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

VEDOLIZUMAB ELISA
REF: 710501

VEDOLIZUMAB ELISA

apDia

EN ISO 13485: 2016 CERTIFIED COMPANY

VEDOLIZUMAB (VDZ) ELISA

Therapeutic Drug Monitoring

Vedolizumab (VDZ) is a humanised monoclonal antibody that binds exclusively to the lymphocyte integrin α4β7. VDZ inhibits the interaction of α4β7-expressing cells with mucosal addressin cell adhesion molecule-1 on endothelial cells, thereby hampering the infiltration of the α4β7-expressing cells into the gastrointestinal mucosa and gut-associated lymphoid tissue. VDZ suppresses gut inflammation and has therefore been approved for the treatment of patients with moderate to severe ulcerative colitis (UC) and Crohn's disease (CD). It has been shown that VDZ can induce clinical remission and improve the patient's quality of life.

A drug can only exert its pharmacologic effect when adequate concentrations are achieved in the circulation. The serum concentration of biologicals just before their next infusion, defined as trough concentration, has been used for therapeutic drug monitoring (TDM). Recent data on TDM have shown a positive relationship between VDZ trough serum concentrations and clinical outcomes in patients with UC and CD. TDM may therefore be very instrumental to optimize treatment. The apDia Vedolizumab ELISA uses highly specific monoclonal antibodies developed at the KU Leuven. Anti-TNF drugs (infliximab, adalimumab, golimumab) do not interfere with the measurement. As an example of TDM, the use of VDZ trough concentration measurements in UC and CD is described.

Immunogenicity

Secondary loss of response is often due to the development of anti-drug antibodies. The immunogenicity rate during treatment with VDZ is very low (4%).

Ulcerative colitis

VDZ is given at week 0, week 2 and week 6 (induction) and upon good clinical response at week 14, treatment is continued by infusions every 8 weeks (maintenance). The exposure-efficacy relationships of VDZ evaluated in GEMINI 1 revealed a positive exposure-response relationship for clinical remission, clinical response, and mucosal healing for VDZ induction therapy in UC. VDZ trough concentration measurements during or shortly after induction may thus be used to identify undertreated patients.

It has been demonstrated that higher VDZ concentrations are associated with deep remission in patients with UC on maintenance therapy. Thus, regularly checking VDZ trough concentrations during maintenance therapy may be useful to evaluate the VDZ treatment schedule.

Crohn's Disease

VDZ is given at week 0, week 2 and week 6 (induction) and upon good clinical response at week 14, treatment is continued by infusions every 8 weeks (maintenance). The exposure-efficacy relationships of VDZ evaluated in GEMINI 2 and 3 revealed a modest positive exposure-response relationship. Clinical remission rates were higher at week 10 than at week 6 in both studies. The European Medicines Agency allows an additional dose at week 10 before assessment of an induction response at week 14.

Due to the dosing regimen, trough concentrations during induction at week 2, week 6, week 10 (CD) & 14 (CD) are higher compared to trough concentrations during maintenance when VDZ is given every 8 weeks. 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 VDZ ELISA is validated on the Dynex instruments (DS2 and DSX) and can also be used on other automated ELISA instruments.

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VDZ/10-2020