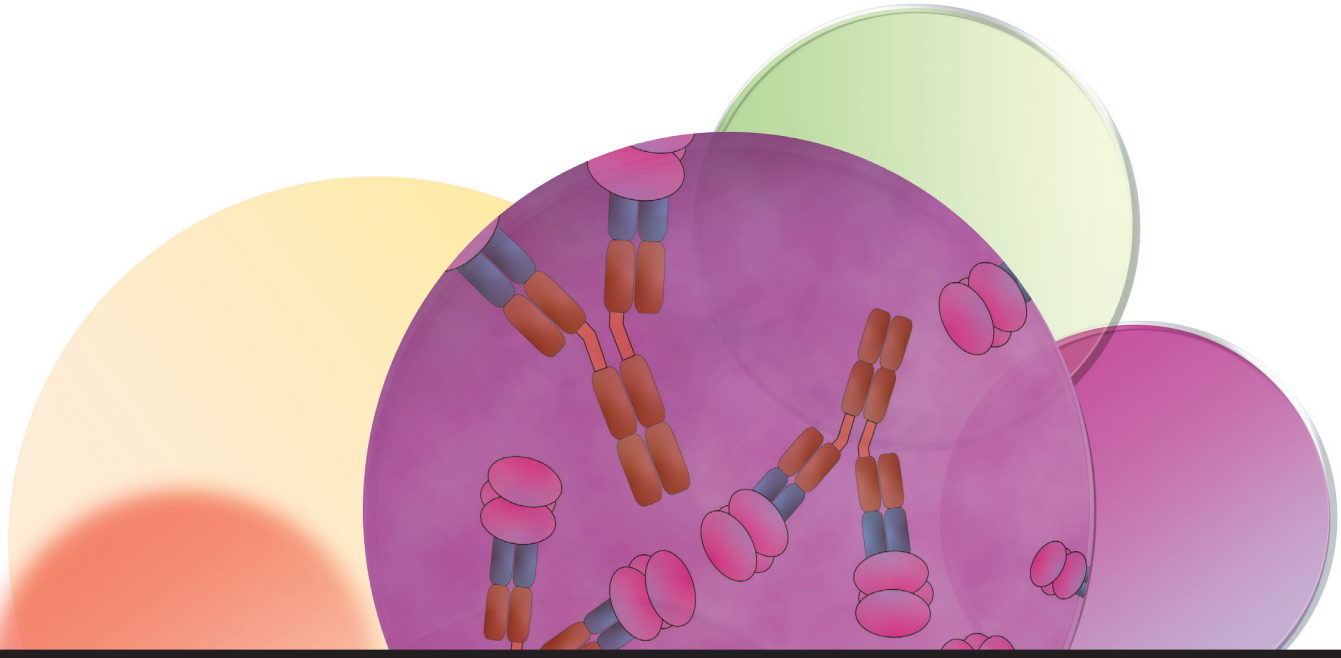

ANTI-INFLIXIMAB ELISA
REF: 710101

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

ANTI-INFLIXIMAB ELISA

apDia

EN ISO 13485: 2016 CERTIFIED COMPANY

ANTI-INFLIXIMAB (ATI) ELISA

Therapeutic Drug Monitoring

Infliximab (IFX) is a chimeric antibody that targets the pro-inflammatory cytokine TNF-alpha. The introduction of infliximab has revolutionized the treatment of chronic inflammatory diseases like inflammatory bowel disease (IBD), rheumatoid arthritis (RA) and spondyloarthritis. It has been shown that infliximab can induce deep remission and improve the patient's quality of life. Some patients do not respond to infliximab 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-infliximab antibodies (ATI), because of the immunogenic character of the drug. ATI can develop in any patient undergoing infliximab therapy and are primarily neutralizing the activity of infliximab through immune complex formation. In addition these immune complexes are rapidly cleared from the system. Analytically, they are responsible for subtherapeutic infliximab concentrations. Therefore, in the case of very low trough concentrations of infliximab (< 1 µg/ml), subsequent measurement of ATI may be helpful to determine the optimal treatment strategy.

The apDia Anti-Infliximab ELISA uses a highly specific monoclonal antibody – clone 10F9, developed at the KU Leuven – that only binds with infliximab (Remicade®) and is used as a calibrator and as control.

Diagnostic Value

The diagnostic value of the Anti-Infliximab ELISA lies in its ability to stratify patients with subtherapeutic infliximab concentrations (< 1 µg/ml) in patients who would benefit from infliximab dose intensification from those who would benefit from treatment stop. Patients with low infliximab concentrations (< 1 µg/ml) and low ATI titers can benefit from infliximab dose intensification, as shown in several studies. However, the ATI titer of patients with low ATI titers undergoing a dose intensified treatment regimen must be adequately monitored. Patients that have high ATI titers are preferably switched to another drug, both within class or out of class.

The apDia ATI ELISA is based on microtiter strips coated with infliximab (Remicade®) and a biotin-conjugated infliximab (Remicade®) recognizing the ATI 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 ATI in patient samples is determined by interpolation from the calibration curve and is expressed in ng/ml equivalents of the antibody clone 10F9.

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

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