

# **GeneXpert MTB/RIF**

## **Frequently Asked Questions (FAQs)**

### **1. What is CBNAAT?**

Cartridge based nucleic acid amplification testing (CB-NAAT) is a rapid molecular beacon-based Xpert MTB/RIF assay technology. The test detects Mycobacterium Tuberculosis (MTB) and Rifampicin (Rif) resistance conferring mutations directly from specimen.

### **2. How long does it take to give results?**

It provides results within 2 hours that enables same day diagnosis and prompt treatment initiation. This is the fastest turn around time with any technology as compared to three days (72 hrs) in Line Probe Assay (LPA), 75 days (two and half months) in Liquid culture and DST (MGIT) and 120 days (four months) in solid culture and DST technology.

### **3. Is CBNAAT recommended?**

CBNAAT was endorsed by WHO in December 2010. CB-NAAT is endorsed by RNTCP as a rapid molecular diagnostic tool. Its use is recommended under the following programmatic settings:

1. For rapid diagnosis of Rif resistance in MDR-TB suspects under criteria (A, B and C) as per RNTCP PMDT guidelines
2. For rapid diagnosis of MTB in presumptive TB cases amongst prioritized high risk groups like people living with HIV (PLHIV) to prevent mortality
3. Presumptive TB cases among Paediatric group

### **4. What samples can be processed on CBNAAT?**

Sputum or induced sputum

Aseptically collected specimens, usually free from other microorganisms (sterile) fluids like spinal, pleural, pericardial, synovial, ascitic, bone marrow, tissues (lymph node, tissue biopsies-to be sent in normal saline) and fine needle aspirates (FNAs)

Specimens contaminated by normal flora or specimens not collected aseptically (not sterile) – gastric lavage, bronchial washings and pus

### **5. How do we collect and transport specimens?**

Specimens can be collected in sterile Falcon tubes placed at the facility and tightly wrapped using parafilm. Every specimen must be accompanied by the Lab request form giving details of referring doctor, patient and sample. The sample may be transported by human carrier preferably the parents or relatives of child. The samples must reach the lab within 6 hours of collection and can be placed in refrigerator (DO NOT FREEZE) if it exceeds 6hrs.

## 6. Are there alternate mechanisms of transport?

Samples may be transported using local courier or an identified voluntary worker. When it is transported by courier it must be ensured that the sample is packed under biosafety precautions, triple packaging system and cold chain.

## 7. How are the results conveyed?

A copy of result sheet from the Gene X-pert Machine is mailed to the referring doctor and a hard copy is sent to the referring paediatrician by post provided all details are available in the lab request form accompanying the sample.

## 8. How do we interpret results and treat patients?

For use of CB-NAAT results in decision making on treatment of the diagnosed cases, the guidelines are as follows:

- a. For MTB positive and Rif sensitive results, treat the patient with first line drug regimen
- b. For MTB positive and Rif resistance results, take the history of past exposure of the patient to anti-TB drugs and carefully ascertain whether the patient is a new TB case or a re-treatment TB case.
  - i. *In re-treatment TB cases, treat with regimen for MDR-TB and offer second-line DST wherever available*
  - ii. *In new TB cases, treat with regimen for MDR-TB after reconfirming Rif resistance with another technology.*
- c. In smear positive cases, reconfirm with LPA
- d. In smear negative cases, offer liquid or solid culture and if culture is positive, the culture isolates must be subjected to LPA as per RNTCP PMDT guidelines

## 9. Should the referring doctor maintain any records?

The referring physician may ideally place a register in the health facility and record the details of every patient sample sent, results conveyed and whether or not the patient is initiated on treatment. This will serve as a ready reference to both the referring paediatrician and the programme if needed.

## 10. Where and how the samples need to be sent?

The samples can be sent to the **following address** accompanied by the study specific request form (**Request form for Gene Xpert**):

*Kind Attention: GeneXpert Section  
Department of Bacteriology  
National Institute of Research in Tuberculosis  
No.1, Satyamoorthy Road,  
Chetpet, Chennai 600031  
Ph no:044-2836-9620/9643  
E-mail: nirtgenexpert@gmail.com*