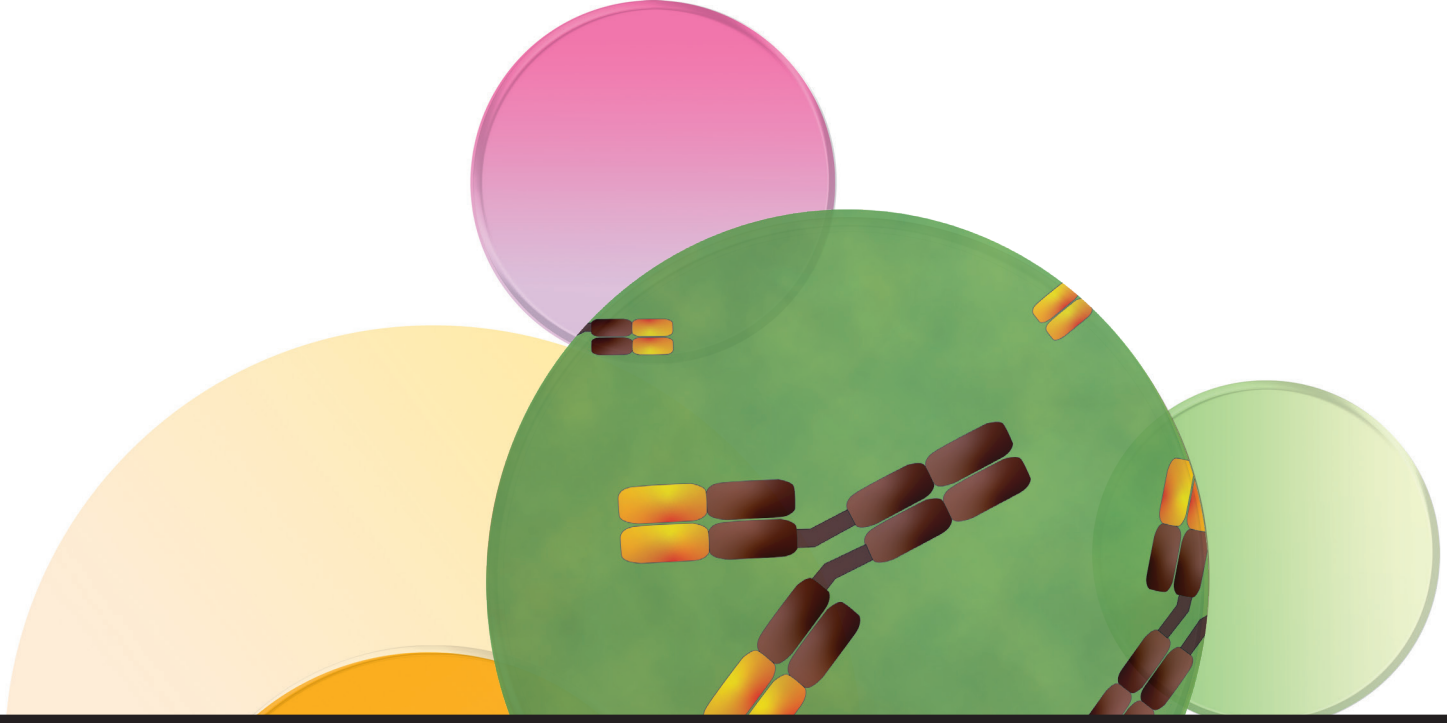

USTEKINUMAB ELISA
REF: 710601

- **CE MARKED**
- **QUANTITATIVE ASSAY**
- **INCUBATION TIME:** 100 MIN
- **AUTOMATABLE**
- **AVAILABLE FORMAT:** 96T

USTEKINUMAB ELISA

apDia

EN ISO 13485: 2016 CERTIFIED COMPANY

USTEKINUMAB (UST) ELISA

Therapeutic Drug Monitoring

Ustekinumab (UST) is a fully human monoclonal antibody that binds to the p40 subunit common to IL-12 and IL-23 thereby preventing the interaction with the cytokine receptors on T cells, natural killer cells and antigen-presenting cells. UST has been approved for treatment of moderate to severe Crohn's disease (CD), plaque psoriasis and psoriatic arthritis.

A drug can only exert its pharmacological effect when adequate concentrations are achieved in the circulation. The serum concentration of biologicals just before the next administration, defined as trough concentration, has been used for therapeutic drug monitoring (TDM). Recent data have shown a positive relationship between UST serum concentration, either measured at trough or at an intermediate time point, and clinical outcomes in patients with Crohn's disease and plaque psoriasis, respectively. TDM may therefore be very instrumental to optimize treatment.

The apDia Ustekinumab ELISA uses highly specific monoclonal antibodies developed at the University of Leuven, Belgium (KU Leuven). Anti-TNF drugs (like infliximab, adalimumab, golimumab) or anti-integrin α4β7 drugs (like vedolizumab) do not interfere with the measurement.

As an example of TDM, the use of UST concentration measurements in plaque psoriasis and CD is described.

Immunogenicity

It has been shown that the immunogenicity of ustekinumab is very low.

Crohn's Disease

UST is administered intravenously (IV) at week 0 and thereafter every 8 weeks subcutaneously (SC). The UNITI-1 and -2 induction trials demonstrated that 33.7% and 55.5% of patients had a clinical response at week 6, respectively. During maintenance therapy with SC ustekinumab every 8 weeks, 53.1% of patients were in remission at week 44 in the IM-UNITI trial.

Several studies have demonstrated the relationship between ustekinumab trough concentration and clinical, biological and endoscopic response, indicating the usefulness of therapeutic drug monitoring to guide clinical decision-making.

Plaque psoriasis

UST is weight-based administered subcutaneously at week 0, at week 4 and thereafter every 12 weeks. The PHOENIX 1 and 2 trials indicate that treatment with ustekinumab results in rapid, significant improvements in patients with moderate-to-severe psoriasis.

A recent study demonstrated a concentration-response relationship at week 4 upon injection for ustekinumab-treated psoriasis patients, indicating that monitoring 4-week post injection ustekinumab concentrations could timely identify underexposed patients who might benefit from treatment optimization.
Reagents commonly used in the TDM assays – Sample Diluent, Wash Solution, Chromogen Solution and Stop Solution – are interchangeable across the TDM assays**.**
The different apDia TDM assays for the biologicals IFX-ADM-GLM-VDZ-UST can be combined on a microtiterplate.

The apDia UST ELISA is validated on the Dynex instruments (DS2 and DSX) and can also be used on other automated ELISA instruments.

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