

<b>Infliximab ELISA</b>	REF 710001
<b>Anti-Infliximab ELISA</b>	REF 710101
<b>Adalimumab ELISA</b>	REF 710201
<b>Anti-Adalimumab ELISA</b>	REF 710301
<b>Golimumab ELISA</b>	REF 710401
<b>Vedolizumab ELISA</b>	REF 710501
<b>Ustekinumab ELISA</b>	REF 710601
<b>Secukinumab ELISA</b>	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 ACCORDING TO IVDR (EU) 2017/746

TWO YEAR SHELF LIFE

AUTOMATABLE

READY-TO-USE REAGENTS

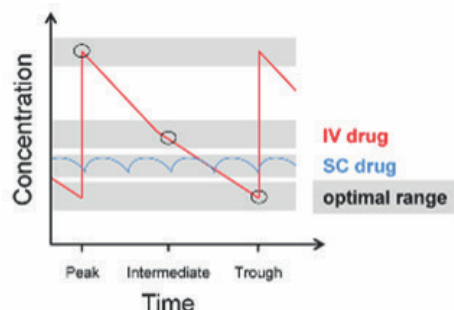
QUANTITATIVE ASSAYS

Pharmacokinetics of these biologicals are dependent on the way of administering the drug, and bio availability 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 Castele 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)

### Strengths:

- CE marked according to IVDR (EU) 2017/746
- 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](http://www.apdiagroup.com) or contact us at [admin@apdia.be](mailto:admin@apdia.be)**