

QuantiFERON®

Policy

The Tennessee Tuberculosis Elimination Program (TTBEP) will utilize the QuantiFERON® (QFT) assay in lieu of the Tuberculin Skin Test (TST) in regional TB clinics and health departments in all counties across Tennessee. QFT should only be used to test individuals who are dispositioned as at “high-risk” for TB infection and/or the progression of TB infection to active TB disease as indicated through administration of the “TB Risk Assessment Tool” (TB RAT).

Exclusions:

1. Children < 5 years old¹
2. Any child, regardless of age, requiring TB testing as part of the EPSDT exam
3. Any person determined to be “low-risk” through the TB RAT
4. Health Care Workers (HCWs) and other individuals required by an employer or educational institution to have a baseline or serial TB test (e.g., annually) as a condition of employment or enrollment. QFT should not be used for any employment/admission testing or serial testing.
5. Persons requesting a TB test for employment purposes (excludes eligible health department employees that have a risk factor(s) for TB exposure or progression). QFT should not be used for any employment/admission testing or serial testing.
6. County jail inmates and jail employees in jurisdictions in which targeted TB testing is financially supported by the TTBEP

Procedure

1. Obtain relevant clinical history and complete the TB RAT.
2. If the patient is determined to be “high-risk” based on the responses on the TB RAT and does not meet any of the exclusion criteria listed above, proceed with QFT blood draw. Refer to Testing for TB Infection located in PHN 3.460 “Testing for TB Infection: Tuberculin Skin Testing (TST) or Interferon-gamma release assay (IGRA)” or Figure 1 “TB Testing Algorithm.”

Specimen Collection

1. Prior to blood draw for QFT and HIV screening test, explain the following point(s) to the patient using appropriate terms for patient understanding:

¹ CDC. “Updated Guidelines for Using Interferon Gamma Release Assays to Detect *Mycobacterium tuberculosis* Infection—United States, 2010.” MMWR, June 25, 2010/Vol.59/no.RR-5

- ***“I am now going to draw a sample of blood to test for TB infection and for HIV infection.”***

- If the patient voices no question or concern about the intent of these tests, proceed with blood draw for both QFT and HIV following Step 3 below. Also refer to QuantiFERON® (QFT) Assay in the Lab Manual.
- If the patient voices concern about the intent to test for HIV infection (i.e., “opt-out HIV testing”), provide patient education before drawing any blood:

Explain:

“It is important to also check for HIV infection because:

- a) If we know that a person has TB infection, we can treat it to prevent the infection from becoming TB disease;***
- b) If HIV infection is present, it may cause a false-negative test for TB infection, and we would miss the chance to prevent TB disease; and***
- c) Persons who have both HIV infection and TB infection are at very high risk to get sick with TB disease; and***
- d) Screening for HIV infection is the standard of care in Tennessee’s public health clinics.”***

- If the patient then agrees to an HIV screening test, proceed with blood draw for both QFT and HIV following Step 3 below.
 - If the patient states that he/she does not want to have an HIV test, before drawing blood for QFT reassure the patient that the purge tube specimen will not be sent to the lab for an HIV test; then proceed with blood draw under Step 3 below.
2. Using a butterfly blood collection set, first collect blood using a purge tube (standard 7 ml red top filled to capacity, if possible) and set aside for HIV screening test or discard (see Step 1 above), followed by each of the three QFT blood collection tubes. The QFT tubes may be drawn in any order. QFT tubes are identified by a grey top (“Nil”), red top (“TB antigen”), and purple top (“Mitogen”).

NOTE: Red top purge tube should be used for HIV screening unless the patient specifically “opts out” of HIV screening.

3. Fill each of the three (3) QFT tubes to the black indicator mark. The black mark on the side of the tubes indicates the 1mL fill volume. QFT blood collection tubes have been validated for volumes ranging from 0.8 mL–1.2 mL. Specimen amounts 1mm over or below the black indicator mark require immediate re-draw with a new QFT tube of the same color.

4. Immediately after blood collection (filling tubes), invert all three (3) QFT tubes 10 times just firmly enough to ensure the entire inner surface of each tube is coated with blood. Antigens have been applied onto the inner wall of the blood collection tubes, so it is essential that the contents of the tubes be thoroughly mixed with the blood. If you have to make a second attempt to draw an additional tube(s), shake the one(s) that you have already drawn and then shake the other(s) as you finish drawing.
 - QFT tubes should be between 17-25°C (63-77°F) at the time of filling
 - Over-energetic shaking may cause gel disruption and could lead to aberrant results
5. Make sure the tubes are correctly identified to the corresponding patient. You may either:
 - Write directly on the tubes themselves. Two identifiers **must be** on each tube: (1) Patient's name and (2) Patient's DOB

OR

 - You may use the label template provided by Central Office. NOTE: Central Office may have labels to provide you with initially but if you chose to continue using labels, you will be responsible for ordering your own labels. For reference, the label size is ¾" x 2 ¼"
6. Place the QFT tubes with blood specimens upright in a rack. NOTE: Specimens only have to be kept upright during incubation.

Currently specimens can be collected Monday-Wednesday. Due to incubation and mailing limitations, if draws need to be done on Thursday or Friday, arrangements should be made with the TDH State Lab to check on feasibility and coordinate.

Incubation by Health Department

1. Incubation of the QFT specimens must occur within 8 hours of blood collection. DO NOT refrigerate or freeze the blood samples.
2. Incubate QFT specimen tubes upright at 37°C (98°F) ($\pm 1^\circ\text{C}$) for 16-24 hours. NOTE: Incubators used for GC incubation can be used for QFT incubation as long as the incubator is set between 36-37°C
3. If the blood is not incubated immediately after collection, re-mixing of the tube by inverting 10 times must be performed immediately prior to incubation.
4. Following incubation, the blood collection tubes may then be held between 4-27°C (39.2-80.6°F) for up to three (3) days prior to centrifugation at the laboratory. The tubes must be received by the TDH State Lab by the third day after incubation ends.

BEST PRACTICE: If collecting multiple specimens from a large contact investigation and having to incubate at a health department, it is critical to batch and monitor incubation times carefully.

Completing the Requisition

1. Complete the QFT requisition. NOTE: 10 patients can be entered on one requisition ASSUMING they are all incubated at the same time and removed from the incubator at the same time.
2. The following items must be completed **LEGIBLY** on the requisition:
 - Collection Site: This is the actual site that the specimen(s) was collected. Example: Sumner County Health Department, Joe's Factory, 4th Street bridge, etc.
 - Date Collected: This is the date the specimen(s) was collected
 - Date Sent to Lab: This is the date the specimen(s) were sent to the TDH State Lab in Nashville
 - Submitter: This is the submitting organization. Example: Sumner County Health Department, West Tennessee Regional Office, etc. An individual should NEVER be recorded as the submitter
 - Time Collected: This is the time of collection for each specimen
 - Last Name: Record the patient's last name
 - First Name: Record the patient's first name
 - DOB: Record the patient's DOB in the format mm/dd/yy
 - Sex: Record the patient's sex
 - County of Residence: Record the patient's county of residence. NOTE: In some contact investigations, you may be drawing QFT on patients that reside in counties outside of your region
 - Drawn by: Record initials of the person that is drawing each specimen
 - Incubation Started: Record the date that you began incubating the specimens
 - Time Started: Record the time you started incubating the specimens

- Date Incubation Ended: Record the date that the specimens were removed from the incubator
- Time Ended: Record the time the specimens were removed from the incubator
- Total Time Incubated ____ hrs ____ mins: Record the total length of time (hours and minutes) that the specimens were incubated. **REMEMBER SPECIMENS SHOULD BE INCUBATED AT 37⁰C (±1⁰C) FOR 16-24 HOURS.**
- Accession Number: Will be completed by the TDH State Lab

NOTE: All times on the requisition **must be** recorded in military time.

NOTE: If a requisition is incomplete, the submitter will be asked to fax in a corrected requisition.

NOTE: You may also use a PTBMIS label in place of writing some of the information on the requisition (see Figure 3). You will still need to include the patient's sex (even though it is on the PTBMIS label as well as the patient's county of residence. If you choose to use a PTBMIS label you will not be able to fit 10 patients on one requisition but may use multiple requisitions.

The original requisition should be sent with the specimens themselves (see **“Packaging and Shipping”** section below). A copy of the requisition should be sent to Trudy Stein-Hart either by scanning and emailing Trudy.Stein-Hart@tn.gov or by faxing to her attention at 615-253-1370. If scanning and emailing please copy (cc) Jason Cummins at Jason.Cummins@tn.gov. The Regional TB Nurse may also request that his/her counties send a copy to him/her (this would be beneficial so that the Regional TB Nurse knows how many QFT specimens are being drawn in his/her counties).

QFT Packing and Mailing Procedures

1. Packing of specimens is seasonally-dependent. Between October-March the three specimen tubes per patient may be placed in a large ready-to-use cans (already pre-labeled) (not the regular specimen cans used for sputum specimens). The requisition should be placed between the inner and outer can. The number of specimens in the shipment should equal the number of patients on the requisition. For example, if there are three cans each with specimens for five patients (5 patients = 15 tubes) then there should be 15 patients listed on the requisition (meaning more than one requisition will be part of the shipment). During the spring and summer months, specimens should be packaged in FedEx boxes with Styrofoam (can be obtained from FedEx) and a cold pack should be used. A

barrier should be placed between the cold pack and specimens so that the specimens are not directly touching the cold pack.

The following should be marked on the FedEx label (see Figure 2. "Sample FedEx Label for QFT Shipping):

Express Package Service: Mark "FedEx Standard Overnight"

Express Freight Service: Leave all fields blank

Packaging: Mark "FedEx Pak"

Special Handling and Delivery Signature Options: Mark "No Signature Required"

Does this shipment contain dangerous goods? Mark "No"

Payment *Bill to*: Mark "Sender"

Specimens (in the large ready-to-use specimen cans) should be placed in a FedEx Large Clinical Pak and sent to the TDH State Lab.

2. HIV specimens may be packaged with the QFT specimens. Lab Order Entries (LOEs) should be completed in PTBMIS for all HIV specimens.

Results

Receipt of a QFT result can take between 3-5 days. The qualitative result will be indicated on the laboratory form as "**Positive,**" "**Negative,**" or "**Indeterminate.**" Patients for whom the QFT result is "Indeterminate" should have the QFT repeated within 1-2 weeks.

Results will be faxed to the **Regional Office of the county in which the patient resides**. Hard copies will be mailed to the Submitter of the specimens. If you are drawing QFT on a patient that resides outside of your region, you must coordinate with the corresponding regional office to receive a copy of the results if results are needed prior to receiving the mailed copy.

Coding

Procedure code for drawing QFT: 86480.

Diagnosis code: V741

Code results on Lab Screen

Negative QFT

Lab code: NEG

Positive QFT

Lab code: POS

Indeterminate QFT

Lab code: IND

Ordering QFT Supplies

The TDH State Lab will provide a supply sheet that must be completed and returned to the lab when supplies need to be reordered. The lab **will not** take verbal requests or email requests where the order request is typed in the body of the email. Requests will only be filled if a supply sheet is completed. One supply sheet must be completed for each order placed and multiple orders for multiple counties may not be placed on the same order sheet. These order forms may be faxed to the TDH State Lab (at the fax number listed on the supply sheet) or scanned and emailed to the email address provided on the supply sheet. NOTE: If the supply sheet(s) are not completed correctly or are illegible, it is up to the discretion of the TDH State Lab personnel where to send the supplies.

Regional/Metro TB Nurse Responsibilities

1. Regional/Metro TB Nurse will be responsible for ordering QFT tubes directly from the TDH State Lab. The Regional/Metro TB Nurse will write on the order sheet what address to ship the supplies to (if applicable). For example West Tennessee Regional TB Nurse will order supplies but indicate on the form to have them shipped to the Dyer County Health Department.
2. The Regional/Metro TB nurse will be responsible for ensuring that his/her county (if applicable) received the supplies requested.
3. The Regional/Metro TB Nurse will coordinator movement of supplies from one county to another (if applicable).
4. Regional/Metro TB Nurse will ensure that incubators used for QFT are maintained within specified temperature range.
5. Regional/Metro TB Nurse will be responsible for coordinating with other regions to obtain copies of lab results on patients who reside in counties outside of his/her region.

TTBEP Central Office Responsibilities

1. Central Office epidemiology staff and nurse consultants will monitor results of positivity rates, indeterminate results, and if HIV testing was performed. Regional office TB nurse will be notified for questions/problems.

**Figure 1.
TB Testing Algorithm**

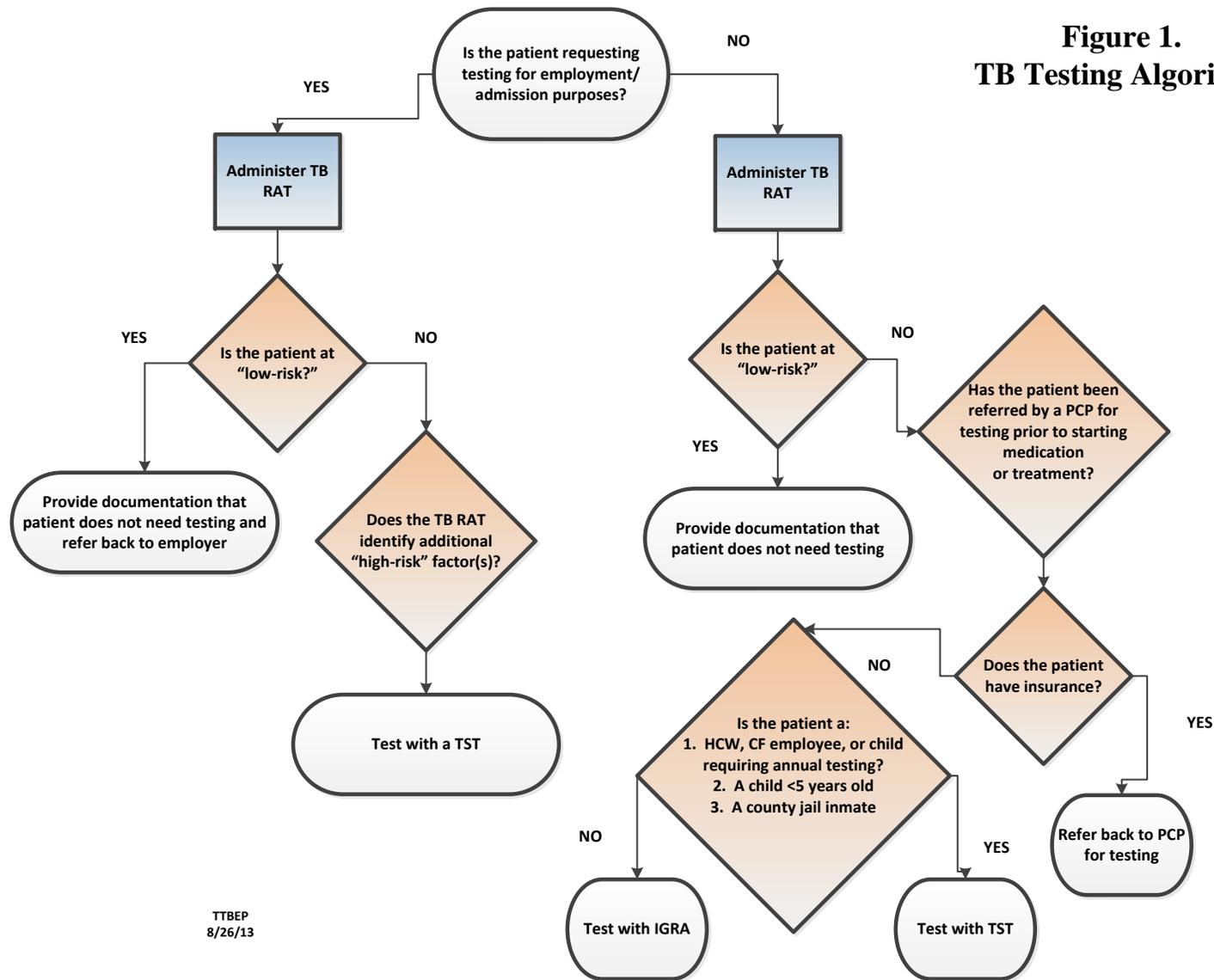


Figure 2. Sample FedEx Label for QFT Shipping

Express Package US Airbill FedEx Tracking Number **8044 9801 5401**

OTM *Please print and press hard.*
to **10-8-13** Sender's FedEx Account Number **4581-2956-8**

Sender's name **Susan Esquivias** Phone **731, 421-6758**

Company **West Tennessee Regional Office**

Address **295 Summar Ave.** Dept./Floor/Suite/Room

City **Jackson** State **TN** ZIP **38301**

Internal Billing Reference OPTIONAL
24 characters will appear on invoice.

Recipient's name **Tennessee Dept of Health** Phone ()

Company **Laboratory Services**

Address **630 Hart Lane** Dept./Floor/Suite/Room
cannot deliver to P.O. boxes or P.O. ZIP codes.

Address **Nashville** State **TN** ZIP **37216**

HOLD Weekday FedEx location address REQUIRED *NOT available for FedEx First Overnight.*

HOLD Saturday FedEx location address REQUIRED *Available ONLY for FedEx Priority Overnight and FedEx 2Day to select locations.*

0111693803



Form ID No. **0215** Sender's Copy

4 Express Package Service *To most locations. *Packages up to 150 lbs. For packages over 150 lbs., use the new FedEx Express Freight US Airbill.*

Next Business Day

FedEx First Overnight
Earliest next business morning delivery to select locations. Friday shipments will be delivered on Monday unless SATURDAY Delivery is selected.

FedEx Priority Overnight
Next business morning.* Friday shipments will be delivered on Monday unless SATURDAY Delivery is selected.

FedEx Standard Overnight
Next business afternoon.* Saturday Delivery NOT available.

2 or 3 Business Days

FedEx 2Day A.M.
Second business morning.* Saturday Delivery NOT available.

FedEx 2Day
Second business afternoon.* Thursday shipments will be delivered on Monday unless SATURDAY Delivery is selected.

FedEx Express Saver
Third business day.* Saturday Delivery NOT available.

5 Packaging *Declared value limit \$500.

FedEx Envelope* FedEx Pk* FedEx Box FedEx Tube Other

6 Special Handling and Delivery Signature Options

SATURDAY Delivery
NOT available for FedEx Standard Overnight, FedEx 2Day A.M., or FedEx Express Saver.

No Signature Required
Package may be left without obtaining a signature for delivery.

Direct Signature
Someone at recipient's address may sign for delivery. *Fee applies.*

Indirect Signature
If no one is available at recipient's address, someone at a neighboring address may sign for delivery. For residential deliveries only. *Fee applies.*

Does this shipment contain dangerous goods?
One box must be checked.

No Yes As per attached Shipper's Declaration. Yes Shipper's Declaration not required. Dry Ice Dry Ice, 6 UN 1845 _____ x _____ kg

Cargo Aircraft Only

7 Payment Bill to: Enter FedEx Acct. No. or Credit Card No. below.

Sender Acct. No. in Section 1 will be billed. Recipient Third Party Credit Card Cash/Check

FedEx Acct. No. Credit Card No. Exp. Date

Total Packages Total Weight Total Declared Value*

_____ lbs. \$ _____ .00

611

*Our liability is limited to US\$100 unless you declare a higher value. See back for details. By using this Airbill you agree to the service conditions on the back of this Airbill and in the current FedEx Service Guide, including terms that limit our liability.

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Figure 3. Sample QFT Requisition with PTBMIS Label

Oct. 8. 2013 9:10AM

No. 4331 P. 3

Quantiferon-TB Gold In-Tube
Log/Testing Request

Collection Site: KKR
Date Collected: 10/7/13
Date Sent to Lab: 10/8/13

Submitter: KKR
DOB:
Sex: M

First Name:
County of Residence:
Accession Number:
Result:

Time Collected*	Last Name	First Name	DOB	Sex	County of Residence	Drawn by	Accession Number	Result	
1 11:30	<div style="border: 2px solid black; padding: 5px;"> PT N: <u> </u> COSITE: <u>047 12 ENCH</u> DOB: <u> </u> DATE <u>10/07/13</u> NAME: <u> </u> <u> </u> <u> </u> M SEX F SSN: <u> </u> <u> </u> <u> </u> YRS: <u>28</u> MON <u>4</u> DAYS <u>24</u> ADDR: <u> </u> CITY: <u> </u> </div>		<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	
2			<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
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5			<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
6			<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
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8			<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
9			<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
10			<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>

*All time should be in military format
Specimens to be submitted via overnight delivery to:
Tennessee Department of Health, Laboratory Services
630 Hart Lane
Nashville, TN 37216
Dr. David Summey, Director

TTDET Form 8/17/10

Date Incubation Started: 10/7/13 Time Started: 16:30
Date Incubation Ended: 10/8/13 Time Ended: 09:00
Total Time Incubated 16 hrs 30 mins

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