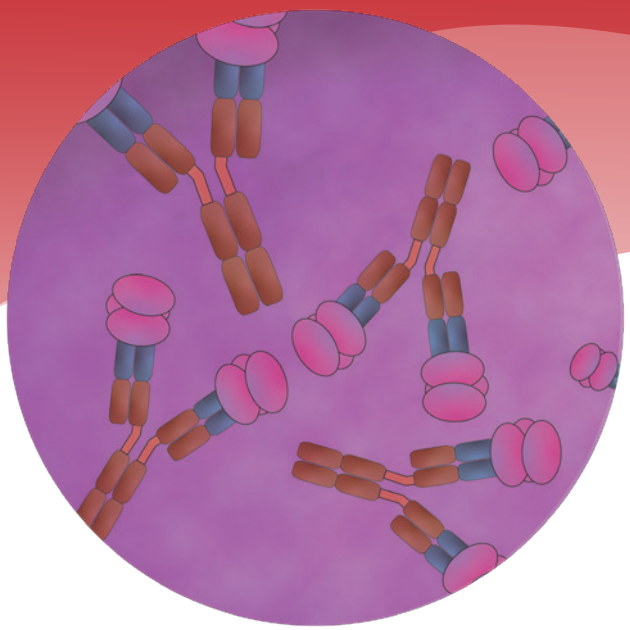

Infliximab ELISA	REF 710001
Anti-Infliximab ELISA	REF 710101
Adalimumab ELISA	REF 710201
Anti-Adalimumab ELISA	REF 710301
Golimumab ELISA	REF 710401
Vedolizumab ELISA	REF 710501
Ustekinumab ELISA	REF 710601
Secukinumab ELISA	REF 710701

Therapeutic Drug Monitoring (TDM) of Infliximab, Adalimumab, Golimumab, Vedolizumab, Ustekinumab and Secukinumab

Individual dose adjustment by measuring drug levels and immunogenicity

TDM is a useful tool in the management of inflammatory diseases such as inflammatory bowel disease (IBD). TDM involves measuring the concentration levels of a biological drug and anti-drug antibodies in a patient's blood to optimize drug dosing, targeting a therapeutic window in order to maximize clinical benefits. This approach can help improve treatment efficacy, reduce adverse effects and improve cost-effectiveness. The use of TDM in infliximab therapy for instance, has been shown to improve treatment outcomes, including clinical remission and mucosal healing, in patients with IBD.

CE MARKED

TWO YEAR SHELF LIFE

AUTOMATABLE

READY-TO-USE REAGENTS

QUANTITATIVE ASSAYS

apDia

Pharmokinetics of these biologicals are dependent on the way of administering the drug, and bioavailablity in a patient's body, which differs from person to person. The trough level (TL) is defined as the drug concentration in the blood measured just before the next dose administration.
Figure 1 shows an example of TL measurement for an intravenously (IV) administered TNF inhibitor infliximab and a subcutaneously (SC) administered one, adalimumab.
Moreover, immunogenicity has an impact on the efficacy of the drug and may lead to loss of response (LOR). The so called anti-drug antibodies (ADA) bind to the drug and can lead to an increased clearance as well as to allergic reactions.

LOR due to immunogenicity is more prevalent in patients treated with infliximab and adalimumab. Therefore, ELISA assays are available for measuring ADA levels. The occurrence of ADA is less prevalent for the other biologicals.

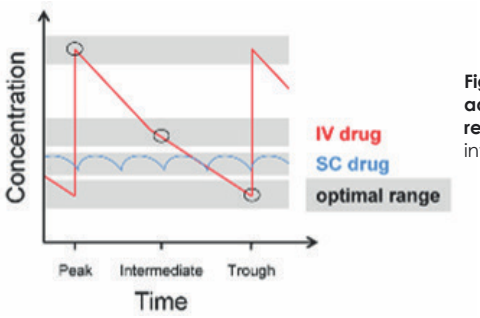

Figure 1: Pharmacokinetic profile of an intravenous (IV, red line) or subcutaneous (SC, blue line) administered anti-tumor necrosis factor agent according to a theoretical maintenance dosing regimen. (Vande Casteele N, Gils A. Pharmacokinetics of anti-TNF monoclonal antibodies inflammatory bowel disease: Adding value to current practice. J Clin Pharmacol. 2015)

Available products: apDia TDM portfolio

ELISA kits manufactured by apDia

Infliximab ELISA REF 710001
Measurement of infliximab (Remicade® and biosimilars)

Anti-Infliximab ELISA REF 710101
Measurement of antibodies to infliximab

Adalimumab ELISA REF 710201
Measurement of adalimumab (Humira® and biosimilars)

Anti-Adalimumab ELISA REF 710301
Measurement of antibodies to adalimumab

Golimumab ELISA REF 710401
Measurement of golimumab (Simponi®)

Vedolizumab ELISA REF 710501
Measurement of vedolizumab (Entyvio®)

Ustekinumab ELISA REF 710601
Measurement of ustekinumab (Stelara®)

Secukinumab ELISA REF 710701
Measurement of secukinumab (Cosentyx®)

Rapid tests distributed by apDia

RidaQuick IFX rapid test REF GN3041
Measurement of infliximab (Remicade® and biosimilars)

RidaQuick ADM rapid test REF GN3043
Measurement of adalimumab (Humira® and biosimilars)

Strenghts:

- CE marked according to IVDR (EU) 2017/746
  Except Secukinumab ELISA, CE marked according to IVDD 98/79/EC
- Based on monoclonal antibodies developed by the University of Leuven, Belgium. Clinically validated.
- Assays calibrated against WHO International Reference Standards (infliximab, adalimumab)
- Highly sensitive and specific
- Common protocols and non-specific reagents
- Monitored by measuring EQAS samples (SKML)
- Two year shelf life
- Ready-to-use reagents
- Usable on open ELISA automates
- Rapid tests available, manufactured by R-Biopharm, correlating well with the ELISA kits

For more information, please visit our website at www.apdiagroup.com or contact us at admin@apdia.be

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