VACUETTE®

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Evacuated Blood Collection System

For In Vitro Diagnostic Use

Intended Use

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

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, volume of liquid additives, and their permitted tolerances, as well as the blood-to-additive ratio, are in accordance with the requirements and recommendations of the international standard 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 Colour Codes*

Description	Safety Cap Colour	Cap Inner Ring Colour
No Additive Tubes		
Z No Additive	white	black
Coagulation Tubes		
9NC Coagulation Sodium Citrate 3.2%	light blue	black
9NC Coagulation Sodium Citrate 3.8%	light blue	black
CTAD	light blue	yellow
Serum Tubes		
CAT Serum	red	black
CAT Serum Sep	red or gold	yellow or gold
CAT Serum Fast Sep	orange	yellow
Heparin Tubes		
LH Lithium Heparin	green	black
LH Lithium Heparin Sep	green or mint green	yellow
AH Ammonium Heparin	green	black
NH Sodium Heparin	green	black
EDTA Tubes		
K2E K2EDTA	lavender	black
K3E K3EDTA	lavender	black
K2E K2EDTA Sep	lavender	yellow
Glycolytic Inhibitor Tubes		
FE Sodium Fluoride / K3EDTA	grey	black
FX Sodium Fluoride / Potassium Oxalate	grey	black
LH Lithium Heparin and Iodoacetate	grey	black
FH Sodium Fluoride / Sodium Heparin	grey	black
FC Mix Tubes	grey pink	black black
Crossmatch Tubes		
CAT Crossmatch Serum	pink	black
K3E Crossmatch K3EDTA	pink	black
Blood Grouping Tubes		
ACD-B	yellow	black
ACD-A	yellow	black
CPDA	yellow	black
Trace Element Tubes		
NH Trace Elements Sodium Heparin	royal blue	black
Z Trace Elements No Additive	royal blue	black
ESR Tubes (IFU 980232)		
Special Tubes		
Homocysteine Detection Tubes	white	red

***Example of standard colours. Cap colour may vary for specific item numbers and/or due to local requirements.**
Separator (Sep) Tubes are containing a separator gel. CAT indicates Clot Activator Tubes.

(Tubes with a white inner cap ring have smaller draw volumes of 1ml or 2 ml. Black rings identify standard draw and yellow rings identify Sep tubes.)

Coagulation Sodium Citrate Tubes and CTAD Tubes
VACUETTE® 9NC Coagulation Sodium Citrate 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 buffered citrate solution, theophylline, adenosine and dipyridamole.
Coagulation and CTAD tubes are used for coagulation tests.

Serum Tubes
All Serum Tubes are coated with micronized silica particles which activate clotting when tubes are gently inverted.
VACUETTE® CAT Serum Sep Tubes 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.
Serum tubes are used for determinations in serum for routine clinical chemistry tests and hormones, serology, immunohaematology and TDM. Therapeutic drugs (TDM) were partially tested in gel tubes (for more details consult studies on https://www.gbo.com/preanalytics).
VACUETTE® CAT Serum Fast Sep Tubes are coated with a clotting activator containing thrombin to accelerate the clotting process. They are used for determinations in serum for routine clinical chemistry tests. The product is not suitable for patients under heparin or thrombin inhibitor therapy or fibrinogen deficiency. For more details on tested parameters consult studies on https://www.gbo.com/preanalytics.

Heparin Tubes
The interior of the tube wall is coated with lithium heparin, ammonium heparin or sodium heparin. The anticoagulant heparin activates antithrombin, which blocks the coagulation cascade to produce a whole blood / plasma sample making it ideal for rapid analysis and analysis of blood from patients under anticoagulant therapy.
VACUETTE® LH Lithium Heparin Sep Tubes contain a barrier gel that is present in the bottom of the tube. The specific gravity of this material lies between that of the blood cells and plasma. During centrifugation the gel barrier moves upward, where it forms a stable barrier separating the plasma from the cells. Plasma may be aspirated directly from the collection tube, which eliminates the need for manual transfer to another container.
Heparin tubes are used for plasma determinations of routine clinical chemistry tests. ***NOTE****: Lithium determinations should not be performed in Lithium Heparin tubes. Ammonium determinations should not be performed in Ammonium Heparin tubes. Sodium determinations should not be performed in Sodium Heparin tubes.*

EDTA Tubes
The interior of the tube wall is coated with either K2EDTA or K3EDTA. The anticoagulant EDTA binds calcium ions thus blocking the coagulation cascade.
VACUETTE® K2E K2EDTA Tubes and **VACUETTE**® K3E K3EDTA Tubes are used for testing whole blood in haematology. For parameter stability information, i.e., whole blood count (CBC) and differential blood count (DIFF), follow the recommendations of the instrument manufacturer. Refer to specific documents (i.e., guidelines, standards) for additional information. Blood smears should be prepared within four hours of blood collection.
EDTA Tubes may also be used for routine immunohaematology testing i.e. red cell grouping, Rh typing and antibody screens, viral marker testing in screening laboratories and molecular diagnostics.
VACUETTE® K2E K2EDTA Sep Tubes are used for testing plasma in molecular diagnostics and viral load detection.

Glycolytic Inhibitor Tubes
These tubes are available with different additives. The tubes contain a stabilizer and an anticoagulant: Sodium Fluoride / K3EDTA, Sodium Fluoride / Potassium Oxalate, Sodium Fluoride / Sodium Heparin. They are suitable for the analysis of glucose concentration within 48 hrs. Please refer to the test kit instruction for the tube of choice, especially for lactate analysis.
VACUETTE® FC Mix Tubes are used to stabilize the in-vivo glucose concentration in whole blood and/or plasma. They contain an additive mix of Na_2EDTA, sodium fluoride, citric acid and sodium citrate. ***NOTE:*** *Proper mixing (10x) is important!*
VACUETTE® FC Mix Tubes (Primary Tubes) can be stored after correct inversion for up to 24 hours at room temperature without centrifugation.

- Should the tubes be expected to be stored longer than 24 hours at room temperature, samples should be centrifuged immediately after blood collection in order to be stored for up to 48 hours at room temperature.
- Centrifuged aliquots from **VACUETTE**® FC Mix Tubes can be stored for up to 48 hours at room temperature. Tubes should be centrifuged as soon as possible.
- Cooling of the samples (4-8°C, 39–46°F) is also suitable for 48 hours glucose stabilization.

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

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

Trace Element Tubes
Trace Element Tubes contain sodium heparin or no additive and are used to test trace elements. **VACUETTE**® Trace Element Z 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® Homocysteine Detection Tubes
VACUETTE® Homocysteine Detection Tubes contain a buffered sodium citrate / citric acid solution (pH=4.2) to stabilize homocysteine in whole blood.
The analysis result of the homocysteine concentration must be multiplied by the factor 1.11 to compensate for dilution by the citrate. In some cases, the factor may be subject to natural, physiological fluctuations. ***NOTE****: Not suitable for enzymatic test methods.* Assay evaluations show that there is not always compatibility. Therefore the assay compatibility should be verified prior to use. Incompatibility could lead to erroneous or invalid test results.

No Additive Tubes
VACUETTE® Z No Additive Tubes do not contain any additive but are evacuated and the interior is sterile. They can be used as discard tubes or for the collection of blood.

Precautions/Cautions

1. Do not use tubes if foreign matter is present!
2. To ensure accurate test results, all **VACUETTE®** Blood Collection Tubes must be allowed to fill completely.
3. 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.
4. 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.
5. Discard all blood collection "sharps" in biohazard containers approved for their disposal.
6. For safety reason, we do not recommend transferring biological material with a syringe to a **VACUETTE®** Tube. Additional manipulation of sharps increases the potential for needlestick injury. In addition, depressing the syringe plunger during transfer can create a positive pressure, forcefully displacing the stopper and sample and causing potential blood exposure. The use of the **VACUETTE®** Blood Transfer Unit is highly recommended. 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.
7. 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.
8. Do not use tubes containing lithium iodoacetate if they become coated with a yellow film along the tube walls.
9. Liquid preservatives and anticoagulants are clear and colourless. CPDA tubes contain a yellowish liquid, the clot activator may appear white and EDTA tubes may have a slightly white to yellow appearance which does not affect the performance of these tubes.
10. Tubes with visible floating clots occurrence increases when centrifugation conditions are not followed according to recommended g-force and/or time.
11. 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.
12. 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.)*

Limitations

1. Refer to the instrument assay instructions for use for information on the correct sample material, correct storage and stability.
2. Heparin plasma should be separated from cells within 2 hours, either by collection and centrifugation with a separator tube or by transferring plasma into a secondary container if a separator tubes is not used. ***NOTE****: Primary* **VACUETTE®** *Heparin Sep Tubes are not recommended to be frozen.*
3. Assay compatibility for the **VACUETTE®** Homocysteine Detection Tube is not ensured in every case (e.g. in case of enzymatic methods). Please verify the compatibility prior to use. If there is no assay compatibility, it could lead to false or invalid analysis results.
4. Not all therapeutic drugs have been tested. Consult studies on www.gbo.com/preanalytics
5. **VACUETTE®** CAT Serum Tubes are not suitable for the determination of trace elements such as Ag, Al, As, Ba, Be, Cd, Cr, Co, Cu, Hg, I, Li, Mn, Mo, Ni, Pb, Se, Sb, Sn, Te, Th, Tl, U, Zn.
6. **VACUETTE®** CAT Serum Fast Sep Tubes with visible floating clots lead to deviations in LDH values.
7. Fluoride is known to cause an increase in haemolysis. For further information on substances that may interfere, please consult the assay instructions for use.
8. Venous blood collected in heparinized vacuum tubes is not suitable for blood gas analysis.
9. **VACUETTE®** amber tubes protect specimens against light of wavelengths below 380nm.

Specimen Collection and Handling

READ THIS ENTIRE DOCUMENT 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. Disposable gloves and personal protective equipment
3. Labels for positive patient identification of samples
4. 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.*
5. Alcohol swab for cleansing site
6. Tourniquet

7. Adhesive plaster or bandage
8. Sharps disposal container for safe disposal of used material

Recommended Order of Draw: (based on: CLSI GP41-ED7)
1 Blood culture
2 Sodium Citrate
3 Serum / Serum Sep / Serum Fast Sep (Clot activator)
4 Heparin / Heparin Sep
5 EDTA / EDTA Sep
6 Glycolytic inhibitor tubes
7 Other additives
NOTE: *If a winged blood collection set is used, the first tube in the series will be under-filled. Therefore, if a Sodium Citrate specimen is drawn first, a discard tube (No Additive) is recommended to be drawn prior to this tube to ensure the proper additive-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*
NOTE*: For* **VACUETTE**® Trace Element Tubes *(Sodium Heparin) we recommend a separate blood collection to avoid contamination of the samples.*

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.

Freezing/ Thawing
Following the WHO recommendations (WHO/DIL/Lab/99.1 Rev.02), it is recommended to separate serum/plasma from blood cells before freezing. Filled primary tubes (except tubes with dimension 16x100) withstand a freezing down to -80°C.
NOTE: the total volume inside the tubes should not be more than 2/3 of the nominal volume. After complete filling of the tube during the blood collection, it may be necessary to remove serum/plasma from the centrifuged tube to obtain the correct fill volume for freezing.
It is recommended to keep the samples in the refrigerator for 2 hours prior to freezing. Freeze centrifuged serum gel tubes upright in an open metal rack at -20°C for ≥ 2 hours. The tubes can remain at -20°C or be transferred to -80°C. Thawing is recommended at room temperature or in the refrigerator.
For long-term storage, it is recommended to use special cryo vials. Users should also establish their own freezing protocol.
NOTE*: The stability of the parameters refers to the instrument assay instructions for use.*

High Altitude
For collection at high altitude (1600 m/5250 ft or 3000 m/9850 ft) we recommend high altitude tubes. The vacuum in these tubes compensates for the lower outer pressure.

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 as necessary (max. 1 minute)
5. Prepare venipuncture site with an appropriate antiseptic. DO NOT PALPATE VENIPUNCTURE AREA AFTER CLEANSING.
6. Place patient's arm in a downward position.
7. Remove needle shield. Perform venipuncture WITH ARM DOWNWARD AND TUBE CAP UPPER-MOST.
8. Push tube into the holder and onto the needle valve puncturing the rubber diaphragm. Centre tubes in holder when penetrating the cap to prevent sidewall penetration and subsequent premature vacuum loss. Hold in place by pressing the tube with the thumb or finger to ensure complete vacuum draw. The fill mark allows for visual control of the correct filling of the tube. A tolerance of +/-10% is allowed.
9. 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.
   NOTE*: Blood may occasionally leak from the needle sleeve. Practice universal standard 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) Ensure the tube is pushed fully forward in the holder.
   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.
10. When the first tube is full and blood flow ceases, gently remove it from holder.
11. Place succeeding tubes in holder, puncturing diaphragm to begin flow. Draw tubes without additives before tubes with additives. Refer to the recommended Order of Draw.
12. 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.*

13. As soon as blood stops flowing in the last tube, remove the tube and then the 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.*
14. Dispose of the used needle with holder using a suitable biohazard disposal 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**: 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 **VACUETTE**® Safety Cap from the tube.
***NOTE**: Prior to centrifugation,* **VACUETTE**® CAT Serum (Sep) Tubes *must be allowed to clot thoroughly (minimum 30 minutes) in an upright position after blood collection to minimize the build-up of fibrin in serum. Recommended time is based on intact clotting process. Patients with abnormal clotting require more time to complete the clot formation.*
VACUETTE® Z No Additive Tubes *do not contain a clot activator and have to remain in an upright position until the blood has fully clotted (minimum 60 minutes). Incomplete clotting may lead to contamination of the instrument and to erroneous results.*
VACUETTE® CAT Serum Fast Sep Tubes *can be centrifuged 5 minutes after blood collection. Inadequate mixing may lead to post clotting in* **VACUETTE**® CAT Serum Fast Sep Tubes*.*

Tube Type	Inversions (mixing)	Recommended g-force relative centrifugal force (rcf)	Time (min)
Serum Fast Sep	5-10x	1800 g	10
		3000 g	5
Serum Tubes / with Sep		1800 - 2200 g	10-15
EDTA Tubes / with Sep			
Heparin Plasma Tubes / with Sep			
Standard Glucose Tubes			
Homocystein Detection Tubes		2000 – 2200 g	10
VACUETTE® FC Mix Tubes	10x	1800 g	10
Coagulation Tubes			
- Platelet tests (PRP)	4-5x	150 g	5
- Routine tests (PPP)		1500 – 2000 g	10
- Preparation for deep freeze plasma (PFP)		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.
***NOTE:** If the gel movement is occasionally not adequate (especially due to a haematocrit >50%), it is recommended to use a higher g-force and longer centrifugation time.*
Centrifugation should be done in a temperature-controlled centrifuge that maintains 18-25°C (64-77°F). Higher temperatures could have negative effects on the physical properties of the gel. The yield of serum or plasma is ideal at 18-25°C (64-77°F).
***NOTE**: 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, hence centrifugation might be necessary sooner depending on the analyte. It is not recommended to re-centrifuge gel tubes once the barrier has been formed. The debris underneath the gel might contaminate the supernatant.*

VACUETTE® Caps

The **VACUETTE**® blood collection system features a unique safety cap design. There are two different closure systems available depending on the size of the tube:
13mm tubes:
Premium tubes 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 Removed the cap by a simple pull action.
16 mm tubes:
Non-ridged tubes: 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 prevent 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

	Manufacturer		Temperature limit
	Use-by date		Do not re-use
	Batch code		Consult instructions for use
	Catalogue number		*In vitro* diagnostic medical device
	Sterilized using irradiation		

References:
ISO / EN / ANSI/AAMI Standards
ISO 6710 “Single-use containers for venous blood specimen collection”
EN 14820 “Single-use containers for human venous blood specimen collection”
ISO 11137 “Sterilisation of health care products – Requirements for validation and routine control – Radiation sterilisation”

Literature:
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 ”Collection of Diagnostic Venous Blood Specimens”, 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
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.
WHO/DIL/LAB/99.1 Rev02 ”WORLD HEALTH ORGANIZATION, et al. Use of anticoagulants in diagnostic laboratory investigations. Geneva: World Health Organization, 2002”

Greiner Bio-One GmbH
Bad Haller Str. 32,
4550 Kremsmünster, Austria

www.gbo.com/preanalytics
office@at.gbo.com
Phone +43 7583 6791