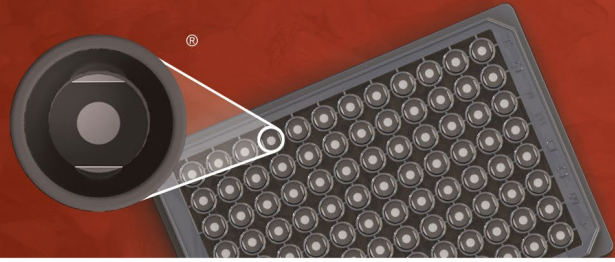
U-PLEX®

Human FSH



www.mesoscale.com®

Ordering Information
MSD Customer Service
Phone: 1-240-314-2795
Fax: 1-301-990-2776
Email: CustomerService@mesoscale.com

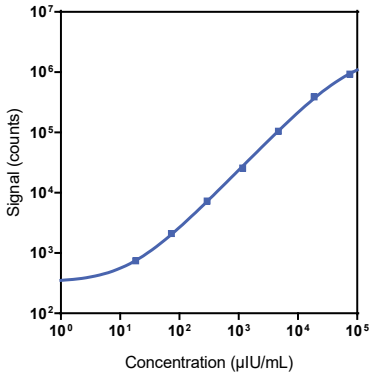
Scientific Support
Phone: 1-240-314-2798
Email: ScientificSupport@mesoscale.com

Company Address
Meso Scale Discovery
A division of
Meso Scale Diagnostics, LLC.
1601 Research Boulevard
Rockville, MD 20850-3173 USA

Product Options	Catalog Number	Description
Multiplex	K151ACM, K251ACM	U-PLEX Metabolic Group 1 (human)
Singleplex	K1516GK-1/-2/-4	U-PLEX Human FSH Assay with SECTOR™ plates
	K1516GK-21/-22/-24	U-PLEX Human FSH Assay with QuickPlex Ultra™ plates
	K2516GK-2/-4	U-PLEX Human FSH Assay with 384-well plates
Antibody Set	B216G-2/-3	U-PLEX Human FSH 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 FSH 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 (µIU/mL)	LLOD Range (µIU/mL)
FSH	9.0	4.3-16

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. (µIU/mL)	Average Intra-run Conc. (%CV)	Inter-run Conc. (%CV)
High	37,300	4.3	104
Mid	7,070	3.6	16.4
Low	1,290	4.1	16.8

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.

MSD® U-PLEX Human FSH

Tested Samples

Sample Type	Serum (N=12)	EDTA Plasma (N=12)	P800 Plasma (N=8)
Median (µIU/mL)	1,050	695	875
Range (µIU/mL)	191-18,100	294-7,000	195-2,230
% 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	97	90-101	2	99	88-104	2	94	92-98	2	99	97-101
8	98	95-101	8	97	90-103	8	98	95-102	8	95	91-96
16	95	91-102	16	93	88-97	16	96	90-99	16	90	86-93

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.

% 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	97	89-105	92	81-102	98	91-109	101	96-107
Mid	94	86-103	92	89-98	98	87-105	102	99-105
Low	90	80-100	90	85-96	92	82-101	100	96-106

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.

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

Specificity

To assess specificity, the FSH 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-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, PlGF, 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%.

% Nonspecificity = (nonspecific signal / specific signal) x 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 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: FSH is included in Calibrator 14. The human FSH Calibrator is a native protein.
Antibodies: the U-PLEX® Human FSH 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.