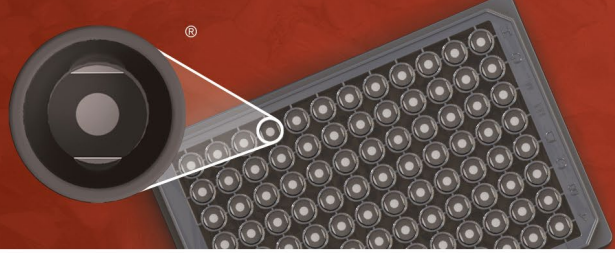
U-PLEX®

# Human CD20



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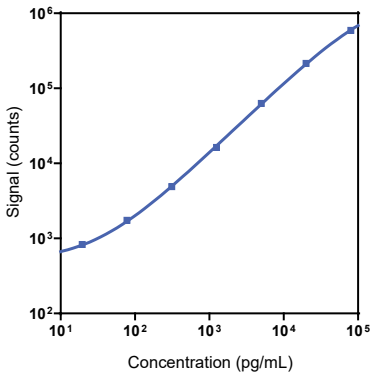
| Product Options | Catalog Number | Description |
|---|---|---|
| Multiplex | K151AEM, K251AEM | U-PLEX Immuno-Oncology Group 1 (human) |
| Singleplex | K151F7K-1/-2/-4 | U-PLEX Human CD20 Assay with SECTOR™ plates |
| | K151F7K-21/-22/-24 | U-PLEX Human CD20 Assay with QuickPlex® plates |
| | K251F7K-2/-4 | U-PLEX Human CD20 Assay with 384-well plates |
| Antibody Set | B21F7-2/-3 | U-PLEX Human CD20 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 CD20 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 (pg/mL) | LLOD Range (pg/mL) |
|---|---|---|
| CD20 | 5.7 | 0.35-13 |

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 | 2,520 | 3.8 | 7.3 |
| Mid | 906 | 3.7 | 9.6 |
| Low | 289 | 5.9 | 11.0 |

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.

# MSD® U-PLEX Human CD20

## Tested Samples

| Sample Type | Serum (N=10) | EDTA Plasma (N=10) | Normal Lysate (N=5) | Tumor Lysate (N=5) |
|---|---|---|---|---|
| Median (pg/mL) | 435 | 828 | 842 | 198 |
| Range (pg/mL) | 121-1,480 | 309-1,250 | ND-1,560 | ND-20,000 |
| % Detected | 100 | 100 | 80 | 80 |

Normal serum and plasma samples were diluted 4-fold prior to the assay. Lysates were tested at a protein concentration of 0.5 mg/mL. ND = non-detectable (<LLOD).

## Dilution Linearity

| Serum | | | EDTA Plasma | | |
|---|---|---|---|---|---|
| Fold Dilution | Average % Recovery | % Recovery Range | Fold Dilution | Average % Recovery | % Recovery Range |
| 2 | 92 | 87 - 96 | 2 | 90 | 82 - 96 |
| 8 | 98 | 95 - 100 | 8 | 97 | 86 - 111 |
| 16 | 103 | 88 - 136 | 16 | 115 | 97 - 145 |

Normal human serum and EDTA plasma 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 | |
|---|---|---|---|---|
| Spike Level | Average % Recovery | % Recovery Range | Average % Recovery | % Recovery Range |
| High | 91 | 70 - 117 | 96 | 87 - 111 |
| Mid | 82 | 54 - 114 | 100 | 92 - 117 |
| Low | 109 | 72 - 171 | 97 | 86 - 114 |

Normal serum and plasma 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

The CD20 Antibody Set was tested for nonspecific binding against all of the analytes in the Immuno-Oncology Group 1 and the majority of analytes in Biomarker Group 1. Any cross-reactivity greater than 2.0% is noted below. The U-PLEX Assay Designer shows all of the compatible assays.

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

The following assays are not compatible with the CD20 assay: EPO, FGF-23, G-CSF, GLP-1 (inactive), IL-10, IL-15, IP-10, PYY (total), TPO.

## Diluent Compatibility

Diluents 58 (supplemented with 0.5% Triton X-100 ) and 3 when this is ordered in singleplex and multiplex assays.

## Assay Components

**Calibrator:** CD20 is included in Calibrator 20. The human CD20 Calibrator is a full-length recombinant protein expressed in a human cell line.
**Antibodies:** The U-PLEX Human CD20 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.