IBL INTERNATIONAL

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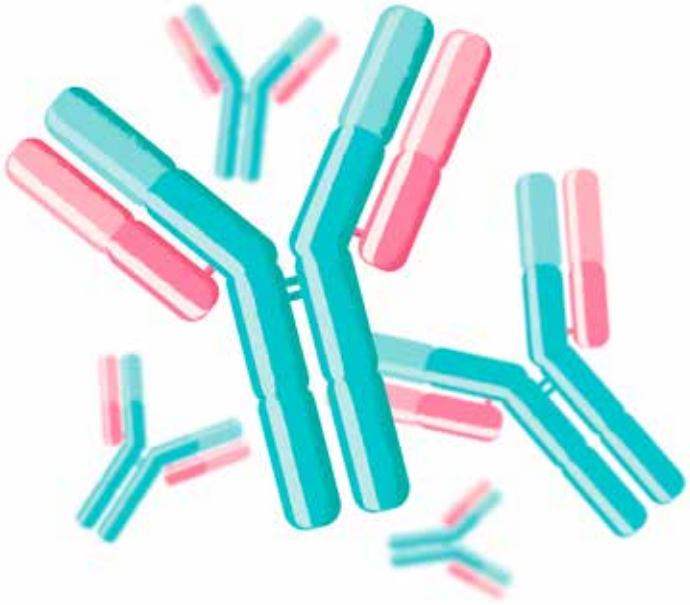
Autoimmunity

- Myasthenia gravis
- Rheumatic disease
- Vasculitis / Nephritis
- Thrombosis / APS
- Celiac disease
- Thyroid disease



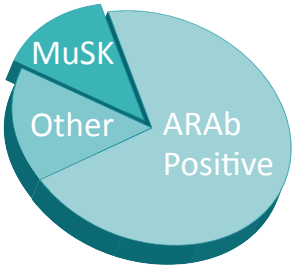
Autoimmune Diagnostics

A comprehensive product line for the detection of autoantibodies

Autoimmune diseases are chronic inflammatory processes with an indeterminate etiology. They may be either organ-specific, or systemic in nature; they preferentially affect females, and correlate with the production of disease associated autoantibodies (Auto-Ab). The impact of autoimmune disease on the cost of healthcare and adequate patient therapies makes accurate and reliable methods for the diagnosis, prognosis and monitoring of autoimmune disease absolutely necessary.

Myasthenia Gravis

Myasthenia gravis (MG) is a common autoimmune neuromuscular disease, in which the post-synaptic signal transmission between nerves and muscle is disturbed. It is characterized by muscle weakness that increases with exercise and improves with inactivity. In only 10% - 20% of patients, the weakness is limited to the eye muscles (ocular MG). In the majority of patients, the weakness spreads to other muscle groups (generalized MG).



Known autoantibodies associated with MG

- Acetylcholine Receptor antibodies (ARAb) are detectable in 80% - 90% of patients with generalized MG, and in approximately 50% with the ocular form
- Muscle-specific receptor tyrosine kinase (MuSK) antibodies are found in 40% - 70% of ARAb seronegative patients

Comprehensive diagnosis of MG involves detection of both acetylcholine receptor and MuSK antibodies

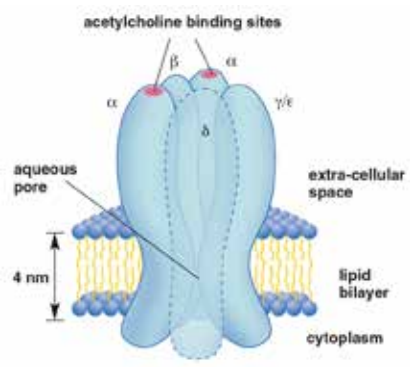
Measurement of Acetylcholine Receptor Antibodies (ARAb)

- All patients with suspected MG should be tested ("gold" standard for diagnosis and management of MG)
- The follow-up of titers can allow conclusions to prognosis of individual patients (a 50% reduction is often associated with marked improvement in the condition)
- The measurement of ARAb blocking antibodies is of additional value in patient management because there is a significant correlation between the degree of receptor blockade and generalization of muscle weakness

Products

Acetylcholine Receptor-Ab (ARAb) Binding RRA

Acetylcholine Receptor-Ab (ARAb) Blocking RIA



The IBL product range for acetylcholine receptor antibodies includes assays for the detection of binding antibodies and blocking antibodies

- We offer unique commercial assays using acetylcholine receptors isolated from fresh human muscle
- Our assays are sensitive, highly specific and easy to perform
- Excellent reproducibility has been achieved through 20 years' of experience in myasthenia gravis diagnostics

Measurement of Muscle-specific Receptor Tyrosine Kinase (MuSK) Antibodies

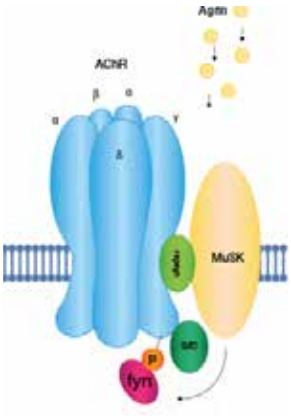
- Suspected myasthenia gravis in ARAb negative patients
- Consideration might be given to initial MuSK antibody testing together with ARAb in cases of clinically severe MG (primary with bulbar and facial symptoms)
- There is a correlation between disease severity and titer of MuSK antibodies

For the detection of MuSK antibodies we offer:

- The world's first commercially available ELISA
- Excellent clinical sensitivity (98.5%) and specificity (100%)
- High-performance assay (low cross-reactivity, good linearity and high precision)
- Qualitative (cut-off) & quantitative (standard curve) evaluation of results

Products

Muscle-specific Receptor Tyrosine Kinase (MuSK)-Ab ELISA



Agrin-induced clustering of acetylcholine receptors via MuSK

Rheumatic disease

According to the World Health Organization (WHO), rheumatic diseases form the most widespread health care problem in the world. The primary rheumatic diseases include rheumatoid arthritis (inflammation of various joints) and inflammatory diseases in connective tissues, such as systemic lupus erythematosus, Sjögren's syndrome, systemic sclerosis, dermato/polymyositis, and mixed connective tissue diseases (MCTD).

Rheumatoid Arthritis (RA)

Rheumatoid arthritis (RA) is a common, systemic autoimmune disease characterized by chronic inflammation of the synovial joints. Early diagnosis of RA is critical in preventing irreversible joint damage. Antibodies to cyclic citrullinated peptides have become established as the marker of choice for diagnosing early RA.

Products

Cyclic citrullinated peptides (CCP)-Ab ELISA

Rheuma factors (RF) IgA, IgG, IgM ELISA

ANA / ENA Screening and Differentiation

Major laboratory screening tests for detection of systemic rheumatic diseases is the detection of antinuclear antibodies (ANA) and antibodies against extractable nuclear antigens (ENA). Subsets of these antinuclear antibodies can be used for differential diagnosis of specific autoimmune diseases.

Disease

Active / inactive Systemic Lupus Erythematosus (SLE)

Medicine induced Systemic Lupus Erythematosus (SLE)

CREST syndrome / Scleroderma

Polymyositis / Dermatomyositis

Systemic Lupus Erythematosus (SLE)

Mixed Connective Tissue Diseasis (MCTD)

Neonatal LE / Sjögren's syndrome / SLE

Scleroderma

Products

Screen / Profile

ANA Screen 8 ELISA

ANA HEp-2 Screen ELISA

ANA Profile 8 ELISA

ENA Screen 6 ELISA

ENA Profile 6 ELISA

Single parameter / Differentiation

dsDNA-Ab ELISA; ssDNA-Ab ELISA

Histon-Ab ELISA

CENP-B-Ab ELISA

Jo-1-Ab ELISA

Sm-Ab ELISA

U1-RNP-Ab ELISA

SS-A/Ro-Ab ELISA; SS-B/La-Ab ELISA

Scl-70-Ab ELISA

Quantification of circulating immune complexes (CIC)

Circulating immune complexes are present in many individuals with Systemic Lupus Erythematosus (SLE) and Rheumatoid Arthritis (RA), especially with any of the vasculitic complications. Levels of CICs have been reported to show correlation with disease activity, in that higher levels are reported during active phases of the disease.

Products

CIC-C1q ELISA

CIC-C3d ELISA

Vasculitis / Nephritis

Vasculitis is a general term for a group of diseases characterized by inflammatory destruction of blood vessels. Anti-neutrophil cytoplasmic antibodies (ANCAs) are associated with systemic vasculitis, so called ANCA-associated vasculitides (Wegener's granulomatosis, Microscopic polyangiitis or Churg-Strauss syndrome). These antibodies act against nonnuclear cytoplasm in white blood cells and occur in two primary forms: cANCA (PR3-Ab) and pANCA (MPO-Ab).

Goodpasture's syndrome can elicit symptoms very similar to those of ANCA-associated vasculitis. Diagnostic indicators are antibodies against glomerular basement membrane (GBM) of the kidney.

Products

PR3 (c-ANCA)-Ab ELISA

MPO (p-ANCA)-Ab ELISA

GBM-Ab ELISA

Also available

Vasculitis screen ELISA

Cathepsin-Ab ELISA

Elastase-Ab ELISA

Thrombosis / APS

Anti-phospholipid syndrome (APS) is one of the most common autoimmune diseases. The features of APS include venous and arterial thrombosis, recurrent spontaneous abortions, neurological complications and phospholipid antibody expression. Antibodies against cardiolipin (CL) and beta2-gycoprotein 1 (beta2-GP1) are very important diagnostic markers and part of the classification criteria for APS. Antibodies against other phospholipids can also be of clinical value, especially if the antibodies listed above cannot be detected. It is known that patients with multiple phospholipid antibodies are at a higher risk of APS than those with cardiolipin antibodies alone.

Products

Screen / Profile

Beta2-Glycoprotein 1 Screen ELISA

Phospholipid Screen ELISA

Phospholipid IgG/IgM Screen ELISA

Phospholipid-8 Profile ELISA

Single parameter

Cardiolipin IgA, IgG, IgM ELISA

Beta2-Glycoprotein IgA, IgG, IgM ELISA

Annexin V-Ab ELISA

Thrombin-Ab ELISA

Prothrombin-Ab ELISA

Ethanolamine-Ab ELISA

Inositol-Ab ELISA

Serin-Ab ELISA

Phosphatidic acid-Ab ELISA

Serin-Prothrombin-Ab ELISA

Celiac disease

Celiac disease (CD) is a gluten-triggered, autoimmune mediated enteropathy (villous atrophy of the small intestine with resulting malabsorption symptoms) in genetically susceptible persons. It is characterized by a broad variety of clinically manifestations. Besides antibodies against the trigger agent gliadin (part of the gluten protein), antibodies against tissue transglutaminase (tTG) are a highly specific marker of celiac disease. Recently the use of deamidated gliadin peptides (modified gliadin peptides or MGP) in immunoassays has significantly improved the effectiveness of gliadin antibodies in the diagnosis of celiac disease.

With the novel approach to measuring antibodies against tissue transglutaminase neoepitopes (neoepitope = complex of deamidated gliadin peptides crosslinked with tissue transglutaminase) we offer an ideal screening tool for the diagnosis of coeliac disease by comparison with normal tissue translutaminase (tTG):

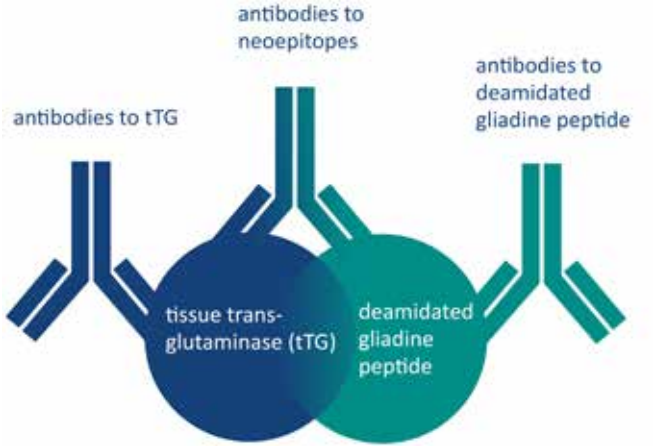
- Higher sensitivity than the classic tTG antigen
- Better correlation with biopsy findings
- Better detection in paediatric samples

Products

tissue Transglutaminase (Neoepitope) IgA, IgG ELISA

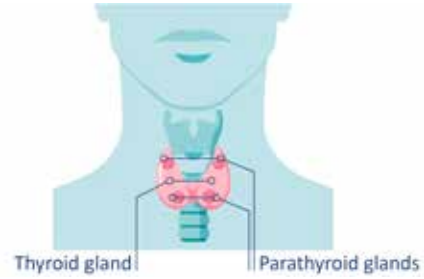
Gliadin IgA, IgG ELISA

Modified Gliadin Peptide (MGP) IgA, IgG ELISA



Thyroid disease

Autoimmune thyroiditis (AIT) is one of the most common human autoimmune diseases. Clinical manifestations are extremely variable, and symptoms range from hypothyroid to hyperthyroid. Thyroid peroxidase (TPO) is the major autoantigen in AIT. On this basis, there is a moderate positive correlation between antibody titers for TPO and a risk of future hypothyroidism. Graves' (or Basedow's) disease (GD) is the only autoimmune disease caused by stimulation of the target organ: clinical manifestations are hyperthyroidism and (often) endocrine opthalmopathy. TSH receptor autoantibodies should be measured for a diagnosis of GD.



Products

Thyroid Peroxidase (TPO)-Ab ELISA

Thyreoglobulin (Tg)-Ab ELISA

TSH-Receptor-Ab ELISA

Miscellaneous

Aside from the disease groups mentioned above, IBL International offers many more ELISAs for the detection of autoantibodies. One specialty in this range is the IBL Spermatozoa-Ab ELISA. Spermatozoa antibodies are produced by the body as a response against the proteins contained in sperm. They have harmful effects on sperm function (e.g. preventing motion, or sperm death) and are one of the main causes of immunological infertility. They can be found in males (antibodies to own sperm) or females (antibodies to partner‘s sperm).

Products

ASCA (Saccharomyces cervisiae) IgA, IgG ELISA

ASCA Screen ELISA

Intrinsic Factor-Ab ELISA

Parietalcell-Ab ELISA

LC1 (Liver cytosol type 1)-Ab ELISA

LKM-1 (Liver / Kidney microsomes)-Ab ELISA

Mitochondrial (AMA)-M2-Ab ELISA

Spermatozoa-Ab ELISA

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