

# Product Information

## VACUETTE® Trace Element

## General Information

### Application

**VACUETTE®** Trace Element Tubes are used for determinations in serum / heparinised plasma for the determination of trace elements.

### Materials

**VACUETTE®** Trace Element Tubes are made out of PET (polyethyleneterephtalate). 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.

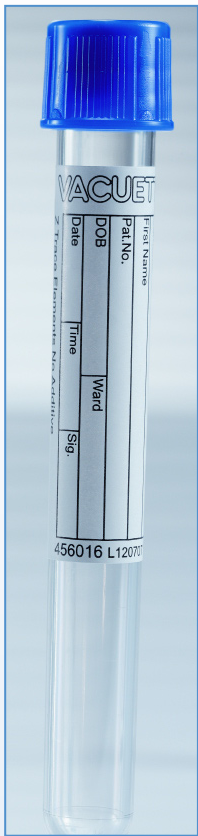
### Shelf life

18 months

# Product Information

## VACUETTE® Trace Element

### General Information



Labelling	Tube Label	Rack Label	Outer Carton
Manufacturers logo	X	X	X
<b>VACUETTE®</b> 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.