



NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
Mary T. Bassett, MD, MPH
Commissioner

2016 Advisory #17:

Use of Cepheid Xpert MTB/RIF® assay in making decisions to discontinue airborne infection isolation of patients suspected with infectious tuberculosis

- Cepheid Xpert MTB/RIF® (Xpert) should not be used *alone* to rule out tuberculosis (TB)
- Xpert should not be used to monitor response to treatment or to release a confirmed TB patient from airborne infection isolation.
- Patients with acid fast bacilli (AFB) smear positive results must still be reported to the Health Department regardless of Xpert results

Please distribute to all clinical staff in Internal Medicine, Pediatrics, Geriatrics, Primary Care, Infectious Diseases, Emergency Medicine, Family Medicine, Laboratory Medicine and Infection Control.

June 30, 2016

Dear Colleagues,

In April 2016, the National Tuberculosis Controllers Association (NTCA) and the Association of Public Health Laboratories (APHL) issued a [Consensus statement for the use of the Cepheid Xpert MTB/RIF® assay \(Xpert\)](#) in making decisions to discontinue airborne infection isolation (AII) for individuals suspected to have infectious pulmonary TB. The purpose of this alert is to disseminate information about the guidelines to clinicians, nurses, and hospital infection control staff.

Clinicians can *consider* discontinuing AII after obtaining two negative Xpert test results on two sputum specimens taken at least eight hours apart, from individuals suspected of having infectious pulmonary TB, if TB is no longer a significant clinical consideration. The accuracy of this decision is greatest when two sputum smears are AFB positive and both Xpert test results are negative. If both AFB smears are negative and both Xpert tests are negative, infectious TB is unlikely, but the decision to discontinue AII should be made in conjunction with available clinical data.

NTCA/APHL Consensus Recommendations for Health Care Providers

1. **Positive Xpert Result:** *M. tuberculosis* complex detected. Diagnosis of TB is highly likely. Continue AII until deemed non-infectious during hospital stay or until discharged to home isolation.
2. **Negative First and Second Xpert Results:** If the first Xpert result is negative (*M. tuberculosis* complex not detected), a second specimen collected at least eight hours after the first specimen should be tested if TB still is clinically suspected. If the second Xpert result is negative, infectious TB is not likely. Consider release from AII if infectious TB is no longer a significant clinical consideration.

3. **Negative Xpert Results with Positive or Discordant AFB Sputum Smears:** Two negative Xpert results with positive AFB sputum smears likely indicate presence of nontuberculous mycobacteria (NTM). One negative Xpert result in a patient with positive AFB sputum smears is suspicious for NTM, and collection of sputum for a second Xpert test is recommended. If the second Xpert result is still negative, infectious TB is not likely. If smears are discordant (i.e., one AFB positive, one AFB negative), decisions should be based on clinical suspicion.
4. **Invalid Xpert Result:** An invalid result represents a failure of the assay; this is a rare event, estimated to occur with 1-2% of specimen-runs. If an invalid result is reported, the laboratory likely has repeated the test on leftover specimen and the presence or absence of *M. tuberculosis* complex cannot be determined. If an invalid result is reported with the initial specimen and TB still is clinically suspected, repeat the test using a new specimen. If the second result also is invalid, use AFB smear results and clinical judgment to make the decision to discontinue AII. If this result is negative, if infectious TB still is clinically suspected, and an additional specimen is available, a repeat test using this new specimen is recommended to improve sensitivity. Alternatively the clinician may use the single negative Xpert result with smear results and clinical information to make the decision to discontinue AII.

In addition, no matter the result of the Xpert, all sputum specimens should have AFB cultures performed.

Discontinuation of Anti-TB Treatment

Although not specifically covered in the NTCA/APHL Consensus Statement, the discontinuation of anti-TB treatment (if initiated) should also be considered when making the decision to discontinue AII after two negative Xpert test results. If anti-TB treatment is continued, the individual should remain in AII until: the patient has received at least two weeks of treatment, has several consecutive AFB smear negative sputum specimens, and has had resolution, or near resolution of symptoms consistent with TB. Patients must still be reported to the health department.

It is important to note that:

- Xpert is not to be used *alone* to rule out TB; Xpert negative or AFB smear negative sputum may contain viable organisms and represent infectious TB.
- The FDA approval for the use of Xpert to aid in the decision to discontinue AII for patients with suspected pulmonary TB applies only to the Xpert assay performed on raw sputum or concentrated sputum sediment prepared from expectorated or induced sputum. It does not include other FDA-approved or laboratory developed nucleic acid amplification (NAA) tests on sputum or other specimens. Hospitals that use other NAA tests for this purpose should validate the test they use for making a decision to release patients from AII.
- Sputum quality is critical both for the diagnosis of pulmonary TB and for the performance of this assay. Sputum may be spontaneously expectorated after deep coughing, or induced following facility-approved procedures for sputum induction with deep inhalation of aerosolized saline and deep coughing to generate sputum. At least 3 good quality sputum specimens should be obtained at least 8 hours apart (one of these obtained in the early morning, on rising) for AFB smear and culture.
- Xpert test results should *not* be used to monitor treatment response for individuals confirmed to have TB. Xpert and other NAA tests of sputum measure the presence of nucleic acid in the sputum; they do not test for viable organisms.

- AFB smear and culture must still be performed for growth detection/identification of *M. tuberculosis* complex, for antimicrobial susceptibility testing, for genotyping and to track response to treatment.
- Patients with a positive AFB smear must still be reported to the health department regardless of the Xpert result.

If you have any questions about the test or the guidelines, please call the Provider Access Line at 866-692-3641.

Sincerely,

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Assistant Commissioner
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