Testing for TB Infection Video:
Tuberculin Skin Test & IGRA Blood Test
Student Guide

To jump to different sections of this document, select "Ctrl" hover your mouse over the blue hyperlink text, and click.

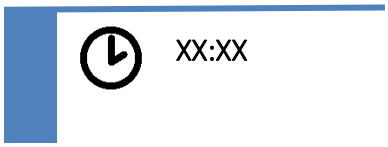
Notes for the Student

This video is presented by the Michigan Department of Health and Human Services, Communicable Disease Division, Tuberculosis Control Unit. It is based on a video prepared by the CDC[1] and intended only for use in the MDHHS Tuberculin Skin Test Workshop. Below are a few notes and symbols, which will help you grasp the most important points in the video.

Student notes are incorporated within the transcript and offer suggestions for further critical thought during the video. Student notes are identified by a note symbol next to a blue text box, like the one below.

Student Note Example

Video time is provided at the beginning of each section for identifying different parts of the video. Video time is identified next to a clock symbol within a blue header, like the one below.



Summary boxes, like the one below, will appear at the end of each section to summarize the main points of the section.

Summary:

- Example of one summary point
-

Citations are indicated by a small, superscript number next to the text (example below). These numbers correspond to the references in Appendix B of this document, where you can find further information about a topic.

Citation example: "The CDC recommends targeted testing to help identify those with disease and those with LTBI who are at risk of advancing to active TB disease.[2-3]"

Introduction

00:22

The CDC recommends targeted testing to help identify those with disease and those with LTBI who are at risk of advancing to active TB disease.[2-3] This video will review the two most commonly used methods used to test for TB infection:

- The Tuberculin Skin Test (TST)
- The Interferon-Gamma Release Assay (IGRA)

TST Guidelines

- The CDC recommends the TST test should always be "placed and read by a designated, trained health care worker."[4]
- MIOSHA's guidelines state, "Administering, reading, and interpreting of the tuberculin skin test shall be performed as described in the CDC Guidelines."[5]

IGRA Guidelines[6]

- Follow established FDA protocols
- Use in place of, but NOT in addition to, a TST
- Use in children 5 years and older
- Report both qualitative interpretation and quantitative measurements
- Availability, cost, and benefits should be considered before use

Patient education is an important step in TB testing. Ensure that you discuss with each patient why the test is being given, what is involved in the procedure, and when the patient should either return or when they should expect to hear from you. Encourage the patient to ask questions and talk about any concerns he or she may have about the test.

Consider using a translator or translated material for those who do not speak English. Does you program have a consent form that must be signed, to ensure informed consent?

Follow your institution's standards for infection control, and sanitize your hands using an appropriate handwashing technique.

Discuss your institution's policies for infection control while placing the TST. Discuss whether gloves are used in your facility, and under what circumstances.

Important Note

Neither the TST nor IGRA can differentiate LTBI from active TB disease. LTBI diagnosis should be based on[3]:

- Patient's medical history and epidemiological history
- TST or IGRA result
- Chest radiograph
- Physical exam, including sputum smear
- Exclusion of active TB disease diagnosis

Part One: Administering the Tuberculin Skin Test

03:45

1. Collect
   - ☐ Tuberculin solution (PPD) – stored in a cold, dark place
   - ☐ Tuberculin syringe
   - ☐ Millimeter ruler
   - ☐ Gauze pads/cotton balls
   - ☐ Alcohol wipes
   - ☐ Sharps disposal container
   - ☐ Record-keeping forms
   - ☐ Culturally appropriate educational material

2. Educate
   - ☐ Schedule a return appointment within 48-72 hours of administration
   - ☐ Give TB resources and encourage questions
   - ☐ Injection site maintenance

3. Check
   - ☐ Confirm injection of 5 tuberculin units (1/10th of a milliliter)
   - ☐ Locate the expiration and open dates. If you open a new vial, document date and initials on new vial

Each facility may require different documentation on the vial. What type of documentation is required at your facility?

4. Site
   - ☐ Typically on palm-side-up surface of the forearm
   - ☐ Free from muscle margins, heavy hair, veins, sores, tattoos, or scars
   - ☐ Clean the injection site and top of tuberculin vial with two different alcohol swabs and allow to dry completely

5. Prepare
   - ☐ Insert the needle into the tuberculin vial, and invert the vial. The tip of the needle should be below the fluid level
   - ☐ Draw out slightly more than one tenth of a milliliter

- ☐ Remove the needle and draw back slightly on the plunger
- ☐ Tap the syringe and expel excess air and fluid, leaving exactly one tenth of a milliliter of tuberculin solution

6. Inject
   - ☐ Stretch taut the skin
   - ☐ Insert the needle bevel-up, slowly, at a five- to fifteen-degree angle
   - ☐ You should be able to see the bevel just below the skin surface
   - ☐ Release the stretched skin, inject the tuberculin solution
   - ☐ Tense, pale wheal will appear over the needle bevel
   - ☐ Remove needle without pressing, massaging, or disturbing the area; dispose of the syringe.

The video demonstrates consistent placement on the left arm.

- What is the standard arm used for placement at your facility?
- What is the standard alternative site if there are barriers to placing on that arm?
- Are there any other alternative sites?

7. Measure
   - ☐ Immediately measure the wheal; should be at least six millimeters in diameter

8. Record
   - ☐ Date and time
   - ☐ Manufacturer
   - ☐ Lot number
   - ☐ Expiration date
   - ☐ Site where the injection was given
   - ☐ Name who administered the test

Summary: Administering the Tuberculin Skin Test

- ☐ Ensure patient can return within 48-72 hours
- ☐ Inspect PPD for correct storage, expiration date
- ☐ Intradermal injection at a 5-15 angle; 1/10 milliliter
- ☐ Wheal measures 6 mm
- ☐ Remind patient to return

Part Two: Reading the Tuberculin Skin Test

12:03

1. Collect
   - ☐ Millimeter ruler
   - ☐ Pen
   - ☐ Alcohol wipes
   - ☐ Record-keeping forms
   - ☐ Culturally appropriate educational material
   - ☐ Gloves (optional)

2. Locate
   - ☐ Inspect arm in good light on a firm surface
     i. Induration (a hard, dense, raised formation) is measured
     ii. Do **NOT** measure erythema

3. Palpate
   - ☐ Gently sweep fingertips over surface of forearm in all four directions
   - ☐ Mark edges of induration, using fingertip as guide

4. Measure
   - ☐ Transversely, across forearm, with a millimeter ruler
     i. Zero ruler line inside left dot edge, read ruler line inside right dot edge
     ii. May need to require second opinion for challenging readings

The orientation of the line of measurement can be remembered by visualizing the direction in which a watchband lies across the arm.

5. Record
   - ☐ Measurement in millimeters
     i. Do **NOT** record in centimeters, "positive", or "negative"
     ii. Presence of adverse effects: blistering, swelling, redness, even if no induration is present
   - ☐ Date and time test was read
   - ☐ Name and signature of person who read the test

6. Interpret
   - Should be performed by a trained health care provider in accordance with institutional policies based on CDC guidelines.[3-4, 7]

Discuss your facility's policy for interpretation of the TST measurement. If interpretation is conducted by the same person who reads the skin test, discuss cut points for interpretation (see Appendix A). If interpretation is conducted by someone else at your facility, discuss evaluation and referral procedures.

Summary: Reading the Tuberculin Skin Test

- Palpate to locate the margins of induration
- Mark margins and measure diameter transversely
- Record results in millimeters
- Refer to CDC guidelines for interpretation

Part Three: IGRA Specimen Collection and Shipment

16:10

1. Two FDA-approved IGRA tests
   - ☐ T-SPOT®.TB test (T-SPOT)
   - ☐ QuantiFERON®-TB Gold-in-Tube test (QFT-GIT)

2. Requires whole blood specimens and shipment to processing lab

3. Store test kits and ship specimens at room temperature

- What's your facility's policy for phlebotomy? Where is phlebotomy done?
- What courier service does your facility use? When and where does the courier service pick-up packages?

QuantiFERON®-TB Gold-in-Tube[8-9]

16:35

1. Prepare
   - ☐ Decide where to incubate the blood specimens (draw site or lab)
   - ☐ Three tubes per patient tested:
     1. Nil tube (negative control) – grey cap
     2. TB Antigen tube – red cap
     3. Mitogen tube (positive control) – purple cap

2. Collect
   - ☐ One milliliter of blood by venipuncture
     i. Black line on side of tube is one milliliter indicator, must be between 0.8 and 1.2 mL
     ii. Use a purge tube first if you use a butterfly needle

3. Shake
   - ☐ All three tubes ten times, or for five seconds, using exaggerated handshake
     i. Blood may froth; do **NOT** shake aggressively

4. Label
   - ☐ Patient name
   - ☐ Date of birth
   - ☐ Date and time of blood draw
   - ☐ Any additional unique identifier (if necessary)
   - ☐ Incubation status (choose one)
     i. "Not Incubated" or
     ii. "Incubated"

A "unique identifier" is any type of identifying information that your facility may use to differentiate one specimen from another. It could be a birthdate, patient initials, medical record number, etc.

5. Incubate (optional)
   - ☐ Upright, 37 °C as soon as possible for 16-24 hours
   - ☐ Specimens must be incubated within 16 hours of collection

6. Ship
   - ☐ If you chose not to incubate at the draw site, specimens must be shipped the day of collection

T-SPOT®.TB[10-12]

20:05

1. Prepare
   - ☐ Use 9 mL, green-top blood collection tubes, containing either:
     i. Lithium heparin
     ii. Sodium citrate, or
     iii. Sodium heparin
     iv. Do **NOT** use tubes with EDTA

2. Collect
   - ☐ Adults and children 10 years and older:
     i. One 8 mL CPT tube
     ii. Two 4 mL CPT tubes, or
     iii. Two 6 mL lithium heparin tubes

- ☐ Children 5-9 years old:
  i. One 4 mL CPT or lithium heparin tube
- ☐ Immunosuppressed
  i. Draw twice the volume

3. Shake
   - ☐ All three tubes ten times, or for five seconds, using exaggerated handshake
     i. Blood may froth; do **NOT** shake aggressively

4. Label
   - ☐ Patient name
   - ☐ Date of birth
   - ☐ Date and time of blood draw
   - ☐ Any additional unique identifier (if necessary)

A "unique identifier" is any type of identifying information that your facility may use to differentiate one specimen from another. It could be a birthdate, patient initials, medical record number, etc.

Summary: IGRA Specimen Collection and Shipment

- ☐ Use the recommended number and types of tubes
- ☐ Collect recommended volume of blood
- ☐ Invert the specimens ten times, or for five seconds
- ☐ Incubate, pack and ship the specimens using directions on day of collection
- ☐ Store test kits and specimens at room temperature

Part Four: Interpreting IGRA Test Results

QuantiFERON®-TB Gold-in-Tube[9]

21:51

1. Three Quantitative Values Reported
   - Nil
   - Mitogen minus Nil
   - TB Antigen minus Nil

2. Three Possible Interpretations
   - Positive
   - Negative
   - Indeterminate
     i. Could be due to immune status, errors in specimen collection, or lab processing
     ii. Repeat test with new blood specimens

3. Steps for Reading a QFT Lab Report
   - Review Patient and Specimen Information
   - Check the "Test Name" Section:
     i. Specifies if the specimen was incubated at the draw site or processing lab.
   - Read Final Result:
     i. Negative results are located in the "In Range" column
     ii. Positive results are located in the "Out of Range" column
     iii. Disregard "Reference Range" column
   - Check Quantitative Values and Confirm Result:
     i. Nil value should be more than or equal to 8.0
     ii. Some values may be very close to the cut-off point, so it is always important to confirm the result and interpretation of the test.

A table that defines positive, negative, and indeterminate QFT test results is located in Appendix E of this document.

T-SPOT®.TB[12]

25:00

1. Three Quantitative Values Reported
   - **Nil** (negative control)
   - **Mitogen** (positive control)
   - **Panel A**
   - **Panel B**

2. Four Possible Interpretations
   - Positive
   - Negative
   - Borderline (result lies between positive and negative spot counts, and is too close to call)
   - Invalid (test not performing as designed)
     i. Repeat test free of charge with new specimens

3. Steps for Reading a QFT Lab Report
   - Review Patient and Specimen Information
   - Read Final Result
   - Check Quantitative Values and Confirm Result:
     i. **Nil** value should be less than or equal to 10 spots
     ii. Some values may be very close to the cut-off point, so it is always important to confirm the result and interpretation of the test.

A table that defines positive, negative, borderline, and invalid T-SPOT test results is located in Appendix E of this document.

Examples of QFT and T-SPOT test results are located in Appendix F of this document.

Summary: Interpreting IGRA Test Results

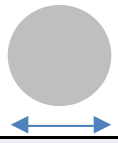
- Identify numeric values on IGRA test results
- Check test interpretation and apply towards a diagnosis using epidemiological and medical evidence

Appendix A: Tuberculin Skin Test Interpretation Table

TST interpretation depends on:

1. The measurement in millimeters (mm) of the induration and
2. The person's risk of being infected with TB and/or the progression to disease if infected.

The following three cut points should be used to determine whether the TST reaction is *positive*. A measurement of 0mm or anything below the defined cut point for each category is considered *negative*.

		
5 or more millimeters	10 or more millimeters	15 or more millimeters
Indurations of **5 or more millimeters** is considered positive in:	Indurations of **10 or more millimeters** is considered positive in:	Indurations of **15 or more millimeters** is considered positive in:
• HIV-infected persons • Recent contacts of persons with infectious TB • People who have fibrotic changes on a chest radiograph • Patients with organ transplants and other immunosuppressed patients (including patients taking a prolonged course of oral or intravenous corticosteroids or TNF-α antagonists)	• People who have come to the United States within the last five years from areas of the world where TB is common • Injection drug users • Mycobacteriology lab workers • People who live or work in high-risk congregate settings • People with certain medical conditions that place them at high risk for TB (silicosis, diabetes mellitus, severe kidney disease, certain types of cancer, and certain intestinal conditions) • Children younger than 5 years of age • Infants, children, and adolescents exposed to adults in high-risk categories	• People with no known risk factors for TB

Appendix B: References

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11. Oxford Diagnostic. Packaging, Handling Blood Samples, and Shipping Instructions videos: http://www.oxforddiagnosticlabs.com/client-support/send-specimens/how-to-videos/, last accessed 5/26/17.
12. T-SPOT®.TB Package Insert: http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/MicrobiologyDevicesPanel/UCM260552.pdf, last accessed 8/17/16.

Appendix C: Abbreviations

CDC	Centers for Disease Control and Prevention
EDTA	Ethylene-diaminetetra acetic acid
FDA	Food and Drug Administration
IGRA	Interferon-Gamma Release Assay
LTBI	Latent Tuberculosis Infection
MDHHS	Michigan Department of Health and Human Services
MIOSHA	Michigan Occupational Safety Health Administration
mL	Milliliter
mm	Millimeter
PPD	Purified Protein Derivative
QFT-GIT	QuantiFERON®-TB Gold-in-Tube
TB	Tuberculosis
T-SPOT	T-SPOT®.TB
TST	Tuberculin Skin Test

Appendix D: Glossary

Aplisol®	One of two commercially available, FDA approved purified protein derivatives used in the tuberculin skin test.
Bevel	Section of a syringe located at the end of the needle that is angled to form a point. When administering a tuberculin skin test, the needle bevel should be perpendicular to the flange of the syringe.
Borderline	A possible test result for a T-SPOT®.TB Test. A borderline test result quantitatively falls in between positive and negative results and is too close to both to make an accurate determination. Borderline test results should be repeated with a new specimen.
Erythema	An area of redness around the injection site of a TST injection; reaction should not be measured.
Flange	A part of a syringe designed for index and middle finger to hold while the thumb plunger is pushed. Before administering a tuberculin skin test, ensure that the needle bevel is perpendicular to the flange of the syringe.
Indeterminate	A possible test result for a QFT-GIT IGRA. Indeterminate results can be due to a number of factors and should be repeated with a new blood specimen.
Induration	A palpable area that is often raised, hardened, or swollen at the site of purified protein derivative injection, which signifies an immune reaction and possible positive tuberculin skin test.
Invalid	A possible test result for a T-SPOT IGRA. Invalid results can be due to a number of factors and should be repeated with a new blood specimen.
Mitogen Control	The positive control for the QFT-GIT IGRA blood test.
Nil Control	The negative control for the QFT-GIT IGRA blood test.
Palpate	A method used to touch the site of tuberculin skin test injection to determine the size and margin of induration.
QuantiFERON®-TB Gold-in-Tube	One of two commercially available and FDA approved interferon-gamma release assays; manufactured by Qiagen.
TB Antigen	The test tube for the QFT-GIT IGRA blood test.
T-SPOT®.TB	One of two commercially available and FDA approved interferon-gamma release assays; manufactured by Oxford Immunotech.
Tuberculin Syringe	Single dose syringe used to administer purified protein derivative for a tuberculin skin test, with a ¼- to ½-inch 27-gauge needle and short bevel.
Tubersol®	One of two commercially available, FDA approved purified protein derivatives used in the tuberculin skin test.
Wheal	A tight, pale elevation produced intradermally during administration of tuberculin solution for a tuberculin skin test. Production of a 6mm wheal is poof of correct tuberculin administration.

Appendix E: Interpreting IGRA Lab Results

QuantiFERON®-TB Gold-in-Tube

	Nil	Mitogen – Nil	TB Antigen - Nil
POSITIVE	≤ 8.0	Any value	≥ 0.35 and ≥ 25% of the Nil
NEGATIVE	≤ 8.0	≥ 0.5	< 0.35 **OR**
			≥ 0.35 and < 25% of the Nil
INDETERMINATE	> 8.0	Any value	Any value
	≤ 8.0	< 0.5	< 0.35 **OR**
			≥ 0.35 and < 25% of the Nil

T-SPOT®.TB

	Nil	Mitogen	Panel A – Nil		Panel B - Nil
POSITIVE	≤ 10	Any value	≥ 8	**OR**	≥ 8
NEGATIVE	≤ 10	≥ 20	≤ 4	**AND**	≤ 4
BORDERLINE	≤ 10	Any value	5, 6, or 7	**OR**	5, 6, or 7
INVALID	≤ 10	< 20	≤ 4	**AND**	≤ 4
	< 10	Any value	Any value		Any value

Example of Negative QFT Lab Report
Specimen Incubated at the Lab

Quest Diagnostics™

QUEST DIAGNOSTICS INCORPORATED
CLIENT SERVICE 866.697.8378

PATIENT INFORMATION
SAMPLE,19453

DOB: 11/03/1970 AGE: 45
GENDER: F

REPORT STATUS FINAL REPRINT

ORDERING PHYSICIAN

SPECIMEN INFORMATION
SPECIMEN: CB078863E
REQUISITION: 4689696

1

ID:
PHONE:

CLIENT INFORMATION
HQTEST QQQQQQQ
TEST CLIENT (HQ) WDL
TEST DEPARTMENT
400 EGYPT RD
NORRISTOWN, PA 19403-3406

COLLECTED: 10/17/2016
RECEIVED: 10/17/2016 13:39 CT
REPORTED: 10/17/2016 13:43 CT

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2 Test Name	3 In Range	Out of Range	Reference Range	Lab
QUANTIFERON(R)-TB GOLD	NEGATIVE		NEGATIVE	CB

Final Result

Quest's interpretation of the result: Negative test result. M. tuberculosis complex infection unlikely.

4

NIL	0.05	Nil is less than 8.0
MITOGEN-NIL	8.17	Mitogen-Nil is more than 0.5
TB-NIL	0.06	TB-Nil is less than 0.35

The Nil tube value is used to determine if the patient has a preexisting immune response which could cause a false-positive reading on the test. In order for a test to be valid, the Nil tube must have a value of less than or equal to 8.0 IU/mL.

The mitogen control tube is used to assure the patient has a healthy immune status and also serves as a control for correct blood handling and incubation. It is used to detect false-negative readings. The mitogen tube must have a gamma interferon value of greater than or equal to 0.5 IU/mL higher than the value of the Nil tube.

The TB antigen tube is coated with the M. tuberculosis specific antigens. For a test to be considered positive, the TB antigen tube value minus the Nil tube value must be greater than or equal to 0.35 IU/mL.

For additional information, please refer to http://education.questdiagnostics.com/faq/QFT (This link is being provided for informational/ educational purposes only.)

Steps For Reading a QFT Lab Report

1. **Review Patient and Specimen Information**
2. **Check Test Name**: Will specify if specimen was incubated at draw site
3. **Read Final Result**:
   - Negative results are located in the "In Range" column
   - Positive results are located in the "Out of Range" column
   - Disregard "Reference Range" column to the right
4. **Check Quantitative Values and Confirm Result**:

Nil ≤ 8.0
Mitogen - Nil
TB - Nil

PERFORMING LABORATORY INFORMATION
CB QUEST DIAGNOSTICS WOOD DALE, 1355 MITTEL BOULEVARD, WOOD DALE, IL 60191-1024
Laboratory Director: ANTHONY V. THOMAS, MD, CLIA: 14D0417052

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PATIENT INFORMATION
SAMPLE,19453

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QUEST DIAGNOSTICS INCORPORATED

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DOB: 11/03/1970 AGE: 45
GENDER: F

COLLECTED: 10/17/2016
REPORTED: 10/17/2016 13:43 CT

DUPLICATE REPORT WILL BE SENT TO:

TEST - HQ
ATTN: TEST DEPARTMENT
400 EGYPT RD
NORRISTOWN, PA 19403-3406

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Example of Negative QFT Lab Report
Specimen Incubated at Draw Site

Quest Diagnostics™

QUEST DIAGNOSTICS INCORPORATED
CLIENT SERVICE 866.697.8378

PATIENT INFORMATION
SAMPLE,16603

DOB: 11/11/1983 AGE: 32
GENDER: F

REPORT STATUS FINAL REPRINT

ORDERING PHYSICIAN

SPECIMEN INFORMATION
SPECIMEN: CB078865E
REQUISITION: 4689708

1

ID:
PHONE:

CLIENT INFORMATION
HQTEST QQQQQQQ
TEST CLIENT (HQ) WDL
TEST DEPARTMENT
400 EGYPT RD
NORRISTOWN, PA 19403-3406

COLLECTED: 10/17/2016
RECEIVED: 10/17/2016 13:47 CT
REPORTED: 10/17/2016 13:49 CT

Test Name	In Range	Out of Range	Reference Range	Lab
QUANTIFERON(R) TB GOLD, (DRAW SITE INCUBATED)				CB
QUANTIFERON(R)-TB GOLD, (INCUBATED)	NEGATIVE		NEGATIVE	
NIL	0.03			
MITOGEN-NIL	>10.00			
TB-NIL	<0.00			

2

3

Final Result

Quest's interpretation of the result: Negative test result. M. tuberculosis complex infection unlikely.

4

Nil is less than 8.0

Mitogen-Nil is more than 0.5

TB-Nil is less than 0.35

The Nil tube value is used to determine if the patient has a preexisting immune response which could cause a false-positive reading on the test. In order for a test to be valid, the Nil tube must have a value of less than or equal to 8.0 IU/mL.

The mitogen control tube is used to assure the patient has a healthy immune status and also serves as a control for correct blood handling and incubation. It is used to detect false-negative readings. The mitogen tube must have a gamma interferon value of greater than or equal to 0.5 IU/mL higher than the value of the Nil tube.

The TB antigen tube is coated with the M. tuberculosis specific antigens. For a test to be considered positive, the TB antigen tube value minus the Nil tube value must be greater than or equal to 0.35 IU/mL.

For additional information, please refer to http://education.questdiagnostics.com/faq/QFT (This link is being provided for informational/ educational purposes only.)

Steps For Reading a QFT Lab Report

1. Review Patient and Specimen Information
2. Check Test Name: Will specify if specimen was incubated at draw site
3. Read Final Result:
   - Negative results are located in the "In Range" column
   - Positive results are located in the "Out of Range" column
   - Disregard "Reference Range" column to the right
4. Check Quantitative Values and Confirm Result:

Nil ≤ 8.0
Mitogen - Nil
TB - Nil

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REPORTED: 10/17/2016 13:49 CT

PATIENT INFORMATION
SAMPLE,16603

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ORDERING PHYSICIAN

PERFORMING LABORATORY INFORMATION
CB QUEST DIAGNOSTICS WOOD DALE, 1355 MITTEL BOULEVARD, WOOD DALE, IL 60191-1024
Laboratory Director: ANTHONY V. THOMAS, MD, CLIA: 14D0417052

DUPLICATE REPORT WILL BE SENT TO:

TEST - HQ
ATTN: TEST DEPARTMENT
400 EGYPT RD
NORRISTOWN, PA 19403-3406

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Example of Positive QFT Lab Result
Specimen Incubated at the Lab

Quest Diagnostics™

QUEST DIAGNOSTICS INCORPORATED
CLIENT SERVICE 866.697.8378

1

PATIENT INFORMATION
SAMPLE,19453

DOB: 08/21/1970 AGE: 46
GENDER: M

ID:
PHONE:

REPORT STATUS FINAL REPRINT

ORDERING PHYSICIAN

CLIENT INFORMATION
HQTEST QQQQQQQ
TEST CLIENT (HQ) WDL
TEST DEPARTMENT
400 EGYPT RD
NORRISTOWN, PA 19403-3406

SPECIMEN INFORMATION
SPECIMEN: CB078866E
REQUISITION: 4690521

COLLECTED: 10/17/2016
RECEIVED: 10/17/2016 13:56 CT
REPORTED: 10/17/2016 14:00 CT

---

2 Test Name

QUANTIFERON(R)-TB GOLD

3

	In Range	Out of Range	Reference Range	Lab
Final Result		POSITIVE	NEGATIVE	CB

Quest's interpretation of the result: In healthy persons who have a low likelihood both of M. tuberculosis infection and of progression to active tuberculosis if infected, a single positive QFT result should not be taken as reliable evidence of M. tuberculosis infection. Repeat testing, with either the initial test or a different test, may be considered on a case-by-case basis.

4

NIL	0.07	Nil is less than 8.0
MITOGEN-NIL	>10.00	Any value is reported

TB-Nil value located on second page

Steps For Reading a QFT Lab Report

1. **Review Patient and Specimen Information**
2. **Check Test Name**: Will specify if specimen was incubated at draw site
3. **Read Final Result**:
   - Negative results are located in the "In Range" column
   - Positive results are located in the "Out of Range" column
   - Disregard "Reference Range" column to the right
4. **Check Quantitative Values and Confirm Result**:

Nil ≤ 8.0
Mitogen - Nil
TB - Nil

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Quest Diagnostics™

PATIENT INFORMATION
SAMPLE,19453

REPORT STATUS FINAL REPRINT

QUEST DIAGNOSTICS INCORPORATED

ORDERING PHYSICIAN

DOB: 08/21/1970 AGE: 46
GENDER: M

COLLECTED: 10/17/2016
REPORTED: 10/17/2016 14:00 CT

Test Name	In Range	Out of Range	Reference Range	Lab
TB-NIL	0.73		TB-Nil is more than 0.35 and more than 25% of the Nil value	

The Nil tube value is used to determine if the patient has a preexisting immune response which could cause a false-positive reading on the test. In order for a test to be valid, the Nil tube must have a value of less than or equal to 8.0 IU/mL.

The mitogen control tube is used to assure the patient has a healthy immune status and also serves as a control for correct blood handling and incubation. It is used to detect false-negative readings. The mitogen tube must have a gamma interferon value of greater than or equal to 0.5 IU/mL higher than the value of the Nil tube.

The TB antigen tube is coated with the M. tuberculosis specific antigens. For a test to be considered positive, the TB antigen tube value minus the Nil tube value must be greater than or equal to 0.35 IU/mL.

For additional information, please refer to http://education.questdiagnostics.com/faq/QFT (This link is being provided for informational/ educational purposes only.)

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Example of Positive QFT Lab Result
Specimen Incubated at the Draw Site

Quest Diagnostics™

QUEST DIAGNOSTICS INCORPORATED
CLIENT SERVICE 866.697.8378

PATIENT INFORMATION
SAMPLE,16603

DOB: 05/01/1950 AGE: 66
GENDER: M

REPORT STATUS FINAL REPRINT

ORDERING PHYSICIAN

SPECIMEN INFORMATION
SPECIMEN: CB078861E
REQUISITION: 4689692

1

ID:
PHONE:

CLIENT INFORMATION
HQTEST QQQQQQQ
TEST CLIENT (HQ) WDL
TEST DEPARTMENT
400 EGYPT RD
NORRISTOWN, PA 19403-3406

COLLECTED: 10/17/2016
RECEIVED: 10/17/2016 13:38 CT
REPORTED: 10/17/2016 13:53 CT

2

Test Name	In Range	Out of Range	Reference Range	Lab
QUANTIFERON(R) TB GOLD, (DRAW SITE INCUBATED)				CB
QUANTIFERON(R)-TB GOLD, (INCUBATED)				

3

Final Result: POSITIVE NEGATIVE

Quest's interpretation of the result:
In healthy persons who have a low likelihood both of M. tuberculosis infection and of progression to active tuberculosis if infected, a single positive QFT result should not be taken as reliable evidence of M. tuberculosis infection. Repeat testing, with either the initial test or a different test, may be considered on a case-by-case basis.

4

NIL	0.04	Nil is less than 8.0
MITOGEN-NIL	8.70	Any value is reported

TB-Nil value located on second page

Steps For Readinga QFT Lab Report

1. **Review Patient and Specimen Information**
2. **Check Test Name**: Will specify if specimen was incubated at draw site
3. **Read Final Result**:
   - Negative results are located in the "In Range" column
   - Positive results are located in the "Out of Range" column
   - Disregard "Reference Range" column to the right
4. **Check Quantitative Values and Confirm Result:**

Nil ≤ 8.0
Mitogen - Nil
TB - Nil

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Quest Diagnostics™

PATIENT INFORMATION
SAMPLE,16603

REPORT STATUS FINAL REPRINT

QUEST DIAGNOSTICS INCORPORATED

ORDERING PHYSICIAN

DOB: 05/01/1950 AGE: 66
GENDER: M

COLLECTED: 10/17/2016
REPORTED: 10/17/2016 13:53 CT

Test Name	In Range	Out of Range	Reference Range	Lab
TB-NIL	1.01		TB-Nil is more than 0.35 and more than 25% of the Nil value	

The Nil tube value is used to determine if the patient has a preexisting immune response which could cause a false-positive reading on the test. In order for a test to be valid, the Nil tube must have a value of less than or equal to 8.0 IU/mL.

The mitogen control tube is used to assure the patient has a healthy immune status and also serves as a control for correct blood handling and incubation. It is used to detect false-negative readings. The mitogen tube must have a gamma interferon value of greater than or equal to 0.5 IU/mL higher than the value of the Nil tube.

The TB antigen tube is coated with the M. tuberculosis specific antigens. For a test to be considered positive, the TB antigen tube value minus the Nil tube value must be greater than or equal to 0.35 IU/mL.

For additional information, please refer to http://education.questdiagnostics.com/faq/QFT (This link is being provided for informational/ educational purposes only.)

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Oxford Diagnostic Laboratories
5846 Distribution Drive
Memphis, TN 38141
1-877-59TBLAB

Example of Negative T-SPOT Test Result

CLIA ID# 44D2035207
Charles Handorf, MD PhD, Medical Director

1

Patient Name: Test, Negative Example
Patient ID: TEST2
Sex: M
DOB:6/1/2012
Collection Date: 2/17/2015 11:15

Provider: Handorf, Charles R., MD
Location: Oxford Diagnostic Laboratories
Customer Number: **ODL01**
Sample ID: 154147937
Received Date: 2/18/2015 04:00
Approval Date: 2/19/2015 15:16

T-SPOT.*TB* Test Results JMATSUBARA

T-SPOT.TB

2 Negative Final Result

The test result is Negative if both (Panel A minus Nil Control) and (Panel B minus Nil Control) are less than or equal to 4. This includes values less than zero. Note: Diagnosing or excluding tuberculosis disease, and assessing the probability of LTBI, requires a combination of epidemiological, historical, medical and diagnostic findings that should be taken into account when interpreting T-SPOT.TB test results. Refer to the most recent CDC guidance (http://www.cdc.gov/nchstp/tb) for detailed recommendations about diagnosing TB infection (including disease) and selecting persons for testing.

T-SPOT's interpretation of result

3

Nil (Neg) Control Spot Count	0	Nil is less than 10
Panel A Spot Count	0	Panel A-Nil is less than 4 and
Panel B Spot Count	1	Panel B-Nil is less than 4
Positive Control Spot Count	>20	Mitogen is more than 20

Steps for Reading a T-SPOT Lab Report

1. Review Patient and Specimen Information
2. Read Final Result
3. Check Quantitative Values and Confirm Result:
   - Nil ≤ 10
   - Mitogen (Positive Control)
   - Panel A-Nil
   - Panel B-Nil

Limitations (from the T-SPOT.TB Package Insert, p.15)

Results from T-SPOT.TB testing must be used in conjunction with each individual's epidemiological history, current medical status and results of other diagnostic evaluations.

The performance of T-SPOT.TB has not been adequately evaluated with specimens from individuals younger than 17 years, in pregnant women, and in patients with hemophilia.

A false positive result was obtained for T-SPOT.TB when tested in subjects with M. xenopi, M. kansasii and M. gordonae. While ESAT-6 and CFP10 antigens are absent from BCG strains of M. bovis and from most environmental mycobacteria, it is possible that a positive T-SPOT.TB result may be due to infection with M. kansasii, M. szulgai, M. gordonae or M. marinum. Alternative tests would be required if these infections are suspected.

A negative test result does not exclude the possibility of exposure to, or infection with M. tuberculosis. Patients with recent exposure to TB infected individuals exhibiting a negative T-SPOT.TB result should be considered for retesting within 6 weeks or if other relevant clinical symptoms indicate possible infection.

A positive test result does not rule in active TB disease; other tests should be performed to confirm the diagnosis of active TB disease such as sputum smear and culture, PCR, and chest radiography.

T-SPOT.TB has not been evaluated in subjects who have received >1 month of anti-TB therapy.

Refrigerated and frozen samples are not recommended for use with T-SPOT.TB test.

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Oxford Diagnostic Laboratories
5846 Distribution Drive
Memphis, TN 38141
1-877-59TBLAB

Example of Positive T-SPOT Test Result

CLIA ID# 44D2035207
Charles Handorf, MD PhD, Medical Director

1

Patient Name: Test, Positive Example
Patient ID: TEST1
Sex: F
DOB:8/1/2008
Collection Date: 2/17/2015 15:15

Provider: Handorf, Charles R., MD
Location: Oxford Diagnostic Laboratories
Customer Number: **ODL01**
Sample ID: 154147936
Received Date: 2/18/2015 04:00
Approval Date: 2/19/2015 15:16

T-SPOT.*TB* Test Results JMATSUBARA

T-SPOT.TB

2 Positive Final Result

The test result is Positive if (Panel A minus Nil Control) and/or (Panel B minus Nil Control) is greater than or equal to 8. Note: Diagnosing or excluding tuberculosis disease, and assessing the probability of LTBI, requires a combination of epidemiological, historical, medical and diagnostic findings that should be taken into account when interpreting T-SPOT.TB test results. Refer to the most recent CDC guidance (http://www.cdc.gov/nchstp/tb) for detailed recommendations about diagnosing TB infection (including disease) and selecting persons for testing.

T-SPOT's interpretation of result

3

Nil (Neg) Control Spot Count	0	Nil is less than 10
Panel A Spot Count	22	Panel A-Nil is more than 8 or
Panel B Spot Count	>50	Panel B-Nil is more than 8
Positive Control Spot Count	>20	Mitogen value is reported

Steps for Reading a T-SPOT Lab Report

1. Review Patient and Specimen Information
2. Read Final Result
3. Check Quantitative Values and Confirm Result:
   - Nil ≤ 10
   - Mitogen (Positive Control)
   - Panel A-Nil
   - Panel B-Nil

Limitations (from the T-SPOT.TB Package Insert, p.15)

Results from T-SPOT.TB testing must be used in conjunction with each individual's epidemiological history, current medical status and results of other diagnostic evaluations.

The performance of T-SPOT.TB has not been adequately evaluated with specimens from individuals younger than 17 years, in pregnant women, and in patients with hemophilia.

A false positive result was obtained for T-SPOT.TB when tested in subjects with M. xenopi, M. kansasii and M. gordonae. While ESAT-6 and CFP10 antigens are absent from BCG strains of M. bovis and from most environmental mycobacteria, it is possible that a positive T-SPOT.TB result may be due to infection with M. kansasii, M. szulgai, M. gordonae or M. marinum. Alternative tests would be required if these infections are suspected.

A negative test result does not exclude the possibility of exposure to, or infection with M. tuberculosis. Patients with recent exposure to TB infected individuals exhibiting a negative T-SPOT.TB result should be considered for retesting within 6 weeks or if other relevant clinical symptoms indicate possible infection.

A positive test result does not rule in active TB disease; other tests should be performed to confirm the diagnosis of active TB disease such as sputum smear and culture, PCR, and chest radiography.

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