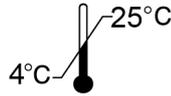


QuantiFERON Monitor® (QFM®)



IVD



Blood Collection Tubes

Blood Collection Tubes	1 pack
Catalog no.	0650-0101
QFM Blood Collection Tubes (white cap, white ring)	100 tubes
QFM Blood Collection Tubes package insert	1

Important note: The blood collection volume of a tube is affected by altitude. QFM Blood Collection Tubes should be used between sea level and 810 m (2650 ft). If using QFM Blood Collection Tubes outside this altitude range, or if low blood draw volume occurs, blood can be collected using alternate collection methods described below. The QFM Blood Collection Tubes are intended for use only with the QFM assay. The following instructions relate solely to the use of QFM Blood Collection Tubes. Instructions for use, performance characteristics, and results interpretation of the entire QFM assay can be found in the QuantiFERON Monitor ELISA package insert.

Caution: Handle human blood and plasma as if potentially infectious. Observe relevant blood and blood product handling guidelines. Dispose of samples and materials in contact with blood or blood products in accordance with federal, state, and local regulations.

Important note: One (1) QFM LyoSphere™ pellet must be added to 1 ml blood in the QFM Blood Collection Tubes and dissolved. Then the QFM Blood Collection Tubes must be transferred to a 37°C incubator as soon as possible and within 8 hours of blood collection. Prior to incubation, maintain the blood samples at room temperature (22°C ± 5°C).

The following procedures should be followed for optimal results.

Blood Collection:

1. Label tubes appropriately.

Label tube with the patient's details and time of blood collection.

2. For each patient, collect 1 ml of blood by venipuncture directly into one QFM Blood Collection Tube. This procedure should be performed by a trained phlebotomist.

Important note: QFM Blood Collection Tubes should be between 17° to 25°C at the time of blood filling.

Note: Under- or over-filling of the tubes outside of the desired range may lead to erroneous results. QFM Blood Collection Tubes are manufactured to draw 1 ml ± 10% and perform optimally within this range. If the level of blood in any tube is outside the range of the indicator mark, a new blood sample should be obtained.

As 1 ml tubes draw blood relatively slowly, keep the tube on the needle for 2–3 seconds once the tube appears to have completed filling. This will ensure that the correct volume is drawn. The black mark on the side of the tubes indicates the range of 0.9–1.1 ml fill volume. 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 QFM tube being used. If a tourniquet is being used, it must be loosened as soon as the needle is inserted into the vein, to avoid variations in pressure which could impact blood volume.▶



Note: If using QFM Blood Collection Tubes at an altitude higher than 810 meters (2650 ft), or if low blood draw volume occurs, users can collect blood with a syringe and immediately transfer 1 ml of blood to the QFM tube. For safety reasons, this is best performed by removing the syringe needle, ensuring appropriate safety procedures, removing the cap from the QFM tube, and adding 1 ml of blood to the tube (to the center of the black mark on the side of the tube label). Replace the cap securely and mix as described below.

Alternatively, blood may be collected in a single generic blood collection tube containing lithium heparin as the anticoagulant and then transferred to a QFM tube. Only use lithium heparin as a blood anticoagulant because other anticoagulants interfere with the assay. Fill a blood collection tube (minimum volume 3 ml) and gently mix by inverting the tube several times to dissolve the lithium heparin. Blood should be maintained at room temperature ($22^{\circ}\text{C} \pm 5^{\circ}\text{C}$) before transfer to QFM Blood Collection Tube for stimulation with a QFM LyoSphere. If blood has been collected in a lithium heparin tube, samples must be evenly mixed by gentle inversion before dispensing into QFM Blood Collection Tube. Dispensing should be performed aseptically (ensuring appropriate safety procedures) by removing the cap from the QFM Blood Collection Tube and adding 1 ml of blood (to the center of the black mark on the side of the tube label). Replace the tube cap securely.

3. Immediately after filling the QFM Blood Collection Tube, gently mix by inverting several times to dissolve the heparin.

Important note: Tubes should be between 17° to 25°C at the time of mixing. Overly vigorous shaking may cause gel disruption and could lead to aberrant results.

Stimulating Blood, Incubating Tubes, and Harvesting Plasma:

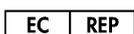
Detailed instructions for blood stimulation, incubation, and plasma harvesting can be found in the package inserts for QuantiFERON Monitor LyoSpheres™ (cat. no. 0650-0701) and QuantiFERON Monitor 2 Plate Kit ELISA (cat. no. 0650-0201).

IFN- γ ELISA:

Detailed instructions for IFN- γ ELISA can be found in the package insert for QuantiFERON Monitor 2 Plate Kit ELISA (cat. no. 0650-0201).

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