AUTOIMMUNE DISEASES DIAGNOSTIC

BioSystems

REAGENTS & INSTRUMENTS

PRODUCT LIST

FOREWORD

The immune response in autoimmune diseases is itself part of the disease process, where the immune system reacts against components naturally present in the human being as if they were a menace for the organism. Consequently, it is possible to use autoantibodies as markers of disease.

In some of these diseases, autoantibodies can predict both the likelihood of clinical disease and the rate of progression to disease, but also autoantibodies can be detected in diseases with a long period before the onset of clinical symptoms. This is the case of type 1 diabetes and thyroiditis, in which the destruction of hormone-secreting cells may take place years before the first clinical symptoms.

A long experience and a deep know-how, resulting from a close work together with thousands of satisfied professionals worldwide, are the basis for our products for Autoimmune Diseases Diagnostic. All the products have been developed to keep the pace with leading research on Autoimmunity. Being pioneers in areas such as Celiac Disease, Organ-Specific Autoimmunity or Cell Culture, we have become one of the leader companies around the world.

BioSystems S.A. develops, manufactures and commercializes Reagents and Instruments for clinical analysis since 1981. Quality of products and quality of service have always been our two main targets, as well as the fulfilment of current regulations: ISO13485:2003, CE mark of products...

With this catalogue we are pleased to offer to the users a quick and user-friendly guide to the products that best fit their needs.

SUMMARY

Disclaimer

1. Sale of positive controls is subject to availability.
2. Complete kits include dilution/washing buffer, specific conjugate, mounting medium, blotters, positive and negative controls, except when explicitly stated otherwise.
3. Tissues “For Research Use Only” (RUO) are not CE-labelled and are subject to special sale conditions. Ask your distributor.
4. The most updated instruction for use are available at **www.biosystems-sa.com.**

Systemic Diseases

General screening of autoantibodies allows a quick and reliable identification of many autoantigens coexistent in several autoimmune diseases, without compromise of its organ dependence. Furthermore, many of the connective tissue autoimmune diseases have been associated to specific autoantigens that act as markers.
The most accepted screening method is a two-step approach, where after an initial screening to detect potential positives, a more refined search is made to identify the antigen or antigens triggering the immune response. In this two-step approach, the most common methods are Immunofluorescence Assay, either on tissue or cultured cells, and ELISA methods.

ANA

Sensitivity of antinuclear antibodies determination is higher than 95% for Systemic Lupus Erythematosus (SLE), although specificity is fairly low.The presence of high levels of specific ANA is also indicative of other systemic rheumatic diseases such as drug-induced lupus (DIL), Sjögren's syndrome, scleroderma and variants, polymyositis and dermatomyositis, CREST syndrome, mixed connective tissue disease and rheumatoid arthritis.

• Homogeneous: Indicative of SLE.

• Speckled: Highly related to SLE, mixed connective tissue disease, Sjögren's syndrome, polymyositis or scleroderma.

• Centromeric: In patients with systemic sclerosis, especially in a cutaneous limited form of the disease (80%). Occasionally, in some other connective diseases.

• Nucleolar: In approximately 50-70% of the patients with overlapping scleroderma and polymyositis/dermatomyositis syndromes. They are found in up to 33% of patients with systemic scleroderma, specially those with renal complications.

ENA

The presence of high levels of specific ENA antibodies is indicative of systemic rheumatic diseases such as SLE, Sjögren's syndrome, scleroderma, polymyositis, mixed connective tissue disease or rheumatoid arthritis. Some individuals may have high levels of antibodies to ENA with no evidence of clinical disease. By contrast, patients with systemic rheumatic diseases may have undetectable levels of such antibodies. It is recommended that sera, which are positive for ENA, are tested to determine the specific antibody with single specificity kits.

• SSA(Ro) is indicative of primary Sjögren's syndrome and SLE. These antibodies are found in approximately 60-70% of the patients with Sjögren's syndrome and 40-50% of the patients with SLE.

• SSB (La) is indicative of primary Sjögren's syndrome and SLE. These antibodies are found in approximately 10-40% of the patients with Sjögren's syndrome and 6-15% of the patients with SLE.

• Sm is strongly indicative of SLE. These antibodies are found in approximately 20-30% of the patients with the disease.

• Sm/RNP is indicative of SLE and mixed connective tissue disease. These antibodies are found in approximately 30-40% of the patients with SLE and 100% of the patients with Mixed Connective Tissue Disease.

• Scl-70 are directed against DNA-topoisomerase I. They are highly specific for systemic scleroderma and give a hint for a severe course.

• Jo-1 are directed against histidyl-tRNA synthetase (cytoplasmic protein involved in protein biosynthesis) and are found in 20-40 % of patients with polymyositis and dermatomyositis.

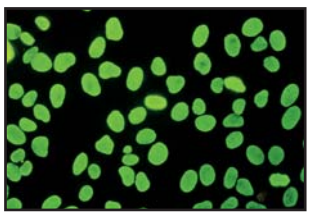
• CENP-B (80kDa centromere protein B): Anti-centromere B antibodies are found in patients with systemic sclerosis (SSc), specially in a cutaneous limited form of the disease and with the absence of pulmonary involvement. They are typical for the CREST syndrome (69% of CREST patients), a subclase of SSc which is a more protracted type of systemic sclerosis.

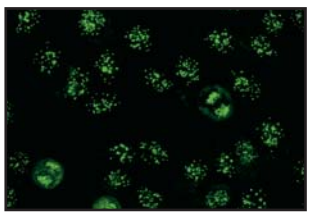
RIBOSOME P

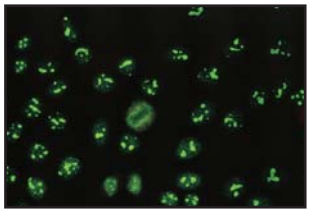
Autoantibodies to ribosomal P protein are present in 10-20% of patients with SLE, but frequencies up to 38% are found in different ethnic groups and young onset SLE. Association of anti-ribosomal P protein antibodies with active SLE, kidney disease and liver disease has been demonstrated, but correlation with neuropsychiatric lupus is not clear.

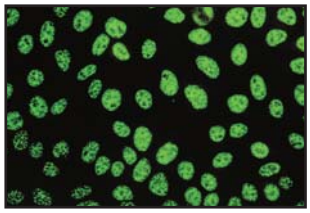
HISTONES

Antibodies against histones are observed in 20-50% of patients with spontaneous SLE and in 50-90% of drug induced lupus erythematosus. These autoantibodies are not specific for SLE since they are found also in drug induced lupus erythematosus (three times higher incidence than in SLE) and in rheumatoid arthritis.


Homogeneous pattern


Anti-centromere antibodies


Nucleolar pattern


Speckled pattern

ANTINUCLEAR ANTIBODIES HEp-2 (ANA-HEp-2)

44508 IFA – Complete kit, 10 slides x 6 wells
44509 IFA – Complete kit, 10 slides x 12 wells
44546 IFA – Slide Box, 10 slide x 6 wells
44547 IFA – Slide Box, 10 slide x 12 wells

AUTOANTIBODIES DUO

44874 IFA – Slide Box, 10 slide x 6 wells / HEp2/ML.

ANA — SCREENING

44785 ELISA kit, 96 test
Purified SSA(Ro), SSB(La), Sm/RNP, RNP (70, A and C), Sm, Scl70, Jo1, dsDNA, ssDNA, nucleosomes, total histones, PMScl 100, Centromere B

EXTRACTABLE NUCLEAR ANTIGENS ELISA 96 Test

44740 ENA 6-SCREENING
Highly purified SSA (Ro), SSB (La), Sm, Sm/RNP, Jo1, Scl70

44910 ENA 6-PROFILE
Highly purified SSA (Ro), SSB (La), Sm, Sm/RNP, Jo1, Scl70

44775 ENA 4-PROFILE
Highly purified SSA, SSB, Sm, Sm/RNP

44755 ANTI-Sm ANTIBODIES
Highly purified human antigen

44770 ANTI Sm/RNP ANTIBODIES
Highly purified human antigen

44765 ANTI SSA (Ro) ANTIBODIES
Highly purified antigen

44750 ANTI SSB (La) ANTIBODIES
Highly purified antigen

44865 ANTI-CENTROMERE B ANTIBODIES (CENP-B)
Recombinant antigen

44864 ANTI-Jo1 ANTIBODIES
Highly purified antigen

44863 ANTI-Scl70 ANTIBODIES
Highly purified antigen

ANTI-RIBOSOMAL P ANTIBODIES (Rib P)

44866 ELISA kit 96 Test.
Highly purified antigen

ANTI-HISTONES ANTIBODIES (HIST)

44862 ELISA kit 96 Test.
Highly purified antigen

ANTI-NUCLEOSOME ANTIBODIES (NUCL)

44861 ELISA kit 96 Test.
Purified antigen

NUCLEOSOME

Anti-nucleosome antibodies are recognized to be especially prevalent in SLE and drug-induced lupus, since they are detected in 84 - 88 % of patients. A percentage of 16 - 30 % of patients with lupus have been reported to have anti-nucleosome antibodies without anti-dsDNA and anti-histone antibodies.

nDNA / dsDNA

The *Crithidia luciliae* immunofluorescence test for anti-nDNA antibodies has a high diagnostic specificity, but a fairly high diagnostic sensitivity for SLE. They are the most frequently detected autoantibodies associated to SLE: 95% in SLE patients with renal involvement, 50 – 70% in SLE patients without renal involvement and 40% in patients with inactive SLE. Anti-nDNA antibodies are rarely found in healthy individuals. Enzyme immunoassay for anti-dsDNA antibodies shows a specificity of 98-100 % for SLE and a sensitivity of 40-60 %. These antibodies are specially relevant in the course of the disease and they are believed to be involved in associated kidney diseases.

ANTI-nDNA ANTIBODIES (nDNA)

44818 IFA – Complete kit, 10 slides x 6 wells
44817 IFA – Complete kit, 10 slides x 12 wells
44820 IFA – Slide Box, 10 slides x 6 wells
44819 IFA – Slide Box, 10 slides x 12 wells
Crithidia luciliae

ANTI-dsDNA ANTIBODIES

44705 ELISA kit 96 Test.
Calf thymus antigen

FILAGGRIN

The presence of high levels of antikeratin antibodies (AKA) is strongly indicative of rheumatoid arthritis. The diagnostic sensitivity for this disease varies from 30 to 87%, and the diagnostic specificity from 90 to 99%, depending on the study design and the method used. AKA are also found in one third of rheumatoid arthritis patients with rheumatoid factor negative. Filaggrin present in the rat esophagus middle third, recognized by antibodies anti-keratin antibodies (AKA), is extremely sensitive to temperature changes and may lose its antigenicity when the slides are not properly refrigerated (2-8ºC) during shipment or storage. Recently developed methods based on ELISA using citrullinated proteins have shown to be a more sensitive and specific marker for rheumatoid arthritis, with a high value as predictors of disease persistance and radiographic joint damage in early arthritis.

ANTI-KERATIN ANTIBODIES (AKA)

44618 IFA – Complete kit, 48 tests
Controls not included
44517 IFA – Slide Box, 12 slides x 4 wells
Rat Esophagus.

ANTI-CITRULLINATED PROTEIN ANTIBODIES (ACPA)

44860 ELISA kit 96 Tests
Highly purified antigen

Anti-phospholipid Syndrome

Although first described in patients with SLE, anti-phospholipid antibodies (ACA) are present in patients with antiphospholipid syndrome. ACA react with negatively charged phospholipids, including cardiolipin.

CARDIOLIPIN

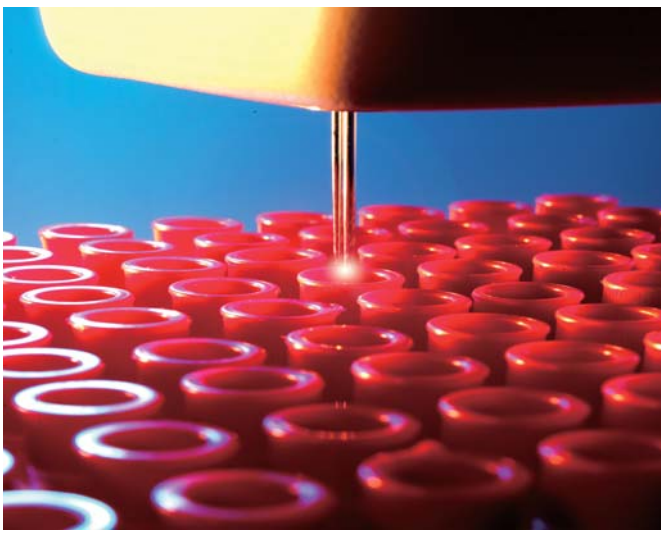
Although first described in patients with systemic lupus erythematosus, ACA are present in patients with antiphospholipid syndrome (APS). Anti-phospholipid antibodies react with negatively charged phospholipids, including cardiolipin. High levels of anti-cardiolipin IgG or IgM antibodies in serum or plasma are associated with an increased risk of thrombosis and pulmonary embolism, and an important risk factor for stroke and recurrent fetal loss. Anti-cardiolipin antibodies titers may decrease during treatment with corticosteroids.

β2-GLYCOPROTEIN I

Anti-β2-GP1 antibodies are present in the IgG, IgM or IgA isotypes. IgG anti-β2-GP1 antibodies are more specific than IgM, and are found in progressive stages of manifested autoimmune disorders. IgM anti-β2-GP1 antibodies are useful in the diagnosis of early stages of autoimmune disorders. IgA anti-β2-GP1 antibodies may have a pathogenic role in thrombosis and APS5. Determination of anti-β2-GP1 antibodies is indicated for SLE, thrombosis, thrombocytopenia, recurrent abortion and intrauterine death.

ANNEXIN V

Autoantibodies against annexin V are present in high levels in APS patients, but also can be found, especially the IgG isotype, in serum samples of patients with SLE, rheumatoid arthritis, and recurrent fetal loss and pre-eclampsia.



ANTI-CARDIOLIPIN ANTIBODIES (ACA-IgG/IgM)

44780 ELISA 96 T
Highly purified antigen

ANTI-PHOSPHOLIPID ANTIBODIES IgA/IgM (APLA)

44867 ELISA 96 T
Mixture of cardiolipin, phosphatidyl serine, phosphatidyl inositol, phosphatidic acid and β2-Glycoprotein 1

ANTI-β2-GLYCOPROTEIN I ANTIBODIES IgG/IgM (β2-GP1)

44868 ELISA 96 T.
Highly purified antigen

ANTI-ANNEXIN V ANTIBODIES IgG/IgM (ANX)

44869 ELISA 96 T.
Highly purified antigen

Vasculitis

Vasculitis is a group of diseases featuring inflammation of the wall of blood vessels due to leukocyte migration and resultant damage. While most vasculitides are rare, they generally affect several organ systems and can cause severe disability.

PR-3

There is a strong association between anti-PR3 antibodies and Wegener's granulomatosis. Specificity has been found of 95-98%. Sensitivity depends on the phase and the activity of the disease, and has been found around 90% for expanded Wegener's granulomatosis (i.e. with necrotizing glomerulonephritis, systemic vasculitis and granulomatous inflammation of the respiratory tract), and around 75% for limited Wegener's granulomatosis (i.e. without renal involvement).

MPO

High levels of anti-MPO antibodies are found in 65% of patients with idiopathic necrotizing glomerulonephritis, 60% of patients with Churg-Strauss syndrome, 30-40% of patients with Goodpasture's syndrome and 10% of patients with Wegener's granulomatosis. Specificity for systemic vasculitis and idiopathic necrotizing glomerulonephritis goes up to 95%.

ANTI-NEUTROPHIL CYTOPLASM ANTIBODIES (ANCA)

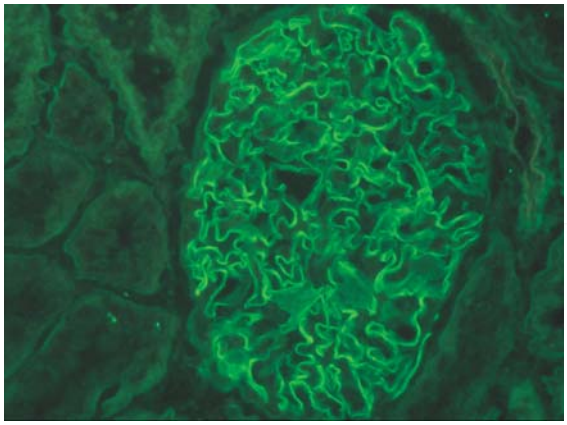
44850	Ethanol fixed, IFA Complete kit, 4 slides x 6 wells
44851	Ethanol fixed, IFA Complete kit ,10 slides x 6 wells
44852	Ethanol fixed, IFA Slide Box ,10 slides x 6 wells
44878	Formalin fixed, IFA Slide Box, 10 slides x 6 wells
44898	Formalin fixed, IFA Complete kit, 10 slides x 6 wells

ANTI-PR3 ANTIBODIES (C-ANCA)

44791	ELISA 96 T Purified human antigen

ANTI-MPO ANTIBODIES (P-ANCA)

44790	ELISA 96 T Purified human antigen



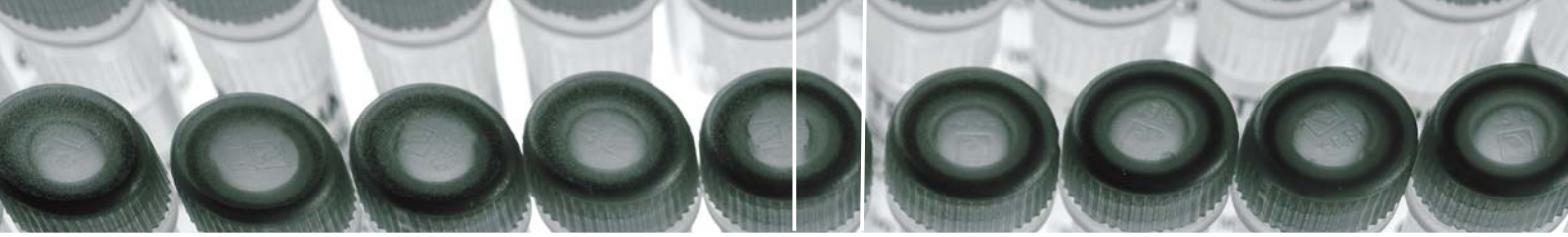
Glomerular basement membrane antibodies
Monkey kidney

GBM

Indirect immmunofluorescence assay is the conventional method for the determination of anti-glomerular basement membrane antibodies (GBMA). Antibodies to GBM are present in patients with Goodpasture's syndrome. The disease presents a progressive glomerulonephritis with or without massive pulmonary hemorrhage. The finding of GBMA confirms a diagnosis of a life threatening disease that causes loss of kidney, and indicates a grave prognosis. Results obtained in a comparative study do not show significant systematic differences compared to an ELISA for anti-type IV collagen alpha chain antibodies.

ANTI-GLOMERULAR BASEMENT MEMBRANE ANTIBODIES (GBMA)

44588	IFA – Slide box, 12 slides x 4 wells Monkey Kidney
44870	ELISA kit 96 T Highly purified antigen



CELIAC DISEASE

Celiac disease is an autoimmune disease associated with total or sub-total villous atrophy leading to malabsorption from the gut. As with diabetes, antibodies associated with celiac disease can predict progression to clinical disease and can be used to define the cause of malabsorption. The disease is associated with endomysial antibodies (tissue transglutaminase) and antibodies to gliadin and reticulin.

AGA

The presence of high levels of anti-gliadin antibodies (AGA) is indicative of celiac disease. AGA sensitivity for celiac disease is reported between 95 – 100%. IgG type AGA are more sensitive but less specific and IgA type AGA are less sensitive but more specific. AGA are detected also in two thirds of dermatitis herpetiformis patients. Celiac disease patients with selective IgA deficiency can only be detected by measuring IgG type AGA.

Enzyme immunoassay for anti-gliadin antibodies show a specificity for celiac disease of 80 – 90.5% for IgA class antibodies and of 100% for IgG class antibodies. As for specificity, up to 21% of patients with other gastrointestinal disorders show positivity for IgG anti-gliadin antibodies, whereas IgA anti-gliadin antibodies were found only in 3% of them. Combined IgG and IgA antibodies determination shows 96% sensitivity and a specificity of 97%. The progress of the concentration of these antibodies is also useful to monitor the fulfillment of a gluten free diet.

AEA / tTG

Antiendomysium antibodies (AEA) of the IgA class are found in patients with active celiac disease or dermatitis herpetiformis. The diagnostic sensitivity for celiac disease is 68-100% in untreated patients, and the diagnostic specificity is 99-100% suggesting a high positive and negative predictive value. IgA-AEA sensitivity for dermatitis herpetiformis is 70-80% but increases to 100% when associated to gluten-sensitive enteropathy. In the case of celiac disease patients presenting IgA deficiency, specific antibodies can be detected by using IgG FITC/Evans (M) conjugate.

Tissue transglutaminase (tTG) is the prominent autoantigen in celiac disease. Anti-tTG of the IgA class are found in patients with celiac disease or dermatitis hepertiformis. Specificity of anti-tTG ELISA assay for celiac disease is 94-100% and sensitivity is 92-100%. In the case of dermatitis herpetiformis, specificity is 98% and sensitivity is 89%. Provided the high incidence of IgA deficiency in celiac patients, is recommended to assay the anti-tTG IgG when a negative result is obtained for the anti-tTG IgA.

ANTI-tTRANSGLUTAMINASE ANTIBODIES

44754 Anti-tTRANSGLUTAMINASE IgA ANTIBODIES
ELISA kit 96 T
Recombinant human antigen activated by calcium and gliadin

44798 Anti-tTRANSGLUTAMINASE IgG ANTIBODIES
ELISA kit 96 T
Recombinant human antigen activated by calcium and gliadin

ANTI-ENDOMYSIUM ANTIBODIES

44548 IFA – Complete kit, 12 slides x 4 wells
44715 IFA – Complete kit, 12 slides x 8 wells
44557 IFA – Slide Box, 12 slides x 4 wells
44710 IFA – Slide Box, 12 slides x 8 wells
Monkey Esophagus, distal section

ANTI-GLIADIN ANTIBODIES

44704 ANTI-GLIADIN ANTIBODIES (AGA-IgG/IgA)
ELISA kit 96 T
Gliadin

44884 ANTI-DEAMIDATED GLIADIN (DGP-IgG)
ELISA kit 96 T
Synthetic deamidated gliadin

44885 ANTI-DEAMIDATED GLIADIN (DGP-IgA)
ELISA kit 96 T
Synthetic deamidated gliadin

INFLAMMATORY BOWEL DISEASE

Determination of ASCA antibodies is useful in the diagnosis of inflammatory bowel disease, particularly in the differentiation between Crohn's disease and ulcerative colitis, especially indeterminate colitis, using a combination of perinuclear anti-neutrophil cytoplasmic autoantibodies (p-ANCA) and ASCA tests.

ASCA

ASCA are strongly associated to Crohn's disease (50%-80%), compared to patients with ulcerative colitis (2%-14%) and to normal healthy subjects (1%-7%). Approximately two-thirds of the Crohn's disease patients with ASCA IgG are also positive for ASCA IgA, but 0%-19% of the patients have only ASCA IgA antibodies. In Crohn's disease, up to 90% specificity has been reported in specimens positive for both ASCA IgG and IgA antibodies, especially when concentration of both the IgG and IgA ASCA antibodies is high.

ANTI-SACCHAROMYCES CEREVISIME ANTIBODIES IgG/IgA (ASCA)

44872 ELISA kit 96 T
Highly purified mannan from *Saccharomyces cerevisiae*

X-ANCA

Among the IBD, X-ANCA are more common in ulcerative colitis (44.1%) than in Chron´s disease (8.1%) and the combination of ANCA methanol fixed test by IIF and ASCA test by IIF or ELISA often becomes an aid for their differentiation. X-ANCA pattern (or atypical P-ANCA) is the result of the autoantibody binding to proteins such as lactoferrin, elastase, BPI, cathepsin G among others

ANTI-NEUTROPHIL CYTOPLASM ANTIBODIES (ANCA)
44895 Methanol fixed, IFA Slide Box, 10 slides x 6 wells

ANTI-BPI ANTIBODIES
44905 ELISA 96 T / Purified human antigen

ANTI CATHEPSIN G ANTIBODIES
44906 ELISA 96 T / Purified human antigen

ANTI-ELASTASE ANTIBODIES
44907 ELISA 96 T / Purified human antigen

ANTI-LACTOFERRIN ANTIBODIES
44908 ELISA 96 T / Purified human antigen

ANTI-LYSOZYME ANTIBODIES
44909 ELISA 96 T / Purified human antigen

AUTOIMMUNE HEPATITIS

Autoimmune hepatitis (AIH) is a progressive inflammation of liver that has been identified by a number of different names, including autoimmune chronic active hepatitis (CAH), idiopathic chronic active hepatitis, and lupoid hepatitis. There are three types of autoimmune hepatitis (AIH), each of them has a different pattern of autoantibodies.

Type 1: Is the more frequent type of AIH. ANA and/or ASMA and sometimes ANCA are positive.

Type 2: Is more frequent in children. LKM-1 (antibodies against a component of cytochrome P-450, CYP 2D6) are positive. ANCA are always negative.

Type 3: SLA (Soluble Liver Antigen, a UGA repressor tRNA-associated protein) is positive.

AMA

Granular fluorescence of mitochondria in the cytoplasm of renal tubular cells. The presence of anti-mitochondrial antibodies is associated with primary biliary cirrhosis (over than 95% of patients).

M2

Nine mitochondrial antibody subtypes have been described up to now, but only four are related with primary biliary cirrhosis (PBC): M2, M4, M8 and M9. However, it is well established that only anti-M2 antibodies are specific for PBC. These antibodies can be detected years, even decades, before the onset of clinical and histological symptoms. Due to its high sensitivity and specificity, determination of anti-M2 by ELISA is recommended for differential diagnostic of the PBC.

ASMA

Staining of the muscularis mucosae, the muscle layers of blood vessels and the interglandular fibers, in rat stomach. Anti-smooth muscle antibodies are the standard diagnostic marker of autoimmune hepatitis. Anti-actin antibodies, a subgroup of smooth muscle antibodies, are found in the sera of 52-85% of patients with autoimmune chronic active hepatitis and 22% of patients with primary biliary cirrhosis. Its presence in other autoimmune diseases as cholangyopathy reflects overlapping features of those diseases.

LKM

Anti-LKM type I antibodies are considered as markers of autoimmune hepatitis type II.

PERNICIOUS ANEMIA

APCA

Reticular intracellular staining of parietal cells of rat gastric mucosa. Antibodies to gastric parietal cells are found in 90% of patients with pernicious anemia, usually associated with other tissue specific autoimmune diseases.

ANTI-SMOOTH MUSCLE ANTIBODIES (ASMA)
44520 IFA – Complete kit, 12 slides x 4 wells
44524 IFA – Complete kit, 12 slides x 8 wells
44521 IFA – Slide Box, 12 slides x 4 wells
44525 IFA – Slide Box, 12 slides x 8 wells
Rat Stomach

ANTI-MITOCHONDRIAL ANTIBODIES (AMA)
44510 IFA – Complete kit, 12 slides x 4 wells
44514 IFA – Complete kit, 12 slides x 8 wells
44511 IFA – Slide Box, 12 slides x 4 wells
44515 IFA – Slide Box, 12 slides x 8 wells
Rat Kidney

AUTOANTIBODIES RL/RK/RS (ANA-AMA-ASMA-APCA-LKM)
44558 IFA – Complete kit, 12 slides x 4 wells
44648 IFA – Complete kit, 12 slides x 8 wells
44570 IFA – Slide Box, 12 slides x 4 wells
44639 IFA – Slide Box, 12 slides x 8 wells
Rat Liver / Kidney / Stomach

AUTOANTIBODIES MsK/MsS (AMA — ASMA — APCA)
44518 IFA – Slide Box, 12 slides x 4 wells
Mouse Kidney/Stomach,

AUTOANTIBODIES MsL/MsK/MsS
(ANA – AMA – ASMA – APCA – LKM)
44826 IFA – Slide Box, 12 slides x 4 wells
44827 IFA – Slide Box, 12 slides x 8 wells
Mouse Liver/Kidney/Stomach

ANTI-M2 ANTIBODIES (M2)
44871 ELISA kit 96 T
Highly purified mitochondrial M2 subtype antigen

Autoimmune Polyendocrinopathy

The term Autoimmune Polyendocrinopathy (also known as Schmidt's syndrome) refers to an autoimmune disease affecting multiple endocrine organs like pancreas, adrenal gland or thyroid gland.

ADDISON'S DISEASE

Indirect immmunofluorescence assay is the conventional method for the determination of anti-adrenal cortex antibodies (AACA).
The presence of cytoplasmic adrenal antibodies (AACA) is strongly indicative of Addison's disease, an uncommon disorder due to a deficiency of adrenocortical hormones. Almost all individuals with a primary amenorrhea and Addison's disease have detectable cytoplasmic adrenal antibodies. These autoantibodies are useful markers for the prediction of the development of Addison's disease. Results obtained in a comparative study do not show significant systematic differences compared to an anti-21 hydroxylase antibodies radioimmunoassay.

ANTI-ADRENAL CORTEX ANTIBODIES (AACA)

44574 IFA Slide Box, 12 slides x 4 wells
Monkey Adrenal

AUTOIMMUNE THYROIDITIS

Antibodies to human thyroid peroxidase (Anti-TPO) are present typically in patients with Hashimoto's disease (90-100% of the patients), primary hypothyroidism or myxedema (80%), Grave's disease (50-80%), type I diabetes mellitus (40%) and pregnant women (14%). They are also detected, together with anti-Tg antibodies, in other diseases: endemic goiter, subacute thyroiditis, Addison's disease, polyendocrine autoimmunopathies and in members of families prone to organ specific autoimmunity. Nevertheless, they can be also present in a 5-20% of healthy individuals.

Anti Thyroglobulin (Anti-Tg) antibodies are present typically in patients with Hashimoto's disease (80-90% of the patients), primary myxedema (80%), Grave's disease (50-70%), type I diabetes mellitus (40%) and pregnant women (14%). Although elevated anti-Tg antibodies are common in differentiated cancer, but they have no clinical value. They are also detected, together with anti-TPO antibodies, in other diseases: endemic goitrous, subacute thyroiditis, Addison's disease, polyendocrine autoimmunopathies and in members of families prone to organ specific autoimmunity. Nevertheless, they can be also present in a 5-20% of healthy individuals.

ANTI-THYROID ANTIBODIES

44550 IFA – Complete kit, 12 slides x 4 wells
44551 IFA – Slide Box, 12 slides x 4 wells
Monkey Thyroid

ANTI-THYROID PEROXIDASE ANTIBODIES (TPO)

44795 ELISA kit, 96 T.
Recombinant human antigen

ANTI-THYROGLOBULIN ANTIBODIES (Tg)

44796 ELISA kit, 96 T.
Highly purified human antigen

DIABETES MELLITUS

Indirect immmunofluorescence assay is the conventional method for the determination of anti- islet cell antibodies (AICA). Islet cells antibodies (AICA) are strongly associated with insulin-dependent diabetes mellitus. Results obtained in a comparative study with anti-GAD and anti-IA2 antibodies detection tests showed a good concordance.

INSULIN

Autoantibodies against insulin are present in patients with type I diabetes along with other autoantibodies (mainly, anti-glutamic acid decarboxylase 65, anti-tyrosine phosphatase IA 2 and cytoplasmic islet cell antibodies), but anti-insulin antibodies are usually the first to appear. Anti-insulin antibodies are detectable in 50-70% of children at the onset of type I diabetes and only 20-30% in older patients.

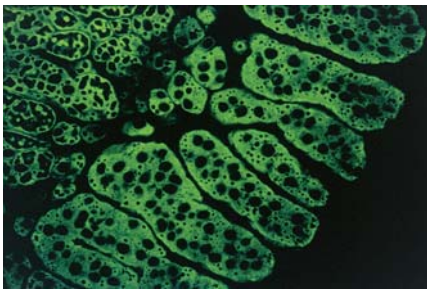
ANTI-ISLET CELLS ANTIBODIES

44609 IFA – Complete kit, 12 slides x 4 wells
Controls not included

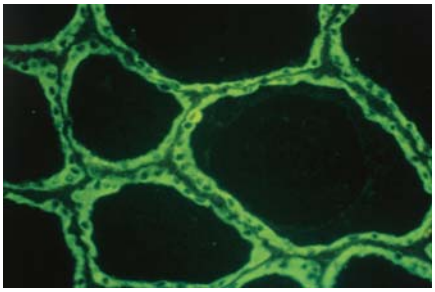
44572 IFA – Slide Box, 12 slides x 4 wells
Monkey Pancreas

ANTI-INSULIN ANTIBODIES

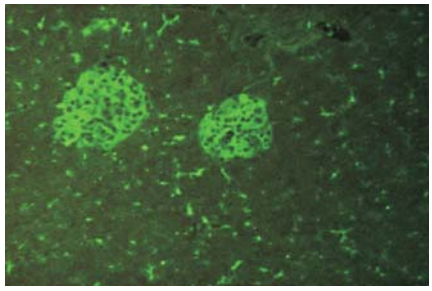
44873 ELISA KIT 96 T
Mixture of recombinant and purified insulin



Anti-adrenal cortex antibodies
Monkey adrenal cortex



Anti-thyroid peroxidase antibodies
Monkey thyroid



Anti-islet cell antibodies
Monkey pancreas

Bullous Diseases

ASA

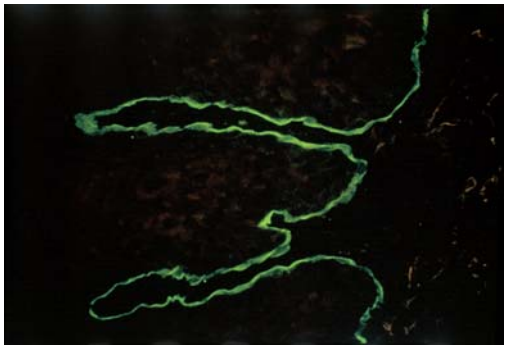
Anti-skin antibodies directed to the intercellular space of the stratified squamous epithelia are characteristic of pemphigus vulgaris, pemphigus foliaceus and paraneoplastic pemphigus. Although results obtained by indirect immunofluorescence are very specific for pemphigus, the type of pemphigus cannot be differentiated by indirect immunofluorescence. In a small percentage of patients with pemphigus, no circulating antibodies can be demonstrated, since the antibody already bound to the patient's skin.

Anti-basement membrane antibodies are found in 70% of patients with bullous pemphigoid by using indirect immunofluorescence, in 20-25% of patients with herpes gestationis and in 10% of patients with cicatricial pemphigoid.

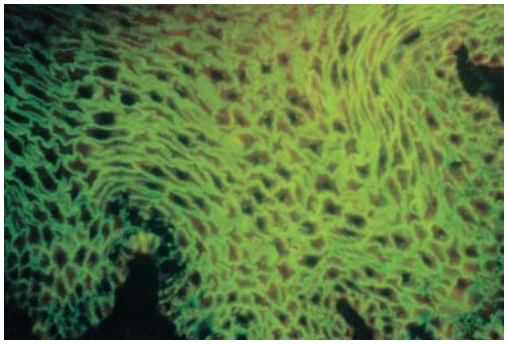
ANTI-SKIN ANTIBODIES (ASA)

44560 IFA – Complete kit, 12 slides x 4 wells
Controls not included

44561 IFA – Slide Box, 12 slides x 4 wells
Monkey Esophagus



Anti-skin antibodies.
Basement membrane Monkey esophagus



Anti-skin antibodies.
Intercellular substance Monkey esophagus

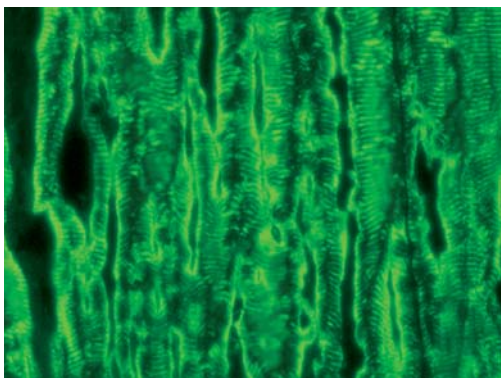
Miasthenia Gravis

AStMA

Anti-striated muscle antibodies react against the antigens localized in the I,A and Z bands of the muscle fiber, which act as the contractile elements of the skeletal muscle. Its presence has been described in 30-60% of patients with myasthenia gravis. The frequency of these antibodies in MG patients suffering from thymoma can reach up to 80-100%, depending on the study, becoming a valuable thymoma serological marker especially in patients with onset MG younger than 45 years. It is more predictive of thymoma when accompanied by a muscle acetylcholine receptor (AChR) modulating antibody. Its presence is also useful as a screening test for MG in older patients, especially when tests for muscle AChR antibodies are negative.

These antibodies mainly react with the intracellular skeletal muscle protein titin and the ryanodine receptor.

44649 **ANTI-STRIATED MUSCLE ANTIBODIES (AStMA)**
IFA – Slide Box, 12 slides x 4 wells
Rat striated muscle



Anti-Striated Muscle Antibodies
Rat striated muscle

Tissue Slides for Research Use Only (RUO)

Slides are provided as it, to be used according users' own procedures. Biosystems warrants a correct morphology and general reactivity as checked with anti-nuclear homogeneus positive control. Specific reactivity for an autoantigen is not checked or otherwise assumed for a particular tissue.

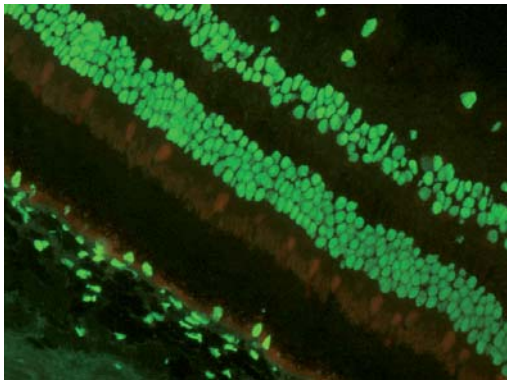
Not a complete kit. Other components are necessary to perform the test.

Usage of auxiliary reagents from different lots does not compromise the result.

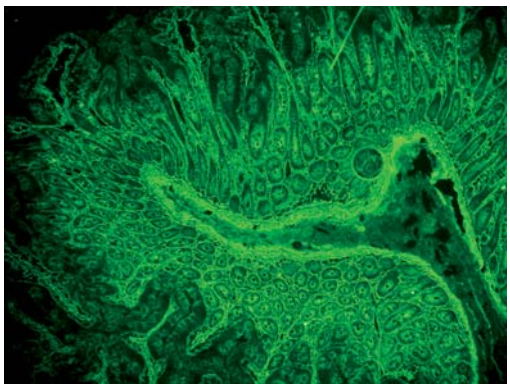
Tissues "For Research Use Only" (RUO) are not CE-labelled and are subject to special sale conditions.

(Only available under special request and subject to minimum orders. Ask your distributor for availability)

44571	Monkey Hearth
44679	Monkey Stomach
44573	Monkey Ovary
44685	Monkey Sciatic Nerve
44687	Monkey Brain
44684	Monkey Cerebellum
44589	Monkey Hypophysis
44688	Monkey Jejunum
44638	Monkey Submaxilary
44566	Monkey Testicle
44516	Rat Colon
44527	Rat Sciatic Nerve



Anti-Nuclear Antibodies
Monkey Retina



Anti-Endomysium antibodies
Monkey Jejunum

Conjugates

POLYVALENT CONJUGATES FOR USE WITH RAT AND MOUSE TISSUES

Goat anti-human immunoglobulines conjugated with fluorescein isothiocyanate (FITC) and adsorbed with rat serum, sodium azide 0.95 g/L. FITC/Evans conjugate (R) is valued against the WHO International Standard for FITC labeled sheep anti-human immunoglobulin.

44590	FITC/Evans (R)	3.5 mL	Contains Evans blue
44836	FITC/Evans (R)	10 mL	Contains Evans blue

BioSystems recommeds this conjugate for use with AUTOANTIBODIES SCREENING, AMA and ASMA.

IgG CONJUGATE

Goat anti-human IgG conjugated with fluorescein isothiocyanate (FITC), sodium azide 0.95 g/L. IgG FITC/Evans conjugate is valued against the WHO International Standard for FITC labeled sheep anti-human immunoglobulin.

44697	IgG FITC/Evans	3 mL	Contains Evans blue
44834	IgG FITC/Evans	10 mL	Contains Evans blue

BioSystems recommends this conjugate for use with ANA-HEp-2 cells, ANCA, nDNA, AKA and AStMA.

IgG CONJUGATE FOR USE WITH MONKEY TISSUES

Goat anti-human IgG conjugated with fluorescein isothiocyanate (FITC) and adsorbed with monkey serum. Evans blue 0.01g/L and sodium azide 0.95 g/L. IgG FITC/Evans (M) conjugate is valued against the WHO International Standard for FITC labeled sheep anti-human IgG immunoglobulin.

44847	IgG FITC/Evans (M)	3.5 mL
44882	IgG FITC/Evans (M)	10 mL

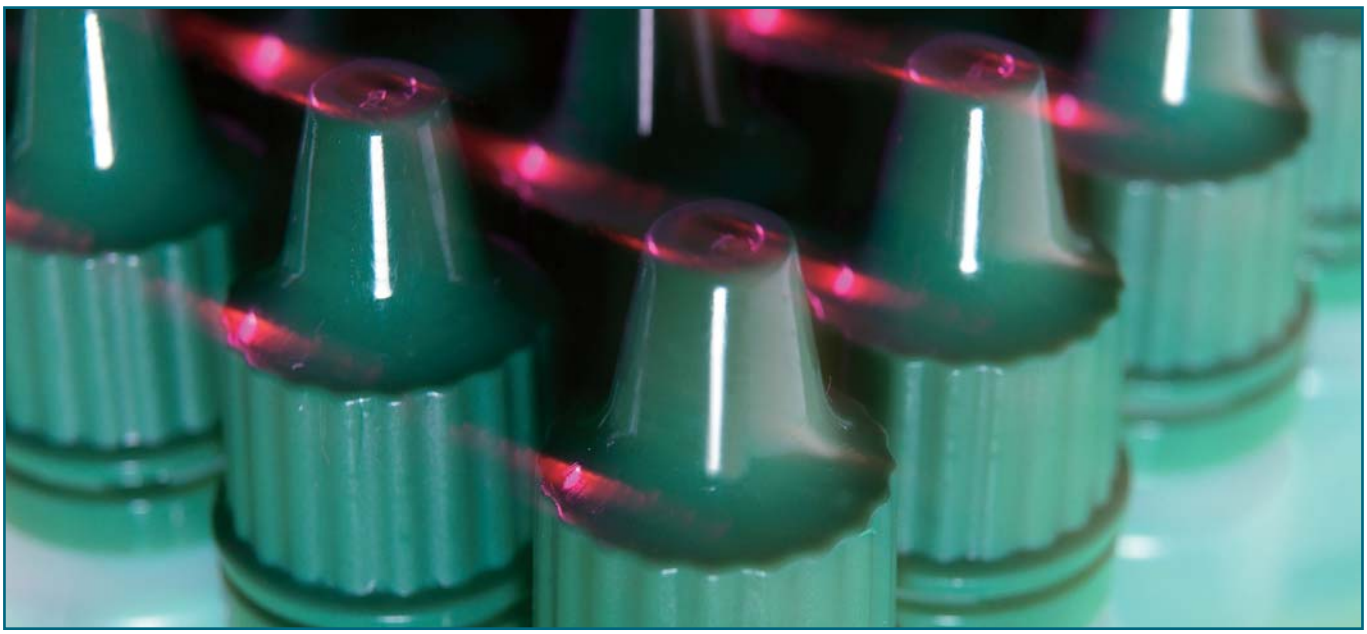
BioSystems recommends this conjugate for use with AEA, AACA,GBMA, ATA, ASA and AICA.

IgA CONJUGATE FOR USE WITH MONKEY TISSUES

Goat anti-human immunoglobulines conjugated with fluorescein isothiocyanate (FITC) and adsorbed with monkey serum. Sodium azide 0.95 g/L. IgA FITC/Evans conjugate is valued against the WHO International Standard for FITC labeled sheep anti-human immunoglobulin.

44692	IgA FITC/Evans	3.5 mL	Contains Evans blue
44835	IgA FITC/Evans	10 mL	

BioSystems recommends this conjugate for use with AEA.

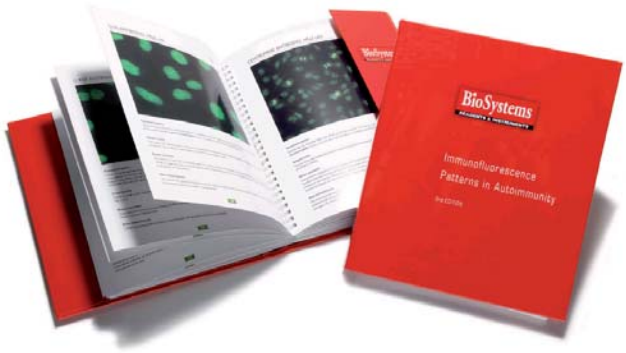


Auxiliary Reagents

44846	Glycin Solution	10 mL	For use with immunofluorescence GBMA kit
44592	PBS (10x)	100 mL	For use with all immunofluorescent kits
44694	Mounting Medium	3 mL	For use with all immunofluorescent kits

Immunofluorescence Controls

44549	ANTI-ENDOMYSIUM ANTIBODIES POSITIVE CONTROL	0.3 mL
44512	ANTI-MITOCHONDRIAL ANTIBODIES POSITIVE CONTROL	0.3 mL
44585	ANTI-NUCLEAR ANTIBODIES – Centromere POSITIVE CONTROL	0.3 mL
44730	ANTI-NUCLEAR ANTIBODIES – Homogeneous - POSITIVE CONTROL	0.3 mL
44504	ANTI-NUCLEAR ANTIBODIES – Nucleolar - POSITIVE CONTROL	0.3 mL
44503	ANTI-NUCLEAR ANTIBODIES – Speckled - POSITIVE CONTROL	0.3 mL
44522	ANTI-SMOOTH MUSCLE ANTIBODIES POSITIVE CONTROL	0.3 mL
44553	ANTI-THYROID ANTIBODIES POSITIVE CONTROL	0.3 mL
44542	ANTI-nDNA ANTIBODIES POSITIVE CONTROL	0.3 mL
44696	NEGATIVE CONTROL	0.3 mL
44854	C-ANCA POSITIVE CONTROL	0.3 mL
44855	P-ANCA POSITIVE CONTROL	0.3 mL
44896	X-ANCA POSITIVE CONTROL	0.3 mL
44889	NEGATIVE CONTROL	2.0 mL
44893	ANTI-ENDOMYSIUM ANTIBODIES POSITIVE CONTROL	2.0 mL
44891	ANTI-MITHOCONDRIAL ANTIBODIES POSITIVE CONTROL	2.0 mL
44892	ANTI-SMOOTH MUSCLE ANTIBODIES POSITIVE CONTROL	2.0 mL
44894	ANTI-nDNA ANTIBODIES POSITIVE CONTROL	2.0 mL
44888	ANTI-NUCLEAR ANTIBODIES – Homogeneous - POSITIVE CONTROL	2.0 mL



QUALITY CONTROL SCHEME & SUPPORT MATERIAL

Prevecal Autoimmunity
One year program with monthly report

18046 Prevecal Anti-Nuclear Antibodies Module

18047 Prevecal Anti-nDNA Module

18051 Prevecal Celiac Module

Support material

99729 HEp-2 Immunofluorescence Patterns

99698 Immunofluorescence Patterns in Autoimmunity Atlas

FLUORESCENCE MICROSCOPE (LED TECHNOLOGY)

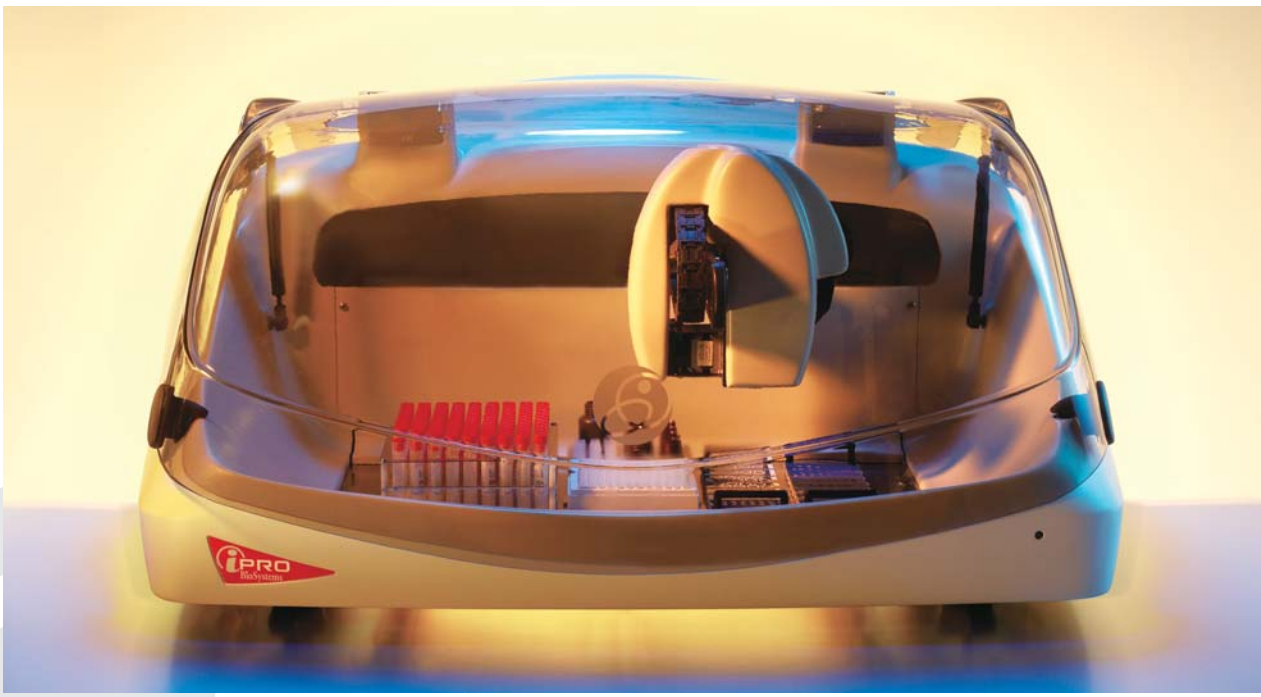
Optical system Infinity corrected plan objectives,
(10x, 20x and 40x)
Head & Eyepieces WF10x paired eyepiece.
Bright Field Ilumination 12V, 20W halogen light source with pre-centred light condenser bulb coupled with a collector lens system provides optimum brightness along the optical path.
Fluorescence Light Source High power blue LED (470-480nm).
Fluorescence Filters FITC
Power Supply 110 - 240V AC. 50Hz. Single phase.

Code **84201**

iPRO

IMMUNOFLUORESCENCE PROCESSOR

By Specialists, for Specialists

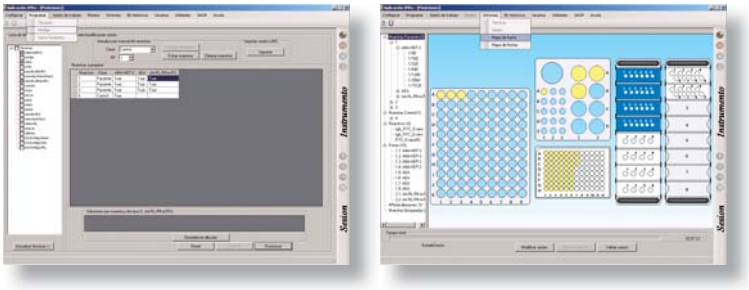


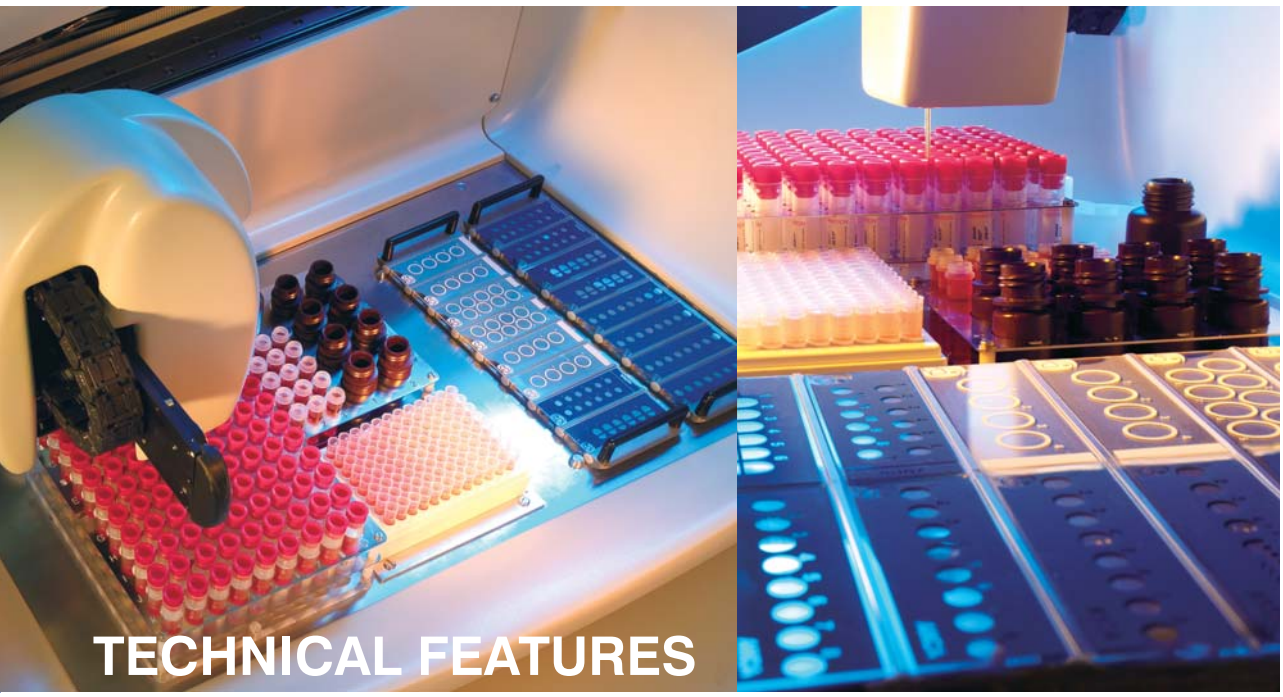
- A global approach to the immunofluorescence process: Automation, Traceability and Standardization. Biosystems Autoimmune Diseases products fulfil the complete system, providing the highest quality and a fully standardized process.
- The instrument can manage up to 8 conjugates on the same run, 2 sample diluents and washing buffer.
- Optimised working session times: 16 slides processing in a single step.
- Processes permit the automation of all tasks, including predilution, sample transfer, serial dilution, slide washing, incubation and conjugate addition.
- Robustness and reliability: The i-PRO automatic immunofluorescence processor permits real walk-away IF assays.
- "User-proof" setting up of the instrument: preprogrammed methods and slides.
- Hand-held barcode reader for sample ID and reagents identification (test, type of slide, lot and serial number). Everything to ensure maximum traceability in the process.
- Extremely sensitive probe height adjustment.
- Absolute confidence: from routine to speciality and research, Biosystems products are supported by thousands of satisfied professionals worldwide.
- Carefully designed to achieve optimal performance.

Code **84101**

USER-FRIENDLY SOFTWARE

The i-PRO software requires minimum operator training. The working process can be followed on screen, where sample, predilution, reagent and slide trays are shown.
At the end of each session, a layout of slides area can be printed to annotate the results obtained with microscope. LIMS interface can also be used to manage patients' data.





TECHNICAL FEATURES

Sample predilution cycle	26 s (with 2 mL of buffer solution)
Sample dispensation cycle	17 s (with 2 mL of buffer solution)
Reagent dispensation cycle	40 s for a 12 well slide for 25 µL each, including 1.5 mL of washing solution
Reagent volume	20 µL minimum by steps of 1 µL
Sample volume	3 µL minimum
Sample dispensation	CV<2% at 2.5 µL
Reagent dispensation	CV<2% at 25 µL
Sample tray	Interchangeable racks (13mm x 100 mm, 15 mm x 100 mm or 2 mL)
Dilution tray	96 vials (1.2 mL)
Slides (plates)	16 (2)
Reagent tray	8 conjugates (15 mL), 15 controls (2 mL), 1 additional diluent (50 mL)
Auxiliary reagents	1 L bottle washing solution, 1 L waste bottle, 1 L buffer bottle
Level sensor probe	Conductive
Slide washing	Flux system utilizing simultaneous use of dispense and aspirate probes
Barcode reader	Hand-held barcode reader (traceable slides)
Weight	68 Kg
Dimensions	101 x 62 x 50 cm (l x d x h); h:94 cm with cover opened
Power requirements	110-240 VAC, 50-60 Hz, 150 VA
Certificates	98/79/CE

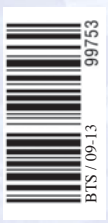
Immunofluorescence Laboratory Software

IMMUNOFLUORESCENCE LABORATORY SOFTWARE: TOTAL INTEGRATION

- LIMS Communication
- Bidirectional communication with iPro: import sessions and request new test
- Patterns, titers and images of controls configurable by test
- Patient results management in association with images from the camera (TWAIN compatible)
- Patient historical of results and images: SQL Server Database
- Possibility to print results report with images
- Image reference Atlas

Code **84301**

Alphabetical Index



Ginper Group | BioSystems

- Certified Management System
- EN ISO 9001
- EN ISO 13485

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