**Approved by:**

Medical Director

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Section Director

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Name) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Signature)

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Laboratory Manager/Supervisor

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Name) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Signature)

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**Revision Record**

|  |  |  |  |
| --- | --- | --- | --- |
| Revision No. | Date | Responsable Person | Description of Change |
| 1.0 |  |  |  |
| 1.1 |  |  |  |
| 1.2 |  |  |  |
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| **Archival Date:** | Department Supervisor/Manager : |

**Biennial Review**

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**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.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_ \_\_\_\_\_\_\_

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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

1. Specimen transport: Room temperature
2. 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

1. 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.
2. Ship at room temperature.
3. Do not centrifuge or refrigerate tubes.
4. Indicate on the test request form for the tube incubation temperature and hours of incubation.

Unacceptable Specimens from Client

1. Specimens >16 hours old on receipt by lab, not incubated.
2. Specimens received >48 hours after incubation.
3. 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

1. Upon receipt in processing, check the following criteria:
2. Was the specimen transported at room temperature? Yes – proceed; No – testing cannot be performed/give to Coordinator
3. Was the specimen collected less than 16 hours ago and received unincubated? Yes – proceed; No – testing cannot be performed/give to Coordinator
4. Was the specimen incubated less than 48 hours ago? Yes – proceed; No – testing cannot be performed/give to Coordinator
5. Was the specimen centrifuged? No – proceed; Yes – testing cannot be performed/give to Coordinator
6. Upon receipt in processing, check the incubation status of the tubes as indicated on the requisition
7. If already incubated, enter the tube incubation temperature and hours of incubation on line 14; proceed to step F.
8. If not incubated continue on to step C.
9. Fill out the Quantiferon TB Gold Incubation Log located next to the incubator for each set of patient samples received.
10. **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.
11. 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.
12. 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).
13. 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