

CERTIFICATE OF ANALYSIS

Cat No: KBI2086

Product: KRIBIOLISA® Anti-Pertuzumab (PERJETA™) ELISA

Lot No: APER0925

Mfg. Date: 06th September 2025

Exp. Date: 31st August 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
HRP Conjugate concentrated	Seal Ok	2 x 10 ul	2 x 12 ul	Pass
Detection Diluent	Clear Solution, Seal Ok	12 ml	13 ml	Pass
(1X) Standard Diluent	Clear Solution, Seal Ok	10 ml	12 ml	Pass
(1X) Sample Diluent	Clear Solution, Seal Ok	50 ml	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

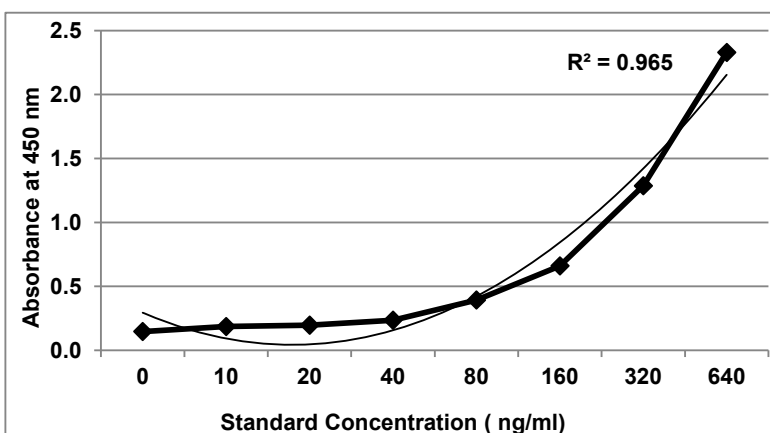
Assay Parameters:

Standard Concentration (ng/ml)	Mean Absorbance	Interpolated Concentration	% Interpolated Concentration against Actual Concentration
0	0.146	--	--
10	0.186	11.4	114.0
20	0.197	21.1	105.3
40	0.236	35.8	89.5
80	0.392	84.5	105.6
160	0.659	156.9	98.1
320	1.287	321.2	100.4
640	2.329	639.8	100.0

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. Sneha Hande

06-09-2025



Quality Control

Dated

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REAGENT PREPARATION SHEET

Cat No: KBI2086

Product: KRIBIOLISA® Anti-Pertuzumab (PERJETA™) ELISA

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Reagent Preparation

Working Pertuzumab:HRP Conjugate Preparation:

1. Remove the Pertuzumab:HRP Conjugate concentrated available in the kit.
2. To use in the experiment, it is recommended to do a two-step (2-step) dilution, prior to running the assay to avoid dilution error. Always prepare Pertuzumab: HRP Conjugate to be used in the assay fresh. Discard the unused reagents and do not store this diluted Pertuzumab:HRP Conjugate

NOTE THIS DILUTION FACTOR PROVIDED IS LOT SPECIFIC AND WILL VARY FROM LOT TO LOT.
Estimate the amount of diluted Pertuzumab:HRP Conjugate Working Solution (ready to use) required by calculating the number of wells into the volume required per well.

3. In the 1st-Step dilution, Dilute 1 ul of the Pertuzumab:HRP Conjugate concentrated provided in the kit with 54ul of the Detection Diluent provided in the kit into a fresh tube.
4. In the 2nd-Step dilution, to prepare the Pertuzumab:HRP Conjugate Working Solution for use in the assay, dilute the 1st-Step solution at 1:100 using Detection diluent.

Procedure Step No	Particulars	Pertuzumab: HRP Conjugate concentrated	Diluted Stock from 1st Step	Detection diluent	Total Volume	No of Wells to be Used
1 st Step	Pertuzumab:HRP Conjugate concentrated	1 ul		54 ul	55 ul	
2 nd Step	Pertuzumab:HRP Conjugate working solution		1 ul	99 ul	100 ul	
	for example; from step 2 above, pipette ...		10 ul	990 ul	1000 ul	8 wells
			20 ul	1980 ul	2000 ul	16 wells

