



RFE MEMO

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Product Description(s): V-PLEX® and V-PLEX Plus Human Insulin Kit

Catalog Number(s) / Size(s): K151S5-Series

Lot Number: K0081320

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0081320 has been extended to 28 FEB 2023.

The expiration dates for the following kit components have also been extended:

| Description | Lot Number | Original Expiration Date | New Expiration Date |
|---------------------|------------|--------------------------|---------------------|
| Human Insulin Plate | Z0047169 | 28 FEB 2022 | 28 FEB 2023 |
| Diluent 56 | M0560001 | 30 Apr 2022 | 28 FEB 2023 |
| Diluent 11 | M0110042 | 28 Feb 2022 | 28 FEB 2023 |

| Function | Name | Signature | Date |
|----------|---------------|-----------|-------------|
| Quality | Karen Hamilla | | 19 NOV 2021 |

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

CERTIFICATE OF ANALYSIS

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Product Description: V-PLEX® and V-PLEX Plus Human Insulin Kit

Kit Catalog Numbers: K151S5-Series

Kit Lot Number: K0081320

Expiration Date: 28 Feb 2022

Acceptance Data/ Percent Recovery Specifications:

| Spot | Name | Calibrator | | Metabolic Panel 1 Control 1 | | Metabolic Panel 1 Control 2 | | Metabolic Panel 1 Control 3 | |
|------|---------|------------|-------|-----------------------------|-------|-----------------------------|-------|-----------------------------|-------|
| | | Recovery | CV | Recovery | CV | Recovery | CV | Recovery | CV |
| 1 | Insulin | 80% - 120% | < 20% | 80% - 120% | < 20% | 80% - 120% | < 20% | 80% - 120% | < 20% |

| Spot | Name | LLOQ | | | ULOQ | | |
|------|---------|--------|------------|-------|-------|------------|-------|
| | | Value | Recovery | CV | Value | Recovery | CV |
| 1 | Insulin | 0.0690 | 80% - 120% | < 20% | 19.5 | 80% - 120% | < 20% |

Stock Concentration of Material Tested :

| Spot | Name | Item | Conc | Units |
|------|---------|-----------------------------|-------|--------|
| 1 | Insulin | Calibrator | 30.6 | µIU/mL |
| | | Metabolic Panel 1 Control 1 | 12 | µIU/mL |
| | | Metabolic Panel 1 Control 2 | 1.65 | µIU/mL |
| | | Metabolic Panel 1 Control 3 | 0.293 | µIU/mL |

Controls tested may not be the same lot as shipped.

Standard Curve Data:

| Insulin - Spot 1 | | |
|------------------|---------------|-----|
| Conc. µIU/mL | ECL Signal | %CV |
| 30.6 | 177,000 | 1.7 |
| 7.65 | 43,400 | 1.5 |
| 1.91 | 10,700 | 2.1 |
| 0.478 | 2,690 | 2.1 |
| 0.120 | 766 | 2.3 |
| 0.0299 | 274 | 2.3 |
| 0.00747 | 154 | 3.7 |
| 0.00 | 114 | 4.6 |

CERTIFICATE OF ANALYSIS

Components:


| Description | Lot Number | Storage Temperature | Expiration Date |
|------------------------------------|------------------|---------------------|-----------------|
| Human Insulin Plate | Z0047169 | 2-8°C | 28 Feb 2022 |
| Human Insulin Antibody | D0081371 | 2-8°C | 31 Mar 2023 |
| Metabolic Panel 1 Calibrator Blend | A0080230 | 2-8°C | 30 Sep 2024 |
| Diluent 56 | M0560001 | ≤ -10°C | 30 Apr 2022 |
| Diluent 11 | M0110042 | ≤ -10°C | 28 Feb 2022 |
| MSD Gold Read Buffer B | Not Kit Specific | Not Kit Specific | N/A |

Additional Components Included in V-PLEX Plus

| | |
|-----------------------------|------------------|
| Plate Seals | Not Kit Specific |
| Wash Buffer (20X), 100mL | Not Kit Specific |
| Metabolic Panel 1 Control 1 | Not Kit Specific |
| Metabolic Panel 1 Control 2 | Not Kit Specific |
| Metabolic Panel 1 Control 3 | Not Kit Specific |

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 |  | 25 FEB 2020 |