



CERTIFICATE OF ANALYSIS

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Product Description: V-PLEX® SARS-CoV-2 Panel 22 Kit
Kit Catalog Numbers: K15559-Series; K15560-Series; K15561-Series; K15562-Series; K15563-Series; K15564-Series; K15565-Series
Kit Lot Number: K0081928
Expiration Date: 31 JUL 2023

Kit Components:

| Description | Lot Number | Storage Temperature | Expiration Date |
|------------------------------------|------------------|---------------------|-----------------|
| SARS-CoV-2 Plate 22 | Z0057085 | 2-8°C | 30 JUN 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 | D0081708 | 2-8°C | 31 JUL 2023 |
| SULFO-TAG™ Anti-Human IgG Antibody | D00V0019 | 2-8°C | 30 APR 2025 |
| 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, or IgM, 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 |
| RBD (Omicron) (B.1.1.529; BA.1) | ≤ 18% | ≤ 10% | ≤ 13% | Pass | 1,500 – 1,000,000 |
| RBD (Beta) (B.1.351) | ≤ 25% | ≤ 15% | ≤ 18% | Pass | 1,500 – 1,000,000 |
| RBD (Gamma) (P.1) | ≤ 18% | ≤ 10% | ≤ 13% | Pass | 1,500 – 1,000,000 |
| RBD (Alpha) (B.1.1.7) | ≤ 18% | ≤ 10% | ≤ 13% | Pass | 1,500 – 1,000,000 |
| RBD (Delta) (B.1.617.2) | ≤ 18% | ≤ 10% | ≤ 13% | 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 | RBD (Omicron) (B.1.1.529; BA.1) | Pass |
| 2 | RBD (Beta) (B.1.351) | Pass |
| 4 | RBD (Gamma) (P.1) | Pass |
| 6 | RBD (Alpha) (B.1.1.7) | Pass |
| 9 | RBD (Delta) (B.1.617.2) | 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 Test:Reference | Control Recovery | Control Conc. CV | Avg % Difference Test:Reference | Slope Test:Reference |
| RBD (Omicron) (B.1.1.529; BA.1) | 50 – 200% | 70 – 130% | < 20% | ± 25% | 0.80 – 1.2 |
| RBD (Beta) (B.1.351) | 50 – 200% | 70 – 130% | < 20% | ± 25% | 0.80 – 1.2 |
| RBD (Gamma) (P.1) | 50 – 200% | 70 – 130% | < 20% | ± 25% | 0.80 – 1.2 |
| RBD (Alpha) (B.1.1.7) | 50 – 200% | 70 – 130% | < 20% | ± 25% | 0.80 – 1.2 |
| RBD (Delta) (B.1.617.2) | 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 22 (Z0057085), SULFO-TAG Anti-Human IgG Antibody (D00V0019), 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 | | 21 JAN 2022 |