Single-use containers for human venous blood specimen collection Instructions For Use

PRODUCT NAME
Common Name: Single-use containers for human venous blood specimen collection

SPECIFICATION
See attachment.

INTENDED USE
For clinical trial use, based on the preset vacuum and additives in the tubes and the mark and classification of the various color caps. The blood collection tubes assure the correct sampling of the testing material and play an anti-coagulation or coagulation role, based on each requirement (see Table 1).

Item No.	Additive	Recommended color code	Application
Plain tube	None	Red	Mainly used in blood collection and storage for biochemistry, immunology and serology tests.
Pro-coagulation tube	Clot Activator	Red	Mainly used in blood collection and storage for biochemistry and immunology tests, especially for Emergency biochemical tests.
Gel & Clot activator tube	Gel & Clot activator	Yellow	
EDTA tube	K2EDTA	Lavender	Mainly used in hematology or immu-no-hematology tests such as routine blood tests, etc.
	K3EDTA		
	Na2EDTA		
ESR tube	Sodium Citrate	Black	Mainly used for RBV Sedimentation Ratio test.
PT tube		Blue	Mainly used for the testing of blood coagulation mechanisms (PT, APTT, Coagulation factors).
Lithium Heparin tube	Lithium Heparin	Green	Mainly used in blood collection and anti-coagulation for routine clinical biochemistry tests, emergency biochemistry tests and some tests in blood rheology.
	Sodium Heparin		
Glucose tube	Sodium Fluoride +Potassium Oxalate	Gray	Mainly used in blood collection and anti-coagulation for analyses such as blood sugar, sugar tolerance, anti-alkali hemoglobin and sugar water.
	Sodium Fluoride+K2EDTA		
	Sodium Fluoride+ Lithium		
	Inhibitor for Glycolysis		

*Note: The color code represents auxiliary information aimed for product recognition. The above color code can be designed for each customer's special inquiry.

INSTRUCTIONS FOR USE

Vacuum Tubes Vacuum Tubes

Gel + Clot Activator, Clot Activator

1. The test tube's inside wall is treated with silicone that can effectively prevent blood cells and fibrin adhering to the tube wall and therefore preventing the physical hemolysis of the blood sample. The tubes have an added or coated coagulator that can rapidly accelerate the blood coagulation speed therefore shortening the blood coagulation time. To ensure the coagulation effect, after collecting the blood, shake slightly for 5-8 times to mix. Acute vibrations should be avoided because they can cause hemolysis.
2. To increase the blood collection speed, quantitative large Vacuum Tubes may be used. The blood collection volume is determined by test needs (for example if you are using a 5ml Vacuum Tube to collect 3ml of blood, then after blood collection the capping plug should be loosened in order to eliminate the residual negative pressure and avoid blood sample hemolysis). This method cannot ensure that the blood sample collection volume will be consistent with the quantitative nominal line.
3. The Gel + Clot Activator separation Vacuum Tubes have an added quantitative inert separation gel in the tube, which can provide a rapid separation of the serum. The excellent quality, inspection process and serum storage ensure that the physical and chemical performances of the separated serum is kept stable and manifests no changes for 72 hours.
4. The maximum centrifugal force used for the Glass Vacuum Tubes (containing blood samples) in a non-automatically balanced level centrifuge should be no more than 2200g. The centrifugal force in an angled centrifuge should be no more than 1300g, while the centrifugal force in an automatically balanced level centrifuge can be increased a certain volume.
5. Clot Activator – When using this product to collect blood samples, in order to obtain satisfying serum samples the blood needs to be completely coagulated before the centrifuging operation. The Vacuum Tube blood sample shall be placed in the centrifuge at least 15 minutes after collection.
6. These 2 types of products are usable for clinical Serum biochemical tests, Immunological tests, etc. collection, transportation, storage and treatment of venous blood samples.

Vacuum Tubes

K2 EDTA, K3 EDTA, N2 EDTA

1. The inside wall of the test tube is particularly treated so that it can effectively prevent physical hemolysis of the blood cells and ensure the stability of the blood samples. At the same time, they have an added or coated anticoagulant, according to the blood collection volume, accurately and quantitatively.
2. The blood samples collected with this product may be stored at room temperature for no more than 6 hours. If a blood smear is needed to be prepared, this shall be done in 2 hours.
3. In order to make the blood adequately mix with the anticoagulant, avoid blood coagulation and ensure an even distribution of blood cells, after blood collection and during the test shake slightly and overturn the tube for 5-8 times to mix. Acute shaking should be avoided in order to prevent hemolysis.
4. This product is mainly suitable for collection, transportation, storage and treatment of blood samples used for clinical haematological examination or blood cell analysis.

Vacuum Tubes

PT 9NC

1. These Blood Collection Vacuum Tubes are used for the coagulation mechanism test. The concentration of the sodium citrate anticoagulant in the tube is 0.109mol/L or 0.129mol/L (i.e. 3. 2%Na3C6H5O7·2H2O solution or 3. 8%Na3C6H5O7·5H2O solution). The proportion of blood and anticoagulant is controlled and is of a ratio of 1:9 strictly. The capacity error is less than 10%. During blood collection try to ensure that the vacuum in the tube disappears before drawing out the tube. This will ensure the accurate proportion of blood and anticoagulant. Different blood cell specific volume (Hct) will potentially cause changes in the proportion of serum and anticoagulant, therefore test results may become unreliable if the blood cell specific volume (Hct) increases to more than 55% or is reduced to less than 25%.
If a blood platelet function test and heparin monitoring test is performed, in order to ensure that the blood platelets are not being activated in the in vitro test, it is recommended to use the blue-headed Blood Collection Vacuum Tube with anti-coagulant CTAD solution (sodium citrate, adenosine and theophylline). The blood samples collected with blood collection tubes containing additives cannot be used for the blood platelet congregation test. If a fiberlytic test and thrombolytic therapy is performed, it is recommended to use the blue-head Blood Collection Vacuum Tube with additives.
2. In clinical blood collection, the blue-headed Blood Collection Vacuum Tube is not suitable to be taken as a first tube for blood sample collection, as the blood collection shall be smooth, slow or hard and may cause inaccurate test results. This product shall be used together with needles for blood collection from the No. 21 upward (the outer diameter should be more than 0. 8mm). For children a No. 23 needle may be used.
3. To make the blood adequately mix with the anticoagulant and avoid blood coagulation, which can potentially affect the test results, after blood collection shake slightly by overturning for 5-8 times/ Acute shaking should be avoided in order to prevent damage of the blood coagulation factor.
4. This product is mainly used for collection, transportation, storage and treatment of venous blood samples for the clinical coagulation mechanism test (PT, APTT, blood coagulation factor test etc.).
5. Transportation of blood samples with this product shall be made at room temperature. For some hemostasis or coagulation tests, such as β-blood platelet protein, fourth factor of blood platelet and part of the blood coagulation factor tests, the samples need to be transported at less than 4°C.

Vacuum Tubes

1. These Vacuum Tube are used for the blood sedimentation rate test. The concentration of the sodium citrate anticoagulant in the tube is 0.109mol/L or 0.129mol/L (i.e. 3. 2%Na3C6H5O7·2H2O solution or 3.8% Na3C6H5O7·5H2O solution). The proportion of blood and anticoagulant is maintained at a ratio of 1:4, with a capacity error of less than 10%. During blood collection ensure the vacuum in the tube disappears before drawing out the tube. This will ensure the collection of the accurate proportion of blood and anticoagulant. The physical and chemical characters, purification degree, concentration, pH value, cleanliness, osmosis pressure performances of the anticoagulant are according to the requirements of Pharmacopoeia. Volumes: 1,6ml; 1,8ml, 2ml.
2. To make the blood adequately mix with the anticoagulant, after blood collection, immediatelly overturn the tube slightly for 5-8 times. Acute shaking should be avoided in order to prevent hemolysis.
3. This product is suitable for clinical blood cell sedimentation rate measuring and transportation, storage and treatment of venous blood.
4. The blood samples collected with this product shall be kept at 18-25°C room temperature. If the room temperature is either too high or too low, or in case of anemia, the test results will be affected. Fat blood shall be avoided during blood sample collecting.

Vacuum Tubes

Sodium Fluoride

1. The product is suitable for collection, transportation, storage and treatment of venous blood samples intended for the clinical blood sugar test or glucose sugar tolerance test.
2. To make the blood adequately mix with the anticoagulant and sugar degradation inhibitor, avoid blood coagulation by shaking slight for 5-8 times immediately after collection. Acute shaking should be avoided in order to prevent hemolysis.
3. Because there is an added sodium fluoride sugar degradation inhibitor in the tube, after blood collection, there may be a slight hemolysis of the blood sample. This will usually not affect the clinical test results, but severe hemolysis of the sample will affect the clinical test results.

Vacuum Tubes

LIH and NAH

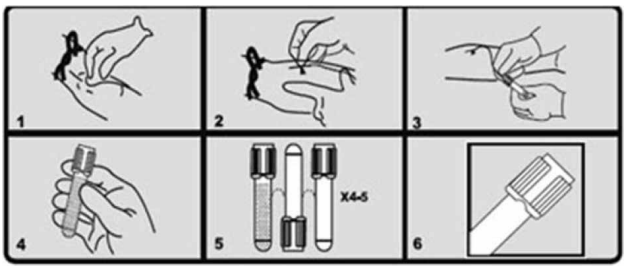
1. To make the blood adequately mix with the anticoagulant and avoid blood coagulation, the tubes shall be shaken slightly for 5-8 times immediately after collection. Acute shaking should be avoided in order to prevent hemolysis.
2. In case of clinical emergency treatment biochemical tests where there is a need to separate the serum rapidly, it is recommended to use the green-headed Blood Collection Vacuum Tubes which have an inert separation gel that can completely make a rapid separation of the serum. The excellent quality, inspection process and serum storage ensure the physical and chemical performances of the additive and allow that after separation, the serum may be kept stable for 72 hours.
3. Blood samples collected with this product for the blood rheology test shall be placed at room temperature for 20 minutes before determination. The longest time for which they can be kept at this temperature is no more than 4 hours under 15-18°C.
4. This product is suitable for the collection, transportation, storage and treatment of blood samples used for the blood rheology test in clinical emergency treatment biochemical tests.

APPLICATION RANGE
Used for human blood collection, storage, transportation and pre-treatment in clinical examination.

APPLICATION METHOD

1. Before using, please make sure there that the packages contain the proper certifications, specifications and mark-ups. Check for damage, contamination or leakage.
2. Check the blood collection tube's specifications and blood test projects.
3. These products are used together with disposable blood collection needles.
4. Use a tourniquet, sterilize the puncturing area and do not touch the sterilized area.
5. Make sure the patient's arm is in a downward position.
6. Push the venous blood collection needle into the vein: this step is successful if you have blood return. Then push the rear tip of the bi-directional needle through the rubber plug perpendicularly.
7. Remove the tourniquet once the blood flow is active.
8. Avoid the needle touching with anticoagulants when sampling (see backflow prevention).
9. Pull out the blood collection tube when blood stops flowing into the tube, then remove the needle, press the puncture wound with a disinfection swab at least 10 minutes, until the blood stops flowing.
10. Invert the tube and mix well for 5-6 times after sampling the blood, to mix additional agents and blood. However, in order to avoid the occurrence of hemolysis, you cannot apply a strong force to the tube.
11. Inspection time: See the following Diagram 1.

Diagram 1. Blood collection schematic diagram



BACKFLOW PREVENTION

Anticoagulants are present in the tube, therefore the risk of black flow should be avoided.
Please follow the next instructions carefully:
1. Make sure the patient's arm is in a downward position
2. Remove the tourniquet once blood flow is visible
3. Avoid the needle getting in touch with anticoagulants, when collecting

NOTES

1. The blood collection tubes should be used by professionals and be a proven IVD. In order to protect the physicians from infection, it is recommended to wear gloves, protective glasses and other personal protective equipment during blood collection and sample processing.
2. All glass items have a potential to get broken, therefore before use, the glass blood collection tubes should be checked whether they have suffered any damaged and take the corresponding preventive measures.
3. Using a syringe to collect and transfer blood into the blood collection tube is not advised. If there is a need to do this, then the needle should be removed and the cap should be opened, so as not to cause the rubber to pop-up and the blood to splatter or induct hemolysis.
4. If the blood is collected by intravenous infusion, please confirm that the solution has been completely removed, in order to avoid getting the wrong test result due to the pollution of the blood.
5. If the blood collection volume is too large or too small, this will lead to an incorrect ratio of additives and blood, which can cause wrong test results.
6. Before using the product, the altitude should be identified carefully (it is generally marked on the package). If the altitude is not correctly assessed, it can lead to blood loss or excess.
7. Try to avoid centrifuging the gel & activator tubes twice as this may change the test results of the analytes.
8. Long time storage with an open cap will lead to the evaporation of the additives/ blood and lead to errors of analysis, so please seal-capping in time.
9. Please follow the instructions for sampling.
10. Do not revert the tube.
11. Do not use the tube after expiry.
12. Do not use damaged, impure or tubes with foreign matters in them.
13. Do not heat the tubes before use.
14. Dispose as dangerous items after sampling. This is because they contain biological material. Follow the local disposing rules in order to execute correctly.

STORAGE RANGE

1. Store the empty tubes at a temperature of between 0-40°C (32-104 F).
2. Do not store the sampling tubes in an environment with below 0°C, to prevent the tube's rupture or hemolysis of the blood.
3. If the inspection is carried out immediately after sampling, store the blood collection tubes in the range of 4-25°C.
4. If inspection is made in 8 hours after the sampling, store the blood collection tubes in the range of 4-8°C.

EXPIRY

Glass tubes: 18 months, PET tubes: 12 months

ATTACHMENT • SPECIFICATION MODEL

CLINICAL CHEMISTRY & IMMUNOLOGY			Code
Siliconized (activating clot) • detachable double label • provided with unique code for easy patient identification	13 x 75 mm, plastic, red cap	4 ml	C48VT1006DL
	13 x 75 mm, STERILE, plastic, red cap	4 ml	C48VT1035DL
	13 x 100 mm, plastic, red cap	6 ml	C48VT1007DL
	13 x 100 mm, STERILE, plastic, red cap	6 ml	C48VT1036DL
	16 x 100 mm, plastic, red cap	8 ml	C48VT1008DL
	16 x 100 mm, STERILE, plastic, red cap	8 ml	C48VT1037DL
Siliconized (activating clot) pediatric use • simple label	10 x 45 mm, PP, polypropylene, red cap	0.5 ml	C48VT1026
COAGULATION			**Code**
Sodium citrate 3.2% • detachable double label • provided with unique code for easy patient identification	13 x 75 mm, plastic, blue cap	1.8 ml	C48VT1009DL
	13 x 75 mm, STERILE, plastic, blue cap	1.8 ml	C48VT1038DL
	13 x 75 mm, plastic, blue cap	2.7 ml	C48VT1010DL
	13 x 75 mm, STERILE, plastic, blue cap	2.7 ml	C48VT1039DL
	13 x 75 mm, glass, blue cap	4.5 ml	C48VT1011DL
CLINICAL CHEMISTRY & IMMUNOLOGY			**Code**
Activating gel • detachable double label • provided with unique code for easy patient identification	13 x 75 mm, plastic, yellow cap	3 ml	C48VT1001DL
	13 x 75 mm, STERILE, plastic, yellow cap	3 ml	C48VT1030DL
	13 x 100 mm, plastic, yellow cap	5 ml	C48VT1002DL
	13 x 100 mm, STERILE, plastic, yellow cap	5 ml	C48VT1031DL
	16 x 100 mm, plastic, yellow cap	8 ml	C48VT1003DL
	16 x 100 mm, STERILE, plastic, yellow cap	8 ml	C48VT1032DL
Activating gel pediatric use • simple label	10 x 45 mm, PP, polypropylene, yellow cap	0.5 ml	C48VT1029
GLUCOSE			**Code**
Potassium oxalate/Sodium fluoride • detachable double label • provided with unique code for easy patient identification	3 x 75 mm, plastic, grey cap	3 ml	C48VT1012DL
	13 x 75 mm, STERLE, plastic, grey cap	3 ml	C48VT1040DL
CLINICAL CHEMISTRY & IMMUNOLOGY			**Code**
Lithium heparin • detachable double label • provided with unique code for easy patient identification	13 x 75 mm, plastic, green cap	4 ml	C48VT1004DL
	13 x 75 mm, STERILE, plastic, green cap	4 ml	C48VT1033DL
	13 x 100 mm, plastic, green cap	6 ml	C48VT1005DL
	13 x 100 mm, STERILE, plastic, green cap	6 ml	C48VT1034DL
Heparin pediatric use • simple label	10 x 45 mm, PP, polypropylene, green cap	0.5 ml	C48VT1028
ESR			**Code**
ESR • detachable double label • provided with unique code for easy patient identification • reading on a rack with scale	8 x 120 mm, glass, black cap	1.6 ml	C48VT1021
	8 x 120 mm, glass, black cap	1.8 ml	C48VT1022
	8 x 120 mm, glass, black cap	2.0 ml	C48VT1023
ESR rack with scale, 10 positions			C34VT1024
HEMATOLOGY			**Code**
EDTA K2 • detachable double label • provided with unique code for easy patient identification	13 x 75 mm, plastic, purple cap	2 ml	C48VT1013DL
	13 x 75 mm, STERILE, plastic, purple cap	2 ml	C48VT1041DL
	13 x 75 mm, plastic, purple cap	3 ml	C48VT1014DL
	13 x 75 mm, STERILE, plastic, purple cap	3 ml	C48VT1042DL
	13 x 75 mm, plastic, purple cap	4 ml	C48VT1015DL
	13 x 75 mm, STERILE, plastic, purple cap	4 ml	C48VT1043DL
	13 x 100 mm, plastic, purple cap	6 ml	C48VT1016DL
	13 x 100 mm, STERILE, plastic, purple cap	6 ml	C48VT1044DL
EDTA K2 • detachable double label • provided with unique code for easy patient identification	13 x 75 mm, plastic, purple cap	2 ml	C48VT1017DL
	13 x 75 mm, STERILE, plastic, purple cap	2 ml	C48VT1045DL
	13 x 75 mm, plastic, purple cap	3 ml	C48VT1018DL
	13 x 75 mm, STERILE, plastic, purple cap	3 ml	C48VT1046DL
	13 x 75 mm, plastic, purple cap	4 ml	C48VT1019DL
	13 x 75 mm, STERILE, plastic, purple cap	4 ml	C48VT1047DL
	13 x 100 mm, plastic, purple cap	6 ml	C48VT1020DL
	13 x 100 mm, STERILE, plastic, purple cap	6 ml	C48VT1048DL
EDTA K3 pediatric use • simple label	10 x 45 mm, PP, polypropylene, purple cap	0.5 ml	C48VT1027
HOLDERS			**Code**
Holders for collection needles 18G, 20G, 21G, 22G and needles flashback or visio type 21G, 22G			NH001

Rev.

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