EVALUATION OF A TRUE POC VIRAL LOAD TEST: SAMBA LEUCO-DEPLETED WHOLE BLOOD HIV ASSAY

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Gary Brook[1], Tetiana Stepchenkova[2], Innocent M.Ali[3], Sandra Chipuka[4], Helen Lee[5]

[1]London North West University Healthcare NHS Trust, London, UK [2]Kiev City AIDS Center, Kiev, Ukraine [3]University of Dschang, Cameroon
[4]National Microbiology Reference Laboratory, Harare Central Hospital, Zimbabwe [5]University of Cambridge, UK

BACKGROUND

- The UNAIDS 90:90:90 target requires access to HIV-VL testing and yet in many developing countries 50% or fewer patients are tested, and turnaround times for results can be 4 or more weeks leading to adverse treatment outcomes.
- Point-of-care (POC) VL testing that detects treatment failure will enable timely clinical decisions
- Most currently available HIV-VL assays work on plasma requiring venous blood and centrifugation of the sample.
- The SAMBA assay is a robust and portable sample-in/result-out technology that works on venous or finger-prick/capillary whole blood, which is automatically leucodepleted to remove integrated cellular DNA/RNA.
- Results within 2 hours, allowing immediate clinical decision making.
- Quantification is set at the WHO definition of ART treatment failure (≥1000 cps/ml)

METHODS

- **Analytical sensitivity** of the SAMBA II whole blood assay was determined by probit analysis on dilution series of HIV-1 standard and 11 seroconversion panels.
- **Analytical specificity** was determined by testing 500 HIV-1 negative whole blood samples and samples containing Hepatitis B, C and HTLV-I or II as well as potentially interfering substances such as bilirubin and ART drugs.
- **Clinical ('real-life') performance** was determined using venous and finger-prick capillary blood collected from consecutive HIV-positive patients attending clinics for routine testing in four countries (Cameroon, UK, Ukraine, Zimbabwe).
- SAMBA HIV VL results **using whole blood** were compared with Abbott Realtime PCR assay **using plasma** and analysed as a binary results (<1000 cp/ml or >1000 cp/ml ±0.3 Log).
- Samples with discrepant results were tested with a second gold standard HIV VL assay (Roche, Hologic or BioMerieux) as a 'tie-breaker'

The SAMBA HIV POC Whole Blood VL Assay:

- Shows a high degree of concordance **(c.95%)** with plasma – based HIV VL assays in the clinical setting
- Gives point-of-care rapid results in **<2 hours**
- Works on 150µl **finger-prick** samples
- Is robust technology that is not laboratory-dependent - it can be transported to **remote locations** making long turn-around times, missing results and lost-to-follow-up **a thing of the past**

RESULTS

- The **limit of detection** of the SAMBA II HIV-1 Semi-Q WB Test using Probit analysis is 1,037cp/ml (95% CI: 868- 1,362cp/ml) with a 95% probability of detection at 1,000 cp/ml.
- **Specificity** was 100% in 500 HIV-1 negative samples (95% CI 99.4-100%).
- **No cross-reaction or interference** was observed with common ART drugs or samples containing other infections or potentially interfering substances.

Clinical Performance of the SAMBA leucodepletion based whole-blood assay using capillary or venous samples compared with the gold standard plasma assays.

	Venous	Capillary
Total number of samples tested	1528	854
True negative (<1000 cps/ml)	1264	631
True positive (>1000 cps/ml)	227	188
False negative(<1000 cps/ml)	13	24
False positive (>1000 cps/ml)	24	11
Concordance with gold standard	1491/1528 97.6%	819/854 95.9%
Positive Predictive Value (≥1000 cps/ml)	227/251 90.4%	188/199 94.5%
Negative Predictive Value (<1000 cps/ml)	1264/1277 99.0%	631/655 96.3%

CONCLUSIONS

- Commercial HIV VL assays often 'disagree', especially at higher viral loads.
- Significant differences apply in 5-10% of VL results when commercial assays are compared
- There is >95% concordance between SAMBA leucodepletion based whole blood assay and the other VL assays - Difference between SAMBA and the other VL assays seen here may therefore be explained by the expected 'normal' inter-assay variability
- What SAMBA does offer are big advantages over other assays:
  - Point-of-care rapid results – <2 hours from sample collection to result and clinical decision
  - It works on finger-prick (capillary) samples – venesection not required
  - Robust technology that is not laboratory-dependent
  - It can be transported to remote locations making long turn-around times, missing results and lost-to-follow-up a thing of the past

ADDITIONAL KEY INFORMATION

Visit Diagnostics for the Real World: www.drw-ltd.com

Author Contact Information: gary.brook@nhs.net

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SAMBA II platform

