SUMMARY AND EXPLANATION OF THE TEST
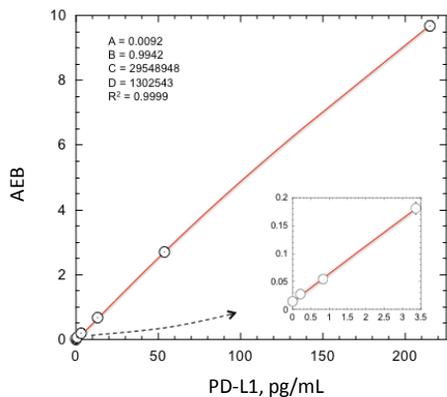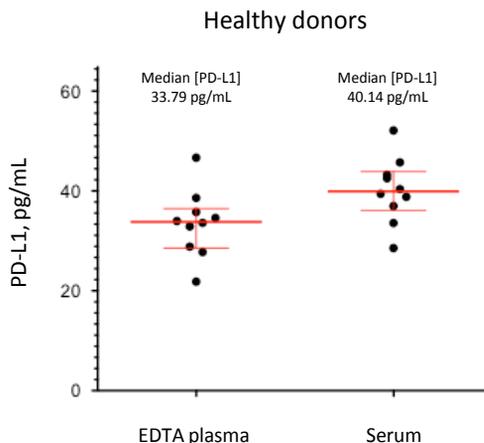
PD-L1, or "programmed-death ligand 1" (also known as CD274 or B7-H1) is a membrane bound glycoprotein in the B7 family of cell surface ligands involved in regulation of the immune system. PD-L1 is expressed on a variety of inflammatory-activated cells, some carcinomas, and in melanoma (ovary, colon, 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.

Figure 1: Simoa™ Human PD-L1 immunoassay calibration curve. Four-parameter curve fit parameters are depicted.

$A = 0.0092$
$B = 0.9942$
$C = 29548948$
$D = 1302543$
$R^2 = 0.9999$

Healthy donors

Median [PD-L1] 33.79 pg/mL   Median [PD-L1] 40.14 pg/mL

Figure 2: [PD-L1] in EDTA plasma (n = 10), matched serum (n = 10). Error bars depict median and interquartile ranges.

Table 1: General characteristics of Simoa Human PD-L1 immunoassay

Calibration range	0-215 pg/mL
Dynamic range[1]	0-4300 pg/mL
Lower limit of detection (2.5SD; 3 reps x 5 runs, 2 instruments, 1 reagent lot; mean LoD[2]	0.044 pg/mL
Lower limit of quantification (5 runs, 2 instruments, 1 reagent lot)[3]	0.105 pg/mL
Spike-recovery (PD-L1 spiked into 4 serum samples at 2 levels, mean[4])	90.4%
Dilution Linearity (Spiked serum diluted 2x serially from MRD to 64X with Sample Diluent, mean recovery[5])	105.6%
Typical sample volume (Includes dead volume; see Package Insert for details)	10 μL

The Simoa Human PD-L1 immunoassay quantifies PD-L1 in serum and plasma with median PD-L1 values well above the sensitivity limit.

[1]Samples pre-diluted 20X. [2]SD 0.0266 pg/mL; range 0.027-0.091 pg/mL. [3]≤20%CV, 80-120% recovery; pooled CV 17.8%, mean recovery 109%; not corrected for pre-dilutions; 20X LoQ 2.10 pg/mL. [4]Range 71.8-97.8%. [5]Range 99.3-112.2%; minimum recommended dilution (MRD) 1:20.

Table 2: Precision characteristics of Simoa Human PD-L1 immunoassay. 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 PD-L1 (pg/mL)	Within Run %CV (n=5)	Between Run %CV (n=5)
Serum panel 1	125.5	6.6	9.6
Serum panel 2	1192.1	4.6	5.2
Plasma panel 3	387.7	5.4	8.2

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.