VACUETTE® ESR Blood Collection Tubes

Instruction for Use

Intended Use

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.

Product Description

VACUETTE® ESR Tubes are plastic tubes with a pre-defined vacuum for exact draw volume. They are fitted with colour-coded **VACUETTE®** Safety Cap (13/75 mm tube) and Brom Butyl Caoutchouc Cap (9/120 mm tube). 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”.
The **VACUETTE®** ESR Tubes contain a 3.2 % buffered tri-sodium citrate solution (0.109 mol/l). The mixing ratio is 1 part citrate solution to 4 parts blood. Tube interiors are sterile.

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 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. 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. Liquid preservatives and anticoagulants are clear and colourless. 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.)*

Handling

Closed VACUETTE® ESR System
Equipment required for ESR measurements:

- A 9/120 mm, graduated, plastic tube with a citrate solution. Draw volume 1.5 ml and 2.75 ml.
- A 9/120 mm glass tube with a citrate solution. Draw volumes of 1.6 ml or 2.9 ml are available.
- ESR rack with scale suitable for 1.5 ml/1.6 ml tubes, respectively ESR rack with scale suitable for 2.75 ml/ 2.9 ml tubes.

Procedures:
After blood 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 1.5 ml, 1.6 ml or 2.75 ml**,** 2.9 ml tube into the corresponding rack vertically. Align the 0 mark at top of scale with the bottom of the meniscus of the blood at the blood-air interface.
   For the 1.5 ml/1.6 ml **VACUETTE®** ESR tube set timer for 30 minutes. The ESR rack suitable for 1.5 ml/1.6 ml tubes delivers only the 1-hour Westergren value after 30 minutes reading time.
   For the 2.75 ml or 2.9 ml ESR tube set timer for 60 minutes. The ESR rack for 2.9 ml tubes delivers the 1 hour and if required 2 hour Westergren value after 120 minutes reading time.
2. Discard **VACUETTE®** ESR Tubes without opening.

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

1.5 ml and 1.6 ml tubes can be used with the following **VACUETTE®** ESR instruments:
SRT 10II, SRS 20II, SRS 100II.
The instrumentation allows for 1h Westergren results after 15 minutes or 30 minutes.
*(For further information contact Greiner Bio-One or see “**VACUETTE®** Automated ESR Systems Brochure”)*

Open VACUETTE® ESR System
The system consists of 3 parts:

- A 13/75 mm plastic tube with a citrate solution.
- A graduated pipette with rubber adapter.
- ESR rack without any scale.

Procedures:
After blood 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. Remove the cap of the tube.
2. Insert the pipette into the opened tube and the blood will fill automatically to the zero-line of the pipette. ***NOTE****: If there is a bubble in the column of the pipette, the determination is not valid!*
3. Place tube and pipette into the suitable rack. Tube and pipette must be in a vertical position.
4. After 60 and if required 120 minutes, read level between settled erythrocytes and the supernatant plasma from pipette.
5. Afterwards dispose of the tube and pipette together in a suitable biohazard disposal container.

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. Contaminated ESR Pipette and **VACUETTE®** tubes must be disposed of together in suitable biohazard disposal containers for infectious material.
5. 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 “Singel-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:
GP39-A6 "Tubes and Additives for Venous and Capillary Blood Specimen Collection", Approved Standard - 6th Edition
GP41-Ed7 “Collection of Diagnostic Venous Blood Specimens", 7th Edition
GP44-A4 ”Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests”, Approved Guideline – 4th Edition
H02-A5 “Procedures for the Erythrocyte Sedimentation Rate Test”, Approved Standard – 5th Edition

(Not available in USA)
For more information please refer to the instructions for use with reference number: 980200.

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