

Failure of the Alere Determine 4th Generation HIV POC test to Detect an Acute Case of HIV-1 Infection

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Conflicts of Interest statement

- Nothing to Disclose

Project Background

NH Division of Public Health Services in conjunction with PH Partners: Goals

- Increase the number of clients who receive their test results at time of visit
- Identify HIV + patients earlier in the course of disease
- Prevent ongoing transmission
- Link patients to care

3 testing sites in NH



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Switch from Orasure 2nd gen HIV test to Alere Determine 4th gen test

- Alere came to market in 2013
- Widely adopted by Health Departments across the U.S. and elsewhere.
- Can detect HIV-1 Antigen and HIV-1/2 Antibody
- Fingertick whole blood at POC, or serum, plasma, venous whole blood in lab setting.

Patient Population

- Experiencing Homelessness or Housing Insecure
- Experiencing Substance Use Disorder



Patient X Sought Care at Hospital

Symptoms

- Fevers of 4-5 days duration
- Cough, chest and sinus congestion
- Chest heaviness, shortness of breath
- Body aches, and increasing lumbar back pain for 1 month
- Confirmed to have acute HIV-1 infection.

Contact Investigation

Numerous High Risk Contacts Identified

- Sexual Contact
- Shared Needles
- Both

All experiencing unstable housing (living in cars, camps, etc)

Testing of Contacts

- Initially performed at city Health Department
- Alerie Determine using fingerstick whole blood
- 13 identified, 8 were tested in first round
- Epidemiologist requested serum draw for lab testing

Results of Contact Testing

8 Non-Reactive by Alere Determine (fingerstick whole blood)

7 Non-Reactive by BioRad HIV Ag/Ab Combo and HIV RNA Not Detected

1 Reactive by BioRad HIV, Negative HIV Geenius, Reactive HIV-1 RNA → Acute HIV Infection

Patient Y (newly diagnosed)

Time between diagnosis of Patient X and serum draw of Patient Y: 18 days

HIV Subtype: B

Viral Load: >10,000,000 copies

Performance of Alere: Detection of Acute Infections

p24 reactive/Ab non-reactive = Acute

Source	Number of Participants	Sample Type	Alere P24 Antigen reactive/Ab Nonreactive	NAT HIV Pos	Total True Acute Infections (NAT Positive)	Alere Acute Infection Sensitivity
2014 Duong, et.al.; JCM 52:10 2014	18,172 (Field use)	Whole blood	12	0	13	0%
2012 Rosenberg, et. Al.; JID 2012:205	1009 (Field use)	Whole blood	14	0	8	0%

Performance of Alere: Detection of Acute Infections

Source	Number of Samples	Sample Type	Alere Non-reactive	Alere Antigen Reactive/ Antibody Non-reactive	Alere Antibody Reactive	Alere Acute Infection Sensitivity
2018 Parker, et. Al.; Clinical Virology 104 (2018) 89–91	159 (All acute infections)	Serum	54	18	87	66%

Take Away Message

Alere Determine performs comparably to laboratory based EIAs in detection of HIV antibody

Alere Determine is not as sensitive as laboratory based 4th generation HIV assays for antigen detection

Users of the test should be aware of this limitation, especially when utilizing the test for high risk exposure patients. Laboratory based tests should be ordered for these patients.

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