

DATE:	2022 July 11
TO:	All Health Care Providers, North, Edmonton, and Central Zones
FROM:	University of Alberta Hospital, Alberta Precision Laboratories (APL), North Sector
RE:	Performance of the Athena Anti-Double Stranded DNA Immunoassay (Luminex) on the New Commercial Antigen Preparation

PLEASE POST OR DISTRIBUTE AS WIDELY AS APPROPRIATE

Key Message

- The Athena Anti-Double Stranded DNA (anti-dsDNA) immunoassay on the new commercial antigen source tends to give a higher value than the original assay using crude antigen.
- The positivity rate is slightly higher on the anti-dsDNA assay using the new commercial antigen.
- Alternative anti-dsDNA immunoassays are available in Alberta to confirm anti-dsDNA results that do not fit the clinical picture.

Background

- On April 29, 2022, the Special Chemistry Laboratory in Edmonton switched the Athena anti-dsDNA test antigen preparation to a new, highly purified, commercial source.
- Method verification by Alberta Precision Laboratories confirms that the new antigen preparation has improved precision. The observed benefit is less lot to lot variation between batches of reagent, and tighter control of anti-dsDNA levels when monitoring known lupus patients.
- The new version of the anti-dsDNA assay is also more sensitive. It is better at detecting systemic lupus erythematosus (SLE).
- However, the gain in sensitivity comes with a slight decline in the specificity of the immunoassay.
- The University of Alberta Hospital Special Chemistry Lab and rheumatology have observed some false positive results during transition of known lupus patients to the new version of the anti-dsDNA assay.

How this will impact you

- The clinical biochemist is reviewing all anti-dsDNA results. The occasional sample is being sent out to APL-Calgary to confirm the anti-dsDNA result by an alternative method (Bioplex)
- This is a transient solution until the Special Chemistry Lab in Edmonton can switch to the Bioplex.
- The APL test directory has been updated to show the difference between the two anti-dsDNA assays
- Samples run by the Immunochemistry Lab in Calgary will have a different report and longer TAT.

	Edmonton Special Chemistry Lab	Calgary Immunochemistry Lab
Antigen Preparation*	Commercial source	Commercial source
Test Format	Multiplex bead immunoassay	Multiplex bead immunoassay
Instrument Platform	Athena Luminex 200	BioRad Bioplex 2200
Units	Mean fluorescence units (MFU)	kiU/L
Reference Interval	<120 MFU or (IU/mL)	Negative ≤4 kiU/L Indeterminate 5-9 kiU/L Positive >9 kiU/L

*Both anti-dsDNA assays are traceable to reference material Wo/80 dsDNA standard from the World Health Organization



Action Required

- If a discrepant anti-dsDNA result is observed during transition of known patients to the new version of the anti-dsDNA assay, contact the University of Alberta Hospital switchboard and page the on-call clinical biochemist.
- Become familiar with the APL test directory for anti-dsDNA especially reporting differences between the Edmonton and Calgary assays
- Anti-dsDNA test results should always be correlated with clinical features and other biomarkers of SLE.

Questions/Concerns

- Dr. Kareena Schnabl, Clinical Biochemist, Edmonton Special Chemistry Lab, (780) 407-3186, Kareena.Schnabl@aplabs.ca
- Dr. Dennis Orton, Clinical Biochemist, Calgary Immunochemistry Lab, (403) 770-3219, Dennis.Orton@aplabs.ca
- Dr. Jessica Gifford, Clinical Biochemist, Calgary Immunochemistry Lab, (403) 770-3779, Jessica.Gifford@aplabs.ca

Approved by

- Dr. Michael Mengel, Medical Director, APL, North Sector
- Dr. Paul Klonowski, Medical Director, APL, South Sector
- Dr. Hossein Sadrzadeh, Section Chief Biochemistry, APL, South Sector