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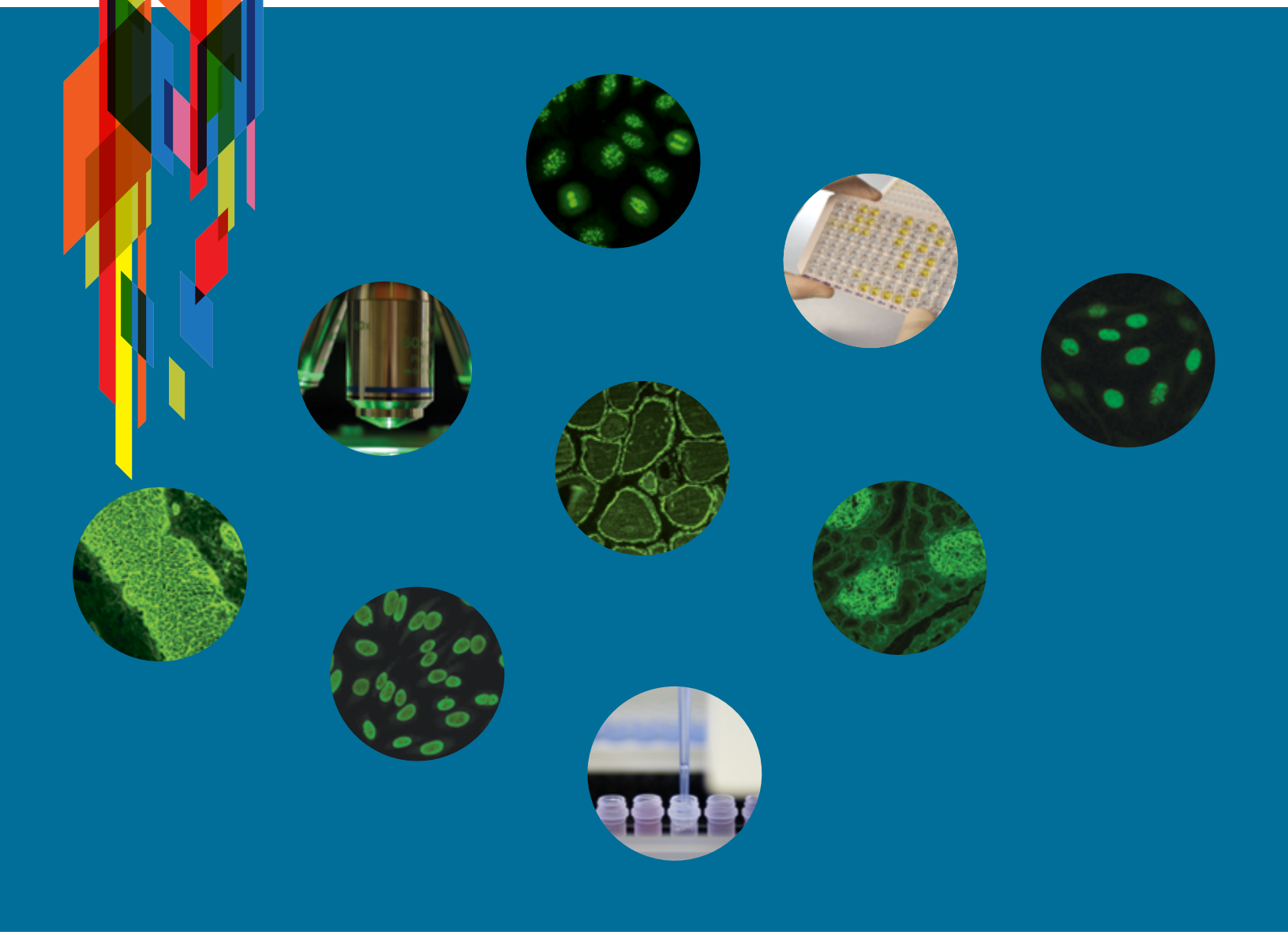
SZABO SCANDIC

# 2017 Product Catalog



www.trinitybiotech.com

immco DIAGNOSTICS
A Trinity Biotech Company

immco DIAGNOSTICS
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# 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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info@novacentury.com
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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:

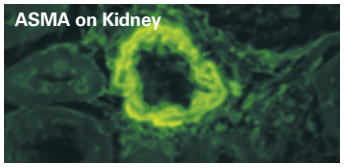
## Better Sensitivity + Better Specificity = Better Lab Results

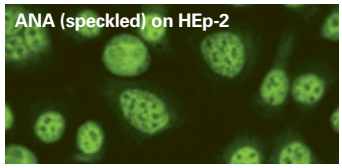
# Table of Contents

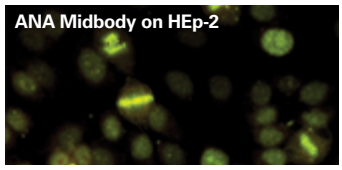
## Connective Tissue Disorders

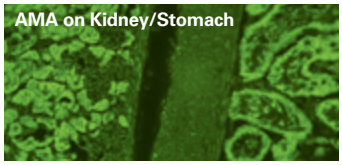
### Antinuclear Antibodies (ANA)

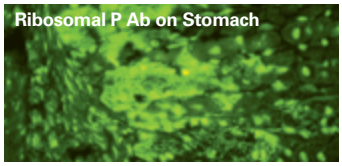
Serological tests for ANA play an important role in the diagnosis of various autoimmune connective tissue disorders, especially systemic lupus erythematosus (SLE), systemic sclerosis (SSc), mixed connective tissue disease, and Sjögren's syndrome. ANA constitute one of the American College of Rheumatology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

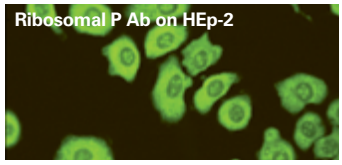



### Incidence of ANA

| 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 |

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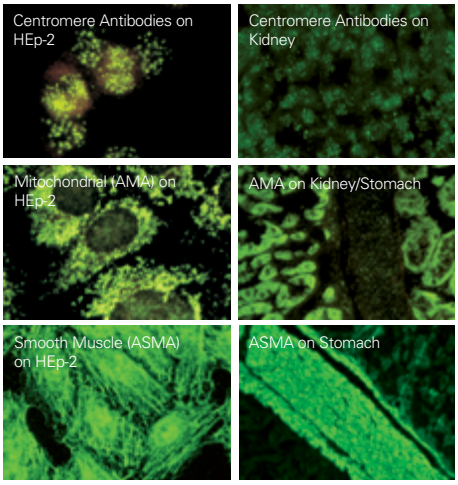
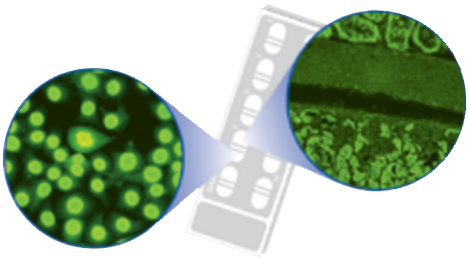
| | | HEp-2 | | |
|---|---|---|---|---|
| | | **Pos** | **Neg** | **Total** |
| 5175 | Pos | 41 | 3 | 44 |
| | Neg | 5 | 47 | 52 |
| | Total | 46 | 50 | 96 |

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

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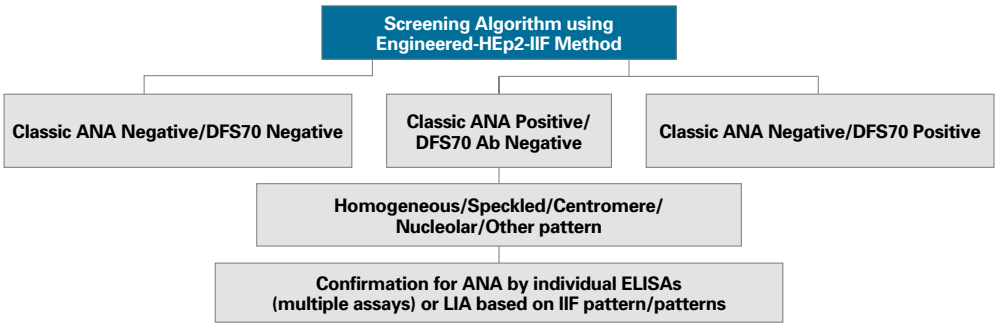
## DFS70 Antibodies

### Simple ANA Detection/DFS70 Ab discrimination

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

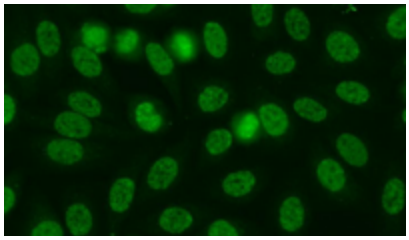
***"It is of utmost importance that the homogeneous pattern should be differentiated from the dense fine speckled (DFS) pattern in routing practice since the clinical significance of both patterns is quite different"[3]***



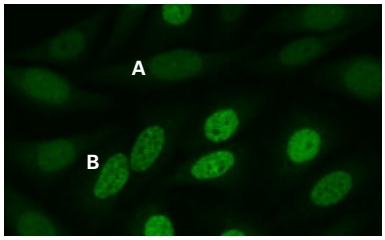

| Code | Description | Determinations |
|---|---|---|
| **ImmuGlo™ Immunofluorescence** | | |
| 1108* | HEp-2/DFS70KO Substrate Kit | 60 |
| 1108-120* | HEp-2/DFS70KO Substrate Kit | 120 |
| 1108-240* | HEp-2/DFS70KO Substrate Kit | 240 |
| **ImmuGlo™ Slides** | | |
| 2298* | HEp-2/DFS70KO | 12 well |
| **ImmuGlo™ 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 |
| **Immulisa™ ELISA** | | |
| 5188* | Enhanced DFS70 antibody ELISA | 96 |

*All kits are FDA approved and CE marked for IVD use unless otherwise noted. All Products may not be licensed for sale in Canada, please contact your Canadian distributor for more information.*For research use only in the US. 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.*


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

**DFS70 antibodies on conventional HEp-2 Substrate**




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

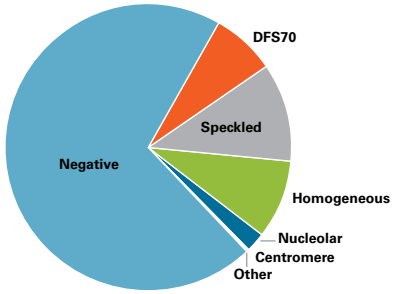
## Immco HEp-2 ELITE™

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

### Typical Breakdown of HEp-2 Screening Results




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

# 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 |

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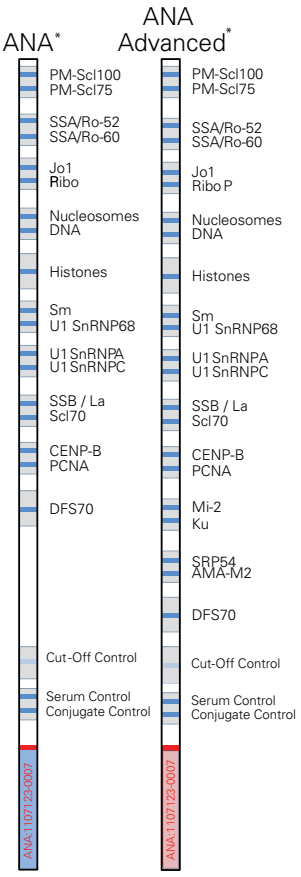


### Extractable Nuclear Antigen (ENA) Autoantibodies

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 |
|---|---|---|
| **ImmuLisa™ 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/Scl-70/Jo-1 ELISA | 96 |
| 5150 | Enhanced Scl-70 antibody ENA ELISA | 96 |
| 5151* | Enhanced Jo-1antibody ENA ELISA | 96 |
| 5196* | Enhanced ENA Profile ELISA | 12 |
| 5188* | Enhanced DFS70 antibody ELISA | 96 |

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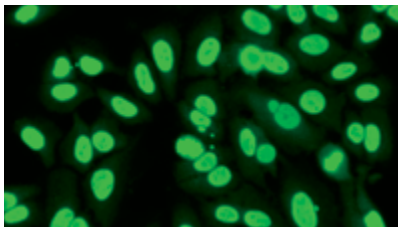
### Sensitivity and Specificity of ANA and its Clinically Important Subtypes[1,2]

| 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 |
| Scl-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.*

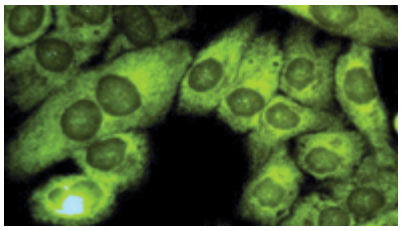
## Antinuclear Antibody Detection on HEp-2 Cells[1]



### Homogenous (Peripheral)
**with Mitotic Cells Positive Reaction**

DsDNA, Nucleosome, Histone Ab Positive
- SLE

Only Histone Positive
- Drug Induced LE



### Cytoplasmic
**Fine Speckled**

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

**Homogenous**

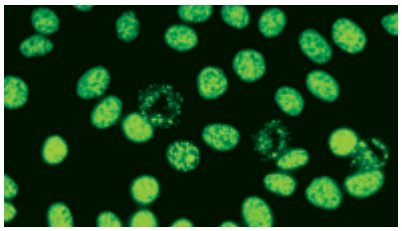
Ribosomal P Positive
- SLE

**Fibrillar**

Actin or other cytoskeleton antigen Positive
- Autoimmune Hepatitis?

**Coarse Granular**

Mitochondria Positive
- PBC



### Speckled
**Large/Coarse**

RNP Positive
- MCTD
- SLE
- SSc

Sm Positive
- SLE

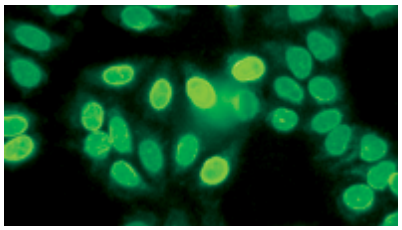
**Fine**

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

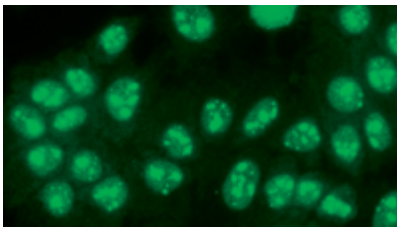
**Nuclear Dots (SP-100)**
- PBC

**Discrete Speckled**

Mitotic Cell, Centromere Positive
- Limited Scleroderma



### Nuclear Membrane
**With Mitotic Cells Negative Reaction**
- Autoimmune Liver Disease (PBC)



### Nucleolar
**Homogenous Pattern**

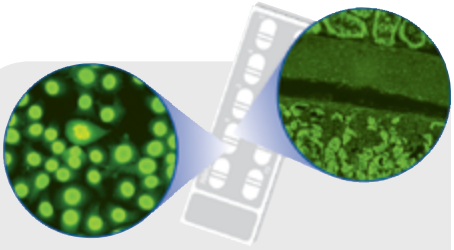
PM-Scl Positive
- Polymyositis
- Polymyositis/Scleroderma Overlap

**Clumpy**

Fibrillaran Positive
- Scleroderma

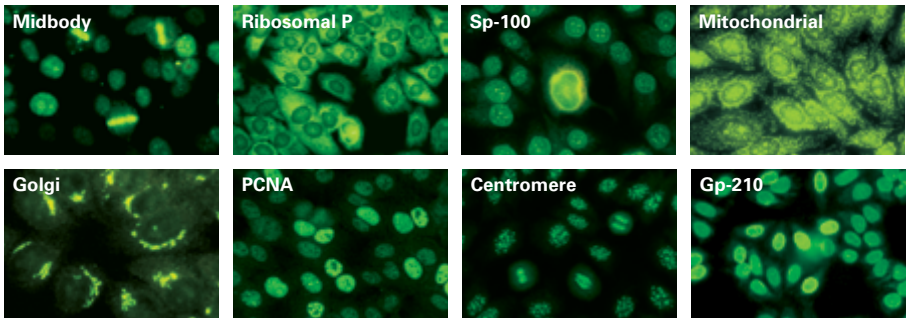
**Speckled**

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



### ImmuGlo™ COMVI™ slides

By combining HEp-2 with various tissue substrates, ImmuGlo™ COMVI™ slides represent a significant advance in technology and offer an ideal choice for the detection of ANA and other autoantibodies.
- Unsurpassed quality, convenience and economy with more diagnostic information available at a glance.
- Simultaneous reading of multiple antibody specificities: ANA, AMA, ASMA, AGPA and others.




**ABBREVIATIONS**

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

**REFERENCES**

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

# 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.

| Code | Description | Determinations |
|---|---|---|
| **ImmuGlo™ IFA** | | |
| 1106 | nDNA antibody *(Crithidia luciliae)* | 48 |
| 1106-2 | nDNA antibody *(Crithidia luciliae)* | 96 |
| 1106-6 | nDNA antibody *(Crithidia luciliae)* | 120 |
| **ImmuGlo™ Slides** | | |
| 2151-6 | *Crithidia luciliae* | 6 well |
| **ImmuGlo™ 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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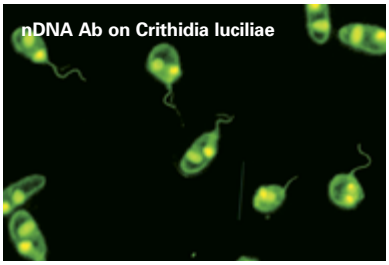
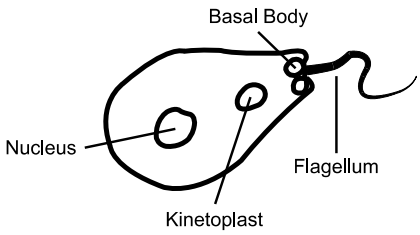



**Diagram of *Crithidia Morphology***




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

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

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

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

## 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).

**Incidence of Nucleosome,dsDNA, and Histone Antibodies in SLE**

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

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 PM-Scl Antibodies[1]**

| Disease Group | n | n + | % + |
|---|---|---|---|
| **PM-Scl Group** | | | |
| Polymyosits/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, Raijmakers 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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## 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.

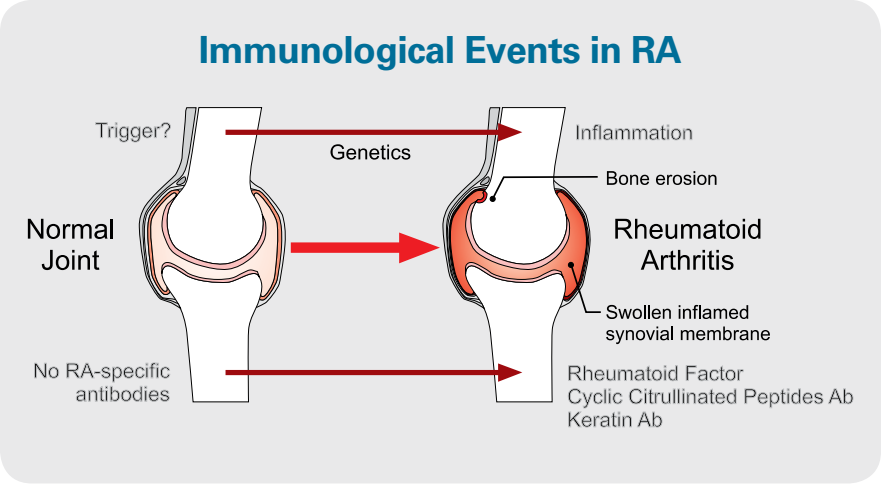
### Cyclic Citrullinated Peptides (CCP) Antibodies

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]

**Diagnostic Significance of Immunological Markers of Rheumatoid Arthritis[3]**

| Pre-RA | Sensitivity % | Specificity % |
|---|---|---|
| *>1.5 years before symptom onset* | | |
| 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 |
| <1.5 years before symptom onset | | |
| 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

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.

## 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.

| Code | Description | Determinations |
|---|---|---|
| **ImmuGlo™ Immunofluorescence** | | |
| 1122* | Keratin antibodies | 48 |
| **Slides** | | |
| 2120* | Rat esophagus | 6 well |
| **ImmuGlo™ 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 |
| **ImmuLisa™ 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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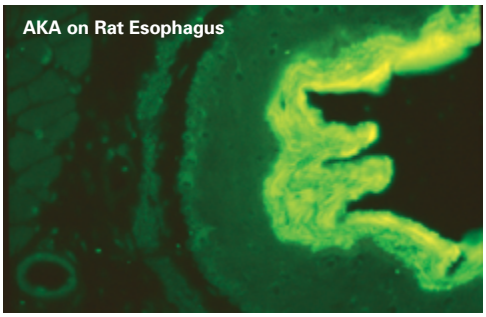
### Diagnostic Value of Rheumatoid Factor

| 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.*




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


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

# 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 ß2-glycoprotein I (ß2GPI). The presence of ß2GPI facilitates the binding of aCL to cardiolipin antigen. Thus the detection of aCL and antibodies to ß2GPI 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 ß2GPI, a comparative study shows the Enhanced ImmuLisa™ ß2GPI 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/ß2GPI 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/ß2GPI: ß2-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 |
|---|---|---|
| **ImmuLisa™ 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 ß2-glycoprotein I (ß2GPI) IgA ELISA | 96 |
| 5152G* | Enhanced ß2-glycoprotein (ß2GPI) IgG ELISA | 96 |
| 5152M* | Enhanced ß2-glycoprotein (ß2GPI) IgM ELISA | 96 |
| 5152S* | Enhanced ß2-glycoprotein I (ß2GPI) Screen ELISA | 96 |

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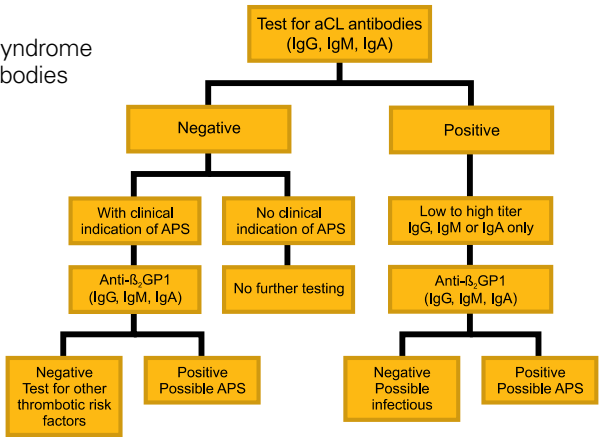
**ImmuLisa™ aCL Antibody Test: Significantly Higher Specificity and Clinical Agreement**

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

**Immco Antiphospholipid Antibody Testing Algorithm**

APS: Antiphospholipid Syndrome
aCL: Anticardiolipin Antibodies



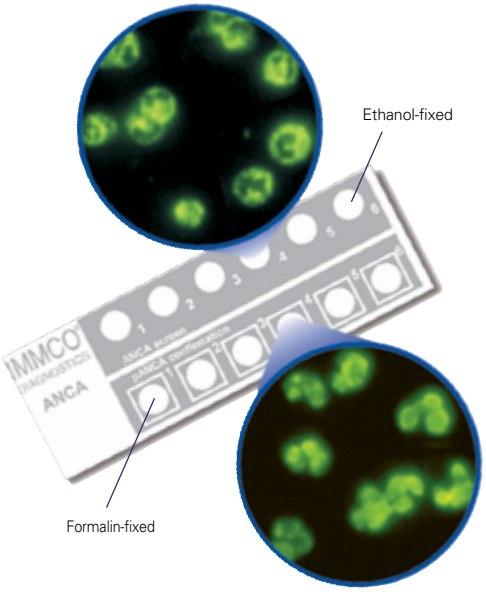
## Vasculitis

### 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 inderminate 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<br>10-15% others (e.g. cathepsin G) | 90% MPO<br>10% others (e.g. elastase, lactoferrin) |

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

# 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 polyangitis (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 complexsmall vessel vasculitis
- Henoch-Schönlein purpura
- Cryoglobulinemic vasculitis
- Cutaneous leukoclastic vasculitis
- Goodpasteur's syndrome

## Antineutrophil Cytoplasmic Antibodies Reaction Patterns

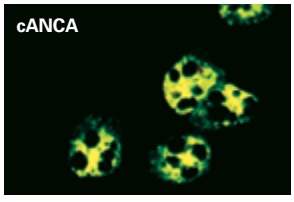
1. ImmuGlo™ IFA pattern with ImmuLisa™ anti-PR3 positive indicates diagnosis: GP

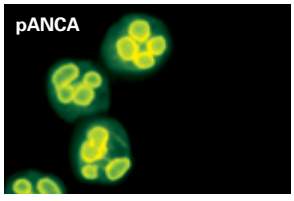
2. ImmuGlo™ IFA pattern with ImmuLisa™ anti-MPO positive indicates possible diagnosis: GP, CSS or MPA

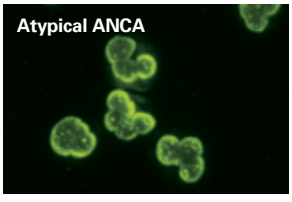
3. ImmuGlo™ IFA pattern with ImmuLisa™ ANCA negative indicates diagnosis: Inflammatory Bowel Disease

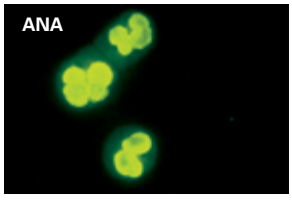
4. ImmuGlo™ IFA pattern on ANA in combination with ImmuGlo™ on HEp-2 indicates possible diagnosis: Connective Tissue Diseases

Ethanol-fixed

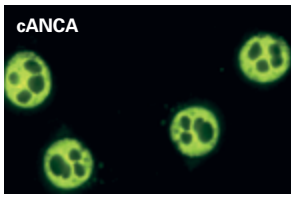


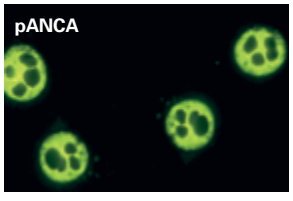



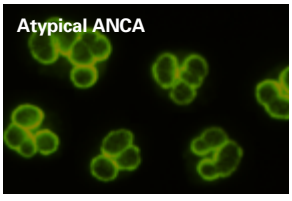



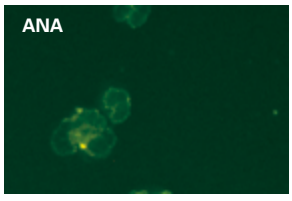



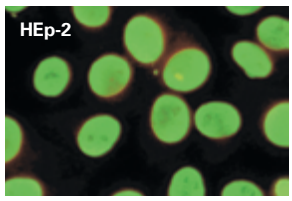

Formalin-fixed



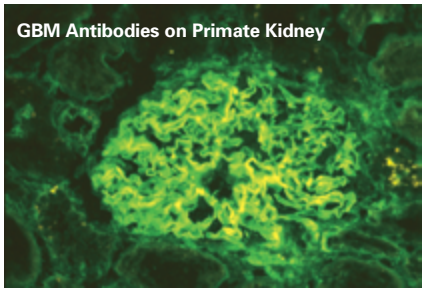



# Collagen Vascular

## 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.

| 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 |

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**For research use only in the US.*
*‡Contains ImmuGlo™ anti-human IgG FITC primate adsorbed conjugate.*
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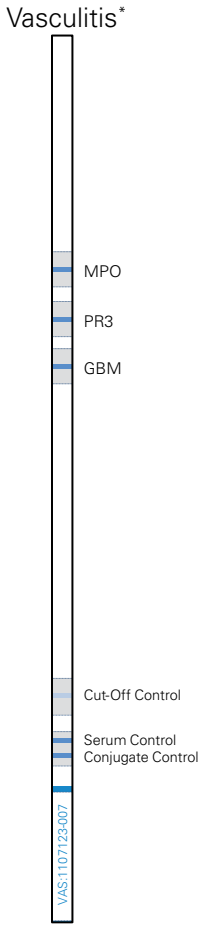


## Antigen Enhancing Buffer

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

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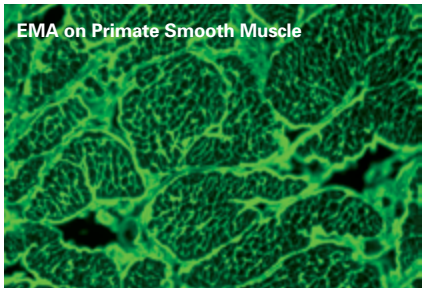
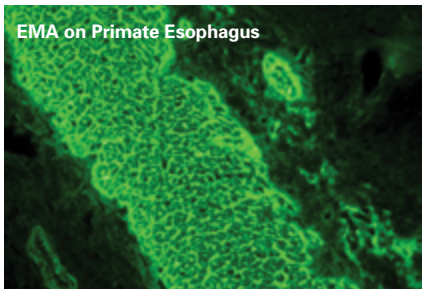
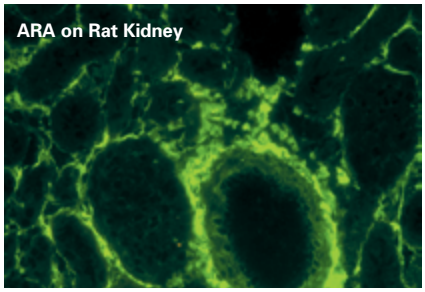

EMA on Primate Smooth Muscle


EMA on Primate Esophagus


ARA on Rat Kidney

# 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.

| Code | Description | Determinations |
|---|---|---|
| **ImmuLisa™ ELISA** | | |
| 5144A† | Enhanced Celiac tTG IgA ELISA | 96 |
| 5144G† | Enhanced Celiac tTG IgG ELISA | 96 |

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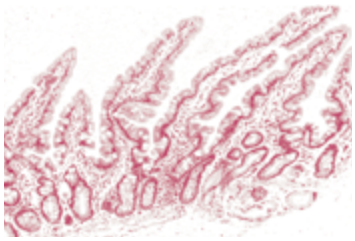
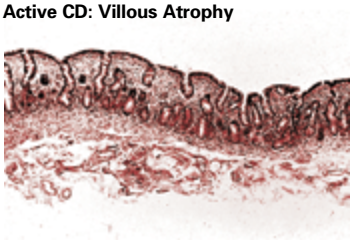
**For research use only in the US.*
*†Manufactured by Immco Diagnostics; distributed in Europe by A. Menarini Diagnostics S.r.l. Patent on file.*

**Normal: Healthy Villi**



**Active CD: Villous Atrophy**



## 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*

| 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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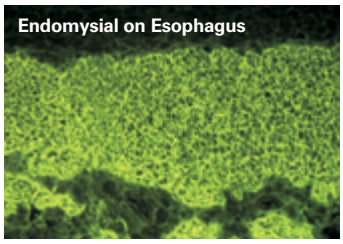
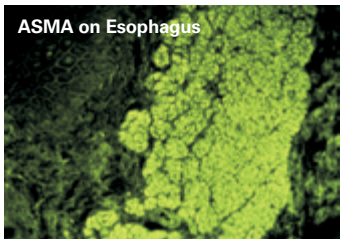
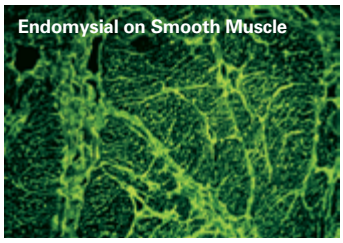
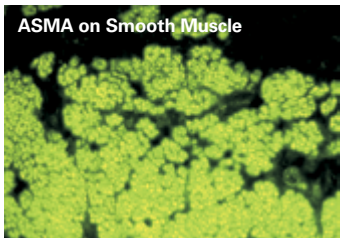
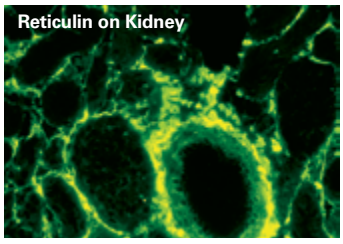
**Gluten Sensitive Enteropathy**

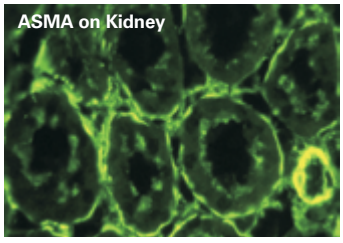




1. *Savilahti E et al. Lancet 1973; I:320-322.*
2. *Kumar V et al. J Pediatr Gastroenterol Nutr 1986; 5:730-734.*
3. *Montgomery AMP et al. Gut 1988; 29:1564-1568.*
4. *Weiss JB et al. J Clin Invest 1983; 72:96-101.*
5. *Mearin ML et al. J Pediatr Gastroenterol Nutr 1984: 3:373-377.*
6. *Levenson SD et al. Gastroenterology 1985; 89:1-5.*
7. *Lerner A et al. J Pediatr Gastroenterol Nutr 1991; 12:407-409.*
8. *Lebenthal E et al. J Pediatr 1983; 102:711-712.*
9. *Kumar V et al. J Pediatr Gastroenterol Nutr 1984; 3:815.*
10. *Tucker NT et al. J Pediatr 1988; 113:286-289.*
11. *Unsworth DJ et al. Clin Exp Immunol 1981; 46:286-293.*
12. *Bürgin-Wolff A et al. J Pediatr 1983; 102:655-660.*
13. *Kelly J et al. Arch Dis Child 1987; 62:469-473.*

# 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 |

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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 inhomogenous staining of the perinuclear area with fluorescent dots in the nuclei, has been reported to occur in patients with IBD and primary sclerosing cholangitis (PSC).

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

| 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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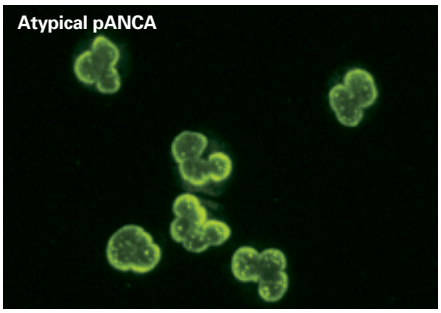
**Various ANCA Staining Patterns**

| | PMN Cells | |
|---|---|---|
| **Pattern** | **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) |




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 primarilyin 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.

| 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 |

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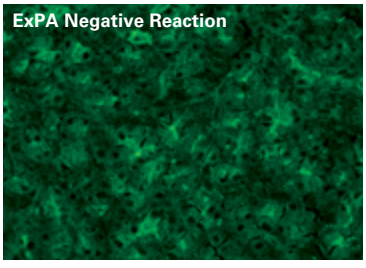
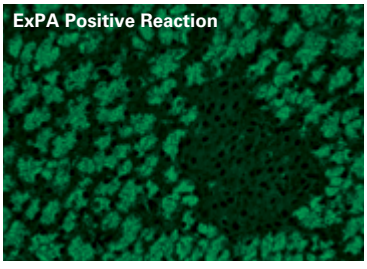
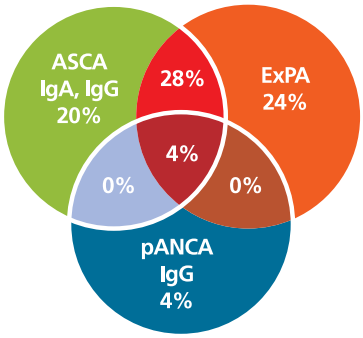



### ExPA as a Diagnostic Tool for Crohn's Disease

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**



## Pernicious Anemia and Autoimmune Gastritis

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

### Intrinsic Factor

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

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

Both types I and II result in the same pathological effect, prevention of cobalamine 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.

| 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 |

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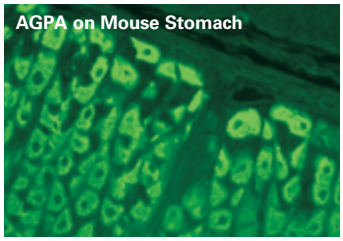
### Advantages of ImmuLisa™ Intrinsic Factor antibody

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

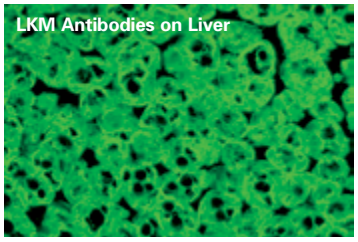


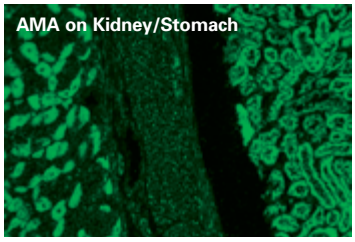
# Liver Diseases

## 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

| Code | Description | Determinations |
|---|---|---|
| **ImmuGlo™ 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 |
| **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 |
| 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 |
| **ImmuGlo™ Controls / Components** | | |
| 2099 | Anti-human IgG FITC primate adsorbed conjugate *Contains Evan's Blue* | 5 ml |
| 2100 | Anti-human IgG FITC conjugate | 5 ml |
| 2200 | Autoantibody negative control | 0.5 ml |
| 2211 | Smooth muscle antibody positive control | 0.5 ml |
| 2212 | Gastric parietal cell antibody positive control | 0.5 ml |
| 2242* | LKM antibody control | 0.5 ml |
| 2302 | Buffered diluent | 60 ml |
| **ImmuLisa™ ELISA** | | |
| 1168* | Liver/Kidney Microsomal (LKM-1) antibody ELISA | 96 |

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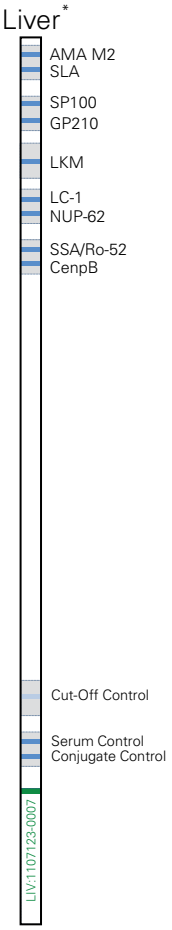
**ImmcoStripe™ LIA**



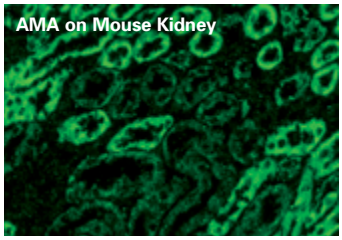
# Liver Diseases

## 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 *Contains Evan's Blue* | 5 ml |
| 2100 | Anti-human IgG FITC conjugate | 5 ml |
| 2200 | Autoantibody negative control | 0.5 ml |
| 2210 | Mitochondrial antibody positive control | 0.5 ml |
| 2210-1* | Mitochondrial antibody low titer positive control | 0.5 ml |
| 2302 | Buffered diluent | 60 ml |
| **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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## 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 *Contains Evan's Blue* | 5 ml |
| 2100 | Anti-human IgG FITC conjugate | 5 ml |
| 2200 | Autoantibody negative control | 0.5 ml |
| 2211 | Smooth muscle antibody positive control | 0.5 ml |
| 2213 | Intercellular (IC) antibody positive control | 0.5 ml |
| 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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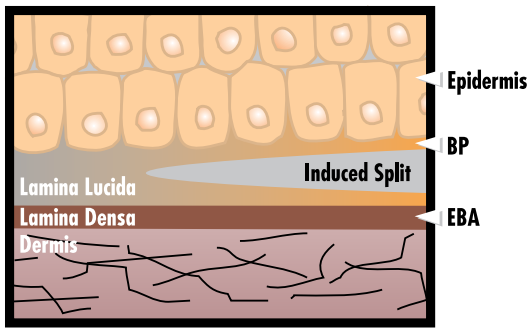
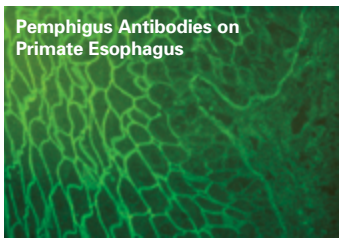
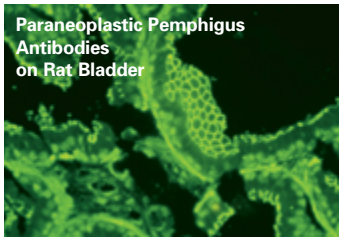
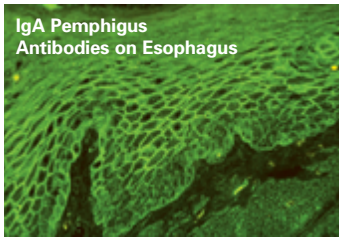
### Diagram of Induced Split

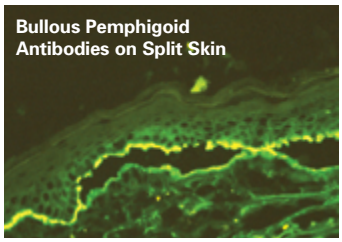


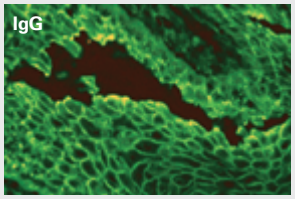


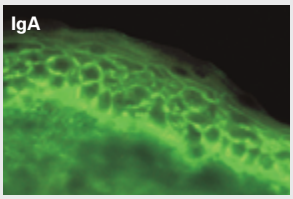


# Vesiculo-Bullous

## Immunological Findings in Vesiculo-Bullous Disorders

### Pemphigus – Direct Immunofluorescence (IFA)



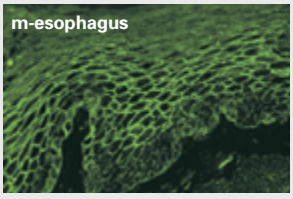



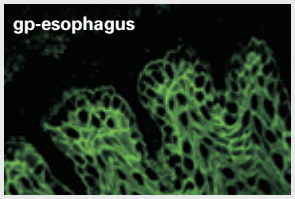

Serological Differentiation of *Pemphigus Vulgaris* from *Pemphigus Foliaceus* Based on Substrate Reactivity

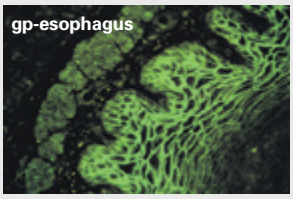
| Higher Titer/ Brighter Staining | P.Vulgaris Sera | | P. Foliaceus Sera | |
|---|---|---|---|---|
| | Number | Percent | Number | Percent |
| Monkey Esophagus | 73 | 97% | 0 | 97% |
| Guinea Pig Esophagus | 0 | 0% | 25 | 0% |
| No Difference | 2 | 3% | 5 | 3% |

### Pemphigus – Indirect Immunofluorescence (IFA)

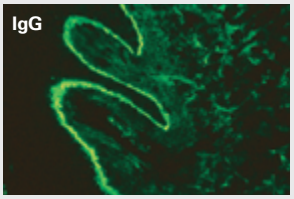
**Pemphigus Vulgaris** | **Pemphigus Foliaceus**

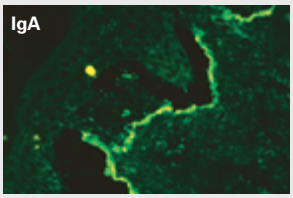




### Pemphigoid – Direct Immunofluorescence (IFA)



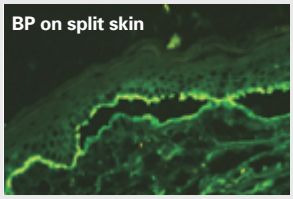

- *Bullous Pemphigoid (BP)*
- *Epidermolysis Bullosa Acquisista (EBA)*
- *Cicatricial Pemphigoid (CP)*
- *Herpes Gestationis (HG)*

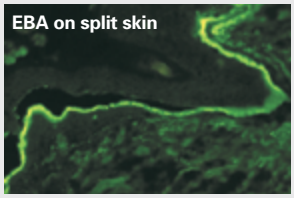
- *Linear IgA Bullous Dermatosis (LABD)*
- *Mucous Membrane Pemphigoid (MMP)*

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

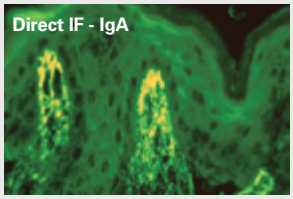
| Clinical Diagnosis | Epidermal Staining | Dermal & Epidermal | Dermal Only |
|---|---|---|---|
| BP | 71% | 17% | 12% |
| EBA | 14% | 0% | 86% |
| Normal | 0% | 0% | 0% |

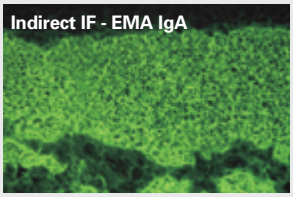
### Pemphigoid – Indirect Immunofluorescence (IFA)


### Dermatitis Herpetiformis (DH)




### Sensitivity, Specificity, and Predictive Values in Markers for DH

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

## Type I Diabetes

### Islet Cell Antibodies (ICAb)

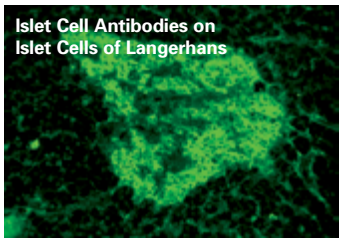
Antibodies to the pancreatic islet cells of Langerhans occur almost exclusively in Type I diabetes and rarely, if ever, in Type II diabetes. The development of islet cell antibodies (ICAb) in insulin dependent Type I diabetes is provoked by an unknown stimulus. Islet cell antibodies may occur years before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

### Incidence of Islet Cell Antibodies

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

| 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<br>*Contains Evan's Blue* | 5 ml |
| 2118X* | Conjugate B | 5 ml |
| 2200 | Autoantibody negative control | 0.5 ml |
| 2233* | Islet cell antibody (ICAb) positive control | 0.5 ml |
| 2313* | ICA Buffered diluent | 60 ml |

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




### 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.

# Endocrine

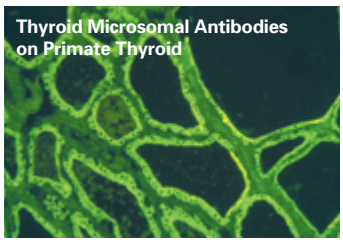
## Thyroid Disorders

### 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 opthalmopathy. 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.

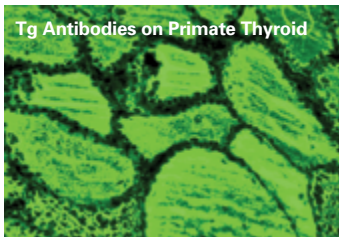
| Code | Description | Determinations |
|---|---|---|
| **ImmuGlo™ Immunofluorescence** | | |
| 1143*‡ | Thyroid antibody | 48 |
| **ImmuGlo™ Slides** | | |
| 2180* | Primate thyroid | 6 well |
| **ImmuGlo™ Controls / Components** | | |
| 2099 | Anti-human IgG FITC primate adsorbed conjugate *Contains Evan's Blue* | 5 ml |
| 2200 | Autoantibody negative control | 0.5 ml |
| 2239* | Thyroid antibody positive control (microsomal) | 0.5 ml |
| 2302 | Buffered diluent | 60 ml |
| **ImmuLisa™ ELISA** | | |
| 5131* | Enhanced Tg antibody ELISA | 96 |
| 5132* | Enhanced TPO 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.*
*‡Contains ImmuGlo™ anti-human IgG FITC primate adsorbed conjugate.*
*All products may not be licensed for sale in Canada, please contact your Canadian distributor for more information.*




### 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





### Significance of Thyroid Antibodies

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

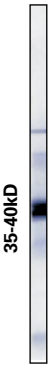
Peripheral neuropathies, autoimmune responses of the peripheral nervous system, are associated with autoantibodies against various neural glycoconjugates. Neuropathies associated with anti-MAG with IgM paraproteinemia are often slowly progressive with evidence of demyelination and a variable degree of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

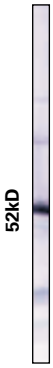
## Paraneoplastic Syndromes

### Neuronal Antibodies

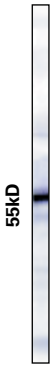
Autoimmune responses of the central nervous system, recognized as paraneoplastic neurologic disorders are manifestations of an antitumor immune response. The following autoantibodies are found in paraneoplastic syndromes:




1. **anti-Hu**, type I anti-neuronal nuclear antibody (ANNA-1), is associated with small cell lung cancer resulting in paraneoplastic encephalomyelitis (PE).




2. **anti-Yo**, anti-purkinje cell antibodies (PCA-1), is associated with ovarian and breast carcinomas resulting in paraneoplastic cerebellar degeneration (PCD).




3. **anti-Ri**, type II anti-neuronal nuclear antibody (ANNA-2), is associated with neuroblastoma (children) and fallopian or breast cancer (adults) resulting in paraneoplasticopsoclonus myoclonus ataxia (POMA).

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.*
**For research use only in the US.*
*‡Contains ImmuGlo™ anti-human IgG FITC primate adsorbed conjugate.*
*All products may not be licensed for sale in Canada, please contact your Canadian distributor for more information.*

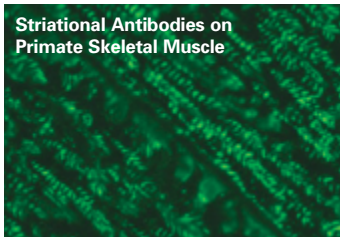
## Myasthenia Gravis (MG)

### 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*
*All products may not be licensed for sale in Canada, please contact your Canadian distributor for more information.*




### 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 therosclerotic plaque. According to the oxidative modification hypothesis, LDL initially accumulates in the subendothelial space of arteries and is mildly oxidized by the resident vascular cells. oxLDL induces production of chemoattractants by monocytes and macrophages causing further oxidation of LDL.

## Heart Antibodies

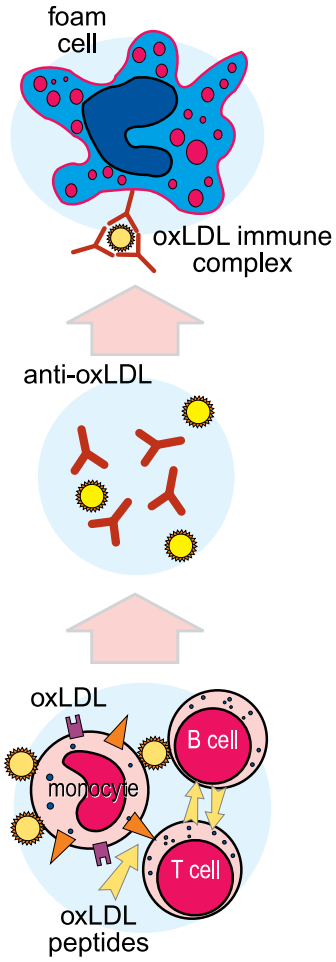
Heart antibodies as detected by IFA have been described in 40% of patients with biopsy proven myocarditis and in 20% of patients with dilated cardiomyopathy. No antibodies have been detected in healthy controls.

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

| 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 |

*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.*

**The role of oxLDL antibodies**

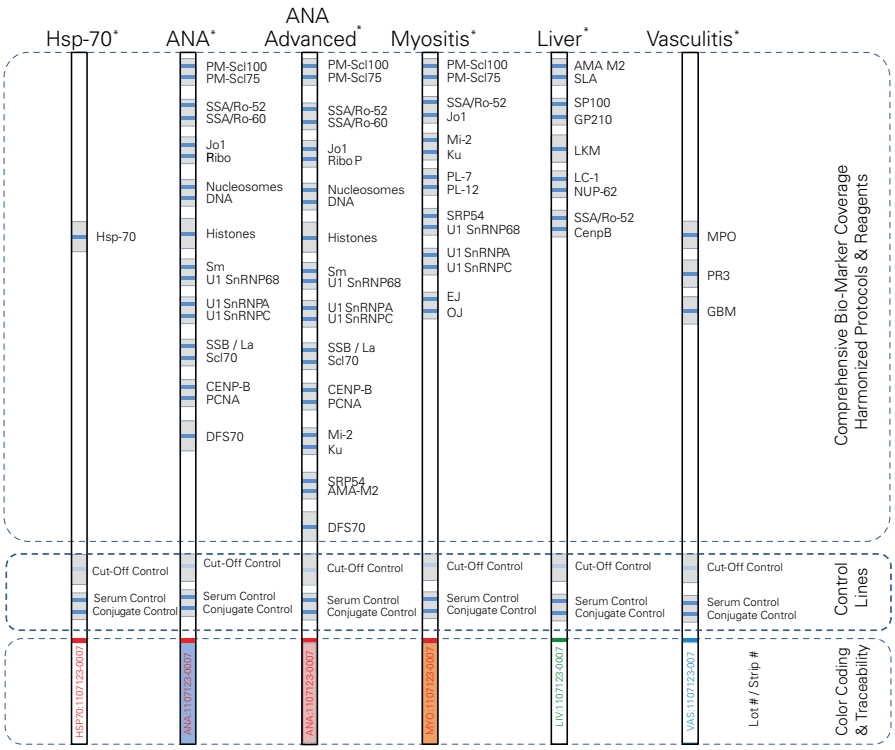



# Featured Products

## 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.




*For Research Use Only in the USA

| 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 |

** For Research Use Only in the US.*
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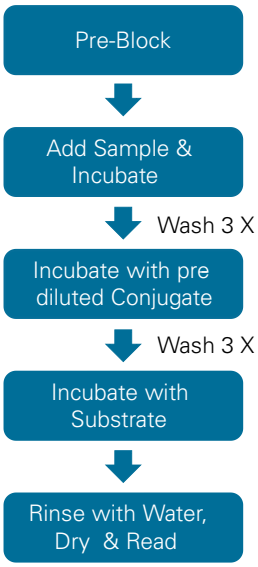
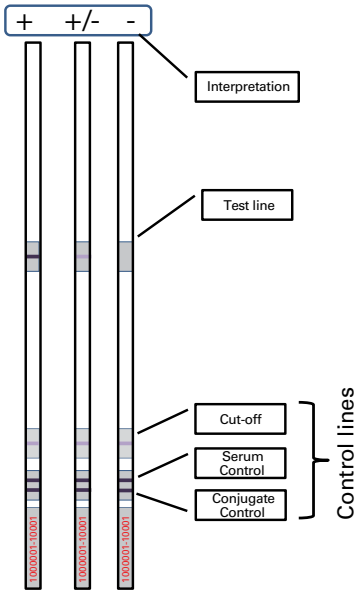
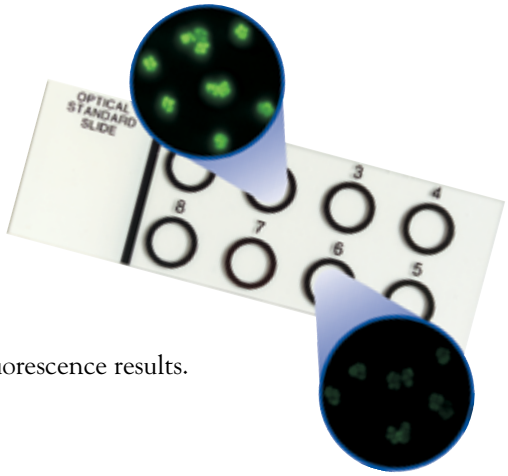
### LIA Test Protocol




### Quality Control/Interpretation



## 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.

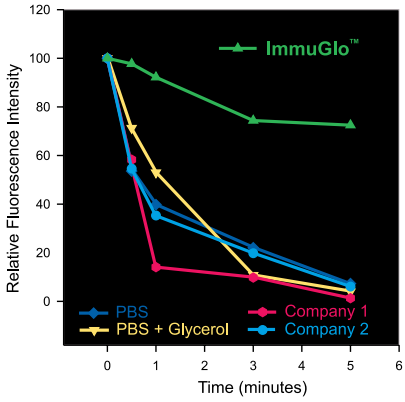
| Code | Description |
|---|---|
| **ImmuGlo™ IFA Component** | |
| 2550OS | Optical Standard Slide |

*All products may not be licensed for sale in Canada, please contact your Canadian distributor for more information.*

## 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**



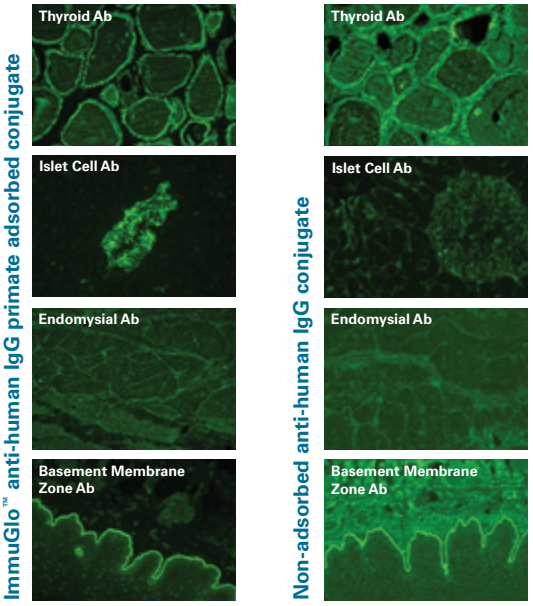

| Code | Description | Volume |
|---|---|---|
| **ImmuGlo™ IFA Component** | | |
| 2505 | Mounting Medium | 5 ml |
| 2506 | Mounting Medium | 60 ml |

*All products may not be licensed for sale in Canada, please contact your Canadian distributor for more information.*

## 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 Epithilium | 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 |
| 2200GBM* | GBM negative control | 0.5 ml | 22, 24-26, 28-29, 33-34 |
| 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 (ICAb) 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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# Product Index

## 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



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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 phosphotase) | 12 ml | — |
| 2514 | TMB Enzyme substrate (HRP) | 12 ml | — |
| 2310 | Stop solution (alkaline phosphotase) | 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 Cardiolipin 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 | Immublot Serum Diluent | 60 ml | — |
| 2314-1 | Immublot 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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