

Product Information

VACUETTE® K2EDTA Sep

General Information

Application

VACUETTE® K2EDTA Sep Tubes are used for determinations in EDTA plasma for molecular biological identification of viruses, parasites and bacteria.

Materials

VACUETTE® K2EDTA Sep 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 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. Each box is filled with 1200 tubes.

Shelf life

4-8ml tubes spray-dried: 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

Wear gloves during venipuncture and when handling blood collection tubes to minimise exposure hazard.