Prioritizing Quality HIV Testing

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Presentation Outline

1. **Retesting for HIV**
2. **The 3-test Strategy and verification**

Retesting for HIV

World Health Organization

1. **Verification (prior ART initiation): same algorithm twice:** WHO recommends that programs retest people diagnosed with HIV prior to ART initiation. To avoid clerical errors, sample mix ups etc. (full algorithm at testing site, test again using full algorithm at ART site.)
2. **After screening in the community (HIVST)** - testing at least once with full algorithm completed by the trained tester.

3. **Retesting individuals to resolve an HIV-inconclusive status:** people coming back after 14 days

4. **Retesting as an entry point for re-engagement in treatment and care** (NOT for everyone)

For Example

- Those who re-engage through HIV testing services on their own should be welcomed back
- Those who say they are HIV positive without any evidence should be re-tested using the full algorithm *as long as they are not taking ART*
- Those who say they are on ART in the past and want to be given medication without any documentation can be tested using full algorithm for re-engagement

WHO does NOT recommend re-testing individuals on ART – the risk of false negative. However, if they have a concern about their test results this should be discussed with appropriate follow-up actions

Re-testing HIV-negative individuals

- **PrEP, PEP, PMTCT, etc**

Principles for the Selection of HIV Testing Algorithms

World Health Organization

WHO recommends to use only quality-assured products: HIV assays that have undergone stringent regulatory assessments (product & manufacturing)

Performance characteristics	
Highest sensitivity (to rule in all positives [true + false])	**A1**
Highest specificity (>A1) (to rule out all false positives)	**A2** and **A3**

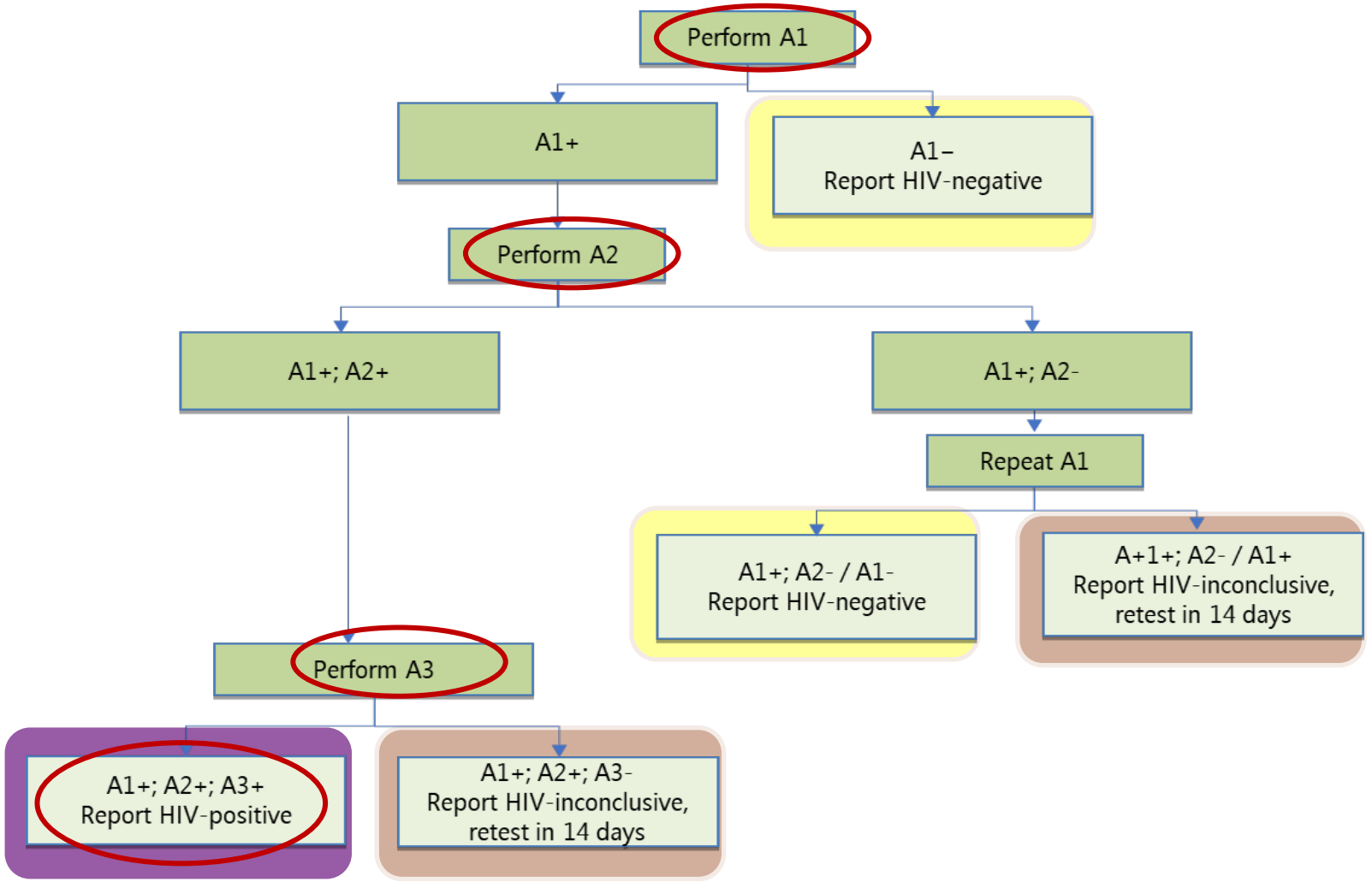
Correctness of the final HIV status is dependent on:

- Specificity of the individual products used (for A1, A2, A3), and
- Probability that any specimen that is falsely-reactive on the first assay (A1) is not also falsely-reactive on the second assay (A2) and third assay (A3) – **this can vary by region**

It is suggested to conduct a **verification study of the new testing algorithms** in order to:

1. Identify the **combination of products which have minimum possible common cross-reactivity** to reduce the risk of false HIV-positive diagnosis. (Note: *Products from the same manufacturer should not be used as part of the testing algorithm to minimize common cross-reactivity*)
2. Identify **flexible algorithms**: replacement tests in case of a "problem" with one of the selected tests, e.g. stock out, lot recall, etc
3. **Not intended to reevaluate sensitivity and specificity of individual products**!

Universal HIV 3 - tests strategy and verification studies (for adults and children over age of 18 months)



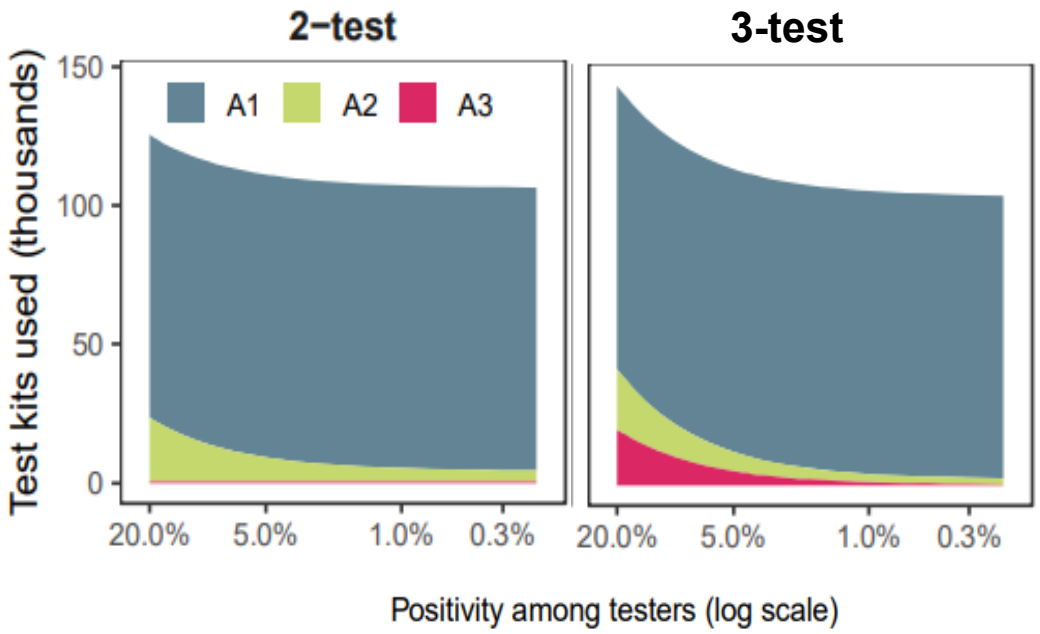
This is NOT a tie-breaker strategy

Note: A1 = Assay 1; A2 = Assay 2; A3 = Assay 3

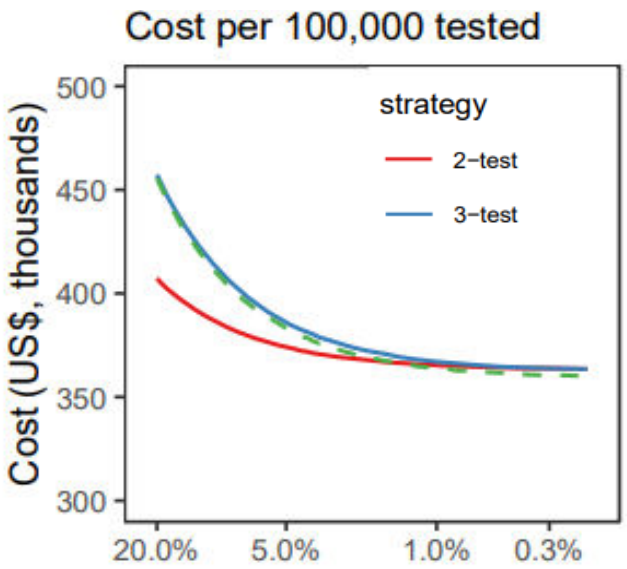
Test kits used and cost considerations

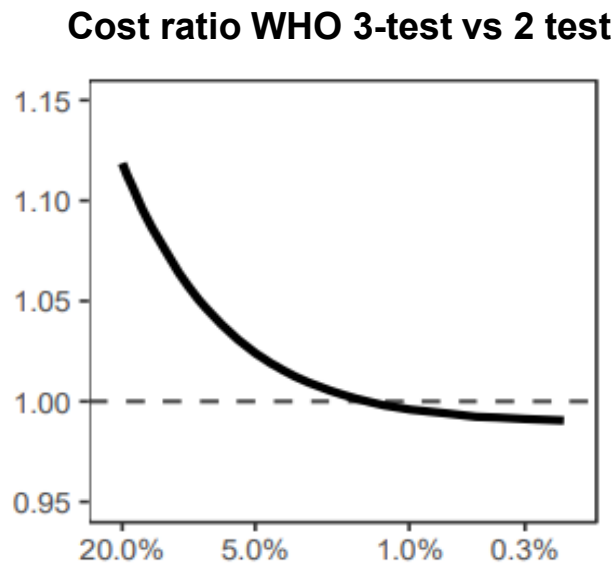
World Health Organization

Test kits used



Cost differences





Additional third test has limited impact on cost
First test in national algorithm drives costs

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How to select products - verification of testing algorithms

1

Shortlist 8 to 12 products, order sufficient quantities (2 different batches per product)

2

Collect 250 specimens in routine testing sites, characterize and select 250 negative specimens

3

Choose site for characterizing specimens and a site for testing products

4

Analyze results select best combination of products (no shared false reactivity) + 2 replacement tests.

No need to reevaluate sensitivity/specificity of individual products

World Health Organization

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Thank you!

World Health Organization