

PRECISION

Intra-assay Precision (Precision within an assay): CV%<8%

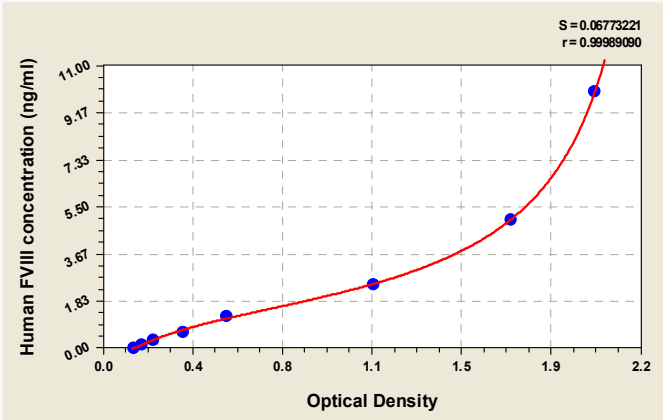
Three samples of known concentration were tested twenty times on one plate to assess.

Inter-assay Precision (Precision between assays): CV%<10%

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

TYPICAL DATA

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



ng/ml	OD1	OD2	Average	Corrected
10	2.099	1.997	2.048	1.910
5	1.748	1.652	1.700	1.562
2.5	1.142	1.122	1.132	0.994
1.25	0.531	0.515	0.523	0.385
0.625	0.348	0.336	0.342	0.204
0.312	0.229	0.215	0.222	0.084
0.156	0.175	0.172	0.174	0.036
0	0.138	0.137	0.138	

LOD

0.039 ng/ml

for research use only

LINEARITY

To assess the linearity of the assay, samples were spiked with high concentrations of human FVIII 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)
1:5	Average %	90
	Range %	86-97
1:10	Average %	94
	Range %	89-98
1:20	Average %	98
	Range %	95-102
1:40	Average %	94
	Range %	87-98

RECOVERY

The recovery of human FVIII spiked to levels throughout the range of the assay in various matrices was evaluated. Samples were diluted prior to assay as directed in the Sample Preparation section.

Sample Type	Average % Recovery	Range
Serum (n=5)	101	97-108
EDTA plasma (n=4)	96	90-99