



### Testing and interpretation of Xpert TB PCR for Inpatients Suspected to have Pulmonary Mycobacterium tuberculosis (TB)

#### General considerations

- TB PCR testing is limited to adult (≥18 years old) inpatients with clinical suspicion of TB requiring Airborne precautions.
- Smear and culture must be performed on all TB suspected patients (including those tested with PCR) for growth detection/identification of M. tuberculosis complex, for antimicrobial susceptibility testing, genotyping and to track response to treatment.
- Interpretation of a TB PCR result must be made in the context of the clinical and radiographic presentation, risk factors, and the clinician’s suspicion for infectious TB.
- A patient with a negative TB PCR result can only be taken off Airborne precautions if another diagnosis explains their clinical presentation. This decision must **never** be made based on test results alone.
- Discontinuation of Airborne precautions must be approved by Infection Prevention and Control (IPAC).
- TB PCR is performed automatically (where applicable) on two separate samples submitted for routine AFB smear and mycobacterial culture.
- TB PCR should not be used to monitor response to treatment or to release a newly confirmed TB patient from Airborne isolation.

#### Collection Instructions for TB testing

- Specimen type: Expecterated sputum, induced sputum, endotracheal suction, bronchoscopy specimen (BAL) collected in a sterile screw top container.
- Sputum quality is critical for the diagnosis of pulmonary TB. Sputum should be representative of secretions from the lungs after a productive deep cough. Saliva or nasopharyngeal secretions are not acceptable specimens and will not be processed .
- Always collect three consecutive sputum specimens for AFB smear and culture as per [Sputum collection Procedure](#) (Elsevier Clinical Skills).
- If patient is able to produce high quality sputum samples, they may be collected on the same day, at least 1 hour apart. Ideally, one sample will be collected in the morning, prior to eating or drinking. Alternatively, samples can be collected every 8 hours or when high quality sputum is obtained (e.g. daily, preferably in the morning).
- Volume required: Minimum 5 mL. Please note if insufficient volume received, specimen will NOT be eligible for on-site PCR testing and will be sent to reference laboratory for smear and culture.
- If patient is not able to cough spontaneously, order induced sputum.

#### Interpretation of TB PCR Results with AFB Smear Results

PCR TB	AFB smear	Interpretation
Positive	Pending	Continue Airborne precautions
	Positive	Diagnosis of TB is highly likely. Continue Airborne precautions.
	Negative (x3)	Consistent with smear-negative TB. The patient can be presumed to have TB if specimen is PCR TB positive, pending culture results. Continue Airborne precautions.
Negative (2 PCR tests from separate specimens)	Pending	TB is not likely. Review clinical presentation carefully and consult IPAC before stopping Airborne precautions.
	Positive	Not consistent with active TB. A patient can be presumed to have an infection with nontuberculous mycobacteria (NTM) if only AFB smear is positive and two (2) PCR TB tests are negative.
	Negative	TB is not likely. Infectious TB is not likely if tests are negative, pending culture results.

#### Discontinuation of Airborne Precautions

- 1) Review laboratory results**
  - TWO** NEGATIVE TB PCR results from specimens collected at least one hour apart.

OR

  - THREE** NEGATIVE AFB smears from specimens collected at least one hour apart.
- 2) Review patient history**
  - Patient has an alternative diagnosis to explain their symptoms (e.g.: community acquired pneumonia)
- 3) Who is eligible for de-isolation?**
  - ◆ Two (2) PCR TB NEGATIVE specimens **AND** alternate diagnosis for presentation
  - ◆ Discontinuation of Airborne precautions must be approved by Infection Prevention and Control (IPAC)
  - ◆ For combination of PCR and smear results that don’t meet criteria above discontinuation of Airborne precautions requires assessment by Infection Prevention and Control.

- Notes:**
- \* The process described herein is not to be used alone to rule out TB. Interpretation of a TB PCR result **must be made** in the context of the clinical and radiographic presentation and the clinician’s suspicion for infectious TB.
  - \* Always use clinical judgment regarding Airborne precautions and whether to begin anti-TB treatment while awaiting culture results. Questions concerning appropriate use of PCR TB and interpretation of results should be directed to the Medical Microbiologist on Call and Infection Prevention and Control.
  - \* For additional guidance regarding treatment, consult with Infectious Diseases physician or Respiriologist. Furthermore, PCR TB testing should not be used to monitor response to treatment or to release a newly confirmed TB patient from Airborne isolation.