



CERTIFICATE OF ANALYSIS

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Product Description: V-PLEX® COVID-19 Coronavirus Panel 2 Kit
Kit Catalog Numbers: K15369-Series; K15370-Series; K15371-Series; K15378-Series
Kit Lot Number: K0081806
Expiration Date: 31 DEC 2022

Kit Components:

| Description | Lot Number | Storage Temperature | Expiration Date |
|------------------------------------|------------------|---------------------|-----------------|
| Coronavirus Plate 2 | Z0057021 | 2-8°C | 31 JAN 2024 |
| SULFO-TAG™ Anti-Human IgG Antibody | D00V0014 | 2-8°C | 31 DEC 2024 |
| SULFO-TAG™ Anti-Human IgM Antibody | D00V0011 | 2-8°C | 31 AUG 2024 |
| SULFO-TAG™ Anti-Human IgA Antibody | D00V0010 | 2-8°C | 31 JUL 2024 |
| Reference Standard 1 | A0080286 | ≤ -70°C | 28 FEB 2026 |
| Serology Control 1.1 | A00C0771 | ≤ -70°C | 28 FEB 2026 |
| Serology Control 1.2 | A00C0772 | ≤ -70°C | 28 FEB 2026 |
| Serology Control 1.3 | A00C0773 | ≤ -70°C | 28 FEB 2026 |
| SULFO-TAG™ Human ACE2 Protein | D0081619 | 2-8°C | 31 DEC 2022 |
| ACE2 Calibration Reagent | A0080285 | 2-8°C | 31 AUG 2024 |
| 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, IgA, IgM, and 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 |
| HCoV-NL63 Spike | ≤ 25% | ≤ 15% | ≤ 18% | Pass | 1,500 – 1,000,000 |
| SARS-CoV-2 Nucleocapsid | ≤ 18% | ≤ 10% | ≤ 13% | Pass | 1,500 – 1,000,000 |
| SARS-CoV-1 Spike | ≤ 18% | ≤ 10% | ≤ 13% | Pass | 1,500 – 1,000,000 |
| SARS-CoV-2 S1 NTD | ≤ 18% | ≤ 10% | ≤ 13% | Pass | 1,500 – 1,000,000 |
| HCoV-HKU1 Spike | ≤ 18% | ≤ 10% | ≤ 13% | Pass | 1,500 – 1,000,000 |
| HCoV-OC43 Spike | ≤ 18% | ≤ 10% | ≤ 13% | Pass | 1,500 – 1,000,000 |
| HCoV-229E Spike | ≤ 25% | ≤ 15% | ≤ 18% | Pass | 1,500 – 1,000,000 |
| SARS-CoV-2 S1 RBD | ≤ 18% | ≤ 10% | ≤ 13% | Pass | 1,500 – 1,000,000 |



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Coating Confirmation Testing Results:

| Spot | Description | Result |
|------|-------------------------|--------|
| 1 | SARS-CoV-2 Spike | Pass |
| 2 | HCoV-NL63 Spike | Pass |
| 3 | SARS-CoV-2 Nucleocapsid | Pass |
| 4 | SARS-CoV-1 Spike | Pass |
| 6 | SARS-CoV-2 S1 NTD | Pass |
| 7 | HCoV-HKU1 Spike | Pass |
| 8 | HCoV-OC43 Spike | Pass |
| 9 | HCoV-229E Spike | Pass |
| 10 | SARS-CoV-2 S1 RBD | Pass |

Functional Testing Results:

| Sample Type | Calibrator | Controls | | Samples | |
|-------------------------|--|------------------|------------------|--|-------------------------|
| Metric | Average Signal Ratio Test:Reference | Control Recovery | Control Conc. CV | Average % Difference Test:Reference | Slope Test:Reference |
| SARS-CoV-2 Spike | 50 – 200% | 70 – 130% | < 20% | ± 25% | 0.80 – 1.2 |
| HCoV-NL63 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-1 Spike | 50 – 200% | 70 – 130% | < 20% | ± 25% | 0.80 – 1.2 |
| SARS-CoV-2 S1 NTD | 50 – 200% | 70 – 130% | < 20% | ± 25% | 0.80 – 1.2 |
| HCoV-HKU1 Spike | 50 – 200% | 70 – 130% | < 20% | ± 25% | 0.80 – 1.2 |
| HCoV-OC43 Spike | 50 – 200% | 70 – 130% | < 20% | ± 25% | 0.80 – 1.2 |
| HCoV-229E Spike | 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 Coronavirus Plate 2 (Z0057021), SULFO-TAG Anti-Human IgG Antibody (D00V0014), Reference Standard 1 (A0080286), and Serology Controls (A00C0771, A00C0772, A00C0773).

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 SEP 2021 |