

Human FGF-23



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

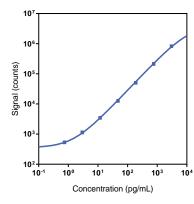
Company Address

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 K151AEM, K251AEM | U-PLEX Metabolic Group 1 (hu) U-PLEX Immuno-Oncology Group 1 (hu) | | |
| | K1516EK-1/-2/-4 | U-PLEX Human FGF-23 Assay with SECTOR™ plates | | |
| Singleplex | K1516EK-21/-22/-24 | U-PLEX Human FGF-23 Assay with QuickPlex® plates | | |
| | K2516EK-2/-4 | U-PLEX Human FGF-23 Assay with 384-well plates | | |
| Antibody Set | B216E-2/-3 | U-PLEX Human FGF-23 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 FGF-23 Assay tested on U-PLEX 96-well 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 (pg/mL) | LLOD Range (pg/mL) | | |
|--------|------------------------|-----------------------|--|--|
| FGF-23 | 0.75 | 0.62-0.78 | | |

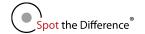
The Calibrator curve was fitted with a 4-parameter logistic model with a $1/Y^2$ weighting. The lower limit of detection (LLOD) is a calculated concentration corresponding to 2.5 standard deviations above the background (zero Calibrator).

Precision

| Control | Average Conc. (pg/mL) | Average Intra-run Conc. (%CV) | Inter-run Conc. (%CV) | | |
|---------|--------------------------|----------------------------------|--------------------------|--|--|
| High | 1,050 | 3.5 | 8.2 | | |
| Mid | 231 | 3.0 | 13.2 | | |
| Low | 46 | 4.9 | 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 FGF-23

Tested Samples

| Sample Type | Serum (N=12) | EDTA Plasma (N=12) | P800 Plasma (N=8) | | |
|----------------|-----------------|-----------------------|----------------------|--|--|
| Median (pg/mL) | 6.8 | 17 | 42 | | |
| Range (pg/mL) | 1.7-27 | 7.2-45 | 14-108 | | |
| % 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 | | | |
|-------|--------------|-----------------------|---------------------|------------------|-----------------------|---------------------|------------------|-----------------------|---------------------|------------------|-----------------------|---------------------|
| | old ution | Average % Recovery | % Recovery Range | Fold Dilution | Average % Recovery | % Recovery Range | Fold Dilution | Average % Recovery | % Recovery Range | Fold Dilution | Average % Recovery | % Recovery Range |
| | 2 | 93 | 86-102 | 2 | 98 | 92-103 | 2 | 97 | 93-100 | 2 | 101 | 99-104 |
| | 8 | 103 | 99-105 | 8 | 98 | 95-104 | 8 | 99 | 97-102 | 8 | 95 | 94-96 |
| | 16 | 105 | 102-108 | 16 | 99 | 95-105 | 16 | 99 | 93-103 | 16 | 95 | 91-98 |

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 Le | evel | Average % Recovery | % Recovery Range | Average % % Recovery Range | | Average % Recovery | % Recovery Range | Average % Recovery | % Recovery Range |
| High | | 88 | 76-95 | 92 | 89-96 | 99 | 95-103 | 98 | 95-102 |
| Mid | | 88 | 80-95 | 91 | 84-94 | 96 | 92-99 | 99 | 95-104 |
| Low | | 84 | 76-94 | 91 | 82-95 | 94 | 89-97 | 97 | 94-103 |

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 FGF-23 Antibody Set was tested individually against a larger panel of analytes for nonspecific binding (APRIL/TNFSF13, BAFF, BAFF-R/TNFRSF13C, BCMA/TNFRSF17, BDNF, C-Peptide, CD20, CD27, CD28, CD40L (soluble), CD276/B7-H3, CTACK, CTLA-4, Desghrelin, ENA-78, Eotaxin, Eotaxin-2, Eotaxin-3, EPO, E-Selectin, FGF (basic), FGF-21, FGF-23, FLT3L, Fractalkine, FSH, Galectin-9, G-CSF, GITRL/TNFSF18, GITR/TNFRSF18, Ghrelin (Ser3-octanoylated), gp130 (soluble), GIP (1-42), GIP (3-42), GLP-1 (7-36), GLP-1 (9-36), Glucagon, GM-CSF, Granzyme A, Granzyme B, GRO-α, HAVCR2/TIM-3, HVEM/TNFRSF14, ICOS, ICOS-L/B7-H2, I-309, $IFN-\alpha 2a$, $IFN-\beta$, $IFN-\gamma$, $IL-1\alpha$, $IL-1\beta$, IL-1RA, IL-2, $IL-2R\alpha$, 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-18A, IL-1IL-17C, IL-17D, IL-17E/IL-25, IL-17F, IL-18, IL-21, IL-22, IL-23, IL-27, IL-29/IFN-A1, IL-31, IL-33, Insulin, IP-10, LAG3, Leptin, LH, LIGHT/TNFSF14, MCP-1, MCP-2, MCP-4, M-CSF, MDC, MIF, MIG, MIP-1α, MIP-1β, MIP-5, MMP-1, MMP-7, Nectin-4, OX40/TNFRSF4, PD1, PD-L1, PD-L2, Pentraxin 3, Perforin, PIGF, PP, Proinsulin, proMMP-9, P-Selectin, PYY (3-36), RAGE (soluble), RANKL/TNFSF11, RANTES, S100A12, SDF-1α, Tie-2, TIGIT, TLR1, TNF-α, TNF-β, TNF-RI, TNF-RI, TPO, TRAIL, TSLP, VEGF-A, VEGF-D, VEGFR-1/Flt-1, 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 klU/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: FGF-23 is included in Calibrator 14. The human FGF-23 Calibrator is a full-length recombinant protein expressed in a mouse cell line.

Antibodies: The U-PLEX Human FGF-23 Assay uses a goat polyclonal antibody for capture and a goat polyclonal 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.

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