

Autoimmunity

# Lead your lab to the forefront

2022 Catalog



**werfen**

# 2022 Catalog

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## Redefining Autoimmune testing with innovative systems and reagents

Werfen is redefining autoimmunity by delivering solutions to address the needs of the Autoimmune laboratory. We develop new biomarkers to enhance patient care, and systems to help improve efficiency and quality.

Our innovative Integrated Lab systems include BIO-FLASH, a rapid-response chemiluminescent analyzer; Aptiva, a multi-analyte system; NOVA View, an automated digital IFA microscope; QUANTA-Lyser, for increased EIA/IFA processing speed and flexibility; and QUANTA Link data management system to make workflow management.

Our comprehensive portfolio of reagents supports diagnosis, stratification and follow-up of complex disorders, such as connective tissue disease, autoimmune liver disease, rheumatoid arthritis, antiphospholipid syndrome, vasculitis, inflammatory bowel disease and celiac disease.

At Werfen, we want to be your first choice for Autoimmune disease testing. We work to accomplish this through a persistent focus on quality customer needs, and leading new product innovation. We look forward to working with you.

\* Inova Diagnostics, Inc. will remain a legal entity that is part of Werfen.



## Innovative Instruments and Assays

### INSTRUMENTS

- Aptiva multi-analyte system
- QUANTA Link data management system
- BIO-FLASH random access chemiluminescent system
- NOVA View digital IFA microscope
- QUANTA-Lyser automated EIA/IFA analyzer platforms
- AUTOloader automated slide handling

### ASSAYS

- Aptiva multi-analyte
- QUANTA Flash CIA
- QUANTA Lite ELISA
- NOVA Lite IFA

## The Integrated Lab

### Data Driven Workflow and Cost Efficiency

Autoimmunity instruments seamlessly connect to the LIS by QUANTA Link, a centralized data management system. This integrated system delivers increased productivity, improved sample integrity and more streamlined workflow for the autoimmune laboratory.

#### **QUANTA Link®**

Seamlessly integrates autoimmune instruments with your LIS to efficiently manage workflow and quality control

#### **Aptiva®**

Multi-analyte benchtop system with continuous load and STAT functionality

#### **BIO-FLASH®**

Fully automated random access chemiluminescent benchtop analyzer

#### **QUANTA-Lyser®**

EIA/IFA slide processor that automatically records EIA/IFA reagent identity, lot number and expiration date and scans IFA barcoded slides

#### **NOVA View®**

Automates IFA slide interpretation



# Systems and Instrumentation



## Aptiva<sup>®</sup> Multi-Analyte System

Giving you the power to move clinicians and your laboratory forward

**Increase diagnostic confidence** by offering clinicians the most comprehensive Autoimmune test menu and improved clinical performance

**Improve diagnostic accuracy** by helping to close the seronegative gap with clinically significant, novel biomarkers

**Increase lab efficiency** by improving resource utilization and realizing the full potential of multi-analyte testing with advanced automation

Description	Part Number
Optical Calibrator Kit	AC1001
Optical Control Kit	AC1002
Optical Cleaning Solution Kit	AC1003
Aptiva System Rinse	AC1004
Instrument System Cuvettes	AC1005

### Intuitive touchscreen



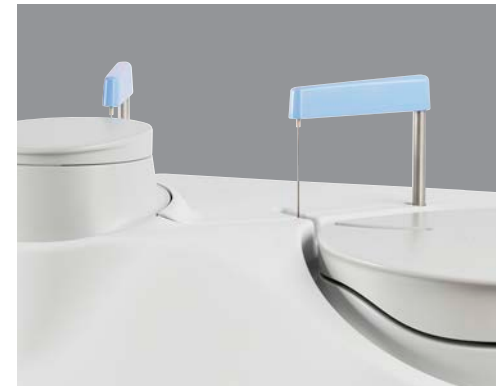
Easy-to-use, icon-driven software

### Sample bay



Holds 150 patient samples, continuous load, random-access sample loading and barcode reading with available STAT

### Dedicated sample and reagent probes



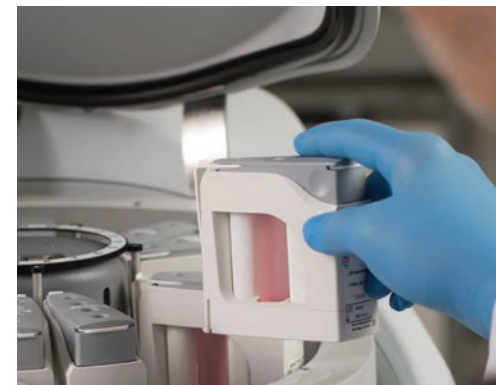
Eliminates sample carryover

### Cuvette tower



Allows access to replenish cuvettes during instrument operation

### Carousel



Holds 20 cartridges in temperature-controlled environment with RFID Scanner

# Systems and Instrumentation



## QUANTA Link<sup>®</sup>

Centralized Intelligent Network

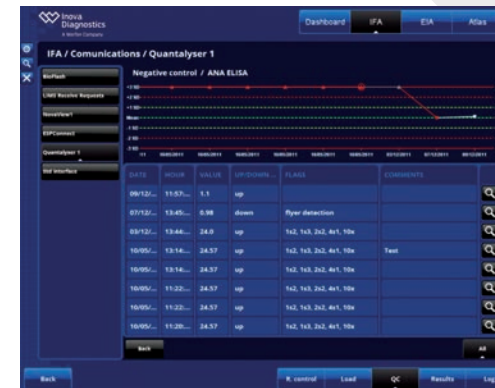
Workflow management made easy

Data management system that consolidates autoimmune results from Autoimmunity instruments in a centralized location to improve workflow

- Single-point location to access patient data and result history
- Centralized QC data
- Review and report IFA results
- Digital image training atlas for IFA
- Single LIS connection
- Positive patient identification for IFA

Description	Part Number
QUANTA Link Workstation License	LINK001
QUANTA Link Workstation	LINK010
Barcode Scanner	LINK019

### Optimize Quality Control



All quality control information is centralized in a single location using Levy-Jennings and employing Westgard rules.

### Paperless Interpretation



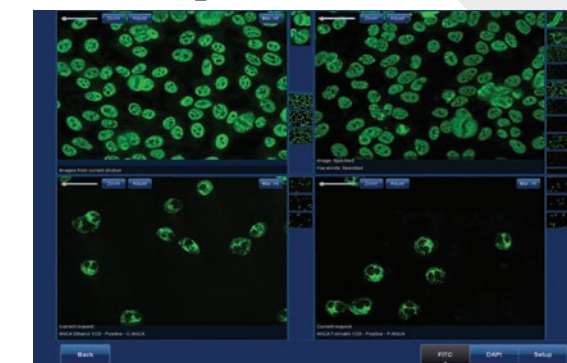
Transform your dark room into a paperless, transcription free environment. Simply enter the information directly on the touchscreen.

### Atlas



User defined atlas used for reference and training.

### Multi-Analyte Screen



Allows the technologist to view ANCA Ethanol, ANCA Formalin and HEp-2 results from the same patient simultaneously.



- Interpretation screen displays high-resolution images for operator interpretation.
- Each patient image is supplemented with images of mitotic cells (as needed), access to additional information and interpretation validation
- Touch screen monitor and icon driven software offers ease of use and allows for rapid navigation to complete your workflow

# Systems and Instrumentation



## BIO-FLASH®

### Random Access Chemiluminescent System

#### A progressive solution to common problems

Eliminates isotype batching and reagent waste

- Stable on-board reagents allow for samples to be run as they arrive
- Controls should be run only once per day independent of the number of samples run
- Calibration per reagents and triggers lot

Improves turn-around time

- Simultaneous random access processing of all isotypes and assays on a single sample
- Delivers results, including STAT orders, in as little as 30 minutes
- Generates up to 450 results in a single shift

Helps reduce test send outs

- Makes even the most specialized assays efficient to perform with stable calibration curves

Frees up floor space

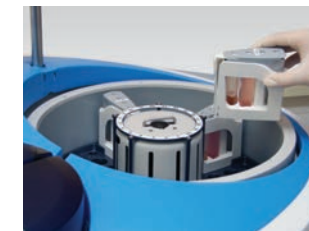
- Small benchtop analyzer achieves excellent throughput

Description	Part Number
BIO-FLASH System	T3710-0344
High Capacity Rinse Accessory	T3410-0887



#### QUANTA Flash® reagents

- Chemiluminescent technology delivers precise quantitation and a broad analytical measuring range
- Cartridge barcode is internally scanned to import the master calibration curve, lot number, expiration date and assay type



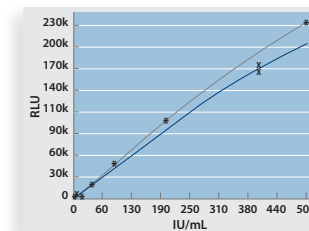
#### Reagent carousel

- Stores up to 20 reagent packs with on-board refrigeration
- Monitors reagent use and reports inventory
- Dedicated reagent probe



#### Sample carousel

- Primary samples placed directly onto the rack and scanned by internal barcode reader
- Samples processed in random access with continuous load capability
- STAT orders can be run at any time
- Dedicated sample probe



#### Calibration curves

- Master calibration curve uploaded through the reagent pack barcode
- Calibrators are processed in the sample carousel
- BIO-FLASH determines a stable working calibration curve
- Calibration is requested under reagent or triggers lot changes only



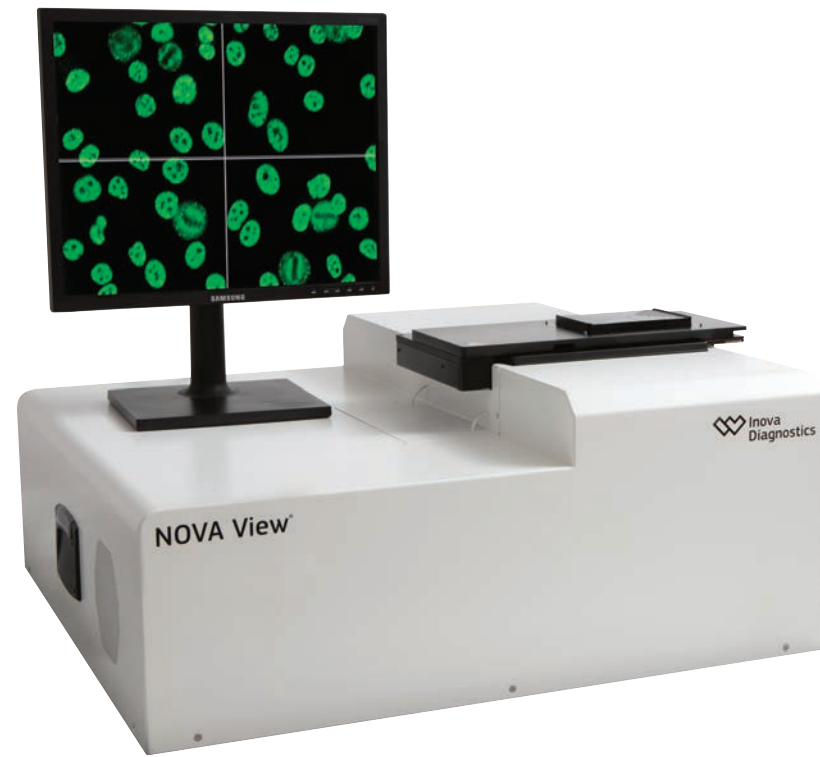
#### Intuitive software and touchscreen

- Simplifies training and day-to-day operation
- Status screen allows immediate access to system information

### BIO-FLASH Common Components

NAME	DESCRIPTION	PACKAGE	PART #
BIO-FLASH System Rinse	System rinse for use with the BIO-FLASH instrument	1 X 5 L	T3000-8205
Trigger 1&2	Package of both triggers for use with the BIO-FLASH instrument	2 x 250 mL	T3000-8204
Cuvettes	Cuvettes for use with the BIO-FLASH instrument	1400 per box	T3000-8206
System Cleaning Solution	Cleaning solution for BIO-FLASH instrument maintenance	6 x 4 mL	T3000-8211
Low Volume Cups	Low volume sample cups for use with the BIO-FLASH instrument	500 Cups	T3000-8209
Low Volume Caps	Low volume sample cup caps for use with the BIO-FLASH system	500 Caps	T3000-8210

# Systems and Instrumentation



## NOVA View<sup>®</sup> Automated digital IFA microscope

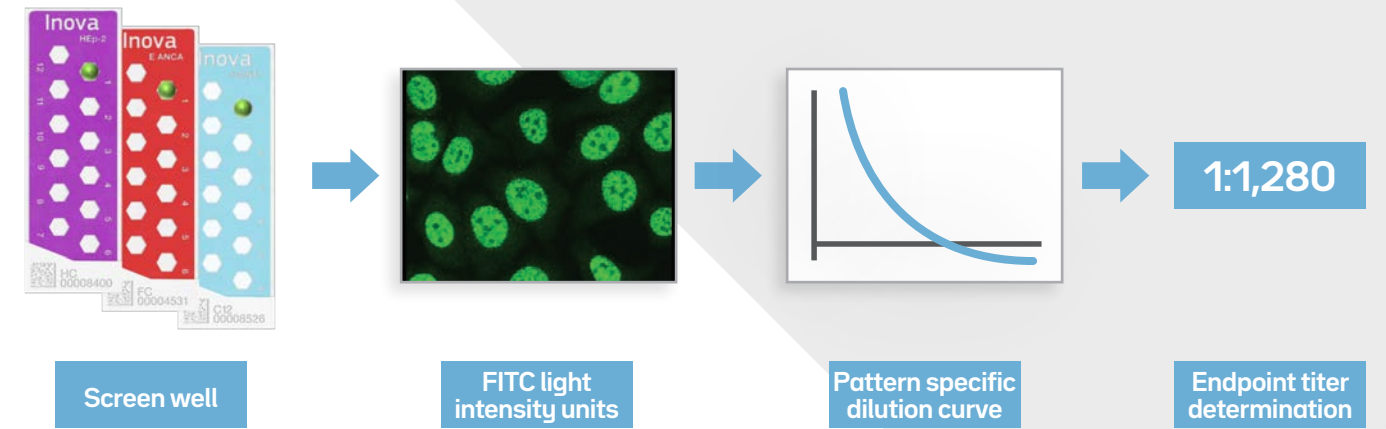
An automated digital microscope for use with indirect fluorescence assay (IFA) technology

- NOVA View automatically acquires and presents digital images for operator review and confirmation
- Software modules for HEp-2, ANCA<sup>ef</sup>, *Crithidia luciliae* (dsDNA) and EMA/LKS tissues are available\*
- NOVA View recognizes and displays the most common ANA and ANCA patterns
- Single well titer determination for HEp-2, ANCA and dsDNA can reduce IFA workload and lower material costs
- DAPI stain provides built-in control to visualize cells in a negative well with HEp-2, ANCA, dsDNA and EMA slides
- Calibration technique facilitates standardization

Description	Part Number
NOVA View Instrument HEp-2 Module	NV2000
ANCA Module	NV1051
dsDNA Module	NV1052
Tissue Module	NV1053

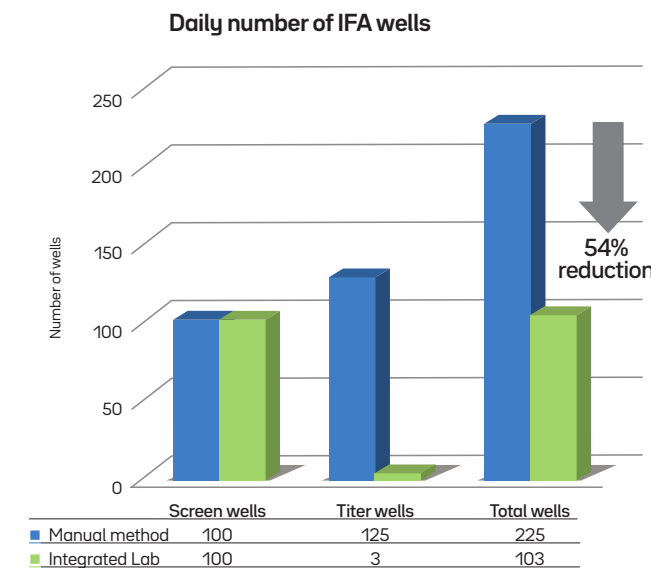
\* CE mark only

### Single well titer (SWT) determination



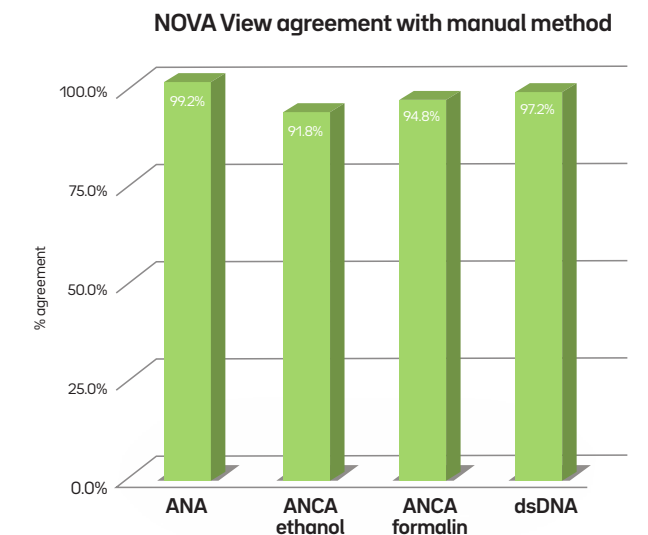
- SWT is available for HEp-2, ANCA ethanol and dsDNA slides
- NOVA View uses pattern specific dilution curves to determine the endpoint titer of a sample using light intensity units (LIU) captured from the screening well

### SWT reduces the number of IFA wells required to determine endpoint titers



- NOVA View SWT does not change the number of screening wells
- NOVA View SWT reduces the number of extra dilution wells by approximately 54% or 122 wells each day.  
Example: Assume 100 screens per day, 25% positive rate, 2.5% mixed patterns, 5 dilutions to endpoint

### Images acquired by NOVA View provide excellent agreement with manual reading after operator<sup>1</sup>



<sup>1</sup> Data on file

# Systems and Instrumentation



## QUANTA-Lyser<sup>®</sup> 3000

High-throughput EIA and IFA processor

A new dimension in processing to increase your lab's productivity

- Safeguards reagent and patient traceability to ensure integrity of results
- High throughput processing with 240 sample capacity and 4 independent probes
- Frees up valuable staff time by minimizing interventions
- Eliminates disposable tips for significantly lower operational costs

Description	Part Number
QUANTA-Lyser 3000 EIA/IFA combo	VS3000
QUANTA-Lyser 3000 EIA/IFA combo with incubator	VS3000i
QUANTA-Lyser 3000 IFA	VS3002

High throughput and automated scanning



Holds up to 240 primary samples for high volume processing

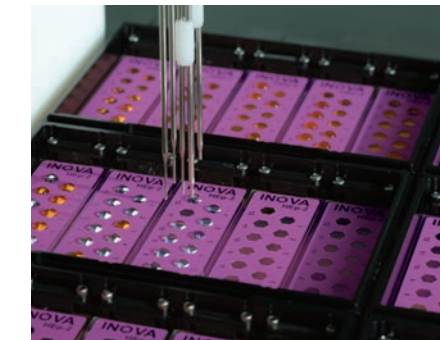


Automated 2D barcode camera captures reagent identity, lot number and expiration date and scans NOVA Lite IFA slide barcodes.

Pipettes mounting media

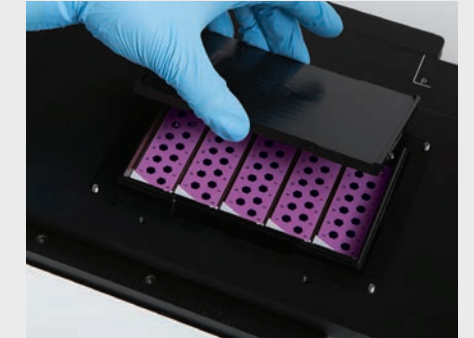


5-slide carrier lid minimizes exposure to ambient light and evaporation



Pipettes mounting media to protect processed cells  
Slides do not require a coverslip when using NOVA View

Directly transfer slides to NOVA View



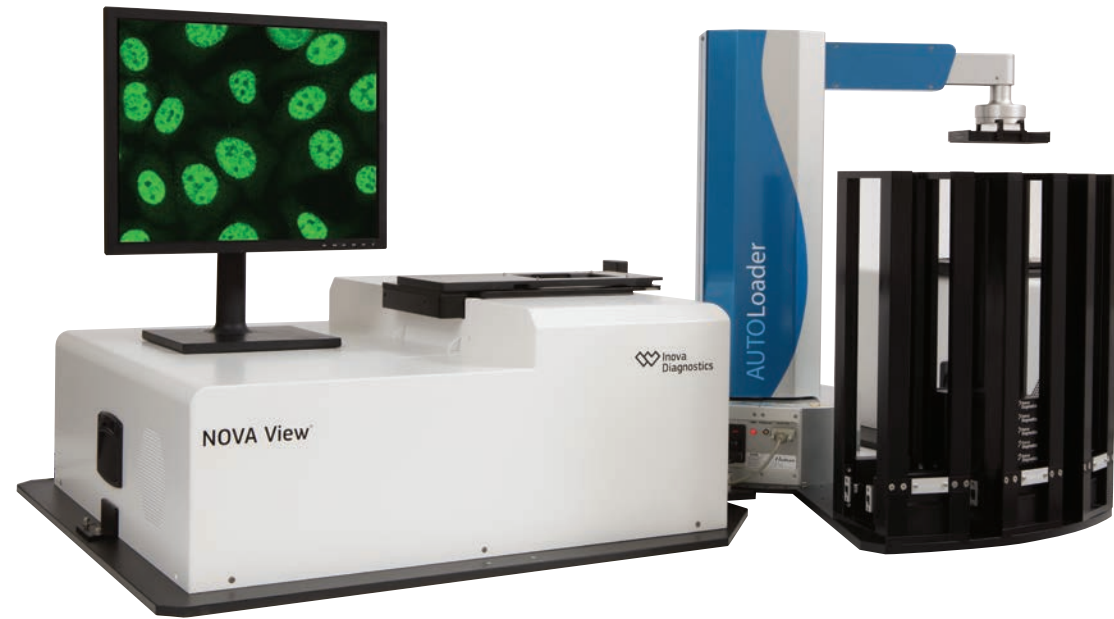
5-slide carrier with open base can be transferred directly to NOVA View to reduce individual slide handling

### QUANTA-Lyser Common Components

NAME	DESCRIPTION	PACKAGE	PART #
Dilution Block	U Bottom Dilution Block for sample predilution	50/box	QL0310
2 mL Standard/Control Vials	Spare vials compatible with the standard/control racks.	33/bag	D65940
25mL Reagent Bottles	Spare bottles compatible with the reagent rack	50/bag	07665950
120mL Diluent Bottles	Spare bottles compatible with the diluent rack	250/bag	QL0063
2L Buffer Bottle	Replacement wash station bottles	1 each	QL0088
Sample Rack Adapter	Used with 12 mm Tubes on Sample Racks	20/bag	QL0452
5-Slide Carrier	Holds 5 IFA Slides for processing	1 each	NV2016
System Liquid Filter Buffers	Required for Preventative Maintenance 1	4/bag	QL0429
Plastic Buffer Filters	Required for Preventative Maintenance 1 on ELISA/IFA units	10/bag	QL0430



# Systems and Instrumentation



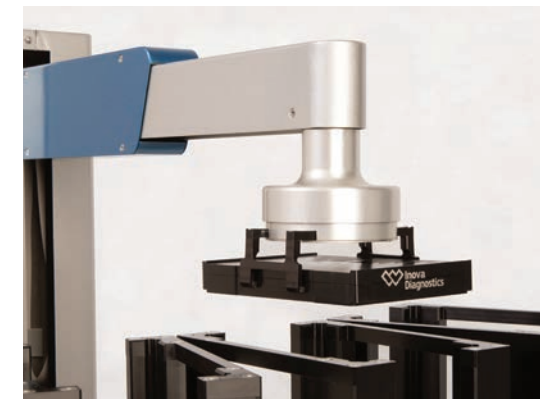
## AUTOloader

Efficiently automates slide transfer with NOVA View®

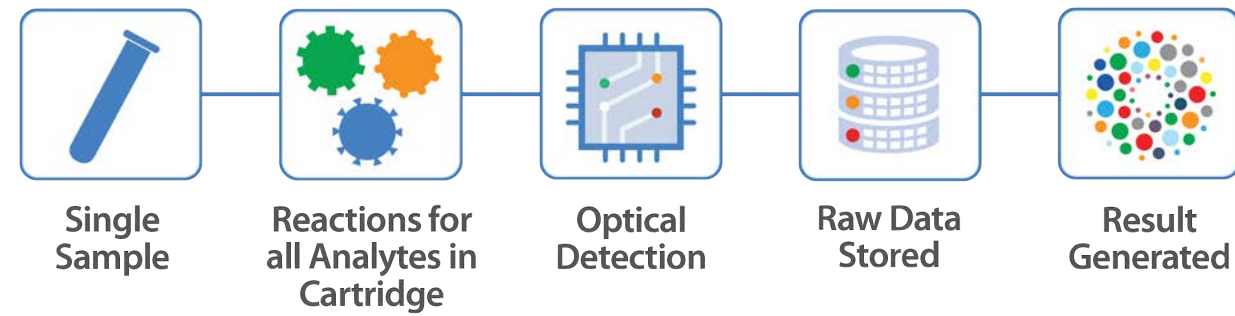
A fully automated robotic system that transfers NOVA Lite® IFA slides to NOVA View®

- Direct transfer of 5-slide carrier from QUANTA-Lyser® 3000 to AUTOloader eliminates the need to handle individual slides
- Slides can be added to AUTOloader at any time without interrupting NOVA View interpretation
- Automated barcode scanner ensures positive patient identification
- Capacity for up to 100 slides or 1,200 wells allows for overnight interpretation

Description	Part Number
AUTOloader	ALDR1000



Autoimmunity  
Reagents

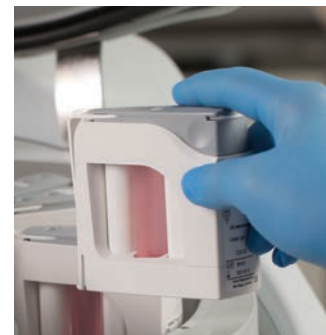


# Aptiva®

## Multi-analyte Testing

Aptiva uses a particle-based multi-analyte technology (PMAT), that processes multiple analytes simultaneously from a patient sample. Aptiva closes the seronegative gap with novel biomarkers and provides the most comprehensive menu for Autoimmune disease.

- Antiphospholipid Syndrome
- Celiac Disease
- Inflammatory Bowel Disease
- Connective Tissue Disease
- Autoimmune Liver Disease
- Myositis
- Rheumatoid Arthritis
- Vasculitis



## Celiac Disease

Aptiva Celiac Disease Reagents provide accurate results across multiple markers and isotypes.

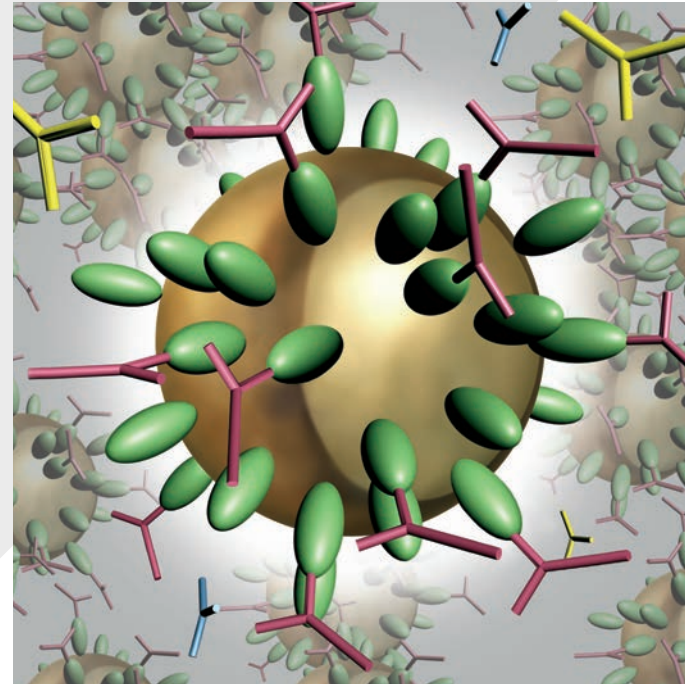
NAME	DESCRIPTION	PRODUCT ITEM	PACKAGE	PART #
Aptiva Celiac Disease IgA	Semi-quantitative determination of anti-tissue transglutaminase IgA autoantibodies and anti-deamidated gliadin peptide IgA autoantibodies in human serum	Reagents	250 Test Cartridge	724120
		Calibrators	2 X 3 vials (0.3mL each)	724121
		Controls	2 X 2 vials (0.5mL each)	724122
Aptiva Celiac Disease IgG	Semi-quantitative determination of anti-tissue transglutaminase IgG autoantibodies and anti-deamidated gliadin peptide IgG autoantibodies in human serum	Reagents	200 Test Cartridge	724100
		Calibrators	2 X 3 vials (0.3mL each)	724101
		Controls	2 X 2 vials (0.5mL each)	724102

## Connective Tissue Disease

Aptiva CTD Reagents detect disease specific antibodies associated with the most common connective tissue diseases including SLE, Sjogrens Syndrome, Systemic Sclerosis and Mixed Connective Tissue disease.

NAME	DESCRIPTION	PRODUCT ITEM	PACKAGE	PART #
Aptiva CTD Essential*	Semi-quantitative determination of IgG autoantibodies against anti-RNP, anti-Sm, anti-Ro60, anti-Ro52, anti-SS-B, anti-Scl-70, anti-Jo-1, anti-Centromere, anti-Ribo-P, and anti-DFS70 in human serum; and quantitative detection of anti-ds-DNA antibodies in human serum.	Reagents	250 Test Cartridge	723100
		Calibrators	2 X 4 vials (0.3mL each)	723101
		Controls	2 X 6 vials (0.5mL each)	723102

\* CE mark only



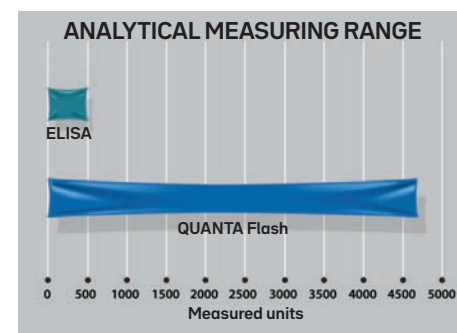
# QUANTA Flash®

## Chemiluminescent Immunoassays (CIA)

QUANTA Flash CIA technology offers a faster response, reproducibility and broader analytical measuring range, than enzyme-based assays for more precise quantitation and confidence in results.

Broad panel of tests to cover the following disease states:

- Antiphospholipid Syndrome
- Connective Tissue Diseases
- Celiac Disease
- Rheumatoid Arthritis
- Vasculitis
- Liver Disease
- Gastrointestinal Disease



Chemiluminescence immunoassay (CIA) technology can significantly increase the analytical measuring range<sup>1</sup>

1. Martis P, et al. The QUANTA Flash® Chemiluminescent Immunoassays for Celiac Disease Show Excellent Analytical and Clinical Performance Characteristics. AMLI Minneapolis, 2011.

## Celiac Disease

QUANTA Flash celiac assays provide accurate results across multiple markers and isotypes.

NAME	DESCRIPTION	PRODUCT ITEM	PACKAGE	PART #
QUANTA Flash h-tTG IgA	Semi-quantitative determination of IgA anti-human tissue transglutaminase [h-tTG] antibodies in human serum	Reagents	50 Test Cartridge	701103
			100 Test Cartridge	701100
		Calibrators	2 X 2 vials (0.3 mL each)	701101
		Controls	2 X 2 vials (0.5 mL each)	701102
QUANTA Flash h-tTG IgG	Semi-quantitative determination of IgG anti-human tissue transglutaminase [h-tTG] antibodies in human serum	Reagents	50 Test Cartridge	701108
			2 X 2 vials (0.3 mL each)	701106
		Calibrators	2 X 2 vials (0.3 mL each)	701107
		Controls	2 X 2 vials (0.5 mL each)	701107
QUANTA Flash DGP IgA	Semi-quantitative determination of IgA anti-deamidated gliadin peptide [DGP] antibodies in human serum	Reagents	50 Test Cartridge	701168
			2 X 2 vials (0.3 mL each)	701166
		Calibrators	2 X 2 vials (0.3 mL each)	701167
		Controls	2 X 2 vials (0.5 mL each)	701167
QUANTA Flash DGP IgG	Semi-quantitative determination of IgG anti-deamidated gliadin peptide [DGP] antibodies in human serum	Reagents	50 Test Cartridge	701173
			100 Test Cartridge	701170
		Calibrators	2 X 2 vials (0.3 mL each)	701171
		Controls	2 X 2 vials (0.5 mL each)	701172
QUANTA Flash DGP Screen	Semi-quantitative measurement of IgG and IgA anti-deamidated gliadin peptide [DGP] antibodies in human serum	Reagents	50 Test Cartridge	701113
			2 X 2 vials (0.3 mL each)	701111
		Calibrators	2 X 2 vials (0.3 mL each)	701112
		Controls	2 X 2 vials (0.5 mL each)	701112

## Vasculitis

QUANTA Flash MPO, PR3 and GBM allow for rapid response in critical cases.

NAME	DESCRIPTION	PRODUCT ITEM	PACKAGE	PART #
QUANTA Flash MPO	Semi-quantitative determination of IgG autoantibodies to myeloperoxidase (MPO) in human serum	Reagents	50 Test Cartridge	701133
		Calibrator	2 X 2 vials (0.7 mL each)	701131
		Controls	2 X 2 vials (0.5 mL each)	701132
QUANTA Flash PR3	Semi-quantitative determination of IgG autoantibodies to serine protease 3 (PR3) in human serum	Reagents	50 Test Cartridge	701138
		Calibrator	2 X 2 vials (0.3 mL each)	701136
		Controls	2 X 2 vials (0.5 mL each)	701137
QUANTA Flash GBM	Semi-quantitative determination of IgG autoantibodies to glomerular basement membrane (GBM) in human serum	Reagents	50 Test Cartridge	701143
		Calibrator	2 X 2 vials (0.7 mL each)	701141
		Controls	2 X 2 vials (0.5 mL each)	701142

# QUANTA Flash® (CIA)

## Rheumatoid Arthritis

QUANTA Flash CCP3 and RF isotype assay adds certainty to the diagnosis of Rheumatoid Arthritis.

NAME	DESCRIPTION	PRODUCT ITEM	PACKAGE	PART #
QUANTA Flash CCP3	Semi-quantitative determination of IgG autoantibodies to CCP3 in human serum	Reagents Calibrator Controls	100 Test Cartridge 2 X 2 vials (0.7 mL each) 2 X 2 vials (0.5 mL each)	701125 701126 701127
QUANTA Flash RF IgM	Quantitative determination of IgM rheumatoid factor (RF) antibodies in human serum	Reagents Calibrator Controls	100 Test Cartridge 2 X 2 vials (0.7 mL each) 2 X 2 vials (0.5 mL each)	701340 701341 701342
QUANTA Flash RF IgA	Semi-quantitative determination of IgA rheumatoid factor (RF) antibodies in human serum	Reagents Calibrator Controls	100 Test Cartridge 2 X 2 vials (0.7 mL each) 2 X 2 vials (0.5 mL each)	701345 701346 701347

## Connective Tissue Disease

QUANTA Flash CTD assays accurately detect analytes at a combined screening level as well as the more disease specific autoantibodies.

NAME	DESCRIPTION	PRODUCT ITEM	PACKAGE	PART #
QUANTA Flash CTD Screen Plus*	Qualitative detection of total anti-nuclear antibodies against dsDNA, Ro52, Ro60, SS-B, Scl-70, centromere, Mi-2, Ku, Th/To, RNA Pol III, Pm/Scl, PCNA, Jo-1, Sm, RNP and Ribosomal-P	Reagents Calibrators Controls	100 Test Cartridge 2 x 2 vials (0.7 mL each) 2 x 2 vials (0.5 mL each)	701220 701221 701222
QUANTA Flash ENA7	Qualitative determination of IgG anti Sm, anti-RNP, anti-Ro60, anti-Ro52, anti-SS-B, anti-Scl-70 and anti-Jo-1 antibodies	Reagents Calibrators Controls	50 Test Cartridge 100 Test Cartridge 2 X 2 vials (0.7 mL each) 2 X 2 vials (0.5 mL each)	701258 701255 701256 701257
QUANTA Flash Jo-1	Semi-quantitative determination of anti-Jo-1 antibodies	Reagents Calibrators Controls	50 Test Cartridge 2 X 2 vials (0.3 mL each) 2 X 2 vials (0.5 mL each)	701163 701161 701162
QUANTA Flash RNP	Semi-quantitative determination of anti-RNP antibodies	Reagents Calibrators Controls	50 Test Cartridge 2 X 2 vials (0.3 mL each) 2 X 2 vials (0.5 mL each)	701118 701116 701117
QUANTA Flash Sm	Semi-quantitative determination of anti-Sm antibodies	Reagents Calibrators Controls	50 Test Cartridge 2 X 2 vials (0.3 mL each) 2 X 2 vials (0.5 mL each)	701123 701121 701122
QUANTA Flash Ro60	Semi-quantitative determination of anti-Ro60 (SSA) antibodies	Reagents Calibrators Controls	50 Test Cartridge 2 X 2 vials (0.3 mL each) 2 X 2 vials (0.5 mL each)	701148 701146 701147
QUANTA Flash Ro52	Semi-quantitative determination of anti-Ro52 (TRIM21) antibodies	Reagents Calibrators Controls	50 Test Cartridge 2 X 2 vials (0.3 mL each) 2 X 2 vials (0.5 mL each)	701263 701261 701262
QUANTA Flash SS-B	Semi-quantitative determination of anti-SSB (La) antibodies	Reagents Calibrators Controls	50 Test Cartridge 2 X 2 vials (0.3mL each) 2 X 2 vials (0.5mL each)	701153 701151 701152
QUANTA Flash Scl-70	Semi-quantitative determination of anti-Scl-70 antibodies	Reagents Calibrators Controls	50 Test Cartridge 2 X 2 vials (0.3mL each) 2 X 2 vials (0.5mL each)	701328 701326 701327
QUANTA Flash Centromere	Semi-quantitative determination of anti-centromere antibodies	Reagents Calibrators Controls	50 Test Cartridge 2 X 2 vials (0.3 mL each) 2 X 2 vials (0.5 mL each)	701198 701196 701197
QUANTA Flash Ribosomal P*	Semi-quantitative determination of anti-RiboP antibodies	Reagents Calibrators Controls	50 Test Cartridge 2 X 2 vials (0.7 mL each) 2 X 2 vials (0.5 mL each)	701193 701191 701192
QUANTA Flash DFS70*	Semi-quantitative determination of anti-DFS70 antibodies	Reagents Calibrators Controls	50 Test Cartridge 2 X 2 vials (0.3 mL each) 2 X 2 vials (0.5 mL each)	701268 701266 701267
QUANTA Flash dsDNA	Quantitative determination of anti-dsDNA antibodies	Reagents Calibrators Controls	50 Test Cartridge 100 Test Cartridge 2 X 2 vials (0.7 mL each) 2 X 2 vials (0.5 mL each)	701178 701175 701176 701177
QUANTA Flash HMGCR	Semi-quantitative detection of IgG anti-HMGCR antibodies in human serum	Reagents Calibrators Controls	50 Test Cartridge 2 X 2 vials (0.3 mL each) 2 X 2 vials (0.5 mL each)	701333 701331 701332

\* CE Mark only

## Autoimmunity

# QUANTA Flash® (CIA)

## Antiphospholipid Syndrome

QUANTA Flash APS assays can bring clarity to the complicated diagnosis of Antiphospholipid Syndrome.

NAME	DESCRIPTION	PRODUCT ITEM	PACKAGE	PART #
QUANTA Flash aPL Controls	aPL controls are intended for the quality control of the QUANTA Flash aCL and $\beta_2$ GP1 IgM and IgG assays	Low aPL Controls High aPL Controls	2 X 3 vials (2 mL each) 2 X 3 vials (2 mL each)	701060
QUANTA Flash aCL IgG	Semi-quantitative determination of anti-cardiolipin (aCL) IgG antibodies in human citrated plasma and serum	Reagents Controls	50 Test Cartridge 100 Test Cartridge 2 X 3 vials (1 mL each)	701233 701230 701232
QUANTA Flash aCL IgM	Semi-quantitative determination of anti-cardiolipin (aCL) IgM antibodies in human citrated plasma and serum	Reagents Controls	50 Test Cartridge 100 Test Cartridge 2 X 3 vials (1 mL each)	701238 701235 701237
QUANTA Flash aCL IgA	Semi-quantitative determination of anti-cardiolipin (aCL) IgA antibodies in human citrated plasma and serum	Reagents Controls	50 Test Cartridge 100 Test Cartridge 2 X 3 vials (1 mL each)	701228 701225 701227
QUANTA Flash $\beta_2$ GP1 IgG	Semi-quantitative determination of anti- $\beta_2$ glycoprotein-1 ( $\beta_2$ GP1) IgG antibodies in human citrated plasma and serum	Reagents Controls	50 Test Cartridge 100 Test Cartridge 2 X 3 vials (1 mL each)	701248 701245 701247
QUANTA Flash $\beta_2$ GP1 IgM	Semi-quantitative determination of anti- $\beta_2$ glycoprotein-1 ( $\beta_2$ GP1) IgM antibodies in human citrated plasma and serum	Reagents Controls	50 Test Cartridge 100 Test Cartridge 2 X 3 vials (1 mL each)	701253 701250 701252
QUANTA Flash $\beta_2$ GP1 IgA	Semi-quantitative determination of anti- $\beta_2$ glycoprotein-1 ( $\beta_2$ GP1) IgA antibodies in human citrated plasma and serum	Reagents Controls	50 Test Cartridge 100 Test Cartridge 2 X 3 vials (1 mL each)	701243 701240 701242
QUANTA Flash $\beta_2$ GP1-Domain1	Semi-quantitative determination of anti- $\beta_2$ GP1 Domain1 antibodies in human citrated plasma and serum	Reagents Controls	50 Test Cartridge 2 X 3 vials (1 mL each)	701188 701187

Calibrators are included in the QUANTA Flash aCL and  $\beta_2$  GP1-kits

## Liver Disease

QUANTA Flash Liver assays increase confidence in the diagnosis of autoimmune liver disease and aid the discrimination of its distinct subtypes.

NAME	DESCRIPTION	PRODUCT ITEM	PACKAGE	PART #
QUANTA Flash LKM-1	Semi-quantitative determination of IgG autoantibodies against LKM-1 (cytochrome P450 2D6) antigens in human serum	Reagents Calibrators Controls	50 test Cartridge 2 X 3 vials (0.3 mL each) 2 X 2 vials (0.5 mL each)	701298 701296 701297
QUANTA Flash M2 (MIT3)	Semi-quantitative determination of IgG autoantibodies against mitochondrial antigens in human serum	Reagents Calibrators Controls	50 test Cartridge 2 X 3 vials (0.3 mL each) 2 X 2 vials (0.5 mL each)	701303 701301 701302

## Gastrointestinal Disease

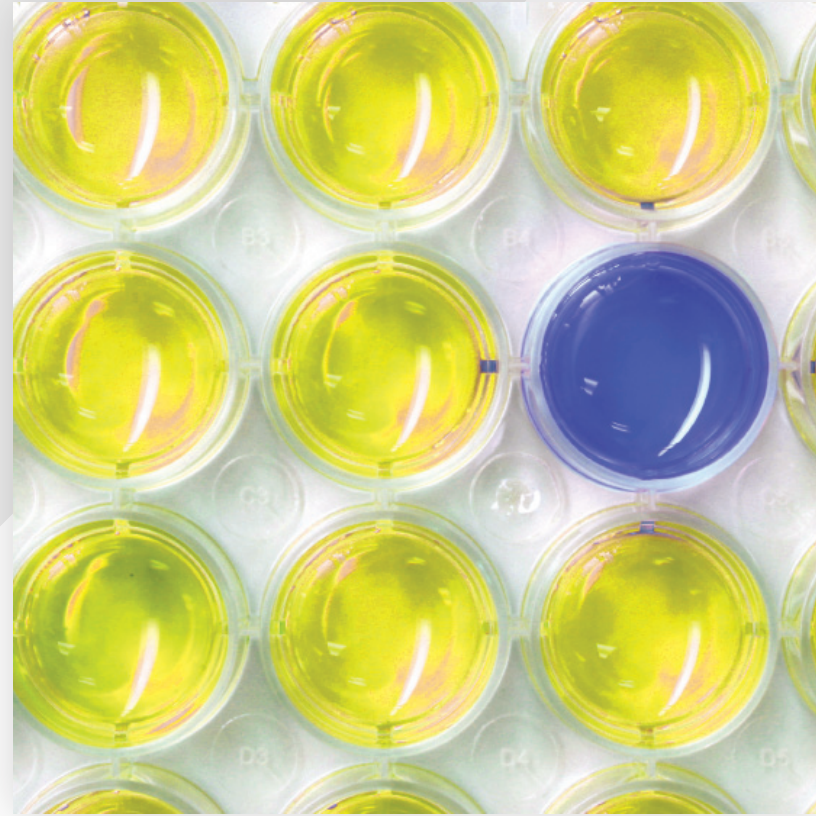
QUANTA Flash Calprotectin assay differentiates between Irritable Bowel Syndrome (IBS) and Inflammatory Bowel Disease (IBD) with a non-invasive marker of inflammation.

NAME	DESCRIPTION	PRODUCT ITEM	PACKAGE	PART #
QUANTA Flash Calprotectin	Quantitative determination of fecal calprotectin in extracted human stool samples	Reagents Calibrators Controls Extraction Buffer	100 Test Cartridge 2 X 2 vials (0.3 mL each) 2 X 2 vials (0.5 mL each) 2 bottles (125 mL each)	701350 701351 701352 701354
QUANTA Flash Intrinsic Factor*	Semi-quantitative determination of IgG autoantibodies against intrinsic factor in human serum	Reagents Calibrators Controls	50 Test Cartridge 2 X 2 vials (0.3 mL each) 2 X 2 vials (0.5 mL each)	701358 701356 701357
Fecal Extraction Device	This device has been designed as an aid in the preparation of fecal samples	Extraction Device	100 Devices	504837

## Additional Reagents

NAME	DESCRIPTION	PRODUCT ITEM	PACKAGE	PART #
QUANTA Flash Circulating Calprotectin*	Quantitative determination of calprotectin in human serum and plasma (sodium citrate and potassium EDTA)	Reagents Calibrators Controls	100 Test Cartridge 2 X 2 vials (0.3 mL each) 2 X 2 vials (0.5 mL each)	701365 701366 701367

\* CE mark only



## QUANTA Lite<sup>®</sup> ELISA

QUANTA Lite ELISA tests are made of the highest quality components to enable semi-quantitative\* detection of autoantibodies for a variety of disease states:

- Antiphospholipid Syndrome
- Connective Tissue Diseases
- Rheumatoid Arthritis
- Gastrointestinal Disease
- Celiac Disease
- Liver Disease
- Vasculitis
- Autoimmune Thyroid Disease

\* QUANTA Lite ELISA tests are semi-quantitative unless otherwise indicated in the product description

## Rheumatoid Arthritis

QUANTA Lite CCP3.1 IgG/IgA ELISA offers superior detection of early RA compared with CCP2<sup>1</sup>. Clearly defined positive and high positive cut-offs provide results that rheumatologists require.

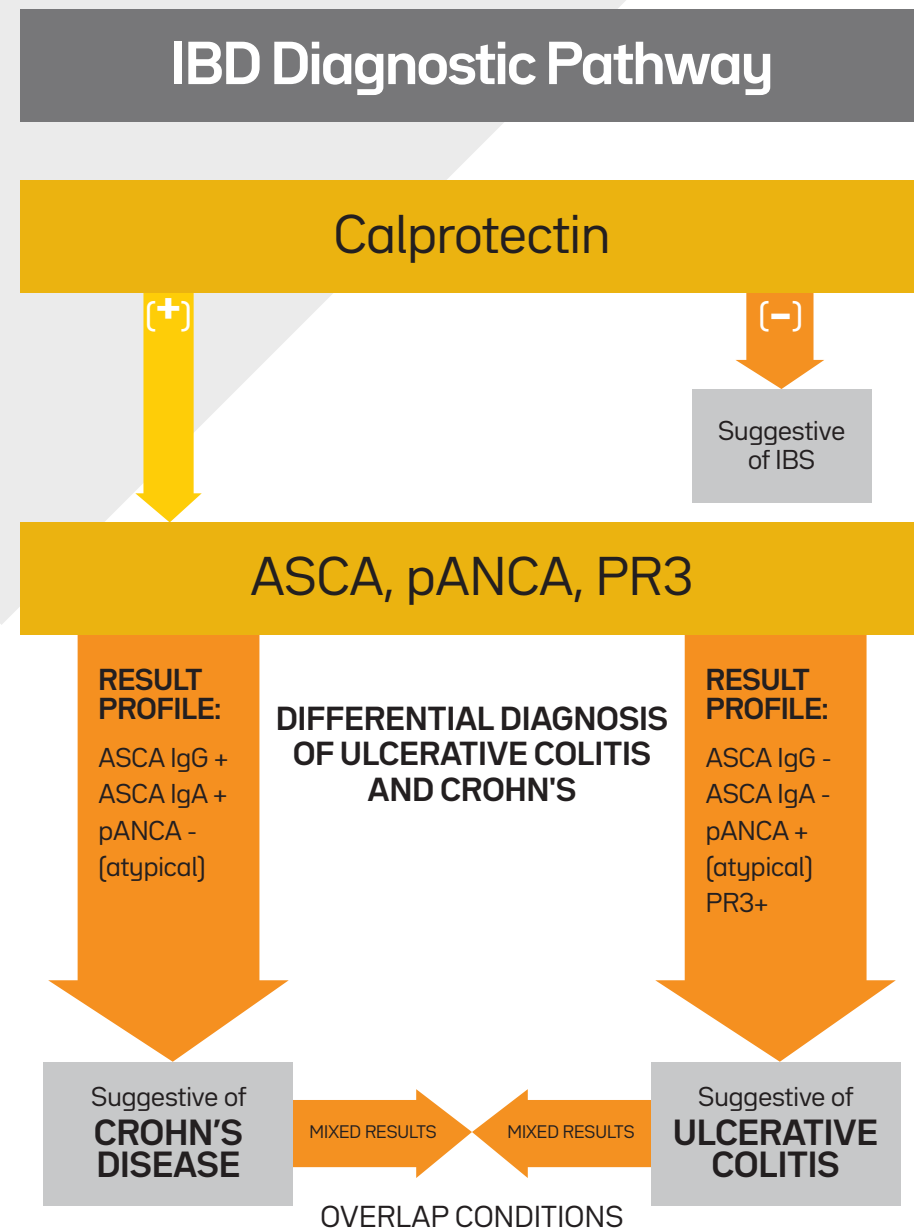
NAME	DESCRIPTION	ANTIGEN	PACKAGE	PART #
QUANTA Lite CCP3.1 IgG/IgA	Detection of anti-CCP 3.1 IgG and IgA antibodies in patient sera, citrated or EDTA plasma	Synthetic peptide	1 X 96 wells 10 X 96 wells	704550 704550.10
QUANTA Lite CCP3 IgG	Detection of anti-CCP 3 IgG antibodies in patient sera, citrated or EDTA plasma	Synthetic peptide	1 X 96 wells 10 X 96 wells	704535 704535.10
QUANTA Lite RF IgG	Detection of anti-rheumatoid factor (RF) IgG antibodies in human serum	Native	1 X 96 wells	708685
QUANTA Lite RF IgM	Detection of anti-rheumatoid factor (RF) IgM antibodies in human serum	Native	1 X 96 wells	708690
QUANTA Lite RF IgA	Detection of anti-rheumatoid factor (RF) IgA antibodies in human serum	Native	1 X 96 wells	708695

## Vasculitis

NAME	DESCRIPTION	ANTIGEN	PACKAGE	PART #
QUANTA Lite MPO IgG	Detection of anti-myeloperoxidase (MPO) IgG antibodies in human serum	Native	1 X 96 wells 10 X 96 wells	708700 708700.10
QUANTA Lite PR-3 IgG	Anti-serine protease 3 (PR-3) IgG antibodies in human serum	Native	1 X 96 wells 10 X 96 wells	708705 708705.10
QUANTA Lite GBM	Anti-glomerular basement membrane (GBM) IgG antibodies in human serum	Native	1 X 96 wells 10 X 96 wells	708740 708740.10

## Autoimmune Thyroid Disease

NAME	DESCRIPTION	ANTIGEN	PACKAGE	PART #
QUANTA Lite Thyroid T	Detection of anti-thyroglobulin IgG antibodies in human serum	Native	1 X 96 wells	708595
QUANTA Lite TPO	Anti-thyroid peroxidase (TPO) IgG antibodies in human serum	Recombinant	1 X 96 wells	708725



**Abbreviations**

- ASCA Anti-Saccharomyces cerevisiae antibody
- pANCA Perinuclear anti-neutrophil cytoplasmic antibody
- PR3 Proteinase 3

Testing strategies provided for informational purposes only. Testing and diagnosis should be determined by a licensed clinician.

1. Desplat-Jego, S., Johanet, C., et al. [2007]. "Update on Anti-Saccharomyces cerevisiae antibodies, anti-nuclear associated anti-neutrophil antibodies and antibodies to exocrine pancreas detected by indirect immunofluorescence as biomarkers in chronic inflammatory bowel diseases: results of a multicenter study." World J Gastroenterol 13(16): 2312-2318.
2. Arai, R. [2010]. "Serologic markers: impact on early diagnosis and disease stratification in inflammatory bowel disease." Postgrad Med 122(4): 177-185.
3. Arias-Loste, et al. [2012]. "Presence of Anti-proteinase 3 Antineutrophil Cytoplasmic Antibodies [Anti-PR3 ANCA] as Serologic Markers in Inflammatory Bowel Disease" Clin Rev Allergy Immunol 45(1):109-16.
4. Lewis, JD. "The utility of biomarkers in the diagnosis and therapy of inflammatory bowel disease." Gastroenterology 140(6):1817-1826.
5. Corrocio, A. et al. [2003] Diagnostic Accuracy of fecal calprotectin assay in distinguishing organic causes of chronic diarrhea from irritable bowel syndrome: a prospective study in adults and children. Clin Chem 49:861-7.

Gastrointestinal Disease

NAME	DESCRIPTION	ANTIGEN	PACKAGE	PART #
QUANTA Lite Calprotectin Extended Range	A quantitative ELISA for detecting the concentration of calprotectin in human feces. The presence of calprotectin can aid in the diagnosis of Inflammatory Bowel Diseases (IBD) and to differentiate IBD from Irritable Bowel Syndrome (IBS)	Native	1 x 96 wells	704860
QUANTA Lite Intrinsic Factor	This assay is designed for the detection of anti-Intrinsic Factor IgG antibodies in human serum. The presence of these antibodies can aid in the diagnosis of pernicious anemia	Recombinant	1X 96 wells	708780
QUANTA Lite H. pylori IgA	A qualitative ELISA assay for the detection of anti-H. pylori (Helicobacter pylori) IgA antibodies in human serum. The presence of these antibodies can aid in the diagnosis of H. pylori infection in adult patients with clinical signs and symptoms of gastrointestinal disease	Native	1X 96 wells	708720
QUANTA Lite H. pylori IgG	A qualitative ELISA assay for the detection of anti-H. pylori (Helicobacter pylori) IgG antibodies in human serum. The presence of these antibodies can aid in the diagnosis of H. pylori infections in adult patients with clinical signs and symptoms of gastrointestinal disease	Native	1X 96 wells	708715
QUANTA Lite ASCA IgA (S. cerevisiae)	This assay is designed for the detection of anti-Saccharomyces cerevisiae IgA antibodies in human serum. The presence of these antibodies can aid in the diagnosis of patients with Crohn's disease	Native	1X 96 wells	708870
QUANTA Lite ASCA IgG (S. cerevisiae)	This assay is designed for the detection of anti-Saccharomyces cerevisiae IgG antibodies in human serum. The presence of these antibodies can aid in the diagnosis of patients with Crohn's disease	Native	1X 96 wells	708865
QUANTA Lite GPA (Gastric Parietal Cell Antibody)	This assay is designed for the detection of anti-gastric parietal cell [H+/K+] ATPase IgG antibodies in human serum. The presence of these antibodies can aid in the diagnosis of conditions with elevated levels of anti-gastric parietal cell antibodies including pernicious anemia	Native	1X 96 wells	708765

Common Components

NAME	DESCRIPTION	PACKAGE	PART #
Fecal Extraction Device	This device has been designed as an aid in the preparation of fecal samples	100 devices	504837

# QUANTA Lite® (ELISA)

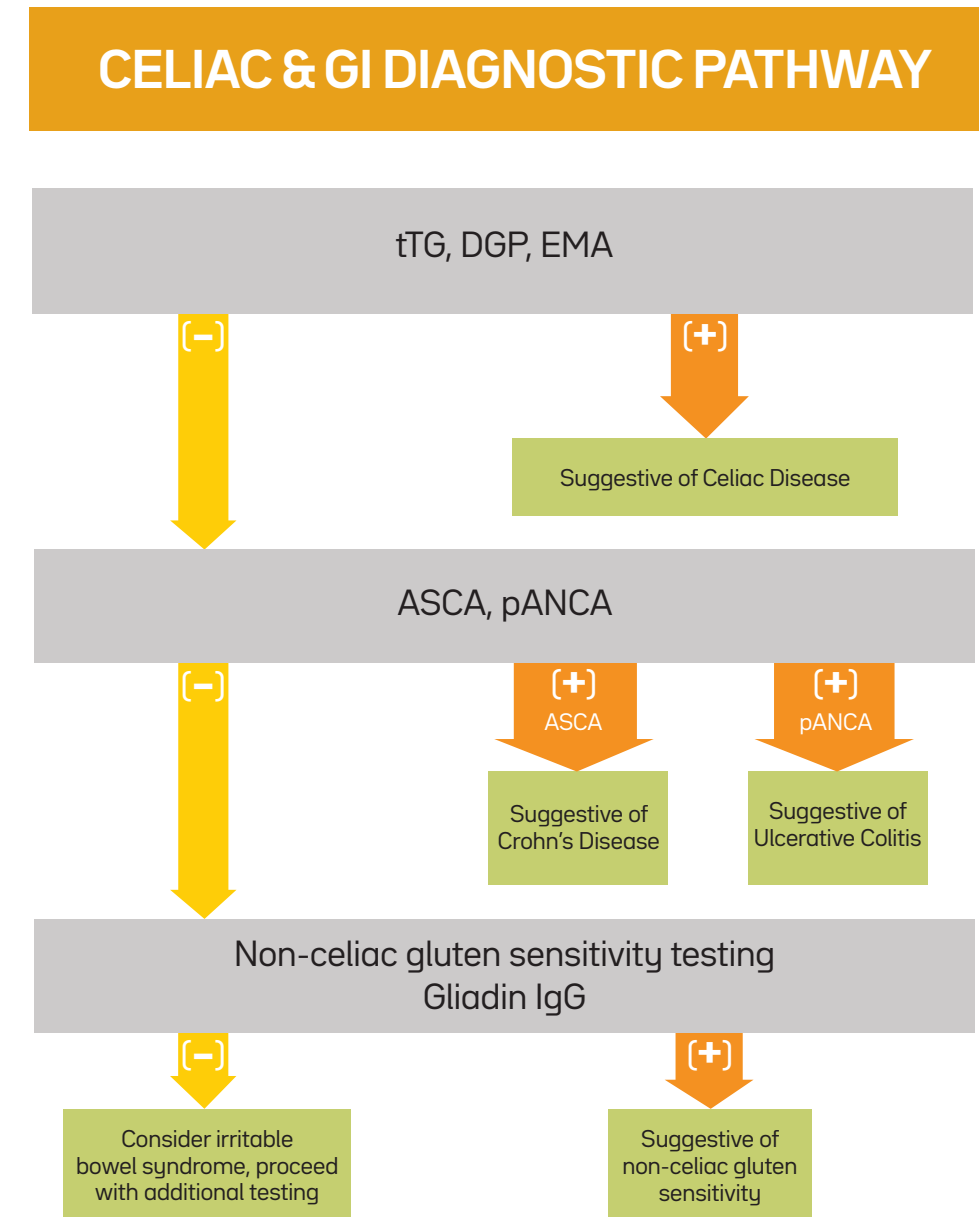
## Celiac Disease

Celiac disease remains highly under diagnosed, especially in children. QUANTA Lite Gliadin II (DGP) is particularly useful in pediatric population diagnosis.

NAME	DESCRIPTION	ANTIGEN	PACKAGE	PART #
QUANTA Lite R h-tTG IgA	In-vitro measurement of specific IgA autoantibodies against tissue transglutaminase (tTG) present in human serum, as an aid in the diagnosis of celiac disease	Recombinant	1 X 96 wells 10 X 96 wells	704605 704605.10
QUANTA Lite R h-tTG IgG	In-vitro measurement of specific IgG autoantibodies against tissue transglutaminase (tTG) present in human serum, as an aid in the diagnosis of celiac disease	Recombinant	1 X 96 wells 10 X 96 wells	704610 704610.10
QUANTA Lite Gliadin IgA II	Detection of IgA antibodies to synthetic, deamidated gliadin-derived peptides (DGP) in human serum	Synthetic, deamidated peptide	1 X 96 wells 10 X 96 wells	704525 704525.10
QUANTA Lite Gliadin IgG II	Detection of IgG antibodies to synthetic, deamidated gliadin-derived peptides (DGP) in human serum	Synthetic, deamidated peptide	1 X 96 wells 10 X 96 wells	704520 704520.10
QUANTA Lite Celiac DGP Screen	Detection of IgA and IgG antibodies to synthetic, deamidated gliadin-derived peptides in human serum	Synthetic, deamidated peptide	1 X 96 wells	704545
QUANTA Lite Gliadin IgA	Detection of anti-gliadin IgA antibodies in human serum	Native	1 X 96 wells	708655
QUANTA Lite Gliadin IgG	Detection of anti-gliadin IgG antibodies in human serum	Native	1 X 96 wells	708650
QUANTA Lite F-Actin IgA	Detection of IgA antibodies to the F-Actin component of smooth muscle in human serum	Native	1 X 96 wells	704500

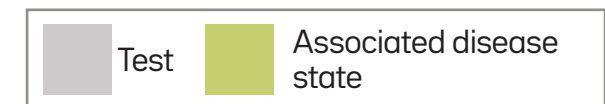
## Gastrointestinal Disease

The cause of chronic intestinal upset can come from a number of sources, often making diagnosis difficult. The QUANTA Lite and NOVA Lite (in the case of ANCA) tests below provide reliable results to help clinicians assess the root cause.



**Abbreviations**

- ANCA Anti-neutrophil cytoplasmic antibodies
- ASCA Anti-Saccharomyces cerevisiae antibody
- DGP Anti-deamidated gliadin peptide
- EMA Anti-endomysial antibody
- tTG Anti-tissue transglutaminase antibody

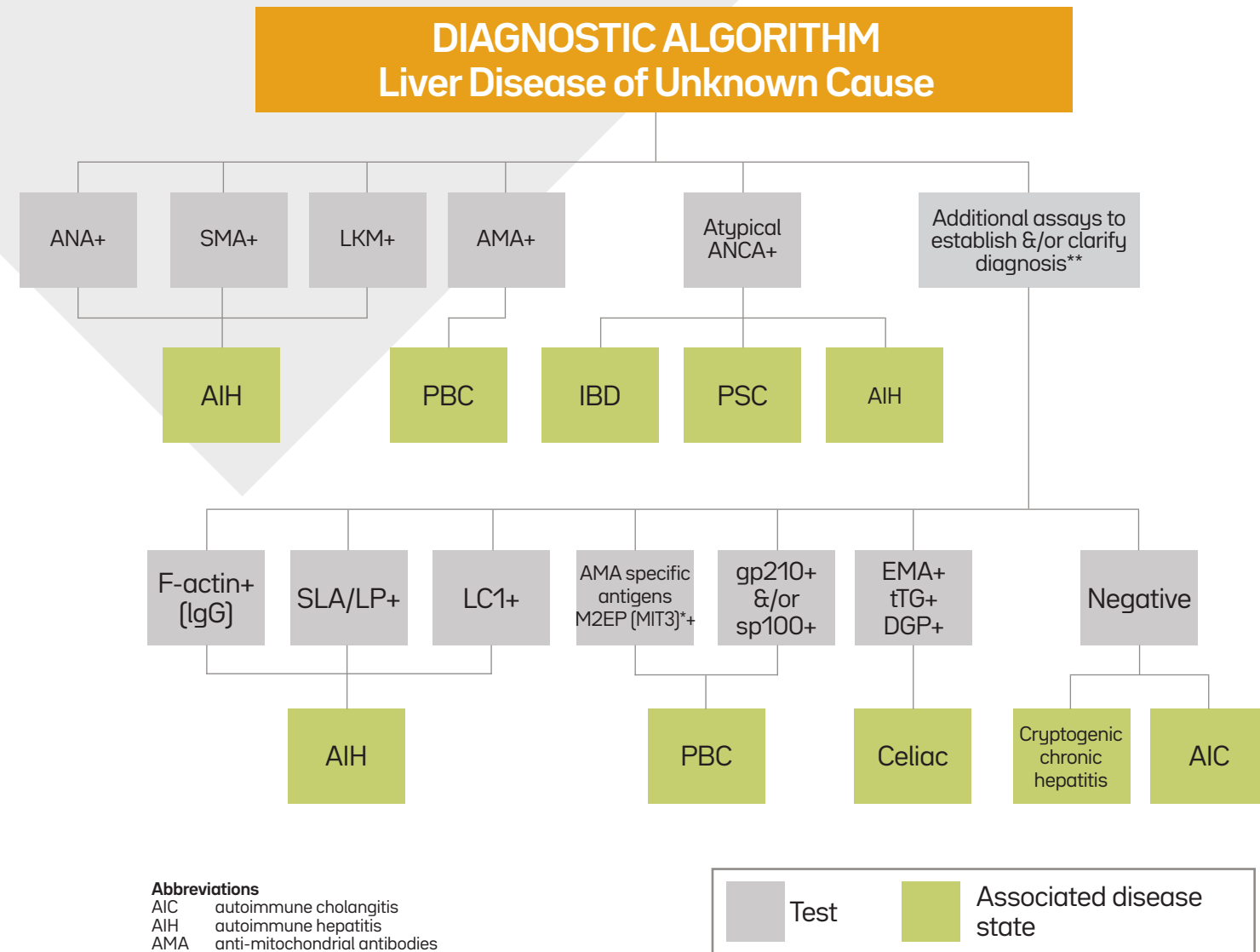


Testing strategies provided for informational purposes only. Testing and diagnosis should be determined by a licensed clinician.

1. Green, P. H. [2009]. "Mortality in celiac disease, intestinal inflammation, and gluten sensitivity." JAMA 302[11]: 1225-1226.
2. Rubio-Tapia, A. and Murray, J. A. [2010]. "Celiac disease." Curr Opin Gastroenterol 26[2]: 116-122.
3. Leffler, D. A. and D. Schuppan [2010]. "Update on serologic testing in celiac disease." Am J Gastroenterol 105[12]: 2520-2524.



Liver Disease



Testing strategies provided for informational purposes only. Testing and diagnosis should be determined by a licensed clinician.

From: A.J. Czaja & G.L. Norman, J. Clin. Gastroenterol, 2003, 37:315-327, modified by G.L. Norman 01/09

\*\* Other assays with possible prognostic value: chromatin and dsDNA

\* M2 EP [MIT3] ELISA contains immunodominant epitope of PDC-E2, OGDC-E2 & BCOADC-E2

Liver Disease

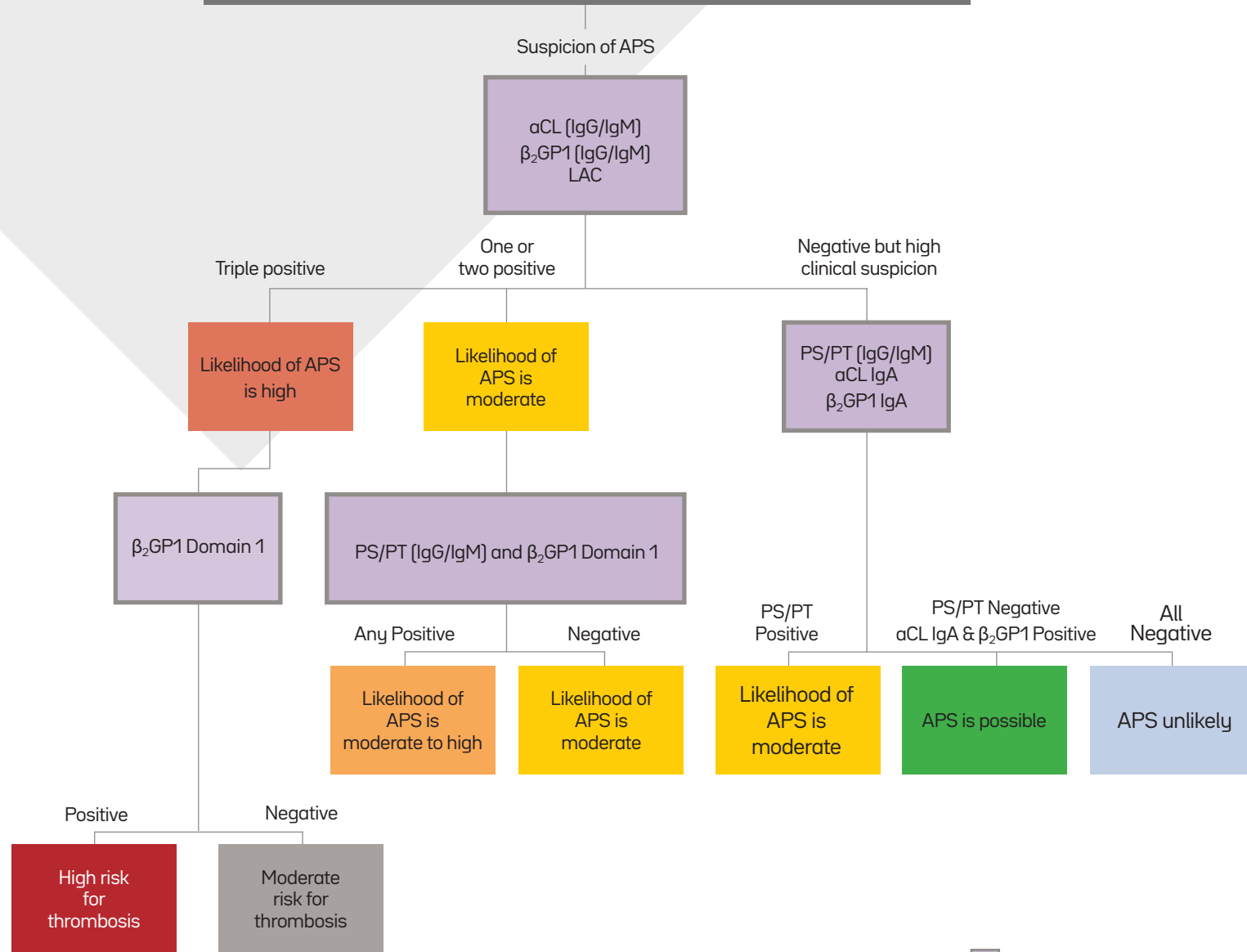
Werfen offers a comprehensive menu of tests to aid in the diagnosis of autoimmune hepatitis (AIH) and primary biliary cholangitis (PBC).

NAME	DESCRIPTION	ANTIGEN	PACKAGE	PART #
QUANTA Lite Actin IgG	Detection of IgG antibodies to the actin component of smooth muscle in human serum	Native	1 X 96 wells 10 X 96 wells	708785 708785.10
QUANTA Lite M2 EP [MIT3]	Detection of anti-mitochondrial IgG antibodies in human serum	Recombinant	1 X 96 wells 10 X 96 wells	704540 704540.10
QUANTA Lite gp210	Detection of anti-gp210 IgG antibodies in human serum	Synthetic peptide	1 X 96 wells	708995
QUANTA Lite sp100	Detection of anti-sp100 IgG antibodies in human serum	Synthetic peptide	1 X 96 wells	708990
QUANTA Lite PBC Screen IgG/IgA	Detection of anti-mitochondrial, gp210 and sp100 IgG and/or IgA antibodies in human serum	MIT3 recombinant; sp100 & gp210 synthetic peptides	1 X 96 wells	704560
QUANTA Lite SLA [Soluble Liver Antigen]	Detection of anti-Soluble Liver Antigen (SLA) IgG antibodies in human serum	Recombinant	1 X 96 wells	708775
QUANTA Lite LKM-1	Detection of anti-LKM-1 IgG antibodies in human serum	Recombinant	1 X 96 wells	708745

Autoimmunity  
**QUANTA Lite** (ELISA)

**Antiphospholipid Syndrome (APS)**

**Potential APS Testing Algorithm**



Likelihood of APS based on testing outcome	Risk outcome
High	• Triple positivity is the strongest risk factor for clinical manifestations <sup>2-6,9</sup>
Moderate to high	• Titers and isotype need to be considered <sup>4-6</sup> • Inclusion of PS/PT results in excellent diagnostic accuracy and a predictor of adverse events <sup>2-6,9</sup>
Moderate	• PS/PT may identify patients with APS who are negative for serological criteria markers <sup>10</sup> • Positivity for at least one of the criteria markers increases likelihood for APS • Titers and isotype need to be considered (Antibodies of IgG isotype represent higher risk than that of IgM, and higher antibody level implies higher risk) <sup>4-6</sup>
Possible	• All criteria markers negative but one or more esoteric marker positive; APS possible, but likelihood only marginally increased <sup>11-12</sup> • Isolated IgA antibody positivity has been described in association with APS <sup>9,13-14</sup>
Unlikely	• All markers are negative which makes APS unlikely, but can not be excluded <sup>11-12</sup>

**Antiphospholipid Syndrome**

Comprehensive menu of serological markers, including criteria as well as specialty non-criteria markers.<sup>1</sup>

NAME	DESCRIPTION	ANTIGEN	PACKAGE	PART #
QUANTA Lite ACA IgG III	Detection of anti-cardiolipin IgG antibodies in human serum	Native	1 X 96 wells 10 X 96 wells	708625 708625.10
QUANTA Lite ACA IgM III	Detection of anti-cardiolipin IgM antibodies in human serum	Native	1 X 96 wells 10 X 96 wells	708630 708630.10
QUANTA Lite ACA IgA III	Detection of anti-cardiolipin IgA antibodies in human serum	Native	1 X 96 wells 10 X 96 wells	708635 708635.10
QUANTA Lite ACA Screen III	Detection of anti-cardiolipin IgG, IgM and IgA antibodies in human serum	Native	1 X 96 wells	708620
QUANTA Lite β <sub>2</sub> GPI IgG	Detection of anti-β <sub>2</sub> GPI IgG antibodies in human serum	Native	1 X 96 wells 10 X 96 wells	708665 708665.10
QUANTA Lite β <sub>2</sub> GPI IgM	Detection of IgM anti-β <sub>2</sub> GPI antibodies in human serum	Native	1 X 96 wells 10 X 96 wells	708670 708670.10
QUANTA Lite β <sub>2</sub> GPI IgA	Detection of anti-β <sub>2</sub> GPI IgA antibodies in human serum	Native	1 X 96 wells 10 X 96 wells	708675 708675.10
QUANTA Lite β <sub>2</sub> GPI Screen ELISA	A qualitative ELISA assay for the detection of anti-β <sub>2</sub> GPI IgG, IgM and IgA antibodies in human serum	Native	1 X 96 wells	708660
QUANTA Lite aPS/PT IgG	Detection of IgG class antibodies to phosphatidylserine/prothrombin complex (PS/PT) in serum or plasma	Native	1 X 96 wells	708835
QUANTA Lite aPS/PT IgM	Detection of IgM class antibodies to phosphatidylserine/prothrombin complex (PS/PT) in serum or plasma	Native	1 X 96 wells	708845

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# QUANTA Lite (ELISA)

## Connective Tissue Diseases

Lupus and lupus-like diseases present clinicians with a tremendous diagnostic challenge. To help QUANTA Lite ANA ELISA offers a broad array of antigens, as well as HEp-2 nuclear extracts and the QUANTA Lite C1q CIC.

NAME	DESCRIPTION	ANTIGEN	PACKAGE	PART #
QUANTA Lite ANA	Detection of anti-nuclear IgG antibodies (ANA) in human serum	Native,	1 X 96 wells	708750
QUANTA Lite dsDNA	Detection of anti-dsDNA IgG antibodies in human serum	Native	1 X 96 wells	708510
QUANTA Lite Chromatin	Detection of anti-chromatin IgG antibodies in human serum	Native	1 X 96 wells	708710
QUANTA Lite C1q CIC	In-vitro measurement of circulating immune complexes (CIC) that bind C1q, present in human serum. It is intended for the determination of CIC in serum of patients with various autoimmune and other CIC-related diseases, and is used in conjunction with other clinical findings	Native	1 X 96 wells	704620
QUANTA Lite Anti-C1q*	Detection of anti-C1q antibodies in human serum	Native	1 X 96 wells	704565
QUANTA Lite Centromere	Detection of anti-centromere IgG antibodies specifically reactive to the CENP-A and CENP-B antigens in human serum		1 X 96 wells	708770
QUANTA Lite ENA 6 [Sm, RNP, SS-A, SS-B, Scl-70 and Jo-1 Screening Test]	This assay is designed for the detection of anti-Sm, RNP, SS-A (60kDa and 52kDa), SS-B, Scl-70 and Jo-1 IgG antibodies in human serum	SS-A 52	1 X 96 wells	708615

\* CE mark only

## Connective Tissue Diseases (continued)

NAME	DESCRIPTION	ANTIGEN	PACKAGE	PART #
QUANTA Lite HMGCR*	Semi-quantitative detection of IgG anti-HMGCR antibodies in human serum	Native	1 x 96 wells	704760
QUANTA Lite Histone	Detection of anti-histone IgG antibodies in human serum	Native	1 X 96 wells	708520
QUANTA Lite Jo-1	Detection of anti-Jo-1 IgG antibodies in human serum		1 X 96 wells	708585
QUANTA Lite Ribosome P	Detection of anti-Ribosome P IgG antibodies in human serum	Synthetic peptide	1 X 96 wells	708600
QUANTA Lite RNA Pol III	Detection of anti-RNA Polymerase III IgG antibodies in human serum		1 X 96 wells	704555
QUANTA Lite RNP	Detection of anti-RNP IgG antibodies in human serum	Native	1 X 96 wells	708565
QUANTA Lite Scl-70	Detection of anti-Scl-70 IgG antibodies in human serum	Native	1 X 96 wells	708580
QUANTA Lite Sm	Detection of anti-Sm IgG antibodies in human serum	Native	1 X 96 wells	708560
QUANTA Lite SS-A	Detection of anti-SS-A (60kDa & 52kDa) IgG antibodies in human serum	SS-A 52	1 X 96 wells	708570
QUANTA Lite SS-A 52	Detection of anti-SS-A 52 IgG antibodies in human serum		1 X 96 wells	704505
QUANTA Lite SS-B	Detection of anti-SS-B IgG antibodies in human serum		1 X 96 wells	708575

# NOVA Lite (IFA)



## Barcoded Slides

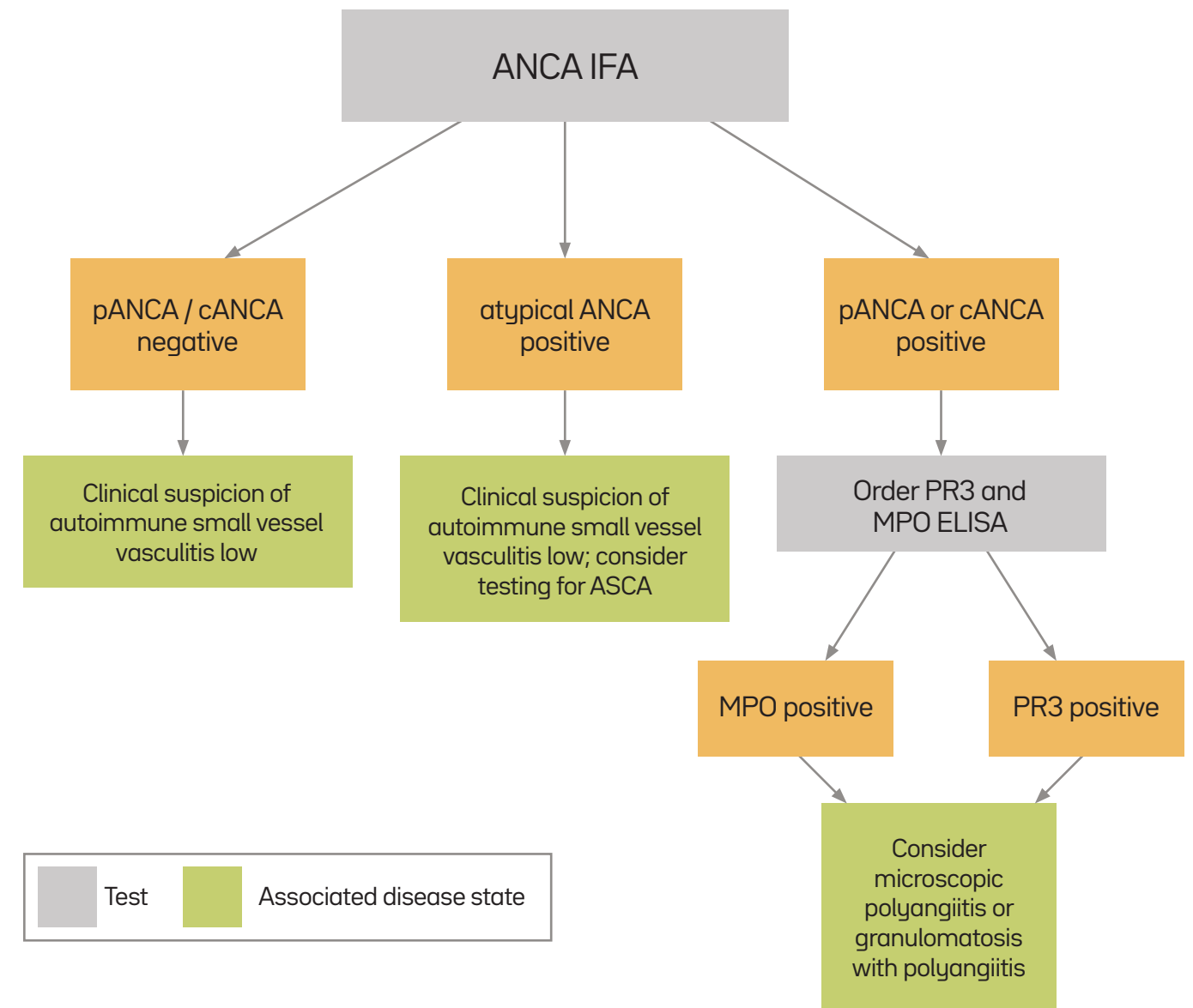
Barcoded slides, in combination with QUANTA Link software and QUANTA-Lyser:

- Eliminate transcription and related errors for enhanced efficiency
- Patient sample traceability

## IFA Slide Kits

NOVA Lite has long been synonymous with quality immunofluorescence assays. Proprietary methods used to craft our slides make NOVA Lite assays easy to read and interpret, helping your lab provide the reliable and consistent results.

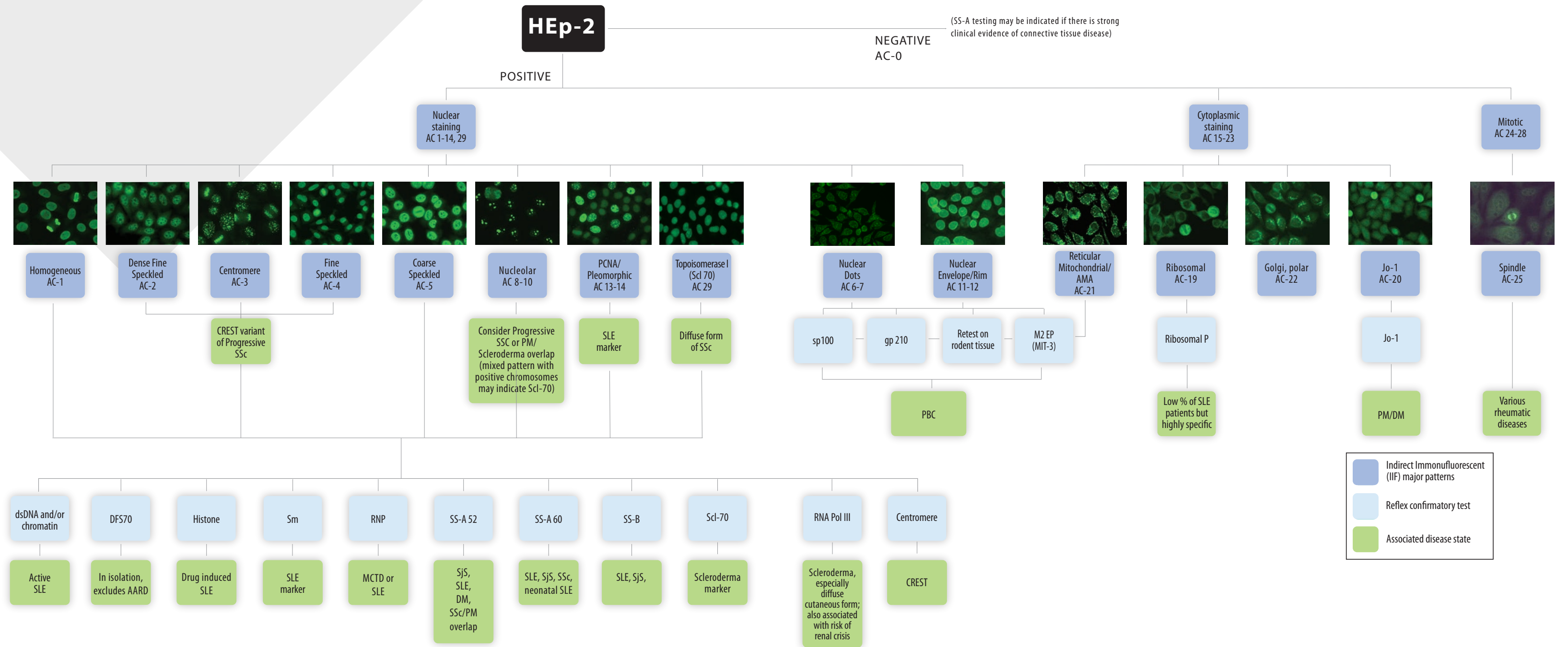
## Potential Testing Algorithm for Vasculitis



- Abbreviations**
- MPO myeloperoxidase
  - PR-3 proteinase 3
  - ANCA anti-neutrophil cytoplasmic antibodies
  - ASCA anti-Saccharomyces cerevisiae antibody

Testing strategies provided for informational purposes only. Testing and diagnosis should be determined by a licensed clinician.

## HEp-2 Diagnostic Algorithm



**Abbreviations**

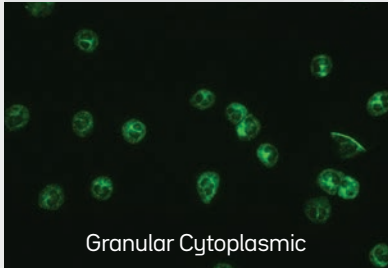
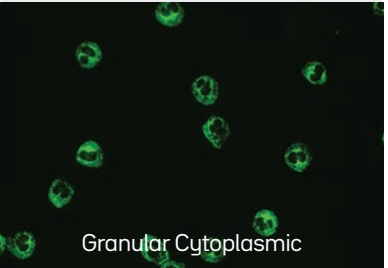
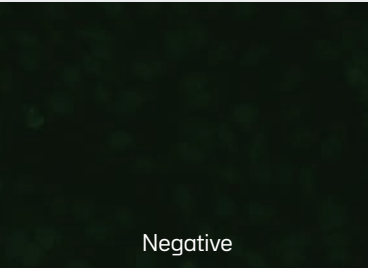
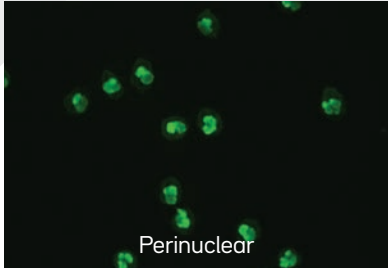
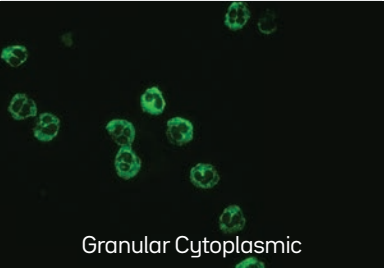
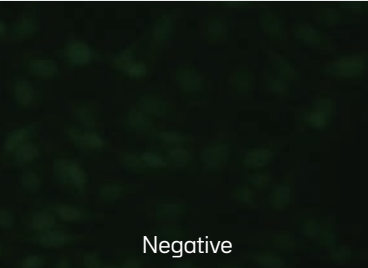

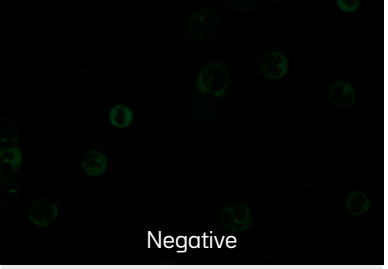

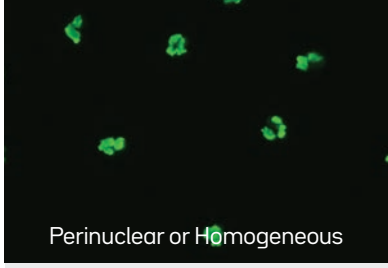
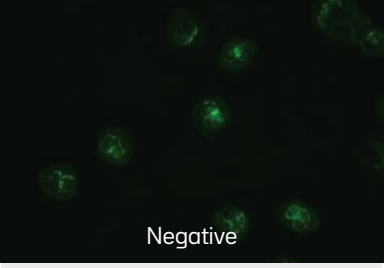
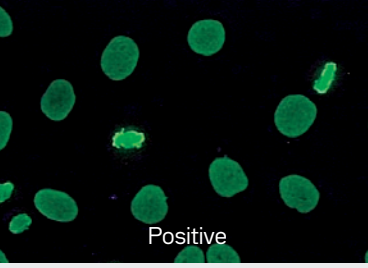
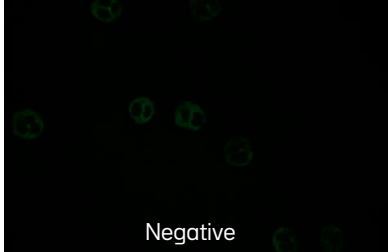
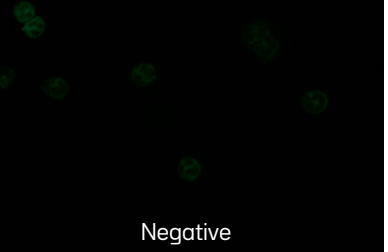
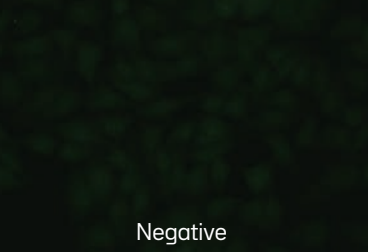
AARD	ANA Associated Rheumatic Disease	PM/DM	Polymyositis/Dematomyositis
CREST	Calcinosis, Raynaud's phenomenon, Esophageal dysmotility, Sclerodactyly, Telangiectasia	RNP	Ribonucleoprotein
ds-DNA	Double Stranded DNA	Scl-70	Scleroderma antigen (70kD)
ENA	Extractable Nuclear Antigen	SS-A	Sjögren's Syndrome A antigen
MCTD	Mixed Connective Tissue Disease	SS-B	Sjögren's Syndrome B antigen
PBC	Primary Biliary Cholangitis	Sm	Smith antigen
PCNA	Proliferating Cell Nuclear Antigen	SjS	Sjögren's Syndrome
		SSC	Systemic Sclerosis

This diagnostic algorithm was assembled by a panel of experts and is based on years of experience in conjunction with published guidelines. It is provided as a guide to aid in the diagnosis of disease based on laboratory results and is not intended as a definitive diagnosis of any disease condition. Please consider all clinical findings when making diagnostic decisions.

Testing strategies provided for informational purposes only. Testing and diagnosis should be determined by a licensed clinician.

ANCA Patterns - Substrate Pattern Chart

ANCA-ASSOCIATED PATTERN CHART

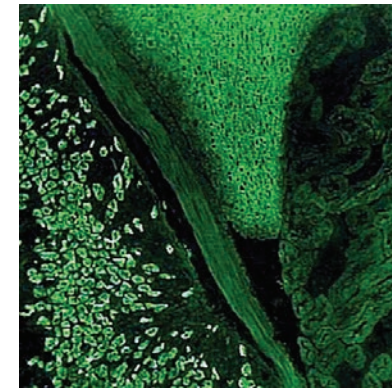
SUBSTRATE	ETHANOL FIXED SLIDE	FORMALIN FIXED SLIDE	HEp-2 SLIDE
C-ANCA*	 Granular Cytoplasmic	 Granular Cytoplasmic	 Negative
P-ANCA*	 Perinuclear	 Granular Cytoplasmic	 Negative
ATYPICAL P-ANCA*	 Very Perinuclear	 Negative	 Negative
ANA POSITIVE	 Perinuclear or Homogeneous	 Negative	 Positive
NEGATIVE	 Negative	 Negative	 Negative

\* Consider confirmatory testing with QUANTA Lite or QUANTA Flash MPO and PR3.

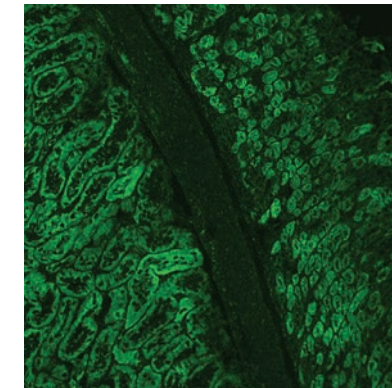
Additional IFA Substrates

Selected Images

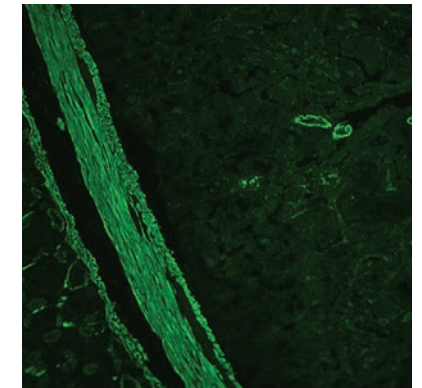
IFA images highlight substrate slides.



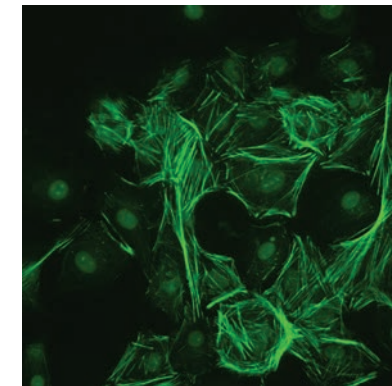
AMA on NOVA Lite  
[rat kidney/stomach/liver]



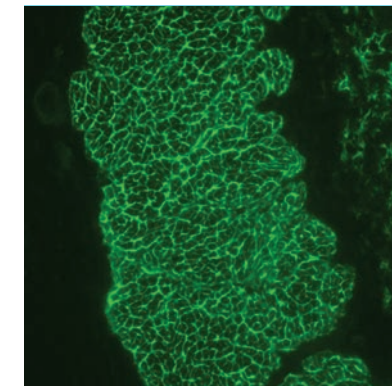
AMA on NOVA Lite ANA KSL



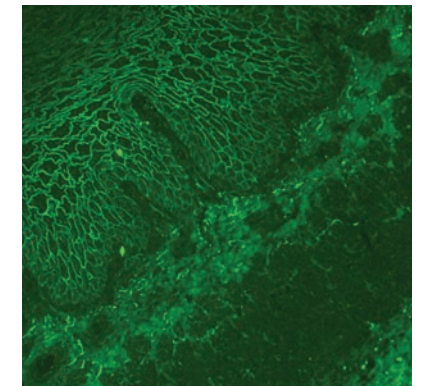
ASMA on NOVA Lite ANA KSL



F-Actin antibody on IEC-6  
NOVA Lite IgG F-Actin



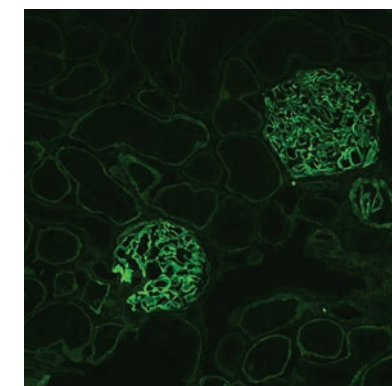
Endomysial antibody on NOVA Lite  
[monkey esophagus]



Pemphigus antibody on NOVA Lite  
Endomysial [primate esophagus]



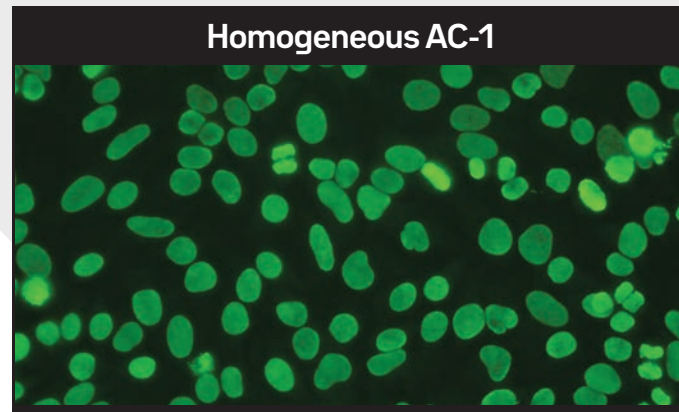
Pemphigoid antibody on NOVA Lite  
Endomysial [primate esophagus]



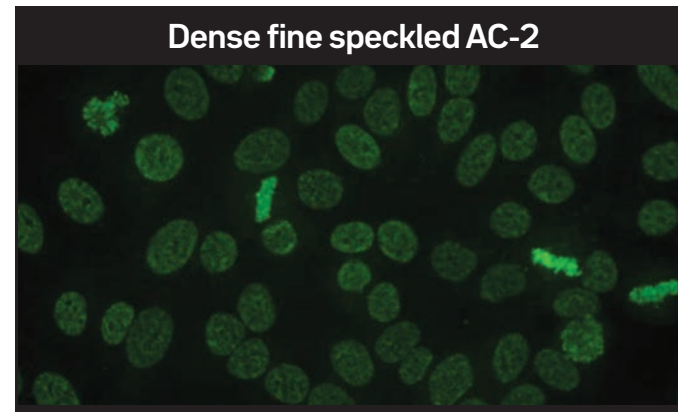
GBM antibody on NOVA Lite GBM  
[primate kidney]

## NOVA Lite HEp-2 Immunofluorescence Patterns

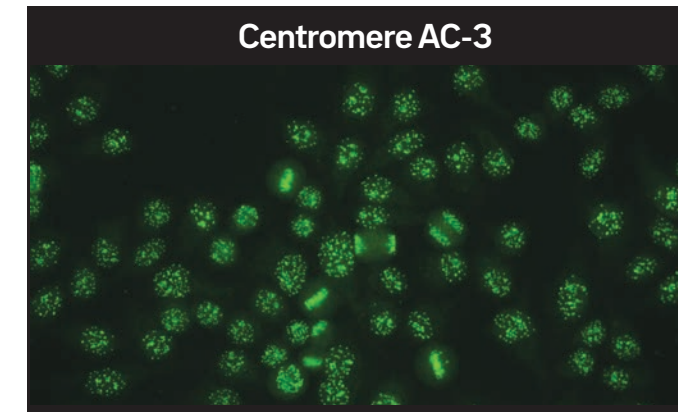
HEp-2 cell substrate provides a valuable test for the screening and titration of circulating autoantibodies in human serum. The ability to identify key patterns aids in the laboratory diagnosis of systemic lupus erythematosus (SLE), Sjögren's Syndrome, Scleroderma and other connective tissue disorders. AC designation refers to the International Consensus on ANA Patterns (ICAP) competent level patterns. [www.ANAPatterns.org](http://www.ANAPatterns.org)



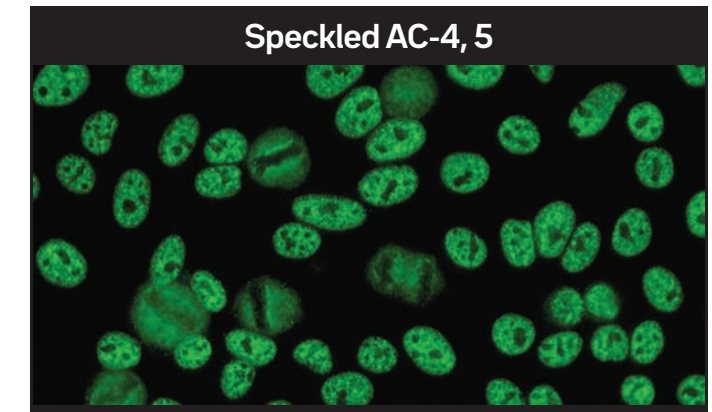
Diffuse uniform staining of interphase cells with chromatin plate of metaphase cells, showing homogeneous staining.



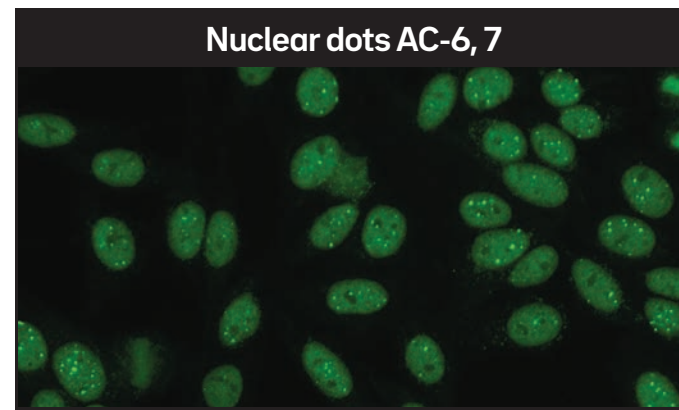
Dense, fine speckled staining of both nucleus of interphase cells and metaphase chromatin plate.



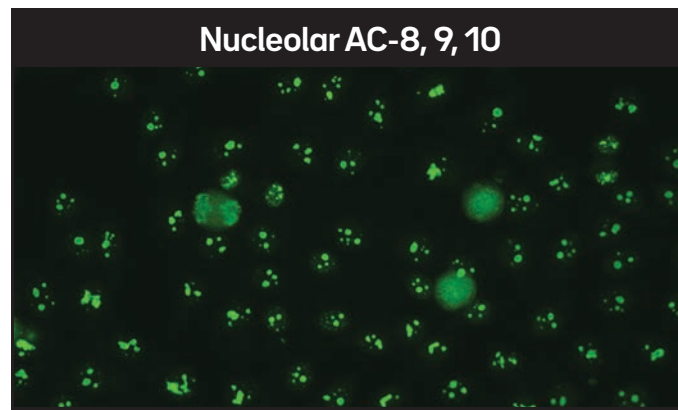
Discrete uniform speckles throughout interphase cell. Mitotic chromatin demonstrates centromere staining.



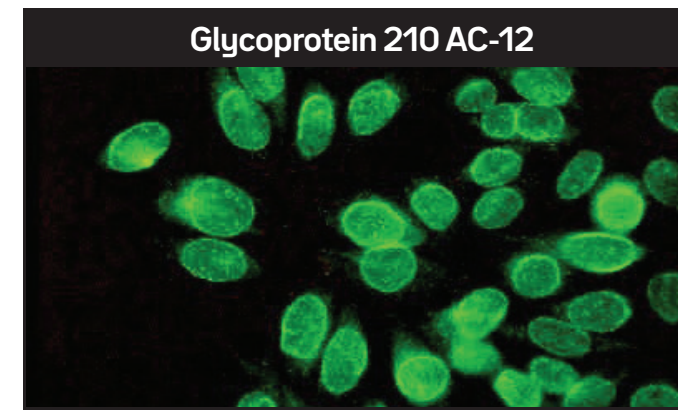
Fine or coarse granular staining in nucleus of interphase cells. Nucleoli and mitotic chromatin show no staining.



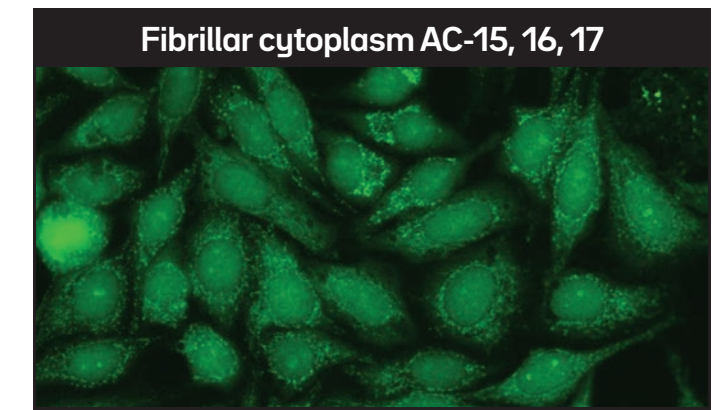
Discrete nuclear dots, seen in nucleus of interphase cells, are 6-20 dots variable in size. Cytoplasmic staining may be observed due to co-existence of mitochondrial antibodies.



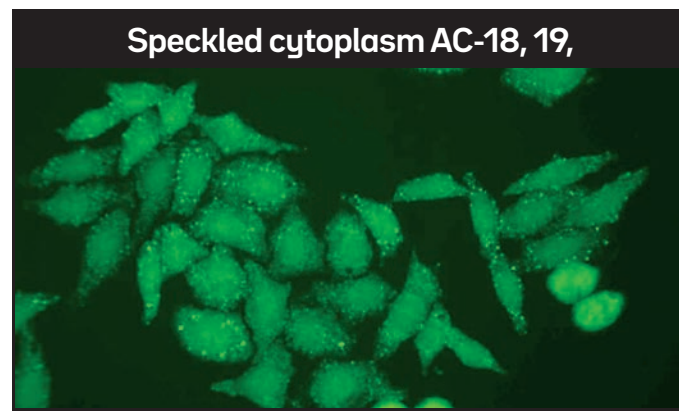
Nuclei of the interphase cells demonstrate fluorescence of nucleoli. Different antibodies can cause nucleoli fluorescence, resulting in various appearances. The metaphase chromatin plate may be negative or positive.



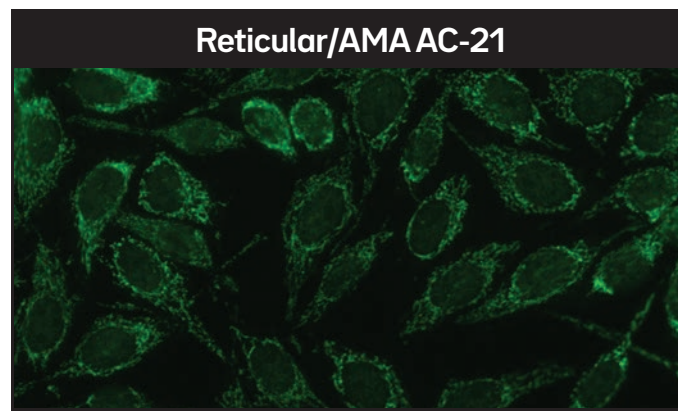
Granular stain of nuclear envelope.



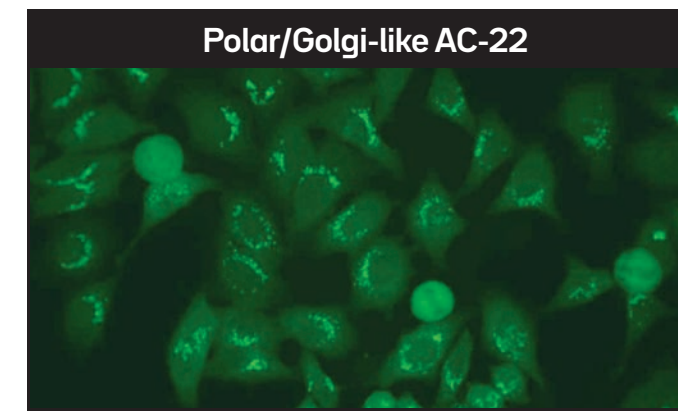
Cytoplasmic staining of linear, filamentous, or segmental patterns.



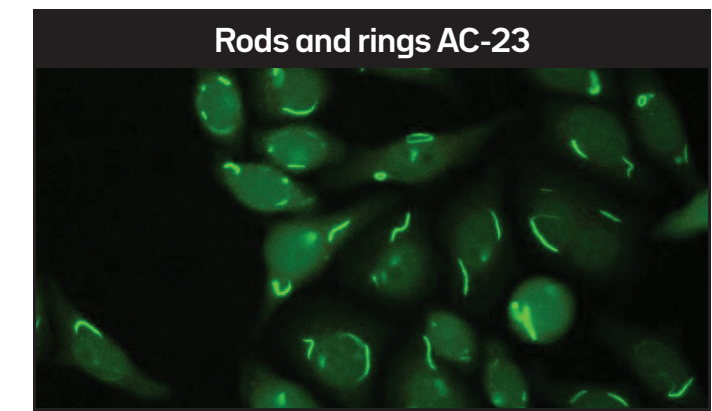
Staining of fine, small speckles scattered in the cytoplasm.



Coarse granular filamentous staining extending from nuclear envelope and tapering off near outer cytoplasm and cell membrane.



Perinuclear staining coarse granules arrangement on one pole of the cell, corresponding to stacks of Golgi complex.



Cytoplasmic staining in two major forms "rods," 3-10 mm in length, or "rings," 2-5 mm in diameter. Associated with HCV under treatment with alpha-interferon and ribavirin.

## NOVA Lite (IFA)

## IFA Slide Kits

NAME	DESCRIPTION	PACKAGE	PART #
NOVA Lite ANCA (Ethanol Fixed)	An indirect immunofluorescent assay for the screening and semi-quantitative determination of anti-neutrophil cytoplasmic IgG antibodies (ANCA) in human serum. The presence of these antibodies can aid in the assessment of various systemic vasculitides. Fluorescein labeled anti-human IgG conjugate with Evan's Blue - ready to use	10 X 6 wells (new formulation)	708299
		(classic formulation)	708290
		20 X 12 wells (new formulation)	708298
		(classic formulation)	708296
NOVA Lite ANCA (Formalin Fixed)	An indirect immunofluorescent assay for the screening and titration of circulating anti- neutrophil cytoplasmic antibodies (ANCA). These antibodies are markers to aid in the diagnosis and treatment of various systemic vasculitides. Fluorescein labeled IgG conjugate with Evan's Blue - ready to use	10 X 6 wells 20 X 12 wells	708295 708297
NOVA Lite HEp-2 ANA	An indirect immunofluorescent assay for the screening and semi-quantitative determination of anti-nuclear IgG antibodies (ANA) in human serum. The presence of these antibodies can aid in the diagnosis of systemic lupus erythematosus (SLE), or other connective tissue or rheumatic diseases. Fluorescein labeled anti-human IgG conjugate with Evan's Blue - ready to use	5 X 12 wells 20 X 12 wells	708101 708100
NOVA Lite dsDNA <i>Crithidia luciliae</i>	An indirect immunofluorescent assay for the screening and semi-quantitative determination of anti-double stranded DNA (dsDNA) IgG antibodies in human serum. The presence of these antibodies can aid in the diagnosis of systemic lupus erythematosus (SLE). Fluorescein labeled anti-human IgG conjugate no Evan's Blue - ready to use	10 X 6 wells 20 X 12 wells	708200 708205
NOVA Lite ANA KSL	An indirect immunofluorescent assay for the screening and semi-quantitative determination of IgG anti-nuclear antibodies (ANA), anti-mitochondrial (AMA), anti-smooth muscle (ASMA) and gastric parietal antibodies (GPA) in human serum. The presence of these antibodies can aid in the diagnosis of systemic lupus erythematosus (SLE), or other connective tissue or rheumatic diseases. Fluorescein labeled anti-human IgG conjugate with Evan's Blue - ready to use	10 X 4 wells 25 X 8 wells	708390 708380

## IFA Slide Kits (continued)

NAME	DESCRIPTION	PACKAGE	PART #
NOVA Lite Rat Liver, Kidney, Stomach	This product is intended for use in the screening and titration of circulating autoantibodies in human serum as an aid in the diagnosis and treatment of various autoimmune diseases. The four major autoantibodies detected are antinuclear antibodies (ANA), antimitochondrial antibodies (AMA), antismooth muscle antibodies (ASMA) and anti-parietal cell antibodies (APCA). Fluorescein labeled anti-human IgG (H&L) conjugate - ready to use	10 X 5 wells 25 X 10 wells	704170 704180
NOVA Lite IgG F-Actin*	An indirect immunofluorescent assay for the screening and semi quantitative determination of IgG anti-F-Actin antibodies in human serum. The presence of IgG anti-F-Actin antibodies can be used in conjunction with clinical findings and other laboratory tests to aid in the diagnosis of autoimmune liver diseases such as autoimmune hepatitis (AIH) and primary biliary cirrhosis (PBC)	5 x 6 wells	708255
NOVA Lite Monkey Esophagus' (IgG and IgA conjugates)	Monkey esophagus sections are intended for use as a substrate for the screening of antibodies to intra-epidermal antigens or basement membrane zones in human serum, as an aid in the diagnosis of pemphigus and bullous pemphigoid respectively. The sections can also be used for detection of endomysial antibodies as an aid in the diagnosis of celiac disease. Fluorescein labeled anti-human IgG (H&L) conjugate and anti-human IgA conjugate - ready to use	10 X 5 wells 25 X 10 wells	704145 704150
NOVA Lite Monkey Esophagus' (IgA conjugate only)	Monkey esophagus sections are intended for use as a substrate for the detection of endomysial antibodies as an aid in the diagnosis of celiac disease. Includes IgA conjugate only. Fluorescein labeled anti-human IgA conjugate - ready to use	25 X 10 wells	704155

\* Monkey and Primate used interchangeably  
\* CE mark only



## NOVA Lite (IFA)

## IFA Slide Kits for Use with NOVA View Automated Digital IFA Microscope

NOVA View uses DAPI as a quality check to determine the presence of cells on each well and to identify the location of the nuclei. In these kits, Evans Blue is replaced with DAPI in the conjugate.

NAME	DESCRIPTION	PACKAGE	PART #
NOVA Lite DAPI ANA Kit	An indirect immunofluorescent assay for the screening and semi-quantitative determination of anti-nuclear IgG antibodies (ANA) in human serum.	20 X 12 wells DAPI conjugate	704320
NOVA Lite DAPI (Ethanol Fixed)	An indirect immunofluorescent assay for the screening and semi-quantitative determination of anti-neutrophil cytoplasmic IgG antibodies (ANCA) in human serum.	20 X 12 wells DAPI conjugate	704338
NOVA Lite DAPI (Formalin Fixed)	An indirect immunofluorescent assay for the screening of circulating anti- neutrophil cytoplasmic antibodies (ANCA).	20 X 12 wells DAPI conjugate	704337
NOVA Lite DAPI dsDNA Crithidia luciliae Kit	An indirect immunofluorescent assay for the qualitative and/or semi-quantitative determination of anti-double stranded DNA (dsDNA) IgG antibodies in human serum.	20 X 12 wells DAPI conjugate	708215
NOVA Lite DAPI EMA Kit* (IgA conjugate only)	Monkey esophagus sections are intended for use as a substrate for the detection of endomysial antibodies as an aid in the diagnosis of celiac disease.	25 X 10 wells	704265

\* CE mark only

## Components

NAME	DESCRIPTION	PACKAGE	PART #
IFA System Negative Control	IFA System Negative Control - ready to use	1 X 1.0 mL	508007
PBS II Concentrate (40X)	40X concentrate of PBS	1 X 25.0 mL	508998
Mounting Medium	Mounting medium - ready to use	1 X 10.0 mL 3 x 10.0 mL	508005 508005.03
Anti AB Neutralising Reagent *	Anti AB Neutralising Reagent	1 X 5.0 mL	504056

\* Item not part of a kit, analytical and performance characteristics are not established.

\* CE mark only

## NOVA Lite (IFA)

## IFA Antibody Controls\*

Designed for use with the NOVA Lite slides. Convenient volumes and ready-to-use.

NAME	DESCRIPTION	PACKAGE	PART #
ANA PCNA Pattern Control	Pre-diluted human serum antibodies to PCNA	1X 0.5 mL	508192
Autoantibody Control Panel	Panel of five vials of pre-diluted controls including ANA Homogeneous/dsDNA Pattern, ANA Speckled Pattern, ANA Nucleolar Pattern, ANA Centromere Pattern and ANA Scl-70 Pattern	5 X 0.5 mL	708180
ANA Homogenous Pattern Control	Pre-diluted human serum antibodies to the cell nucleus	1X 1.0 mL	5040541
ANA Titratable Pattern	Pre-diluted human serum antibodies to the cell nucleus	1X 0.5 mL	508171
dsDNA Positive Control	Pre-diluted human serum antibodies to dsDNA	1X 0.5 mL	508211
Yo (Purkinje Cell) Positive Control	Pre-diluted human serum antibodies to Yo (Purkinje cell)	1X 0.5 mL	504009
Hu ANNA-1 Positive Control	Pre-diluted human ANNA-1 positive control	1X 0.5 mL	504073
Pancreatic Islet Cell Positive Control	Pre-diluted human serum antibodies to pancreatic islet cell	1X 0.5 mL	504005

\* Item not part of a kit, analytical and performance characteristics are not established.

## IFA Conjugates\*

Conjugates are the most critical component of the immunofluorescence assay process.

## Prediluted Antibody Conjugates

NAME	DESCRIPTION	PACKAGE	PART #
FITC IgA Conjugate with EB	Fluorescein labeled anti-human IgA conjugate with Evan's Blue	1X 7.0mL	508153
FITC IgG (H+L) Monkey Adsorbed Conjugate no EB	Fluorescein labeled anti-human monkey adsorbed IgG (H+L) conjugate no Evan's Blue	1X 7.0 mL	504011
FITC IgG Conjugate EB	Fluorescein labeled anti-human IgG conjugate with Evan's Blue	1X 15.0 mL	508113
FITC IgG Conjugate no EB	Fluorescein labeled anti-human IgG conjugate no Evan's Blue	1X 15.0 mL	508114
FITC IgG Conjugate Primate Adsorbed EB	Fluorescein labeled primate adsorbed anti-human IgG conjugate with Evan's Blue	1X 7.0 mL	508128
FITC IgGAM Conjugate no EB	Fluorescein labeled anti-human IgG, IgA and IgM conjugate no Evan's Blue	1X 4.0 mL	508127
FITC IgG Conjugate with DAPI	Fluorescein labeled anti-human IgG conjugate with DAPI	1 x 15.0 mL	508102
FITC IgA Conjugate no EB*	Fluorescein labeled anti-human IgA conjugate no Evan's Blue	1 x 15 mL	504023

\* Item not part of a kit, analytical and performance characteristics are not established.

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[werfen.com](http://werfen.com)

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- Orders: Orders may be placed by fax or e-mail. Please specify the catalog number and product description.
- Shipments: All shipping charges will be prepaid FOB San Diego, CA and added to the invoice. Unless otherwise specified, shipments will be made via Federal Express or UPS. Customers requesting other carriers should specify at the time of order.
- Terms: All invoices are net 30 days unless otherwise prearranged. All invoices are in U.S. dollars.
- Title: Title to the products passes to the customer upon delivery of items ordered to the carrier.
- Loss or damage: Claims for loss or damage of products are the responsibility of the customer and should be reported to Inova at the earliest possible time.

- Partial shipments: Werfen will make every possible attempt to fill orders promptly and completely. When this cannot be done, we will make partial shipments unless otherwise notified at the time of order confirmation.
- Returns: Prior to returning any products, customers must contact Werfen technical services for approval. Please provide the reason for the return (ordering error, shipping error, technical problem, etc.). A restocking fee may apply.
- Conditions: Unless otherwise indicated the products listed herein are for 'in vitro' diagnostic use only. Nothing disclosed herein is to be construed as a recommendation to use our products in violation of any patents. The information presented is believed to be accurate. However, said information and products are offered without warranty or guarantee since the ultimate conditions of use and the variability of the materials tested are beyond our control. We cannot be responsible for patent infringements or other violations that may occur with the use of these products.

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