

## CERTIFICATE OF ANALYSIS

Cat No: KBI1676

Product: KRIBIOLISA™ Teplizumab ELISA

Lot No: TEP0525

Mfg. Date: 17<sup>th</sup> May 2025

Exp. Date: 30<sup>th</sup> April 2026

### Physical Parameters:

Kit Component	Visual Check	Volume Label Claim	Actual Fill Volume Claim	Remarks
Coated Plate	Polybag Seal Ok	12 x 8 wells	12 x 8 wells	Pass
Standard	Seal Crimping Ok	2 vials (lyophilized)	2 vials (lyophilized)	Pass
Anti-Human IgG kappa:HRP Conjugate	Clear Solution, Seal Ok	12 ml	13 ml	Pass
Standard Diluent	Clear Solution, Seal Ok	10 ml	12 ml	Pass
Sample Diluent	Clear Solution, Seal Ok	2 x 50 ml	2 x 52 ml	Pass
(20X) Wash Buffer	Clear Solution, Seal Ok	25 ml	27 ml	Pass
TMB Substrate	Seal Ok	12 ml	13 ml	Pass
Stop Solution	Clear Solution, Seal Ok	12 ml	13 ml	Pass
Plate Sealers	Ok	2	2	Pass
IFU manual	Ok	1	1	Pass

### Assay Parameters:

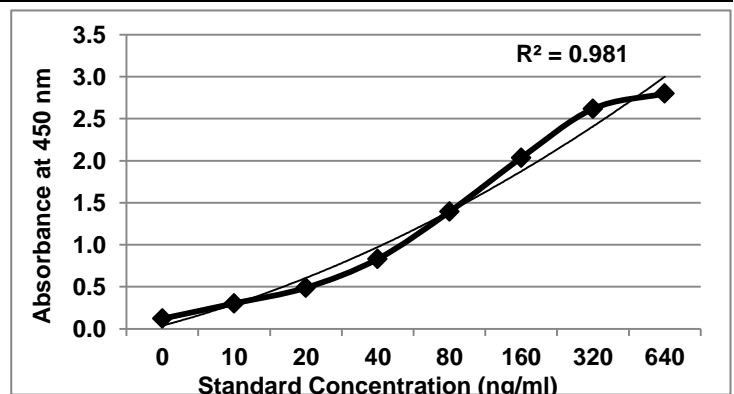
Standard Concentration (ng/ml)	Mean Absorbance	Interpolated Concentration	% Interpolated Concentration against Actual Concentration
0	0.120	--	--
10	0.302	11.0	109.9
20	0.488	21.0	105.1
40	0.831	39.8	99.6
80	1.393	78.6	98.2
160	2.035	156.3	97.7
320	2.617	361.0	112.8
640	2.800	565.8	88.4

Note-

\* Abs = Absorbance at 450 nm.

The controls are run in in-house buffers.

Absorbance Results are read on ELISA plate reader  
And interpreted using GraphPad  
Prism® ver8.0



**The Lot is Passed.**

*Dr. Prairna Balyan*

17-05-2025

Quality Control

Dated

