Certification Of Analysis

Product Name：Human Bone alkaline phosphatase (BALP) ELISA Kit

Catalog Number: AAA13282

Species Reactivity: Human (Homo sapiens)

Lot No: L10WBA11 **Mfg:** Oct 11, 2023 **Exp:** Apr 10, 2024

Introduction

Item	Standard		Test Result
Description	For the quantitative detection of Human Bone alkaline phosphatase (BALP) concentration in serum, plasma and other biological fluids.		Conform
Identification	Sandwich		Positive
Composition	Assay plate (96 Wells) Standard (lyophilized) Sample Diluent Biotin-Conjugate (concentrate 100 x) Biotin-Conjugate Diluent Streptavidin-HRP (concentrate 100 x) Streptavidin-HRP Diluent Substrate Solution Stop Solution Wash Buffer (concentrate 25 x) Adhesive Films Instruction manual	1 2 1 × 20 mL 1 × 120 µL 1 × 20 mL 1 × 120 µL 1 × 20 mL 1 × 12 mL 1 × 10 mL 1 × 20 mL 4 1	Conform
Assay Range	0.156 - 10 ng/mL		Conform

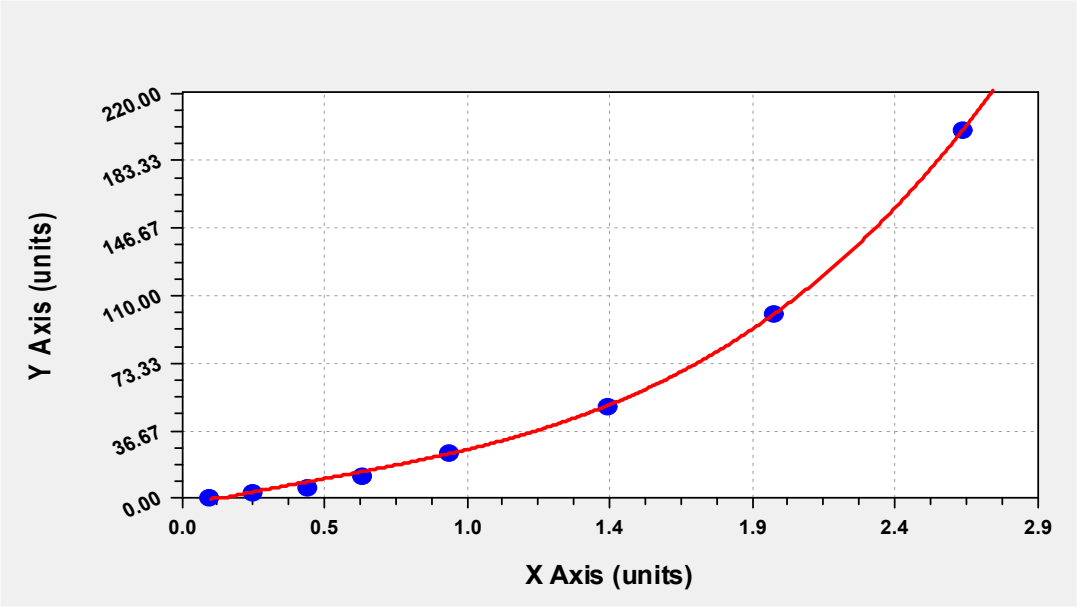
Sensitivity

The limit of detection of Human BALP defined as the analyte concentration resulting in an absorbance significantly higher than that of the dilution medium (mean plus 2 standard deviations) was determined to be 0.1 ng/mL (mean of 6 independent assays).

Typical data

For convenience in result calculation, absorbance as abscissa and standard concentrations can be used as ordinate. The standard curve provided in the manual is only for reference, experimenters should draw the standard curve based on data of themselves.

ng/mL	Standard		Average
200	2.618	2.630	2.624
100	1.983	2.001	1.992
50	1.451	1.427	1.439
25	0.886	0.928	0.907
12.5	0.605	0.629	0.617
6.25	0.427	0.435	0.431
3.12	0.241	0.259	0.250
0	0.111	0.087	0.099



3rd degree Polynomial Fit: y=a+bx+cx^2+dx^3...

Coefficient Data:

a = -4.87402554483E+000

b = 3.77957069312E+001

c = -1.72913623912E+001

d = 1.24347612754E+001

Recovery

The recovery of Human BALP spiked to levels throughout the range of the assay was evaluated.

Sample Type	Number	Recovery range (%)	Average(%)
Human serum	10	91-98	95
Human plasma	10	89-97	93

Linearity

To assess the linearity of the assay, samples containing high concentrations of Human BALP were serially diluted with Sample Diluent to produce samples with values within the dynamic range of the assay.

Sample Type	1：2	1：4	1：8	1：16
Human serum	90-96%	89-94%	92-99%	94-101%
Human plasma	89-96%	90-95%	92-98%	92-99%

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 forty separate assays to assess inter-assay precision.
CV (%) = SD/meanX100

	Intra-assay Precision			Inter-assay Precision		
Sample	1	2	3	1	2	3
n	20	20	20	20	20	20
Mean (ng/mL)	0.344	0.605	0.927	0.275	0.663	1.194
SD	0.023	0.044	0.070	0.020	0.050	0.101
CV (%)	6.7	7.3	7.6	7.3	7.5	8.5

Date: *2023.10.11*