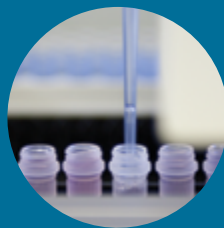
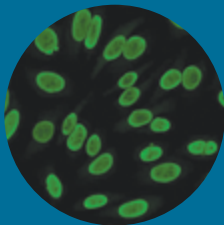
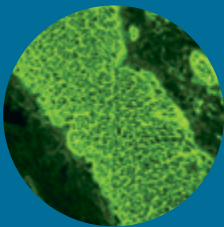
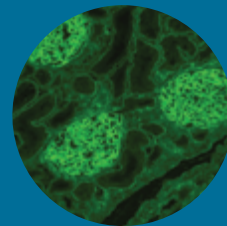
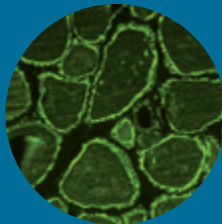
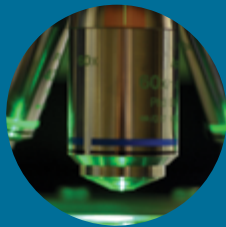
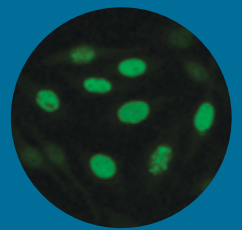
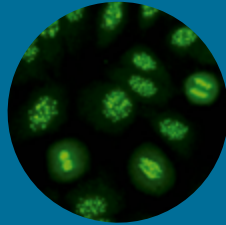
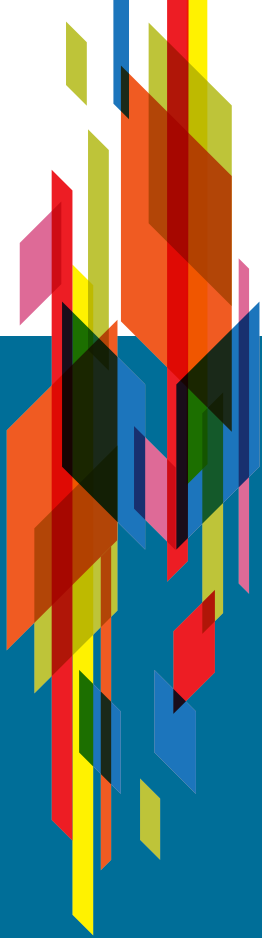


2017 Product Catalog



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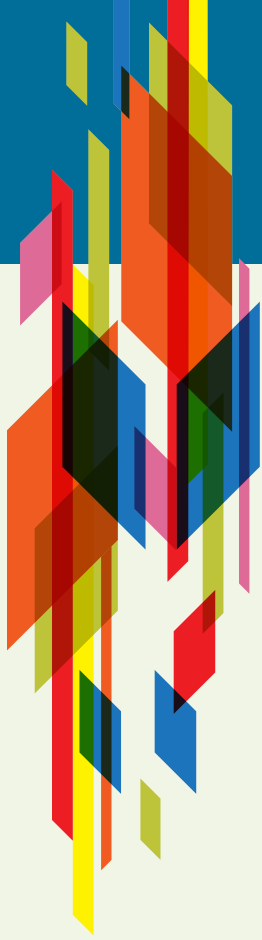


SZABO
SCANDIC



A Trinity Biotech Company

www.trinitybiotech.com



The total solution in autoimmunity.™

- A pioneer in innovative IFA assay development, including the first for detecting celiac disease
- The leader in enhanced ELISA assays featuring superior accuracy and standard calibration systems — 28 enhanced assays recently introduced
- The first LIA assay for autoimmune hearing loss
- Worldwide distribution in more than 55 countries and vasculitis antigens

All Immco kits are made in compliance with:

- ISO 13485:2003
- US FDA cGMP
- EU IVD Directive
- Health Canada CMDCAS

Accuracy. Quality. Reliability.

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Welcome to Immco Diagnostics, A Trinity Biotech Company.

Since the beginning, autoimmunity has been our focus. Our company is founded on the strength of our research and development and commercialization of novel assays. Immco has evolved from a reference laboratory specializing in autoimmune testing, to an international organization that has innovated to deliver high quality diagnostic products and services worldwide.

Over 40 Years in Autoimmunity

Celebrating over 40 years in autoimmunity, our commitment to the field of autoimmunity is stronger than ever. We manufacture and distribute autoimmune diagnostic products and instrumentation in over 55 countries. Our reference laboratory offers an extensive menu of autoimmune testing for the US healthcare market, and has recently expanded to include immunogenetics and transplant immunology. Our contract research organization supports clinical research trials for a diverse set of pharmaceutical and biotechnology clients.

Our Mission

Our goal is to be the total solution in autoimmunity™ for diagnostic laboratories, researchers and health care professionals. And because we are a reference laboratory ourselves, we know the challenges labs face and can develop solutions that work for you in the laboratory.



Our People

Our knowledgeable and focused staff looks to build relationships and embraces customer care as a priority. Behind every one of our products and services is an Immco employee who cares passionately about finding quality solutions for the detection and diagnosis of autoimmune disease. We recognize that at the end of every one of our test results is a laboratory that relies on our product for accuracy and a healthcare professional and patient who needs answers.

Our Innovation

Our broad range of autoimmune diagnostics encompasses collagen vascular, gastrointestinal, vesiculo-bullous, endocrine, neurological and cardiovascular diseases. Significant investment in research and development continues to ensure a steady pipeline of innovative diagnostic solutions to support this growing and changing field.

Our Quality Promise

We promise to provide innovative, superior quality products and services at a competitive price combined with responsive technical support and customer service. Our promise is in every one of our tests:

Better Sensitivity + Better Specificity = Better Lab Results

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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 indirect immunofluorescence (IFA) 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.

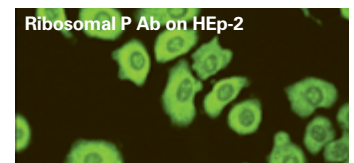
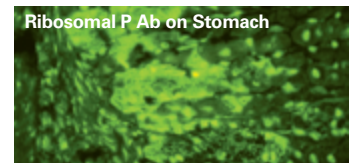
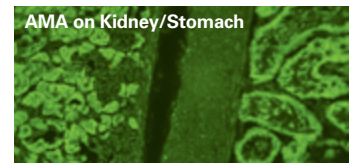
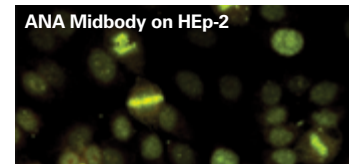
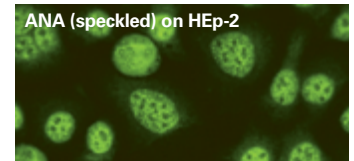
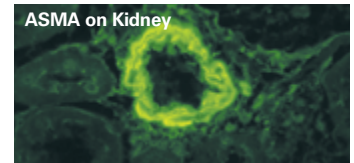
Incidence of ANA

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.



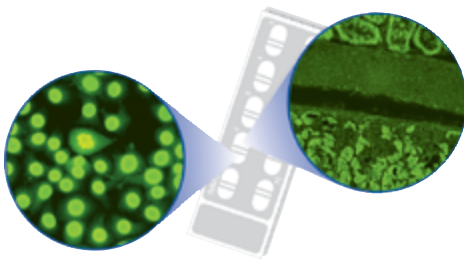
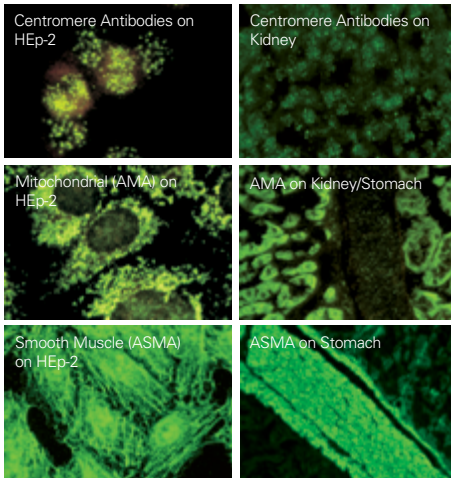
Code	Description	Determinations
ImmuLisa™ ELISA 5175	ANA Screen ELISA	96
<small>All kits are FDA approved and CE marked for IVD use unless otherwise noted. Please refer to the product index for complete listing of configurations and determinations. *For research use only in the US. All products may not be licensed for sale in Canada, please contact your Canadian distributor for more information.</small>		

		HEp-2		
		Pos	Neg	Total
5175	Pos	41	3	44
	Neg	5	47	52
	Total	46	50	96

Positive % Agreement 89%
 Negative % Agreement 94%
 Overall % Agreement 92%

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.

Collagen Vascular



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.

Code	Description	Determinations
ImmuGlo™ Immunofluorescence		
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
1125	COMVI™ HEp-2/mouse kidney	96
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		
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
2190RLKM	COMVI™ HEp-2/rat liver/kidney/stomach	6 well
2191	COMVI™ HEp-2/mouse kidney	6 well
2194	COMVI™ rat kidney/stomach/liver	8 well
ImmuGlo™ Controls / Components		
1602	ANA Pattern Control I <i>(Homogeneous/Speckled/Centromere/Nucleolar/Peripheral Controls)</i>	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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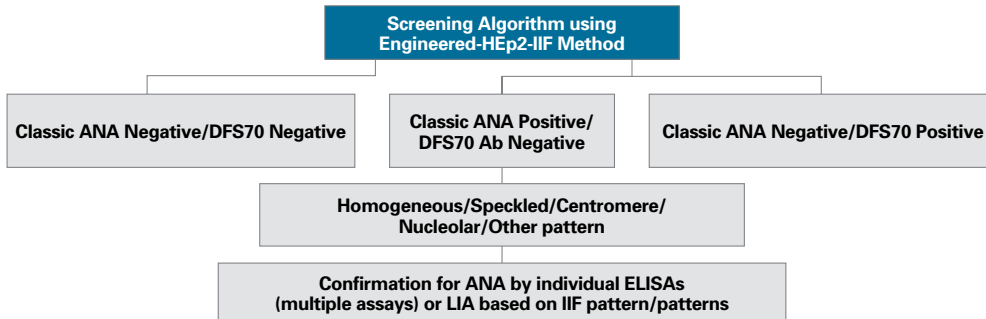
DFS70 Antibodies

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 (DFS70) on HEp-2 cells, and tend to occur in 0.8%-11% of the screening population for ANA^{1,2}. 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.

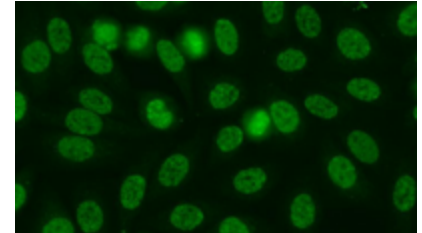
“It is of utmost importance that the homogeneous pattern should be differentiated from the dense fine speckled (DFS) pattern in routing practice since the clinical significance of both patterns is quite different”³



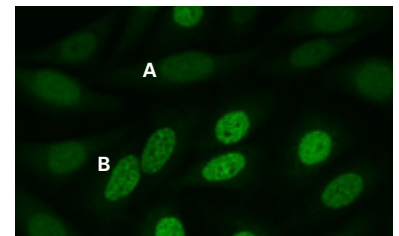
Code	Description	Determinations
Immulo™ Immunofluorescence		
1108*	HEp-2/DFS70KO Substrate Kit	60
1108-120*	HEp-2/DFS70KO Substrate Kit	120
1108-240*	HEp-2/DFS70KO Substrate Kit	240
Immulo™ Slides		
2298*	HEp-2/DFS70KO	12 well
Immulo™ Controls / Components		
2100	IgG Conjugate	5 ml
2200	Autoantibody negative control	0.5 ml
2284*	DFS70 Positive Control	0.5 ml
2302	Buffer diluent	60ml
Immulo™ ELISA		
5188*	Enhanced DFS70 antibody ELISA	96

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- Bizzaro N, Tonutti E, Tampona M, Infantino M, Cucchiari F, Pesente F, et al. Specific chemoluminescence and immunoabsorption tests for anti-DFS70 antibodies avoid false positive results by indirect immunofluorescence. Clinica chimica acta; international journal of clinical chemistry 2015; 451:271-7.
- Watanabe A, Koderu 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.
- 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.



DFS70 antibodies on conventional HEp-2 Substrate



DFS70 antibodies on HEp-2/DFS70KO Substrate

A. Engineered HEp-2
B. Conventional HEp-2

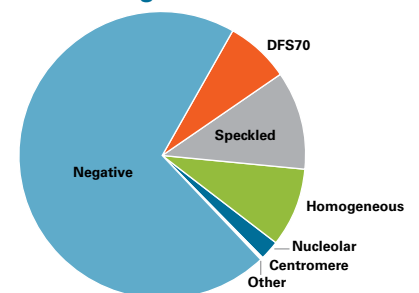
Immco HEp-2 ELITE™

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 DFS70 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

Typical Breakdown of HEp-2 Screening Results



Ann Rheum Dis 2001;60:1131-1136
Rev Assoc Med Bras 2007; 53(5): 429-45
Ann. N.Y. Acad. Sci. 2009; 1173: 166-173

Collagen Vascular

Connective Tissue Disorders

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.

Code	Description	Determinations
ImmcoStrip™ Line Immunoassay (LIA)		
6010*	ANA	20
6011*	ANA Advanced	20

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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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.

Code	Description	Determinations
Immuliisa™ ELISA		
5126	Enhanced RNP antibody ENA 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
5148	Enhanced Centromere Antibody ELISA	96
5149*	Enhanced ENA for antibodies RNP/Sm/Ro/La/ScI-70/Jo-1 ELISA	96
5150	Enhanced ScI-70 antibody ENA ELISA	96
5151*	Enhanced Jo-1 antibody ENA ELISA	96
5196*	Enhanced ENA Profile ELISA	12
5188*	Enhanced DFS70 antibody ELISA	96

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ANA*	ANA Advanced*
PM-Scl100	PM-Scl100
PM-Scl75	PM-Scl75
SSA/Ro-52	SSA/Ro-52
SSA/Ro-60	SSA/Ro-60
Jo1	Jo1
Ribo	Ribo P
Nucleosomes DNA	Nucleosomes DNA
Histones	Histones
Sm U1 SnRNP68	Sm U1 SnRNP68
U1 SnRNPA U1 SnRNPC	U1 SnRNPA U1 SnRNPC
SSB / La ScI70	SSB / La ScI70
CENP-B PCNA	CENP-B PCNA
DFS70	Mi-2 Ku
	SRP54 AMA-M2
	DFS70
Cut-Off Control	Cut-Off Control
Serum Control Conjugate Control	Serum Control Conjugate Control

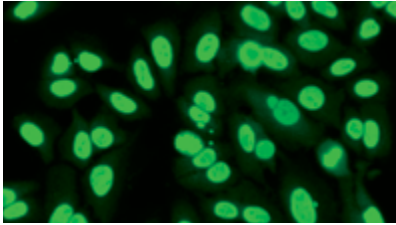
Sensitivity and Specificity of ANA and its Clinically Important Subtypes^{1,2}

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
ScI-70	SSc	20	100
Jo-1	PM	30	95

*Precise data not available.

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.

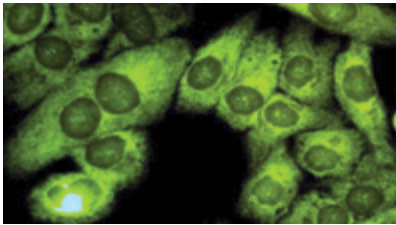
Antinuclear Antibody Detection on HEP-2 Cells¹



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

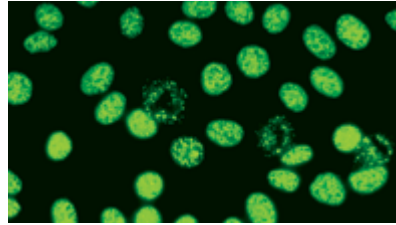
Actin or other cytoskeleton antigen Positive

- 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

- Sjögren's Syndrome
- SCLE

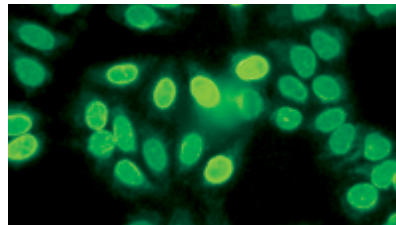
Nuclear Dots (SP-100)

- PBC

Discrete Speckled

Mitotic Cell, Centromere Positive

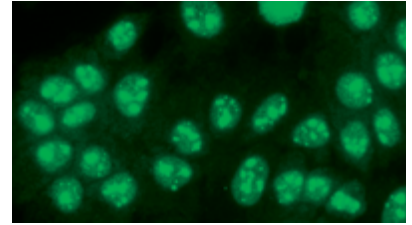
- Limited Scleroderma



Nuclear Membrane

With Mitotic Cells Negative Reaction

- Autoimmune Liver Disease (PBC)



Nucleolar

Homogenous Pattern

PM-Scl Positive

- Polymyositis
- Polymyositis/Scleroderma Overlap

Clumpy

Fibrillar Positive

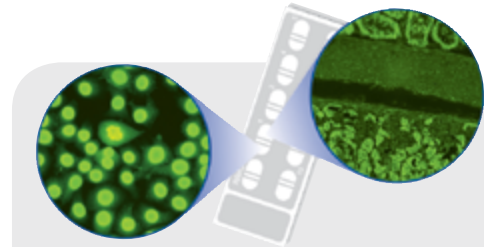
- Scleroderma

Speckled

Topoisomerase (Scl70),

RNA Polymerase I/III Positive

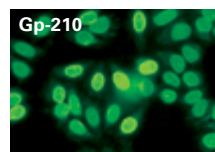
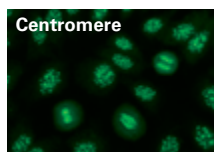
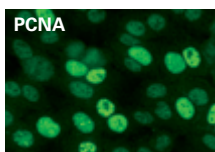
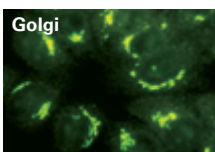
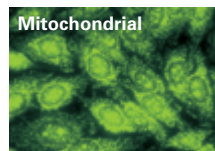
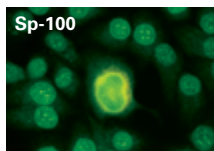
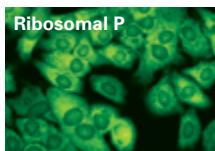
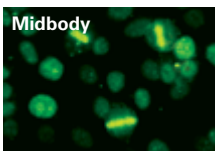
- Scleroderma



Immulo™ COMVI™ slides

By combining HEP-2 with various tissue substrates, Immulo™ 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.



ABBREVIATIONS

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

REFERENCES

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

Collagen Vascular

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.

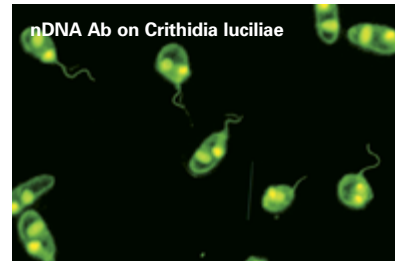
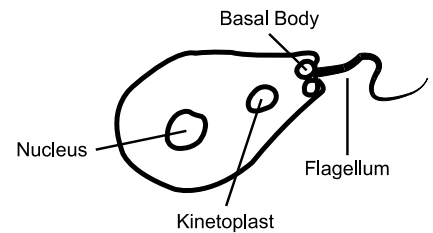


Diagram of *Crithidia Morphology*



Comparison of Kits Using *Crithidia lucilliae* 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%

Code	Description	Determinations
Immulo™ IFA		
1106	nDNA antibody (<i>Crithidia lucilliae</i>)	48
1106-2	nDNA antibody (<i>Crithidia lucilliae</i>)	96
1106-6	nDNA antibody (<i>Crithidia lucilliae</i>)	120
Immulo™ Slides		
2151-6	<i>Crithidia lucilliae</i>	6 well
Immulo™ Controls / Components		
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		
5120	Enhanced dsDNA antibody ELISA	96

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Connective Tissue Disorders

Histone Antibodies

Antibodies to histone, a protein associated with DNA in the nucleus of eukaryotic cells, occur in a number of clinical conditions, primarily in systemic lupus erythematosus (SLE), drug induced Lupus Erythematosus (LE) and drug induced ANA positive patients. Histone antibodies of IgG and IgM are found in approximately 50% of unselected SLE and in 83% of active SLE patients. Almost all patients with drug induced LE and 22% of patients on certain drugs and positive for ANA have antibodies to histone. 10% to 15% of patients with mixed connective tissue disease (MCTD) are also anti-histone antibody positive. The ELISA detects histone antibodies of the IgG and IgM isotype. Values are expressed in ELISA Units per milliliter (EU/ml).

Antinuclear antibodies (ANA) are a characteristic feature in the serum of patients suffering from connective tissue diseases (CTD) such as polymyositis (PM), dermatomyositis (DM), systemic sclerosis (SSc) and SLE. A subset of ANAs, anti nucleolar antibodies, are directed against autoantigens located in the nucleolar compartment of the cell. This includes antibodies to the Polymyositis-Scleroderma (PM-Scl) complex, also known as the human exosome complex, which are found in patients with polymyositis-scleroderma (PM-SSc) overlap syndrome and related diseases. PM-Scl antibodies represent a specific serological marker for a subset of patients with scleroderma (Scl) and polymyositis (PM), and especially with PM-Scl overlap syndrome. PM-Scl reactivity is found in 24% of PM-Scl overlap patients and 3–10% of Scl and PM patients. This results in optimal presentation of the antigen, reducing background without sacrificing sensitivity. Immulisa™ PM-Scl antibody ELISA incorporates a peptide rather than the whole molecule antigen used in competitor assays.

Incidence of Nucleosome, dsDNA, and Histone Antibodies in SLE

Antibody Specificity	%Incidence
Nucleosome	56%
Histone	22%
dsDNA	33%

Incidence of PM-Scl Antibodies¹

Disease Group	n	n +	% +
PM-Scl Group			
Polymyositis/Scleroderma	40	22	55
Polymyositis	40	3	7.5
Scleroderma	205	27	13
Disease Controls			
Rheumatoid Arthritis	69	0	0
Systemic lupus erythematosus	114	3	2.5
Rheumatic disease controls	452	33	7

1. Mahler M, Rajmakers R, et al. Clinical Evaluation of Autoantibodies to a Novel PM/Scl Peptide Antigen. *Arthritis Res Ther.* 2005;7(3):R704-R713.

Code	Description	Determinations
Immulisa™ ELISA		
1119	Histone antibody ELISA	96
5101*	Enhanced PM-Scl antibody ELISA	96

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Collagen Vascular

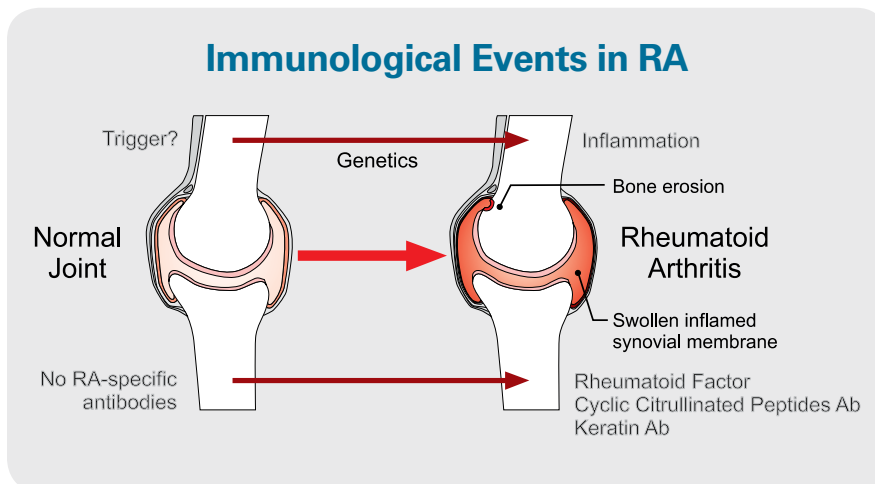
Rheumatoid Arthritis

Rheumatoid Arthritis (RA) is one of the most common autoimmune disorders, affecting 1-2% of the population. RA is a connective tissue disorder marked by chronic inflammation of synovial joints with cartilage and bone destruction, progressively disabling the patient. There is increasing emphasis on early and precise diagnosis of RA so that effective therapies may be instituted to prevent this erosive disorder. The American College of Rheumatology (ACR) includes Rheumatoid Factor (RF) as one of the diagnostic criteria of RA. Recently, the ACR and the European League Against Rheumatism (EULAR) have approved new criteria that includes testing for antibodies against Cyclic Citrullinated Peptides (CCP) because of its clinical utility in establishing early diagnosis of RA. The value of these diagnostic markers lies in their sensitivity and specificity, early presence, ability to predict development of erosive arthritis, and in therapy management.

Cyclic Citrullinated Peptides (CCP) Antibodies

Recent studies have shown antibodies to citrullinated antigens in the sera of RA patients to be useful for determining diagnosis and prognosis of RA. Clinical studies have demonstrated positive CCP antibody ELISA results in a significant number of well defined RA patient sera with excellent specificity disease controls. The diagnostic and prognostic value of the measurement of CCP antibodies has been determined in relation to joint involvement and radiological damage in early RA. CCP antibodies can be detected years before the development of clinical symptoms. A prospective cohort study showed that 93% of the anti-CCP positive patients with undifferentiated arthritis developed RA, indicating the strong positive predictive value of these antibodies.¹

The ImmuLisa™ CCP antibody ELISA test utilizes highly purified synthetic peptides containing cyclic citrulline residues. With this assay, CCP antibodies are detected in approximately 80% of established RA patients, in no healthy controls and in less than 5% of non-RA disease controls.^{2,3} Approximately 40% of RF-seronegative RA patients are positive for antibodies to CCP.⁴



1. Van Gaalen et al. *Arthr and Rheum.* 50 (3): 709-715. 2004.
 2. Van Venrooij et al. *Neth J Med.* 60:383-388. 2002.
 3. Vasishta A. *Am Clin Lab.* 21: 34-36. 2002.
 4. Vossenaar et al. *Clin App Imm Rev.* 4: 239-262. 2004.

Diagnostic Significance of Immunological Markers of Rheumatoid Arthritis³

Pre-RA	Sensitivity %	Specificity %
<i>>1.5 years before symptom onset</i>		
CCP	25	98
IgM-RF	15	95
IgG-RF	12	94
IgA-RF	29	95
CCP+IgM-RF	11	99
CCP+IgG-RF	6	99
CCP+IgA-RF	17	99
<i><1.5 years before symptom onset</i>		
CCP	52	98
IgM-RF	30	95
IgG-RF	27	98
IgA-RF	39	94
CCP+IgM-RF	24	100
CCP+IgG-RF	18	100
CCP+IgA-RF	30	99
Early RA	Sensitivity %	Specificity %
CCP	70	98
IgM-RF	73	95
IgG-RF	46	95
IgA-RF	70	95
CCP+IgM-RF	58	99
CCP+IgG-RF	39	99
CCP+IgA-RF	60	99

Advantages of ImmuLisa™ CCP antibody ELISA

- Superior specificity and sensitivity for the diagnosis of RA
 - 40% more sensitive than RF ELISA methods
 - 98% specific for RA
- Greater range than other commercially available anti-CCP ELISA methods
 - 25-1900 U/ml
- Anti-CCP can be detected prior to the onset of clinical symptoms in RA patients
 - Increased anti-CCP levels are predictive of the severity of bone erosion in RA patients

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.

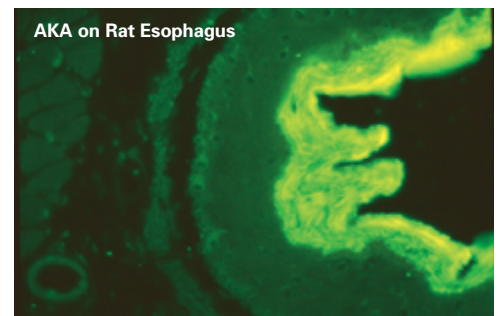
Keratin Antibodies

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.

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.



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

Code	Description	Determinations
Immulo™ Immunofluorescence		
1122*	Keratin antibodies	48
Slides		
2120*	Rat esophagus	6 well
Immulo™ Controls / Component		
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
Immulo™ ELISA		
5138A	Enhanced RF IgA ELISA	96
5138G	Enhanced RF IgG ELISA	96
5138M	Enhanced RF IgM ELISA	96
5138S	Enhanced RF Screen ELISA	96
8001P	CCP antibodies ELISA	96

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

Collagen Vascular

Vasculitis

Phospholipid/Cardiolipin Antibodies (aCL)

Antiphospholipid (aPL) antibodies are a heterogeneous group of autoantibodies against negatively charged phospholipids. The primary antigen associated with aPL antibodies is cardiolipin. The presence of anticardiolipin antibodies (aCL) helps to identify patients at risk for antiphospholipid syndrome (APS). High levels of aCL are associated with thrombosis, fetal loss and thrombocytopenia.

A serum cofactor is needed for the detection of aCL. This cofactor is identified as a 50 kD protein known as β 2-glycoprotein I (β 2GPI). The presence of β 2GPI facilitates the binding of aCL to cardiolipin antigen. Thus the detection of aCL and antibodies to β 2GPI are essential to the identification of APS syndrome.

A study of 155 serum specimens obtained from patients both normal and suspected of APS, as well as disease controls were tested for aCL antibody levels. The Enhanced Immulisa™ aCL, IgG, IgM and Screen demonstrate significantly higher specificity than the competitor and equal or greater clinical agreement with the disease state. For β 2GPI, a comparative study shows the Enhanced Immulisa™ β 2GPI IgG and IgM Antibody assays to have significantly higher specificity than the competitor.

Sensitivity, Specificity and Odds Ratio of aPL Tests for Diagnosis of APS

Sensitivity (95% CI)	Specificity (95% CI)	Odds ratio for diagnosis of APS (95% CI)
LA 84% (74–91%)	79% (71–85%)	19.8 (9.6–40.6)
aCL/ β 2GPI 56% (45–67%)	86% (79–91%)	15.4 (7.2–32.7)
aPS/PT 57% (46–68%)	92% (86–96%)	7.9 (4.1–15.2)

Abbreviations: APS: antiphospholipid syndrome, aCL: anticardiolipin antibodies, LA: lupus anticoagulant, aCL/ β 2GPI: β 2-glycoprotein I dependent anticardiolipin antibodies, aPS/PT: phosphatidylserine dependent antiprothrombin antibodies. Data taken from Atsumi et al. 10 95% Confidence intervals (CI) for sensitivity and specificity were calculated using the binomial method. Adapted from Atsumi and Koike. Lupus 2010; 19: 436-439.

Code	Description	Determinations
Immucor™ ELISA		
5118A	Enhanced aCL IgA antibody ELISA	96
5118G	Enhanced aCL IgG antibody ELISA	96
5118M	Enhanced aCL IgM antibody ELISA	96
5118S	Enhanced aCL Screen IgA/IgG/IgM ELISA	96
5152A*	Enhanced β 2-glycoprotein I (β 2GPI) IgA ELISA	96
5152G*	Enhanced β 2-glycoprotein (β 2GPI) IgG ELISA	96
5152M*	Enhanced β 2-glycoprotein (β 2GPI) IgM ELISA	96
5152S*	Enhanced β 2-glycoprotein I (β 2GPI) Screen ELISA	96

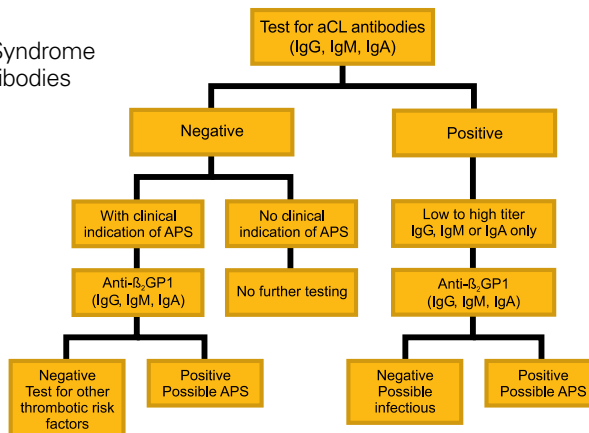
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Immucor™ aCL Antibody Test: Significantly Higher Specificity and Clinical Agreement

aCL	Immucor		Competitor	
	IgG	IgM	IgG	IgM
Sensitivity	100%	98%	100%	100%
Specificity	94%	92%	91%	75%
Clinical Agreement	96%	94%	94%	83%

Immucor Antiphospholipid Antibody Testing Algorithm

APS: Antiphospholipid Syndrome
aCL: Anticardiolipin Antibodies



Vasculitis

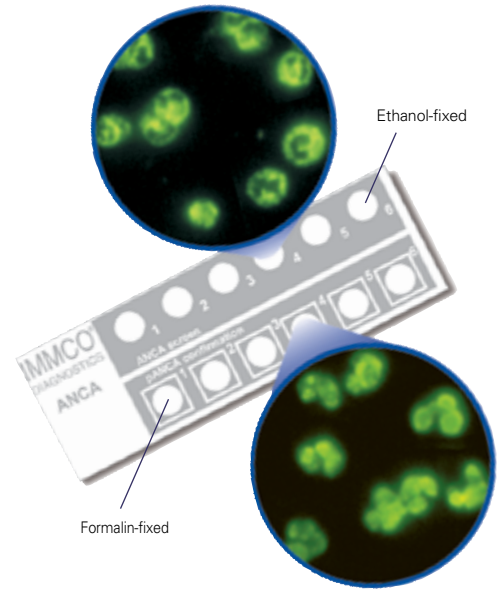
Antineutrophil Cytoplasmic Antibodies (ANCA)

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.

COMVI™ ANCA Slide



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)

Assay		ImmuLISA™ ELISA Assay			Competitor		
		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

Collagen Vascular

Code	Description	Determinations
ImmuGlo™ Immunofluorescence		
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		
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		
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		
5160	Ethanol ANCA ELISA for PR3 and MPO antibodies	96
5161	Enhanced Myeloperoxidase (MPO) antibody ELISA	96
5162	Enhanced Proteinase 3 (PR3) antibody ELISA	96

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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

Significance of ANCA in Vasculitis

	Sensitivity %			
	N	cANCA+PR3	pANCA+MPO	cANCA/PR3 or pANCA/MPO
Granulomatosis with polyangiitis (GP)	97	56-58	16	73
Microscopic polyangiitis (MPA)	44	37-41	49	67
Idiopathic RPGN	12	36	46	82
Classical polyarteritis nodosa	10	10	10	20
Churg-Strauss syndrome (CSS)	6	0-33	33	56

	Specificity %			
	N	cANCA+PR3	pANCA+MPO	cANCA/PR3 or pANCA/MPO
Disease Controls	184	99	99	98
Healthy Controls	740	100	100	100

Types of Vasculitis

ANCA Associated Vasculitis

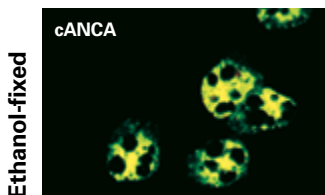
- Granulomatosis with polyangiitis
- Microscopic polyangiitis
- Churg-Strauss syndrome
- Drug induced

Non ANCA Associated Vasculitis

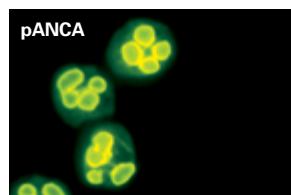
- Immune complex small vessel vasculitis
- Henoch-Schönlein purpura
- Cryoglobulinemic vasculitis
- Cutaneous leukoclastic vasculitis
- Goodpasture's syndrome

Antineutrophil Cytoplasmic Antibodies Reaction Patterns

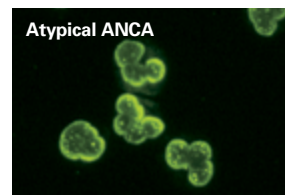
1. ImmuGlo™ IFA pattern with ImmuLisa™ anti-PR3 positive indicates diagnosis: GP



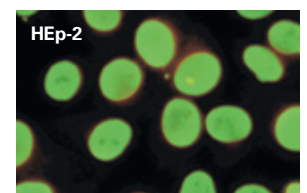
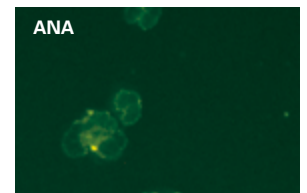
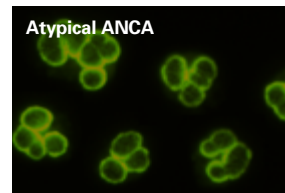
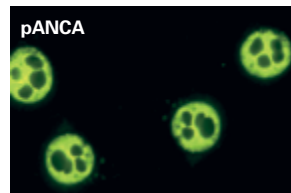
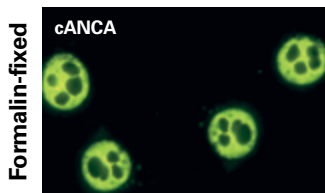
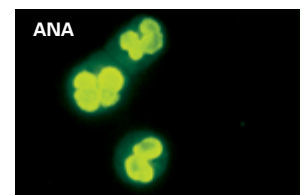
2. ImmuGlo™ IFA pattern with ImmuLisa™ anti-MPO positive indicates possible diagnosis: GP, CSS or MPA



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



Collagen Vascular

Vasculitis

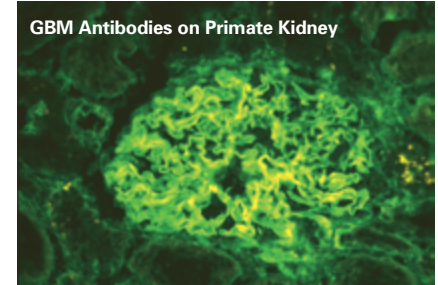
Glomerular Basement Membrane (GBM) Antibodies

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.

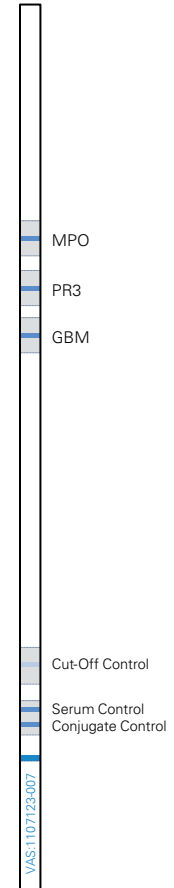
Using the above criteria RPGN may be classified into:

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.



Vasculitis*



Code	Description	Determinations
ImmuGlo™ Immunofluorescence		
1124*†	GBM antibody	48
ImmuGlo™ Slides		
2163*	Primate kidney	6 well
2167-8	Mouse kidney	8 well
ImmuGlo™ Controls / Components		
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
ImmuLisa™ ELISA		
5154*	Enhanced GBM antibody ELISA	96
ImmcoStrip™ Line Immunoassay (LIA)		
6030*	Vasculitis	20

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.

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Antigen Enhancing Buffer

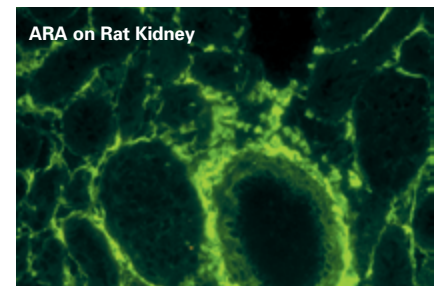
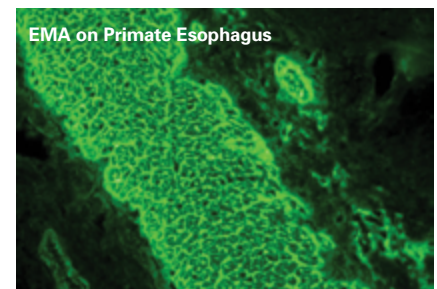
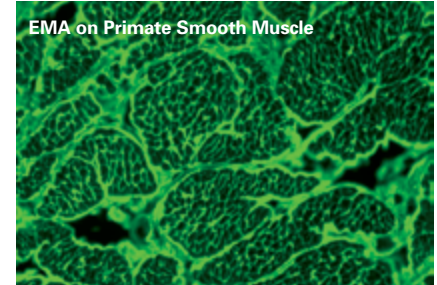
The GBM antibody IFA kit includes an exclusive antigen enhancing buffer to provide excellent sensitivity for the detection of GBM autoantibodies.

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.



Code	Description	Determinations
ImmuGlo™ Immunofluorescence		
1114	EMA (smooth muscle) IgA/IgG	48
1114-96	EMA (smooth muscle) IgA/IgG	96
1114A*	EMA (smooth muscle) IgA	48
1114A-PDE	EMA (primate distal esophagus) IgA	48
1114A-PDE-250	EMA (distal esophagus) IgA	250
1114G-PDE [†]	EMA (distal esophagus) IgG	48
1115	Reticulin IgA/IgG IFA	48
ImmuGlo™ Slides		
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		
2099	Anti-human IgG FITC primate adsorbed conjugate <i>Contains Evan's Blue</i>	5 ml
2100	Anti-human IgG FITC conjugate <i>(For use with 1114G-PDE)</i>	5 ml
2107	Anti-human IgA FITC conjugate <i>(For use with 1114A and 1114A-PDE)</i>	5 ml
2113	Anti-human IgA/IgG FITC conjugate <i>(For use with 1114 and 1115)</i>	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 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.

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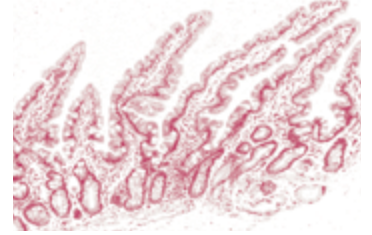
Gastrointestinal

Celiac Disease

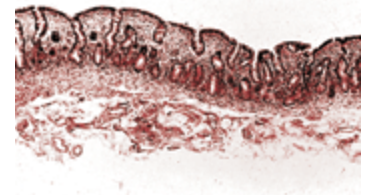
Tissue Transglutaminase (tTG) Antibodies

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.

Normal: Healthy Villi



Active CD: Villous Atrophy



Code	Description	Determinations
ImmuLisa™ ELISA		
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.

Celiac Disease

Antibodies Against Deamidated Gliadin Peptides (DGP)

Anti-gliadin antibodies (AGA) in combination with other serological assays are commonly used in the diagnosis of Celiac Disease (CD). Both IgA and IgG gliadin antibodies are detected in the sera of patients with CD. IgG gliadin antibody tests are important in the diagnosis of IgA deficient CD patients. Studies show that 1-2% of the general population is IgA deficient and that the incidence of CD in IgA deficient subjects is significant. Because of relatively weaker clinical associations with CD, Immco developed new Enhanced ImmuLisa™ Celiac G+ for detection of gliadin antibodies incorporating proprietary deamidated gliadin peptides (DGP) to improve sensitivity and specificity.

Published literature suggests gliadin antibody tests as a useful method to monitor compliance with the prescribed gluten-free diet. Compliance will cause antibody levels to drop. Levels of EMA, ARA and IgA AGA drop rather quickly, while IgG AGA taper off to normal levels over a period of months to years.¹⁻¹³

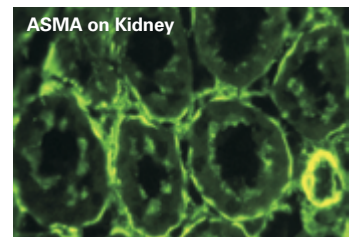
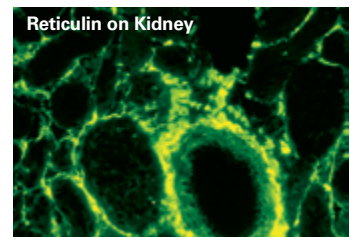
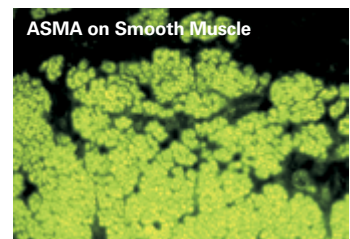
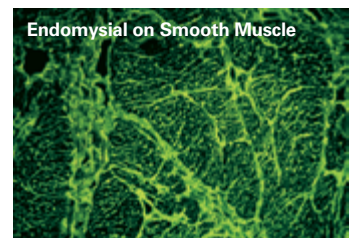
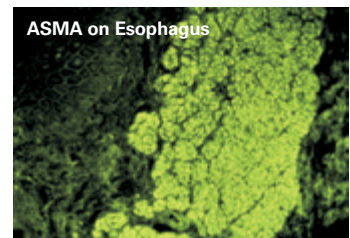
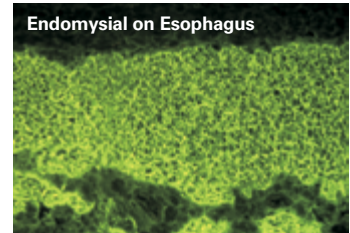
Comparative product studies were conducted using challenging samples against competitors to determine relative accuracy in detecting CD. A study of 117 serum specimens obtained from patients suspected of CD, in addition to disease controls and healthy normals, were tested for DGP and tTG antibodies. The ImmuLisa™ Celiac G+ and ImmuLisa™ tTG ELISAs performed at significantly higher sensitivity, specificity, and clinical agreement than the competitor's assays for both IgA and IgG isotypes.

Superiority of ImmuLisa™ Celiac G+ and tTG ELISAs

	DGP				tTG			
	ImmuLisa™ Celiac G+		Competitor		ImmuLisa™ Celiac tTG		Competitor	
	IgA	IgG	IgA	IgG	IgA	IgG	IgA	IgG
Sensitivity	80%	91%	62%	90%	98%	56%	88%	47%
Specificity	97%	99%	92%	98%	96%	93%	97%	90%
Clinical Agreement	89%	95%	76%	94%	97%	74%	93%	68%

Study conducted using well-characterized CD patient sera, disease controls, and healthy normal subjects

Gluten Sensitive Enteropathy



Code	Description	Determinations
ImmuLisa™ ELISA		
5117A*	Enhanced Gliadin IgA antibody ELISA	96
5117G*	Enhanced Gliadin IgG antibody ELISA	96
5159A	Enhanced Celiac G+ Gliadin IgA ELISA	96
5159G	Enhanced Celiac G+ Gliadin IgG ELISA	96

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Please refer to the product index for complete listing of configurations and determinations.
*For research use only in the US.

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Gastrointestinal

Celiac Disease

ImmuLisa™ Celiac Fusion™ tTG/DGP

In order to detect the presence of antibodies for Celiac Disease (CD) more efficiently, Immco has developed the next generation ELISA assay, ImmuLisa™ Celiac Fusion™ tTG/DGP. ImmuLisa™ Celiac Fusion™ tTG/DGP detects both human tissue transglutaminase (tTG) and deamidated gliadin peptide (DGP) antibodies of IgA and IgG isotypes and provides an ideal first line test for diagnosing CD.

A study of 119 samples were tested including 65 EMA positive samples and low titer specimens, and compared against two competitors' tTG/DGP screen assays. The comparative study using challenging samples shows the superior accuracy of ImmuLisa™ Celiac Fusion™ tTG/DGP compared to competitors.

	ImmuLisa™ Celiac Fusion™ tTG/DGP	Competitor A	Competitor B
Sensitivity	95%	94%	86%
Specificity	94%	94%	78%
Clinical Agreement	95%	94%	82%

Code	Description	Determinations
ImmuLisa™ ELISA 5157	Celiac Fusion™ tTG/DGP 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.

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

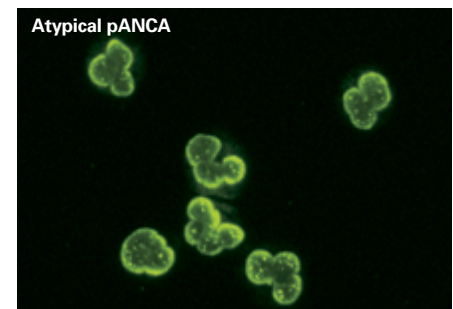
Antineutrophil Cytoplasmic Antibodies (ANCA)

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 inhomogeneous 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)



Code	Description	Determinations
ImmuGlo™ Immunofluorescence		
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		
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		
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		
5160	Enhanced ANCA ELISA for PR3 and MPO antibodies	96
5161	Enhanced Myeloperoxidase (MPO) antibody ELISA	96
5162	Enhanced Proteinase 3 (PR3) antibody ELISA	96

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Testing for ANCA by immunofluorescence aids physicians in diagnosing cases of IBD and differentiating ulcerative colitis from Crohn's disease.

Gastrointestinal

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

Anti-Saccharomyces Cerevisiae Antibodies (ASCA)

Differentiation of Crohn's disease and Ulcerative Colitis (UC) can be problematic clinically. ASCA and ANCA studies are useful in screening tests for inflammatory bowel diseases (IBD), in differentiating UC from Crohn's and in proper identification of patients with indeterminate colitis.

The staining pattern of ANCA in IBD is atypical pANCA. The prevalence of pANCA in UC is 50-80% while in Crohn's the prevalence is 10-20%. In contrast, ASCA occur primarily in Crohn's (50-60%) and rarely in UC.

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.

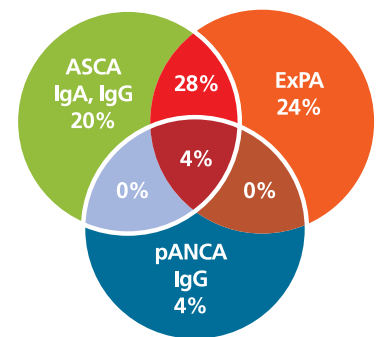
Clinical studies report an ExPA prevalence of 30-50% in patients with Crohn's disease. In spite of the relatively low sensitivity ExPA detects a subpopulation of Crohn's patients that are negative for other Crohn's markers (ASCA), and are therefore very useful in combination with other IBD diagnostic 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.

ExPA as a Diagnostic Tool for Crohn's Disease

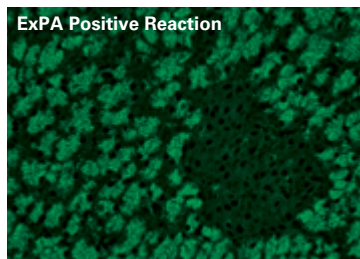
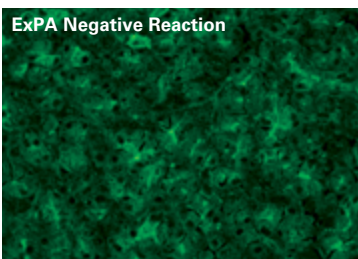
1. ExPA is a very specific diagnostic marker for Crohn's disease.
2. ExPA has a sensitivity similar to that of ASCA, but it is also able to identify a subpopulation of Crohn's patients that are ASCA negative.
3. Combining detection of ExPA with ASCA and ANCA offers superior results both in IBD diagnosis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

Incidence of ASCA, ExPA and ANCA in IBD



Code	Description	Determinations
ImmuGlo™ Immunofluorescence		
1194 ⁺	ExPA	40
ImmuLisa™ ELISA		
5156A*	Enhanced Saccharomyces Cerevisiae IgA (ASCA) ELISA	96
5156G*	Enhanced Saccharomyces Cerevisiae IgG (ASCA) 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.
#Contains ImmuGlo™ anti-human IgG FITC primate adsorbed conjugate.
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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 cobalamin 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 cobalamin complex to the ileal receptors.

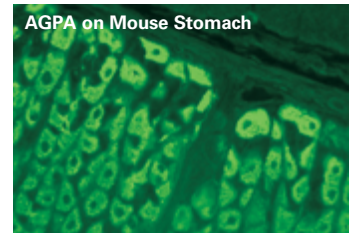
Both types I and II result in the same pathological effect, prevention of cobalamin absorption. Type II antibodies rarely occur in the absence of type I antibodies.

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.

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



Code	Description	Determinations
ImmuGlo™ Immunofluorescence		
1107	COMVI™ mouse kidney/stomach	48
1107R*	COMVI™ rat kidney/stomach	48
ImmuGlo™ Slides		
2148*	COMVI™ rat kidney/stomach	8 well
2152	COMVI™ mouse kidney/stomach	8 well
2169*	Mouse stomach	8 well
2173*	Rat stomach	6 well
ImmuGlo™ Controls / Components		
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
2212	Gastric parietal cell antibody positive control	0.5 ml
2302	Buffered diluent	60 ml
ImmuLisa™ ELISA		
5164*	Enhanced Intrinsic Factor Antibody ELISA	96
1165* ~	Gastric Parietal Cell antibody 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.
~Special order

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Liver Diseases

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.

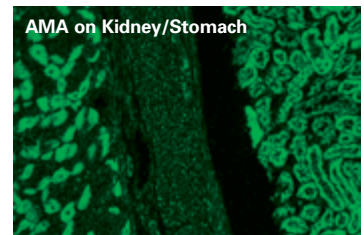
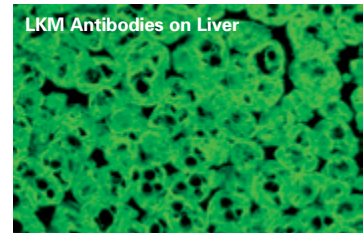
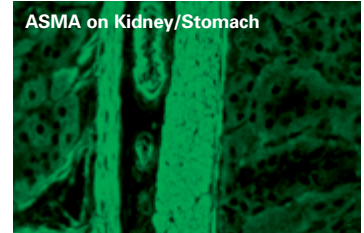
Comparison of Antibodies in Patients with AIH-2 and HCV Infection

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.



Liver Diseases

ImmcoStrip™ LIA

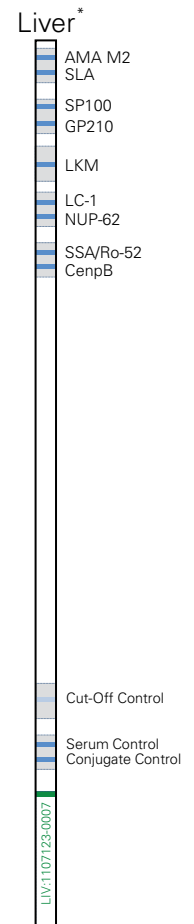
Code	Description	Determinations
ImmunoGlo™ Immunofluorescence		
1107	COMVI™ mouse kidney/stomach	48
1107R*	COMVI™ rat kidney/stomach	48
1107-1	Mouse Kidney antibody	48
1134	COMVI™ HEp-2/mouse kidney/stomach	96
1134LKM*	COMVI™ HEp-2/mouse liver/kidney/stomach	48
1134RLKM*	COMVI™ HEp-2/rat liver/kidney/stomach	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)		
6040*	Liver	20
ImmunoGlo™ Slides		
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
2190RLKM*	COMVI™ HEp-2/rat liver/kidney/stomach	6 well
2194*	COMVI™ rat kidney/stomach/liver	8 well
ImmunoGlo™ Controls / Components		
2099	Anti-human IgG FITC primate adsorbed conjugate <i>Contains Evan's Blue</i>	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
ImmunoLisa™ ELISA		
1168*	Liver/Kidney Microsomal (LKM-1) antibody 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.

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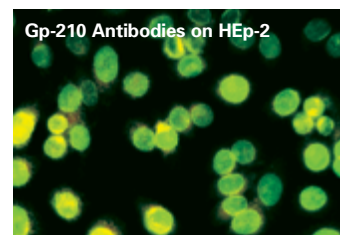
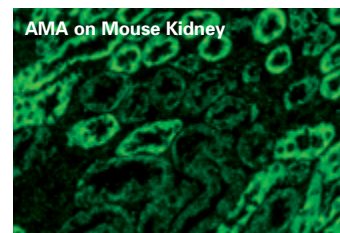
Liver Diseases

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, or by ImmuLisa™ Mitochondrial M2 antibody ELISA.

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.



Code	Description	Determinations
ImmuGlo™ Immunofluorescence		
1107	COMVI™ mouse kidney/stomach	48
1107R*	COMVI™ rat kidney/stomach	48
1125	COMVI™ HEp-2/mouse kidney	96
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		
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
2190RLKM*	COMVI™ HEp-2/rat liver/kidney/stomach	6 well
2194*	COMVI™ rat kidney/stomach/liver	8 well
ImmuGlo™ Controls / Components		
2099	Anti-human IgG FITC primate adsorbed conjugate <i>Contains Evan's Blue</i>	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
ImmuLisa™ ELISA		
5163A*	Enhanced Mitochondria antibody (AMA) IgA ELISA	96
5163M*	Enhanced Mitochondria antibody (AMA) IgM ELISA	96
5163G*	Enhanced Mitochondria antibody (AMA) IgG ELISA	96
5163S*	Enhanced Mitochondria antibody IgA/IgG/IgM (AMA) Screen ELISA	96

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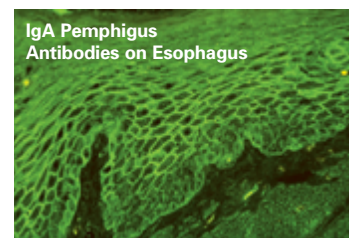
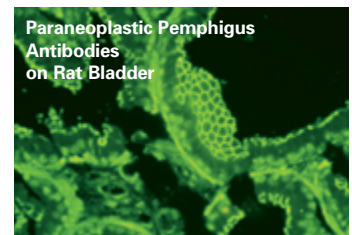
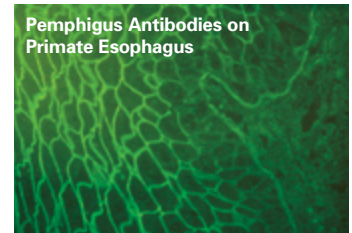
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Vesiculo-Bullous Disorders

Skin Antibodies

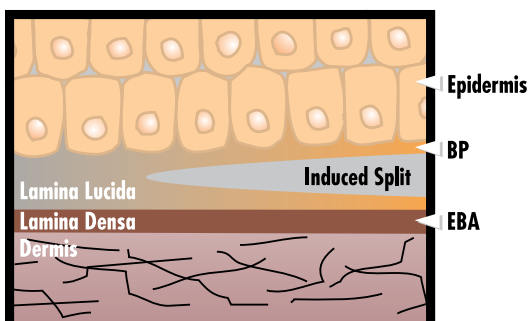
The detection of anti-skin antibodies aids in the diagnosis and prognosis of chronic vesiculo-bullous diseases, including pemphigus, pemphigoid, mucous membrane (cicatricial) pemphigoid, and epidermolysis bullosa acquisita (EBA). Epithelial intercellular (IC) antibodies are diagnostic for pemphigus. 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.



Code	Description	Determinations
ImmuGlo™ Immunofluorescence		
1104	COMVI™ skin (IC/BMZ) antibody — primate/guinea pig esophagus	48
1105	Skin (IC/BMZ) antibody — primate esophagus	48
ImmuGlo™ Slides		
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		
2099	Anti-human IgG FITC primate adsorbed conjugate <i>Contains Evan's Blue</i>	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
2213-1*	Intercellular (IC) antibody low titer 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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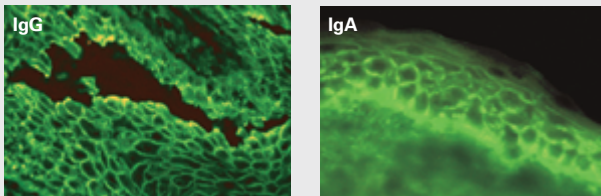
Diagram of Induced Split



Vesiculo-Bullous

Immunological Findings in Vesiculo-Bullous Disorders

Pemphigus – Direct Immunofluorescence (IFA)

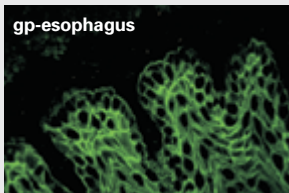
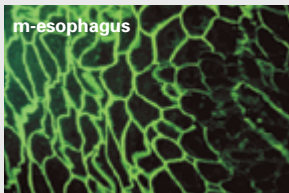


Serological Differentiation of *Pemphigus Vulgaris* from *Pemphigus Foliaceus* Based on Substrate Reactivity

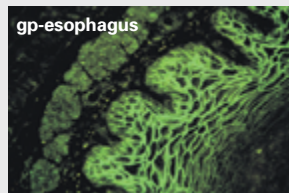
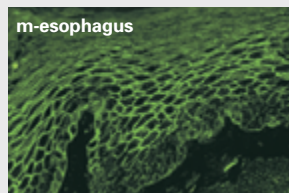
Higher Titer/ Brighter Staining	P. Vulgaris Sera		P. Foliaceus Sera	
	Number	Percent	Number	Percent
Monkey Esophagus	73	97%	0	97%
Guinea Pig Esophagus	0	0%	25	0%
No Difference	2	3%	5	3%

Pemphigus – Indirect Immunofluorescence (IFA)

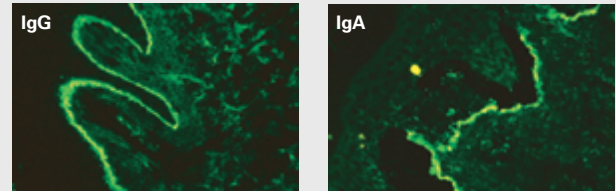
Pemphigus Vulgaris



Pemphigus Foliaceus



Pemphigoid – Direct Immunofluorescence (IFA)

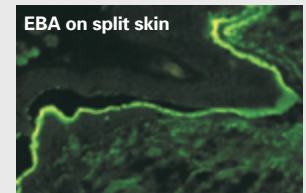
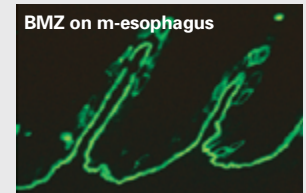


- Bullous Pemphigoid (BP)
- Epidermolysis Bullosa Acquisita (EBA)
- Cicatricial Pemphigoid (CP)
- Herpes Gestationis (HG)
- Linear IgA Bullous Dermatitis (LABD)
- Mucous Membrane Pemphigoid (MMP)

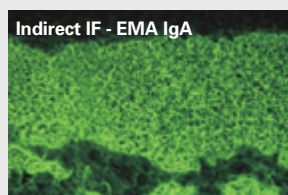
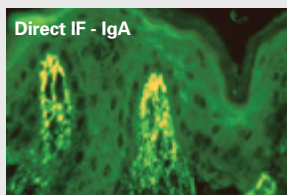
Immunolocalization of BMZ Antibodies on *In Vitro* Split Skin by Indirect Immunofluorescence

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)



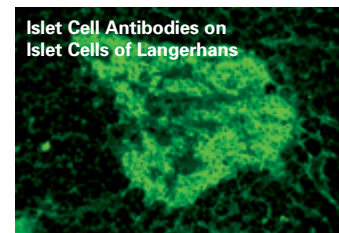
Sensitivity, Specificity, and Predictive Values in Markers for DH

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

Type I Diabetes

Islet Cell Antibodies (ICA_b)

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 (ICA_b) 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

Islet Cell antibody IFA Positive Control

The ICA Positive Control included in the anti-Islet Cell kit is standardized against the 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.

Code	Description	Determinations
ImmuGlo™ Immunofluorescence		
1123 ⁺	Islet Cell antibody	40
ImmuGlo™ Slides		
2165*	Primate pancreas	4 well
ImmuGlo™ Controls / Components		
2099	Anti-human IgG FITC primate adsorbed conjugate <i>Contains Evan's Blue</i>	5 ml
2118X*	Conjugate B	5 ml
2200	Autoantibody negative control	0.5 ml
2233*	Islet cell antibody (ICA _b) positive control	0.5 ml
2313*	ICA Buffered diluent	60 ml

All kits are FDA approved and CE marked for IVD use unless otherwise noted.
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#Contains ImmuGlo™ anti-human IgG FITC primate adsorbed conjugate.
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Thyroid Disorders

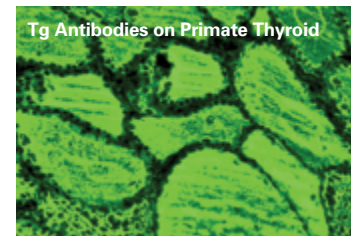
Thyroglobulin (Tg) and Thyroid Peroxidase (TPO) Antibodies

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 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



Code	Description	Determinations
ImmuGlo™ Immunofluorescence		
1143 [†]	Thyroid antibody	48
ImmuGlo™ Slides		
2180*	Primate thyroid	6 well
ImmuGlo™ Controls / Components		
2099	Anti-human IgG FITC primate adsorbed conjugate <i>Contains Evan's Blue</i>	5 ml
2200	Autoantibody negative control	0.5 ml
2239*	Thyroid antibody positive control (microsomal)	0.5 ml
2302	Buffered diluent	60 ml
ImmuLisa™ ELISA		
5131*	Enhanced Tg antibody ELISA	96
5132*	Enhanced TPO antibody ELISA	96

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†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

ImmuLisa™ TPO Antibody Test Demonstrates Superior Performance

	ImmuLisa™ TPO	Competitor
Sensitivity	79%	70%
Specificity	96%	100%
Clinical Agreement	87%	84%

Neuropathies

Myelin Associated Glycoproteins (MAG) Antibodies

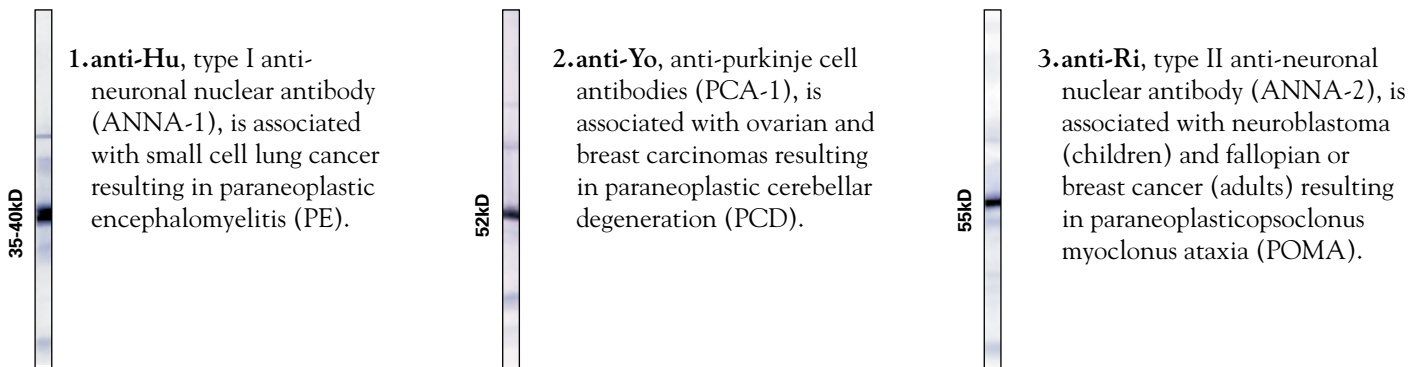
Peripheral neuropathies, autoimmune responses of the peripheral nervous system, are associated with autoantibodies against various neural glycoconjugates. Neuropathies associated with anti-MAG with IgM paraproteinemia are often slowly progressive with evidence of demyelination and a variable degree of 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.

Paraneoplastic Syndromes

Neuronal Antibodies

Autoimmune responses of the central nervous system, recognized as paraneoplastic neurologic disorders are manifestations of an antitumor immune response. The following autoantibodies are found in paraneoplastic syndromes:



These markers help in discriminating between true paraneoplastic disorders and other inflammatory disorders of the nervous system that mimic a paraneoplastic syndrome. IFA provides a sensitive method of detecting these autoantibodies. Hu and Ri autoantibodies, which characteristically stain the granular cell nucleus, are easily distinguished from the Purkinjee cell cytoplasm staining Yo antibodies. Specimens found positive by IFA can be confirmed using the Western Blot method.

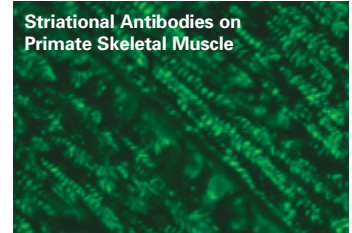
Code	Description	Determinations
ImmuGlo™ Immunofluorescence		
1172*	MAG antibody	48
ImmuBlot™ Western Blot		
1173*	MAG antibody	20
1174*	Neuronal antibody	20

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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 †Contains ImmuGlo™ anti-human IgG FITC primate adsorbed conjugate.
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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.



Code	Description	Determinations
ImmuGlo™ Slides		
2158*	Primate skeletal muscle	6 well
2172*	Rat skeletal muscle	6 well
ImmuGlo™ Controls / Components		
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

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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Striational Antibodies In Patients with Thymoma

Clinical	Striational Ab
MG Only	74%
Neurological Disorders with MG	87%
Neurological Disorders w/o 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.

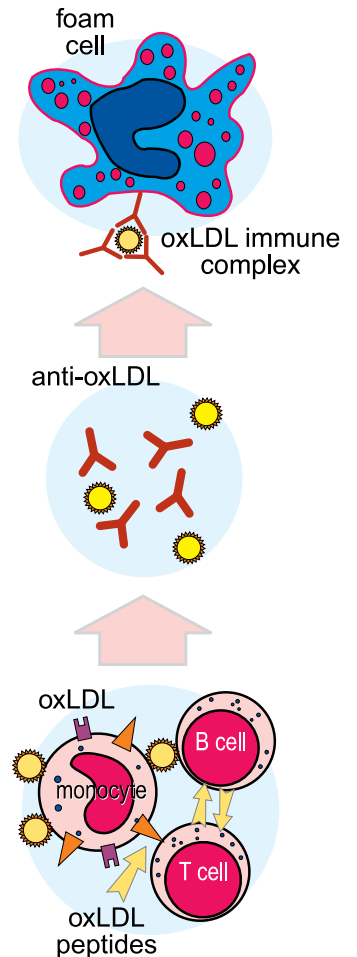
Oxidative modification of low density lipoproteins (LDL) and oxLDL antibodies play an important role in the formation of atherosclerotic plaque. According to the oxidative modification hypothesis, LDL initially accumulates in the subendothelial space of arteries and is mildly oxidized by the resident 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: sarcolemmal, diffuse cytoplasmic and striational, producing the so-called fibrillar pattern.

The role of oxLDL antibodies



Code	Description	Determinations
ImmuGlo™ Immunofluorescence		
1101H*	Heart antibody	48
ImmuGlo™ Slides		
2157*	Primate heart	6 well
2171*	Rat heart	6 well
ImmuGlo™ Controls / Components		
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
ImmuLisa™ ELISA		
5158*	Enhanced oxLDL antibody ELISA	96

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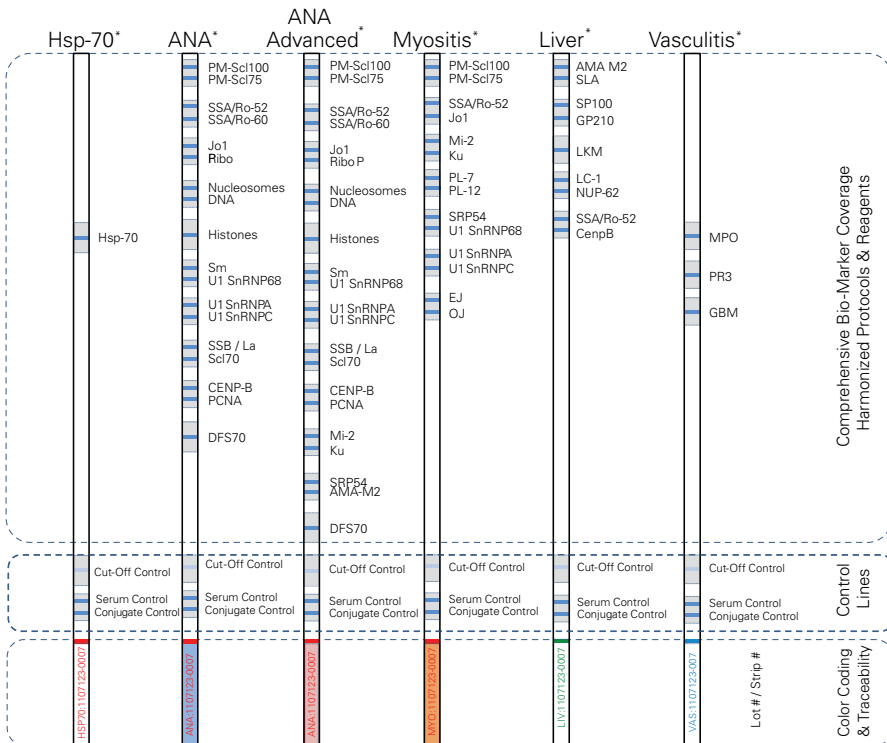


Featured Products

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.

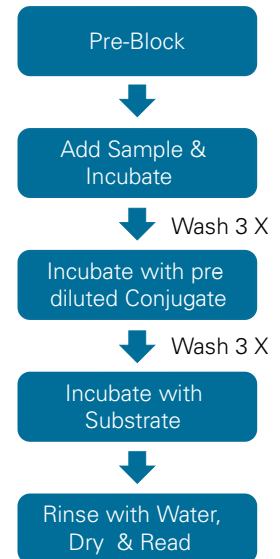


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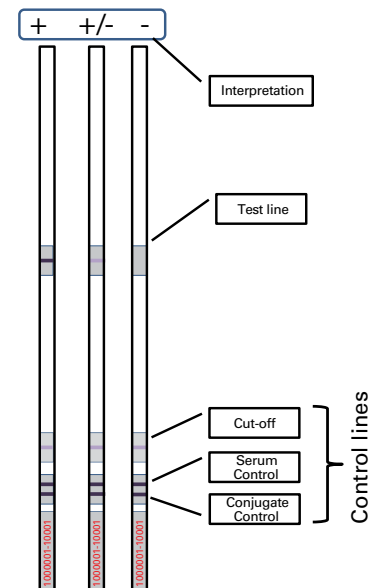
Code	Description	Determinations
6001*	ImmcoStripe™ Hsp-70	20
6010*	ImmcoStripe™ ANA	20
6011*	ImmcoStripe™ ANA Advanced	20
6020*	ImmcoStripe™ Myositis	20
6030*	ImmcoStripe™ Vasculitis	20
6040*	ImmcoStripe™ Liver	20

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LIA Test Protocol



Quality Control/Interpretation

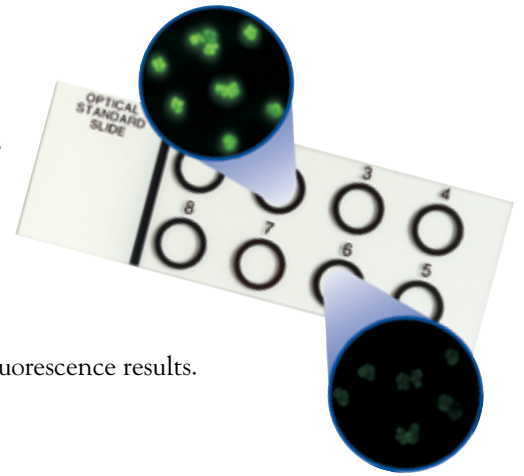


Accessories & Special Orders

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.



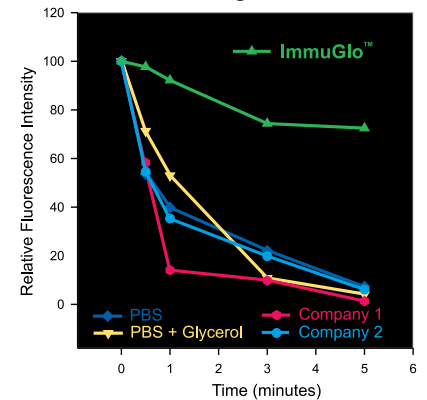
Code	Description
ImmuGlo™ IFA Component	
2550OS	Optical Standard Slide

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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.

Performance of ImmuGlo™ Mounting Medium



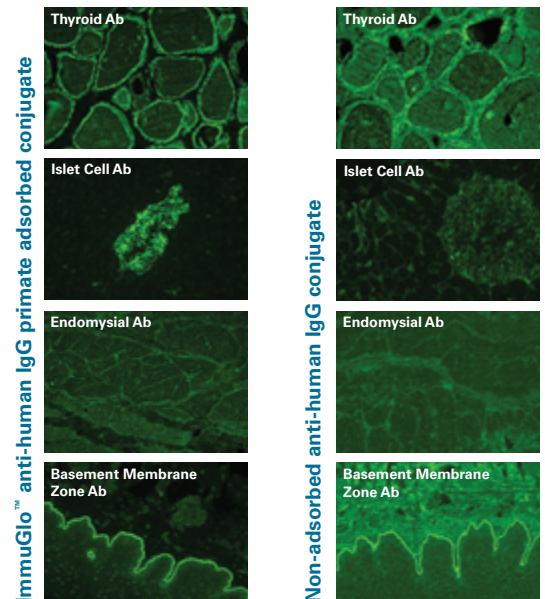
Code	Description	Volume
ImmuGlo™ IFA Component		
2505	Mounting Medium	5 ml
2506	Mounting Medium	60 ml

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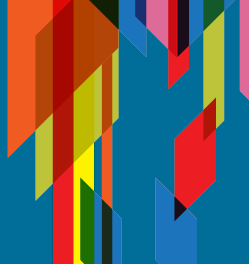
ImmuGlo™ Conjugates

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

Please refer to the product index for complete listing of configurations and determinations. All products may not be licensed for sale in Canada, please contact your Canadian distributor for more information.



Product Index



ImmuGlo™ IFA Kits

CODE	PRODUCT NAME	DESCRIPTION	DETERMINATIONS	PAGE
1101H*	Heart IFA	8x6 well rat heart slides with heart antibody control	48	32
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	26
1105	Skin (IC/BMZ) IFA	8x6 well primate esophagus slides with IC and BMZ antibody controls	48	26
1106	nDNA IFA (crithidia luciliae)	8x6 well crithidia luciliae slides with nDNA antibody control	48	7
1106-2	nDNA IFA (crithidia luciliae)	16x6 well crithidia luciliae slides with nDNA antibody control	96	7
1106-6	nDNA IFA (crithidia luciliae)	20x6 well crithidia luciliae slides with nDNA antibody control	120	7
1107	COMVI™ IFA	6x8 well mouse kidney/stomach substrate with ANA and AMA controls	48	3, 22, 24-25
1107R*	COMVI™ IFA	6x8 well rat kidney/stomach substrate with ANA and AMA controls	48	3, 22, 24-25
1107-1	Autoantibody Test System I Kit	6x8 well mouse kidney slides with ANA control	48	3
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	4
1108-120*	HEp-2/DFS70KO Substrate	10x12 well HEp-2/DFS70-KO slides with DFS70 positive control	120	4
1108-240*	HEp-2/DFS70KO Substrate	20x12 well HEp-2/DFS70-KO slides with DFS70 positive control	240	4
1114	EMA (smooth muscle) IgA/IgG IFA	8x6 well primate smooth muscle slides with EMA control	48	16
1114-96	EMA (smooth muscle) IgA/IgG IFA	16x6 well primate smooth muscle slides with EMA control	96	16
1114A*	EMA (smooth muscle) IgA IFA	8x6 well primate smooth muscle slides with EMA control	48	16
1114A-PDE	EMA (distal esophagus) IgA IFA	8x6 well primate distal esophagus slides with EMA control	48	16
1114A-PDE-250	EMA (distal esophagus) IgA IFA	25x10 well primate distal esophagus slides with EMA control	250	16
1114G-PDE‡	EMA (distal esophagus) IgG IFA	8x6 well primate distal esophagus slides with EMA IgG control	48	16
1115	Reticulin IgA/IgG IFA	8x6 well rat kidney slides with ARA control	48	16
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	13, 20
1122*	Keratin antibody IFA	8x6 well rat esophagus slides with AKA control	48	10
1123*‡	Islet Cell IFA	10x4 well primate pancreas slides with ICAb control	40	28
1124*‡	Glomerular Basement Membrane IFA	8x6 well primate kidney slides with GBM antibody control	48	15
1125	COMVI™ HEp-2/mouse kidney IFA	16x6 well HEp-2/mouse kidney slides with ANA and AMA controls	96	3, 25
1134	COMVI™ HEp-2/mouse kidney/stomach IFA	16x6 well HEp-2/mouse kidney/stomach slides with ANA and AMA controls	96	3, 24-25
1134LKM*	COMVI™ HEp-2/mouse liver/kidney/stomach IFA	8x6 well HEp-2/mouse liver/kidney/stomach slides with ANA and AMA controls	48	3, 24-25
1134RLKM*	COMVI™ HEp-2/rat liver/kidney/stomach IFA	8x6 well HEp-2/rat liver/kidney/stomach slides with ANA and AMA controls	48	3, 24-25
1136	COMVI™ mouse liver/kidney/stomach IFA	8x6 well mouse liver/kidney/stomach slides with ANA and AMA controls	48	3, 25
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	24
1136R*	COMVI™ IFA rat liver/kidney/stomach	6x8 well rat liver/kidney/stomach slides with ANA and AMA controls	48	3, 25
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	13, 20
1140-2	ANCA IFA (ethanol fixation)	16x6 well ethanol fixed slides with cANCA control	96	13, 20
1140-240	ANCA IFA (ethanol fixation)	20x12 well ethanol fixed slides with cANCA control	240	13, 20
1141	ANCA IFA (formalin fixation)	8x6 well formalin fixed slides with pANCA control	48	13, 20
1142	COMVI™ ANCA IFA	8x6 ethanol fixed + 6 formalin fixed well slides with cANCA and pANCA controls	48	13, 20
1143*‡	Thyroid IFA	8x6 well primate thyroid slides with ATA control	48	29
1172*	Myelin Associated Glycoprotein IFA	8x6 well primate peripheral nerve slides with MAG antibody control	48	30
1194*‡	ExPA IFA	10x4 well primate pancreas slides with ExPA control	40	21

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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Product Index

ImmuGlo™ IFA Slides

CODE	DESCRIPTION	WELLS	PAGE
2120*	Rat esophagus	6	10
2123*	Primate adrenal gland	6	—
2124*	Primate salivary gland	6	—
2125-4*	Primate ovary	4	30
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	26
2148*	COMVI™ rat kidney/stomach	8	3, 22, 24-25
2150	HEp-2 cells	10	3
2150-6	HEp-2 cells	6	—
2150-21	HEp-2 cells	21	—
2150-12	HEp-2 cells	12	—
2151-6	Cithidia luciliae	6	7
2152	COMVI™ mouse kidney/stomach	8	3, 22, 24-25
2152-3	COMVI™ mouse kidney/stomach/liver	8	3, 24-25
2152-10	COMVI™ mouse kidney/stomach/liver	10	—
2154	COMVI™ primate/guinea pig esophagus	6	26
2155	Primate esophagus	6	16, 26
2155-1	Primate distal esophagus	6	16,
2155-8	Primate esophagus	8	26
2155-1/10	Primate distal esophagus	10	16
2155-18	Primate distal esophagus	8	16
2156*	Transitional Epithelium	6	26
2157*	Primate heart	6	34
2158*	Primate skeletal muscle	6	33
2160*	Primate smooth muscle	6	16
2161	Rat kidney	6	3, 16, 25
2162	Ethanol fixed human PMN cells	6	13, 20
2162-12	Ethanol fixed human PMN cells	12	13, 20
2163*	Primate kidney	6	3, 15, 25
2165*	Primate pancreas	4	28
2167-8	Mouse kidney	8	15
2169*	Mouse stomach	8	22, 24
2171*	Rat heart	6	34
2172*	Rat skeletal muscle	6	33
2173*	Rat stomach	6	22, 24
2180*	Primate thyroid	6	29
2186*	Formalin fixed human PMN cells	6	13, 20
2189	COMVI™ ethanol+formalin fixed PMN cells	6+ 6	13, 20
2190	COMVI™ HEp-2/mouse kidney/stomach	6	3, 24-25
2190LKM*	COMVI™ HEp-2/mouse liver/kidney/stomach	6	3, 24-25
2190RLKM*	COMVI™ HEp-2/rat liver/kidney/stomach	6	3, 24-25
2191	COMVI™ HEp-2/mouse kidney	6	3
2194*	COMVI™ rat kidney/stomach/liver	8	3, 24-25
2298*	HEp-2/DFS70KO	12	4

ImmuGlo™ IFA Demonstration Slides

CODE	DESCRIPTION
2150-12-DEMO	ANA on HEp-2
2151-6-DEMO	nDNA on Crithidia luciliae
2152-3-DEMO	COMVI™ mouse kidney/stomach/liver
2155-1-DEMO	EMA- Distal Esophagus
2160-DEMO	EMA- Smooth Muscle
2162-DEMO	Ethanol fixed ANCA
2298-DEMO	Hep-2/DFS70-KO

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Product Index

ImmuGlo™ IFA Controls

CODE	DESCRIPTION	VOLUME	PAGE
1602	ANA Pattern Control I (homogeneous/speckled/centromere/nucleolar/peripheral)	5 x 0.5 ml	3
2200	Autoantibody negative control	0.5 ml	3, 4, 7, 10, 13, 15-16, 20 22, 24-26, 28-29, 33-34
2200GBM*	GBM negative control	0.5 ml	
2201	ANA positive control (homogeneous)	0.5 ml	3
2201-1*	ANA low titer control (homogeneous)	0.5 ml	3
2202	ANA positive control (speckled)	0.5 ml	3
2203	ANA positive control (centromere)	0.5 ml	3
2204	ANA positive control (nucleolar)	0.5 ml	3
2205	ANA positive control (peripheral)	0.5 ml	3
2209*	MAG antibody positive control	0.5 ml	—
2210	Mitochondrial antibody positive control	0.5 ml	3, 25
2210-1*	Mitochondrial antibody low titer positive control	0.5 ml	3, 25
2211	Smooth muscle antibody positive control	0.5 ml	3, 24, 26
2212	Gastric parietal cell antibody positive control	0.5 ml	3, 22, 24
2213	Intercellular (IC) antibody positive control	0.5 ml	26
2213-1*	Intercellular (IC) antibody low titer positive control	0.5 ml	26
2214	Intercellular (IC) antibody positive control (pemphigus vulgaris)	0.5 ml	26
2215	nDNA antibody positive control	0.5 ml	7
2215-1*	nDNA antibody low titer positive control	0.5 ml	7
2216	Intercellular (IC) antibody positive control (pemphigus foliaceus)	0.5 ml	26
2217	BMZ antibody positive control (pemphigoid)	0.5 ml	26
2233*	Islet cell antibody (ICA) positive control	0.5 ml	28
2235*	Heart/skeletal muscle antibody positive control	0.5 ml	33, 34
2236*	PCNA positive control	0.5 ml	3
2239*	Thyroid microsomal antibody positive control	0.5 ml	29
2240	pANCA positive control	0.5 ml	13, 20
2241*	Paraneoplastic pemphigus positive control	0.5 ml	—
2242*	LKM antibody positive control	0.5 ml	3, 24
2245*	Keratin antibody positive control	0.5 ml	10
2250	Endomysial antibody positive control	0.5 ml	16
2250-1*	Endomysial antibody low titer positive control	0.5 ml	16
2250G	Endomysial IgG antibody positive control	0.5 ml	16
2251	Reticulin antibody positive control	0.5 ml	16
2252	cANCA positive control	0.5 ml	13, 20
2252-1*	cANCA low titer positive control	0.5 ml	13, 20
2261*	Ribosomal P antibody positive control	0.5 ml	3
2267*	GBM antibody positive control	0.5 ml	15
2284*	DFS70 positive control	0.5 ml	4

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ImmuGlo™ IFA Conjugates

CODE	DESCRIPTION	VOLUME	PAGE
2099	Anti-human IgG FITC primate adsorbed conjugate contains Evan's Blue	5 ml	34
2099-15	Anti-human IgG FITC primate adsorbed conjugate contains Evan's Blue	15.0 ml	—
2099X	Anti-human IgG FITC primate adsorbed conjugate without Evan's Blue	5 ml	—
2099X-15	Anti-human IgG FITC primate adsorbed conjugate without Evan's Blue	15.0 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	—
2107X-15	Anti-human IgA FITC conjugate without Evan's Blue	15 ml	—
2107-15	Anti-human IgA FITC conjugate contains Evan's Blue	15 ml	—
2113	Anti-human IgA+IgG FITC conjugate for EMA & ARA kits contains Evan's Blue	5 ml	—
2113X-15	Anti-human IgA+IgG FITC conjugate for EMA & ARA kits without Evan's Blue	15 ml	—
2113-15	Anti-human IgA+IgG FITC conjugate for EMA & ARA kits contains Evan's Blue	15 ml	—
2116	Anti-human polyvalent FITC conjugate IgG, IgA, IgM for direct IF	1 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	
2301	PBS	for 1 liter	—
2302	Buffered diluent	60 ml	3, 4, 7, 10, 13, 16
2302-375	Buffered diluent	375 ml	20, 22, 24-26,
2302-60	Buffered diluent	60 ml	—
2303*	GBM Buffered diluent	60 ml	15
2312*	GBM Enhancing Buffer for GBM Kit	5 ml	15
2313*	ICA Buffer D.I.	60 ml	28
2500	Microscope Slide Coverglass 24x60mm	box of 12	—
2500long	Microscope Slide Coverglass 22x70mm	box of 12	—
2505	Mounting Medium Dropper Vial	5 ml	34
2506	Mounting Medium Dropper Vial	60 ml	34
2510	Counterstain (Evan's Blue)	1 ml	—
2550OS	Optical Standard Slide	8 wells	34
2600*	Reagent Set primate split skin/esophagus	48 wells	—

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Product Index

ImmuLisa™ ELISA Kits

CODE	DESCRIPTION	VOLUME	PAGE
5101*	Enhanced PM-Scl antibody ELISA	96	8
5117A*	Enhanced Gliadin IgA antibody ELISA	96	18
5117G*	Enhanced Gliadin IgG antibody ELISA	96	18
5118A	Enhanced ACA IgA antibody ELISA	96	11
5118G	Enhanced ACA IgG antibody ELISA	96	11
5118M	Enhanced ACA IgM antibody ELISA	96	11
5118S	Enhanced ACA Screen ELISA	96	11
1119	Histone antibody ELISA	96	8
5120	Enhanced Double stranded DNA antibody ELISA	96	7
5126	Enhanced RNP antibody ENA ELISA	96	5
5127	Enhanced Sm antibody ENA ELISA	96	5
5128	Enhanced Ro/SS-A antibody ENA ELISA	96	5
5129	Enhanced La/SS-B antibody ENA ELISA	96	5
5131*	Enhanced Tg ELISA	96	29
5132*	Enhanced TPO ELISA	96	29
5138A	Enhanced RF IgA ELISA	96	10
5138M	Enhanced RF IgM ELISA	96	10
5138G	Enhanced RF IgG ELISA	96	10
5138S	Enhanced RF Screen ELISA	96	10
5144A	Enhanced Celiac tTG IgA ELISA	96	17
5144G	Enhanced Celiac tTG IgG ELISA	96	17
5148	Enhanced Centromere Antibody ELISA	96	5
5149*	Enhanced ENA ELISA for RNP/Sm/Ro/La/Scl-70/Jo-1 antibodies	96	5
5150	Enhanced Scl-70 antibody ENA ELISA	96	5
5151*	Enhanced Jo-1 antibody ENA ELISA	96	5
5152A*	Enhanced β 2-glycoprotein I (β 2GPI) IgA ELISA	96	11
5152G*	Enhanced β 2-glycoprotein I (β 2GPI) IgG ELISA	96	11
5152M*	Enhanced β 2-glycoprotein I (β 2GPI) IgM ELISA	96	11
5152S*	Enhanced β 2-glycoprotein I (β 2GPI) Screen ELISA	96	11
5154*	Enhanced Glomular Basement Membrane antibody ELISA	96	15
5156A*	Enhanced Saccharomyces Cerevisiae IgA (ASCA) ELISA	96	21
5156G*	Enhanced Saccharomyces Cerevisiae IgG (ASCA) ELISA	96	21
5157	Enhanced Celiac Fusion™ tTG/DGP ELISA	96	19
5158*	Enhanced Oxidized Low Density Lipoprotein antibody ELISA	96	33
5159A	Enhanced Celiac G+ DGP IgA Antibody ELISA	96	18
5159G	Enhanced Celiac G+ DGP IgG Antibody ELISA	96	18
5160	Enhanced ANCA ELISA for PR3 and MPO antibodies	96	13, 20
5161	Enhanced Myeloperoxidase (MPO) antibody ELISA	96	13, 20
5162	Enhanced Proteinase 3 (PR3) antibody ELISA	96	25
5163A	Enhanced Mitochondria antibody (AMA) IgA ELISA	96	25
5163G	Enhanced Mitochondria antibody (AMA) IgG ELISA	96	25
5163M	Enhanced Mitochondria antibody (AMA) IgM ELISA	96	25
5163S	Enhanced Mitochondria antibody (AMA) IgA/IgG/IgM Screen ELISA	96	25
5188*	Enhanced DFS70 ELISA	96	4
5164*	Enhanced Intrinsic Factor (EIF) antibody ELISA	96	22
1165*~	Gastric Parietal Cell (GPA) antibody ELISA	96	22
1168*	Liver/Kidney Microsomal (LKM-1) antibody ELISA	96	24
5175	Enhanced ANA Screen ELISA	96	3
5196*	Enhanced ENA Profile ELISA	96	—
8001P	Cyclic Citrullinated Peptide (CCP) ELISA	96	10

All kits are FDA approved and CE marked for IVD use unless otherwise noted

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~Special order

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Product Index

ImmuLisa™ ELISA Components

CODE	PRODUCT NAME	DETERMINATIONS	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 phosphatase)	12 ml	—
2514	TMB Enzyme substrate (HRP)	12 ml	—
2310	Stop solution (alkaline phosphatase)	15 ml	—
2316	HRP stop solution	15 ml	—
2318*	Serum diluent for oxLDL	60 ml	—
5308	Serum diluent for Enhanced ELISAs	60 ml	—
5305	Serum diluent for Cardioplin Enhanced ELISAs	60 ml	—

ImmuBlot™ Western Blot Kits

CODE	PRODUCT NAME	DETERMINATIONS	PAGE
1173*	MAG Western Blot	20	31
1174*	Neuronal Western Blot	20	31
1192*	PO Blot Anti-PO Kit	20	—

ImmuBlot™ Western Blot Components

CODE	PRODUCT NAME	U/M	PAGE
2309	Immunoblot Serum Diluent	60 ml	—
2314-1	Immunoblot Wash Buffer	for 1 liter	—

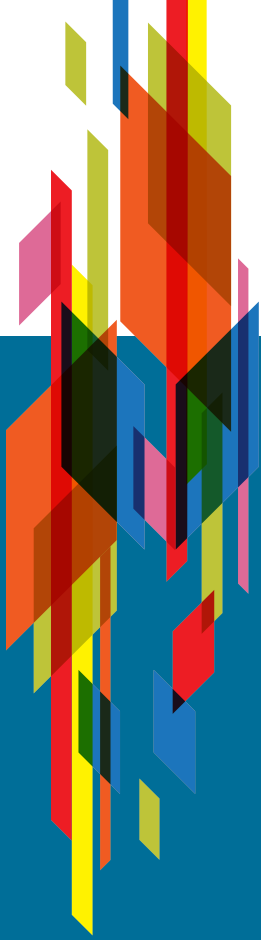
ImmcoStripe™ Line ImmunoAssay Kits

CODE	PRODUCT NAME	DETERMINATIONS	PAGE
6001*	Hsp-70	20	33
6010*	ANA	20	5,33
6011*	ANA Advanced	20	5,33
6020*	Myositis	20	33
6030*	Vasculitis	20	15,33
6040*	Liver	20	24,33

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We offer a complete line of autoimmune diagnostics kits and reference lab services

ImmuGlo™ IFA

- Comprehensive line of assays

ImmuLisa™ ELISA

- Superior sensitivity and specificity
- Multiple and cutoff calibrators for greater accuracy at decision point
- Standardized component sets and methods for reproducibility
- Longer shelf life up to 18 months

ImmuBlot™ Western Blot

- Sensitive confirmatory and esoteric markers

ImmcoStripe™ Line ImmunoAssay

- Comprehensive panels with test strips coated with highly purified antigens for maximum sensitivity and specificity

United States

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1-800-325-3424
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