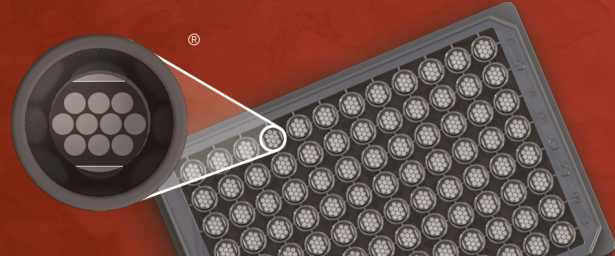


U-PLEX[®] Human Proinsulin Assay



www.mesoscale.com[®]

Ordering Information

MSD[®] Customer Service
 Phone: 1-301-947-2085
 Fax: 1-301-990-2776
 Email: CustomerService@mesoscale.com

Scientific Support

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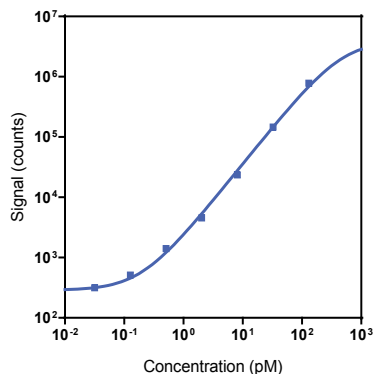
Company Address

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

Product Options	Available in: U-PLEX Metabolic Group 1 (hu) K151ACL
	Individual assay: K1516MK provided with Diluent 13 and Diluent 11
	Antibody Set: B216M
Assay Protocol	U-PLEX product inserts are provided with the assays, and are available at www.mesoscale.com/U-PLEX-documents .

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 Proinsulin Assay tested on U-PLEX plates run as a multiplex. The data were generated during the development of the assay and do not represent the product specifications. Under your experimental conditions and with your specific multiplex, the assay may perform differently than the representative data shown. U-PLEX assays are available in multiplex format with other compatible assays. The same assay can also be used to detect a single analyte on MSD GOLD[™] Small Spot Streptavidin plates.

Representative Calibration Curve and Sensitivity



Assay	Median LLOD (pM)	LLOD Range (pM)
Proinsulin	0.05	0.05-0.07

The calibration curves used to calculate analyte concentrations were established by fitting the signals from the Calibrators using a 4-parameter logistic (or sigmoidal dose-response) model with a $1/Y^2$ weighting. Analyte concentrations were determined from the electrochemiluminescence signals by back-fitting to the calibration curve. The lower limit of detection (LLOD) is a calculated concentration corresponding to the signal 2.5 standard deviations above the background (zero Calibrator).

Precision

Control	Average Conc. (pM)	Average Intra-run Conc. (%CV)	Inter-run Conc. (%CV)
High	57	4.1	8.1
Mid	23	3.4	10.7
Low	9.4	2.9	13.1

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.

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

MSD® U-PLEX Assays

Tested Samples

Sample Type	Serum (N=12)	EDTA Plasma (N=12)	P800 Plasma (N=8)
Median (pM)	0.23	0.77	1.4
Range (pM)	ND-0.79	0.07-2.3	0.70-2.9
% Detected	83	100	100

ND = non-detectable (<LLOD). Normal serum, EDTA plasma, and P800 plasma samples were diluted 4-fold prior to the assay.

Dilution Linearity

Serum			EDTA Plasma			P800 Plasma			Cell Culture Media		
Fold Dilution	Average % Recovery	% Recovery Range	Fold Dilution	Average % Recovery	% Recovery Range	Fold Dilution	Average % Recovery	% Recovery Range	Fold Dilution	Average % Recovery	% Recovery Range
2	90	60-108	2	84	64-101	2	83	61-101	2	108	99-116
4	100	NA	4	100	NA	4	100	NA	4	100	NA
8	111	99-147	8	116	98-144	8	110	91-139	8	96	91-102
16	114	94-169	16	125	100-180	16	114	93-152	16	97	91-102

Normal human serum, EDTA plasma, P800 plasma, and cell culture media 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 require additional dilution with assay diluent to reduce matrix effects.

% Recovery = (measured concentration / expected concentration) x 100. NA = not applicable.

Spike Recovery

Spike Level	Serum		EDTA Plasma		P800 Plasma		Cell Culture Media	
	Average % Recovery	% Recovery Range	Average % Recovery	% Recovery Range	Average % Recovery	% Recovery Range	Average % Recovery	% Recovery Range
High	90	58-99	86	53-106	94	79-108	103	99-108
Mid	90	62-99	88	56-107	95	88-100	103	97-111
Low	95	67-104	87	59-104	96	90-100	106	101-111

Normal human serum, EDTA plasma, P800 plasma, and cell culture media 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 Proinsulin Antibody Set was tested individually against a larger panel of analytes for nonspecific binding (BAFF, BDNF, β -NGF, C-Peptide, CTACK, ENA-78, Eotaxin, Eotaxin-2, Eotaxin-3, EPO, FGF-21, FGF-23, FLT3L, Fractalkine, FSH, G-CSF, Ghrelin (octanoylSer3), Desghrelin, GIP (1-42), GIP (3-42), GLP-1 (7-36), GLP-1 (9-36), Glucagon, GM-CSF, GRO- α , 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, Leptin, LH, MCP-1, MCP-2, MCP-4, M-CSF, MDC, MIF, MIP-1 α , MIP-5, PP, Proinsulin (25-110), PYY (3-36), SDF-1 α , TARC, TNF- α , TNF- β , TPO, TRAIL, TSLP, VEGF-A, and YKL-40). Nonspecific binding was less than 0.5%. % Nonspecificity = (nonspecific signal / specific signal) x 100.

C-Peptide cross-reacts 0.7% with the Proinsulin assay. We do not recommend multiplexing the Proinsulin assay with the Insulin or C-peptide assays on the same plate.

Diluent Compatibility

The data included in this document have been collected with Assay Diluent 13 (supplemented with 1000 KIU/mL aprotinin [provided] and 100 μ M diprotin A [not provided]) and Antibody Diluent 11. MSD offers a range of assay and antibody diluents for separate purchase. Depending on assay needs, customers may wish to test other diluents.

Assay Components

Calibrator: The human Proinsulin Calibrator is a full length recombinant protein expressed in *E. coli*. The Calibrator for the U-PLEX Human Proinsulin Assay has been anchored to a NIBSC/WHO standard. Please see the product insert for a table of conversion factors.

Antibodies: The U-PLEX Human Proinsulin Assay uses a mouse monoclonal antibody for capture and a mouse monoclonal antibody for detection.

Assay generation: B

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

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