

Trastuzumab (Herceptin®) – ADA ELISA

Cat# SB-06-035

For the qualitative determination of antibodies to 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.
Positive Control	Mouse anti-Trastuzumab
Sensitivity	100 ng/mL
Drug Tolerance	TBD
Sample Pre-Treatment	Drug tolerance can be improved with acid dissociation. For further details please contact tec@somrubioscience.com
Precision	Intra-assay precision ranges from 3 to 7% . Inter-assay mean precision is 12% . Determined by analysis of samples at 100 ng/mL in 6 replicates, on 6 different occasions.
Interpretation of Results	Results are reported as positive or negative relative to a pre-determined cutpoint. To determine the cutpoint, run 4-10 negative controls and calculate their mean, then add 2* standard deviations to the calculated mean.
Statistical CutPoint	We strongly recommend each lab develop their own statistical cutpoint in the appropriate study population using methodologies as described by G. Shankar, et al. (2008). (Recommendations for the Validation of Immunoassays Used for Detection of Host Antibodies Against Biotechnology Products. J. Pharmaceutical and Biomedical Analysis 48:1267–1281). For further details please contact tec@somrubioscience.com .
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.