

Product Information

VACUETTE® ESR Sodium Citrate

General Information

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. The sodium citrate concentration is in accordance to the requirements of the international standards for evacuated blood collection systems - ISO 6710, CLSI H1-A5).

Application

VACUETTE® ESR Sodium Citrate tubes are for the collection of venous blood specimens for the measurement of ESR.

Materials

VACUETTE® 13/75mm ESR Sodium Citrate tubes are made out of PET (polyethylenetherephtalate). 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).

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

Manufactured by

Greiner Bio-One GmbH, Austria

Certified according to SN EN ISO 9001:2008 and SN EN ISO 13485:2003 + AC 2007

Sterility

Sterile interior: SAL 10^{-6} (SAL = Sterility Assurance Level)

Standards: EN 552, EN 556, ANSI/AAMI/ISO 11137

Conformity

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

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

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

1.5ml , 2ml tubes: 12 months

1.6ml and 2.9ml tubes: 18 months

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Labelling	Tube Label	Rack Label	Outer Carton
Manufacturers 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	
CE mark	X	X	X
Sterile R mark	X	X	X
Single use sign	X	X	X
Sterility indicator			X
Additive description	X	X	X
Cap description			X
Packaging information		X	X
Storage guidelines		X	X
Barcode label	(X)	X	X

