



### PRECISION

#### **Intra-assay Precision (Precision within an assay): CV%<15%**

Three samples of known concentration were tested twenty times on one plate to assess.

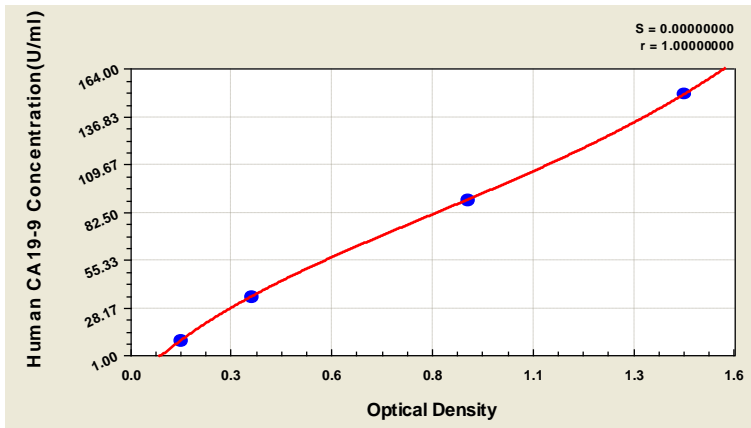
#### **Inter-assay Precision (Precision between assays): CV%<20%**

Three samples of known concentration were tested in twenty assays to assess.

Sample	Intra-Assay Precision			Inter-Assay Precision		
	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

### LOD

2.5 U/ml

### LINEARITY

To assess the linearity of the assay, samples were spiked with high concentrations of Human carbohydrate 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
1:2	Range %
	95-105
1:4	Average %
	85
1:8	Range %
	80-90
1:16	Average %
	89
1:32	Range %
	85-92
1:64	Average %
	96
1:128	Range %
	90-101