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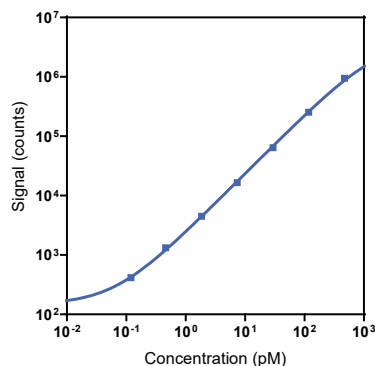
Company Address

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)
	K151AYKK-1/-2/-4	U-PLEX Human Proinsulin Assay with SECTOR™ plates
	K151AYKK-21/-22/-24	U-PLEX Human Proinsulin Assay with QuickPlex Ultra™ plates
Singleplex	K251AYKK-2/-4	U-PLEX Human Proinsulin Assay with 384-well plates
	B21AYK-2/-3	U-PLEX Human Proinsulin Antibody Set
Antibody Set	B21AYK-2/-3	U-PLEX Human Proinsulin Antibody Set
Protocol	U-PLEX Product Inserts are available at www.mesoscale.com	

The MESO SCALE DISCOVERY® 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	0.03	0.02 – 0.06

The Calibrator curve was fitted with a 4-parameter logistic model with a $1/Y^2$ 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	94.6	2.6	7.6
Mid	18.9	2.8	8.5
Low	3.78	2.7	11.4

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=8)	EDTA Plasma (N=8)	P800 Plasma (N=5)
Median (pM)	22	33	32
Range (pM)	3.4 – 174	12 – 69	8.9 – 199
% Detected	100	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	96	89 – 103	2	84	66 – 99	2	91	91 – 92	2	93	89 – 97
8	109	105 – 119	8	111	93 – 133	8	104	100 – 109	8	102	94 – 107
16	117	109 – 120	16	116	104 – 139	16	137	130 – 144	16	114	105 – 119

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	68	63 – 76	70	67 – 73	107	103 – 111	83	71 – 88
Mid	85	75 – 99	96	89 – 105	101	96 – 106	78	74 – 85
Low	106	88 – 122	118	113 – 127	124	121 – 126	92	87 – 100

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, Desghrelin, 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- 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, I-TAC, Leptin, LH, MCP-1, MCP-2, MCP-4, M-CSF, MDC, MIF, MIP-1 α , MIP-1 β , MIP-5, PIGF, PP, Proinsulin, PYY (3–36), SDF-1 α , TNF- α , TNF- β , TPO, TRAIL, TSLP, VEGF-A, YKL-40, and β -NGF). Nonspecific binding was less than 2.0%.

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

Diluent Compatibility

The data included in this document were collected with Assay Diluent 13 (supplemented with 1,000 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 your assay needs, other diluents may be tested. Diprotin A should be purchased separately.

Assay Components

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

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

Assay generation: C

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

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