

SPECIFICATION

APPLICATION:	VACUETTE® Glucose Tubes are used for determinations in stabilised whole blood
	or plasma for glucose testing.

MATERIALS:VACUETTE® Glucose Tubes are made out of PET (polyethylenetherephtalate).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® Glucose Tubes are available with different additives. The tubes contain a stabilizer and an anticoagulant: Sodium Fluoride / K3EDTA, Sodium Fluoride / Potassium Oxalate, Sodium Fluoride / Sodium Heparin, Lithium Heparin / lodoacetate, Sodium Fluoride / Na2EDTA / Citric Acid and Sodium Citrate.

MANUFACTURED BY:Greiner Bio-One GmbH, AustriaCertified 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 "Tubes and Additives for Venous and Capillary Blood SpecimenCollection"; Approved Standard- Sixth Edition

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:



VACUET First Name Pat. No. Date Time Ward Sig. A54221 A090801

	Tube Label	Rack Label	Carton Label
Manufacturer's logo	х	х	х
VACUETTE [®] logo	х	х	х
Item number	х	х	х
Lot number	х	х	х
Expiry date	х	х	х
Fill volume	х	x	х
Fill line	х		
Tube dimension		x	х
CE mark	х	х	x
Sterile R mark	х	х	х
Single use-symbol	х	х	x
Sterility mark			х
Additive description	х	х	x
Cap description			х
Packaging information		х	х
Storage guidelines		х	х
SPSA no.			х
IVD	х	х	х

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Sodium fluoride is used in **VACUETTE**[®] Glucose Tubes as glycolysis inhibitors to preserve glucose when combined with an anticoagulant such as EDTA, potassium oxalate or heparin.

The tubes are used for determinations in the following areas:

- Glucose testing
- Lactat testing; Please refer to the test kit instruction for the tube of choice, especially for lactate analysis.

TUBE TYPES



VACUETTE® GLUCOSE TUBES

VACUETTE® FE Glucose tubes contain the following per 1 ml blood:
2-4mg sodium fluoride and 1.2-2mg K3EDTA
VACUETTE® FH Glucose tubes contain the following per 1 ml blood:
2-4mg sodium fluoride and 10-30 IU sodium heparin
VACUETTE® FX Glucose tubes contain the following per 1 ml blood:
2-4mg sodium fluoride and 2.0mg potassium oxalate
VACUETTE® LH Lithium Heparin and lodoacetate tubes contain the following per 1 ml blood:
5.5 mg iodoacetate, 10-30 IU lithium heparin
VACUETTE® FC Mix Glucose tubes contain Sodium Fluoride / Na2EDTA, Citric Acid and Sodium Citrate

VACUETTE[®] FC Mix Tubes are used to stabilize the in-vivo glucose concentration in whole blood and/or plasma. They are sterile, single-use, plastic evacuated tubes with **VACUETTE**[®] safety caps containing an additive mix of Na2EDTA, sodium fluoride, citric acid and sodium citrate.

Proper mixing (10x) is important!



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VACUETTE® FC Mix Tubes (Primary Tubes) can be stored after correct inversion for up to 24 hours at room temperature without centrifugation.

Should the tubes be expected to be stored longer than 24 hours at room temperature, samples should be centrifuged immediately after blood collection in order to be stored for up to 48 hours at room temperature. Centrifuged aliquots from **VACUETTE**[®] FC Mix Tubes can be stored for up to 48 hours at room temperature. Tubes should be centrifuged as soon as possible.



Cooling of the samples (4-8°C, 39–46°F) is also suitable for 48 hours glucose stabilization.

VACUETTE® GLUCOSE TUBES - LOW DRAW VOLUME

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