

DIAGNOSTIC ACCURACY OF DRIED BLOOD SPOT AND PLASMA SEPARATION CARD SAMPLES FOR TESTING HEPATITIS C VIRUS RNA

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Introduction

Dried blood spots (DBS) have the potential to improve access to diagnostic testing for hepatitis C virus. A number of studies have shown good performance of centralized HCV RNA assays with DBS specimens. There was, however, no standard protocol for DBS collection, storage and processing and DBS samples were limited to “off-label” use. Here, we evaluated the performance of three centralized HCV RNA assays from capillary blood collected on DBS and Plasma Separation Cards (PSC) using manufacturers’ protocols.

Methods

Participants were enrolled at four sites located in Cameroon, Rwanda, Georgia, and Greece. DBS and PSC samples were prepared from capillary (fingerstick) and venous whole blood samples. Collected samples were tested locally and sent for further testing to the central laboratory facility at NRL Australia (Melbourne, Australia). The diagnostic accuracy of these sample types for detecting hepatitis C virus RNA was assessed using three platforms (Abbott m2000sp/rt, Roche cobas® 4800 and Roche cobas® 6800) as the reference tests, with plasma tested using the respective plasma assays on each of the platforms.

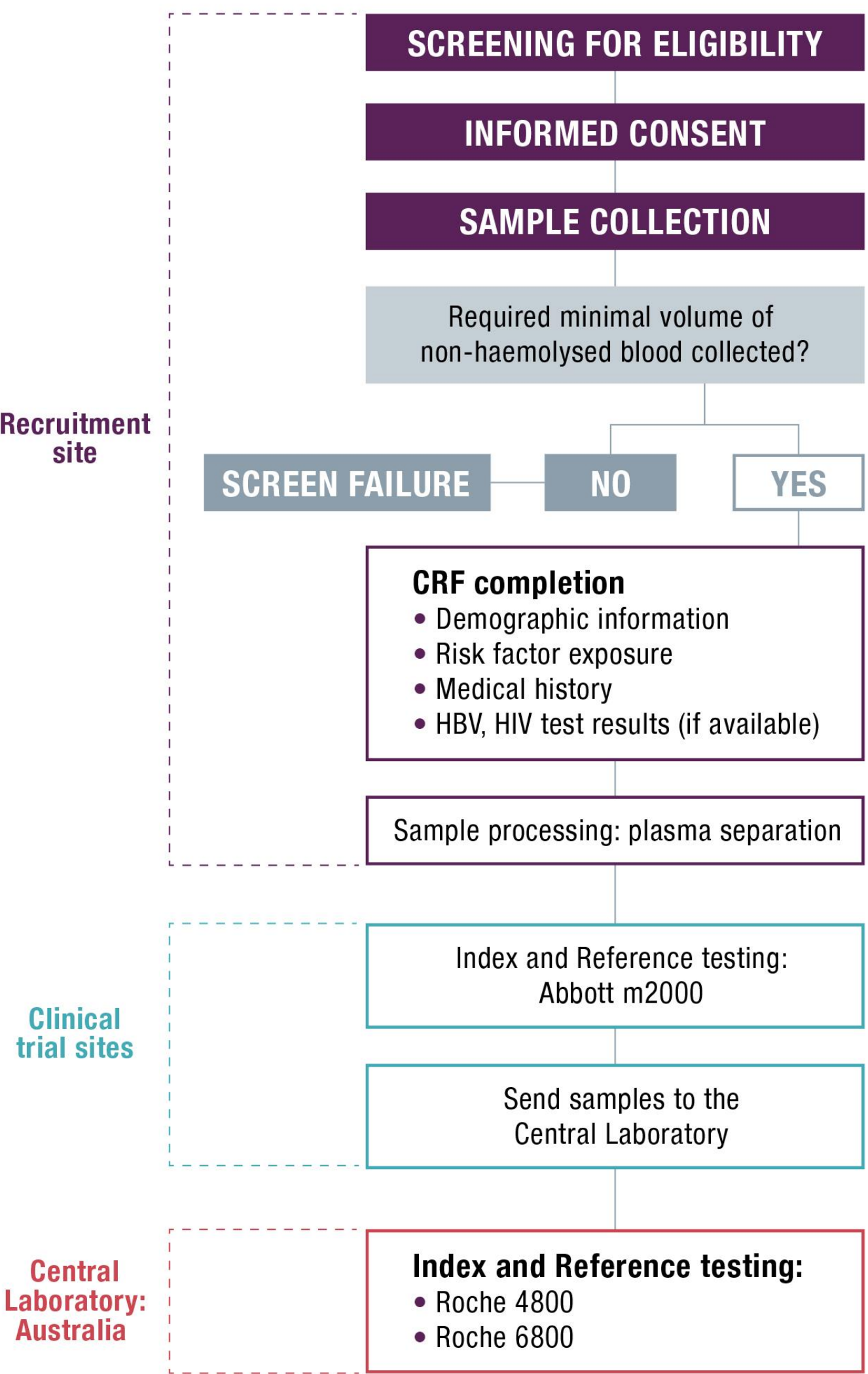


Figure 1. Overall trial workflow

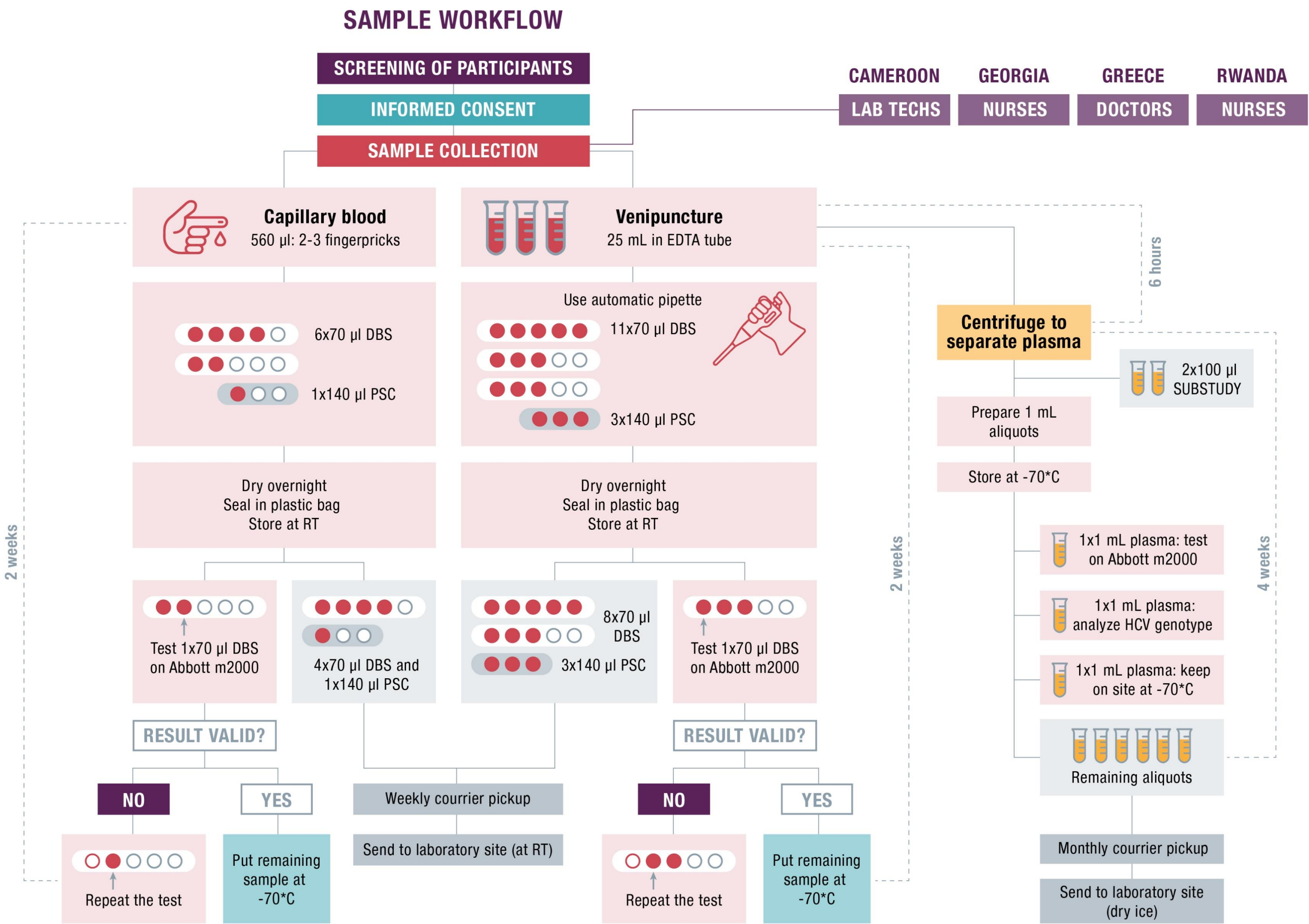


Figure 2. Sample workflow

Results

A total of 946 participants were enrolled. The sensitivity and specificity of the Abbott RealTime assay was 95.2% and 95.6%, respectively, using capillary DBS samples. The sensitivity and specificity of the Roche cobas® 6800 was 97.3% and 95.9%, respectively, on the DBS samples. Sensitivity and specificity were high on the Roche cobas® 4800 and 6800 assays using PSC samples.

* People who inject drugs

Conclusion

The diagnostic accuracy of DBS and PSC samples for detecting HCV RNA was high on all platforms evaluated, confirming that these sample types can be used as an alternative to plasma, to screen for HCV infection, thus facilitating access to testing.

Acknowledgements

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