December 8, 2021

Troponin, High-Sensitivity (hsTroponin) Assay

Effective **Monday, December 20, 2021**, the current test code for Troponin, TROPI, will be phased out at all HNL Lab Medicine testing locations (excluding Holy Redeemer Hospital System). The replacement test will be a new cardiac troponin assay, **High Sensitivity Troponin I (HS Troponin I)**. The new test code will be **HSTRP**.

The new assay's results will be presented in whole numbers, with units reported as ng/L, and new reference ranges.

HS Troponin I is used for the quantitative determination of cardiac troponin I in human plasma and can aid in diagnosing acute myocardial infarction (AMI). High-sensitivity refers to the assay's performance characteristics, not a difference in the form of cardiac troponin being measured.

HS Troponin I has a higher analytic precision at lower concentrations, returning greater clinical sensitivity for myocardial injury and providing accurate recognition of small changes in troponin concentration (rise or fall) within a short time frame. The improved precision of HS Troponin I assay allows for more precise determination of the 99th percentile upper reference limit (URL) and an ability to report distinct reference ranges for males and females. Ninety-nine percent (99%) of the suspected healthy individuals have HS Troponin I values that are termed as the 99th percentile value, the upper limit of normal (ULN), or the upper reference limit (URL) and is the limit used for the current cardiac troponin tests.

This test will be performed on different platforms at HNL Lab Medicine: **Beckman Coulter** and **Siemens**. The table below lists the instruments, 99th percentile for male and female population, and critical values.

***** IMPORTANT INFORMATION *****

Table 1

Lab Site	Analyzer	99% Ref. Range Male	99% Ref. Range Female	Critical Value Male	Critical Value Female
Roble Road ACL–Hecktown ACL–Muhlenberg ACL–Pocono ACL–Schuylkill CH–Allentown CH–Bethlehem	BECKMAN COULTER **Access 2 /DxI**	**≤20 (ng/L)**	**≤12 (ng/L)**	>200 (ng/L)	>120 (ng/L)
ACL–Cedar Crest ACL–CC RedLab ACL–Hazleton	SIEMENS **Vista**	**≤79 (ng/L)**	**≤54 (ng/L)**	>800 (ng/L)	>500 (ng/L)
ACL–17th ACL–Tilghman	SIEMENS **EXL**	**≤76 (ng/L)**	**≤51 (ng/L)**	>800 (ng/L)	>500 (ng/L)

Variability can occur depending on the HNL Lab Medicine site performing the testing, the equipment, and the platforms.

Variability of instrumentation and 99th percentile information can be found in the chart above or HNL Lab Medicine's online handbook.

Transition Plan for Go-Live:

- Pending tests as of 12/20/21: will be completed using conventional Troponin I (TROPI)
- Existing orders that have not been collected: will be completed using HS Troponin I (HSTRP)
- Timed Troponin I tests in progress as of 12/20/21: will be completed using conventional Troponin I (TROPI)

Table 2

NEW Test Information:	
Effective Date	12/20/2021
Test Name	High Sensitivity Troponin I
Order Code	HSTRP
CPT Code	84484
Methodology	Immunoassay
Testing Schedule	7 days a week, 24 hours a day
Reporting Unit	ng/L
Reporting Decimals	Whole Number
Report Availability	1 day
Minimum Volume	1 mL
Container	Light Green top (Lithium Heparin, plasma separator) 
Reference Range & Critcal Values	Reference ranges and clinical values will vary depending on the laboratory site and platform the testing was performed on. Refer to the Table 1 of this communication or on HNL Lab Medicine's online handbook.
Clinical Utility	High sensitivity troponin is a cardiac marker that may be used to assist in the diagnosis of myocardial infarction.

REFERENCES:

1. Recommendations for Institutions Transitioning to High-Sensitivity Troponin Testing. James L. Januzzi, JR, MD, Simon A. Mahler, MD, MS, Robert Christenson, PhD, Jennifer Rhymer, MD, MBA, L. Kristen Newby, MD, MHS, Richard Body, MBChB, PhD, David A. Morrow, MD, MPH, Allan S. Jaffe, MD, , J Am Coll Cardiol . 2019 Mar 12;73(9):1059-1077.
2. High-Sensitivity Troponin I Assay Conversion guide, Siemens Healthcare Diagnostics
3. High Sensitivity Troponin I Immunoassay Instructions for use , Beckman Coulter