Abstract: 
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Minicare high sensitivity troponin: a novel point-of-care tool to improve ACS workflows

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Topic(s):
Acute Coronary Syndromes: Biomarkers

Citation:

Background: Cardiac troponin (cTn) has been broadly accepted as the biomarker of choice in the diagnosis of patients presenting with Acute Coronary Syndrome (ACS). Point-of-care (POC) cTn testing, defined as testing near the patient with rapid availability of results, has attracted a strong interest in the emergency department (ED) setting. It offers the potential to improve workflows, expedite clinical decisions and to reduce the length of stay. Workflows could be further optimized when a first measurement can already be performed by the emergency medical services prior to admission to the hospital.

Advances in assay technology have led to high sensitive (HS) cTn assays that have a profound impact on clinical practice, providing early results at presentation and 1 hour after admission which speed up clinical decision-making. Here we evaluate the Minicare HS cTnI POC test under development, which has the potential to combine the benefits of HS-cTnI protocols with a POC workflow.

Objective: Evaluate the analytical and clinical capability of the Minicare HS-cTnI test under development to meet the criteria‡ for HS cTn of having a 10% CV < 99th percentile and a percentage measurable (>LoD) of >50%.

Methods: The evaluation is based on the Clinical Laboratory Standards Institute (CLSI) guidelines. Li-heparin whole blood and Li-heparin plasma samples were used to establish LoB, LoD, and LoQ, sample matrix comparison and linearity in the low range. The clinical performance for Minicare HS-cTnI was assessed and compared to Abbott Architect high-sensitivity troponin using banked samples from patients with ACS and collected at t=2-4h after admission. The percentage measurable was assessed and compared to Abbott Architect high-sensitivity troponin in a healthy population of 165 individuals.

Results: With a time to result within 10 minutes, the LoB is determined at 1.0 ng/L and the LoD at 2.1 ng/L. Plasma and whole blood results correlated well and showed comparable results. The 10% and 20% CV LoQ are established at 7.9 ng/L and 3.1 ng/L, well below the anticipated 99th percentile of 26 ng/L. With a percentage measurable of 77%, the criteria for a HS-cTnI assay are met in a POC device. A sensitivity of 93% and an NPV of 99% are found for Minicare HS-cTnI for a t=2-4h protocol vs 90% and 98% for Abbott Architect high-sensitivity troponin. In this study the area under the curve is 0.98 for Minicare HS-cTnI and 0.97 for Architect HS-cTnI.

Conclusions: With HS-cTnI capability on the Minicare platform, we show the potential to support a 0/1 h sampling protocol, combined with the speed of a POC workflow. This may enable even more rapid and safe rule-out of patients with ACS.

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Diagram:

The diagram shows the Receiver Operating Characteristic (ROC) curve comparing the performance of Minicare HS-cTnI and Abbott Architect HS-cTnI. The curve for Minicare HS-cTnI is positioned above and to the right of the curve for Abbott Architect HS-cTnI, indicating superior performance. The area under the curve (AUC) for Minicare HS-cTnI is 0.98, compared to 0.97 for Abbott Architect HS-cTnI.