

PRODUCT INFORMATION

VACUETTE® Blood Collection Tubes ESR Sodium Citrate

SPECIFICATION

APPLICATION:

VACUETTE® ESR Sodium Citrate tubes are for the collection of venous blood specimens for the measurement of erythrocyte sedimentation rate (referring to the Westergren method).

MATERIALS:

VACUETTE® 13/75mm ESR Sodium Citrate tubes are made out of PET (polyethylenetherephthalate). The caps are produced from PE (polyethylene) and are coloured by pigments purified in accordance with EN 71/3. The rubber cap is composed of Brom Butyl Caoutchouc. The stabilisation ring is composed of PP (polypropylene).

Vacurette 19/120mm ESR Sodium Citrate tubes are made of coated polypropylene. The cap is composed of Brom Butyl Caoutchouc.

ADDITIVE:

The tubes contain a 3.2% (0.109 mol/L) trisodium citrate solution. The mixing ratio is 1 part citrate solution to 4 parts blood.

MANUFACTURED BY:

Greiner Bio-One GmbH, Austria
Certified according EN ISO 9001 and EN ISO 13485

STERILITY:

Sterile interior: SAL 10^{-6} (SAL = Sterility Assurance Level)
Standards: EN ISO 11137-1

CONFORMITY:

SO 6710 "Single-use containers for venous blood specimen collection"
EN ISO 14820 "Single-use containers for human venous blood specimen collection"
CLSI GP39-A6 "Tubes and Additives for Venous and Capillary Blood Specimen Collection"; Approved Standard- Sixth Edition
H2-A5 "Procedures for the Erythrocyte Sedimentation Rate Test"; Approved Standard - Fifth Edition

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CE MARK:

IVDD 98/79/EC "Directive 98/79/EC of the European Parliament and council of 27th of October 1998 on in vitro diagnostic medical devices" Classification: Other device (all devices except Annex II and self-testing devices).

PACKAGING:

Tubes are packed in 50 pieces per rack wrapped with a polyethylene foil. Tubes are packed in 24 racks of 50 tubes (13x75mm) or 18 racks of 50 tubes (9x120mm). Each box is filled with either 1200 (13/75mm) or 800 (9/120mm) tubes.

SHELF LIFE:

Depending on tube size

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LABELLING:

	Tube Label	Rack Label	Carton Label
Manufacturer's logo	x	x	x
VACUETTE® logo	x	x	x
Item number	x	x	x
Lot number	x	x	x
Expiry date	x	x	x
Fill volume	x	x	x
Fill line	x		
Tube dimension		x	x
CE mark	x	x	x
Sterile R mark	x	x	x
Single use sign	x	x	x
Sterility mark			x
Additive description	x	x	x
Cap description			x
Packaging information		x	x
Storage guidelines		x	x
SPSA no.			x
IVD	x	x	x

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ESR Sodium Citrate

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The erythrocyte sedimentation rate (ESR) can be used as a nonspecific search technique for inflammatory reactions and observing their development.

Two versions of the **VACUETTE®** Manual ESR System are available. The open sedimentation system consists of an ESR tube made of PET plastic, ESR Pipette with graduated adapter and ESR Rack with graduation.

The closed system consists of an ESR rack with graduation and a special ESR plastic tube.

The tubes are used for determinations in the following area:

- Erythrocyte sedimentation rate testing - ESR measurements refer to the Westergren method

TUBE TYPES



VACUETTE® 4NC ESR SODIUM CITRATE 3.2 %, PET

VACUETTE® ESR Tubes contain a 3.2% (0.109 mol/L) buffered tri-sodium citrate solution. The mixing ratio is 1 part citrate solution to 4 parts blood.

The tubes are used together with **VACUETTE®** ESR Pipette with rubber adapter for open blood sedimentation rate testing according to the original Westergren method.



VACUETTE® 4NC ESR SODIUM CITRATE 3.2 %, PP, CLOSED SYSTEM

These tubes are used for the measurement of ESR within the blood collection tube with **VACUETTE®** Automated ESR Systems Sed Rate Screener and Sed Rate Timer.