

DIAGNOSTIC ACCURACY VALIDATION OF ABBOTT M2000 FOR HIV VIRAL LOAD TESTING ON DBS SAMPLES (VERSION1.0); MALAWI PILOT STUDY

Keywords: HIV-1 Viral load, Dried blood spot, low-resource settings

Authors:

Marketa Hajna¹, Carol Metcalf², Maryam Rumaney², Ronald Khunga¹, Zibusiso Ndlovu², Reinaldo Ortuño¹

Affiliations:

¹Médecins Sans Frontières, Thyolo, Malawi

²Médecins Sans Frontières, Southern Africa Medical Unit, Cape Town, South Africa

Corresponding author:

Zibusiso Ndlovu
zee.ndlovu@joburg.msf.org

Background:

The strict requirements for storage and transport of plasma samples from clinics to laboratories for HIV viral load (VL) testing, limits access to HIV VL monitoring among patients on antiretroviral therapy (ART) in resource-limited settings. Dried blood spots (DBS) provide an alternative to plasma because there are no cold chain requirements and DBS can be stored at room temperature for up to three months. The Malawi Ministry of Health has adopted the Abbott m2000 system (Abbott) as the national standard for VL testing. As part of the switch from bioMérieux NucliSENS EasyQ/Easy Mag (NucliSENS) to Abbott, we did a study in Thyolo District Laboratory in Malawi to assess the diagnostic accuracy of the Abbott m2000 system for HIV VL testing on BDS samples.

Methods:

EDTA venous blood was collected from 412 patients on ART in August and September 2015, and processed into DBS and plasma samples. Plasma samples were tested on NucliSENS, and DBS samples were tested on Abbott and NucliSENS. The diagnostic accuracy of DBS VL at a threshold of 1,000 cells/ml was assessed using the plasma VL result as the reference.

Results:

Of the 412 study participants, 257 (62.4%) were females. DBS VL measured on Abbott had a sensitivity of 88.2% (95% CI: 72.5 – 96.7%) and specificity of 91.1% (95% CI: 87.8 – 93.7%) compared to plasma NucliSENS. DBS VL measured on NucliSENS had a sensitivity of 91.4% (95% CI: 76.9-98.2%) and specificity of 92.0% (95% CI: 88.8 – 94.6%) compared to plasma NucliSENS. Assuming a prevalence of VL \geq 1,000 copies/ml of 10%, DBS had a positive predictive value (PPV) of 52.4% and negative predictive value (NPV) of 98.6% on Abbott, and a PPV of 55.9% and NPV of 99.0% on NucliSENS.

Conclusion:

DBS had satisfactory diagnostic accuracy, making DBS samples suitable for VL testing on Abbott.