

U-PLEX[®] NHP IL-16 Assay



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Ordering Information

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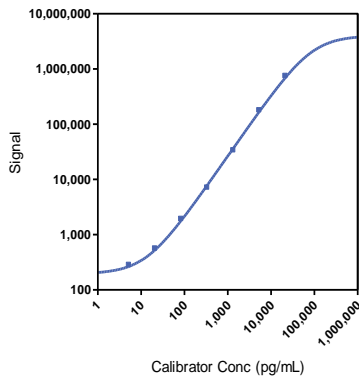
Company Address

MESO SCALE DISCOVERY[®]
A division of
Meso Scale Diagnostics, LLC.
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| | |
|---------------------------------|--|
| Product Options | Available as part of U-PLEX Biomarker Group 1 (NHP) multiplex combination: K15068L-1/-2/-4 Individual assay: K156USK-1/-2/-4; Antibody Set: B26US-2/B26US-3 For more ordering options, please visit www.mesoscale.com |
| Instrument Compatibility | SECTOR [®] Imager 2400, SECTOR Imager 6000, MESO [®] SECTOR S 600, MESO QuickPlex [®] SQ 120 |
| Sample Type | NHP (Cynomolgus monkey and Rhesus monkey) serum, EDTA plasma, and cell culture supernatants |
| Assay Protocol | Refer to the U-PLEX Biomarker Group 1 (NHP) product insert 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 NHP IL-16 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 than 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) |
|-------|---------------------|--------------------|
| IL-16 | 6.6 | 4.3-8.7 |

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 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 |
|-------|---------|-----------------------|-----------------------------|---------------------|
| IL-16 | High | 7,778 | 4.2 | 4.9 |
| | Mid | 719 | 3.6 | 10.1 |
| | Low | 82 | 4.7 | 14.7 |

For Research Use Only.
Not for use in diagnostic procedures.

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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Spike Recovery

| | Spike Level | Serum | | Plasma | | Cell Culture Media | |
|-------------------|-------------|--------------------|------------------|--------------------|------------------|--------------------|------------------|
| | | Average % Recovery | % Recovery Range | Average % Recovery | % Recovery Range | Average % Recovery | % Recovery Range |
| Cynomolgus Monkey | High | 88 | 83-96 | 82 | 69-90 | 98 | 91-103 |
| | Mid | 82 | 77-85 | 78 | 73-86 | 89 | 83-92 |
| | Low | 84 | 79-87 | 79 | 75-87 | 81 | 76-84 |
| Rhesus Monkey | High | 91 | 84-102 | 86 | 67-110 | 98 | 91-103 |
| | Mid | 90 | 82-99 | 83 | 64-99 | 89 | 83-92 |
| | Low | 93 | 86-104 | 85 | 75-91 | 81 | 76-84 |

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

Tested Samples

| | Sample Type | Serum | Plasma | Spiked Serum | Spiked Plasma |
|-------------------|----------------|-------|--------|--------------|---------------|
| Cynomolgus Monkey | Median (pg/mL) | 12 | 25 | 28 | 53 |
| | Range (pg/mL) | ND-20 | 16-42 | 8.2-38 | 29-66 |
| | % Detected | 60 | 100 | 100 | 100 |
| Rhesus Monkey | Median (pg/mL) | 47 | 54 | 172 | 174 |
| | Range (pg/mL) | 32-92 | 26-194 | 108-260 | 123-251 |
| | % Detected | 100 | 100 | 100 | 100 |

ND = non-detectable (< LLOD)

Normal serum and EDTA plasma samples were tested without dilution prior to the assay. Spiked serum and spiked plasma represent samples that were spiked with Calibrator and/or cell culture supernatants derived from cells (PBMCs and THP-1) stimulated with different compounds in vitro.

Dilution Linearity

| | Serum | | | Plasma | | | Cell Culture Media | | |
|-------------------|---------------|--------------------|------------------|---------------|--------------------|------------------|--------------------|--------------------|------------------|
| | Fold Dilution | Average % Recovery | % Recovery Range | Fold Dilution | Average % Recovery | % Recovery Range | Fold Dilution | Average % Recovery | % Recovery Range |
| Cynomolgus Monkey | 2 | 113 | 105-119 | 2 | 107 | 98-116 | 2 | 105 | 99-110 |
| | 4 | 114 | 104-127 | 4 | 108 | 96-118 | 4 | 101 | 95-108 |
| | 8 | 118 | 106-129 | 8 | 109 | 101-119 | 8 | 98 | 92-106 |
| Rhesus Monkey | 2 | 111 | 110-115 | 2 | 113 | 106-123 | 2 | 105 | 99-110 |
| | 4 | 116 | 112-119 | 4 | 115 | 108-122 | 4 | 101 | 95-108 |
| | 8 | 121 | 114-124 | 8 | 117 | 103-134 | 8 | 98 | 92-106 |

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

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Specificity

To assess specificity, IL-16 Antibody Set was tested individually against a larger panel of recombinant nhp analytes for nonspecific binding (CTACK, ENA-78, Eotaxin, Eotaxin-3, Fractalkine, G-CSF, GM-CSF, IFN- α 2a, IFN- γ , IL-1 α , IL-1 β , IL-2, IL-4, IL-5, IL-6, IL-7, IL-8, IL-10, IL-12/IL-23p40, IL-12p70, IL-13, IL-15, IL-16, IL-17A, IL-18, IP-10, I-TAC, MCP-1, MCP-4, MDC, MIP-1 α , MIP-1 β , MIP-3 α , MIP-3 β , SDF-1 α , TARC, TNF- α , TNF- β , TPO, and VEGF-A). Nonspecific binding was less than 0.5%.

$\% \text{ Nonspecificity} = (\text{nonspecific signal} / \text{specific signal}) \times 100$

Diluent Compatibility

The data included in this document has been collected using Diluents 3 and 43. 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: NHP IL-16 is included in Calibrator 3 blend. The full-length recombinant protein expressed in *E. coli* is used.

Antibodies: The U-PLEX NHP IL-16 Assay uses mouse monoclonal antibody for capture and 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 than the representative data shown.

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