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

Abstract 614
Session PM-1

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on behalf of the UW-Dakar HIV-2 Study Group.

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BACKGROUND:

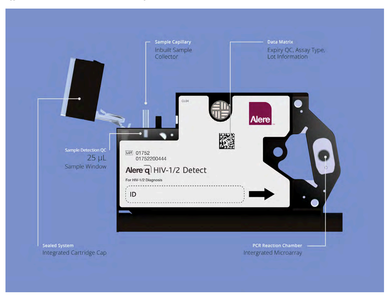
Rapid point-of-care (POC) nucleic acid testing (NAT) that can detect, differentiate and quantify HIV-1 and HIV-2 RNA/DNA has the potential to improve the cascade of care and antiretroviral therapy monitoring. In addition, the new 4th-generation CDC algorithm for HIV diagnostic testing specifies differential 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 25µL 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-naïve 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 (pictured below) .



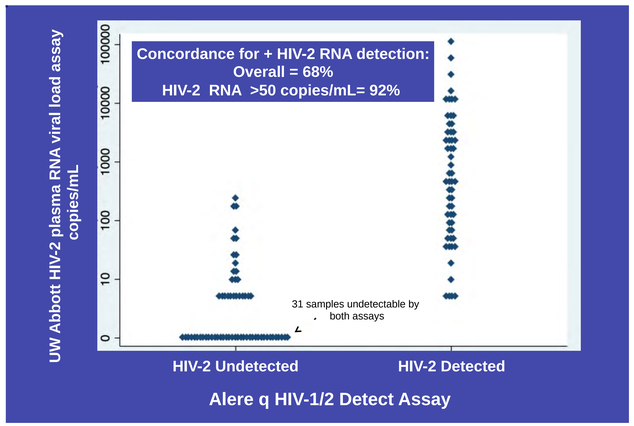


	Alere q HIV-1/2 Detect	UW Abbott m2000 HIV-2 Assay
Samples type & volume	**25uL of plasma or blood**	**1mL of plasma**
Assay Time	**<1 hour**	**~6 hours**
Run Format	**1 sample per run using a single cartridge**	**High throughput multiple samples (N=21) per run**
Report for clinical samples	**Qualitative results for HIV-1 M/N, HIV-1 O & HIV-2 (RUO: Quantitative HIV copies/mL)**	**Quantitative HIV-2 plasma RNA LOD: 10 copies/mL Range: 10-100,000 copies/mL**

RESULTS:

Alere q detection rates in HIV-1, HIV-2, HIV-1/2 & HIV-negative plasma

HIV serological status	Number of plasma samples	Alere HIV-1 M/N		Alere HIV-2	
		Undetected	Detected	Undetected	Detected
HIV seronegative	4	4	0	4	0
HIV-1 seropositive	22	5	17	23	0
HIV-2 seropositive	111	111	0	57	54
HIV-1 and HIV-2 seropositive	8	5	3	5	3



Alere q detection of HIV-1/HIV-2 dual seropositive samples

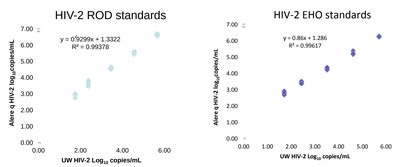
Dual HIV-1/HIV-2 Seropositive Samples	HIV-2 UW-Abbott results RNA copies/mL	HIV-2 Alere results	HIV-1 Abbott Results RNA copies/mL	HIV-1 Alere Results
HD01 (07.14.10)	Undetected	Undetected	Undetected	Undetected
HD02 (05.04.09)	2592	Detected	85120	HIV-1M/N detected
HD06 (09.29.09)	311	Detected	510596	HIV-1M/N detected
HD09 (01.06.11)	Undetected	Undetected	Undetected	Undetected
HD10 (01.06.11)	Undetected	Undetected	13730	HIV-1M/N detected
HD12 (08.11.11)	Undetected	Undetected	Undetected	Undetected
HD13 (09.08.11)	28726	Detected	Detected, <40c/ml	Undetected
HD14 (04.28.11)	Undetected	Undetected	Undetected	Undetected

Alere q HIV-2 RNA: Limit of detection (LOD)

HIV-2 ROD viral standards RNA copies/mL	Log $_{10}$ RNA copies /mL	Number of replicas tested	Number detected	Number undetected	Percent detected
651	2.81	9	9	0	100%
136	2.13	9	9	0	100%
55	1.74	9	9	0	100%
14	1.15	9	2	7	22%
7	0.85	9	0	9	0%

Alere q HIV-2 VL Linearity-Precision

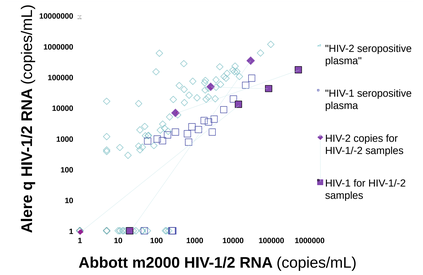
HIV-2 Strain	Nominal Log$_{10}$ RNA copies/mL	Mean of observed Log$_{10}$ RNA copies/mL	Total SD Log$_{10}$ RNA copies/mL	CV (%)
HIV-2 group A, ROD strain	1.74	2.88	0.10	20
	2.37	3.63	0.14	30
	3.45	4.56	0.05	11
	4.55	5.51	0.07	14
	5.65	6.61	0.05	12
HIV-2 group B, EHO strain	1.71	2.77	0.08	19
	2.43	3.40	0.06	14
	3.51	4.25	0.06	15
	4.61	5.22	0.08	20
	5.70	6.25	0.03	6



WHO HIV-2 Standard & HIV-2 NIH-Z detection by Alere q

HIV-2 Strain	Number detected	Percent detected
WHO HIV-2 STD 1000IU/mL	2/2	100%
E-M counted HIV-2 NIH-Z ~10,000 RNA copies/mL	10/10	100%

Alere q vs. Abbott HIV Viral Load



CONCLUSIONS:

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; 25µL) 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.

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