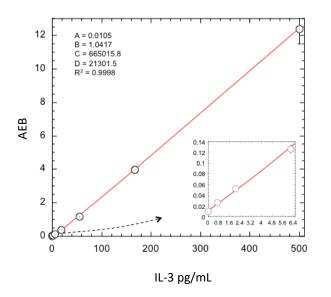


Simoa[®] IL-3 Discovery Kit HD-1/HD-X Data Sheet Item 102462

Description

Interleukin 3 (IL-3) is a hematopoietic cytokine related to GM-CSF and IL-5. The IL-3 receptor is a heterodimer composed of an IL-3 specific but low affinity α -chain, and non-specific but high affinity β -chain. The β -chain is common to the IL-3, IL-5 and GM-CSF receptors. IL-3 is a potent growth promoting cytokine, primarily produced by Type 2 helper T cells, that regulates hematopoietic cells and leukocytes. IL-3 is clinically important in protective immunity and is also implicated in a variety of inflammatory disorders, notably allergic inflammation. IL-3 receptor is highly expressed on the surface of various cancer cells (e.g., leukemia stem cells), and it is associated with the initiation and development of acute myeloid leukemia and acute lymphoblastic leukemia.

Calibration Curve: Four-parameter curve fit parameters are depicted.

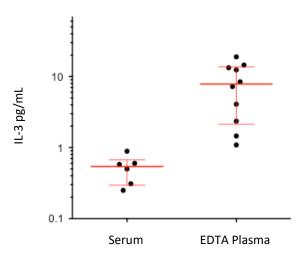


Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 1 reagent lot on 1 instrument (5 runs total).

Limit of Detection (LOD): Calculated as 2.5 standard deviations from the mean of background signal read back on each calibration curve over 1 reagent lot on 1 instrument (11 runs total).

| LLOQ | 0.686 pg/mL pooled CV 21.1% | |
|-------------------------------------|---------------------------------------|--|
| | mean recovery 110% | |
| LOD | 0.226 pg/mL | |
| | range 0.076–0.448 pg/mL | |
| Dynamic range (serum and plasma) | 0-2000 pg/mL | |
| Diluted Sample volume* | 152 μL | |
| | per measurement | |
| Tests per kit | 192 | |
| *See Kit Instruction for details | | |

Endogenous Sample Reading: Healthy donor matched EDTA plasma (n=10) and serum (n=6) were measured. 4 of 10 normal serum samples were below LOD. Error bars depict median and interquartile ranges.



| Sample Type | Median IL-3 pg/mL | % Above LOD |
|-------------|----------------------|-------------|
| EDTA Plasma | 7.84 | 100% |
| Serum | 0.279 | 60% |

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Precision: Representative precision was estimated with repeated assay of serum and plasma panels using one instrument and one reagent lot. Within-run and between-run CVs are depicted in the following table. Within-run CVs reflect average CVs across 11 experiments of 3 replicates each.

| Sample | Mean (pg/mL) | Within run CV | Between run CV |
|----------------|-----------------|------------------|-------------------|
| Plasma Panel 1 | 3.54 | 16.7% | 19.7% |
| Serum Panel 2 | 63.6 | 4.8% | 7.1% |
| Plasma Panel 3 | 327 | 5.7% | 5.9% |
| Plasma Panel 4 | 13.8 | 6.5% | 6.0% |

Spike and Recovery: IL-3 spiked into 1 serum and 3 plasma samples at 2 levels.

Dilution Linearity: Spiked serum diluted 2x serially from MRD (4x) to 64x with Sample Diluent.

| Spike and Recovery | Mean = 80.3% |
|---------------------------|--------------------|
| (Serum/Plasma) | Range: 66–100% |
| Dilution Linearity | Mean = 105.6% |
| (64x) | Range: 92.2–121.1% |