Evaluation of blood sampling with standardised filter paper technology for commercial molecular and serological analysis of hepatitis B-, C and HIV

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Background

Achieving the 2030 elimination targets for hepatitis B (HBV) and C (HCV) requires increased testing in high-risk populations. Venous sampling is often challenging in people who inject drugs. Capillary blood collection using dried blood spots (DBS), standardized by the Capitainer® device offers a potential alternative. However, clinical validation for use with commercial analytical platforms remains unavailable.

Results

Whole blood lysates were successfully analysed using serological (CLIA) and molecular (TMA-based real-time PCR) methods without evidence of inhibitory effects. Standards diluted in whole blood and applied to Capitainer® DBS cards showed good matrix agreement, though with slightly reduced sensitivity (Table 1). Lower sensitivity was observed in DBS from contrived historical samples, likely due to smaller sample volume. After applying a 1:20 correction factor to estimate viral load in DBS, whole blood lysates and plasma showed comparable sensitivity. Preliminary patient data (n=5) indicate consistent results between whole blood lysates and serum/plasma (Table 2).

Material and method

Part 1 included analysis of known historical samples (6 per virus) and international standards, and part 2 (ongoing) involves prospectively collected clinical DBS samples (n=5) (Figure 1). Historical samples were diluted 1:2 in negative whole blood, and standards were serially diluted (2-fold for serology, 10-fold for molecular assays). Contrived sample/standard was applied to Capitainer® DBS cards. The material was eluted 1:10 in PBS the following day and analyzed using the Advia Centaur XPT (Siemens) or Panther (Hologic) platforms. Historical serum/plasma results served as reference.

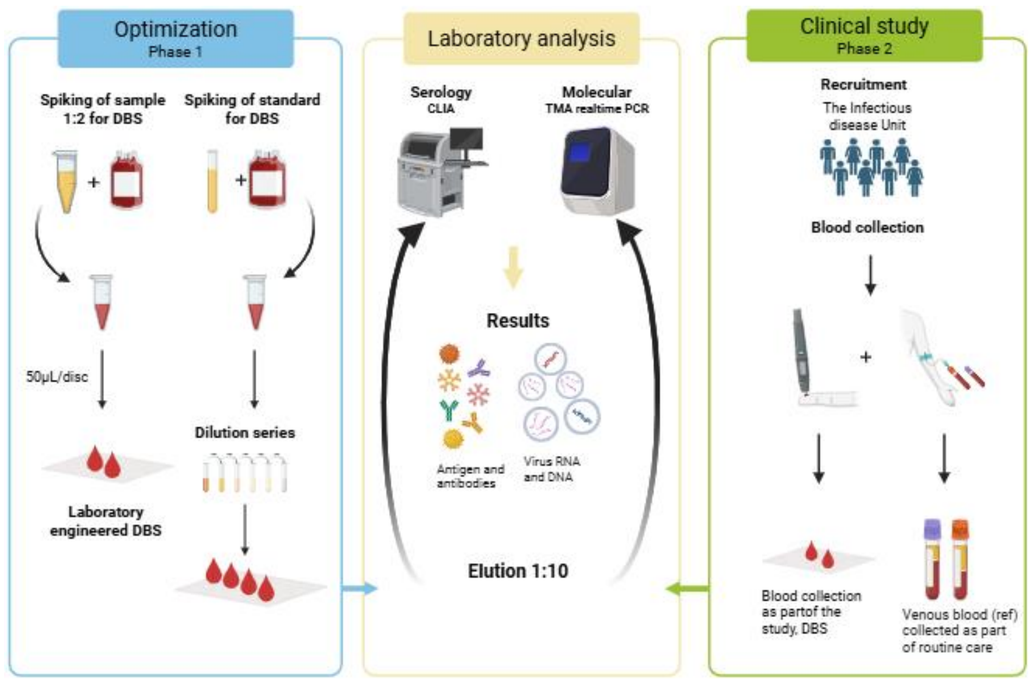

Figure 1. Study overwiev

Table 1. Detection level of NIBSC standards diluted in whole blood compared to reference matrix

Marker	DBS detection	Compared to the reference matrix
HBV DNA	49 IU/mL	One dilution step (5x) higher than plasma
HCV RNA	23 IU/mL	One dilution step (10x) higher than plasma
HIV-1 RNA	44 c/mL	One dilution step (10x) higher than plasma
HBsAg	0.03 s/co	Equal dilution step as serum
HIV p24-antigen	1.563 s/co	Equal dilution step as serum

Table 2. Results of capillary collected DBS (n=5), compared to reference matrix. Log IU/mL (HBV DNA, HCV RNA), Log c/mL (HIV-1 RNA), and s/co (serological markers) are reported. Both measured and calculated concentrations (adjusted for elution factor) are presented. SID: Sample-ID. ND: Not detected.

SID	HBV DNA		HBsAg		SID	HCV RNA		anti-HCV		SID	HIV-1 RNA		HIV ag/ab	
	Plasma	DBS	Serum s/co	DBS s/co		Plasma	DBS Obs/ calc.	Serum s/co	DBS s/co		Plasma	DBS Obs/ calc.	Serum s/co	DBS s/co
1	1.81	Detected	>1000	>1000	2	5.02	4.22/ 5.52	>11	>11	4	<30	ND	>12	>12
					3	6.74	5.06/ 6.37	>11	7.07	5	5.01	3.70/ 5.00	>12	>12

Conclusion

Our findings demonstrate that whole blood lysates from Capitainer® DBS cards are compatible with fully automated serological and molecular assays for HBV, HCV and HIV detection. Slightly reduced sensitivity was observed in contrived DBS-samples, primarily due to limited sample volume. These results support continued evaluation in patient samples ahead of potential implementation in the needle exchange program.

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