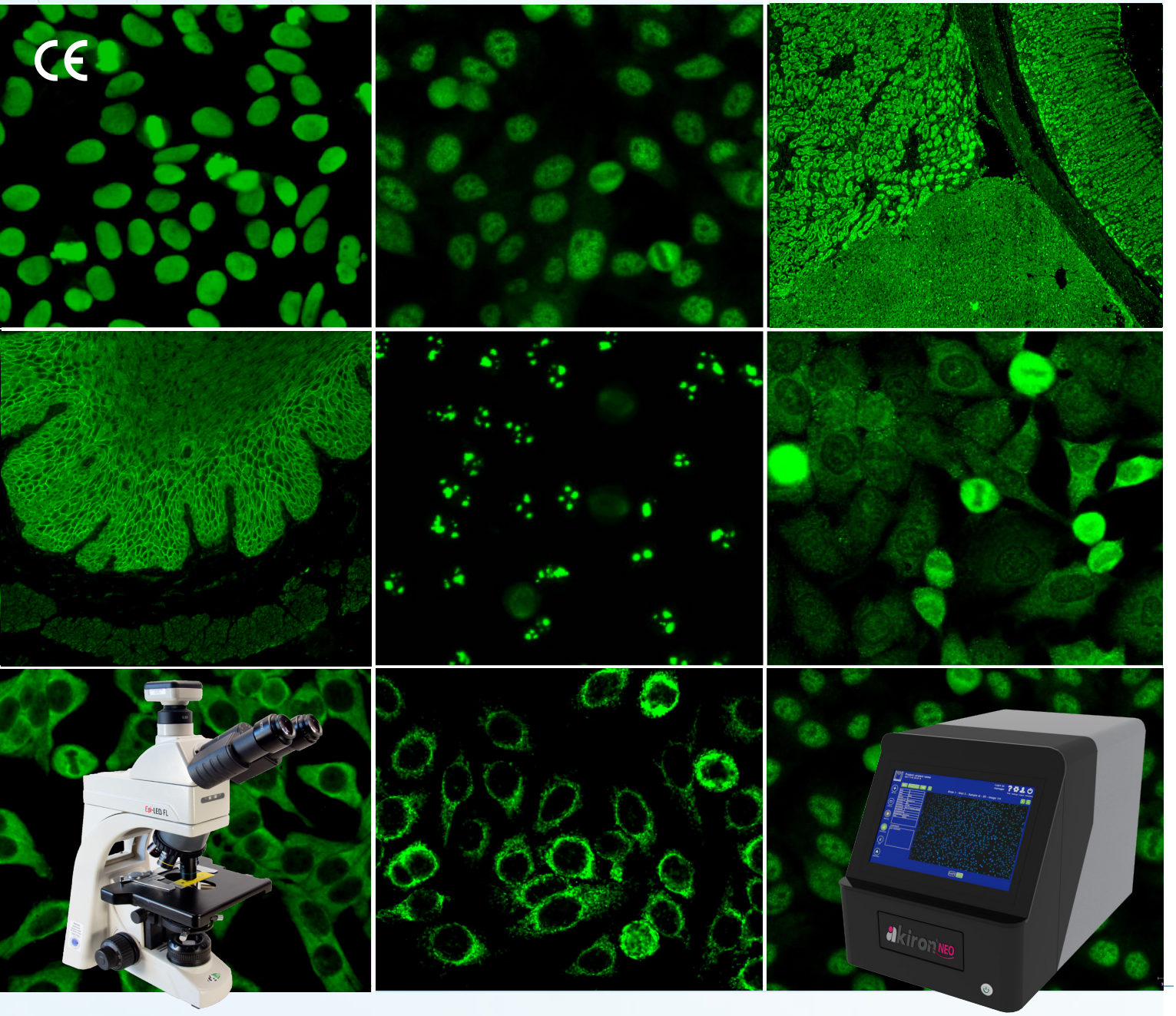
IFA

Immunofluorescence Assays

IFA Product Portfolio

MEDIPAN GA Generic Assays



Product Highlights

- High Sensitivity through Native Antigen Structure Preservation
- Broad Screening Capability for Autoimmune Diseases
- Suitable for Automated Imaging and Evaluation

Medipan & GA Generic Assays

Your Reliable Partners in Autoimmune Diagnostics

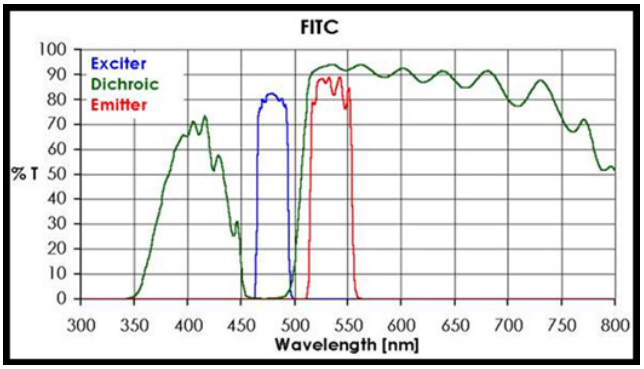
We are German market-leading companies in developing, manufacturing, and marketing *in vitro* diagnostic (IVD) assays and instruments. Together, we have extensive experience in IFA, ELISA, RIA, and LINE & Dot Immunoblot Assays for the diagnosis of rheumatic and other autoimmune diseases of neurological, vascular, hepatic, renal, or gastrointestinal origin. As a growing companies in the diagnostics market, we are looking for innovative research and distribution partners worldwide to strengthen our existing network of partners and customers.

We offer a comprehensive portfolio of tissue and cell-based IFA test systems for autoantibodies detection. Our high-quality solutions support precise diagnostics for autoimmune diseases, empowering healthcare professionals worldwide in accurate and reliable diagnostic practices.

Indirect Immunofluorescence Assay (IFA)

A Leading Method for Autoantibody Detection

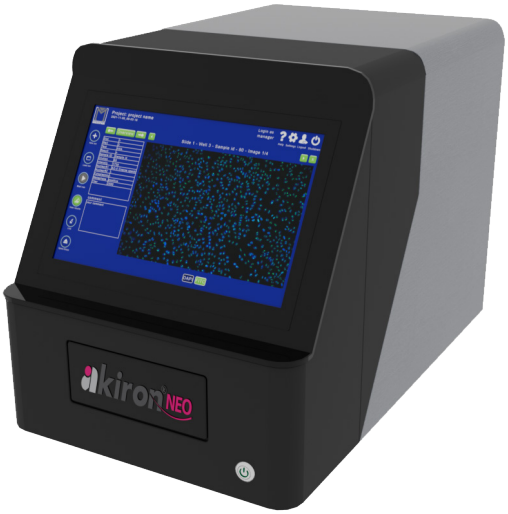
Indirect Immunofluorescence Assays (IFA) is a highly sensitive technique for detecting antibodies in samples by their selective binding to antigens at specific locations within cells or tissues. These bound antibodies are then labeled with a secondary antibody carrying a fluorescent dye. Upon exposure to excitation light, the fluorescent dye generates an emission that can be observed through a microscope ocular or detected by a camera system.



Depending on the specific location of the antigens within the cell or tissue substrate, typical fluorescence patterns are generated that can be correlated to specific antibodies and/or a specific clinical condition of the patient. The method is referred to as "indirect immunofluorescence" because the antibody itself is not directly visible, but rather the site of its binding.

Automated IFA

The akiron® NEO is a compact, automated benchtop IFA analyzer. It is designed for digital imaging of stained immunofluorescence slides without darkroom. The akiron® NEO enables objective positive/negative classification of cell based immunofluorescence assays (ANA, ANCA, CLIFT) in less than 35 seconds per well. At the same time, the software, based on artificial intelligence (AI), delivers automated pattern recognition, for ANA (up to 14 ICAP patterns , competent level) and ANCA (up to 5 patterns), and precise endpoint titer estimation, ensuring consistent and standardized interpretation. Validated assays for akiron® NEO enable standardized evaluation of a wide range of immunofluorescence tests, including antibody detection against HEp-2 cells (ANA), granulocytes (ANCA), CLIFT (dsDNA), multiple tissue substrates, as well as quantification of antigen specific antibodies using CytoBead® Technology.



CytoBead® Technology

Next Generation Multiparameter IFA Technology

CytoBead® Technology

The CytoBead® Technology is an innovative approach in the analysis of autoantibodies (AAb) associated with autoimmune diseases. It simplifies the interpretation of indirect immunofluorescence (IFA) on cellular and tissue substrates, as well as the quantitative multiplex analysis of AAb using addressable microbead immunoassays combining these processes into a single reaction environment. Fundamentally, the CytoBead® Technology integrates two crucial steps of AAb analysis:

1. Screening of Autoantibodies: By employing cell- or tissue-based immunofluorescence tests (IFA), the CytoBead® Technology allows for the screening of AAb in patient samples. This initial screening phase identifies potentially positive samples containing autoantibodies targeting various cellular components.

2. Confirmation of Autoantibodies: Through the use of microbead immunoassays, the CytoBead® Technology facilitates the differentiation of AAb and determination of their specificity.

Combining screening and confirmation into a single step significantly enhances the efficiency and accuracy of autoimmune disease diagnosis with CytoBead® Technology. Moreover, it enables multiplex analysis, allowing for the simultaneous detection of multiple AAb within a single sample.

Using specialized automated platforms, such the akiron® NEO systems, complements the CytoBead® Technology by facilitating the automated interpretation of results. These systems use advanced AI-based software to interpret fluorescence patterns and quantify the presence of AAb in patient samples.

With the CytoBead® Technology, laboratories can streamline their analysis processes, resulting in faster turnaround times, increased accuracy, and reduced variability in result interpretation. Ultimately, this integration enhances the efficiency and reliability of autoimmune disease diagnosis and management.[1,2]

CytoBead®

Available for:
ANA/ANA 2 | ANCA | CeliAK

[1] Sowa M., Hiemann R., Schierack P., Reinhold D., Conrad K., Roggenbuck. D., Next-Generation Autoantibody Testing by Combination of Screening and Confirmation—the CytoBead® Technology, Clinic Rev Allerg Immunol 2017, 53:87–104.

[2] Sowa M, Grossmann K, Scholz J, Röber N, Rödiger S, Schierack P, Conrad K, Roggenbuck D, Hiemann R., The CytoBead assay - a novel approach of multiparametric autoantibody analysis in the diagnostics of systemic autoimmune diseases, J Lab Med 2014, 38:309-17.

CytoBead® Technology

Next Generation Multiparameter IFA Technology

CytoBead® Technology

1 - Step Strategy

Screening & Confirmation 1.5 - 2h

Confirmed Results

- Save Time
- Save Material
- Save Costs

Standard workflow in Autoimmune Diagnostics

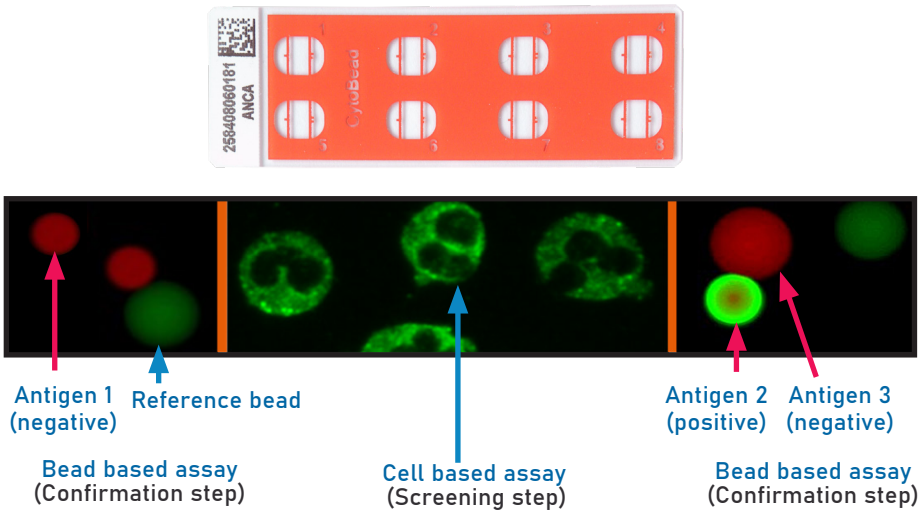
2 - Step Strategy

1. Screening test: 1.5 - 2h
2. Confirmation test: 1.5 - 2h

> 4h

Confirmed Results

How do CytoBead® assays work?



Compartmented slide well:

- Screening on cells (classic IFA) in the central compartment
- Confirmation with a bead based assay in the side compartments

Diagnosis of Systemic Autoimmune Diseases

Nuclear and Cytoplasmic Antibodies (ANA)

Systemic Autoimmune Diseases

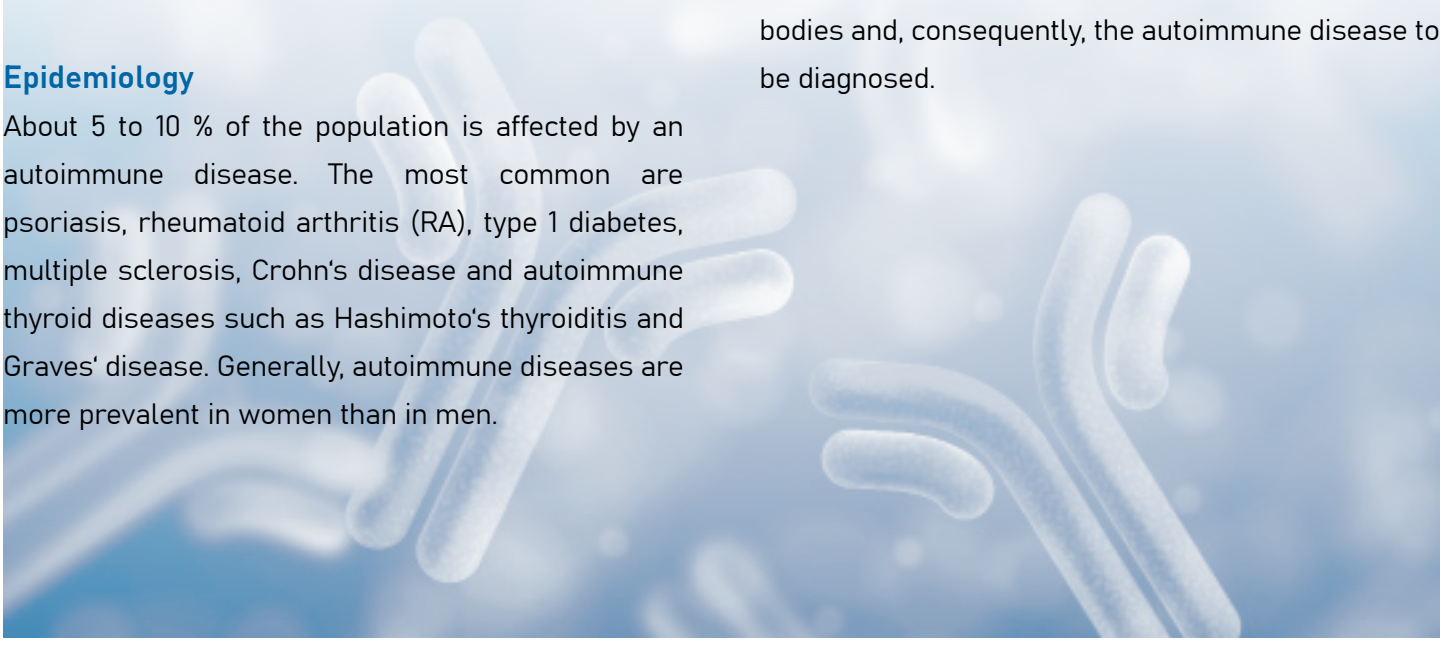
Autoimmune diseases are based on disorders of the immune system. These diseases occur when synthesized antibodies and autoreactive T cells attack endogenous structures, leading to local or systemic inflammatory reactions. Any organ or tissue can potentially be affected by an autoimmune disease. As a result, hundreds of autoimmune diseases have been identified, which can be divided into three general categories. Organ-specific autoimmune diseases affect individual organs. Non-organ-specific autoimmune diseases include, for example, collagenosis and other systemic, inflammatory rheumatic diseases. Often, antibodies against nuclear or cytoplasmic antigens, which are found in almost all cells in the body, are detected in this case. Additionally, different mixed forms of organ-specific and systemic autoimmune diseases have been described.

Epidemiology

About 5 to 10 % of the population is affected by an autoimmune disease. The most common are psoriasis, rheumatoid arthritis (RA), type 1 diabetes, multiple sclerosis, Crohn's disease and autoimmune thyroid diseases such as Hashimoto's thyroiditis and Graves' disease. Generally, autoimmune diseases are more prevalent in women than in men.

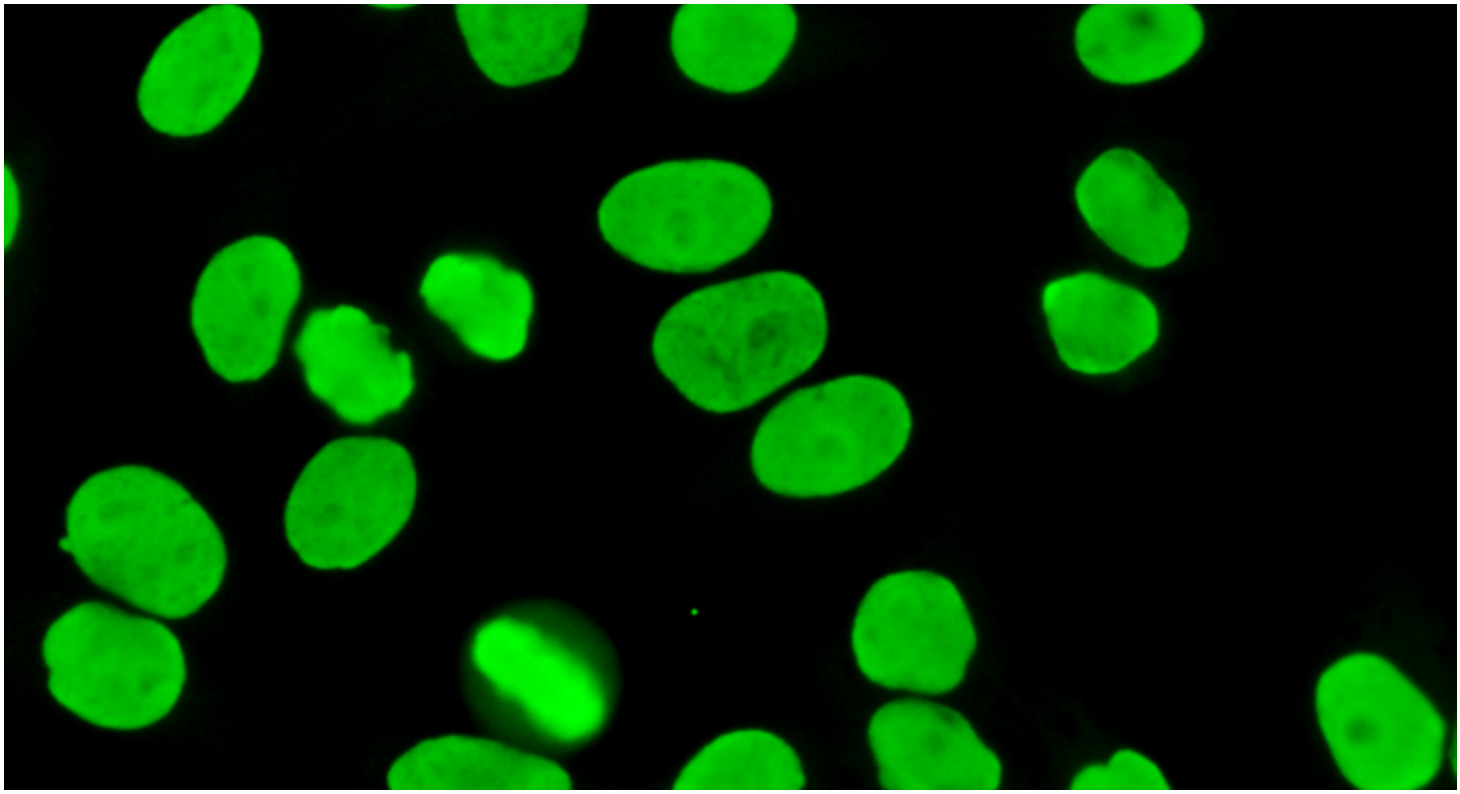
Diagnosis

The diagnosis of autoimmune diseases is made based of the clinical symptoms and laboratory medical examinations. Clinical suspicion is confirmed in particular by detectiing of antibodies against nuclear or cytoplasmic antigens (ANA), which are a characteristic of systemic autoimmune diseases such as systemic lupus erythematosus (SLE), Sjögren's syndrome, progressive systemic sclerosis (PSS), mixed connective tissue disease (MCTD), rheumatoid arthritis (RA), and dermatomyositis. Using HEp-2 cells fixed on slides for immunofluorescence assays (IFA) has proven to be particularly effective for determining autoantibodies. These immunoassays allow for highly sensitive detection of antibodies against nuclear or cytoplasmic antigens (ANA). The observed fluorescence pattern also indicates the antigen specificity of the detected antibodies and, consequently, the autoimmune disease to be diagnosed.



ANA Assays (HEp-2)

IFA for Determining Antibodies Against Nuclear and Cytoplasmic Antigens



The ANA HEp-2 plus and the AKLIDES® ANA plus are immunofluorescence assays (IFA) for the qualitative and semi-quantitative determination of IgG antibodies in human serum against nuclear and cytoplasmic antigens using HEp-2 cells. Both tests serve as an aid in the diagnosis of systemic autoimmune diseases in conjunction with other clinical and laboratory findings. The ANA HEp-2 plus is intended for visual interpretation. On the other hand, AKLIDES® ANA plus is designed for automated positive/negative classification, pattern recognition and precise endpoint titer estimation, using the akiron® NEO. This ensures consistent and standardized interpretation.

Manual	REF	Automated	REF
ANA HEp-2 plus	8101; 81040	AKLIDES® ANA plus	4063; 4065

CytoBead® Technology – ANA / ANA 2

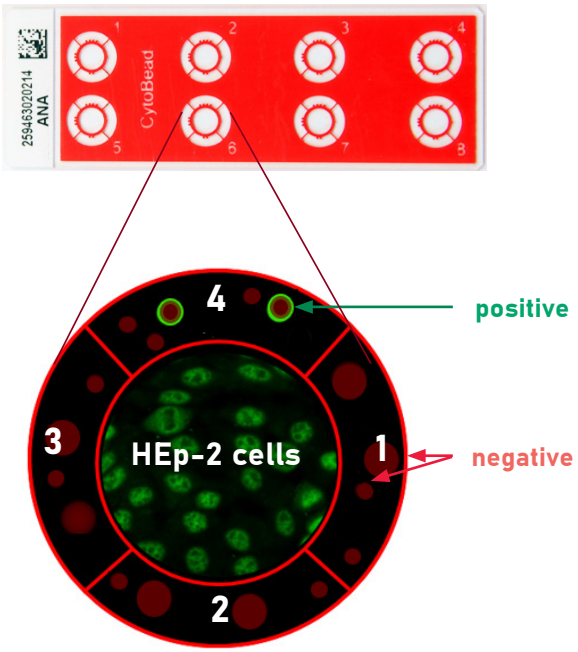
IFA for the Determination of ANA as well as Antibodies Against dsDNA, Scl-70, SS-A/Ro60, SS-A/Ro52, SS-B, Sm, Sm/RNP, and CENP-B or Jo-1

CytoBead® Technology

The CytoBead® Technology enables both the screening and confirmation of autoantibodies within a single test well. In the center, HEp-2 cells are used for indirect immunofluorescence to screen for the presence of autoantibodies in the patient sample. A green fluorescent signal indicates a positive result.

Surrounding the central area are microbeads coated with specific autoantigens. If these beads emit a green signal, the presence and specificity of certain autoantibodies are confirmed. A lack of fluorescence indicates a negative result for that particular autoantibody.

This integrated approach allows for fast, precise, and multiplex-capable diagnostics of autoimmune diseases.

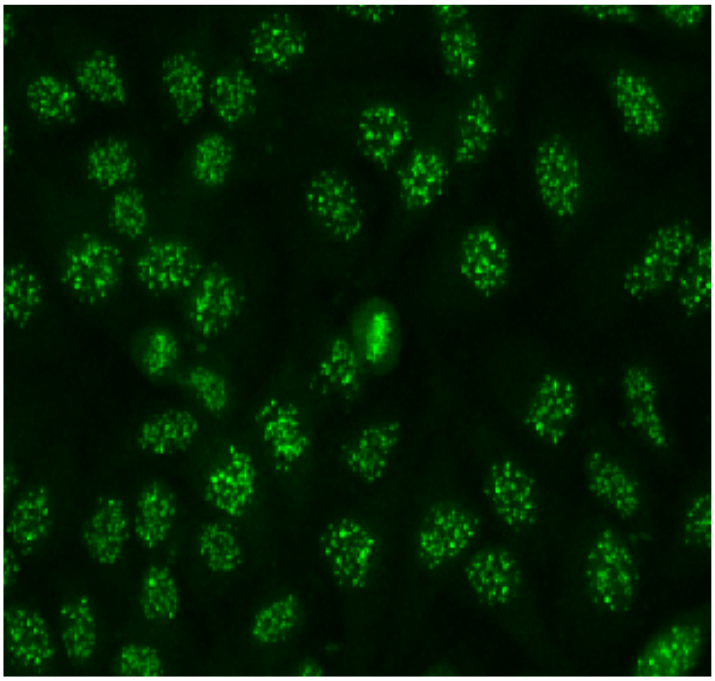


Manual	REF	Automated	REF
CytoBead® ANA IFA	8065	AKLIDES® CytoBead® ANA	4272
CytoBead® ANA 2 IFA	8220	AKLIDES® CytoBead® ANA 2	4277

CytoBead® Technology – ANA / ANA 2

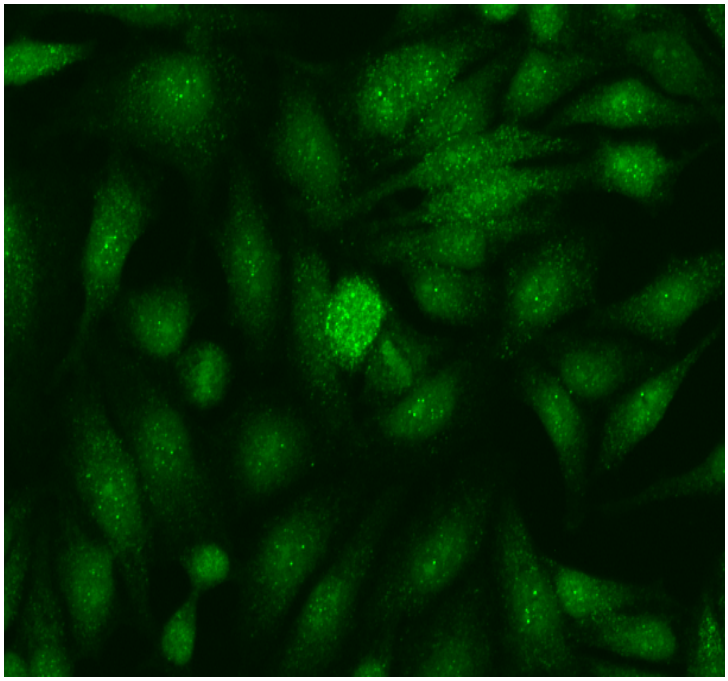
IFA for the Determination of ANA as well as Antibodies Against dsDNA, Scl-70, SS-A/Ro60, SS-A/Ro52, SS-B, Sm, Sm/RNP, and CENP-B or Jo-1

CytoBead® ANA



CENP-B

CytoBead® ANA 2



Jo-1

The CytoBead® ANA family tests are immunofluorescence assays (IFA) designed to detect IgG antibodies in human serum against nuclear and cytoplasmic antigens (ANA) as well as dsDNA, Scl-70, SS-A/Ro60, SS-A/Ro52, SS-B, Sm, Sm/RNP, and CENP-B or Jo-1. These assays serve as an aid in diagnosing systemic autoimmune diseases when used in conjunction with other clinical and laboratory findings.

The CytoBead® ANA and CytoBead® ANA 2 are intended for visual interpretation with qualitative and semi-quantitative detection of all the antibodies. On the other hand, the AKLIDES® CytoBead® ANA and AKLIDES® CytoBead® ANA 2 are designed for automated positive/negative classification, pattern recognition, and precise endpoint titer estimation, as well as the quantitative determination of antibodies against 8 different antigens, using the akiron® NEO. This ensures consistent and standardized interpretation.

Diagnosis of Myasthenia Gravis

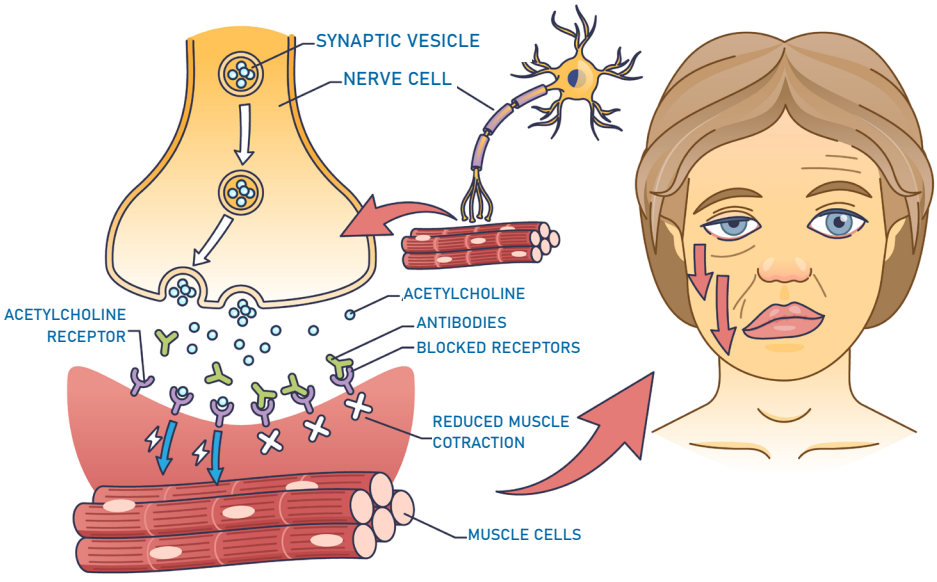
Muscle Specific Tyrosine Kinase (MuSK) Autoantibodies

Myasthenia gravis (MG)

Myasthenia gravis (MG) belongs to a group of neurological diseases characterized by impaired signal transmission between nerves and muscles. The clinical presentation is characterized by exercise-induced muscle weakness of the skeletal muscles, which typically increases during the course of the day and improves after periods of rest. MG is an autoimmune disease caused by autoantibodies against structures of the postsynaptic membrane in the area of the neuromuscular endplate of striated muscles.

Antibodies against the acetylcholine receptor (AChRAb) are by far the most common in MG, accounting for about 85% of cases. If these antibodies are not detectable, the condition is referred to as "seronegative MG". In these patients, antibodies against the muscle-specific tyrosine kinase (MuSK) are detected in up to 10% of cases. Other possible antibodies are directed against the lipoprotein receptor-related protein 4 (LRP4). In some patients with a high probability of suffering from MG, no antibodies can be detected.

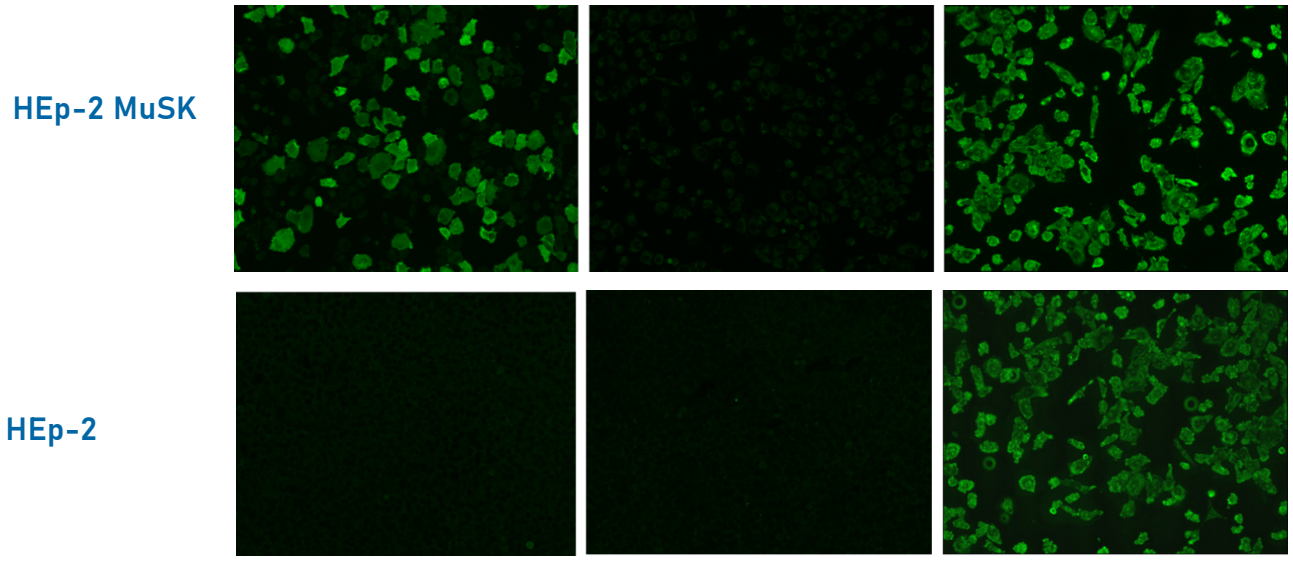
Myasthenia Gravis (MG)



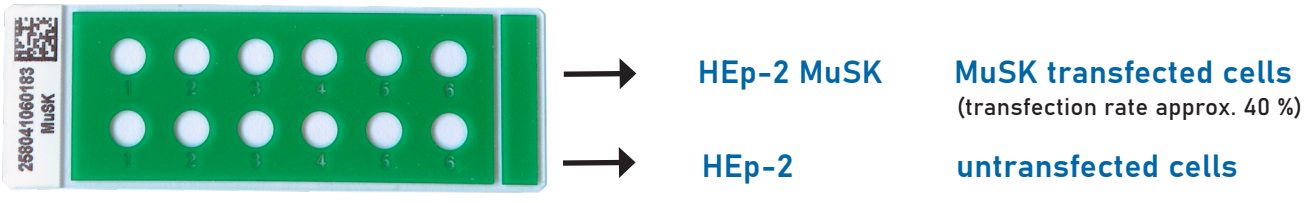
Anti-MuSK Assay (Transfected HEp-2)

IFA for Determining IgG Antibodies Against Muscle Specific Tyrosine Kinase

Parallel processing to exclude cross-reactivity and unspecific binding



The Anti-MuSK IFA is an immunofluorescence assay (IFA) for the qualitative and semi-quantitative determination of IgG antibodies in human serum against muscle specific tyrosine kinase (MuSK) on transfected HEp-2 cells. The Anti-MuSK IFA serves as an aid in the diagnosis of myasthenia gravis (MG) in conjunction with other clinical and laboratory findings. The immunoassay is intended for visual interpretation.



Anti-MuSK IFA slide

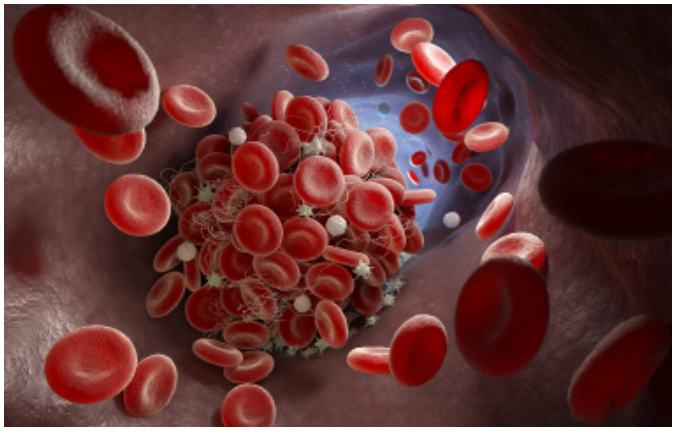
Manual	REF
Anti MuSK	8049

Diagnosis of Systemic Vasculitis

ANCA Antibodies

Systemic Vasculitis

Systemic vasculitis (SV) is characterized by inflammation of blood vessel walls, leading to morphological changes that can affect both arteries and veins. Clinical manifestations are often non-specific, such as fatigue, fever, and weight loss, with the severity and progression depending on the vascular territory involved. Anti-neutrophil cytoplasmic antibodies (ANCA) are a group of autoantibodies primarily associated with systemic vasculitides, especially small vessel vasculitis.



These antibodies are directed against components of the neutrophil cytoplasm and play a central role both in the pathogenesis and diagnosis of several ANCA-associated vasculitides, including granulomatosis with polyangiitis (GPA), microscopic polyangiitis (MPA), and eosinophilic granulomatosis with polyangiitis (EGPA).

Diagnosis

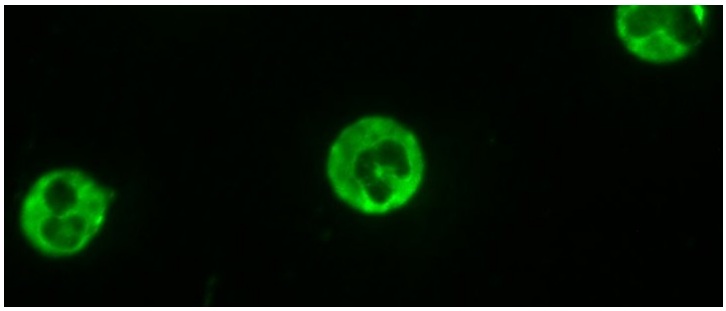
A key diagnostic tool for SV is the detection of ANCA, typically performed through indirect immunofluorescence using ethanol-fixed human neutrophils. ANCA are classified into two main patterns based on their fluorescence distribution: cytoplasmic ANCA (cANCA) and perinuclear ANCA (pANCA).

Ethanol fixation disrupts neutrophil granule membranes, causing positively charged proteins to migrate toward the negatively charged nucleus. This redistribution forms the basis for ANCA pattern recognition: cANCA shows granular cytoplasmic fluorescence, while pANCA displays a perinuclear pattern. However, pANCA can resemble fluorescence from antinuclear antibodies (ANA), making distinction challenging. To resolve this, formalin fixation is used in parallel, as it preserves cellular structure and prevents protein redistribution. This allows for clearer differentiation between true pANCA and ANA patterns, increasing the specificity of ANCA interpretation in immunofluorescence assays.

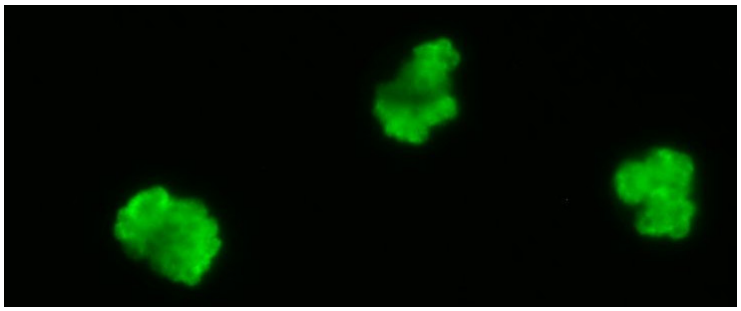
Ethanol Fixed Granulocytes Assays

IFA for Determining IgG Antibodies Against Neutrophil Cytoplasmic Antigens

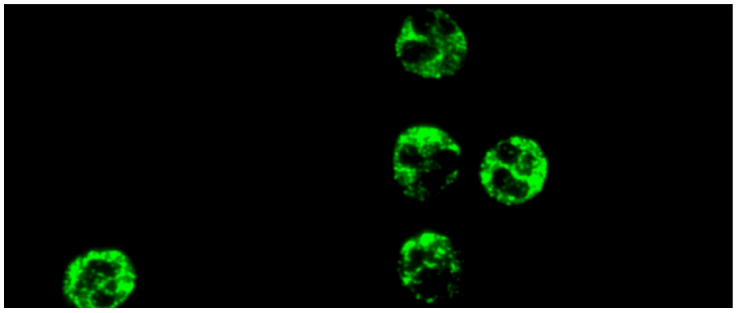
cANCA on ethanol fixed neutrophils (anti-PR3)



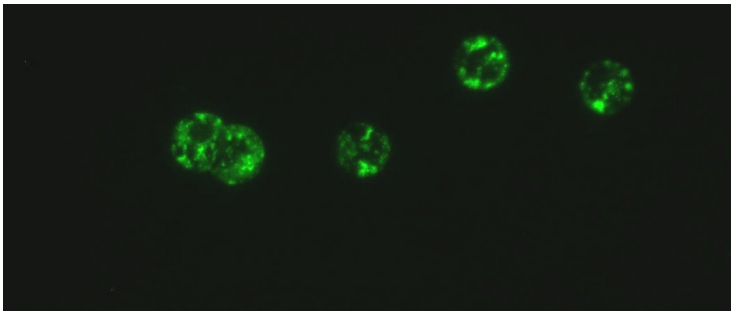
pANCA on ethanol fixed neutrophils (anti-MPO)



cANCA by PR3 antibodies on formalin fixed neutrophils



cANCA by MPO antibodies on formalin fixed neutrophils



The cANCA IFA Plus is a manual immunofluorescence test designed for the detection of cytoplasmic ANCA (cANCA) patterns using ethanol-fixed human granulocytes. The pANCA IFA Plus assay is based on formalin-fixed human granulocytes and is used for the detection of perinuclear ANCA (pANCA) patterns. They require visual interpretation by trained personnel and plays a key role in the diagnosis of systemic vasculitis.

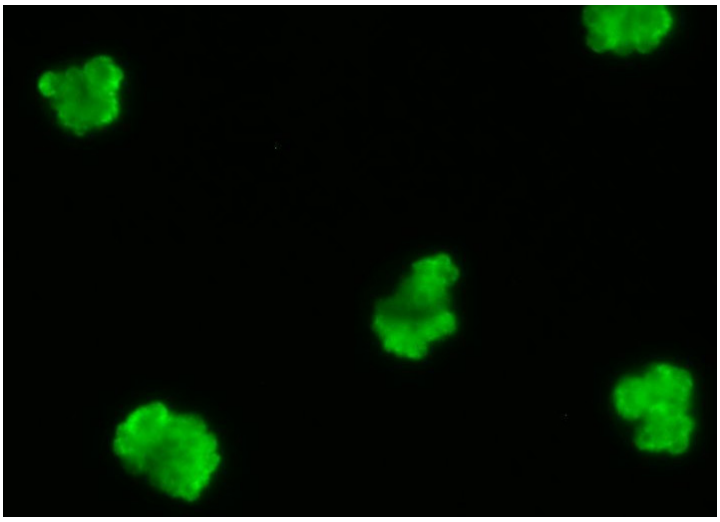
The corresponding automated assay, AKLIDES® cANCA, and AKLIDES® pANCA use the same biological principle but is performed on the akiron® NEO, allowing for standardized evaluation, automated positive/negative classification, pattern recognition, and objective titer estimation.

Manual	REF	Automated	REF
cANCA IFA plus	87061	AKLIDES® cANCA	4060
pANCA IFA plus	87161	AKLIDES® pANCA	4072

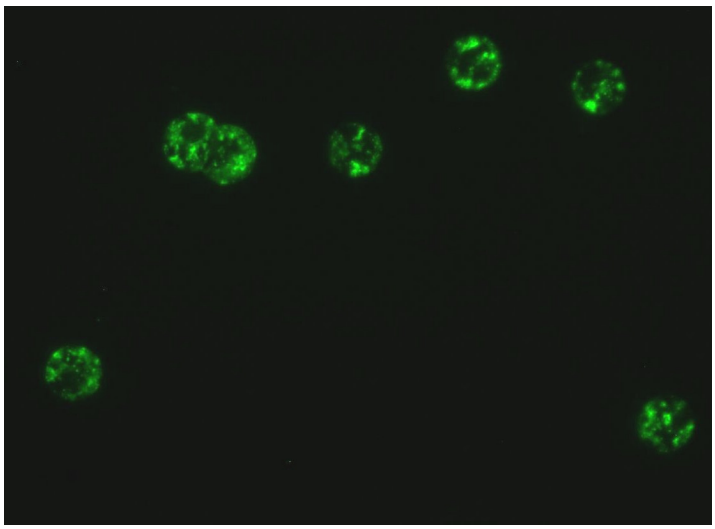
Ethanol and Formalin Fixed Granulocytes Assays

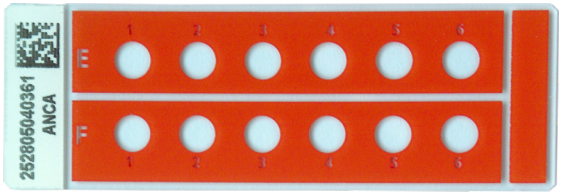
IFA for Determining IgG Antibodies Against Neutrophil Cytoplasmic Antigens

pANCA on ethanol fixed neutrophils (anti-MPO)



cANCA on formalin fixed neutrophils (anti-MPO)





ethanol fixed neutrophils

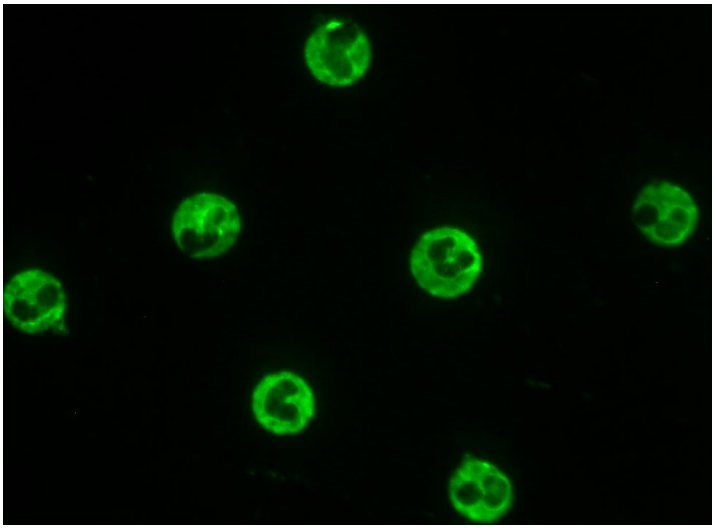
formalin fixed neutrophils

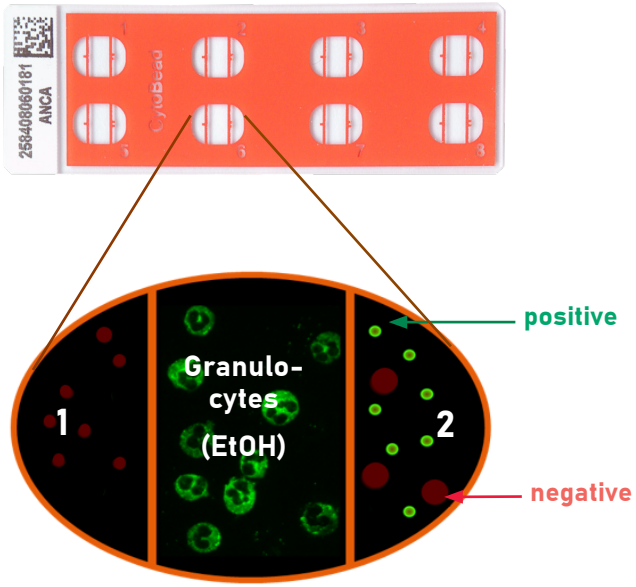
The ANCA IFA dual assay combines both ethanol- and formalin-fixed substrates in a single slide, enabling the simultaneous detection of cANCA and pANCA patterns in one test. This dual approach increases diagnostic accuracy and saves time in complex cases. The automated version, AKLIDES® ANCA dual, integrates this concept into a fully digital workflow, offering automated dual-pattern recognition and precise titer determination ideal for laboratories seeking maximum efficiency with uncompromisable quality using the akiron® NEO.

Manual	REF	Automated	REF
ANCA IFA dual	87261	AKLIDES® ANCA dual	4472

CytoBead® Technology – ANCA

IFA for Determining IgG Antibodies Against Neutrophil Cytoplasmic Antigens (ANCA) as well as PR3, MPO and GBM





The CytoBead® ANCA and the AKLIDES® CytoBead® ANCA are immunofluorescence assays (IFA) designed to detect IgG antibodies in human serum against neutrophil cytoplasmic antigens (ANCA) as well as proteinase 3 (PR3), myeloperoxidase (MPO), and glomerular basement membrane (GBM). These assays serve as an aid in diagnosing systemic vasculitis and autoimmune renal disorders when used in conjunction with other clinical and laboratory findings.

The CytoBead® ANCA is intended for visual interpretation with qualitative and semi-quantitative detection of all the antibodies. On the other hand, the AKLIDES® CytoBead® ANCA is designed for automated positive/negative classification, pattern recognition, and precise endpoint titer estimation, as well as the quantitative determination of antibodies against PR3, MPO, and GBM, using the akiron® NEO. This ensures consistent and standardized interpretation.

Manual	REF	Automated	REF
CytoBead® ANCA	8063	AKLIDES® CytoBead® ANCA	4270

Diagnosis of Systemic Lupus Erythematosus

Native Double-Stranded DNA (nDNA) Antibodies

Systemic lupus erythematosus (SLE)

SLE is an autoimmune disease characterized by the production of antinuclear antibodies (ANAs), specifically those that target native double-stranded deoxyribonucleic acid (dsDNA). SLE is rare and it affects women more frequently than men. Depending on which organs or organ systems are affected, SLE can manifest with different symptoms, that may also change over the course of the disease. Butterfly erythema occurs in a large number of patients and spreads symmetrically from the bridge of the nose to the cheeks. Additionally, common symptoms includinge fatigue, fever, and weight loss are often described.

Diagnosis

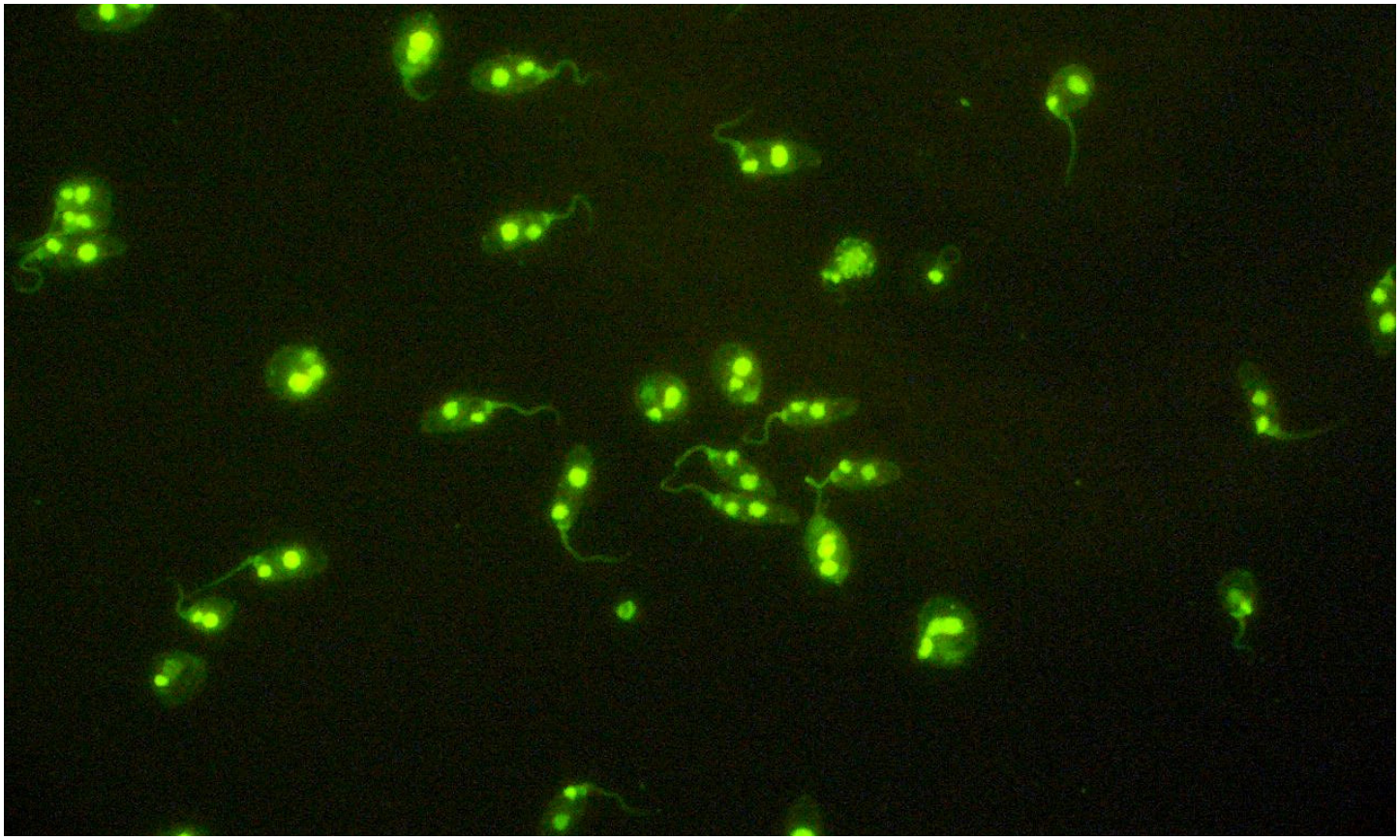
The diagnosis is made on the basis of the clinical symptoms and laboratory medical examinations. Clinical suspicion is paricularly based in particular on the detection of anti-nuclear antibodies. Antibodies against nDNA are pathognomonic for SLE. These antibodies occur in about 65 % of patients and, alongside antibodies against the Smith antigen (Sm) and phospholipids, are part of the classification criteria established by American and European rheumatologists (ACR/EULAR).

Detection of Antibodies against dsDNA

Crithidia luciliae is a eukaryotic, protozoan parasite of the Trypanosomatidae family. A so-called kinetoplast in a large mitochondrion, which essentially consists of circular nDNA, is characteristic of this microorganism. The high concentration of DNA in the kinetoplast, coupled with the absence of other human nuclear antigens, makes *C. luciliae* valuable for detecting antibodies against nDNA immunofluorescence test (CLIFT).

nDNA Assays (CLIFT)

IFA for Determining IgG Antibodies Against nDNA



The nDNA IFA plus and the AKLIDES® nDNA are immunofluorescence assays (IFA) for the qualitative and semi-quantitative determination of IgG antibodies in human serum against native double-stranded DNA using *Crithidia luciliae*. Both tests serve as an aid in the diagnosis of systemic lupus erythematosus in conjunction with other clinical and laboratory findings. The nDNA IFA plus is intended for visual interpretation. On the other hand, AKLIDES® nDNA plus is designed for automated positive/negative classification, using the akiron® NEO, ensuring consistent and standardized interpretation.

Manual	REF	Automated	REF
nDNA IFA plus	81050; 81100	AKLIDES® nDNA	4082; 4083

Diagnosis of Systemic Autoimmune and Disorders

Liver, Kidney, Stomach (LKS) Antibodies

The appearance of autoantibodies directed against components of the cell nucleus is characteristically associated with systemic autoimmune diseases, especially; systemic lupus erythematosus (SLE), Sjögren's syndrome, progressive systemic sclerosis (PSS), mixed connective tissue disease (MCTD), rheumatoid arthritis (RA) and dermatomyositis. These antibodies interfere with the cellular and/or humoral immune response, which typically occurs in response to external stimuli. Under certain circumstances , they may turn against the body itself, causing various disorders, known as autoimmune diseases.

Anti-mitochondrial antibodies (AMA) primarily interact with the phospholipid-rich inner membrane of mitochondria. The appearance of AMA is mostly evident in diseases such as primary biliary cirrhosis, pseudo-lupus erythematosus syndrome and different forms of chronic aggressive hepatitis. As a diagnostic indicator, elevated AMA titers are primarily associated with non-suppurating gallbladder infections or primary biliary cirrhosis. In such cases, antibodies are seen prior to the clinical manifestations and are not significantly affected by therapy during the course of the disease. Reduced antibody titers are observed with scleroderma, Sjörgen syndrome, rheumatoid arthritis and other autoimmune disorders.

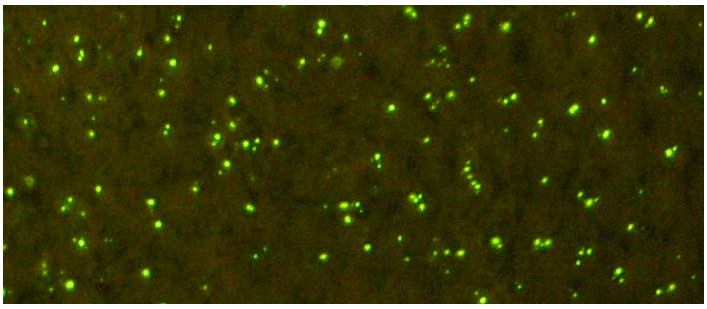
Antibodies against smooth, unstriated, muscle (ASMA) occur in various liver diseases, especially in acute and chronic hepatitis, primary biliary cirrhosis and other types of liver cirrhosis. In addition, the detection of ASMA supports the diagnosis of SLE, breast and ovarian carcinoma, infectious mononucleosis, and malignant melanomas.

Pernicious anemia is generally due to circulating antibodies against the structures of the parietal cell structures in the gastric mucosa (APCA). They may also be detected in other stomach diseases such as chronic atrophic gastritis, gastric ulcers, thyroid diseases (Hashimoto´s thyroiditis, myxoedema), and rarely with hypoferric anemia, diabetes mellitus, and in older patients.

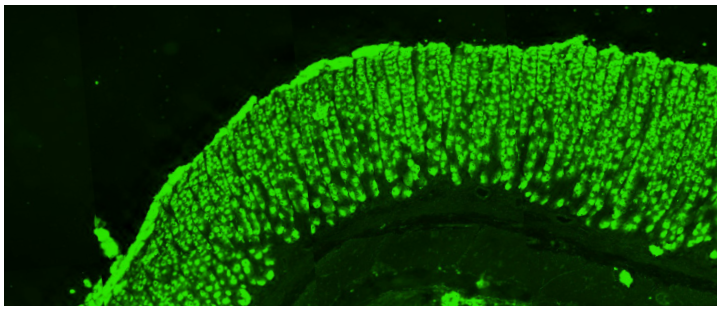
Triple Tissues (LKS) Assays

IFA for Determining IgG Antibodies (ANA/AMA/ASMA/APCA)

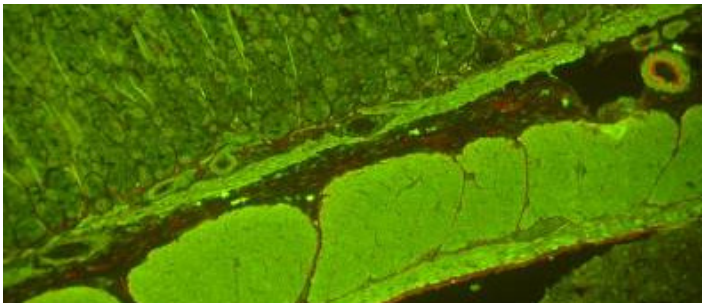
ANA



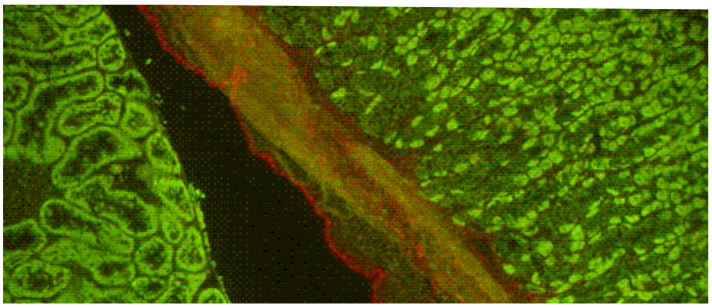
APCA



ASMA



AMA



The Triple IFA and the AKLIDES® Triple are immunofluorescence assays (IFA) for the qualitative and semi-quantitative determination of IgG antibodies (ANA, AMA, ASMA, APCA) in human serum on tissue sections of rat liver, stomach, and kidney. Both tests serve as an aid in the diagnosis of diagnosis of autoimmune diseases in conjunction with other clinical and laboratory findings. The Triple IFA is intended for visual interpretation, while the AKLIDES® Triple is designed for automated imaging using the akiron® NEO.

Manual	REF	Automated	REF
Triple IFA	**85048; 85096**	AKLIDES® Triple	**4121; 4122**

Diagnosis of Autoimmun Liver Disease

Anti-mitochondrial antibodies (AMA)

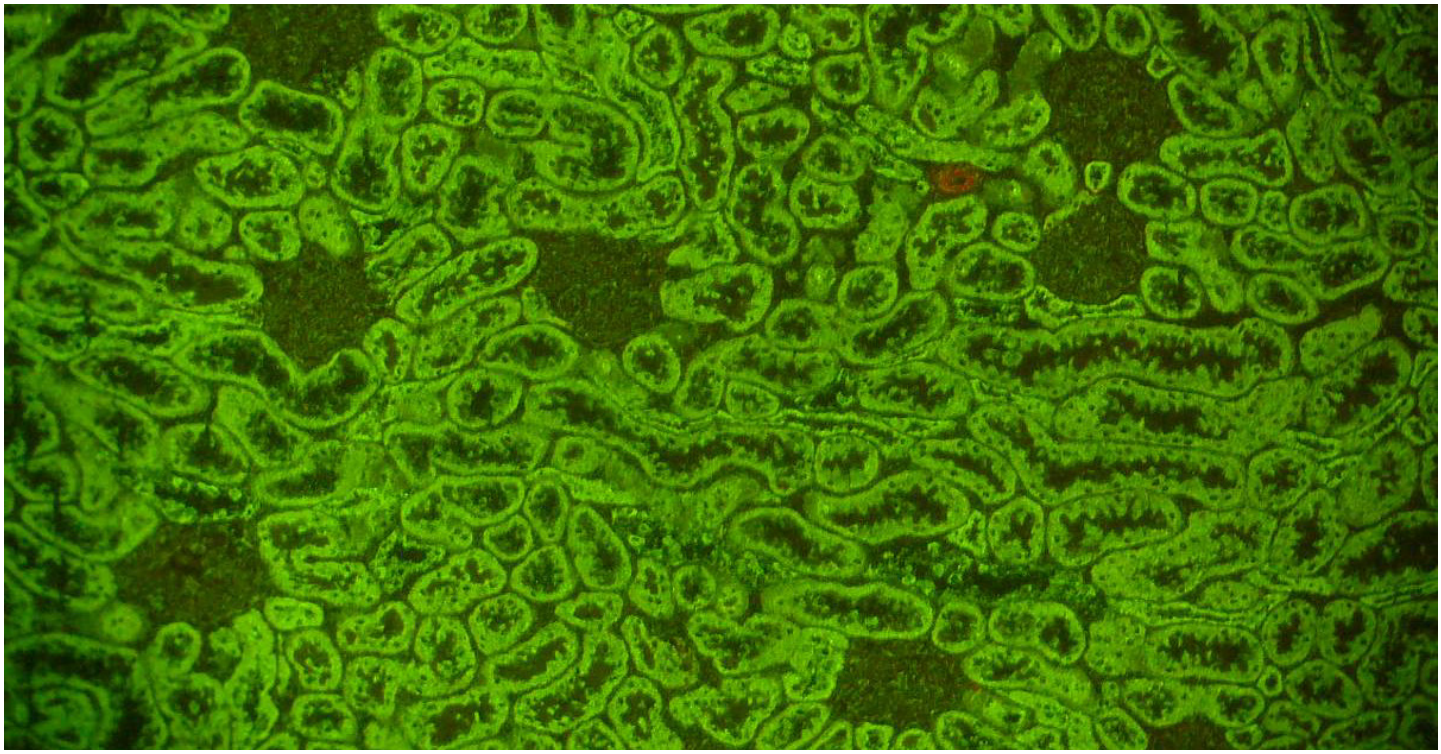
Autoimmune diseases are caused by disorders specifically in the cellular and/or humoral responses, which cause the immune system to mistakenly attack the body's own cells. These self-directed immune reactions result in various diseases. An important marker of autoimmune conditions is the presence of anti-mitochondrial antibodies (AMA), which primarily target the inner mitochondrial membrane. This membrane is particularly rich in phospholipids, which leads to its frequent involvement in AMA activity. AMAs are most commonly associated with diseases such as primary biliary cirrhosis (PBC), pseudo-lupus erythematosus syndrome, an certain forms of chronic aggressive hepatitis.

High levels of AMA are especially prevalent in PBC and non-suppurative gallbladder infections, with positive results observed in approximately 90% of PBC cases. Notably, these antibodies tend to appear before clinical symptoms manifest, serving as an early diagnostic marker. Moreover, once present, the antibody levels remain largely unaffected by therapeutic interventions throughout the course of the disease. Conversely, lower AMA titers can occur in a range of other autoimmune diseases, such as scleroderma, Sjögren syndrome, and rheumatoid arthritis.

Since mitochondria are present in nearly all cell types, AMAs can be detected using indirect immunofluorescence on various tissues. Rat kidney tissue is commonly employed as a reference substrate in this diagnostic technique. The characteristic pattern that is observed involves a fine granular fluorescence within the cytoplasm of kidney tubule cells. Distal tubules exhibit a more intense fluorescence pattern compared to proximal tubules, reflecting their higher mitochondrial content. This differential staining reliably identifies AMAs and assesses their presence in the context of autoimmune diseases.

AMA Assays

IFA for Determining IgG Antibodies Against Mitochondrial Antigens



The AMA IFA and the AKLIDES® AMA are immunofluorescence assays (IFA) for the qualitative and semi-quantitative determination of IgG antibodies in human serum against mitochondrial antigens on tissue sections of rat kidney. Both tests serve as an aid in the diagnosis of diagnosis of primary biliary cirrhosis (PBC) in conjunction with other clinical and laboratory findings. The AMA IFA is intended for visual interpretation, while the AKLIDES® AMA is designed for automated imaging using the akiron® NEO.

Manual	REF	Automated	REF
AMA IFA	83048	AKLIDES® AMA	4117

Diagnosis of Autoimmune Liver Disease

Smooth, Unstriated, Muscles Antibodies (ASMA)

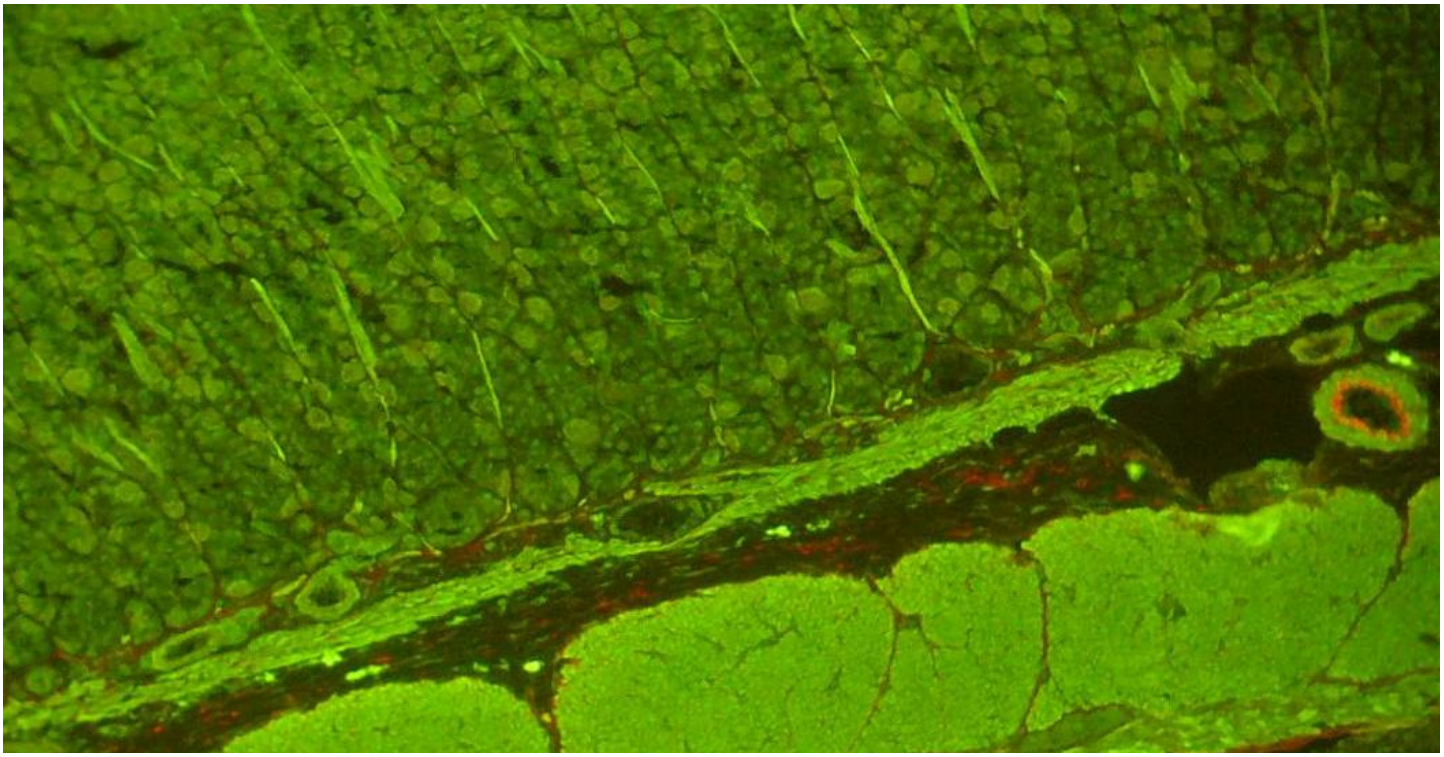
Liver diseases, including acute and chronic hepatitis, primary biliary cirrhosis, and other forms of liver cirrhosis, are commonly associated with the presence of antibodies against smooth, unstriated, muscles. These antibodies, known as anti-smooth muscle antibodies (ASMA), serve as a key diagnostic marker for these conditions. Detecting ASMA can significantly aid in diagnosing liver diseases because their presence is a characteristic feature of the immune response seen in such disorders. In addition to liver diseases, ASMA is also essential for diagnosing other autoimmune and infectious conditions, including systemic lupus erythematosus (SLE), infectious mononucleosis, and various cancers, such as breast and ovarian carcinomas, as well as malignant melanomas.

ASMA is crucial for identifying autoimmune diseases, which result from a malfunction in the body's immune system. This malfunction causes the immune system to mistakenly attack the body's own cells, leading to the development of a variety of diseases. Autoimmune diseases occur when the immune system targets and damages tissues, leading to inflammation and other complications. Detecting ASMA provides valuable diagnostic information in these cases, helping physicians identify and differentiate between various conditions with overlapping symptoms.

Indirect immunofluorescence assays are commonly used to detect ASMA. These assays employ rat stomach tissue to visualize the presence of ASMA. The method involves staining the smooth muscle fibers of the muscularis mucosa, or the tunica muscularis ventriculi, and examining the resulting fluorescence patterns. The fluorescence can also be seen in the inter-glandular contractile fibers within the stomach mucosa. This staining method helps to identify the presence of antibodies and confirm a related disease diagnosis. Fluorescence microscopy allows for clear visualization of the smooth muscle fibers, and the presence of fluorescence indicates the presence of the antibodies against smooth muscle tissue, making it a reliable method for diagnosis.

ASMA Assays

IFA for Determining IgG Antibodies Against Smooth Muscle



The ASMA IFA and the AKLIDES® ASMA are immunofluorescence assays (IFA) for the qualitative and semi-quantitative determination of IgG antibodies in human serum against smooth muscle on tissue sections of rat stomach. Both tests serve as an aid in the diagnosis of diagnosis of autoimmune liver diseases in conjunction with other clinical and laboratory findings. The ASMA IFA is intended for visual interpretation, while the AKLIDES® ASMA is designed for automated imaging using the akiron® NEO.

Manual	REF	Automated	REF
ASMA IFA	84048	AKLIDES® ASMA	4119

Diagnosis of Celiac Disease

Endomysial Antibodies (EmA)

Celiac Disease

Celiac disease, also known as gluten-sensitive enteropathy, is an autoimmune disorder that primarily affects the small intestine. It causes mucosal damage, including villous atrophy and flattening of the intestinal lining, which impairs nutrient absorption and leads to deficiencies. Damage to the enterocyte membrane reduces brush border enzyme activity, further contributing to malabsorption and triggering local immune responses and inflammation.

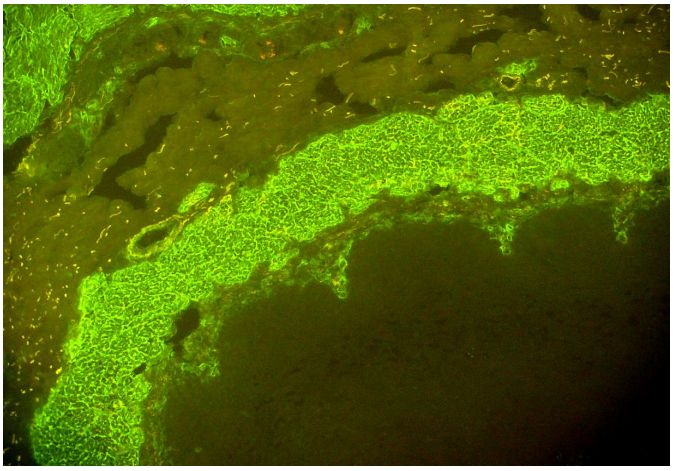
A related condition, dermatitis herpetiformis, is a chronic autoimmune skin disease often associated with celiac disease. It presents with subepidermal blisters and IgA deposits along the basement membrane, accompanied by neutrophil and eosinophil infiltration, reflecting a similar underlying immune mechanism.

Diagnosis of celiac disease relies on serological testing, especially the detection of IgA and IgG antibodies against tissue transglutaminase (tTG), deamidated gliadlin (DG) and endomysial antibodies (EmA). EmA IgA is particularly accurate, with approximately 98% specificity and over 95% sensitivity, enabling reliable diagnosis and early intervention.

EmA Assays

IFA for Determining IgA Antibodies Against Endomysium

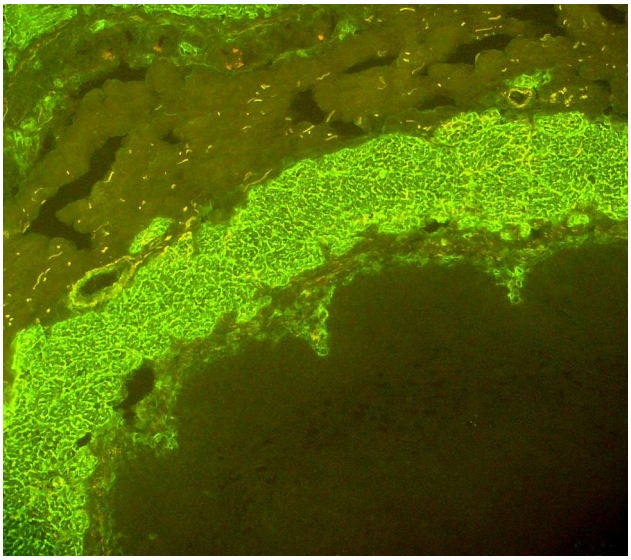
The EmA IFA and the AKLIDES® EmA are immunofluorescence assays (IFA) designed for the qualitative and semi-quantitative detection of IgA antibodies in human serum against endomysium on tissue sections of monkey esophagus. Both tests serve as an aid in the diagnosis of celiac disease in conjunction with other clinical and laboratory findings. The EmA IFA is intended for visual interpretation, while the AKLIDES® EmA is designed for automated imaging using the akiron® NEO.

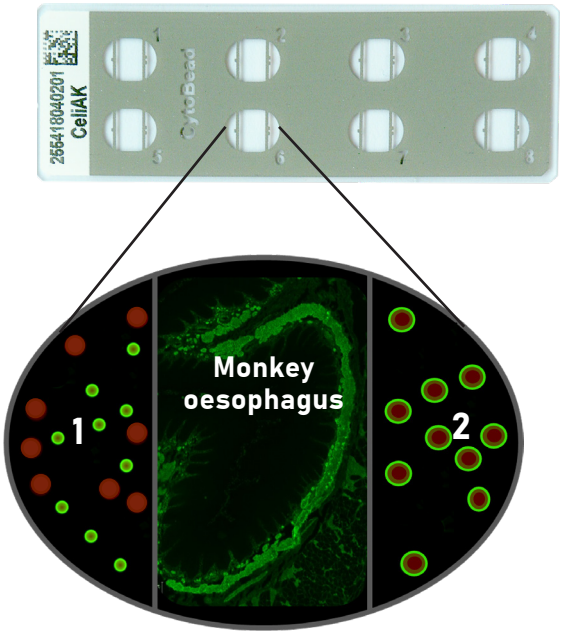


Manual	REF	Automated	REF
EmA IFA	86048; 86096	AKLIDES® EmA	4131; 4132

CytoBead® Technology – CeliAK

IFA for the Determination of IgA or IgG Antibodies Against Endomysium, Tissue Transglutaminase (tTG) and Deamidated Gliadin (DG) as well as for Control of IgA Antibodies





The CytoBead® CeliAK and AKLIDES® CytoBead® CeliAK are immunofluorescence assays (IFA) designed to detect IgA or IgG antibodies in human serum against endomysium (EmA), tissue transglutaminase (tTG), and deamidated gliadin (DG), as well as for IgA antibody control. These assays serve as an aid in diagnosing celiac disease when used in conjunction with other clinical and laboratory findings.

The CytoBead® CeliAK is intended for visual interpretation with qualitative and semi-quantitative detection of all the antibodies. On the other hand, the AKLIDES® CytoBead® CeliAK is designed for automated imaging of the endomysial fluorescence, as well as the quantitative determination of antibodies against tTG, DG well for total IgA antibodies using the akiron® NEO. This ensures consistent and standardized interpretation.

Manual	REF	Automated	REF
CytoBead® CeliAK	8064	AKLIDES® CytoBead® CeliAK	4271

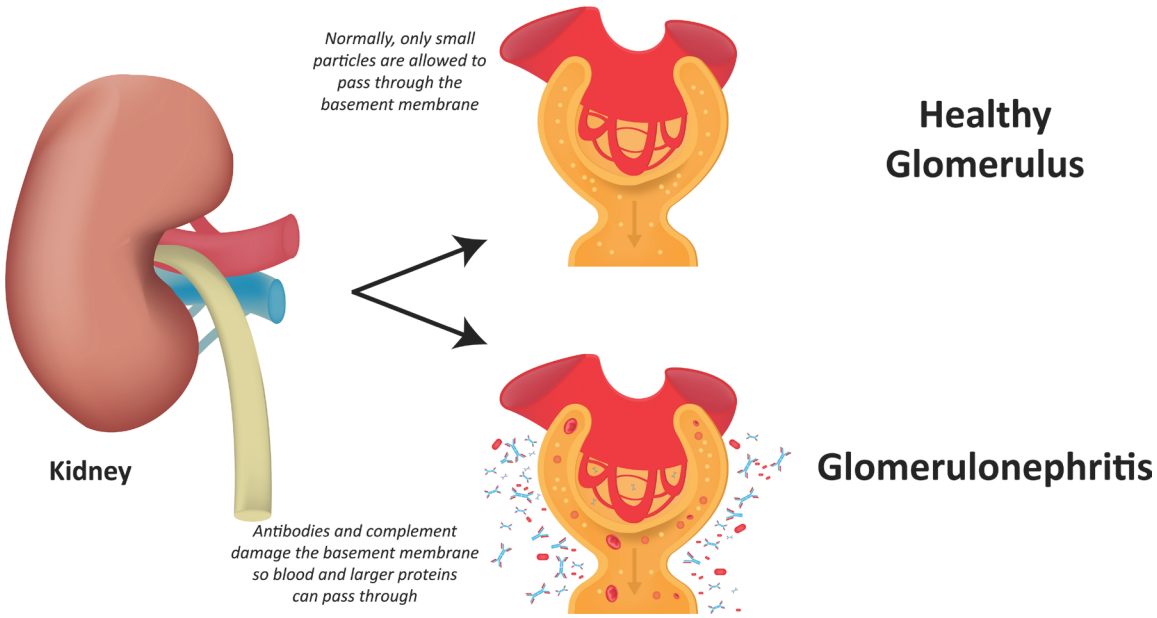
Diagnosis of Goodpasture Syndrome

Glomerular Basement Membrane (GBM) Antibodies

Goodpasture syndrome

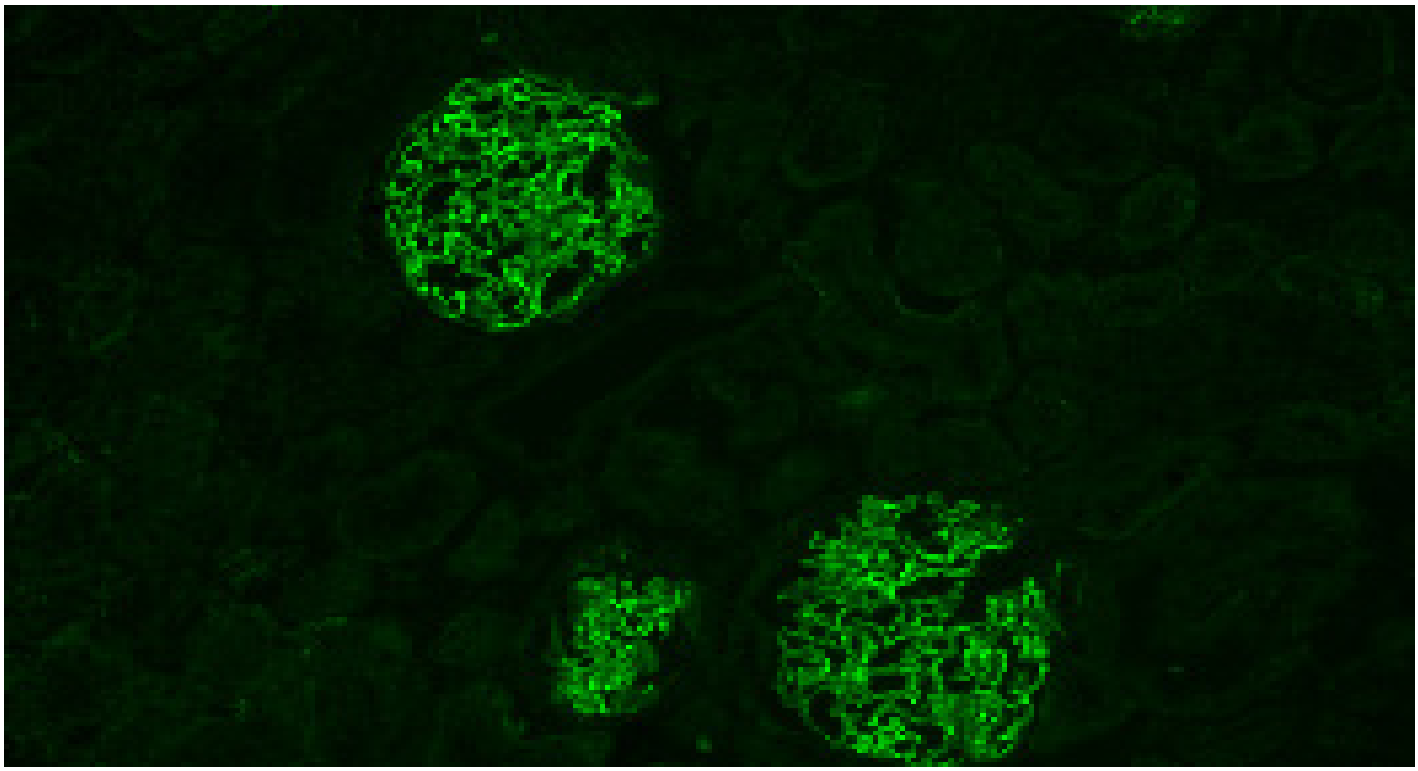
Goodpasture syndrome is an autoimmune kidney disorder, is characterized by the coexistence of proliferative glomerulonephritis with lung hemorrhage and the formation of autoantibodies against the glomerular basement membrane (GBM). The detection of the pathogenic circulating anti-GBM antibodies is a key diagnostic parameter of Goodpasture syndrome. The GBM is an anatomical barrier between the kidney epithelia and connective tissue playing an important role in ultrafiltration. Rapid progressive glomerulonephritis (RPGN) is a common feature of many autoimmune disorders. A differential diagnosis of autoimmune nephritis requires determining antibodies to GBM together with the determination of antibodies to neutrophilic cytoplasmic antigens (ANCA), which are characteristic of granulomatosis with polyangiitis (GPA), formerly known as Wegener's granulomatosis, and vasculitis-associated RPGN. It also requires determining nuclear antibodies (ANA), which are characteristic of lupus nephritis.

Goodpasture Syndrome



Anti-GBM Assays

IFA for Determining IgG Antibodies Against Glomerular Basement Membran



The Anti-GBM IFA and the AKLIDES® Anti-GBM are immunofluorescence assays (IFA) for the qualitative and semi-quantitative determination of IgG antibodies in human serum against glomerular basement membrane (GBM) on tissue sections of monkey kidney. Both tests serve as an aid in the diagnosis of diagnosis of autoimmune glomerulonephritides in conjunction with other clinical and laboratory findings. The Anti-GBM IFA is intended for visual interpretation, while the AKLIDES® Anti-GBM is designed for automated imaging using the akiron® NEO.

Manual	REF	Automated	REF
Anti-GBM IFA	86448	AKLIDES® Anti GMB	4123

Diagnosis of Diabetes Mellitus Type 1

Islet Cell Antibodies (ICA)

Diabetes mellitus type 1

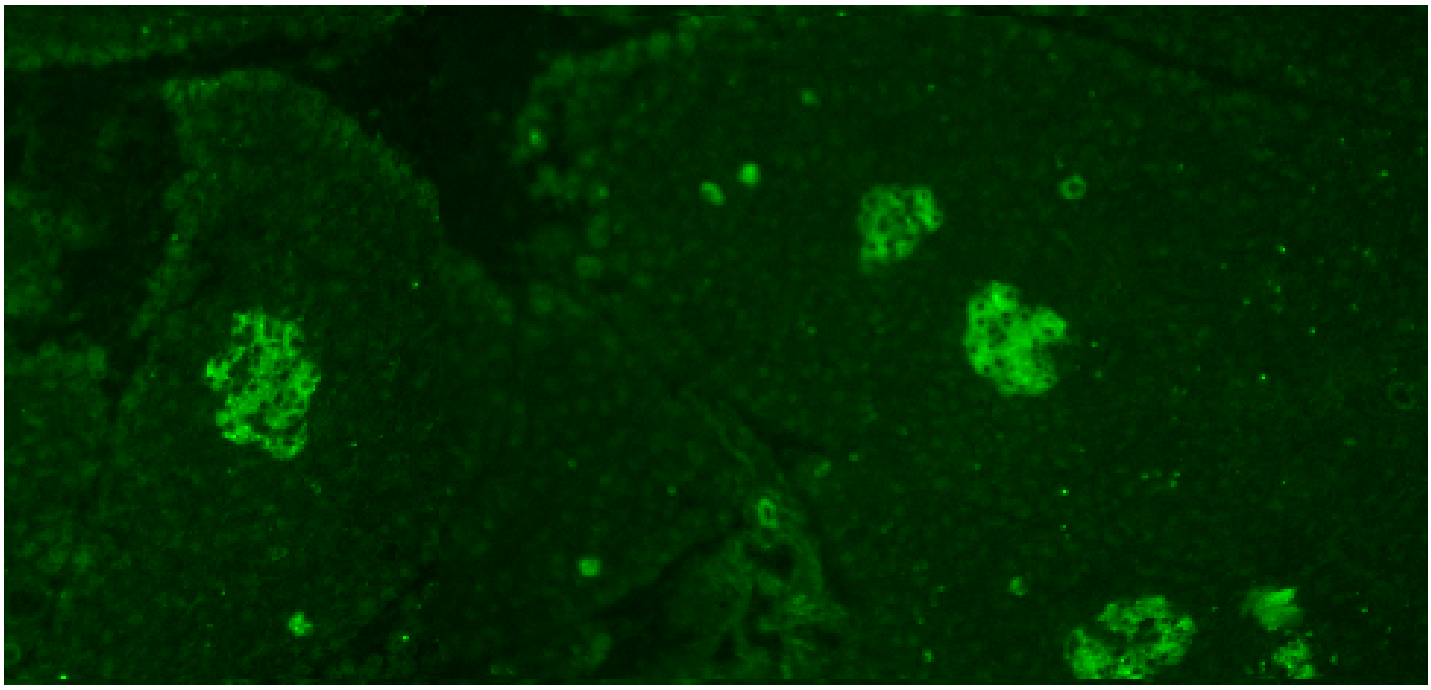
Diabetes mellitus type 1 is a chronic autoimmune disease in which the insulin-producing beta cells of the islets of Langerhans in the pancreas are destroyed. This destruction leads to reduced insulin production, resulting in high blood sugar levels characteristic of diabetes mellitus. While genetic predispositions and viral infections are considered risk factors, the exact causes remain unclear.

The destruction of beta cells is associated with the presence of islet cell antibodies (ICA), which target various antigens in the pancreatic islet cells. These antigens include glutamic acid decarboxylase (GAD65), tyrosine phosphatase (insulinoma-associated antigen 2, IA2), the zinc transporter 8 (ZnT8), and insulin. ICA can be detected in 70–80% of patients with diabetes mellitus type 1. Importantly, these antibodies often appear months to years before elevated blood sugar levels manifest, making them valuable prognostic markers for identifying individuals at increased risk of developing diabetes mellitus type 1.

The combined detection of ICA and antibodies against GAD65, IA2, ZnT8, and insulin has become a cornerstone in the diagnostic approach to diabetes mellitus type 1. This approach is especially important at the onset of the disease when accurate diagnosis can guide timely management strategies. By understanding and identifying these autoimmune markers, healthcare professionals can better predict, diagnose, and monitor this complex disease, ultimately improving outcomes for affected individuals. Depending on the age of the patient, different autoantibody testing strategies are used.

ICA Assays

IFA for Determining IgG Antibodies Against Islet Cells



The ICA IFA and the AKLIDES® ASA are immunofluorescence assays (IFA) designed for the qualitative and semi-quantitative determination of IgG antibodies in human serum against islet cell antigens (ICA) on tissue sections of monkey pancreas. Both tests serve as an aid in the diagnosis of diabetes mellitus type 1 in conjunction with other clinical and laboratory findings. The ICA IFA is intended for visual interpretation, while the AKLIDES® ICA is designed for automated imaging using the akiron® NEO.

Manual	REF	Automated	REF
ICA IFA	85848	AKLIDES® ICA	4129

Diagnosis of Blistering Skin Disease

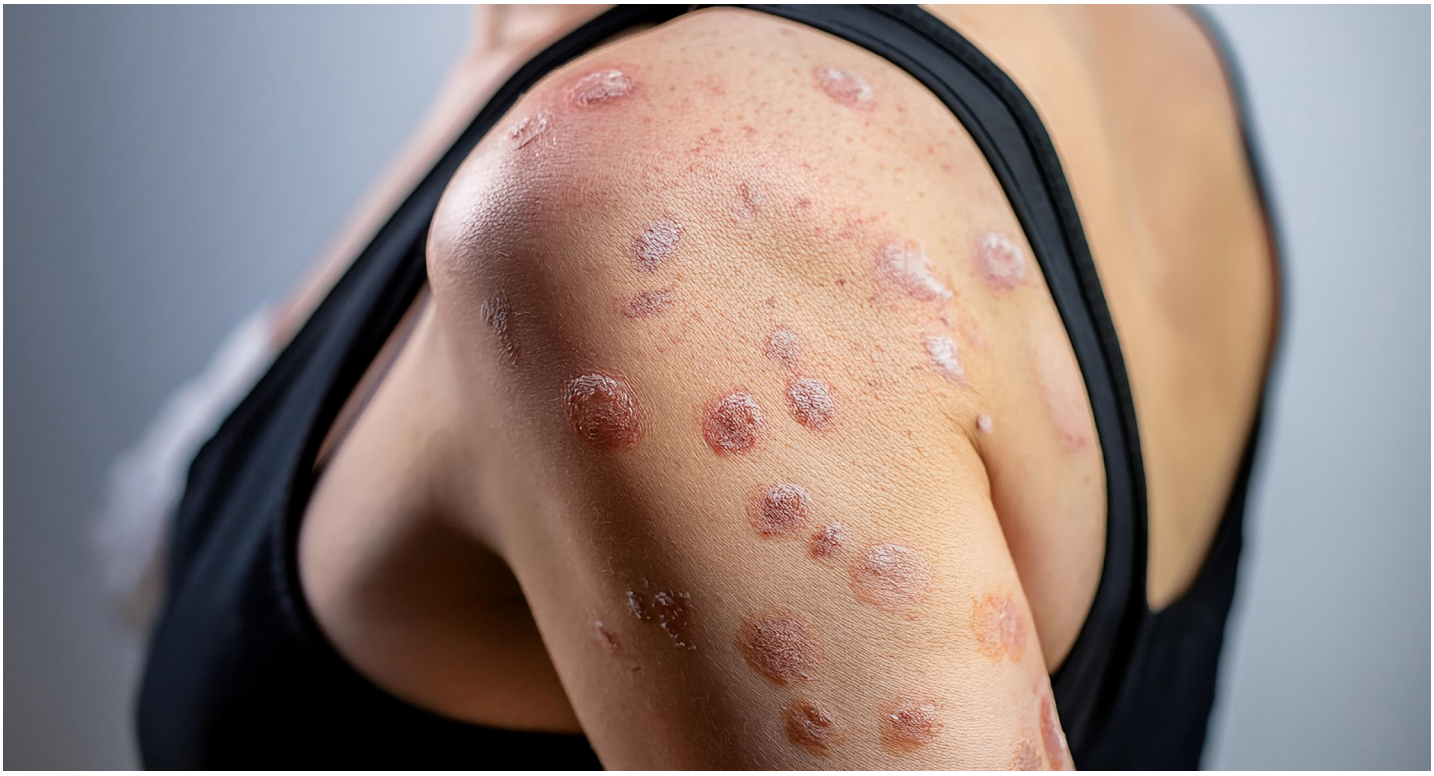
Anti-Skin Autoantibodies (ASA)

Blistering Skin Diseases

Blistering skin diseases encompass a group of chronic disorders primarily driven by immunological mechanisms. These disorders can be clinically differentiated based on histological findings and the detection of specific autoantibodies. Key diagnostic tools include indirect immunofluorescence tests on epithelial tissue sections, particularly at the basement membrane (BM), and immunohistological analysis of skin biopsies.

In conditions like pemphigoid, autoantibodies of the IgG class target structural components such as hemidesmosomes in basal keratinocytes. Approximately 70% of patients with pemphigoid exhibit highly specific BM antibodies, which are absent in healthy individuals.

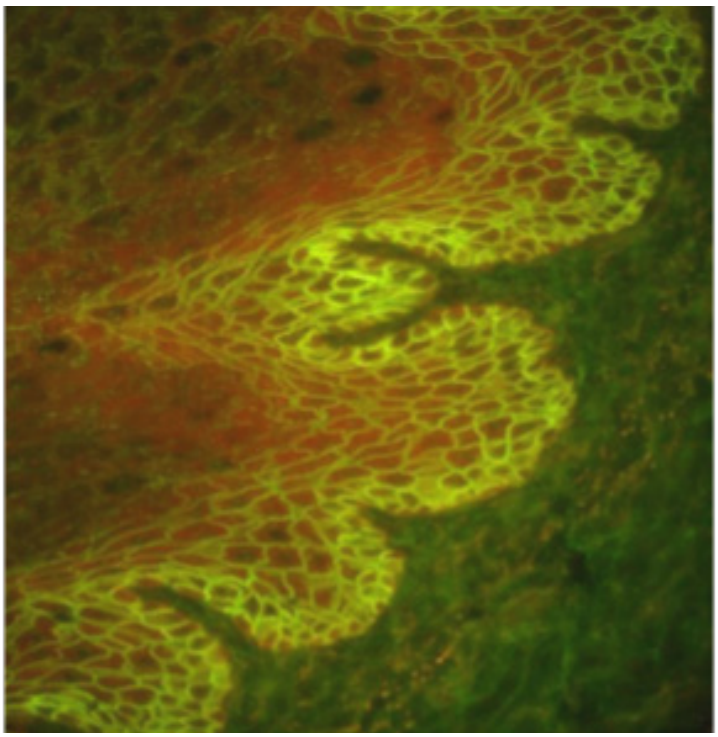
Pemphigus disorders involve IgG autoantibodies against intercellular epithelial antigens, such as desmoglein III and I. Clinical symptoms strongly correlate with the pathogenic antibody response. Antibody titers in pemphigus are closely associated with disease activity, rising during active phases and declining with effective treatment. These findings underline the role of immune dysregulation in blistering skin diseases and highlight the importance of serological and histological analysis in their diagnosis and management.



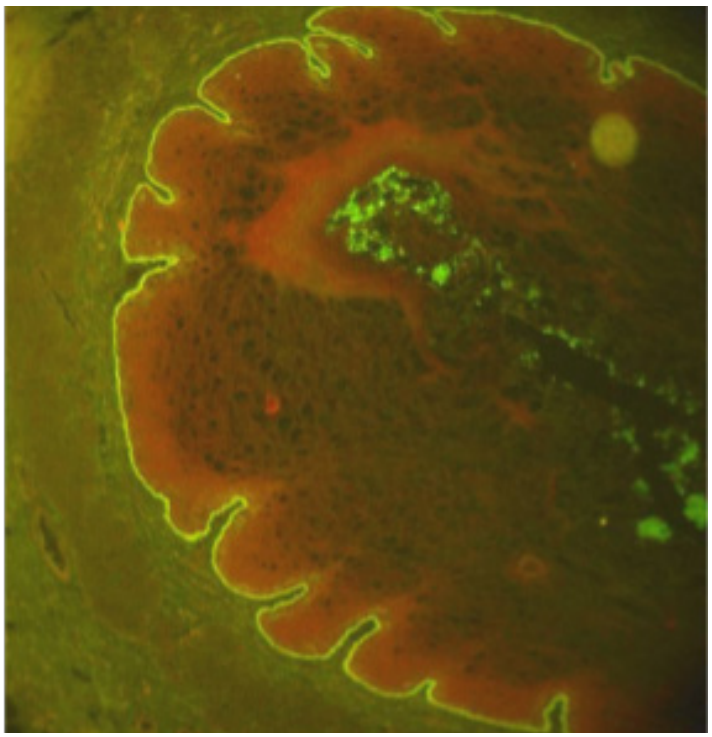
ASA Assays

IFA for Determining IgG Antibodies Against Skin Antigens

ICS – epithelial intercellular substance



BM – epithelial basement membran



The ASA IFA and the AKLIDES® ASA are immunofluorescence assays (IFA) designed for the qualitative and semi-quantitative detection of IgG antibodies in human serum against skin antigens (ASA) on tissue sections of monkey esophagus. Both tests serve as an aid in the diagnosis of autoimmune skin diseases in conjunction with other clinical and laboratory findings. The ASA IFA is intended for visual interpretation, while the AKLIDES® ASA is designed for automated imaging using the akiron® NEO.

Manual	REF	Automated	REF
ASA IFA	86148	AKLIDES® ASA	4125

Immunfluorescence Assays (IFA)

Order Information

Celiac

Manual	REF	Automated	REF
CytoBead® CeliAK	8064	AKLIDES® CytoBead® CeliAK	4271
EmA IFA	86048 86096	AKLIDES® EmA	4131 4132

Diabetes

Manual	REF	Automated	REF
ICA IFA	85848	AKLIDES® ICA	4129

Immunfluorescence Assays (IFA)

Order Information

Hepatology

Manual	REF	Automated	REF
AMA IFA	83048	AKLIDES® AMA	4117
ASMA IFA	84048	AKLIDES® ASMA	4119
Triple IFA	85048 85096	AKLIDES® Triple	4121 4122

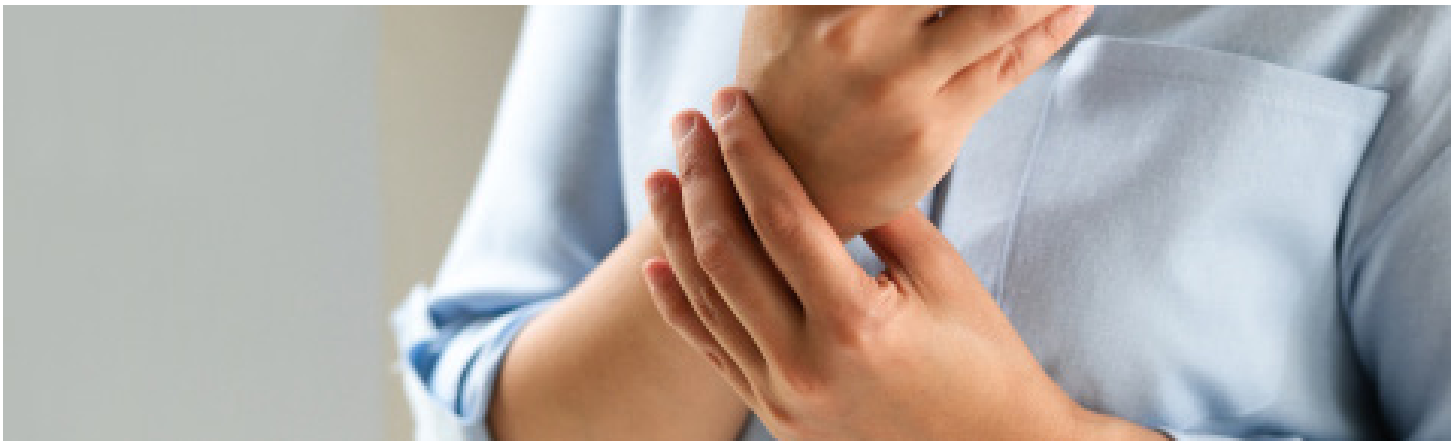
Dermatology

Manual	REF	Automated	REF
ASA IFA	86148	AKLIDES® ASA	4125

Immunfluorescence Assays (IFA)

Order Information

Rheumatology



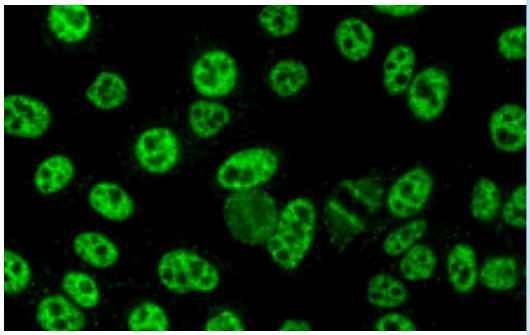
Manual	REF	Automated	REF
ANA HEp-2 plus	8101 81040	AKLIDES® ANA plus	4065 4063
CytoBead® ANA	8065	AKLIDES® CytoBead® ANA	4272
CytoBead® ANA 2	8220	AKLIDES® CytoBead® ANA 2	4277
nDNA IFA plus	81050 81100	AKLIDES® nDNA	4282 4283
cANCA IFA plus	87061	AKLIDES® cANCA	4060
pANCA IFA plus	87161	AKLIDES® pANCA	4072
ANCA IFA dual	87261	AKLIDES® ANCA dual	4472
CytoBead® ANCA	8063	AKLIDES® CytoBead® ANCA	4270
Anti-GBM IFA	86448	AKLIDES® Anti-GBM	4123

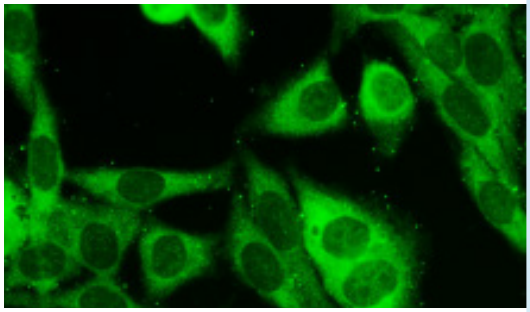
Immunfluorescence Assays (IFA)

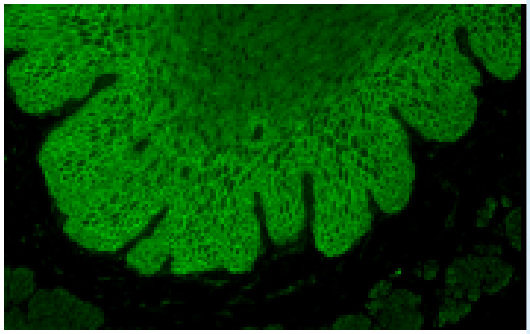
Order Information

Neurology

Manual	REF
Anti-MuSK IFA	8049







Immunoflourescence Assays

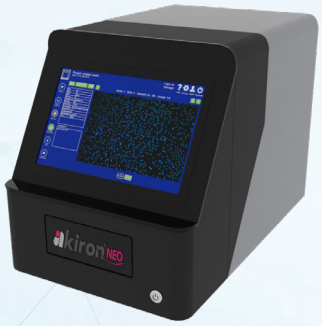
IFA Product Portfolio

HIGH QUALITY - MADE IN GERMANY

We provide a comprehensive range of IFA test systems for autoantibody detection. Our high-quality assays support accurate and reliable diagnostics in autoimmune diseases, trusted by healthcare professionals worldwide. IFA offers a sensitive and broad screening method, enabling visualization of autoantibody patterns for deeper clinical insight. Designed for flexibility and compatibility with automation, our systems ensure consistent performance across diverse clinical settings.

Manual Assays

Automated Assays



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