Datasheet for ABIN5608475

Ustekinumab Specific ELISA Kit

2 Images

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Overview

Quantity:	96 tests
Target:	Ustekinumab Specific
Reactivity:	Chemical
Method Type:	Sandwich ELISA
Detection Range:	0-600 ng/mL
Minimum Detection Limit:	0 ng/mL
Application:	ELISA

Product Details

Purpose:	Enzyme immunoassay for the specific quantitative determination of free Ustekinumab in serum and plasma
Sample Type:	Plasma, Serum
Analytical Method:	Quantitative
Detection Method:	Colorimetric
Cross-Reactivity (Details):	There is no cross reaction with any other proteins present in native human serum. A screening test was performed with 21 different native human sera. All produced OD450/620 nm values (ranged from 0.036 to 0.068) less than the mean OD (0.120) of standard D (2 ng/mL). In addition, binding of Ustekinumab to the solid phase is inhibited by p40-containing recombinant human interleukin-12 (hIL-12) protein. Therefore, the ImmunoGuide Ustekinumab ELISA (mAb-Based) measures the biologically active free form of Ustekinumab, i.e. not pre-occupied by human IL-12 or IL-23 antigen. No cross reaction was observed with sera spiked with the other

	therapeutic antibodies including Infliximab, Rituximab, Cetuximab, Vedolizumab, Tocilizumab, Trastuzumab, Nivolumab and Bevacizumab at concentrations tested up to 40 µg/mL. All produced mean OD450/620 nm values (ranging from 0.035 to 0.058) less than standard D.
Sensitivity:	1.5 ng/mL
Characteristics:	The drug Ustekinumab (trade name Stelara®) is a humanized immunoglobulin G1kappa monoclonal antibody that binds with high specificity to the p40 protein subunit used by both the IL-12 and IL-23 cytokines. Ustekinumab is indicated for the treatment of adult patients with: - moderate to severe plaque psoriasis (Ps) who are candidates for phototherapy or systemic therapy. - active psoriatic arthritis (PsA), alone or in combination with methotrexate. - moderately to severely active Crohn's disease (CD) who have - failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed a tumor necrosis factor (TNF) blocker or - failed or were intolerant to treatment with one or more TNF blockers. Steady state Ustekinumab concentration was achieved by the start of the second maintenance dose. There was no apparent accumulation of Ustekinumab concentration over time when given subcutaneously every 8 weeks. According to the prescribing information the mean steady-state trough concentration was 2.51 ±2.06 µg/mL for 90 mg Ustekinumab administered every 8 weeks. In a phase II study it was reported that the median trough serum levels of Ustekinumab reached steady state by week 12 (1.59 µg/mL) in the every-8-week group and by week 16 (0.61 µg/mL) in the every-12-week group, and were maintained through week 28 (1.77 µg/mL and 0.54 µg/mL, respectively). Identification of biomarkers for (non-) response and risk factors might be beneficial for adverse drug reactions that might be related to serum drug levels and maintaining the effective concentration in order to potentially avoid some side effects with a reliable method.
Components:	Microtiter ELISA Plate Ustekinumab Standards A-E, Concentrate (10X) Assay Buffer Dilution Buffer Biotinylated alpha-hIgG Enzyme Conjugate TMB Substrate Solution Stop Solution Wash Buffer

Product Details

	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:	Ustekinumab Specific

Application Details

Application Notes:	Optimal working dilution should be determined by the investigator.
Sample Volume:	10 µL
Assay Time:	2 - 3 h
Plate:	Pre-coated
Protocol:	This ELISA is based on Ustekinumab-specific monoclonal antibody (catcher Ab, clone 9C7). Diluted standards and samples are incubated in the microtiter plate coated with IG-9C7 mAb. After incubation, the wells are washed. A biotinylated anti-human IgG monoclonal antibody (clone 1B5, specific for the Fc part of all human IgG i.e. IgG1, IgG2, IgG3 and IgG4) is added and binds to the Fc part of Ustekinumab. Following incubation, wells are washed and the horseradish peroxidase (HRP)-conjugated streptavidin is added and binds to the biotinylated 1B5 mAb. Following incubation, wells are washed and the bound enzymatic activity is detected by addition of chromogen-substrate. The color developed is proportional to the amount of Ustekinumab in the sample or standard. Results of samples can be determined by using the standard curve. Preincubation of Ustekinumab with recombinant human interleukin-12 (IL-12), contains p40 protein subunit as that of IL-23, inhibited the reaction. Therefore, the Ustekinumab ELISA (mAb-based) measures the free form of Ustekinumab.
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 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:	12 months

Images

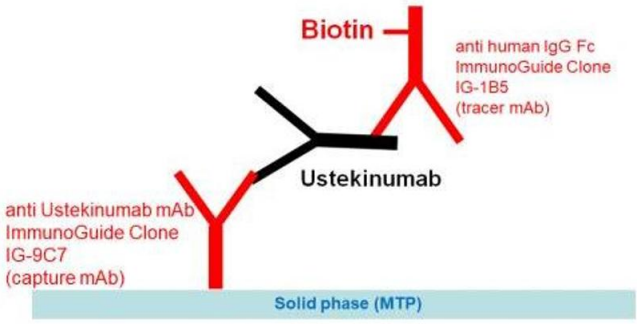

Image 1.

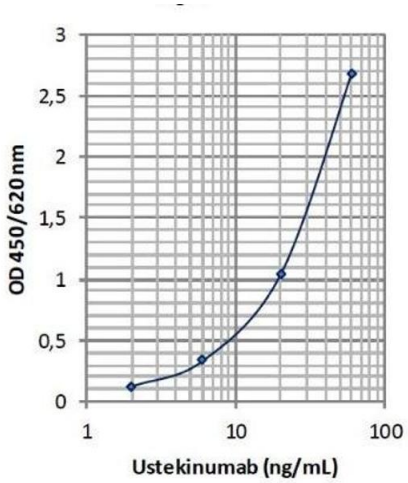

Image 2.