

Title	QuantiFERON-TB Gold Plus (QFT-Plus tube collection)
Specimen Requirements	<ol style="list-style-type: none"> 1. Required specimen: Whole blood collected in QFT-Plus tubes 2. Minimum volume required: 1 mL for each tube (Nil, TB1, TB2, Mitogen) 3. Specimens lacking complete information will not be tested until the missing information has been provided. 4. QFT-Plus tubes must be incubated at 37°C (± 1°C) within 16 hours of collection. Incubation may be completed at the collection site or at the testing laboratory.
Sampling Materials	<ol style="list-style-type: none"> 1. QFT-Plus collection tubes (must not be expired) 2. Blood collection supplies 3. Category B shipping materials (insulated, with ice packs) meeting UN3373 Biological Substances standards
Procedural Notes	<ol style="list-style-type: none"> 1. Label each QFT-Plus tube with the patient name, DOB, and date and time of collection, including a minimum of two unique identifiers on the tube. 2. Collect 1 mL of blood by venipuncture directly into each QFT-Plus collection tube: <ul style="list-style-type: none"> • Tubes should be at room temperature (17-25°C) at the time of collection. • 1 mL tubes draw slowly, so be sure to keep the tube on the needle for 2-3 seconds once the tube appears to have completed filling. • The black box on the side of the tube indicates the correct filling volume (0.8 mL to 1.2 mL). Ensure that the tubes are filled within this range. If the blood level is not in this range, a new tube should be collected. • If a butterfly needle is being used to collect blood, a purge tube should be used first to ensure that the tubing is filled with blood prior to the QFT-Plus collection tubes being filled. • 3. Immediately after filling the tubes, shake them 10 times just firmly enough to make sure the inner surface of the tube is coated in blood in order to dissolve the antigens on the tube walls. <ul style="list-style-type: none"> • Caution: Overly vigorous shaking may cause gel disruption and could lead to aberrant results. • 4. After collection, shaken QFT-Plus tubes must be transferred to a 37°C (± 1°C) incubator within 16 hours of collection. <ul style="list-style-type: none"> • Option 1: Ship tubes to the testing laboratory so as to arrive within 16 hours. • Option 2: Incubate tubes at the site of collection. If the tubes are not incubated immediately after collection, remix the tubes by inverting them 10 times immediately prior to incubation. Incubate the tubes upright for 16-24 hours at 37°C (± 1°C). After incubation, tubes may be held between 4°C and 27°C for up to 3 days prior to centrifugation at the testing laboratory. • 5. QFT-Plus tubes may be centrifuged at the collection site or the testing laboratory. Tubes should be centrifuged for 15 minutes at 2000-3000 RFT (g). Centrifuged QFT-Plus tubes are stable for up to 28 days when stored and shipped at 2-8°C. <ul style="list-style-type: none"> • 6. Ensure the collection tubes are capped securely. Leaking specimens are unacceptable for testing and will be discarded. <ul style="list-style-type: none"> • 7. Complete the LimsNet test request for QuantiFERON-TB, ensuring that the patient information on the specimen tube matches the information entered into the submission form. Note whether the tubes have been incubated or centrifuged prior to shipment. <ul style="list-style-type: none"> •
Shipping Instructions	<p>Ship specimens to: Indiana State Department of Health Laboratories Attn: TB Lab 550 West 16th Street Suite B Indianapolis, IN 46202</p> <ol style="list-style-type: none"> 1. Place the blood collection tubes in the specimen transport bag with absorbent material. Seal the bag using the adhesive at the top.

2. Place the LimsNet coversheet in the outer pouch of the specimen transport bag or outside of the Styrofoam box to prevent contamination from the specimen.
3. Place the specimen transport bag and frozen ice packs inside of the Styrofoam cooler and close the outer shipping box.
4. The outer shipping box should be labelled using an ISDH 6A label and then placed inside of the UPS Laboratory Pak bag.
5. Complete the pre-addressed shipping label and affix it to the outer packaging with a return address and appropriate shipping labels. Specimens may be shipped via private service, such as UPS or Fed Ex. Alternatively, specimens may be delivered to ISDH in-person during normal business hours.
6. Specimens should be shipped to arrive at ISDH Monday through Friday. Specimens should not be shipped to be in transit during the weekend or holiday.
7. All patient specimens should be labeled, packaged and shipped in accordance with federal shipping regulations, using Biological Substances, Category B.

Reporting and TAT

1. Results will be reported by LimsNet and will be available in 3-5 business days.
2. Results will be reported as Positive, Negative or Indeterminate as per the manufacturer's reporting criteria:
Results table copied from Qiagen website <https://www.quantiferon.com/us/products/quantiferon-tb-gold-plus-us/package-inserts/>
3. Additional information on result interpretation and specimen collection can be found at:
<https://www.quantiferon.com/us/products/quantiferon-tb-gold-plus-us/package-inserts/>