May
2022

CLINICAL PATHOLOGY LABORATORIES
A Sonic Healthcare Clinical Laboratory

Client Communication

Change in testing: Troponin T

Effective May 02, 2022:

Clinical Pathology Laboratories is pleased to announce the conversion of troponin testing from the current troponin T assay to the enhanced generation 5 cardiac troponin T (Roche, cTnT GEN5) for the comprehensive evaluation of AMI. The new assay is a high-sensitivity cardiac troponin that enables more sensitive and precise detection at low troponin concentrations.

Troponin T (TnT) is a component of the contractile apparatus of the striated musculature. Although the function of TnT is the same in all striated muscles, the cardiac isoform of TnT originating exclusively from the myocardium (cardiac TnT, molecular weight 39.7 kDa) clearly differs from skeletal muscle TnT. As a result of its high tissue-specificity, cardiac troponin T (cTnT) is a cardio-specific, highly sensitive marker for myocardial damage.

Rapid, precise, and accurate detection of clinical, imaging, electrophysiological, and biomarker findings are the foundation for the diagnosis of acute myocardial infarction (AMI). Although current cardiac-specific assays are effective, they are often limited by decreased sensitivity and impression.

The Universal Definition of Myocardial Infarction (UDMI) recommends as an "optimal precision" the coefficient of variation (CV) at the 99th percentile upper reference limit to be less than 10%. The Roche Generation 5 Cardiac Troponin T meets the UDMI criteria for "guideline acceptable" precision and the International Federation of Clinical Chemistry (IFCC) definition of a high sensitivity assay.

Important points:

- **Units of Measure:** Results are currently reported in ug/L. The new troponin 5th generation will be reported in ng/L.
- **Sex-Specific Reference Ranges:** < 14 ng/L for females, < 22 ng/L for males, and < 19 ng/L for not specified.
- **Critical Value Has Changed:** The new critical value for the 5th generation troponin assay will be ≥14 ng/L for Females, ≥ 22 ng/L for Males, and ≥ 19 ng/L for not specified.
- **Only Li-Heparin Plasma Specimens:** Test is not FDA approved on serum. Serum specimens will be rejected.

Clinical Pathology Laboratories
9200 Wall Street, Austin, TX 78754

For further information, please refer to our website, **www.cpllabs.com** or call us at **512.339.1275**

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Name	Order Code
Troponin T	**4017**

Changes in reporting:

Assay	Order Code	Previous Clinical Reporting Range	New Clinical Reporting Range
Troponin T	4017	0.010 - 250 ug/L	6-10,000 ng/L

Assay	Order Code	Previous Reference Range	New Reference Range
Troponin T	4017	< 0.010 ug/L	< 14 ng/L for females < 22 ng/L for males < 19 ng/L for not specified

Assay	Order Code	Previous Critical Value	New Critical Value
Troponin T	4017	≥ 0.010 ug/L	≥ 14 ng/L for females ≥ 22 ng/L for males ≥ 19 ng/L for not specified

Order-Unit Codes and Test Names:	**4017 Troponin T**
Specimen Requirements:	*1 ML LI-HEPARIN PLASMA.* *LI-HEPARIN PLASMA TUBES CONTAINING SEPARATING GEL CAN BE USED.* *CENTRIFUGE SAMPLE WITHIN 2 HRS OF COLLECTION.* *TRANSFER PLASMA TO A PLASTIC TRANSPORT TUBE.* *CLEARLY LABEL AS HEPARIN PLASMA.* *FREEZE.* *CRITICAL FROZEN (CFZ).* *WHEN MULTIPLE TESTS ARE ORDERED, SUBMIT SEPARATE TUBE FOR THIS TEST.* *NOTE: DO NOT COLLECT SAMPLES FROM PATIENTS RECEIVING THERAPY WITH HIGH BIOTIN DOSES (>5 MG/DAY) UNTIL AT LEAST 8 HOURS FOLLOWING THE LAST BIOTIN ADMINISTRATION.*
Transport Temperature:	Critical Frozen
Stability (collection to initiation of testing):	Ambient, 15-25°C: N/A Refrigerated, 2-8°C: 24 Hrs Frozen, (-15) - (-25)°C: 12 Months
Performed:	Monday through Friday / PM Shift
Analytic Time:	1 day
CPT Code:	84484

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