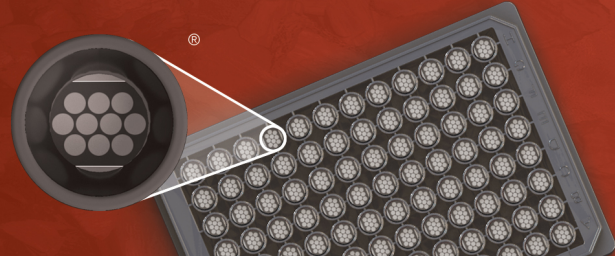


U-PLEX® Rat FGF-21 Assay



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

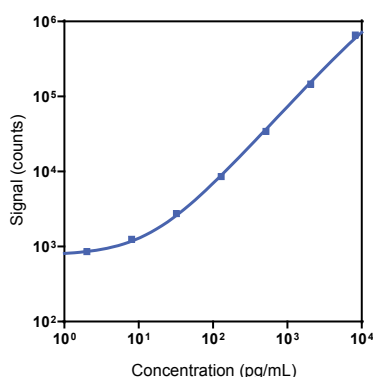
Company Address

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

Product Options	Available in: U-PLEX Metabolic Group 1 (rat) K153ACL
	Individual assay: K1535WK provided with Diluent 13 and Diluent 11
	Antibody Set: B215W
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 FGF-21 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 (pg/mL)	LLOD Range (pg/mL)
FGF-21	2.8	2.0-3.0

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. (pg/mL)	Average Intra-run Conc. (%CV)	Inter-run Conc. (%CV)
High	4,180	2.5	8.7
Mid	846	3.6	10.5
Low	202	4.3	12.1

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.

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Not for use in diagnostic procedures.

MSD® U-PLEX Assays

Tested Samples

Sample Type	Serum (N=12)	EDTA Plasma (N=12)	P800 Plasma (N=9)
Median (pg/mL)	722	1,380	4,230
Range (pg/mL)	259-3,110	719-4,950	2,460-8,010
% 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	98	91-106	2	112	100-120	2	98	92-104	2	107	96-113
4	100	NA	4	100	NA	4	100	NA	4	100	NA
8	101	93-107	8	94	90-99	8	102	95-108	8	100	97-103
16	75	46-102	16	93	84-102	16	113	103-126	16	99	96-106

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

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	81	75-91	88	72-97	82	75-91	133	107-146
Mid	84	76-94	92	75-104	86	80-94	130	111-152
Low	88	77-97	96	81-104	90	80-97	128	108-152

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 FGF-21 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: FGF-21 is included in Calibrator 18. The FGF-21 Calibrator is a full length recombinant protein expressed in *E. coli*.

Antibodies: The U-PLEX Rat FGF-21 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.

