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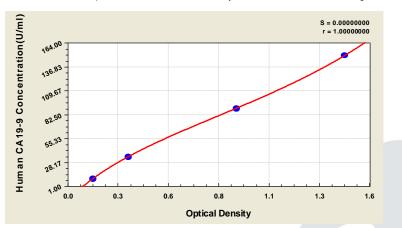
PRECISION

Intra-assay Precision (Precision within an assay): CV%<15% Three samples of known concentration were tested twenty times on one plate to assess. Inter-assay Precision (Precision between assays): CV%<20% Three samples of known concentration were tested in twenty assays to assess.

	Intra-Assay Precision			Inter-Assay Precision		
Sample	1	2	3	1	2	3
n	20	20	20	20	20	20
Mean(U/ml)	34.881	33.567	35.826	34.167	37.109	35.237
SD	0.022	0.022	0.025	0.030	0.030	0.033
CV(%)	6.147	6.359	7.011	8.516	8.197	9.214

TYPICAL DATA

These standard curves are provided for demonstration only. A standard curve should be generated for each set of samples assayed.



U/ml	OD1	OD2	Average
150	1.445	1.505	1.475
90	0.900	0.928	0.914
25	0.341	0.367	0.354
10	0.161	0.181	0.171

2.5 U/ml

LOD

LINEARITY

To assess the linearity of the assay, samples were spiked with high concentrations of Human carbonhydrate antigen 19-9 (CA19-9) in various matrices and diluted with the Sample Diluent to produce samples with values within the dynamic range of the assay.

	Sample	Serum (n=4)
1:1	Average %	98
	Range %	95-105
1:2	Average %	85
	Range %	80-90
1:4	Average %	89
	Range %	85-92
1:8	Average %	96
1.0	Range %	90-101