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Munson Medical Center's microbiology lab has successfully validated and will begin testing for extractable nuclear antibodies (ENA) and tissue transglutaminase IgA and IgG (tTG). The INOVA immunoassay system is the testing platform that will be utilized.

Celiac disease serology testing cascades will be offered at Munson Medical Center in the same sequence as the testing currently sent to Mayo Medical Laboratories. Information regarding celiac disease testing algorithms can be found at:

• <u>https://www.mayomedicallaboratories.com/articles/resources/algorithms.html</u>

ENA screening (including Sm, RNP, SS-A, SS-B Scl-70, and Jo-1) results should be used in conjunction with clinical findings and other serological tests since these connective tissue diseases are clinico-pathologic diagnoses. Positive ENA screening assays will be automatically sent to Mayo Medical Laboratories for individual antibody characterization.

ENA testing has clinical limitations. These limitations include:

- As with all antibody testing, the presence of immune complexes or other immunoglobulin aggregates in the patient sample may cause an increased level of non-specific binding and produce false positives.
- Not all SLE patients are positive for Sm, RNP, SS-A, SS-B, Scl-70 or Jo-1.
- Some samples may have low-level concentrations of Sm, RNP, SS-A, SS-B, ScI-70 and Jo-1 antibodies that would be below the positive cutoff for each individual test, yet the cumulative effect might cause the ENA screening test results to be positive.

References:

https://www.mayomedicallaboratories.com/test-catalog/Overview/89035 https://www.mayomedicallaboratories.com/test-catalog/Overview/83631 QUANTA Lite ENA 6 ELISA Package Insert, Inova Diagnostics, Inc.