

September 8, 2022

IMMUNOLOGY

Anti-Nuclear Antibody Testing

Date effective: October 1, 2022

Clinical Practice Change:

The Shared Health Immunology Laboratory at St Boniface Hospital will no longer be performing ANA Screening or Anti-dsDNA testing using the Bioplex Multiplex method.

Background Information:

The laboratory is currently offering ANA testing by two different platforms, multiplex bead immunoassay and indirect immunofluorescence assay (IFA). The increasing use of this test in patients with a low pre-test probability has resulted in lower test specificity and increased operating costs. Although requests for repeated tests are prevalent, they are rarely indicated since changes in titers do not correlate with disease activity, and negative test results need to be repeated only if the autoimmune disease is evolving or if there is a need for a diagnosis revision.

Changes in Test Procedure:

Effective October 1, all ANA testing will be performed by IFA. Antibodies to Extractable Nuclear Antigens (ENA), previously orderable as stand alone tests, will now only be performed by reflex testing based on known antigen associations, as per the table below:

ANA Pattern ($\geq 1:160$ Titre)	dsDNA	ENA
NUCLEAR PATTERN		
Homogeneous	√	√
Speckled	√	√
Centromere		√
Nucleolar		√
PCNA		√
Cytoplasmic Pattern		
Cyto-Speckled		√
Cyto-AMA		√

Visit the [International Consensus on Antinuclear Antibody Patterns website](#) for additional information about pattern and disease/antigen associations.

- dsDNA will be performed by ELISA and remain orderable as a stand alone test. However, it should be used as a secondary screening for systemic lupus erythematosus (SLE) based on ANA results and only ordered for follow-up monitoring of SLE disease activity.
- ENA testing will be performed by Line Immunoassay and will include nRNP/Sm, Sm, SS-A, Ro-52, SS-B, Scl-70, PM-Scl, Jo-1, CENP B, PCNA, Nucleosomes, Histones, Rib P Protein, AMA-M2 and DFS70.

References/Resources:

Test: Anti-Nuclear Antibodies HEP2 Substrate [Laboratory Information Manual - HEP2](#)
Anti-Double Stranded DNA [Laboratory Information Manual - dsDNA](#)

Delphic Codes: HEP2; dsDNA

Sample: Serum 1.0 ml

Normal Range: ANA: <1:80 TITRE

dsDNA: 0 – 99 IU/ml

Availability: Weekdays (5-7day TAT)

Requisition: Immunology Autoimmune Laboratory Requisition (R250-10-85 v02 Effective Oct 1, 2022)

Patient Impact:

The objective is to simplify the patient work-up: a single visit to the doctor's office, a single visit to the laboratory, and thus a more rapid clinical diagnosis. Eliminate the discrepancy of dual methodology.

System Improvements:

Restricting ENA/dsDNA testing to known pattern associations will provide both cost and labor efficiencies.

Contact Information:

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