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Off-label evaluation of alternative specimen types: Cobas® plasma separation card for HIV viral load and dried blood spots for COVID-19 serology testing

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ABSTRACT

Plasma is the preferred specimen for HIV viral load (VL) monitoring and COVID-19 serology testing but poses a challenge in resource-limited settings due to the need for venous blood, skilled phlebotomy, and cold storage for specimen integrity. In this study dried blood spots and novel plasma separation devices (PSC, HSSE, and VLPlasma) versus plasma were investigated as alternative specimen types.

The plasma separation devices (PSD) were compared to DBS to determine if eliminating cell-associated nucleic acids could improve HIV VL performance. Paired PSD (n=72), DBS (n=72) and plasma (n=72) were prepared from HIV positive residual whole blood. Similarly, paired PSC, DBS (n=91) and plasma (n=91) were prepared from HIV positive prospective whole blood to assess PSC as an alternative specimen for use on the Abbott m2000. The eluates were processed on the GeneXpert (residual blood), Abbott m2000 (residual and prospective blood) and Roche cobas® 68/8800 (prospective blood). Using plasma as reference, residual blood: DBS outperformed PSC, HSSE and VLPlasma in terms of accuracy 91.8%, compared to 87.8%, 79.1% and 75%. Prospective blood: PSC had improved performance over DBS in terms of sensitivity (92.2% and 87.1%), specificity (65% and 61.9%), and accuracy (86.9% and 80.7%).

Additionally, the performance of DBS was evaluated for COVID-19 serology testing in 45 PCR-confirmed, COVID-19 positive individuals by preparing laboratory paired DBS-plasma samples. DBS were eluted using two diluents followed by manual ELISA and results compared to reference plasma testing. DBS-PBS and DBS-manufacturer's diluent showed the same accuracy (93.6%). Kappa values (0.817 and 0.845) and sensitivity (100% and 91.4%) were similar, but DBS-PBS showed low specificity (75%) compared to DBS-diluent (100%).

Off-Label use of the cobas® PSC for HIV VL and DBS for COVID-19 serology testing provides expanded options for testing in resource-limited settings. Further evaluation on capillary blood and automated laboratory workflow optimisation would still be required prior to scaled implementation.

Keywords: HIV/AIDS, Plasma, Plasma Separation Device, Plasma Separation Card, Dried Blood Spot, COVID-19