# Consensus statement on the use of **Cepheid Xpert MTB/RIF®** assay in making decisions to discontinue **airborne infection isolation** in healthcare settings

## PURPOSE

The purpose of this consensus statement is to provide guidance for clinicians, nurses, and hospital infection preventionists on the use of the FDA-approved Cepheid Xpert MTB/RIF® (Xpert) Nucleic Acid Amplification (NAA) test when making decisions to discontinue airborne infection isolation (A.I.I.) for persons with suspected, infectious pulmonary tuberculosis (TB).

- It is important to note that the process described herein **is not to be used *alone* to rule out TB**; Xpert negative or acid-fast bacilli (AFB) smear-negative sputum may contain viable organisms and represent infectious tuberculosis.
- Furthermore, NAA testing should **not be used to monitor response to treatment or to release a newly confirmed TB patient from A.I.I.**

**Note:** FDA-approved labeling (and this document) applies for this instrument and this purpose **only**.

See **Appendix I** for **Definition of Terms**

# BACKGROUND

In February 2015, the U.S. Food & Drug Administration (FDA) approved a change in the package insert for the Xpert to reflect expanded claims related to A.I.I. According to this change, negative results using this assay on "either one or two sputum specimens" can be used as an alternative to examination of serial acid-fast stained sputum smears to aid in the decision to discontinue A.I.I. for patients with suspected pulmonary TB.[1] **This label change and its subsequent announcement, however, lack detail. Concerns that various interpretations of this change will result in premature discharge from A.I.I. prompted the creation of this document.**

**This statement does not represent an endorsement of Xpert or of any other specific product; it provides consensus guidance from a group of experts in tuberculosis** convened by the National TB Controllers Association (NTCA) and the Association of Public Health Laboratories (APHL) for the use of Xpert in making decisions to discontinue A.I.I. for suspected infectious TB as now indicated by its revised FDA-approved labeling. Members of the work group represent the TB Laboratory (APHL and private/commercial laboratories), TB Controllers (NTCA and its TB nursing, clinician, and epidemiology sections) and Hospital Infection Preventionists and Respiratory Therapy experts. Work group members are listed in Appendix IV at the end of the document.

Traditionally, algorithms for removing patients from A.I.I. have been based on sputum AFB smear results. The FDA approval for this label change was based on reported improved sensitivity and specificity of Xpert *versus* sputum AFB smear in early detection of culture-confirmed pulmonary TB in adults. The results of a study that has since been published demonstrated that negative Xpert results from 1 or 2 sputum specimens are highly predictive of the results of 2 or 3 AFB sputum smears being negative. When compared with the results of 2 or 3 serial sputum AFB smears, one Xpert result detected 97% of patients who were AFB smear-positive and culture confirmed with *M. tuberculosis* disease. Two serial Xpert tests detected 100% of AFB smear-positive, culture-positive patients.[2,3,4]

Other published studies using the Xpert and other NAA systems also suggest these assays may be useful in predicting infectiousness:

- In 2008, 3 serially obtained sputum specimens from 493 patients with suspected TB admitted to A.I.I. (74% HIV+) were tested using the Amplified *M. tuberculosis* Direct test by Hologic Gen-Probe (MTD) and a laboratory-developed ("in house") polymerase chain reaction (PCR) platform. Campos et al[5] reported that the 1st sputum specimen PCR test detected 100% of all AFB smear positive patients, even if the 1st specimen was AFB smear negative. The MTD and PCR assays also were more sensitive than the AFB smear in culture-positive patients (87% versus 76%).
- In a prospective study of 139 patients admitted to rule out TB (30% HIV+),[6] serial sputum AFB smear microscopy and a single concentrated sputum Xpert had identical sensitivity (89%) and similar specificity (99%) referenced to culture positivity.
- In another study of 207 admissions to A.I.I. (23% HIV+),[7] Xpert detected 5 of 6 culture-confirmed cases on the initial submitted specimen; the sixth culture-positive case was detected on a second specimen. Sensitivity again was similar for Xpert and AFB smear: 93%.

Finally, although not focused on the assay's ability to predict infectiousness, another study has suggested that the use of NAA could provide cost savings by reducing patient time in A.I.I. and length of hospital stay.[8]

# PROCEDURES

**Patient Selection:** Persons at-risk for a diagnosis of infectious TB of the respiratory system must be placed into an A.I.I. room.

**Sputum Collection:** Sputum should be collected using procedures for obtaining sputum specimens that have been approved by hospital infection preventionists (see procedures for obtaining induced or spontaneously produced sputum, **Appendix IIa** and **IIb**, respectively), and then transported in a sealed container approved by the laboratory for infectious specimens.

**Note: Xpert is FDA-approved only for raw sputum or concentrated sputum sediment prepared from expectorated or induced sputum from patients who have received no, or fewer than 3 days, anti-tuberculosis therapy.**

**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. This often requires focused instruction and/or coaching of the patient by the respiratory therapist, nurse, or physician supervising the sputum collection. 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.[9] AFB smear and culture **must** be performed for growth detection/identification of *M. tuberculosis* complex, for antimicrobial susceptibility testing, for genotyping and to track response to treatment.

**Sputum submission for Xpert:** The first sputum obtained from the patient, **preferably a first morning, good quality sputum,** also should be subject to Xpert testing, regardless of the AFB smear result. If the first sputum is Xpert negative, a second specimen should be tested if TB is still clinically suspected.

Sputum should be submitted to the laboratory as quickly as possible. Specimens tested with the Xpert shall be stored and transported according to the requirements in the Xpert package insert.[10]

**Spontaneously expectorated sputum:** should be representative of secretions from the lower respiratory tract; it usually appears purulent and should not be solely saliva.

**Induced sputum:** purulence is desirable, but induced sputum may have the appearance of saliva due to the saline that is used for its generation.

**Laboratory considerations:** If concentrated specimens are used, sputum decontamination and concentration should be performed using NaOH or NALC-NaOH procedures recommended by CDC.[10] **A minimum of 0.5 mL of sputum sediment resuspended in 67 mM phosphate buffer from this process is required** for the Xpert assay. If unprocessed raw sputum is used, at least 1 mL is required.[10] The same specimen for smear and culture (recommended volume of 5-10 mL) can also be used for the Xpert assay. Doing this will allow interpretation of the Xpert result in correlation with the AFB smear result, as recommended by CDC.

## General Considerations

**Interpretation of an Xpert result must be made in the context of the clinical and radiographic presentation and the clinician's suspicion for infectious TB. A decision to remove a patient with a negative Xpert result from A.I.I. must consider the clinical presentation and the risk of possible transmission of TB from an infectious patient to others. *Such a decision should not be based on sputum test results alone.* The sensitivity of sputum testing for TB is subject to variability from a variety of factors, including sampling (e.g., poor specimen quality), inappropriate transport and processing of the specimen, errors in performance of the assay itself, and errors in labelling or reporting.**

Ultimately, decisions to remove a person from A.I.I. must comply with local jurisdictional public health laws and regulations where applicable. **Consult with the appropriate public health authority if you have questions.**

## Assay performance and reporting

The Xpert is performed according to the package insert; the result is reported to the requesting clinician and to infection control as either "*M. tuberculosis* complex Detected", "*M. tuberculosis* complex **Not** Detected", or "Invalid," **and** "Rifampin Resistance Detected," "Rifampin Resistance **Not** Detected," or "Rifampin Resistance Indeterminate."

## Recommendations: (see also Flow Charts, Appendix III)

1. **Positive Xpert Result:** *M. tuberculosis* complex detected. **Diagnosis of TB is highly likely.** Continue A.I.I. 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 A.I.I. 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); Appendix IIIb. 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., 1 AFB positive, 1 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[10] and the presence or absence of *Mycobacterium 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 (go to**

**Step 2, of Flow Chart, Appendix IIIa).** If the second result also is Invalid, use AFB smear results and clinical judgment to make the decision to discontinue A.I.I. If this result is Negative, if infectious TB still is clinically suspected, and an additional specimen is available, a repeat test (repeat Step 2) 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 A.I.I.

**Note:** This process does **not** rule out infectious TB with 100% certainty. In addition to Xpert testing, a complete series of 3 sputa for AFB smear and culture should be collected for diagnostic purposes.

## LIMITATIONS

1. The FDA approval for the use of Xpert to aid in the decision to discontinue airborne infection isolation 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 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 A.I.I.
2. **Collection of quality sputum specimens is critical** to obtaining accurate Xpert, AFB smear and culture results. For TB diagnosis, a minimum of 2 sputum specimens, with 3 specimens preferred, must be submitted for mycobacterial AFB smear and culture in addition to Xpert testing.
3. Xpert and other NAA tests of sputum measure the presence of nucleic acid in sputum; they are **not** tests for viable organisms and serial testing should **not** be used to monitor response to treatment. NAA testing of sputum should **not** be used solely to determine when a **laboratory confirmed** case of pulmonary TB can be released from A.I.I.; for this, please refer to CDC Guidelines.[9]
4. The FDA approval for the use of Xpert to aid in the decision to discontinue A.I.I. for patients with suspected pulmonary TB applies only to A.I.I. in healthcare facilities.
5. The FDA approval for the use of Xpert to aid in the decision to discontinue A.I.I. for patients with suspected pulmonary TB was based upon research investigations of persons aged 18 years and older.

## DATA RECORDING AND EVALUATION

Infection Control programs should collaborate with the TB Laboratory and local and state public health officials to collect and analyze data to determine and evaluate the effectiveness of institutional methods used to determine discharge from A.I.I.

**As always, contact your local health department for assistance with TB-related problems.**

# REFERENCES


1. US Food and Drug Administration. New data shows test can help physicians remove patients with suspected TB from isolation earlier. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm434226.htm (Accessed on February 19, 2015).

2. Revised Device Labeling for the Cepheid Xpert® MTB/RIF Assay for Detecting Mycobacterium tuberculosis. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6407a8.htm?s_cid=mm6407a8_e (Accessed on February 26, 2015).

3. Luetkemeyer A, Firnhaber C, Kendall M, et al., on behalf of the ACTG A5295/TBTC 34 study teams. Xpert® MTB/RIF versus AFB smear to determine respiratory isolation of U.S. TB suspects. Presented at the Conference on Retroviruses and Opportunistic Infections, February 23–26, 2015, Seattle, Washington.

4. Luetkemeyer, A, Firnhaber, C, Kendall, MA, et al., Evaluation of Xpert MTB/RIF to identify pulmonary tuberculosis in tuberculosis suspects from low and higher prevalence settings compared to acid fast smear and culture. Clin Infect Dis epub 2/06/2016.

5. Campos M, Quartin A, Mendes E, et al. Feasibility of shortening respiratory isolation with a single sputum nucleic acid amplification test. Am J Respir Crit Care Med 2008; 178:300.

6. Chaisson LH, Roemer M, Cantu D, et al. Impact of Gene Xpert® MTB/RIF assay on triage of respiratory isolation rooms for inpatients with presumed tuberculosis: a hypothetical trial. Clin Infect Dis 2014; 59:1353.

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8. Millman AJ, Dowdy DW, Miller CR, et al. Rapid molecular testing for TB to guide respiratory isolation in the U.S.: a cost-benefit analysis. PLoS One 2013; 8: e79669.

9. CDC. Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health-care settings, 2005. MMWR 2005;54 (No. RR-17). http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf

10. Cepheid Xpert® MTB/RIF Assay package insert: http://www.cepheid.com/manageddownloads/xpert-mtb-rif-english-package-insert-301-1404-rev-c.pdf :

# APPENDIX I

## DEFINITION OF TERMS

**Airborne infection isolation (A.I.I.) precautions:** containment of a person with suspected pulmonary tuberculosis in a single-occupancy patient-care room that is maintained under negative pressure.

**Infectious tuberculosis:** active tuberculosis disease of the lungs or respiratory tract that can be spread to other persons through the air *via* respiratory droplet nuclei generated by coughing, sneezing, singing, or talking.

**Sputum:** spontaneously expectorated or induced sputum (latter generated by inhalation of hypertonic saline using a facility-approved protocol for induction), mucous secretion from the lungs, bronchi and trachea.

Note: The Xpert is **not** approved for use with secretions or fluids other than raw sputum or concentrated sputum sediment prepared from expectorated sputum (i.e., **not** on bronchoscopy samples).

**Concentrated/decontaminated sputum:** Sputum that has been processed and concentrated by standardized, validated laboratory procedures using sodium hydroxide (NaOH) and N-Acetyl cysteine and centrifugation.

# APPENDIX IIa

## NEBULIZED SPUTUM INDUCTION FOR TUBERCULOSIS

### Purpose

To obtain sputum specimens for AFB smear microscopy and culture from a patient who has a dry, non-productive cough.

**Ensure that the patient is placed in an appropriate negative air pressure room with the door shut. The air in the negative air pressure room should be drawn out of the room and vented outside of the building.**

### Materials and Equipment Required

- Sterile, filtered water or normal saline (150-250mL)
- Hand-held nebulizer with mouthpiece and 15mL vial of 3% saline

  **Note:** A mask may be used if a patient absolutely cannot use the mouthpiece; 3% saline may be available from the pharmacy if not available in department stock.
- N95 mask (particulate respirator) for AFB
- Gloves
- Box of tissues
- Sterile specimen container approved by the laboratory for sputum collection and transport

### Procedure

#### PREPARATION

1. Assure that the patient is NPO for three hours prior to sputum induction.

   **Note:** Three hours NPO reduces the potential risk of vomiting and aspiration.

2. Instruct the patient to gently brush his/her teeth, gingival margins, tongue, and buccal surfaces using sterile, filtered water or normal saline to rinse

   **Do not** use toothpaste, commercial mouth wash preparations, nose drops, or any medications containing alcohol, or oil. Instruct the patient to avoid taking oral antibiotics immediately before the sputum collection procedure.

3. Instruct the patient to gargle several times with sterile, filtered water or normal saline after brushing.

   **Do not** use tap water or bottled water, as it may contain nontuberculous mycobacteria that may alter findings.

## SPUTUM COLLECTION

1. Observe standard precautions at all times.

   **Note:** N95 masks must worn by healthcare personnel for AFB cough-producing procedures.

2. The patient must be in an appropriate negative air pressure room.

3. Place approximately 5 mL of 3% saline into the hand-held nebulizer. Set the flow at 6-8 L/min and nebulize saline for 7-10 minutes or until sputum is expectorated. The maximum nebulization time is 20 minutes.

   **Note:** More saline may be added to the nebulizer if more than 10 minutes is needed to produce an adequate cough.

4. Ask the patient to inhale the nebulized 3% saline deeply 2-3 times followed by a vigorous cough. This will assist in expectorating quality sputum. Collect the sputum into a sterile specimen container.

   **Note:** Coaching the patient is very important in order to get quality results in a timely manner.

   **Note:** High-quality sputum is required for smear, culture, and NAA testing. For AFB NAA testing alone, a minimum of 1mL of raw sputum (or 0.5mL of sputum sediment) is needed. It is preferred to collect 5-10 mL of raw sputum.

5. Label the specimen with time and date of its collection and place it in a specimen bag. Attach a laboratory request form, if applicable.

6. Document the procedure in the appropriate flow sheet or medical record.

   **Note:** Documentation also is required for unsuccessful procedures.

Adapted from CDC: ***Controlling TB in Correctional Facilities.*** Atlanta, GA, 1995.
https://books.google.com/books?id=5ed_o0LWDFYC&pg=PA26&lpg=PA26&dq=sputum+coaching&source=bl&ots=z-r23D9aQ4U&sig=6DHzW_3x0KwI6GjfVUMZljZWwcc&hl=en&sa=X&ved=0CCYQ6AEwA2oVChMIsc6f5oTWxwIVxR4eCh1O-3A6O#v=onepage&q=sputum%20coaching&f=false

# APPENDIX IIb

## SPONTANEOUSLY PRODUCED SPUTUM COLLECTION FOR TUBERCULOSIS

### Purpose

To obtain sputum specimens for AFB smear microscopy and culture from a patient who has a productive cough.

**Ensure that the patient is outdoors or placed in an airborne isolation room or negative-pressure sputum collection booth with the door shut. The air in the negative-pressure room or booth should be drawn out of the space and vented outside of the building.**

### Materials and Equipment Required

- Sterile, filtered water or normal saline (150-250mL)
- N95 mask (particulate respirator) for AFB
- Gloves
- Box of tissues
- Sterile specimen container approved by the laboratory for sputum collection and transport

### Procedure

#### PREPARATION

1. Instruct the patient to gently brush his/her teeth, gingival margins, tongue, and buccal surfaces using sterile, filtered water or normal saline to rinse

   **Do not** use toothpaste, commercial mouth wash preparations, nose drops, or any medications containing alcohol, or oil. Instruct the patient to avoid taking oral antibiotics immediately before the sputum collection procedure.

2. Instruct the patient to gargle several times with sterile, filtered water or normal saline after brushing.

   **Do not** use tap water or bottled water, as it may contain nontuberculous mycobacteria that may alter findings.

#### SPUTUM COLLECTION

1. Observe standard precautions at all times.

   **Note:** N95 masks must worn by healthcare personnel for AFB cough-producing procedures.

2. The patient must be outdoors or in an appropriate negative air pressure room or booth.

3. Coach the patient and supervise the first sputum collection, at a minimum, in order to obtain a good quality sputum sample that represents secretions from the lower respiratory tract.

   **Note:** The patient should understand that sputum is material that is brought up from the lungs and that **nasal secretions and saliva or spit are not acceptable.**

4. Instruct the patient to inhale deeply, as far as possible, and then exhale slowly three times.

5. After the third breath, direct the patient to inhale completely and try to cough hard to produce sputum from deep in the lungs. The patient may feel a rattle or tickle as the sputum moves up from the lungs into the throat.

6. Instruct the patient to expectorate the sputum into a sterile specimen container.

7. When there is at least 5 mL (1 teaspoon) of sputum, replace the lid on the container and tighten it so it does not leak.

   **Note:** High-quality sputum is required for smear, culture, and NAA testing. For AFB NAA testing alone, a minimum of 1mL of raw sputum (or 0.5mL of sputum sediment) is needed. It is preferred to collect 5-10 mL of raw sputum.

8. If the patient is in a negative air pressure room or booth, ask the patient remain in the booth or room until cleared to leave.

9. Label the specimen with time and date of its collection and place it in a specimen bag. Attach a laboratory request form, if applicable.

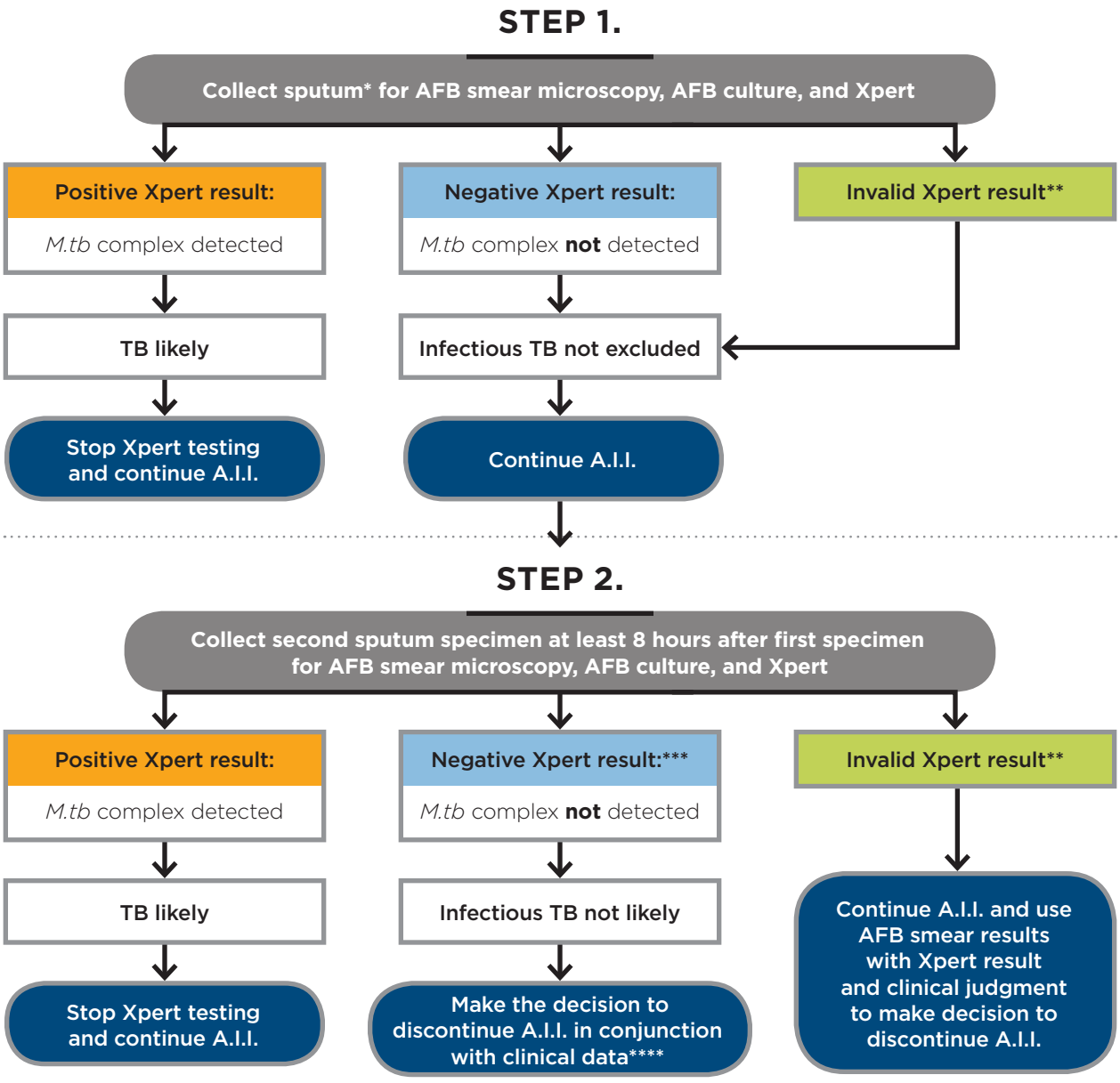
10. Document the procedure in the appropriate flow sheet or medical record.

    **Note:** Documentation also is required for unsuccessful procedures.

Adapted from CDC: ***Controlling TB in Correctional Facilities.*** Atlanta, GA, 1995.
https://books.google.com/books?id=5ed_o0LWDFYC&pg=PA26&lpg=PA26&dq=sputum+coaching&source=bl&ots=z-r23D9aQ4U&sig=6DHzW_3x0KwI6GjfVUMZljZWwcc&hl=en&sa=X&ved=0CCYQ6AEwA2oVChMIsc6f5oTWxwIVxR4eCh1O-3A6O#v=onepage&q=sputum%20coaching&f=false

# APPENDIX IIIa

## USE OF GENEXPERT IN DISCONTINUING AIRBORNE INFECTION ISOLATION




***M. tb:*** *Mycobacterium tuberculosis* **A.I.I.:** Airborne infection isolation

* First morning specimen preferred to maximize diagnostic yield of AFB sputum smear, culture, and Xpert (see text, pages 8-11 for specifics on sputum collection.)

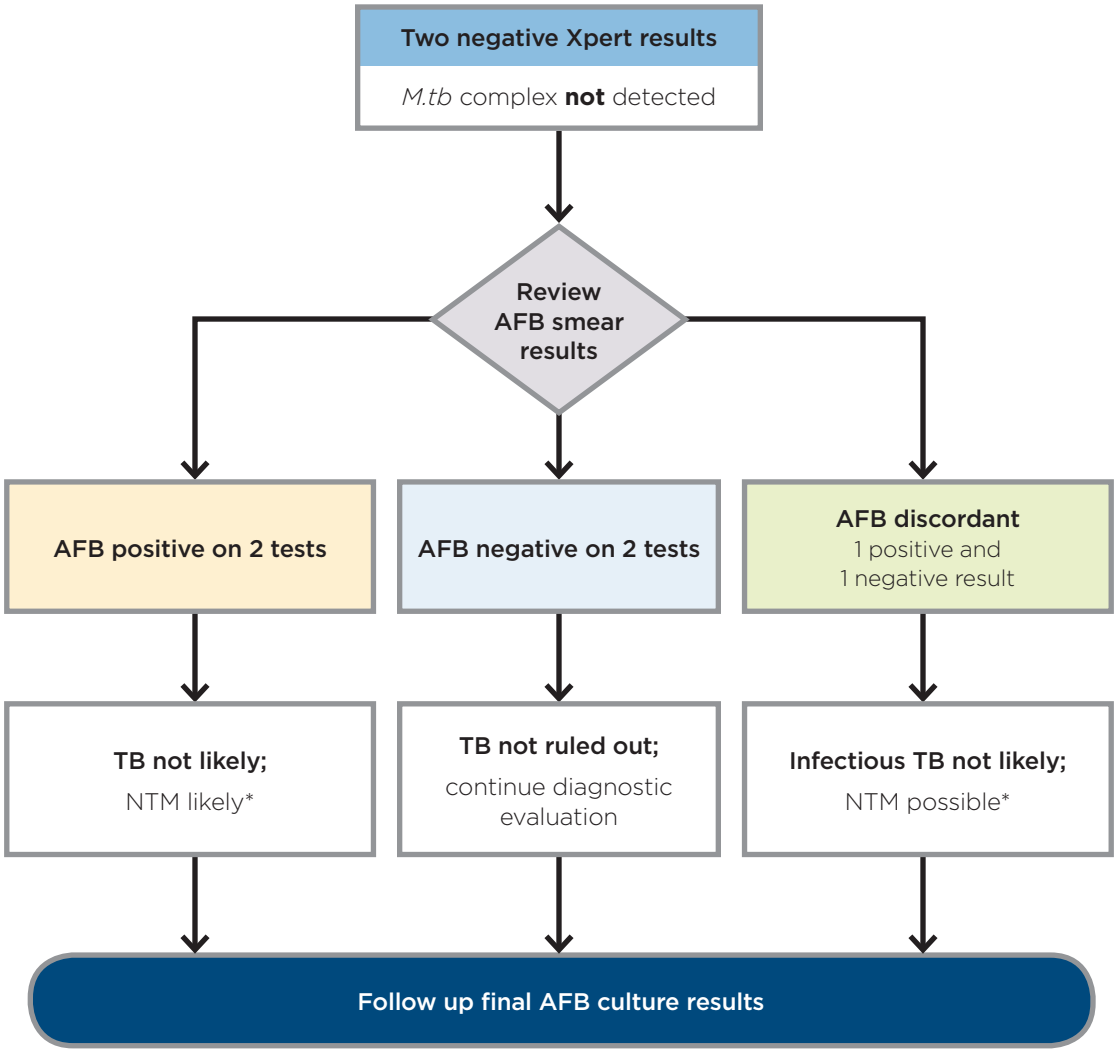
** Most laboratories/protocols will automatically retest leftover sample if an initial invalid (failed) result is obtained; in such cases, a reported invalid result reflects repeat testing of a single specimen (see text, page 4 for interpretation.)

*** If this result is Negative following an initial invalid result in Step 1 and infectious TB still is clinically suspected, a repeat test (repeat Step 2) using a new specimen, if available, is recommended in order to improve sensitivity. Alternatively, the clinician may use the single Negative Xpert result from Step 2 with smear results and clinical information to make the decision to discontinue or maintain A.I.I.

**** **Note:** This process does not rule out tuberculosis with 100% certainty. Refer to Appendix IIIb *Application of AFB Smear Microscopy to Negative Xpert Results* to assist in diagnostic evaluation.

# APPENDIX IIIb

## APPLICATION OF AFB SPUTUM SMEAR MICROSCOPY TO NEGATIVE XPERT RESULTS




**NTM:** nontuberculous mycobacteria

*Refer to text, page 4, Recommendations, item 3.

# APPENDIX IV

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