The POC Alere q HIV-1/2 Detect test for detection and quantification of HIV-2

Ming Chang1, Katja Weimar2, Dana Raugi3, Robert Smith3, Selly Ba4, Moussa Seydi1, Katrin Steinmetzer2, Robert Coombs1,3, Geoffrey Gottlieb1,5;
on behalf of the UW-Dakar HIV-2 Study Group.

Departments of Laboratory Medicine,2 Medicine, and 3Global Health, University of Washington, Seattle, Washington, USA,
4Alere Technologies GmbH, Germany,
5Service des Maladies Infectieuses IribaSma DIOP Mar, Centre Hospitalier Universitaire de Fann, Universite Cheikh Anta Diop de Dakar, Dakar, Senegal

Abstract 614
Session PM-1

**Background:**

Rapid point-of-care (POC) nucleic acid testing (NAT) that can detect, differentiate and quantify HIV-1 and HIV-2 RNA/DNA has the potential to improve the cascade of care and antiretroviral therapy monitoring. In addition, the new 4th-generation CDC algorithm for HIV diagnostic testing specifies differential HIV-1 and HIV-2 serologic and nucleic acid testing, but there are no FDA-approved confirmatory HIV-2 NAT assays currently available.

**Aims:**

To evaluate the Alere q HIV-1/2 Detect for detection and quantification of HIV-2 plasma RNA

**Methods:**

We compared the ability of the Alere q HIV-1/2 Detect test with 25uL of sample input and the University of Washington (UW)-Abbott m2000 HIV-2 viral load assay (Chang et al. JCV 2012) and the Abbott RealTime HIV-1 assay (Abbott Molecular) to detect and differentiate between HIV-1 and HIV-2. Under a “research use only” protocol, the Alere q HIV-1/2 platform was used to quantify HIV-2 plasma RNA viral load. Clinical samples from HIV-1, HIV-2 and HIV-1/2 dually-infected patients from Senegal and the US (ART-naive and ART experienced) were tested, along with the WHO HIV-2 international standard and HIV-2 reference strains (HIV-2 ROD and HIV-2 EHO). All testing was performed in the CLIA-certified UW Clinical Retrovirology Laboratory using 4 Alere q HIV-1/2 Detect devices (picture below).

**Results:**

- **Background results:**
  - Alere q detection rates in HIV-1, HIV-2, HIV-1/2 & HIV-2 negative plasma
  - HIV-2 ROD viral load assay: 54 results, Number detected: 45, 136, 55, 14, 7
  - Overall detection rates in HIV-1, HIV-2, HIV-1/2 & HIV-negative plasma
  - WHO HIV-2 Standard & HIV-2 NIH2 detection by Alere q

**Conclusion:**

The Alere q HIV-1/2 Detect test is a novel, rapid and simple device that detects HIV-2 RNA in clinical samples and differentiates between HIV-1 and HIV-2 with a high level of specificity. It is designed to use small samples (finger prick; 25uL) of whole blood and plasma and has the potential for use as a rapid HIV-2 NAT-based diagnostic and a viral load monitoring device in resource-limited settings, as well as providing confirmation of HIV-2 infection in the new CDC algorithm for HIV testing.