Cardiac troponin I (cTnI) testing with a recommended turnaround time (TAT, time from blood draw to reporting of result) of 1 hour is a key element in the evaluation of patients with chest pain and suspected acute coronary syndromes. Point-of-care (POC) testing for cTnI in the emergency setting may offer a solution when central lab testing does not meet the 1-hr TAT requirement. bioMérieux in collaboration with Philips Handheld Diagnostics are developing a novel cTnI POC test using a handheld device that allows testing from a single droplet of whole blood in less than 10 minutes. The objective of this study is to show equivalence in cTnI values between whole blood and corresponding plasma samples from patients.

METHODS

The cTnI POC test is a one-step sandwich immunoassay that is completed in a compact plastic disposable cartridge with on-board dry reagents and superparamagnetic nanoparticles. With this Magnotech technology the amount of bound nanoparticles, proportional to the amount of cTnI in the sample, is optically detected [1] and expressed as a percentage of maximum light intensity (Signal%). The optics and actuating electromagnets are integrated in a handheld analyzer.

Patient samples are applied onto the disposable cartridge that contains a filter to remove blood cells. The Signal% from fresh venous whole blood and corresponding plasma samples from patients.

RESULTS

Recovery

Samples were measured on cartridges with filter. The average recovery percentage between whole blood and plasma (5 replicates each) was calculated.

Although the cartridge filling time tends to increase with patient hematocrit, it remains below 40 seconds. As such this has minimal impact on the total time-to-result of the Magnotech cTnI assay which remains below 10 minutes.

Sample stability

Four (4) lithium heparinized whole blood samples (ranging from 3 to 47 Signal%) were tested for stability at room temperature in primary tubes up to 24h. Signal% recovery compared to initial testing point was plotted for each sample (3 replicates for each test point) in Figure 4.

CONCLUSION

The current development status of the Magnotech technology-based cTnI POC assay shows expected recovery of cTnI in whole blood samples compared to plasma. Cartridge filling time is lower than 1 minute contributing to a rapid assay (<10 min). Venous whole blood samples in lithium-heparin tubes can be stored at least 8h before testing without significantly impacting the observed Signal%.

The fitted relationship between venous whole blood and plasma is:

\[
\text{Signal\% whole blood} = 0.94 \times \text{Signal\% plasma} + 0.45
\]

Pearson coefficient is 0.99.

Using a filter, the Magnotech cTnI assay can quantify similarly both whole blood and plasma samples.

Filling time

Filling time is the time measured between the sample inlet in the cartridge and the entrance of filtered plasma in the reaction chamber. Cartridge filling time was recorded for 29 whole blood samples (average of 5 measures). Results are plotted according to patient hematocrit levels.

Venous whole blood samples in lithium-heparin tubes can be stored for several hours (at least 8h) before testing without significantly impacting the observed Signal%.