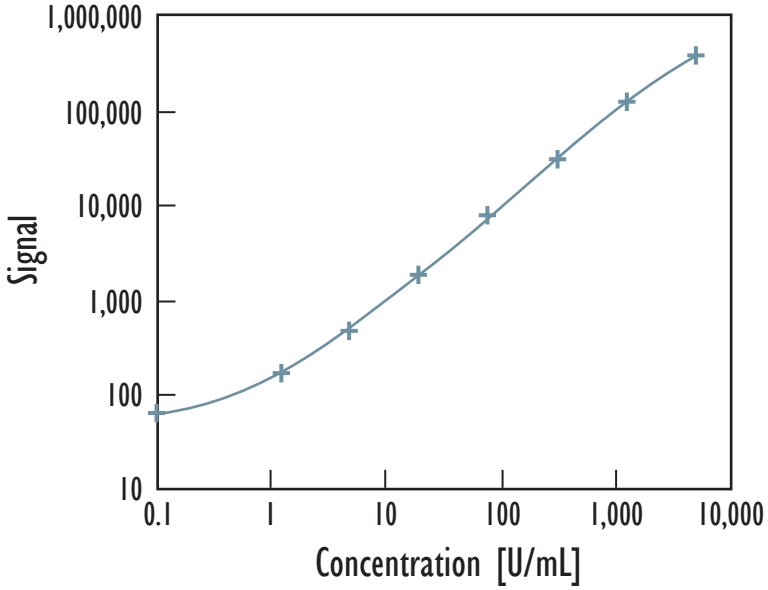
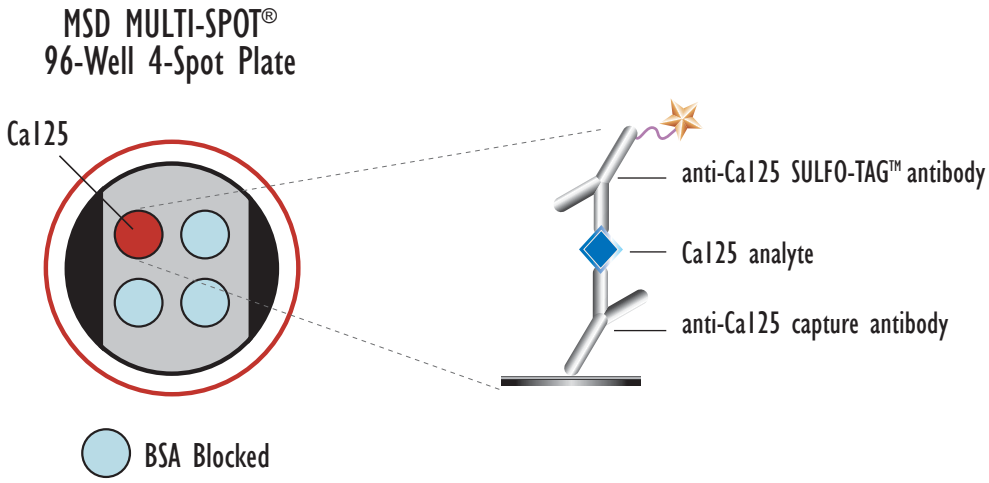
MULTI-ARRAY® Human Cancer Antigen 125 Assay

Detection of Cancer Antigen 125 (Ca 125) in Human Serum and Plasma Samples





Concentration (U/mL)	Average	%CV
0	66	20
1.2	165	14
5	479	6
20	1,874	3
78	7,786	4
313	30,797	5
1,250	126,656	3
5,000	387,403	5

Standard curve data is from a representative experiment

Ca125 LLOD	0.30 (U/mL)

LLOD (Lower Limit of Detection) is defined as 2.5x stdev above the background

Kit Size	SI2400	SI6000
1 plate	K151IWC-1	K111IWC-1
5 plates	K151IWC-2	K111IWC-2
20 plates	K151IWC-3	K111IWC-3
20 plates (Base)	K151IWA-3	K111IWA-3

Meso Scale Discovery
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Spike Recovery

- Measured analyte spiked into apparently normal human samples

$$\% \text{ recovery} = \frac{(\text{measured value} * 100)}{\text{expected value}}$$

	Spike Level (U/mL)	% Recovery Ca125
Sample 1	500	91
Sample 2	500	95
Sample 3	500	95
Sample 4	500	98
Sample 5	500	88
Sample 6	500	93
Sample 7	500	96

Endogenous Levels in Human Samples

- 95 normal human donors, Serum
- Average CVs for measured samples was less than 7%

N (U/mL)	Mean (U/mL)	Median (U/mL)	Range (U/mL)
95	27	16	4 - 796

Dilutional Linearity

- Samples from 4 apparently healthy donors were diluted in Calibrator Diluent

$$\% \text{ recovery} = \frac{(\text{measured value} * \text{dilution factor} * 100)}{\text{predicted value}}$$

	Dilution Factor	% Recovery Ca125
Sample 1	3/4	73
	1/2	82
	1/4	85
Sample 2	3/4	103
	1/2	108
	1/4	95
Sample 3	3/4	90
	1/2	78
	1/4	78
Sample 4	3/4	122
	1/2	110
	1/4	121

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