

Human PD1 (epitope 2)

www.mesoscale.com[®]

Ordering Information

MSD[®] Customer Service
 Phone: 1-240-314-2795
 Fax: 1-301-990-2776
 Email: CustomerService@mesoscale.com

Scientific Support

Phone: 1-240-314-2798
 Email: ScientificSupport@mesoscale.com

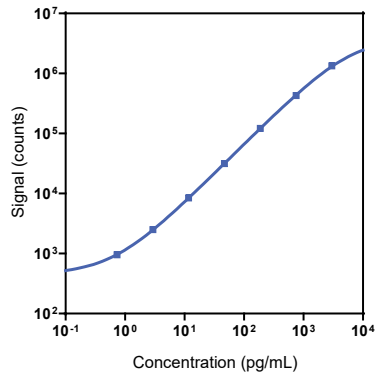
Company Address

MESO SCALE DISCOVERY[®]
 A division of
 Meso Scale Diagnostics, LLC.
 1601 Research Boulevard
 Rockville, MD 20850-3173 USA

Product Options	Catalog Number	Description
Multiplex	K151AEL	U-PLEX Immuno-Oncology Group 1 (hu)
Singleplex	K151V7K-1/-2/-4	U-PLEX Human PD1 (epitope 2) Assay with SECTOR [™] plates
	K151V7K-21/-22/-24	U-PLEX Human PD1 (epitope 2) Assay with QuickPlex [®] plates
Antibody Set	B22V7-2/-3	U-PLEX Human PD1 (epitope 2) Antibody Set
Protocol	U-PLEX [®] Product Inserts are available at www.mesoscale.com	

The U-PLEX platform was designed to provide ultimate flexibility for detection of biomarkers in a wide variety of sample types. This datasheet provides the representative performance of the U-PLEX Human PD1 (epitope 2) Assay tested on U-PLEX plates run as a multiplex. The data do not represent the product specifications. Under your experimental conditions, the assay may perform differently from the representative data. U-PLEX assays are available in multiplex format with other compatible assays. The same assay can also be used to detect a single analyte using MSD GOLD[™] Small Spot Streptavidin SECTOR or MSD GOLD Small Spot Streptavidin QuickPlex plates. See a U-PLEX product insert for instrument compatibility.

Representative Calibration Curve and Sensitivity



Assay	Median LLOD (pg/mL)	LLOD Range (pg/mL)
PD1 (epitope 2)	0.11	0.09-0.19

The Calibrator curve was fitted with a 4-parameter logistic model with a 1/Y² weighting. The lower limit of detection (LLOD) is a calculated concentration corresponding to 2.5X the standard deviations above the background (zero Calibrator).

Precision

Control	Average Conc. (pg/mL)	Average Intra-run Conc. (%CV)	Inter-run Conc. (%CV)
High	255	3.7	4.8
Mid	47	5.4	3.7
Low	7.7	9.0	3.3

Controls were made by spiking Calibrator into assay diluent at 3 levels within the quantitative range of the assay. Average intra-run concentration %CV is the average %CV of the control replicates within an individual run. Inter-run concentration %CV is the variability of controls across multiple runs.

Note: PD1 (epitope 2) is significantly impacted by Nivolumab (Opdivo[®]) and by Pembrolizumab (Keytruda[®]). PD1 (epitope 1) is not effected by these therapeutic antibodies.

For Research Use Only.
 Not for use in diagnostic procedures.

MSD® U-PLEX Human PD1 (epitope 2)

Tested Samples

Sample Type	Serum (N=10)	Normal Lysate (N=5)	Tumor Lysate (N=5)
Median (pg/mL)	166	37	74
Range (pg/mL)	140-223	10-125	5.3-513
% Detected	100	100	100

Normal serum and plasma samples were diluted 4-fold prior to the assay. Lysates were tested at a protein concentration of 0.5 mg/mL.

Dilution Linearity

Serum			EDTA Plasma		
Fold Dilution	Average % Recovery	% Recovery Range	Fold Dilution	Average % Recovery	% Recovery Range
2	95	93-97	2	80	76-85
8	100	98-101	8	100	99-102
16	99	97-100	16	100	98-101

Normal human serum and EDTA plasma were spiked with Calibrator and tested at different dilutions. Percent recovery at each dilution level was normalized to the dilution-adjusted, 4-fold concentration. Samples may benefit from additional dilution with assay diluent to reduce matrix effects.

% Recovery = (measured concentration / expected concentration) x 100.

Spike Recovery

Spike Level	Serum		EDTA Plasma	
	Average % Recovery	% Recovery Range	Average % Recovery	% Recovery Range
High	102	98-105	101	97-107
Mid	105	102-107	100	91-105
Low	104	95-109	96	86-103

Normal serum and plasma were spiked with Calibrator at 3 levels. Spiked samples were diluted 4-fold to determine the expected concentration of the analyte. Samples may require additional dilution with assay diluent to reduce matrix effects.

% Recovery = (measured concentration / expected concentration) x 100

Specificity

To assess specificity, the PD1 (epitope 2) Antibody Set was tested individually against a larger panel of analytes for nonspecific binding (BAFF, BAFF-R/TNFRSF13C, BCMA/TNFRSF17, BDNF, C-Peptide, CD20, CD27, CD28, CD40L (soluble), CD276/B7-H3, CTACK, CTLA-4, Desghrelin, ENA-78, Eotaxin, Eotaxin-2, Eotaxin 3, EPO, FGF (basic), FGF-23, FLT3L, Fractalkine, FSH, G-CSF, GITRL/TNFSF18, GTR/TNFRSF18, Ghrelin (Ser3-octanoylated), gp130 (soluble), GIP (1-42), GIP (3-42), GLP-1 (7-36), GLP-1 (9-36), GM-CSF, Granzyme A, Granzyme B, GRO- α , HAVCR2/TIM-3, I-309, IFN- α 2a, IFN- β , IFN- γ , IL-1 α , IL-1 β , IL-1RA, IL-2, IL-2R α , IL-3, IL-4, IL-5, IL-6, IL-7, IL-8, IL-9, IL-10, IL-12/IL-23p40, IL-12p70, IL-13, IL-15, IL-16, IL-17A, IL-17A/F, IL-17C, IL-17D, IL-17E/IL-25, IL-17F, IL-18, IL-21, IL-22, IL-23, IL-27, IL-29/IFN- λ 1, IL-31, IL-33, Insulin, IP-10, LAG3, Leptin, LH, MCP-1, MCP-2, MCP-4, M-CSF, MDC, MIF, MIP-1 α , MIP-1 β , MIP-5, OX40/TNFRSF4, PD1, PD-L1, PD-L2, PIGF, PP, Proinsulin, PYY (3-36), RANKL/TNFSF11, SDF-1 α , Tie-2, TIGIT, TLR1, TNF- α , TNF- β , TPO, TRAIL, TSLP, VEGF-A, VEGF-C, VEGF-D, and YKL-40). Nonspecific binding was less than 0.5%.

% Nonspecificity = (nonspecific signal / specific signal) x 100

PD1 (epitope 2) assay should not be combined with PD1 (epitope 1) assay in the same plate.

Diluent Compatibility

The data included in this document has been collected with Assay Diluent 2 and Antibody Diluent 3. MSD offers a range of assay and antibody diluents for separate purchase. Depending on your assay needs, other diluents may be tested.

Assay Components

Calibrator: PD1 is included in Calibrator 20. The human PD1 Calibrator is PD1 (25-168) expressed in a human cell line.

Antibodies: The U-PLEX Human PD1 (epitope 2) Assay uses a mouse monoclonal antibody for capture and a mouse monoclonal antibody for detection.

Assay generation: A

Note: This datasheet contains representative assay performance data. In custom multiplex formats, the assay may perform differently from the representative data shown.

