

IMPLEMENTING HIGH-SENSITIVITY CARDIAC TROPONIN ASSAYS IN PRACTICE



The 99th Percentile Value is Universally Endorsed as the Reference Cut-off to Aid in the Diagnosis of Acute Myocardial Infarction (AMI)¹

Key Components to Implement High-Sensitivity Cardiac Troponin (hs-cTn) Assays In Practice

- 99th percentile should be determined in a healthy population^{1,2}
- 99th percentile from either peer-reviewed literature or from manufacturers' product information are acceptable
- 99th percentile for hs-cTn assays should be measured with an analytical imprecision of $\leq 10\%$ (% CV; coefficient of variation)^{1,2}
- hs-assays should measure cTn above the limit of detection in $\geq 50\%$ of healthy subjects^{2,3,4}

IMPLEMENTING HIGH-SENSITIVITY CARDIAC TROPONIN ASSAYS IN PRACTICE

Factors That May Influence hs-cTn Assay 99th Percentile

Age – cTn increases with increasing age, especially above 60 y⁵

Gender – Men have higher values than women^{3,4,6}

Assay Method – The 99th percentile should be determined for each assay, as assays are not standardized

Specimen Type – The 99th percentile should be determined for serum, plasma and/or whole blood.

99th Percentile Values Should be Established or Confirmed

With the appropriate statistical power for each gender (men and women):

- Using a minimum 300 male and 300 female subjects (by gender) if establishing 99th percentiles³
- Using a minimum of 20 subjects if confirming 99th percentiles³

With an appropriate 1-tailed nonparametric statistical method²

References

1. Thygesen K, Alpert JS, Jaffe AS, Simoons ML, Chaitman BR, White HD, the Writing Group on behalf of the Joint ESC/ACCF/AHA/WHF Task Force for the Universal Definition of Myocardial Infarction. *Eur Heart J* 2012; 33: 2551-67 [see also *Circulation* 2012; 126:2020-35 and *JACC* 2012; 60:1581-68].
2. Collinson PO, Heung YM, Gaze D, Boa F, Senior R, Christenson R, et al. Influence of population selection on the 99th percentile reference value for cardiac troponin assays. *Clin Chem* 2012; 58:219-25.
3. Apple FS, Collinson PO, and for the IFCC Task Force on Clinical Applications of Cardiac Biomarkers: analytical characteristics of high-sensitivity cardiac troponin assays. *Clin Chem* 2012; 58:54-61.
4. Apple FS, Ler R, Murakami MM. Determination of 19 cardiac troponin I and T assay 99th percentile values from a common, presumably healthy, population. *Clin Chem* 2012; 58:1574-81.
5. Venge P, Lindahl B. Cardiac troponin assay classification by both clinical and analytical performance characteristics: a study on outcome prediction. *Clin Chem* 2013; 59:976-81.
6. Kavsak PA, Allen LC, Apple FS, Booth R, Chan P, Delvin E, et al. Cardiac troponin testing in the acute care setting: ordering, reporting, and high sensitivity assays – an update from the Canadian Society of Clinical Chemists (CSCCC). *Clin Biochem* 2011; 44:1273-7.