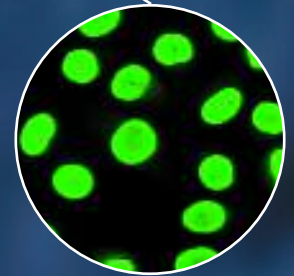
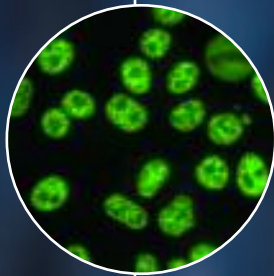
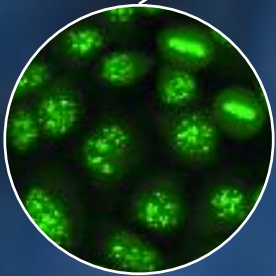


 **immuno  
concepts®**

# CATALOG



**800-251-5115 • 916-363-2649**

# COMPANY HISTORY

Immuno Concepts was founded in 1979 with a commitment to advance the quality of diagnostic assays for systemic rheumatic diseases. Over twenty years later we still honor that commitment. Our company motto, "Quality People Setting the Quality Standard", further reflects this commitment. We are proud to display that we have a quality system that is certified to ISO 13485 and we are actively pursuing CE mark certification for our products.

In 1979 Immuno Concepts pioneered the conversion from rodent tissue to HEp-2 cells for detection of anti-nuclear antibodies (ANA's). Using genetic engineering we developed HEp-2000<sup>®</sup>, an ANA substrate with increased sensitivity for detection of auto antibodies to SS-A/Ro. The advantages of the HEp-2000<sup>®</sup> substrate over conventional HEp-2 have been documented in several published papers from well-known institutions and are discussed later in this catalog. Immuno Concepts was the first company to offer a non-fluorescent ANA. Our Colorzyme<sup>®</sup> methodology uses a patented stabilized color reagent system that allows slide-based assays to be read using common bright field microscopy. The Colorzyme<sup>®</sup> format is available for ANA, nDNA and EBV assays.

From the beginning Immuno Concepts has been committed to education. Each year we offer workshops to educate clinicians and laboratorians on the valuable information that can be gained from the proper use of ANA and related testing. We offer self-help training in the form of our Visions<sup>™</sup> II and III Training Series, pattern atlases, and pocket guides. Our Physician Pocket Guide is offered free of charge to clinicians and laboratories world wide to assist them in maintaining their levels of expertise.

Today the laboratory is an ever-changing environment. With advancements in ELISA assays and increased attention being paid to the bottom-line, laboratory management are facing complex options. Immuno Concepts is ready to assist you in understanding these options and selecting what is best for your laboratory. As you will see on the following pages, we offer many options in methodology and kit configuration.

We would like to thank you for your vote of confidence that has allowed us to serve you over the many years and we will continue to work hard to deserve your trust.



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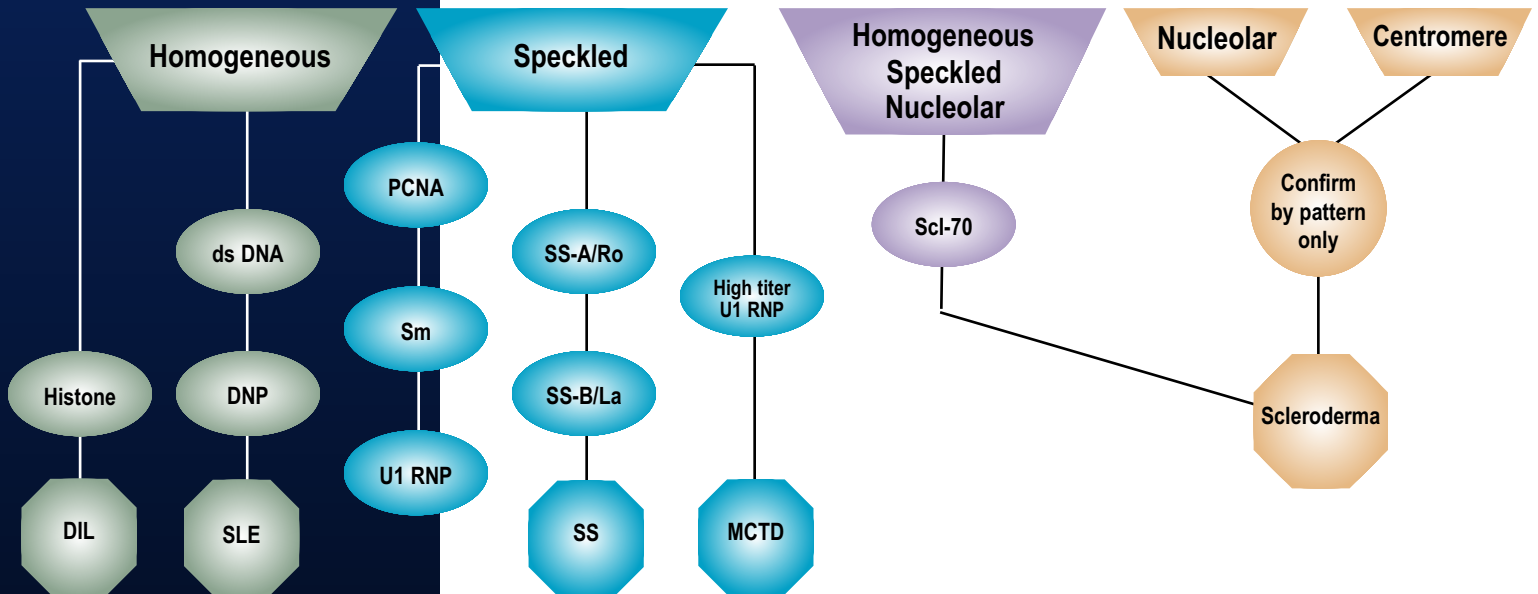
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# SYSTEMIC RHEUMATIC DISEASE

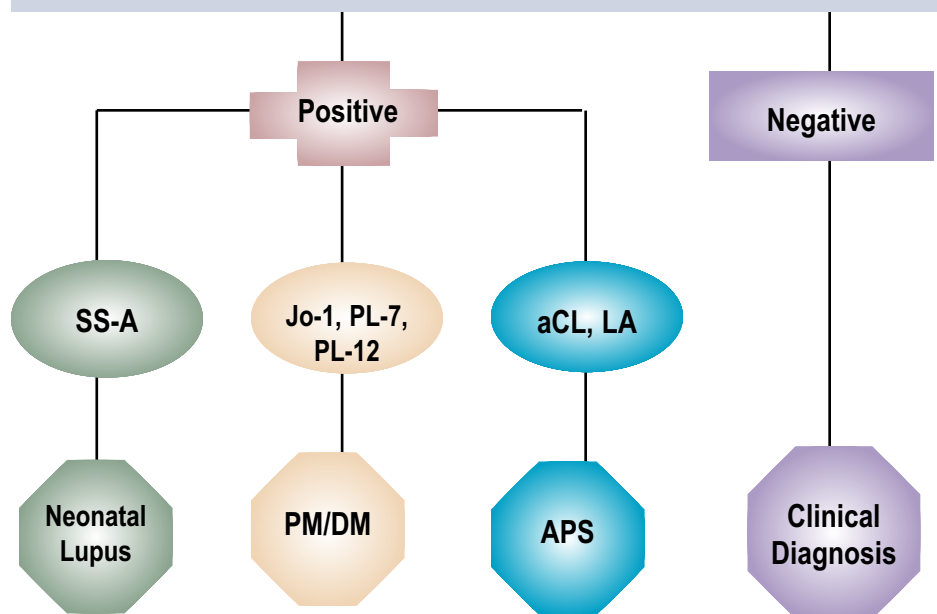
## ANA POSITIVE

The charts presented here are designed as a guide to pattern recognition, antigen specificity and disease association.



## ANA NEGATIVE

If the ANA is negative, but disease is suspected, test for specific autoantibodies.



# SUMMARY OF ANTINUCLEAR ANTIBODY DETECTION

Pattern observed by indirect immuno fluorescence	Type of antibody	Disease(s) in which antibodies are seen	Characteristics of antigenic determinants	Tests used to confirm specific antibody
Homogeneous or peripheral	React with double stranded DNA (nDNA, dsDNA)	Characteristic of SLE, lower levels in other rheumatic diseases	Double-stranded DNA	IFA or Colorzyme using <i>Crithidia luciliae</i> , RIA, ELISA
	Nucleohistone	SLE, Drug-induced lupus	DNA-histone complex	RIA, ELISA
	Histone	Drug-induce LE, SLE	Different classes of histone	ELISA, RIA, WB,
Atypical Homogeneous	Nuclear Membrane	Lupoid hepatitis	Nuclear Lamins A, B, C and gp210	WB
Speckled	Sm	Marker antibody for SLE	Proteins B', B, D, E, F and G complexed with U1, U2, U5, U4/6 RNP	ID, ELISA, WB, IP
	U1-RNP	High levels in MCTD and SLE, low levels in other rheumatic diseases	70 kDa, A and C proteins	ED, ELISA, WB, IP
	SS-A (Ro)	High prevalence in Sjögren's syndrome sicca complex, lower prevalence in other rheumatic diseases	52 and 60 kDa proteins complexed with Y1-Y5 RNA's	HEp-2000 <sup>®</sup> staining pattern is confirmatory ,ID, ELISA, WB, IP, CIEP
	SS-B (La)	High prevalence in Sjögren's syndrome sicca complex, lower prevalence in other rheumatic diseases	48 kDa protein complexed with RNA with RNA polymerase III	ID ELISA, CIEP, IP, WB
	Scl-70	Marker antibody for scleroderma	100 kDa protein of topoisomerase I	ID, ELISA, WB
	PCNA	Marker antibody for SLE	Auxiliary protein to DNA polymerase $\theta$	ID, CIEP
	Nuclear Matrix	Seen in some patients with evolving connective tissue disease	hnRNP and other antigens	None
Atypical Speckled	NSp I, sp-100, MND, PBC 95	Associated with Primary Biliary Cirrhosis	95-100 kDa protein	WB
	NSpII, CENP F	Unknown, some association with malignancies	400 kDa protein	WB
	Midbody	Low percentage of patients with scleroderma		Confirmed by staining pattern
	p80 (coilin)	Unknown	80 kDa protein in the coiled body	WB
Centromere	Centromere	Seen in 57-82% of patients with limited form (CREST) of scleroderma and Raynaud's phenomenon	CENP A, CENP B, CENP C	Confirmed by staining pattern, WB
Nucleolar	Clumpy Nucleolar	Scleroderma	Fibrillarin, others?	WB, IP
	Speckled Nucleolar	Scleroderma and other connective tissue diseases	RNA polymerase I, NOR-90, others?	WB
	Smooth Nucleolar	Polymyositis/Scleroderma	PM-1 (PM/Scl), others?	WB

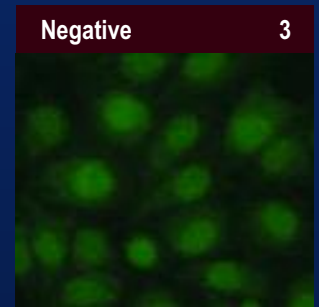
# SELECT FLUORESCENT ANA PATTERNS



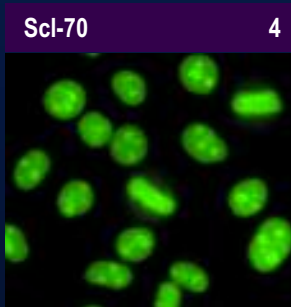
**Report as:** Homogeneous  
**Suspected antigen specificity:** nDNA, DNP, Histone, DNA binding proteins, others?  
**Clinical significance:** nDNA positive: Marker antibody seen in 60% of SLE patients  
**Follow-up testing:** Confirm nDNA antibodies



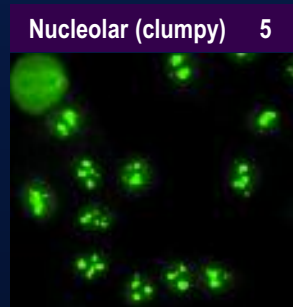
**Report as:** Atypical Homogeneous/Nuclear membrane  
**Suspected antigen specificity:** Nuclear lamins, others?  
**Clinical significance:** May be seen in patients with SLE, RA, autoimmune hepatitis  
**Follow-up testing:** None required



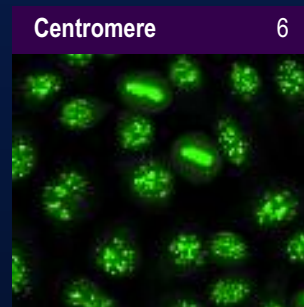
**No clearly discernible pattern seen**  
**Report as:** ANA negative  
**Follow-up testing:** If applicable, specific testing for SS-A/Ro, Jo-1 and other antibodies is suggested.



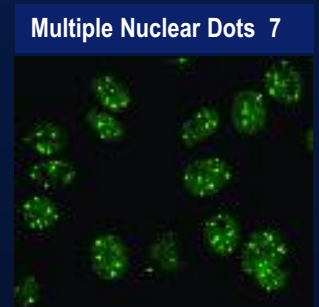
**Report as:** Homogeneous, Speckled, and Nucleolar  
**Suspected antigen specificity:** Topoisomerase I  
**Clinical significance:** Topoisomerase I positive: Marker antibody seen in 15-20% of patients with scleroderma  
**Follow-up testing:** Confirm by ENA testing



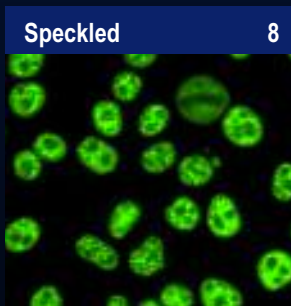
**Report as:** Nucleolar  
**Suspected antigen specificity:** Fibrillarin, others?  
**Clinical significance:** Seen in patients with scleroderma  
**Follow-up testing:** None required



**Report as:** Centromere  
**Suspected antigen specificity:** Centromere  
**Clinical significance:** Seen in 57-96% of patients with the CREST variant of scleroderma  
**Follow-up testing:** None required, pattern confirmed by ANA staining pattern



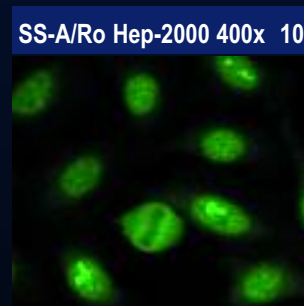
**Report as:** Atypical Speckled  
**Suspected antigen specificity:** 95-100 kD Protein  
**Clinical significance:** Seen in 27-44% of patients with PBC  
**Follow-up testing:** None required



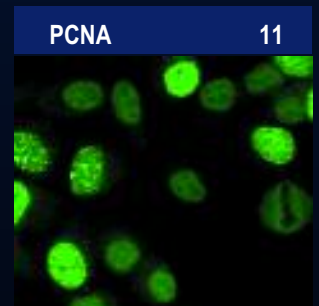
**Report as:** Speckled  
**Suspected antigen specificity:** Sm, RNP, others  
**Clinical significance:** Sm positive: Marker antibody seen in 4-40% of SLE patients. RNP positive: Seen in high titers in patients with MCTD and SLE  
**Follow-up testing:** Confirm by ENA testing



**SS-A/Ro positive pattern on HEp-2000® substrate:** A distinct bright speckled pattern with predominant staining of the nucleoli in 10-20% of the interphase nuclei. These are the hyperexpressing cells. The remaining 80-90% of the interphase cells may or may not demonstrate a fine speckled and nucleolar staining pattern. In the metaphase mitotic cells, the non-chromosome region demonstrates staining while the chromosomal region is negative.



**Report as:** SS-A/Ro pattern  
**Suspected antigen specificity:** SS-A/Ro  
**Clinical significance:** SS-A/Ro positive: Seen in 60-70% of primary Sjögren's Syndrome patients, 30-40% of lupus patients  
**Follow-up testing:** This pattern is confirmatory for SSA/Ro antibodies. Suggest ENA testing to rule out the presence of antibodies to other ENA's.



**Report as:** Speckled, possible PCNA  
**Suspected antigen specificity:** DNA polymerase  $\delta$  (cyclin)  
**Clinical significance:** PCNA positive: Marker antibody seen in 2-10% of SLE patients  
**Follow-up testing:** Confirm by ENA testing

*Immuno Concepts manufactures slides that are compatible with multichannel pipettors, which allows the technologist to decrease the number of pipetting steps required to prepare and place the patient sample dilutions on the slides. Ask Immuno Concepts for more information about this procedure and these slides. These slide formats are noted with an "\*" after the catalog number, and are available in both fluorescent and Colorzyme® test kits.*

For ease of use, Immuno Concepts' ANA test kits feature ready-to-use conjugates and controls, and come with...

- Substrate slides
- Positive pattern controls
- Titratable control referenced to the WHO standard
- Negative control
- Conjugate
- PBS
- Mounting medium

A number of different kit and slide formats are available in addition to those listed in the catalog. Please ask Immuno Concepts or your local representative for these other options.

## HEP-2000® ANA

HEP-2000® ANA uses a patented HEp-2 cell line that has been genetically engineered to increase the sensitivity to SS-A/Ro autoantibodies, without affecting the other ANA patterns seen. Several independent studies have been published worldwide on the HEP-2000® ANA substrate, which show increased sensitivity to SS-A/Ro autoantibodies when used in place of standard HEp-2 cells as the routine ANA screening test.<sup>1,2,3,4</sup>

- Genetically engineered HEp-2 cells hyperexpress the native 60kD SS-A/Ro antigen
- Differentiation of positive SS-A/Ro samples by the distinctive staining pattern
- Increased concentration of SS-A/Ro antigen detects more SS-A/Ro positive samples<sup>1</sup>
- Considered as confirmatory for SS-A/Ro autoantibodies when distinctive hyperexpressing pattern is seen
- HEP-2000® cells exhibit the same ANA patterns for all of the other antibody specificities as HEp-2 cells

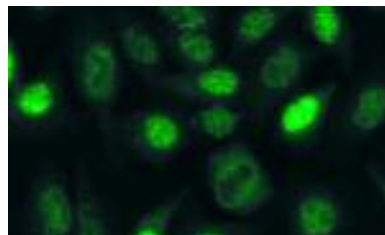
1. Fritzier M. J., Miller B. J. Detection of Autoantibodies to SS-A/Ro by Indirect Immunofluorescence Using a Transfected and Overexpressed Human 60 kD RoAutoantigen in HEp-2 Cells. J. Clin. Lab. Anal. 9:218-224, 1995.
2. Keech C. L., Howarth S., Coates T., Rischmueller M., McCluskey J., Gordon T. P. Rapid and Sensitive Detection of Anti-Ro (SS-A) Antibodies by Indirect Immunofluorescence of 60kDa Ro HEp-2 Transfectants. Pathology 28:54-57, 1996.
3. Keech C. L., McCluskey J., Gordon T. P. Transfection and Overexpression of the Human 60-kDa Ro/SS-A Autoantigen in HEp-2 Cells. Clin. Immunol. Immunopathol. 73:146-151, 1994.
4. Pollock, W. and Toh, B.H. Routine immunofluorescence detection of Ro/SS-A autoantibody using HEp-2 cells transfected with human 60 kDa Ro/SS-A. J.Clin.Pathol. 52:684-687, 1999.

# FLUORESCENT HEP-2000® ANA

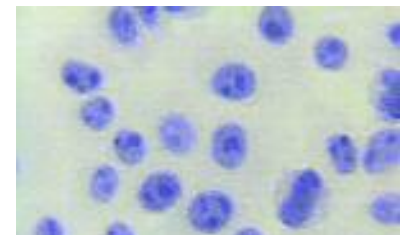
HEp-2000® ANA uses a patented HEp-2 cell line that has been genetically engineered to increase the sensitivity to SS-A/Ro autoantibodies, without affecting the other ANA patterns seen. Several independent studies have been published worldwide on the HEp-2000® ANA substrate, which show increased sensitivity to SS-A/Ro autoantibodies when used in place of standard HEp-2 cells as the routine ANA screening test.<sup>1,2,3</sup>

- Enhanced detection of SS-A/Ro autoantibodies
- Includes a positive SS-A/Ro control as recommended in NCCLS document I/LA2-A, "Quality Assurance for the Indirect Immunofluorescence Test for Autoantibodies to Nuclear Antigen (IF-ANA); Approved Guideline".
- Abundant easy-to-read mitotic cells
- Clear pattern identification
- Ready-to-use pattern controls and conjugates
- Positive pattern controls for:
  - homogeneous
  - centromere
  - SS-A/Ro
  - speckled
  - nucleolar
- Titratable control referenced to the WHO standard 66/233 for ANA

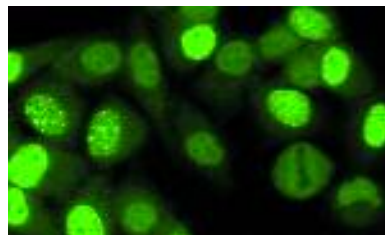
The following pictures illustrate several of the patterns seen on the Fluorescent HEp-2000® ANA.



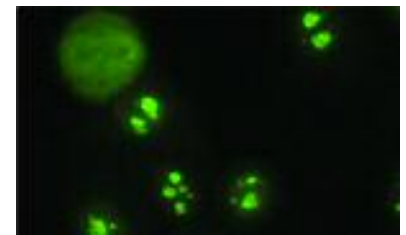
SS-A/Ro



Scl-70



PCNA



Nucleolar

## ORDERING INFORMATION

2040-Ro	10	x	7	wells
2100-Ro	10	x	13	wells
2200-Ro	20	x	13	wells
2200-14-Ro*	20	x	14	wells
2000-Ro	100	x	13	wells
2000-14-Ro*	100	x	14	wells

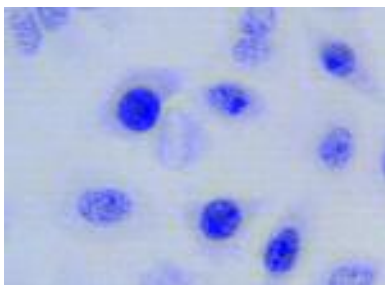
*Other kit configurations are available upon request*



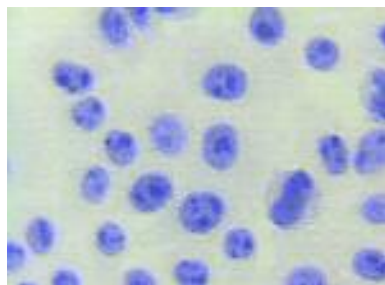
# COLORZYME® HEP-2000® ANA

Colorzyme HEP-2000® uses a patented color reagent system that eliminates the variability seen with fluorescent methods such as type of light source, filters and extraneous room light.

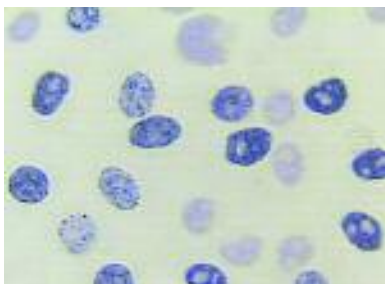
- Enhanced detection of SS-A/Ro autoantibodies
- An immunoenzyme technique using a patented color reagent system
- Results can be read on a standard light microscope
- Stable color reaction allows for storage of slides for later review
- Uses the same HEP-2000® substrate as our fluorescent test system
- Easy to read sharp clear patterns



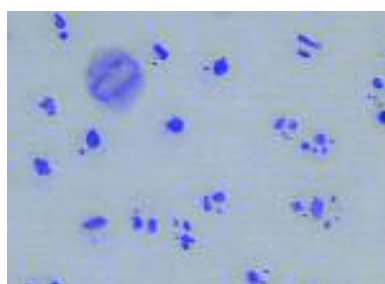
SS-A/Ro



Scl-70



PCNA



Nucleolar

## ORDERING INFORMATION

4040-Ro	10	x	7	wells
4200-Ro	20	x	13	wells
4200-14-Ro*	20	x	14	wells
4000-Ro	100	x	13	wells
4000-14-Ro*	100	x	14	wells

*Other kit configurations are available upon request*

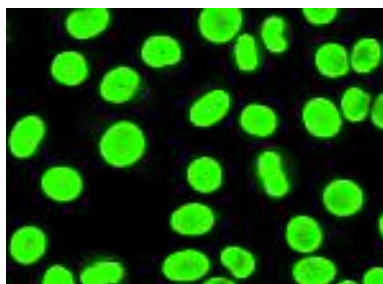
# FLUORESCENT HEP-2 ANA

These test systems incorporate many of the same features as the HEP-2000® test kits such as...

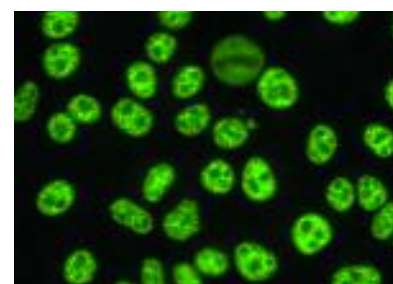
- Abundant easy-to-read mitotic cells
- Clear pattern identification
- Ready-to-use pattern controls and conjugates
- Substrate slides
- Positive pattern controls for:
  - homogeneous
  - speckled
  - centromere
  - nucleolar
- Titratable control referenced to the WHO standard 66/233 for ANA
- Negative control
- Conjugate
- PBS
- Mounting medium

## FLUORESCENT HEP-2 ANA

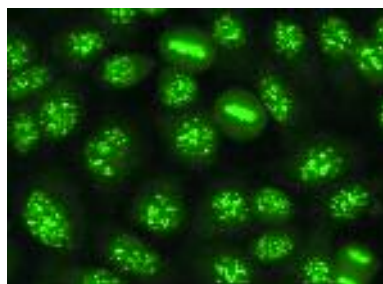
The following pictures illustrate several patterns seen on Immuno Concepts' HEP-2 ANA.



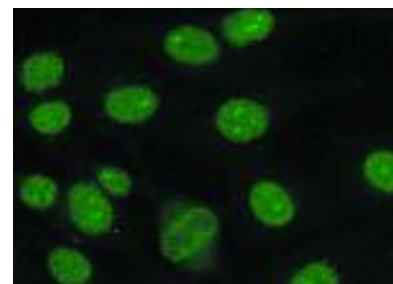
Homogeneous



Speckled



Centromere



SS-A/Ro

## ORDERING INFORMATION

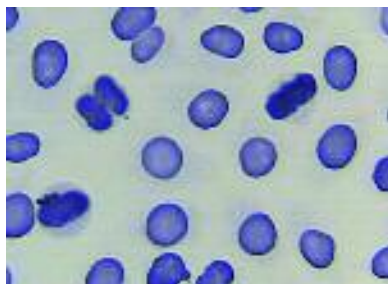
2040	10	x	7	wells
2100	10	x	13	wells
2200	20	x	13	wells
2200-14*	20	x	14	wells
2000	100	x	13	wells
2000-14*	100	x	14	wells

*Other kit configurations are available upon request*

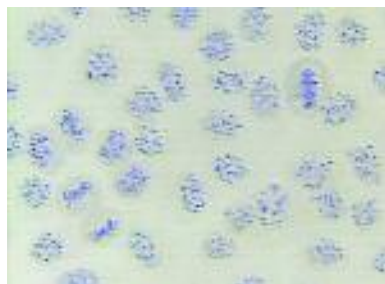
# COLORZYME® HEp-2 ANA

Colorzyme® HEp-2 ANA uses a patented color reagent system that eliminates the variability seen with fluorescent methods such as type of light source, filters and extraneous room light.

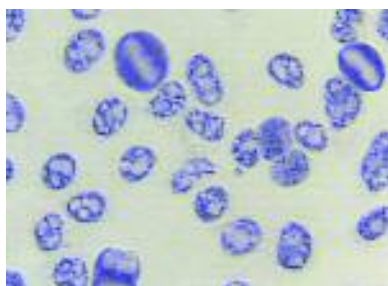
- An immunoenzyme technique using a patented color reagent system
- Results can be read on a standard light microscope
- Stable color reaction allows for storage of slides for later review
- Uses the same HEp-2 substrate as our fluorescent test system
- Easy to read sharp clear patterns



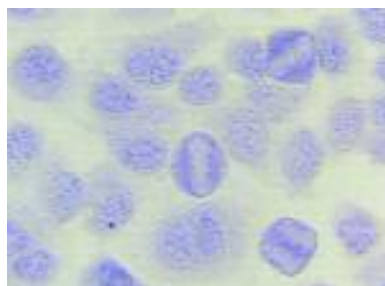
Homogeneous



Centromere



Speckled



SS-A/Ro

## ORDERING INFORMATION

4040	10	x	7 wells
4200	20	x	13 wells
4200-14*	20	x	14 wells
4000	100	x	13 wells
4000-14*	100	x	14 wells

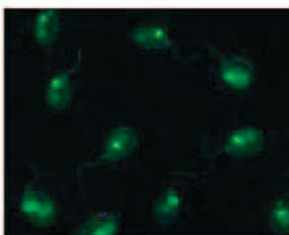
*Other kit configurations are available upon request*

nDNA antibodies show a high correlation with active systemic lupus erythematosus (SLE). Slide tests featuring the *Crithidia luciliae* substrate continue to be the most widely used assay for anti-DNA autoantibody testing worldwide.

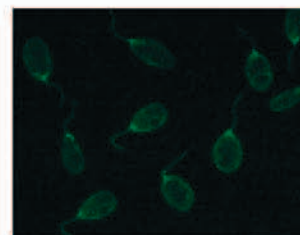
- Similar procedure as Immuno Concepts' ANA assay
- Easy-to-read results
- Features ready-to-use conjugates and controls, and comes with...
  - Substrate slides
  - Titratable control
  - PBS
  - Conjugate
  - Positive and negative controls
  - Mounting medium

## FLUORESCENT DNA

The following pictures illustrate the typical reactions seen on Immuno Concepts' fluorescent anti-DNA assay.



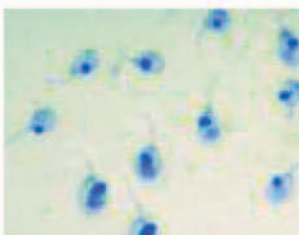
Positive



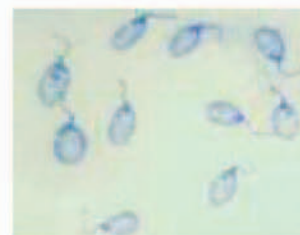
Negative

## COLORZYME<sup>®</sup> DNA

Colorzyme<sup>®</sup> DNA uses a patented color reagent system that eliminates the variability seen with fluorescent methods such as type of light source, filters and extraneous room light.



Positive



Negative

## ORDERING INFORMATION

### Fluorescent DNA:

3040	10	x	7 wells
3200	20	x	14 wells
3000	50	x	7 wells
3001	100	x	14 wells
3005	50	x	14 wells

### Colorzyme<sup>®</sup> DNA:

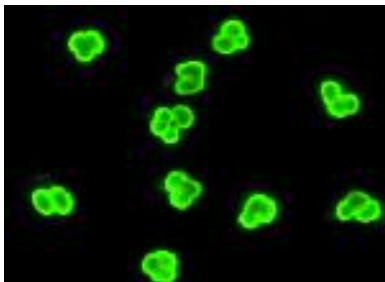
5040	10	x	7 wells
5200	20	x	14 wells
5000	50	x	7 wells
5005	50	x	14 wells

# ANCA (anti-neutrophil cytoplasmic antibodies)

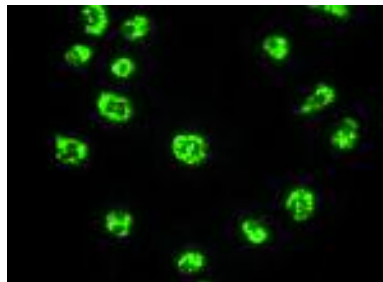
ANCA are associated with vasculitic diseases including Wegener's granulomatosis and microscopic polyangiitis as well as diseases such as inflammatory bowel disease. The immunofluorescent technique using human neutrophils is widely accepted as the best method of screening for ANCA. The Immuno Concepts' kits include...

- Designated control wells on each slide to assist with quality control
- Substrate slides
- Conjugate
- Positive controls for P-ANCA & C-ANCA
- Mounting medium
- Titratable controls for P-ANCA & C-ANCA
- Sample diluent
- Negative control
- PBS

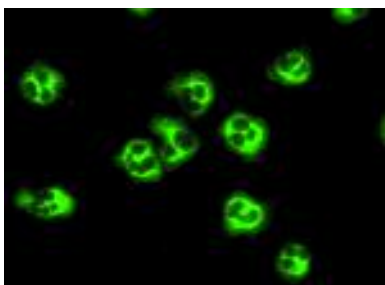
The following pictures illustrate the typical patterns seen on Immuno Concepts' ANCA assay.



P-ANCA on ethanol fixed slide



P-ANCA on formalin fixed slide



C-ANCA on ethanol fixed slide

## ORDERING INFORMATION

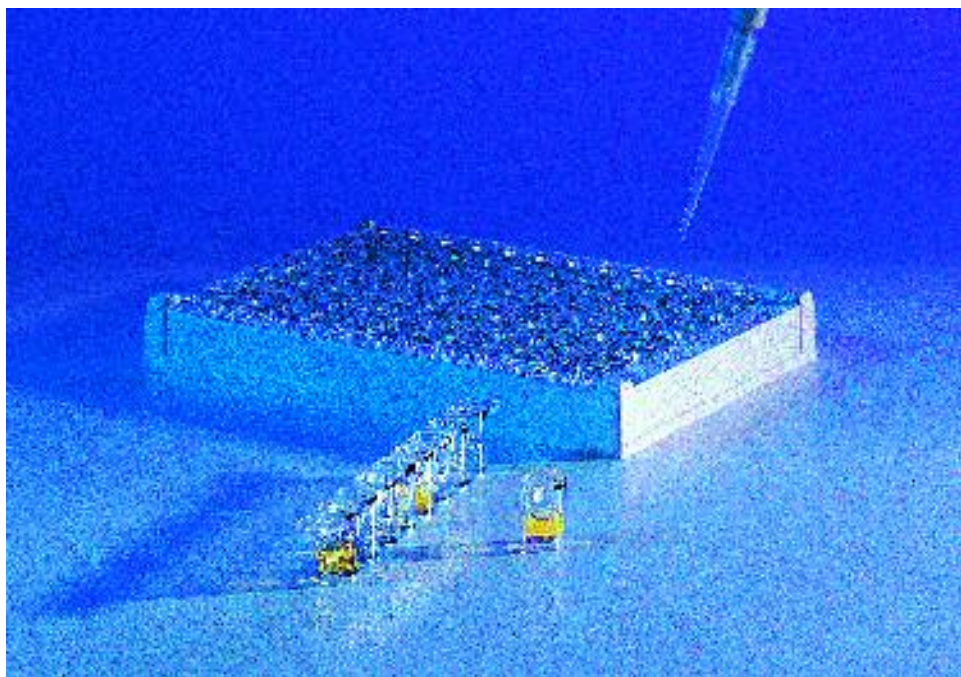
10060-11	Ethanol	10 x 10 wells
10300-11	Ethanol	50 x 10 wells
10060-12	Formalin	10 x 10 wells
10300-12	Formalin	50 x 10 wells

# RELISA<sup>®</sup> ANA SCREENING SYSTEM

For laboratories that have decided to change to the ELISA methodology for their ANA screens, we believe the RELISA<sup>®</sup> ANA's correlation with IFA and many user friendly features provide an advantage over the competition.

While no ELISA ANA currently on the market is capable of 100% correlation with IFA, our RELISA<sup>®</sup> ANA screen has been shown to be quite effective at detecting clinically significant autoantibodies to nuclear antigens including: Sm/RNP, SS-A/Ro, SS-B/La, dsDNA, Scl-70, and others. These are autoantibodies often seen in patients with SLE or other systemic rheumatic diseases.

- Easily automated
- Test strips are color coded and feature break-away wells
- Liquid stable ready-to-use conjugates
- Liquid stable ready-to-use controls
- Total assay time of 65 minutes
- Same 1:40 dilution can be used for the IFA test
- Test strips are individually pouched to provide kit stability



## ORDERING INFORMATION

7096-11	96 wells per kit
7696-11	576 wells per kit

## ENA (extractable nuclear antigens)

The RELISA® ENA assays were designed with the proper sensitivity and specificity to help the clinician in the diagnosis of autoimmune disease. Sera from over 2,000 patients with rheumatic disease and 1,000 normal individuals were tested during the development of the RELISA® ENA Test System. Immuno Concepts compared the results to reference methods such as Ouchterlony immunodiffusion, counterimmunoelectrophoresis, other ELISA methods and Western blotting. To verify the clinical utility of the assay, the laboratory results were also compared to the clinical history and diagnosis of the patient.

- Affinity purified native mammalian antigens
- Specificity and sensitivity are designed to provide diagnostically meaningful results
- Liquid stable ready-to-use controls and conjugates
- Total assay time of 65 minutes
- Test strips are individually pouched to provide kit stability

Test system comes with...

- Antigen coated microtiter wells
- Positive and negative controls
- Sample diluent
- PBS
- Conjugate
- Substrate solution
- Stopping reagent
- Wash Buffer Concentrate

### RELISA® ENA Single Well Screening Kit

The RELISA® ENA Single Well Screening Kit is designed to screen patient samples for six of the most common autoantibodies. Each microtiter well is coated with Sm, RNP, SS-A, SS-B, Scl-70 and Jo-1 autoantigens. This allows the laboratory to cost effectively screen out the ENA negative patient samples prior to determining the ENA specificity on any of the company's other RELISA® ENA Test Systems. The strips are color-coded for easy identification and feature break-away wells.

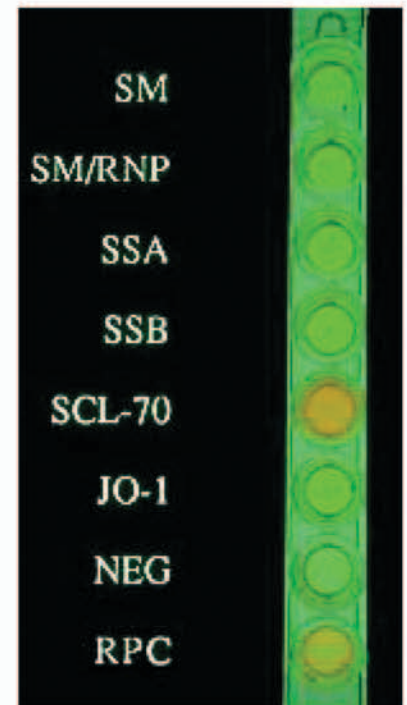
#### ORDERING INFORMATION

7096-10	96 wells per kit
7696-10	576 wells per kit



# RELISA<sup>®</sup> ENA Multiparameter Kit

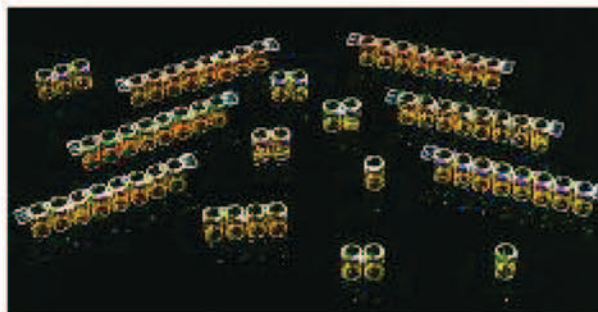
The RELISA<sup>®</sup> ENA Multiparameter Kit is designed for testing patient samples for six of the most common autoantibodies. This kit features a unique quality control system. The built-in RPC<sup>™</sup> (RELISA<sup>®</sup> Procedure Check) well in each strip gives the laboratory maximum flexibility in determining their quality control procedures.



## RELISA<sup>®</sup> ENA Single Parameter Kits

RELISA<sup>®</sup> ENA Single Parameter Kits are designed for testing patient samples for smaller subsets of the six most common autoantibodies. These kits are designed for laboratories that may choose not to test for all six autoantibodies.

- Contain strips with each well coated with a specific autoantigen
- Test strips are color-coded for easy identification and feature break-away wells
- Test strips are individually pouched to provide kit stability.



## ORDERING INFORMATION

RELISA<sup>®</sup> ENA Multiparameter Kit

7096-09

96 wells per kit

7696-09

576 wells per kit



# CARDIOLIPIN

Immuno Concepts' RELISA® Cardioliipin Test Kits provide maximum flexibility for anti-cardiolipin testing by offering both a screening kit using a polyvalent conjugate and an isotype specific test kit. Test kits feature ready-to-use reagents and controls, and come complete with...

- Test strips are color-coded, feature break-away wells and are pouched to provide kit stability
- Positive and negative controls
- Single point calibration
- Sample diluent
- PBS
- Liquid stable ready-to-use conjugate
- Substrate solution
- Stopping reagent

## RELISA® Cardioliipin Screening Kit

The RELISA® Cardioliipin Screening Kit is designed to screen patient samples for IgG, IgM and IgA anti-cardiolipin antibodies using a polyvalent conjugate. This kit allows the laboratory to cost effectively screen out anti-cardiolipin negative patient samples prior to determining the antibody specificity using Immuno Concepts' RELISA® Cardioliipin IgG & IgM test kit.

## RELISA® Cardioliipin IgG & IgM Antibody Test Kit

This isotype specific RELISA® Cardioliipin Kit is designed to determine the individual concentrations of IgG and IgM anti-cardiolipin antibodies in patient samples. The kit includes isotype specific conjugate, calibrators and controls.



## ORDERING INFORMATION

7096-01	IgG, IgM & IgA Screen	96 wells/kit
7696-01	IgG, IgM & IgA Screen	576 wells/kit
7096-02	IgG & IgM	96 wells/kit
7696-02	IgG & IgM	576 wells/kit



## ANTIBODY TEST KIT

Autoantibodies to MPO-ANCA and PR3-ANCA have been shown to be associated with pauci-immune crescentic glomerulonephritis and Wegener's granulomatosis respectively. Using ethanol fixed neutrophils in an indirect immunofluorescence assay (IIF), autoantibodies to MPO-ANCA most often produce a perinuclear or P-ANCA staining pattern and autoantibodies to PR3-ANCA produce a cytoplasmic or C-ANCA pattern. However, IIF patterns alone are not confirmatory for MPO- or PR3-ANCA. Our RELISA® MPO and PR3 Antibody Test Kit is a convenient method for confirmation of MPO- or PR3-ANCA autoantibodies.

The importance of detecting and confirming these autoantibodies cannot be overlooked. The International Group for Consensus on Testing and Reporting of Antineutrophil Cytoplasmic Antibodies (ANCA) has recommended as a minimum that both indirect immunofluorescence (IIF) and confirmatory ELISA testing be done on all samples. It has been shown that about 10% of ANCA positive sera are only detected by IIF and about 5% are positive only by ELISA.<sup>1</sup> And, in a separate publication, an independent study reported combining (IIF) patterns with an ELISA assay such as the Immuno Concepts RELISA® MPO- and PR3-ANCA can improve the diagnostic specificity of ANCA testing to 99%.<sup>2</sup>

In addition to the diagnostic value of identifying which ANCA antibodies are present, monitoring the level of PR3- and MPO-ANCA antibodies can be useful. These antibody levels usually correlate with disease activity in patients with Wegener's granulomatosis, microscopic polyangiitis, and pauci-immune segmental necrotising glomerulonephritis.<sup>1</sup>

- Test strips are color coded and feature break-away wells
- Easily automated
- Purified native human antigens
- Liquid stable ready-to-use controls and conjugates
- Kit contains reagents and procedures for both single point qualitative and multi-point semi-quantitative assays
- Total assay time of 65 minutes
- Test strips are individually pouched to provide kit stability

1. Savige, J., Gillis, D., Benson, E., Davies, D., Esnault, V., Falk, R.J., Hagen, E.C., Jayne, D., Jennette, J.C., Paspaliaris, B., Pollock, W., Pusey, C., Savage, C.O.S., Silvestrini, R., Van der Woude, F., Wieslander, J., Wiik, A. International consensus statement on testing and reporting of antineutrophil cytoplasmic antibodies (ANCA). *Am.J.Clin.Pathol.* 111:507-513, 1999.

2. Hagen EC, Daha MR, Hermans J, et al. EC BCR Project ANCA Assay Standardization: Diagnostic value of standardized assays for anti-neutrophil cytoplasmic antibodies in idiopathic systemic vasculitis. *Kidney Int* 53:743-753, 1998

## ORDERING INFORMATION

7096-15	RELISA® MPO-ANCA Test System	96 wells/kit
7096-16	RELISA® PR3-ANCA Test System	96 wells/kit
7096-17	RELISA® MPO/PR3-ANCA Combination Test System	96 wells/kit

# IMMUNODIFFUSION

## AUTO I.D.<sup>®</sup> ENA (extractable nuclear antigens)

AUTO I.D.<sup>®</sup> ENA Test Kits offer a cost effective method for identification of patient autoantibodies to seven different ENAs. All of the optional controls can be used with any of the Auto I.D.<sup>®</sup> Test Kits, which come complete with...

- universal antigen (contains Sm, RNP, SS-A, SS-B, Scl-70, PCNA & Jo-1 autoantigen)
- agarose plates
- positive controls
- worksheets



The Sm/RNP kits include positive controls for Sm/RNP and for RNP.

The SS-A/SS-B kits include positive controls for SS-A/SS-B and for SS-A.

The Sm/RNP/SS-A/SS-B kits include all four of these controls.

## ORDERING INFORMATION

### KITS

6030	Sm/RNP	6 plates/kit
6060	Sm/RNP	12 plates/kit
6070	Sm/RNP/SS-A/SS-B	12 plates/kit
6700	Sm/RNP/SS-A/SS-B	50 plates/kit
7030	SS-A/SS-B	6 plates/kit
7060	SS-A/SS-B	12 plates/kit

### CONTROLS

6001	RNP control	0.5ml
6002	Sm/RNP control	0.5ml
6004	Jo-1 control	0.5ml
6005	Scl-70 control	0.5ml
6006	PCNA control	0.5ml
7001	SS-A control	0.5ml
7002	SS-A/SS-B control	0.5ml
7003	SS-B control	0.5ml

## EDUCATION

Since its inception, Immuno Concepts has made a dedicated effort to promote education in our field. In support of this commitment we have funded research projects, donated product to schools and developed training aids for clinicians and laboratorians. Each year, through our workshops and PSITS programs, hundreds of technologists and clinicians are enlightened to the significant contribution that ANA and related testing can have on the diagnosis of the patient.

## WORKSHOPS

Each year Immuno Concepts conducts educational workshops in various locations worldwide. The workshops primarily focus on autoantibodies seen in the systemic rheumatic diseases, but also include current information on topics such as ANCA related vasculitis and anti-phospholipid syndrome. These workshops are continuously updated with current information from scientific journals. In the United States and selected foreign countries the workshops are certified for Continuing Education Credits (CEU). Ask Immuno Concepts or your local representative for information on the next workshop nearest you.

## VISIONS™ TRAINING PROGRAM

Maintaining a well-trained staff is essential. The Visions™ training program is a self-taught, on-site training program for ANA's. These programs, now available on CD-ROM, cover basic to advanced information on ANA methodology, patterns, follow-up testing, and troubleshooting. The CD-ROM version includes two quizzes on ANA patterns.

Each series, II and III, consists of sixty (60) 35 mm slides or color plates and accompanying text. Visions™ II focuses on basic ANA methodology, patterns and follow-up testing, while Visions™ III looks at HEp-2000®, ANA titering, troubleshooting, ANCA, and cytoplasmic patterns. Visions™ III is most effective when used in conjunction with Visions™ II. The CD-ROM combines both series together in a user-friendly format.

## ORDERING INFORMATION

6000-11 Visions™ II & III  
6000-11-Sp Visions™ II & III

CD-ROM with voice narration and quiz  
CD-ROM with voice narration and quiz  
-Spanish Version

## TECHNICAL SUPPORT

Immuno Concepts' commitment to quality continues after the sale with our comprehensive Technical Support. Our trained professionals are ready to answer your questions on testing procedures, troubleshooting techniques, interpretation of results, or other topics related to our products or Autoimmune diseases in general. Because we maintain an extensive library of current references, and have working relationships with recognized experts in the field, we are able to offer our customers support that is up to date with current research.

One of the long-standing features of our Technical Support has been assisting with pattern interpretation. Laboratories from around the world often send unusual samples for consultation on pattern identification and clinical significance. Now, by combining the power of the internet with our in-house digital optics, we are able to test the samples and e-mail photos of the patterns along with our comments back to our customers. This gives the customer a record of how the pattern appeared and tips on identification of the pattern in the future.

Although we are not a licensed reference laboratory, we are happy to offer this full support free of charge to our customers. Simply call Technical Support at (800) 251-5115, (916) 363-2649, or e-mail us at [techservice@immunoconcepts.com](mailto:techservice@immunoconcepts.com).

## PATIENT SAMPLE INTERPRETIVE TRAINING SERIES (PSITS)

This program is a valuable on-going training tool for the laboratory. Every three months a patient sample and history are sent to each participating laboratory. Based upon the ANA test results, each laboratory determines which follow-up tests to perform on the sample. Returned results are compiled and each participating laboratory is sent:

- A summary report including the expected results
- A comparison to other methods and laboratories
- A summary of the clinical diagnosis of the patient based upon the laboratory results
- A color image of the ANA pattern

## ORDERING INFORMATION

1800 PSITS\*

\* Enrollment at any time in the program will include the next four quarterly samples.

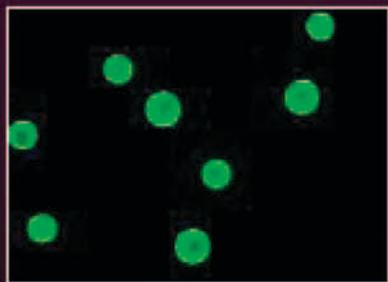
[www.immunoconcepts.com](http://www.immunoconcepts.com)

Visit our web page on-line  
to learn more about  
Immuno Concepts' product line,  
exciting news, and workshop  
dates and locations.

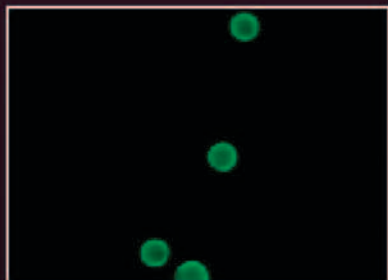


## FITC-QC™ SLIDE

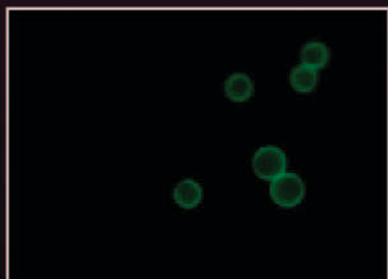
The FITC-QC™ Slide is an independent quality control check for assessing the level of fluorescent intensity provided by each laboratory's microscope. Each slide has five different wells of microbeads containing FITC, ranging from "4+" to "+/-" in intensity. The concentration of FITC in the microbeads is calibrated by flow cytometry. The FITC-QC™ Slide allows the laboratory to verify proper performance of the optical system of their fluorescent microscope before beginning each run. This conforms to the NCCLS-approved guidelines as outlined in document I/LA2-A. The pictures on the left illustrate the beads as viewed under the microscope.



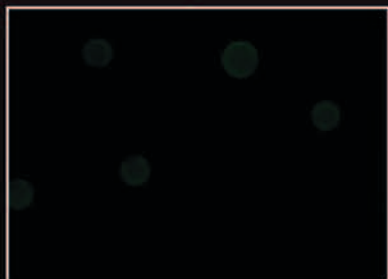
4+



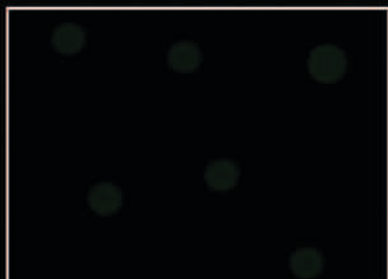
3+



2+



1+



+/-

## OPTIONAL CONTROLS

Immuno Concepts has always realized that correct pattern recognition is critical for accurate reporting of ANA results. This is why many of our standard ANA kits include four positive ANA controls (homogeneous, speckled, centromere and nucleolar). To augment these more common patterns, we offer a variety of optional controls to assist with pattern recognition. These optional controls come pre-diluted in ready-to-use dropper vials.

## ORDERING INFORMATION

1900 FITC-QC™ slide

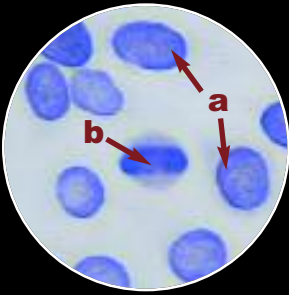
### ANA Optional Controls

Ready-to-use and packaged in dropper vials for ease of use.

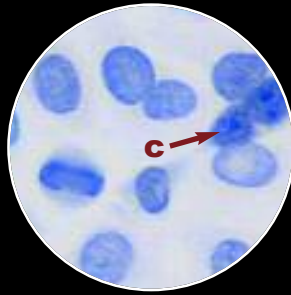
2021	ANA Homogeneous Control		5.0ml
2022	ANA Speckled Control	2 x	1.0ml
2023	ANA Nucleolar Control	2 x	1.0ml
2025	ANA Centromere Control	2 x	1.0ml
2026	ANA Titratable Control (not packaged in dropper vial)		1.0ml
2027	ANA Mitochondrial Control		0.5ml
2029	ANA Golgi Control		0.5ml
2031	ANA Negative Control		5.0ml
2032	ANA Control Set (Homogeneous, Speckled, Nucleolar, Centromere, Negative)		
2035	ANA SS-A Control		0.5ml
2037	ANA PCNA Control		0.5ml
2041	ANA Scl-70 Control		0.5ml

## HOMOGENEOUS WITH HIDDEN SS-A/RO PATTERN ON HEP-2000®

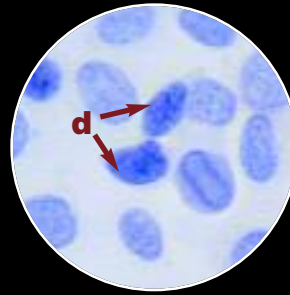
The photographs below demonstrate how a strong homogeneous ANA pattern can mask over another ANA pattern. In this case, the homogeneous pattern is masking over an SS-A/Ro pattern.



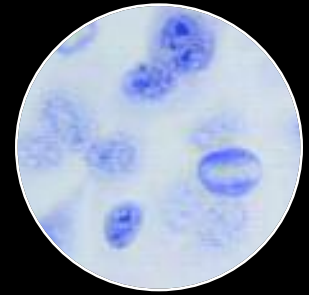
At the 1:40 dilution a strong homogeneous pattern is seen. Notice that there is smooth staining in the nucleus of the interphase cells (a) and strong staining in the chromosome region of the metaphase mitotic cells (b).



At the 1:80 dilution the strong homogeneous staining continues to dominate. However, notice the nucleolar staining visible in some of the cells (c). This is the SS-A/Ro pattern becoming visible. It was hidden by the stronger homogeneous pattern at the 1:40 dilution.



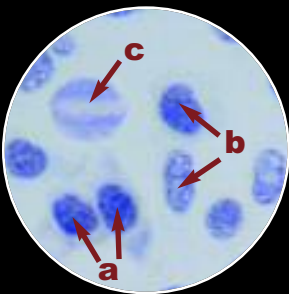
At the 1:160 dilution the homogeneous pattern is fading and the hyperexpressing cells associated with antibodies to SS-A/Ro are clearly identifiable (d).



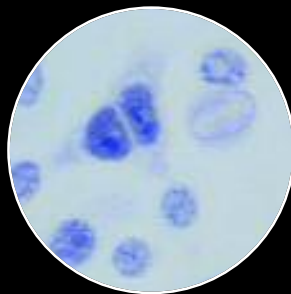
At the 1:320 dilution the homogeneous pattern is no longer visible, leaving only the characteristic pattern associated with antibodies to SS-A/Ro. Further titering of this sample continues to show only the SS-A/Ro pattern. Because there is little correlation between ANA titer and disease severity, titering of the SS-A/Ro pattern is not necessary. When seen alone, the SS-A/Ro pattern will not mask over other ANA patterns.

## SPECKLED AND SS-A/RO MIXED PATTERN SEEN ON HEP-2000®

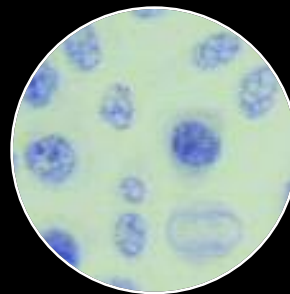
The photographs below demonstrate how a speckled and SS-A/Ro pattern will appear on HEP-2000®



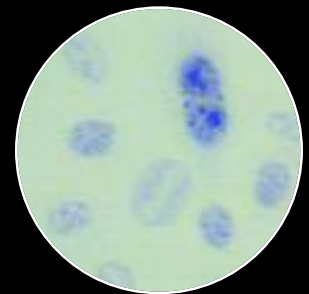
At the 1:40 dilution the 10-15% of cells which hyperexpress the SS-A/Ro autoantigen demonstrate stronger staining of the nucleus and nucleoli (a). Some may show staining in the cytoplasm. The non-hyperexpressing cells demonstrate speckled staining (b). There is no staining in the chromosome area of the metaphase mitotic cells (c). This is a mixed pattern, ANA positive. The two patterns present are speckled and SS-A/Ro.



At the 1:80 dilution both the speckled and the SS-A/Ro pattern are present.



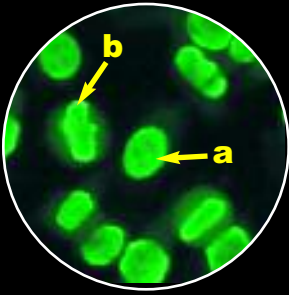
At the 1:160 dilution the speckled pattern is fading but still visible. The SS-A/Ro pattern is still clearly visible.



At the 1:320 dilution the speckled pattern has disappeared leaving only the SS-A/Ro pattern.

## HOMOGENEOUS WITH HIDDEN SS-A/RO PATTERN ON HEP-2000®

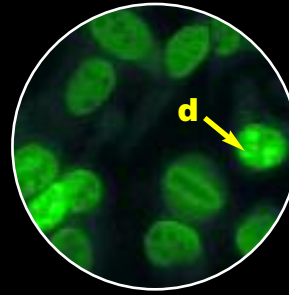
The photographs below demonstrates how a strong homogeneous ANA pattern can mask over another ANA pattern. In this case, the homogeneous pattern is masking over an SS-A/Ro pattern.



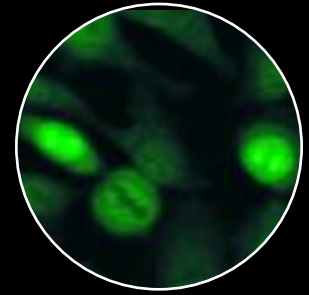
At the 1:40 dilution a strong homogeneous pattern is seen. Notice that there is smooth staining in the nucleus of the interphase cells (a) and strong staining in the chromosome region of the metaphase mitotic cells (b).



At the 1:80 dilution the strong homogeneous staining continues to dominate. However, notice the nucleolar staining visible in some of the cells (c). This is the SS-A/Ro pattern becoming visible. It was hidden by the stronger homogeneous pattern at the 1:40 dilution.



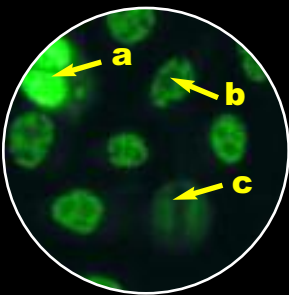
At the 1:160 dilution the homogeneous pattern is fading and the hyperexpressing cells associated with antibodies to SS-A/Ro are clearly identifiable (d).



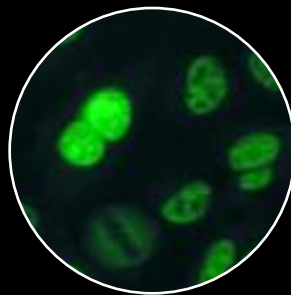
At the 1:320 dilution the homogeneous pattern is no longer visible, leaving only the characteristic pattern associated with antibodies to SS-A/Ro. Further titering of this sample continues to show only the SS-A/Ro pattern. Because there is little correlation between ANA titer and disease severity, titering of this SS-A/Ro pattern is not necessary. When seen alone, the SS-A/Ro pattern will not mask over other ANA patterns.

## SPECKLED AND SS-A/RO MIXED PATTERN SEEN ON HEP-2000®

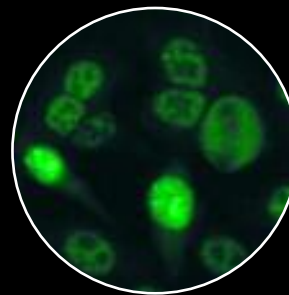
The photographs below demonstrate how a speckled and SS-A/Ro pattern will appear on HEP-2000®



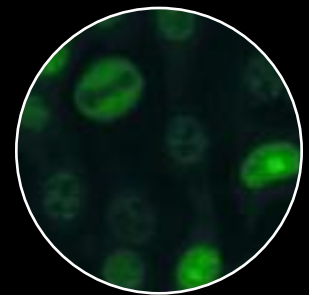
At the 1:40 dilution the 10-15% of cells which hyperexpress the SS-A/Ro autoantigen demonstrate stronger staining of the nucleus and nucleoli (a). Some may show staining in the cytoplasm. The non-hyperexpressing cells demonstrate speckled staining (b). There is no staining in the chromosome area of the metaphase mitotic cells (c). This is a mixed pattern, ANA positive. The two patterns present are speckled and SS-A/Ro.



At the 1:80 dilution both the speckled and the SS-A/Ro pattern are present.



At the 1:160 dilution the speckled pattern is fading but still visible. The SS-A/Ro pattern is still clearly visible.



At the 1:320 dilution the speckled pattern has disappeared leaving only the SS-A/Ro pattern.

Immuno Concepts, N.A. Ltd. | 9779 "D" Business Park Drive | Sacramento, CA 95827

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