INTRODUCTION

Cardiac troponin I (cTnI) is a protein found in myocardial muscle. It is the preferred biomarker for detection of cardiac injury in the diagnosis of myocardial infarction (MI) (1,2). cTnI levels increase within 3-6 hours after the onset of symptoms, peak at 18-24 hours and remain elevated for 4-7 days (3). Due to the high positive predictive value of cTnI for MI, a positive result can contribute to early triage/risk stratification of at-risk patients (4). Early detection of myocardial damage is essential. It is recommended to implement Point-of-care tests for troponins when a central laboratory cannot consistently provide test results within 60 min (5). Community-based studies have shown that the overall mortality rate of patients with presumed MI or acute coronary syndrome in the first month is ~50%, and about 50% of these deaths occur within the first 2 hours (6).

MATERIALS AND METHODS

bioNexia® Troponin I test is a qualitative lateral flow immunoassay for the detection of cTnI in whole blood, serum or plasma. The membrane is pre-coated with capture reagent on the test line region (T) of the test. During testing, the cTnI in the whole blood, serum or plasma specimen reacts with two specific anti-cTnI antibodies. One of the antibodies mediates binding to the capture reagent, the other antibody is red particle labelled. The cTnI-antibody complexes migrate by capillary action along the membrane. In the test line region (T), the cTnI-antibody complex is captured by the immobilized capture reagent. The presence of a red line in the test line region (T) indicates a positive result. If the sample does not contain cTnI no line will appear in the test line region (T), the cTnI-antibody complex is captured by the immobilized capture reagent. In comparison with another rapid immuno-chromatographic test (detection limit at 1.0 ng/mL), a relative sensitivity of 96.27% [91.51-98.78%] 95% CI and relative specificity of 99.43% [96.84-99.99%] 95% CI was obtained.

RESULTS

Using the two different standards, it was shown that the analytical sensitivity of the bioNexia® test is at least 1.14 ng/mL.

In comparison with another rapid immuno-chromatographic test (detection limit: 1ng/ml), a relative sensitivity of 96.27% [91.51-98.78%] 95% CI and relative specificity of 99.43% [96.84-99.99%] 95% CI was obtained.

For the total cohort of 308 samples, only 6 discrepancies were observed, giving a concordance of 98.05% [95.81 – 99.28%] 95% CI. For 4 samples, the TnI values obtained with a quantitative immunoassay were very close to the bioNexia® Troponin I test cut-off, and 1 sample was re-tested with the other rapid test and detected as negative.

No interferences were observed with HAMA and RF samples. No cross-reactivity was observed with samples containing high levels of skeletal Troponin I, skeletal Troponin T, cardiac Troponin C and cardiac Troponin T.

CONCLUSION

bioNexia® Troponin I assay results demonstrate state-of-the art performance for qualitative rapid immunoassay test detection of cTnI, with results available in 10 minutes. bioNexia® Troponin I is an assay that has utility as a first-step aid in the diagnosis of myocardial infarction. A positive result indicates a high risk for MI. However, a negative result does not exclude MI and further follow-up is required including quantitative cTnI testing.