



PRECISION

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

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

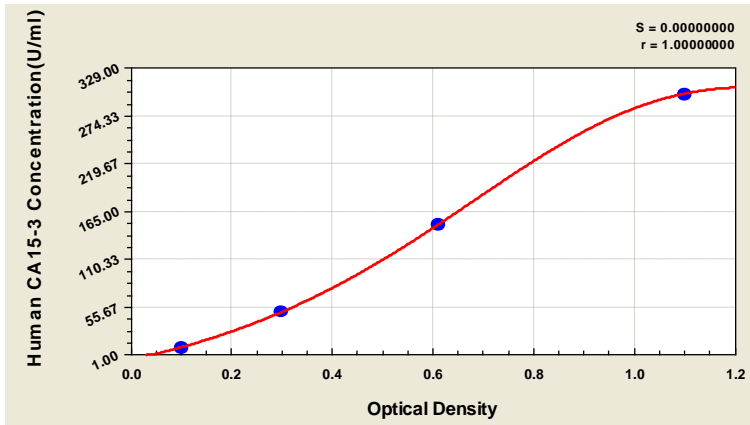
Inter-assay Precision (Precision between assays): CV%<20%

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)	47.941	52.357	48.966	51.567	46.168	51.042
SD	0.022	0.019	0.023	0.030	0.024	0.028
CV(%)	7.548	6.375	8.071	9.678	8.647	9.375

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
300	1.111	1.009	1.060
150	0.608	0.576	0.592
50	0.283	0.307	0.295
10	0.100	0.112	0.106

LOD

2.5 U/ml

LINEARITY

To assess the linearity of the assay, samples were spiked with high concentrations of Human mammary carcinoma marker CA15-3 (CA15-3) in various matrices and diluted with the Sample Diluent to produce samples with values within the dynamic range of the assay.

Sample	Sample	Serum (n=4)
1:1	Average %	98
	Range %	90-100
1:2	Average %	85
	Range %	80-90
1:4	Average %	87
	Range %	85-91
1:8	Average %	95
	Range %	90-102