

Alere Determine TB LAM Antigen rapid screening test

Alere Determine TB LAM Ag is a qualitative rapid test for the detection of lipoarabinomannan (LAM) antigen of *Mycobacteria* in human urine as an aid in the diagnosis of active mycobacterial infection in HIV positive individuals with clinical symptoms of tuberculosis. *Mycobacteria species* cause Tuberculosis (TB), which is one of the most common opportunistic infection in AIDS patients

Who to test?

- **Automatically test** all patients samples with CD4<200cells/ μ l
- Or when the patient is at WHO stage III/IV. Or when requested by a clinician.

Materials and test procedure

- **Materials needed:** Alere Determine TB LAM test strips, pipette, gloves. **Specimen:** Use urine only.
- **Procedure** (fig 1&2): Label test strip with patient number on urine sample container, add the urine specimen to the sample pad. Read results after 25minutes. A positive result (visible purple/gray line) indicates that LAM antigen of *Mycobacteria* is present in the sample; whereas a negative result (no visible purple/gray line) indicates that it is not present or below detection limit. To ensure assay validity, a procedural control bar is incorporated in the assay device. *Refer to package insert and SOP for more details.*

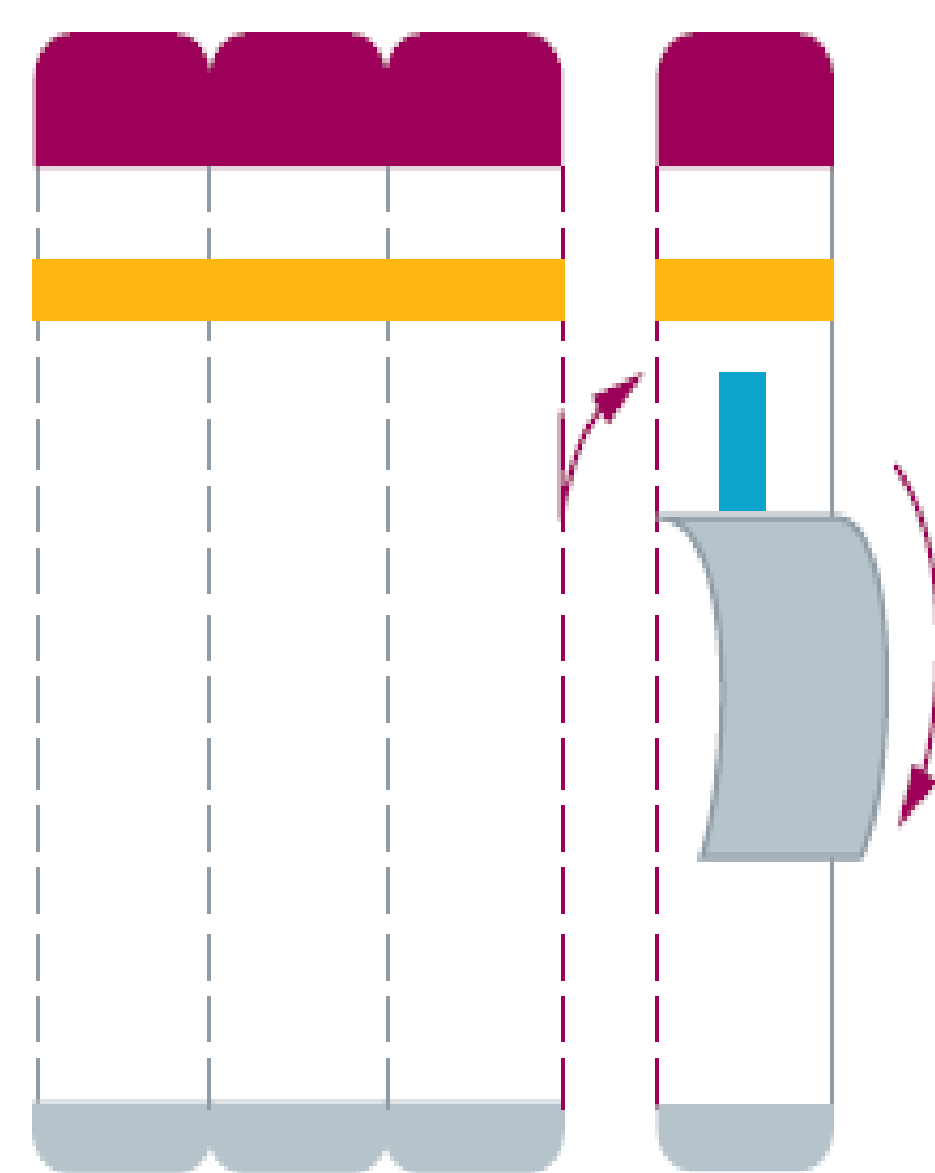
Quality control

Conduct QC for TB LAM test weekly. Follow steps in the SOP to evaluate accuracy of the test kit using inhouse +ve and –ve controls.

Screen in just 3 easy steps:

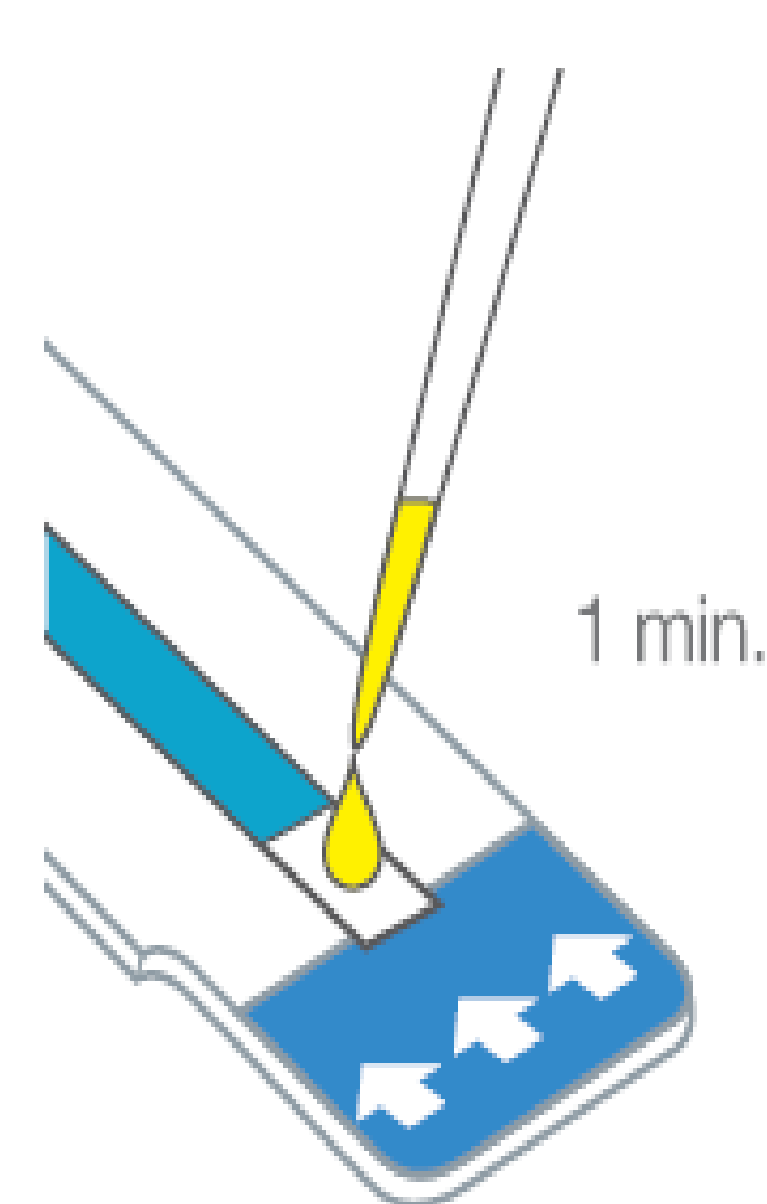
1. Prepare Test

Tear one strip from the right and remove cover.



2. Add Sample

Apply 60 μ L of urine to sample pad.



3. Read Results

Wait 25 minutes and read the results.



| Line | Positive | Negative | Invalid |
|---------|----------|----------|---------|
| Control | | | |
| Patient | | | |

Refer to the User Guide and Product Insert for complete instructions.

Figure 1: Alere Determine TB LAM Ag rapid screening procedure

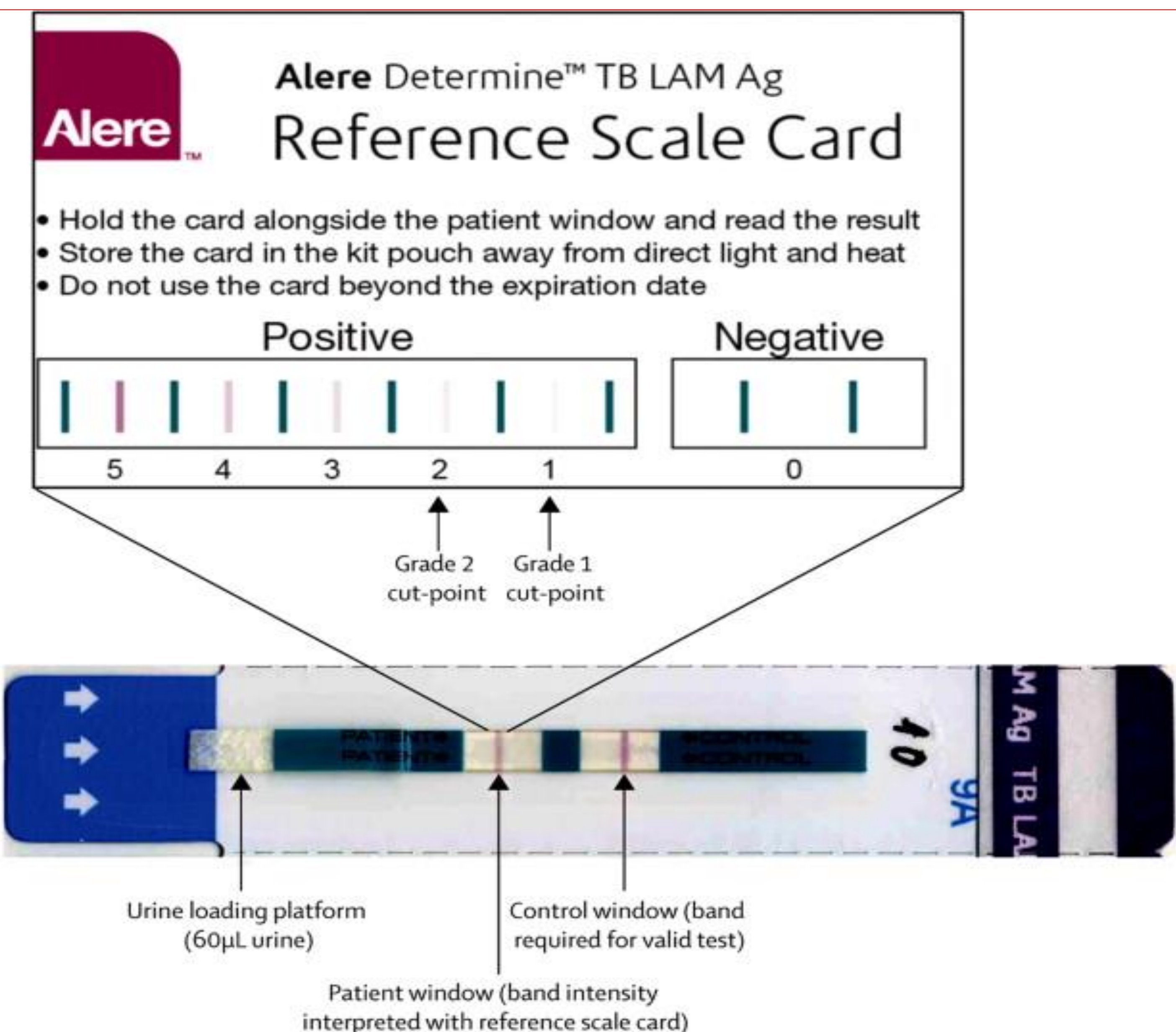


Figure 2: Alere Determine TB LAM Ag screening result

Alere Determine TB LAM Ag does not differentiate between the various species of *Mycobacterium*, (e.g *M. tuberculosis*, *M. leprae*, and *M. avium*). In addition, TB LAM can be positive for patients undergoing TB treatments (median LAM clearance in the urine +/-3weeks).