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Mayo Hospital
Mercy Hospital
Sebasticook Valley Hospital

MEMO

Date: February 27, 2025

To: NLH Mayo Clinical Staff

From: Dr. Buetens, Laboratory Medical Director and Hunter Martinsky, Laboratory Director

Re: High Sensitivity Troponin T Assay Update

WHEN: March 2025

WHERE: **The change will affect the following venue(s):**

- Acute/Inpatient (to include ED & Peri-Op)
- Ambulatory

At the following NLH Member Organization(s):

- Northern Light Mayo Hospital
- Northern Light Internal Medicine Dexter
- Northern Light Orthopedics Dover-Foxcroft
- Northern Light Pain Management Dover-Foxcroft
- Northern Light Primary Care Corinth
- Northern Light Primary Care Dover-Foxcroft
- Northern Light Primary Care Milo
- Northern Light Surgery Dover-Foxcroft
- Northern Light Women's Health Dover-Foxcroft

WHO: **This will affect the following staff at the above noted locations:**

- All Clinical Staff
- Laboratory Staff

WHAT & WHY: Northern Light Mayo Hospital Laboratory will replace its current High Sensitivity Troponin T assay with the Siemens High Sensitivity Troponin I assay (hsTnI).

Key differences with this new assay include:

- Measuring range of 4-25,000 pg/mL; values below 4 pg/mL will be reported as < 4 pg/mL while values greater than 25,000 will be reported as >25,000 pg/mL.

- Gender specific reference (normal) ranges (as defined by the 99th percentile upper reference limit):
    - Women: ≤ 51 pg/mL
    - Men: ≤ 76 pg/mL

Similar to our current assay, values greater than the 99th percentile upper reference limit by gender will be "flagged" as abnormal in the electronic medical record and will be considered critical values. To distinguish this assay from other cardiac troponin assays in the medical record (still in use at other Northern Light member organizations), the new assay will be reported as Troponin I HS. The previous conventional Troponin T assay will no longer be available at Northern Light Mayo Hospital.

Since a high percentage of "normal" individuals will have detectable troponin when tested using a highly sensitive assay, serial monitoring to detect rising or falling values (aka "dynamic" pattern) is key to proper interpretation of results. In addition, values from this troponin assay cannot be compared to any other troponin assay.

Troponin I is released during the process of myocyte necrosis. While extremely specific for cardiac muscle injury, an elevated value, in isolation, is neither specific for MI nor does it distinguish between various types of myocardial injury (e.g. arrhythmia, acute aortic syndrome, acute heart failure, hypertensive crisis, myocarditis, pericarditis, pulmonary embolism and Takotsubo cardiomyopathy). Serial testing (as described in the ACC/EHA/AHA guidelines and the Universal Definition of MI), in combination with all available clinical information is required to properly interpret the results and distinguish acute from chronic elevations. It is important to remember that cardiac Troponin (cTn) is a heart specific biomarker, not a disease specific biomarker and one must consider cTn as a marker of cardiac injury, not just ischemic damage from acute MI. Markedly elevated values (>5X URL), however, do have a high (>90%) positive predictive value for acute type 1 MI. Regardless of the etiology, however, elevated highly sensitive Troponin I values (dynamic or stable), should be considered high risk and are highly associated with increased morbidity and mortality.

HOW: **To assist in the use and interpretation of this new assay and to allow for efficient and safe cardiac rule-outs, it is recommended that providers routinely follow an algorithm validated for each individual troponin assay.**

Although various terms such as accelerated diagnostic protocols or disposition pathways have been used to describe chest pain protocols, they can collectively be referred to as clinical decision pathways (CDPs). Compared with an unstructured clinical assessment, CDPs have been shown to decrease unnecessary testing and reduce admissions while maintaining high sensitivity for detection of acute myocardial injury and 30-day major adverse cardiac events (MACE).

It is important to remember, however, that while the terms “rule in/out” are frequently used, these CDPs are designed to assign cardiac risk and maximize negative predictive value (not to make the official final diagnosis of MI).

The 0 and 2 hr algorithm for the Siemens hsTnI (Mueller et. al. Clinical Chemistry 64:9, 1347-1360 (2018)) is one such algorithm (see below). This algorithm demonstrated a

high negative predictive value (NPV) for early cardiac rule out (>99%) with positive predictive value of 69%.

This algorithm is as follows:

- 0 hr < 8 pg/mL AND 2 hr change < 7 pg/mL: Low-risk; MI "ruled out"
- 0 hr ≥ 120 pg/mL OR 2 hr change ≥ 20 pg/mL: High risk; MI "ruled in"
- Does not meet either of the above: Intermediate risk; "Observe".

Baseline (0 hr) and 2 hr samples will be drawn following the initial order. For those patients who do not meet the initial "rule in or rule out" criteria above (observation category), a third troponin will be reflexively drawn 2 hours after the second troponin. A change in troponin ≥ 20 pg/mL compared to the baseline troponin supports the diagnosis of acute myocardial injury.

The following interpretative comment will chart with each result:

“Results exceeding the upper reference limit (as defined by the 99th percentile by sex) indicate myocardial injury. While cardiac specific, troponins are not specific for myocardial infarction (MI) and elevated levels may be seen in other disease states that involve the heart muscle. ACC/ESC/AHA guidelines and the Universal Definition of MI recommend serial sampling to determine a rising and/or falling pattern to distinguish an acute etiology from other etiologies. Troponin results should always be used in conjunction with clinical signs and symptoms.