

NOVA Lite (IFA)



Barcoded Slides

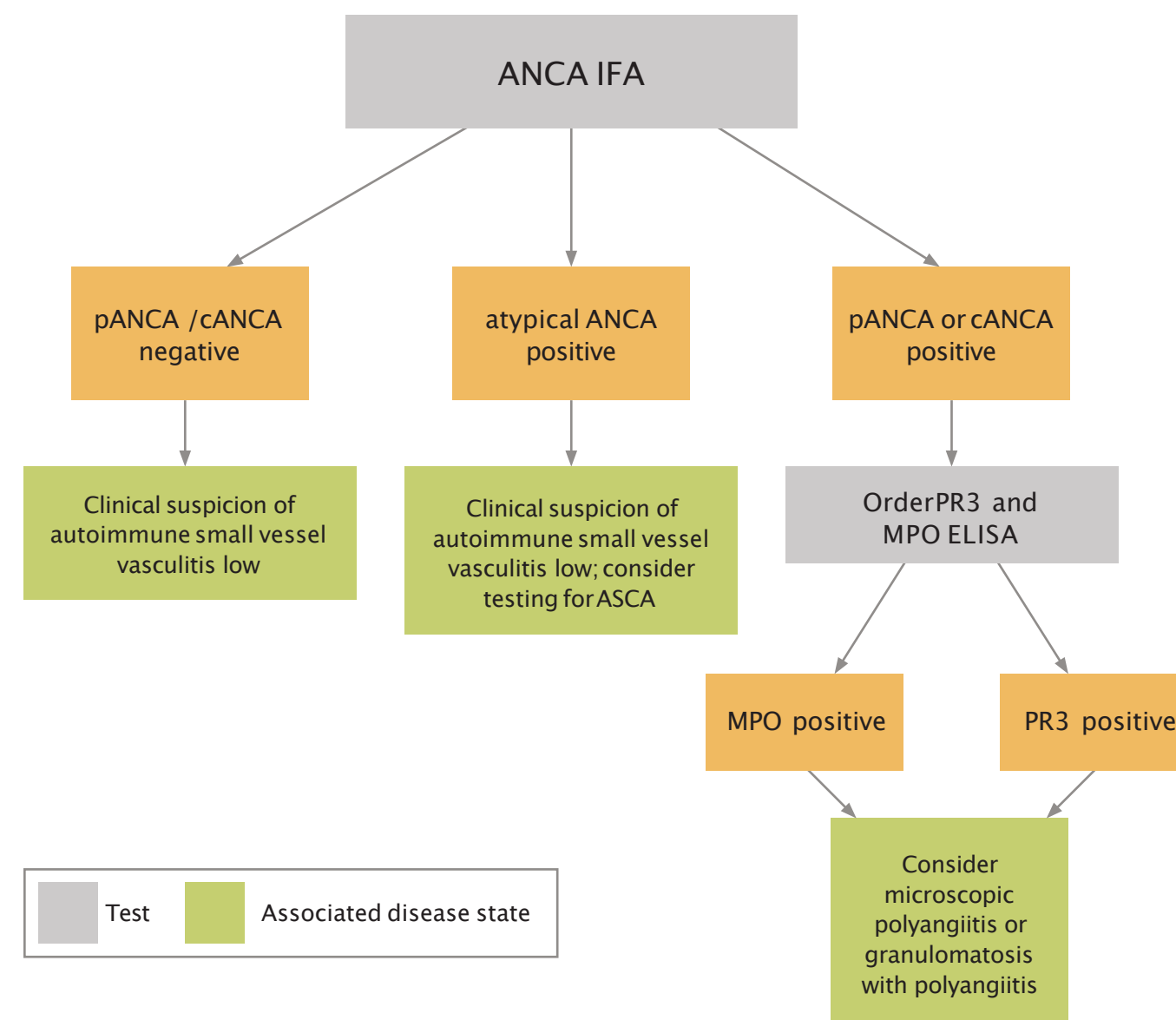
Barcoded slides, in combination with QUANTA Link software and QUANTA-Lyser:

- 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.

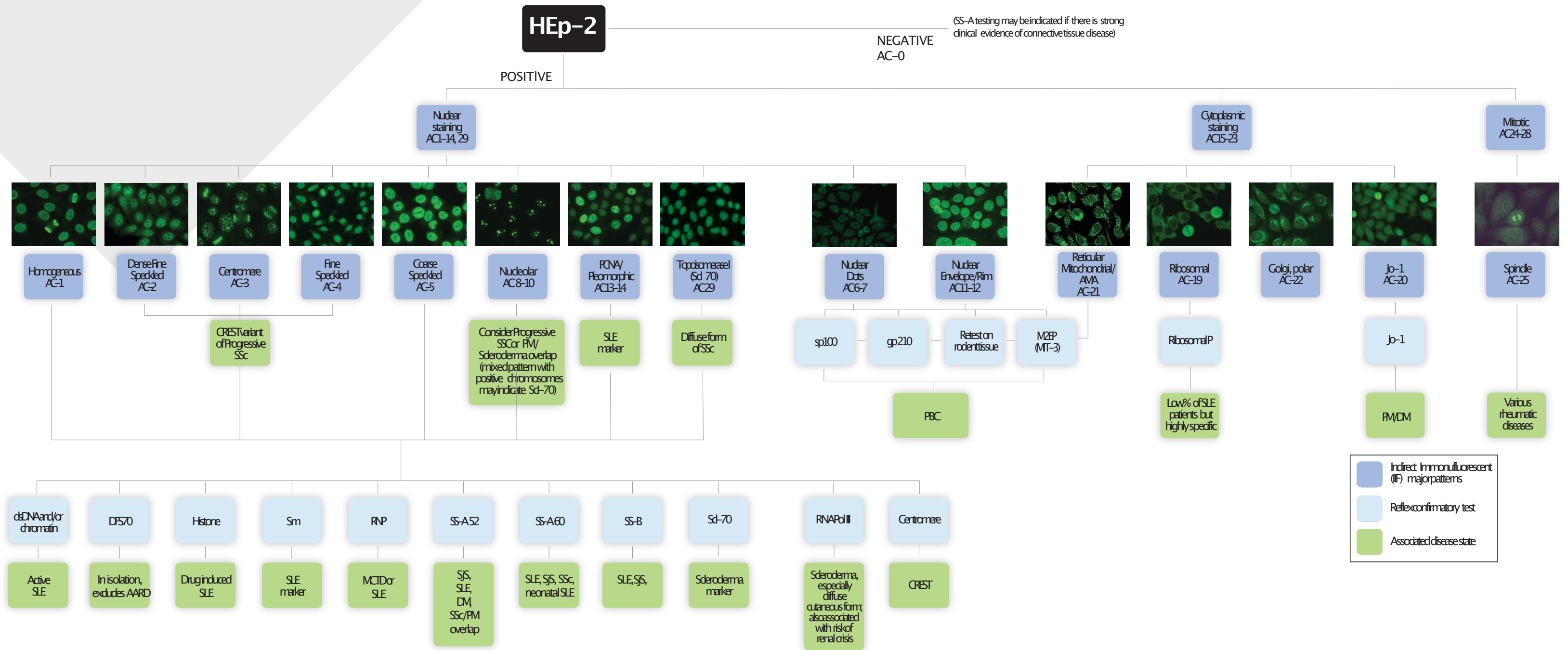
Potential Testing Algorithm for Vasculitis



Abbreviations
 MPO myeloperoxidase
 PR-3 proteinase 3
 ANCA anti-neutrophilcytoplasmic 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

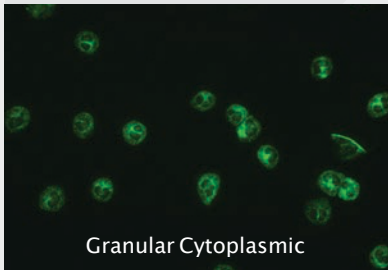
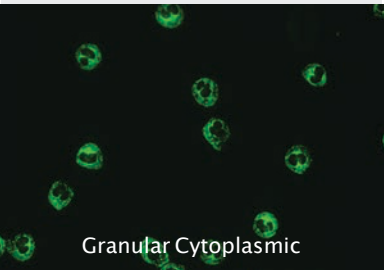
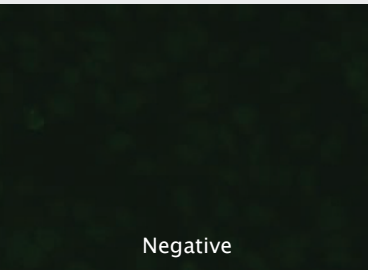


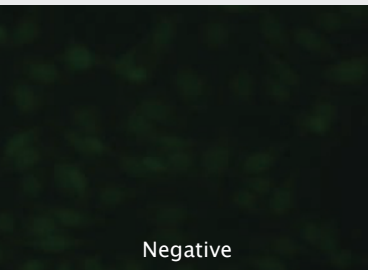

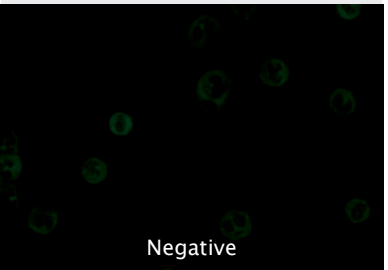

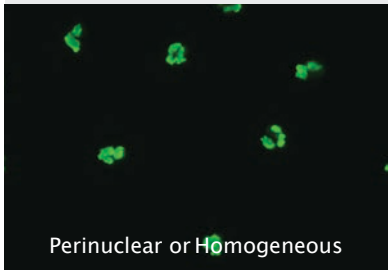
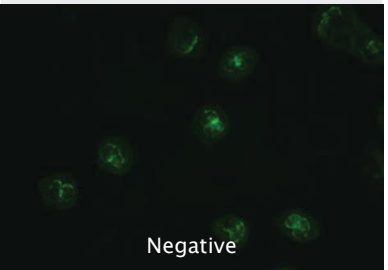
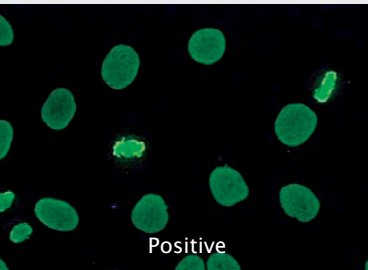
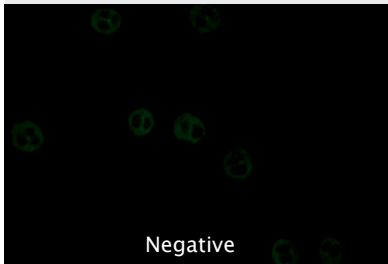
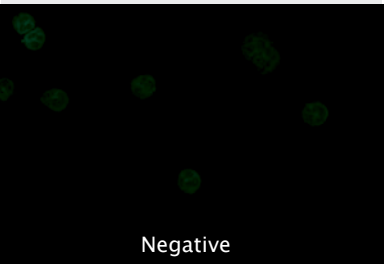
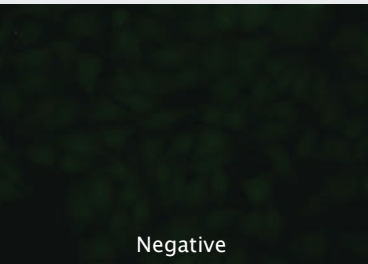
AARD	ANA Associated Rheumatic Disease	PM/DM	Polymyositis/Dematomyositis
CREST	Calcinosis, Raynaud's phenomenon, Esophageal dysmotility, Sclerodactyly, Telangiectasia	RNP	Ribonucleoprotein
ds-DNA	Double Stranded DNA	Scl-70	Scleroderma antigen (70kD)
ENA	Extractable Nuclear Antigen	SS-A	Sjögren's Syndrome 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.

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ANCA Patterns –Substrate Pattern Chart

ANCA-ASSOCIATED PATTERN CHART

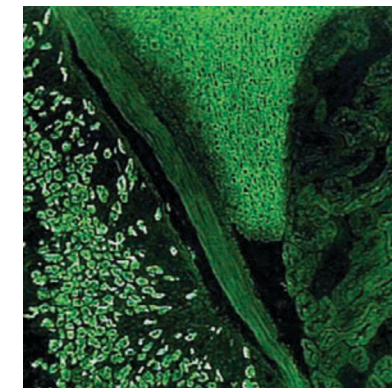
SUBSTRATE	ETHANOL FIXED SLIDE	FORMALIN FIXED SLIDE	HEp-2 SLIDE
C-ANCA*	 Granular Cytoplasmic	 Granular Cytoplasmic	 Negative
P-ANCA*	 Perinuclear	 Granular Cytoplasmic	 Negative
ATYPICAL P-ANCA*	 Very Perinuclear	 Negative	 Negative
ANA POSITIVE	 Perinuclear or Homogeneous	 Negative	 Positive
NEGATIVE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

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

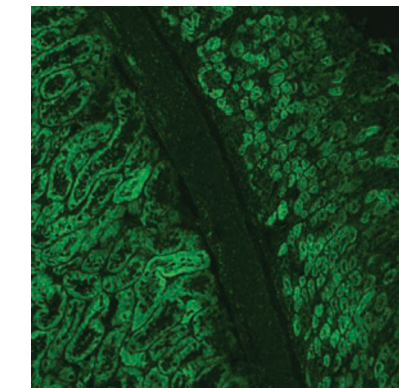
Additional IFA Substrates

Selected Images

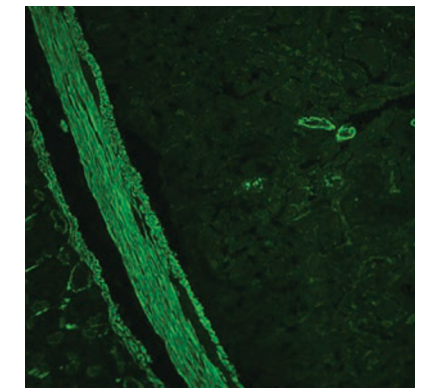
IFA images highlight substrate slides.



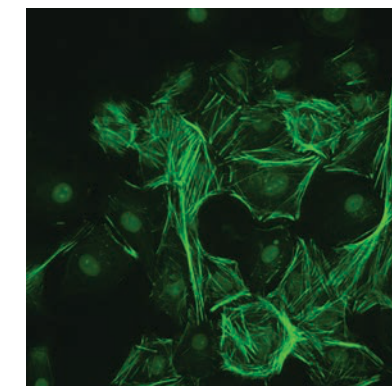
AMA on NOVA Lite (rat kidney/stomach/liver)



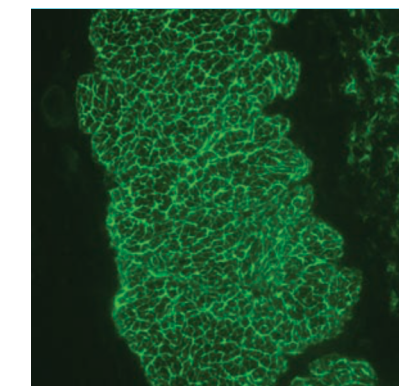
AMA on NOVA Lite ANA KSL



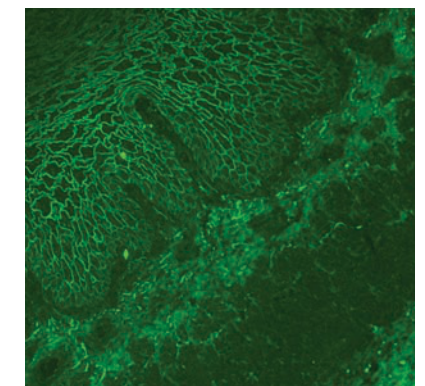
ASMA on NOVA Lite ANA KSL



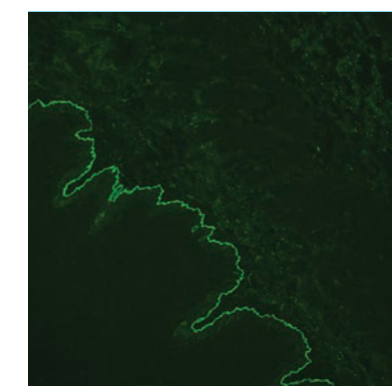
F-Actin antibody on IEC-6 NOVA Lite IgG F-Actin



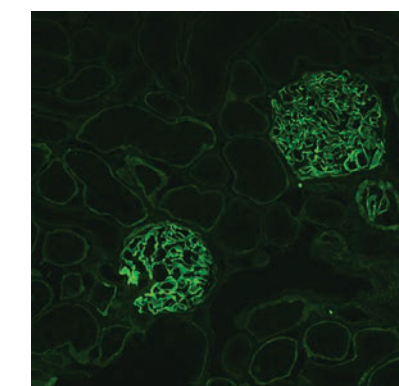
Endomysial antibody on NOVA Lite (monkey esophagus)



Pemphigus antibody on NOVA Lite Endomysial (primate esophagus)



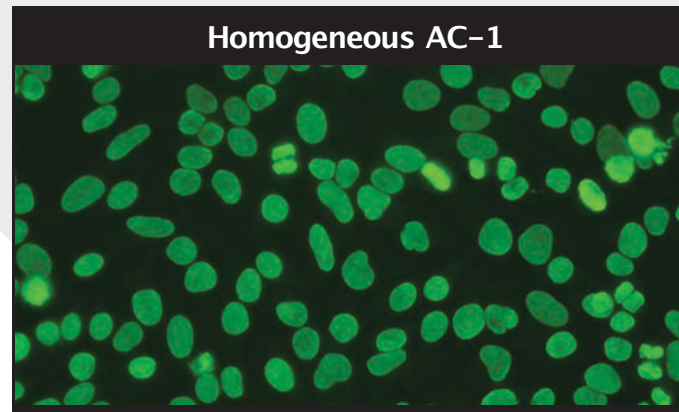
Pemphigoid antibody on NOVA Lite Endomysial (primate esophagus)



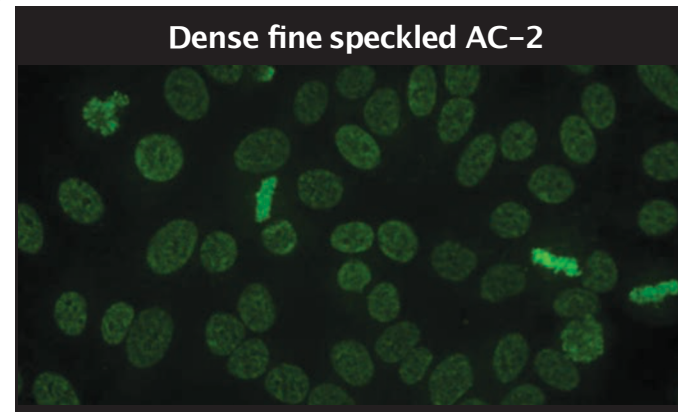
GBM antibody on NOVA Lite GBM (primate kidney)

NOVA Lite HEp-2 Immunofluorescence Patterns

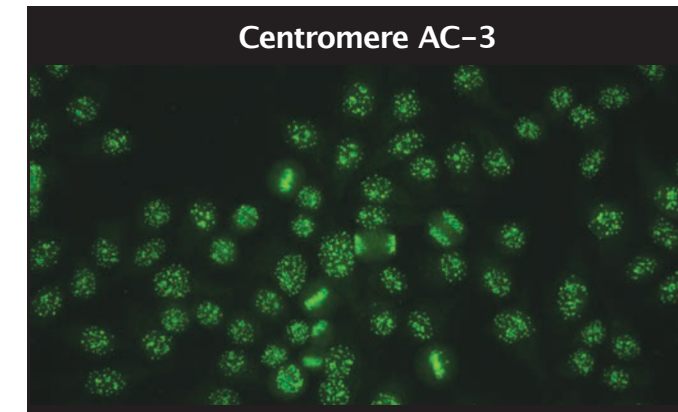
HEp-2 cell substrate provides a valuable test for the screening and titration of circulating autoantibodies in human serum. The ability to identify key patterns aids in the laboratory diagnosis of systemic lupus erythematosus (SLE), Sjögren's Syndrome, Scleroderma and other connective tissue disorders.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



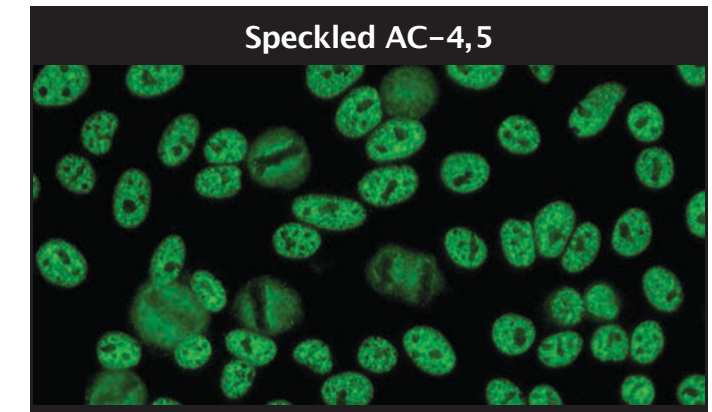
Diffuse uniform staining of interphase cells with chromatin plate of metaphase cells, showing homogeneous staining.



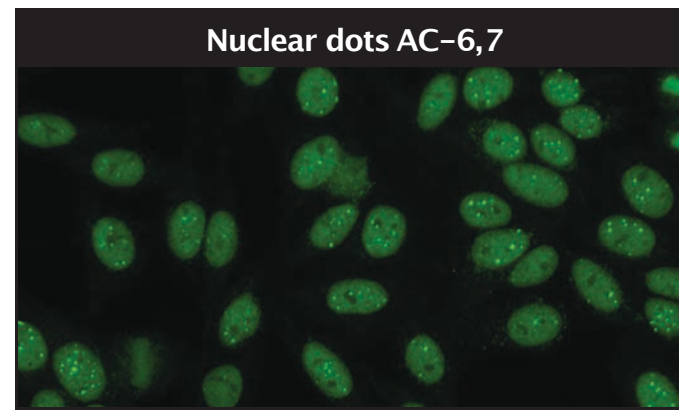
Dense, fine speckled staining of both nucleus of interphase cells and metaphase chromatin plate.



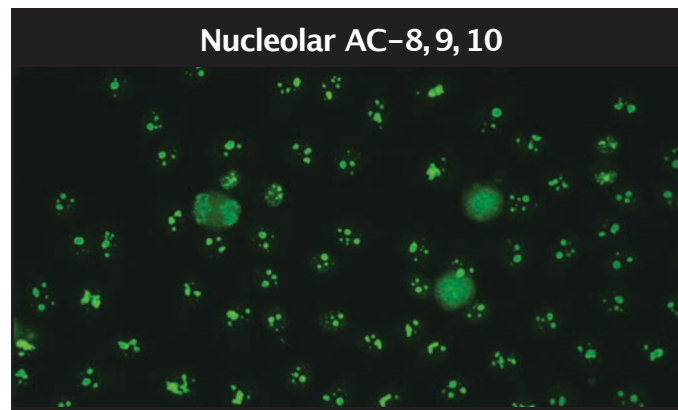
Discrete uniform speckles throughout interphase cell. Mitotic chromatin demonstrates centromere staining.



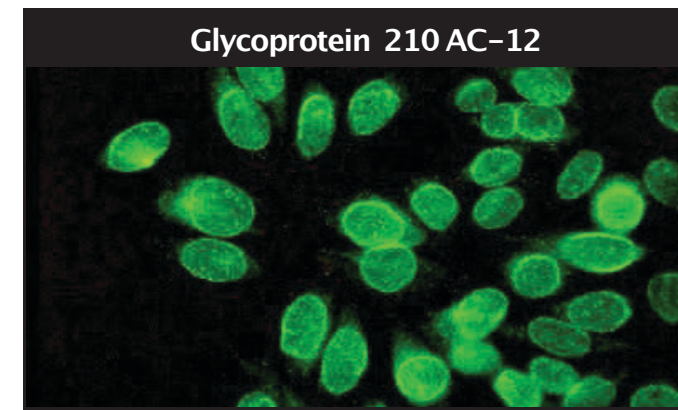
Fine or coarse granular staining in nucleus of interphase cells. Nucleoli and mitotic chromatin show no staining.



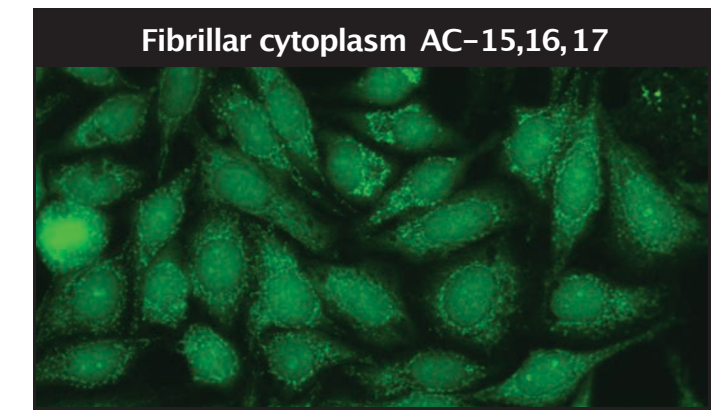
Discrete nuclear dots, seen in nucleus of interphase cells, are 6-20 dots variable in size. Cytoplasmic staining may be observed due to co-existence of mitochondrial antibodies.



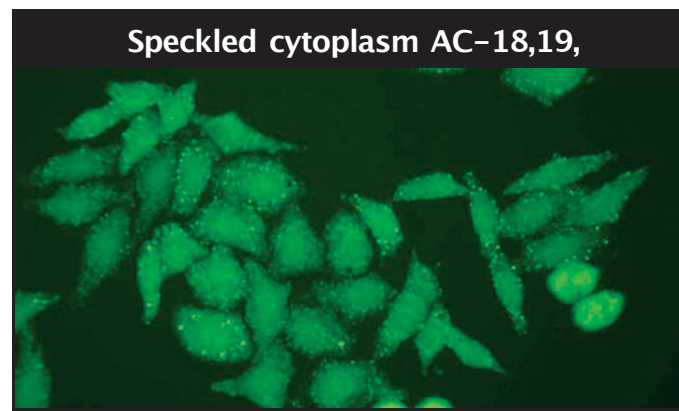
Nuclei of the interphase cells demonstrate fluorescence of nucleoli. Different antibodies can cause nucleoli fluorescence, resulting in various appearances. The metaphase chromatin plate may be negative or positive.



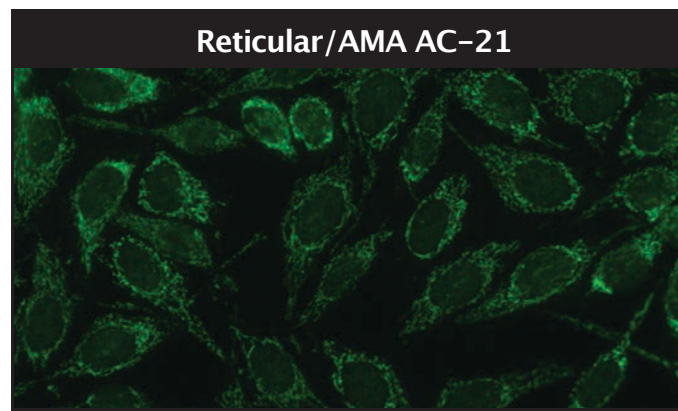
Granular stain of nuclear envelope.



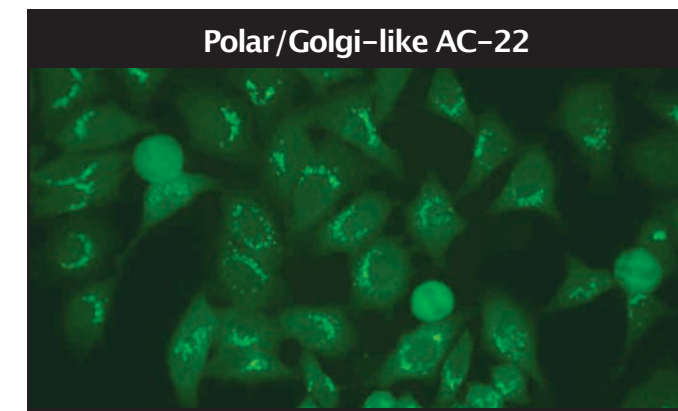
Cytoplasmic staining of linear, filamentous, or segmental patterns.



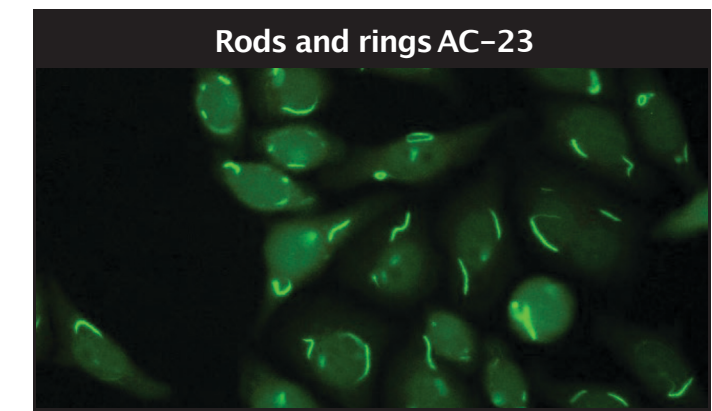
Staining of fine, small speckles scattered in the cytoplasm.



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
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	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 Crithidia luciliae	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 12wells 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 12wells DAPI conjugate	704338
NOVA Lite DAPI (Formalin Fixed)	An indirect immunofluorescent assay for the screening of circulating anti-neutrophil cytoplasmic antibodies (ANCA).	20 X 12wells DAPI conjugate	704337
NOVA Lite DAPI dsDNA Crithidia luciliae Kit	An indirect immunofluorescent assay for the qualitative and/or semi-quantitative determination of anti-doublestranded DNA (dsDNA) IgG antibodies in human serum.	20 X 12wells 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 10wells	704265

*CE mark only

Components

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

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

*CE mark only

Autoimmunity

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.