

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<100cells/ 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.*

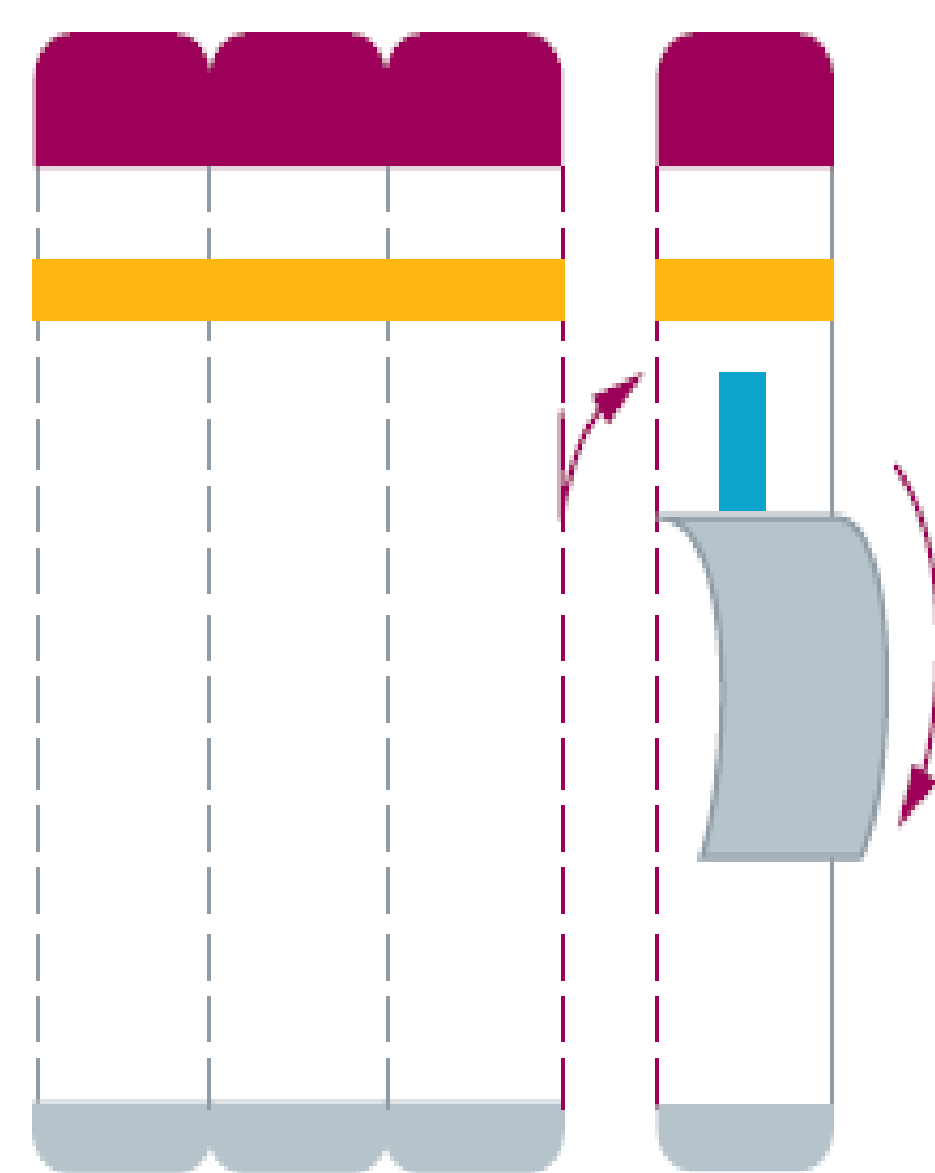
Quality control

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

Screen in just 3 easy steps:

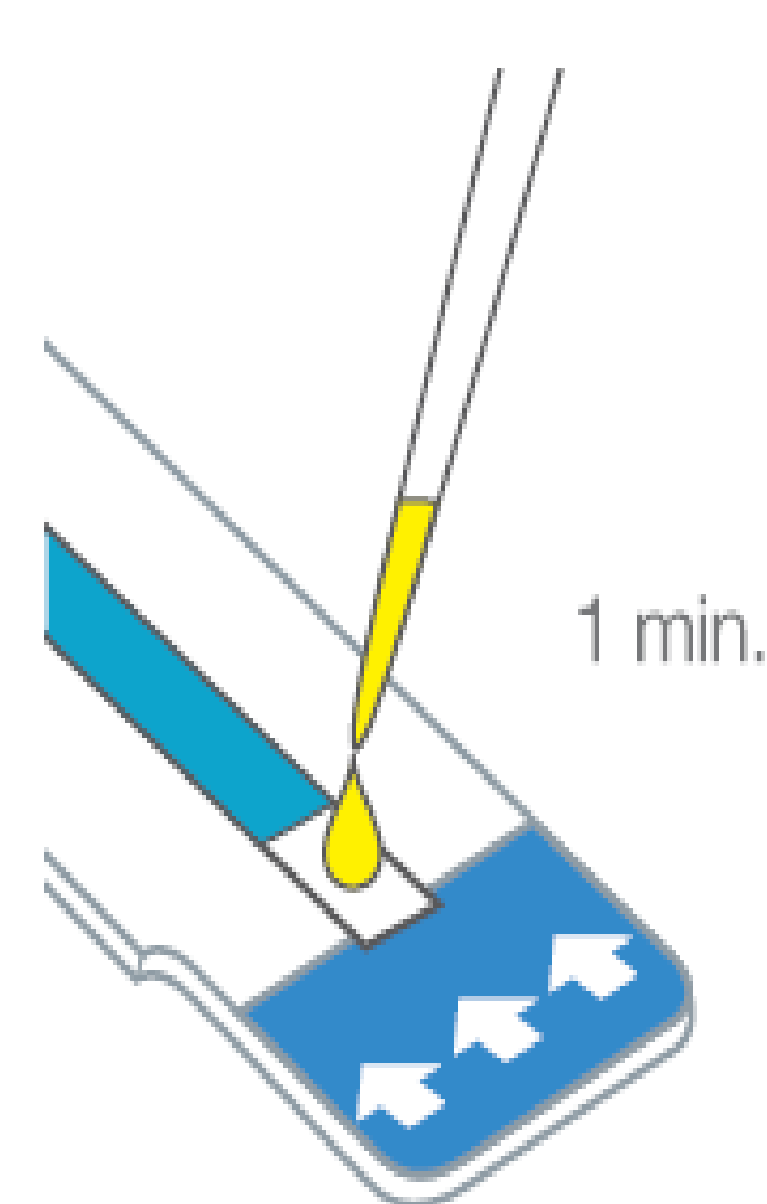
1. Prepare Test

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

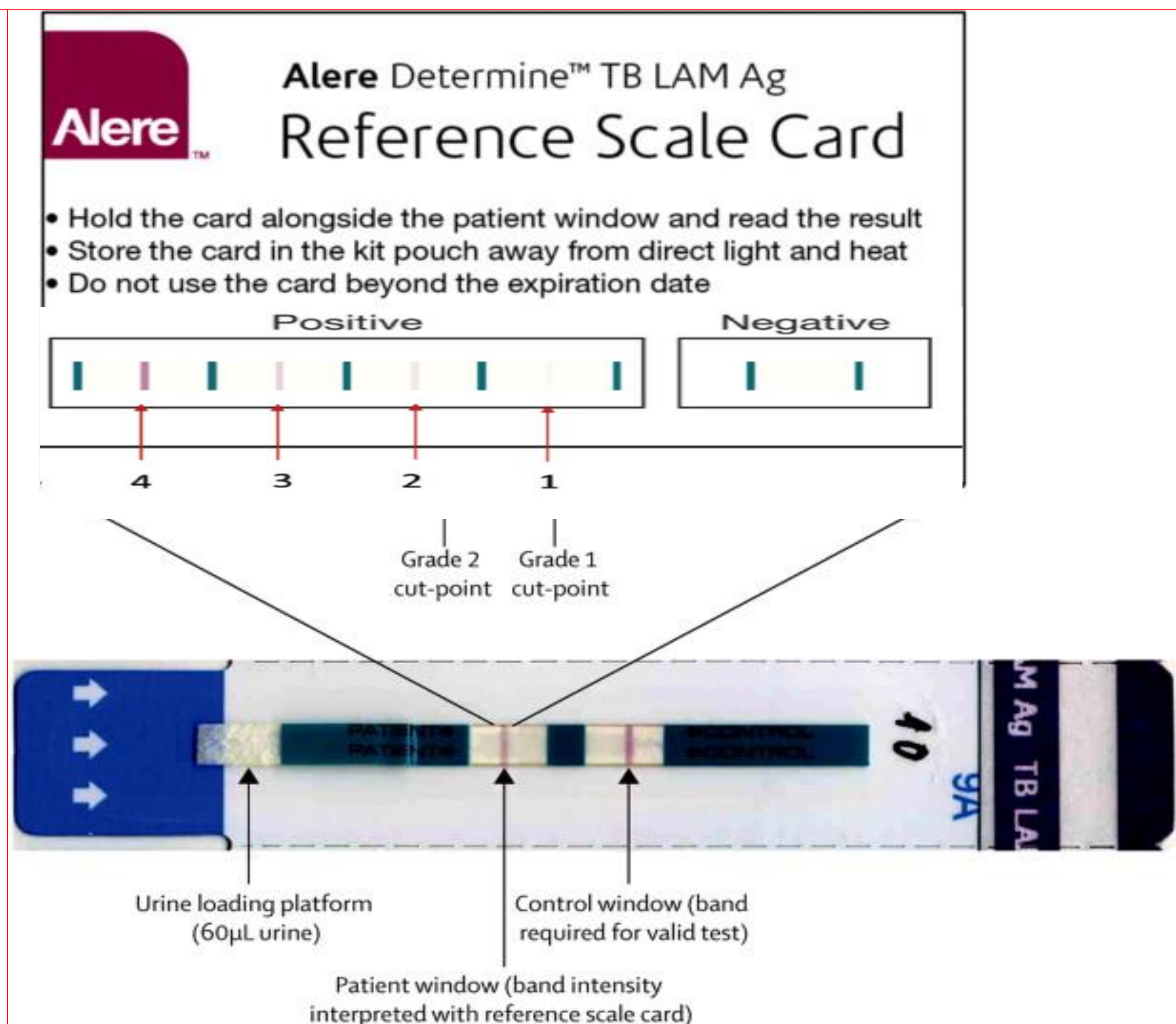


Figure 2: Alere Determine TB LAM Ag screening result

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).