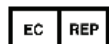


Cell-Free DNA Storage Tube Instructions for Use

Basic Information



Jiangsu CoWin Biotech Co., Ltd.
4F, Building TQB No.1, China Medicine City Avenue, Taizhou, Jiangsu,
China
Manufacturing address:
1F and 2F No. 58, 4F East Side of No. 59, West Side of Koutai Road,
China Medicine City, Taizhou City, Jiangsu Province, China
Post code: 225300
Tel: +86-523-86201352 Fax: +86-523-86816890
Website: www.cwbiosciences.com
After-sales service Tel: +86-10-56953015
E-mail: info@cwbio.com



CMC Medical Devices & Drugs S.L
Address: C/Horacio Lengo N° 18 CP 29006, Málaga-Spain
Tel: +34 951 214054 Email: info@cmcmedicaldevices.com

Packaging Specifications

5mL tube, 50 tubes/box
10mL tube, 50 tubes/box

Intended Use

Cell-Free DNA Storage Tube is a direct draw whole blood collection tube intended for collection, transport and storage of blood samples. This device also stabilizes and preserves Cell-Free DNA in whole blood.

Cell-Free DNA (cfDNA) is a DNA fragment derived from apoptosis or necrosis, free from extracellular cells, and is widely found in human serum, plasma, cerebrospinal fluid, urine, or saliva. Currently, cfDNA has been used as a new biomarker in clinical areas of prenatal diagnosis, tumor detection, post-organ transplant rejection, and infection detection.

The Cell-Free DNA Storage Tube is intended for use by qualified clinical personnel *in vitro* diagnostic procedures.

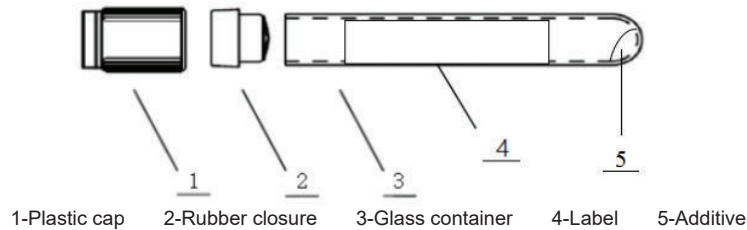
Principle

Cell-Free DNA Storage Tube is a single use, direct-draw blood collection tube. The nominal liquid capacity is a 5/10mL, each tube has a fill indicator. The reagent composition includes an anticoagulant EDTA•K₂•2H₂O and a preservative.

The preservative reagent contained in Cell-Free DNA Storage Tube stabilizes nucleated blood cells, preventing the release of cellular genomic DNA, and inhibits nuclease mediated degradation of cfDNA, contributing to the overall stabilization of cfDNA. Samples collected in Cell-Free DNA Storage Tube stabilizes Cell-Free DNA for up to 14 days at temperatures between 6-37°C, allowing convenient sample collection, transport and storage.

Main Structure

Cell-Free DNA Storage Tube consists of glass container, rubber closure, plastic cap, additive reagent, label.



Contraindications

This product is not suitable for people with jaundice and hyperlipidemia.

Materials and Equipment Required but Not Provided

Blood collection needle, needle holder

Storage Condition and Shelf Life

Manufacturing and expiration dates are printed on the label.

Cell-Free DNA Storage Tube can be stored at 2-35°C for 18 months before use, and can be transported at 2-35°C for a long time.

Blood samples collected are stable for up to 14 days at temperatures between 6-37°C.

Note: Beyond the recommended storage temperature range may damage the quality of Cell-Free DNA Storage Tube (e. g., vacuum loss, liquid additive drying, discoloration, etc.).



GHS05



GHS06



GHS07



GHS08

H370 Causes damage to organs via dermal, oral, and respiratory routes.

H350 May cause cancer

H341 Suspected of causing genetic defects

H317 May cause an allergic skin reaction

H314 Causes severe skin burns and eye damage

H318 Causes serious eye irritation

H311 Toxic in contact with skin

H331 Toxic if inhaled

H301 Toxic if swallowed

Glossary of Symbols

Symbol	Meaning	Symbol	Meaning
	In vitro diagnostic medical device		Temperature limit
	Manufacturer		Use-by date
	Date of Manufacture		Do not re-use
	Batch code		Consult instructions for use
	Authorized representative in the European Community / European Union		CE Symbol
	Caution		Unique device identifier
	Catalogue number		Do not use if package is damaged and consult instructions for use
	Fragile, hand with care		Keep Dry

8. All glass has a potential risk of rupture. The Cell-Free DNA Storage Tube should be checked for damage before use and treated with corresponding preventive treatment;
9. All biological hazard specimens and blood sampling "sharp device" (such as blood sampling needle, syringe needle, etc.) should be handled in accordance with the regulations and procedures of the product. Improper treatment may cause biological risks (e. g., when accidental stabbing, it may lead to infection of viral hepatitis, HIV virus or other infectious diseases);
10. It is not recommended to use syringe blood sampling and transfer collected blood samples into Cell-Free DNA Storage Tube. If necessary, operate after removing the syringe needle and rubber closure, so as not to cause rubber closure ejection, blood splash, or hemolysis;
11. If the blood sample is collected by intravenous injection, it should be confirmed that the solution in the pipeline has been thoroughly removed prior to avoid erroneous experimental results due to contamination of the in-tube solution;
12. Too large or too small blood collection can lead to an incorrect ratio of additives to blood, which may lead to incorrect analysis results;
13. Product use should carefully identify the applicable altitude area of the product, and mixing with storage tubes at different elevations will lead to insufficient or excessive blood suction.

Warnings

1. Do not use Cell-Free DNA Storage Tube when it is damaged, has foreign impurities, abnormal color of additives and exceeds the validity period.
2. Keeping glass free DNA tubes with blood at less than 0oC may cause tube rupture;
3. Do not centrifuge tube over 3000g Relative centrifugal force in order to avoid prevent tube breakage. Do not take the centrifugal broken tubes directly by hand.
4. Do not use tubes after expiration date.
5. Do not use tubes for collection of materials to be injected into patients.
6. Do not use tubes for any purpose other than cell-free DNA collection and storage.
7. Do not freeze the plasma directly in the original plasma tubes after centrifugation, avoiding contaminate the plasma with erythroid cells.
8. Do not open Cell-Free DNA Storage Tube for a long time which will causes water evaporation, resulting in the wrong analysis results. So please pay attention to seal the cover in time.
9. This product is glass, fragile, pay attention to take certain protection measures when operation and transportation.

Detection Methods

Read the following completely before performing a venipuncture:

1. Prepare before blood collection - Wear masks, gloves and other necessary personal protective equipment;
2. Prepare before blood collection - Disinfectant, dry disinfection cotton swabs, tourniquet, Cell-Free DNA Storage Tube, blood collection needle, etc. ;
Reconfirm - The specifications, draw volume and additives, and mark the patient information on the label if necessary;
Prevention of backflow - Cell-Free DNA Storage Tube contains chemical additives, it's necessary to prevent backflow. The following measures can be taken to prevent backflow.
 - (1) Choose the blood collection needle with the anti-reverse flow device;
 - (2) Keep the patient's arm in the downward position;
 - (3) Keep the tube cap part head up during blood collection;
 - (4) Release the tourniquet immediately when the blood begins to enter the storage tube.
- Blood collection operation procedure:
 5. (1) When blood collection is performed with a soft-connected blood collection needle:
 - ① Put the tourniquet on the patient, disinfect the collection site with disinfectant and ensuring that the skin area is in contact with the disinfectant for at least 30 seconds. (DO NOT touch the collection site once the skin has been disinfected).
 - ② Rip the small bag of the blood collection needle, remove the needle and remove the plastic cover of venipuncture needle. The recommended length of the hose for blood collection needle is 16-25mm, and the pipe capacity is 0.25-0.35mL.
 - ③ After the disinfectant naturally dries out, perform the venipuncture, when the blood flow is established indicates that the venipuncture is successful.
 - ④ Pierce the plug needle vertically through the rubber closure, release the tourniquet after the blood begins to enter Cell-Free DNA Storage Tube .
 - ⑤ Wait for the vacuum of blood collection tube to be exhausted and blood flow to stop, then pull out the blood collection tube from the needle holder/blood collection needle to ensure sufficient blood collection and the correct ratio of blood to additives. If multi-tube collection is required, continue blood collection according to the international standards.

⑥ After blood collection, mix by gently reversion 180 degrees 10 times immediately, so that the additive and blood samples are fully mixed. Place the test tube vertically in time.

⑦ Pull the last blood collection tube out of the blood collection needle/needle holder, withdraw the needle gently and apply gentle pressure to the site with a dry disinfection cotton swab. Ask the patient to hold the cotton swab in place, with the arm extended and raised. Ask the patient NOT to bend the arm, because doing so causes a haematoma.

⑧ Discard the used blood collection needles in medical waste collectors and do not reuse.

⑨ After collection, transport and store tubes within the recommended temperature range. And send it to the testing lab in time.

(2) When blood collection is conducted with a pen type blood collection needle:

① Unscrew the protective cover at the end of tube plug puncture needle.

② Screw the pipe plug puncture needle into the needle holder and tighten it;

③ Put the tourniquet on the patient, disinfect the collection site with disinfectant and ensuring that the skin area is in contact with the disinfectant for at least 30 seconds. (DO NOT touch the collection site once the skin has been disinfected).

④ After the disinfectant naturally dries out, let the patient's arm droop, remove the blood collection needle vein puncture needle sheath, and puncture;

⑤ Cover the tail of the test tube with the thumb and push it into the needle holder, make the blood collection needle penetrate the glue plug (keep the needle pipe penetrating from the center of the glue plug as much as possible), release the tourniquet when seeing the blood flowing into the tube;

⑥ Wait for the vacuum of blood collection tube to be exhausted and blood flow to stop, then pull out the blood collection tube from the needle holder/blood collection needle to ensure sufficient blood collection and the correct ratio of blood to additives.

⑦ After blood collection, mix by gently reversion 180 degrees 10 times immediately, so that the additive and blood samples are fully mixed. Place the test tube vertically in time.

⑧ Pull the last blood collection tube out of the blood collection needle/needle holder, withdraw the needle gently and apply gentle pressure to the site with a dry disinfection cotton swab. Ask the patient to hold the cotton swab in place, with the arm extended and raised. Ask the patient NOT to bend the arm, because doing so causes a haematoma.

⑨ Discard the used blood collection needles in medical waste collectors and do not reuse.

⑩ After collection, transport and store tubes within the recommended temperature range. And send it to the testing lab in time.

6. Cell-Free DNA extraction

(1) Plasma separation: Centrifuge cell-free DNA storage tube at 1,500×g for 10 minutes, carefully transfer the upper plasma into a new centrifugal tube, and do not to absorb the leukocytes in the middle layer. Then centrifuge the plasma at 15,000×g for 10 minutes and transfer plasma into a new centrifuge tube.

(2) Cell-Free DNA extraction: The separated plasma can be used for the extraction of cell-free DNA using commercial related kits.

Limitations of the Test

1. The amount of blood collection is affected by altitude, environmental temperature, atmospheric pressure, production time, venous pressure, blood collection technology and other factors. Under different conditions, the amount of blood collected by the same Cell-Free DNA Storage Tube will vary.
2. The blood collection speed of Cell-Free DNA Storage Tube also varies with draw volume. Under the condition of the same volume of Cell-Free DNA Storage Tube , the blood collection speed is faster with the larger draw volume; Blood cells after centrifugation are still being metabolized, changing not only the
3. blood cells themselves, but also the concentration of analytes in the plasma after centrifugation, thus requiring timely detection, which may otherwise lead to incorrect detection results.

Precautions

1. For *in vitro* diagnostic use (IVD) only.
2. This product is intended for professional use only.
3. Check the package before use it. If damaged, it is strictly prohibited to use.
4. Avoid reuse.
5. Product is intended for use as supplied. Do not dilute or add other components to Cell-Free DNA Storage Tube.
6. Safety Data Sheet (SDS) can be obtained by contacting manufacturer.
7. Wear gloves, masks and other personal protective equipment when collecting and handling blood samples to avoid blood spillage, leakage and exposure to potential pathogens. Counter-current needle shall be used in blood collection, and all used "sharp instruments" (such as blood collection needle, syringe needle, etc.) shall be discarded in the designated medical collection container according to regulations;