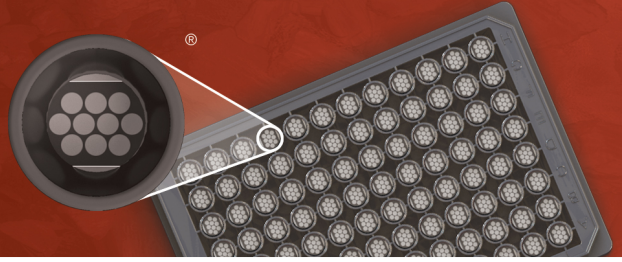
U-PLEX® Rat Insulin Assay



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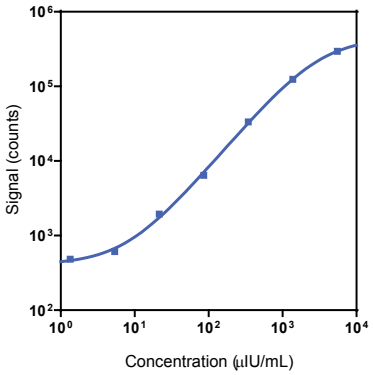
Product Options	Available in: U-PLEX Metabolic Group 1 (rat) K153ACL
	Individual assay: K1536HK provided with Diluent 13 and Diluent 11
	Antibody Set: B206H
Assay Protocol	U-PLEX product inserts are available at www.mesoscale.com/U-PLEX-documents.

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 Rat Insulin 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 from 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 (µIU/mL)	LLOD Range (µIU/mL)
Insulin	3.0	1.3-12

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. (µIU/mL)	Average Intra-run Conc. (%CV)	Inter-run Conc. (%CV)
High	604	6.3	12.4
Mid	223	4.8	11.9
Low	71	6.9	20.9

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.

Tested Samples

Sample Type	Serum (N=12)	EDTA Plasma (N=12)	P800 Plasma (N=9)
Median (µIU/mL)	1,117	986	1,126
Range (µIU/mL)	334-1,870	509-3,830	795-2,120
% Detected	100	100	100

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	88	72-99	2	87	68-100	2	97	88-118	2	94	87-99
4	100	NA	4	100	NA	4	100	NA	4	100	NA
8	111	91-126	8	103	91-107	8	109	102-128	8	97	92-103
16	112	95-122	16	109	60-137	16	108	99-114	16	104	91-128

Normal rat 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.

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

Spike Recovery

	Serum		EDTA Plasma		P800 Plasma		Cell Culture Media	
Spike Level	Average % Recovery	% Recovery Range	Average % Recovery	% Recovery Range	Average % Recovery	% Recovery Range	Average % Recovery	% Recovery Range
High	100	80-118	96	59-119	88	59-110	120	94-138
Mid	102	83-117	105	79-120	114	107-125	121	97-145
Low	104	93-113	108	92-118	109	100-124	113	98-145

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 require additional dilution with assay diluent to reduce matrix effects.

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

Specificity

To assess specificity, the Mouse/Rat Insulin Antibody Set was tested individually against a larger panel of analytes for nonspecific binding (BDNF, C-Peptide, Desghrelin, FGF-21, Ghrelin (octanoylSer3), GLP-1 (7-36), GLP-1 (9-36), Glucagon, Insulin, Leptin, PYY (3-36)). Nonspecific binding was less than 0.5%.

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

Diluent Compatibility

The data included in this document has been collected with Assay Diluent 13 (supplemented with aprotinin and diprotin A) 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: Insulin is included in Calibrator 19. The Insulin Calibrator is a full length recombinant protein expressed in *E. coli*.
Antibodies: The U-PLEX Rat Insulin 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.