

PRODUCT INFORMATION

VACUETTE® Blood Collection Tubes

COAGULATION

SPECIFICATION

| | |
|-------------------------|--|
| APPLICATION: | VACUETTE® Coagulation Tubes are used for determinations in citrated plasma for coagulation testing. |
| MATERIALS: | VACUETTE® Coagulation outer tubes are made out of PET (polyethylenetherephthalate). VACUETTE® Coagulation inner tubes are made out of PP (polypropylene). The caps are produced from PE (polyethylene) and are coloured by pigments. The rubber component of the cap is composed of Brom Butyl Caoutchouc. The stabilisation ring is composed of PP (polypropylene). |
| ADDITIVE: | VACUETTE® Coagulation tubes contain a buffered sodium citrate solution. It is available with a citrate concentration of 0.109 mol/l (3.2%) or 0.129 mol/l (3.8%). The mixing ratio is: 1 part citrate solution to 9 parts blood. In addition to buffered sodium citrate, VACUETTE® CTAD tubes contain theophylline, adenosine and dipyridamol. |
| MANUFACTURED BY: | Greiner Bio-One GmbH, Austria Certified according EN ISO 9001 and EN ISO 13485 |
| STERILITY: | Sterile interior: SAL 10 ⁻⁶ (SAL = Sterility Assurance Level) Standards: EN ISO 11137-1 |
| CONFORMITY: | ISO 6710 "Single-use containers for venous blood specimen collection" EN ISO 14820 "Single-use containers for human venous blood specimen collection" CLSI GP39-A6 "Evacuated Tubes and Additives for Blood Specimen Collection-6th 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: | Depending on tube size. |

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LABELLING:

| | Tube Label | Rack Label | Carton Label |
|-----------------------|------------|------------|--------------|
| Manufacturer's 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 | x |
| CE mark | x | x | x |
| Steril R mark | x | x | x |
| Single use-symbol | x | x | x |
| Sterility mark | | | x |
| Additive description | x | x | x |
| Cap description | | | x |
| Packaging information | | x | x |
| Storage guidelines | | x | x |
| SPSA no. | | | x |
| IVD | x | x | x |

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VACUETTE® Blood Collection Tubes COAGULATION

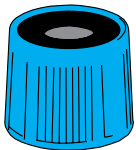
SPECIFICATION

Citrate blood is the most commonly obtained examination sample for coagulation determinations. No further preparation is necessary. Citrate plasma is obtained by centrifuging citrate blood. Sodium citrate functions as an anticoagulant by chelating calcium.

The tubes are used for determinations in the following area:

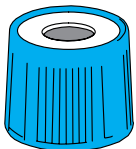
- ◀ Coagulation testing

TUBE TYPES



VACUETTE® 9NC SANDWICH TUBES

These sandwich coagulation tubes contain a buffered tri-sodium citrate solution. The concentration is either 3.2% (0.109mol/L) or 3.8% (0.129 mol/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 GP39-A6 "Tubes and Additives for Venous and Capillary Blood Specimen Collection" Approved Standard - Sixth Edition.



VACUETTE® 9NC SANDWICH TUBES - LOW DRAW VOLUME

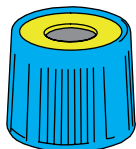
These tubes contain the same anticoagulant. The draw volume is either 1 or 2ml of blood and is therefore suitable for children and elderly patients.

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VACUETTE® CTAD TUBES

In addition to buffered sodium citrate, CTAD tubes contain theophylline, adenosine and dipyridamole.