ 25%                      | ≤ 15%                  | ≤ 18%              | Pass       | 1,500 – 1,000,000 |
| CoV-2 N     | ≤ 18%                      | ≤ 10%                  | ≤ 13%              | Pass       | 1,500 – 1,000,000 |
| CoV-1 Spike | ≤ 18%                      | ≤ 10%                  | ≤ 13%              | Pass       | 1,500 – 1,000,000 |
| CoV-2 NTD   | ≤ 18%                      | ≤ 10%                  | ≤ 13%              | Pass       | 1,500 – 1,000,000 |
| HKU1 Spike  | ≤ 18%                      | ≤ 10%                  | ≤ 13%              | Pass       | 1,500 – 1,000,000 |
| OC43 Spike  | ≤ 18%                      | ≤ 10%                  | ≤ 13%              | Pass       | 1,500 – 1,000,000 |
| 229E Spike  | ≤ 25%                      | ≤ 15%                  | ≤ 18%              | Pass       | 1,500 – 1,000,000 |
| CoV-2 RBD   | ≤ 18%                      | ≤ 10%                  | ≤ 13%              | Pass       | 1,500 – 1,000,000 |



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### Coating Confirmation Testing Results:

| Spot | Description | Result |
|------|-------------|--------|
| 1    | CoV-2 Spike | Pass   |
| 2    | NL63 Spike  | Pass   |
| 3    | CoV-2 N     | Pass   |
| 4    | CoV-1 Spike | Pass   |
| 6    | CoV-2 NTD   | Pass   |
| 7    | HKU1 Spike  | Pass   |
| 8    | OC43 Spike  | Pass   |
| 9    | 229E Spike  | Pass   |
| 10   | CoV-2 RBD   | Pass   |

### Functional Testing Results:

| Sample Type | Calibrator                             | Controls            |                     | Samples                                |                         |
|-------------|--|---------------------|---------------------|--|-------------------------|
| Metric      | Average Signal Ratio<br>Test:Reference | Control<br>Recovery | Control<br>Conc. CV | Average % Difference<br>Test:Reference | Slope<br>Test:Reference |
| CoV-2 Spike | 50 – 200%                              | 70 – 130%           | < 20%               | ± 25%                                  | 0.80 – 1.2              |
| NL63 Spike  | 50 – 200%                              | 70 – 130%           | < 20%               | ± 25%                                  | 0.80 – 1.2              |
| CoV-2 N     | 50 – 200%                              | 70 – 130%           | < 20%               | ± 25%                                  | 0.80 – 1.2              |
| CoV-1 Spike | 50 – 200%                              | 70 – 130%           | < 20%               | ± 25%                                  | 0.80 – 1.2              |
| CoV-2 NTD   | 50 – 200%                              | 70 – 130%           | < 20%               | ± 25%                                  | 0.80 – 1.2              |
| HKU1 Spike  | 50 – 200%                              | 70 – 130%           | < 20%               | ± 25%                                  | 0.80 – 1.2              |
| OC43 Spike  | 50 – 200%                              | 70 – 130%           | < 20%               | ± 25%                                  | 0.80 – 1.2              |
| 229E Spike  | 50 – 200%                              | 70 – 130%           | < 20%               | ± 25%                                  | 0.80 – 1.2              |
| CoV-2 RBD   | 50 – 200%                              | 70 – 130%           | < 20%               | ± 25%                                  | 0.80 – 1.2              |

### Additional Comments:

Functional testing was executed using Coronavirus Plate 2 (Z0056815), SULFO-TAG Anti-Human IgG Antibody (D00V0005), Reference Standard1 (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        |
|------------------------|--------------------|----------|-----------|-------------|
| <b>Review/Approval</b> | Carissa B. Hubbard | Quality  |           | 13 NOV 2020 |