



User's Manual

Human Zonulin ELISA Kit



DEIA2225



96T



This product is for research use only and is not intended for diagnostic use.

For illustrative purposes only. To perform the assay the instructions for use provided with the kit have to be used.

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PRODUCT INFORMATION

Intended Use

For the quantitative determination of human Haptoglobin concentrations in serum-free cell culture supernates, serum, plasma, saliva, and urine.

Storage

Store the unopened kit at 2-8°C. Do not use past kit expiration date.

Precision

Intra-assay Precision (Precision within an assay)

Three samples of known concentration were tested twenty times on one plate to assess intra-assay precision.

Inter-assay Precision (Precision between assays)

Three samples of known concentration were tested in twenty separate assays to assess inter-assay precision. Assays were performed by at least three technicians using two lots of components.

Sample	Intra-Assay Precision			Inter-Assay Precision		
	1	2	3	1	2	3
n	20	20	20	20	20	20
Mean (ng/mL)	18.7	58.3	116	18.8	57.8	113
Standard deviation	0.690	1.42	3.66	1.40	3.47	6.30
CV (%)	3.7	2.4	3.2	7.4	6.0	5.6

Sensitivity

Twenty-five assays were evaluated and the minimum detectable dose (MDD) of human Haptoglobin ranged from 0.031-0.529 ng/mL. The mean MDD was 0.192 ng/mL.

The MDD was determined by adding two standard deviations to the mean optical density value of twenty zero standard replicates and calculating the corresponding concentration.

Specificity

No significant cross-reactivity or interference was observed.

Linearity

To assess the linearity of the assay, samples containing and/or spiked with high concentrations of human Haptoglobin were diluted with Calibrator Diluent to produce samples with values within the dynamic range of the assay.



		Serum-free cell culture media (n=4)	Serum* (n=4)	EDTA plasma* (n=4)	Heparin plasma* (n=4)	Saliva* (n=4)	Urine (n=4)
1:2	Average % of Expected	103	102	106	104	101	107
	Range (%)	96-107	95-107	101-112	102-107	97-106	102-111
1:4	Average % of Expected	103	103	106	107	98	105
	Range (%)	99-107	98-109	98-114	100-114	97-106	97-109
1:8	Average % of Expected	100	106	110	106	100	109
	Range (%)	98-105	101-113	106-118	100-114	96-102	106-117
1:16	Average % of Expected	96	104	108	106	99	110
	Range (%)	93-101	99-111	102-118	96-115	87-106	104-115

*Samples were diluted prior to assay as directed in the Sample Preparation section.

Recovery

The recovery of human Haptoglobin spiked to levels throughout the range of the assay was evaluated.

Sample Type	Average % Recovery	Range
Serum-free cell culture media (n=4)	101	94-107%