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QuantiFERON® SARS-CoV-2 Extended Set Blood Collection Tube Instructions for Use (Handbook)



For Research Use Only
Not for use in diagnostic procedures

REF

626215



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Intended Use

The QuantiFERON SARS-CoV-2 Extended Set Blood Collection Tubes (QFN SARS-CoV-2 Extended Set BCT) consists of one Antigen tube, SARS-CoV-2 Ag3 that uses a combination of specific antigens inherited from the full genome of the SARS-CoV-2 virus to stimulate lymphocytes in heparinized whole blood involved in cell-mediated immunity. Plasma from the stimulated samples can be used for detection of IFN- γ . Detection of IFN- γ can be done using QuantiFERON ELISA.

The QFN SARS-CoV-2 Ag3 BCT is for Research Use Only and not for diagnostic use.

Materials Provided

Kit contents

Blood Collection Tubes		100 tubes
Catalog no.		626215
QuantiFERON SARS-CoV-2 Ag3 Tube (black cap, black ring)	Ag3	100 tubes
Language Sheet	–	1


The QFN SARS-CoV-2 Ag3 BCT is designed to draw the required volume of blood for stimulation. The contents of the BCT have been dried onto the inner wall, and it is essential that the BCT is thoroughly mixed with the blood to resolubilize it. Blood collected directly into the QFN SARS-CoV-2 Ag3 BCT must be transferred to a 37°C incubator as soon as possible and within 16 hours of blood collection (see Direct draw into QFN SARS-CoV-2 BCT)

Alternatively, blood may be collected into a single lithium-heparin or sodium-heparin tube for storage prior to transfer to the QFN SARS-CoV-2 Ag3 BCT and incubation. Blood specimens collected in heparin tubes can be stored at room temperature (17–25°C) but held for no more than 16 hours from the time of collection prior to transfer to the QFN SARS-CoV-2 BCT and subsequent incubation (see Blood collection into a heparin tube and then transfer to QFN SARS-CoV-2 Ag3 BCT with room temperature storage and handling). Blood specimens in heparin tubes may also be stored at 2–8°C for up to 48 hours prior to transfer to the QFN SARS-CoV-2 Ag3 BCT (see Blood collection into a heparin tube and then transfer to the QFN SARS-CoV-2 BCT 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 QFN SARS-CoV-2 Ag3 BCT

1. Label the BCT appropriately.

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

Important: QFN SARS-CoV-2 Ag3 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 QFN SARS-CoV-2 Ag3 BCT.

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 BCT 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 QFN SARS-CoV-2 Ag3 BCT being used.
- QFN SARS-CoV-2 Ag3 BCT can be used up to an altitude of 2650 feet (810 meters) above sea level.
- If using QFN SARS-CoV-2 Ag3 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 caps from the QFN SARS-CoV-2 Ag3 BCT 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.

3. Immediately after filling the BCT, shake them ten (10) times just firmly enough to ensure that the entire 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.

4. Following labelling, filling, and shaking, the BCT 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 BCT at room temperature ($22^{\circ}\text{C} \pm 5^{\circ}\text{C}$ [$71.6^{\circ}\text{F} \pm 9^{\circ}\text{F}$]). If QFN SARS-CoV-2 Ag3 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 .
5. Incubate the QFN SARS-CoV-2 Ag3 BCT **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.

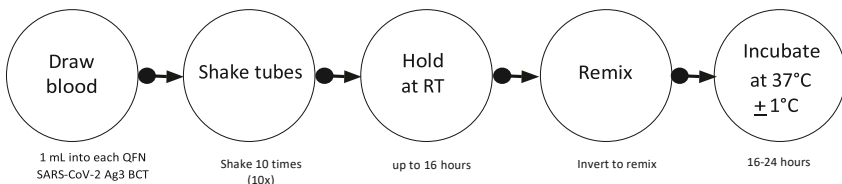


Figure 1. Blood collection option: Direct draw into QFN SARS-CoV-2 Ag3 BCT and hold at room temperature. The total time from blood draw in QFN SARS-CoV-2 Ag3 BCT to 37°C incubation must not exceed 16 hours.

Blood collection into a heparin tube and then transfer to QFN SARS-CoV-2 Ag3 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 QFN SARS-CoV-2 Ag3 BCT. Only use heparin as the blood containing coagulant because other anticoagulants interfere with the assay. Label tubes appropriately.

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

2. Fill a heparin blood collection tube (≥ 2 ml for the QFN SARS-CoV-2 Ag3 BCT, and additional for any other tubes being tested) and gently mix by inverting the BCT several times to dissolve the heparin.

Important: This procedure must 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 16 hours from the time of collection prior to transfer to QFN SARS-CoV-2 Ag3 BCT and subsequent incubation.
4. Transfer of blood specimen from a heparin tube to QFN SARS-CoV-2 Ag3 BCT.
 - Label each QFN SARS-CoV-2 Ag3 BCT appropriately.
 - Samples must be evenly mixed by gentle inversion before dispensing into QFN SARS-CoV-2 Ag3 BCT.
 - Dispensing should be performed aseptically, ensuring appropriate safety procedures, removing the caps from the QFN SARS-CoV-2 Ag3 BCT, and adding 1 ml of blood to BCT. Replace the BCT cap securely and mix as described in the next steps.
5. Mix BCT. Immediately after filling the QFN SARS-CoV-2 Ag3 BCT, shake it 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 wall.

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

6. Incubate the QFN SARS-CoV-2 Ag3 BCT **upright** at 37°C \pm 1°C for 16 to 24 hours.

Note: The incubator does not require CO₂ or humidification.

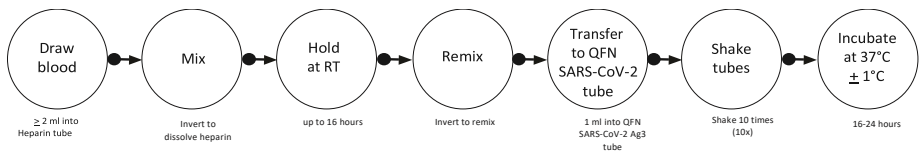


Figure 2. Blood collection option: Draw into heparin tube and hold at room temperature. The total time from blood draw in heparin tube to 37°C incubation must not exceed 16 hours.

Blood collection into a heparin tube and then transfer to QFN SARS-CoV-2 Ag3 BCT with refrigerated storage and handling

1. Fill a heparin blood collection tube (≥ 2 ml for the QFN SARS-CoV-2 Ag3 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.

2. Before refrigeration, blood drawn into heparin tube may be held at room temperature ($17\text{--}25^{\circ}\text{C}$) up to 3 hours after blood collection.
3. Blood drawn into heparin tube may be refrigerated ($2\text{--}8^{\circ}\text{C}$) up to 48 hours.
4. After refrigeration, heparin tube must equilibrate to room temperature ($17\text{--}25^{\circ}\text{C}$) for 1 hour prior to transfer to QFN SARS-CoV-2 Ag3 BCT.
 - Aliquoted QFN SARS-CoV-2 Ag3 BCT should be placed in the 37°C incubator within 2 hours of removing the heparin tube from $2\text{--}8^{\circ}\text{C}$.
 - Label the QFN SARS-CoV-2 Ag3 BCT appropriately.
 - Samples must be evenly mixed by gentle inversion before dispensing into QFN SARS-CoV-2 Ag3 BCT.
 - Dispensing should be performed aseptically, ensuring appropriate safety procedures, removing the caps from the QFN SARS-CoV-2 Ag3 BCT, and adding 1 ml of blood to the BCT. Replace the BCT cap securely and mix as described below.
5. Following labelling, filling, and shaking, the BCT must be transferred to a $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$ incubator within 2 hours of removing heparin tubes from $2\text{--}8^{\circ}\text{C}$. If QFN SARS-CoV-2 Ag3 BCT is not incubated at 37°C directly after blood collection and shaking, invert the BCTs to mix 10 times prior to incubation at 37°C . (See Figures 1–3 for blood collection options.)

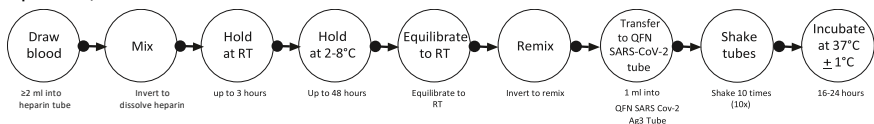


Figure 3. Blood collection option: Draw into heparin tube and hold at $2\text{--}8^{\circ}\text{C}$. The total time from blood drawing heparin tube to 37°C incubation must not exceed 53 hours. **Note:** Aliquoted QFN SARS-CoV-2 Ag3 BCT should be placed in a 37°C incubator within 2 hours of removing heparin tube from $2\text{--}8^{\circ}\text{C}$.

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

Things to do before starting

- Prior to harvesting plasma, samples in QFN SARS-CoV-2 Ag3 BCT 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 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 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 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 QFN SARS-CoV-2 Ag3 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 labelling:

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

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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 | QFN SARS-CoV-2 Ag3 BCT can be used up to an altitude of 2650 feet (810 meters) above sea level.
If using QFN SARS-CoV-2 Ag3 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. |
| 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 Ag3 BCT being used. |
| d) BCT is past their expiration date | BCT 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 BCT, 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

- | | |
|---|--|
| Insufficient centrifugation speed or time | Harvesting of the plasma is facilitated by centrifuging the BCT for 15 minutes at 2000–3000 RCF (g). The gel plug will separate the cells from the plasma. If this does not occur, the BCT should be re-centrifuged. |
|---|--|

Comments and suggestions

Gel disruption

Tubes shaken too vigorously

Immediately after filling the BCT, 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 call toll-free 800-362-7737, see our Technical Support Center at [**www.qiagen.com/contact**](http://www.qiagen.com/contact) or contact one of the QIAGEN Technical Service Departments (see back cover or visit [**www.qiagen.com**](http://www.qiagen.com)).

Ordering Information

Product	Contents	Cat. no.
QuantiFERON SARS-CoV-2 Extended Pack	Contains QuantiFERON Extended Set (cat. no. 626215 SARS-CoV-2 Ag3 tube) and QuantiFERON Control Set (cat. no. 626015 Nil and Mitogen)	626815
Related Products		
QuantiFERON SARS-CoV-2 Starter Pack	Contains QuantiFERON Starter Set (cat. no. 626115 SARS-CoV-2 Ag1 and Ag2 tube) and QuantiFERON Control Set (cat. no. 626015 Nil and Mitogen)	626715
QuantiFERON Control Set	Contains Nil tube and Mitogen tube	626015
QuantiFERON Monitor Direct	Contains Monitor Direct tube	626315
QuantiFERON ELISA	Contains Microtiter Plate, Conjugate (100x), IFN Gamma Standard, Green Diluent, Wash Buffer (x20), 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, April 2021	Initial release

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