

Certification of analysis

Product Name: Human Alkaline Phosphatase, Placental (ALPP) ELISA Kit

Catalog No.: AAA14032

Organism: Homo sapiens human

Lot :EDL2019081698

Introduction

Item	Standard		Test Result
Description	The kit is a sandwich enzyme immunoassay technique for the in vitro quantitative measurement of ALPP in human serum, plasma, tissue homogenates or other biological fluids.		Conform
Identification	Colorimetric		Positive
Composition	Pre-coated, ready to use 96-well strip plate Standard (freeze dried) Diluent Buffer Detection Reagent A Detection Reagent B TMB Substrate Stop Solution Wash Buffer(30 x concentrate) Plate sealer for 96 wells Instruction manual	1 2 1 × 45ml 1 × 120µl 1 × 120µl 1 × 9ml 1 × 6ml 1 × 20ml 2 1	Conform
Assay Range	12.5-800pg/mL		Conform

Sensitivity

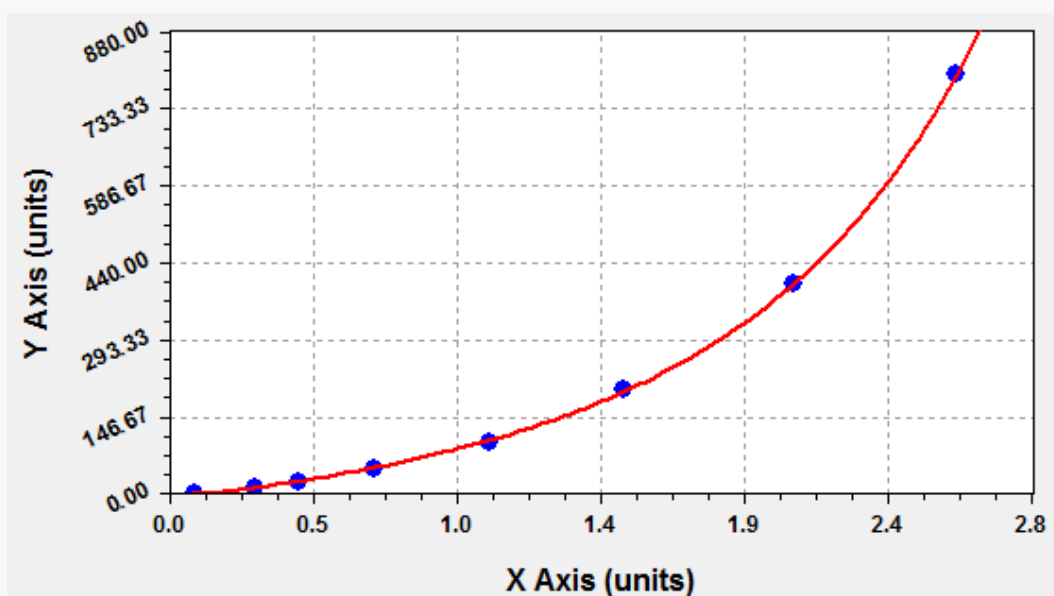
The minimum detectable dose of human ALPP is typically less than 5.1pg/mL.

The sensitivity of this assay, or Lower Limit of Detection (LLD) was defined as the lowest protein concentration that could be differentiated from zero. It was determined by adding two standard deviations to the mean optical density value of twenty zero standard replicates and calculating the corresponding concentration.

Standard curve

The standard curve is provided for demonstrated only. The client should perform the standard test in each independent experiment.

pg/mL	Standard		Average	Corrected
0	0.097	0.089	0.093	---
12.5	0.284	0.297	0.2905	0.1975
25	0.416	0.456	0.436	0.343
50	0.663	0.701	0.682	0.589
100	1.017	1.102	1.0595	0.9665
200	1.494	1.506	1.5	1.407
400	2.003	2.112	2.0575	1.9645
800	2.578	2.607	2.5925	2.4995



Recovery

Matrices listed below were spiked with certain level of recombinant human ALPP and the recovery rates were calculated by comparing the measured value to the expected amount of ALPP in samples.

Matrix	Recovery range (%)	Average(%)
serum(n=5)	98-103%	100%
EDTA plasma(n=5)	79-102%	90%
heparin plasma(n=5)	87-91%	89%

Linearity

The linearity of the kit was assayed by testing samples spiked with appropriate concentration of human ALPP and their serial dilutions. The results were demonstrated by the percentage of calculated

concentration to the expected.

Sample	1: 2	1: 4	1: 8	1: 16
serum(n=5)	79-93%	90-99%	93-103%	83-96%
EDTA plasma(n=5)	84-103%	78-92%	80-98%	85-102%
heparin plasma(n=5)	88-96%	86-94%	83-93%	80-89%

Precision

Intra-assay Precision (Precision within an assay): 3 samples with low, middle and high level human ALPP were tested 20 times on one plate, respectively.

Inter-assay Precision (Precision between assays): 3 samples with low, middle and high level human ALPP were tested on 3 different plates, 8 replicates in each plate.

$CV(\%) = SD/mean \times 100$

	Intra-assay Precision			Inter-assay Precision		
Sample	1	2	3	1	2	3
n	20	20	20	8	8	8
Mean (pg/mL)	218.55	361.81	742.16	98.700	366.34	773.29
SD	15.98	26.41	50.62	5.95	26.16	57.69
CV (%)	7.31	7.30	6.82	6.03	7.14	7.46

Date: 21th Aug 2019