

SUMMARY AND EXPLANATION OF THE TEST

IL-22 is a member of IL-10 superfamily. It is produced by Th17 cells and NK cells, especially in epithelial cells. Human IL-22 cDNA encodes a 179 amino acid (aa) residue protein with a putative 33 aa signal peptide that is cleaved to generate a 147 aa mature protein. Mouse IL-22 shares 79% similarity to human IL-22. IL-22 binds to a receptor complex consisting of IL-22 R and IL-10 R beta. IL-22 and IL-10 receptor chains play a role in cellular targeting and signal transduction to selectively initiate and regulate immune responses. IL-22 can contribute to immune disease through the stimulation of inflammatory responses. IL-22 also promotes hepatocyte survival in the liver and epithelial cells in the lung and gut similar to IL-10.

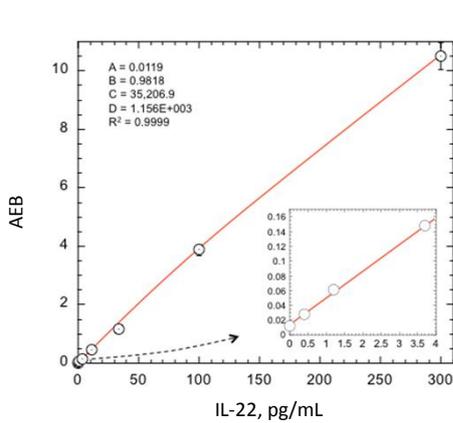


Figure 1: Simoa™ IL-22 immunoassay calibration curve. Four-parameter curve fit parameters are depicted.

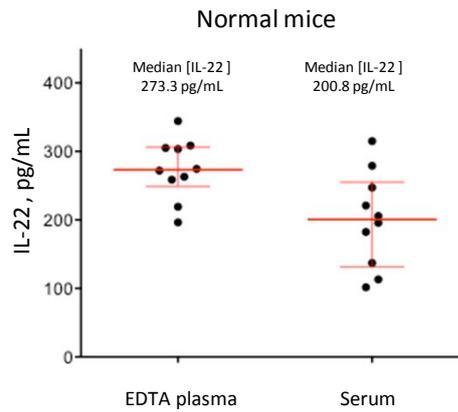


Figure 2: [IL-22] in EDTA plasma pools (n = 10) and serum pools (n = 10) from non-medicated, non-immunized mice. Error bars depict median and interquartile ranges.

Table 1: General characteristics of Simoa mouse IL-22 immunoassay

Calibration range	0-300 pg/mL
Dynamic range ¹	0-1200 pg/mL
Lower limit of detection (2.5SD; 3 reps x 5 runs, 3 instruments, 1 reagent lot; mean LoD ²)	0.095 pg/mL
Lower limit of quantification (5 runs across 3 instruments, 1 reagent lot) ³	0.206 pg/mL
Spike-recovery (mouse IL-22 spiked into 2 serum and 1 plasma samples at 2 levels, mean ⁴)	101%
Dilution Linearity (Plasma pool pre-diluted 2x serially to 64x with Sample Diluent, mean recovery ⁵)	102.3%
Typical sample volume (Includes dead volume; see Package Insert for details)	33 µL
Minimum sample volume (See Package Insert for details)	< 1 µL

The Simoa mouse IL-22 immunoassay quantifies IL-22 in serum and plasma, with median IL-22 values well above the detection limit.

¹Samples auto-diluted 4X. ²SD 0.0412; range: 0.0603-0.1493 ³≤20%CV, 80-120% recovery; pooled CV 20%, mean recovery 100%; not corrected for pre-dilutions; 4X LoQ 0.824 pg/mL. ⁴Range 93.5-111%. ⁵Range 94-115%; total dilution including auto-dilution 256X.

Table 2: Precision characteristics of Simoa mouse IL-22 immunoassay. Representative precision was estimated with repeated assay of mouse serum and plasma pools using three instruments and one reagent lot. Within-run and between-run CVs are depicted in the following table. Within-run CVs reflect average CVs across 5 experiments of 3 replicates each.

Sample	Mean IL-22 (pg/mL)	Within Run %CV (n=5)	Between Run %CV (n=5)
Serum pool 1	94.4	3.1	7.0
Serum pool 2	105.9	3.2	6.5
Plasma pool 1	323.8	8.7	6.3



Simoa HD-1 Analyzer

Representative data. Individual results may vary depending upon samples tested and protocols followed. For Research Use Only. Not for use in diagnostic procedures.