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 nucleic acid test for use on the **cobas**® 6800/8800 Systems (**cobas**® Babesia). 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

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

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.

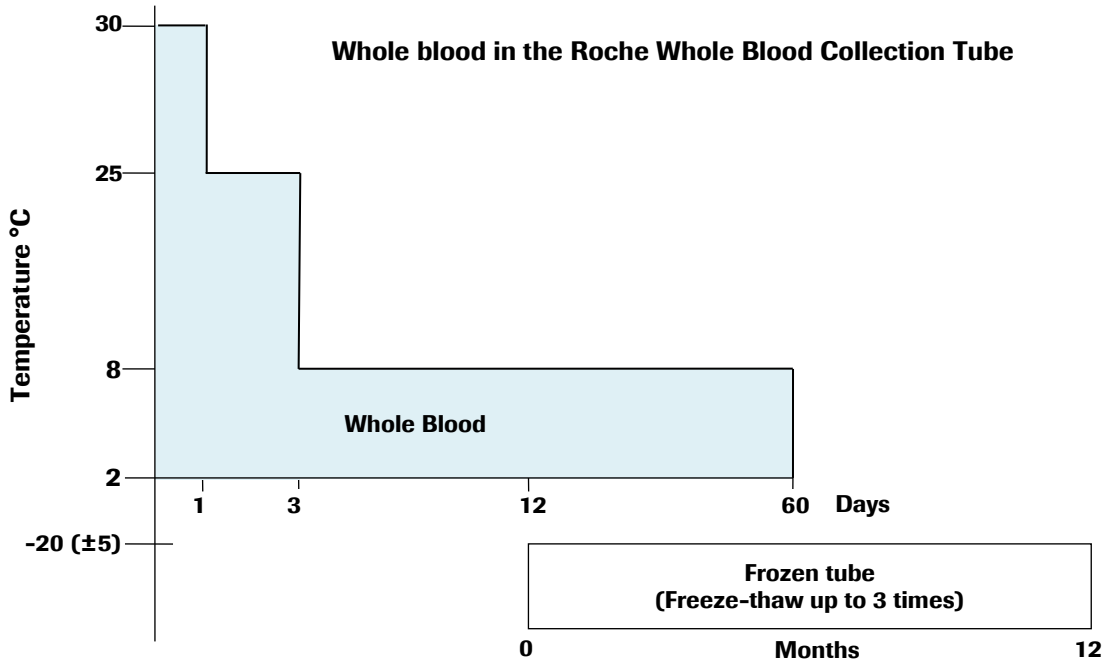
Specimen collection, transport and storage

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

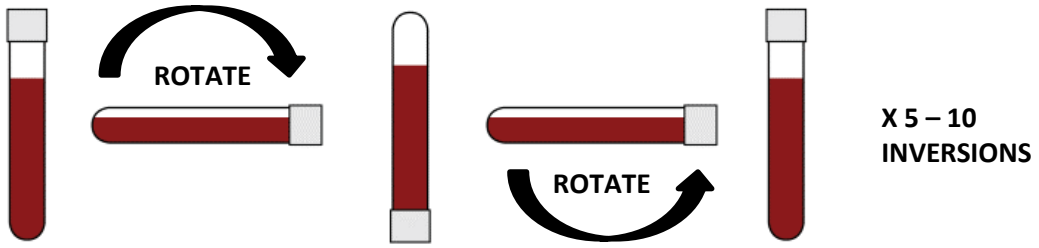
Procedural notes

- 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.

	Batch code		*In Vitro* diagnostic medical device
	Biological risks		Manufacturer
	Catalogue number		Contains sufficient for <*n*> tests
	Consult instructions for use		Temperature limit
	Contents of kit		Use-by date
	Distributed by		Global Trade Item Number
Rx Only	US Only: Federal law restricts this device to sale by or on the order of a physician.		Do not reuse
	Date of Manufacture		This product fulfills the requirements of the European Directive 98/79 EC for *in vitro* diagnostic medical devices.

US Customer Technical Support 1-800-526-1247

Manufacturer and distributors

Manufactured for:

Roche Molecular Systems, Inc.
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Branchburg, NJ 08876 USA
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Roche Response Center
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Trademarks and patents

See http://www.roche-diagnostics.us/patents

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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. 1.0 08/2019	First Publishing.
Doc Rev. 2.0 03/2020	Increased the storage to 12 months at -20°C in the **Sample collection, transport and storage** section. Please contact your local Roche Representative if you have any questions.