**URINE COLLECTION AND STORAGE FOR USE AS ABBOTT/ALERE DETERMINE TB LAM Ag TEST EXTERNAL QUALITY ASSURANCE MATERIAL**

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| **Country:**  | **Department/ Division:** | **Unit/ Team:** |
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1. **PURPOSE**

The purpose of this document is to describe the method of collection, storage, and eventual use of urine as external quality assurance material for the lateral flow Abbott/ Alere Determine Tuberculosis Lateral Flow Lipoarabinomannan antigen (Determine TB LAM Ag) test.

1. **ABBREVIATIONS AND DEFNITIONS**

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| **Term/ Abbreviation** | **Definition** |
| Ag | Antigen |
| CD4 | Cluster of differentiation 4 |
| LF-LAM | Lateral Flow Lipoarabinomannan |
| MTB | *Mycobacterium tuberculosis* |
| mWRD | Molecular WHO-recommended rapid diagnostic test |
| NPA | Nasopharyngeal aspirate |
| PPE | Personal protective equipment |
| QA | Quality Assurance |
| TB | Tuberculosis |
| TB-LAMP | Tuberculosis-Loop-Mediated Isothermal Amplification |
| Truenat MTB | Chip-based Nucleic acid amplification (NAA) test for detection of MTB |
| Truenat MTB Plus | Chip-based Nucleic acid amplification (NAA) test for detection of MTB with higher primer sensitivity and specificity compared to Truenat MTB |
| Xpert MTB/RIF | Nucleic acid amplification (NAA) test for detection of MTB and rifampin resistance mutations. |
| Xpert MTB/RIF Ultra | A more sensitive (and slightly less specific) nucleic acid amplification (NAA) test for detection of MTB and rifampin resistance mutations, compared to Xpert MTB/RIF. |

1. **EQUIPMENTS AND MATERIALS**

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| **Equipment and Materials** |
| 1 | \*Centrifuge (with a capacity to spin at 10,000g) |
| 2 | \*Centrifuge tubes; required if the specimen is being transferred from the urine collection container for long term storage. |
| 3 | Gloves and other PPE (as per the site-specific guidelines) for healthcare workers receiving and storing the specimen(s) from the patient. |
| 4 | \*Freezer (if storing for > 3 days and ≤ 3 years) |
| 5 | Urine collection container |
| 6 | Screw capped, freezer safe vials (if storing urine long term) |
| 7 | Labels for urine collection/ storage containers |
| 8 | Pipette  |
| 9 | Refrigerator (if storing for > 8 hours and ≤ 3 days) |
| 10 | Sterile cleansing wipes or towelettes for human external skin surfaces. |
| 11 | Sterile urine collection container (urine container, screw cap vial, or centrifuge tube) |

\*Equipment and consumables required if freezing urine specimens.

1. **SAFETY PRECAUTIONS**
	1. Wear appropriate personal protective equipment (PPE) when handling urine samples. Refer to the site-specific Safety Manual and manufacturer Instructions for Use document for selection and proper use of PPE.
	2. Always comply with the testing site’s general safety precautions. Refer to the site-specific Safety Manual.
	3. Always manipulate samples (transferring between containers) in an aseptic manner in a well-ventilated and clean working space.
	4. Dispose all contaminated waste as biohazard waste (refer to the site-specific Safety Manual).
2. **PROCEDURE**
	1. **Urine Collection Area**
		* 1. Identify and designate an area within the clinic with adequate privacy (a toilet or a

covered shed) for the patient to collect the urine sample privately.

* + - 1. Ensure that there is facility for handwashing (with soap and clean water) within or close to the designated urine collection area for the patient and/or the caregiver and the healthcare worker to use before and after collecting and handling the urine sample.
	1. **Procedure for Urine Collection in Urine Collection Container**
1. Label the urine collection container with the following information at the time of urine collection.

**Label for Sample Container**

|  |  |
| --- | --- |
| **Unique ID** |  |
| **Date of collection** |  |
| **Date of storage #** |  |
| **Temperature of storage #** | [ ]  18 to 24 °C [ ]  2 to 8 °C [ ]  ≤ -20 °C |
| **Thaw date(s) (if frozen) #**  | [ ]  [ ]  [ ]   |
| **LF-LAM result #** | [ ]  Positive [ ]  Negative  |

 # Indicates information that will be filled as an when it has occurred/is obtained.

1. Prior to sample collection, instruct the patient or caregiver to:
	* + 1. Clean the urogenital area with a sterile cleansing wipe and dispose of the wipe according to biowaste disposal procedures.
			2. After cleansing, to collect a minimum of 1 ml of midstream urine in the labelled urine collection container.

**Important Note:** A sample (like sputum) for microbiological confirmation (by mWRD or culture) of the presence or absence of TB should be collected from the patient at the same visit.

1. If the sample is to be tested immediately, proceed according to the standard operating procedure for Determine TB LAM Ag testing and indicate the results on the *Label for Sample Container*and the *Sample Information Sheet*.

If the sample is not used immediately, store the sample as described in the Sample Storage section below.

* 1. **Sample Storage**
		1. Store the sample in a screw cap urine collection container, screw cap vial, or centrifuge tube that is labeled appropriately. If a large volume of urine is collected, aliquot the samples into freezer screw cap vials, with at least >100 µl/ container, using a sterile pipette.
		2. Store the samples according to the storage conditions below or those that are most current according to the manufacturer’s Instructions for Use.

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| --- | --- | --- | --- |
| **Temperature** | Room temperature (18 to 24 °C) | Refrigerated temperature2 to 8 °C | Frozen temperature≤ -20 °C |
| **Storage times** | ≤ 8 hours | 3 days | 3 years# |

# Samples may only undergo freeze thaw three times prior to testing.

* 1. **Preparation of urine for use as Quality Assurance samples for Abbott DetermineTB LAM Ag test**
1. Before using a urine sample for use as QA material for an LF-LAM assay, collect the following information associated with the sample (shown in the *Sample Information Sheet*) and enter in the site-specific Laboratory Specimen Management Database, LF-LAM Quality Control Sample Log, or a similar record. These parameters are important to determine the expected sensitivity and specificity of the sample when tested using the DetermineTB LAM Ag test.

**Example Sample Information Sheet**

|  |  |
| --- | --- |
| **Unique ID** |  |
| **Date of collection** |  |
| **Date of storage** |  |
| **Storage temperature** | [ ]  18 to 24 °C [ ]  2 to 8 °C [ ]  ≤ -20 °C |
| **Date tested for LF-LAM** |  |
| **LF-LAM results**  | [ ]  Positive [ ]  Negative |
| **Date tested for MTB^**  |  |
| **Test used to confirm MTB^** | [ ]  mWRD [ ]  Culture |
| **Specimen type used to confirm MTB^** | [ ]  Sputum [ ] Stool [ ]  NPA [ ] Other \_\_\_\_\_\_\_ |
| **mWRD initial test used^** | [ ]  Not used [ ]  Xpert MTB/RIF Ultra[ ]  Truenat MTB Plus [ ]  TB-LAMP [ ]  Other\_\_\_\_\_\_\_\_\_ [ ]  Not Done |
| **mWRD MTB result^** | [ ]  Not done [ ]  Positive [ ]  Negative |
| **MTB Culture result^** | [ ]  Not done [ ]  Positive [ ]  Negative |
| **Setting of Patient Presentation**  | [ ]  In-patient [ ]  Outpatient |
| **CD4 assessment**  | [ ]  <100 [ ]  100-200 [ ]  >200 [ ]  Not Done |

**^ This data will be from the sample collected simultaneously from the patient for microbiological confirmation of the presence or absence of MTB at the same visit and NOT the urine sample.**

1. Check the sample for acceptability before using it for quality assurance by reviewing and ensuring that it meets each of the below criteria.

[ ]  Appropriate volume (> 100 µl/ container)

[ ]  If refrigerated or frozen, cold chain maintained

[ ]  Appropriately labelled

[ ]  Intact/ non-leaking vials, tubes, or containers

[ ]  Appropriate clinical and microbiological information associated with the patient

 available.

1. Bring all the samples to room temperature 1 hour before testing.
2. If frozen samples are used-
	1. Complete the *Label for Sample Container* ‘**Thaw date’** row with a check mark in the box and enter the date each time the sample is thawed (*Note:* *It is important not to use the samples after 3 cycles of freeze thaws*).
	2. Centrifuge the samples at 10,000g for 5 minutes at room temperature to remove any aggregates, small clumps, or sediments that may be present.

**Use of Quality Assurance urine samples for Abbott DetermineTB LAM Ag testing: Refer to site-specific LF-LAM testing procedure.**

1. **REFERENCES/ RELATED DOCUMENTS**
	1. Abbott/ Alere Determine TB LAM Ag Package Insert
	2. Abbott/ Alere Determine TB LAM Ag Testing Procedure
	3. Practical implementation of lateral flow urine lipoarabinomannan assay (LF-LAM) for detection of active tuberculosis in people living with HIV. Global Laboratory Initiative (GLI) 2021.
	4. Abbott/ Alere Determine TB-LAM Ag Method Validation. Quality Assurance Package for TB-LAM Testing. Global Laboratory Initiative (GLI) 2023.