EVALUATION OF AN OPEN MODE PROTOCOL FOR HIV-1 RNA QUANTIFICATION IN DRIED BLOOD SPOTS ON THE ABBOTT m2000sp AND m2000rt PLATFORM

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Control Number: 251

BACKGROUND

• Many HIV positive (HIV+) persons have poor retention in care for various reasons: travel time/cost, depression and poor adherence to antiretroviral therapy (ART).
• Dried blood spots (DBS) are utilized in developing countries where health care access and advanced laboratory equipment is limited.
• The stability and transport of DBS could be amenable to home self-collection for viral load (VL) monitoring, which could help bridge the gaps of HIV care retention in the United States.
• We evaluated an open mode protocol on the m2000sp/rt platform (Abbott Molecular, Des Plaines, IL) for use with the HemaSpot DBS device (Spot On Sciences Inc.) as a method for quantitative HIV VL monitoring.

METHODS

• Eighty microliters of whole blood was spotted on the HemaSpot devices and air dried overnight at room temperature (RT).
• HemaSpot samples were eluted for 45 minutes at RT in 1.3mL of Abbott DBS Elution Buffer and processed by using the m2000_1.0ml_HIV_DBS_Quant protocol.
• Analytical sensitivity (AS), measuring range (MR) and precision were evaluated across 3 different runs in order to evaluate the performance of HemaSpot device with the above open mode protocol.
• EDTA anti-coagulated whole blood from patients with known HIV-1 RNA viral load was used to develop accuracy panels; the HemaSpot device results were compared to plasma viral load results obtained by Cobas AmpliPrep/Cobas Taqman HIV-1 v2.0 (Roche Molecular, Indianapolis, IN). 5 replicates of each specimen (ranging in concentration from ≥2.0 log < 7.0 log) were tested.
• Specificity was evaluated with EDTA anti-coagulated whole blood from known seronegative patients.

RESULTS

Analytical Performance
• LOD probit analysis was determined with 95% probability to be 3.44 log copies/mL (2771.63 cps/mL).
• Intra run and inter run precision was <0.19 log copies/mL.
• 100% Specificity was observed when the assay was tested with known seronegative patients.
• Qualitative detectability of the HemaSpot device was assessed between 3.7 log copies/mL and 2.8 log copies/mL (Figure 1).

Concordance between plasma and HemaSpot ≥ 1000 cps/mL
• 100% agreement was observed between the two sample types with viral load ranging between 3-7 log copies/mL.

Concordance between plasma and HemaSpot <1000 cps/mL
• 86% agreement was observed between the two sample types with viral load <1000 cps/mL. Of note all 7 plasma samples were below 400 cps/mL by the CAPCTM v2 HIV-1 assay.

Measuring Range
• Good correlation was observed between the HemaSpot device and plasma viral load with R2=0.965.

Method bias
• Bland-Altman plot analysis demonstrated an overall bias of 0.17 log copies/mL with the SD of 0.359 (p=0.04).
• 22/22 (100%) patient samples were within 1 log copies/mL, and 19/22 (86%) were within 0.5 log copies/mL.

CONCLUSIONS

• HemaSpot device LOD by probit analysis was 3.44 log cps/mL using RT incubation and the m2000_1.0ml_HIV_DBS_Quant protocol. This sensitivity could be further optimized by utilizing a recently developed RealTime HIV-1 DBS protocol which incorporates an incubation step at 55°C for 30 minutes before the m2000sp extraction.
• One limitation of this study is that plasma viral load values were determined by the CAP/CTM V2 assay, while the HemaSpot device viral load values were obtained using the Abbott open mode DBS HIV-1 quantitative assay. Previous studies have demonstrated a method bias between different platforms which in turn could impact LOD and accuracy assessment.

“The project described is supported by Grant Number 1C1CMS331343 from the U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. The content of this abstract is solely the responsibility of the authors and does not necessarily represent the official views of the U.S. Department of Health and Human Services or any of its agencies. The research presented was conducted by the awardee. Findings may or may not be consistent with or confirmed by the findings of the independent evaluation contractor.”