



# ***Lab Updates***

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## **CHANGES IN ANTINUCLEAR ANTIBODY (ANA) TESTING**

Antinuclear Antibodies are serologic hallmarks of patients with systemic autoimmune disease. At UMass Memorial Laboratories, we currently perform ANA screens using an enzyme immuno-assay (EIA) technique, where purified antigens from Hep-2 cells are coated to the tube and the color reactions caused by the bound antibodies will determine the test positivity. All positive tests in this screen are automatically tested by Immuno-fluorescence Assay (IFA), where the type of nuclear pattern (ex. Homogenous, speckled etc) and the titer (1:80, 1:160 etc) are reported.

A variety of nuclear staining patterns that are reported basically reflect the presence or absence of antibodies to one or a combination of nuclear antigens. Although this is commonly used, the pattern type is recognized to have relatively low sensitivity and specificity for different autoimmune disorders.

At present, specific tests have largely supplanted the use of patterns, mainly because accurate interpretation of these patterns is confounded by many variables:

- The recognition of specific patterns is operator-dependent, and does not produce a permanent record.
- Different serum dilutions can produce varying nuclear patterns.
- One nuclear pattern may obscure and prevent the recognition of another pattern if several antibodies are present simultaneously.
- Certain antibodies like SSA, Jo-1, and Ribo-P are not easily detected.
- Nuclear patterns are neither sensitive nor specific. As a result, no single pattern denotes a single disease and, conversely, several diseases may produce a particular ANA pattern.

Due to the above difficulties, specific nuclear pattern recognition is not as useful as previously thought. Pattern recognition has been increasingly supplanted by assays that detect specific antibodies to an ever-increasing array of nuclear antigens and to antigens not normally found in the nucleus.

For these reasons, we are very excited about the new multiplex technology developed by BioRad, which is FDA approved this year. This new Bioplex 2200 ANA screen is intended for qualitative screening of specific ANA's, the quantitative detection of DSDNA Ab, and semi quantitative detection of 10 separate antibody assays (Chromatin, Ribosomal-P, SSA, SSB, Sm, SmRNP, RNP, Scl-70, Jo-1 and Centromere-

B). This new ANA Screen utilizes multiplex flow immunoassay, which permits the simultaneous detection and identification of many antibodies in a single tube.

In this ANA screening format, results of initial ANA screen is reported as Negative or Positive based on the absence or presence of one or more antibodies (total 11) in concentrations exceeding its assigned cut-off. At your discretion, positive ANA results in this format may be further analyzed by selecting individual antibodies or user defined test grouping containing antibodies as "add-on" tests for immediate reporting of results.

DsDNA is a quantitative assay calibrated against WHO Wo/80 Standard. Results are expressed in terms of IU/mL. Results of  $\leq 4$  IU/mL are Negative, 5-9 IU/mL are Indeterminate, and  $\geq 10$  IU/mL are Positive. All other antibody assays are semi-quantitative and results are expressed in terms of AI (Antibody Index). Results of  $< 1.0$  are Negative and results  $\geq 1.0$  are positive.

Based on several clinical trials and lab internal validation studies, the correlation between EIA, IFA and this multiplex testing is excellent. The main advantages are:

- Better specificity
- Better sensitivity for antibodies of clinical relevance
- Significant improvements in turn around time
- Elimination of subjectivity in interpretation
- Ability to get all above test results at one time point
- Significant improvements in the quality and reliability of the test result lead to better management of the patient.

**Effective December 11, 2006**, ANA by Multiplex technology will be available. No traditional EIAs or IFAs (Pattern and titer) will be performed. ANA by IFA will be performed only by specific request. There are no changes in specimen collection requirements (one SST tube).

Checking ANA on the requisition translates to ANA Multiplex. Other ANA testing options are as follows:

Test Name	Mnemonic	Comment
ANA Multiplex	ANAMP	The test result, negative or positive, is dependent upon the presence or absence of 11 specific clinically relevant antibodies as mentioned above. Positive outcomes will not be automatically reflexed. You can order individual tests up to 30 days of the initial test result.
ANA Multiplex with Reflex	ANAREF	If ANA test result is positive, it will be automatically reflexed to all 11 antibodies (DsDNA, Chromatin, Sm, Ribo- P, SS-A, SS-B, SmRNP, RNP, Scl-70, Centromere B, and Jo-1) as mentioned above.

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Test Name	Mnemonic	Comment
Lupus Panel	LUPUS	ANA Reflex to dsDNA, Chromatin, Sm, Ribosomal P, SS-A, and RNP.
MCTD Panel	MCTD	ANA Reflex to RNP, Sm, SmRNP, and Chromatin.
Sjögren's Panel	SJOGREN	ANA Reflex to SS-A and SS-B.
Scleroderma Panel	SCLEROD	ANA Reflex to Scl-70 and Centromere B
DS DNA Abs	DSDNA	Can be ordered individually
SSA Abs	SSA	Can be ordered individually
SSB Abs	SSB	Can be ordered individually
Sm RNP Abs	SMRNP	Can be ordered individually
RNP Abs	RNP	Can be ordered individually
Sm Abs	SM	Can be ordered individually
Scl-70 Abs	SCL70	Can be ordered individually
Chromatin Abs	CHROMAT	Can be ordered individually
Ribosomal P Abs	RIBOP	Can be ordered individually
Jo-1 Abs	JO1	Can be ordered individually
Centromere Abs	CENTRO	Can be ordered individually

If you have questions, comments or suggestions, please contact:  
 Dr. L.V. Rao, Director, at 508-334-7593 or via email at [RaoL@ummhc.org](mailto:RaoL@ummhc.org) or  
 Ms. Rachel Ambacher, Manager, at 508-334-7316 or via email at [Ambacher@ummhc.org](mailto:Ambacher@ummhc.org)

### **RECOMMENDATIONS FOR ORDERING D-DIMER ASSAY**

The Coagulation Laboratory at UMass Memorial would like to remind you of the need to be specific when ordering the D-dimer assay. Two D-dimer assays are offered.

1. The DIC D-dimer is a latex-based test indicated for detecting the presence of multiple clots, as seen in patients with DIC. It is part of the DIC screen we recommend or it can be ordered separately.
2. The DVT/PE D-dimer is a quantitative assay recommended for the exclusion of deep vein thrombosis (DVT) and/or pulmonary embolism (PE), when there is a low or intermediate probability for these diagnoses.

Whenever ordering either one of these tests, please ask your nurse or clerk to be specific as to which of the two is required.

### **REFERENCE RANGE CHANGES**

Effective December 13, 2006, please note the following changes:

Test	Current Reference Range	New Reference Range
Factor II	60 – 150%	70 – 120%
Factor V	60 – 150%	70 – 160%
Factor VII	60 – 170%	70 – 150%
Factor X	60 – 150%	70 – 160%

## UMASS MEMORIAL MEDICAL CENTER LABORATORIES

### PATIENT SERVICE CENTER (PSC) LOCATIONS

#### **Worcester, Massachusetts PSC Locations**

##### **UMass Memorial - University Campus**

55 Lake Avenue North  
Worcester, MA 01655  
Mon - Fri 7:30 am - 5:30 pm  
**508-856-7797**

##### **UMass Memorial - Memorial Campus**

119 Belmont Street  
Worcester, MA 01605  
Mon - Fri 7:00 am - 6:00 pm  
Sat & Sun 8:00 am - 1:00 pm  
**508-334-6486**

##### **UMass Memorial - Hahnemann Campus**

281 Lincoln Street  
Worcester, MA 01605  
Mon - Fri 7:00 am - 5:30 pm  
**508-334-8100**

##### **UMass Memorial - City Hospital Campus**

26 Queen Street  
Worcester, MA 01610  
Mon - Fri 8:00 am - 5:00 pm  
Closed 12:00 pm - 1:00 pm  
**508-334-7881**

##### **116 Belmont Street PSC**

116 Belmont Street  
Worcester, MA 01605  
Mon, Wed, Fri 8:00 am - 5:00 pm  
Tues & Thurs 8:00 am - 8:00 pm  
**508-753-6854**

##### **291 Lincoln Street PSC**

291 Lincoln Street  
Worcester, MA 01605  
Mon - Fri 8:30 am - 5:00 pm  
Closed 12:30 pm - 1:00 pm  
**508-792-8208**

##### **City Campus - Grove Medical PSC**

26 Queen Street / 6th FL.  
Worcester, MA 01610  
Monday - Friday 8:00 am - 5:00 pm  
Closed 12:15 pm - 1:15 pm  
**(508) 334-0275**

##### **67 Belmont Street PSC**

67 Belmont Street  
Worcester, MA 01605  
Mon - Fri 8:00 am - 5:00 pm  
Closed 12:15 pm - 1:15 pm  
**508-334-5396**

##### **255 Park Avenue PSC**

Endocrinology Associates, Suite 210  
255 Park Avenue, Worcester, MA 01609  
Monday - Friday 8:00 am - 5:00 pm  
Closed 12:15 pm - 1:15 pm  
**(508) 798-5127**

##### **Vernon Medical Center PSC**

10 Winthrop Street  
2<sup>nd</sup> floor, Building 1  
Worcester, MA 01604  
Mon - Fri 8:00 am - 5:00 pm  
**508-831-0624**

##### **100 Central Street PSC**

Women's Health, 3rd Floor  
100 Central Street, Worcester, MA 01605  
Monday - Friday 8:00 am - 5:00 pm  
Closed 12:15 pm - 1:15 pm  
**(508) 757-4637**

#### **Other Central Massachusetts PSC Locations**

##### **Douglas Medical Building PSC**

15 West Street  
Douglas, MA 01516  
Mon - Fri 8:00 am - 12:00 pm  
**508-476-2365**

##### **Fitchburg - Community Health Connections**

HealthAlliance - Burbank Hospital Campus  
275 Nichols Street  
Fitchburg, MA 01420  
Mon - Fri 8:30 am - 5:30 pm  
Closed 12:30 pm - 1:30 pm  
**978-665-5914**

##### **Holden Medical Building PSC**

52 Boyden Street  
Holden, MA 01520  
Mon 8:30 am - 2:30 pm  
Tue - Fri 7:00 am - 3:30 pm  
Closed 12:30 pm - 1:00 pm  
**508-829-8262**

##### **Marlborough Medical Center Office Bldg**

320 Bolton Street, Suite G1  
Marlborough, MA 01752  
Mon - Fri 8:00 am - 5:00 pm  
Closed 11:00 pm - 12:00 pm

##### **Northborough Medical Building PSC**

112 Main Street  
Northborough, MA 01532  
Mon - Fri 8:00 am - 5:00 pm  
Closed 12:15 pm - 1:15 pm  
**508-393-3704**

##### **Shrewsbury, Main Street PSC**

604 Main Street  
Shrewsbury, MA 01545  
Mon - Fri 8:00 am - 5:00 pm  
Closed 12:15 pm - 1:15 pm  
**508-845-6521**

**UMASS MEMORIAL MEDICAL CENTER LABORATORIES**  
**PATIENT SERVICE CENTER (PSC) LOCATIONS (continued)**

**Other Central Massachusetts PSC Locations (continued)**

**Shrewsbury, Julio Drive PSC**

26 Julio Drive  
Shrewsbury, MA 01545  
Mon - Fri 8:00 am - 5:00 pm  
Closed 12:00 pm - 1:00 pm  
**508-845-3615**

**Sterling Medical Building PSC**

104 Leominster Road  
Sterling, MA 01564  
Mon - Fri 8:00 am - 5:00 pm  
Closed 12:15 pm - 1:15 pm  
**978-422-5109**

**Westborough Medical Building PSC**

154 Main Street, Westborough, MA 01581  
Mon 7:30 am - 4:30 pm  
Tues - Thurs 8:30 am - 5:30 pm  
Friday 7:00 am - 4:00 pm  
Closed 12:30 pm - 1:30 pm  
**508-836-3674**

**Eastern Massachusetts PSC Locations**

**Brockton PSC and Laboratory**

1073 Pleasant Street  
Brockton, MA 02301  
Monday - Friday 8:00 am - 5:00 pm  
**(508) 559-2158**

**Framingham, Lincoln Street PSC**

61 Lincoln Street  
Framingham, MA 01702  
Monday - Friday 8:00 am - 5:00 pm  
Closed 12:15 pm - 1:15 pm  
**(508) 370-7259**

**Hyannis Medical Building PSC**

700 Attucks Lane - Suite 1D  
Hyannis, MA 02601  
Monday - Friday 8:00 am - 5:00 pm  
Closed 12:15 pm - 1:15 pm  
**(508) 790-5723**

**North Andover, Andover Street PSC**

451 Andover Street - Suite 206  
North Andover, MA 01845  
Monday - Friday 7:30 am - 4:30 pm  
Closed 12:15 pm - 1:15 pm  
**(978) 989-9238**

**North Andover, Turnpike Street PSC**

630 Turnpike Street  
North Andover, MA 01845  
Monday - Friday 8:00 am - 5:00 pm  
Closed 12:15 pm - 1:15 pm  
**(978) 989-9416**

**Waltham Hospital Campus PSC**

20 Hope Avenue - Suite G03  
Waltham, MA 02453  
Mon - Fri 8:00 am - 5:00 pm  
Closed 12:15 pm - 1:15 pm  
**781-899-2586**

**Waltham, Lexington Street PSC**

6 Lexington Street, 2nd Fl.  
Waltham, MA 02453  
Monday - Friday 8:00 am - 5:00 pm  
Closed 12:15 pm - 1:15 pm  
**(781) 647-0352**

**Wilmington PSC**

64 Concord Street, Suite D  
Wilmington, MA 01887  
Monday - Friday 8:30 am - 5:00 pm  
Closed 12:15 pm - 12:45 pm  
**(978) 694-1581**

**New Hampshire PSC Locations**

**Exeter New Hampshire PSC**

19 Hampton Road, Unit 10-B  
Exeter, New Hampshire 03833  
Monday - Friday 8:00 am - 5:00 pm  
Closed 12:15 pm - 1:15 pm  
**(603) 775-0165**

**Salem New Hampshire PSC**

(Scheduled to open December 26, 2006)  
32 Styles Rd, Suite 209, Salem, NH 03079  
Monday - Friday 8:00 am - 5:00 pm  
Closed 12:15 pm - 1:15 pm  
**(603) 890-0165**