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Certificate of Analysis

Product Name: ELISA Kit for Ovalbumin (OVA)

Cat.No.: AAA20053 Organism: Pan-species (General)

Lot.No. L240916286

Introduction

Item	Standard	Test Result	
Description	This immunoassay kit allows for the specific mea		
	ovalbumin concentration in serum, plasma, tissue home	Conform	
	lysates, cell culture supernates and other biological fluids.		
Identification	Colorimetric	Positive	
Composition	Pre-coated, ready to use 96-well strip plate	1	
	Standard	2	
	Standard Diluent	1 × 20ml	
	Detection Reagent A (green)	1	
	Reagent Diluent	$1 \times 300 \mu l$	
	Detection Reagent B (red)	$1 \times 120 \mu l$	
	Assay Diluent A	1 × 12ml	Conform
	Assay Diluent B	1 × 12ml	
	TMB Substrate	1 × 9m1	
	Stop Solution	1 × 6ml	
	Wash Buffer(30 x concentrate)	1 × 20ml	
	Plate sealer for 96 wells	4	
	Instruction manual	1	
Assay Range	16-10,000pg/mL		Conform

Sensitivity

The minimum detectable dose of ovalbumin is typically less than 6pg/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.

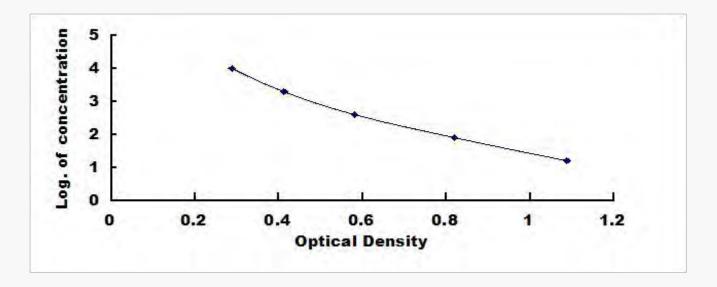
Standard curve

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

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na/m1	Standard		A varaga	Log of	
pg/ml	Stan	daru	Average	concentration	
16	1.098	1.083	1.091	1.204	
80	0.835	0.807	0.821	1.903	
400	0.587	0.578	0.583	2.602	
2000	0.413	0.416	0.415	3.301	
10000	0.298	0.274	0.286	4.000	



Recovery

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

Matrix	Recovery range (%)	Average(%)	
serum(n=5)	91-104	98	
EDTA plasma(n=5)	84-95	90	
heparin plasma(n=5)	86-99	92	

Linearity

The linearity of the kit was assayed by testing samples spiked with high concentration of recombinant ovalbumin 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)	81-94%	92-106% 84-99%		83-97%	
EDTA plasma(n=5)	82-101%	79-90%	86-103%	80-93%	
heparin plasma(n=5)	94-105%	85-97%	78-95%	87-102%	

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Precision

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

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

	Intra-assay Precision			Inter-assay Precision		
Sample	1	2	3	1	2	3
n	20	20	20	24	24	24
Mean (pg/ml)	81.14	402.98	2120.36	83.06	406.55	2126.95
SD	3.599	20.641	138.693	3.876	22.539	145.547
CV (%)	4.4	5.1	6.5	4.7	5.5	6.8

Date: <u>2024.09.23</u>