

# PRODUCT INFORMATION

## VACUETTE® Blood Collection Tubes

### EDTA

## SPECIFICATION

---

**APPLICATION:**

**VACUETTE®** K2 EDTA Tubes and K3 EDTA Tubes are used for determinations in EDTA whole blood for haematology, immunohaematology, viral marker testing in screening laboratories or molecular biology after centrifugation.

**MATERIALS:**

**VACUETTE®** EDTA Tubes are made out of PET (polyethyleneterephthalate). 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®** EDTA Tubes contain EDTA (Ethylenediaminetetraacetic acid) K2 or K3 as the additive of choice for the collection of blood specimens intended for haematological parameters. EDTA functions as an anticoagulant by binding calcium.

**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 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.

# PRODUCT INFORMATION

## VACUETTE® Blood Collection Tubes

### EDTA

## SPECIFICATION



### LABELLING:

	Tube Label	Rack Label	Carton Label
Manufacturer's 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	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

## PRODUCT INFORMATION

# VACUETTE® Blood Collection Tubes

# EDTA

## SPECIFICATION

---

EDTA (Ethylenediaminetetraacetic acid) is the additive of choice for the collection of blood specimens intended for haematological parameters. EDTA functions as an anticoagulant by binding calcium. K2 (Dipotassium) and K3 (Tripotassium) EDTA is available.

The tubes are used for determinations in the following areas:

- ☞ Haematology
- ☞ Immunohaematology (i.e. red cell grouping, Rh typing and antibody screening)
- ☞ Molecular diagnostics and viral load detection

## TUBE TYPES



### VACUETTE® K2 EDTA AND K3 EDTA TUBES

The tube interior of all EDTA spray-dried tubes is coated with 1.2-2 mg 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 GP39-A6 "Tubes and Additives for Venous and Capillary Blood Specimen Collection"; Approved Standard-Sixth Edition.



### VACUETTE® K2 EDTA AND K3 EDTA TUBES - LOW DRAW VOLUME

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

## PRODUCT INFORMATION

# VACUETTE® Blood Collection Tubes

# EDTA

## SPECIFICATION

---



### VACUETTE® K2 EDTA TUBES WITH GEL

These tubes contain (besides the K2EDTA) a barrier gel that is present in the bottom of the tube. The specific gravity of this material lies between the blood clot and the plasma. During centrifugation gel barrier moves upward providing a stable barrier separating the plasma from cells. Plasma may be aspirated directly from the collection tube, eliminating the need for manual transfer to another container. **VACUETTE®** EDTA Tubes with Gel improve the plasma yield and enable plasma to be left in the primary tube. This allows stability of certain parameters, when kept under specified conditions.