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Certification Of Analysis

Product Name: Pig Hyaluronic acid (HA) ELISA Kit

Catalog Number: 'AAA13239

Species Reactivity: Pig (Sus scrofa; Porcine)

Lot No: L05WHA29 Mfg: May 29, 2023 Exp: Nov 28, 2023

Introduction

Item	Standard	Test Result	
Description	For the quantitative detection of Pig Hyaluronic	acid (HA)	Conform
	concentration in serum, plasma and other biological fluids.		
Identification	Sandwich		Positive
Composition	Assay plate (96 Wells)	1	
	Standard (lyophilized)	2	
	Sample Diluent	1 × 20 mL	
	Biotin-Conjugate (concentrate 100 x)		
	Biotin-Conjugate Diluent		
	Streptavidin-HRP (concentrate 100 x)	Conform	
	Streptavidin-HRP Diluent		
	Substrate Solution		
	Stop Solution		
	Wash Buffer (concentrate 25 x)	1 × 20 mL	
	Adhesive Films	4	
	Instruction manual		
Assay Range	7.8-500 ng/mL		Conform

Sensitivity

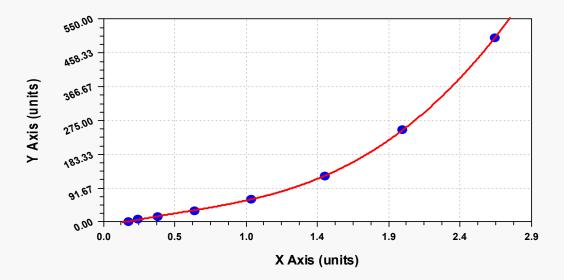
The limit of detection of Pig HA defined as the analyte concentration resulting in an absorbance significantly higher than that of the dilution medium (mean plus 2 standard deviations) was determined to be 3.9 ng/mL (mean of 6 independent assays).

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.

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ng/mL	Standard		Average	
500	2.623	2.605	2.614	
250	1.994	2.012	2.003	
125	1.493	1.481	1.487	
62.5	0.990	1.002	0.996	
31.25	0.622	0.628	0.625	
15.6	0.386	0.372	0.379	
7.8	0.252	0.242	0.247	
0	0.173	0.199	0.186	



4th Degree Polynomial Fit: $y=a+bx+cx^2+dx^3...$

Coefficient Data:

a = -1.66266077766E+001

b = 1.08539160444E+002

c = -8.06586625621E+001

d = 5.44453702622E+001

e = -4.03502210428E+000

Recovery

The recovery of Pig HA spiked to levels throughout the range of the assay was evaluated.

Sample Type	Number	Recovery range (%)	Average(%)	
Human serum	10	91-99	95	
Human EDTA plasma	10	89-101	95	

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Linearity

To assess the linearity of the assay, samples containing high concentrations of Pig HA were serially diluted with Calibrator 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	91-102%	89-100%	91-97%	92-101%
Human EDTA plasma	88-96%	92-99%	91-101%	90-103%

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)	0.398	0.799	1.016	0.425	0.864	1.148
SD	0.027	0.058	0.078	0.031	0.069	0.101
CV (%)	6.8	7.3	7.7	7.3	8.0	8.8

Approved Date: 2023.05.29