Euro Diagnostica is a full service diagnostic solutions company based in Malmö, Sweden. During the last two decades, our world class scientists have been the first to develop and produce top quality assays for ANCA, anti-CCP, Complement and Chromogranin A testing, which are now in use all over the world.

Our aim is to constantly develop solutions to aid clinicians in diagnostic, prognosis, monitoring and treatment of autoimmune and related diseases. With so much at stake, our focus is on getting the correct diagnosis every time.

For more information please visit www.wieslab.com and www.eurodiagnostica.com.

Wieslab
Wieslab Analytical Service Laboratory offers clinical testing and disease assessment within autoimmunity by qualified diagnostic specialists, every day of the year. Wieslab offers a comprehensive range of individual and panel tests, and we pride ourselves on speed ensuring accurate and fast results. Testing is available for a wide range of autoimmune diseases.

Wieslab is present in Malmö, Sweden. Our lab is certified in accordance with SS-EN ISO/IEC 17025:2005 and accredited by SWEDAC since 1996. Wieslab has been a trusted partner in autoimmunity testing for more than 20 years. Since 2004 Wieslab has been an integrated part of Euro Diagnostica.

Monitoring the activity of biological drugs to optimise treatment strategy
Monitoring the activity of biological drugs

An important step in optimising treatment strategy for the patients who do not respond well to treatment.

Experience shows that the majority of patients with various autoimmune diseases, such as rheumatoid and inflammatory bowel diseases, have an excellent primary response to treatment with biological drugs (TNF blockers). However, a significant group of patients (up to 30%) do not respond well to the initial treatment (Vincent et al. Ann Rheum Dis 2012; Bendtzen, Arthritis Rheum 2013). Moreover, a proportion of patients that respond well initially lose their response over time. Understanding why these patients, on an individual level, do not respond is key to optimising treatment, both therapeutically and economically.

Using monitoring of biologicals to improve treatment efficacy for the individual patient

Monitoring tests can be a valuable tool for understanding why patients do not respond to a biological drug. Furthermore, there is a large variation between patients in terms of response, treatment dose and interval between dosing. Addressing the unique and individual needs of a patient being treated with biologicals is important and necessary to optimise the effect of the treatment and to prevent development of the drug resistance using immunological monitoring blood test. These tests are now available and will provide important clinical information. Taken together with the current clinical assessment, the accumulated information will form a solid foundation for decisions regarding the treatment strategy for the individual patient.

Treatment challenges with biological drugs

A major challenge associated with the use of biological drugs is the lack of initial response or loss of treatment response over time. The mechanism behind this is often related to:
- Immunogenicity
- Pharmacokinetics
- Bioavailability

Degree and form of immunogenicity is of great importance and biological drugs vary in structure and hence in their immunogenicity. Immunogenicity has a range of consequences for treatment efficacy, and in some cases, patients will develop neutralizing anti-drug antibodies (NAbs) which will reduce the activity of the drug, diminishing treatment efficacy. Consequently, establishing whether a patient has NAbs will be an important guidance tool for treatment decisions.

Theoretical effect of NAbs on the drug activity

![Diagram of Drug Administration vs. Drug activity](image)

Benefits of monitoring

The benefits of biological drug monitoring tests are several and are an important aid for individualised patient treatment strategy. The test can provide answers to the following questions:
- Is the effect of treatment sustained?
- Is the treatment correct for the patient?
- Is the drug dose and dosage interval correct?
- Is the chosen drug correct for the patient?

Establishing answers to the above critical questions can optimise the individual patient treatment regimen and hence, reduce hospitalisation time and side-effects associated with biological drug treatment. Moreover, studies have established that drug monitoring tests can reduce costs significantly as the patients are treated with the correct drug and correct dosage at correct interval.

A new unique functional cell-based test that measures biological activity

Euro Diagnostica provides a reporter cell technology that measures the biological activity of the drug, which gives a high therapeutic significance. If the test shows that the patient has low concentrations of the TNF blocker, the test has developed NAbs. It is both clinically and economically important to make adjustments in the treatment regimen.

Experimental result of Vincenzo et al. (Ann Rheum Dis 2012; Bendtzen, Arthritis Rheum 2013).

Drug activity level > 0.65 μg/mL

NO DRUG

High Luminescence

LOW DRUG

Moderate Luminescence

HIGH DRUG

No Luminescence

In summary Euro Diagnostica’s neutralising antibodies assay provides important clinical information that will reduce the activity of the drug, diminishing treatment efficacy. Moreover, studies have established that drug monitoring tests can reduce costs significantly as the patients are treated with the correct drug and correct dosage at correct interval.

A new unique functional cell-based test that measures biological activity

![Diagram of Drug activity level assay measurement principle](image)

In summary Euro Diagnostica’s NEW monitoring assay provides a number of benefits:
- A new unique cell-based assay that measures drug activity as well as neutralising antibodies
- Allows the provision of objective data in order to aid the clinician to optimise treatment efficacy
- Allows the clinician to control health care costs through optimized patient management

Neutralising antibodies assay principle

![Diagram of Neutralising antibodies assay principle](image)

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