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 at publicly funded counseling and testing sites is described.

Methods: Initial fingerstick testing by either OraQuick or OraQuick 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 immunoassay, Epstein-Barr virus (EBV), and Rheumatoid factor (RF); collection of additional plasma for ultrasensitive, quantitative RNA determination of HIV. Demographic data were collected using the standard CDC form.

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 (0.06%) 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 were Oraquick 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 HAV polyvalent antibody positive, 1 of 12 (8%) had acute HBV, 2 of 9 (22%) had HCV infection, 1 of 12 (8%) had RF, 12 of 12 (100%) 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 0.06% 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 prior to traditional EIA or Western Blot
- Cross-reacting non-specific antibodies
- Over-reading by testing personnel

Rapid Testing in New Jersey – NJ HIV

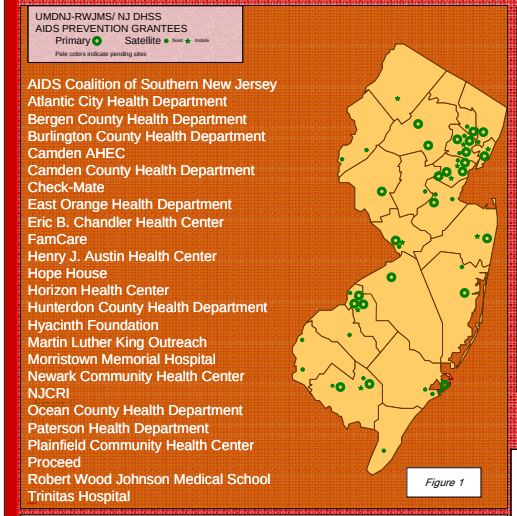
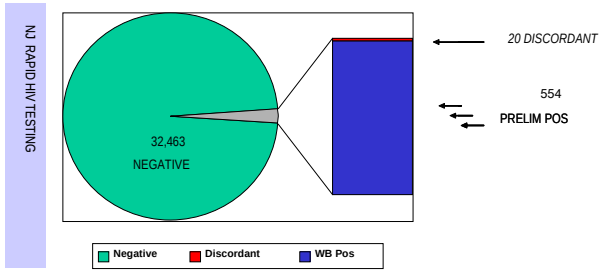


Figure 1

METHODS:

- The NJ Rapid HIV Program is a large, centralized QA effort (Fig. 1)
- After an initial positive Oraquick result and negative confirmationoccurs at any site NJ HIV technical support is contacted (http://www.njhiv.org)
- At 4-6 WEEKS:
  - Repeat HIV by Oraquick
  - Venipuncture. Collect SST, white top, & purple top tube. Centrifuge and prepare ASAP (< 4 hrs).
  - Ship to reference laboratory (ARUP)
    - Repeat HIV1/2 EIA — Qualitative HIV PCR
    - HIV/1 Western blot — Ultrasenstive Quantitative RNA PCR
    - HAV (Polyvalent) — Hepatitis B surf. Ag, Ab, HBcAb
    - HCV Ab — EBV, RF,
  - 4-6 weeks Independent confirmation of the original negative Western blot,
- Demographic data were collected using the standard Centers for Disease Control and Prevention counseling and testing form

Frequency of Discordants – NJ (2003-5)



TOTAL TESTS 11/1/03 – 10/5/05	HIV PRELIM POSITIVE	WESTERN BLOT – Discordant
32,463	554 (1.7 %)	20 (3.6 % of Prelim Pos. – 0.06% Overall)

Figure 2

Correlations with Disease States – NJ (2003-5)

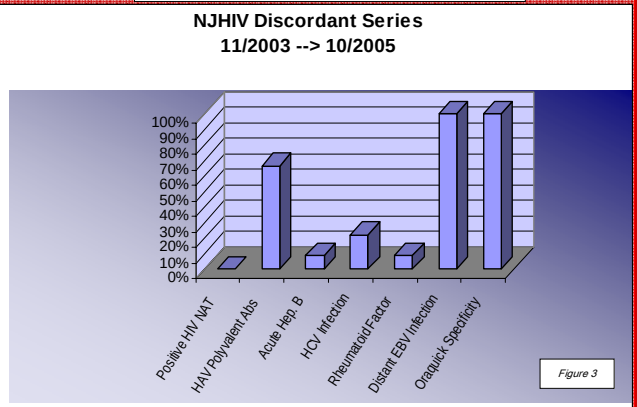


Figure 3

NEW JERSEY DISCORDANTS - 2006

Month to Month

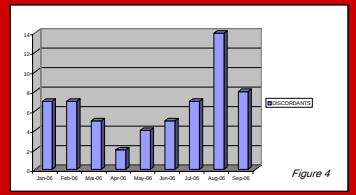


Figure 4

Specimen Type

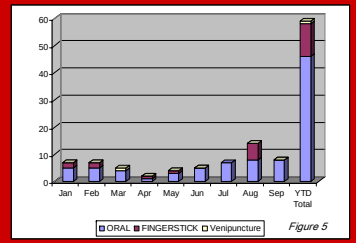


Figure 5

Outcome

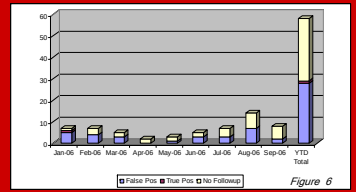


Figure 6

CONCLUSIONS:

- Between 2003-5, 20 discordant rapid HIV tests were identified (Fig. 2).
- A discordant occurs when a + Rapid HIV test fails to confirm by confirmatory Western blot.
- While evidence of distant EBV and HAV infection exist in more than half of individuals with discordant HIV results, the frequency is similar to that in the US population (Fig. 3)
- With the growth of NJ statewide program, additional discordant results have been identified. Through September 2006, 58 additional discordants have been identified. Of these, 78% were associated with oral specimens, while 20% were associated with fingerstick specimens. A slightly lower degree of specificity is reported by the manufacturer when using oral specimen types and is apparent in NJ.
- The possibility of seasonal variation is suggested by monthly data, but remains within the manufacturer's specificity claims.
- With the exception of a single NJ case, 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 HIV1/2 EIA testing.