

Approved by:

Medical Director

_____ (Name) _____
(Signature)

_____ (Initials) _____ (Date)

Section Director

_____ (Name) _____
(Signature)

_____ (Initials) _____ (Date)

Laboratory Manager/Supervisor

_____ (Name) _____
(Signature)

_____ (Initials) _____ (Date)

Revision Record

Revision No.	Date	Responsible Person	Description of Change
1.0			
1.1			
1.2			
1.3			
1.4			
1.5			
1.6			
1.7			
1.8			
1.9			

Archival Date:	Department Supervisor/Manager :
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Biennial Review

Signature

Title

Date

Signature

Title

Date

Signature

Title

Date

Signature

Title

Date

Signature

Title

Date

Training Record and Signature Log

The following laboratory staff have read and agree to follow the current procedure. In addition, these staff are responsible for signing and/or initialing laboratory records.

_____ Signature	_____ Name	_____ Initials	_____ Date
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_____ Signature	_____ Name	_____ Initials	_____ Date
_____ Signature	_____ Name	_____ Initials	_____ Date

PURPOSE:

The purpose of this procedure is the incubation and processing of specimens in the Processing Department for Quantiferon Gold Tuberculosis Testing.

SCOPE:

Processing Department, Core Lab

RESPONSIBILITY:

All processors are responsible for reading, understanding and competently performing this procedure.

EQUIPMENT:

- Standard order entry equipment including barcode printer
- 37°C ± 1°C incubator (Does not require CO₂ or humidification)
- Centrifuge capable of centrifuging the blood tubes at least to 3,000 RCF(g).
- Timer

SUPPLIES: N/A

SAFETY PRECAUTION:

Follow guidelines within the Boyce and Bynum Pathology Laboratories safety manual.

SAMPLE TYPE AND VOLUME: Whole Blood, 1mL per tube

PROCEDURE:

Specimen Transport and Stability

- A. Specimen transport: Room temperature
- B. Specimen stability:
 1. Prior to incubation: stable for 16 hours at room temperature.
 2. Following 37°C ± 1°C incubation, blood collection tubes may be held between 4-27°C for up to 3 days prior to centrifugation.

Acceptable Specimens from Client

- A. After collection and mixing, Quantiferon tubes may be transferred to a 37°C ± 1°C incubator within 16 hours of collection, incubated upright for 16-24 hours, and then shipped to the laboratory within 48 hours following incubation.
- B. Ship at room temperature.

- C. Do not centrifuge or refrigerate tubes.
- D. Indicate on the test request form for the tube incubation temperature and hours of incubation.

Unacceptable Specimens from Client

- A. Specimens >16 hours old on receipt by lab, not incubated.
- B. Specimens received >48 hours after incubation.
- C. Specimens that have been processed and stored in the following conditions outside of the sequence listed above:
 - 1. Centrifuged
 - 2. Refrigerated
 - 3. Frozen

Sample Incubation

- A. Upon receipt in processing, check the following criteria:
 - 1. Was the specimen transported at room temperature? Yes – proceed; No – testing cannot be performed/give to Coordinator
 - 2. Was the specimen collected less than 16 hours ago and received unincubated? Yes – proceed; No – testing cannot be performed/give to Coordinator
 - 3. Was the specimen incubated less than 48 hours ago? Yes – proceed; No – testing cannot be performed/give to Coordinator
 - 4. Was the specimen centrifuged? No – proceed; Yes – testing cannot be performed/give to Coordinator
- B. Upon receipt in processing, check the incubation status of the tubes as indicated on the requisition
 - 1. If already incubated, enter the tube incubation temperature and hours of incubation on line 14; proceed to step F.
 - 2. If not incubated continue on to step C.
- C. Fill out the Quantiferon TB Gold Incubation Log located next to the incubator for each set of patient samples received.
- D. **Re-mix the tubes by forcefully inverting 10 times immediately prior to incubation. DO NOT SHAKE.** Blood must coat the entire inside of the tube before incubation.
- E. Incubate the tubes UPRIGHT at 37°C ± 1°C for 16 to 24 hours. See Appendices A and B for charts to assist in time to begin incubation, minimum incubation, and maximum incubation.

- F. Blood collection tubes may be held between 4°C and 27°C for up to 3 days prior to centrifugation. Place the incubated tubes in the QFT Completed Incubation Rack located near the incubator (room temperature).
- G. The QFT Completed Incubation Rack(s) are to be taken to the Core Laboratory on Monday, Wednesday, and Friday morning at 0800 for testing. Any tubes that have completed incubation by 0800 on these days should be included in the racks.

APPENDICES:

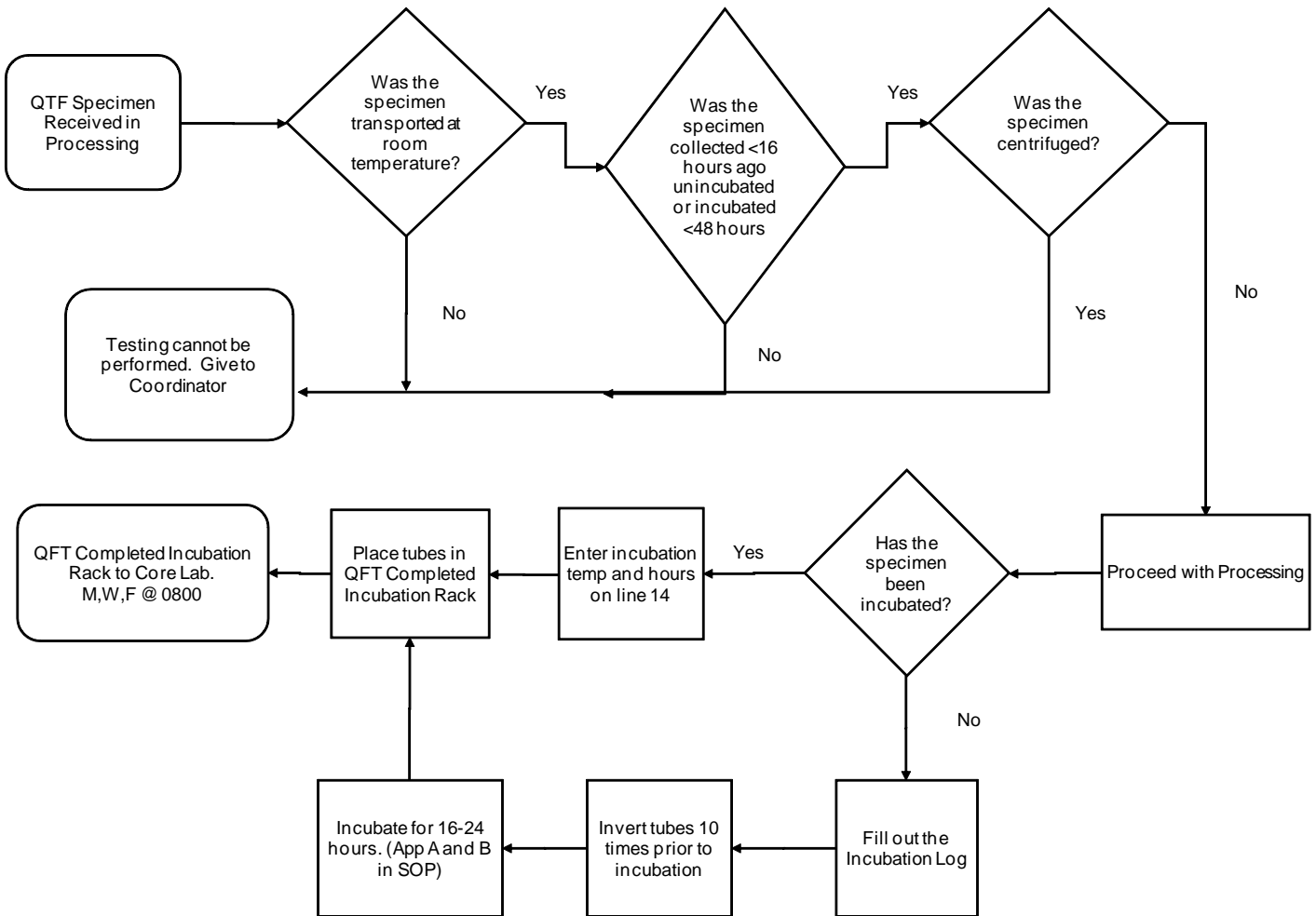
**Appendix A
Time Collected to Time Tubes Have to Begin Incubation**

Time Collected	16 Hours - Incubate by
0000	1600
0100	1700
0200	1800
0300	1900
0400	2000
0500	2100
0600	2200
0700	2300
0800	0000
0900	0100
1000	0200
1100	0300
1200	0400
1300	0500
1400	0600
1500	0700
1600	0800
1700	0900
1800	1000
1900	1100
2000	1200
2100	1300
2200	1400
2300	1500

**Appendix B
Time Incubation Begins to Removal, Minimum and Maximum Times**

Time Incubation Starts	16 Hours – Remove From Incubation Minimum	24 Hours – Remove From Incubation Maximum
0000	1600	0000
0100	1700	0100
0200	1800	0200
0300	1900	0300
0400	2000	0400
0500	2100	0500
0600	2200	0600
0700	2300	0700
0800	0000	0800
0900	0100	0900
1000	0200	1000
1100	0300	1100
1200	0400	1200
1300	0500	1300
1400	0600	1400
1500	0700	1500
1600	0800	1600
1700	0900	1700
1800	1000	1800
1900	1100	1900
2000	1200	2000
2100	1300	2100
2200	1400	2200
2300	1500	2300

Appendix C
Quantiferon Gold Processing Flowchart



QUALITY CONTROL:N/A

INTERPRETATION:N/A

REFERENCE RANGE:N/A

REAGENTS/MEDIA/SUPPLIES:N/A

METHOD:N/A

REFERENCES:N/A

PERFORMANCE SPECIFICATIONS:N/A

CALCULATIONS:N/A

CRITICAL VALUES:N/A

REPORTING RESULTS:N/A

RELATED DOCUMENTS:N/A