

Trastuzumab - (Herceptin®) – PK ELISA

Cat# SB-07-035

For the quantitative determination of trastuzumab in human serum and plasma.

Description	Sandwich enzyme immunoassay.
Detection Method	Colourmetric
Storage	Kit ships at 2 to 8°C. Multiple storage temperatures upon arrival.
Calibrator	Herceptin®
Assay Range	2000 to 62.5 ng/mL
Sensitivity	62.5 ng/mL.
Precision	Intra-assay precision ranges from 4 to 11%. Inter-assay mean precision is 13%. Determined by analysis of samples at 62.5 ng/mL in 6 replicates, on 6 different occasions.
Accuracy	Determined by analyzing three levels of quality control samples in 6 replicates on 6 different occasions. The Mean %bias is $\leq 20\%$.
Total Error	Calculated by adding the mean %bias with inter-assay variability (%CV). The Total Error is $\leq 20\%$
Interpretation of Results	A calibration curve is constructed by plotting the absorbance values on a 4-point parameter fit curve. Concentration of trastuzumab in test samples is interpolated from the calibration curve.
Safety Warnings and Precautions	All reagents and samples should be handled as if potentially hazardous and infectious. It is recommended that all kit reagents are handled by trained laboratory staff and are used in accordance with GLP.