Date: 10/24/2022

From: Mark A. Cervinski, PhD

 Director of Clinical Chemistry

RE: Anti-Nuclear Antibody Testing, Change in Methodology and Screening Algorithm

Please be advised that on Tuesday, 25 October 2022, there will be a change in the testing methodology and reference intervals for antinuclear antibody (ANA) and double-stranded DNA antibody (dsDNA) tests at DHMC.

This change in methodology is associated with the reinternalization of these tests that were temporarily sent to Mayo Medical Laboratories. These tests will now be performed in the Special Chemistry Laboratory at Dartmouth-Hitchcock Medical Center.

The new ANA profile begins with a qualitative ANA screen and quantitative dsDNA assessment by two separate automated fluoroenzymatic immunoassays. A positive result on the ANA screen portion of the profile will generate an automatic reflex to an Extractable Nuclear Antigen (ENA) profile to differentiate which of the seven autoantibody targets elicited the positive ANA screen result. Please see the algorithm on page three for clarification.

In association with this change, there will be a change in the methods and reference intervals for the ENA profile. These seven individual assays are detailed in the table on the following page.

In addition, both the dsDNA antibody and the individual components of the ENA profile are also available as individually orderable tests.

For questions concerning this notice please contact Dr. Cervinski at mark.a.cervinski@hitchcock.org

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| Test Description  | New Interpretive Criteria | Old Interpretive Criteria |
| ANA Screen | (Qualitative Results)NegativeEquivocalPositive | Negative: Titer < 1:80 |
| dsDNA | Negative: < 10 IU/mLEquivocal: 10 – 15 IU/mLPositive: > 15 IU/mL | Negative: < 30 IU/mLBorderline: 30 – 75 IU/mLPositive: > 75 IU/mL |
|  |  |  |
| Individual ENA Profile Components  |
| Centromere B  | Negative: < 7 U/mLEquivocal: 7 – 10 U/mLPositive: > 10 U/mL | Negative: < 1.0 UPositive: ≥ 1.0 U |
| Jo-1 | Negative: < 7 U/mLEquivocal: 7 – 10 U/mLPositive: > 10 U/mL | Negative: < 1.0 UPositive: ≥ 1.0 U |
| SSA/Ro | Negative: < 7 U/mLEquivocal: 7 – 10 U/mLPositive: > 10 U/mL | Negative: < 1.0 UPositive: ≥ 1.0 U |
| SSB/La | Negative: < 7 U/mLEquivocal: 7 – 10 U/mLPositive: > 10 U/mL | Negative: < 1.0 UPositive: ≥ 1.0 U |
| Scl-70 | Negative: < 7 U/mLEquivocal: 7 – 10 U/mLPositive: > 10 U/mL | Negative: < 1.0 UPositive: ≥ 1.0 U |
| Sm | Negative: < 7 U/mLEquivocal: 7 – 10 U/mLPositive: > 10 U/mL | Negative: < 1.0 UPositive: ≥ 1.0 U |
| U1RNP | Negative: < 5 U/mLEquivocal: 5 – 10 U/mLPositive: > 10 U/mL | Negative: < 1.0 UPositive: ≥ 1.0 U |

