

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

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

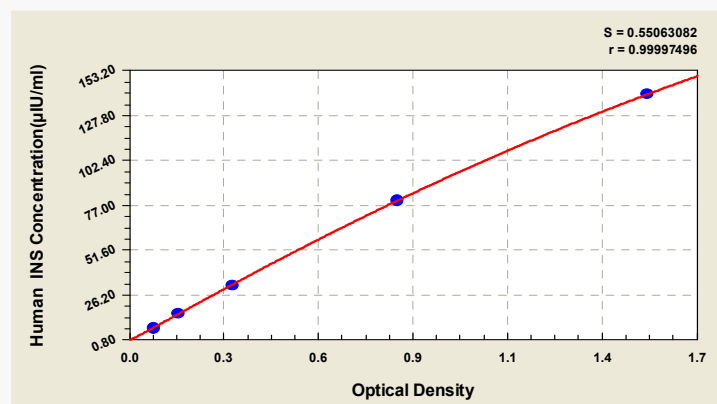
Inter-assay Precision (Precision between assays): CV%<15%

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(μIU/ml)	31.922	30.809	32.629	30.606	32.023	32.730
SD	0.019	0.019	0.021	0.022	0.023	0.026
CV(%)	6.123	6.247	6.548	7.198	7.247	8.055

TYPICAL DATA

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



μIU/ml	OD1	OD2	Average
140	1.580	1.562	1.571
80	0.796	0.835	0.816
32	0.308	0.332	0.320
16	0.156	0.150	0.153
8	0.086	0.076	0.081

LOD

5μIU/ml

LINEARITY

To assess the linearity of the assay, samples were spiked with high concentrations of Human Insulin (INS) 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
	Range %	90-103
1:2	Average %	86
	Range %	80-93
1:4	Average %	94
	Range %	88-100
1:8	Average %	97
	Range %	92-100