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<200 cells/µl
- 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 25 minutes. 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 60µL of urine to sample pad.

3. **Read Results**
   - Wait 25 minutes and read the results.

#### 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).