Datasheet for ABIN2862662

Trastuzumab Antibody ELISA Kit

3 Images

Go to Product page

Overview

Quantity:	96 tests
Target:	Trastuzumab Antibody
Binding Specificity:	Free Chain
Reactivity:	Human, Chemical
Method Type:	Sandwich ELISA
Application:	ELISA

Product Details

Purpose:	Enzyme immunoassay for the semi-quantitative determination of free antibodies to Trastuzumab in human serum and plasma samples.
Brand:	ImmunoGuide®
Sample Type:	Serum, Plasma (EDTA - heparin)
Analytical Method:	Semi-Quantitative
Detection Method:	Colorimetric
Specificity:	Free antibodies against Trastuzumab (Herceptin®) Screening test was performed with 80 different native and RF-negative human sera. All produced OD450nm values (ranged from 0.051 to 0.094) less than the cut-off value (3x0.068).
Sensitivity:	10 ng/mL
Characteristics:	This test does not measure the antibodies if they already are bound to the drug Trastuzumab
Components:	• 1 x 12 x 8 Microtiter Plate Break apart strips pre-coated with the drug Trastuzumab.

Product Details

	• 1 x 2 mL Positive Control Ready to use. Contains reactive antibody, proteins, stabilizer and <15 mM NaN3. • 1 x 2 mL Negative Control Ready to use. Contains human serum, stabilizer and <15 mM NaN3. • 1 x 60 mL Assay Buffer Blue colored. Ready to use. Contains proteins and <15 mM NaN3. • 1 x 12 mL Enzyme Conjugate Red colored. Ready to use. Contains horseradish peroxidase(HRP)-conjugated Trastuzumab, Proclin® and stabilizers. • 1 x 12 mL TMB Substrate Solution Ready to use. Contains 3,3',5,5'-Tetramethylbenzidine (TMB). • 1 x 12 mL Stop Solution Ready to use. 1 N Hydrochloric acid (HCl). • 1 x 50 mL Wash Buffer, Concentrate (20x) Contains buffer, Tween® 20 and KathonTM. • 2 x 1 Adhesive Seal For sealing microtiter plate during incubation.
Material not included:	• Micropipettes (< 3 % CV) and tips to deliver 5-1000 µL. • Bidistilled or deionised water and calibrated glasswares (e.g. flasks or cylinders). • Wash bottle, automated or semi-automated microtiter plate washing system. • Microtiter plate reader capable of reading absorbance at 450 nm (reference wavelength at 600-650 nm is optional). • Absorbent paper towels, standard laboratory glass or plastic vials, and a timer.

Target Details

Target:	Trastuzumab Antibody
Abstract:	Trastuzumab Antibody Products
Target Type:	Antibody
Background:	Trastuzumab is a recombinant DNA-derived humanized monoclonal antibody that selectively targets the extracellular domain of the human epidermal growth factor receptor 2 protein (HER2). The antibody is an IgG1 kappa that contains human framework regions with the complementarity-determining regions of a murine anti- p185 HER2 antibody that binds to HER2. Accoring to the prescribing information, the use of Trastuzumab might be associated to the development of anti-Trastuzumab antibodies in various percentages of patients during therapy with the drug. The Antibody to Trastuzumab ELISA Kit can be efficiently used for monitoring Anti- Trastuzumab antibodies during therapy and offers the clinician a tool for decision on possible preventive measures.
Molecular Weight:	144 kDa

Application Details

Application Notes:	• Before performing the assay, samples and assay kit should be brought to room temperature (about 30 minutes beforehand) and ensure the homogeneity of the solution. • All Standards should be run with each series of unknown samples. • Standards should be subject to the same manipulations and incubation times as the samples being tested. • All steps of the test should be completed without interruption. • Use new disposable plastic pipette tips for each reagent, standard or specimen in order to avoid cross contamination.
Comment:	Antibody to Trastuzumab ELISA is suitable also for using by an automated ELISA processor.
Sample Volume:	5 µL
Assay Time:	2.5 h
Plate:	Pre-coated
Protocol:	The Antibody to Trastuzumab ELISA is a sandwich type ELISA for the determination of free antibodies against Trastuzumab in serum and plasma samples. During the first incubation period, the drug Trastuzumab, coated on the wall of the microtiter wells, captures the antibodies to Trastuzumab in patient serum and plasma samples. After washing away the unbound components from samples, a Peroxidase-labelled Trastuzumab conjugate is added to each well and then incubated. Antibody to Trastuzumab, if present in sample, will make a bridge, with its two identical Fab arms, between the Trastuzumab coated on the well and the other Trastuzumab labeled with peroxidase. After a second washing step, the bound enzymatic activity is detected by addition of tetramethylbenzidine (TMB) chromogen-substrate. Finally, the reaction is terminated with an acidic stop solution. The intensity of the reaction color is related to the presence and quantity of antibodies to Trastuzumab in the sample.
Reagent Preparation:	Wash Buffer: Dilute 10 mL Wash Buffer (up to 200 mL) at the ratio of 1:20 with distilled water. Warm up at 37 °C to dissolve crystals. Mix vigorously. Store at 2-8 °C for up to 4 weeks. Prepare Wash Buffer before starting the assay procedure.
Sample Collection:	Normal serum or plasma collection
Sample Preparation:	Serum/ Plasma: Dilute Serum/ Plasma (Sample) at the ratio of 1:101 with Assay Buffer. For dilution at 1:101, 5 µL Sample + 500 µL Assay Buffer Negative and Positive Controls are ready-to-use and should NOT be diluted with the assay buffer. Serum, Plasma (EDTA, Heparin): The usual precautions for venipuncture should be observed. It

	is important to preserve the chemical integrity of a blood specimen from the moment it is collected until it is assayed. Do not use grossly hemolytic, icteric or grossly lipemic specimens. Samples appearing turbid should be centrifuged before testing to remove any particulate material. Storage: 2-8 °C &leq,-20 °C (Aliquots) Keep away from heat or direct sun light. Avoid repeated freeze-thaw cycles. Stability: 3 days at 2-8 °C, 6 months at -20 °C
Assay Procedure:	1. Pipette 100 µL of each Ready-to Use Negative Control, Positive Control, and 1:101 Diluted Samples (as described in section 10.2) into the respective wells of microtiter plate. Wells A1: Negative Control B1: Negative Control C1: Positive Control D1 and so on: Diluted samples (Serum/Plasma) 2. Cover the plate with adhesive seal. Shake plate carefully. Incubate 60 min at room temperature (RT) (18-25 °C). 3. Remove adhesive seal. Aspirate or decant the incubation solution. Wash the plate 3 X 300 µL of Diluted Wash Buffer per well. Remove excess solution by tapping the inverted plate on a paper towel. 4. Pipette 100 µL of Enzyme Conjugate (HRP-Trastuzumab) into each well. 5. Cover plate with adhesive seal. Shake plate carefully. Incubate 60 min at RT. 6. Remove adhesive seal. Aspirate or decant the incubation solution. Wash the plate 3 X 300 µL of Diluted Wash Buffer per well. Remove excess solution by tapping the inverted plate on a paper towel. 7. Pipette 100 µL of Ready-to-Use TMB Substrate Solution into each well. 8. Incubate 20 min at RT. Avoid exposure to direct sunlight. 9. Stop the substrate reaction by adding 100 µL of Stop Solution into each well. Briefly mix contents by gently shaking the plate. Color changes from blue to yellow. 10. Measure optical density (OD) with a photometer at 450 nm (Reference at OD620nm is optional) within 15 min after pipetting the Stop Solution.
Calculation of Results:	For the run to be valid, the OD450 nm of the Positive Control should be ≥ 1.000 and the OD450 nm of each Negative Control should be ≤0.150. If not, improper technique or reagent deterioration may be suspected and the run should be repeated. The results are evaluated by dividing all individual results by the mean OD450nm of the Negative Controls. The results are expressed in arbitrary units (AU/mL). Range: > 3 AU/mL (Positive) Range: &leq, 3 AU/mL (Negative)

Application Details

	The results themselves should not be the only reason for any therapeutical consequences. They have to be correlated to other clinical observations. Sample calculation for a positive sample: OD of sample = 0.740 Cut-off = 3 x Average OD of Negative Controls = 3 x 0.100 = 0.300 = 3 AU/mL Concentration of sample = 0.740/0.100 = 7.4 AU/mL (positive)
Assay Precision:	Intra-assay CV: <10%. Inter-assay CV: <10%
Restrictions:	For Research Use only

Handling

Buffer:	< 15mM NaN3
Preservative:	Sodium azide
Precaution of Use:	This product contains Sodium azide: a POISONOUS AND HAZARDOUS SUBSTANCE which should be handled by trained staff only.
Storage:	4 °C
Storage Comment:	The kit is shipped at ambient temperature and should be stored at 2-8°C. Keep away from heat or direct sun light. The storage and stability of specimen and prepared reagents is stated in the corresponding chapters. The microtiter strips are stable up to the expiry date of the kit in the broken, but tightly closed bag when stored at 2-8°C.
Expiry Date:	24 months

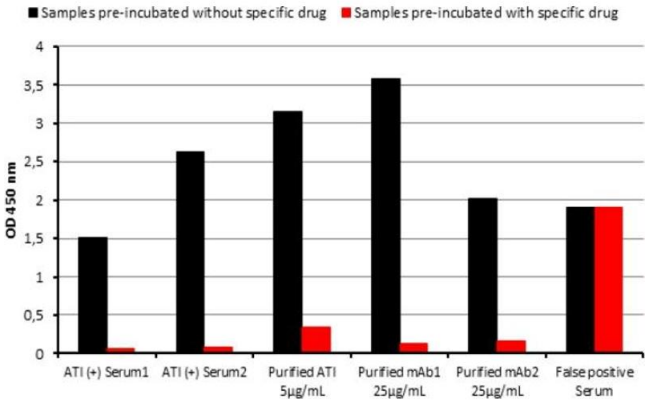

Image 1.

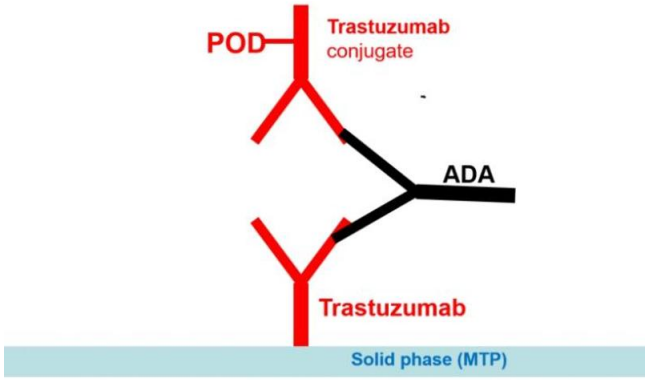

Image 2.

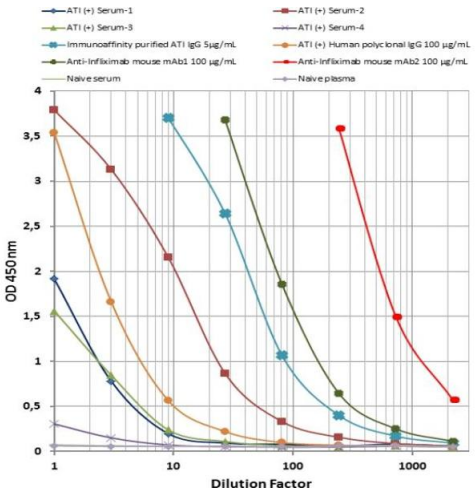

Image 3.