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QuantiFERON[®]-EBV Blood Collection Tubes Instructions for Use (Handbook)



For Research Use Only

Not for use in diagnostic procedures

REF



627212

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Intended Use

The QuantiFERON®-EBV Blood Collection Tubes Single-Patient Pack (QF-EBV BCTs SPP) is for Research Use Only and is not for use in diagnostic procedures.

Materials Provided

Kit contents

Blood Collection Tubes		30 tubes
Catalog no.		627212
QuantiFERON-EBV Ag Tube (pink cap, black ring)	Ag	10 tubes
QuantiFERON Nil Tube (gray cap, white ring)	Negative Control	10 tubes
QuantiFERON Mitogen Tube (lavender cap, white ring)	Positive Control	10 tubes
Language Sheet	-	1

The QF-EBV BCTs SPP consists of ten tube sets, with each set including one EBV Antigen (Ag) Blood Collection Tube, one Nil Blood Collection Tube and one Mitogen Blood Collection Tube. The EBV Ag tube uses a combination of CD4+ and CD8+ antigens specific to Epstein-Barr Virus (EBV) nuclear antigen proteins (EBNA-1, EBNA-3A, and EBNA-3B) to stimulate lymphocytes in heparinized whole blood involved in cell-mediated immunity. The QuantiFERON Nil and QuantiFERON Mitogen Blood Collection Tubes (BCTs) included in the tube set serve as negative and positive controls, respectively, for lymphocyte whole blood stimulation. Plasma from the stimulated samples can be used for the detection of IFN- γ . Detection of IFN- γ can be done using QuantiFERON ELISA.

QF-EBV BCTs are designed to draw 1 ± 0.2 mL of blood for stimulation. The contents of the BCTs have been dried onto the inner walls, and it is essential that the BCTs be thoroughly mixed with the blood to resolubilize them. Blood collected directly into the QF-EBV BCTs must


be transferred to a 37°C incubator as soon as possible and within 16 hours of blood collection (see Direct draw into QF-EBV BCTs).

Alternatively, blood may be collected into a single lithium heparin tube for storage prior to transfer to QF-EBV BCTs and incubation. Blood specimens collected in lithium heparin tubes can be stored at room temperature (17–25°C [62.6–77°F]) but held for no more than 16 hours from the time of collection prior to transfer to QF-EBV BCTs and subsequent incubation (see Blood collection into a lithium heparin tube and then transfer to QF-EBV BCTs with room temperature storage and handling). Blood specimens in lithium heparin tubes may also be stored at 2–8°C for up to 48 hours prior to transfer to the QF-EBV BCTs (see Blood collection into a lithium heparin tube and then transfer to QF-EBV BCTs with refrigerated 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 PDF format at www.qiagen.com where you can find, view, and print the SDS for each QIAGEN kit and kit component.

<p>CAUTION</p> 	<p>Handle human blood as if potentially infectious. (C1)</p> <p>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.</p>
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Procedures

Stage 1 : Blood collection and hold time options

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

Direct draw into QF-EBV BCTs

1. Label BCTs appropriately. Ensure that each BCT (Ag, Nil, and Mit) is identifiable by its label or other means once the cap is removed.

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

Important: QF-EBV BCTs 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 each of the QF-EBV BCTs.

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

- 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.
- The black mark on the side of the BCTs indicates the validated range of 0.8 to 1.2 mL. If the level of blood in any BCT is outside of the indicator mark, a new blood sample should be obtained. Under- or over-filling of the BCTs 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 QF-EBV BCTs being used.
- QF-EBV BCTs can be used up to an altitude of 2650 feet (810 meters) above sea level.
- If using QF-EBV BCTs outside the recommended altitude range or if low blood draw volume occurs, users can collect blood with a syringe, and immediately transfer 1 mL

to each of the BCTs. For safety reasons, this is best performed by removing the syringe needle, ensuring appropriate safety procedures, removing the caps from the QF-EBV BCTs, and adding 1 mL of blood to each (to the black mark on the side of the BCT label which indicates the validated range of 0.8 to 1.2 mL). Replace the caps securely and mix as described below. Ensure each BCT (Ag, Nil, and Mit) is identifiable by its label or other means once the cap is removed.

3. Immediately after filling the BCTs, shake them ten (10) times just firmly enough to ensure that the entire inner surface of the BCT is coated with blood. This will dissolve antigens and other materials on the BCT walls.

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

4. Following labelling, filling, and shaking, the BCTs must be transferred to a $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$ incubator as soon as possible, and within 16 hours of collection. Prior to incubation, maintain BCTs at room temperature, $17\text{--}25^{\circ}\text{C}$ ($62.6\text{--}77^{\circ}\text{F}$). If QF-EBV BCTs are not incubated at 37°C directly after blood collection and shaking, invert the BCTs to mix 10 times prior to incubation at 37°C .
5. Incubate the QF-EBV BCTs **upright** at $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$ for 16 to 24 hours.

Note: The incubator does not require CO_2 or humidification.

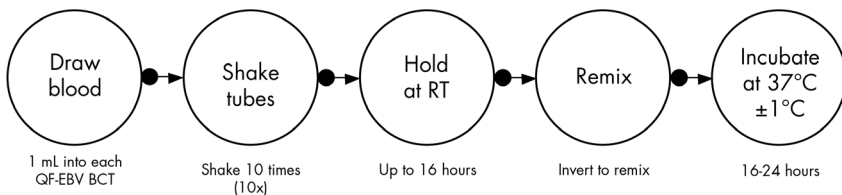


Figure 1. Blood collection option: Direct draw into QF-EBV BCTs and hold at room temperature. The total time from blood draw in QF-EBV BCTs to 37°C incubation must not exceed 16 hours.

Blood collection into a lithium heparin tube and then transfer to QF-EBV BCTs with room temperature storage and handling

1. Blood may be collected in a blood collection tube containing lithium heparin as the anticoagulant and then transferred to the QF-EBV BCTs. Only use lithium heparin as the blood containing coagulant because other anticoagulants have the potential to interfere with product performance. Label tubes appropriately.

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

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

2. Fill a lithium heparin blood collection tube (≥ 3 mL for the QF-EBV BCTs, and additional for any other tubes being tested) and gently mix by inverting the tube several times to dissolve the lithium heparin.

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

3. Blood collected in lithium heparin tubes must be maintained at room temperature (17–25°C [62.6–77°F]) for no more than 16 hours from the time of collection prior to transfer to QF-EBV BCTs and subsequent incubation.

4. Transfer the blood specimen from a lithium heparin tube to QF-EBV BCTs.

Important: QF-EBV BCTs should be at room temperature, 17–25°C (62.6–77°F), at the time of blood transfer.

- Label each QF-EBV BCT appropriately.

Note: Ensure each BCT is identifiable by its label or other means once the cap is removed. It is recommended to transfer the recorded time and date of blood collection from the lithium heparin tubes to the QF-EBV BCTs .

- Samples must be evenly mixed by gentle inversion before dispensing into QF-EBV BCTs.
- Dispensing should be performed aseptically, ensuring appropriate safety procedures, removing the caps from the QF-EBV BCTs, and adding 1 mL of blood to each BCT. Replace the BCT caps securely and mix as described in the next steps.

5. Mix BCTs. Immediately after filling the QF-EBV BCTs, shake them ten (10) times just firmly enough to ensure that the entire inner surface of the BCT is coated with blood. This will dissolve antigens on BCT walls.

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

6. Incubate the QF-EBV BCTs **upright** at $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$ for 16 to 24 hours.

Note: The incubator does not require CO_2 or humidification.

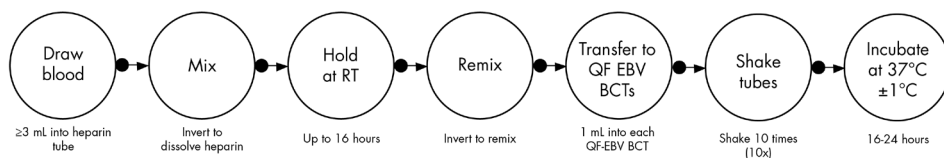


Figure 2. Blood collection option: Draw into lithium heparin tube and hold at room temperature. The total time from blood draw in heparin tube to 37°C incubation must not exceed 16 hours.

Blood collection into a lithium heparin tube and then transfer to QF-EBV BCTs with refrigerated storage and handling

1. Fill a lithium heparin blood collection tube (≥ 3 mL for the QF-EBV BCTs, and additional for any other tubes being tested) and gently mix by inverting the tube several times to dissolve the lithium heparin.

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

2. Before refrigeration, blood drawn into the lithium heparin tube may be held at room temperature (17–25°C [62.6–77°F]) up to 3 hours after blood collection.
3. Blood drawn into lithium heparin tubes may be refrigerated (2–8°C) up to 48 hours.
4. After refrigeration, lithium heparin tubes must equilibrate to room temperature (17–25°C [62.6–77°F]) for at least 1 hour prior to transfer to QF-EBV BCTs.
 - Aliquoted QF-EBV BCTs should be placed in the 37°C incubator within 2 hours of removing the lithium heparin tube from 2–8°C.
 - Label each QF-EBV BCT appropriately.
 - **Note:** Ensure each BCT is identifiable by its label or other means once the cap is removed. It is recommended to transfer the recorded time and date of blood collection from the lithium heparin tubes to the QF-EBV BCTs.
 - Samples must be evenly mixed by gentle inversion before dispensing into QF-EBV BCTs.
 - Dispensing should be performed aseptically, ensuring appropriate safety procedures, removing the caps from the QF-EBV BCTs, and adding 1 mL of blood to each BCT. Replace the BCT caps securely and mix as described below.
5. Mix BCTs. Immediately after filling the QF-EBV BCTs, shake them ten (10) times just firmly enough to ensure that the entire inner surface of the BCT is coated with blood. This will dissolve antigens on BCT walls.

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

6. Following labelling, filling, and shaking, the BCTs must be transferred to a $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$ incubator within 2 hours of removing lithium heparin tubes from $2-8^{\circ}\text{C}$. If QF-EBV BCTs are not incubated at 37°C directly after aliquoting from lithium heparin tubes and shaking, invert the BCTs to mix 10 times prior to incubation at 37°C .

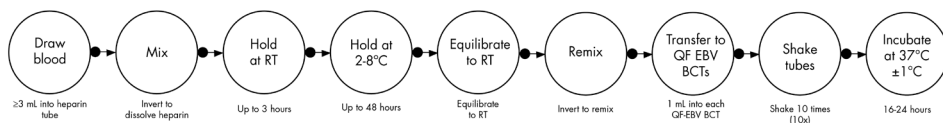


Figure 3. Blood collection option: Draw into lithium heparin tube and hold at $2-8^{\circ}\text{C}$. The total time from blood drawing in the lithium heparin tube to 37°C incubation must not exceed 53 hours. **Note:** Aliquoted QF-EBV BCTs should be placed in a 37°C incubator within 2 hours of removing the lithium heparin tube from $2-8^{\circ}\text{C}$.

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

Things to do before starting

- Prior to harvesting plasma, samples in QF-EBV BCTs must be incubated at 37°C for 16–24 hours. The incubator does not require CO₂ or humidification.

Procedure














1. After incubation at 37°C ± 1°C, the BCTs may be held between 4°C and 27°C for up to 3 days prior to centrifugation.
2. After incubation of the BCTs at 37°C ± 1°C, harvesting of the plasma is facilitated by centrifuging the BCTs 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 BCTs 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 QF-EBV BCTs 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 in the instructions for use or on the packaging and labeling:

Symbol	Symbol definition
	Manufacturer
	Catalog number
	Lot number
	Global Trade Item Number
	Material number (i.e., component labeling)
	Components
	Number
	Use by
	Temperature limitation
	Consult instructions for use
	Do not reuse
	Sterilized using irradiation
	For Research Use Only. Not for use in diagnostic procedures.

Symbol

Symbol definition



Warning/caution



Unique Device Identifier



Date of manufacture



For 1 test



Single sterile barrier sterilization



Do not resterilize



Contains biological material of animal origin



Do not use if package is damaged and consult Instructions for Use

Troubleshooting Guide

This troubleshooting guide may be helpful in solving any problems that may arise. For more information, see also the Frequently Asked Questions page at our Technical Support Center: www.qiagen.com/FAQ/FAQList.aspx (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 | QF-EBV BCTs can be used up to an altitude of 2650 feet (810 meters) above sea level.
If using QF-EBV 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

- | | |
|---|---|
| a) 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

- | | |
|------------------------|---|
| a) 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 BCT walls. |
|------------------------|---|

Plasma not separated by gel

- a) 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.

Gel disruption

- a) 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 BCT walls.
Important: Over vigorous shaking may cause gel disruption and could lead to aberrant results.

Contact Information

For technical assistance and more information, please see our Technical Support Center at www.qiagen.com/Support, call 00800-22-44-6000, or contact one of the QIAGEN Technical Service Departments or local distributors (see back cover or visit www.qiagen.com).

Ordering Information

Product	Contents	Cat. no.
QuantiFERON-EBV Blood Collection Tubes Single Patient Pack (RUO)	Contains 10 Sets of QuantiFERON-EBV BCTs: QuantiFERON-EBV Ag tubes, QuantiFERON NIL tubes, and QuantiFERON Mitogen tubes	627212
Related products		
QuantiFERON ELISA (RUO)	Contains Microtiter Plate, Conjugate (100x), IFN Gamma Standard, Green Diluent, Wash Buffer, Enzyme Substrate Solution, and Enzyme Stopping Solution	626410
QuantiFERON ELISA Analysis Software (RUO)		Download from web

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

Dates

Changes

September 2023

Initial release

Limited License Agreement for QuantiFERON® EBV Blood Collection Tubes Single Patient Pack

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