

# VACUSENCE

## BLOOD COLLECTION TUBES

### INSTRUCTION FOR USE



#### INTENDED OF USE

VACUSENCE Blood Collection Tubes, Holders and Needles are used together as a system for the collection of venous blood. VACUSENCE tubes are used to collect, transport and process blood for testing serum, plasma or whole blood in the clinical laboratory.

#### PRODUCT DESCRIPTION

VACUSENCE tubes are plastic tubes with a pre-defined vacuum for exact draw volumes. They are fitted with colour 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" and the National Committee for Clinical Laboratory and Approved Standards (CLSI) H1-A6 "Tubes and Additives for Venous and Capillary Blood Specimen Collection; Approved Standart – Sixth Edition". 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.

#### VACUSENCE Coagulation Tubes

VACUSENCE 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. VACUSENCE Coagulation Tubes are used for coagulation tests.

#### VACUSENCE Serum Tubes

All VACUSENCE Serum Tubes are coated with micronised silica particles which activate clotting when tubes are gently inverted. VACUSENCE 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. VACUSENCE Serum tubes are used for determinations in serum for routine clinical chemistry tests and hormones, TDM.

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

#### VACUSENCE EDTA Tubes

K2 EDTA and K3 EDTA Tubes are used for testing whole blood in haematology. VACUSENCE 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. VACUSENCE EDTA K2/Gel Tubes are used for testing plasma in molecular diagnostics and viral load detection.

#### VACUSENCE Glucose Tubes

VACUSENCE Glucose Tubes are available with different additives. The tubes contain an anticoagulant and a stabilizer. EDTA and sodium fluoride. VACUSENCE Glucose Tubes are suitable for the analysis of glucose concentration within 48 hours.

#### VACUSENCE ESR Tubes

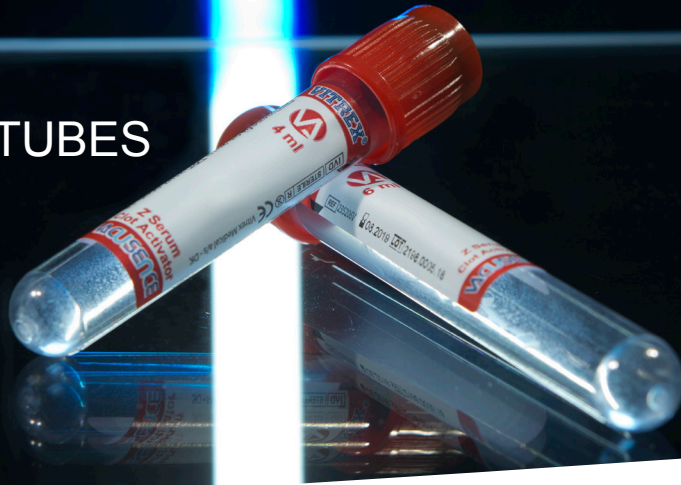
VACUSENCE ESR Tubes are used for blood sedimentation rate testing. ESR measurements refer to the Westergren method. VACUSENCE ESR Tubes contain a 3.2% buffered tri-sodium citrate solution (0.109 mol/l). Choice of the concentration depends on the laboratory policy. The mixing ratio is 1 part citrate solution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



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### 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.



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#### 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:** VACUSENCE 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 analyser 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 recentrifuge tubes once the barrier has been formed.

#### 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 sterilisation).

#### 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, colouring, 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.

Draw Vol.	Color	Tube type	Description	Mixing	Centrifuge speed and time
1 ml / 1.8 ml / 2.7 ml / 4 ml	Light Blue	Sodium Citrate	Coagulation Test	3-4	2.000-2.500 g (RCF) 10 - 15 min 3.500-4.500 RPM 10 - 15 min
1 ml / 2 ml / 3 ml / 4 ml / 6 ml / 9 ml / 10 ml	Red	Clot Activator	Serum Test	5-6	1.300 g (RCF) 10 min 2.500-3.500 RPM 10 min
2 ml / 3.5 ml / 5 ml / 8 ml	Yellow	Clot Activator + Gel	Serum Test	5-6	2.000 g (RCF) 10 min 3.000-4.000 RPM 10 min
4 ml / 6 ml / 9 ml	Green	Lithium Heparin Sodium Heparin	Plasma Test	8-10	1.300 g (RCF) 10 min 3.000-4.000 RPM 10 min
3 ml / 5 ml / 8 ml	Green	Lithium Heparin + Gel	Plasma Test	8-10	1.300 - 2.000 g (RCF) 10 min 3.000-4.000 RPM 10 min
1 ml / 2 ml / 3 ml / 4 ml / 4.5 ml / 6 ml / 9 ml	Purple	EDTA	Haematology Test	8-10	
3 ml / 5 ml / 8 ml	Purple	EDTA + Gel	Molecular Diagnostic Test	8-10	1.100 - 1.500 g (RCF) 10 min 2.500 - 3.500 RPM 10 min
2 ml / 4 ml	Gray	FE / Sodium Fluoride + Gel	Glucose Test	8-10	1.300 g (RCF) 10 min 2.500-3.500 RPM 10 min
2ml / 4 ml	Gray	FX / Sodium Fluoride + Potassium Oxalate	Glucose test	8-10	1.300 g (RCF) 10 min 2.500-3.500 RPM 10 min

#### SYMBOLS OF DESCRIPTION

	Reference number
	LOT number
	Expiration date
	Do not reuse
	Do not use if package is damaged
	Radiation Sterilization
	Consult instructions for use
	In Vitro Diagnostic Medical Device
	Temperature limitation

