

Product Information

Greiner Bio-One Technical Sheet

VACUETTE® Crossmatch K₃ EDTA

General information

Additive

The tube interior of all EDTA K₃ tubes is spray dried with 1.8mg anhydrous EDTA per 1ml blood. The EDTA concentration is in accordance to the requirements of the international standards for evacuated blood collection systems - ISO 6710, CLSI H1-A5.

Application

VACUETTE® Crossmatch Tubes are used for determinations in serum / EDTA whole blood for crossmatch testing.

Materials

VACUETTE® Crossmatch Tubes are made out of PET (polyethyleneterephthalate). 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

18 months

Product Information

VACUETTE® Crossmatch K₃ EDTA



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

Item No:	Cap Color	Ring Color	Size	Volume ml	Content	Label
456052	Pink	Black	13x100	6	EDTA	Standard