VACUSERA® BLOOD COLLECTION TUBES

INSTRUCTION FOR USE

INTENDED USE

VACUSERA® Blood Collection Tubes, Holders and Needles are used together as a system for the collection of venous blood. VACUSERA® tubes are used to collect, transport and process blood for testing serum, plasma or whole blood in the clinical laboratory. The patient population can be children and adults. The user profile can be doctors, nurses, and adequately trained healthcare personnel.

NOTE: Please refer to Table 1.1 to see detailed intended use according to tube types.

PRODUCT DESCRIPTION

VACUSERA® tubes are fitted with color coded caps.

The tubes, additive concentrations, volumes of liquid additives, and their permitted tolerances, as well as the blood-to-additive ratio, are in accordance to the requirements and recommendations of the international standards ISO 6710 "Single- use containers for venous blood specimen collection".

Additive choice depends on the analytical test method. It is specified by the manufacturer of the test reagents and/or instrument on which the test is performed. Tube interiors are sterile.

VACUSERA® Coagulation Tubes

VACUSERA® Coagulation Tubes are filled with buffered tri-sodium citrate solution. Citrate concentrations of either 0.109 mol/l (3.2 %) or 0.129 mol/l (3.8 %) are available. The choice of the concentration depends upon the policies of the laboratories. The mixing ratio is 1 part citrate to 9 parts blood.

VACUSERA® Coagulation Tubes are used for coagulation tests.

VACUSERA® CTAD Tubes

VACUSERA® CTAD Tubes are used for coagulation tests especially for patients taking heparin therapy.

In addition to main component sodium citrate, VACUSERA® CTAD Tubes contain theophylline, adenosine and dipyridamole which help prevention of *in vitro* platelet activation. Thereby provides high accuracy in hemostasis tests of patients even taking heparin therapy.

Citrate concentrations of VACUSERA® CTAD Tubes is 0.109 mol/l (3.2 %). The mixing ratio is 1 part citrate to 9 parts blood.

VACUSERA® Serum Tubes

All VACUSERA® Serum Tubes are coated with micronised silica particles which activate clotting when tubes are gently inverted.

VACUSERA® Serum Tubes with Gel contain a barrier gel that is present in the bottom of the tube. The specific gravity of this material lies between the blood clot and the serum. During centrifugation the barrier gel moves upward to the serum - clot interface, where it forms a stable barrier separating the serum from fibrin and cells.

Serum may be aspirated directly from the collection tube, eliminating the need for transfer to another container.

VACUSERA® Serum tubes are used for determinations in serum for routine clinical chemistry tests and hormones, TDM.

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VACUSERA® Heparin Tubes

The interior of the tube wall is coated with lithium heparin or sodium heparin. The anticoagulant heparin activates antithrombins, thus blocking the coagulation cascade and producing a whole blood / plasma sample instead of clotted blood plus serum.

VACUSERA® Plasma Tubes with Lithium Heparin and Gel contain a barrier gel in the tube. The specific gravity of this material lies between the blood cells and plasma. During centrifugation the gel barrier moves upward providing a stable barrier separating the plasma from cells. Plasma may be aspirated directly from the collection tube, eliminating the need for manual transfer to another container.

VACUSERA® Heparin Tubes are used for plasma determinations of routine clinical chemistry tests. Lithium determinations should not be performed in VACUSERA® Lithium Heparin tubes. Sodium determinations should not be performed in VACUSERA® Sodium Heparin tubes.

VACUSERA® EDTA Tubes

K2 EDTA and K3 EDTA Tubes are used for testing whole blood in haematology. VACUSERA® EDTA Tubes may be used for routine immunohematology testing (i.e. red cell grouping), Rh typing and antibody screens, viral marker testing in screening laboratories. The interior of the tube wall is coated with either EDTA K2 or EDTA K3. The EDTA binds calcium ions thus blocking the coagulation cascade. Blood smearing should be done within 3 hours after blood collection.

Tubes are used for testing whole blood in the clinical haematology laboratory within 24 hours at room temperature. VACUSERA® EDTA K2/Gel Tubes are used for testing plasma in molecular diagnostics and viral load detection.

VACUSERA® Glucose Tubes

VACUSERA® Glucose Tubes are available with different additives. The tubes contain an anticoagulant and a stabilizer. EDTA, sodium fluoride and potassium oxalate.

VACUSERA® Glucose Tubes are suitable for the analysis of glucose concentration within 48 hours.

VACUSERA® ESR Tubes

VACUSERA® ESR Tubes are used for blood sedimentation rate testing. ESR measurements refer to the Westergren method. VACUSERA® ESR Tubes contain a 3.2% buffered tri-sodium citrate solution (0.109 mol/l). Choice of the concentration depends on the laboratory policy. The mixing ratio is 1 part citrate solution to 4 parts blood.

VACUSERA® Cross Match Tubes

VACUSERA® Cross Match Tubes are used to test compatibility of recipient and donor blood prior to blood transfusion. Potential risk of hemolytic reactions can be avoided by this way.

VACUSERA® Cross Match Tubes are available with different additives. The interior of tubes are coated with either clot activator or anticoagulant (K2EDTA or K3EDTA) thus enables crossmatch tests with both serum and whole blood.

VACUSERA® Cross Match Tubes have pink-colored caps that make them easily identified. There is no specified color code for the closures of crossmatch tubes.

VACUSERA® Blood Grouping Tubes

VACUSERA® Blood Grouping Tubes help preservation of erythrocytes by means of citric acid, dextrose and anticoagulant sodium citrate and used for cell preservation or blood grouping.

VACUSERA® Blood Grouping Tubes are available with two different formulations of the additives: ACD-A or ACD-B.

VACUSERA® Blood Grouping Tubes have yellow-colored caps but there is no specified color code for the closures of blood grouping tubes.

VACUSERA® Trace Element Tubes

VACUSERA® Trace Element Tubes are used to test presence of trace elements such as Iron, Zinc, Copper, Mercury, and Lead in the blood.

VACUSERA® Trace Element Tubes contains clot activator or K2EDTA or sodium heparin in order to enable tests of serum, plasma or whole blood.

VACUSERA® Trace Element Tubes have dark blue-colored caps but there is no specified color code for the closures of trace element tubes.

VACUSERA® Thrombin-based Serum Tubes

VACUSERA® Thrombin-based Serum Tubes allow rapid blood clotting (maximum 5 minutes) meeting the requirements of units that have patients with blood clotting problems or units that require rapid test results.

VACUSERA® Thrombin-based Serum Tubes are plastic tubes with a pre-defined vacuum for exact draw volumes. They are fitted with orange-colored caps according to the defined color codes.

Additive choice depends on the analytical test method. It is specified by the manufacturer of the test reagents and/or instrument on which the test is performed. Tube interiors are sterile.

VACUSERA® Thrombin-based Serum Tubes are coated with micronized silica particles. In order to provide rapid clotting, a thrombin-based clot activator reagent is sprayed to the tube interior. When tubes are gently inverted, blood clotting is activated by complete mixing of blood with thrombin-based clot activator.

VACUSERA® Thrombin-based Serum Tubes with Gel contain a barrier gel that is present in the bottom of the tube. The specific gravity of this material lies between the blood clot and the serum. During centrifugation the barrier gel moves upward to the serum - clot interface, where it forms a stable barrier separating the serum from fibrin and cells.

Serum may be aspirated directly from the collection tube, eliminating the need for transfer to another container.

VACUSERA® Thrombin-based Serum tubes are used for determinations in serum for routine clinical chemistry tests and hormones, TDM especially which requires rapid results.

APPLICATIONS

Specimen Collection and Handling

Recommended Order of Draw: (according to CLSI H3-A6 standard)

1. Blood culture/ no additive tubes

2. Coagulation*

3. Serum with and without gel

4. Heparin with and without gel

5. EDTA

6. Glucose

7. Others

*When drawn first then only suitable for routine tests (i.e. PT and APTT)

Prevention of Backflow

Most evacuated blood collection tubes contain chemical additives. Therefore it is important to avoid possible backflow from the tube, due to the possibility of adverse patient reactions. To prevent backflow from tube into the patient's arm, observe the following precautions:

1. Place patient's arm in a downward position.

2. Hold tube with the cap uppermost.

3. Release tourniquet as soon as blood starts to flow into tube.

4. Make sure tube contents do not touch cap or end of the needle during venipuncture.

Venipuncture Technique

WEAR GLOVES DURING VENIPUNCTURE AND WHEN HANDLING BLOOD COLLECTION TUBES TO MINIMIZE EXPOSURE HAZARD.

1. Select tube or tubes appropriate for required specimen.

2. Remove the cover over the valve section of the needle.

3. Thread the needle into the holder. Be sure needle is firmly seated to ensure needle does not unthread during use.

4. Apply tourniquet (max. 1 minute) Prepare venipuncture site with an appropriate antiseptic. DO NOT PALPATE VENIPUNCTURE AREA AFTER CLEANSING.

5. Place patient's arm in a downward position.

6. Remove needle shield. Perform venipuncture WITH ARM DOWNWARD AND TUBE CAP UPPER-MOST.

7. Push tube into the holder and onto the needle valve puncturing the rubber diaphragm. Center tubes in holder when penetrating the cap to prevent sidewall penetration and subsequent premature vacuum loss.

8. REMOVE TOURNIQUET AS SOON AS BLOOD APPEARS IN TUBE. DO NOT ALLOW CONTENTS OF TUBE TO CONTACT THE CAP OR END OF THE NEEDLE DURING PROCEDURE. Always hold in place by pressing the tube with the thumb to ensure complete vacuum draw.

NOTE: Blood may occasionally leak from the needle sleeve. Practice universal safety precautions to minimize hazard exposure.

If no blood flows into tube or if blood flow ceases before an adequate specimen is collected, the following steps are suggested to complete satisfactory collection:

a) Push tube forward until tube cap has been fully penetrated. Always hold in place by pressing the tube with the thumb to ensure complete vacuum draw.

b) Confirm correct position of needle in vein.

c) If blood still does not flow, remove tube and place new tube onto the holder.

d) If second tube does not draw, remove needle and discard. Repeat procedure from step 1.

9. When the first tube is full and blood flow ceases, gently remove it from holder.

10. Place succeeding tubes in holder, puncturing diaphragm to begin flow. Draw tubes without additives before tubes with additives. See recommended Order of Draw.

11. Gently invert the tubes immediately after blood collection to reach a proper mix of additive and blood. Turn the filled tube upside-down and return it to upright position. This is one complete inversion.

NOTE: Do not shake the tubes. Vigorous mixing may cause foaming or haemolysis. Insufficient mixing or delayed mixing in serum tubes may result in delayed clotting. In tubes with anticoagulants, inadequate mixing may result in platelet clumping, clotting and /or incorrect test results.

12. As soon as blood stops flowing in the last tube, remove needle from vein, applying pressure to puncture site with dry sterile swab until bleeding stops. Once clotting has occurred, apply bandage if desired.

NOTE: After venipuncture, the top of the cap may contain residual blood. Take proper precautions when handling tubes to avoid contact with this blood. Any needle holder that becomes contaminated with blood is considered hazardous and should be disposed of immediately.

13. Dispose of the used needle with holder using an appropriate disposal device. DO NOT RECAP. Recapping of needles increases the risk of needle stick injury and blood exposure.

It is the laboratory's ultimate responsibility to verify that a change from one tube to another does not significantly affect analytical results obtained from patient samples.

NOTE: Keep the tubes, especially serum, in an upright position.

Centrifugation

Ensure that tubes are properly seated in the centrifuge carrier; incomplete seating could result in the separation of the cap from the tube.

NOTE: VACUSERA® Serum Tubes should be centrifuged 30 minutes after blood collection to minimize post clotting (build up fibrin) in serum. This could lead to contamination of the analyzer and to erroneous results.

Centrifugation should be done in a cooled centrifuge. Higher temperatures could have negative effects on the physical properties of the gel. The yield of serum or plasma is ideal at temperatures between 20°C-22°C.

NOTE: Gel separation tubes should be centrifuged no later than 2 hours after collection. Extended contact of blood cells with the serum or plasma, may lead to erroneous analysis results. It is not recommended to re-centrifuge tubes once the barrier has been formed.

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TABLE 1.1

TUBE TYPE	COLOR CODES	ADDITIVES	DUTY OF THE ADDITIVE	LETTER CODES	SAMPLE TYPE	INTENDED USE	NUMBER OF INVERT	SPEED AND TIME OF CENTRIFUGE
COAGULATION / CTAD	 BLUE	SODIUM CITRATE	Prevents blood clotting (anticoagulant)	9NC	PLASMA	COAGULATION TEST	3-4	2000-2500 g (RCF) 10-15 min
SERUM	 RED	CLOT ACTIVATOR	Activates blood clotting to obtain serum separation from blood cells	CAT	SERUM	BIOCHEMISTRY AND HORMONE TESTS	5-6	1300 g (RCF) 10 min
SERUM+GEL	 ORANGE	CLOT ACTIVATOR + GEL	Clot activator: Activates blood clotting to obtain serum separation from blood cells Gel: It is located between the blood cells and serum during the centrifuge, creates a barrier and prevents re-mixing.	CAT	SERUM	BIOCHEMISTRY AND HORMONE TESTS	5-6	2000-3000 g (RCF) 10-15 min
HEPARIN	 GREEN	LITHIUM HEPARIN SODIUM HEPARIN	Prevents blood clotting (anticoagulant)	LH/NH	PLASMA	MOLECULAR DIAGNOSTIC TESTS	8-10	1300 g (RCF) 10 min
HEPARIN+ GEL	 GREEN	HEPARIN+ GEL	Heparin: Prevents blood clotting (anticoagulant) Gel: It is located between the blood cells and serum during the centrifuge, creates a barrier and prevents re-mixing.	LH/NH	PLASMA	MOLECULAR DIAGNOSTIC TESTS	8-10	1300-2000 g (RCF) 10 min
EDTA	 PURPLE	EDTA	Bonds Ca^2 + ions and prevents blood clotting (anticoagulant)	K2E/K3E	WHOLE BLOOD	HEMATOLOGY, BLOOD GROUPING, HEMOGRAM, PERIPHERAL SMEAR	8-10	
EDTA+GEL	 PURPLE	EDTA+GEL	EDTA: Bonds Ca^2 + ions and prevents blood clotting (anticoagulant) Gel: It is located between the blood cells and serum during the centrifuge, creates a barrier and prevents re-mixing.	K2E/K3E	PLASMA	MOLECULAR DIAGNOSTIC TESTS	8-10	1100-1500 g (RCF) 10 min
GLUCOSE	 GREY	SODIUM FLUORIDE + K3EDTA	EDTA: Bonds Ca^2 + ions and prevents blood clotting (anticoagulant) Sodium Fluoride: Stabilizes glucose by preventing glycolysis	FE	PLASMA	GLUCOSE, ALCOHOL	8-10	1300 g (RCF) 10 min
GLUCOSE	 GREY	SODIUM FLUORIDE + Na2EDTA	EDTA: Bonds Ca^2 + ions and prevents blood clotting (anticoagulant) Sodium Fluoride: Stabilizes glucose by preventing glycolysis	FE	PLASMA	GLUCOSE, ALCOHOL	8-10	1300 g (RCF) 10 min
GLUCOSE	 GREY	SODIUM FLUORIDE + POTASSIUM OXALAT	Potassium Oxalate: Prevents blood clotting (anticoagulant) Sodium Fluoride: Stabilizes glucose by preventing glycolysis	FX	PLASMA	GLUCOSE, ALCOHOL	8-10	1300 g (RCF) 10 min
ESR	 BLACK	SODIUM CITRATE	Prevents blood clotting (anticoagulant)	4NC	WHOLE BLOOD	SEDIMENTATION TESTS	3-4	
CROSS MATCH	 PINK	CLOT ACTIVATOR	Activates blood clotting to obtain serum separation from blood cells	CAT	SERUM	CROSSMATCH TESTS	5-6	1300 g (RCF) 10 min
CROSS MATCH	 PINK	EDTA	Activates blood clotting to obtain serum separation from blood cells	K2E/K3E	WHOLE BLOOD	CROSSMATCH TESTS	8-10	
ACD	 YELLOW	ACD-A & ACD-B	Blood grouping tubes are used for blood grouping or cell preservation.	ACD-A ACD-B	WHOLE BLOOD	BLOOD GROUPING	8-10	
TRACE ELEMENT	 DARK BLUE	CLOT ACTIVATOR	Activates blood clotting to obtain serum separation from blood cells	CAT	SERUM	TRACE ELEMENT TESTS (ZINC, COPPER, LEAD, MERCURY, etc.)	5-6	1300 g (RCF) 10 min
TRACE ELEMENT	 DARK BLUE	SODIUM HEPARIN	Prevents blood clotting (anticoagulant)	NH	PLASMA	TRACE ELEMENT TESTS (ZINC, COPPER, LEAD, MERCURY, etc.)	8-10	1300 g (RCF) 10 min
TRACE ELEMENT	 DARK BLUE	EDTA	Activates blood clotting to obtain serum separation from blood cells	K2E/K3E	WHOLE BLOOD	TRACE ELEMENT TESTS (ZINC, COPPER, LEAD, MERCURY, etc.)	8-10	
THROMBIN	ORANGE	CLOT ACTIVATOR (THROMBİN) + GEL	Clot activator (thrombin): Provides rapid (max. 5 min) blood clotting for emergency analysis. Gel: It is located between the blood cells and serum during the centrifuge, creates a barrier and prevents re-mixing.	CAT	SERUM	BIOCHEMISTRY AND HORMONE TESTS	5-6	2000-3000 g (RCF) 10-15 min

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Disposal

1. The general hygiene guidelines and legal regulations for the proper disposal of infectious material should be considered and followed.

2. Disposable gloves prevents the risk of infection.

3. Contaminated or filled blood collection tubes must be disposed of in suitable biohazard disposal containers, which can then be autoclaved and incinerated afterwards.

4. Disposal should take place in an appropriate incineration facility or through autoclaving (steam sterilization).

STORAGE CONDITIONS

Store tubes at 4–25°C (40–77° F).

NOTE: Avoid exposure to direct sunlight. Exceeding the maximum recommended storage temperature may lead to impairment of the tube quality (i.e. vacuum loss, drying out of liquid additives, coloring, etc.)

WARNING/PRECAUTIONS

1. Do not use tubes if foreign matter is present!

2. Handle all biological samples and blood collection "sharps" (lancets, needles, luer adapters, and blood collection sets) according to the policies and procedures of your facility.

3. Obtain appropriate medical attention in the case of any exposure to biological samples (for example, through a puncture injury), since they may transmit HIV (AIDS), viral hepatitis, or other blood-borne pathogens.

4. Discard all blood collection "sharps" in biohazard containers approved for their disposal.

5. Transferring a sample from a syringe to a tube is not recommended. Additional manipulation of sharps increases the potential for needle stick injury. In addition, depressing the syringe plunger during transfer can create a positive pressure, forcefully displacing the stopper and sample and causing a potential blood exposure. Using a syringe for blood transfer may also cause over or under filling of tubes, resulting in an incorrect blood-to-additive ratio and potentially incorrect analysis results.

6. Do not use tubes after their expiration date.

7. Blood Collection Tubes are for single use. Do not reuse the tube after use, as pressure and sterility loss may occur in the tube that contacts the needle.

CONTRAINDICATIONS

It is not anticipated that there may be a direct harm as it does not have direct contact with people. However, contraindications may occur due to misdiagnosis if the product does not fulfill its intended use.

SYMBOLS OF DESCRIPTION

REF	Reference Number
LOT	Batch Code
	Use by
	Single Use
	Keep away from sunligth
STERILE R	Radiation Sterilization
	See the Instruction for Use
IVD	In Vitro Diagnostic Device
	Temperature Limits

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