

# Performance of Determine™ HIV-1/2 Ag/Ab Combo Test to Detect Acute Infections in a High-Prevalence Cross-Sectional Population in Swaziland

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## BACKGROUND

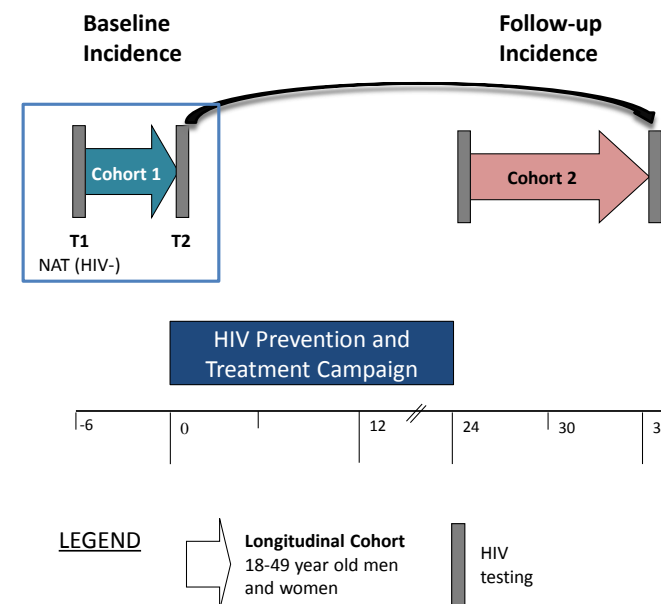
Fourth-generation HIV rapid tests (RTs) incorporate p24 antigen detection for early identification of acute infections. Inclusion of p24 detection in a diagnostic rapid test may allow for a decrease in the diagnostic window period. Identification of acute HIV infections may be an important approach in preventing HIV transmission and reducing HIV incidence.

## METHODS

As a part of the Swaziland HIV Incidence Measurement Survey (SHIMS):

- 18,154 individuals were household tested for HIV infection using a two-RT serial algorithm; Determine™ HIV-1/2 Ag/Ab Combo followed by UniGold™ as the confirmatory RT (Figure 1).
- Discordant samples were resolved by tiebreaker EIAs. Determine Ag+ only samples were further tested for viral load using Roche CAPTaq HIV-1 Test, V2.0.
- All RT non-reactive samples had nucleic acid amplification testing (NAAT) performed in plasma pools of 10 to identify true acute infections.
- Determine™ Combo Ag+/Ab- and NAAT-positive acute cases had follow-up testing to confirm seroconversion.

## SHIMS STUDY DESIGN

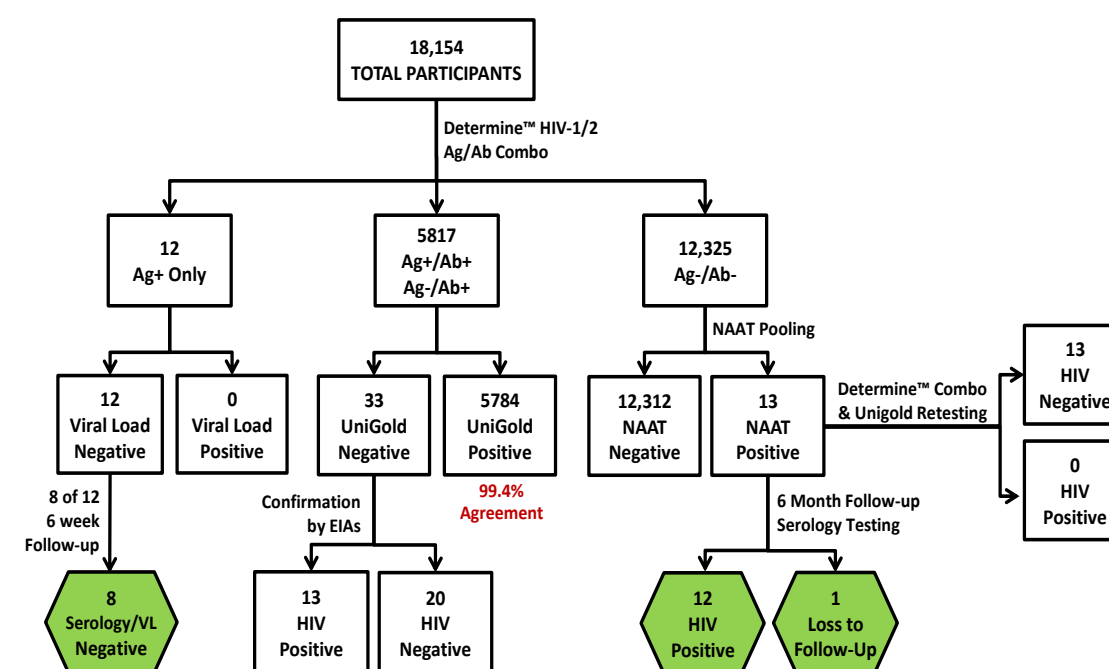


## RESULTS

Of 18,154 whole blood specimens tested:

- 5817 specimens Ab+ by Determine™ Combo and of those, 5784 confirmed reactive by UniGold (99.4% agreement)
- Identified 12 Ag+/Ab- samples by Determine™ Combo - all VL negative and therefore were not confirmed acute infections
- Of the 12 individuals with Ag+/Ab- results, 8 had a 6-week follow-up visit and were found to be HIV-negative
- Plasma pooling on the 12,325 Ag-/Ab- non-reactive Determine™ Combo specimens revealed:
  - 13 NAAT-pos specimens with HIV RNA values ranging from 300 to >10,000,000 copies/mL
  - Repeat HIV serology 13 NAAT-pos specimens confirmed all Ag and Ab non-reactive
  - Follow-up testing of 12 of the 13 NAAT-pos individuals at 6 months showed 12 seroconversions (1 case lost to follow-up)
  - Determine™ Combo had a sensitivity of 0% (95% CI 0%-25%) and positive predictive value of 0% for detection of acute infections

## HIV TESTING RESULTS



## CONCLUSIONS

The ability of Determine™ Combo to detect HIV antibodies was excellent but the sensitivity to detect antigen was extremely poor. Thus, Determine™ Combo RT should not be used in this population to detect acute infections because it does not add any value to the current testing algorithm, rather it adds unnecessary costs and complexity.

