LYNX HIV p24 Antigen Test

Northwestern Global Health Foundation

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LYNX HIV p24 Antigen Test Summary

- Type of assay, principal of test
  - Qualitative p24 antigen based immunochromatographic assay
- Target of test (subtypes)
  - HIV-1
- Specimen types
  - 80µl whole blood
- Reference test
  - Roche Diagnostics COBAS AmpliPrep/COBAS Taqman HIV-1 Test (TNA PCR) alternate approved test (e.g., Abbott)
- Components
  - Instrument, blood collection tube, plasma separator, buffer, test strip, test strip reader

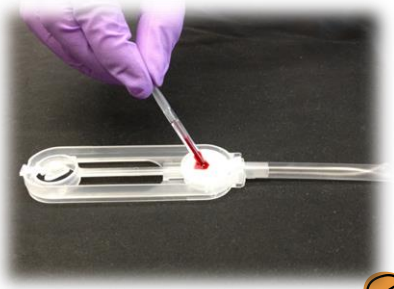
Target setting

- Target patient
  - 4 weeks to 18 months, although studies in infants less than 4 weeks are planned.
- Level of HCC targeted
  - Expected target: DBS collection sites, but studies are planned to assess this
- Type of health care worker suitable for
  - Expected target: All staff levels, but studies are planned to assess this
- Footprint (dimensions and weight)
  - Dimensions: 20.2cm x 15.6cm x 13.4cm / Weight: 1.7kg
- Pluripotency
  - Dedicated instrument used solely for EID; no future tests anticipated
- Cold chain, kit stability and storage
  - No cold chain required; stability studies on locked design still underway
- Training requirements
  - Less than 1 day
- Throughput per day, time to results
  - No batching. The platform can test 11.7 tests per 8 hour day
  - 53 minutes (allowing two minutes for specimen collection)
- Power requirements
  - The platform has a built-in rechargeable battery (up to 8 hours)
- 3rd Party consumables
  - Finger/heel stick consumables (gloves, lancet, alcohol swab, gauze pad)
- Waste
  - Blood collection tube, test strip, plasma separator

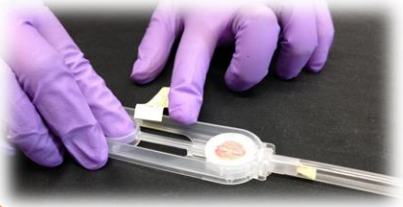
Procedure

Step 1: Collect blood

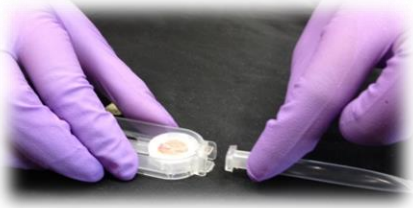
Step 2: Apply blood to LYNX Plasma Separator



Step 3: Plunge Plasma Collection Pad into the Reaction Tube

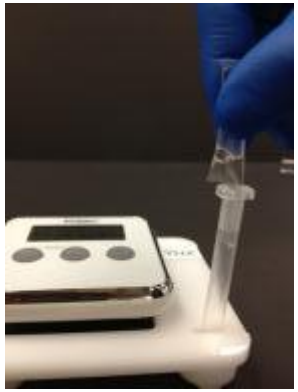


Step 4: Separate Reaction Tube from LYNX Plasma Separator



10 minutes

Step 5: Add LYNX Buffer



Step 6: Heat

11 minutes

Step 7: Insert LYNX Test Strip

30 minutes

Step 8: Read Test

Product availability

- Cost per test and per equipment, maintenance, ancillary equipment (details of volume tiers)
  - Initial pricing $2000 and $500 for reader; lower prices as volumes increase
  - Initial pricing $15; lower prices as volume increase
- Lock down product
  - As of Nov. 2014, the test format and instrument designs are locked down; a prototype reader is in the final design stage
- Regulatory status and plans
  - CDC and ERPD by 2016; WHO approval by 2017
- Manufacturing capacity (Q1 Q2, Q3, Q4 2015 n= tests and equipment)
  - Will not be available for commercial use by Q1 2015
- Commercial availability?
  - High volume manufacturing in place by Q1 2016 but laboratory and field evaluations still need to be completed
- Global in country support
  - Regional support under development

Technology Performance to Date

- No evaluations have been performed on the latest locked design.
- Prior studies indicate assay performs in laboratory settings
  - Verified on residual specimens being tested by total nucleic acid (TNA) PCR (Roche AmpliPrep/COBAS Taqman HIV-1) at the National Health Laboratory Service Virology Laboratory in Groote Schuur Hospital, Observatory, South Africa.
  - A total of 691 subjects were tested, of which 642 were between the ages of 4 weeks and 18 months. Of these, 80% originated in clinics and 20% in hospitals.
  - TNA PCR detected 32 (5.0%) positives, of which, 30 were positive by the LYNX p24 Test and 2 were equivocal.
  - Classifying equivocals as positive, the sensitivity was 100% (95% confidence interval: 90 - 100%).
  - Classifying equivocals as negative, the sensitivity was 94% (78 - 97%). In both cases, specificity was 99% (99 - 100).
  - Robustness was 100%, since there were no invalids, and turnaround times were less than one hour.
- But user variability in POC settings necessitated product changes

Table 1: Review of Evaluations of LYNX HIV p24 Antigen Test, Northwestern Global Health Foundation

Phase	Phase I	Phase II	Phase IIIa	Phase IIIb
Country, site, n size, # positives	Evanston, USA n=200, +50 (2015 Q1)	Cape Town, ZA n=1000, +50 (2015 Q1)	Cape Town, ZA n=1000, +50 (2015 Q1)	
		TM Cape Town, ZA + TBD n=1000, +50 (2015 Q4)	TM Cape Town, ZA + TBD n=3000, +150 (2015 Q4)	TM TBD n=3000, +150 (2016)

Key

Evaluation with locked down product	TM
Evaluation with Prototype	⊗
Developer led evaluation	✋
Evaluation In progress	💧
Evaluation Scheduled (start date)	🕒
No information	NA

LYNX HIV p24 Antigen Test Development Team

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