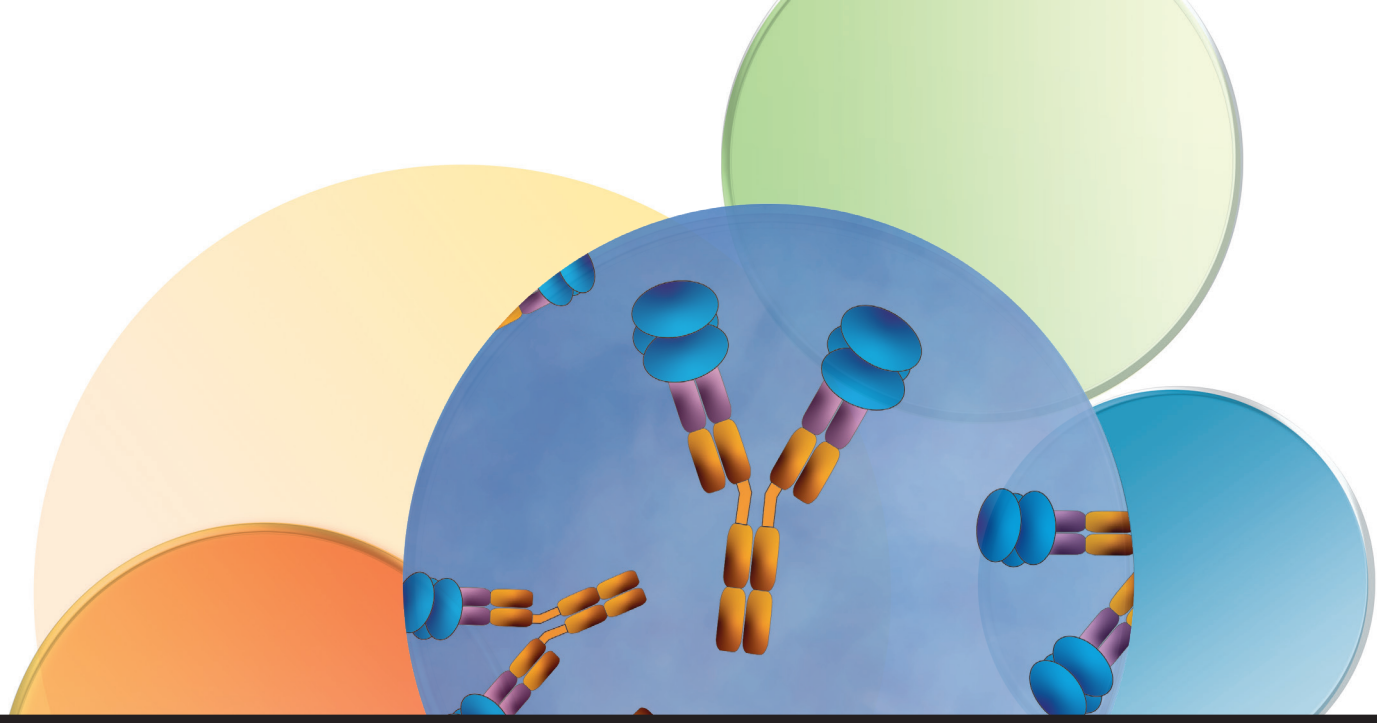

- CE MARKED
- QUANTITATIVE ASSAY
- INCUBATION TIME: 115 MIN
- AUTOMATABLE
- AVAILABLE FORMAT: 96T

**ANTI-ADALIMUMAB ELISA**
**REF: 710301**

# ANTI-ADALIMUMAB ELISA

apDia

EN ISO 13485: 2016 CERTIFIED COMPANY

# ANTI-ADALIMUMAB (ATA) ELISA

**Therapeutic Drug Monitoring**

Therapeutic Drug Monitoring

Adalimumab (ADM) is a fully human antibody that targets the pro-inflammatory cytokine TNF-alpha. The introduction of therapeutic antibodies has revolutionized the treatment of chronic inflammatory diseases like inflammatory bowel disease (IBD), rheumatoid arthritis (RA), 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 adalimumab therapy upon induction (primary non-responders), while others lose response over time (secondary non-responders).

**Immunogenicity**

Secondary loss of response is often due to the development of anti-adalimumab antibodies (ATA), which have been observed despite of the fully human character of the drug. ATA can develop in any patient undergoing adalimumab therapy and are primarily neutralizing the activity of adalimumab through immune complex formation. In addition these immune complexes are rapidly cleared from the system. Analytically, they are responsible for subtherapeutic adalimumab concentrations. Therefore, in the case of very low trough concentrations of adalimumab (< 1 µg/ml), subsequent measurement of ATA may be helpful to determine the optimal treatment strategy.

The apDia Anti-Adalimumab ELISA uses a highly specific monoclonal antibody – clone 6A10, developed at the KU Leuven – that only bridges adalimumab.

**Diagnostic Value**

The diagnostic value of the Anti-Adalimumab ELISA lies in its ability to stratify patients with subtherapeutic adalimumab concentrations (< 1 µg/ml) in patients who need dose intensification or a drug (class) switch. Patients with low adalimumab concentrations (< 1 µg/ml) and low ATA titers can benefit from adalimumab dose intensification, as shown in several studies.

However, the ATA titer of patients with low ATA titers undergoing a dose intensified treatment regimen must be adequately monitored. Patients that have high ATA titers are preferably switched to another drug, both within class or out of class.

The apDia ATA ELISA is based on microtiter strips coated with adalimumab (Humira®) and a biotin-conjugated adalimumab (Humira®) recognizing the ATA 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 ATA in patient samples is determined by interpolation from the calibration curve and is expressed in ng/ml equivalents of the antibody clone 6A10.

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

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