

Manufacturer

Cellectis Inc.

Kit/Reagent Purpose

To preserve whole blood samples for the following test: QuantiFERON[®]-TB Gold In-Tube (ARUP test code 0051729)

Kit/Reagent Contents

Three tubes containing nil control, TB antigen, and mitogen control

Specimen Requirements

1 mL whole blood in each of the three collection tubes (nil control, TB antigen, and mitogen control)

Specimen Collection

1. Collect 1 mL of patient blood into each of the specialized blood-collection tubes: nil control tube (grey cap), TB antigen tube (red cap), and mitogen control tube (purple cap). Total volume will be 3 mL.
 - Tubes should be between 17°C and 25°C (63°F to 77°F) at the time of blood filling.
 - As 1 mL tubes draw blood relatively slowly, keep the tube on the needle for two to three seconds once the tube appears to have completed filling to ensure that the correct volume is drawn.
 - The black mark on the side of the tubes indicates the 1mL fill volume. The blood collection tubes are manufactured to draw 1 mL ±10 percent and perform optimally within the range of 0.8 to 1.2 mL. If the level of blood in any tube is not close to the indicator line, it is recommended that another blood sample be collected using a syringe and 1mL transferred to each of the three tubes. For safety reasons, this is best performed by removing the syringe needle, while ensuring appropriate safety procedures, removing the caps from the three QFT-Gold IT tubes, and adding 1 mL of blood to each (to the black mark on the side of the tube label). Replace the tube caps securely and mix as described in step 2 below. Under- or over-filling the tubes outside of the 0.8 to 1.2 mL range may lead to erroneous results.
 - If a "butterfly needle" is being used to collect blood, a "purge" tube should be used to ensure that the tubing is filled with blood prior to the QuantiFERON[®]-TB Gold IT tubes being used.
2. **Immediately after filling tubes, shake them 10 times just firmly enough to ensure that the entire inner surface of the tube is coated with blood to solubilize antigens on tube walls.**
 - Overenergetic shaking may cause gel disruption and could lead to aberrant results.

Specimen Storage/Transport

(Between collection and incubation)

- Tubes may be stored (up to 16 hours post collection) at room temperature; do not refrigerate or freeze the blood samples.

COLLECTION INSTRUCTIONS FOR QUANTIFERON®-TB GOLD IN-TUBE

QUALITY, TRUST, & RELIABILITY

Incubation

1. Place tubes in a 37°C incubator within 16 hours of collection.
 - If the blood is not incubated immediately after collection, mix the tubes by gentle inversion ten times prior to incubation.
2. Incubate the tubes **UPRIGHT** at 37°C for 16–24 hours. The incubator does not require CO₂ or humidification.
Note: If the blood is not incubated immediately after collection, remixing of the tubes by inverting 10 times must be performed immediately prior to incubation.

Post Incubation

1. After incubating at 37°C, tubes may be held between 2–27°C for up to three days pre-centrifugation.
Note: All tubes MUST be centrifuged before being sent to ARUP.
2. Centrifuge for 15 minutes at 2,000–3,000 RCF (g). If the gel plug does not move to separate the cells from the plasma (as may be evident with refrigerated tubes), the tubes should be recentrifuged at a higher speed. The blood collection tubes contain a gel plug that separates the plasma from the cells when centrifuged.
3. After centrifugation, the plasma must be stored in original collection. Plasma should be stored at 2–8°C no longer than four weeks before shipping to ARUP Laboratories.

Specimen Storage/Transport

(After harvesting)

- Transport original collection tubes at a refrigerated temperature.
- Ambient and non-centrifuged specimens are unacceptable for submission to ARUP Laboratories.