

Certificate of Analysis

Product Name: ELISA Kit for Alanine Aminotransferase (ALT)

Cat.No. OKCD06132 Organism: Homo sapiens (Human)

Lot.No. L230817185

Introduction

Item	Standard		Test Result
Description	This immunoassay kit allows for the specific measurement of ALT concentration in human serum, plasma, tissue homogenates, cell lysates, cell culture supernates and other biological fluids.		Conform
Identification	Colorimetric		Positive
Composition	Pre-coated, ready to use 96-well strip plate	1	Conform
	Standard	2	
	Standard Diluent	1 × 20ml	
	Biotinylated ALT Detector Antibody	1 × 120µl	
	Avidin-HRP Conjugate	1 × 120µl	
	Detector Antibody Diluent	1 × 12ml	
	Conjugate Diluent	1 × 12ml	
	TMB Substrate	1 × 9ml	
	Stop Solution	1 × 6ml	
	Wash Buffer(30 x concentrate)	1 × 20ml	
	Plate sealer for 96 wells	4	
	Instruction manual	1	
Assay Range	1.56-100ng/mL		Conform

Sensitivity

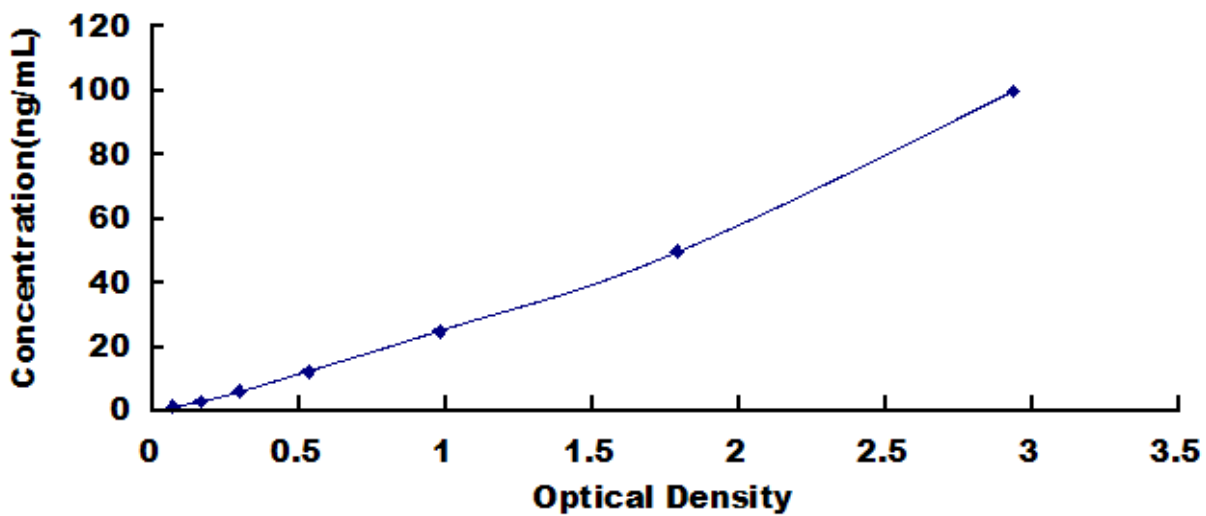
The minimum detectable dose of human ALT is typically less than 0.61ng/mL.

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 the mean O.D. Value of 20 replicates of the zero standard added by their three standard deviations.

Standard curve

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

ng/ml	Standard		Average	Corrected
0	0.041	0.053	0.047	—
1.56	0.105	0.121	0.113	0.066
3.12	0.241	0.189	0.215	0.168
6.25	0.368	0.318	0.343	0.296
12.5	0.597	0.561	0.579	0.532
25	0.998	1.058	1.028	0.981
50	1.956	1.722	1.839	1.792
100	2.903	3.083	2.993	2.946



Recovery

Different matrices were spiked with certain level of recombinant human ALT and the recovery rates were evaluated.

Matrix	Recovery range (%)	Average(%)
serum(n=5)	87-98	93
EDTA plasma(n=5)	85-99	90
heparin plasma(n=5)	90-101	96

Linearity

The linearity of the kit was assayed by testing samples spiked with high concentration of recombinant human ALT and also several dilutions of these samples. 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)	93-107%	89-103%	78-97%	83-93%
EDTA plasma(n=5)	85-99%	90-101%	86-103%	88-98%
heparin plasma(n=5)	85-102%	78-95%	85-93%	97-109%

Precision

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

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

Sample	Intra-assay Precision			Inter-assay Precision		
	1	2	3	1	2	3
n	20	20	20	24	24	24
Mean (ng/ml)	4.08	13.25	48.47	4.11	14.17	51.36
SD	0.253	0.716	2.181	0.267	0.808	2.363
CV (%)	6.2	5.4	4.5	6.5	5.7	4.6