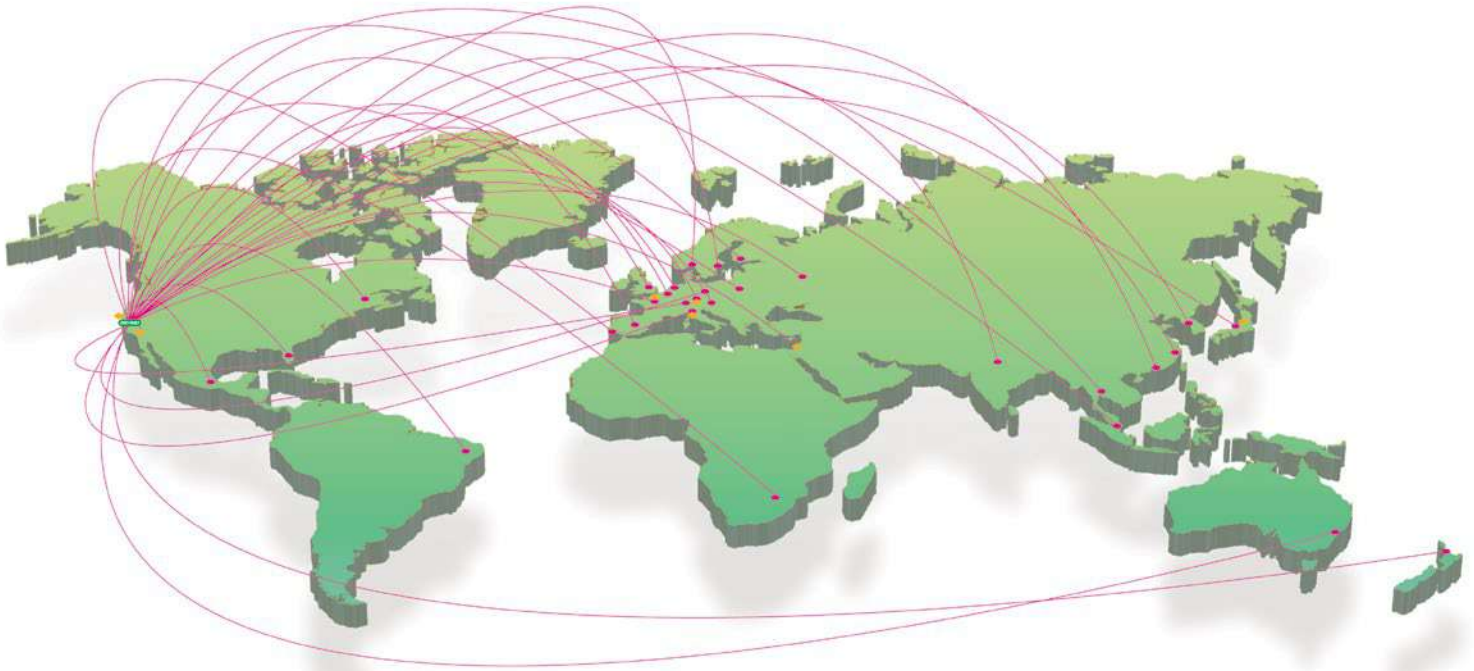
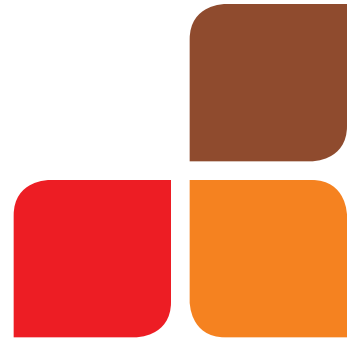


Autoimmune Testing Product Catalog

BIO-RAD

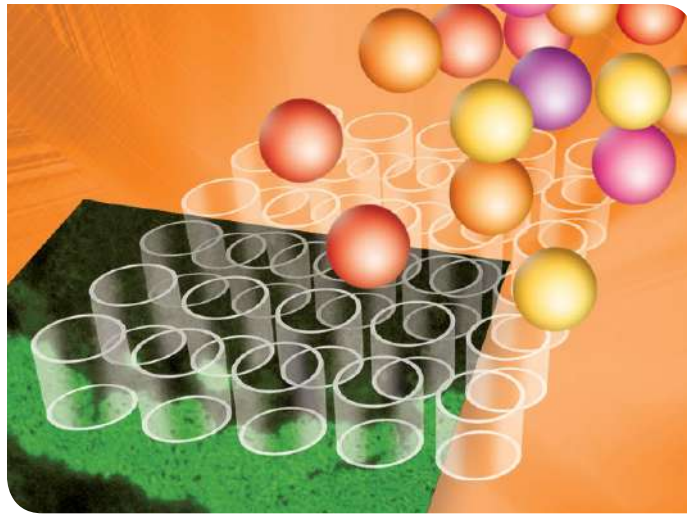


Bio-Rad provides unique solutions to improve patient care and laboratory efficiency.

Bio-Rad has remained at the center of scientific discovery for more than 60 years manufacturing and distributing a broad range of products for the life science research and clinical diagnostic markets. The company is renowned worldwide among hospitals, universities, major research institutions, as well as biotechnology and pharmaceutical companies for its commitment to quality and customer service. Founded in

1952, Bio Rad is headquartered in Hercules, California and serves more than 85,000 research and industry customers worldwide through its global network of operations. The company employs more than 7,000 people globally.

Bio-Rad's Clinical Diagnostics Group develops, manufactures, sells, and supports a large portfolio of products for medical screening and diagnostics. Bio-Rad is one of the top specialty



People/Service

All of our products are backed by Bio-Rad's superior customer support and highly skilled sales consultants. Our staff of field representatives, customer service technicians and technical support personnel are here to assist you when you need it.

Products

Bio-Rad provides you with an extensive product line to meet a wide range of testing needs. Our expertise in the areas of autoimmune, diabetes testing, hemoglobin screening, quality control, virology, infectious disease and toxicology testing enables us to provide customized testing solutions for your everchanging laboratory environment.

Expertise

As a diagnostics partner with a high-performing team of Research and Development, manufacturing and logistics experts, Bio-Rad can help you improve both patient care and economic outcomes through advanced technologies and efficient information management.

diagnostic companies in the world, and is well-known for its quality controls and products for diabetes testing, autoimmune testing, blood virus testing and detection, blood typing, toxicology, genetic disorders testing, special chemistry and molecular pathology. Bio-Rad's clinical diagnostics products incorporate a broad range of technologies used to detect, identify, and quantify

substances in bodily fluids and tissues. Test results are used as aids for medical diagnosis, detection, evaluation, and the monitoring and treatment of diseases and other medical conditions.



Products by Disease State

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Three Technologies,

Autoimmune Multiplex Testing

The BioPlex 2200 System is a fully automated, random access, multiplex testing platform that provides core lab level workflow for laboratories with autoimmune and infectious disease testing needs. The BioPlex 2200 System uses a patented multiplex detection magnetic bead technology in which up to 25 color-coated microspheres can be bound with a unique antigen. Bead sets are then mixed together in a

single reagent pack allowing for simultaneous detection of multiple analytes. The dual-laser, multiplex flow detection method processes a minimum of 150 measurements per analyte at the rate of 100,000 measurements per minute.





One Solution

Autoimmune Immunofluorescence Assays (IFA)

The “Gold Standard” Bio-Rad Kallestad IFA slides provide your laboratory with a wide range of ordering options to meet your testing needs. In addition, our ergonomic well spacing and automation options provide you with opportunities to improve your laboratory’s workflow and efficiency.



Autoimmune Enzyme Immunoassays (EIA)

Autoimmune EIA is an important part of testing algorithms for the diagnosis of an extremely broad range of autoimmune conditions from lupus to rheumatoid arthritis and celiac disease to antiphospholipid syndrome.







Systemic Autoimmune Testing

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Systemic Algorithm

The Bio-Rad solution encompasses three key technologies and a menu of clinically relevant markers to help laboratories identify markers that aid in the diagnosis of systemic autoimmune diseases and help patients recapture a normal lifestyle.¹

Bio-Rad Multiplex Testing Products



Use with: **BioPlex 2200 System**

**BioPlex 2200
ANA Screen with
MDSS* Kit**

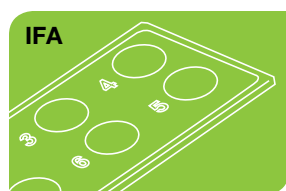
**BioPlex 2200
Anti-CCP Kit**

**ANA
Screen**

**dsDNA
(quant)**

Chromatin

Bio-Rad Systemic Autoimmune Testing Products



IFA processing systems include:
PhD Ix System

Screening

**HEp-2 IFA Kit
30472**

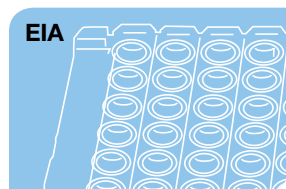
Speckled Pattern

Homogeneous Pattern

Nucleolar Pattern

Centromere Pattern

Cytoplasmic Pattern



EIA processing systems include:
PhD Ix System
EVOLIS System
EVOLIS Twin Plus System†

**ANA Screen EIA Kit
96AN**

**Anti-CCP II EIA Kit
96CP**

Key Legends

■ IFA ■ EIA ■ Multiplex

The algorithms presented here illustrate Bio-Rad's comprehensive product offering for clinically relevant markers. They are not meant for clinical diagnostic purposes.

* For use on the Bio-Rad BioPlex 2200 System. ANA Screen is a composite of all individual results. Please check with your Bio-Rad representative for more details.

^a Individual results available outside the US only.

[†] Available only outside of the US

Ribosomal P Protein SS-A (52 & 60)^a SS-B Sm/RNP RNP (A & 68)^a Scl-70 Jo-1 Centromere B

Identification

EIA Products

Crithidia luciliae Kit
31069

Mouse Stomach Kidney Kit
30443

Rat Liver/Kidney with Medulla/Stomach Slides
29020[†]

ANA Screen
96EP

ANA Profile
12A6[†]

Anti-SS-A 96SA

Anti-SS-B 96SB

Anti-Sm 96SM

Anti-SmRNP 96SR

Anti-Jo-1 96JO

Anti-Scl-70 96SC

Anti-dsDNA Kit
96DS (1-point calibrator)
31008 (qualitative/quantitative)

Anti-Centromere Kit
96CE

Anti-Mitochondrial Kit
31021

The BioPlex 2200 ANA Screen with MDSS reports results for the following:

- ANA Screen*
- dsDNA (quant)
- Chromatin
- Ribosomal P
- SS-A (52 and 60)**
- SS-B
- Sm
- Sm/RNP
- RNP (A and 68)**
- Scl-70
- Jo-1
- Centromere B



BioPlex 2200 ANA Screen Reagent Pack

BioPlex 2200 ANA Screen with MDSS*

The BioPlex 2200 ANA Screen with MDSS* is intended for the qualitative screening of specific antinuclear antibodies (ANA), the quantitative detection of antibody to dsDNA, and the semi-quantitative detection of twelve (12) separate antibody assays (Chromatin, Ribosomal P, SS-A (52kD), SS-A (60kD), SS-B, Sm, Sm/RNP, RNP (A), RNP (68), Scl-70, Jo-1, and Centromere B) in human serum and/or EDTA or heparinized plasma. The test system is used as an aid in the diagnosis of Systemic Autoimmune Diseases.

The ANA Screen detects the presence of clinically relevant circulating autoantibodies which may be useful as an aid in the diagnosis of systemic autoimmune diseases such as systemic lupus erythematosus (SLE), mixed connective tissue disease (MCTD), undifferentiated connective tissue disease (UCTD), Sjögren's syndrome (SS), scleroderma (systemic sclerosis), dermatomyositis, polymyositis, CREST syndrome, and Raynaud's phenomenon.

ANA Screen Reagent Pack

Contains all the necessary reagents – sample diluent, beads, conjugate – for the BioPlex 2200 System to automatically process 100 samples and generate up to 14 results per patient sample.

ANA Calibrator Set

The BioPlex 2200 ANA Screen Calibrators are liquid, ready-to-use and multiplexed. For dsDNA, a six point 4 PL fitted curve is used to calculate quantitative results. For other analytes, a point-to-point curve using 4 calibrators is generated to calculate qualitative and/or semi-quantitative results.

ANA Control Set

The BioPlex 2200 ANA Screen Controls are liquid and ready-to-use. The set includes a negative control as well as a multi-analyte positive control containing antibodies for analytes within the ANA Screen Reagent Pack.

* ANA Screen is a composite of all individual results.

** Individual results available outside US only.

Ordering Information

Catalog	Description	
665-1150	BioPlex 2200 ANA Screen Reagent Pack, 100 Samples	1 pack
663-1101	BioPlex 2200 ANA Screen Calibrator Set	1 set
663-1121	BioPlex 2200 ANA Screen Calibrator CD	1 CD
663-1131	BioPlex 2200 ANA Screen Control Set	2 sets
663-1141	BioPlex 2200 ANA Screen Control CD	1 CD

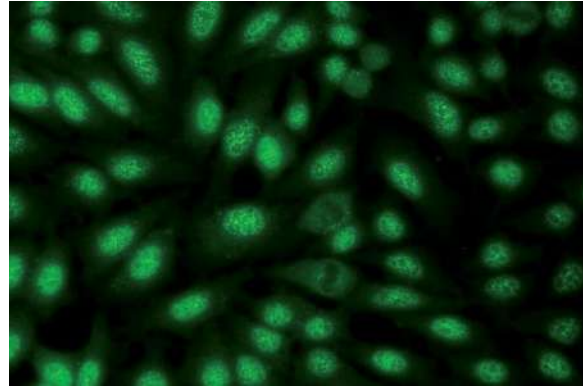
Kallestad HEp-2 Autoimmune IFA

Indirect fluorescent antibody (IFA) testing on HEp-2 cells is commonly used as a screen for the detection and semi-quantitation of autoantibodies to nuclear (ANA) antigens. A positive ANA screen result usually occurs in patients with autoimmune disorders such as systemic lupus erythematosus (SLE), mixed connective tissue disease (MCTD), rheumatoid arthritis (RA), Sjögren's syndrome (SS), and progressive systemic sclerosis (PSS). However, the incidence of low-titer ANA positives increases with age in normal individuals. Therefore, the presence of low-titer antibody should be interpreted within the context of other clinical information.²

Our process for manufacturing HEp-2 slides uses acetone fixation, which results in higher sensitivity for anti-SS-A detection. The formulation of our FITC Conjugate, provided in our HEp-2, *Crithidia* and MSK kits, has the added benefit of significantly reduced background for better differentiation between cytoplasm and nucleus. In addition, our semi-permanent mounting media improves fade resistance enabling easier IFA reading.³

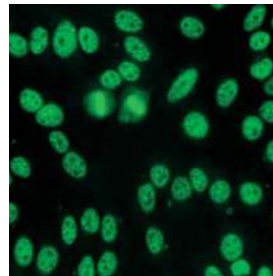
HEp-2 Complete Kits

- Common procedure (HEp-2, MSK and *Crithidia luciliae*)
- FITC conjugate
- Mounting media improves fade resistance
- Wells spaced for use with a multi-channel pipette
- Ready-to-use pattern positive controls
- Flexible ordering options
- Automation available with the PhD Ix System (user validation required)



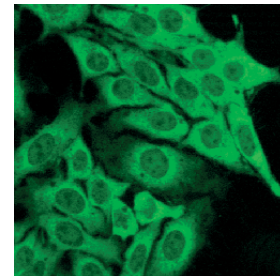
HEp-2 Substrate

Positive fine speckled pattern is indicative of anti-SS-A antibodies commonly associated with systemic autoimmune diseases such as Sjögren's syndrome and SLE.⁴



HEp-2 Substrate

Positive mixed homogeneous/ speckled pattern commonly associated with systemic autoimmune diseases such as SLE and MCTD.⁴



HEp-2 Substrate

Positive anti-ribosomal antibodies; follow-up testing on a tissue substrate or the BioPlex 2200 ANA Screen is recommended for pattern confirmation.⁴

Ordering Information

Catalog	Description	
32583	Kallestad HEp-2 Kit (8 x 6w slides)	48 tests
30471	Kallestad HEp-2 Kit (5 x 12w slides)	60 tests
30472	Kallestad HEp-2 Kit (20 x 12w slides)	240 tests

Ordering Information for Components

Catalog	Description	
26100	Kallestad HEp-2 Slide/6-well	8 slides/PK
26101	Kallestad HEp-2 Slide/6-well	20 slides/PK
26102	Kallestad HEp-2 Slide/12-well	5 slides/PK
26103	Kallestad HEp-2 Slide/12-well	20 slides/PK
26104	Kallestad HEp-2 Slide/12-well	100 slides/PK
26106	Kallestad HEp-2 Slide/24-well	100 slides/PK
30446	FITC Conjugate	2.5 mL
30480	FITC Conjugate	100 mL
30403	Mounting Medium	2.5 mL
31098	Phosphate Buffered Saline (PBS) (1 liter reconstituted)	11.34 grams
31996	HEp-2 Sample Diluent	100 mL
30431	Evans Blue Counterstain	2.5 mL
12000660	Slide Blotters (6-well)	20 blotters/PK
12000661	Slide Blotters (12-well)	20 blotters/PK
12000668	Slide Blotters (24-well)	20 blotters/PK
12000872	Cover Slips (24 x 60 mm)	50 per box
12000664	Cover Slips for 24-well slides	1000 per box
25005	Slide Incubation Chamber	1 unit

All HEp-2 kits include the following components:

- FITC Conjugate
- PBS
- Mounting Media
- Negative Control
- Positive Homogeneous Control
- Evans Blue Counterstain
- Blotters

ANA Controls

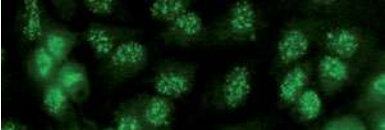
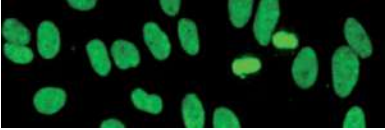
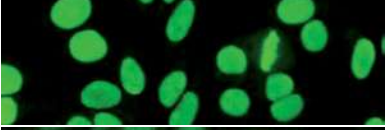
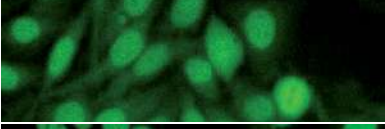
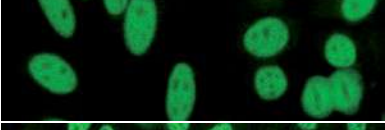
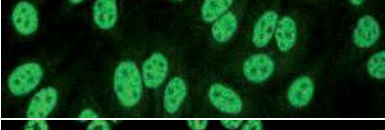
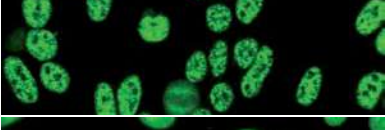
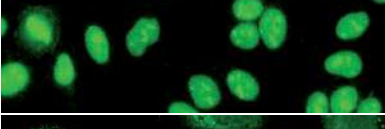
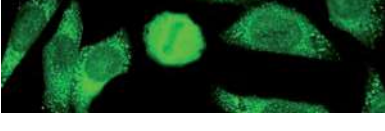
Controls are pre-diluted and ready-to-use. Each control is provided with an endpoint titer. Therefore, the ANA positive controls may be used as either a pattern positive control or to monitor sensitivity of the ANA testing system.

Ordering Information

Catalog	Description	
130	Liquichek Autoimmune Negative Control	3 x 0.5 mL
107	Liquichek ANA Control, Homogeneous Pattern	3 x 0.5 mL
108	Liquichek ANA Control, Speckled Pattern	3 x 0.5 mL
111	Liquichek ANA Control, Nucleolar Pattern	3 x 0.5 mL
112	Liquichek ANA Control, Centromere Pattern	3 x 0.5 mL
113	Liquichek Anti-SS-B Control	2 x 0.5 mL
114	Liquichek Anti-SS-A Control	2 x 0.5 mL
115	Liquichek Anti-Sm Control	2 x 0.5 mL
116	Liquichek Anti-RNP Control	2 x 0.5 mL
117	Liquichek Anti-Scl-70 Control	2 x 0.5 mL
118	Liquichek ANA Control, Mitotic Spindle Pattern	2 x 0.5 mL
119	Liquichek Anti-nDNA Control	3 x 0.5 mL
131	Liquichek ANA Controls Set, Positive (Homogeneous, Speckled, Centromere and Nucleolar Patterns)	Box of 4

HEp-2 IFA Testing Overview

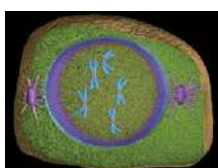
Common HEp-2 IFA Patterns⁵

Pattern	HEp-2 Pattern	Antibody	Disease
	Discrete Speckled	Centromere	CREST
	Homogeneous	dsDNA	SLE
	Homogenous/Strong Chromatin in Mitotic	Histone	SLE (also drug induced)
	Fine Speckled	SS-A/Ro	Sjögren's Syndrome
	Fine Speckled	SS-B/La	Sjögren's Syndrome
	Coarse Speckled	Sm (Smith)	SLE
	Coarse Speckled	RNP	SLE, MCTD
	Speckled Nucleolar	Scl-70	Scleroderma
	Speckled Cytoplasmic	Jo-1	Myositis

Cell Division Process⁶

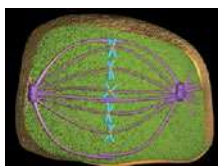
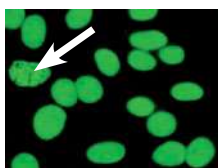
Cell division is a process that enables organisms to grow and reproduce. Through a sequence of steps, replicated genetic material in a parent cell is equally distributed to two daughter cells. While there are subtle differences, mitosis is similar across organisms. Examining the staining patterns of dividing cells is an important part of pattern recognition.

Before a dividing cell enters mitosis, it undergoes a period of growth called interphase. Interphase is the holding stage or stage between two cell divisions. In this stage, a cell replicates its genetic material in preparation for division. Mitosis is comprised of several stages:



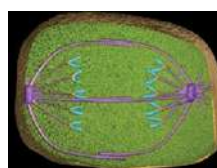
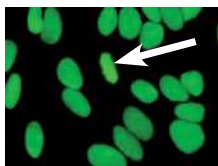
1. Prophase

- In prophase, the chromatin condenses into discrete chromosomes. The nuclear envelope breaks down and spindles form at opposite “poles” of the cell.
- When viewing cells on IFA, prophase cells may appear a little larger than interphase cells. The chromatin condensation may be visible if antibodies that bind chromatin are present.



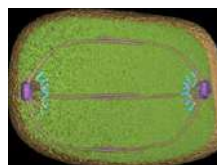
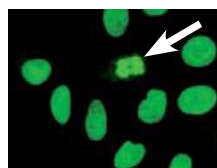
2. Metaphase

- In metaphase, the chromosomes align in the center of the cell, at the metaphase plate (a plane that is equally distant from the two spindle poles). The nuclear membrane disappears in metaphase.
- Cells in metaphase have a distinctive appearance that is easy to recognize.



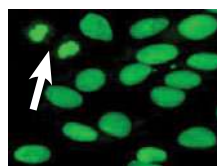
3. Anaphase

- In anaphase, the paired chromosomes separate and move to opposite ends of the cell, towards the “poles” of the cell.



4. Telophase

- In telophase, the chromosomes are cordoned off in distinct new nuclei in the emerging daughter cells. The nuclear membrane begins to form, and the cells begin to separate (cytokinesis). At the end of mitosis, two distinct cells with identical genetic material are produced.
- It may be difficult to distinguish the chromatin staining seen in telophase cells from nuclear staining in cells that have finished dividing (daughter cells). Small daughter cell nuclei often resemble telophase chromatin. Some patterns that do not have staining of the chromatin, have intense staining of daughter cell nuclei. For this reason, it is best to avoid using telophase cells when deciding if the chromatin is positive.



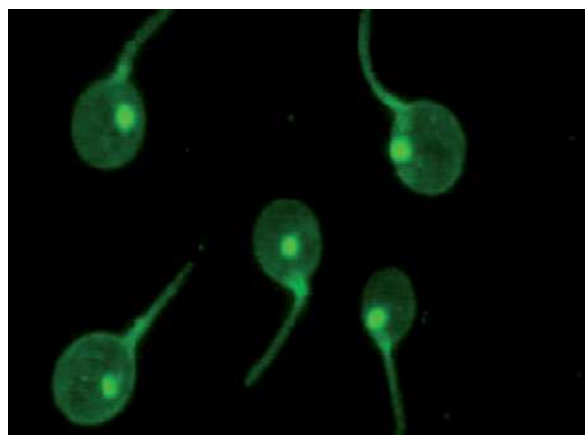
Kallestad *Crithidia luciliae* Autoimmune IFA

Anti-DNA antibodies may be specific to native/double stranded DNA (dsDNA) or denatured/single stranded DNA (ssDNA). Antibodies to dsDNA can be identified by indirect immunofluorescence using *Crithidia luciliae* as the substrate. Anti-dsDNA antibodies are highly specific for systemic lupus erythematosus (SLE). In contrast, anti-ssDNA antibodies are not disease specific. For example, these antibodies are often found in patients with various forms of hepatitis, sclerosis, and rheumatoid arthritis. Thus, distinction between the antibody types is important in the diagnosis of patients with SLE. Antibodies to dsDNA are considered to be diagnostic as well as prognostic markers for SLE. As anti-dsDNA titers in SLE patients may decrease with successful therapy and increase in acute recurrence of the disease, quantitative monitoring of anti-dsDNA antibodies may also be therapeutically important.^{7,8}

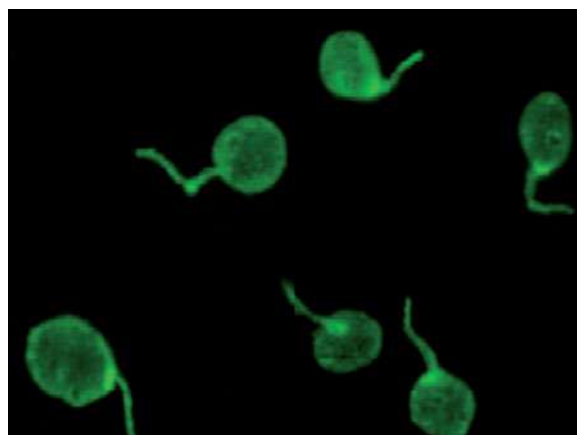
Multiple antibodies, including anti-histone, dsDNA and chromatin, may result in a positive ANA screen. Thus, confirmatory testing for the presence of anti-dsDNA antibodies is required for the diagnosis of SLE. IFA slides using *Crithidia luciliae* provide a substrate for such testing. These non-pathogenic hemoflagellates contain a giant mitochondria, the kinetoplast, which contains a large amount of dsDNA.^{7,8}

Crithidia luciliae Complete Kits

- Larger kinetoplast for easier interpretation
- Common procedure (HEp-2, MSK and *Crithidia luciliae*)
- FITC conjugate
- Mounting media improves fade resistance
- Wells spaced for use with a multi-channel pipette
- Pre-diluted, ready-to-use controls
- Flexible ordering options
- Automation available with the PhD Ix System (user validation required)



***Crithidia luciliae*: Positive for anti-dsDNA⁹**



***Crithidia luciliae*: Negative for anti-dsDNA⁹**

Ordering Information

Catalog	Description	
30404	Kallestad <i>Crithidia luciliae</i> Kit (6 x 4w slides)	24 tests
31069	Kallestad <i>Crithidia luciliae</i> Kit (6 x 8w slides)	48 tests

Components

26107	Kallestad <i>Crithidia luciliae</i> Slide/4-well	6 slides/PK
26108	Kallestad <i>Crithidia luciliae</i> Slide/4-well	20 slides/PK
26109	Kallestad <i>Crithidia luciliae</i> Slide/8-well	6 slides/PK
26110	Kallestad <i>Crithidia luciliae</i> Slide/8-well	20 slides/PK
30446	FITC Conjugate	2.5 mL
30480	FITC Conjugate	100 mL
30403	Mounting Medium	2.5 mL
31098	Phosphate Buffered Saline (PBS) (1liter reconstituted)	11.34 grams
30431	Evans Blue Counterstain	2.5 mL
12000666	Slide Blotters (4-well)	20 blotters/PK
12000667	Slide Blotters (8-well)	20 blotters/PK
12000872	Cover Slips (24 x 60 mm)	50 per box
25005	Slide Incubation Chamber	1 unit

Anti-dsDNA Controls

Ordering Information

Catalog	Description	
130	Liquichek Autoimmune Negative control	3 x 0.5mL
119	Liquichek Anti-nDNA control	3 x 0.5mL

All *Crithidia luciliae* kits include the following components:

- FITC Conjugate
- PBS
- Mounting Media
- Negative Control
- Positive Anti-dsDNA Control
- Evans Blue Counterstain
- Blotters

ANA Screening Autoimmune EIA

ANA and ENA Assays

The ANA test can be used to rule out the diagnosis of various systemic rheumatic diseases such as systemic lupus erythematosus (SLE or Lupus), Sjögren's syndrome, mixed connective tissue disease, progressive systemic sclerosis, scleroderma, polymyositis/dermatomyositis and Raynaud's phenomenon in patients who are negative for the presence of antinuclear antibodies. ENA Plus Screening Test can also be used in conjunction with individual antibody assays to identify specific autoantibodies.¹⁰



ANA Screen Kit

Ordering Information

Catalog	Description	
96AN	ANA Screening Test	96 tests
576AN	ANA Screening Test	576 tests
96EP	ENA Plus Screening Test (six antigens per well)	96 tests
12A6*	ANA 6 profile (96-wells)	12 tests

* Available only outside of the US.

Individual Autoantibody EIA Profiling

Ordering Information

Catalog	Description	
96DS	Anti-dsDNA (1 point calibrator) (Standardized against the WHO Reference Preparation Wo/80)	96 tests
96SS	Anti-ssDNA	96 tests
96SA	Anti-SS-A	96 tests
96SB	Anti-SS-B	96 tests
96SM	Anti-Sm	96 tests
96SR	Anti-Sm/RNP	96 tests
96JO	Anti-Jo-1	96 tests
96SC	Anti-Scl-70	96 tests
96CE	Anti-Centromere	96 tests
31008	Kallestad Anti-dsDNA (qualitative/quantitative) (Standardized against the WHO Reference Preparation Wo/80)	96 tests

Autoimmune EIA Accessory Components

Ordering Information

Catalog	Description	
230AW	Wash Concentrate, 16.7X (For 96AN, 576AN, 96EP, 96SA, 96SB, 96SM, 96SR, 96JO, 96SC and 96CE)	60 mL
230AD	Sample Diluent (For 96AN, 576AN, 96EP, 96SA, 96SB, 96SM, 96SR, 96JO, 96SC and 96CE)	30 mL
240DW	DNA Wash Concentrate, 16.7X (For 96DS and 96SS)	30 mL
240DD	DNA Sample Diluent (For 96DS and 96SS)	30 mL

Rheumatoid Arthritis Testing

Rheumatoid arthritis (RA), a chronic inflammatory disorder of the synovial membrane, is one of the most common autoimmune diseases. It affects approximately 1.3 million people in the U.S. with a worldwide prevalence of 0.3-1% of the adult population. The inflammation of the joints in RA causes swelling, pain, stiffness and redness. The surrounding tissues (tendons, ligaments and muscles) are also affected. This chronic inflammation can cause permanent joint destruction and deformity, leading to functional disability. Since RA is a systemic autoimmune disease, the inflammation can also affect other organs in the body. The lung lining can become inflamed (pleuritis) and cause chest pain while breathing deeply or coughing. The tissue surrounding the heart can also become inflamed (pericarditis) and cause chest pain in certain types of movement.^{11,12} Due to the serious ramifications of rheumatoid arthritis, early and accurate diagnosis is key to starting early treatment. RA diagnosis depends on both clinical manifestations and a multitude of laboratory tests, that may include anti-CCP and anti-Keratin (Rat Esophagus) assays.

BioPlex 2200 Anti-CCP Kit

The BioPlex 2200 Anti-CCP kit is a multiplex flow immunoassay intended for the semi-quantitative detection of IgG antibodies to Cyclic Citrullinated Peptide (CCP) in human serum or plasma (EDTA and sodium heparin). Detection of CCP antibodies is used as an aid in the diagnosis of rheumatoid arthritis and should be used in conjunction with other clinical findings and laboratory results.

The new ACR/EULAR 2010 diagnostic criteria for rheumatoid arthritis (RA) now includes anti-CCP as one serological element.

Anti-CCP Reagent Pack

Contains all the necessary reagents - sample diluent, beads, conjugate - for the BioPlex 2200 system to automatically process 100 samples.

Anti-CCP Calibrator Set

The BioPlex 2200 Anti-CCP Calibrators are liquid and ready-to-use. A six point 4 PL fitted curve is used to calculate semi-quantitative results.

Anti-CCP Control Set

The BioPlex 2200 Anti-CCP Controls are liquid and ready-to-use. The set includes a negative control and a positive control containing anti-CCP IgG.

The BioPlex 2200 Anti-CCP reports results for the following:

- Anti-CCP IgG



BioPlex 2200 Anti-CCP Reagent Pack

Ordering Information

Catalog	Description	
665-3250	BioPlex 2200 Anti-CCP Reagent Pack	1 pack
663-3200	BioPlex 2200 Anti-CCP Calibrator Set	1 set
663-3220	BioPlex 2200 Anti-CCP Calibrator CD	1 CD
663-3230	BioPlex 2200 Anti-CCP Control Set	2 sets
663-3240	BioPlex 2200 Anti-CCP Control CD	1 CD

Anti-CCP Autoimmune EIA

The Kallestad Anti-CCP II test kit is an enzyme-linked immunosorbent assay (ELISA) for detection and semi-quantitation of IgG antibodies to Cyclic Citrullinated Peptides (CCP) in human serum or plasma. The results of the assay are to be used as an aid to the diagnosis of rheumatoid arthritis (RA), in conjunction with other laboratory and clinical findings.

Ordering Information

Catalog	Description	
96CP	Anti-CCP II	96 tests

Rat Esophagus Autoimmune IFA

Indirect immunofluorescent antibody testing utilizing the middle third sections of rat esophagus is intended for the detection of anti-keratin antibodies (AKAs) in human serum. AKAs are highly specific for rheumatoid arthritis (RA) and can even precede the onset of joint symptoms.

Ordering Information

Catalog	Description	
29015*	Rat Esophagus (CE) (12 x 4w slides)	48 tests
29038*	Anti-Keratin Control	0.3 mL
29043*	Negative Control	0.3 mL
29063*	Anti-human IgG FITC Conjugate with Evans Blue	3.0 mL

* Available only outside of the US.





Vasculitis Testing

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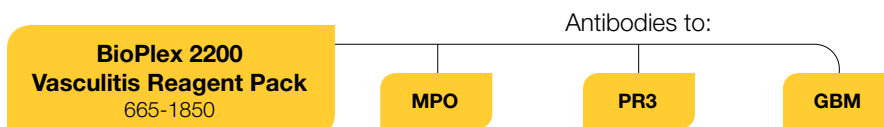
Vasculitis Algorithm

The Bio-Rad solution encompasses three key technologies and a menu of clinically relevant markers to help laboratories and physicians diagnose autoimmune vasculitic diseases, where time and accuracy can save a life.¹³

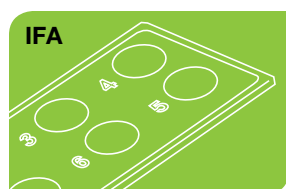
Bio-Rad Multiplex Testing Products



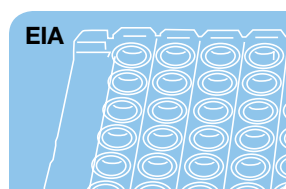
Use with: BioPlex 2200 System



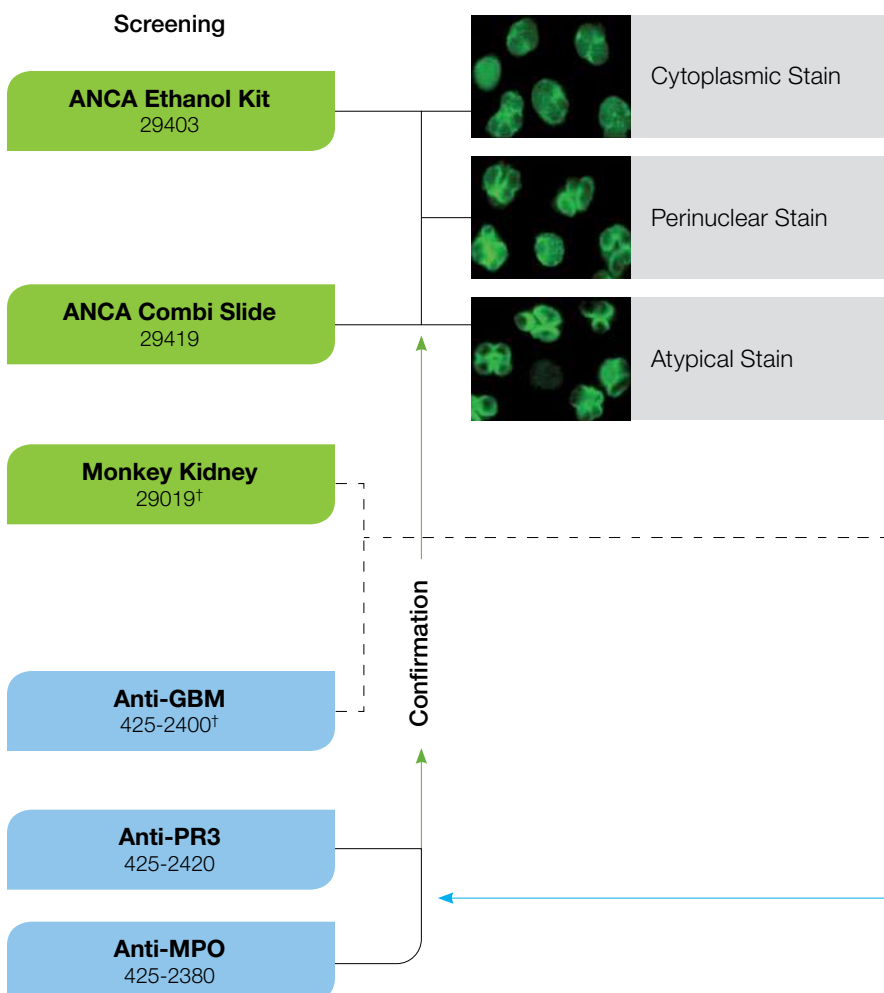
Bio-Rad Vasculitis Autoimmune Testing Products



IFA processing systems include:
PhD Ix System



EIA processing systems include:
PhD Ix System
EVOLIS System
EVOLIS Twin Plus System†

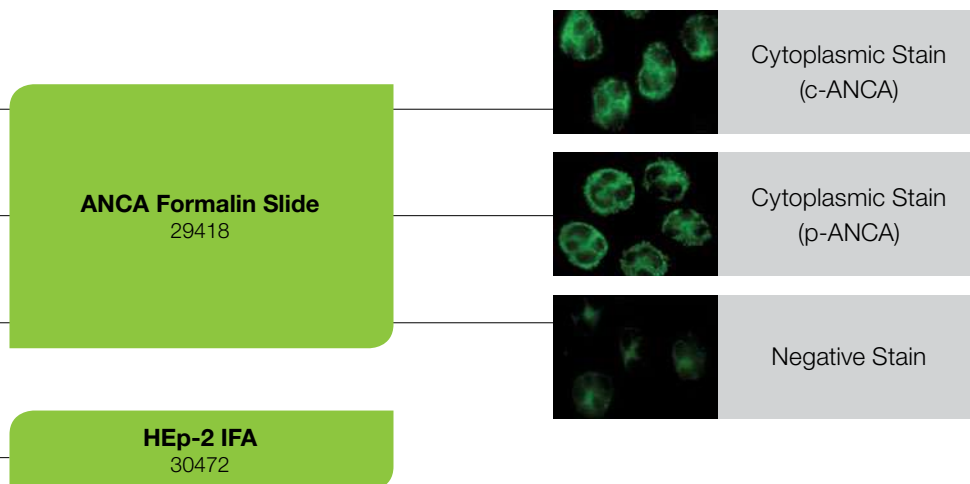


Key Legends

■ IFA ■ EIA ■ Multiplex

The algorithms presented here illustrate Bio-Rad's comprehensive product offering for clinically relevant markers. They are not meant for clinical diagnostic purposes.

† Available only outside of the US

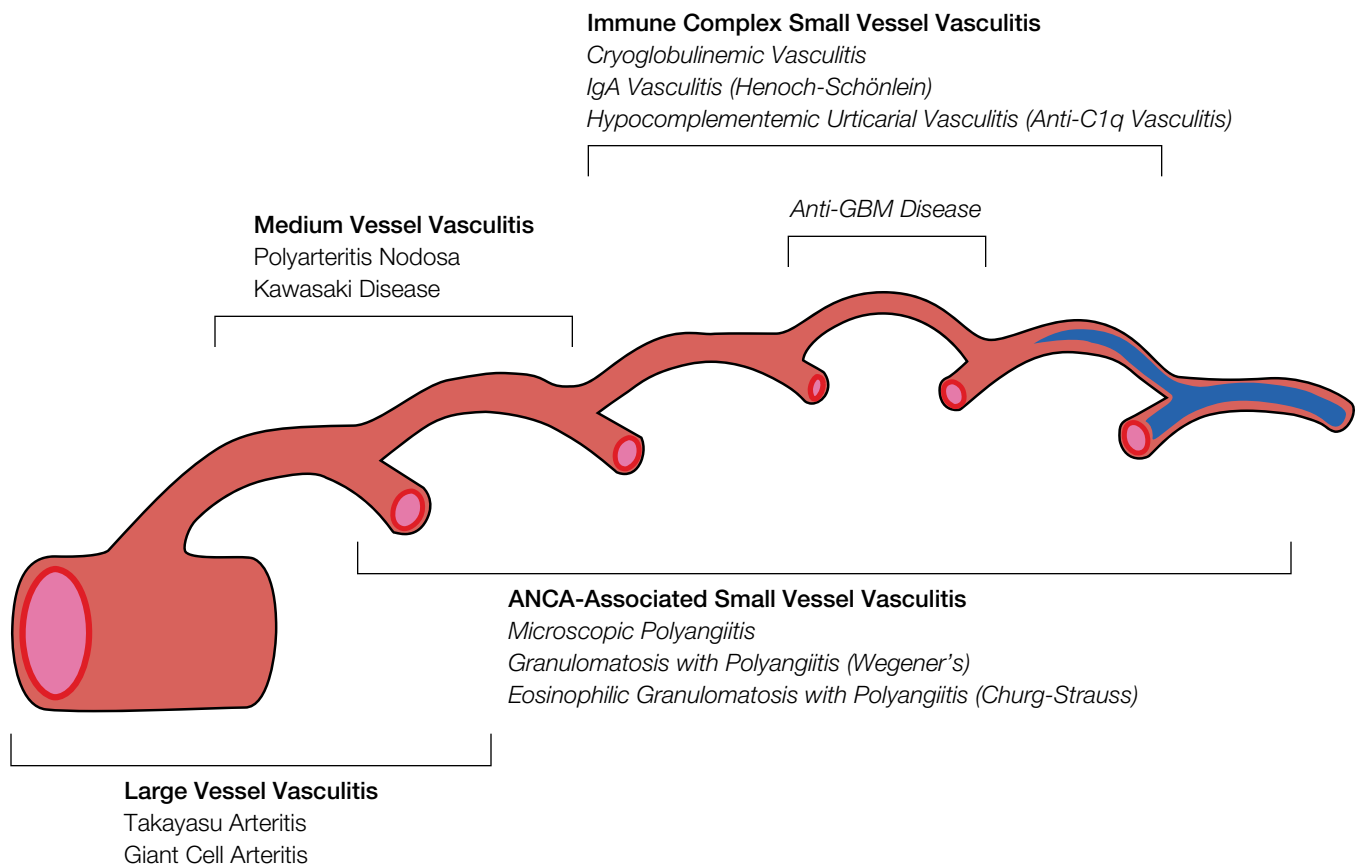


Patients with anti-GBM disease may exhibit clinical features suggestive of certain types of autoimmune vasculitic disorders. Therefore, anti-GBM should be included in a vasculitis panel as part of the serum analysis of patients with suspected renopulmonary syndrome to aid in the differential diagnosis. Anti-GBM antibodies are recognized as being important in the pathogenesis of rapidly progressive glomerulonephritis of anti-GBM disease.

Bio-Rad ANCA Autoimmune

Systemic vasculitides are inflammatory diseases of blood vessels and comprise a heterogeneous group of disorders, the causes of which are generally unknown. The diseases have diverse presentations, and are often rapidly progressive, causing irreversible damage to kidney and lung blood vessels. Systemic small vessel vasculitides are diagnosed and monitored

using a combination of testing technologies and clinical features as recommended in the "International Consensus Statement on Testing and Reporting of Anti-Neutrophil Cytoplasmic Antibodies (ANCA)." Bio-Rad offers a comprehensive line of testing technologies including: IFA, EIA and Multiplex for diagnosing vasculitic diseases.^{13,14}



BioPlex 2200 Vasculitis Panel

The BioPlex 2200 Vasculitis Panel is intended for the semi-quantitative detection of IgG autoantibodies to myeloperoxidase (MPO), proteinase 3 (PR3) and glomerular basement membrane (GBM) in human serum. The BioPlex 2200 Vasculitis kit time to first result is 45 minutes and the instrument can process up to 100 samples per hour.

In conjunction with clinical findings, the test system is used as an aid in the diagnosis of anti-neutrophil cytoplasmic antibodies (ANCA)-associated vasculitides: microscopic polyangiitis (MPA), necrotizing glomerulonephritis, eosinophilic granulomatosis with polyangiitis (Churg-Strauss), granulomatosis with polyangiitis (Wegener's) and the autoimmune renal disorder, anti-GBM disease.

Vasculitis Reagent Pack

Contains all the necessary reagents – sample diluent, bead set, conjugate – for the BioPlex 2200 System to automatically process 100 samples.

Vasculitis Calibrator Set

The BioPlex 2200 Vasculitis Calibrator Set contains four (4) distinct serum based calibrators used in the semi-quantitative measurement of anti-MPO, anti-PR3 and anti-GBM.

Vasculitis Control Set

The BioPlex 2200 Vasculitis Controls are liquid and ready-to-use. The set includes one positive multi-analyte control containing antibodies to MPO, PR3 and GBM and one control negative for all three antibodies.

The BioPlex 2200 Vasculitis Panel reports results for the following:

- MPO
- PR3
- GBM



Ordering Information

Catalog	Description	
665-1850	BioPlex 2200 Vasculitis Reagent Pack, 100 samples	<u>1 pack</u>
663-1800	BioPlex 2200 Vasculitis Calibrator Set	<u>1 set</u>
663-1820	BioPlex 2200 Vasculitis Calibrator CD	<u>1 CD</u>
663-1830	BioPlex 2200 Vasculitis Control Set	<u>2 sets</u>
663-1840	BioPlex 2200 Vasculitis Control CD	<u>1 CD</u>

ANCA IFA Testing

c-ANCA is found primarily in patients with granulomatosis with polyangiitis (Wegener's) and microscopic polyangiitis, whereas p-ANCA occurs in various vasculitic disorders, ulcerative colitis (UC) and primary sclerosing cholangitis (PSC). Eighty percent of p-ANCA positive patients have histologic evidence of vasculitis, UC or PSC. ANCA occurs in more than 90% of patients with active generalized granulomatosis with polyangiitis and in 67% of patients with active limited disease. The incidence of ANCA varies in patients with clinical remission. Therefore, patients with active granulomatosis with polyangiitis may occasionally be ANCA negative.¹³

ANCA Complete Kit

- Ability to test for p-ANCA and c-ANCA on one slide
- Large cells with clear reactivity
- Wells spaced for use with a multi-channel pipette
- Pre-diluted, ready-to-use controls
- Flexible ordering options
- Automation available with the PhD Ix System (user validation required)



ANCA Kit

Ordering Information

Catalog	Description	
29403	ANCA Ethanol Kit (10 x 6w ethanol fixed slides)	60 tests
ANCA Slides and Components		
29419	ANCA Combi Slide (6 + 6w)	5 x 12 wells
29418	ANCA Slide Formalin Fixation	5 x 6 wells
29417	ANCA Slide Ethanol Fixation	5 x 12 wells
29416	ANCA Slide Ethanol Fixation	5 x 6 wells
29411	ANCA IgG FITC Conjugate	5 mL
29407	Sample Diluent	60 mL
29410	Mounting Media	5 mL
29414	ANCA 6-well Blotters	12 per box
29415	ANCA 12-well Blotters	12 per box
29412	ANCA Wash Buffer	1L
29409	ANCA Evans Blue Counterstain	1mL
29413	ANCA Cover Slips	12 per box
ANCA Controls		
29400	c-ANCA Positive Control	0.5 mL
29401	p-ANCA Positive Control	0.5 mL
29408	ANCA Negative Control	0.5 mL

Vasculitis Testing Overview¹⁵

ANCA IFA Slides with Ethanol Fixation

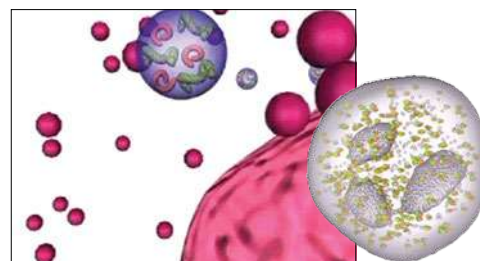
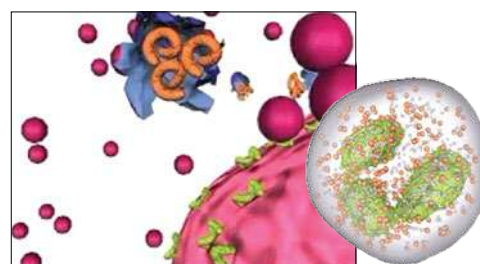
The antigens associated with the c-ANCA pattern, proteinase-3 (PR3), and the p-ANCA pattern, primarily myeloperoxidase (MPO), are located in the azurophilic granules of neutrophils.

As shown, during ethanol fixation, the p-ANCA antigens (in green) migrate from the granules to the surface of the nucleus. Antibodies to these antigens will show a perinuclear staining pattern on IFA.

The c-ANCA antigens (in orange) remain in the granules. Antibodies to c-ANCA produce cytoplasmic staining on IFA.

ANCA IFA Slides with Formalin Fixation

Formalin is a stronger fixative than ethanol. As shown, the ANCA antigens remain associated with the azurophilic granules when the cells are fixed with formalin. Antibodies to both c-ANCA and p-ANCA have cytoplasmic staining on formalin fixed cells.

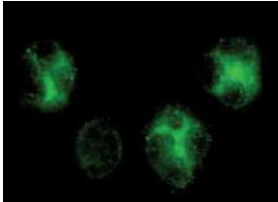


ANCA IFA Patterns¹⁶

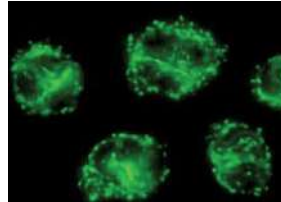
ANCA testing is conducted on both ethanol and formalin fixed slides to differentiate between c-ANCA, p-ANCA and atypical ANCA.

Lymphocytes are present to help distinguish between ANCA and ANA reactions.

c-ANCA

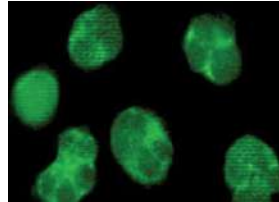


Ethanol:
Cytoplasmic staining;
lymphocytes negative

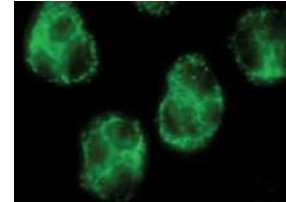


Formalin:
Cytoplasmic staining;
lymphocytes negative

c-ANCA and ANA

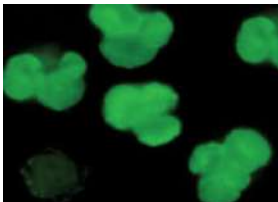


Ethanol:
Cytoplasmic staining;
lymphocytes positive

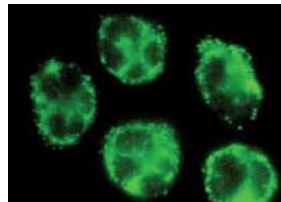


Formalin:
Cytoplasmic staining;
lymphocytes positive

p-ANCA

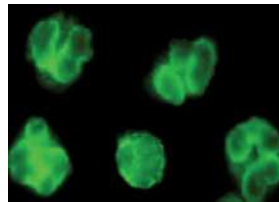


Ethanol:
Nuclear/perinuclear staining;
lymphocytes negative

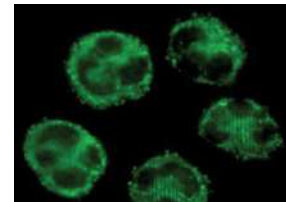


Formalin:
Cytoplasmic staining;
lymphocytes negative

p-ANCA and ANA

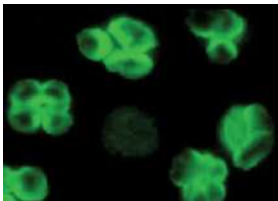


Ethanol:
Nuclear/perinuclear staining;
lymphocytes positive

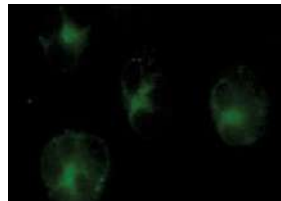


Formalin:
Cytoplasmic staining;
lymphocytes positive

Atypical ANCA

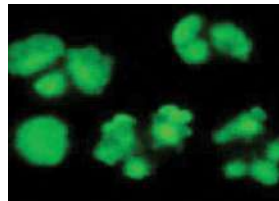


Ethanol:
Perinuclear staining

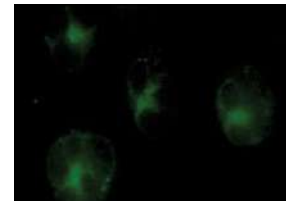


Formalin:
Negative staining

ANA Positive

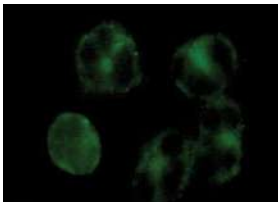


Ethanol:
Nuclear/perinuclear staining;
lymphocytes positive

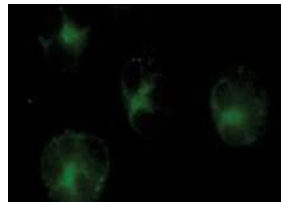


Formalin:
Negative staining;
lymphocytes positive

Negative



Ethanol:
Negative staining



Formalin:
Negative staining

Anti-PR3 and Anti-MPO Autoimmune EIA

The Bio-Rad Anti-Proteinase 3 (anti-PR3, c-ANCA) is a semi-quantitative/qualitative EIA for the detection of autoantibodies specific for proteinase 3 antigen in human serum or plasma. It is intended to aid in the diagnosis of granulomatosis with polyangiitis (Wegener's) and other conditions associated with increased levels of anti-neutrophil cytoplasmic antibodies (ANCA). The Bio-Rad Anti-Myeloperoxidase (anti-MPO, p-ANCA) is a semi-quantitative/qualitative EIA for the detection of autoantibodies specific for myeloperoxidase antigen in human serum or plasma. It is intended to aid in the diagnosis of conditions associated with increased levels of ANCA. Anti-MPO is associated with eosinophilic granulomatosis with polyangiitis (Churg-Strauss), microscopic polyarteritis and necrotising glomerulonephritis.^{17,18}



Anti-PR3 (c-ANCA)

Ordering Information

Catalog	Description	
425-2420	Anti-PR3 (c-ANCA) (qualitative/semi-quantitative)	96 tests
425-2380	Anti-MPO (p-ANCA) (qualitative/semi-quantitative)	96 tests

Vasculitis Antigen Association¹³

Vasculitis	c-ANCA	p-ANCA	Target Antigen
Granulomatosis with Polyangiitis (Wegener's)	X	X*	PR-3
Eosinophilic Granulomatosis with Polyangiitis (Churg-Strauss)	X	X	PR-3, MPO
Microscopic Polyangiitis	X*	X	MPO
Henoch-Schönlein Purpura	X*		
Cryoglobulinemic Vasculitis			
Leucocytoclastic Vasculitis			
Polyarteritis Nodosa	X*	X*	
Kawasaki Arteritis			
Giant Cell Arteritis	X*		
Takayasu Arteritis			

* Occasional.

Anti-GBM Autoimmune IFA

Anti-GBM disease

Renopulmonary syndrome is characterized by pulmonary hemorrhages and rapidly progressive glomerulonephritis. Patients with anti-GBM disease can exhibit clinical features suggestive of certain types of autoimmune vasculitis. Therefore anti-GBM should be included in a vasculitis panel as part of the serum analysis of patients with suspected renopulmonary syndrome to help in the differential diagnostic. Anti-GBM antibodies are recognized as being important in the pathogenesis of rapidly progressive glomerulonephritis of anti-GBM disease.^{19,20}

Ordering Information

Catalog	Description	
29019*	Monkey Kidney (CE)	28 tests

Ordering Information

Catalog	Description	
29047*	Glomerular Basement Membrane Positive Control	0.3 mL
29043*	Negative Control	0.3 mL
29048*	Anti-human IgG FITC Conjugate with Evans Blue (for use with monkey tissue)	3.5 mL

* Available only outside of the US.

Anti-GBM Autoimmune EIA

The Bio-Rad Anti-Glomerular Basement Membrane (GBM) kit is intended to aid in the diagnosis of Anti-GBM mediated diseases, including Anti-GBM disease.

Ordering Information

Catalog	Description	
425-2400*	Anti-GBM Kit (qualitative/semi-quantitative)	96 tests

* Available only outside of the US.



Anti-GBM EIA Kit





Antiphospholipid Syndrome (APS) Testing

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Anti- β 2 Glycoprotein I (anti- β 2GPI) Assays	37
Anti-Phosphatidylserine (aPS) Assays	37

Antiphospholipid Syndrome (APS) Overview

Antiphospholipid syndrome (APS) is a systemic autoimmune disorder characterized by venous or arterial thrombosis and/or pregnancy in which the blood has a tendency to clot quickly. The clotting can affect any vein or artery in the body. The clinical manifestations of APS include thrombosis, headaches, strokes and recurrent pregnancy loss. The tendency to clot is associated with a particular group of antibodies—antibodies against phospholipid and some protein cofactors, hence the name “antiphospholipid syndrome” and “antiphospholipid antibodies.” Diagnosis of APS requires the combination of at least one clinical and one laboratory criterion.

Laboratory Testing for APS

Anti-cardiolipin assays are the most commonly used tests for APS diagnosis. Cardiolipin (phosphatidylglycerol) is an anionic phospholipid. Antibodies against cardiolipin have been detected in primary and secondary APS patients as well as in patients with syphilis and other infections.

β 2 glycoprotein I was identified in 1990 as a protein cofactor for antiphospholipid antibody binding. It is a glycoprotein synthesized by the liver and present in normal patient plasma. Anti- β 2 glycoprotein I assays are commonly used as confirmatory tests for positive anti-cardiolipin tests. Recent studies have shown that in 10% of patients with APS, anti- β 2GPI antibodies are the sole antibodies present, and therefore, the diagnosis of APS is dependent on anti- β 2GPI tests as screening tests, as included in the Sydney APS Criteria.²²

Anti-phosphatidylserine assays may also be used when APS is suspected. Testing for both aPS and aCL increases the sensitivity and specificity of APS diagnosis.²¹

Current Laboratory Criteria for APS²²

The most recent international consensus statement for classification criteria of APS was released in 2006 by Miyakis et al. These criteria are often referred to as the 2006 Sydney Criteria. Laboratory criteria within this consensus statement are as follows:

1. Lupus anticoagulant (LA) present in plasma, on two or more occasions at least 12 weeks apart
2. Anti-cardiolipin (aCL) antibody of IgG and/or IgM isotype in serum or plasma, present in medium or high titer (i.e. >40 GPL or MPL, or > the 99th percentile), on two or more occasions, at least 12 weeks apart
3. Anti- β 2-Glycoprotein-I, antibody of IgG and/or IgM isotype in serum or plasma (in titer > the 99th percentile), present on two or more occasions, at least 12 weeks apart

In the previously released criteria for APS, medium to high titers of aCL IgG and IgM antibodies were included as laboratory criteria for diagnosis. However, due to the lack of standardized reference material for aCL antibody testing, the definition of medium to high titers was unknown. Until international consensus is reached, the Sydney Criteria has defined medium to high titers as >40 GPL or MPL units for existing assays and >99th percentile for new assays on the market. The aCL IgG and IgM assays are still the most commonly ordered assays to aid in APS diagnosis.

The anti- β 2GPI IgG and IgM assays were added when the Sydney Criteria were developed. These assays show higher specificity than aCL assays for APS diagnosis. Again, due to the lack of standardization, a cut-off of 99th percentile of controls was used for these assays.

Given the low disease prevalence of APS, false-positive results have historically represented a more significant clinical burden. The revised criteria reflect the medical consensus that diagnostic tests for APS will provide greater clinical utility if false-positive results could be minimized.

BioPlex 2200 APLS Panel

The BioPlex 2200 APLS Panel reports results for the following:

- Anti-Cardiolipin IgG
- Anti-β2GPI IgG
- Anti-Cardiolipin IgM
- Anti-β2GPI IgM
- Anti-Cardiolipin IgA
- Anti-β2GPI IgA



BioPlex 2200 APLS IgG, IgM and IgA Reagent Packs

The BioPlex 2200 Antiphospholipid Syndrome (APLS) Panel is intended for the semi-quantitative detection of IgG, IgM and IgA antibodies to cardiolipin (aCL) and beta 2 glycoprotein I (β2GPI) in human serum and heparinized or citrated plasma. In conjunction with other clinical findings, these panels are used as an aid in the diagnosis of primary antiphospholipid syndrome (APS) and those secondary to systemic lupus erythematosus (SLE) or SLE-like disorders. The BioPlex 2200 APLS assays utilize the 99th percentile cut-off recommended by the 2006 Sydney Criteria for APS classification.²²

APLS IgG, IgM & IgA Reagent Packs

Each BioPlex 2200 APLS IgG, IgM and IgA reagent pack contains all the necessary reagents (sample diluent, beads and conjugate) to process 100 samples and up to 2 results per sample.

APLS IgG, IgM & IgA Calibrator Sets

The BioPlex 2200 APLS IgG, IgM and IgA Calibrator sets are liquid and ready-to-use. A point-to-point curve fit, using four calibrators (two calibrators for APLS IgA), is used to calculate semi-quantitative results.

APLS IgG, IgM & IgA Control Sets

The BioPlex 2200 APLS IgG, IgM and IgA Control Sets are liquid and ready-to-use. The bi-level set includes a negative control as well as a positive control for each aCL and aβ2GPI analyte within the APLS IgG, IgM and IgA Reagent Packs.

Ordering Information

Catalog	Description	
665-1950	BioPlex 2200 APLS IgG Reagent Pack, 100 samples	1 pack
663-1900	BioPlex 2200 APLS IgG Calibrator Set	1 set
663-1920	BioPlex 2200 APLS IgG Calibrator CD	1 CD
663-1930	BioPlex 2200 APLS IgG Control Set	2 sets
663-1940	BioPlex 2200 APLS IgG Control CD	1 CD
665-2050	BioPlex 2200 APLS IgM Reagent Pack, 100 samples	1 pack
663-2000	BioPlex 2200 APLS IgM Calibrator Set	1 set
663-2020	BioPlex 2200 APLS IgM Calibrator CD	1 CD
663-2030	BioPlex 2200 APLS IgM Control Set	2 sets
663-2040	BioPlex 2200 APLS IgM Control CD	1 CD
665-2150	BioPlex 2200 APLS IgA Reagent Pack, 100 samples	1 pack
663-2100	BioPlex 2200 APLS IgA Calibrator Set	1 set
663-2120	BioPlex 2200 APLS IgA Calibrator CD	1 CD
663-2130	BioPlex 2200 APLS IgA Control Set	2 sets
663-2140	BioPlex 2200 APLS IgA Control CD	1 CD

Antiphospholipid Assays Autoimmune EIA

With nine EIA kits, Bio-Rad offers an extensive assay panel menu for APS diagnosis. Studies have shown that a panel testing approach increases the sensitivity and specificity of APS testing.²¹ In addition to assays for aCL and anti- β 2GPI antibody isotypes, Bio-Rad also offers EIA kits for the detection of anti-phosphatidylserine (aPS) antibodies. Although recognized for some level of association with APS, aPS antibodies are not included in the current laboratory criteria as they were determined to decrease diagnostic specificity.

All Bio-Rad APS EIA assays share the following features:

- Common assay protocol
- Color-coded reagents and reagent bottle caps
- Common reagents
- Breakaway wells
- Automation available
- Linear calibration curve
- Four-point and one-point calibration options



Anti-Cardiolipin EIA Kit

Anti-Cardiolipin (aCL) Assays

Bio-Rad aCL assays are used for the semi-quantitative determination of anti-cardiolipin (aCL) antibodies in human serum or plasma.²³

Ordering Information

Catalog	Description	
425-2000	Anti-Cardiolipin IgG	96 tests
425-2020	Anti-Cardiolipin IgM	96 tests
425-2040	Anti-Cardiolipin IgA	96 tests

Anti-β2 Glycoprotein I (anti-β2GPI) Assays

Bio-Rad anti-β2GPI assays are used for the semi-quantitative determination of anti-β2 Glycoprotein I (anti-β2GPI) antibodies in human serum or citrated plasma.

Ordering Information

Catalog	Description	
425-2060	Anti-β2 Glycoprotein I IgG	96 tests
425-2080	Anti-β2 Glycoprotein I IgM	96 tests
425-2100	Anti-β2 Glycoprotein I IgA	96 tests

Anti-Phosphatidylserine (aPS) Assays

Bio-Rad aPS assays are used for the semi-quantitative determination of anti-Phosphatidylserine (aPS) antibodies in human serum or citrated plasma.

Ordering Information

Catalog	Description	
425-2120	Anti-Phosphatidylserine IgG	96 tests
425-2140	Anti-Phosphatidylserine IgM	96 tests
425-2160	Anti-Phosphatidylserine IgA	96 tests



no
Gluten
allowed





Gastrointestinal (GI) Testing

Gastrointestinal Algorithm	40
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Gastrointestinal Algorithm

The Bio-Rad solution encompasses innovative products using three technologies to help laboratories accurately diagnose autoimmune gastrointestinal diseases early and help patients improve their quality of life.²⁴

Celiac Disease

Screening

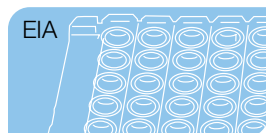
Confirmation



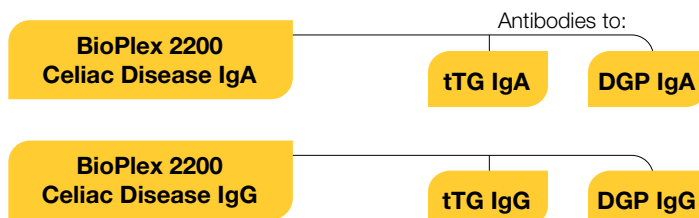
Use with: **BioPlex 2200 System**



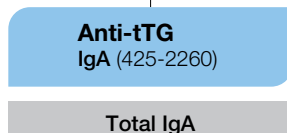
IFA processing systems include:
PhD Ix System



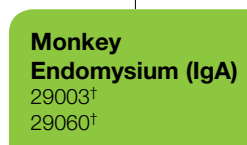
EIA processing systems include:
PhD Ix System
EVOLIS System
EVOLIS Twin Plus System†



Positive



IgA deficiency



Positive

Negative

Negative

and

Normal

Inflammatory Bowel Disease

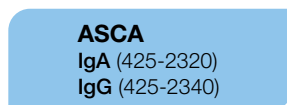
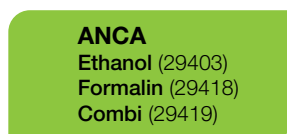
Screening and/or Confirmation



IFA processing systems include:
PhD Ix System



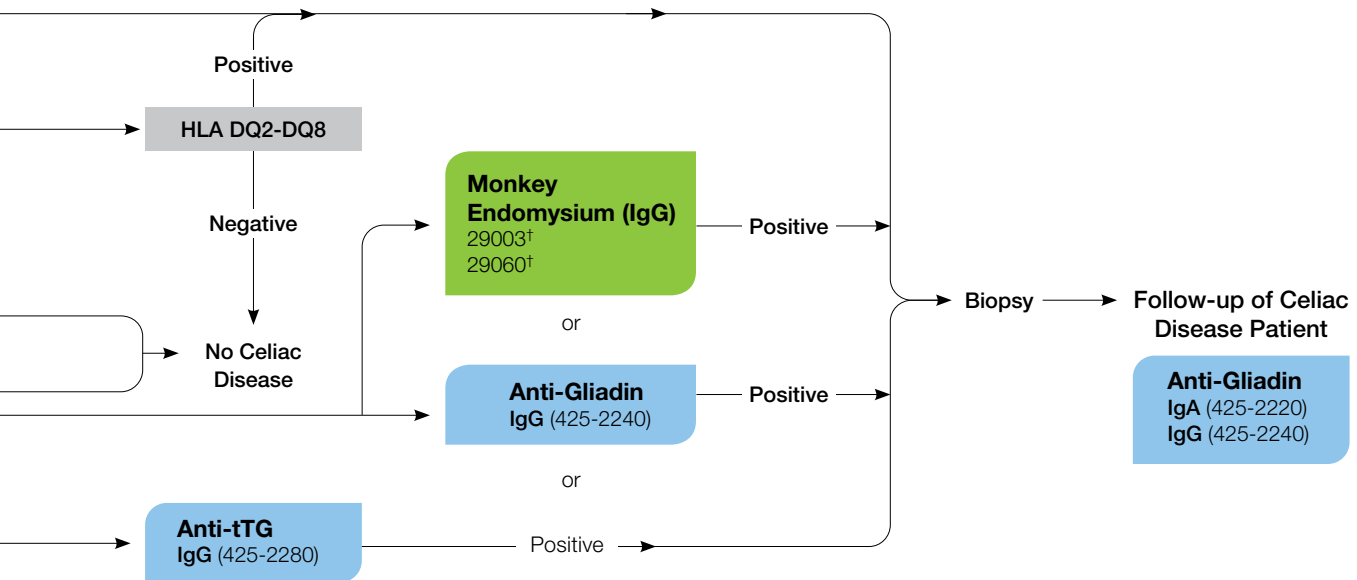
EIA processing systems include:
PhD Ix System
EVOLIS System
EVOLIS Twin Plus System†



Key Legends		
■ IFA	■ EIA	■ Multiplex

The algorithms presented here illustrate Bio-Rad's comprehensive product offering for clinically relevant markers. They are not meant for clinical diagnostic purposes.

† Available only outside of the US



Celiac Disease

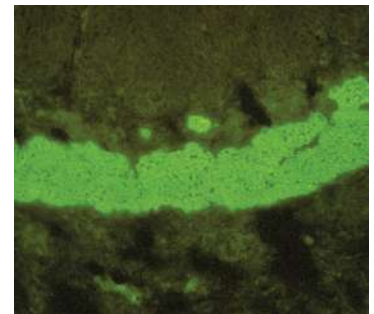
Celiac disease (CD) is one of the most common, lifelong disorders in western countries. It is characterized by immune-mediated damage to the jejunal mucosa of the gastrointestinal tract that is triggered by gliadin, a protein component of gluten. Gluten is found in wheat, rye and barley. Clinical manifestations of celiac disease are highly variable. Gastrointestinal manifestations may include diarrhea, weight loss, failure to grow, vomiting, abdominal pain, bloating and distension. Extraintestinal manifestations are also common. The management of celiac disease is a gluten-free diet for life.

It has been demonstrated that the enzyme, tissue transglutaminase (tTG), is the predominant endomysial autoantigen present in celiac disease. tTG is a calcium dependent ubiquitous enzyme that catalyzes the cross-linking of proteins via the glutamine and lysine residues. In addition, under certain conditions, tTG can also hydrolyse peptide-bound glutamine to glutamic acid. This process is referred to as deamidation. Peptides found within gliadin serve as substrates for tTG. The binding of gliadin to tTG and the subsequent deamidation of gliadin ultimately leads to villous atrophy of the small intestine.^{25,26} The deamidation of gliadin peptides also renders them more immunogenic than unprocessed gliadin peptides, creating a more sensitive and specific target for antibodies to gliadin, which are produced in CD patients.

Serological testing is the first step in pursuing a diagnosis of celiac disease. In the past, patients were first tested for anti-endomysial antibodies (anti-EMA). tTG has now been identified as the target antigen of anti-endomysial antibodies. The development of highly sensitive and specific anti-tTG IgA and IgG assays has led to use of the anti-tTG IgA assay as the initial test for celiac disease. If a patient is suspected of being IgA deficient, the anti-tTG IgG or anti-DGP IgG assays are more sensitive for aiding in the detection of celiac disease in these types of patients. Anti-EMA assays as well as anti-DGP assays are also used by laboratories in routine testing algorithms for the diagnosis of celiac disease.



Celiac disease is a digestive disease. People with celiac disease cannot tolerate gluten, a protein found in wheat, rye and barley.



EMA IgA specific staining of the areas surrounding the sarcolemma of the smooth muscle fibers.³⁵

BioPlex 2200 Celiac Panel

The BioPlex 2200 Celiac Panel is intended for the semi-quantitative detection of IgA and IgG antibodies to tissue transglutaminase (anti-tTG) and deamidated gliadin peptide (anti-DGP) in human serum or plasma.

In conjunction with clinical findings, these tests are used as an aid in the diagnosis of celiac disease.

Celiac Panel Reagent Pack

Contains all the necessary reagents—sample diluent, beads, conjugate—for the BioPlex 2200 System to automatically process 100 samples.

Celiac Panel Calibrator Set

The BioPlex 2200 Celiac Panel Calibrators are liquid and ready-to-use. A 4PL curve is used to calculate semi-quantitative results. The set comes with nine (9) vials – five (5) levels are used for anti-tTG, and five (5) are used for anti-DGP calibration.

Celiac Panel Control Set

The BioPlex 2200 Celiac Panel Controls are liquid and ready-to-use. Three (3) vials come with the set. The negative control can be used with both anti-tTG and anti-DGP IgA and IgG kits. There are separate positive controls for each analyte.

The Celiac IgA kit also includes a novel IgA Verification Bead (AVB) to accurately identify samples with low IgA values. This flag is based on the actual measurement of Total IgA, in contrast to other commercial tests that use an estimation of IgA level using anti-tTG signal. With the AVB, it is no longer necessary to run a Total IgA assay before running celiac disease serological tests for IgA autoantibodies.

Ordering Information

Catalog	Description	
665-2350	BioPlex 2200 Celiac IgA Reagent Pack	1 pack
663-2300	BioPlex 2200 Celiac IgA Calibrator Set	1 set
663-2320	BioPlex 2200 Celiac IgA Calibrator CD	1 CD
663-2330	BioPlex 2200 Celiac IgA Control Set	2 set
663-2340	BioPlex 2200 Celiac IgA Control CD	1 CD
665-2250	BioPlex 2200 Celiac IgG Reagent Pack	1 pack
663-2200	BioPlex 2200 Celiac IgG Calibrator Set	1 set
663-2220	BioPlex 2200 Celiac IgG Calibrator CD	1 CD
663-2230	BioPlex 2200 Celiac IgG Control Set	2 set
663-2240	BioPlex 2200 Celiac IgG Control CD	1 CD

Monkey Endomysium (EMA) Staining Autoimmune IFA

Endomysial antibodies (EMA) react with the reticulin portion of the smooth muscle of monkey esophagus. Detection of these antibodies aids in the diagnosis of celiac disease and dermatitis herpetiformis. EMA staining is considered more specific but less sensitive than anti-tTG assays and tends to be used as a confirmatory test.

Ordering Information

Catalog	Description	
29003*	Monkey Endomysium (CE) (12 x 4 well)	48 tests
29060*	Monkey Endomysium (CE) (12 x 8 well)	96 tests
29033*	Endomysium Antibody Positive Control	0.3 mL
29061*	Anti-human IgA FITC Conjugate with Evans Blue	3.5 mL
29043*	Negative Control	0.3 mL

* Available only outside of the US.

Rat Liver/Kidney with Medulla/Stomach Autoimmune IFA

Anti-reticulin antibodies are also found in patients with celiac disease and can be identified using rat liver/kidney with medulla/stomach IFA slides.

Ordering Information

Catalog	Description	
29021*	Rat Liver/Kidney with Medulla/Stomach (CE) (12 x 4w slides)	48 tests
29020*	Rat Liver/Kidney with Medulla/Stomach (CE) (12 x 8w slides)	96 tests
29041*	Reticulin Positive	0.3 mL
29043*	Negative Control	0.3 mL
29062*	Anti-human Immunoglobulin FITC Conjugate with Evans Blue (for use with rat tissue)	3.5 mL

* Available only outside of the US.

Anti-Tissue Transglutaminase (tTG) Assays Autoimmune EIA

Bio-Rad's anti-tTG EIA kits are coated with a novel antigen: tissue transglutaminase (tTG) cross-linked with deamidated gliadin peptides (DGP). This complex presents a neo-epitope that mimics the physiological epitopes formed in vivo.²⁶ Therefore, Bio-Rad's anti-tTG kits are able to detect the following celiac disease-specific antibodies:

- Antibodies to the neo-epitope formed by tTG-DGP complexes
- Antibodies to natural deamidated gliadin peptides
- Antibodies to tTG

Bio-Rad anti-tTG assays are used for the semi-quantitative and qualitative determination of IgA or IgG antibodies to tissue transglutaminase in human serum.

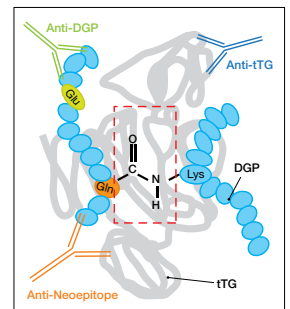


Illustration of tTG-DGP Complex²⁸

Ordering Information

Catalog	Description	
425-2260	Anti-tissue Transglutaminase IgA (quantitative and qualitative)	96 tests
425-2280	Anti-tissue Transglutaminase IgG (quantitative and qualitative)	96 tests

Anti-Gliadin Assays Autoimmune EIA

Gliadin comprises 50% of wheat proteins. It is the most celiac toxic protein. Bio-Rad anti-Gliadin assays are used for the semi-quantitative and qualitative determination of IgA or IgG antibodies to alpha gliadin in human serum.

Ordering Information

Catalog	Description	
425-2220	Anti-Gliadin IgA (quantitative and qualitative)	96 tests
425-2240	Anti-Gliadin IgG (quantitative and qualitative)	96 tests

Inflammatory Bowel Disease

ASCA Assays Autoimmune EIA

ASCA assays aid in diagnosing Crohn's disease, a chronic inflammatory disorder of the gastrointestinal tract. *Saccharomyces cerevisiae* is commonly known as "bakers yeast" or "brewers yeast." A positive anti-*Saccharomyces cerevisiae* antibody (ASCA) test and a negative perinuclear anti-neutrophil cytoplasmic antibody (p-ANCA) test help to differentiate Crohn's disease from ulcerative colitis, the other form of inflammatory bowel disease.²⁹

Bio-Rad ASCA assays are used for the semi-quantitative and qualitative determination of IgA or IgG antibodies to cell wall proteoglycans of *Saccharomyces cerevisiae* in human serum.

Ordering Information

Catalog	Description	
425-2320	ASCA IgA (quantitative and qualitative)	96 tests
425-2340	ASCA IgG (quantitative and qualitative)	96 tests

The following features are common to all Bio-Rad GI EIA assays:

- Common assay protocol
- Color-coded reagents and reagent bottle caps
- Common reagents
- Breakaway wells
- Automation available with the PhD Ix System (user validation required)





Other Organ-Specific Autoimmune Testing

Autoimmune Liver Testing	48
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Autoimmune Liver Disease

Kallestad Rodent Tissues Autoimmune IFA

Bio-Rad offers highly sensitive tissue sections of Mouse Stomach/Kidney (MSK) and Rat Liver/Kidney with Medulla/Stomach to better differentiate organ-specific autoantibodies indicative of liver disease. High titers of anti-mitochondrial antibodies (AMA) strongly support the diagnosis of primary biliary cirrhosis. Low AMA titers may be detected in other liver disorders including chronic active hepatitis and cryptogenic cirrhosis. Liver Kidney Microsomal (LKM) autoantibodies are associated with certain types of hepatitis and cirrhosis.³⁰

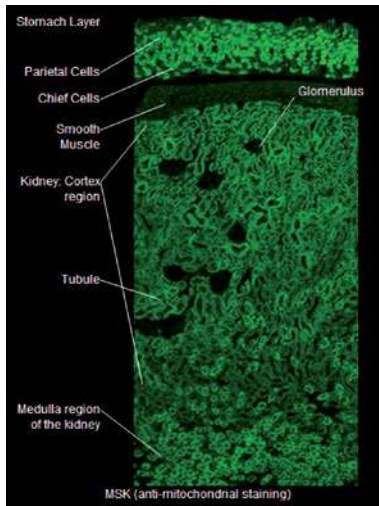
Mouse Complete Kits

Ordering Information		
Catalog	Description	
30443	Kallestad Mouse Stomach/Kidney Kit (6 x 8w slides)	48 tests
Components		
26111	Kallestad Mouse Stomach/Kidney Slide/8-well	6 slides/PK
26115	Kallestad Mouse Stomach/Kidney Slide/8-well	20 slides/PK
26112	Kallestad Mouse Stomach/Kidney Slide/8-well	100 slides/PK
30446	FITC Conjugate	2.5 mL
30480	FITC Conjugate	100 mL
30403	Mounting Medium	2.5 mL
31098	Phosphate Buffered Saline (PBS) (1 liter reconstituted)	11.34 grams
30431	Evans Blue Counterstain	2.5 mL
Accessories		
12000667	Slide Blotters (8-well)	20 blotters/PK
12000872	Cover Slips (24 x 60 mm)	50 per box
25005	Slide Incubation Chamber	1 unit
Tissue Controls		
130	Liquichek Autoimmune Negative Control	3 x 0.5 mL
127	Liquichek Anti-Mitochondrial Control	3 x 0.5 mL
129	Liquichek Anti-Smooth Muscle Control	3 x 0.5 mL

The mouse kit includes the following components:

- PBS
- FITC Conjugate
- Negative Control
- Positive Homogeneous Control
- Evans Blue Counterstain
- Blotters
- Mounting Media

MSK Staining³¹

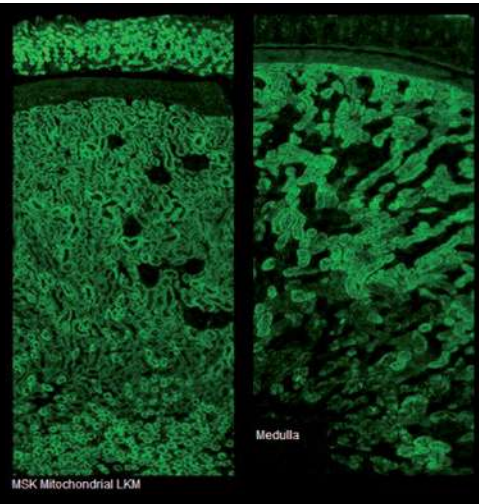


The MSK slide shows the inner stomach layer at the top of the photo. Below the top layer is the outer layer of the stomach, which clearly differentiates the stomach tissue from the kidney tissue.

Stomach Layer:
Mitochondrial antibodies stain the parietal cells. LKM antibodies are negative.





Kidney Layer, Cortex:
Mitochondrial antibodies stain most tubules. Distal tubules may be stronger. LKM antibodies only stain proximal tubules.




Kidney Layer, Medulla:
Mitochondrial antibodies are strongly positive. LKM antibodies are negative.



The MSK slide demonstrates the difference of staining patterns between LKM and mitochondrial antibodies.

MSK Antibody Association³²

	Pattern	Associated Antigens	Clinical Associations
Mitochondrial		Variety of antigens, most associated with pyruvate dehydrogenase complex	Primary biliary cirrhosis, other conditions
Parietal cell		Antigens associated with H ⁺ /K ⁺ ATPase in parietal cells	Pernicious anemia, gastric atrophy, and other conditions
Smooth muscle		Actin	Autoimmune liver disease, and other conditions
Liver-kidney microsomes (LKM)		Antigens on cytochrome P450II	Autoimmune liver disease, drug-induced liver disease

	Pattern	Associated Antigens	Clinical Associations
Ribosomal		Ribosomal antigens including phosphoprotein (ribosomal-P)	SLE
Brush Border		Antigens on the microvilli of proximal tubules	Undefined
Retioulin		Antigens on reticular fibers	Celiac disease, gluten sensitive enteropathy and other conditions

Rat Liver/Kidney with Medulla/Stomach

Rat Tissues and Components

Ordering Information

Catalog	Description	
29020*	Rat Liver/Kidney with Medulla/Stomach (CE) (12 x 8w slides)	96 tests
29021*	Rat Liver/Kidney with Medulla/Stomach (CE) (12 x 4w slides)	48 tests
29051*	Anti-Parietal Cell Antibody Positive Control	0.3 mL
29065*	Homogeneous Positive	0.3 mL
29068*	AMA Positive Control	0.3 mL
29069*	ASMA Positive Control	0.3 mL
29070*	LKM-1 Positive Control	0.3 mL
29043*	Negative Control	0.3 mL
29062*	Anti-human Immunoglobulin FITC Conjugate with Evans Blue (for use with rat tissue)	3.5 mL

* Available only outside of the US.

Kallestad Anti-Mitochondrial Assay Autoimmune EIA

Detection of IgG and IgM autoantibodies against the M2 antigen of the mitochondrial membrane is a useful aid in the diagnosis of primary biliary cirrhosis (PBC), a chronic and often fatal cholestatic autoimmune liver disease primarily affecting young to middle-aged women. The disease is characterized by a slow progressive destruction of intrahepatic bile ducts, portal inflammation and scarring, leading eventually to cirrhosis and liver failure. Diagnosis is based on clinical manifestations, biochemical tests and the detection of circulating anti-mitochondrial antibodies (AMAs).³³

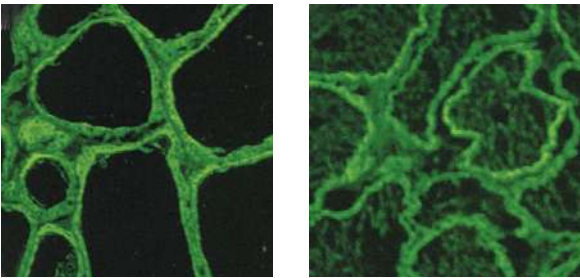
Ordering Information

Catalog	Description	
31021	Kallestad Anti-Mitochondrial (qualitative/quantitative)	96 tests

Thyroid Disease

The detection of anti-thyroid antibodies is important in the diagnosis of thyroid diseases, particularly in patients with subclinical autoimmune thyroiditis. Autoimmune diseases such as Hashimoto's thyroiditis, Grave's disease and primary autoimmune hypothyroidism are characterized by the presence of autoantibodies to thyroglobulin and microsomal antigens. Thyroid autoantibodies may also be found in other non-thyroid disorders including myasthenia gravis, Addison's disease and Sjögren's syndrome.³⁴

Monkey Thyroid Staining



Microsomal Ab *Thyroglobulin Ab*
IFA slides are used to detect autoantibodies to thyroglobulin and thyroid microsomal peroxidase.³⁵

Kallestad Monkey Tissues Autoimmune IFA

Ordering Information		
Catalog	Description	
29012*	Monkey Thyroid (CE) (12 x 4 well)	48 tests
29039*	Microsomal Positive	0.3 mL
29043*	Negative Control	0.3 mL
29048*	Anti-human IgG FITC Conjugate with Evans Blue (for use with monkey tissue)	3.5 mL

* Available only outside of the US.

Kallestad Anti-Thyroid Autoimmune EIA

Ordering Information		
Catalog	Description	
31025	Kallestad Anti-Thyroglobulin (Tg) (qualitative/quantitative) Standardized against the International Ref. Preparation 65/93	96 tests
25087	Kallestad Anti-Thyroid Peroxidase (TPO) (qualitative/quantitative) Standardized against the Ref. Preparation NIBSC 66/387	96 tests

Rare Tissue Autoimmune IFA

Diabetes Assays

Pancreas

The detection of anti-islet cell antibodies (AICA) by immunofluorescence on a pancreas substrate is a conventional method for the determination of AICA for insulin-dependent diabetes mellitus (IDDM – Type 1 Diabetes). The concentration of these antibodies are often highest just prior to the onset of Type 1 diabetes and diminish progressively afterwards.²⁷

Ordering Information

Catalog	Description	
29009*	Monkey Pancreas (CE) (12 x 4 well)	48 tests
29037*	Islet Cell Positive	0.3 mL
29043*	Negative Control	0.3 mL
29048*	Anti-human IgG FITC Conjugate with Evans Blue (for use with monkey tissue)	3.5 mL

* Available only outside of the US.

Pemphigus Assays

Esophagus

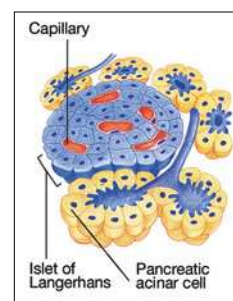
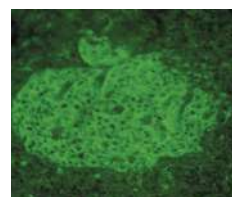
The detection of anti-skin antibodies (ASA) aids in the diagnosis of chronic vesicular-bullous diseases including pemphigus, pemphigoid, etc. Anti-basal membrane antibodies are most commonly found in patients with active bullous pemphigoid, followed by vesicular and cicatricial pemphigoid, respectively. Epithelial antibodies are diagnostic of pemphigus.³⁶

Ordering Information

Catalog	Description	
29004*	Monkey Esophagus (CE) (12 x 4 well)	48 tests
29031*	Basal Membrane Positive	0.3 mL
29036*	Intercellular Positive	0.3 mL
29043*	Negative Control	0.3 mL
29048*	Anti-human IgG FITC Conjugate with Evans Blue (for use with monkey tissue)	3.5 mL

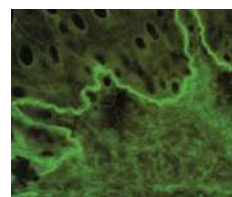
* Available only outside of the US.

Primate Pancreas Staining

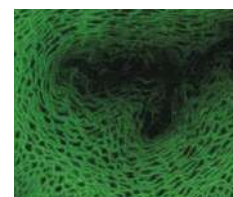


Primate pancreas IFA slides are used to detect islet cell autoantibodies such as those against GAD-65.³⁵

Primate Esophagus Staining



Basal Membrane



Intercellular Substance

Basal membrane and intercellular substance staining patterns are seen when using monkey esophagus slides. Positive basal membrane staining is indicative of autoantibodies against 230kD and 180kD. Positive intercellular substance staining is indicative of autoantibodies against desmoglein 1 and 3.³⁵

Rat Tissues and Accessories***Ordering Information**

Catalog	Description	
29015	Rat Esophagus (CE) (12 x 4 well)	48 tests
29017	Rat Striated Muscle (CE) (12 x 4 well)	48 tests
29062	Anti-human Immunoglobulin FITC Conjugate with Evans Blue (for use with rat tissue)	3.5 mL
29063	Anti-human IgG FITC Conjugate with Evans Blue	3.0 mL
29038	Anti-Keratin Control	0.3 mL
29071	Anti-Striated Muscle Antibody Positive Control	0.3 mL
29044	4-Well Blotters (12 x 4 well)	48 tests

Monkey Tissues and Accessories***Ordering Information**

Catalog	Description	
29022	Monkey Adrenal Slides (CE) (12 x 4 well)	48 tests
29018†	Monkey Heart Slides (12 x 4 well)	48 tests
29019	Monkey Kidney Slides (CE) (12 x 4 well)	48 tests
29047	Glomerular Basal Membrane Positive Control	0.3 mL
29005†	Monkey Hypophysis Slides (12 x 4 well)	48 tests
29010†	Monkey Submaxillary Slides (12 x 4 well)	48 tests
29011†	Monkey Testicle Slides (12 x 4 well)	48 tests
29002†	Monkey Cerebellum Slides (12 x 4 well)	48 tests
29013†	Monkey Sciatic Nerve Slides (12 x 4 well)	48 tests
29048	Anti-human IgG FITC Conjugate with Evans Blue (for use with monkey tissue)	3.5 mL
29044	4-Well Blotters (12 x 4 well)	48 tests
29045	4-Well Blotters (12 x 4 well)	48 tests
29049	8-Well Blotters (12 x 8 well)	48 tests
29043	Negative Control	0.3 mL

Additional Conjugates***Ordering Information**

Catalog	Description	
30240	Anti-Human IgA FITC Conjugate	1 mL
30242	Anti-Human IgG FITC Conjugate	1 mL
30243	Anti-Human IgM FITC Conjugate	1 mL
30244	Anti-Human IgG/IgM/IgA FITC Conjugate	1 mL

* Available only outside of the US.

† For research use only.





Instrumentation

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Autoimmune Systems Overview

Innovative and Efficient Platforms



BioPlex 2200 System

BioPlex 2200 System

Leveraging the power of multiplex testing, the BioPlex 2200 System brings significant workflow improvements to your laboratory. As the only fully automated, random access multiplex testing system, the BioPlex 2200 System dramatically reduces labor and turnaround time for specialty testing while reducing errors through direct LIS connection and lowering total laboratory costs due to vendor and platform consolidation.



PhD Ix System

PhD Ix System

The PhD Ix System's unique versatile design provides laboratories with the ability to efficiently process both IFA and EIA assays. Simply designed, the system easily switches between technologies with minimal components to minimize maintenance requirements and instrument downtime. Additionally, the modular design allows you to control multiple workstations with a single computer, making the PhD Ix System an effective solution for both low-volume and high-volume laboratories.

*EVOLIS System*

EVOLIS System

The EVOLIS is a self-contained, high-throughput microplate processor designed to completely automate microtiter plate-based EIA techniques. The system is dedicated to smooth and safe handling of materials encountered in today's busy laboratories. The EVOLIS is an open system that offers a high degree of flexibility to maximize functionality within your laboratory.

*EVOLIS Twin Plus System*

EVOLIS *Twin Plus* System*

The EVOLIS *Twin Plus* System is a self-contained, high-throughput microplate processor designed to completely automate microtiter plate-based EIA techniques. The ETP is a compact instrument that operates easily on a laboratory benchtop. The system is dedicated to smooth and safe handling of materials encountered in today's busy laboratories such as central hospitals, public health laboratories and reference laboratories. The EVOLIS *Twin Plus* System is an open system that offers a high degree of flexibility to maximize functionality within your laboratory.

* Available only outside of the US.

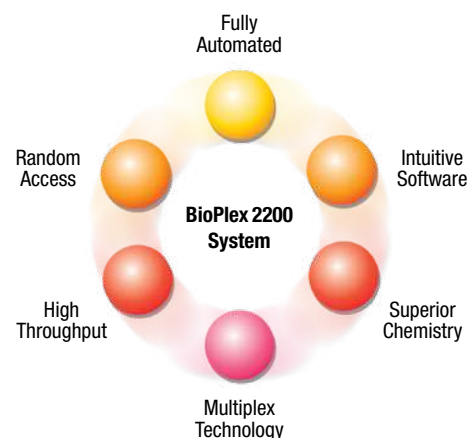


BioPlex 2200 System

A fully automated, random access, multiplex testing platform.

The BioPlex 2200 System combines the diagnostic power of proprietary multiplex chemistry, a state-of-the-art software package, and the benefits of full automation and random access capability. By leveraging the power of multiplex testing, the BioPlex 2200 System brings significant workflow improvements to your laboratory.

The BioPlex 2200 System immunoassays use heterogeneous sets of magnetic 8 μm beads. The beads are infused with varying ratios of fluorescent dyes, creating unique bead sets. Beads within each set are coated with a ligand (i.e., antigen, antibody, analyte, etc.) specific to a particular assay. Bead sets are then mixed together in a single reagent pack allowing for simultaneous detection of multiple analytes from a single sample. The dual-laser, multiplex flow detection method processes individual bead results for each analyte, representing an average of 200 individual assay readings, before giving a final result. The benefit is a high confidence in consistent results and low CVs.



Ordering Information

Catalog	Description	
660-0000	BioPlex 2200 System	1 instrument
660-0800	Sample Racks (30 per box)	1 box
660-0801	Sample Tray	1 tray
660-0817	Instrument Sheath Fluid (2 per box)	1 box
660-0818	Instrument Wash Buffer	1 box
660-2003	Reaction Vessels (1000 per bag)	1 bag
666-0001	Instrument Detector Calibration Pack	1 pack
666-0002	Instrument Detector Clean Pack	1 pack
666-0003	Instrument Probe Cleaning Solution Bottles (4 per box)	1 box

System Specifications

Physical Dimensions

Height	1.3 m (4'-5")
Width	1.3 m (4'-3")
Depth	0.9 m (2'-10")
Weight	Approximately 468 kg (1032 lbs.)

Performance Characteristics

Maximum Throughput	Up to 100 samples per hour (panel dependent)
Time to First Result	As little as 45 minutes (panel dependent)
Sample Tubes	Any CLSI primary sample tube and most secondary, pour over tubes
Sample Racks	10, 5 position BioPlex 2200 racks
Sample Aspiration Volume	As little as 5 uL (panel dependent)
STAT Capability	Continuous access
Operational Mode	Random and continuous access, priority (STAT) loading
Operator Interfaces	Touchscreen monitor, keyboard, trackball mouse and handheld barcode scanner
Sample Types	Assay specific (refer to specific kit instructions for use with serum or plasma samples)
Sample Dilutions	1:4, 1:10, 1:100 (panel dependent)
Walkaway Capability	8 hours of continuous use
Access During Use	Continuous loading and unloading of sample racks, consumables replenishment and disposal of liquid waste without interruption of sample processing
Aspiration Capability	Robotic precision with clot detection
Quality Control	Levey-Jennings, Westgard Rules
Sample Barcode Acceptable Symbolologies	Code 128, Codabar, Code 39, Interleaved 2 of 5
Laser	Class 2 Laser Product
LIS Connectivity	Bi-Directional, Host Query or Broadcast Download; ASTM Standard
Remote Connectivity (Optional)	System support via internet connection
Unity Connection (Optional)	Transmission of quality control results to the Bio-Rad Unity database (additional package offered from Bio-Rad)

IFA Slide and EIA Microplate Processing

Dual Processing for IFA and EIA

PhD Ix System

The PhD Ix System is a reliable, versatile and secure IFA and EIA processing system with an automated pipetting workstation and flexible software capable of programming IFA and EIA worklists and reading and reporting user validated EIA results.

Reliable Performance

The PhD Ix System leverages the same robust hardware design as the PhD System.

Versatile Design

With an adjustable reagent rack to accommodate reagent bottles from most kits, an assay programming wizard, and the ability to network multiple workstations together, PhD Ix is one system to automate the processing of all the laboratory's Autoimmune and Infectious Disease assays.

Secure IFA/EIA Processing

Including audit trails, user passwords and supervisor-level digital signatures, the user can have confidence that robust security features are in place with the PhD Ix System.



PhD Ix System

Ordering Information

Catalog	Description	
426-0400	PhD Ix System IFA and EIA processing system includes workstation with IFA and EIA hardware, microplate reader, barcode scanner and computer	1 system
426-0401	PhD Ix Workstation additional workstation to allow networking of multiple workstations in a single PhD Ix system	1 unit



Hardware

Versatile Reagent Rack

Accepts most bottle sizes—
minimizes pouring off reagents

Cap Valet

Securely organize reagent
caps in an integrated drawer
to prevent cross-contaminate

Well-to-Well Timing

Ensure each EIA sample is treated
identically for consistent quality

Hyperwash

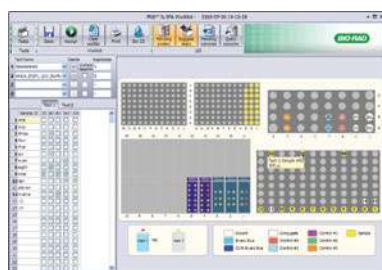
Eliminate background staining
in IFA testing with this efficient
washing mode

Dark Cover

Place the PhD Ix System
anywhere in the lab while
protecting light sensitive reagents

In-Well Dilution

Save time and reagents by
diluting EIA samples directly
in the microplate



Software

The PhD Ix software has evolved with the times to strengthen security.
Not only that, the user interface has a sleek new design with a more
intuitive appearance.

Bi-Directional LIS (Broadcast download or host query)

Save time by importing test
orders directly to a worklist

Network

Multiple workstations multiply
the testing throughput

Customizable Software

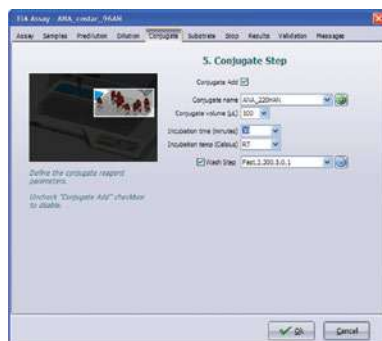
Hide unnecessary buttons
to streamline daily activities

Custom Assays

Create custom assays using the
new assay programming wizard

Up to 8 EIA or 4 IFA Assays Per Run

Get through the day's testing
all at once by loading up each
run with multiple assays



High Volume EIA Testing

EVOLIS System

The EVOLIS System is a self contained microplate processor designed to completely automate microtiter plate-based EIA testing. The system is dedicated to smooth and safe handling of materials encountered in today's busy laboratories, such as central hospitals, public health laboratories and reference laboratories.

The EVOLIS System is a state-of-the-art microplate processor offering an extensive menu of assays with a high degree of analytical performance.

Fully Automated

- Walkaway
- Processes four microplates (U-bottom or flat bottom) at a time, with up to 4 assays per plate
- Comprehensive, multitasking software
- Full bi-directional functionality
- Designed for 30,000 to 100,000 tests per year



*EVOLIS
System*

Ordering Information

Catalog	Description	
89700	EVOLIS System (includes EVOLIS analyzer, PC, monitor and printer)	1 system
97230	EVOLIS Support Table	1 unit
89611	Conductive Tips (300 µL) (samples)	18 x 960
89612	Conductive Tips (1100 µL) (reagents)	10 x 960

Highly Flexible

- Continuous loading of samples (up to 180 primary tubes at a time), reagents and microplates (up to 7 at a time)
- Sample racks for 11-16 mm diameter tubes
- Reagent racks designed to hold various tube sizes
- Dilution capacity (288 samples)
- 4 independent incubators (temperature controlled)
- 4 ambient incubators (light protected)
- 3 different wash buffers
- Network multiple EVOLIS Systems to centralize result management with one uni-/bi-directional connection to the LIS

Highest Level of Safety

- Positive identification of samples, reagents and microplates
- Disposable tips with clot detection for reagents and samples
- Colorimetric verification of sample and reagent additions
- Password protection and complete traceability
- Pre-defined, validated assay protocols
- In-process control, including log documentation



EVOLIS System is a fully automated microplate processor (viewed from above/cover not shown)

Mid Volume EIA Testing

EVOLIS *Twin Plus* System*

EVOLIS *Twin Plus* System is a self-contained microplate processor designed to completely automate microtiter plate-based EIA techniques. The system has a compact design for benchtop use. The system is dedicated to smooth and safe handling of materials encountered in today's busy laboratories, such as central hospitals, public health laboratories and reference laboratories.

EVOLIS *Twin Plus* System is a state-of-the-art microplate processor offering an extensive menu of assays with a high degree of analytical performance.



EVOLIS *Twin Plus* System

Fully Automated

- Walkaway
- Processes three microplates (U-bottom or flat bottom) at a time, with up to 4 assays per plate
- Comprehensive, multitasking software
- Full bi-directional functionality
- Designed for 10,000 to 50,000 tests per year

Highly Flexible

- Continuous loading of samples (up to 144 primary tubes at a time), reagents and microplates (up to 3 at a time)
- Sample racks for 11–16 mm diameter tubes
- Reagent racks designed to hold various tube sizes
- Dilution capacity 72/192 (via tubes/plate)
- 2 independent incubators (temperature controlled)
- 3 ambient incubators (light protected)
- 2 different wash buffers
- Multiple networked EVOLIS *Twin Plus* Systems have the ability to centralize result management with one uni-/bi-directional connection to the LIS

Highest Level of Safety

- Positive identification of samples, reagents and microplates
- Disposable tips with clot detection for reagents and samples
- Colorimetric verification of sample and reagent additions
- Password protection and complete traceability
- Pre-defined, validated assay protocols
- In-process control, including log documentation

Ordering Information

Catalog	Description
93500	EVOLIS <i>Twin Plus</i> System (includes EVOLIS <i>Twin Plus</i> analyzer and accessory box)

* Available only outside of the US.

Reader

PR 4100 Absorbance Microplate Reader

The PR 4100 is the next generation 8-channel absorbance microplate reader from Bio-Rad. It provides accurate, reproducible, and fast measurements out of a compact and innovative design. Controlled via a Notebook PC with Windows® 7-based software, the system is validated with the complete menu of Bio-Rad EIA tests.

Improved Reliability

- Latest LED technology for long life and maintenance free operation
- 8-channel absorbance microplate reader for fast measurements
- Comprehensive QC function with multicheck plate

Innovative Design

- Compact footprint
- Standalone reader operated through a Notebook PC
- Windows® 7-based software

Comprehensive Data Analysis Software

- Validated protocols according to Bio-Rad quality assurance process
- Power Data Analysis with full qualitative and quantitative EIA analysis
- Full traceability

Blood Bank Software

- Dedicated Data Management Software for use in Blood Banks



PR 4100 Absorbance Microplate Reader

Ordering Information

Catalog	Description	
94196	PR 4100 Absorbance Microplate Reader	1 unit

Washer

PW 40

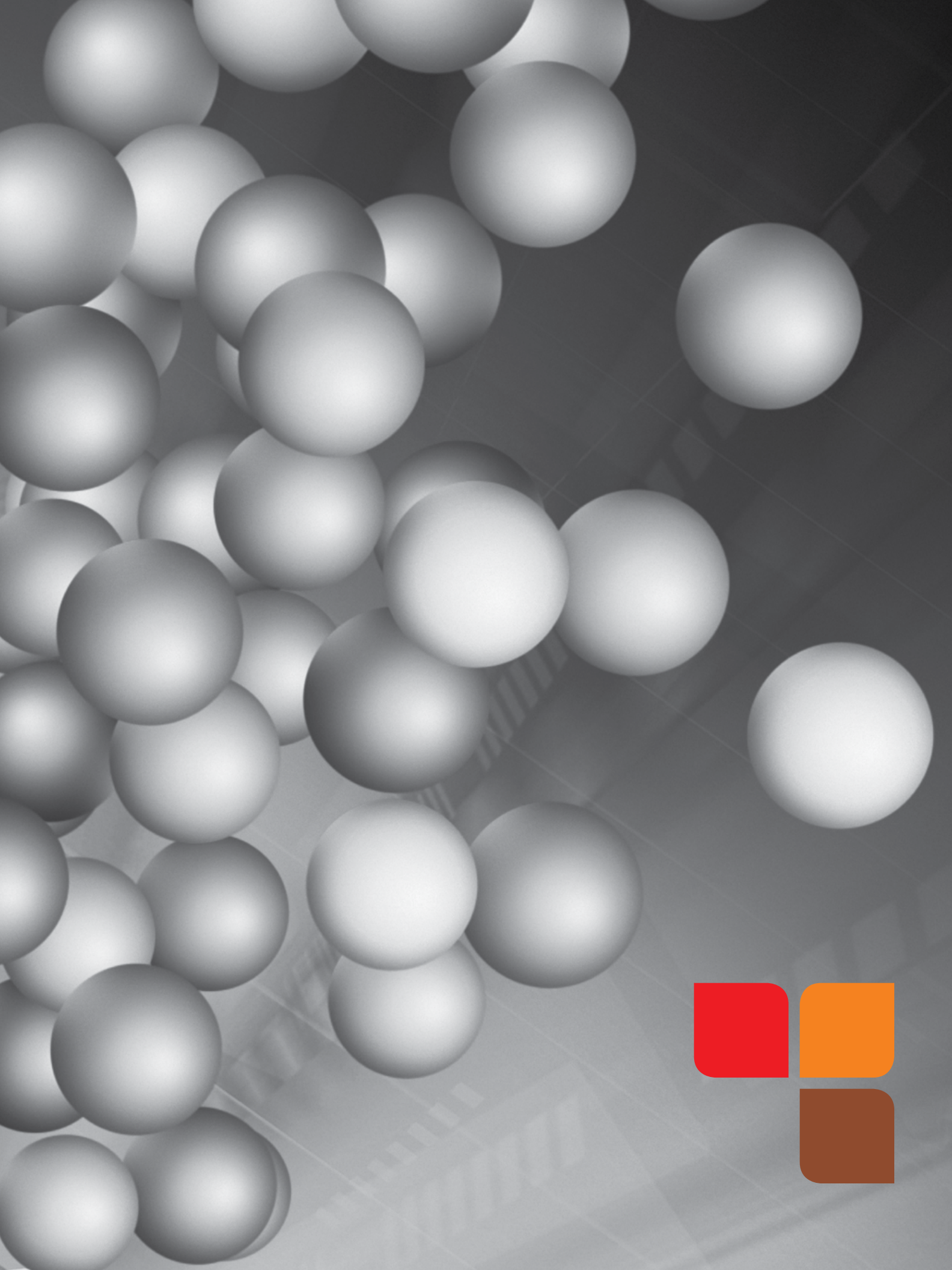
The PW 40 is a powerful, compact and programmable 1 x 8-channel microplate washer/aspirator, with a built-in vacuum and dispensing pump. It has been designed for use with 96-well flat, U- or V-bottom plates. Dispense and aspirate head heights are user-adjustable, with vertical and horizontal needle positioning in the well (0.1 mm accuracy).

Ordering Information

Catalog	Description	
85499K	PW 40, 1 x 8-channel manifold microplate washer (includes bottles, tubing set, user maintenance kit and instruction manual)	1 unit



PW 40 Washer





Autoimmune Education

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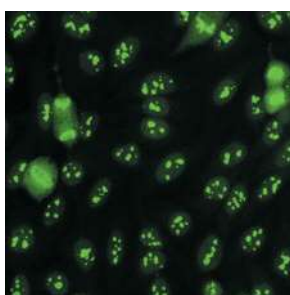


Autoimmune Educational Literature

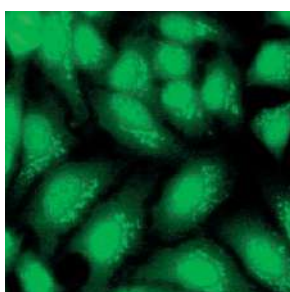
Autoimmune Educational CD

In the complex world of autoantibodies, training plays a vital role in reaching the goal of quality laboratory results. Bio-Rad's Autoimmune CD is designed to provide and document this training using a variety of interesting, flexible tools. It provides the basics needed when training new employees, cross-training lab personnel, introducing new assays into the laboratory or teaching students. It can help experienced technologists deal with difficult or unusual results. This can be done within the laboratory setting, reducing problems often associated with off-site training workshops. The Autoimmune CD provides access to AutoimmuneWEB where continuing education credits are available.

(Literature Number Q-767)



HEp-2 cells as substrate. Nucleolar pattern with positive staining on mitotic cells associated with autoantibodies to fibrillarin antigen, which could be indicative of scleroderma.



HEp-2 cells as substrate. Three mixed patterns – nucleolar and speckled nucleolar staining and Golgi cytoplasmic staining.

Autoimmune CD Contains the Following Applications:

AutoimmuneTUTOR

Learn about testing for ANA, ANCA and cytoplasmic antibodies and how these tests are used in the clinical correlation and teaching case studies sections.

IFA Wizard

Need some help with a staining pattern? IFA Wizard provides a quick and easy 3-step process for identification of most ANAs.

Competency Assessment

Image based competency assessment tests are provided for ANA, ANCA and MSK substrates

Image Atlas

A reference that allows rapid access to images in ANA, MSK, and ANCA

Pattern Plus Auditor

An image based competency assessment system for immunofluorescent assays

Autoantibody Atlas

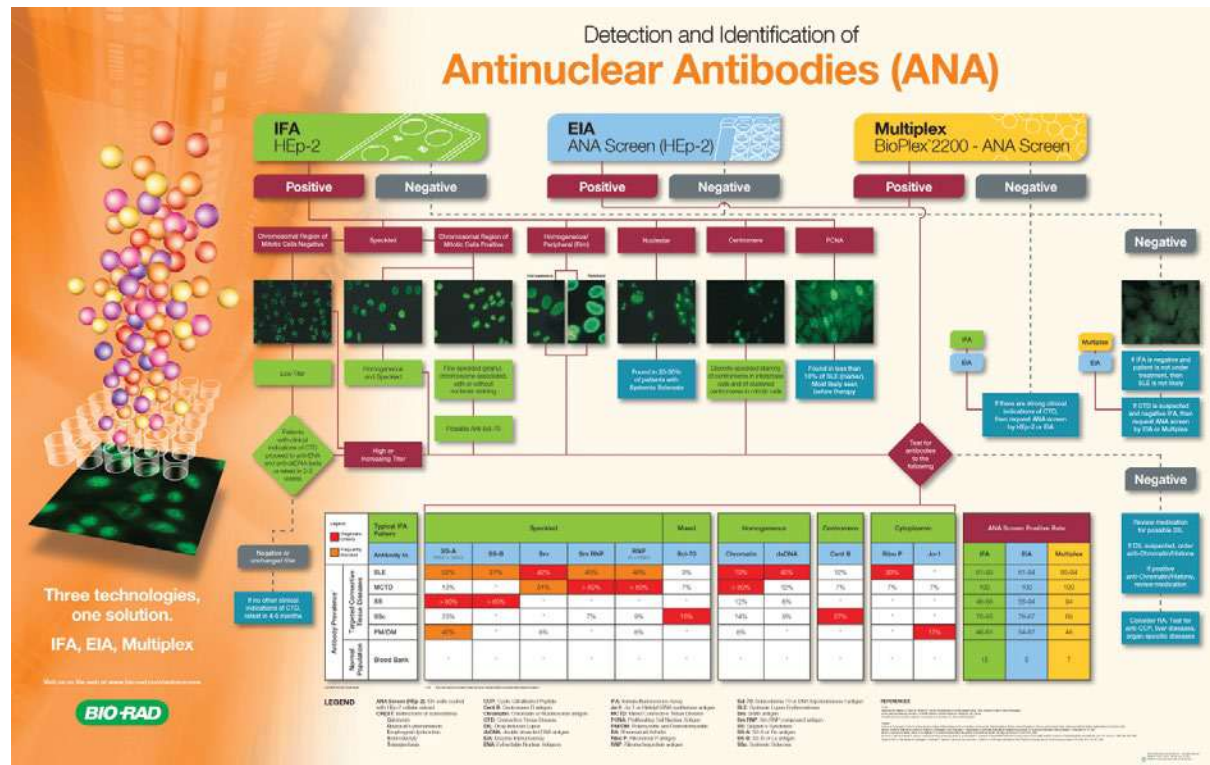
An autoantibody reference with information about the antigen, alternate names, clinical correlations and other helpful notes.

Autoimmune Educational Tools

Detection and Identification of Antinuclear Antibodies (ANA) Poster

The *Detection and Identification of Antinuclear Antibodies (ANA)* poster shows the suggested testing algorithms for ANA screening. It illustrates the most common IFA staining patterns and associated diseases, as well as recommended follow-up testing for IFA, EIA and multiplex.

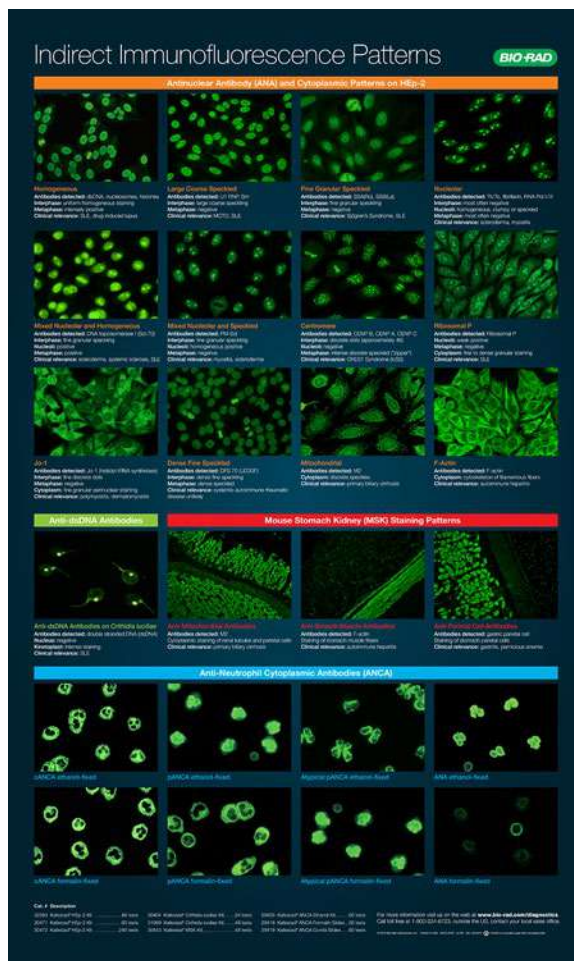
(Literature Number Q-703)



Indirect Immunofluorescence Patterns Poster

The Indirect Immunofluorescence Patterns poster displays the well-defined IFA staining patterns found on HEp-2, Crithidia, ANCA, and tissue substrate slides. The poster is a valuable reference for laboratories interpreting immunofluorescence tests.

(Literature Number Q-702)



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07. Kallestad Crithidia luciliae Kit Insert, 506448a.
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30. Autoimmune Education CD/Al Tutor/MSK/MSK Overview: Q-767.
31. Autoimmune Education CD/Al Tutor/MSK/MSK Histology: Q-767.
32. Autoimmune Education CD/Al Tutor/MSK/Antibody Association: Q-767.
33. Kallestad Anti-Mitochondrial EIA Kit Insert, L50337102.
34. Kallestad Anti-Thyroid Antibodies (ATA) IFA Kit Insert, L27000002.
35. Slides provided by Professor Humbel, LLIP, Laboratoire Lumxembourgeois d'Immunologie, Luxembourg.
36. Kallestad Anti-Skin Antibodies (ASA) IFA Kit Insert, L27003503.

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