Datasheet for ABIN5519325

Vedolizumab Antibody ELISA Kit

3 Images

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Overview

Quantity:	96 tests
Target:	Vedolizumab Antibody
Reactivity:	Chemical, Human
Method Type:	Sandwich ELISA
Application:	ELISA

Product Details

Purpose:	Enzyme immunoassay for the semi-quantitative determination of free antibodies to Vedolizumab in serum and plasma
Sample Type:	Plasma, Serum
Analytical Method:	Semi-Quantitative
Detection Method:	Colorimetric
Specificity:	The Antibody to Vedolizumab ELISA kit has been designed for the measurement of free antibodies against this drug. It does not detect such antibodies which already are bound to the drug.
Components:	Microtiter ELISA Plate Negative Control Positive Control Assay Buffer Dilution Buffer Enzyme Conjugate TMB Substrate Solution

Product Details

	Stop Solution Wash Buffer Adhesive Seal
Material not included:	1. Micropipettes (< 3 % CV) and tips to deliver 5-1000 µL. 2. Bidistilled or deionised water and calibrated glasswares (e.g. flasks or cylinders). 3. Wash bottle, automated or semi-automated microtiter plate washing system. 4. Microtiter plate reader capable of reading absorbance at 450 nm (reference wavelength at 600-650 nm is optional). 5. Absorbent paper towels, standard laboratory glass or plastic vials, and a timer.

Target Details

Target:	Vedolizumab Antibody
Target Type:	Antibody
Background:	The drug Vedolizumab (trade name Entyvio®) is a humanised immunoglobulin G1 monoclonal antibody that binds exclusively to the lymphocyte integrin α4β7, is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis [UC] or Crohn's disease [CD]. According to the prescribing information, the mean ± SD of Vedolizumab steady-state trough serum concentrations in patients with UC and CD are reported to be 11.2±7.2 µg/mL (n=77) and 13.0±9.1 µg/mL (n=72) respectively. It was also reported in another study that higher Vedolizumab trough concentrations were associated with greater efficacy in patients with both UC and CD. Higher Vedolizumab trough concentrations also were associated with numerically higher rates of clinical response and mucosal healing at week 6 in patients with UC. As with all therapeutic proteins, there is potential for immunogenicity. According to the prescribing information, in patients who received Vedolizumab, the frequency of antibodies detected in patients was 13 % at 24 weeks after the last dose of the drug. During treatment, 56 of 1434 (4 %) of patients treated with Vedolizumab had detectable anti-Vedolizumab antibody at any time during the 52 weeks of continuous treatment. Nine of 56 patients were persistently positive for anti-Vedolizumab antibody and 33 of 56 patients developed neutralizing antibodies to Vedolizumab. The presence of persistent anti-Vedolizumab antibody was observed to substantially reduce serum concentrations of Vedolizumab, either to undetectable or negligible levels at weeks 6 and 52.

Application Details

Application Notes:	Optimal working dilution should be determined by the investigator.

Application Details

Comment:	The Anti Drug Antibody (ADA) ELISA kits are suitable also for being used by an automated ELISA processor.
Sample Volume:	5 µL
Plate:	Pre-coated
Protocol:	This anti-drug antibody(ies) (ADA) kit is a bridging type ELISA for the determination of free antibodies against the drug Vedolizumab in serum and plasma samples. During the first incubation period, ADA in serum or plasma samples are captured by the drug coated to the microtiter wells. After washing away the unbound components from samples, a peroxidase-labelled drug conjugate is added and then incubated. ADA, if present in the sample, will make a bridge, with its identical Fab arms, between the drug coated on the well and the other drug molecule labelled 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 by adding a stop solution. The positive reaction is expected to be related to the presence of ADA in the sample.
Reagent Preparation:	Prepare Wash Buffer before starting the assay procedure. Negative and Positive Controls are ready-to-use and should NOT be diluted with the dilution buffer.
Sample Collection:	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.
Sample Preparation:	Incubate 1:10 diluted serum/plasma samples for 15 min at room temperature (20-25 °C) before pipetting 50 µL of each 1:10 diluted sample per well for analysis.
Calculation of Results:	For the run to be valid, the OD450 nm of the Positive Control should be ≥ 0.500 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 each individual OD results by the Cut-off OD value. The results are expressed in arbitrary units (AU/mL). Cut-off value = 2 x the mean OD450 nm of Negative Control = 3 AU/mL 80 different naive samples have been measured for estimating the cut-off value. In order to avoid a sample from being reported as false positive the cut-off value was determined by 2 times of the mean of Negative Control. All 80 screened naive samples show ODs (ranged

Application Details

	between 0.045 and 0.079) lower than the cut-off value. Samples which have an equal and higher OD than the cut-off value are considered to be positive.
Assay Precision:	Intra-assay CV: < 10%. Inter-assay CV: < 10%
Restrictions:	For Research Use only

Handling

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 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.

Images

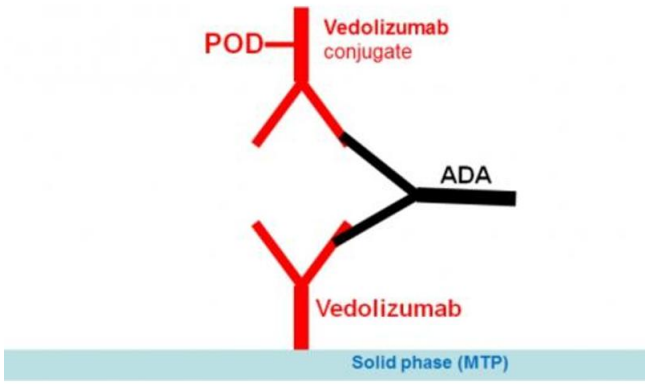

Image 1.

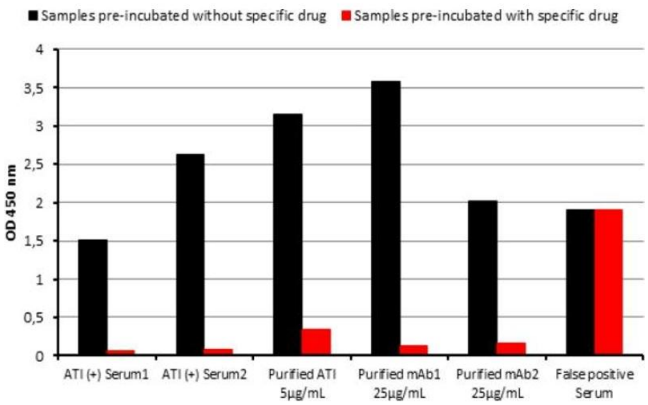

Image 2.

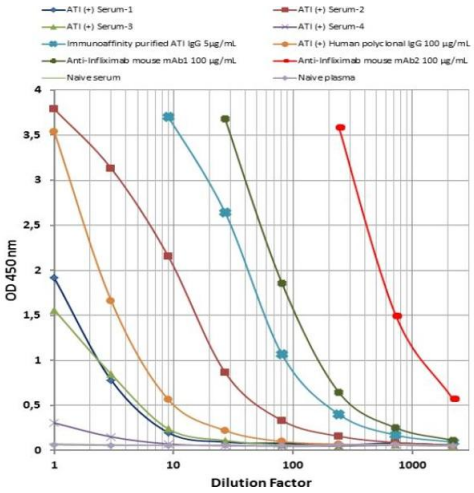
ATI (+) Serum-1
ATI (+) Serum-2
ATI (+) Serum-3
ATI (+) Serum-4
Immunoaffinity purified ATI IgG 5µg/mL
ATI (+) Human polyclonal IgG 100 µg/mL
Anti-Infliximab mouse mAb1 100 µg/mL
Anti-Infliximab mouse mAb2 100 µg/mL
Naive serum
Naive plasma
OD 450 nm
Dilution Factor
4
3,5
3
2,5
2
1,5
1
0,5
0
1
10
100
1000

Image 3.