July 16, 2026

IMMUNOLOGY

Anti-dsDNA Testing Methodology Migration & Reference Range Update

Date effective: July 20, 2026

Clinical Practice Change:
The Reference Range for anti-dsDNA antibody testing is being updated.

Background Information:
The Shared Health Immunology Laboratory at St. Boniface Hospital migrated anti-dsDNA antibody testing on February 10, 2026. The platform shifted from a manual enzyme-linked immunosorbent assay (EUROIMMUN NcX ELISA) to an automated chemiluminescence microparticle platform (IDS-iSYS).

Old Assay Limitations: The historical EUROIMMUN NcX kit did not look at pure dsDNA in isolation. It utilized a matrix linking dsDNA to nucleosomes. This matrix co-detected anti-nucleosome antibodies, anti-histone antibodies, and low-avidity (weak-binding) IgG. Patients with general, non-lupus autoimmune presentations regularly tested positive due to these overlapping target complexes.

New Assay Specificity: The automated IDS-iSYS platform isolates high-avidity pathogenic antibodies specific to native dsDNA. It utilizes highly purified native dsDNA held in a liquid-phase suspension on magnetic particles. The physics of this assay prioritize high-avidity antibodies. In clinical immunology, only high-avidity antibodies are tightly linked to active Systemic Lupus Erythematosus (SLE) and lupus nephritis.

Lack of Interchangeability: Because these two platforms test entirely different antibody structures, their numerical values are not interchangeable.

Changes in Test Procedure:
The historical 0.0 – 9.9 IU/ml reference range was established using a cohort of 200 normal, healthy control subjects. However, this validation cohort did not account for other active disease states or non-lupus autoimmune conditions that regularly induce an upregulation of low-avidity (weak-binding) anti-dsDNA cross-reactivity. The new, elevated thresholds filter out this non-specific background expression. Low-level positive flags on the prior 9.9 IU/ml threshold did not reflect clinical disease.

- < 30.0 IU/ml: Negative
- 30.0 – 50.0 IU/ml: Borderline (Low positive predictive value; clinical tracking recommended)
- > 50.0 IU/ml: Positive (Highly specific for Systemic Lupus Erythematosus)

Note: Please use these new limits alongside broader CRA/ACR/EULAR diagnostic criteria.

References/Resources:

Test:	dsDNA Laboratory Information Manual - dsDNA
Delphic Code:	DNA
Delphic Labels:	CLIA
Sample:	Serum 1.0 ml
Normal Range:	0.0 – 29.9 IU/ml
Availability:	Weekdays (3-5day TAT)
Requisition:	Immunology Autoimmune Laboratory Requisition

Patient Impact:

- **Calibration**: The assay remains calibrated against the first Wo/80 (WHO) international standard and is expressed in International Units (IU/ml).
- **Patient Monitoring**: There is no linear correlation between the CLIA and ELISA methods. Patients undergoing active monitoring require clinical rebaselining.
- **Clinical Reassurance**: A "drop" or negative shift in numerical values under the new platform represents a clearing of non-specific background noise rather than a missed diagnosis. This provides true diagnostic clarity for pathogenic SLE activity.

System Improvements

- Improved turnaround time (TAT).
- Enhanced clinical specificity for severe systemic autoimmune conditions.

Contact Information:

- Dr. Ping Sun, Hematopathologist, Medical Director Hematology & Immunology, Shared Health Manitoba, (phone: 204-787-4682) psun@sharedhealthmb.ca
- Jason Warren, Immunology Technical Director, Shared Health Manitoba, (phone: 204-471-0370) jwarren3@sharedhealthmb.ca