

## QuantiFERON Monitor<sup>®</sup> LyoSpheres<sup>™</sup>

### Package Insert

QuantiFERON Monitor LyoSpheres	1 pack
Catalog no.	0650-0701
QuantiFERON Monitor LyoSphere <sup>™</sup>	10 vials
<i>QuantiFERON Monitor LyoSpheres Package Insert</i>	1

The QuantiFERON Monitor (QFM<sup>®</sup>) lyophilized stimulants (LyoSpheres) are intended for use only with the QuantiFERON Monitor assay. The following instructions relate solely to the use of QFM LyoSphere pellets. Instructions for use, performance characteristics, and results interpretation of the entire QFM assay can be found in the package insert for the QuantiFERON Monitor 2 Plate Kit ELISA (cat. no. 0650-0201).

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

**Important:** Inspect LyoSphere vials prior to use. Do not use a LyoSphere if the vial shows signs of damage or if the rubber seal has been compromised. Do not handle broken vials. Take appropriate safety precautions to dispose of them safely.

Recommended: Use a vial decrimper to open LyoSphere vials to minimize the risk of injury from the metal crimp.

The following procedures should be followed for optimal results.

#### **Blood Collection:**

Detailed instructions for blood collection can be found in the package inserts for the QuantiFERON Monitor Blood Collection Tubes (cat. no. 0650-0101) and the QuantiFERON Monitor 2 Plate Kit ELISA (cat. no. 0650-0201).

#### **Blood Incubation and Plasma Harvesting:**

1. **If using a generic lithium heparin tube, label a QFM Blood Collection Tube appropriately.**  
Label tube with the patient's details and time of blood collection.
2. **If blood was collected in a generic lithium heparin tube, aseptically transfer 1 ml of blood into the QFM Blood Collection Tube.**  
Ensure that the blood is thoroughly mixed by gentle inversion immediately prior to dispensing into QFM tube.
3. **Equilibrate QFM LyoSpheres to room temperature (22°C ± 5°C) just before use.**

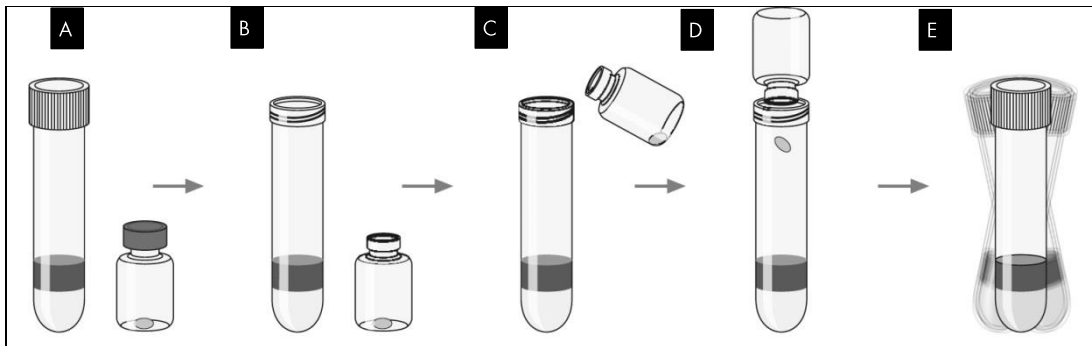


4. Uncap the blood collection tubes.
5. Tap the QFM LyoSphere vial gently on a hard surface to ensure the QFM LyoSphere pellet is located at the bottom of the vial. Then, uncap the QFM LyoSphere vial by first removing the metal crimp cap and next removing the rubber stopper.
6. Carefully drop the QFM LyoSphere pellet into the 1 ml blood by aligning the lip of the glass vial to the lip of the blood collection tube, then invert the vial gently to transfer the pellet (Figure 1).

**Note:** If the QFM LyoSphere falls outside the blood collection tube, discard it and open another QFM LyoSphere vial.

**Note:** Do not leave the QFM LyoSphere vial open for extended periods of time. The QFM LyoSphere should be added to the blood as soon as its vial has been uncapped.

If QFM LyoSphere is added to blood that has been collected in the QFM Blood Collection Tube, ensure tube cap is returned to the correct sample.



**Figure 1. Adding QFM LyoSphere.**

**A** QFM Blood Collection Tubes and QFM LyoSphere vial. **B** Remove cap from QFM Blood Collection Tube. Remove metal crimp and rubber stopper from QFM LyoSphere vial. **C** Immediately add the QFM LyoSphere to the blood by aligning the lip of the glass vial to the lip of the collection tube. **D** Next, invert the vial gently to transfer pellet into the tube. **E** Recap the QFM Blood Collection Tube and shake 5 to 10 times.

**7. Cap the QFM Blood Collection Tube and gently shake 5–10 times or until the pellet has completely dissolved.**

A QFM LyoSphere adhering to the inner tube surface can be dissolved by coating with blood while inverting the tube.

Make sure the QFM Blood Collection Tube is recapped as soon as the LyoSphere has been added, to prevent the addition of a second QFM LyoSphere in the same tube.

Because the QFM LyoSphere is white, once it has dissolved it will no longer be visible in the blood.

Overly vigorous shaking of the tube may cause gel disruption and could lead to aberrant results.

**8. After the QFM LyoSphere has been added and subsequently dissolved, the QFM Blood Collection Tube must be transferred to a 37°C ± 1°C incubator as soon as possible (and within 8 hours of the blood being collected).**

**9. Incubate the tubes UPRIGHT at 37°C for 16 to 24 hours. The incubator does not require CO<sub>2</sub> or humidification.**

**10. After incubation at 37°C, QFM Blood Collection Tubes may be held between 4°C to 27°C for up to 3 days, prior to centrifugation.**

**11. Harvesting of plasma (after incubation) is facilitated by centrifuging tubes for 15 minutes at 2000 to 3000 x g (RCF). The gel plug will separate the cells from the plasma. If this does not occur, the tubes should be centrifuged again.**

**Important note:** After centrifugation, avoid pipetting up and down or mixing plasma by any means prior to harvesting. At all times, take care not to disturb the material on the surface of the gel.

**Important note:** When harvesting plasma samples, harvest at least 150 µl of plasma to allow for repeat testing, if required.

It is possible to harvest the plasma without centrifugation. However, additional care is required to remove the plasma without disturbing the cells. Plasma samples should only be harvested using a pipet.

**12. Plasma samples can be loaded directly from centrifuged blood collection tubes into the QFM ELISA plate. This may also be done when automated ELISA workstations are used.**

**13. Plasma samples can be stored for up to 28 days at 2°C–8°C, or if harvested, below –20°C for extended periods of time.**

**IFN- $\gamma$  ELISA:**

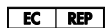
Detailed instructions for the IFN- $\gamma$  ELISA can be found in the package insert for the QuantiFERON Monitor 2 Plate Kit ELISA (cat. no. 0650-0201).



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