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Can dried blood spots or whole blood liquid transport media extend access to HIV viral load testing?

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INTRODUCTION

Plasma viral load (VL) for monitoring HIV patients receiving ART has limitations in resource limited settings where logistical constraints often prevent storage and transport of plasma. Dried Blood Spots (DBS) are being investigated as an option to extend VL testing.

DBS technology is a simple and relatively inexpensive technique which allows transport of specimens at ambient temperatures without RNA degradation (1). For this reason, DBS technology may also have a place for HIV VL testing and impact on laboratory costs and sample stability for assay testing, thus simplifying the process for resource limited settings where logistical constraints often prevent the storage and transport of plasma (2).

One of the main limitations of DBS technology specifically for VL testing, is that it compromises on assay sensitivity due to small specimen volume (~50 to 100ul). This has accelerated the need for the development of new technologies which can more accurately estimate HIV VL and thus be used more reliably to determine treatment failure and switch to second line.

References
1.McDade TW, et al. Demography, Volume 44 (4), 2007: 899–925.
2.Johannessen A, et al. Clin Infect Dis. 2009 Sep 15;49(6):976-81.

OBJECTIVE

To compare the performance of VL using different whole blood (WB) transport media against existing plasma methodology on a single specimen.

METHODS

- HIV+ patients presenting at Themba Lethu clinic, JHB for ART monitoring were consented and enrolled in the study to provide 4xEDTA tubes.
- Specimens sent to R&D Laboratory site for processing and testing by a scientist
- The following volumes of whole blood were added to media (according to each manufacturers guidelines) and tested on the Abbott RealT*ime* HIV-1 as per Figure 1:

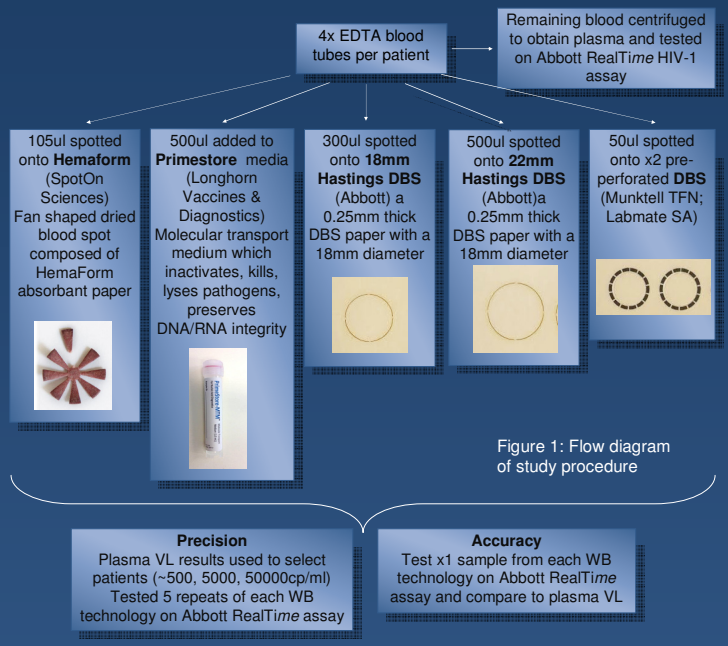

Figure 1: Flow diagram of study procedure

KEY FINDINGS:

Qualitative analysis					Quantitative analysis								
					Accuracy		Precision (intra-replicates n=5)						
					Bland Altman (≤0.3 acceptable)		SD on log cp/ml (≤0.19 acceptable)			%CV on cp/ml (<35%CV acceptable)		
Technologies	total n=	mean VL log cp/ml	Median VL log cp/ml	TND* n (%)	n	Mean bias log cp/ml (SD)	2 log	3 log	4 log	~500cp/ml	~5000cp/ml	~50000cp/ml
Plasma VL	96	3.89	4.2	4 (4.17%)	Reference method							
Primestore	87	4.7	4.67	20 (22.99%)	83	0.17 (1.59)	0.16	0.14	0.32	34.5	34.7	46.9
18mm DBS	95	4.54	4.57	29 (30.53%)	91	0.59 (1.25)	1.8	0.23	0.11	70.7	48.5	24
22mm DBS	96	4.62	4.76	31 (32.29%)	92	0.61 (1.24)	tnd	0.27	0.16	tnd	45.6	37.5
DBS	96	4.58	4.67	32 (33.33%)	92	0.73 (1.4)	Not performed					
Hemaform	96	4.52	4.7	32 (33.33%)	92	0.76 (1.36)	1.61	1.55	0.07	108.6	77.8	16.2

*TND = target not detected

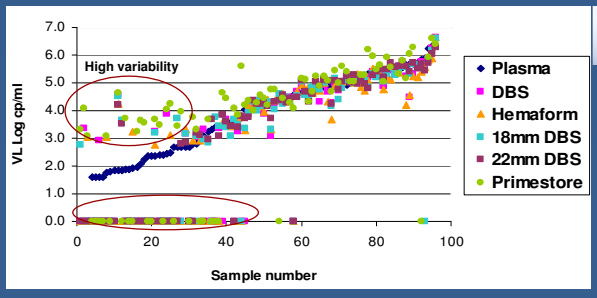

Figure 1: Qualitative results on WB technologies

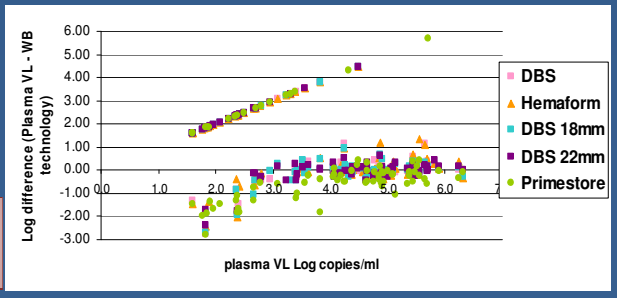

Figure 2: Bland altman difference plot of plasma VL and WB technologies

CONCLUSION

•Plasma, sooner than any whole blood specimens, remains the most sensitive and accurate specimen for ART monitoring across all VL ranges.
•Whole blood technologies showed greater variability in the <3.0cp/ml VL range (under and over quantification).
•Primestore, the only whole blood *liquid* technology, showed overall better performance (accuracy and precision) in the clinically relevant range (<5000cp/ml) than *dried blood* technologies.