



Important Announcement

ACL Offers High Sensitivity Troponin (TROPIH)

October 2021

Effective Thursday, October 21, 2021, ACL Laboratories will replace the current ultrasensitive Troponin I (TROPI) on the Siemens Vista and Dimension platforms with high sensitivity Troponin I (TROPIH).

Background:

- Cardiac troponin I is a marker that aids in the diagnosis of acute myocardial infarction. Over the years there have been improvements in assay performance to more accurately measure lower concentrations of troponin I.
- This new assay has increased sensitivity and lower limit of detection compared to the previous-generation assay for cardiac troponin.
- High sensitivity of troponin assays allows for the detection of smaller areas of necrosis and earlier detection of cardiac injury or infarction.
- The IFCC Task Force on Clinical Applications of Cardiac Biomarkers defines a troponin assay as a high-sensitivity assay if it meets the following criteria:
 - 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 subjects.
 - It is recommended that sex-specific reference ranges be used to better interpret results.

Specimen Requirements:

| | |
|-------------------|--|
| Collect: | One light green (lithium heparin gel) 4.5 mL |
| Transport: | One 1.0 mL (Min: 0.5 mL) plasma refrigerated or frozen |
| Stability: | Ambient 8 Hours |
| | Refrigerated 24 Hours |
| | Frozen 14 days |
| Test Performance: | Daily |
| Final Result: | 24 hours (Stat 1 hour) |

Summary of Changes with High Sensitivity Troponin (TROPIH):

1. Troponin I values will be reported as whole numbers with ng/L as units. (i.e. 0.04 ng/mL would now be reported as 40 ng/L).
2. The limit of detection is 4 ng/L (vs 15 ng/L for the current assay)
3. 10% CV is 12 ng/L (vs 40-50 ng/L for the current assay)
4. Sex-specific cut-offs based on the 99th percentiles will be implemented:

| Current (TROPI) | hs Troponin I (TROPIH) | |
|------------------------|-------------------------------|-----------|
| < 0.05 ng/mL | Male | < 77 ng/L |
| | Female | < 52 ng/L |

Notes:

1. The High Sensitivity Troponin assay is not interchangeable with either the current in-lab assay or Point of Care Troponin tests.
2. During the transition period, patients who have started serial measurements will continue with the existing troponin assay. Those patients presenting after “go-live” will be monitored using the new assay.
3. At this point no change in rule-in or rule-out protocols will be implemented.
4. The use of Rapid troponin testing using the iSTAT in Wisconsin will not be modified at this time. Users need to be aware of the differences in the assay performance and units of reporting.

For additional information regarding this test, as well as specimen collection requirements, please contact ACL Client Services at 1.800.877.7016 or visit our website at acllaboratories.com/test-catalog/.