



RFE MEMO


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Product Description(s): S-PLEX® Human IL-5 Kit
Catalog Number(s) / Size(s): K151J3S-Series; K156J3S-Series
Lot Number: K00S0026

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K00S0026 has been extended to 31 JAN 2023.

The expiration date for the following kit component has been extended:

| Description | Lot Number | Original Expiration Date | New Expiration Date |
|-------------|------------|--------------------------|---------------------|
| Diluent 43 | M0430033 | 31 JAN 2022 | 31 JAN 2023 |

| Function | Name | Signature | Date |
|----------|--------------------|---|-------------|
| Quality | Carissa B. Hubbard |  | 25 APR 2022 |

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



CERTIFICATE OF ANALYSIS

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Product Description: S-PLEX[®] Human IL-5 Kit
Catalog Number: K151J3S-Series; K156J3S-Series
Lot Number: K00S0026
Expiration Date: 31 Jan 2022

Precision, Accuracy, and Sensitivity Specifications:

| Calibrator | | |
|------------|------------|-------|
| Name | Recovery | CV |
| IL-5 | 80% - 120% | < 20% |

| LLOQ | | | | | |
|------|--------------|----------|-------|------------|-------|
| Name | Range Tested | Observed | Units | Recovery | CV |
| IL-5 | 3.00 – 48.0 | 48.0 | fg/mL | 80% - 120% | < 20% |

| LLOD | | |
|------|----------|-------|
| Name | Observed | Units |
| IL-5 | 1.91 | fg/mL |

Stock Concentration of Calibrator:

| Name | Item | Concentration | Units |
|------|----------------|---------------|-------|
| IL-5 | 30X Calibrator | 962000 | fg/mL |

Lot-Specific Components:

| Description | Lot Number | Storage Temperature | Expiration Date |
|----------------------------------|------------|---------------------|-----------------|
| TURBO-BOOST™ Human IL-5 Antibody | D00T0030A | 2-8°C | 30 Nov 2023 |
| Biotin Human IL-5 Antibody | B00T0030A | 2-8°C | 31 Mar 2024 |
| Human IL-5 Calibrator | A00S0008 | 2-8°C | 31 Jul 2024 |
| Diluent 43 | M0430033 | ≤ -10°C | 31 Jan 2022 |
| Diluent 3 | M0030104 | ≤ -10°C | 30 Jun 2023 |
| S-PLEX Coating Reagent C1 | 314374 | ≤ -70°C | 28 Feb 2023 |
| Blocker S1 | R0140004 | ≤ -10°C | 30 Apr 2023 |
| S-PLEX Enhance E1 | Y0550004 | ≤ -10°C | 28 Feb 2023 |
| S-PLEX Enhance E2 | Y0560004 | ≤ -10°C | 31 Jan 2023 |
| S-PLEX Enhance E3 | Y0570004 | ≤ -70°C | 31 Jan 2023 |
| S-PLEX Detect D1 | Y0580006 | ≤ -70°C | 31 Mar 2023 |
| S-PLEX Detect D2 | Y0590004 | ≤ -70°C | 31 Jan 2023 |

Additional components may be provided to execute the assay. Additional components are not lot-specific.

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 FEB 2021 |