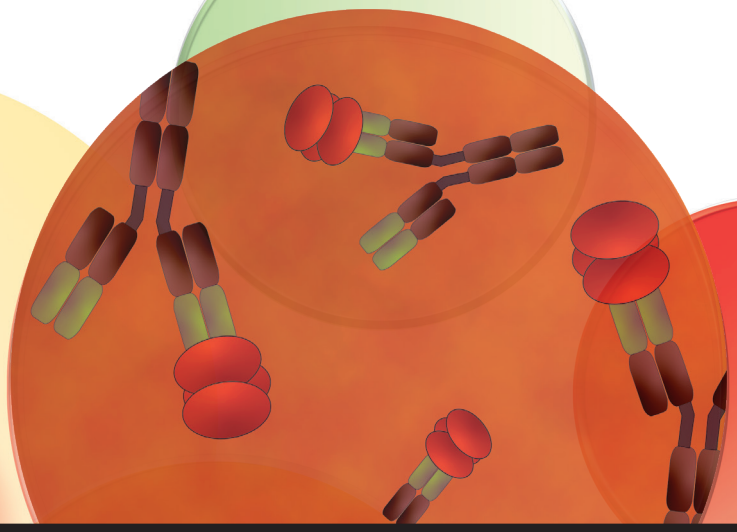


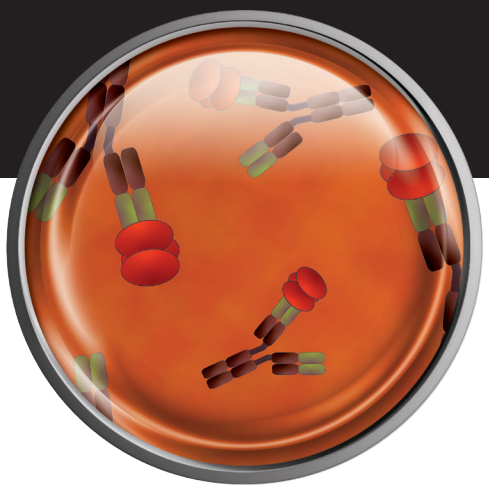
GOLIMUMAB ELISA
REF: 710401

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

GOLIMUMAB ELISA

apDia

EN ISO 13485: 2016 CERTIFIED COMPANY



GOLIMUMAB (GLM) ELISA

Therapeutic Drug Monitoring

Golimumab (GLM) is a human monoclonal antibody, derived from TNF-alpha immunized transgenic mice engineered to express human IgGs. Golimumab binds to both the soluble and transmembrane bioactive forms of human TNF-alpha, giving rise to stable high-affinity complexes thereby preventing the binding of TNF-alpha to its receptors. Golimumab has been approved for the treatment of various chronic immune-mediated inflammatory disorders in which TNF-alpha plays an important role, including rheumatoid arthritis (RA), psoriatic arthritis, ankylosing spondylitis and ulcerative colitis (UC).

A drug can only exert its pharmacologic effect when adequate concentrations are achieved in the circulation.

The serum concentration of golimumab just before the next infusion, defined as the trough concentration, has been used for therapeutic drug monitoring (TDM). Recent data on TDM have shown a positive relation between GLM trough serum concentrations and clinical outcomes in patients with RA and UC. TDM may therefore be very instrumental to optimize treatment.
The apDia Golimumab ELISA uses a highly specific monoclonal antibody – clone 171D8, developed at the KU Leuven – that only detects golimumab (Simponi®). Other anti-TNF drugs (infliximab, adalimumab) do not interfere with the measurement. As an example of TDM, the use of GLM trough concentration measurements in UC is described.

Immunogenicity

Currently, it is unclear of loss of response to GLM is due to formation of anti-drug antibodies since studies have reported a low rate of immunogenicity. However, in the case of undetectable trough concentrations, subsequent measurement of anti-drug antibodies may be helpful to determine the optimal treatment strategy.

Ulcerative colitis

In most European countries, patients receive the same induction treatment in daily clinical practice (200mg at week 0 and 100mg at week 2) followed by a body weight based dose stratification during maintenance, i.e. 50 mg every four weeks for patients with a body weight of less than 80 kg and 100 mg golimumab every four weeks for patients with a body weight of at least 80 kg. Results from PURSUIT and real-world observational studies reported clinical response rates of around 50% after golimumab induction therapy. An exposure-response relationship was observed, as patients with higher drug exposure were more likely to achieve improved outcomes.

GLM trough concentration measurements during or shortly after induction may thus be used to identify undertreated patients. In PURSUIT-M, week 6 non-responders had lower serum drug levels compared to responders at week 6. These early non-responders received 100 mg golimumab maintenance, and their drug exposure was increased to levels comparable with that of responders by week 14. Since July 2018, the posology has therefore changed and patients with an inadequate response to induction can be dose increased to 100mg at week 6 and every four week thereafter. Regularly checking GLM trough concentrations during induction or maintenance therapy may thus be useful to evaluate the GLM treatment schedule.
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 GLM ELISA is validated on the Dynex instruments (DS2 and DSX) and can also be used on other automated ELISA instruments.

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GLM/10-2020