Evaluation of the point-of-care m-PIMA[™] HIV-1/2 viral load assay to support public health responses for infants and children living with HIV in Papua New Guinea

Starr M¹, Palmer M¹, Kelly A¹, Danwilai T¹, Catlett B¹, Kelly-Hanku A^{2,3}, Gare J³, Willie B^{2,3}, Schulz M², Cunningham P^{1,2}, Kelleher A^{1,2}, Badman SG²

¹St Vincent's Centre for Applied Medical Research, NSW State Reference Laboratory for HIV, St Vincent's Hospital, Sydney, ²The Kirby Institute for Infection and Immunity, UNSW, Sydney, ³Papua New Guinea Institute of Medical Research

Background:

Papua New Guinea (PNG) has the highest rates of HIV incidence and prevalence in the Pacific region, with an estimated mother-to-child transmission rate of ~25%. HIV viral load (VL) testing options to monitor infants and children living with HIV are extremely limited and confined to the national capital. The only point-of-care (PoC) platform approved for HIV VL testing in PNG requires a volume of blood not recommended for children <10 years. We performed an evaluation of the Abbott m-PIMATM PoC HIV-1/2 VL assay, which requires 50uL of plasma, to determine performance and suitability in a near patientcare setting for infants and children. This is the first evaluation of the m-PIMATM HIV-1/2 VL assay in Australia.

Methods:

Fourty-six remnant samples from routine HIV monitoring at St Vincent's Hospital, Sydney were evaluated for performance against the Roche Cobas Ampliprep/Taqman (CAP/CTM) HIV-1/2 VL assay (ethics: 2022/ETH00021). A total of sixty-eight on-label plasma samples and twenty-one off-label dried blood spots (DBS) were evaluated. Operator acceptability of analyser, assay and consumables was also conducted.

Results:

The difference between the m-PIMATM and Roche CAP/CTM log results ranged from -0.58 to 0.50 for plasma-based specimens within the quantitative range (n = 26) and the average log difference was 0.19. Pearsons correlation demonstrated a strong positive correlation (r = 0.89) to the reference. DBS was successful, however, had a high failure rate (33%) and is not an approved sample type. The analyser was easy to use and occupies minimal bench space.

Conclusion:

This limited evaluation demonstrates the m-PIMATM's easy set-up, ease of use, small footprint, short time-to-result at the point of care, small sample input volume and strong positive correlation to the reference. These attributes make this analyser and assay valuable to improving access to HIV VL monitoring for infants and children, in resource limited settings, such as PNG.

Disclosure of Interest Statement:

The m-PIMATM HIV-1/2 VL cartridges were purchased by the Department of Foreign Affairs (DFAT) and the use of the m-PIMATM analyser for this evaluation was provided based on a loan agreement by Abbott.