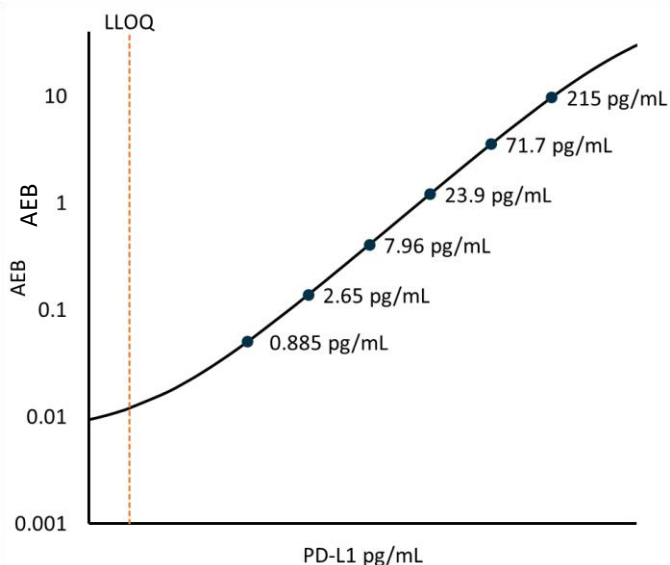


Description

PD-L1, or “programmed-death ligand 1” (also known as CD274 or B7-H1) is a membrane bound glycoprotein in the B7 family of cell surface ligands involved in regulation of the immune system. PD-L1 is expressed on a variety of inflammatory-activated cells, some carcinomas, and in melanoma (ovary, colon, lung, breast, and renal cell carcinomas). PD-L1 expression on tumor cells is correlated with poor prognosis in patients with cancers such as NSCLC, esophageal cancer, and pancreatic carcinoma. Levels of PD-L1 are increased in the plasma of cancer patients as well as in cerebrospinal fluid of gliomas. sPD-L1 is a biomarker of poor survival in patients with B cell lymphoma, renal cell carcinoma, metastatic melanoma or lung cancer, and is associated with advanced tumor stage. PD-L1 contributes to immune evasion by binding to PD-1 and CD80 to suppress the activation and proliferation of T cells and induce apoptosis of activated T cells. Blocking the PD-1/PD-L1 pathway to prevent this immune evasion and restore anti-tumor immunity has emerged as a promising anti-cancer strategy.

Calibration Curve: Calibrator concentrations and Lower Limit of Quantification depicted.



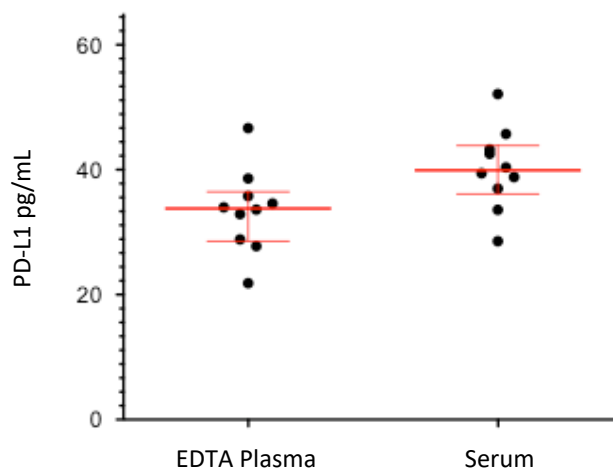
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 1 reagent lot across 2 instruments (5 runs total).

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 across 2 instruments (5 runs total).

LLOQ	0.105 pg/mL pooled CV 17.8% mean recovery 109%
LOD	0.044 pg/mL range 0.027–0.091 pg/mL
Dynamic range (serum and plasma)	0–4300 pg/mL
Diluted Sample volume*	100 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=10) were measured. Error bars depict median with interquartile range.



Sample Type	Median PD-L1 pg/mL	% Above LOD
Serum	40.14	100%
EDTA Plasma	33.79	100%

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 5 experiments of 3 replicates each.

Sample	Mean (pg/mL)	Within run CV	Between run CV
Serum Panel 1	125.5	6.6%	9.6%
Serum Panel 2	1192	4.6%	5.2%
Plasma Panel 3	387.7	5.4%	8.2%

Spike and Recovery: PD-L1 spiked into 2 serum samples and 2 plasma samples at 2 levels, mean.

Dilution Linearity: Spiked serum diluted 2x serially from MRD (20x) to 1280x with Sample Diluent.

Spike and Recovery (Serum, plasma)	Mean = 90.4% Range: 71.8–97.8%
Dilution Linearity (1280x)	Mean = 105.6% Range: 99.3–112.2%

The Simoa PD-L1 Discovery assay kit is formulated for use on the SR-X®, HD-1, or HD-X® platform. Data in this document was obtained from runs on the HD-1 platform unless otherwise noted. Some differences in performance claims between SR-X and HD-1/HD-X may be observed when comparing datasheets for these platforms. This may be due to experiments run at different time-points with different reagent lots and different samples, or it may be due to minor differences in antibody and analyte behavior in the different assay formats.