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| **QuantiFERON Collection and Processing** |
| **Purpose** | This procedure provides instructions for collection and processing of QuantiFERON TB Gold Plus samples for the DiaSorin LIAISON XL® in St. Paul.  |
| **Policy Statements** | This procedure applies to all laboratory staff responsible for collecting and processing QuantiFERON samples for the DiaSorin LIAISON XL® in St. Paul. |
| **Clinical Significance** | Tuberculosis (TB) is a communicable disease, transmitted almost exclusively by cough aerosols carrying pathogens of the M. tuberculosis complex. TB continues to be a major public health threat, causing an estimated 10.4 million new cases and 1.3 million deaths from TB in 2016 (1). Pathogenesis is characterized by a period of asymptomatic subclinical infection, defined broadly as latent tuberculosis infection (LTBI), which might last for weeks or decades. However, there is no diagnostic gold standard for LTBI. Two tests are available for the identification of LTBI: the tuberculin skin test (TST) and the interferon gamma release assay (IGRA). They represent indirect markers of M. tuberculosis exposure and indicate a cellular immune response to M. tuberculosis.From an operational point of view, LTBI may best be defined as a state of persistent immune response to M. tuberculosis antigens detected either by the TST or by IGRA without evidence of clinically symptomatic TB. Based on this definition, individuals with LTBI carry an increased risk of progression to active TB disease. However, an unknown but large number of those with LTBI will not develop active TB disease, either because their immune system persistently controls mycobacterial replication or because the mycobacteria are no longer viable.In most individuals, initial M. tuberculosis infection is eliminated or contained by the host’s defenses, and infection remains latent. However, latent TB bacilli may remain viable and “reactivate” later to cause active TB disease. Identification and treatment of LTBI can substantially reduce the risk of developing active disease.The goal of testing for LTBI is to identify individuals who are at increased risk of developing active TB; these individuals would benefit most from treatment of LTBI (also termed preventive therapy or prophylaxis).In general, testing for LTBI is indicated when the risk of developing disease from latent infection (if present) is increased; examples include likely recent infection (e.g., close contact of a person with TB) or a decreased capacity to contain latent infection (e.g., because of immunosuppression, as in the case of young children in contact with those with active TB, people living with human immunodeficiency virus [HIV] infection, or otherwise immunosuppressed persons because of medications or conditions such as uncontrolled diabetes). |
| **Sunquest Test Code** | **QFTB**: QuantiFERON-TB, battery includes test for Nil, TB1, TB2, and Mitogen tubes.T1NIL: Nil tube IF-γ T2QT1: TB1 tube IF-γT3QT2: TB2 tube IF-γT4MT: Mitogen tube IF-γ |
| **Sample** | **Tube:** QFT-Plus blood Collection is set of 4 tubes in a Kit supplied by Qiagen.1. QuanitFERON Nil (Gray tube)
2. QuanitFERON TB1 (Green tube)
3. QuanitFERON TB2 (Yellow tube)
4. QuanitFERON Mitogen (Purple tube)

**NOTE:** *Unlike routine blood collection tubes, the color does not indicate anticoagulant.***Minimum volume**: 4 mL whole blood total, 0.8-1.2 mL per tube**Stability**: Before incubation: samples can sit at room temperature up to 16 hours.Post centrifuge: 28 days at 2-8C **Rejection criteria**: Unlabeled tube, over/under filled (must be at the black line), incorrect temperature storage conditions (see below)**Preparation:** See sample collection and processing procedures below. |

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| **Materials** | ***Product Description*** | ***Product Code*** | ***Stability*** |
| QuantiFERON®-TB Gold Plus Collection kit (25 count) | MFR #622433CHC #34454 | Store at: RT until used or until lot expiration |
| Routine phlebotomy supplies & PPE |  |  |
| Incubator set to 37°C +/- 1°C |  |  |
| Centrifuge set to 15 minutes at 3000 RCF(g) |  |  |
| Test tube racks |  |  |
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| **Risk and Safety** | Always follow Children’s Policy and Procedures regarding sample collection and processing. All blood and body fluids must be considered potentially infectious. See procedure [SA 10.01 Standard Precautions.](https://starnet.childrenshc.org/References/labsop/gen/safety/sa/sa10.01-standard-precautions.pdf)For specific precautions when collecting samples for TB exposure screening, Respiratory Protection Program, or when collecting samples from a patient with suspected or confirmed TB, see procedure [SA 10.82 Tuberculosis Exposure Control Plan](https://starnet.childrenshc.org/References/labsop/gen/safety/sa/sa10.82-tuberculosis-exposure-control-plan.pdf).  |
| **Sample Collection Procedure** | **Sample Collection Procedure****NOTE:** All collection tubes must be at room temperature (17-27C) at the time of draw.1. **Collection** - For each patient collect 1 mL of blood by venipuncture directly into each of the QuantiFERON-TB Gold (QTB) blood collection tubes (see fig. 1). A trained phlebotomist should perform this procedure:
	1. Tubes will fill **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 is drawn.
	2. The black mark on the side of the tubes indicates the 1mL fill volume. If the level of blood in any tube is not close to the indicator line, it is recommended to obtain another blood sample or to collect blood via a syringe as described below. Under or over-filling of the tubes outside of the 0.8mL to 1.2mL range may lead to erroneous results. (See fig. 2)
	3. If low blood draw volume does occur, blood can be collected using a syringe and 1mL transferred to each of the four tubes. For safety reasons, this is best performed by removing the syringe needle and removing the caps from the three tubes and adding 1mL of blood to each (to the black mark on the side of the tube label). Replace the tube caps securely and mix as directed below.
	4. If a butterfly needle is used, first collect other required tubes or use a “purge” tube to remove the air. Then proceed with collecting the QuantiFERON tubes.
2. **Shake tubes** - Immediately after filling tubes, shake them ten (10) times; just firmly enough to ensure the entire inner surface of the tube is coated with blood, to dissolve antigens on tube walls.
	1. Overly vigorous shaking may cause gel disruption and could lead to aberrant results.
3. **Label tubes** - Label tubes appropriately according to Children's Hospitals & Clinics of MN standards.
4. **Transport to St. Paul Lab** – Tubes must be transported to the St. Paul laboratory at room temperature and must arrive to be incubated within 16 hours of collection.
	1. Prior to incubation, maintain tubes at room temperature (22+/-5°C). Do not refrigerate or freeze the blood samples.
	2. **Specimens collected in Minneapolis**: Processing Staff will receive sample and immediately place in red cooler for transport to St. Paul lab. Verify courier transport will arrive in St. Paul within 16 hours of collection, if not, then utilize STAT courier.
	3. **Specimens collected at the Children’s Business Campus** (EHS) **or Clinic sites** will be directly routed to St. Paul lab via routine courier.

  Fig. 1. QuantiFERON collection kit Fig. 2. Fill tubes to black indicator line |
| **Sample Processing Procedure** | **Sample Processing Procedure** **NOTE**: Tubes must be received at the St. Paul Lab at room temperature.1. Receipt in St. Paul Lab and Incubation–
	1. Follow normal specimen receipt process
	2. Verify samples meet minimum requirements (room temperature, fill volume, collected within last 16 hours)
	3. Once received, re-mix all tubes by inverting 10 times before placing in the incubator.
	4. Place samples in QuantiFERON incubator (37C) and document incubation start time on front of incubator.
2. Removal from Incubation –
	1. At the start of each shift, the Manual Chemistry tech will check the QuantiFERON incubator for samples of between 16 and 24 hours of incubation.
	2. Remove samples with 16 - 24 hours of incubation move to next step.
3. Centrifugation and storage –
	1. Centrifuge tubes removed from incubation for 15 minutes at 2000 – 3000 RCF(g). The gel plug will separate the cells from the plasma. If this does not occur, the tubes should be centrifuged again at a higher speed.
	2. Place centrifuged tubes in the Liaison refrigerator in the QuanitFERON Rack. Tubes are stable up to 28 days at 2-8 C once incubated and centrifuged.
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| **Procedural Notes** | Use worksheet LIAS for pending list  |
| **References** | 1. DiaSorin QuantiFERON Instructions for Use, LIAISON® QuantiFERON®-TB Gold Plus ([REF] 311020) 1 / 20 EN - 200/007-002, 01 - 2019-11
2. DiaSorin QuantiFERON Controls Instructions for Use, LIAISON® Control QuantiFERON®-TB Gold Plus ([REF] 311021), 18 / 20 EN - 200/007-002, 01 - 2019-11
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| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
|  | Matt Johnson | 8/30/2022 | Initial Version |
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