Guangdong Kindly
Medical Device Group Co.,Ltd.

INSTRUCTION FOR USE

Single-use Containers For Human Venous Blood Specimen Collection

1. Intended use

As a venous blood collection system, a disposable human venous blood collection container is used with blood collection needle and needle holder for the collection, storage, transport and pretreatment of blood samples for venous serum, plasma or whole blood testing in clinical laboratory.

1) Intended users: Medical professionals, including doctors, nurses, etc.

2) Intended use environment: The device is mainly used in medical institutions.

3) Intended patient population:

① Age group: unlimited, including newborns to the elderly;

② Weight range: all;

③ Health: all;

4) The body part or type of tissue with which it interacts:

①The product is an in vitro diagnostic medical device;

②Used in conjunction with blood collection needles without direct contact with patient body tissue sites;

5) Clinical benefit:

①Utilizing vacuum principle to realize automatic collection of venous blood samples, safe and reliable;

②Convenient for the transit and short-term storage of blood samples before testing;

③Convenient for observation and identification of blood samples and test operation.

2. Product description

Single-use Containers For Human Venous Blood Specimen Collection consists of tube, piston, tube cap, and additives; for products containing additives, additives should conform to the requirements of relevant laws and regulations. A certain amount of negative pressure is maintained in the blood collection tubes; therefore, while using with the disposable venous blood collection needles, it can be used to collect the venous blood by the principle of negative pressure.

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: 6954152720230AsJCXGQ3、6954152720231AsJCXGQL、6954152720232AsJCXGR5.

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

Type	Specifications
No Additives	1mL, 2mL, 3mL, 4mL, 4.5mL, 5mL, 6mL, 7mL, 8mL, 9mL, 9.5mL, 10mL
Clot activator	1mL, 2mL, 3mL, 3.5mL, 4mL, 4.5mL, 5mL, 6mL, 7mL, 8mL, 8.5mL, 9mL, 10mL
Clot activator / Separating Gel	2mL, 3mL, 3.5mL, 4mL, 5mL, 6mL, 7mL, 8mL, 8.5mL, 9mL, 10mL
Sodium fluoride / Sodium heparin	1mL, 1.5mL, 2mL, 2.5mL, 3mL, 3.5mL, 4mL, 4.5mL, 5mL, 5.5mL, 6mL
K2-EDTA	1mL, 1.5mL, 2mL, 2.5mL, 3mL, 3.5mL, 4mL, 4.5mL, 5mL, 5.5mL, 6mL, 6.5mL, 7mL, 8mL, 8.5mL, 9mL, 10mL
K3-EDTA	1mL, 1.5mL, 2mL, 2.5mL, 3mL, 3.5mL, 4mL, 4.5mL, 5mL, 5.5mL, 6mL, 6.5mL, 7mL, 7.5mL, 8mL, 9mL, 10mL
Trisodium citrate 9:1	1mL, 2mL, 3mL, 4mL, 5mL, 6mL, 7mL, 8mL, 9mL, 10mL
Trisodium citrate 4:1	1mL, 1.6mL, 2mL, 3mL, 4mL, 5mL
Sodium heparin	0.5mL, 1mL, 1.5mL, 2mL, 2.5mL, 3mL, 3.5mL, 4mL, 4.5mL, 5mL, 5.5mL, 6mL, 6.5mL, 7mL, 7.5mL, 8mL, 8.5mL, 9mL, 9.5mL, 10mL
Lithium heparin	0.5mL, 1mL, 1.5mL, 2mL, 2.5mL, 3mL, 3.5mL, 4mL, 4.5mL, 5mL, 5.5mL, 6mL, 6.5mL, 7mL, 7.5mL, 8mL, 8.5mL, 9mL, 9.5mL, 10mL
K2-EDTA/Separating Gel	0.5mL, 1mL, 1.5mL, 2mL, 2.5mL, 3mL, 3.5mL, 4mL, 4.5mL, 5mL, 5.5mL, 6mL, 6.5mL, 7mL, 7.5mL, 8mL, 8.5mL, 9mL, 9.5mL, 10mL
ACD-A	2mL, 3mL, 4mL, 5mL, 6mL, 8mL, 8.5mL, 9mL
ACD-B	2mL, 3mL, 4mL, 5mL, 6mL, 8mL, 8.5mL, 9mL
Lithium heparin / Separating Gel	1mL, 1.5mL, 2mL, 2.5mL, 3mL, 3.5mL, 4mL, 4.5mL, 5mL, 5.5mL, 6mL, 6.5mL, 7mL, 7.5mL, 8mL, 8.5mL, 9mL, 9.5mL, 10mL
Trisodium citrate/Separating Gel	2mL, 2.5mL, 3mL, 3.5mL, 4mL, 4.5mL, 5mL, 5.5mL, 6mL, 6.5mL, 7mL, 7.5mL, 8mL
K3-EDTA/Separating Gel	0.5mL, 1mL, 1.5mL, 2mL, 2.5mL, 3mL, 3.5mL, 4mL, 4.5mL, 5mL, 5.5mL, 6mL, 6.5mL, 7mL, 7.5mL, 8mL, 8.5mL, 9mL, 9.5mL, 10mL
Na2-EDTA	1mL, 1.5mL, 2mL, 2.5mL, 3mL, 3.5mL, 4mL, 4.5mL, 5mL, 5.5mL, 6mL, 6.5mL, 7mL
Sodium heparin / Separating Gel	1mL, 1.5mL, 2mL, 2.5mL, 3mL, 3.5mL, 4mL, 4.5mL, 5mL, 5.5mL, 6mL, 6.5mL, 7mL, 7.5mL, 8mL, 8.5mL, 9mL, 9.5mL, 10mL

Sodium fluoride / Lithium heparin	1mL, 1.5mL, 2mL, 2.5mL, 3mL, 3.5mL, 4mL, 4.5mL, 5mL, 5.5mL, 6mL
Sodium fluoride / potassium oxalate	1mL, 1.5mL, 2mL, 2.5mL, 3mL, 3.5mL, 4mL, 4.5mL, 5mL, 5.5mL, 6mL
Sodium fluoride / K2-EDTA	1mL, 1.5mL, 2mL, 2.5mL, 3mL, 3.5mL, 4mL, 4.5mL, 5mL, 5.5mL, 6mL
Sodium fluoride / K3-EDTA	1mL, 1.5mL, 2mL, 2.5mL, 3mL, 3.5mL, 4mL, 4.5mL, 5mL, 5.5mL, 6mL
Sodium fluoride / Na2-EDTA	1mL, 1.5mL, 2mL, 2.5mL, 3mL, 3.5mL, 4mL, 4.5mL, 5mL, 5.5mL, 6mL
No Additives/Separating Gel	1mL, 2mL, 3mL, 4mL, 4.5mL, 5mL, 6mL, 7mL, 8mL, 9mL, 9.5mL, 10mL
Recombinant hirudin	2mL, 3mL, 4mL, 5mL
K2-EDTA/ Aprotinin	2mL, 3mL, 4mL, 5mL, 6mL, 7mL, 8mL, 9mL
K3-EDTA/ Aprotinin	2mL, 3mL, 4mL, 5mL, 6mL, 7mL, 8mL, 9mL

3.Instructions for use

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

1) Select the appropriate model of collection tube based on the purpose of the assay;

2) Properly disinfect the area preparing for venous puncture;

3) Remove the needle protective cap;

4) Perform venous puncture;

5) Place the collection tube on the other end of the blood collection needle and push it forward until the tube plug is penetrated;

6) Once blood enters the collection tube, release the pressure band. If the blood collection volume is insufficient or there is no blood flowing into the collection tube, it is recommended to take the following steps to obtain satisfactory results;

a) Push the collection tube forward to ensure that the rubber plug is penetrated;

b) Adjust the position of the needle in the vein;

c) Replace a new collection tube and push it into the blood collection needle;

d) If the replaced collection tube still cannot collect blood, remove and discard the blood collection needle. Repeat the operation starting from step1;

7) When the blood collected in the collection tube reaches the expected amount and the blood stops flowing into the collection tube, pull out the blood collection needle;

8) When collecting multiple blood samples from a single collection object, repeat steps 5-7;

9) Flip the collection tube that has collected blood up and down, and the number of times to flip up and down should refer to the recommended number of times after blood collection. Shake well, and

then place the end of the collection tube with a safety helmet upright;

10) After completing the sampling, draw the blood sampling needle out of the vein. Use sterile cotton swabs to compress and stop bleeding at the puncture site;

11) There may be a very small amount of residual blood;

12) After use, please dispose of the product according to local regulations.

4. Contraindications

None

5. Precautions and warnings

1) The influence factors for the blood collection volume and speed of human venous blood samples collection container for single use:

Under the condition of proper operation, the collection capacity of single-use human venous blood samples collection container would be different with the changes of sampling altitude, environment temperature, barometric pressure, needle diameter, venous pressure, and blood viscosity. It's a normal situation that the sampling speed of big capacity tubes is faster than small ones. It would be also considered to be a normal situation that the collection capacity of the first blood collection tube will reduce 0.3 to 0.4ml while using 2-way blood collection needles for venous blood collection.

2) Storage Temperature:

The storage environment temperature of Single-use Containers For Human Venous Blood Specimen Collection is 4~30°C. If the storage temperature is 0°C or below 0°C, it may cause fracture of negative pressure pipes; if the storage temperature is more than 30°C, it may cause evaporation of liquid additives within the blood collection tubes, which will finally result in the reduction of negative pressure.

3) Attention:

a) Please do not use the tubes if foreign matters or sediments are founded within the tubes;

b) Please do not use the blood collection tube that exceeds the expiry date;

c) Only for single use, after using, it should be placed in a dedicated processing container waiting for destroy;

d) Medial workers shall wear protective gloves during the blood collection, blood analysis and blood transferring processes to avoid blood infection.

4) While using the blood collection tubes, the liquid level within the tubes shall be kept below the puncture point to avoid the backflow of blood.

As there are additives contained in certain kind of negative pressure tubes, it is necessary to prevent the adverse reaction of patients caused by the backflow of blood. In order to prevent such problem, the following points should be paid attention to:

a) Ensure that the patient arm is placed downward;

b) Ensure the tube cap end is kept in the up position;

c) Ensure that additives do not contact with the piston and blood collection needle during the process

6. Storage, transportation and maintain

The storage environment temperature should be 4°C~30°C.

If the storage temperature is below the specified temperature, the negative pressure pipe may rupture; or above the specified temperature The liquid additive in the collection tube evaporation, negative pressure reduction, the liquid additive dry, discoloration and the collection tube Shtraction deformation and other quality problems.

Drawing	Meaning
CE	“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"
CH REP	"Authorized representative in the Switzerland"

7.Expiry Date

The shelf life of PET tubes is 12 months. The shelf life of glass tubes is 24 months.

8. Handling of Adverse Events

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

EU REP

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