

## CERTIFICATE OF ANALYSIS

### Human PSA-total ELISA Kit

**Product Number:** OKRC00835

**Lot Number:** KH0736

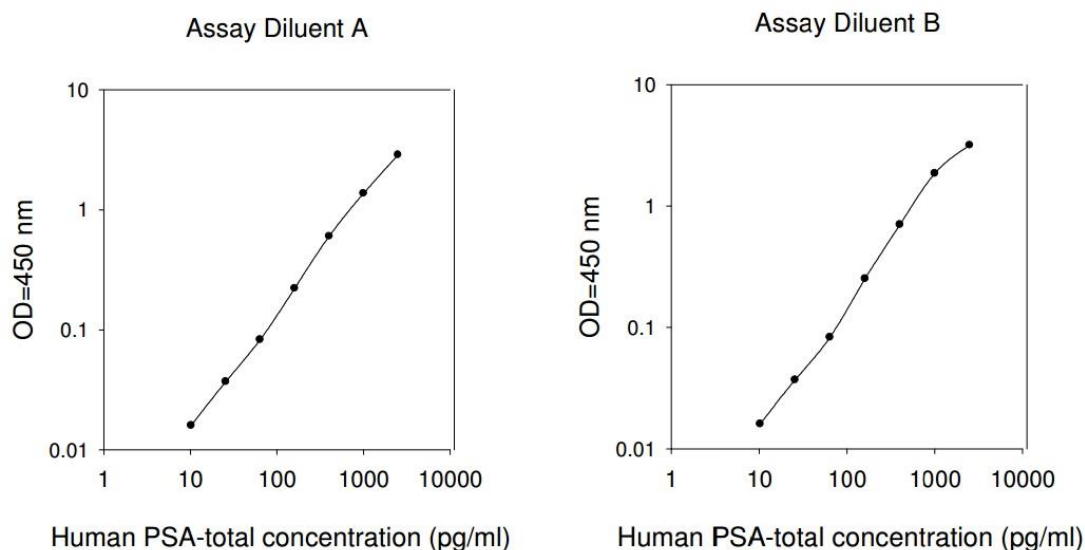
**Maximum Expiration Date:** 10/24/2024

Component	Quantity Per Kit	Description	Lot Number	Expiration Date
	1	Human PSA-total Precoated 96-well Strip Microplate	See label	10/24/2024
	2	Human PSA-total Lyophilized Protein Standard	See bottle label	10/24/2024
	2	Human PSA-total Biotinylated Antibody	See label	10/24/2024
	200uL	HRP-Streptavidin Concentrate	See bottle label	10/24/2024
	25mL	20X Wash Buffer	See bottle label	10/24/2024
	12mL	TMB Substrate Solution	See bottle label	10/24/2024
	8mL	Stop Solution	See bottle label	10/24/2024
	30 ml	Assay Diluent A	See bottle label	10/24/2024
	15 ml	Assay Diluent B	See bottle label	10/24/2024

**Storage:** May be stored for up to 6 months at 2° to 8°C from the date of shipment. Opened microplate wells or reagents may be store for up to 1 month at 2° to 8°C. Return unused wells to the pouch containing desiccant pack, reseal along entire edge. Reconstituted standard can be stored at -80°C for up to 1 week. **Note:** the kit can be used within one year if the whole kit is stored at -20°C. Avoid repeated freeze/thaw cycles.

## A. STANDARD CURVE

These standard curves are from quality control testing and are for demonstration only. A standard curve must be run with each assay.



## B. SENSITIVITY

The minimum detectable dose of Human PSA-total was determined to be 8 pg/ml.

Minimum detectable dose is defined as the analyte concentration resulting in an absorbance that is 2 standard deviations higher than that of the blank (diluent buffer).

## C. SPIKING & RECOVERY

Recovery was determined by spiking various levels of Human PSA-total into the sample types listed below. Mean recoveries are as follows:

Sample Type	Average % Recovery	Range (%)
Serum	105.4	94-112
Plasma	80.63	72-94
Cell culture media	95.25	81-108

**D. LINEARITY**

Sample Type		Serum	Plasma	Cell Culture Media
1:2	Average % of Expected	112.5	107.3	84.77
	Range (%)	103-120	100-115	76-92
1:4	Average % of Expected	87.91	97.14	72.89
	Range (%)	77-95	79-107	67-78

**E. REPRODUCIBILITY**

Intra-Assay CV%: <10%

Inter-Assay CV%: <12%

**IX. SPECIFICITY**

This ELISA kit shows no cross-reactivity with the following cytokines tested: human Angiogenin, BDNF, BLC, CNTF, ENA- 78, FGF-4, IL-1 alpha, IL-1 beta, IL-2, IL-3, IL-4, IL-5, IL-6, IL-7, IL-8, IL-9, IL-11, IL-12 p70, IL-12 p40, IL-13, IL-15, I-309, IP-10, FGF-4, FGF-6, FGF- 7, G-CSF, GDNF, GM-CSF, IFN-gamma, IGFBP-2, IGFBP-3, IGFBP-4, Leptin (OB), MCP-1, MCP-2, MCP-3, MDC, MIF, MIG, MIP-1 alpha, MIP-1 beta, MIP-1 delta, PARC, PDGF, RANTES, SCF, SDF-1 alpha, TARC, TGF-beta, TIMP-1, TIMP-2, TNF-alpha, TNF-beta, TPO, VEGF.

The methods and controls used in this facility for manufacturing, processing, packaging, and holding of products are in accordance with ISO 13485: 2003 Quality Management System.

This product has been fully tested and is deemed functional by Quality Control.

**Date:** 10/24/2023