Laboratory pre-evaluation of triple rapid tests for HIV, syphilis, and hepatitis B in Uganda

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BACKGROUND

Uganda's drive toward triple elimination of mother-to-child transmission of HIV, syphilis, and hepatitis B demands screening tools that are accurate, rapid, and affordable. Triple rapid diagnostic tests (RDTs) that simultaneously detect HIV antigen/antibody, treponemal antibodies, and hepatitis B surface antigen (HBsAg) provide a consolidated approach suitable for antenatal and routine laboratory screening. Currently, testing coverage among pregnant and breastfeeding women is high for HIV (96%) and syphilis (94%) but lags for hepatitis B (67%), largely because services rely on dual HIV/syphilis RDTs alongside single-analyte HBsAg tests. To inform policy and optimize workflow, we conducted a laboratory-only pre-evaluation of a triple RDT to assess diagnostic performance, usability, and programmatic fit.

METHODS

Design	**Retrospective, non-interventional. Used archived plasma samples compared to standard reference assays.**
Samples	Used a total of 300 samples, 50 positive and 50 negative per analyte while overlapping cases were excluded.
Site	Central public health laboratory (CPHL), Uganda; ISO 15189 accredited.
Testing	Reference assay testing first then investigational device (STANDARD Q HIV/Syph/HBsAg Triple Test). Discrepant cases retested with PCR/DNA confirmatory.
Bias Control	Randomized biobank storage, uniform reference methods, triple independent reading.
Analysis	Sensitivity, specificity, inter-reader variability, invalid rate; WHO thresholds applied; R/SAS used.
Ethics	REC & UNCST approval; waiver of consent for archived samples; aligned with international guidelines.

The triple kit will be the game changer to fill the HIV, Syphilis and Hepatis B testing gaps.

RESULTS

The triple RDT showed excellent agreement with reference assays. For HIV, sensitivity and specificity were both 100% (95% CI: 92.9–100 and 98.5–100, respectively; κ = 1.00). For syphilis, sensitivity was 96.0% (95% CI: 86.3–99.5) and specificity 100% (95% CI: 98.5–100), with κ = 0.96. Similarly, hepatitis B, has sensitivity 96.0% (95% CI: 86.3–99.5) and specificity for Hepatitis B of 100% (95% CI: 92.9–100 and 98.5–100; κ = 1.00). Inter-operator agreement exceeded 99% (κ ≥ 0.95), the invalid rate was 1.3% (4/300, with most resolving on repeat), and usability assessments showed a hands-on time of approximately 5 minutes with results available in 15–20 minutes.

	HIV ELISA Positive	HIV ELISA Negative
HIV SD Bioline Positive	50 (True Positives)	0 (False Positives)
HIV SD Bioline Negative	0 (False Negatives)	50 (True Negatives)

	HBsAg CLIA Positive	HBsAg CLIA Negative
HBsAg SD Bioline Positive	48 (True Positives)	0 (False Positives)
HBsAg SD Bioline Negative	2 (False Negatives)	50 (True Negatives)

	Syphilis TPHA Positive	Syphilis TPHA Negative
Syphilis SD Bioline Positive	48 (True Positives)	0 (False Positives)
Syphilis SD Bioline Negative	2 (False Negatives)	50 (True Negatives)

CONCLUSIONS

The results demonstrated excellent diagnostic accuracy for HIV and high performance for syphilis and HBsAg, with strong reproducibility, few invalids, and straightforward usability. These results support integrating triple RDTs into Uganda's laboratory testing approach for pregnant and breastfeeding women to close current coverage gaps, particularly for hepatitis B, while sustaining high HIV and syphilis screening performance.

We recommend conducting targeted field-implementation studies, aligned with national testing algorithms and the triple-elimination strategy, to validate real-world improvements in service uptake, turnaround times, and maternal–infant health outcomes.

ADDITIONAL KEY INFORMATION

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PLAIN LANGUAGE SUMMARY

This study shows that the triple rapid test for HIV, syphilis, and hepatitis B works extremely well and is easy for health workers to use. It could help Uganda close major testing gaps for pregnant and breastfeeding women—especially for hepatitis B—while maintaining strong HIV and syphilis screening. Researchers recommend real-world field studies to confirm how much this test can improve service uptake, speed of results, and health outcomes for mothers and babies.