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Evaluation of the Dried Blood Spot (DBS) method as a tool for the screening of HIV Ag/Ab, HBsAg and anti-HCV using the Abbott Architect

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Introduction

Under-diagnosed and reported infection from Blood-Borne Viruses (BBVs) poses a major public health risk, particularly Hepatitis C in communities of high prevalence (Mental Health and Prison facilities). To increase the uptake a simple convenient screening tool such as Dried Blood Spot Testing (DBST) is therefore required. Our method, uses a novel collection card allowing serological testing of capillary blood obtained from a finger prick on the Abbott Architect.

To our knowledge, this study is the first to use a single 1x6mm DBS (low blood volume) for the simultaneous detection of HIV Ag/Ab, HBsAg and anti-HCV using the Abbott Architect with 100% sensitivity.

Aims & Objectives

The purpose of our study was to evaluate and validate a DBST method enabling diagnostic screening for HCV, HBV and HIV from the same sample, using a single 1X6mm spot and to compare the results of venous whole blood to capillary DBS samples.

The study was also designed to assess and develop new innovative ways of making Pathology services more accessible through alternative phlebotomy methods and to set up robust methodologies closely linked to clinical situations where the use of DBST could make a difference to patient care.

Method

This study was conducted between December 2013 and September 2014 by the Microbiology Department. Samples were collected using DBS collection devices produced by the Biochemistry Department.

A total of 753 samples were analysed to determine the of Cut-Off Absorbance Value (COAV) for HIV Ag/Ab, anti-HCV and HBsAg. Once these COAVs were ascertained, a further 368 samples were analysed for the validation phase of the project. For the final phase (standardisation), 52 paired EDTA and capillary finger-prick samples were tested.

For each sample, 4x3mm and 1x6mm discs were cut and eluted. They were tested on the Abbott Architect and the COAVs, sensitivities and specificities were compared to paired plasma results.

All samples were run according to manufacturer's instructions using the appropriate assay: HIV Ag/Ab Combo; Anti-HCV or HBsAg Qualitative II.

Results

DBS COAVs of 0.4, 0.6 and 0.04 RLUs (relative light units) were determined for HIV Ag/Ab, HBsAg and anti-HCV respectively. The same COAV can be used for both 4x3mm and 1x6mm DBS samples.

Sensitivity of 100% was observed for validation of HIV Ag/Ab, HBsAg and anti-HCV with specificities of 93.33%, 100% & 89.23% using 4x3mm and 95.11%, 100% & 89.23% using 1x6mm respectively.

Table 1- Sensitivity vs Specificity using Venous Samples

	4x3mm DBS		1x6mm DBS	
	Sensitivity %	Specificity %	Sensitivity%	Specificity %
HIV Ag/Ab	100	93.33	100	95.11
HBsAg	100	100	100	100
Anti-HCV	100	86.46	100	89.23

Note: The reduced specificity for anti-HCV in the validation of venous samples. 93.7% of these test results are from patients that are highly reactive for HIV Ag/Ab or HBsAg.

Capillary finger-prick DBS sensitivity was also 100% for all 3 assays with specificities of 95.12%, 100% & 100% using 4x3mm and 95.12%, 100% & 98.07% using 1x6mm for HIV Ag/Ab, HBsAg and anti-HCV respectively.

Table 2 - Sensitivity vs Specificity using Capillary Samples

	4x3mm DBS		1x6mm DBS	
	Sensitivity %	Specificity %	Sensitivity %	Specificity %
HIV Ag/Ab	100	95.12	100	95.12
HBsAg	100	100	100	100
Anti-HCV	100	100	100	98.07

Conclusions

The use of DBST is an innovative way of improving accessibility to Pathology through alternative phlebotomy methods, enabling wider screening for BBVs to combat the problem of undiagnosed infection.

Our DBST method is a simple and convenient screening tool which can be used to collect and analyse a single drop of blood for the presence of BBVs.

Collection is easy to perform, minimising the risks of sharps injuries and requiring minimal training (alleviating the need for trained phlebotomist).
It is an excellent method in situations arising when blood collection is difficult to achieve, due to collapsed veins or from those patients that are needle phobic.

The study showed high sensitivity and specificity for the detection of HIV Ag/Ab, HBsAg and anti-HCV in the DBS samples and would therefore be an ideal choice to be used as a screening tool for BBV infections in the community.