



EXTENSION MEMO

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Product Description(s): Reference Standard 1

Catalog Number(s) / Size(s): C00ADK-2

Lot Number: A0080286

Based on additional testing, the original date of expiration for this Reference Standard has been extended by 60 months. The expiration date of A0080286 has been extended to 28 FEB 2031.

| Function | Name | Signature | Date |
|----------|---------------|--|-------------|
| Quality | Karen Hamilla |  | 06 MAY 2024 |

This memo supersedes all other statements regarding date of expiration for this product.



RFE MEMO

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Product Description(s): Serology Control Pack 1

Catalog Number(s) / Size(s): C4381-1

Lot Number: A00C0825, A00C0826, A00C0827

Based on additional testing, the original date of expiration for this Control Pack has been extended by 60 months. The expiration date of A00C0825, A00C0826, A00C0827 has been extended to 31 MAR 2032

The expiration dates for the following controls have been extended:

| Description | Lot Number | Original Expiration Date | New Expiration Date |
|----------------------|------------|--------------------------|---------------------|
| Serology Control 1.1 | A00C0825 | 31 MAR 2027 | 31 MAR 2032 |
| Serology Control 1.2 | A00C0826 | 31 MAR 2027 | 31 MAR 2032 |
| Serology Control 1.3 | A00C0827 | 31 MAR 2027 | 31 MAR 2032 |

| Function | Name | Signature | Date |
|----------|---------------|--|-------------|
| Quality | Karen Hamilla |  | 03 MAY 2024 |

This memo supersedes all other statements regarding date of expiration for this product.



CERTIFICATE OF ANALYSIS

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Product Description: V-PLEX SARS-CoV-2 Panel 32 Kit
Lot Number: K0082868
Expiration Date: 31 AUG 2027
Catalog Numbers: K15668U-Series, K15669U-Series, K15670U-Series, K15671U-Series, K15672U-Series, K15673U-Series, K15674U-Series

Kit Components:

The kit expiration date provided in the COA is determined by the component with the earliest expiration date. As the kit is supplied with different catalog products, not all configurations include all the components. In such cases, the applicable expiration date is determined by the shortest expiry among the components included in the kit that is received.

| Description | Lot Number | Storage Temperature | Expiration Date |
|---|------------------|---------------------|-----------------|
| SARS-CoV-2 Plate 32, 96-Well 10-Spot SECTOR Plate | Z0057648 | 2-8°C | 30 JUN 2028 |
| SULFO-TAG™ Anti-Human IgG Antibody | D00V0038 | 2-8°C | 31 AUG 2027 |
| Reference Standard 1 | A0080286 | ≤ -70°C | 28 FEB 2031 |
| Serology Control 1.1 | A00C0825 | ≤ -70°C | 31 MAR 2032 |
| Serology Control 1.2 | A00C0826 | ≤ -70°C | 31 MAR 2032 |
| Serology Control 1.3 | A00C0827 | ≤ -70°C | 31 MAR 2032 |
| ACE2 Calibration Reagent | Not Kit Specific | ≤ -70°C | See Label |
| SULFO-TAG™ Human ACE2 Protein | Not Kit Specific | 2-8°C | See Label |
| 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 |

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 Spike (B.1.1.529; BA.1) | ≤ 18% | ≤ 10% | ≤ 13% | Pass | 1,500 – 1,000,000 |
| SARS-CoV-2 Spike (XBB.1) | ≤ 18% | ≤ 10% | ≤ 13% | Pass | 1,500 – 1,000,000 |
| SARS-CoV-2 Spike (BF.7) | ≤ 18% | ≤ 10% | ≤ 13% | Pass | 1,500 – 1,000,000 |
| SARS-CoV-2 Spike (BA.2.75.2) | ≤ 18% | ≤ 10% | ≤ 13% | Pass | 1,500 – 1,000,000 |
| SARS-CoV-2 Spike (BQ.1.1) | ≤ 18% | ≤ 10% | ≤ 13% | Pass | 1,500 – 1,000,000 |
| SARS-CoV-2 Spike (BA.2.75) | ≤ 18% | ≤ 10% | ≤ 13% | Pass | 1,500 – 1,000,000 |
| SARS-CoV-2 Spike (BA.4.6) | ≤ 18% | ≤ 10% | ≤ 13% | Pass | 1,500 – 1,000,000 |
| SARS-CoV-2 Spike (BQ.1) | ≤ 18% | ≤ 10% | ≤ 13% | Pass | 1,500 – 1,000,000 |
| SARS-CoV-2 Spike (BA.5) | ≤ 18% | ≤ 10% | ≤ 13% | Pass | 1,500 – 1,000,000 |



CERTIFICATE OF ANALYSIS

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Coating Confirmation Testing Results:

| Spot | Description | Result |
|------|------------------------------------|--------|
| 1 | SARS-CoV-2 Spike | Pass |
| 2 | SARS-CoV-2 Spike (B.1.1.529; BA.1) | Pass |
| 3 | SARS-CoV-2 Spike (XBB.1) | Pass |
| 4 | SARS-CoV-2 Spike (BF.7) | Pass |
| 5 | SARS-CoV-2 Spike (BA.2.75.2) | Pass |
| 6 | SARS-CoV-2 Spike (BQ.1.1) | Pass |
| 7 | SARS-CoV-2 Spike (BA.2.75) | Pass |
| 8 | SARS-CoV-2 Spike (BA.4.6) | Pass |
| 9 | SARS-CoV-2 Spike (BQ.1) | Pass |
| 10 | SARS-CoV-2 Spike (BA.5) | Pass |

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 |
| SARS-CoV-2 Spike | 50 – 200% | 70 – 130% | < 20% | ± 25% | 0.80 – 1.2 |
| SARS-CoV-2 Spike (B.1.1.529; BA.1) | 50 – 200% | 70 – 130% | < 20% | ± 25% | 0.80 – 1.2 |
| SARS-CoV-2 Spike (XBB.1) | 50 – 200% | 70 – 130% | < 20% | ± 25% | 0.80 – 1.2 |
| SARS-CoV-2 Spike (BF.7) | 50 – 200% | 70 – 130% | < 20% | ± 25% | 0.80 – 1.2 |
| SARS-CoV-2 Spike (BA.2.75.2) | 50 – 200% | 70 – 130% | < 20% | ± 25% | 0.80 – 1.2 |
| SARS-CoV-2 Spike (BQ.1.1) | 50 – 200% | 70 – 130% | < 20% | ± 25% | 0.80 – 1.2 |
| SARS-CoV-2 Spike (BA.2.75) | 50 – 200% | 70 – 130% | < 20% | ± 25% | 0.80 – 1.2 |
| SARS-CoV-2 Spike (BA.4.6) | 50 – 200% | 70 – 130% | < 20% | ± 25% | 0.80 – 1.2 |
| SARS-CoV-2 Spike (BQ.1) | 50 – 200% | 70 – 130% | < 20% | ± 25% | 0.80 – 1.2 |
| SARS-CoV-2 Spike (BA.5) | 50 – 200% | 70 – 130% | < 20% | ± 25% | 0.80 – 1.2 |

Additional Comments:

Functional testing was executed using SARS-CoV-2 Plate 32 (Z0057648), SULFO-TAG Anti-Human IgG Antibody (D00V0038), 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 | | 04 MAR 2026 |