

INSTRUCTION FOR USE

Single-use Containers For Human Capillary Blood Specimen Collection

1. Intended use

As a capillary blood collection system, this terminal blood collection tube is used in conjunction with terminal blood collection needles (e.g., fingertip blood collection needles, heel blood collection needles) to collect, store, transport, and pre-treat terminal blood samples for serum, plasma, or whole blood testing in clinical laboratories.

(1) Intended users: medical professionals, including doctors, nurses, test technicians, etc.

(2) Intended use environment: medical institutions (e.g. hospitals, outpatient clinics, laboratories), primary health care institutions (e.g. community health service centers, township health centers), on-site screening sites (e.g. medical checkup centers, mobile screening vans), and other professionally trained blood collection sites.

(3) Intended patient population:

① Age group: unlimited, including newborns, infants, children, adolescents, adults and the elderly;

② Weight range: all;

③ Health: all, especially for patients who have difficulty in venous blood collection, need to be monitored several times, or only need a trace amount of blood samples;

(4) And its interactions with the body parts or tissue types:

① The product is an in vitro diagnostic medical device;

② By the end of the blood collection needles with the through the end of the blood collection needle and the patient fingertip, heel or other suitable end site of the skin and subcutaneous capillaries contact, obtaining a micro-volume of blood; Peripheral blood collection tube itself does not directly contact the patient's deep tissues;

(5) Clinical Benefits:

① Utilizing vacuum or capillary principles, it achieves automatic and quantitative collection of micro blood samples, with simple operation, safety, and reliability;

② Facilitate the transportation, short-term storage, and pre-treatment of micro blood samples before detection;

③ It facilitates the observation, identification, and subsequent laboratory testing of blood samples, reduces patient pain, and improves blood collection efficiency and comfort.

2. Product description

Single-use Containers For Human Capillary Blood Specimen Collection are mainly used for the collection, transportation and storage of human peripheral blood samples, which are widely used in the fields of clinical examination, physical examination and scientific research. This product is composed of a tube, additives (if applicable), supplements (if applicable), caps (if applicable), rubber stoppers (if applicable), and labels. Among these, the additive-free model contains neither additives nor supplements. The separating gel model contains only supplements, while the clot activator/separating gel and heparin lithium/separating gel models contain both additives and supplements. All other models contain only additives. Type A products are equipped with caps and rubber stoppers, Type B products with caps, and Type C products with rubber stoppers. The product is available in sterile and non-sterile forms, with sterile products undergoing irradiation sterilization.

The biological, chemical and physical properties of the products meet the requirements of the product standards.

The product is irradiation-sterilized and is a sterile product.

The product is an in vitro diagnostic medical device;

This product is a Class A sterile medical device, not implantable.

Basic UDI-DI: 6954152720250AsJMSRQEL、6954152720251AsJMSRQF7、
6954152720252AsJMSRQFS.

The full UDI-DI record is available in the EUDAMED database.

CE Marking: CE 0123 – Conformity assessed under MDR by Notified Body TÜV SÜD Product
Service GmbH Certification Body.

Type and Specifications

No.	Model	Type	Specifications
1	No Additives	Type A	0.1mL, 0.2mL, 0.25mL, 0.3mL, 0.4mL, 0.5mL, 0.6mL, 0.7mL, 0.8mL, 0.9mL, 1mL
		Type B	0.1mL, 0.2mL, 0.25mL, 0.3mL, 0.4mL, 0.5mL
		Type C	0.1mL, 0.2mL, 0.25mL, 0.3mL, 0.4mL, 0.5mL
2	Gel	Type A	0.1mL, 0.2mL, 0.25mL, 0.3mL, 0.4mL, 0.5mL, 0.6mL, 0.7mL, 0.8mL, 0.9mL, 1mL
		Type B	0.1mL, 0.2mL, 0.25mL, 0.3mL, 0.4mL, 0.5mL
		Type C	0.1mL, 0.2mL, 0.25mL, 0.3mL, 0.4mL, 0.5mL
3	Clot activator	Type A	0.1mL, 0.2mL, 0.25mL, 0.3mL, 0.4mL, 0.5mL, 0.6mL, 0.7mL, 0.8mL, 0.9mL, 1mL
		Type B	0.1mL, 0.2mL, 0.25mL, 0.3mL, 0.4mL, 0.5mL
		Type C	0.1mL, 0.2mL, 0.25mL, 0.3mL, 0.4mL, 0.5mL
4	Clot activator/Gel	Type A	0.1mL, 0.2mL, 0.25mL, 0.3mL, 0.4mL, 0.5mL, 0.6mL, 0.7mL, 0.8mL, 0.9mL, 1mL
		Type B	0.1mL, 0.2mL, 0.25mL, 0.3mL, 0.4mL, 0.5mL
		Type C	0.1mL, 0.2mL, 0.25mL, 0.3mL, 0.4mL, 0.5mL

5	EDTAK2	Type A	0.1mL, 0.2mL, 0.25mL, 0.3mL, 0.4mL, 0.5mL, 0.6mL, 0.7mL, 0.8mL, 0.9mL, 1mL
		Type B	0.1mL, 0.2mL, 0.25mL, 0.3mL, 0.4mL, 0.5mL
6	EDTAK3	Type A	0.1mL, 0.2mL, 0.25mL, 0.3mL, 0.4mL, 0.5mL, 0.6mL, 0.7mL, 0.8mL, 0.9mL, 1mL
		Type B	0.1mL, 0.2mL, 0.25mL, 0.3mL, 0.4mL, 0.5mL
		Type C	0.1mL, 0.2mL, 0.25mL, 0.3mL, 0.4mL, 0.5mL
7	Lithium heparin	Type A	0.1mL, 0.2mL, 0.25mL, 0.3mL, 0.4mL, 0.5mL, 0.6mL, 0.7mL, 0.8mL, 0.9mL, 1mL
		Type B	0.1mL, 0.2mL, 0.25mL, 0.3mL, 0.4mL, 0.5mL
		Type C	0.1mL, 0.2mL, 0.25mL, 0.3mL, 0.4mL, 0.5mL
8	Lithium heparin/Gel	Type B	0.1mL, 0.2mL, 0.25mL, 0.3mL, 0.4mL, 0.5mL
		Type C	0.1mL, 0.2mL, 0.25mL, 0.3mL, 0.4mL, 0.5mL
9	Sodium heparin	Type A	0.1mL, 0.2mL, 0.25mL, 0.3mL, 0.4mL, 0.5mL, 0.6mL, 0.7mL, 0.8mL, 0.9mL, 1mL
		Type B	0.1mL, 0.2mL, 0.25mL, 0.3mL, 0.4mL, 0.5mL
		Type C	0.1mL, 0.2mL, 0.25mL, 0.3mL, 0.4mL, 0.5mL

3. Instructions for use

Operation steps of Single-use Containers For Human Capillary Blood Specimen Collection:

(1) Prepare blood collection supplies, wash hands and wear masks, protective clothing, gloves and other necessary personal protective equipment, reconfirm the specifications, blood collection volume

and additives of the collection container, and mark the patient's information on the label if necessary to confirm whether the product is intact, such as whether there is any damage; Let the patient sit down or lie down to prepare for blood collection.

(2) Select an appropriate blood collection site, clean and disinfect the blood collection site with 75% alcohol, and then dry it naturally.

(3) After selecting an appropriate blood collector for puncture, collect the required volume of blood according to the scale mark on the tube or label, immediately cover the lid and shake it well according to the recommended mixing times, so that the sample and the additives in the tube are fully mixed.

(4) When multi-tube collection is required, change the tubes in sequence according to the recommended blood collection sequence.

(5) After blood collection, press the puncture site with sterile gauze until the bleeding stops.

(6) Do a good job in marking wells and send them for inspection within the specified time.

(7) The collection container used to extract serum as a sample should ensure that the clotting time is more than 30 minutes after blood collection.

(9) All used blood sampling materials (such as blood sampling devices and used sterilized gauze, etc.) should be discarded in appropriate containers and disposed of in accordance with the Regulations on Medical Waste Management and other regulations.

4. Contraindications

None

5. Precautions and warnings

(1) It is forbidden to collect blood samples by scraping the skin surface.

(2) Directly squeezing the skin puncture site will cause hemolysis and affect the accuracy of the test results.

(3) When using a microscope to examine blood smears, it is recommended to make slides directly at the puncture site.

(4) In order to ensure more accurate test results, rapid collection and mixing are the keys to success. Because blood coagulation will be triggered immediately after skin puncture, this is also the biggest obstacle encountered in collecting qualified specimens. If the specimen collection time exceeds 2 minutes, the quality of the specimen will often be reduced, and the probability of microcoagulation in tubes containing anticoagulant additives will be higher.

(5) Blood should be collected to the position marked on the tube to ensure the best blood-additive ratio. Too much or too little blood collection may lead to coagulation or wrong analysis results.

(6) EDTA containers used for hematological examination must be tested within 4 hours after sample collection.

(7) When it is found that the collection container is damaged, contains impurities and foreign bodies, and has exceeded the service life, it is forbidden to use it.

(8) It can only be used by professional medical staff. It can be used once and destroyed after use. The waste shall be disposed of in accordance with the Regulations on the Management of Medical Waste and other regulations.

(9) Medical staff should wear gloves, protective clothing, protective eye masks and other personal protective equipment during blood collection, blood analysis and blood transfer to avoid blood

sample spilling, leakage and exposure to potential pathogens.

(10) Since some collection containers contain chemical additives, the collection container should always be kept lower than the blood collection site during the collection of peripheral blood samples to prevent blood from flowing back from the collection container and causing adverse reactions to patients.

(11) If the blood collection volume of the anticoagulation collection container is too large or too small, the ratio of additives to blood will not meet the requirements, which may lead to wrong analysis results.

(12) When the collection container containing separation gel additives, repeated centrifugation should be avoided as much as possible, otherwise the detection results of some analytes may be changed.

(13) Serum or plasma must be separated within two hours after blood collection, otherwise it may lead to wrong test results.

(14) It is not recommended to freeze serum or plasma directly in the original serum tube or plasma tube after centrifugation. In this way, when freezing and then thawing, the spacing of the separation gel may be destroyed, resulting in the serum or plasma being contaminated by red blood cells.

(15) Long-term storage of the collection container with open lid will lead to the loss of carbon dioxide in the blood sample, resulting in wrong analysis results. Therefore, please pay attention to sealing the lid in time and sending it for inspection.

(16) The isolated blood cells are still undergoing metabolism and intrinsic natural degradation of cells, which can continue to affect the concentration/activity of serum/plasma analytes after centrifugation (whether centrifuged or not, and whether separation gel exists or not). The stability of analytes should be evaluated according to the stored container and each laboratory condition. Therefore, all isolated blood samples need to be tested in time, otherwise it may lead to wrong test results.

(17) It is not recommended to separate the hose for some immunohematology tests, which can be used for some TDM tests.

(18) Do not use a collection container containing lithium heparin for lithium ion determination.

(19) It is recommended to use a blood collector with a larger puncture surface with this product.

6. Storage, transportation and maintain

This product should be stored in a dry, well-ventilated, free of corrosive gases, and clean environment with a temperature of 0 °C ~ 40 °C. If the temperature is higher than the specified temperature, it may cause quality problems such as evaporation of the liquid additive in the collection container, drying and discoloration of the liquid additive, and shrinkage and deformation of the collection container.

This product should be protected from heavy pressure, direct sunlight and rain and snow during transportation.

Drawing	Meaning
	"CE mark"

	"Keep dry"
	"The limit of the number of stacking layers"
	"DO NOT REUSE", "single use", "Use only once"
SIZE	"Specifications"
MATERIAL	"Material quality "
PIECES	"Quantity"
REF	"Identification of product"
	"This face up"
	"Temperature limitation "
	"Keep away from sunlight"
	"Fragile,handle with care"
	"Expiry date"
	"DATE OF MANUFACTURE"
	"MANUFACTURER"
LOT	"BATCH CODE"

STERILE	"STERILE "
STERILE R	"STERILE " irradiation sterilization
IVD	"In vitro diagnos-tic medical devices"
EU REP	"Authorized representative in the European Community"

7.Expiry Date

The expiry date is 24 months for PP tubes.

8. Handling of Adverse Events

In the event of a serious incident (e.g., needle breakage, sterility breach, patient injury), Report immediately to Email: zhzbj@kdlchina.com;

National Competent Authority: Use the EU portal: <https://www.adrreports.eu>;

Provide: device name, UDI, batch number, description of incident, and patient outcome.



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