



Subject QuantIFERON-TB Gold Clinic Collection and Processing Procedure	Attachments <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Key words TB, QuantiFERON, Mantoux, Tuberculin Skin Test, Tuberculosis	Number GHI-PC-CLINIC LAB- PROCEDURES-TB Gold Processing v. 11-2013
Category Provision of Care (PC)	Effective Date November 2012
Manual Clinic Laboratory Procedure Manual	Last Review Date November 2013
Issued By Clinic Laboratory Administration	Next Review Date November 2014
Applicable Clinic Laboratory Staff	Origination Date November 2012
	Retired Date
Level of Complexity: Not Applicable	Contact Laboratory Technical Consultants
Review Responsibility Laboratory Technical Consultants	Approval Date November 2012
APPROVAL(S) Laboratory Medical Director	

QuantIFERON-TB Gold Clinic Collection and Processing Procedure
Clinic Lab Procedure (Pages 1-4)
Procedure for Employees (Pages 3-4)

I.
PURPOSE/PRINCIPLE

This procedure provides direction for the collection and processing of the QuantiFERON-TB Gold specimens.

The QuantiFERON-TB Gold IT (In-Tube) system uses specialized blood collection tubes, which are used to collect whole blood via venipuncture. These tubes contain antigens representing certain M.tuberculosis proteins or controls. Incubating of the blood occurs in the tubes for 16 to 24 hours, after which, plasma is harvested and tested for the presence of IFN-γ produced in response to the peptide antigens.

II.
REAGENTS AND MATERIALS

1. Specialized blood collection tubes for QuantiFERON-TB Gold: (Obtain from Central Lab)
 - a. Nil Control (Grey cap with white ring).
 - b. TB Antigen (Red cap with white ring).
 - c. Mitogen Control (Purple cap with white ring).

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2. 37° C ($\pm 1^\circ$ C) incubator

SPECIAL SAFETY PRECAUTIONS

Standard blood handling and safety precautions apply.

III. PROCEDURE(S)

For employee annual testing, employee TB exposure testing, new employee hire testing, or provider credentialing testing, see the Employee section on page 3.

Collection:

1. For each subject, collect 1 ml of blood by venipuncture directly into each of the QuantiFERON blood collection tubes. (1 grey, 1 red and 2 purple).
 - a. The order of draw for QuantiFERON-TB Gold tubes is NIL control, TB Antigen, and Mitogen (Grey-Red-Purple).
 - b. The 1 ml tubes draw relatively slowly. Keep the tube on the needle for 2-3 seconds once the tube appears to have completed filling, to ensure that the correct volume has been drawn.
 - c. The black mark on the side of the tubes indicates the 1 ml fill volume. QuantiFERON blood collection tubes are manufactured to draw 1 ml plus/minus 10%. If the level of blood in any one of the tubes is not close to the indicator line, it is recommended to obtain another sample. Under or over-filling of the tubes outside of the 0.8-1.2 ml range may lead to erroneous results.
 - d. If a "butterfly needle" is used to collect the blood, a gold "purge" tube should be drawn first to ensure that butterfly tubing is filled with blood prior to QuantiFERON tubes being used.
 - e. If all 3 tubes cannot be collected, credit order and recollect.
2. Shake tubes 10 times just firmly enough to ensure the entire inner surface of the tubes is coated with blood to solubilize antigens on the tube walls. This strength of this process should be similar to shaking hands.
3. Label tubes appropriately.
 - a. Ensure each tube (Nil, TB Antigen, Mitogen) is labeled with the accurate specimen type label. (i.e. TB-GRY on the grey top tube).
 - b. QuantiFERON blood collection tubes must remain capped. Aliquoting is not permitted.

Processing and Tracking:

4. Whenever possible, send specimens to Regions the same day it is collected in the next available reroute. Specimens must arrive at Regions Hospital no later than 22:00.
5. If the specimen misses the last reroute of the day, it needs to be incubated between 16-24 hours at the clinic and sent the following day to Regions in the next available reroute. While tubes are good for 16 hours at room temperature before incubation, due to variation in processing and transportation time, the tubes should NEVER be held overnight without incubating.
6. Fill out the TBGLD Incubation Processing Log. There are 6 forms per sheet. Cut forms apart and use one per patient. If samples are not put into 37° incubator immediately after collection, samples should be remixed prior to incubation.
7. Record the time on the form that the incubation begins.
8. The sample MUST be incubated between 16 and 24 hours.
9. Do NOT centrifuge
10. Incubate the tubes in an upright position
11. The Specimen Incubation Processing Log should be left in the send out area as a reminder to the lab staff the next day that there is a TB Gold specimen to send to Regions.
12. Verify that the specimen has incubated between 16 and 24 hours. Use the time grid on the Specimen Incubation Processing Log as a reference.

13. Remove the specimen from the incubator and document on the form, the time of removal.
14. Package the tubes along with the Specimen Incubation Processing Log and place in a plastic transport bag. Store at Room Temperature
15. Transport and track specimens at Room Temperature (17 °C -27°C) to Regions in the next available reroute.

Notes:

- On Friday after last reroute, non-urgent care clinics must send by courier to Regions.
- Holidays: If the clinic will be closed for the holiday, send specimens by courier to Regions.
- Incubated samples are good at 4°C-27°C for up to 3 days.

Specimen Incubation Processing Log



**TB Gold
Specimen Incubated**

**Must incubate specimen
between 16 and 24 hours.**

Time Incubation Started: _____

Time Incubation Stopped: _____

If you

<u>Start at</u>	<u>16 hours</u>	<u>24 hours</u>
4:00 pm	8 am	4 pm
5:00 pm	9 am	5 pm
6:00 pm	10 am	6 pm
7:00 pm	11 am	7 pm
8:00 pm	12 pm	8 pm
9:00 pm	1 pm	9 pm

Record the time incubation was started and stopped. Refer to the reference box as a guide. Incubate in upright position. Send unspun at Room Temperature. Include this Incubation Processing Log with specimen. On Friday after last reroute, non-UC clinics need to call a courier.

Employee TBGold testing Collection

1. The employee will bring a paper order form to the lab. An LOV is not needed. Please see the TB Gold Lab form.
2. Use the Employee Health Medical Record Number on the form. **DO NOT use** the employee’s personal Medical Record number for these Employee TB Gold collections. Please refer to the HPEHS Order and Registration quick reference guide. For example, the chart number on the form is HPEHS-123456. By using this MRN, the results will not go to EPIC and the employee will not be billed.
3. Use the Employee’s name, date of birth, and gender when registering in Sunquest.
4. TB Gold testing is performed by Regions.
5. Hard copies of the results will print at Central Lab and will be sent to Karen Beauclair at 8170.
6. Employees have the right to decline. There is a place on the form for patients to sign if they decline testing. Give the form to your TC.

Registering Patients in Order Entry in Sunquest Gateway:

Open Sunquest Gateway>>Order Entry

1. Select Look up by Patient ID
2. Enter the employee's Employee Health Medical Record number: EPEHS-Employee number (example: HPEHS-123456)
3. If the patient needs to be registered as a new patient, a separate screen will open with a box for demographics.
4. Select the "Create" button
5. The following Prompts for patient information will open:
6. Patient Name: Enter Employee real name. The format is Last name, First Name
7. DOB: Date of Birth
8. Sex: Employee gender
9. New Episode: Select
10. Account Number: Defaults to C1000 which is specific for HPEHS.
11. Event Type & Date Defaults to OS event type and to today's date
12. Provider: Defaults to Abrar, Fozia 22034
13. Verify that all information is correct
14. Save or Exit or Help: Select Save

Note: Go to Step 8 in the Entry of Pre-Registered Patients in Sunquest Order Entry to continue entering orders on the patient/employee.

Entry of Pre-Registered Patients in Sunquest Gateway Order Entry:

1. Open Sunquest Gateway>>Order Entry
2. Select Look up by Patient ID.
3. Enter employee's Employee Health Medical Record number and hit Search. In the Event selection portion displays a list of active events. If there is no Episode for the current calendar year, click on New Episode (Alt-e). If there is a current calendar year episode, click on Modify Event (Alt-d).
4. Click Modify (Alt-f). Remember, yellow highlighted fields are required. If any are blank, the user will need to complete the information before going to the next screen.
5. Location field will default to EPEHS.
6. Change previous event date to today's date.
7. Click Save. A new event with today's date will be created
8. In the next window, fill in the mandatory information in the left hand side; collect time, receive date & time, etc. Do not change default account number or provider.
9. In the Order Codes section, order TBGLD and BLDDR.
10. Click Assign Acc.
11. Click Save.
12. A Container and Specimen Entry window will pop up displaying the recommended container types.
13. Either accept the containers listed by selecting Route (Alt-R) or change them to another acceptable type.

IV. DEFINITIONS

None

V. COMPLIANCE

Failure to comply with this policy or the procedures may result in disciplinary action, up to and including termination.

VI.

ATTACHMENTS

TB Gold Processing Log

TB Gold Blood Collection and Processing Quick Reference Guide

VII.**OTHER RESOURCES**

Quanti-FERON-TB Gold Package Insert, Cellestis Inc., Valencia, CA. October 2007

Quanti-FERON-TB Gold Blood Collection Procedure, Regions Clinical & Pathology Laboratory (v. 080608)

Quanti-FERON-TB Gold Blood Specimen Processing Procedure, Regions Clinical & Pathology Laboratory (v. 080608)

VIII. APPROVAL(S)

Laboratory Medical Director

IX. ENDORSEMENT Laboratory Administration