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”. 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*

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

*(Tubes with smaller draw volumes of 1ml or 2 ml have a white inner ring.)

*Example of standard colours. Colour may vary for specific order numbers and/or due to local requirements.
Coagulation 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® Z 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 providing 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 hor...
Incompatibility could lead to erroneous or invalid test results. For more details visit www.gbo.com/preanalytics - section homocysteine tubes.

No Additive Tubes

VACUETTE® Z No Additive Tubes do neither contain any anticoagulant nor clot activator but are evacuated and the interior is sterile. They can be used as discard tubes or for the collection of blood or other body fluids for IVD use only.

VACUETTE® Precautions/Cautions

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 bloodborne 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 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. 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. 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.
7. Do not use tubes containing lithium iodoacetate if they become coated with a yellow film along the tube walls.
8. 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.
9. Do not use tubes after their expiration date.

Storage

Store tubes at 4°C (39°F) – 25°C (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 gel tube or by transferring plasma into a secondary container if a gel tubes is not used.
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. For more details visit www.gbo.com/preanalytics - section homocysteine tubes.
4. Not all therapeutic drugs have been tested.
5. Vitamin D3 determination by HPLC cannot be carried out with all gel tubes.
6. 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, Ti, U, Zn.
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.

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

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: (Literature: CLSI GP41-A6)

1 Blood culture/ no additive tubes
2 Coagulation*
3 Serum / Serum Sep
4 Heparin / Heparin Sep
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.

Freezing/Thawing
Filled tubes withstand a freezing down to -80°C. It is recommended to keep the samples in the refrigerator for 2 hours prior to freezing. Freeze centrifuged 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. After thawing, mix the sample thoroughly prior to analysis. To achieve perfectly clean heparin plasma, thawed samples should be aliquoted and centrifuged. For long-term storage, it is recommended to use special cryo vials. Users should also establish their own freezing protocol.

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 uppermost.
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.
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. 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.

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. See 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 an appropriate disposal device. 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:** VACUETTE® Z Serum (Sep) Clot Activator Tubes should be centrifuged at the earliest 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. Blood from patients under anticoagulant therapy or patients with coagulation disorders might need longer than 30 minutes to clot. Serum tubes should be allowed to fully clot prior to centrifugation.

<table>
<thead>
<tr>
<th>Tube Type</th>
<th>Inversions (mixing)</th>
<th>Recommended g-force relative centrifugal force (rcf)</th>
<th>Time (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum Tubes / with Sep</td>
<td></td>
<td>1800 - 2200 g</td>
<td>10-15</td>
</tr>
<tr>
<td>EDTA Tubes / with Sep</td>
<td>5-10x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heparin Plasma Tubes / with Sep</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standard Glucose Tubes</td>
<td></td>
<td>2000 – 2200 g</td>
<td>10</td>
</tr>
<tr>
<td>Homocystein Detection Tubes</td>
<td></td>
<td>1800 g</td>
<td>10</td>
</tr>
<tr>
<td>VACUETTE® FC Mix Tubes</td>
<td>10x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coagulation Tubes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Platelet tests (PRP)</td>
<td>4-5x</td>
<td>150 g</td>
<td>5</td>
</tr>
<tr>
<td>- Routine tests (PPP)</td>
<td></td>
<td>1500 – 2000 g</td>
<td>10</td>
</tr>
<tr>
<td>- Preparation for deep freeze plasma (PFP)</td>
<td></td>
<td>2500 – 3000 g</td>
<td>20</td>
</tr>
</tbody>
</table>

Other centrifugation settings may also provide acceptable separation. Plasma tubes should ideally be centrifuged at high g-force (e.g. 2200g). It should be evaluated and validated by the laboratory (e.g. increased g-force and/or decreased time). 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 cooled centrifuge. Higher temperatures could have negative effects on the physical properties of the gel. The yield of serum or plasma is ideal at 20°C-22°C.

**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 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.

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

Special Snap Caps made of only PE are available to recap the tubes for storing.

### 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

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Temperature limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use-by date</td>
<td>Do not re-use</td>
</tr>
<tr>
<td>Batch code</td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td>Catalogue number</td>
<td>In vitro diagnostic medical device</td>
</tr>
<tr>
<td>Authorized representative in the European Community</td>
<td>Sterilized using irradiation</td>
</tr>
</tbody>
</table>
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:

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