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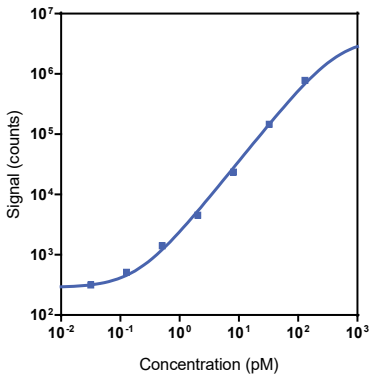
Company Address

MESO SCALE DISCOVERY®
A division of
Meso Scale Diagnostics, LLC.
1601 Research Boulevard
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Product Options	Catalog Number	Description
Multiplex	K151ACM, K251ACM	U-PLEX Metabolic Group 1 (human)
	K1516MK-1/-2/-4	U-PLEX Human Proinsulin Assay with SECTOR™ plates
Singleplex	K1516MK-21	U-PLEX Human Proinsulin Assay with QuickPlex® APT plates
	K2516MK-2/-4	U-PLEX Human Proinsulin Assay with 384-well plates
Antibody Set	B216M-2/-3	U-PLEX Human Proinsulin 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 Proinsulin Assay tested on U-PLEX 96-well SECTOR 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 offered in either singleplex or multiplex; both are available on 96- or 384-well plates. See a U-PLEX product insert for instrument compatibility.

Representative Calibration Curve and Sensitivity



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

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 2.5 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	107
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 Human Proinsulin

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

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

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
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 benefit from additional dilution with assay diluent to reduce matrix effects.

$$\% \text{ Recovery} = (\text{measured concentration} / \text{expected concentration}) \times 100$$

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 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 benefit from additional dilution with assay diluent to reduce matrix effects.

$$\% \text{ Recovery} = (\text{measured concentration} / \text{expected concentration}) \times 100$$

Specificity

To assess specificity, the Proinsulin Antibody Set was tested individually against a larger panel of analytes for nonspecific binding (BAFF, BDNF, C-Peptide, CTACK, Desghreltin, ENA-78, Eotaxin, Eotaxin-2, Eotaxin-3, EPO, FGF-21, FGF-23, FLT3L, Fractalkine, FSH, G-CSF, Ghrelin (Ser3-octanoylated), GIP (1-42), GIP (3-42), GLP-1 (7-36), GLP-1 (9-36), GM-CSF, GRO-α, I-309, IFN-α2a, IFN-β, IFN-γ, IL-1α, IL-1β, IL-1RA, IL-2, IL-2Rα, 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-λ1, IL-31, IL-33, Insulin, IP-10, I-TAC, Leptin, LH, MCP-1, MCP-2, MCP-4, M-CSF, MDC, MIF, MIP-1α, MIP-1β, MIP-5, PIGF, PP, Proinsulin, PYY (3-36), SDF-1α, TNF-α, TNF-β, TPO, TRAIL, TSLP, VEGF-A, YKL-40, and β-NGF). Nonspecific binding was less than 2.0%.

$$\% \text{ Nonspecificity} = (\text{nonspecific signal} / \text{specific signal}) \times 100$$

C-Peptide cross-reacts 07% 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 were collected with Assay Diluent 13 (supplemented with 1,000 KIU/mL Aprotinin [provided] and 100 μM diprotin A [not provided]) and Antibody Diluent 11. MSD offers a range of assay and antibody diluents for separate purchase. Depending on your assay needs, other diluents may be tested. Diprotin A should be purchased separately.

Assay Components

Calibrator: Proinsulin is included in Human Proinsulin Calibrator. The human Proinsulin Calibrator is a full-length recombinant protein expressed in *E. coli*.

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 from the representative data shown.

