February 2022

QuantiFERON® SARS-CoV-2 Blood Collection Tubes Instructions for Use

Σ 50

Version 1

IVD

For In Vitro Diagnostic Use

For use with QuantiFERON® SARS-CoV-2 ELISA

CE

REF 626725

QIAGEN, 19300 Germantown Road, Germantown, MD 20874, USA
Phone: +1-800-426-8157

EC REP QIAGEN GmbH
QIAGEN Strasse 1, 40724
Hilden, GERMANY

R4 MAT 1124422EN

Sample to Insight

QIAGEN

Contents

Intended Use

The QuantiFERON SARS-CoV-2 (QFN SARS-CoV-2) Blood Collection Tubes (BCTs) are intended for the collection, storage, incubation, stimulation, and transportation of human blood.

For use with QuantiFERON SARS-CoV-2 (QFN SARS-CoV-2) assay ELISA.

For in vitro diagnostic use.

Intended User

The QuantiFERON SARS-CoV-2 Blood Collection Tubes are used in settings where a blood sample is collected by a trained healthcare professional and processed in a laboratory environment.

Description and Principle

Summary and explanation

Refer to *QuantiFERON SARS-CoV-2 ELISA Instructions for Use* for the summary and explanation.

Materials Provided

Kit contents

Blood Collection Tubes **Catalog no. 626725**		
QuantiFERON Nil Tube (gray cap, white ring)	Nil	50 tubes/rack
QuantiFERON SARS-CoV-2 Ag 1 Tube (red cap, white ring)	Ag1	50 tubes/rack
QuantiFERON SARS-CoV-2 Ag 2 Tube (ocher cap, white ring)	Ag2	50 tubes/rack
QuantiFERON Mitogen Tube (purple cap, white ring)	Mit	50 tubes/rack

Important: The QFN SARS-CoV-2 Blood Collection Tube(s) are single-use only.

QFN SARS-CoV-2 BCTs are designed to draw the required volume of blood for stimulation. Antigens have been dried onto the inner walls of the BCTs, so it is essential that the BCTs be thoroughly mixed with blood to resolubilize them. Blood collected directly into the QFN SARS-CoV-2 BCTs 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 BCTs).

Alternatively, blood may be collected into a single lithium-heparin or sodium-heparin tube for storage prior to transfer to QFN SARS-CoV-2 BCTs 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 QFN SARS-CoV-2 BCTs and subsequent incubation (see Blood collection into a single heparin tube and then transfer to QFN SARS-CoV-2 BCTs 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 BCTs (see Blood collection into a heparin tube and then transfer to QFN SARS-CoV-2 BCTs with refrigerated storage and handling).

Materials Required but Not Provided

Additional reagents

- QuantiFERON SARS-CoV-2 ELISA kit (catalog no. 626420)

Equipment*

- 37°C ± 1°C incubator (the incubator does not require CO_2 or humidification)
- Calibrated pipette for delivery up to 1000 µl with disposable tips

* Prior to use, ensure that instruments have been checked and calibrated according to the manufacturer's recommendations.

Warnings and Precautions

For customers in the European Union, please be aware that you are required to report serious incidents that have occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Safety information

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 and compact PDF format at www.qiagen.com/safety, where you can find, view and print the SDS for each QIAGEN kit and kit component.

- All chemicals and biological materials are potentially hazardous. Specimens and samples are potentially infectious and must be treated as biohazardous materials.
- Discard sample and assay waste according to your local safety procedures.

Precautions

CAUTION 	Handle human blood as if potentially infectious. 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.	(C1)

For in vitro diagnostic use only.

Note: The QFN SARS-CoV-2 Blood Collections Tube(s) are sterile prior to use.

Important: If you suspect that the QFN SARS-CoV-2 Blood Collection Tube(s) have been damaged or sterilization has been compromised, please contact QIAGEN Technical Services.

Reagent Storage and Handling

Attention should be paid to expiration dates and storage conditions printed on the box and labels of all components. Do not use expired or incorrectly stored components.

Specimen Storage and Handling

The QFN SARS-CoV-2 Blood Collection Tubes are for use with the QFN SARS-CoV-2 ELISA. All samples should be treated as potentially hazardous.

Protocol: Blood Collection

Important points

- Tubes should be at room temperature between 17–25°C (62.6–77°F) at the time of blood filling.
- The black mark on the side of the tubes indicates the validated range of 0.8–1.2 ml. If the level of blood in any tube is outside the range of the indicator mark, obtain a new blood sample. Under or over-filling of the tubes outside of the 0.8–1.2 ml range may lead to erroneous results.
- If using a "butterfly needle" to collect blood, use a "purge" tube to ensure that the tubing is filled with blood prior to using the QFN SARS-CoV-2BCTs.
- Direct blood draw into QFN SARS-CoV-2 BCTs can be performed up to an altitude of 810 meters (2650 feet) above sea level.
- If using QFN SARS-CoV-2 BCTs 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 each of the 4 QFN SARS-CoV-2 BCTs. For safety reasons, this is best performed by removing the syringe needle, ensuring appropriate safety procedures, removing the caps from the 4 QFN SARS-CoV-2 BCTs, and adding 1 ml of blood to each tube (to the center of the black mark on the side of the tube label). Ensure each tube (Nil, Ag1, Ag2, and Mitogen) is identifiable by its label or other means once the cap is removed. Replace the caps securely and mix as described below.
- Alternatively, blood may be collected in a single generic blood collection tube containing lithium-heparin or sodium-heparin as the anticoagulant and then transferred to the QFN SARS-CoV-2 BCTs. Only use lithium heparin or sodium heparin as a blood anticoagulant because other anticoagulants interfere with the assay. Fill a generic blood collection tube (5 ml minimum volume) and gently mix by inverting the tube several times to dissolve the lithium heparin or sodium heparin. Generic blood tubes must be maintained and transported at room temperature (17–25°C) before transfer to QFN SARS-CoV-2 BCTs for incubation, which must be initiated within 16 hours of blood collection. If blood has been

collected in a lithium -heparin or sodium -heparin tube, samples must be evenly mixed by gentle inversion before dispensing into QFN SARS-CoV-2 BCTs. Perform dispensing aseptically (ensuring appropriate safety procedures) by removing the caps from the 4 QFN SARS-CoV-2 BCTs and adding 1 ml of blood to each tube (to the center of the black mark on the side of the tube label). Replace the tube caps securely and mix as described below

Setting up

- Label tubes appropriately.

Handling reagents

- If the blood is not incubated immediately after collection, users must immediately re-mix the tubes by inverting 10 times prior to incubation.

Things to do before starting

- Ensure each tube (Nil, Ag1, Ag2, and Mitogen) is identifiable by its label or other means once the cap is removed.

Stage 1: Blood collection and hold time options

Direct draw into QFN SARS-CoV-2 BCTs

1. For each patient, collect 1 ml of blood by venipuncture directly into each of the QFN SARS-CoV-2 BCTs. The tube should be at room temperature (17–25°C) at the time of blood filling.

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

   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 QFN SARS-CoV-2 BCTs being used.
- QFN SARS-CoV-2 BCTs can be used up to an altitude of 2650 feet (810 meters) above sea level.
- If using QFN SARS-CoV-2 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. 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 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 (Nil, Ag1, Ag2, and Mitogen) is identifiable by its label or other means once the cap is removed.

2. Immediately after filling the BCTs, 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 BCTs walls.

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

3. Following labelling, filling, and shaking, the BCTs must be transferred to a 37°C ± 1°C incubator as soon as possible, and within 16 hours of collection. Prior to incubation, maintain BCTs at room temperature (17–25°C). If QFN SARS-CoV-2 BCTs are not incubated at 37°C directly after blood collection and shaking, invert the BCTs to mix 10 times just prior to incubation at 37°C.
4. Incubate the QFN SARS-CoV-2 BCTs upright at 37°C ± 1°C for 16–24 hours.

   Note: The incubator does not require CO_2 or humidification.

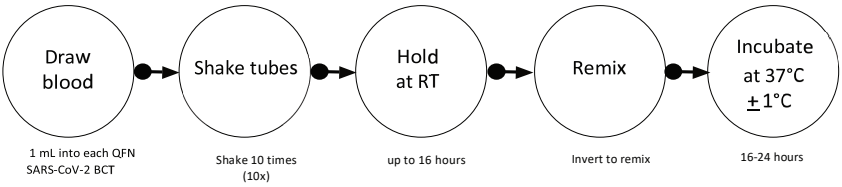

Figure 1. **Blood collection option: Direct draw into QFN SARS-CoV-2 BCTs and hold at room temperature**. The total time from blood draw in QFN SARS-CoV-2 BCTs to 37°C incubation must not exceed 16 hours.

Blood collection into a single heparin tube and then transfer to QFN SARS-CoV-2 BCTs with room temperature storage and handling

1. Blood may be collected in a blood collection tube containing lithium-heparin or sodium-heparin as the anticoagulant and then transferred to the QFN SARS-CoV-2 BCTs. Only use heparin as the anticoagulant because other anti-coagulants interfere with the assay. 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) at the time of blood collection.

2. Fill a heparin blood collection tube (minimum volume 5 ml) 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 the heparin tube must be maintained at room temperature (17–25°C) for no more than 16 hours from the time of collection prior to transfer to QFN SARS-CoV-2 BCTs and subsequent incubation.

4. Transfer the blood specimen from the heparin tube to QFN SARS-CoV-2 BCTs.

   Important: QFN SARS-CoV-2 BCTs should be at room temperature (17–25°C) at the time of blood transfer.

- Label each of the QFN SARS-CoV-2 BCTs appropriately.
  Note: Ensure each BCT (Nil, Ag1, Ag2, and Mitogen) 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 heparin tubes to the QFN SARS-CoV-2 BCTs.
- Samples must be evenly mixed by gentle inversion before dispensing into QFN SARS-CoV-2 BCTs.
- Dispensing should be performed aseptically, ensuring appropriate safety procedures, removing the caps from the 4 QFN SARS-CoV-2 BCTs, and adding 1 ml of blood to each BCT. Replace BCT caps securely and mix as described in the next steps.

5. Mix BCTs. Immediately after filling the QFN SARS-CoV-2 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 the antigens on the BCT walls.

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

6. Incubate the QFN SARS-CoV-2 BCTs upright at 37°C ± 1°C for 16–24 hours.

   Note: The incubator does not require CO_2 or humidification.

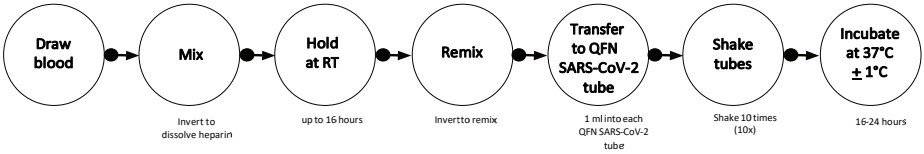

Figure 2. **Blood collection option: Draw into heparin tube and hold at room temperature**. The total time from blood draw in heparin tube to 37°C incubation must not exceed 16 hours.

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

1. Blood may be collected in a single blood collection tube containing lithium or sodium-heparin as the anti-coagulant, and then transferred to the QFN SARS-CoV-2 BCTs. Only use lithium or sodium heparin as a blood anti-coagulant because other anti-coagulants interfere with the assay. Label tubes appropriately.

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

   Important: Blood collection tubes should be at room temperature (17–25°C) at the time of blood collection.

2. Fill a heparin blood collection tube (minimum volume 5 ml) and gently mix by inverting the tube several times to dissolve the heparin.

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

   - Before refrigeration, blood drawn into the heparin tube may be held at room temperature (17–25°C) up to 3 hours after blood collection.
   - Blood drawn into the heparin tube may be refrigerated (2–8°C) up to 48 hours.

3. After refrigeration, the heparin tube must equilibrate to room temperature (17–25°C) prior to transfer to the QFN SARS-CoV-2 BCTs.

   - Aliquoted QFN SARS-CoV-2 BCTs should be placed in the 37°C incubator within 2 hours of removing the heparin tube from 2–8°C.
   - Label each QFN SARS-CoV-2 BCT appropriately.
     Note: Ensure each BCT (Ni, Ag1, Ag2, and Mitogen) 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 heparin tube to the QFN SARS-CoV-2 BCTs.
   - Samples must be evenly mixed by gentle inversion before dispensing into the QFN SARS-CoV-2 BCTs.
   - Dispensing should be performed aseptically, ensuring appropriate safety procedures, removing the caps from the 4 QFN SARS-CoV-2 BCTs, and adding 1 ml of blood to each BCT. Replace the BCT caps securely and mix as described below.

- Mix BCTs. Immediately after filling the QFN SARS-CoV-2 BCTs, shake them 10 times just firmly enough to ensure that the entire inner surface of the BCT is coated with blood. This will dissolve the antigens on the BCT walls.

  Important: Overly 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°C ± 1°C incubator within 2 hours of removing heparin tubes from 2–8°C. If QFN SARS-CoV-2 BCTs are not incubated at 37°C directly after filling and shaking, invert the BCTs to mix 10 times just prior to incubation at 37°C (Figure 3).

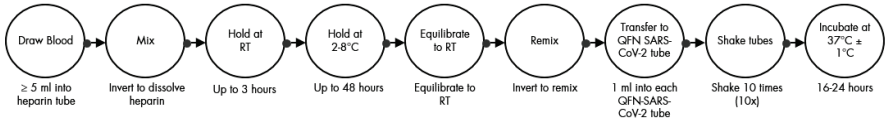

Figure 3. **Blood collection option: Draw into heparin tube and hold at 2–8°C**. The total time from blood drawing in the heparin tube to 37°C incubation must not exceed 53 hours. Note: Aliquoted QFN SARS-CoV-2 BCTs should be placed in a 37°C incubator within 2 hours of removing heparin tube from 2–8°C.

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

Things to do before starting

- Prior to harvesting plasma, samples in QFN SARS-CoV-2 BCTs 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 BCTs may be held from 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 QFN SARS-CoV-2 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 up to 24 months.

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. The scientists in QIAGEN Technical Services are always happy to answer any questions you may have about either the information and/or protocols in this handbook or sample and assay technologies (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 BCTs can be used up to an altitude of 2650 feet (810 meters) above sea level. If using QFN SARS-CoV-2 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 SARS-CoV-2 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) at the time of blood collection.

Symbols

The following symbols may appear in the Instructions For Use or on the packaging and labeling:

Symbol	Symbol definition
	Contains reagents sufficient for <N> reactions
	Use by
IVD	In vitro diagnostic medical device
REF	Catalog number
LOT	Lot number
MAT	Material number (i.e., component labeling)
COMP	Components
CONT	Contains
NUM	Number
GTIN	Global Trade Item Number
Rn	R is for revision of the Instructions for Use and n is the revision number
	Temperature limitation
	Manufacturer

Symbol	Symbol definition
	Authorized representative
	Consult instructions for use
	Warning/caution

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 SARS-CoV-2 Blood Collection Tubes	Contains Nil, Ag1, Ag2, and Mitogen blood collection tubes	626725
Related products		
QuantiFERON SARS-CoV-2 ELISA	2-plate kit	626420

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

Revision	Description
R1, August 2021	Initial release
R2, November 2021	Updated Intended Use and Intended User sections
R3, November 2021	Updated Tube Colors in “Kit contents” section
R4, February 2022	Revised Materials but not Provided section to revise 500 µl to 1000 µl of calibrated pipette for delivery Updated Protocol: Blood Collection section to revise information about altitude range for direct draw into QFN SARS-CoV-2 BCTs Updated Stage 1: Blood collection and hold time options section to add instructions about mixing BCTs in step 3 Updated Stage 2: Post-incubation of BCTs and harvesting of plasma section to specify 24 months for plasma sample storage

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Limited License Agreement for QuantiFERON® SARS-CoV-2 Blood Collection Tubes

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