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QuantiFERON® Monitor Direct Blood Collection Tubes Instructions for Use (Handbook)

For Research Use Only
Not for use in diagnostic procedures

REF	626315
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R2 MAT	1122893

Sample to Insight

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Contents

Intended Use

The QuantiFERON® Monitor Direct (QFM Direct) blood collection tube uses a combination of Toll Like Receptor (TLR) agonist and T-cell receptors (TCR) agonist in heparinized whole blood to stimulate different cell types involved in both the innate (natural killer NK) and adaptive (T-cell) immune system. Plasma from the stimulated samples can be used for detection of IFN-γ. Detection of IFN-γ can be done using QuantiFERON ELISA.

The QFM Direct BCT is for Research Use Only and not for diagnostic use.

Materials Provided

Kit contents

Blood Collection Tubes		**100 tubes**
Catalog no.		**626315**
QuantiFERON Monitor Direct Tube (light blue cap, white ring)	QFM Direct	100 tubes
Language Sheet	–	1

QFM Direct BCT is designed to draw the required volume of blood for stimulation. The contents of the BCT have been dried onto the inner walls, and it is essential that the BCT be thoroughly mixed with the blood to resolubilize them. Blood collected directly into the QFM Direct BCT must be transferred to a 37°C incubator as soon as possible and within 8 hours of blood collection (see Direct draw into QFM BCTs)

Alternatively, blood may be collected into a single lithium-heparin or sodium-heparin tube for storage prior to transfer to QFM Direct BCT and incubation. Blood specimens collected in heparin tubes can be stored at room temperature (17–25°C) but held for no more than 8 hours from the time of collection prior to transfer to QFM Direct BCT and subsequent incubation (see Blood collection into a heparin tube and then transfer to QFM Direct BCT with room temperature storage and handling).

Warnings and Precautions

For Research Use Only. Not for use in diagnostic procedures.

When working with chemicals, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, please consult the appropriate safety data sheets (SDSs). These are available online in convenient in PDF format at www.qiagen.com where you can find, view, and print the SDS for each QIAGEN kit and kit component.

CAUTION 	Handle human blood as if potentially infectious. (C1) Observe relevant blood handling guidelines. Dispose of samples and materials in contact with blood or blood products in accordance with federal, state, and local regulations.

Procedures

Stage 1: Blood collection and hold time options

See Blood Collection Options below (Figures 1–3).

Direct draw into QFM BCTs

1. Label BCT appropriately.

   Note: It is recommended to record the time and date of blood collection.

   Important: QFM Direct BCT should be at room temperature 17–25°C (62.6–77°F) at the time of blood collection.

2. For each patient, collect 1 ml of blood by venipuncture directly into the QFM Direct BCT.
3. Important: This procedure should be performed by a trained phlebotomist.
   - As the 1 ml BCT draws blood relatively slowly, keep the BCT on the needle for 2–3 seconds once the BCT appears to have completed filling. This will ensure that the correct volume is drawn.
   - The black mark on the side of the BCT indicates the validated range of 0.8–1.2 ml. If the level of blood in the BCT is outside of the indicator mark, a new blood sample should be obtained. Under- or over-filling of the BCT outside of the 0.8–1.2 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 QFM Direct BCT being used.
   - QFM Direct BCT can be used up to an altitude of 2650 feet (810 meters) above sea level.
   - If using QFM Direct BCT outside altitude ranges or if low blood draw volume occurs, users can collect blood with a syringe, and immediately transfer 1 ml to the BCT. For safety reasons, this is best performed by removing the syringe needle, ensuring appropriate safety procedures, removing the cap from the QFM Direct BCT, and adding 1 ml of blood (to the black mark on the side of the BCT label which indicates

the validated range of 0.8–1.2 ml). Replace the cap securely and mix as described in the next step.

4. Immediately after filling the BCT, shake it ten (10) times just firmly enough to make sure the entire inner surface of the BCT is coated with blood. This will dissolve antigens on the BCT walls.

   Important: Over vigorous shaking may cause gel disruption and could lead to aberrant results.

5. Following labeling, filling, and shaking, the BCT must be transferred to a 37°C ± 1°C incubator as soon as possible, and within 8 hours of collection. Prior to incubation, maintain the BCT at room temperature (22°C ± 5°C [71.6°F ± 9°F]). If QFM Direct BCT is not incubated at 37°C directly after blood collection and shaking, invert the BCT to mix 10 times prior to incubation at 37°C.

6. Incubate the QFM Direct BCT upright at 37°C ± 1°C for 16 to 24 hours.

   Note: The incubator does not require CO_2 or humidification.

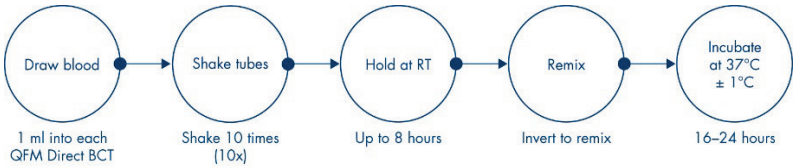

Figure 1. Blood collection option: Direct draw into QFM Direct BCT and hold at room temperature. The total time from blood draw in QFM Direct BCT to 37°C incubation must not exceed 8 hours.

Blood collection into a heparin tube and then transfer to QFM Direct BCT with room temperature storage and handling

1. Blood may be collected in a blood collection tube containing heparin as the anticoagulant and then transferred to QFM Direct BCT. Only use heparin as the blood anticoagulant because other anticoagulants interfere with the assay. Label the BCT appropriately.

   Note: It is recommended to label the tube with the time and date of the blood collection.

2. As per manufacturer instructions, fill a heparin blood collection tube (≥ 2 ml for the QFM Direct BCT, and additional for any other tubes being tested) and gently mix by inverting the tube several times to dissolve the heparin.

   Important: This procedure should be performed by a trained phlebotomist.

3. Blood collected in heparin tube must be maintained at room temperature (17–25°C [62.6–77°F]) for no more than 8 hours from the time of collection prior to transfer to QFM Direct BCT and subsequent incubation.

4. Transfer of blood specimen from a heparin tube to QFM Direct BCT.

   Important: QFM Direct BCT should be at room temperature (17–25°C [62.6 –77°F]) at the time of blood transfer.

   - Label the QFM Direct BCT appropriately.
     Note: It is recommended to transfer the recorded time and date of blood collection from the heparin tubes to the QFM Direct BCT.
   - Samples must be evenly mixed by gentle inversion before dispensing into QFM Direct BCT.
   - Dispensing should be performed aseptically, ensuring appropriate safety procedures, removing the caps from the QFM Direct BCT, and adding 1 ml of blood to the BCT. Replace the BCT cap securely and mix as described below.

5. Mix the BCT. Immediately after filling the QFM Direct BCT, shake it ten (10) times just firmly enough to make sure the entire inner surface of the BCT is coated with blood. This will dissolve antigens on the BCT walls.

Important: Overly vigorous shaking may cause gel disruption and could lead to aberrant results.

6. Incubate the QFM Direct BCT upright at 37°C ± 1°C for 16 to 24 hours.

   Note: The incubator does not require CO_2 or humidification.

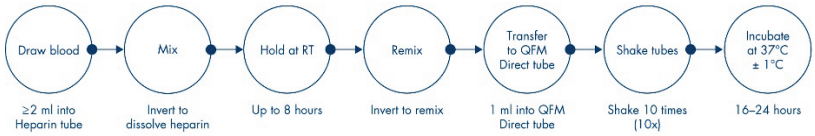

Figure 2. Blood collection option: Draw into heparin tube and hold at room temperature. The total time from blood draw in heparin tube to 37°C incubation must not exceed 8 hours.

Stage 2: Post-incubation of BCT and harvesting of plasma

Things to do before starting

- Prior to harvesting plasma, samples in QFM Direct BCT must be incubated at 37°C for 16–24 hours. The incubator does not require CO_2 or humidification.

Procedure

1. After incubation at 37°C ± 1°C, the BCT may be held between 4°C and 27°C for up to 3 days prior to centrifugation.
2. After incubation of the BCT at 37°C ± 1°C, harvesting of the plasma is facilitated by centrifuging the BCT for 15 minutes at 2000 to 3000 RCF (*g*). The gel plug will separate the cells from the plasma. If this does not occur, the BCT should be re-centrifuged.
3. It is possible to harvest the plasma without centrifugation, but additional care is required to remove the plasma without disturbing the cells.
4. Plasma samples should only be harvested using a pipet.

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

   Plasma samples can be stored in centrifuged QFM Direct BCT for up to 28 days at 2–8°C, or harvested plasma samples can be stored for up to 28 days at 2–8°C. Harvested plasma samples can also be stored below –20°C (preferably less than –70°C) for extended periods.

Symbols

The following symbols may appear on the packaging and labeling:

Symbol	Symbol definition
	Legal manufacturer
	Batch code
	Catalog number
	Global Trade Item Number
	Material number (i.e., component labeling)
	Use by
	Temperature limitation
	Consult instructions for use
	Do not reuse
	Sterilized using irradiation
	For research use only. Not for use in diagnostic procedures.
	Caution

Troubleshooting Guide

This troubleshooting guide may be helpful in solving any problems that may arise. For technical assistance and more information, please see our Technical Support Center at www.qiagen.com/support (for contact information, visit www.qiagen.com).

	Comments and suggestions
Underfilling of BCT	
a) BCT removed from the needle too soon.	As 1 ml BCTs draw blood relatively slowly, keep the BCT on the needle for 2–3 seconds once the BCT appears to have completed filling. This will ensure that the correct volume is drawn.
b) Blood drawn outside the recommended altitude of 2650 feet (810 meters) above sea level	QFM Direct BCTs can be used up to an altitude of 2650 feet (810 meters) above sea level. If using QFM Direct BCTs outside altitude ranges or if low blood draw volume occurs, users can collect blood with a syringe, and immediately transfer 1 ml to each of the BCTs.
c) Tubing not primed while using butterfly needle	If a "butterfly needle" is used to collect blood, a "purge" tube should be used to ensure that the tubing is filled with blood prior to the QFN BCTs being used.
d) BCTs are past their expiration date	BCTs must be used within the expiration date printed on the tube label.
Overfilling of BCT	
Tube not at room temperature during blood collection	BCTs should be at room temperature 17–25°C (62.6–77°F) at the time of blood collection.
Blood clots	
Insufficient mixing	Immediately after filling the BCTs, shake them ten (10) times just firmly enough to make sure the entire inner surface of the BCT is coated with blood. This will dissolve antigens on the BCTs walls.
Plasma not separated by gel	
Insufficient centrifugation speed or time	Harvesting of the plasma is facilitated by centrifuging the BCTs for 15 minutes at 2000–3000 RCF (g). The gel plug will separate the cells from the plasma. If this does not occur, the BCTs should be re-centrifuged.

	Comments and suggestions
Gel disruption	
Tubes shaken too vigorously	Immediately after filling the BCTs, shake them ten (10) times just firmly enough to make sure the entire inner surface of the BCT is coated with blood. This will dissolve antigens on the BCTs walls. Important: Over vigorous shaking may cause gel disruption and could lead to aberrant results.

Contact Information

For technical assistance and more information, please call toll-free 800-362-7737, see our Technical Support Center at www.qiagen.com/contact or contact one of the QIAGEN Technical Service Departments (see back cover or visit www.qiagen.com).

Ordering Information

Product	Contents	Cat. no.
QuantiFERON Monitor Direct	Contains 100x Monitor Direct Tube	626315
Relative Products		
QuantiFERON SARS-CoV-2 Starter Pack	Contains QuantiFERON Starter Set (cat. no. 626115 SARS-CoV-2 Ag1 tube and SARS-CoV-2 Ag2 tube) and QuantiFERON Control Set (cat. no. 626015 Nil and Mitogen)	626715
QuantiFERON Control Set	Contains Nil tube and Mitogen Tube	626015
QuantiFERON ELISA	Contains Microtiter Plate, Conjugate (100x), IFN Gamma Standard, Green Diluent, Wash Buffer, Enzyme Substrate Solution, and Enzyme Stopping Solution	626410

For up-to-date licensing information and product-specific disclaimers, see the respective QIAGEN kit handbook or user manual. QIAGEN kit handbooks and user manuals are available at www.qiagen.com or can be requested from QIAGEN Technical Services or your local distributor.

Document Revision History

Date	Changes
R1, November 2020	Initial release
R2, February 2021	Updated cover page to add symbols for kit temperature limitation and do not reuse instruction Updated Intended Use section Updated Symbols section to add Material number Updated Ordering Information section

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Limited License Agreement for QuantiFERON® Monitor Direct Blood Collection Tube

Use of this product signifies the agreement of any purchaser or user of the product to the following terms:

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