



PRECISION

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

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

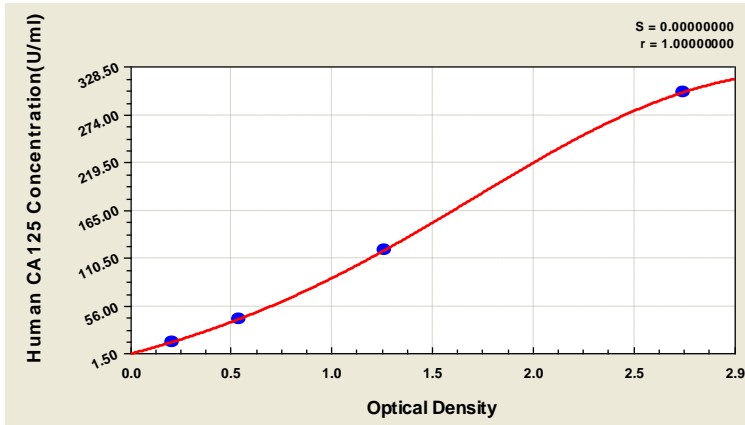
Inter-assay Precision (Precision between assays): CV%<20%

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)	40.730	39.743	41.723	40.460	39.119	41.361
SD	0.038	0.043	0.040	0.052	0.048	0.054
CV(%)	6.979	8.167	7.254	9.671	9.187	9.863

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	2.557	2.839	2.698
120	1.250	1.254	1.252
41	0.537	0.549	0.543
15	0.211	0.231	0.221

LOD

3.8 U/ml

LINEARITY

To assess the linearity of the assay, samples were spiked with high concentrations of Human carbohydrate antigen 125(CA125) 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 %
	96
1:2	Average %
	98
1:4	Average %
	87
1:8	Average %
	101
	Range %
	85-99
	94-101
	85-95
	95-107