

CE Evacuated Blood Collection System GB

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 colour-coded VACUETTE® SAFETY Caps (see table below). 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 (EN 14820) "Single-use containers for venous blood specimen collection" and the Clinical and Laboratory Standards Institute (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 Colour Codes

| Description | SAFETY Cap Colour | Cap Inner Ring Colour |
|--|--|-----------------------------------|
| No Additive Tubes Z No Additive | white | black |
| Coagulation Tubes 9NC Sodium Citrate 3.2% 9NC Sodium Citrate 3.8% CTAD | light blue light blue light blue | black black yellow |
| Serum Tubes Z Clot activator Z Clot activator and gel Z Clot activator and beads | red red red | black yellow red |
| Heparin Tubes LH Lithium Heparin LH Lithium Heparin and Gel AH Ammonium Heparin NH Sodium Heparin | green green green green | black yellow black black |
| EDTA Tubes (haematology) K2E K2EDTA (also immuno haematology) K3E K3EDTA (also immuno haematology) | lavender lavender | black black |
| EDTA Tubes (molecular diagnostics and viral load detection) K2E K2EDTA K2E K2EDTA and Gel | lavender lavender | black yellow |
| Glucose Tubes FE EDTA and Sodium Fluoride FX Potassium Oxalate and Sodium Fluoride LH Lithium Heparin and Iodoacetate FH Sodium Heparin and Sodium Fluoride | grey grey grey grey | black black black black |
| Crossmatch Tubes Z Clot Activator K3E K3EDTA | pink pink | black black |
| Blood Grouping Tubes ACD-B ACD-A CPDA | yellow yellow yellow | black black black |
| Trace Element Tubes NH Sodium Heparin Z Clot Activator | royal blue royal blue | black black |
| ESR Tubes (IFU 980232) | | |
| Homocysteine Detection Tubes Buffered sodium citrate / citric acid solution | white | red |

(Tubes with a white inner cap ring refer to smaller draw volumes of 1ml or 2 ml.)

VACUETTE® Coagulation Tubes and VACUETTE® CTAD Tubes

VACUETTE® 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.

VACUETTE® CTAD Tubes contain besides the buffered citrate solution, theophylline, adenosine and dipyridamole.

VACUETTE® Coagulation and CTAD tubes are used for coagulation tests.

VACUETTE® Serum Tubes

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

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, eliminating the need for transfer to another container.

VACUETTE® Serum Tubes with beads contain polystyrene beads, which are present in the bottom of the tube. The specific gravity of the beads lies between the blood clot and serum. During centrifugation the beads move upward to form a layer between the serum and blood clot. **VACUETTE® Serum tubes** are used for determinations in serum for routine clinical chemistry tests and hormones, TDM, serology and immunohaematology.

VACUETTE® Heparin Tubes

The interior of the tube wall is coated with lithium heparin, ammonium 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.

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 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.

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

VACUETTE® EDTA Tubes

The interior of the tube wall is coated with either K2EDTA or K3EDTA. The tube is also available with an 8% liquid EDTA solution. The EDTA binds calcium ions thus blocking the coagulation cascade. **VACUETTE® EDTA Tubes** can be used in direct sampling analysers without actually being opened.. Blood smearing should be done within 3 hours after blood collection. **VACUETTE® EDTA Tubes** are used for testing whole blood in the clinical laboratory. **VACUETTE® K2EDTA and K3EDTA Tubes** may be used for routine immunohematology testing i.e. red cell grouping, Rh typing and antibody screens, and viral marker testing in screening laboratories.

VACUETTE® K2EDTA Tubes are used for testing whole blood in molecular diagnostics. **VACUETTE® K2EDTA Gel Tubes** are used for testing plasma in molecular diagnostics and viral load detection. However centrifugation for **VACUETTE® K2EDTA /Gel Tubes** should be done within 6 hours after blood collection for best results. Mid- term storage (up to 2 weeks) in primary tubes is recommended at -20°C. For long-term storage (over 2 weeks) at -70°C or at lower temperatures please store aliquots in cryo vials.

VACUETTE® Glucose Tubes

VACUETTE® Glucose Tubes are available with different additives. The tubes contain an anticoagulant and a stabilizer. EDTA and sodium fluoride / Potassium oxalate and sodium fluoride / Sodium heparin and sodium fluoride / Lithium heparin and iodoacetate

VACUETTE® Glucose tubes are suitable for the analysis of blood sugar and lactate.

VACUETTE® Crossmatch Tubes

VACUETTE® Crossmatch Tubes are available in two different versions. One tube type contains clotting activator used to make crossmatch tests with serum, while the other type contains K3EDTA and is used to make crossmatch tests with whole blood. The field of application is crossmatching.

VACUETTE® Blood Grouping Tubes

VACUETTE® Blood Grouping Tubes are available with ACD (Acid Citrate Dextrose) solutions in two formulations (ACD-A or ACD-B) or with CPDA solution (Citrate Phosphate Dextrose Adenin). VACUETTE® Blood Grouping Tubes are used for blood grouping tests or cell preservation.

VACUETTE® Trace Element Tubes

VACUETTE® Trace Element Tubes contain sodium heparin, or clot activator and are used to test trace elements such as Cd, Cr, Cu, Pb, Ni, Zn

VACUETTE® Homocysteine Detection Tubes

VACUETTE® Homocysteine Detection Tubes contain a buffered sodium citrate / citric acid solution (pH=4,2) to stabilize homocysteine in whole blood. During blood collection ensure complete filling of tubes (to the fill mark). Gently invert the tubes 8-10 times immediately after blood collection to reach a proper mix of additive and blood. The analysis result of the homocysteine concentration must be multiplied by the factor 1.11 to compensate for dilution by the citrate.

VACUETTE® Precautions/Cautions

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), since they may transmit HIV (AIDS), viral hepatitis, or other blood-borne pathogens.
3. Discard all blood collection “sharps” in biohazard containers approved for their disposal.
4. 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.
5. If blood is collected through an intravenous (IV) line, ensure that the line has been cleared of IV solution before beginning to fill blood collection tubes. This is critical to avoid erroneous laboratory data from IV fluid contamination
6. Do not use tubes containing lithium iodoacetate if they become coated with a yellow film along the tube walls.
7. All liquid preservatives and anticoagulants are clear and colourless (Exception: CPDA tubes contain a yellowish liquid). Do not use if they are discoloured or contain precipitates.
8. Do not use tubes after their expiration date.

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, colouring, etc.) Filled tubes can be stored at down to –20°C.

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:** VACUETTE® blood collection needles are designed for optimal use with holders from Greiner Bio-One. The use of holders from other manufacturers is under the responsibility of the user.
4. Practice standard precautions, using gloves and appropriate apparel for protection from exposure to blood-borne pathogens.
5. Alcohol swab for cleansing site
6. Tourniquet
7. Adhesive plaster or bandage
8. Sharps disposal container for safe disposal of used needle

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)

NOTE: *In cases where blood culture tubes are not required, GBO recommends no-additive tubes.*

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 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.

High Altitude

For collection at high altitude (1500m/5000ft) we recommend high altitude tubes. The vacuum in these tubes compensates for the lower outer pressure.

Venipuncture Technique and Specimen Collection

General Instructions

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 standard 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 5-10 times (exceptions: coagulation tubes - invert 4 times; EDTA tubes and homocysteine detection tubes - invert 8-10 times) 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.

Centrifugation

Ensure that tubes are properly seated in the centrifuge carrier; incomplete seating could result in the separation of the **VACUETTE®** Safety Cap from the tube.

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

| Tube Type | In-versions | Recommended g-force relative centrifugal force (rcf) | Time [min] |
|--|-------------|--|------------|
| VACUETTE® Serum Tubes | 5-10 | Minimum 1500 g | 10 |
| VACUETTE® Serum Tubes with Gel | 5-10 | 1800 g | 10 |
| VACUETTE® Serum Tubes with Beads | 5-10 | 1800 g | 10 |
| VACUETTE® EDTA Tubes / with Gel | 8-10 | 1800 – 2200 g | 10 |
| VACUETTE® Heparin Plasma Tubes | 5-10 | 2000 – 3000 g | 15 |
| VACUETTE® Heparin Plasma Tubes with Gel | 5-10 | 2200 g | 15 |
| VACUETTE® Homocystein Detection Tubes | 8-10 | 2000 – 2200 g | 10 |
| VACUETTE® Coagulation Tubes | | | |
| - Platelet tests (PRP) | 4 | 150 g | 5 |
| - Routine tests (PPP) | 4 | 1500 – 2000 g | 10 |
| - Preparation for deep freeze plasma (PFP) | 4 | 2500 – 3000 g | 20 |

Barriers are more stable when tubes are spun in centrifuges with horizontal swing-out rotors rather than those with fixed angle heads. 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 15°C-24°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.

VACUETTE® Safety Caps

The **VACUETTE®** blood collection system features a unique safety cap design to minimize aerosol generation. There are two different closure systems available depending on the size of the tube:

13mm tubes: Premium and non-ridged tubes

Premium tubes are fitted with a **VACUETTE®** Safety Screw Cap. Remove the cap from the tube by twisting in an anti clockwise direction. The cap cannot be removed by a simple pull action.

Non-ridged tubes are also fitted with a **VACUETTE®** Safety Screw Cap. However, because of the absence of ridges on the tubes, the cap can be removed by a simple pull action.












Ridged tubes (available in Brasil) are fitted with a **VACUETTE®** Safety Screw Cap. Remove the cap from the tube by twisting in a counter clockwise direction with a twist-pull motion. The cap cannot be removed by a simple pull action.)

16 mm tubes: **VACUETTE®** Safety Grip Cap – Remove the cap from the tube with a simple pull action.

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).

Label Information

| Label information | | | |
|---|--|---|--------------------------------|
|  Ref. | Item number |  | Keep Away From Direct Sunlight |
|  LOT | LOT number: Batch number |  | Handle With Care |
|  | Expiry Date. Use by the end of the month indicated |  | Recyclable |
|  STERILE | Sterilization Using Irridation |  | Authorized Representative |
|  | Do Not Reuse |  | In Vitro Diagnostic Device |
|  | Consult Instructions For Use | | |

References:

ISO / EN / ANSI/AAMI Standards

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

EN 14820:2004 "Single-use containers for human venous blood specimen collection"

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

EN 552 "Sterilisation of medical devices – Validation and routine control of sterilisation by irradiation"

Clinical and Laboratory Standards Institute (CLSI)

H1-A5 "Evacuated Tubes and Additives for Blood Specimen Collection- 5th Edition"; Approved Standard

H3-A6 "Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture"; Approved Standard-6th Edition

H21-A4 "Collection, Transport, and Processing of Blood Specimens for Coagulation Testing and General Performance of Coagulation Assays; Appr. Guidel.-4th Edition

H20-A Reference Leukocyte Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard.

H26-A Performance Goals for the Internal Quality Control of Multichannel Hematology Analyzers; Approved Standard.



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