Therapeutic drug monitoring (TDM) of TNFα blockers (Infliximab, Adalimumab)

- ELISA and rapid assay
- Quantification of drug levels and anti-drug antibodies
- Validated by KU Leuven, Belgium
About TNFα blockers

TNFα blockers are biologic agents which are used for the treatment of inflammatory diseases such as ulcerative colitis, Crohn’s disease and rheumatoid arthritis. **Infliximab** (IFX, Remicade®, Remsima®, Inflectra®) as well as **adalimumab** (Humira®) belong to this group of drugs.

How do TNFα blockers function?

When an inflammation starts, cells of the immune system increase the production of TNFα (see figure 1).

TNFα binds to specific receptors, which trigger the signal for the inflammatory process.

In case of **chronic inflammation the immune system continuously produces TNFα**, so that the inflammation does not cease.

**TNFα blockers interrupt this circle by binding to the messenger TNFα.** Hereby the molecule can no longer bind to the receptor, so that the signaling cascade of the inflammatory process is interrupted.

As a result the inflammation and its symptoms can decrease or cease.

Individual dose adjustment by measuring drug levels and immunogenicity

In order for TNFα blockers to work optimally it is important to check their trough level on a regular basis, since the bioavailability differs from person to person. The trough level (TL) is defined as the drug concentration in the blood measured right before the next infusion (see example of TL measurement of IFX, Figure 2).

Moreover, **immunogenicity** has an impact on the efficacy of the drug. So called anti-drug antibodies (ADA) bind to the drug and can lead to a decrease in drug availability in the metabolism as well as to allergic reactions.

**Monitoring of drug- and anti-drug-antibody-levels of TNFα blockers helps to optimally adjust the therapy to the individual needs of the patient.**
TDM of TNFα blockers using RIDASCREEN® and RIDA®QUICK assays

Key features of R-Biopharm’s TDM assays

- All TDM assays of R-Biopharm AG are validated by KU Leuven, Belgium
- ELISA assays and rapid assays correspond due to identical monoclonal antibodies
- The assays have ready to use reagents
- ELISA assays are validated on automated ELISA readers such as DSX® and have breakable microwell plates

- RIDASCREEN® IFX Monitoring and RIDA®QUICK IFX Monitoring quantify infliximab (Remicade®) and its biosimilars Remsima® and Inflectra®
- RIDA®QUICK IFX Monitoring is a rapid point-of-care assay, which allows for the quantitative determination of infliximab trough levels within 20 minutes.

Therapy adjustment based on therapeutic drug monitoring

The TAXIT-Algorithm (TAXIT = Trough Concentration Adapted Infliximab Treatment, Figure 3) is a recommendation for therapy adaptation based on the results of trough- and anti-drug-antibody-levels of Infliximab. It is a result of the study[1] by Nils Vande Casteele et al. (KU Leuven, Belgium) which investigated the effect of drug monitoring on the outcome of TNFα-treatment. The study shows the positive effect of TDM for therapy optimization and treatment cost reduction. Moreover, it indicates that testing for anti-drug antibodies does not have to be performed on a standard basis but only in patients with undetectable trough level of infliximab (see Figure 3). RIDASCREEN® IFX Monitoring and RIDASCREEN® Anti-IFX Antibodies are based on the assays used in this study.

References:

R-Biopharm therapeutic drug monitoring (TDM) at a glance

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<td>RIDASCREEN® IFX Monitoring</td>
<td>Enzyme immunoassay for the quantification of infliximab</td>
<td>96</td>
<td>Serum/plasma</td>
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<td>RIDASCREEN® Anti-IFX Antibodies</td>
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<td>Immunochromatographic lateral flow assay for the quantitative determination of infliximab</td>
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Also available:
For IBD and IBS diagnostics

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Accessory

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<td>For collection and preparation of stool samples</td>
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<td>GZ3006</td>
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</table>
| RIDA®QUICK IFX Monitoring Control Set | Positiv controls  
  • only use with RIDASCREEN® Calprotectin (G09036) |       |        | GP3041   |
| RIDA®QUICK SCAN II              | Lateral flow reader                                                         |       |        | ZRQS2-KD |

For further details and information visit our website [www.r-biopharm.com](http://www.r-biopharm.com), contact your local distributor or Clinical Sales International.

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