cobas

Rx Only

Roche Whole Blood Collection Tube

For in vitro diagnostic use

IVD

Roche Whole Blood Collection Tube P/N: 08827907001

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Intended use

The Roche Whole Blood Collection Tube is a direct draw whole blood collection tube. It is intended for the collection, transport, storage and lysis of whole blood and subsequent stabilization of DNA and RNA for use with the **cobas**® Babesia test and the **cobas**® Malaria test. It is used in settings where a venous blood sample is collected by a trained healthcare worker.

Materials for use

Roche Whole Blood Collection Tube

All unopened kits shall be stored as recommended in Table 1.

Table 1 Roche Whole Blood Collection Tube

Store at 2-25°C

Component	Additive ingredients	Safety symbol and warning*
Tube	Chaotropic reagent Guanidine HCl**	 **WARNING** H302: Harmful if swallowed. H315: Causes skin irritation. H319: Causes serious eye irritation. P264: Wash skin thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P280: Wear protective gloves/eye protection/face protection. P301 + P312 + P330: IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. Rinse mouth. P337 + P313: If eye irritation persists: Get medical advice/attention. P501: Dispose of contents/container to an approved waste disposal plant. 50-01-1 Guanidinium chloride

* Product safety labeling primarily follows EU GHS guidance

** Hazardous substance

Additional materials required (but not provided)

Table 2 Materials and consumables

Material
Disposable gloves
Personal protective equipment
Blood collection needles and multi-tube collection devices for 16 x 100 mm tubes
Alcohol swab for cleansing the venipuncture site
Tourniquet
Gauze pads
Bandage
Sharps disposal container

Precautions and handling requirements

Warnings and precautions

- For in vitro diagnostic use only.
- Do not use products after their expiration date.
- Avoid contact of reagents with skin, eyes or mucus membranes. In case of eye contact, rinse thoroughly with plenty of water for at least 15 minutes. In case of skin contact, wash off with soap and plenty of water.
- Treat all biological specimens and materials coming in contact with them as biohazards. Handle with proper caution and dispose of in accordance with the policies and procedures of your facility.
- Practice universal precautions. Use protective personal equipment and other engineering controls to protect from blood splatter, blood leakage and potential exposure to blood borne pathogens.
- Handle all biological samples and blood collection "sharps" (lancets, needles, luer adapters and blood collection sets) according to the policies and procedures of your facility.
- Use caution when handling to avoid dropping or breakage of the Roche Whole Blood Collection Tube. If the chaotropic reagent is spilled, **FIRST** clean with a suitable laboratory detergent and water, and then with 0.5% sodium hypochlorite.
- Do not use the Roche Whole Blood Collection Tube for collection of materials intended for injection.
- Do not use the Roche Whole Blood Collection Tube if the contents are cloudy or if foreign matter is present.
- Do not transfer a collection specimen into Roche Whole Blood Collection Tube using a needle and syringe. Additional manipulation of sharps increases the risk of injury.
- Check venipuncture collection system before use.
- Blood should be aspirated fully to avoid an incorrect reagent to blood ratio that could affect results.
- The quantity of blood drawn varies with altitude, ambient temperature, barometric pressure, tube age, venous pressure and filling technique.
- Ensure that collected specimens are packaged and labeled following all of the requirements for transportation of biohazardous materials.
- Safety Data Sheets (SDS) are available upon request from your local Roche office.
- Inform your local competent authority and manufacturer about any serious incidents which may occur when using this assay.

Good laboratory practice

- Always follow Good Laboratory Practices/Good Clinical Practices (GLP/GCP).
- Wear protective disposable gloves, coats, and eye protection when collecting and handling specimens. Wash hands thoroughly after handling specimens.

Specimen collection, transport and storage

Note: Handle all samples and controls as if they are capable of transmitting infectious agents.

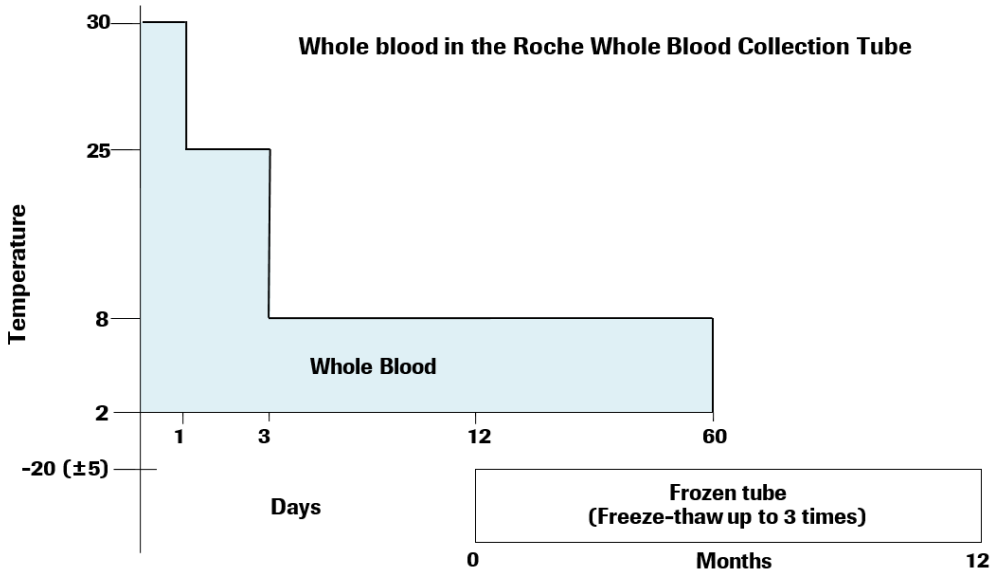
- Store all donor samples at specified temperatures.
- Sample stability is affected by elevated temperatures.
- Centrifuge samples at 1000 RCF (relative centrifugal force) for 2 minutes.

Prior to blood collection, the Roche Whole Blood Collection Tube is stable when stored between 2°C and 25°C. Whole blood collected in the Roche Whole Blood Collection Tube may be stored for up to 60 days with the following conditions:

- For storage above 8°C, samples may be stored for 72 hours at up to 25°C, and up to 30°C for 24 hours during the 72 hours.

Other than noted above, samples are stored at 2-8°C. In addition the Roche Whole Blood Collection Tube may be stored within the first 12 days after collection for up to 12 months at -20°C (± 5°C) with three freeze/thaw cycles. Refer to Figure 1.

Figure 1 Sample storage conditions for samples collected in the Roche Whole Blood Collection Tube



Transportation of collected specimens must comply with all applicable regulations for the transport of etiologic agents.[1]

Instructions for use

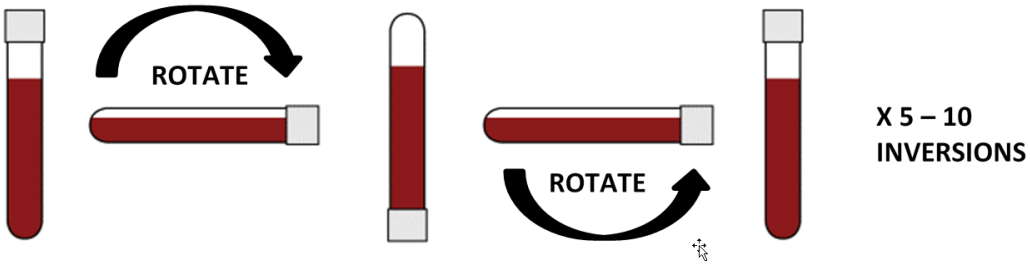
Procedural notes

- Do not use Roche Whole Blood Collection Tubes after their expiry dates.
- Roche Whole Blood Collection Tubes are for one-time use only.

Procedure

1. General guidelines for specimen collection can be found in Clinical and Laboratory Standards Institute (CLSI) H3-A6, Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture.[2]
2. Whole blood can be collected either directly from the vein using a winged blood collection set only or from a diversion collection bag using a collection line that prevents any backflow into the diversion collection bag.
3. Allow the Roche Whole Blood Collection Tube to come to room temperature prior to use.
4. Attach the Roche Whole Blood Collection Tube to the needle/tube holder and needle (not supplied with product) and perform phlebotomy. Blood will be aspirated up to the correct total volume and no further. Blood should be aspirated fully to avoid an incorrect additive to blood ratio that could affect results.
5. Because the Roche Whole Blood Collection Tube contains a chemical additive, it is important to avoid possible backflow. To prevent backflow during blood collection:
   a) Place the patient's arm in a downward position.
   b) Hold the tube in vertical orientation below donor's arm.
   c) Release the tourniquet as soon as blood begins to collect in tube.
   d) Ensure that tube additive does not touch stopper or end of needle.
6. If the Roche Whole Blood Collection Tube is the first tube drawn, it is recommended that a discard tube be used to fill the blood collection tubing's "dead space" with blood. This step will ensure the correct blood-additive ratio of the specimen.
7. Additional tubes should not be drawn with the same butterfly or winged blood collection set to ensure there is no cross-contamination from the needle and the chaotropic reagent to the additional tubes.
8. Remove the tube from the needle holder and immediately mix the whole blood and collection additive by gently inverting the tube 5 to 10 times (Figure 2). Do not shake or vortex. Vigorous mixing can cause foaming.

Figure 2 Tube inversion



Additional information

Symbols

The following symbols are used in labeling for Roche PCR diagnostic products.

Age/DOB — Age or Date of Birth

SW — Ancillary Software

Assigned Range [copies/mL] — Assigned Range (copies/mL)

Assigned Range [IU/mL] — Assigned Range (IU/mL)

EC REP — Authorized representative in the European Community

BARCODE — Barcode Data Sheet

LOT — Batch code

Biological risks

REF — Catalogue number

CE — CE marking of conformity; this device is in conformity with the applicable requirements for CE marking of an in vitro diagnostic medical device

Collect Date — Collect date

Consult instructions for use

Σ — Contains sufficient for <*n*> tests

CONTENT — Content of kit

CONTROL — Control

Date of manufacture

Device for near-patient testing

Device for self-testing

Device not for near-patient testing

Device not for self-testing

Distributor
(Note: The applicable country/region may be designated beneath the symbol)

Do not re-use

Female

For IVD performance evaluation only

GTIN — Global Trade Item Number

Importer

IVD — In vitro diagnostic medical device

LLR — Lower Limit of Assigned Range

Male

Manufacturer

CONTROL − — Negative control

NON STERILE — Non-sterile

Patient Name

Patient number

Peel here

CONTROL + — Positive control

QS copies / PCR — QS copies per PCR reaction, use the QS copies per PCR reaction in calculation of the results.

QS IU/PCR — QS IU per PCR reaction, use the QS International Units (IU) per PCR reaction in calculation of the results.

SN — Serial number

Site — Site

Procedure Standard — Standard Procedure

STERILE EO — Sterilized using ethylene oxide

Store in dark

Temperature limit

TDF — Test Definition File

This way up

Procedure UltraSensitive — Ultrasensitive Procedure

UDI — Unique Device Identifier

ULR — Upper Limit of Assigned Range

Urine Fill Line — Urine Fill Line

Rx Only — US Only: Federal law restricts this device to sale by or on the order of a physician.

Use-by date

Technical support

For technical support (assistance) please reach out to your local affiliate:
https://www.roche.com/about/business/roche_worldwide.htm

Manufacturer, importer, and distributor

Manufactured for:

Roche Molecular Systems, Inc.
1080 US Highway 202 South
Branchburg, NJ 08876 USA
www.roche.com

Made in Austria

EC Importer[1]

Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim, Germany

Distributed by

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(For Technical Assistance call the
Roche Response Center
toll-free: 1-800-526-1247)[2]

[1] Symbol text required by USA only.
[2] For USA only.

Trademarks and patents

See https://diagnostics.roche.com/us/en/about-us/patents

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Germany

References

1. International Air Transport Association. Dangerous Goods Regulations. 59th edition. 2018.
2. Clinical and Laboratory Standards Institute (CLSI). H3-A6, Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard-Sixth Edition. CLSI Document H3-A6:Wayne, PA;CLSI, 2007.

Document revision

Document Revision Information	
Doc Rev. 4.0 09/2023	Added the **cobas®** Malaria test to the intended use Updated **Warnings and Precautions** section Updated **Specimen Collection, Transport and Storage** section. Updated **Trademarks and patents section**, including the link. Please contact your local Roche Representative if you have any questions.