Analytical evaluation of Mindray's new high-sensitivity cardiac troponin I immunoassay on CL-1200i

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CLIA Publication

About the Author

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Introduction

Cardiac troponin (cTn) has been used extensively for diagnosis and risk assessment of acute coronary syndrome (ACS). With the increase of cTnI sensitivity and specificity, the high-sensitivity cardiac troponin (hs-cTn) assays are widely used clinically, significantly improving the sensitivity of cTn detection, accelerating the diagnosis process of ACS.

Mindray High Sensitivity cTnI (CLIA) is a one-step multi-site immunoenzymatic assay to determine the concentration of cTnI in samples.[3]

The present study was designed to evaluate the analytical performance of Mindray's new high-sensitivity cardiac troponin I (hs-cTnI) chemiluminescentimmunoassay on the Mindray CL-1200i chemiluminescence analyzer.

Method

The evaluation of the analytical performance of this hs-cTnI immunoassay encompassed the calculation of the limit of blank (LOB), limit of detection (LOD), functional sensitivity, imprecision, linearity, and 99th percentile upper reference limit (URL), as well as method comparison with Beckman.[1]

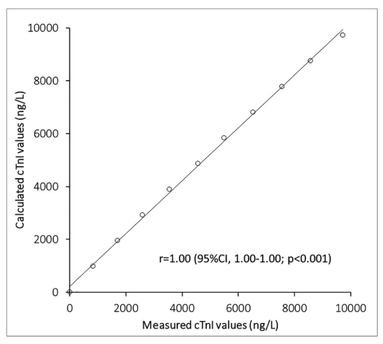
Results

1. LOB, LOD, and functional sensitivity

	Stated by Manufacturer	Measured in Laboratory
LOB	0.5 ng/L	0.32 ng/L (**<0.1 ng/L by C0**)
LOD	0.7 ng/L	0.35 ng/L
Functional sensitivity	/	0.35 ng/L

The LOB and LOD in the analytical evaluation are lower than the values stated by the manufacturer.

2. Linearity



The Spearman's correlation coefficient (r) is 1.00 (95 % CI, 1.00-1.00; p<0.001) across a range of 0.8 to 9,726.9 ng/L.

3. Imprecision

Pools	Intra-assay (n=20)		Inter-assay (n=10)		Total
	Mean ± SD, ng/L	Imprecision, CV %	Mean ± SD, ng/L	Imprecision, CV %	Imprecision, CV %
Low	17.3 ± 0.2	1.3 %	13.8 ± 1.1	8.1 %	8.2 %
Medium	92.2 ± 1.1	1.2 %	84.6 ± 5.9	7.0 %	7.1 %
High	1,753.9 ± 19.1	1.1 %	1,635.5 ± 90.3	5.5 %	5.6 %

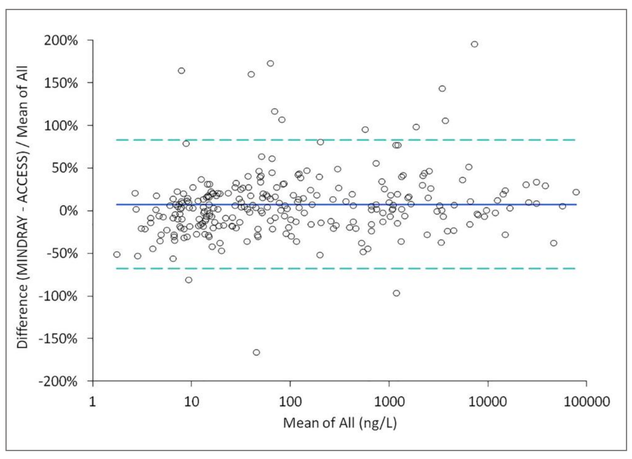
CV, coefficient of variation; SD, standard deviation.

The intra-assay imprecision ranged from 1.1 % to 1.3 %, the inter-assay imprecision from 5.5% to 8.1 %, and the total imprecision from 5.6% to 8.2%. The imprecision data meet one of the definition criteria for high sensitivity cTnI from the IFCC Task Force on Clinical Applications of Biomarkers (TF-CB) that the %CV at the 99th percentile URL should be≤10%.[2]

4. 99th percentile URL

The 99th percentile URL was determined to be 9.2 ng/L, calculated using residual plasma from 246 healthy blood donors (149 males and 97 females; mean age 42 ± 14 years, range 18-66 years) with values of 4.3 ng/L in females and 12.3 ng/L in males.

5. Method comparison



The method comparison study involved 265 subjects (166 males and 99 females; mean age: 73 ± 14 years) admitted to the local emergency department (ED) for suspected acute myocardial infarction (AMI).
The Spearman's correlation coefficient between Mindray hs-cTnI and Access hs-TnI was 0.97 (95 % CI, 0.97–0.98; p<0.001), and the Passing & Bablok linear fit was
[Mindray hs-cTnI] = [Access hs-TnI × 1.09] – [0.98].
The Bland and Altman plot analysis revealed a cumulative percentage bias of 7.2 % (95 % CI, 2.6–11.9 %; p=0.002) between paired patient samples measured with the two immunoassays.

Summary

The results of our study showed that this fully automated method has optimal analytical performance in terms of LOD, LOB, and functional sensitivity and optimal linearity across a wide range of clinically significant measurable values (i.e., r=1.00 between 0.8 and 9,727 ng/L). Furthermore, a strong correlation was found with another commercial hs-cTnI method (Access hs-TnI).

Conclusion

Our evaluation of the novel Mindray hs-cTnI immunoassay on CL-1200i showed that its overall analytical performance is comparable to that of other commercially available cTnI methods, making it a viable alternative to other methods.

[1] Giuseppe Lippi*, Laura Pighi, Elisa Paviati, Davide Demonte, Simone De Nitto, Matteo Gelati, Martina Montagnana, Giorgio Gandini, Brandon M. Henry and Gian Luca Salvagno. Analytical evaluation of the novel Mindray high sensitivity cardiac troponin I immunoassay on CL-1200i. Clin Chem Lab Med 2024; Jan 8. DOI: 10.1515/cclm-2023-1448.
[2] Alan H.B. Wu,* Robert H. Christenson, Dina N. Greene, Allan S. Jaffe, Peter A. Kavsak, Jordi Ordonez-Llanos, and Fred S. Apple. Clinical Laboratory Practice Recommendations for the Use of Cardiac Troponin in Acute Coronary Syndrome: Expert Opinion from the Academy of the American Association for Clinical Chemistry and the Task Force on Clinical Applications of Cardiac Bio-Markers of the International Federation of Clinical Chemistry and Laboratory Medicine. Clinical Chemistry 2018; 64(4):645-655. DOI:10.1373/clinchem.2017.277186.
[3] Ling Li, Xin Shu, Litao Zhang, Ao Xu, Juan Yang, Yisha Jing, Hui Wang and Zhenlu Zhang. Evaluation of the analytical and clinical performance of a new high-sensitivity cardiac troponin I assay: hs-cTnI (CLIA) assay. Clin Chem Lab Med 2023; 62(2):353-360. DOI: 10.1515/cclm-2023-0529.