Datasheet for ABIN4886400

Trastuzumab Antibody ELISA Kit

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Overview

Quantity:	96 tests
Target:	Trastuzumab Antibody
Reactivity:	Human, Mouse, Rat
Method Type:	Bridging ELISA
Detection Range:	31.25-125 ng/mL
Minimum Detection Limit:	31.25 ng/mL
Application:	ELISA

Product Details

Purpose:	Quantification of antibodies to Trastuzumab
Sample Type:	Plasma, Serum
Analytical Method:	Quantitative
Detection Method:	Colorimetric
Specificity:	Anti-Trastuzumab antibodies
Characteristics:	This immunogenicity assay employs the bridging ELISA technique.
Components:	Coated microtiter plate, 96 wells QC samples - 4x50ul 10X wash buffer - 25ml Assay buffer - 50ml 1000X secondary antibody - 17ul 1000X detection reagent - 17ul

Product Details

	TMB - 12ml TMB stop solution - 12ml Plate sealers - 3
Material not included:	Precision pipettes calibrated to deliver 5-1000µL Multi-channel pipette calibrated to deliver 50-200µL Plate shaker Disposable tips Vortex-Mixer Distilled or de-ionized water Microplate reader capable of reading 450nm with background subtrac

Target Details

Target:	Trastuzumab Antibody
Abstract:	Trastuzumab Antibody Products
Target Type:	Antibody
Background:	Trastuzumab (Herceptin®) is a humanized recombinant monoclonal antibody used for the treatment of primary breast cancers overexpressing human epidermal growth factor 2 (HER2). HER2 protein is overexpressed in 25-30 % of breast cancers.
Gene ID:	2064

Application Details

Application Notes:	Optimal working dilution should be determined by the investigator.
Sample Volume:	15 µL
Assay Time:	3.5 h
Plate:	Pre-coated
Protocol:	The Trastuzumab immunogenicity assay employs the bridging ELISA technique. A precoated 96 well capture antibody plate is provided. Quality control and test samples are pipetted into the appropriate wells. Anti-Trastuzumab present in biological matrices binds the immobilized capture antibody. After washing away any unbound substances, secondary antibody is added to the wells and after a final wash a detection reagent is added. The plate is washed to remove any unbound antibody-enzyme reagent and a substrate solution is added to the wells for color development. The color development is proportional to the amount of anti-Trastuzumab

	present in test samples. Four levels of QC samples give a qualitative reference signal which can be used to determine the level (High, Medium, Low, Negative) of anti-Trastuzumab antibody in the unknown samples.
Reagent Preparation:	Prepare only the appropriate amount of required reagent on the day of use. Store all reagents as per instructions stated on the label. 1. Wash Buffer (1X) Preparation: Dilute wash buffer concentrate with ultra-pure water 1/10 before use (for example add 2 mL concentrate to 18 mL ultra-pure water). Mix well. 2. Secondary antibody (1X) Preparation: Dilute secondary antibody with assay buffer 1/1000 before use (for examples add 12 µL concentrate to 12 mL of assay buffer). Mix well. 3. Detection Reagent (1X) Preparation: Dilute detection reagent with assay buffer 1/1000 before use (for example add 12 µL concentrate to 12 mL of assay buffer). Mix well.
Sample Collection:	This kit is compatible with EDTA-plasma, heparinplasma and serum samples. Samples can be stored at or below -20 °C for up to 1 year.
Sample Preparation:	Dilute QC samples and test samples 1/10 with assay buffer (for example add 30µL of prepared calibrator or sample to 270µL of assay buffer). Mix well. Do not store diluted samples. If test samples are out of range, then they may be further diluted.
Assay Procedure:	This immunogenicity assay employs the bridging ELISA technique. Capture antibody is precoated onto a 96 well microplate. Quality control and test samples are pipetted into the appropriate wells. AntiTrastuzumab present in biological matrices is bound by the immobilized capture antibody. After washing away any unbound substances, secondary antibody is added to the wells and after a final wash a detection reagent is added. The plate is washed to remove any unbound antibody-enzyme reagent and a substrate solution is added to the wells for color development. The color development is proportional to the amount of anti-Trastuzumab present in test samples. Three levels of QC samples give a qualitative reference signal which can be used to determine the level of anti-Trastuzumab antibody in the unknown samples. The color development is stopped and the intensity of the color is measured.
Calculation of Results:	1. Because anti-drug antibodies will vary in terms of affinity and concentration, this assay provides a qualitative readout. As such the user should use the comparable positive controls when comparing interassay results. The provided controls are tested for comparability between lots and can be traced. 2. The anti-drug antibody titers in the test samples will fall in the range of high, medium, low or negative. We recommend each lab develop their own statistical cutpoint 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). 3. Any sample undiluted

Application Details

	or diluted still reading greater than the highest standard should be diluted appropriately with assay buffer and retested. If the samples have been diluted, the concentration determined from the standard curve must be multiplied by the dilution factor.
Assay Precision:	Intra-assay precision: < 10% Inter-assay precision: < 10%
Restrictions:	For Research Use only

Handling

Preservative:	Without preservative
Precaution of Use:	Read manual completely before beginning
Storage:	-20 °C
Storage Comment:	Store kit components at -20°C unless specified otherwise. DO NOT USE past kit expiration date. Some vials contain a small amount of reagents. Spin tubes on pulse setting prior to opening.
Expiry Date:	12 months