LABORATORY ALLIANCE
of Central New York, LLC
laboratoryalliance.com

New High-Sensitivity Troponin Assay (HsCTNI)

Effective December 7, 2021, Laboratory Alliance will be offering a new 5th Generation High Sensitivity Troponin I (HsCTNI) assay. The test will be available 24/7 and will be performed on the new Siemens Atellica platform. It will replace the Troponin I assay (CTNI) currently being performed on the Siemens Vista platform. This new assay is defined as high sensitivity based on the criteria set forth by the International Federation of Clinical Chemistry (IFCC) Task Force on Clinical Applications of Cardiac Bio-Markers:

- Total imprecision (CV) at the 99th percentile value should be at or below 10%.
- Measurable concentrations should be attainable at concentrations above the limit of detection (LoD) in at least 50% of healthy individuals.

The increased analytical sensitivity of HsCTNI facilitates expedited evaluation and triage of patients with possible acute coronary syndromes. It allows for the use of accelerated serial collection times, for example, 0 and 1 hour. A single HsCTNI value of >115 ng/L is highly suggestive of myocardial ischemia. HsCTNI will have distinct male and female reference ranges, the results will be in whole numbers and the units will be ng/L instead of the current ng/mL. The results may not be directly comparable to results from the previous assay.

As with other cardiac biomarkers, HsCTNI values must be evaluated in the context of the patient's clinical presentation, risk factors, and EKG. Serial testing is recommended to detect the temporal rise and or fall of troponin levels characteristic of acute myocardial infarction (AMI). The demonstration of a rise and or fall in troponin is needed to distinguish AMI from sustained troponin elevations associated with non-AMI conditions, such as renal failure, arrhythmias, pulmonary embolism, chronic renal disease, myocarditis, and cardiotoxicity.

The patient report will include the following interpretive comment to help providers assess the significance of any change (delta) in repeat Troponin results:

When assessing risk for Acute Coronary Syndrome, an initial HsCTNI below the 99th percentile reference value (females < 34 ng/L and males < 53 ng/L) and a 1-hour delta less than 15 ng/L should be considered low risk for myocardial injury when evaluated in the context of patient history, age, risk factors and EKG. A single HsCTNI value of >115 ng/L is highly suggestive of myocardial ischemia.

LABORATORY ALLIANCE of Central New York, LLC
laboratoryalliance.com

Assay Details:

Test code:	HSCTNI
Method:	Direct chemiluminescent immunoassay
Reference ranges:	99th percentile Reference value: • Female: < 34 ng/L • Male: < 53 ng/L
Analytical range:	3 ng/L – 25,000 ng/L
Specimen requirements:	Lithium heparin plasma **NOT ACCEPTABLE –** Serum or EDTA, sodium heparin and sodium fluoride/potassium oxalate plasma specimens
Specimen stability:	• 8 hours when tightly capped and stored at room temperature. • 24 hours when tightly capped and stored at 2 to 8°C. • 40 days when frozen at ≤ -20°C
Schedule of testing:	Daily, 24/7
CPT code:	84484
Billing code:	1010591

[1]Siemens Atellica IM Analyzer, TnIH Instructions for Use

Questions regarding this test may be directed to Bodhraj Acharya, Ph.D., FAACC, MT (ASCP), Chemistry Manager, at 315-410-7028 or bodhrajacharya@lacny.com.