Weakly Reactive HIV Rapid Diagnostic Test Kits Shouldn't be Reported as Positive

Patrick Karugaba[1], Ali Elbireer[1, 2], Alice Nansamba[1], Timothy Amukele[1, 2],

[1]Makerere University – Johns Hopkins University Research Collaboration Laboratory, [2]Johns Hopkins University School of Medicine

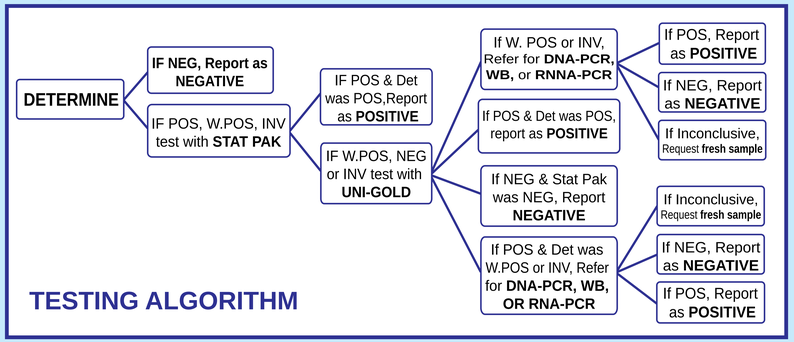
BACKGROUND

- HIV rapid diagnostic test (RDT) kit manufacturers require that all bands observed in the test area of the kit are reported as positive regardless of their color intensity.
- However, not all such bands are truly positive.
- We assessed the percentage of weakly reactive bands in 3rd generation HIV RDT's, subsequently confirmed negative by HIV DNA-PCR



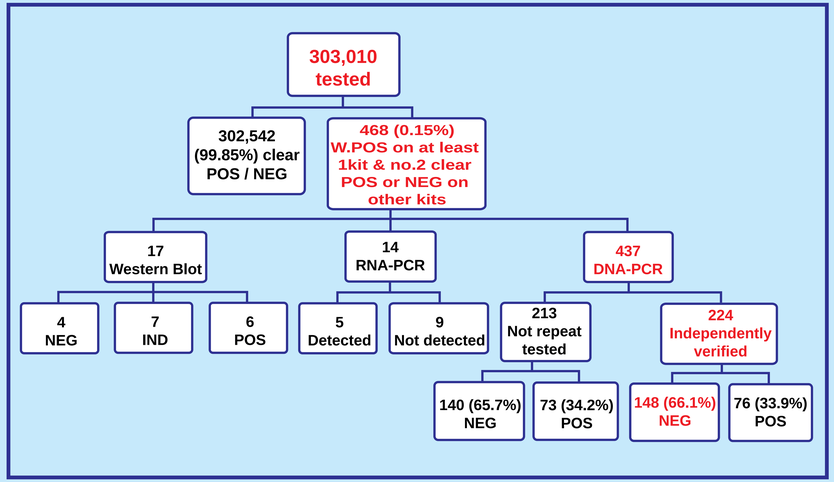
METHODS

- Over an 11 year period (2002 to 2013) we determined the proportion of inconclusive results that were later confirmed negative by DNA PCR.
- Inconclusive results were based on the observance of a weakly reactive band on at least one of three 3rd generation HIV RDT kits used within a sequential testing algorithm, along with the subsequent failure to determine the HIV status based on that algorithm.
- The three kits were Alere Determine, Chembio Stat-Pak, and Uni-Gold. The algorithm was as shown below;

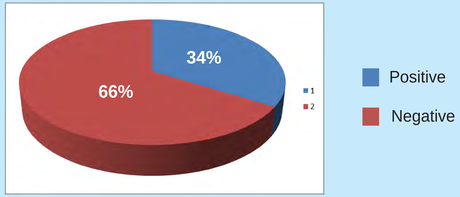


RESULTS

- 468 (0.15%) of 303,010 individuals screened for HIV (from a population with a positivity rate of 12.9%) had inconclusive HIV RDT results. The HIV status of the 468 individuals was resolved by HIV-1 Western Blot (17), HIV-RNA PCR (14), or HIV-DNA PCR (437) confirmatory tests.
- 224 of the 437 cases confirmed by DNA-PCR RDT's were independently repeated by another tech to control for individual variability.
- Only these 224 cases were included in this analysis. Of these 224 cases, 148 (66.1%) were negative by HIV-DNA PCR.



Proportion of inconclusive HIV RDT's confirmed as POS or NEG by DNA-PCR



CONCLUSIONS

- The majority of weakly reactive RDT results from all three kits used turned out to be negative on confirmatory HIV DNA PCR testing.
- This is contrary to manufacturers' instructions to interpret all such tests as positive.
- Our results also lend credence to previously published calls for testing algorithms to refer weakly reactive RDT test results for confirmatory testing.
- This is especially pertinent in the era of ART initiation based solely on HIV RDT results and scaled-up HIV surveillance programs in resource limited settings

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1. MU-JHU Core Laboratory
2. Infectious Diseases Institute
3. Johns Hopkins University
4. MU-JHU Research Collaboration

Contact: Email: pkarugaba@idi.co.ug website: www.idi-makerere.com, www.mujhu.org Tel: +256772428549

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