MAYO CLINIC LABORATORIES

TEST STATUS

Notification Date: November 9, 2021
Effective Date: Immediately

Myasthenia Gravis Evaluation with Muscle-Specific Kinase (MuSK) Reflex, Serum

Test ID: MGMR

Explanation:
Due to assay performance issues, test results may be delayed for reflex component MUSK: Muscle-Specific Kinase (MuSK) Autoantibody, Serum.

The performing laboratory has completed a comprehensive review of the analytical and clinical performance of the assay. A vendor reagent issue was discovered and samples with MuSK antibody titer results 0.03-0.2 nMol/L are unreliable and therefore will not be issued. Once the reagent issue is resolved, testing will be available for those patients impacted by this issue at no charge. The majority of specimens will be resulted without issue (negative results (<0.03 nMol/L) or those greater than 0.2 nMol/L).

Mayo Clinic Laboratories shared these observations with the manufacturer as well as other laboratories utilizing this specific reagent within the United States. The manufacturer is reviewing the data provided by Mayo Clinic Laboratories. A definitive cause and corrective action has not yet been identified by the manufacturer.

Mayo Clinic Laboratories takes great pride in our operations and our patient focused service. Although occurrences such as this are rare, we recognize that they can affect patient care and therefore take this reagent issue seriously. We will continue to hold our vendors to the high standard of quality that you expect. Please do not hesitate to contact Mayo Clinic Laboratories with additional questions or concerns.

A notification will be sent when standard reporting resumes.

Questions

Contact Amy Ennis or Steven Monson, Laboratory Technologist Resource Coordinator at 800-533-1710.