

Product Information

Greiner Bio-One Technical Sheet

VACUETTE® Coagulation Sodium Citrate 3,2%

General information

Additive

These standard coagulation tubes contain a buffered sodium citrate solution.

The concentration is 3.2% (0.109mol/L). The proportion of blood to the sodium citrate anticoagulation volume is 9:1. 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® Coagulation Tubes are used for determinations in citrated plasma for coagulation testing.

Materials

VACUETTE® Coagulation outer tubes are made out of PET (polyethyleneterephthalate). **VACUETTE®** Coagulation inner tubes are made out of PP (polypropylene). The caps are produced from PE (polyethylene) and are coloured by pigments purified in accordance with EN 71/3. The rubber component of the cap is composed of Brom Butyl Caoutchouc. The stabilisation ring is composed of PP (polypropylene).

Manufactured by

Greiner Bio-One GmbH, Austria

Certified according SN EN ISO 9001:2000 and SN EN ISO 13485:2001 (BVQI Cert. No.139239)

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. Each box is filled with 1200 tubes.

Shelf life

1ml tube: 6months

2-3.5ml tubes: 12 months

Product Information

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Labelling	Tube Label	Rack Label	Size
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

Item No:	Cap Color	Ring Color	Size	Volume ml	Content	Label
454322	Light Blue	White	13x75	2	S.Citrate 3.2%	Standard
454328	Light Blue	Black	13x75	4	S.Citrate 3.2%	Standard
454333	Light Blue	White	13x75	3	S.Citrate 3.2%	Clear
454334	Light Blue	Black	13x75	3	S.Citrate 3.2%	Standard
455322	Light Blue	Black	16x100	9	S.Citrate 3.2%	Standard
484334	Light Blue	Black	13x75	3	S.Citrate 3.2%	Barcoded