



## Evacuated Blood Collection System For In Vitro Diagnostic Use



### Intended Use

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

### Product Description

**VACUETTE®** tubes are plastic tubes with a pre-defined vacuum for exact draw volumes. They are fitted with color coded **VACUETTE®** SAFETY Caps – with the exception of ESR tubes (see table below). The tubes, additive concentrations, volumes of liquid additives, and their permitted tolerances, as well as the blood-to-additive ratios, are in accordance to the requirements and recommendations of the international standards ISO 6710 “Single-use containers for venous blood specimen collection” and the Clinical and Laboratory Standards Institute’s Approved Standards (CLSI). 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.

### VACUETTE® SAFETY Cap Color Codes

Description	SAFETY Cap Color	Cap Inner Ring Color
<b>No Additive Tubes</b> No Additive	white	black
<b>Coagulation Tubes</b> Sodium Citrate 3.2%	light blue	black or white
<b>Serum Tubes</b> Clot Activator Clot Activator w/Gel	red red or gold	black or white yellow, gold or white
<b>Heparin Tubes</b> Lithium Heparin Lithium Heparin w/Gel Sodium Heparin	green green green	black or white yellow green
<b>EDTA Tubes</b> K2EDTA K2EDTA w/Gel K3EDTA	lavender or pink lavender or white lavender, pink or white	black, white or pink yellow black or white
<b>Glycolytic Inhibitor Tubes</b> Sodium Fluoride/Potassium Oxalate	grey	black or white
<b>Trace Element Tubes</b> Sodium Heparin No Additive	royal blue royal blue	black black
<b>ESR Tubes (Not available in USA)</b> Sodium Citrate 3.2%	black standard stopper	--

(Tubes with a white inner cap ring indicate lower draw volumes of 2ml or less, black rings indicate standard draw volumes and yellow rings indicate the presence of gel.)

### VACUETTE® Coagulation Tubes

**VACUETTE®** Coagulation Tubes are filled with buffered tri-sodium citrate solution. The citrate concentration is 0.109M (3.2%). The mixing ratio is 1 part citrate to 9 parts blood. High Altitude 3.2% sodium citrate tubes with increased vacuum are available for sites located 5,000 feet or more above sea level.

### VACUETTE® Serum Tubes

**VACUETTE®** Serum Tubes are coated with micronized silica particles which activate clotting when tubes are gently inverted. **VACUETTE®** No Additive Tubes and **VACUETTE®** Serum Clot Activator Tubes may be used for routine immunohematology testing i.e., red cell grouping, Rh typing and antibody screening. **VACUETTE®** No Additive Tubes and **VACUETTE®** Serum Clot Activator Tubes may be used for viral marker testing in screening and clinical laboratories.

**VACUETTE®** 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, which eliminates the need for transfer to another container. For specific parameter stability, refer to the recommendations of the assay and/or instrument manufacturer and/or specific CLSI documents (i.e., guidelines, standards). **VACUETTE®** Serum Clot Activator with Gel Tubes may be used for therapeutic drug monitoring (TDM) testing.

### VACUETTE® Heparin Tubes

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

**VACUETTE®** 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, where it forms a stable barrier separating the plasma from cells. Plasma may be aspirated directly from the collection tube, which eliminates the need for transfer to another container. For specific parameter stability, refer to the recommendations of the assay and/or instrument manufacturer and/or specific CLSI documents (i.e., guidelines, standards).

Do not use **VACUETTE®** Plasma Tubes with Lithium Heparin or with Lithium Heparin and Gel for lithium determinations or blood banking procedures. Do not use **VACUETTE®** Plasma Tubes with Sodium Heparin for sodium determinations or blood banking procedures.

### VACUETTE® EDTA Tubes

The interior of the tube wall is coated with either K2EDTA or K3EDTA. The EDTA binds calcium ions and blocks the coagulation cascade. **VACUETTE®** EDTA Tubes can be used in the closed mode with direct sampling analyzers. For parameter stability information, i.e., whole blood count (CBC) and differential (DIFF), follow the recommendations of the assay and/or instrument manufacturer. Refer to specific CLSI documents (i.e., guidelines, standards) for additional information.

**VACUETTE®** K3EDTA and K2EDTA Tubes may be used for routine immunohematology testing, i.e., red cell grouping, Rh typing and antibody screening. **VACUETTE®** K2EDTA and **VACUETTE®** K3EDTA Tubes may be used for viral marker testing in screening and clinical laboratories.

**VACUETTE®** K3EDTA and K2EDTA Tubes are used for testing plasma in molecular diagnostics. The performance characteristics of this device have not been established for molecular diagnostics in general. Users must validate use of product for their specific molecular diagnostic assay. **VACUETTE®** K2EDTA with Gel Tubes are used for testing plasma in molecular diagnostics.

### VACUETTE® Glycolytic Inhibitor Tubes

The tubes contain an antiglycolytic agent, sodium fluoride, and an anticoagulant, potassium oxalate. VACUETTE® Glycolytic Inhibitor Tubes are suitable for the analysis of blood glucose and lactate.

### VACUETTE® Trace Element Tubes

VACUETTE® Trace Element Tubes contain sodium heparin or no additive and are used to test trace elements. VACUETTE® Trace Element No Additive Tubes do not contain a clot activator and have to remain in an upright position until the blood has fully clotted. Before determination of trace element all devices used in collection, transportation and storage should be evaluated. A blank measure for each tube lot must be carried out beforehand.

### VACUETTE® ESR Tubes (Not available in USA)

VACUETTE® ESR Tubes contains a 0.109M (3.2%) buffered tri-sodium citrate solution. The mixing ratio is 1 part citrate solution to 4 parts blood. VACUETTE® ESR Tubes are used for the collection and transport of venous blood for blood sedimentation rate testing. ESR measurements refer to the Westergren method.

### Closed VACUETTE® ESR System

The system consists of two parts:

- A 9 x 120mm, graduated, plastic tube with a 0.109M (3.2%) buffered tri-sodium citrate solution. Draw volume 1.5ml and 2.75ml
- An ESR rack with a scale suitable for 1.5ml and 2.75ml tubes.

### Procedures for closed VACUETTE® ESR measurement:

After sampling and also before starting the ESR measurement, gently invert the tube 5-10 times to obtain the correct mixture. Use of a rotating mixer is recommended.

**NOTE:** It is recommended to do the determination within the first 4 hours when stored at room temperature. If longer storage is required, keep the specimen at the refrigerator (maximum 24 hours). Note that the sample must be brought to room temperature before use.

1. Place the 1.5ml or 2.75ml tube vertically into the corresponding rack. Align the '0' mark at the top of the scale with the bottom of the meniscus at the blood-air interface. For the 1.5ml ESR tube, set the timer for 30 minutes. The ESR rack suitable for 1.5ml tubes delivers only the 1-hour Westergren value after 30 minutes of reading time. For the 2.75ml ESR tube, set the timer for 60 minutes. The ESR rack suitable for 2.75ml tubes delivers 1 hour and 2-hour Westergren values after 60 and 120 minutes of reading times.
2. Discard the closed VACUETTE® ESR Tube in an approved biohazard container.

**NOTE:** The conversion scale becomes highly compressed above Westergren values of 100mm. If more precise values are required, ESR readings above this value should be repeated using the classic Westergren method.

### VACUETTE® Precautions/Cautions

#### For in vitro diagnostic use

#### Precautions

Do not use tubes if foreign matter is present.

#### Caution

1. 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.
2. Obtain appropriate medical attention in the case of any exposure to biological samples (for example, through a puncture injury), because of the possible transmission of HIV (AIDS), viral hepatitis or other infectious diseases.
3. Discard all blood collection "sharps" in approved biohazard containers.
4. Transferring a sample from a syringe to a tube is not a recommended procedure. Additional manipulation of sharps increases the potential for a needle stick injury. Using a syringe for blood transfer may also cause over or under filling of tubes, an incorrect blood-to-additive ratio and erroneous test results. In addition, depressing the syringe plunger during transfer can create a positive pressure, forcefully displacing the stopper and sample, resulting in a potential blood exposure. The use of the VACUETTE® Blood Transfer Unit is highly recommended. If blood is collected through an intravenous (IV) line, follow the policies and procedures of your institution to ensure that the line has been cleared of IV solution before beginning to fill the blood collection tubes. This is critical to avoid erroneous laboratory data from IV fluid contamination.
5. Liquid preservatives and anticoagulants are typically clear and colorless. However, clot activator additive may appear white on the tube surface and EDTA may have a slightly white to yellow appearance, which has no effect on the performance of the tubes. If any other discoloration or precipitates are present in the tube, it should not be used.
6. The presence of ammonia is an intrinsic property of sterilized EDTA tubes. If used for determination of ammonia in human plasma, the establishment of a baseline is recommended. Alternatively, a lithium heparin plasma tube may be used if appropriate for the test method used.
7. Do not use the tubes after the expiration date.
8. Venous blood collected in heparinized vacuum tubes is not suitable for blood gas analysis.

#### Storage

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.)

### Specimen Collection and Handling

READ THIS ENTIRE CIRCULAR BEFORE PERFORMING VENIPUNCTURE.

#### Equipment required for specimen collection.

Be sure that the following materials are readily accessible before performing venipuncture:

1. All necessary tubes, identified for size, draw and additive.
2. Labels for positive patient identification of samples.
3. Blood collection needles and holders  
**NOTE:** Greiner VACUETTE® devices (needles, single-use holders, safety devices) are designed to be used as a system. Determination of the compatibility of other manufacturer's products with a Greiner VACUETTE® device is solely the responsibility of the user.
4. Appropriate apparel, i.e., gloves laboratory coat, goggles, for protection from exposure to bloodborne pathogens.
5. Alcohol swab for cleansing site.
6. Clean gauze.
7. Tourniquet (i.e., single-use, latex-free).
8. Adhesive plaster or bandage (i.e. hypoallergenic).
9. Approved biohazard container.

**Recommended Order of Draw:** (based on: CLSI GP41-ED7)

- 1 Blood Culture
- 2 Sodium Citrate tube

- 3 Serum tube with or without gel separator (clot activator)
- 4 Heparin tube with or without gel separator
- 5 EDTA tube with or without gel separator
- 6 Glycolytic Inhibitor tube

**NOTE:** If a winged blood collection set is used, the first tube in the series will be under-filled. Therefore, if a coagulation specimen is drawn first, a discard tube (a no-additive or coagulation tube) is recommended to be drawn prior to this tube to ensure the proper anticoagulant-to-blood ratio. In addition, even though studies have shown that PT and APTT tests are not affected if drawn first in a tube series, it is advisable to draw a second tube for other coagulation assays, since it is not known whether or not these tests will be affected.

**NOTE:** Always follow your facility's protocol for Order of Draw.

#### 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 the tube into the patient's arm, observe the following precautions:

1. Place the patient's arm in a downward position.
2. Hold the tube with the cap uppermost.
3. Release the tourniquet as soon as blood starts to flow into the tube.
4. Avoid tube contents coming in contact with cap or end of the needle during venipuncture.

### Venipuncture Technique and Specimen Collection

#### General Instructions

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

1. Select the tube or tubes appropriate for the 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 that the needle does not unthread during usage.
4. Apply the tourniquet. Do not exceed one minute. Localized stasis with hemoconcentration and infiltration of blood into tissue may occur, resulting in erroneously high values for specific analytes, i.e., based analytes, packed cell volume, and other cellular elements.
5. Prepare venipuncture site with an appropriate antiseptic. DO NOT PALPATE VENIPUNCTURE AREA AFTER CLEANSING.
6. Place the patient's arm in a downward position.
7. Remove needle shield. Perform the venipuncture WITH THE ARM DOWNWARD AND TUBE CAP UPPER-MOST.
8. Push the tube into the holder and onto the needle valve puncturing the rubber diaphragm. Center the tubes in the holder when penetrating the cap to prevent sidewall penetration and subsequent premature vacuum loss.
9. REMOVE THE TOURNIQUET AS SOON AS BLOOD APPEARS IN THE TUBE. DO NOT ALLOW CONTENTS OF TUBE TO CONTACT THE CAP OR END OF THE NEEDLE DURING PROCEDURE. Always hold the tube in place by pressing it with a thumb. This will ensure a 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 a satisfactory collection:

- a) Push the tube forward until the tube cap has been penetrated.
- b) Confirm the correct position of the needle in the vein.
- c) If blood still does not flow, remove the tube and place the new tube onto the holder.
- d) If the second tube does not draw, remove the needle and discard. Repeat the procedure from step 1.
10. When the first tube is full and the blood flow ceases, gently remove it from the holder.
11. Place the succeeding tubes in the holder. Refer to the recommended Order of Draw.
12. Gently invert each tube once removed from the holder, using the correct number of inversions to achieve the proper mix of additive and blood. Turn the filled tube upside down and return it to an upright position. This is one complete inversion.  
**NOTE:** Do not shake the tubes. Vigorous mixing may cause foaming or hemolysis. 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.
13. As soon as the blood stops flowing in the last tube, remove the needle from the vein. Activate the safety mechanism of the device. Apply pressure to the puncture site with a dry sterile swab until the bleeding stops. Once clotting has occurred, apply a bandage, if desired. Hypoallergenic adhesives may be advisable.  
**NOTE:** After the completion of the venipuncture procedure, the top of the cap may contain residual blood. Take the proper precautions when handling tubes to avoid contact with this blood.
14. Dispose of the used needle safety device in an approved biohazard container. DO NOT RECAP. Recapping of needles increases the risk of needle stick injury and blood exposure.
15. 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:** It is recommended that filled tubes, especially serum during the clotting process, be kept in an upright position.

#### Centrifugation

Ensure that tubes are properly seated in the centrifuge carrier. Incomplete seating may result in the separation of the **VACUETTE**<sup>®</sup> SAFETY Cap from the tube.

**NOTE:** Prior to centrifugation, **VACUETTE**<sup>®</sup> Serum Tubes must be allowed to clot thoroughly (minimum 30 minutes) after blood collection to minimize the buildup of fibrin in serum. Recommended time is based on intact clotting process. Patients with abnormal clotting require more time to complete the clot formation. Incomplete clotting may lead to contamination of the instrument and to erroneous results.

**NOTE:** **VACUETTE**<sup>®</sup> 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 test results.

Tube Type	Recommended Inversions	Recommended g-force* relative centrifugal force (rcf)	Recommended Time* Minutes
<b>VACUETTE</b> <sup>®</sup> Serum Tubes (Clot Activator, No Additive)	5-10	Minimum 1500 g	10
<b>VACUETTE</b> <sup>®</sup> Serum Clot Activator w/Gel Tubes	5-10	1800 g	10
<b>VACUETTE</b> <sup>®</sup> K2EDTA w/Gel Tubes	8-10	1800 – 2200 g	10
<b>VACUETTE</b> <sup>®</sup> Plasma Tubes (Lithium Heparin, Sodium Heparin, Glycolytic Inhibitor)	5-10	2000 – 3000 g	15
<b>VACUETTE</b> <sup>®</sup> Lithium Heparin w/Gel Tubes	5-10	1800-2200 g	10-15
<b>VACUETTE</b> <sup>®</sup> Coagulation Tubes (Sodium Citrate)			
Platelet tests (PRP)	4	150 g	5
Routine tests (PPP)		1500 – 2000 g	10
Preparation for deep freeze plasma (PFP)		2500 – 3000 g	20

\*Alternate centrifugation settings for g-force and time may provide acceptable sample quality but these settings must be validated by the laboratory.

Barriers are more stable when tubes are spun in centrifuges with horizontal swing-out rotors rather than those with fixed angle heads. Centrifugation temperatures should be maintained at 15-25 °C. Higher temperatures could have negative effects on the physical properties of the gel. Ideal separation of serum or plasma is achieved in this temperature range.

**NOTE:** It is not recommended to re-centrifuge tubes once the barrier has been formed.

#### **VACUETTE**<sup>®</sup> Safety Caps











The **VACUETTE**<sup>®</sup> blood collection system features a unique safety cap designed to minimize aerosol generation.

**Both 13mm and 16mm tubes have pull caps that are removed with a pull action.**

## Disposal

1. Follow OSHA and CDC Universal Precaution procedures to prevent the transmission of human immunodeficiency virus (HIV), hepatitis B virus (HBV), and other bloodborne pathogens.
2. Use protective equipment and wear disposable latex gloves (sensitivity/allergy appropriate) to prevent the risk of infection.
3. Follow OSHA and the policies and procedures of your facility for the disposal of contaminated equipment and specimen collection devices.

## Label Information

	Manufacturer		Temperature limits
	Expiry Date. Use by date		Do not re-use
	LOT number: Batch number		Consult instructions for use
	Item number		<i>In vitro</i> diagnostic medical device
	Authorized representative in the European Community		Sterilized using irradiation

### References:

#### ISO / EN / ANSI/AAMI Standard(s)

ISO 6710 "Single-use containers for venous blood specimen collection"

ANSI/AAMI/ISO 11137 "Sterilization of health care products – Requirements for validation and routine control – Radiation sterilization"

#### Clinical and Laboratory Standards Institute (CLSI)

C38-A "Control of Preanalytical Variation in Trace Element Determinations", Approved Guideline

GP39-A6 "Tubes and Additives for Venous and Capillary Blood Specimen Collection", Approved Standard - 6th Edition

GP41-ED7 "Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture", Approved Standard - 7th Edition

GP44-A4 "Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests", Approved Guideline – 4th Edition

H21-A5 "Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays", Approved Guideline - 5th Edition

H2-A5

H20-A2 "Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods" Approved Standard - 2nd Edition.

H26-A2 "Validation, Verification, and Quality Assurance of Automated Hematology Analyzers", Approved Standard – 2nd Edition.

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