Real-World HIV Diagnostic Testing in the United States: Assessing the 2nd Step of the Algorithm

Sara Blosser, PhD, D(ABMM)[1] ○ James Karichu, MPH, PhD[2] ○ Nicole Robinson, PhD[1] ○ Chakkarin Burudpakdee, PharmD[3] ○ Aimee Near, MPH[3] ○ Jenny Tse, MS[3] ○ Jillian Faccone, MPH[3] ○ Pedro Rodriguez, PhD[1]

1-Roche Diagnostics Corporation; Indianapolis, IN ○ 2-Roche Diagnostic Solutions; Pleasanton, CA ○ 3-IQUVIA; Falls Church, VA

BACKGROUND

There is a quest for earlier, more accurate, HIV laboratory diagnostics. The CDC Testing Algorithm provides increased laboratory uniformity, yet, the second step of the algorithm contains opportunities for improvement. This study evaluated the use of the Bio-Rad Geenius™ HIV 1/2 Supplemental Assay (Geenius) in the CDC Testing Algorithm using real-world data to better understand the hurdles and pitfalls of the algorithm.

METHODS

The study leveraged the Quest Diagnostics (Quest) database from January 1 - December 31, 2017. Specimens from patients with ≥1 valid Geenius test result(s) in 2017 were assessed. The earliest test date for each patient was considered the index date. NAT reflex was a Hologic Aptima HIV-1 qualitative RNA test.

RESULTS

Patient Demographics

Characteristic	Mean or %
Age in years, mean	40.7 yrs
Age, 25 to 34 years	27.2 %
Age, 45 to 54 years	20.4 %
Male sex	66.4 %
Geographic location, South	42.5 %
Geographic location, West	29.3 %

Sara Blosser, PhD, D(ABMM)
Medical & Scientific Affairs
Scientific Liaison
sara.blosser@roche.com

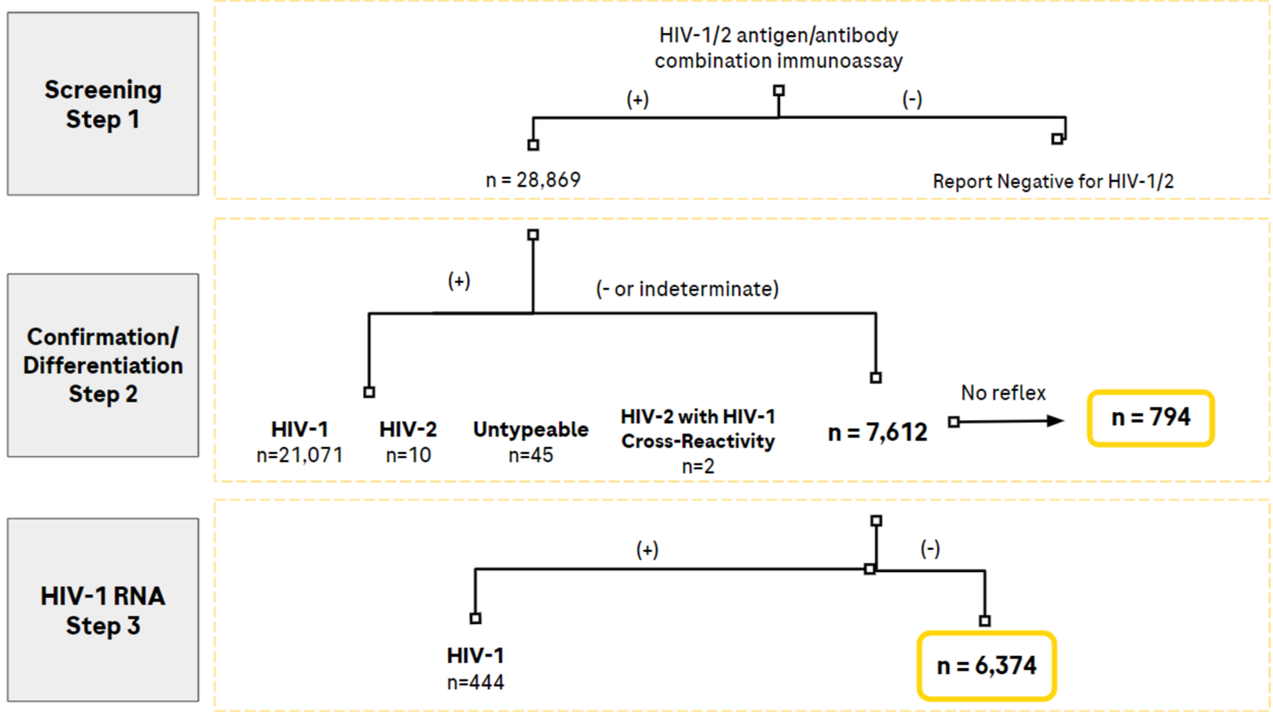

Figure 1. Summary of sequence study findings.

Sequence Analysis

Algorithm performance was examined for 28,869 test sequences (n=26,225 patients). Overall, 73.2% of results were positive for HIV-1 or HIV-2 (n=10) on Geenius, matching the screening test result. Cross-reactive, untypeable, or indeterminate results occurred in 2.2% of sequences. Of the 26.4% of results that were negative or indeterminate on Geenius, 89.6% (n=6,818) were reflexed to NAT, per guidelines. Of these, only 6.5% (n=444) confirmed the initial positive screening result, and based on index test sequence results, a total of 7.0% of patients had acute HIV-1 infections.

26.4%
of step 2 specimens were negative

These specimens should all be reflexed to *Step 3*, NAT. However, in this study 10.4% of eligible specimens were not reflexed. Of those reflexed, only 6.5% were positive. Essentially, 1 out of every 4 Ag/Ab positive specimens required both Geenius and NAT to diagnose.

Opportunities to reduce inefficiencies for both the laboratory and the patient.

Repeat Geenius Ordering

A second Geenius test was ordered for 2,231 patients in our cohort, predominantly by the same physician/ practice within 30 days of initial order; 91.7% were initially positive for HIV-1/2. Of these results, 11.2% (n=250) provided discordant Geenius results (i.e. positive-to-negative). Although the reason repeat testing was not determined, essentially one of out of every nine specimens resulted in a different result than the initial diagnosis.

11.2%
discordant rate for Geenius™ repeats

The majority of these specimens were ordered by the same physician or practice within 30 days of the original result. The initial result was positive, which confirms a diagnosis of HIV.

Opportunities for physician education and engagement. Potential opportunity for improved test performance.

CONCLUSIONS

This data highlights three main needs for improvement:

- Decrease reflex NATs
- Minimize discordant results
- Eliminate indeterminates and false-positives

Future studies are needed to assess these outcomes, and should also evaluate additional real-world sites for rate(s) of discordance. This study also highlights the need for NAT to be considered an approved confirmation/differentiation alternative to eliminate many of the inefficiencies observed with the Geenius™.