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Detection and differentiation of HIV-2 using the point-of-care Alere q HIV-1/2 Detect nucleic acid test

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Abstract

Background—The Alere q HIV-1/-2 Detect test (Alere Detect) is a rapid point-of-care (POC) nucleic acid test (NAT) that can detect and differentiate HIV-1 and HIV-2 in 25-μL whole blood or plasma samples. The Alere Detect test has been validated for early infant diagnosis of HIV-1 infection, and it is the only POC NAT device currently known to detect HIV-2, which is endemic in West Africa.

Objectives—To evaluate the sensitivity detecting HIV-2 RNA and the differential performance of the Alere Detect.

Study Design—Plasma samples from non-HIV (n=4), HIV-1 (n=22), HIV-2 (n=111; 29 Group A, 2 Group B) and HIV-1/HIV-2 dually-seropositive (n=8) participants in Senegal and the United States and HIV-2 reference strains (3 Group A, 1 Group B) were tested by Alere Detect, Abbott RealTime HIV-1 and the University of Washington HIV-2 RNA quantitative (UW HIV-2) assays.

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COMPETING INTERESTS: None

ETHICAL APPROVAL: UW IRB and the Senegal EC (CNERS)

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Results—The Alere Detect correctly differentiated between HIV-1 and HIV-2 in all 80 (100%) patient samples with detectable HIV RNA (n=20 HIV-1, 60 HIV-2). The overall HIV-2 detection concordance between Alere Detect and the UW HIV-2 assay was 68% (54/80); the concordance improved to 100% (30/30) for samples with HIV-2 RNA >300copies/mL. Neither assay detected HIV-2 RNA in 31 of 111 HIV-2 seropositive samples.

Conclusions—The Alere Detect test is a novel device detecting HIV RNA in clinical samples, and differentiating HIV-1 and HIV-2 with a high level of specificity. It has the potential for use as a rapid HIV-2 NAT-based diagnosis tool in resource-limited settings and to confirm HIV-2 infection for the CDC 4th generation HIV-1/2 diagnostic algorithm.

Keywords

HIV-2; diagnosis; point-of-care; nucleic acid test; Alere q HIV-1/-2 Detect; qualitative

BACKGROUND

HIV-2 is endemic in West Africa with limited global spread primarily to countries with socioeconomic ties to the region (1–4); there are an estimated 1–2 million patients infected with HIV-2 worldwide (5–7). Compared to HIV-1, patients infected with HIV-2 often have a longer asymptomatic stage, slower decline in CD4+T-cells and decreased acquired immunodeficiency syndrome (AIDS)-associated mortality (8–11). In areas where HIV-2 and HIV-1 co-circulate, a substantial number of patients are dually-infected with both HIV types (12–14). The correct differentiation between HIV-1 and HIV-2 infection is critical for diagnosis, antiretroviral therapy (ART) and medical management of HIV-infected individuals (15).

Current methods for distinguishing between HIV-1 and HIV-2 rely on differential immunoassays with varying sensitivity and specificity (16, 17). The Alere q HIV-1/-2 Detect (Alere Detect) test is a rapid point-of-care (POC) nucleic acid test (NAT) providing several advantageous characteristics for HIV diagnosis: 1) the requirement for only 25 microliters plasma or whole blood per test; 2) test completion within one hour; 3) detection and differentiation of HIV-1 Group M/N, HIV-1 Group O and HIV-2 nucleic acid; and 4) the only currently available POC NAT able to detect HIV-2 (18). Two studies have demonstrated the feasibility of the Alere Detect test to diagnose HIV-1 infection for HIV-1-exposed infants in South Africa and Mozambique (19, 20). Here, we evaluated the performance of the Alere Detect test for the detection of HIV-1 and HIV-2 in plasma samples collected from HIV-1, HIV-2 and differentiation of HIV-1 from HIV-2, in dually-seropositive patients.

OBJECTIVES

Our objectives were to evaluate the sensitivity detecting HIV-2 RNA in plasma samples and the differential performance between HIV-1 and HIV-2 RNA by the Alere q HIV-1/-2 Detect.

STUDY DESIGN

Patient HIV samples and controls

Clinical plasma samples from HIV-seronegative, HIV-1, HIV-2 and HIV-1/HIV-2 dually-seropositive patients from Senegal and the United States were tested. All study subjects were provided written informed consent, and specimens were collected with human subject approval from the UW Institutional Review Board and the Senegalese Ministry of Health Ethic Committee (CNERS). All clinical specimens were de-identified as required by the UW Humans Subjects Division.

Senegalese HIV-2 and HIV-1/HIV-2 dual-seropositive patient plasma samples were collected as part of ongoing studies of HIV-2 infection in antiretroviral (ARV)-naïve subjects and antiretroviral treated subjects as part of the Senegalese Government Antiretroviral Program (ISAARV) (www.cnls-senegal.org) at the Clinique Des Maladies Infectieuses et Tropicales Ibrahima DIOP MAR, Dakar, and the Centre de Sante, Ziguinchor, Senegal (21–23). Collected HIV seronegative and HIV-1 seropositive samples were from discarded clinical samples tested by the University of Washington (UW) Clinical Retrovirology Laboratory. Reference strains of HIV-2_{NIH-Z}, HIV-2_{ROD} and HIV-2_{EHO} viral stocks were diluted in human HIV-negative plasma to nominal 12,000 copies/mL, 500 copies/mL, and 500 copies/mL, respectively.. WHO HIV-2 RNA International Standard, containing HIV-2_{CAM-2} strain, were reconstituted using molecular grade water to 1000 units/mL. HIV-seropositive status for Senegalese participants was determined using Determine (Alere, Inc., USA) and Immunocomb II (Orgenics, Israel) immunoassays. The status of discarded clinical plasma samples was determined using the BioRad GS HIV-1 Western blot kit or the Multispot HIV-1/HIV-2 Rapid Test (BioRad, USA).

HIV-1 and HIV-2 RNA in plasma samples was quantified by the Abbott RealTime HIV-1 assay (Abbott HIV-1 assay) (Abbott Molecular, USA) and the clinically validated UW-Abbott m2000 HIV-2 RNA quantitative assay (UW HIV-2 assay), respectively (24).

Alere q HIV-1/2 Detect and Alere q Analyzer

Each Alere Detect test consisted of a single-use cartridge that contained reagents for the capture and amplification of HIV-RNA. After loading the sample capillary with 25 μL of plasma, each cartridge was inserted into an Alere q Analyzer where RNA isolation, cDNA synthesis, PCR and signal detection occur. The Alere q Analyzer reported either “detected” or “not detected” results for HIV-1 Group M/N, HIV-1 Group O and HIV-2 (18). The tests described in this study were carried out using four Alere q Analyzers in the Clinical Laboratory Improvement Amendments (CLIA)-certified and College of American Pathologists (CAP)-accredited UW Clinical Retrovirus laboratory.

RESULTS

Qualitative detection of HIV-2 RNA in plasma samples

Of 111 plasma samples collected from HIV-2 seropositive patients, 31 samples (27.9%) were not detected by either the Alere Detect or the UW HIV-2 assay (Table 1). Of the 80

total samples detected or quantified by the UW HIV-2 assay (median=108 copies/mL, range: <10 to 96,000 copies/mL), 54 samples (67.5%) were detected by the Alere Detect. The overall concordance for detection between the Alere Detect and the UW HIV-2 assay was 54/80 (68%; 95%CI. 56.1% to 77.6%); the concordance improved to 42/46 (91%; 95%CI, 79.2% to 97.6%) for samples with HIV-2 RNA level >50 copies/mL and to 30/30 (100%; 95%CI lower bound 90.5%) for samples with >300 HIV-2 RNA copies/mL.

Of the 22 HIV-1 plasma samples with RNA levels detected or quantified by the Abbott HIV-1 assay (median=663 copies/mL, range: <40 to 31,000 copies/mL), the overall concordance for detection between the Alere Detect and the Abbott HIV-1 assay was 17/22 (77%; 95%CI, 54.6% to 92.2%); the concordance was 17/20 (85%; 95% CI, 62.1% to 96.8%) for plasma samples with HIV-1 RNA levels >50 copies/mL and 13/13 (100%; 95%CI lower bound 79.4%) for samples >300 HIV-1 RNA copies/mL.

Differentiation between HIV-1 and HIV-2

To evaluate assay capability, a total of 149 samples, including 4 HIV-seronegative, 22 HIV-1 seropositive, 111 HIV-2 seropositive, 8 dual HIV-1/HIV-2 seropositive and 4 HIV-2 reference strains, were tested using the Alere Detect (Table 2). The Alere Detect accurately differentiated between HIV-1 and HIV-2 in 100% of 80 samples with detectable HIV RNA (20 HIV-1, 60 HIV-2) and had no misclassification errors in samples with undetectable HIV RNA (5 HIV-1; 58 HIV-2; 4 HIV-seronegative).

In addition, 8 HIV-1/HIV-2 dually-seropositive plasma samples were tested using the Alere Detect, and their HIV-1 and HIV-2 RNA levels were measured using the Abbott HIV-1 and the UW HIV-2 assays, respectively (Table 3). Samples HD02 and HD06 had detectable HIV-1 M/N and HIV-2 (both HIV-1 and HIV-2 RNA levels were greater than 300 copies/mL). Neither HIV-1 nor HIV-2 was detected by the Alere Detect test in HD01, HD09, HD12, and HD14 (these samples all had undetectable HIV RNA levels). HIV-2 was detected by the Alere Detect test and the UW HIV-2 assay, while HIV-1 RNA was too low to be detected by the Alere Detect test in HD13. In the sample collected from HD10, only HIV-1 RNA was detected by the Alere Detect test and the Abbott HIV-1 assay; however, HIV-2 RNA was not detected by either the Alere Detect test or the UW HIV-2 assay.

DISCUSSION

In this study, we evaluated the ability of the Alere q HIV-1/2 Detect, a rapid POC NAT platform, to detect and differentiate HIV-1 from HIV-2 RNA in plasma samples collected from HIV-infected persons. To our knowledge, this is the first study of a device that detects and differentiates HIV-1 and HIV-2 nucleic acid, which makes this device suitable for use in HIV-2 endemic regions. The 4th-generation (2014) CDC algorithm for HIV diagnostic testing differentiates HIV-1 from HIV-2 infection (25), which is important for improving diagnostic specificity of unknown or unrecognized and misclassified cases of HIV-2 infection (4). However, one of the unaddressed issues with the 2014 CDC algorithm is the lack of an available and FDA-approved HIV-2 NAT to confirm HIV-2 positive serology and to help determine whether dually HIV-1/HIV-2 reactive or seropositive (so-called “HIV-undifferentiated”) individuals are infected with either HIV-1 or HIV-2 or both. Our study

demonstrates that the Alere Detect test correctly identified HIV-1 M/N and/or HIV-2 with high specificity in 100% of 80 samples with detectable HIV-1 or HIV-2 RNA or both. This unique capability may be useful for reducing the serological misdiagnosis of HIV-2 infection.

The Alere Detect test was first investigated for early infant detection (EID) in Mozambique and South Africa (19, 20). In these two studies, heel-stick blood samples were tested by the Alere Detect test and the Roche COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Qualitative Test (Roche HIV-1 qualitative test). The combined sensitivity and specificity of the POC Alere Detect test were 97% and 99%, respectively, compared to the high-throughput Roche HIV-1 qualitative test. Though the detection limit for whole blood samples has not been published, the sensitivity of the Roche HIV-1 qualitative assay for dried blood spots was reported to be 300 copies/mL (26). Our study yielded results with similar sensitivity: all 13 of the plasma samples, which contained more than 300 copies/mL measured by the Abbott HIV-1 assay, were detected by the Alere Detect test. Our study further showed that the detection limit of the Alere Detect for HIV-2 RNA in plasma samples was similar: 30 of 30 HIV-2–seropositive plasma samples that contained >300 copies/mL HIV-2 RNA were all detected by the Alere Detect. The vast difference of input volumes between the Alere Detect (25 μL) assay and the UW HIV-2 assay (1000μL) influenced the concordance of HIV-2 RNA detection between these two assays. The generation of positive results for samples with >300 HIV-2 RNA copies/mL indicated the ability for the Alere Detect assay to detect ≥ 8 copies HIV-2 RNA in 25 μL plasma samples. In addition, other HIV POC NAT platforms have been documented to detect HIV-1 only, such as the Liat HIV Quant (27, 28) and Cepheid Xpert HIV-1 Qual (29, 30) assays. The Alere Detect test is the only POC device at this time that is currently able to detect HIV-2, which makes it potentially suitable for the detection of HIV-2 infection in mother-to-child transmissions (PMTCT) programs, especially in West Africa; however, formal clinical studies are required to validate the utility of this device in HIV-2 endemic areas.

In conclusion, the Alere q HIV-1/2 Detect test is designed to use small volume samples (25 μL of either finger prick or venous whole blood or plasma) and may also serve as a rapid HIV NAT-based diagnostic test in resource-limited settings. Importantly, the Alere q HIV-1/2 Detect device provides for important NAT confirmation of serologically defined HIV-2 infection and distinguishes HIV types in serologically “undifferentiated” HIV infection, which is required to address a deficiency in the specificity of the contemporary 2014 CDC algorithm for HIV diagnostic testing (25, 31).

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Highlights

- The Alere q HIV-1/-2 Detect, a rapid point-of-care nucleic acid test.
- Qualitatively detect and differentiate HIV-1 and HIV-2 in whole blood or plasma samples.

Table 1

Detection of HIV-2 RNA in HIV-2 seropositive plasma samples by Alere Detect.

		UW HIV-2 RNA assay*			
		Not Detected	**<50 copies/mL**	**50–300 copies/mL**	**>300 copies/mL**
		31	34	16	30
Alere Detect	HIV-2 Detected	0	12	12	30
	HIV-2 Not Detected	31	22	4	0

*The sensitivity of the assay was determined to be 8 copies/mL (95% CI, 5–18 copies/mL) (24)

Table 2

HIV-infected plasma samples and HIV-2 viral stocks tested by Alere Detect

HIV status	Number of plasma samples tested	HIV-1 M/N result*		HIV-2 result	
		Undetected	Detected	Undetected	Detected
HIV seronegative	4	4	0	4	0
HIV-1 seropositive	22	5	17	22	0
HIV-2 seropositive	111^	111	0	57	54
HIV-1 and HIV-2 dual seropositive	8	5	3	5	3
HIV-2 laboratory strain&	4	4	0	0	4

*No samples were detected for HIV-1 Group O.

^Samples were collected from 94 participants; among them, 29 were infected by HIV-2 Group A, 2 by Group B and 1 by HIV-2 A/B recombinant virus, while the genotypes of HIV-2 infecting the rest of the participants were not determined.

&$HIV\text{-}2_{NIH\text{-}Z}$, $HIV\text{-}2_{ROD}$ and $HIV\text{-}2_{EHO}$ and $HIV\text{-}2_{CAM\text{-}2}$ viral stocks.

Table 3

Testing HIV-1/HIV-2 dually-seropositive samples

Dual HIV-1/HIV-2 Seropositive Samples (collection date)	HIV-1 Alere Detect Qualitative Result*	HIV-2 Alere Detect Qualitative Result	HIV-1 Abbott Results RNA copies/mL^	HIV-2 UW-Abbott Results RNA copies/mL^
HD01 (07.14.10)	Undetected	Undetected	Undetected	Undetected
HD02 (05.04.09)	HIV-1 M/N detected	Detected	85,120	2,592
HD06 (09.29.09)	HIV-1 M/N detected	Detected	510,596	311
HD09 (01.06.11)	Undetected	Undetected	Undetected	Undetected
HD10 (01.06.11)	HIV-1 M/N detected	Undetected	13,730	Undetected
HD12 (08.11.11)	Undetected	Undetected	Undetected	Undetected
HD13 (09.08.11)	Undetected	Detected	Detected, <40	28,726
HD14 (04.28.11)	Undetected	Undetected	Undetected	Undetected

*All samples were not detected for HIV-1 Group O.

^Some results listed below were previously published (31).