A Case Series of Discordant Laboratory Results with Statewide Rapid HIV Testing in New Jersey

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Abstract

Background: A statewide case series of patients with discordant rapid HIV results as publicly funded counseling and testing sites is described.

Methods: Initial rapid testing by either OraQuick or OnQuick Advance was confirmed with Vironostika HIV-1 (BioMerieux) enzyme immunoassay (EIA) and HIV-1 Western blot (BioRad). Discordant results (OraQuick positive/Western blot negative) were followed by repeat OraQuick screening at 4-6 weeks, confirmation of the original EIA and Western blot results, collection of additional serum for hepatitis A (HAV), hepatitis B (HBV), hepatitis C (HCV), HIV by standard enzyme immunoassays, Epstein-Barr virus (EBV), and Rheumatoid factor (RF); collection of additional plasma for ultrasensitive, quantitative RNA determination of HIV.

Results: Rapid testing began at a single New Jersey site on 11/1/03. Through 10/5/05, 125 sites were conducting rapid testing with 32,463 tests completed. Twenty (3.6%) patients were discordant with a preliminary positive OraQuick rapid test and a negative Western blot. Two patients refused follow-up testing. Three other patients were lost to follow-up. Nine of 10 patients tested with OraQuick were positive upon re-examination 4-6 weeks later, but continued to test HIV negative by traditional EIA and Western blot. Other testing included: 12 of 12 tested were negative by ultrasensitive RNA analysis. Eight of 12 (67%) were HIV polymerase antibody positive. One of 12 (8%) had acute HBV. Two of 12 (17%) had HIV infection. Two of 12 (17%) had RF. Two of 12 (17%) had evidence of a distant EBV infection. No instances of an evolving HIV infection were identified.

Conclusion: Rapid testing is a reliable, reproducible screening test in publicly funded counseling and testing sites. The 0.3% observed false positive rate in sites with a rigorous QA program is acceptable.

Background – Discordant HIV Result

DEFINITION: A reactive OraQuick rapid HIV test followed by a negative or indeterminate Western blot (WB) or immunofluorescent assay (IFA) result.

TWO TYPES OF DISCORDANTS

TYPE I
Positive OraQuick®, NEGATIVE Western Blot

No bands present
Client is considered HIV negative and not likely to be in an HIV window.

TYPE II
Positive OraQuick®, INDETERMINATE Western Blot

Some bands not meeting the criteria to be declared positive are present
Possibility the client is in the process of seroconverting.

What Causes Discordants?

An evolving infection – HIV screen is positive to traditional EIA or Western Blot
• Cross-reaction non-specific antibodies
• Over-reading by testing personnel

NYJ HIV Discordant Series
11/2003 --> 10/2005

CONCLUSIONS:

Between 2003-5, 20 discordant rapid HIV tests were identified (Fig. 2). A discordant occurs where a Rapid HIV test fails to confirm by confirmatory Western blot.
While evidence of distant HBV and EBV infection exist in more than half of individuals with discordant HIV results, the frequency is similar to that in the US population (Fig. 7).
With the growth of NJ statewide program, additional discordant results have been identified. Through September 2005, 58 additional discordants have been identified. Of these, 78% were associated with oral specimens, while 22% were associated with syphilis specimens. A slightly lower degree of specificity is reported by the manufacturer when using oral specimens and is apparent in NJ.

The possibility of seasonal variation is suggested by monthly data, but remains within the manufacturer’s specificity limits.

In summary, laboratory discordant results in 2006 have not been associated with an evolving infection as demonstrated by > 1 month follow-up utilizing qualitative DNA and quantitative RNA HIV testing, as well as HIV-1/EIA testing.

Figure 1
Figure 2
Figure 3
Figure 4
Figure 5
Figure 6