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

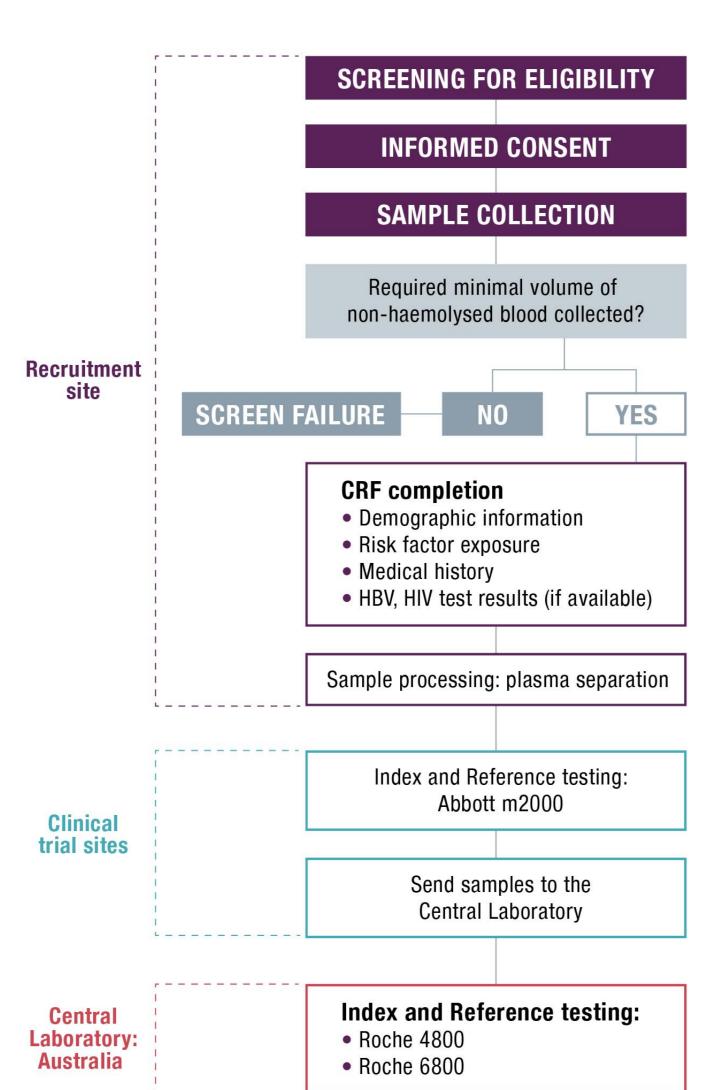
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Dried blood spots (DBS) have the potential to improve access to diagnostic testing for hepatitis C virus. A number of studies have shown good performance of centralized HCV RNA assays with DBS specimens. There was, however, no standard protocol for 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.



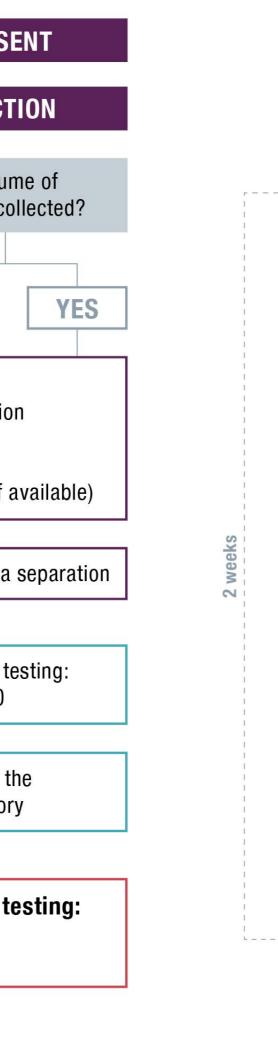


Figure 2. Sample workflow Figure 1. Overall trial workflow

			SAMPLE	WORKFLOW						
			SCREENING O	F PARTICIPANTS			CAMEROON	GEORGIA	GREECE	RWANDA
			INFORME	D CONSENT			LAB TECHS	NURSES	DOCTORS	NURSES
			SAMPLE (	COLLECTION						
			<b>Capillary blood</b> 60 μl: 2-3 fingerpricks		Venipuncture 25 mL in EDTA tube				hours	
		Dry overnight Seal in plastic bag Store at RT		Use automatic pipette  11x70 µl DBS  3x140 µl PSC  Dry overnight Seal in plastic bag Store at RT				Centrifuge to separate plasma		100 μl STUDY
iks							S	Store at -70*C	x1 mL plasma: test	
2 weeks		Test 1x70 µl DBS on Abbott m2000	4x70 µl DBS and 1x140 µl PSC	3x140	8x70 μl DBS Test 1x70 on Abbott	μl DBS	2 weeks	a	on Abbott m2000  1x1 mL plasma: nalyze HCV genotyp  1x1 mL plasma: kee	Abbott m2000  1 mL plasma: te HCV genotype  aL plasma: keep
	N	RESULT VALID?		ourrier pickup				R	on site at -70*C  emaining aliquots	
	0 • 0	Put re sam		ratory site (at RT)				Monthly courrier pickup  Send to laboratory site		
	порбаг	ino tost			nopeat the test	70 0			(dry ice)	

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Index test and sample type	Sensitivity (%) (95% CI)	Specificity (%) (95% CI)	
Abbott RealTime	95.2	95.6	
DBS	(92.9 – 96.8)	(93.3 – 97.1)	
Roche cobas® 4800	97.2	88.6	
DBS	(95.2 - 98.3)	(85.4 – 91.2)	
Roche cobas® 4800	95.2	99.6	
PSC	(92.8 - 96.8)	(98.5 - 99.9)	
Roche cobas® 6800	97.3	95.9	
DBS	(95.4 - 98.5)	(93.7 - 97.3)	
Roche cobas® 6800	96.9	99.8	
PSC	(94.8 – 98.1)	(98.8 - 100)	

Table 1. Diagnostic accuracy of centralized HCV RNA assays using DBS and PSC samples Abbreviations: CI, confidence interval; DBS, dried blood spot; PSC, plasma separation card

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

### 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.

<sup>\*</sup> People who inject drugs



















plasma, to screen for HCV infection, thus facilitating access to testing.







#### Acknowledgements

Conclusion

We would like to thank our partner sites and the participants for their involvement in the project. This project is funded by Unitaid.

