

Instruction for Use

[Product name] Blood Collection Tube

[Model] Vacuum Tube

[Packaging specifications] EDTA-K3 Tube, No additives Tube, SST Tube, Lithium Heparin Tube, Gel+Heparin Lithium Tube, PT Tube, ESR Tube, Glucose Tube, EDTA-K2 Tube, Clot Activator Tube, NaF+EDTA-K2 Tube, Sodium fluoride Tube, Sodium Heparin Tube, Gel+Sodium Heparin Tube, Sodium Citrate Tube, Gel+ Sodium Citrate Tube, ACD+Gel Tube, Imidazole Alkyl Urea/Glycine/EDTA-K3 Tube, see packaging for details

Intended use The device is intended for the collection, transportation and storage of human blood samples (whole blood, serum and plasma). This device is used together with disposable venous blood collection needles to collect venous blood samples.

[Product structure performance] This product is composed of test tube, butyl rubber stopper, safety head cover (if any), additives (if any) and add-ons (if any). After pre-vacuum treatment, it can achieve automatic quantification.

[Principle of Inspection]

One end of the vacuum sampling needle is inserted into the blood vessel of the human body with different vacuum degree, and the other end of the vacuum sampling needle is inserted into the Blood Collection Tube to collect blood automatically. Human venous blood is inside the Blood Collection Tube. Under the action of negative pressure, it is pumped into the blood sample container through the blood collection needle. Under one venipuncture, multi tube collection can be realized without leakage. The volume of the lumen connecting the blood collection needle is very small, and the impact on the blood collection volume can be ignored, but the probability of countercurrent is relatively small. For example, the volume of the lumen is relatively large, which will consume part of the vacuum degree of the blood collection vessel, so as to reduce the collection volume.

[Product storage conditions] This product is Storage at room temperature

[Production date] See product label.

[Validity Period] The validity period of glass tube vacuum blood collection tube is 2 years, and the validity period of PET tube vacuum blood collection tube is 1 year.

[Instructions]

- 1. Determine the type of blood collection tube and venous blood collection needle according to needs, and routinely disinfect the puncture area of the blood collection tube plug.
- 2. Use a blood sampling needle for routine venipuncture. After seeing the blood return, puncture the tube plug with the puncture needle, and the blood can flow in automatically.
- 3. When the blood reaches the nominal filling mark, immediately pull out the tube plug puncture needle (if multiple blood tubes are needed, just pierce the tube plug puncture needle into other certain blood collection tubes), after the blood collection is completed, pull out the tube plug puncture needle Venous puncture needle, local compression to stop bleeding.

File No.: IFU-02-01 Revision: 00 Effective date: 2022.01.16 Page 1 of 3



Instruction for Use

- 4. When blood collection tubes containing additives are used for blood collection, the blood should be gently shaken or mixed upside down after blood collection to ensure that the coagulant or anticoagulant is evenly distributed in the specimen.
- 5. After the blood collection is completed, send it for inspection in time. If the measurement cannot be completed in time, store the specimen at the specified temperature.

[Cautions]

- 1. This product should be used in conjunction with a soft-connected venous blood collection needle. When blood collection is finished, the vacuum blood collection tube should be pulled out first, and then the tourniquet should be loosened before removing the venipuncture needle to avoid blood reflux to the greatest extent.
- 2. During the blood collection process, make the plug end of the vacuum blood collection tube upward to prevent the part of the venous blood collection needle extending into the blood collection tube from contacting the taken blood to form a connected state, so as to avoid blood backflow.
- 3. If this product is used in a high-altitude area (>101KPa), please use the vacuum blood collection tube with the nominal "high-altitude use".
- 4. This product is for one-time use, please destroy it according to regulations after use.
- 5. It is forbidden to use the blood collection tube such as broken tube, loose tube plug or misalignment.

[Symbol] Temperature limit Manufacturer Authorised Representative in the CE mark EC REP European community Batch code **Importer** In vitro diagnostic Date of manufacture medical device Consult instructions Use by for use

File No.: IFU-02-01 Revision: 00 Effective date: 2022.01.16 Page 2 of 3



Instruction for Use



Caution



Keep dry



Do not reuse



Keep away from sunlight



Do not use if package is damaged



Fragile, handle with care



Biological risks



Keep upright during transport



Sterilized using irradiation



Anhui Sinic Laboratory Medicine Technology Co., Ltd.

No.2,Dongyi North Road, Economic & Technology Zone,231400 Tongcheng, Anhui, PEOPLE'S RUPUBLIC OF CHINA



MedPath GmbH

Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

File No.: IFU-02-01 Revision: 00 Effective date: 2022.01.16 Page 3 of 3