Operationalising TB LAM testing

A use case for standardised implementation in the field

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Helen Joseph Hospital

- 500-bed tertiary hospital
- Infectious diseases division falls under department of internal medicine at Helen Joseph Hospital and Wits University.
- ~750 inpatient consults per year.
- 6000 outpatients – HIV Clinic, TB Clinic, Infectious Diseases Outpatients

Helen Joseph Hospital: Medical patient profile

- ~42% of medical admissions PLWHIV.
  - Median CD4 = 67 cells/µL
  - ¼ diagnosed for the first time
  - Of those previously diagnosed with HIV, ¾ on treatment, but
  - Of those on treatment, nearly ½ are failing ART
- AIDS-defining conditions accounted for 40% of the admissions.
- TB in 25% of PLWHIV at time of data collection (probably closer to 30% in total).

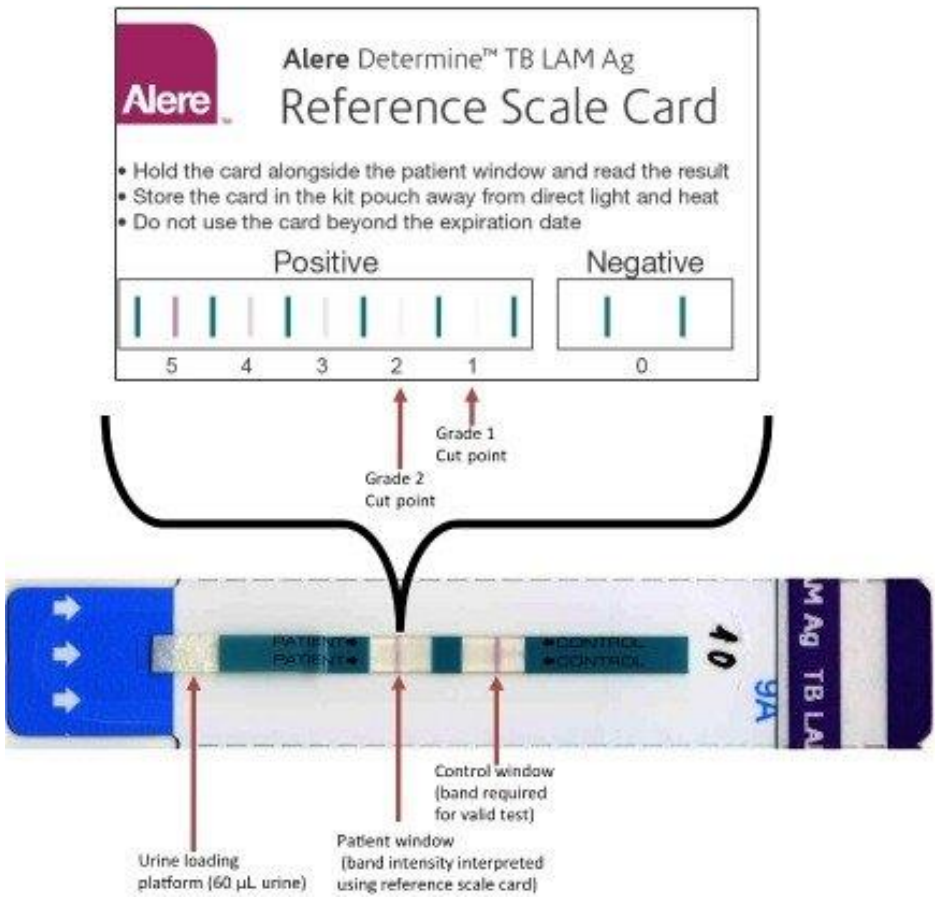
Yudelowitz et al. https://hdl.handle.net/10520/ejc-wjcm-v3-n3-a7

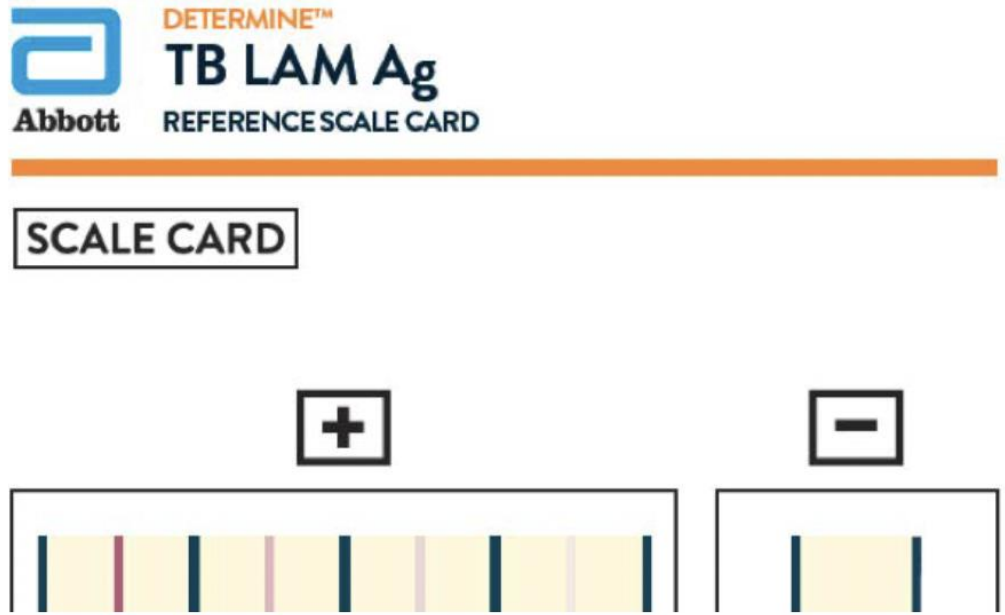
U-LAM as a clinician-performed test

Timing “doesn’t work”: reliability implications

- 25-35 mins “doesn’t work”
  - Clinicians don’t have dedicated time to wait 25 mins
  - Could set an alarm and come back after 25 mins to read strip…
  - …but in practice adherence to this was difficult: patient emergencies/priorities, etc.)

Reliability Issue #2: interpreting faint lines

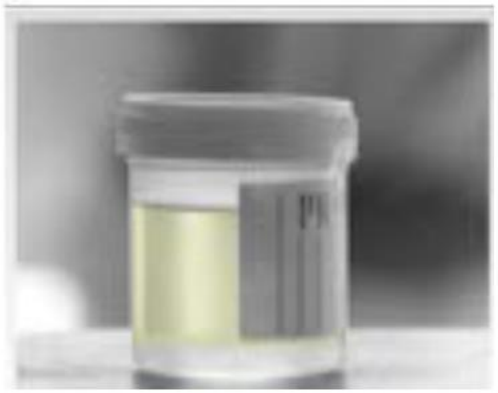




REF 06740101/R1

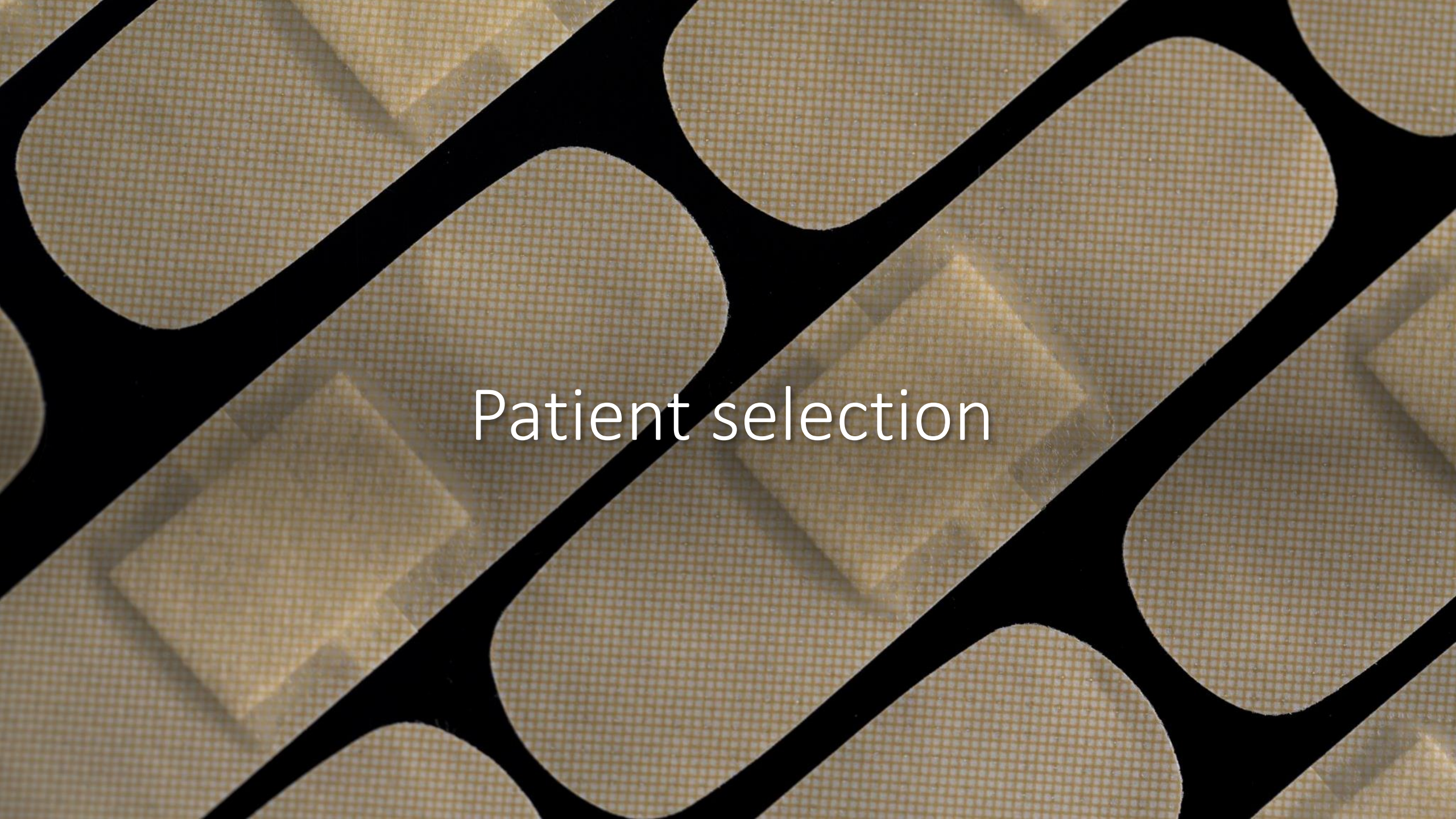
Reliability issue #3: urine volume

- 60 µL urine not well-adhered to, even with bulb pipette
- One drop? Two drops? Whole thing?



Stock control

- Strips taken “en masse” frequently – stock shortages
- Reference card taken/lost
- Pipettes taken/lost – clinicians guessing



Patient selection

Patient selection

Can be confusing (needlessly)

WHO STRONGLY RECOMMENDS USING LF-LAM TO ASSIST IN THE DIAGNOSIS OF ACTIVE TB IN HIV-POSITIVE ADULTS, ADOLESCENTS AND CHILDREN

CLINICAL SETTING	PREVIOUS SOUTH AFRICAN GUIDANCE	WHO RECOMMENDATIONS	CURRENT RECOMMENDATIONS FOR THE SOUTH AFRICAN CONTEXT
Inpatient Setting	LF-LAM can be administered for seriously ill patients, with advanced HIV in hospitalised settings when they are seen for a medical diagnosis in the emergency room or are admitted to medical wards irrespective of whether TB is suspected or not or the patient's CD4+ count.	Irrespective of signs and symptoms of TB (pulmonary and/or extrapulmonary) and with a CD4 cell count of fewer than 200 cells/μL • With AHD Stage 4 or who are seriously ill, irrespective of CD4 count.	The guidance adopts recommendations to include the use of LF-LAM to assist in the diagnosis of active TB in HIV-positive patients irrespective of whether TB is suspected or not (i.e. irrespective of signs and symptoms of TB) and irrespective of the patient's CD4+ count, and irrespective of whether AHD is present or not. A sputum molecular test for TB (e.g. Gene-Xpert) should be performed in parallel. See Algorithm chart on page 17.
Outpatient Setting	For outpatients (ambulatory patients seen in community health care centres, primary health care settings day hospitals, including ART initiation clinics), LF-LAM should only be performed when: • TB is suspected based on symptoms and/or signs AND • CD4 count ≤100 cells.	• With signs and symptoms of TB (pulmonary and/or extrapulmonary) or seriously ill • Irrespective of signs and symptoms of TB and with a CD4 cell count of fewer than 100 cells/mm.[3]	The guidance adopts recommendations to include the use of LF-LAM to assist in the diagnosis of active TB in HIV- positive patients with: • Signs and symptoms of TB (pulmonary and/or extrapulmonary) and • CD4 count < 200 cells/mm[3] or AHD Stage 4 or who are seriously ill.

Interpretation of Results

Clinical implications of U-LAM results

- **A negative result doesn’t rule out TB.**
  - NPV of a U-LAM in a high-burden TB setting is poor.
  - Clinicians may struggle with this diagnostic reasoning.

- **A positive result doesn’t mean it’s TB.**
  - Treat as TB, but what to do about possible false positives due to NTM, Nocardia, etc. hasn’t been well addressed programmatically.

Clin Infect Dis. 2017 Oct 1;65(7):1226-1228

Recording the results

The problem

- All lab-based tests are digitally recorded, and easily accessible in the future, across the healthcare system.

- Not true of clinician-based tests.

- U-LAM result hand-written in file, but file not easy to retrieve quickly if patient is admitted again to our hospital – and impossible to retrieve if healthcare contact at another facility.


Solutions

Centralising who performs the test

- 2 dedicated, trained nurses
- Training, assessment of reliability/validity
- Test performed “opportunistically” when there’s time in their day.
  - In practice, usually performed within 1-4 hours of being dropped off

U-LAM “flow” at our hospital

Doctor collects urine sample from patient

Urine dropped off at TB clinic area by doctor. Patient details & doctor phone number written on request sheet.

Urine LAM test performed by trained nurses

Result phoned out to doctor AND transcribed in records book at TB clinic

Solutions

PROBLEM	SOLUTION
Reliability: timing	2 trained nurses perform all the tests
Reliability: interpreting faint lines	2 trained nurses perform all the tests
Reliability: urine volume	2 trained nurses perform all the tests
Stock control	Nurses keep track of stock & order timeously
Patient selection	Doctor training (ID ward rounds, etc.)
Interpreting U-LAM result implications correctly	Doctor training (ID ward rounds, etc.)
Recording the result accessibly	Results are recorded in one central book (not ideal but better than before)

Conclusions

Conclusions

- Urine LAM as a clinician-performed test had serious reliability issues in our setting.
  - Implications for patient care
  - Implications for research performed using this data
- Solutions: either lab-based, or ≥2 dedicated, trained healthcare workers.
  - Doesn’t increase workload and vastly improves reliability.
- Training HCWs on patient selection and test result implications isn’t hard but needs to be done.