official distributor

SZABO-SCANDIC HandelsgmbH
Quellenstraße 110, A-1100 Wien
T. +43(0)1 489 3961-0
F. +43(0)1 489 3961-7
mail@szabo-scandic.com
www.szabo-scandic.com

SZABO SCANDIC

Trinity Biotech
YOUR DIAGNOSTICS PARTNER

Immco Diagnostics

The Total Solution in Autoimmunity

AUTOIMMUNE | HAEMOGLOBINS | INFECTIOUS DISEASE | POINT OF CARE | CLINICAL CHEMISTRY

AUTOIMMUNE | HAEMOGLOBINS | INFECTIOUS DISEASE | POINT OF CARE | CLINICAL CHEMISTRY

Table of Contents

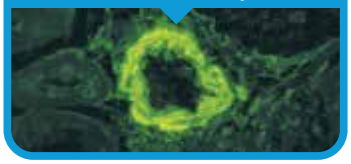
Connective Tissue Disorders

Antinuclear Antibodies (ANA)

Serological tests for ANA play an important role in the diagnosis of various autoimmune connective tissue disorders, especially systemic lupus erythematosus (SLE), systemic sclerosis (SSc), mixed connective tissue disease, and Sjögren's syndrome. ANA constitute one of the American College of Rheumatology (ACR) criteria for the diagnosis of SLE.

ANA are detected by various methods including IIFA (indirect Immunofluorence assay) IFA (Immunofluorence assay) on HEp-2 or other substrates and by ELISA. With IFA, ANA exhibit distinct fluorescent patterns which are associated with a specific disease or a subset of collagen vascular disorders (i.e. nucleolar antibodies are associated with SSc, centromere antibodies are associated with the CREST variant of SSc and homogeneous/ rim antibodies with SLE). HEp-2 cell cultures and tissue sections are the most commonly used substrates to detect ANA. ImmuLisa™ ANA detection methods are well standardized, sensitive and specific.

ASMA on Kidney



ANA (speckled) on HEp-2

ANA Midbody on HEp-2

AMA on Kidney/Stomach

Ribosomal P Ab on Stomach

Ribosomal P Ab on HEp-2

Disease	Titer	Prevalence
SLE – Active	>1:640	99%
SLE – Inactive		95%
SCLE		75%
Discoid LE		30%
Drug Induced Lupus		99%
Mixed connective tissue disease		99%
SSc		95%
Sjögren's Syndrome		75%
Myositis (Polymyositis and Dermatomyositis)		60%
Rheumatoid Arthritis		50%
Juvenile Rheumatoid Arthritis		70%
Autoimmune Hepatitis		40%
Hashimoto's Thyroiditis		40%
Normal[1]	1:40	5–10%

ANA Screen ELISA

The ImmuLisa™ ANA Screen ELISA provides a reliable method for detecting ANA. This assay meets the criteria established by The Italian Society of Laboratory Medicine Study Group on the Diagnosis of Autoimmune Diseases.2 It is a simple, objective and accurate test that can be performed manually or on standard instrumentation.

The ImmuLisa™ ANA Screen ELISA detects antibodies of many specificities including Ro/SS-A, La/SS-B, Sm, RNP, Scl-70, Jo-1, Centromere, Histone, and dsDNA.

ImmuLisa™ ELISA

Code	Description	Determinations
5175	ANA Screen ELISA	96

All kits are FDA approved and CE marked for IVD use unless otherwise noted. Please refer to the product index for complete listing of configurations and determinations.

*For research use only in the US.

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1. *Colglazier C, Sutej G. Laboratory Testing in the Rheumatic Diseases: A Practical Review. Southern Medical Journal. 2005;185-191.*
2. *Tozzoli R, Bizzaro N, et al. Guidelines for the Use of Autoantibody Tests in the Diagnosis and Monitoring of Autoimmune Rheumatic Diseases. Am J Clin Pathol. 2002;117:316-24.*

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COLLAGEN VASCULAR

ImmuGlo™ Immunofluorescence

Code	Description	Determinations
1102-60	ANA HEp-2 Cell IFA	60
1103	ANA HEp-2 Cell IFA	200
1103-240	ANA HEp-2 Cell IFA	240
1103-525	ANA HEp-2 Cell IFA	525
1107	COMVI™ mouse kidney/stomach	48
1107R*	COMVI™ rat kidney/stomach	48
1107-1	Autoantibody Test System 1 Kit	48
1134	COMVI™ HEp-2/mouse kidney/stomach	96
1134LKM*	COMVI™ HEp-2/mouse liver/kidney/stomach	48
1134R-LKM*	COMVI™ HEp-2/rat liver/kidney/stomach	48
1136	COMVI™ mouse liver/kidney/stomach	48
1136R*	COMVI™ rat liver/kidney/stomach	48

ImmuGlo™ Slides

Code	Description	Determinations
2148	COMVI™ rat kidney/stomach	8 well
2150	HEp-2 Cells	10 well
2150-6	HEp-2 Cells	6 well
2150-12	HEp-2 Cells	12 well
2150-21	HEp-2 Cells	21 well
2152	COMVI™ mouse kidney/stomach	8 well
2152-3	COMVI™ mouse kidney/stomach/liver	8 well
2161	Rat kidney	6 well
2163	Primate kidney	6 well
2190	COMVI™ HEp-2/mouse kidney/stomach	6 well
2190LKM	COMVI™ HEp-2/mouse liver/kidney/stomach	6 well
2190R-LKM	COMVI™ HEp-2/rat liver/kidney/stomach	6 well
2194	COMVI™ rat kidney/stomach/liver	8 well

ImmuGlo™ Controls / Components

Code	Description	Determinations
1602	ANA Pattern Control I (Homogeneous/Speckled/Centromere/Nucleolar/Peripheral Controls)	0.5 ml x 5
2099	Anti-human IgG FITC primate adsorbed conjugate	5 ml
2100	Anti-human IgG FITC conjugate	5 ml
2200	Autoantibody negative control	0.5 ml
2201	ANA positive control (homogenous)	0.5 ml
2201-1*	ANA low titer positive control (homogenous)	0.5 ml
2202	ANA positive control (speckled)	0.5 ml
2203	ANA positive control (centromere)	0.5 ml
2204	ANA positive control (nucleolar)	0.5 ml
2205	ANA positive control (peripheral)	0.5 ml
2210	Mitochondrial antibody positive control	0.5 ml
2210-1*	Mitochondrial antibody low titer positive control	0.5 ml
2211	Smooth muscle antibody positive control	0.5 ml
2212	Gastric parietal cell antibody positive control	0.5 ml
2215	nDNA antibody positive control	0.5 ml
2215-1*	nDNA antibody low titer positive control	0.5 ml
2236*	PCNA positive control	0.5 ml
2242*	LKM antibody positive control	0.5 ml
2261*	Ribosomal P antibody positive control	0.5 ml
2302	Buffered diluent	60 ml

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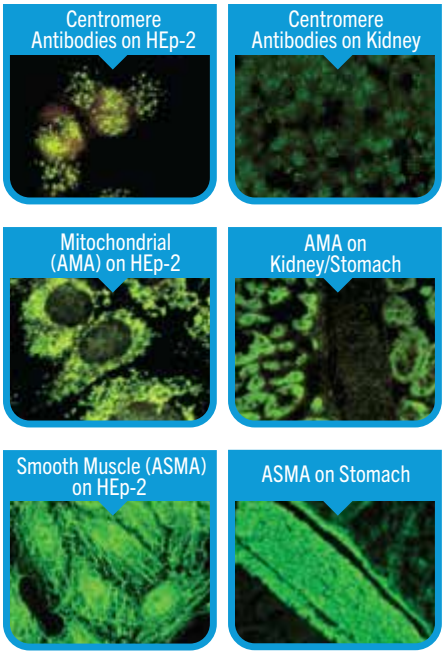
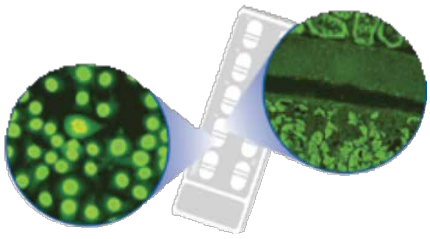


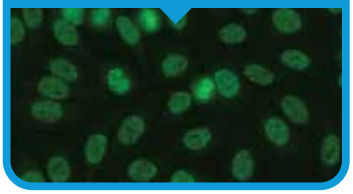


ImmuGlo™ COMVI™ slides

By combining HEp-2 with various tissue substrates, ImmuGlo™ COMVI™ slides represent a significant advance in technology and offer an ideal choice for the detection of ANA and other autoantibodies.

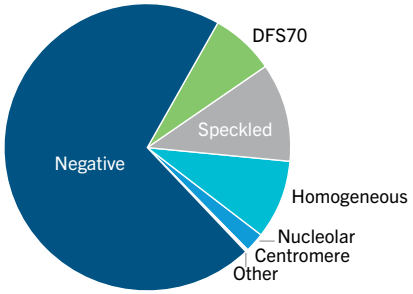
- ✓ Unsurpassed quality, convenience and economy with more diagnostic information available at a glance.
- ✓ Simultaneous reading of multiple antibody specificities: ANA, AMA, ASMA, AGPA and others.
- ✓ Differentiation of anti-centromere from centromere-like reactions.

DFS70 antibodies on conventional HEp-2 Substrate



DFS70 antibodies on HEp-2/DFS70KO Substrate
A. Engineered HEp-2
B. Conventional HEp-2

Typical Breakdown of HEp-2 Screening Results



Ann Rheum Dis 2001;60:1131–1136
Rev Assoc Med Bras 2007; 53(5): 439-45
Ann. N.Y. Acad. Sci. 2009; 1173: 166–173

Immco HEp-2 ELITE™

HEp-2/DFS70-KO IFA: Simple ANA detection/DFS70 Ab discrimination

Advantages of Immco HEp-2/ DFS70KO Substrate:

- ✓ Accurate and reliable detection of all ANA and DSF70 specificities in one single step
- ✓ Ability to reveal mixed pattern masked by DFS70 antibodies
- ✓ Optimal cell morphology and distribution
- ✓ Low cost- eliminates the need for cumbersome and expensive DFS70 Ab confirmation tests
- ✓ Standard procedure- utilizes our universal IFA reagents
- ✓ Ease of use- minimal training required and automatable

DFS70 Antibodies

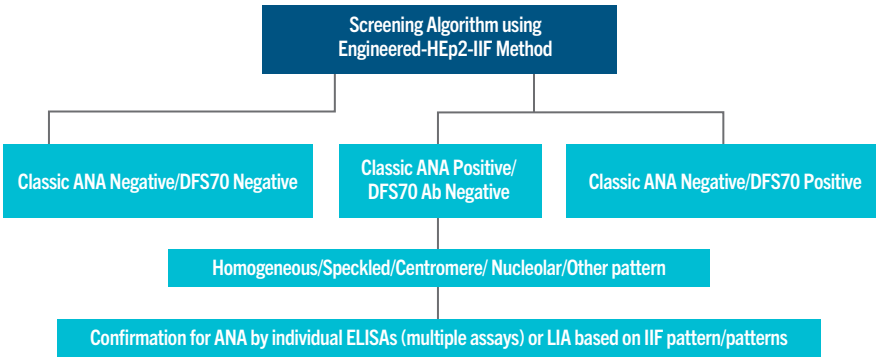
Simple ANA Detection/DFS70 Ab discrimination

HEp-2 IIF provides a great ANA screening substrate due to the variety of antibody specificities that can be detected in one single step, along with high clinical sensitivity and specificity. There are, however, some antibodies that can be detected on Hep-2 substrate that have no known clinical association, such as anti-DFS70 antibodies. Anti-DFS70 antibodies produce a nuclear dense fine speckled immunofluorescence pattern (DSF70) on HEp-2 cells, and tend to occur in 0.8%-11% of the screening population for ANA1,2. Differentiation of these antibodies can be quite challenging as they can resemble other specificities, such as homogeneous and fine speckled, that do have well characterized clinical associations in rheumatic diseases.

Immco HEp-2/DFS70KO (Knock-out) provides an optimal mixture of regular HEp-2 cells and engineered DFS70KO HEp-2 cells. Both types of cell present all classical ANA patterns with known disease association, while the DFS70KO cells inhibit the DFS70 Ab reactions providing clear differentiation of a pattern that can confound the most expert reader. Laboratories can now better differentiate homogeneous, fine speckled, and dense fine speckled in one easy screening step avoiding unnecessary further confirmatory testing.

"It is of utmost importance that the homogeneous pattern should be differentiated from the dense fine speckled (DFS) pattern in routing practice since the clinical significance of both patterns is quite different"[3]

1. *Bizzaro N, Tonutti E, Tampoia M, Infantino M, Cucchiaro F, Pesente F, et al. Specific chemoluminescence and immunoasdorption tests for anti-DFS70 antibodies avoid false positive results by indirect immunofluorescence. Clinica chimica acta; international journal of clinical chemistry 2015; 451:271-7.*
2. *Watanabe A, Kodera M, Sugiura K, Usuda T, Tan EM, Takasaki Y, et al. Anti-DFS70 antibodies in 597 healthy hospital workers. Arthritis and rheumatism 2004; 50:892-900.*
3. *Chan EK, Damoiseaux J, Carballo OG, Conrad K, de Melo Cruvinel W, Francescantonio PL, et al. Report of the First International Consensus on Standardized Nomenclature of Antinuclear Antibody HEp-2 Cell Patterns 2014-2015. Frontiers in immunology 2015; 6:412.*



ImmuGlo™ Immunofluorescence

Code	Description	Determinations
1108*	HEp-2/DFS70KO Substrate Kit	60
1108-120*	HEp-2/DFS70KO Substrate Kit	120
1108-240*	HEp-2/DFS70KO Substrate Kit	240

ImmuGlo™ Slides

Code	Description	Determinations
2298*	HEp-2/DFS70KO	12 well

ImmuGlo™ Controls / Components

Code	Description	Determinations
2100	IgG Conjugate	5 ml
2200	Autoantibody negative control	0.5 ml
2284*	DFS70 Positive Control	0.5 ml
2302	Buffer diluent	60ml

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Antinuclear Antibodies (ANA) Line Immunoassay (LIA)

ANA are sensitive but not disease specific markers of SLE and other connective tissue disorders. Precise identification of their molecular specificities is essential as they may be associated with a particular disease or a disease subset.

ImmcoStrip™ Line Immunoassay (LIA)

Code	Description	Determinations
6010*	ANA	20
6011*	ANA Advanced	20

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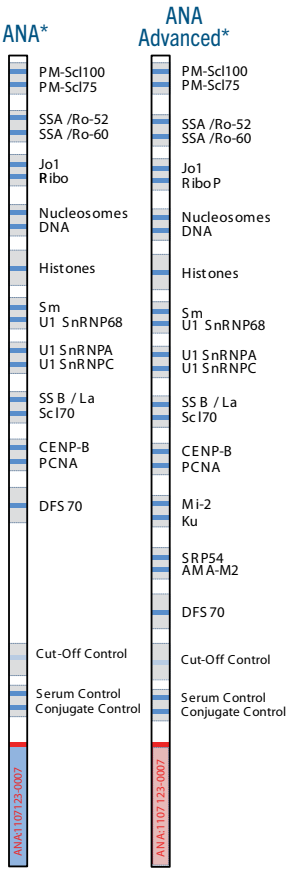


Extractable Nuclear Antigen (ENA) Autoantibodies

Autoantibodies directed against ENA are useful in the diagnosis and monitoring of various systemic connective tissue diseases. Sm antibodies are disease specific and occur in approximately 30-40% of SLE patients. Antibodies to RNP occur in 35-45% of SLE patients and in over 95% of patients with mixed connective tissue disease (MCTD). Antibodies to Ro/SS-A and La/SS-B occur in SLE patients approximately 30-40% and 10-15%, respectively. Antibodies to Ro/SS-A also occur in 60% of patients with subacute cutaneous Lupus Erythematosus (LE), in almost all cases of neonatal LE, in almost all SLE patients with Complement 2 deficiency and in about one half of patients with Sjögren's syndrome.

ImmuLisa™ ELISA

Code	Description	Determinations
5127	Enhanced Sm antibody ENA ELISA	96
5128	Enhanced Ro/SS-A antibody ENA ELISA	96
5129	Enhanced La/SS-B antibody ENA ELISA	96

1. *Colglazier CL, Sutej PG: Laboratory Testing in Rheumatic Diseases: A Practical Review. South Med J. 2005;98:185-191.*
2. *Habash-Bseiso DE, Steven HY, Glurich I, Goldberg JW: Serologic Testing in Connective Tissue Diseases. Clin Med Res. 2005;3:190-193.*

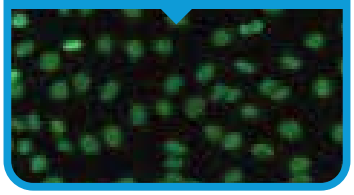
Sensitivity and Specificity of ANA and its Clinically Important Subtype

Autoantibodies	Associated CTD	Sens	Spec
ANA	SLE	93	57
	Sjögren's syndrome	48	52
	SSc	85	54
	PM/dermatomyositis	61	63
	Raynaud's phenomena	64	41
Specific ANA			
Anti-dsDNA	SLE	57	97
Anti-Sm	SLE	25-30	High*
Anti-SSA/Ro	Sjögren's, subacute cutaneous		
	SLE, Neonatal lupus syndrome	8-70	87
Anti-SSB/La	Sjögren's, subacute cutaneous		
	SLE, Neonatal lupus syndrome	16-40	94
Anti-U3-RNP	SSc	12	96
Anticentromere	Limited cutaneous SSc	65	99.9
Scl-70	SSc	20	100
Jo-1	PM	30	95

**Precise data not available.*

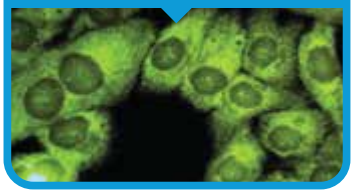
Antinuclear Antibody Detection on HEp-2 Cells[1]

Homogenous (Peripheral)



with Mitotic Cells Positive Reaction
DsDNA, Nucleosome, Histone Ab Positive
- SLE - Only Histone Positive
- Drug Induced LE

Cytoplasmic



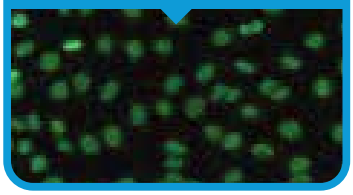
Fine Speckled
Jo-1 or other tRNA synthetase Positive
- Polymyositis
- Dermatomyositis

Homogenous
Ribosomal P Positive
- SLE

Fibrillar
Actin or other cytoskeleton antigen Positive
- Autoimmune Hepatitis?

Coarse Granular
Mitochondria Positive
- PBC

Speckled



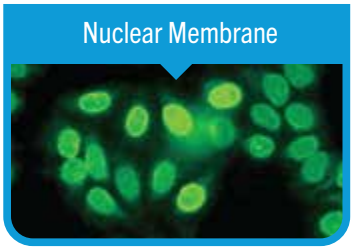
Large/Coarse
RNP Positive
- MCTD
- SLE
- SSc - Sm Positive
- SLE

Fine
Ro/SS-A, La/SS-B Positive
- Sjörgen's Syndrome
- SCLE

Nuclear Dots (SP-100)
- PBC

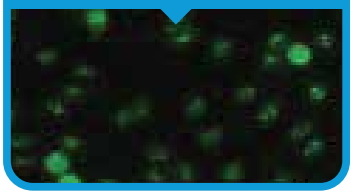
Discrete Speckled
Mitotic Cell, Centromere Positive
- Limited Scleroderma

Nuclear Membrane



With Mitotic Cells Negative Reaction
- Autoimmune Liver Disease (PBC)

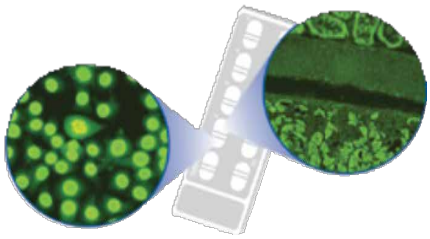
Nucleolar



Homogenous Pattern PM-Scl Positive
- Polymyositis
- Polymyositis/Scleroderma Overlap

Clumpy
Fibrillarin Positive
- Scleroderma

Speckled
Topoisomerase (Scl70), RNA Polymerase I / III Positive
- Scleroderma

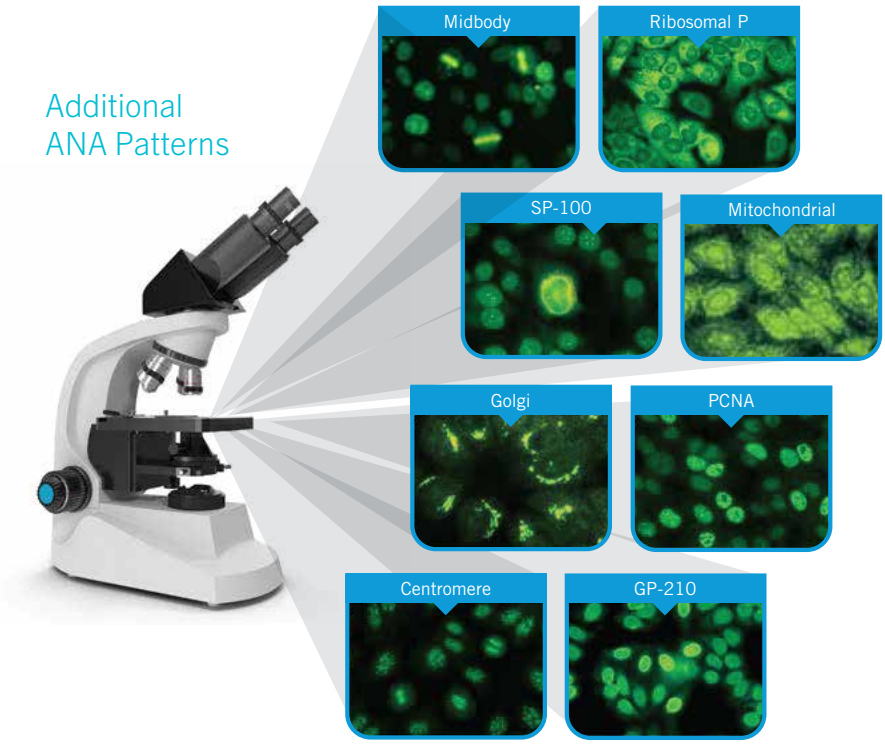


ImmuGlo™ COMVI™ slides

By combining HEp-2 with various tissue substrates, ImmuGlo™ COMVI™ slides represent a significant advance in technology and offer an ideal choice for the detection of ANA and other autoantibodies.

- ✓ Unsurpassed quality, convenience and economy with more diagnostic information available at a glance.
- ✓ Simultaneous reading of multiple antibody specificities: ANA, AMA, ASMA, AGPA and others.

Additional ANA Patterns



ABBREVIATIONS

LE	Lupus Erythematosus
SLE	Systemic Lupus Erythematosus
SCLE	Subacute Cutaneous Lupus Erythematosus
PBC	Primary Billiary Cirrhosis
SSc	Systemic Sclerosis
MCTD	Mixed Connective Tissue Disease

REFERENCES

1. Yoshinao, M. Antinuclear antibodies. Autoimmunity. 2005. 39(1): 3-9.

Connective Tissue Disorders

DNA Antibodies

ANA include antibodies to nuclear antigens such as DNA, histone and various extractable nuclear antigens (ENA). The microorganism Crithidia lucilliae contains a special organelle called the kinetoplast for native DNA (nDNA). This nDNA lacks histones and most other nuclear proteins that may cross react with autoimmune antibodies other than dsDNA antibodies. Three specificities occur within nDNA antibodies:

1. dsDNA antibodies reacting only with dsDNA (double stranded DNA)
2. ssDNA antibodies reacting only with ssDNA (single stranded DNA)
3. ds/ssDNA antibodies reacting with both dsDNA and ssDNA

Antibodies to nDNA are specific for systemic lupus erythematosus (SLE). The frequency and titer of dsDNA antibodies fluctuate with disease activity and tend to disappear upon immunosuppressive treatment and during remission. There is good correlation between disease activity and nDNA antibody levels. The two most commonly employed methods for detecting nDNA antibodies are indirect immunofluorescence (IFA) and enzyme linked immunosorbent assays (ELISA).

The ImmuLisa™ dsDNA antibody ELISA detects dsDNA antibodies of the IgG class. The results are reported in International Units per milliliter (IU/ ml). Both the calibrators and positive control have been standardized against the World Health Organization (WHO) Reference Reagent Wo/80. The ssDNA antibody ELISA detects ssDNA antibodies. Results are expressed in ELISA Units per milliliter (EU/ml).

A study on 245 serum specimens obtained from patients suspected of SLE and disease controls were tested for dsDNA antibody levels. The results of this study show a high degree of specificity and sensitivity of Enhanced ImmuLisa™ dsDNA Antibody test as compared to others in the marketplace. ImmuLisa™ dsDNA antibody test incorporates optimal presentation of a highly purified antigen to minimize non-specific reactions.

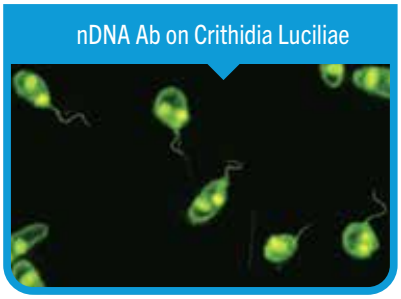
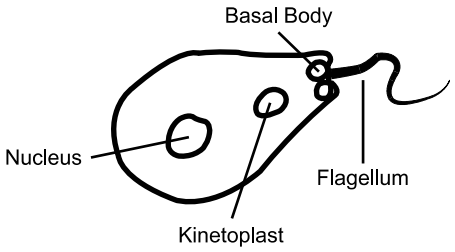


Diagram of Crithidia Morphology



ImmuGlo™ IFA

Code	Description	Determinations
1106	nDNA antibody *(Crithidia luciliae)*	48
1106-2	nDNA antibody *(Crithidia luciliae)*	96
1106-6	nDNA antibody *(Crithidia luciliae)*	120
2151-6	*Crithidia luciliae*	6 well

ImmuGlo™ Controls / Components

Code	Description	Determinations
2100	Anti-human IgG FITC conjugate	5 ml
2200	Autoantibody negative control	0.5 ml
2215	nDNA antibody positive control	0.5 ml
2215-1*	nDNA antibody low titer positive control	0.5 ml
2302	Buffered diluent	60 ml

ImmuLisa™ ELISA

Code	Description	Determinations
2100	Anti-human IgG FITC conjugate	5 ml
2200	Autoantibody negative control	0.5 ml
2215	nDNA antibody positive control	0.5 ml
2215-1*	nDNA antibody low titer positive control	0.5 ml
2302	Buffered diluent	60 ml

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Comparison of Kits Using *Crithidia luciliae* Substrate For Detection of Antibodies to nDNA

Clinical Condition	Immco n	Immco Positive	Immco Positive	Other Positive	Other Positive
SLE	28	19	68%	13	46%
Scleroderma	23	0	0%	0	0%
Rheumatoid Arthritis	8	0	0%	0	0%
Normal Controls	106	0	0%	0	0%

Immco's ImmuLisa™ dsDNA Ab Demonstrates Superior Performance to Support SLE Diagnosis

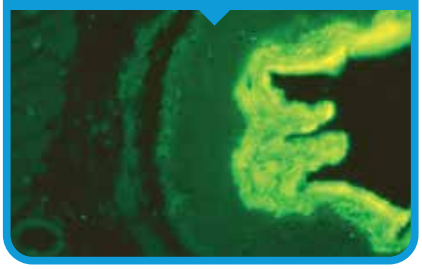
	ImmuLisa™ dsDNA	Competitor dsDNA
Sensitivity	88%	87%
Specificity	98%	94%
Clinical Agreement	94%	91%

Diagnostic Value of Rheumatoid Factor

RF Isotype	Sens.	Spec.	Pred.Val.
IgM	91%	76%	62%
IgG	55%	95%	87%
IgA	80%	80%	77%
IgM/IgG/IgA	53%	99%	57%
Latex Agglutination	83%	46%	57%

Adapted from I Vallbracht et.al. Ann Rheum Dis 2004;63:1079–1084.

AKA on Rat Esophagus



	Immco			Competitor	
RF	Screen	IgG	IgM	IgG	IgM
Sensitivity	100%	74%	96%	65%	84%
Specificity	89%	94%	83%	97%	88%
Clinical Agreement	95%	84%	89%	81%	86%

1. *Young BJJ et al. Br Med J. 1979;ii:97-99.*
2. *Aho K et al. J Rheumatol. 1993;20:1278-1281.*
3. *Kurki P et al. Arthr Rheum. 1992;35:914-917.*
4. *Paimela L et al. Ann Rheum Dis. 1992;51:743-746.*
5. *Von Essen R et al. Scand J Rheumatol. 1993;22:267-272.*
6. *Vincent C et al. Ann Rheum Diseases. 1989;48:712-722.*
7. *Aletaha D et al. Ann Rheum Diseases. 2010;69:1580-1588.*

Rheumatoid Arthritis

Rheumatoid Factor (RF)

RF is present in 70-90% of patients with Rheumatoid Arthritis (RA) and it is included in the ACR classification criteria. According to the revised ACR criteria, if RF is positive in patients with arthritis of three or more joints, the patient has RA. Arthritis of fewer than three joints with RF negative laboratory results excludes diagnosis of rheumatoid arthritis. This algorithm affords 93.5% sensitivity and 89.3% specificity for RA. Although agglutination is used routinely for detection of RF, other methods offer improved specificity, sensitivity and reliability. Enzyme linked immunosorbent assay (ELISA) methods, unlike agglutination, are able to detect the entire range of RF isotypes. Elevated levels of IgM and IgA RF isotypes are highly specific for RA. These RF isotypes are rarely found in rheumatic diseases other than RA. A study of 155 serum specimens obtained from patients both normal and suspected of RA as well as disease controls were tested for RF antibody levels. The Enhanced ImmuLisa™ RF IgG and IgM demonstrate significantly higher sensitivity and clinical agreement than the competitor assays. For the ImmuLisa™ RF Screen, a separate study of 220 serum specimens obtained from rheumatoid factor positive suspected RA patients alongside disease controls and normal human sera were tested for RF antibody levels. The ImmuLisa™ RF Screen performed at significantly higher sensitivity and clinical agreement levels than the competitor's individual assays.

Keratin Antibodies

Antibodies to Keratin (AKA), initially described by Young et al,1 have been found to be highly specific for RA. AKA can be detected by IFA on rat esophagus substrate, even prior to the onset of joint symptoms.2-6 AKA occur in approximately 40% of patients with RA and are present in approximately 33% of RA patients who are RF negative. RF and AKA are closely associated. Circulating immune complexes are found in significantly higher concentrations in RA patients positive for AKA. This may explain the association of AKA with severe forms of RA.

ImmuGlo™ Immunofluorescence

Code	Description	Determinations
1122*	Keratin antibodies	488

ImmuGlo™ Controls / Components

Code	Description	Determinations
2100	Anti-human IgG FITC conjugate	5 ml
2200	Autoantibody negative control	0.5 ml
2245*	Keratin antibody positive control	0.5 ml
2302	Buffered diluent	60 ml

ImmuLisa™ ELISA

Code	Description	Determinations
5138A	Enhanced RF IgA ELISA	96
5138G	Enhanced RF IgG ELISA	96
5138M	Enhanced RF IgM ELISA	96
5138S	Enhanced RF Screen ELISA	96

All kits are FDA approved and CE marked for IVD use unless otherwise noted.
Please refer to the product index for complete listing of configurations and determinations.
*For research use only in the US. All products may not be licensed for sale in Canada, please contact your Canadian distributor for more information.

Vasculitis

Antineutrophil Cytoplasmic Antibodies (ANCA)

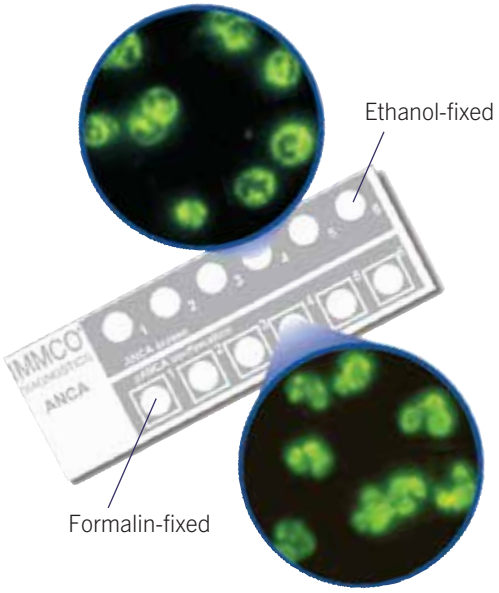
ANCA are serological indicators that aid in the diagnosis of various necrotizing systemic vasculitides, such as in Granulomatosis with polyangiitis and other small vessel vasculitic disorders. In addition, ANCA are also associated with inflammatory bowel disorders (IBD), primarily ulcerative colitis, and hence help in differentiating ulcerative colitis from Crohn's and in the classification of indeterminate colitis. cANCA is primarily associated with Granulomatosis with polyangiitis and the antigen specificity of cANCA is PR3. pANCA occurs in patients with polyarteritis nodosa, Churg-Strauss syndrome and ulcerative colitis. The antigen specificity of the pANCA in small vessel vasculitis is MPO.

A study of more than 200 serum specimens obtained from patients suspected with small vessel vasculitis and disease controls were tested for ANCA antibody levels. The results of these studies show a high degree of specificity and sensitivity of Enhanced ImmuLisa™ PR3, MPO and ANCA Screen antibody tests as compared to the others in the market place. The increased accuracy of ImmuLisa™ antibody assays is due to optimal selection and presentation of the antigen on the microwell that minimizes non-specific interactions.

Reaction Patterns

Fixative	cANCA	pANCA
Ethanol	granular, cytoplasmic	perinuclear
Formalin	granular, cytoplasmic	granular, cytoplasmic
Antigen Specificity	85-90% PR3 10-15% others (e.g. cathepsin G)	90% MPO 10% others (e.g. elastase, lactoferrin)

COMVI™ ANCA Slide



		ImmuLisa™ ELISA Assay			Competitor		
Assay		Sensitivity	Specificity	Clinical Agreement	Sensitivity	Specificity	Clinical Agreement
PR3	202	97%	99%	99%	95%	100%	99%
MPO	201	100%	99%	100%	96%	99%	99%
ANCA Screen	229	99%	94%	96%	n/a	n/a	n/a

ImmuGlo™ COMVI™ ANCA IFA

- ✓ Simultaneous reading and confirmation of cANCA and pANCA reactions on the same slide
- ✓ Allows identification of Atypical pANCA associated with IBD
- ✓ Unsurpassed convenience and economy
- ✓ Kits contain substrate slides, standardized conjugate, controls, serum diluent, wash buffer, mounting medium & cover slips

ImmuGlo™ Immunofluorescence

Code	Description	Determinations
1116	ANCA (ethanol fixation)	24
1140	ANCA (ethanol fixation)	48
1140-2	ANCA (ethanol fixation)	96
1140-240	ANCA (ethanol fixation)	240
1141	ANCA (formalin fixation)	48
1142	COMVI™ ANCA (ethanol/formalin fixation)	48

ImmuGlo™ Slides

Code	Description	Determinations
2162	Ethanol fixed PMN cells	6 well
2162-12	Ethanol fixed PMN cells	12 well
2186	Formalin fixed PMN cells	6 well
2189	COMVI™ ethanol/formalin fixed PMN cells (6 ethanol + 6 formalin)	6+6 well

ImmuGlo™ Controls / Components

Code	Description	Determinations
2100	Anti-human IgG FITC conjugate	5 ml
2200	Autoantibody negative control	0.5 ml
2240	pANCA positive control	0.5 ml
2252	cANCA positive control	0.5 ml
2252-1*	cANCA low titer positive control	0.5 ml
2302	Buffered diluent	60 ml

ImmuLisa™ ELISA

Code	Description	Determinations
5161	Enhanced Myeloperoxidase (MPO) antibody ELISA	96 ml
5162	Enhanced Proteinase 3 (PR3) antibody ELISA	96 ml

Captia™ ELISA Kits

Code	Description	Determinations
2338870	Captia™ Myeloperoxidase (MPO/ p-ANCA) IgG, IgA, IgM EIA	96 ml
2338970	Captia™ Proteinase-3 (PR-3 / c-ANCA) EIA	96 ml

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Significance of ANCA in Vasculitis

Type of Vasculitis	Sensitivity %			
	N	cANCA+PR3	pANCA+MPO	cANCA/PR3 or pANCA/MPO
Granulomatosis with polyangiitis (GPA)	97	56-58	16	7
Microscopic polyangitis (MPA)	44	37-41	49	67
Idiopathic RPGN	12	36	46	82
Classical polyarteritis nodosa	10	10	10	20
Eosinophilic Granulomatosis with Polyangiitis (EGPA)	6	0-33	33	56

Types of Vasculitis

ANCA Associated Vasculitis

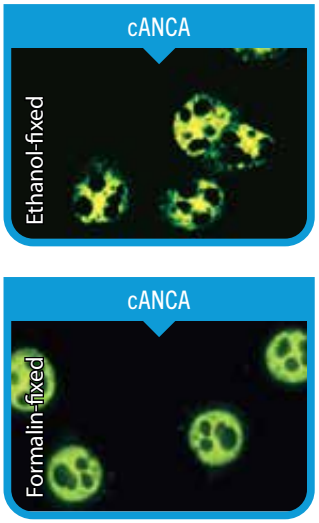
- ✓ Granulomatosis with polyangiitis
- ✓ Microscopic polyangiitis
- ✓ Churg-Strauss syndrome
- ✓ Drug induced

Non ANCA Associated Vasculitis

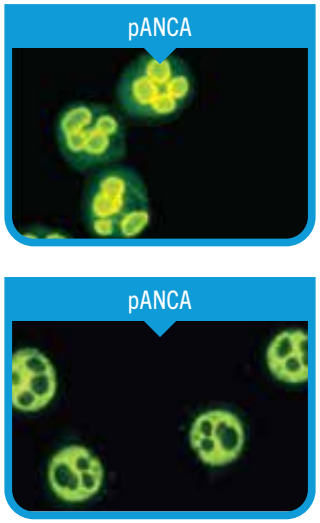
- ✓ Immune complex small vessel vasculitis
- ✓ Henoch-Schönlein purpura
- ✓ Cryoglobulinemic vasculitis
- ✓ Cutaneous leukoclastic vasculitis
- ✓ Goodpasteur's syndrome

Antinuclear Antibody Detection on HEp-2 Cells[1]

1. **ImmuGlo™ IFA** pattern with ImmuLisa™ anti-PR3 positive indicates diagnosis: GP



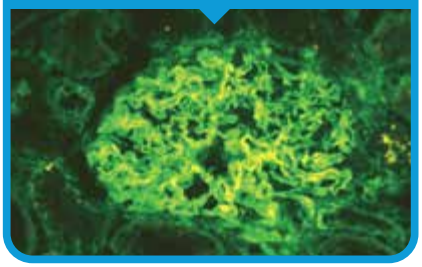
2. **ImmuGlo™ IFA** pattern with ImmuLisa™ anti-MPO positive indicates possible diagnosis: GP, CSS or MPA



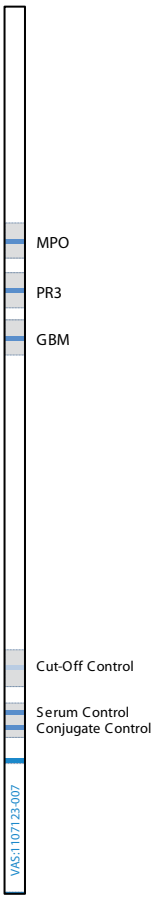
3. **ImmuGlo™ IFA** pattern with ImmuLisa™ ANCA negative indicates diagnosis: Inflammatory Bowel Disease

4. **ImmuGlo™ IFA** pattern on ANA in combination with ImmuGlo™ on HEp-2 indicates possible diagnosis: Connective Tissue Diseases

GBM Antibodies on Promate Kidney



Vasculitis*



Vasculitis

Glomerular Basement Membrane (GBM) Antibodies

Antibodies to GBM occur in glomerulonephritis and Goodpasture Syndrome. Rapidly progressive glomerulonephritis (RPGN) is characterized by crescentic glomerulonephritis. If the condition is not recognized early and an appropriate treatment implemented, the prognosis for RPGN is poor. RPGN may be assessed based on serum studies for various antibodies, direct immunofluorescence and electron microscope evaluations of renal biopsies.

Using the above criteria RPGN may be classified into:

1. Immune complex mediated disease characterized by the presence of DNA antibodies or streptococcal antibodies.
2. GBM mediated glomerulonephritis and Goodpasture syndrome.
3. Antineutrophil cytoplasmic antibody (ANCA) associated glomerulonephritis.

In a study of 889 RPGN suspected patients, 47 (5%) had anti-GBM, 246 (28%) had ANCA and 576 (65%) had neither antibodies. 2% had both ANCA and GBM antibodies.

ImmuGlo™ Immunofluorescence

Code	Description	Determinations
1124*	GBM antibody	48

ImmuGlo™ Slides

Code	Description	Determinations
2163*	Primate kidney	6 well
2167-8	Mouse kidney	8 well

ImmuGlo™ Controls / Components

Code	Description	Determinations
2099	Anti-human IgG FITC primate adsorbed conjugate	5 ml
2100	Anti-human IgG FITC conjugate	5 ml
2200	Autoantibody negative control	0.5 ml
2200GBM*	GBM Negative Control	0.5 ml
2267*	GBM antibody positive control	0.5 ml
2303*	GBM buffered diluent	60 ml
2312*	GBM enhancing buffer for GBM Kit	5 ml

ImmcoStrip™ Line Immunoassay (LIA)

Code	Description	Determinations
6030*	Vasculitis	20 ml

All kits are FDA approved and CE marked for IVD use unless otherwise noted. Please refer to the product index for complete listing of configurations and determinations.
*For research use only in the US.
‡Contains ImmuGlo™ anti-human IgG FITC primate adsorbed conjugate.
All products may not be licensed for sale in Canada, please contact your Canadian distributor for more information.

Antigen Enhancing Buffer

The GBM antibody IFA kit includes an exclusive antigen enhancing buffer to provide excellent sensitivity for the detection of GBM autoantibodies.

Celiac Disease

Endomysial Antibodies (EMA) Reticulin Antibodies (ARA)

Celiac disease (CD), is a common clinically heterogenous gastrointestinal disorder, which can exhibit with non-classic or minimal symptoms. Patients have antibodies to tissue transglutaminase, endomysium, reticulin and gliadin. Early diagnosis in such patients may improve their overall prognosis and strict avoidance of gluten in the diet is recommended to control the disease activity.

The European and North American Societies of Pediatric Gastroenterology and Nutrition recommend the use of serological testing for patients suspected of CD and to monitor dietary compliance. The European Society for Pediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) has recommended inclusion of serological tests in diagnosis to reduce the number of intestinal biopsies needed. These include tests for tissue transglutaminase (tTG), gliadin (AGA) and endomysial antibodies (EMA). Increasingly, deamidated gliadin peptide (DGP) is being used to replace conventional gliadin in CD testing due to increased sensitivity and specificity.

ImmuGlo™ Immunofluorescence

Code	Description	Determinations
1114	EMA (smooth muscle) IgA/IgG	48 ml
1114-96	EMA (smooth muscle) IgNigG	96 ml
1114A*	EMA (smooth muscle) IgA	48 ml
1114A*-PDE	EMA (primate distal esophagus) IgA	48ml
1114A*-PDE-250	EMA (distal esophagus) IgA	250 ml
1114G-PDE*	EMA(distal esophagus) IgG	48 ml
1115	Reticulin IgNigG IFA	48 ml

ImmuGlo™ Slides

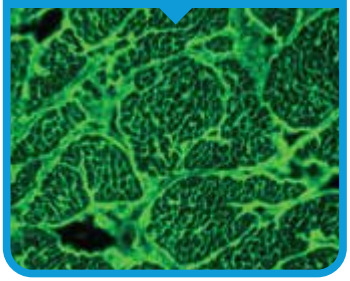
Code	Description	Determinations
2155-1	Primate distal esophagus	6 well
2155-1/10	Primate distal esophagus	10 well
2155-18	Primate distal esophagus	8 well
2160	Primate smooth muscle	6 well
2161	Rat kidney	6 well

ImmuGlo™ Controls / Components

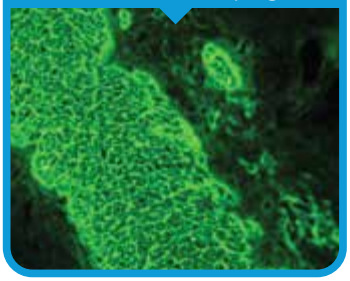
Code	Description	Determinations
2099	Anti-human IgG FITC primate adsorbed conjugate - Contains Evan's Blue	5 ml
2100	Anti-human IgG FITC conjugate (For use with 1114G-PDE)	5 m
2107	Anti-human IgA FITC conjugate (For use with 1114A and 1114A-PDE)	5 ml
2113	Anti-human IgNigG FITC conjugate (For use with 1114 and 1115)	5 ml
2200	Autoantibody negative control	0.5 ml
2250	EMA positive control	0.5 ml
2250-1*	EMA low titer positive control	0.5 ml
2250G	EMA IgG positive control	0.5 ml
2251	Reticulin antibody positive control	0.5 ml
2302	Buffered diluent	60 ml

All kits are FDA approved and CE marked for /VD use unless otherwise noted.
Please refer to the product index for complete listing of configurations and determinations.
*For research use only in the US.
*Contains ImmuGlo™ anti-human /gG FITC primate adsorbed conjugate.
All products may not be licensed for sale in Canada, please contact your Canadian distributor for more information.

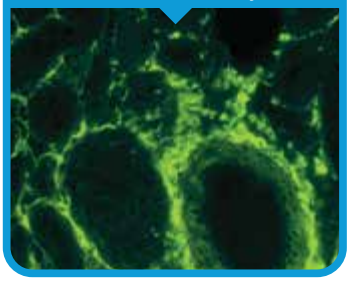
EMA on Primate Smooth Muscle



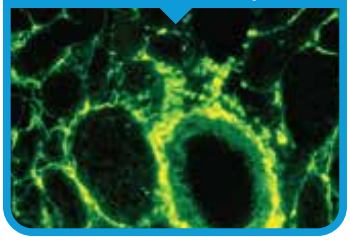
EMA on Primate Esophagus



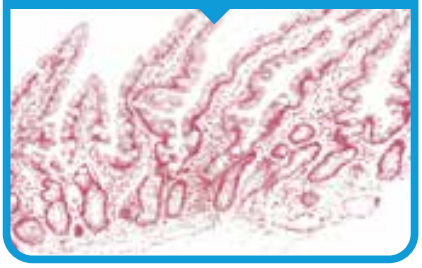
ARA on Rat Kidney



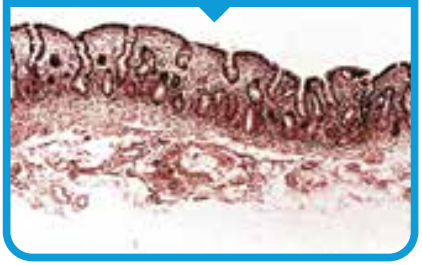
Reticulin on Kidney



Normal: Healthy Villi



Active CD: Villous Atrophy



Celiac Disease

Tissue Transglutaminase (tTG) Antibodies

Tissue Transglutaminase (tTG) has been identified as the endomysial antigen leading to the development of ELISA methods for detecting antibodies in the sera of patients with CD. The advantage of the tTG antibody assay is that it is automatable and less subjective than EMA. In various studies on the efficacy of the tTG antibody method for screening for CD, the specificity and sensitivity of this method has been found to range from 90 percent to

95 percent. Human tTG has been described to improve the sensitivity of the tTG antibody assay for CD. Immco has developed tTG antibody assays using a patented technology that increases sensitivity and specificity for detecting antibodies of IgA and IgG isotypes, thus enabling identification of CD patients that may be IgA deficient.

ImmuLisa™ ELISA

Code	Description	Determinations
5144A†	Enhanced Celiac tTG IgA ELISA	96
5144G†	Enhanced Celiac tTG IgG ELISA	96

All kits are FDA approved and CE marked for IVD use unless otherwise noted.
Please refer to the product index for complete listing of configurations and determinations.
*For research use only in the US.
†Manufactured by Immco Diagnostics; distributed in Europe by A. Menarini Diagnostics S.r.l.
Patent on file.

Inflammatory Bowel Disease (IBD): Ulcerative Colitis (UC) and Crohn's disease

Antineutrophil Cytoplasmic Antibodies (ANCA)

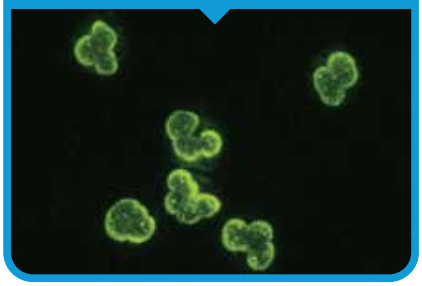
Studies have shown that approximately 80% of patients with UC and PSC and approximately 25% of patients with Crohn's disease have pANCA. The atypical pANCA pattern, as characterized by inhomogenous staining of the perinuclear area with fluorescent dots in the nuclei, has been reported to occur in patients with IBD and primary sclerosing cholangitis (PSC).

Atypical pANCA occur in patients with UC. The specificity of atypical pANCA can be confirmed by testing the positive samples with ANCA reaction for ANA on HEp-2 and for pANCA specificity on formalin fixed slides. Negative ANA and the absence of cANCA reaction on ethanol fixed slides are characteristic of atypical pANCA. Alternatively negative results on MPO ELISA and ANA in conjunction with positive pANCA reactions on ethanol fixed slides are characteristic of atypical pANCA.

Various ANCA Staining Patterns

Pattern	PMN Cells	
	Ethanol-fixed	Formalin-fixed
cANCA	Granular cytoplasmic staining with accentuation between the nuclear lobes	Granular cytoplasmic staining
pANCA	Homogeneous perinuclear staining	Granular cytoplasmic staining
Atypical pANCA	Inhomogeneous perinuclear staining with multiple fluorescent foci (snow drift effect)	Perinuclear staining (rule out ANA positivity)

Atypical pANCA



ImmuGlo™ Immunofluorescence

Code	Description	Determinations
1116	ANCA (ethanol fixation)	24
1140	ANCA (ethanol fixation)	48
1140-2	ANCA (ethanol fixation)	96
1140-240	ANCA (ethanol fixation)	240
1141	ANCA (formalin fixation)	48
1142	COMVI™ ANCA (ethanol/formalin fixation)	48

ImmuGlo™ Slides

Code	Description	Determinations
2162	Ethanol fixed PMN cells	6 well
2162-12	Ethanol fixed PMN cells	12 well
2186	Formalin fixed PMN cells	6 well
2189	COMVI™ ethanol/formalin fixed PMN cells *(6 ethanol + 6 formalin)*	6+6 well

ImmuGlo™ Conjugates / Controls / Components

Code	Description	Determinations
2100	Anti-human IgG FITC conjugate	5 ml
2200	Autoantibody negative control	0.5 ml
2240	pANCA positive control	0.5 ml
2252	cANCA positive control	0.5 ml
2252-1*	cANCA low titer positive control	0.5 ml
2302	Buffered diluent	60 ml

ImmuLisa™ ELISA

Code	Description	Determinations
5161	Enhansed Myeloperoxidase (MPO) antoibody ELISA	96
5162	Enhansed Proteinase 3 (PR3) antoibody ELISA	96

All kits are FDA approved and CE marked for IVD use unless otherwise noted.
Please refer to the product index for complete listing of configurations and determinations.
*For research use only in the US.
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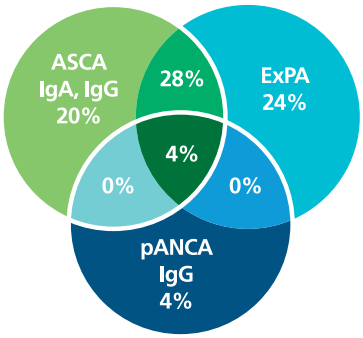
Testing for ANCA by immunofluorescence aids physicians in diagnosing cases of IBD and differentiating ulcerative colitis from Crohn's disease.

ExPA as a Diagnostic Tool for Crohn's Disease

1. ExPA is a very specific diagnostic marker for Crohn's disease.
2. ExPA has a sensitivity similar to that of ASCA, but it is also able to identify a subpopulation of Crohn's patients that are ASCA negative.
3. Combining detection of ExPA and ANCA offers superior results both in IBD diagnosis and in differentiating Crohn's disease from ulcerative colitis.

Incidence of ASCA, ExPA and ANCA in IBD



Inflammatory Bowel Disease (IBD): Ulcerative Colitis (UC) and Crohn's disease

Exocrine Pancreas Antibodies (ExPA)

ExPA have been suggested as a very specific serological markers for Crohn's disease. ExPA are circulating antibodies that react with secretory granules in the cytoplasm of exocrine pancreas cells. Through IFA using a primate pancreas substrate their presence is demonstrated by a specific reticulo-granular green fluorescence in the cytoplasm of the exocrine pancreas cells.

Clinical studies report an ExPA prevalence of 30-50% in patients with Crohn's disease. In spite of the relatively low sensitivity ExPA detects a subpopulation of Crohn's patients that are negative for other Crohn's markers (ASCA), and are therefore very useful in combination with other IBD diagnostic tests. Testing for ExPA is also highly specific. Normal individuals and patients suffering from UC or other gastrointestinal inflammations do not exhibit presence of ExPA in their sera.

The presence of ExPA may also have a prognostic value for Crohn's susceptibility. ExPA have been detected in healthy first-degree relatives of Crohn's patients that display a significant increased risk of developing Crohn's.

ImmuGlo™ Immunofluorescence

Code	Description	Determinations
1194*	ExPA	40

All kits are FDA approved and CE marked for IVD use unless otherwise noted.
Please refer to the product index for complete listing of configurations and determinations.
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Pernicious Anemia and Autoimmune Gastritis

Pernicious anemia is one of the most common causes of Vitamin B12 (Cobalmine) deficiency. Vitamin B12 deficiency can result in hematological, neurological, and psychiatric complications. Histologically, pernicious anemia is characterized by gastric mucosal atrophy, selective loss of parietal and chief cells from the gastric mucosa, and submucosal lymphocytic infiltrate. Immunologically, the hallmark of pernicious anemia is the presence of autoantibodies to gastric parietal cells, proton pump (H+K+ATPase), and to the cobalamine absorbing protein, intrinsic factor. Autoimmune gastritis, leading to pernicious anemia, is characterized by the presence of serum antibodies to gastric parietal cells (AGPA) and intrinsic factor.

Intrinsic Factor

Intrinsic factor is a 60 kD glycoprotein produced by the parietal cells of the stomach lining and enables the absorption of vitamin B12. In acquired pernicious anemia there is a significant decrease in intrinsic factor expression due to the loss of intrinsic factor producing gastric parietal cells, which results in the body's inability to absorb vitamin B12 in the stomach. Intrinsic factor antibodies are of IgG isotype and occur in about 70% of patients with pernicious anemia. Intrinsic factor antibodies are classified into two types:

- **Type I** (blocking antibodies) block the binding of vitamin B12 to intrinsic factor and thereby prevent the uptake of vitamin B12.
- **Type II** (binding antibodies) antibodies bind to a remote site to the blocking antibodies and prevent the attachment of intrinsic factor cobalamine complex to the ileal receptors.

Both types I and II result in the same pathological effect, prevention of cobalamin e absorption. Type II antibodies rarely occur in the absence of type I antibodies.

ImmuGlo™ Immunofluorescence

Code	Description	Determinations
1107	COMVI™ mouse kidney/stomach	48
1107R*	COMVI™ rat kidney/stomach	48

ImmuGlo™ Slides

Code	Description	Determinations
2148*	COMVI™ rat kidney/stomach	8 well
2152	COMVI™ mouse kidney/stomach	8 well
2169*	COMVI™ mouse stomach	8 well
2173*	COMVI™ rat stomach	6 well

ImmuGlo™ Conjugates / Controls / Components

Code	Description	Determinations
2099	Anti-human IgG FITC Primate absorbed conjugate	5 ml
2100	Anti-human IgG FITC conjugate	5 ml
2200	Autoantibody negative control	0.5 ml
2212	Gastric parietal cell antibody positive control	0.5 ml
2302	Buffered diluent	60 ml

All kits are FDA approved and CE marked for IVD use unless otherwise noted.
Please refer to the product index for complete listing of configurations and determinations.
*For research use only in the US.
~Special order
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Advantages of ImmuLisa™ Intrinsic Factor antibody

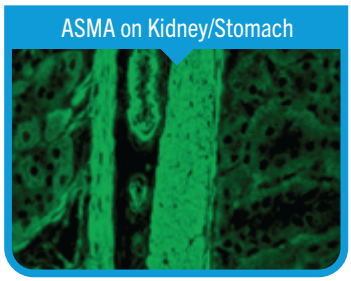
1. Desired sensitivity for pernicious anemia.
2. No false positives as seen with RIA or other B12 inhibition assays.
3. Greater sensitivity.
4. Both type I and II intrinsic factor antibodies are detected.
5. Recombinant intrinsic factor provides greater consistency and higher purity than native purified antigen.

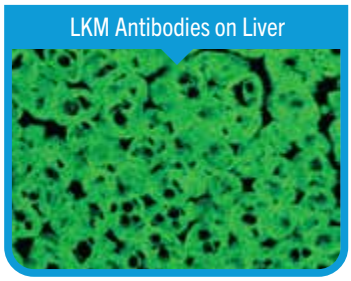
Anti-Gastric Parietal Cell Antibodies (AGPA)

Anti-gastric parietal cell antibody (AGPA) detection primarily aid in the diagnosis of autoimmune gastritis and are also a useful tool in the diagnosis of pernicious anemia along with intrinsic factor antibodies.

AGPA on Mouse Stomach

Gluten Sensitive Enteropathy





Autoimmune Hepatitis

Autoimmune hepatitis (AIH) is a chronic inflammatory liver disease characterized by interface hepatitis, hypergammaglobulinemia, and the presence of certain autoantibodies. The annual incidence of newly diagnosed AIH is approximately 2 in 100,000 people. The overall incidence is 17 in 100,000 people. AIH accounts for 2.6% - 5.9% of the liver transplants in Europe and USA.

Two types of AIH have been described. Type 1 AIH is the most common. It is associated with the presence of anti-smooth muscle antibodies (SMA) and/or antinuclear antibodies (ANA). Type 2 AIH is associated with liver/kidney microsomal 1 (LKM-1) antibodies. These antibodies are usually detected by indirect IFA reactions on composite liver/kidney/stomach sections. AIH in association with LKM antibodies is also associated with 15% of patients with autoimmune polyglandular syndrome 1 (APS1). LKM antibodies need to be differentiated from anti-mitochondrial antibodies (AMA). The latter react on the distal tubules of the kidney, whereas LKM antibodies on kidney are either negative or weak positive reactions of the proximal rather than the distal tubules.

Anti-Smooth Muscle Antibodies (ASMA)
ASMA are detected by immunofluorescence on a composite tissue block of stomach, kidney and liver. The characteristic reaction pattern of ASMA is that of strong homogenous staining of the cytoplasm of the muscularis mucosa and the interglandular muscle strands of the stomach, the media of the blood vessels, the intercellular fibrils of the renal tubules, the mesangial cells of the renal glomerulus on the kidney and the stress fibers on HEp-2 cells.

Liver/Kidney Microsomal 1 (LKM-1) Antibodies
LKM1 antibodies are detected by two methods: immunofluorescence on a composite substrate of liver/ kidney/stomach and by ELISA using a P450IID6 epitope specific assay. LKM1 antibodies provide strong reactions on the liver with reactions of the proximal but not the distal tubules on the kidney, thus differentiating from PBC associated anti-mitochondrial antibodies (AMA). The ImmuLisa™ epitope specific LKM-1 ELISA incorporates a patented technology to detect cases of AIH with a high degree of sensitivity and specificity as well as to help identify patients with an overlap of AIH and viral hepatitis.

Comparison of Antibodies in Patients with AIH-2 and HCV Infection

Antigen	AIH	HCV
Whole LKM	15/15	8/24
ImmuLisa™ Peptide ELISA	14/15	0/8

LKM Antibodies in AIH:

LKM antibodies are specific markers of autoimmune hepatitis. These antibodies can be detected by immunofluorescence on liver and kidney sections. By indirect IFA, these antibodies are also detected in 2-3% of patients infected with hepatitis C virus (HCV).

Immco provides an ELISA method of detecting LKM antibodies using a peptide sequence based immunoassay that eliminates reactions associated with HCV infection.

ImmuGlo™ Immunofluorescence

Code	Description	Determinations
1107	COMVI™ mouse kidney/stomach	48
1107R*	COMVI™ rat kidney/stomach	48
1107-1	Mouse Kidney antibody	48
1134	COMVI™ HEp-2/mouse kidney/stomach	96
1134LKM*	COMVI™ HEp-2/mouse liver/kidney/stomach	48
1134R-LKM*	COMVI™ HEp-2/rat liver/kidney/stomach	48
1136C*	COMVI™ anti-LKM mouse liver/kidney/stomach	48
1136	COMVI™ anti-LKM mouse liver/kidney/stomach	48
1136-96	COMVI™ anti-LKM mouse liver/kidney/stomach	96
1136-250	COMVI™ anti-LKM mouse liver/kidney/stomach	250
1136R*	COMVI™ rat liver/kidney/stomach	48
1136R-240*	COMVI™ rat liver/kidney/stomach	240

ImmcoStrip™ Line Immunoassay (LIA)

Code	Description	Determinations
6040*	Liver	20

ImmuGlo™ Slides

Code	Description	Determinations
2148*	COMVI™ rat kidney/stomach	8 well
2152	COMVI™ mouse kidney/stomach	8 well
2152-3	COMVI™ mouse liver/kidney/stomach	8 well
2152-10	COMVI™ mouse liver/kidney/stomach	10 well
2169*	Mouse stomach	8 well
2173*	Rat stomach	6 well
2190	COMVI™ HEp-2/mouse kidney/stomach	6 well
2190LKM*	COMVI™ HEp-2/mouse liver/kidney/stomach	6 well
2190R-LKM*	COMVI™ HEp-2/rat liver/kidney/stomach	6 well
2194*	COMVI™ rat kidney/stomach/liver	8 well

ImmuGlo™ Controls / Components

Code	Description	Determinations
2099	Anti-human IgG FITC primate adsorbed conjugate Contains Evan's Blue	5 ml
2100	Anti-human IgG FITC conjugate	5 ml
2200	Autoantibody negative control	0.5 ml
2211	Smooth muscle antibody positive control	0.5 ml
2212	Gastric parietal cell antibody positive control	0.5 ml
2242*	LKM antibody control	0.5 ml
2302	Buffered diluent	60 ml

ImmuLisa™ ELISA

Code	Description	Determinations
1168*	Liver/Kidney Microsomal (LKM-1) antibody ELISA	96

Captia™ ELISA

Code	Description	Determinations
2338370	Mitochondria (AMA) IgA	96

All kits are FDA approved and CE marked for IVD use unless otherwise noted.
Please refer to the product index for complete listing of configurations and determinations.
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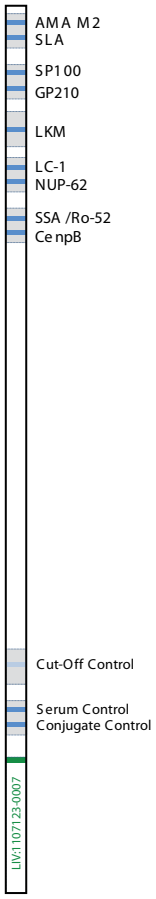
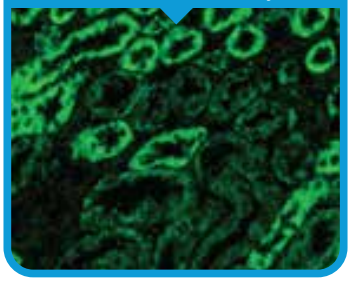
ImmcoStripe™ LIA

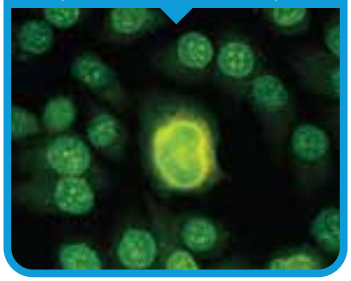
Liver *



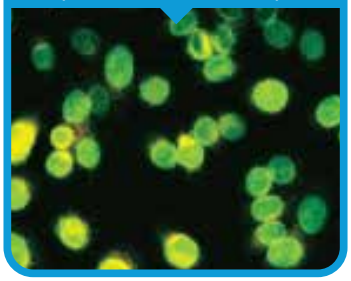
AMA on Mouse Kidney



Sp-100 Antibodies on HEp-2



Gp-210 Antibodies on HEp-2



In addition to AMA, patients with PBC have autoantibodies to two other nuclear antigens, Gp-210 and Sp-100. 28% to 52% of PBC patients have antibodies to nuclear pore complex protein Gp-210, characterized by peripheral staining of the nucleus by indirect IFA. Anti-Sp-100 antibodies are characterized by multiple nuclear dot staining of the nucleus. These antibodies are present in approximately 30% of patients with PBC. Approximately one half of AMA negative PBC patients are positive for antibodies to Gp-210 and Sp-100.

Primary Biliary Cirrhosis

Mitochondrial Antibodies (AMA)

Primary biliary cirrhosis (PBC) and autoimmune hepatitis are chronic disorders of the liver with debilitating effects on the patient. Early diagnosis helps in patient management and significantly improves quality of life. AMA occur in over 90% of PBC cases, 3-11% of chronic active hepatitis patients, and are absent in patients with extrahepatic biliary obstruction as well as in other liver diseases. The presence of AMA in greater than 95% of patients with PBC and their virtual absence in extrahepatic jaundice makes detection of these antibodies extremely valuable in establishing a differential diagnosis. AMA can be detected by IFA on mouse kidney/stomach substrate.

ImmuGlo™ Immunofluorescence

Code	Description	Determinations
1107	COMVI™ mouse kidney/stomach	48
1107R*	COMVI™ rat kidney/stomach	48
1134	COMVI™ HEp-2/mouse kidney/stomach	96
1134LKM*	COMVI™ HEp-2/mouse liver/kidney/stomach	48
1134RLKM*	COMVI™ HEp-2/rat liver/kidney/stomach	48
1136	COMVI™ mouse liver/kidney/stomach	48
1136R*	COMVI™ rat liver/kidney/stomach	48

ImmuGlo™ Slides

Code	Description	Determinations
2148*	COMVI™ rat kidney/stomach	8 well
2152	COMVI™ mouse kidney/stomach	8 well
2152-3	COMVI™ mouse liver/kidney/stomach	8 well
2152-10	COMVI™ mouse liver/kidney/stomach	10 well
2161*	Rat kidney	6 well
2163*	Primate kidney	6 well
2190	COMVI™ HEp-2/mouse kidney/stomach	6 well
2190LKM*	COMVI™ HEp-2/mouse liver/kidney/stomach	6 well
2190R-LKM*	COMVI™ HEp-2/rat liver/kidney/stomach	6 well
2194*	COMVI™ rat kidney/stomach/liver	8 well

ImmuGlo™ Controls / Components

Code	Description	Determinations
2099	Anti-human IgG FITC primate adsorbed conjugate Contains Evan's Blue	5 ml
2100	Anti-human IgG FITC conjugate	5 ml
2200	Autoantibody negative control	0.5 ml
2210	Mitochondrial antibody positive control	0.5 ml
2210-1*	Mitochondrial antibody low titer positive control	0.5 ml
2302	Buffered diluent	60 ml

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Vesiculo-Bullous Disorders

Skin Antibodies

The detection of anti-skin antibodies aids in the diagnosis and prognosis of chronic vesiculo-bullous diseases, including pemphigus, pemphigoid, mucous membrane (cicatricial) pemphigoid, and epidermolysis bullosa acquisita (EBA). Epithelial intercellular (IC) antibodies are diagnostic for pemphigus. Antibodies to basement membrane zone (BMZ) antigens of stratified squamous epithelium occur in active bullous pemphigoid (BP), vesicular pemphigoid, EBA and mucous membrane (cicatricial) pemphigoid patients. Serological differentiation of bullous pemphigoid from EBA can be aided by utilizing tests employing in split skin sections.

ImmuGlo™ Immunofluorescence

Code	Description	Determinations
1104	COMVI™ skin (IC/BMZ) antibody - primate/guinea pig esophagus	48
1105	Skin (IC/BMZ) antibody - primate esophagus	48

ImmuGlo™ Slides

Code	Description	Determinations
2147*	Primate split skin	6 well
2154	COMVI™ primate/guinea pig esophagus	6 well
2155	Primate esophagus	6 well
2155-8	Distal esophagus	8 well
2156*	Transitional Epithelium	6 well

ImmuGlo™ Controls / Components

Code	Description	Determinations
2099	Anti-human IgG FITC primate adsorbed conjugate Contains Evan's Blue	5 ml
2100	Anti-human IgG FITC conjugate	5 ml
2200	Autoantibody negative control	0.5 ml
2211	Smooth muscle antibody positive control	0.5 ml
2213	Intercellular (IC) antibody positive control	0.5 ml
2214	Intercellular (IC) antibody positive control (pemphigus vulgaris)	0.5 ml
2216	Intercellular (IC) antibody positive control (pemphigus foliaceus)	0.5 ml
2217	Basement Membrane Zone (BMZ) positive control (pemphigoid)	0.5 ml
2241*	Paraneoplastic Pemphigus positive control	0.5 ml
2302	Buffered diluent	60 ml

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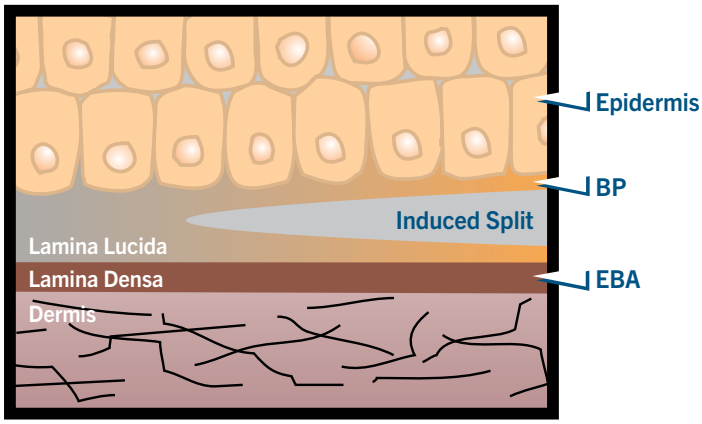
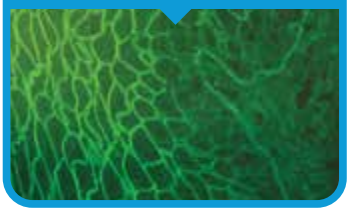
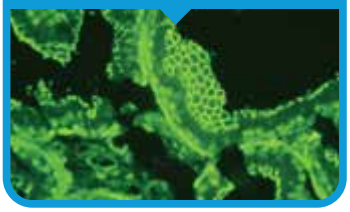
Diagram of Induced Split



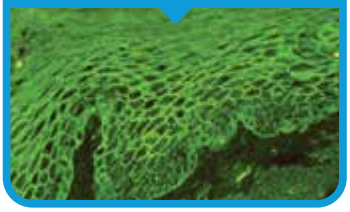
Pemphigus Antibodies on Primate Esophagus



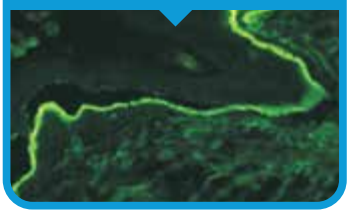
Paraneoplastic Pemphigus Antibodies on Rat Bladder



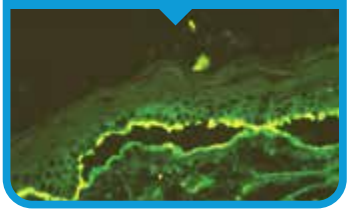
IgA Pemphigus Antibodies on Esophagus



EBA on Salt Split Skin

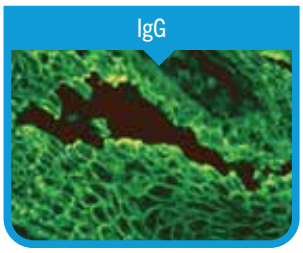


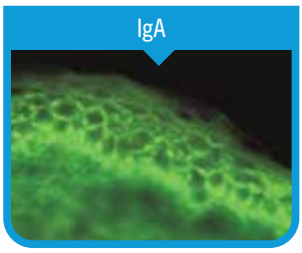
Bullous Pemphigoid Antibodies on Split Skin



Immunological Findings in Vesiculo-Bullous Disorders

Pemphigus – Direct Immunofluorescence (IFA)





Serological Differentiation of *Pemphigus Vulgaris* from *Pemphigus Foliaceus* Based on Substrate Reactivity

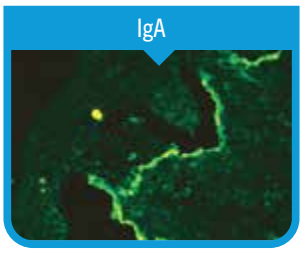
Higher Titer/ Brighter Staining	P.Vulgaris Sera		P. Foliaceus Sera	
	Number	Percent	Number	Percent
Monkey Esophagus	73	97%	0	97%
Guinea Pig Esophagus	0	0%	25	0%
No Difference	2	3%	5	3%

Pemphigus – Indirect Immunofluorescence (IFA)

Pemphigus Vulgaris

Pemphigus Foliaceus

Pemphigoid – Direct Immunofluorescence (IFA)



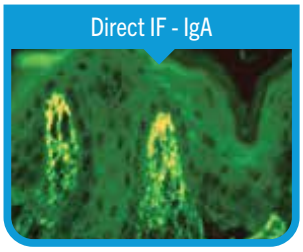
- Bullous Pemphigoid (BP)
- Epidermolysis Bullosa Acquisista (EBA)
- Cicatricial Pemphigoid (CP)
- Herpes Gestationis (HG)
- Linear IgA Bullous Dermatosis (LABD)
- Mucous Membrane Pemphigoid (MMP)

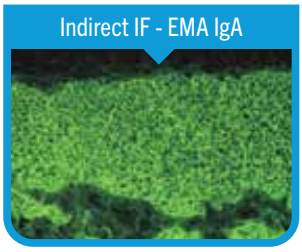
Immunolocalization of BMZ Antibodies on *In Vitro* Split Skin by Indirect Immunofluorescence

Clinical Diagnosis	Epidermal Staining	Dermal & Epidermal	Dermal Only
BP	71%	17%	12%
EBA	14%	0%	86%
Normal	0%	0%	0%

Pemphigoid – Indirect Immunofluorescence (IFA)

Dermatitis Herpetiformis (DH)





Sensitivity, Specificity, and Predictive Values in Markers for DH

Antibody	Sensitivity	Specificity	Positive	Negative
EMA	97%	98%	97%	98%
ARA	65%	100%	100%	72%
AGA-Ig	88%	92%	88%	92%
AAGA-Ig	52%	94%	87%	74%
GtTG-IgA	98%	94%	97%	97%

Type I Diabetes

Islet Cell Antibodies (ICAb)

Antibodies to the pancreatic islet cells of Langerhans occur almost exclusively in Type I diabetes and rarely, if ever, in Type II diabetes. The development of islet cell antibodies (ICAb) in insulin dependent Type I diabetes is provoked by an unknown stimulus. Islet cell antibodies may occur years before clinical symptoms of diabetes and may eventually disappear after the clinical onset of Type I diabetes.

Incidence of Islet Cell Antibodies

Disease Group	Age (Years)	No. Patients	% Positive
Type I Diabetes (IDDM)			
At onset	<1-10	19	63
	11-20	25	60
	21-40	8	25
Long standing	<1-10	22	41
	11-20	71	39
	21-40	26	24
	41-70	13	0
	71-80	3	33
Type II Diabetes			
At onset	<1-40	0	-
	41-80	39	3
Long standing	<1-10	0	-
	11-20	5	20
	21-80	75	1
Non diabetic first degree relatives	<1-30	61	0
	31-50	119	2
	51-80	19	0
Non diabetic controls	>18	200	0

ImmuGlo™ Immunofluorescence

Code	Description	Determinations
1123*	Islet Cell antibody	40

ImmuGlo™ Slides

Code	Description	Determinations
2165*	Primate pancreas	4 well

ImmuGlo™ Controls / Components

Code	Description	Determinations
2099	Anti-human IgG FITC primate adsorbed conjugate Contains Evan's Blue	5 ml
2118X*	Conjugate B	5 ml
2200	Autoantibody negative control	0.5 ml
2233*	Islet cell antibody (ICAb) positive control	0.5 ml
2313*	ICA Buffered diluent	60 ml

All kits are FDA approved and CE marked for /VD use unless otherwise noted.
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*For research use only in the US.
‡Contains ImmuGlo™ anti-human IgG FITC primate adsorbed conjugate.
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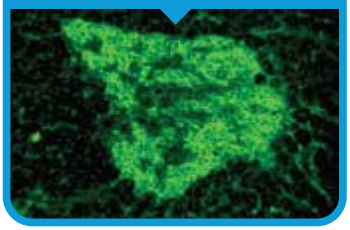
Islet Cell Antibodies on Islet Cells of Langerhans



Islet Cell antibody IFA Positive Control

The ICA Positive Control included in the anti-Islet Cell kit is standardized against he JDF (Juvenile Diabetes Foundation) reference preparation. ImmuGlo™ Islet Cell IFA Positive Control provides a useful standard for inter-laboratory comparison of results and establishes objective performance criteria.

Thyroid Disorders

Thyroglobulin (Tg) and Thyroid Peroxidase (TPO) Antibodies

The clinical spectrum of autoimmune thyroid disorders is broad and patients may be hyper, hypo or even euthyroid. There are two major forms of autoimmune thyroid disorders, Graves disease and Hashimoto's thyroiditis. Thyroid autoimmune reactions can also occur in other thyroid abnormalities such as sporadic and endemic goiter, Plummer's disease and endocrine ophthalmopathy. These disorders are often associated with the presence of autoantibodies to Tg and TPO antigens. Tg is a 660 kD homodimeric glycoprotein which functions as a thyroid prohormone. TPO is a membrane bound enzyme of 105 kD that catalyses thyroid hormone

biosynthesis. Thyroxine and tri-iodo thyronine are generated by the TPO catalyzed iodination and coupling at specific homogenic tyrosines. The measurement of Tg and TPO antibodies are essential parameters in the diagnosis of autoimmune thyroid diseases. A study of 121 serum specimens obtained from patients both normal and suspected of autoimmune thyroid disorder

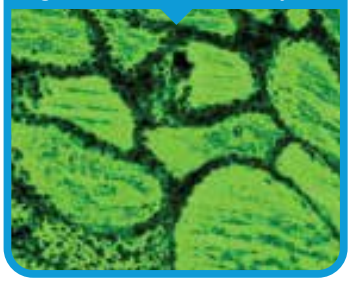
as well as disease controls were tested for TPO antibody levels. The Enhanced ImmuLisa™ TPO antibody assay demonstrates significantly higher sensitivity and clinical agreement than the competitor assay. This superiority of the ImmuLisa™ TPO antibody test is due to the selection of the antigen, the optimal presentation of the antigen on the microwell for the antibodies to bind with, and the use of specific reagents that minimize non-specific interactions.

Thyroid Microsomal Antibodies on Primate Thyroid

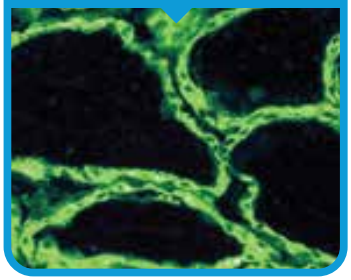
Thyroid Antibodies Commonly Associated With the Following Thyroid Diseases

- Hashimoto's thyroiditis
- Atrophic thyroiditis
- Postpartum thyroiditis
- Graves disease
- Pregnancy with previous or present Graves
- Thyroid carcinoma

Tg Antibodies on Primate Thyroid



TPO Antibodies on Primate Thyroid



ImmuGlo™ Immunofluorescence

Code	Description	Determinations
1143*‡	Thyroid antibody	48

ImmuGlo™ Slides

Code	Description	Determinations
2180*	Primate thyroid	6 well

ImmuGlo™ Controls / Components

Code	Description	Determinations
2099	Anti-human IgG FITC primate adsorbed conjugate Contains Evan's Blue	5 ml
2200	Autoantibody negative control	0.5 ml
2239*	Thyroid antibody positive control (microsomal)	0.5 ml
2302	Buffered diluent	60 ml

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Please refer to the product index for complete listing of configurations and determinations.
*For research use only in the US.
‡Contains ImmuGlo™ anti-human IgG FITC primate adsorbed conjugate.
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Significance of Thyroid Antibodies

Ab Specificity	Disease Association	Indications for use
Thyroglobulin (Tg)	1) Thyroid autoimmune diseases 2) Incorrect thyroglobulin levels	Complement to thyroglobulin
Thyroid Peroxidase (TPO) or Microsomal	Thyroid autoimmune disease	1) Goiter of unknown etiology 2) Hyperthyroidism

Neuropathies

Myelin Associated Glycoproteins (MAG) Antibodies

Peripheral neuropathies, autoimmune responses of the peripheral nervous system, are associated with autoantibodies against various neural glycoconjugates. Neuropathies associated with anti-MAG with IgM paraproteinemia are often slowly progressive with evidence of demyelination and a variable degree of axonal loss associated with gait ataxia. 50% of all peripheral neuropathy cases with IgM paraproteinemia possess MAG antibodies. Detection of MAG autoantibodies is useful for the clinician, as it suggests active demyelination in a peripheral neuropathy.

Immunofluorescence is a sensitive method for the screening and detection of anti-nerve myelin associated proteins and ganglioside autoantibodies. Specimens found positive by immunofluorescence can be confirmed using the Western Blot method.

ImmuGlo™ Immunofluorescence

Code	Description	Determinations
1172*	MAG antibody	48

All kits are FDA approved and CE marked for /VD use unless otherwise noted.
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*For research use only in the US.
‡Contains ImmuGlo™ anti-human IgG FITC primate adsorbed conjugate.
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Western Blot Testing

Western Blot Testing

Myasthenia Gravis (MG)

Striational Muscle Antibodies

Myasthenia gravis has a number of associated autoantibodies. These include antibodies to skeletal muscle which are detected by immunofluorescence using primate skeletal muscle tissue. Significant titers of striational antibodies occur in myasthenia gravis primarily in association with thymomas. A positive striational antibody with negative results for acetylcholine receptor antibody can support the diagnosis of acquired MG and may indicate thymoma. Striational muscle antibodies in titers of 1:80 or greater are essentially disease specific.

Striational Antibodies on Primate Skeletal Muscle

ImmuGlo™ Slides

Code	Description	Determinations
2158*	Primate skeletal muscle	6 well
2172*	Rat skeletal muscle	6 well

ImmuGlo™ Controls / Components

Code	Description	Determinations
2099	Anti-human IgG FITC primate adsorbed conjugate	5 ml
2100	Anti-human IgG FITC conjugate	5 ml
2200	Autoantibody negative control	0.5 ml
2235*	Heart/skeletal muscle positive control	0.5 ml
2302	Buffered diluent	60 ml

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Please refer to the product index for complete listing of configurations and determinations.
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~Special order.
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Striational Antibodies In Patients with Thymoma

Clinical	Striational Ab
MG Only	74%
Neurological Disorders with MG	87%
Neurological Disorders without MG	31%
Unaccompanied Thymoma	14%

Vernino S, Lennon VA Ann NY Acad Sci2003; 998:359-361.

Oxidized Low Density Lipoprotein (oxLDL) Antibodies

Antibodies to oxidized low density lipoproteins (oxLDL) have been described in a variety of vascular diseases with the manifestation of atherosclerosis. Elevated levels of antibodies to oxLDL have been found in coronary artery disease (CAD), antiphospholipid syndrome (APS), systemic lupus erythematosus (SLE), endometriosis, diabetes, hypertension, and individuals predisposed to atherosclerosis. The antibodies to oxLDL appear to be useful serologic markers for predictor of progression in CAD, atherosclerosis and myocardial infarction. It also predicts atherothrombotic risk in autoimmune patients with high specificity for APS.

Oxidative modification of low-density lipoproteins (LDL) and oxLDL antibodies play an important role in the formation of therosclerotic plaque. According to the oxidative modification hypothesis, LDL initially accumulates in the subendothelial space of arteries and is mildly oxidized by the resident vascular cells. oxLDL induces production of chemoattractants by monocytes and macrophages causing further oxidation of LDL.

Heart Antibodies

Heart antibodies as detected by IFA have been described in 40% of patients with biopsy proven myocarditis and in 20% of patients with dilated cardiomyopathy. No antibodies have been detected in healthy controls.

Only 4% of patients with ischemic heart disease are positive for heart antibodies. These autoantibodies generally produce three types of staining reactions: sarcolemma, diffuse cytoplasmic and striational, producing the so-called fibrillar pattern.

ImmuGlo™ Immunofluorescence

Code	Description	Determinations
1101H*	Heart antibody	48

ImmuGlo™ Slides

Code	Description	Determinations
2157*	Primate heart	6 well
2171*	Rat heart	6 well

ImmuGlo™ Controls / Components

Code	Description	Determinations
2099	Anti-human IgG FITC primate adsorbed conjugate	5 ml
2100	Anti-human IgG FITC conjugate	5 ml
2200	Autoantibody negative control	0.5 ml
2235*	Heart/Skeletal muscle positive control	0.5 ml
2302	Buffered diluent	60 ml

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Please refer to the product index for complete listing of configurations and determinations.
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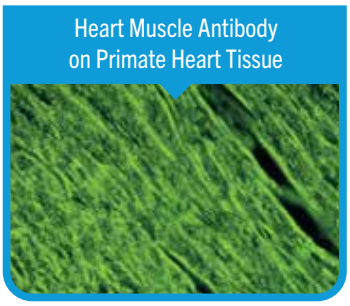
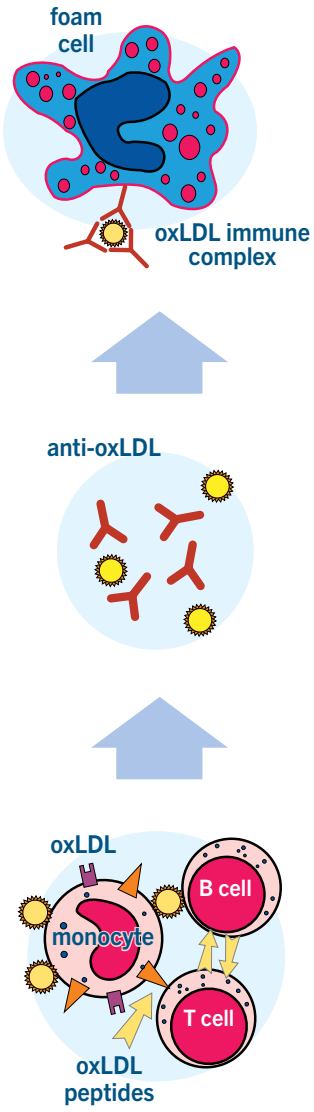


The role of oxLDL antibodies

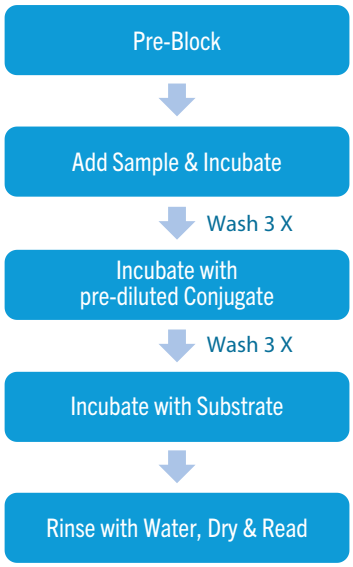


ImmcoStripe™ Line Immunoassays (LIA)

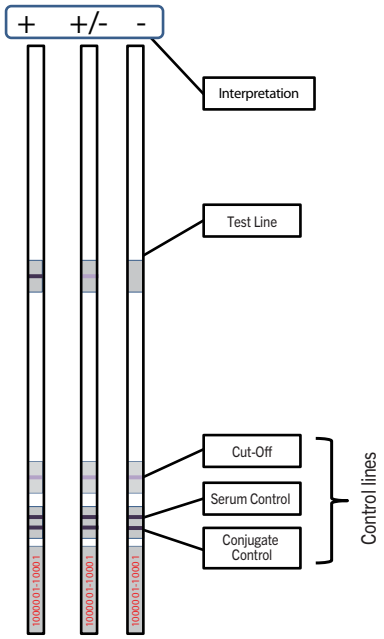
Comprehensive panels for the detection of autoantibodies to Hsp-70 (Autoimmune Hearing Loss), ANA, ANA Advanced and Myositis antigens

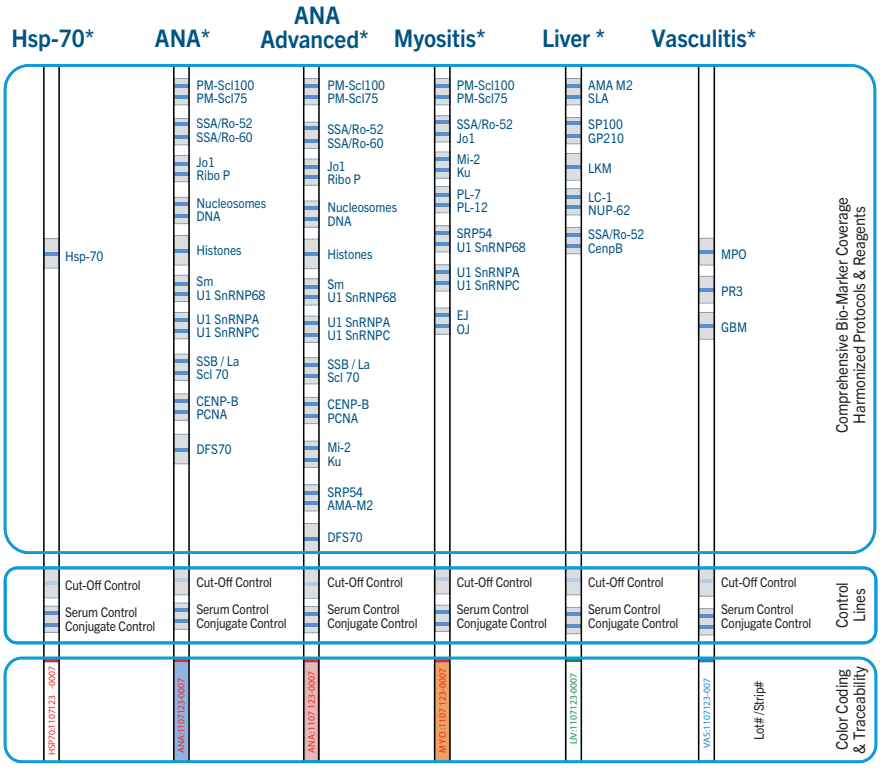
- Robust and accurate alternative to Western Blot
  - Identical protocol to Western Blot with easy to interpret results
  - Every test strip has built-in QC with Three Internal Control lines
  - Clean reactions with minimal background
  - Uniquely numbered strips provide complete traceability
  - High Reproducibility of the results between test strips and lots
- Test Strips are coated with highly purified antigens for maximum sensitivity and specificity.
- 'Ready to Use' reagents with long shelf life and harmonized protocols across the test panels.
- Chromogenic Reactions and comprehensive control lines aid in the accurate interpretation of the test result.

LIA Test Protocol



Quality Control/Interpretation





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Code	Description	Determinations
6001*	ImmcoStripe™ Hsp-70	20
6010*	ImmcoStripe™ ANA	20
6011*	ImmcoStripe™ ANA Advanced	20
6020*	ImmcoStripe™ Myositis	20
6030*	ImmcoStripe™ Vasculitis	20
6040*	ImmcoStripe™ Liver	20

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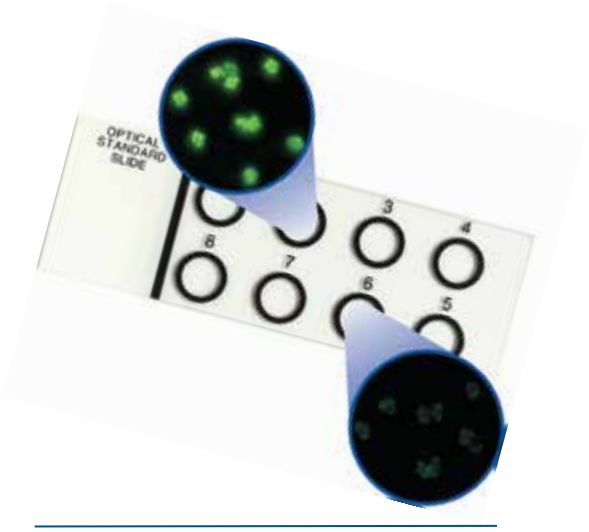
ImmuGlo™ Optical Standard Slide

ImmuGlo™ Optical Standard (OS) microscope slide is an indispensable tool for the laboratory professional committed to Total Quality Management. Each well contains biological cells bound with graduated titers of FITC conjugated antibodies. Use the slide to:

- Monitor the usable life of the light source (mercury vapor bulb). Frequent fluorescent readings of the OS slide is more precise than recording hours of bulb usage alone.
- Assure that optical alignment and filter selection are correct.
- Improve inter/intra-laboratory proficiency and comparability of indirect immunofluorescence results.



ImmuGlo™ IFA

Code	Description
2550OS	Optical Standard Slide

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ImmuGlo™ Mounting Medium

Our product is specially formulated to minimize photobleaching. It exhibits superior performance in direct comparison with standard laboratory and commercial preparations (see graph below). Stained slides, mounted in ImmuGlo™ Mounting Medium, can be observed without appreciable fading and they can be stored at 4°C for prolonged periods for reading at a later date.

ImmuGlo™ IFA Component

Code	Description	Volume
2505	Mounting Medium	5 ml
2506	Mounting Medium	60 ml

ImmuGlo™ Conjugates

Code	Description	Volume
2099	Anti-human IgG FITC primate adsorbed conjugate contains Evan's Blue	5 ml

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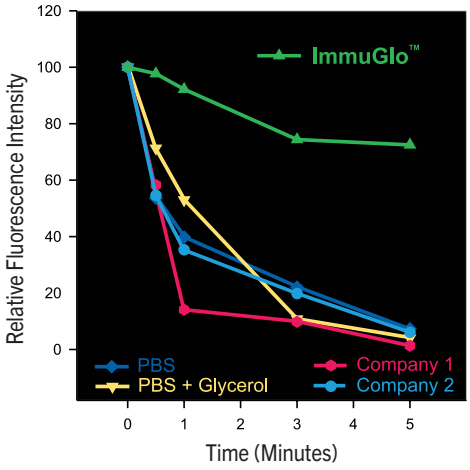
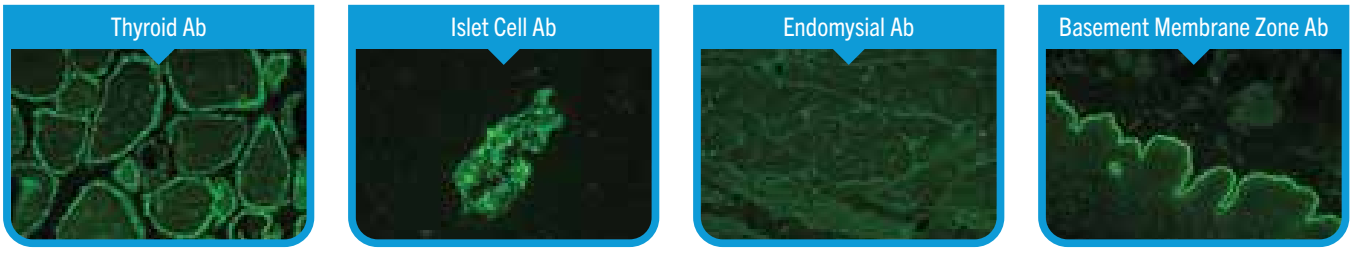
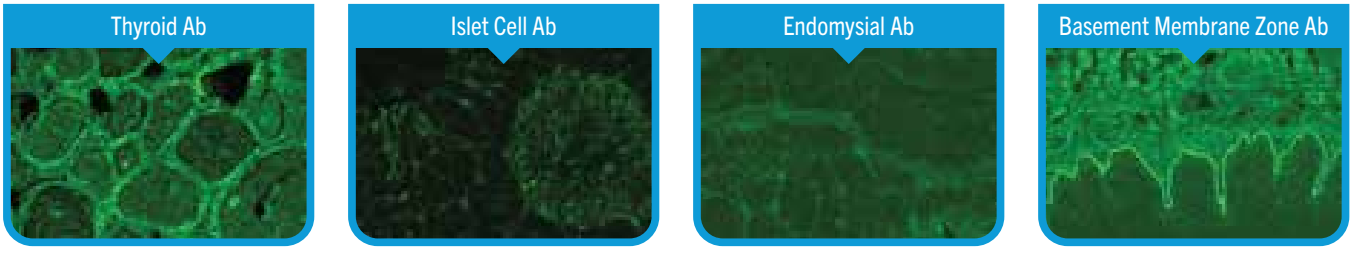
Performance of ImmuGlo™ Mounting Medium



ImmuGlo™ anti-human IgG primate adsorbed conjugate



Non-adsorbed anti-human IgG conjugate



ImmuGlo™ IFA Kits

Code	Product Name	Description	Determinations	Page
1101H*	Heart IFA	8x6 well rat heart slides with heart antibody control	48	
1102-60	ANA HEp-2 Cell IFA	10x6 well slides with ANA control	60	
1103	ANA HEp-2 Cell IFA	20x10 well HEp-2 slides with ANA Control	200	
1103-240	ANA HEp-2 Cell IFA	20x12 well slides with ANA control	240	
1103-525	ANA HEp-2 Cell IFA	25x21 well slides with ANA control	525	
1104	COMVI™ skin (IC/BMZ) IFA	8x6 well primate/guinea pig esophagus slides with IC antibody control	48	
1105	Skin (IC/BMZ) IFA	8x6 well primate esophagus slides with IC and BMZ antibody controls	48	
1106	nDNA IFA (crithidia luciliae)	8x6 well crithidia luciliae slides with nDNA antibody control	48	
1106-2	nDNA IFA (crithidia luciliae)	16x6 well crithidia luciliae slides with nDNA antibody control	96	
1106-6	nDNA IFA (crithidia luciliae)	20x6 well crithidia luciliae slides with nDNA antibody control	120	
1107	COMVI™ IFA	6x8 well mouse kidney/stomach substrate with ANA and AMA controls	48	
1107R*	COMVI™ IFA	6x8 well rat kidney/stomach substrate with ANA and AMA controls	48	
1107-1	Autoantibody Test System I Kit	6x8 well mouse kidney slides with ANA control	48	
1107-2	Autoantibody Test Reagent Pack	20x8 well mouse kidney slides	160	
1108*	HEp-2/DFS70KO Substrate	5x12 well HEp-2/DFS70-KO slides with DFS70 positive control	60	
1108-120*	HEp-2/DFS70KO Substrate	10x12 well HEp-2/DFS70-KO slides with DFS70 positive control	120	
1108-240*	HEp-2/DFS70KO Substrate	20x12 well HEp-2/DFS70-KO slides with DFS70 positive control	240	
1114	EMA (smooth muscle) IgA/IgG IFA	8x6 well primate smooth muscle slides with EMA control	48	
1114-96	EMA (smooth muscle) IgA/IgG IFA	16x6 well primate smooth muscle slides with EMA control	96	
1114A*	EMA (smooth muscle) IgA IFA	8x6 well primate smooth muscle slides with EMA control	48	
1114A-PDE	EMA (distal esophagus) IgA IFA	8x6 well primate distal esophagus slides with EMA control	48	
1114A-PDE-250	EMA (distal esophagus) IgA IFA	25x10 well primate distal esophagus slides with EMA control	250	
1114G-PDE‡	EMA (distal esophagus) IgG IFA	8x6 well primate distal esophagus slides with EMA IgG control	48	
1115	Reticulin IgA/IgG IFA	8x6 well rat kidney slides with ARA control	48	
1115A-240*	Reticulin IgA IFA	20x12 well rat kidney slides with ARA control	240	
1116	ANCA IFA	4x6 well ethanol fixed slides with cANCA control	24	
1122*	Keratin antibody IFA	8x6 well rat esophagus slides with AKA control	48	
1123*‡	Islet Cell IFA	10x4 well primate pancreas slides with ICAb control	40	
1124*‡	Glomerular Basement Membrane IFA	8x6 well primate kidney slides with GBM antibody control	48	
1134	COMVI™ HEp-2/mouse kidney/stomach IFA	16x6 well HEp-2/mouse kidney/stomach slides with ANA and AMA controls	96	
1134LKM*	COMVI™ HEp-2/mouse liver/kidney/stomach IFA	8x6 well HEp-2/mouse liver/kidney/stomach slides with ANA and AMA controls	48	
1134R-LKM*	COMVI™ HEp-2/rat liver/kidney/stomach IFA	8x6 well HEp-2/rat liver/kidney/stomach slides with ANA and AMA controls	48	
1136	COMVI™ mouse liver/kidney/stomach IFA	8x6 well mouse liver/kidney/stomach slides with ANA and AMA controls	48	
1136-96	COMVI™ mouse liver/kidney/stomach IFA	12x8 well mouse liver/kidney/stomach slides with ANA and AMA controls	96	
1136-250	COMVI™ mouse liver/kidney/stomach IFA	25x10 well mouse liver/kidney/stomach slides with ANA and AMA controls	240	
1136C*	COMVI™ anti-LKM mouse liver/kidney/stomach IFA	6x8 well mouse liver/kidney/stomach slides with LKM antibody controls	48	
1136R*	COMVI™ IFA rat liver/kidney/stomach	6x8 well rat liver/kidney/stomach slides with ANA and AMA controls	48	
1136R-240*	COMVI™ IFA rat liver/kidney/stomach	30x8 well rat liver/kidney/stomach slides with ANA and AMA controls	240	
1140	ANCA IFA (ethanol fixation)	8x6 well ethanol fixed slides with cANCA control	48	
1140-2	ANCA IFA (ethanol fixation)	16x6 well ethanol fixed slides with cANCA control	96	
1140-240	ANCA IFA (ethanol fixation)	20x12 well ethanol fixed slides with cANCA control	240	
1141	ANCA IFA (formalin fixation)	8x6 well formalin fixed slides with pANCA control	48	
1142	COMVI™ ANCA IFA	8x6 ethanol fixed + 6 formalin fixed well slides with cANCA and pANCA controls	48	
1143*‡	Thyroid IFA	8x6 well primate thyroid slides with ATA control	48	
1172*	Myelin Associated Glycoprotein IFA	8x6 well primate peripheral nerve slides with MAG antibody control	48	
1194*‡	ExPA IFA	10x4 well primate pancreas slides with ExPA control	40	

All kits are FDA approved and CE marked for IVD use unless otherwise noted
NOTE: All ImmuGlo™ Kits contain conjugate with Evan's Blue counterstain. To order conjugate and Evan's Blue separately, indicate "x" after kit product code.
*For research use only in the US.
‡Contains ImmuGlo™ anti-human IgG FITC primate adsorbed conjugate.
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ImmuGlo™ IFA Slides

Code	Description	Wells	Page
2123*	Primate adrenal gland	6	
2124*	Primate salivary gland	6	
2125-4*	Primate ovary	4	
2127*	Primate pituitary gland	6	
2128*	Primate cerebellum	6	
2131*	COMVI™ primate cerebellum/rat intestine/liver	6	
2134*	Primate nerve	6	
2147*	Primate split skin	6	
2148*	COMVI™ rat kidney/stomach	8	
2150	HEp-2 cells	10	
2150-6	HEp-2 cells	6	
2150-21	HEp-2 cells	21	
2150-12	HEp-2 cells	12	
2151-6	Cithidia luciliae	6	
2152	COMVI™ mouse kidney/stomach	8	
2152-3	COMVI™ mouse kidney/stomach/liver	8	
2152-10	COMVI™ mouse kidney/stomach/liver	10	
2154	COMVI™ primate/guinea pig esophagus	6	
2155	Primate esophagus	6	
2155-1	Primate distal esophagus	6	
2155-8	Primate esophagus	8	
2155-1/10	Primate distal esophagus	10	
2155-18	Primate distal esophagus	8	
2156*	Transitional Epithilium	6	
2157*	Primate heart	6	
2158*	Primate skeletal muscle	6	
2160*	Primate smooth muscle	6	
2161	Rat kidney	6	
2162	Ethanol fixed human PMN cells	6	
2162-12	Ethanol fixed human PMN cells	12	
2163*	Primate kidney	6	
2165*	Primate pancreas	4	
2167-8	Mouse kidney	8	
2169*	Mouse stomach	8	
2171*	Rat heart	6	
2172*	Rat skeletal muscle	6	
2173*	Rat stomach	6	
2180*	Primate thyroid	6	
2186*	Formalin fixed human PMN cells	6	
2189	COMVI™ ethanol + formalin fixed PMN cells	6 + 6	
2190	COMVI™ HEp-2/mouse kidney/stomach	6	
2190LKM*	COMVI™ HEp-2/mouse liver/kidney/stomach	6	
2190R-LKM*	COMVI™ HEp-2/rat liver/kidney/stomach	6	
2191	COMVI™ HEp-2/mouse kidney	6	
2194*	COMVI™ rat kidney/stomach/liver	8	
2298*	HEp-2/DFS70KO	12	

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ImmuGlo™ IFA Controls

Code	Description	Volume	Page
1602	ANA Pattern Control I (homogeneous/speckled/centromere/nucleolar/peripheral)	5 x 0.5 ml	
2200	Autoantibody negative control	0.5 ml	
2200GBM*	GBM negative control	0.5 ml	
2201	ANA positive control (homogeneous)	0.5 ml	
2201-1*	ANA low titer control (homogeneous)	0.5 ml	
2202	ANA positive control (speckled)	0.5 ml	
2203	ANA positive control (centromere)	0.5 ml	
2204	ANA positive control (nucleolar)	0.5 ml	
2205	ANA positive control (peripheral)	0.5 ml	
2209*	MAG antibody positive control	0.5 ml	
2210	Mitochondrial antibody positive control	0.5 ml	
2210-1*	Mitochondrial antibody low titer positive control	0.5 ml	
2211	Smooth muscle antibody positive control	0.5 ml	
2212	Gastric parietal cell antibody positive control	0.5 ml	
2213	Intercellular (IC) antibody positive control	0.5 ml	
2214	Intercellular (IC) antibody positive control (pemphigus vulgaris)	0.5 ml	
2215	nDNA antibody positive control	0.5 ml	
2215-1*	nDNA antibody low titer positive control	0.5 ml	
2216	Intercellular (IC) antibody positive control (pemphigus foliaceus)	0.5 ml	
2217	BMZ antibody positive control (pemphigoid)	0.5 ml	
2233*	Islet cell antibody (ICAb) positive control	0.5 ml	
2235*	Heart/skeletal muscle antibody positive control	0.5 ml	
2236*	PCNA positive control	0.5 ml	
2239*	Thyroid microsomal antibody positive control	0.5 ml	
2240	pANCA positive control	0.5 ml	
2241*	Paraneoplastic pemphigus positive control	0.5 ml	
2242*	LKM antibody positive control	0.5 ml	
2245*	Keratin antibody positive control	0.5 ml	
2250	Endomysial antibody positive control	0.5 ml	
2250-1*	Endomysial antibody low titer positive control	0.5 ml	
2250G	Endomysial IgG antibody positive control	0.5 ml	
2251	Reticulin antibody positive control	0.5 ml	
2252	cANCA positive control	0.5 ml	
2252-1*	cANCA low titer positive control	0.5 ml	
2261*	Ribosomal P antibody positive control	0.5 ml	
2267*	GBM antibody positive control	0.5 ml	
2284*	DFS70 positive control	0.5 ml	

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ImmuGlo™ IFA Conjugate

Code	Description	Volume	Page
2099	Anti-human IgG FITC primate adsorbed conjugate contains Evan's Blue	5 ml	
2099X	Anti-human IgG FITC primate adsorbed conjugate without Evan's Blue	5 ml	
2100	Anti-human IgG FITC conjugate contains Evan's Blue	5 ml	
2100-15	Anti-human IgG FITC conjugate contains Evan's Blue	15 ml	
2100X-8	Anti-human IgG FITC conjugate without Evan's Blue	8 ml	
2100X-15	Anti-human IgG FITC conjugate without Evan's Blue	15 ml	
2107	Anti-human IgA FITC conjugate contains Evan's Blue	5 ml	
2113	Anti-human IgA+IgG FITC conjugate for EMA & ARA kits contains Evan's Blue	5 ml	
2113-15	Anti-human IgA+IgG FITC conjugate for EMA & ARA kits contains Evan's Blue	15 ml	
2118X*	Conjugate B	5 ml	
2130	Anti-human polyvalent conjugate	5 ml	
2140*	Anti-human IgM FITC conjugate contains Evan's Blue	5 ml	
2243	Anti-human IgG FITC Conjugate contains Evan's Blue	60 ml	

ImmuGlo™ IFA Components

Code	Description	Determinations	Page
2301	PBS	for 1 liter	
2302	Buffered diluent	60 ml	
2302-375	Buffered diluent	375 ml	
2302-60	Buffered diluent	60 ml	
2303*	GBM Buffered diluent	60 ml	
2312*	GBM Enhancing Buffer for GBM Kit	5 ml	
2313*	ICA Buffer D.I.	60 ml	
2500	Microscope Slide Coverglass 24x60mm	box of 12	
2500long	Microscope Slide Coverglass 22x70mm	box of 12	
2505	Mounting Medium Dropper Vial	5 ml	
2506	Mounting Medium Dropper Vial	60 ml	
2510	Counterstain (Evan's Blue)	1 ml	
2550OS	Optical Standard Slide	8 wells	
2600*	Reagent Set primate split skin/esophagus	48 wells	

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ImmuLisa™ ELISA Kits

Code	Description	Volume	Page
5175	Enhanced ANA Screen ELISA	96	
5127	Enhanced Sm antibody ENA ELISA	96	
5128	Enhanced Ro/SS-A antibody ENA ELISA	96	
5129	Enhanced La/SS-B antibody ENA ELISA	96	
5127	Enhanced Sm ELISA	96	
5138A	Enhanced RF IgA ELISA	96	
5138M	Enhanced RF IgM ELISA	96	
5138G	Enhanced RF IgG ELISA	96	
5138S	Enhanced RF Screen ELISA	96	
5144A	Enhanced Celiac tTG IgA ELISA	96	
5144G	Enhanced Celiac tTG IgG ELISA	96	
5164	Intrinsic Factor ELISA	96	
5161	Enhanced Myeloperoxidase (MPO) antibody ELISA	96	
5162	Enhanced Proteinase 3 (PR3) antibody ELISA	96	

Captia™ ELISA Kits

Code	Description	Volume	Page
2338170	ENA Profile (SS-A,SS-B, Sm, Sm/RNP, Scl-70) ELISA	96	
2327670/2327671	Double stranded DNA (dsDNA) antibody ELISA	96	
2337070	Ro/SS-A antibody ENA ELISA	96	
2337170	La/SS-B antibody ENA ELISA	96	
2337770	Histones	96	
2337870	Thyroglobulin (Tg)	96	
2328250	RF IgM	96	
2338970	PR3	96	
2338370	Mitochondria (AMA) IgA	96	

ImmuLisa™ ELISA Components

Code	Product Name	Deterimations	Page
2308	Serum diluent	60 ml	
2314	Powder wash buffer	for 1 liter	
2308-1	Powder wash buffer	for 1 liter	
2513	Enzyme substrate (alkaline phosphotase)	12 ml	
2514	TMB Enzyme substrate (HRP)	12 ml	
2310	Stop solution (alkaline phosphotase)	15 ml	
2318*	Serum diluent for oxLDL	60 ml	
5308	Serum diluent for Enhanced ELISAs	60 ml	
5305	Serum diluent for Cardiolipin Enhanced ELISAs	60 ml	

ImmuBlot™ Western Blot Kits

Code	Product Name	Deterimations	Page
1173*	MAG Western Blot	20	

ImmuBlot™ Western Blot Components

Code	Product Name	Deterimations	Page
2309	Immublot Serum Diluent	60 ml	
2314-1	Immublot Wash Buffer	for 1 liter	

ImmcoStripe™ Line ImmunoAssay Kits

Code	Product Name	Deterimations	Page
6001*	Hsp-70	20	
6010*	ANA	20	
6011*	ANA Advanced	20	
6020*	Myositis	20	
6030*	Vasculitis	20	
6040*	Liver	20	

official distributor

SZABO-SCANDIC HandelsgmbH
Quellenstraße 110, A-1100 Wien
T. +43(0)1 489 3961-0
F. +43(0)1 489 3961-7
mail@szabo-scandic.com
www.szabo-scandic.com

SZABO SCANDIC

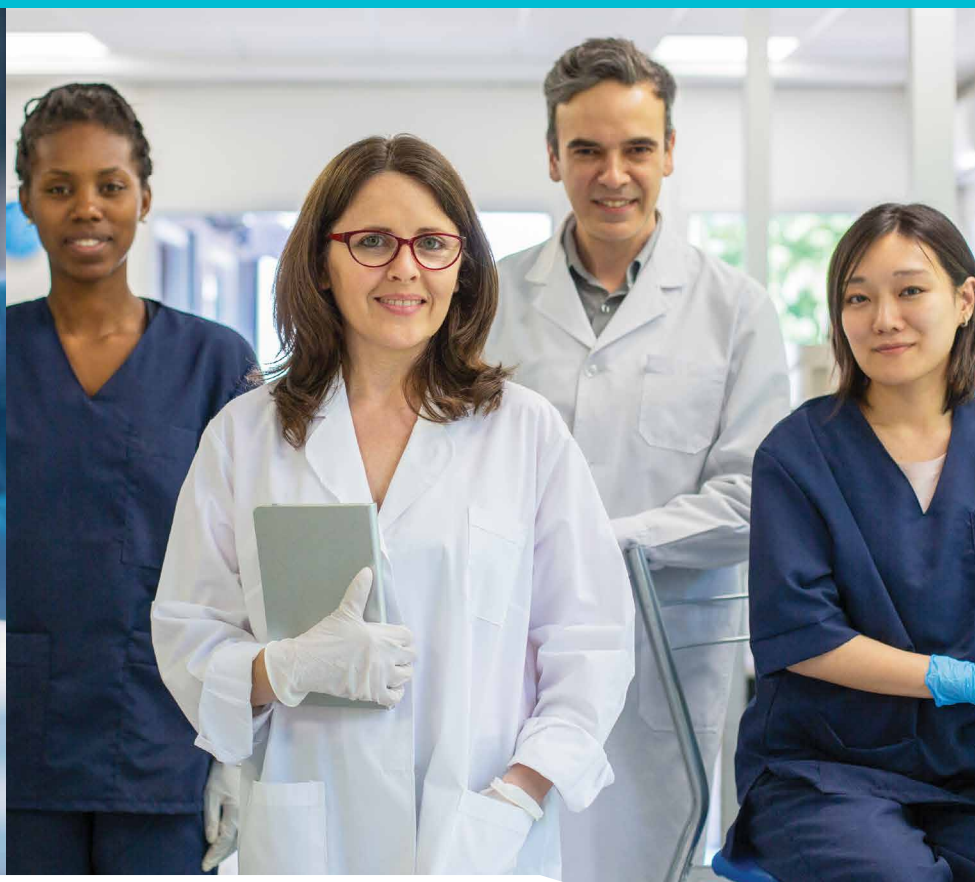
Trinity Biotech
YOUR DIAGNOSTICS PARTNER

Trinity Biotech USA Inc
2823 Girts Rd.
Jamestown, NY 14701
USA

T 1-800-325-3424
Sales and Marketing enquiries:
customerservice@trinityusa.com

Trinity Biotech plc
IDA Business Park
Bray, Co. Wicklow
Ireland

T +353 1 176 9800
F +353 1 276 9888
info@trinitybiotech.com
www.trinitybiotech.com



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