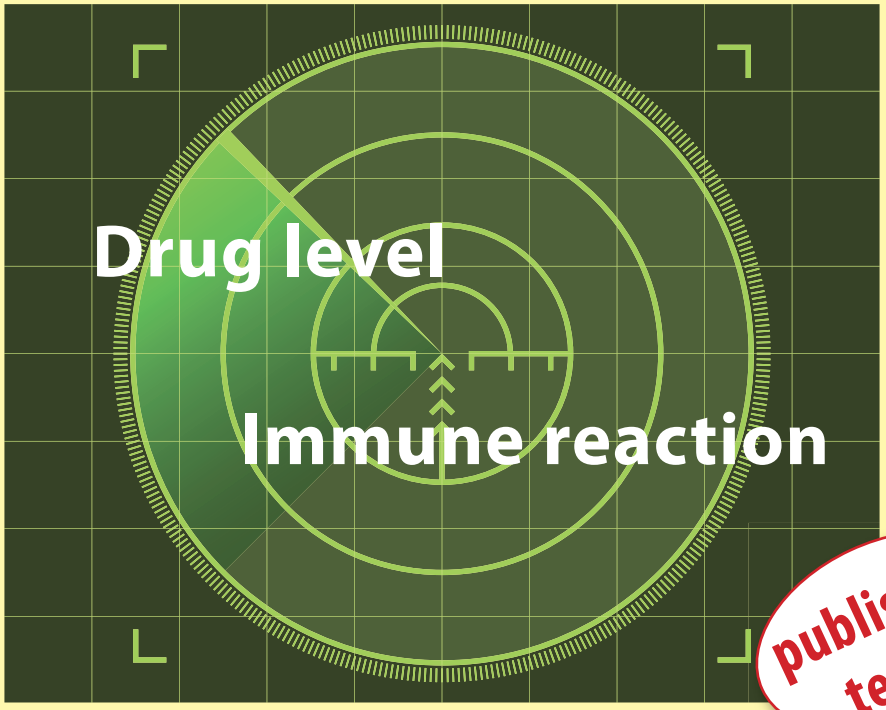
TNFα Blocker Therapy

Everything under control ?



Individual Monitoring Facilitates Therapy Management

TNFα blocker monitoring ELISAs

- For drug level analysis in serum and EDTA-plasma
- Specific determination of the TNFα blockers infliximab or adalimumab (e.g. Remicade® or Humira®)
- High sensitivity

TNFα blocker ADA ELISAs

- For the detection of anti-drug antibodies (ADA)
- For the determination of the immune reaction to infliximab, adalimumab or etanercept (e.g. Remicade®, Humira® or Enbrel®)
- No co-determination of rheuma factors or irregular antibodies

NEW: Contract analyses with both ELISA systems

immun diagnostik

TNFα Blocker Therapy Monitoring

Determination of individual drug efficiency in chronic inflammatory diseases

TNFα – key player of chronic inflammations

Tumor Necrosis Factor alpha (TNFα) belongs to the pro-inflammatory cytokines that encourage and uphold infections. Cytokines, produced by macrophages and T-cells, play a central role in both acute and chronic infections. TNFα concentration is elevated in a variety of chronic inflammatory diseases (e.g. rheumatic diseases or Crohn's disease) which obviously affects pathogenesis and clinical course of these illnesses.

The overproduction of TNFα can be inhibited by TNFα blockers (anti-TNFα antibodies). Infliximab (e.g. Remicade®) and adalimumab (e.g. Humira®) for example are applied in the clinical therapy of chronic inflammations and are approved for the treatment of rheumatoid arthritis. In addition, infliximab is approved for the treatment of Crohn's disease, ankylosing spondylitis, psoriasis and psoriatric arthritis).

TNFα blocker drug level and immunogenicity: The two most influencing parameter of therapy success

The long term effectiveness of TNFα blockers in chronic inflammations is strongly influenced by bioavailability, pharmacokinetics and immunogenicity of the agents. In individual therapy management, these parameters can be governed by dosage variation, choice of compound and, if indicated, additional treatment with immunosuppressants. The goal is to optimally adjust the therapy to the clinical course of an indivdual patient and to reduce adverse effects.

An important tool to assess therapy efficiency is the determination of TNFα blocker serum levels (Seow et al., 2009; Bendtzen et al., 2009). Especially monitoring of the trough level is indicated to ensure an adequate drug concentration in the circulation and to adjust the dosage if necessary.

Furthermore, TNFα blockers may exhibit individually varying grades of immunogenicity which affect efficiency and can lead to hypersensitivity and adverse effects. Some patients for example generate antibodies against TNFα blockers (anti-drug-antibodies, ADA), which impede drug activity and may cause severe allergic reactions. A concommittant therapy with immunosuppressants can reduce antibody formation but is not always indicated (Radstake et al., 2008; Ainsworth et al., 2008; Baert et al. 2007; Bender et al., 2006).

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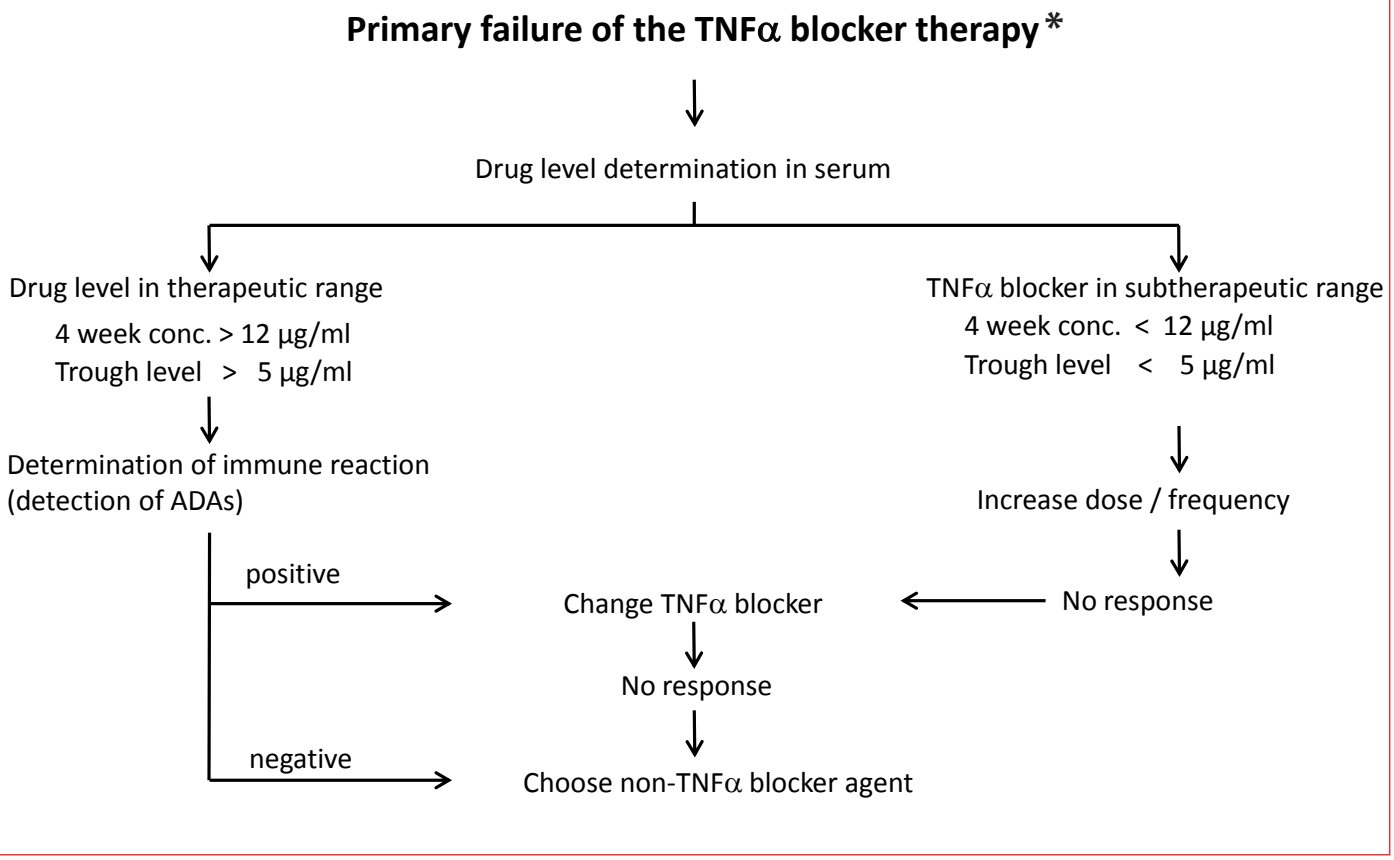
Two ELISA systems enable personalized therapy monitoring

Immundiagnostik offers adequate tools for the individual monitoring of a TNFα blocker therapy: Our ELISAs for the quantitative determination of infliximab or adalimumab drug levels (e.g. Remicade® or Humira®) permit the assessment of bioavailability and our ELISAs for ADA detection provide information on the immune reaction to the respective TNFα blocker (e.g. Remicade®, Humira®, Enbrel®).

These assays are therefore an ideal combination for effective therapy monitoring and control and ultimately enable the implementation of a comprehensive, successful therapy with reduced side effects (see therapy algorithm below).

Immundiagnostik offers contract analyses with both ELISA systems on request.

↓ Therapy management by drug level monitoring and ADA detection ↑



**Algorithm by Prof. Dr. Dr. J. Stein, University of Frankfurt*

Literature

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NEW: We offer contract analyses with all TNFα blocker therapy ELISAs

TNFα blocker monitoring ELISAs

For drug level determination of infliximab or adalimumab (e.g. Remicade®, Humira®)

We offer:

TNFα blocker monitoring (determination of infliximab level, e.g. Remicade®)	
Sample volume	10 µl
Matrix	Serum, EDTA-Plasma
Incubation	2 h
Test principle	ELISA
Tests	96
Cat. No.	**K 9655**

TNFα blocker monitoring (determination of adalimumab level, e.g. Humira®)	
Sample volume	10 µl
Matrix	Serum, EDTA-Plasma
Incubation	2 h
Test principle	ELISA
Tests	96
Cat. No.	**K 9657**

Our ELISAs determine the drug concentration in serum with high sensitivity due to a titer test which uses human recombinant TNFα as antigen.

TNFα blocker ADA ELISAs

For the determination of anti-drug antibodies (ADA) against infliximab, adalimumab or etanercept (e.g. against Remicade®, Humira®, Enbrel®)

We offer:

TNFα blocker ADA (detection of **free** human antibodies against infliximab, e.g. **Remicade®**)	
Sample volume	50 µl
Matrix	Serum, EDTA-Plasma
Incubation	o.n., 1h
Test principle	ELISA
Tests	96
Cat. No.	**K 9650**

TNFα blocker ADA (detection of free antibodies against adalimumab, e.g. **Humira®**)	
Sample volume	25 µl
Matrix	Serum, EDTA-Plasma
Incubation	o.n., 1h
Test principle	ELISA
Tests	96
Cat. No.	**K 9652**

TNFα blocker ADA (detection of **total** human antibodies against infliximab (e.g. **Remicade®**)	
Sample volume	25 µl
Matrix	Serum, EDTA-Plasma
Incubation	20 min., 1h, 1,5h
Test principle	ELISA
Tests	96
Cat. No.	**K 9654**

TNFα blocker ADA (detection of free antibodies against etanercept (e.g. **Enbrel®**)	
Sample volume	25 µl
Matrix	Serum, EDTA-Plasma
Incubation	o.n., 1h
Test principle	ELISA
Tests	96
Cat. No.	**K 9653**

Our ELISAs enable the detection of human antibodies against different compounds. A co-determination of rheuma factors or irregular antibodies can be excluded.

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