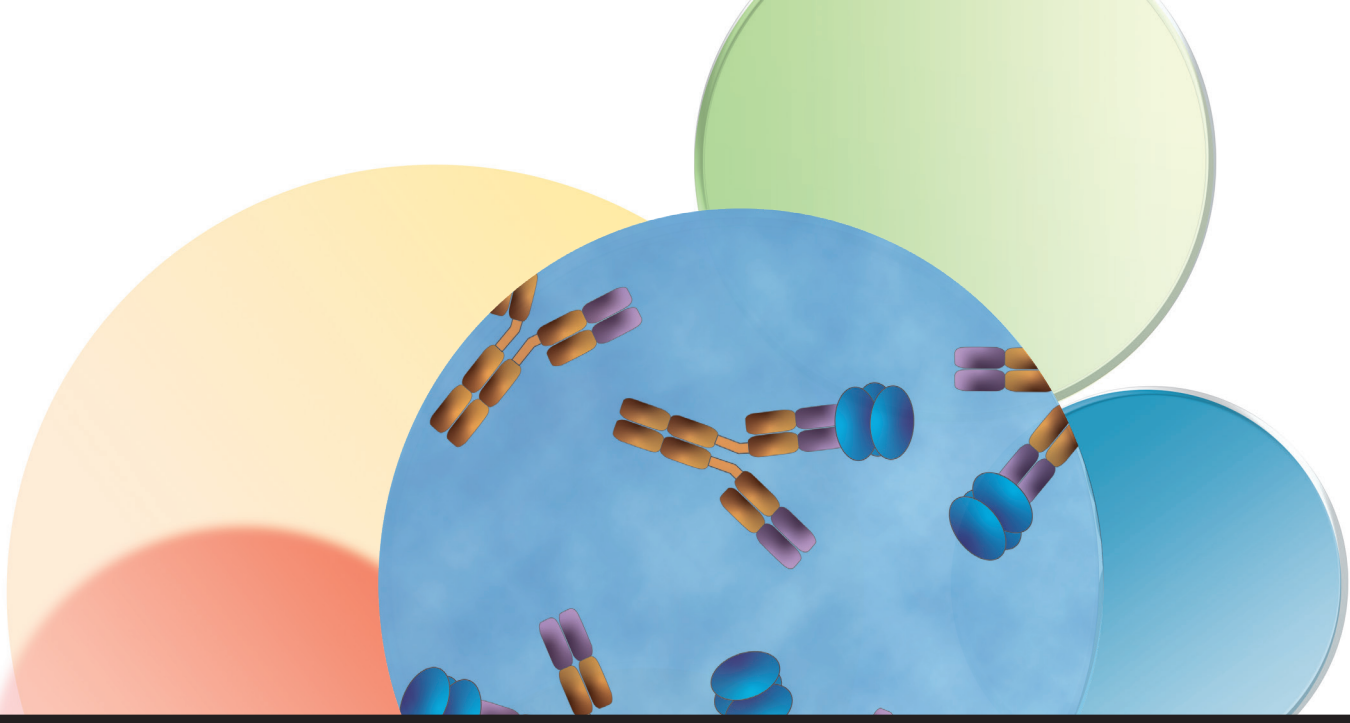


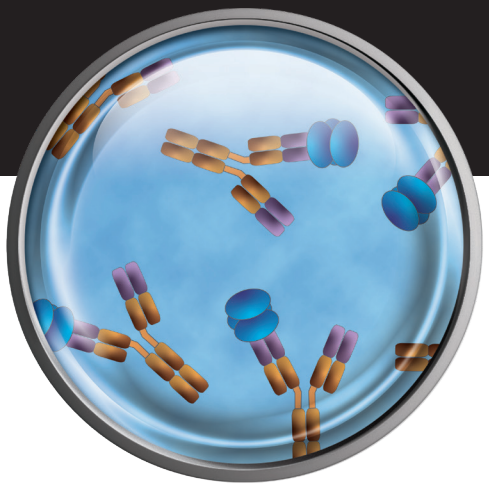
ADALIMUMAB ELISA
REF: 710201

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

ADALIMUMAB ELISA

apDia

EN ISO 13485: 2016 CERTIFIED COMPANY



ADALIMUMAB (ADM) ELISA

Therapeutic Drug Monitoring

Adalimumab (ADM) is a fully human antibody that targets the pro-inflammatory cytokine TNF-alpha and is used to treat chronic inflammatory diseases like inflammatory bowel disease, rheumatoid arthritis, spondyloarthritis and plaque psoriasis. It has been shown that adalimumab can induce deep remission and improve the patient's quality of life. Some patients do not respond to ADM therapy upon induction (primary non-responders), while others lose response over time (secondary non-responders).

A drug can only exert its pharmacologic effect when adequate concentrations are achieved in the circulation. The serum concentration of adalimumab just before the next injection, defined as the trough concentration, has been used for therapeutic drug monitoring (TDM). Recent data on TDM have shown that a good clinical response is associated with adequate trough concentrations in inflammatory bowel disease and rheumatoid arthritis patients. TDM may therefore be very instrumental to optimize treatment and to overcome secondary loss of response.

The apDia ADM ELISA uses a highly specific monoclonal antibody – Clone 40D8, developed at the KU Leuven – that only detects adalimumab (Humira®, and the biosimilars Amgevita® and Imraldi®). Other anti-TNF drugs (infliximab and golimumab) do no interfere with the measurement.

As an example of TDM, the use of adalimumab trough concentration measurements in inflammatory bowel disease patients is described.

Inflammatory bowel disease

Induction therapy of adalimumab consists of a subcutaneous dose of 160 mg at week 0, followed by 80 mg at week 2 and 40 mg every other week from week 4 onwards. Upon good clinical response at week 12-14, treatment is continued (maintenance).

Maintenance phase: It has been shown that patients on maintenance therapy having sustained trough concentrations, are more likely to remain in remission than patients with undetectable trough concentrations. Thus, regularly checking ADM trough concentrations during maintenance therapy may be useful to evaluate the ADM treatment schedule and make adjustments when necessary.

Patients with low or undetectable drug concentrations may benefit from a dose increase or interval shortening, while the interval in patients with very high ADM concentrations can be safely prolonged. Due to the dosing regimen, trough concentrations during induction at w2 and w4 are higher and serum samples need to be diluted more compared to the maintenance phase in which trough concentrations between 0.5-12 µg/ml are common.

Immunogenicity

Secondary loss of response is often due to the development of anti-drug antibodies, which have been observed despite of the fully human character of the drug. In case of undetectable trough concentrations, subsequent measurement of anti-drug antibodies may be helpful to determine the optimal treatment strategy.

The apDia ADM ELISA is based on microtiter strips coated with TNF-alpha and a HRP-conjugated monoclonal antibody recognizing ADM specifically. The kit contains 6 calibrators and 2 controls, all reagents are ready to use. A calibration curve is obtained by plotting the absorbance values versus the corresponding calibrator values. The concentration of ADM in patient samples is determined by interpolation from the calibration curve.

One kit can be used to analyze 1 x 80 samples or 6 x 8 samples (6 runs).

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

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ADM/10-2020