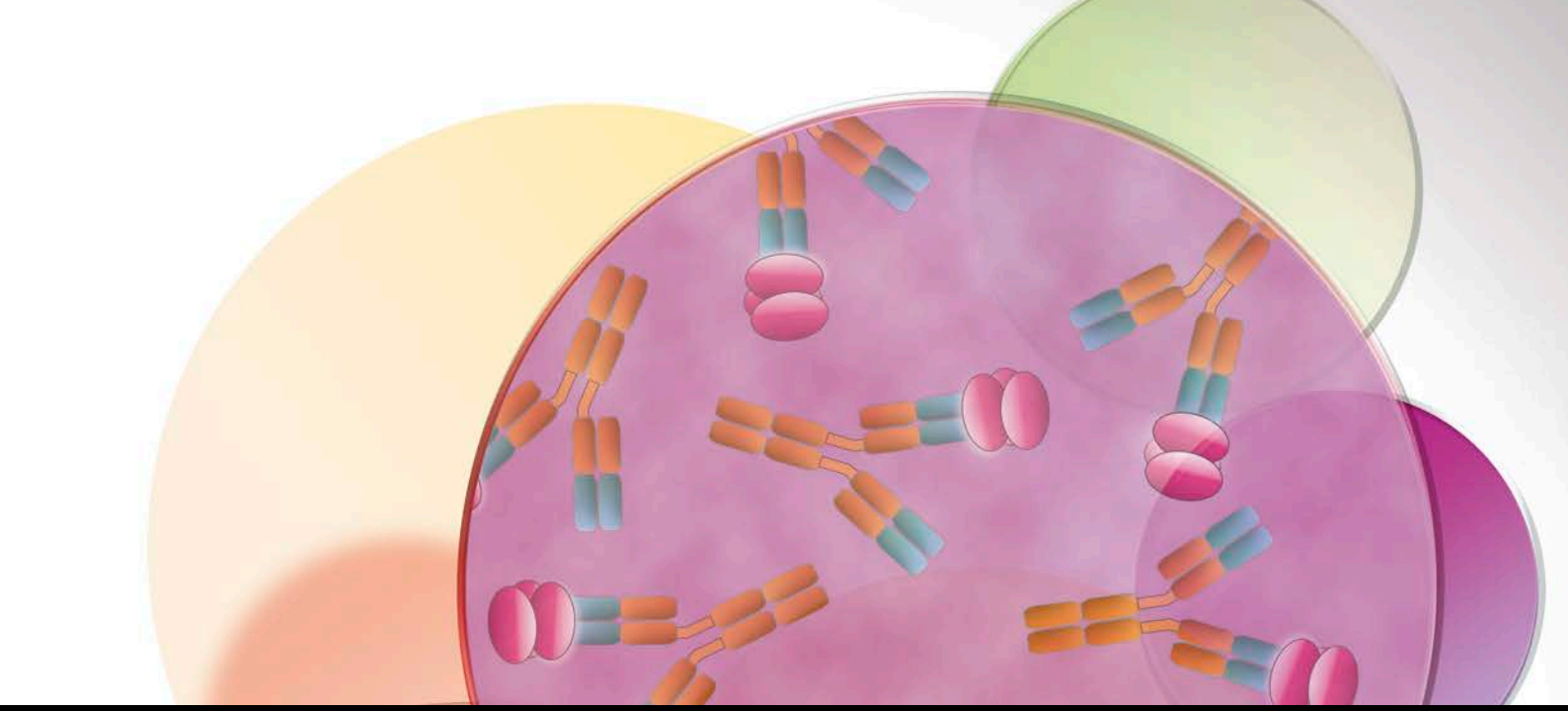

INFLIXIMAB ELISA
REF: 710001

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

INFLIXIMAB ELISA

apDia

EN ISO 13485: 2012 CERTIFIED COMPANY

INFLIXIMAB (IFX) 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 IFX 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 infliximab just before the next infusion, 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 IBD and RA patients. TDM may therefore be very instrumental to optimize treatment and to overcome secondary loss of response.

The apDia IFX ELISA uses a highly specific monoclonal antibody – Clone 6B7, developed at the K.U. Leuven – that only detects infliximab (Remicade®). Other anti-TNF drugs (for example Adalimumab® and Golimumab®) do no interfere with the measurement.

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

Inflammatory bowel disease

Infliximab is given at week 0, week 2 and week 6 (induction). Upon good clinical response at week 14, treatment is continued by infusions every 8 weeks (maintenance). The diagnostic value of therapeutic drug monitoring in IBD patients is described hereunder for both the induction as well as the maintenance phase.

Induction phase: It has been demonstrated that postinduction IFX trough concentrations (week 14) are associated with a sustained clinical response. Infliximab trough concentration measurements during or shortly after induction may thus be used to identify undertreated patients and dose-optimize them.

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 IFX trough concentrations during maintenance therapy may be useful to evaluate the IFX treatment schedule and make adjustments when necessary. On top, it has been shown that patients on maintenance therapy who lost response to infliximab have more benefit from individualized treatment based on the measured IFX serum concentrations than from an empirical strategy that uses all other available therapeutic options.

Due to the dosing regimen, trough concentrations during induction w2 and w6 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, because of the immunogenic character of the drug. In the case of undetectable trough concentrations, subsequent measurement of anti-drug antibodies may be helpful to determine the optimal treatment strategy.

The apDia IFX ELISA is based on microtiterstrips coated with TNF-alpha and a HRP conjugated monoclonal antibody recognizing IFX 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 IFX 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).

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

apDia
Raadsherenstraat 3
2300 Turnhout, Belgium
T +32 14 45 35 99
F +32 14 81 29 45
admin@apdia.be
www.apdiagroup.com