Performance evaluation of the Philips Minicare cTnI assay

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Introduction

Near-patient testing can improve workflows in the Emergency Department (ED) enabling rapid clinical decision making. One of the applications in the ED where time is of the essence is in the diagnosis of acute myocardial infarction (AMI) in which Cardiac Troponin-I (cTnI) testing plays a key role. We present the results of first analytical and clinical studies of the new point-of-care Minicare cTnI assay*.

The Philips Minicare I-20* has been designed as a point-of-care immunoassay system for near-patient testing in the acute care setting. Results are available in less than 10 minutes enabling the physician to have the results available during the first interaction with the patient. The test is very easy to use as it only requires a droplet of blood that can be obtained by capillary draw or from a tube without de-capping.

Methods

The analytical performance of the Minicare cTnI assay was evaluated based on recommendations of the Clinical Laboratory Standards Institute (CLSI). Li-heparin whole blood and Li-heparin plasma samples were used to perform analytical, sensitivity, precision, and matrix comparison studies. The 99th percentile upper reference limit (URL) study was performed using Li-heparin plasma, Li heparin venous whole blood and capillary blood samples from in total 750 healthy male (n=373) and female (n=377) adults, with an age ranging from 18 to 86 years. To evaluate the clinical performance of Minicare cTnI for the diagnosis of AMI a European multi-center, prospective, non-randomized study was performed in 7 hospitals from 4 European countries, on 465 patients suspected of NSTE-ACS at the ED or CCU. Both Li-heparin whole blood and Li-heparin plasma samples, were drawn at three time points: at presentation at the ED and 2 – 4 hours after the first blood draw. Diagnosis of AMI was done by an external adjudication board of cardiologists.

Results

Limit of blank, limit of detection were determined in Li-heparin plasma to be 8.5 ng/l, and 18 ng/l respectively. The 20% limit of quantification was calculated at and 38 ng/l with no significant differences between Li-heparin whole blood and Li-heparin plasma. Total imprecision was found to be 7.7% - 12% between 109.6 ng/l – 5087 ng/l. The sample comparison study between capillary whole blood, venous Li-heparin whole blood and Li-heparin plasma samples demonstrated a correlation coefficient (r) of 0.99 and a slope between 1.03 – 1.08. The 99th percentile URL was calculated to be 43 ng/l with no significant difference between genders, or sample types. Incidence of AMI was 16% in the studied population. Clinical sensitivity of Minicare cTnI for the diagnosis of AMI was found at 92% and 91% at the 2-4 hour and 6-24 hour time points respectively, with an NPV of 98% and 96% and AUC of 95.3% and 96.1%; there were no significant differences in clinical performance between sample types (Li-heparin plasma and Li-heparin whole blood).

Conclusion

The Minicare cTnI assay is a sensitive, easy-to-use and precise test that can be used in the ED near the patient. Analytical evaluation of the Minicare cTnI assay demonstrates good performance; With an AUC of 95%, a sensitivity at 92% and a NPV of 98% for a cutoff at the 99th perc. URL value, Minicare cTnI can be used as an aid in the diagnosis of AMI in a diagnostic protocol including a cTn test at presentation of the patient at the ED and 2-4 hours later (0/3h diagnostic protocol) as recommended in the 2015 ESC guidelines for the management of NSTE-ACS patients.

* Product available in selected countries only