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Ordering Information

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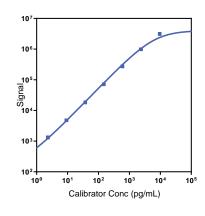
Company Address

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

Product Options	Catalog Number	Description				
Multiplex	K15068M, K25068M	U-PLEX Biomarker Group 1 (NHP)				
Singleplex	K156UMK-1/-2/-4	U-PLEX NHP GM-CSF Assay with SECTOR™ plates				
	K156UMK-21/-22/-24	U-PLEX NHP GM-CSF Assay with QuickPlex® plates				
	K256UMK-2/-4	U-PLEX NHP GM-CSF Assay with 384-well plates				
Antibody Set	B21UM-2/-3	U-PLEX Human GM-CSF Antibody Set				
Assay 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 NHP GM-CSF Assay tested on U-PLEX 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 in 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)		
GM-CSF	0.08	0.05-0.25		

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 2.5X the standard deviations above the background (zero Calibrator).

Precision

	Control	Average Conc. (pg/mL)	Average Intra-run Conc. %CV	Inter-run Conc. %CV
	High	4,550	3.7	4.3
GM-CSF	Mid	464	3.1	5.8
	Low	47.2	4.0	9.0

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 NHP GM-CSF

Spike Recovery

<u> </u>		Serum (N=5)		Plasma (N=5)		Cell Culture Media (N=5)	
	Spike Level	Average % Recovery	% Recovery Range	Average % Recovery	% Recovery Range	Average % Recovery	% Recovery Range
0	High	89	74-101	102	97-107	114	113-121
Cynomolgus Monkey	Mid	94	76-107	104	98-110	115	112-122
	Low	93	78-100	102	95-110	120	117-129
Rhesus Monkey	High	106	102-113	103	98-113	114	113-121
	Mid	104	99-113	104	95-109	115	112-122
	Low	102.4	89-114	102	96-111	120	117-129

Normal serum, EDTA plasma, and cell culture media were spiked with Calibrator at 3 levels. Undiluted samples were tested 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

Tested Samples

	Sample Type	Serum (N=10)	Plasma (N=10)	Spiked Serum (N=5)
Cynomolgus Monkey	Median (pg/mL)	0.27	0.28	0.92
	Range (pg/mL)	ND-1.04	ND-0.30	0.41-1.30
	% Detected	90	80	100
Rhesus Monkey	Median (pg/mL)	0.1	0.1	0.8
	Range (pg/mL)	ND-0.20	ND-0.20	0.40-11.2
	% Detected	90	80	100

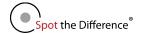
Normal serum and plasma samples were tested without dilution prior to the assay. ND = not detectable (<LLOD)

Dilution Linearity

	Serum (N=5)			Plasma (N=5)			Cell Culture Media (N=5)		
	Fold Dilution	Average % Recovery	% Recovery Range	Fold Dilution	Average % Recovery	% Recovery Range	Fold Dilution	Average % Recovery	% Recovery Range
Cynomolgus Monkey	2	108	84-121	2	109	104-114	2	105	102-108
	4	101	80-120	4	106	100-112	4	106	99-111
	8	104	73-119	8	101	88-112	8	101	100-103
Rhesus Monkey	2	97	62-112	2	94	79-105	2	105	102-108
	4	110	103-120	4	98	82-111	4	106	99-111
	8	108	101-120	8	100	87-115	8	101	100-103

Normal serum, EDTA plasma, and cell culture media were spiked with Calibrator and tested at different dilutions. Undiluted samples were tested 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





MSD U-PLEX NHP GM-CSF

Specificity

To assess specificity, the GM-CSF Antibody Set was tested individually against a larger panel of recombinant human analytes for nonspecific binding (CTACK, Eotaxin, Eotaxin-2, Eotaxin-3, ENA-78, FLT3L, Fractalkine, G-CSF, GM-CSF, GRO-α, I-309, IFN-α2a, IFN-γ, IL-1α, IL-1β, IL-1RA, IL-2, 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-17B, IL-17D, IL-17D, IL-17F, IL-18, IL-22, IL-23, IP-10, I-TAC, MCP-1, MCP-2, MCP-3, MCP-4, M-CSF, MDC, MIF, MIP-1 α , MIP-1 β , MIP-3 α , MIP-3 β , MIP-5, SDF-1 α , TARC, TNF- α , TNF- β , TPO, TRAIL, VEGF-A, and YKL-40). Nonspecific binding was less than 0.5%.

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

Diluent Compatibility

Diluents 57 and 3 are provided with this assay. MSD offers a range of assay and antibody diluents for separate purchase. Depending on your assay needs, other diluents may be tested.

Assay Components

Calibrator: GM-CSF is included in Calibrator 1. The full-length recombinant protein is expressed in E. coli.

Antibodies: The U-PLEX NHP GM-CSF Assay uses a mouse monoclonal antibody for capture and a rat monoclonal antibody for detection.

Assay generation: A

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

MESO SCALE DISCOVERY, Meso Scale Diagnostics, www.mesoscale.com, MSD, MSD (design), QuickPlex, SECTOR, U-PLEX, U-PLEX (design), 96 WELL SMALL-SPOT (design), and Spot the



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