

**CND CODE: W0501010201**

**PRODUCT DESCRIPTION**

Sterile PET vacuum tubes Ø 13x100 mm with K<sub>2</sub>EDTA  
Drawing: 6 ml



Photo code 135400

**Dimensions and specifications:**

Tubes in Polyethylene terephthalate(PET), transparent, shockproof.

Material:	Polyethylene terephthalate
Diameter:	13 mm (external tube size)
Height:	100 mm

**Stopper and repositionable Safety Cap**

Pierceable butyl rubber stopper	PE Safety cap against splashes and aerosol. Safety grip surface of 20 mm, to protect operators.
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**VACUUM: 6 ml**

**SHELF LIFE: 18 (eighteen) months from manufacturing date**

**REFERENCE CODES AND CAP COLOURS**

REFERENCE CODES	CAP COLOR	CAP IMAGE
<b>135400</b>	<b>LAVENDER</b>	
<b>135560</b>	<b>LIGHT GREEN</b>	

**ADDITIVE**

**K<sub>2</sub>EDTA**

Potassium salt of ethylenediaminetetraacetic acid.  
Micronized solution corresponding to 1,8 mg/ml blood ca.

**DESTINATION OF USE**

It is used for the blood samples collection for further hemochrome tests.  
Immediately after the collection the tubes shall be inserted in an agitator that keeping the blood mixed with slow movements.

Tubes could be used for following clinical tests on plasma. In that case, after the collection, shake the tubes slowly at least 6-8 times and then centrifuge them, following the indications written on "recommended use".

This product has to be used by skilled personnel.

**RECOMMENDED USE**

**Mixing indications:** Immediately after blood collection, gently invert the sample 6 – 8 times;

**Centrifugation:** none;

**Sample preservation:**

Storage temperatures	Up to 24 °C	at 2-4 °C
Maximum preservation time	6 hours	≤ 24 hours

## Technical Sheet

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### BEFORE PROCEEDING WITH HEMATOLOGIC TESTS MIX CAREFULLY

**TO OBTAIN PLASMA:** centrifuge at 1300g for 10 minutes at 20-25 °C.

*Conversion formula:  $g=1,118 \times 10^{-5} \times R \times S^2$  ( $g$  = relative centrifugation force,  $R$  = rotating radius expressed in cm,  $S$  = centrifugation RPM) or consult the nomograph on the last page of the technical sheet, to obtain the speed in RPM.*

**Sample preservation:** for plasma separated from blood cells see following table:

Storage temperatures	Up to 24 °C	at 2-4 ° C	≤ -20 °C
Maximum preservation time	≤8 hours	> 8 hours ≤ 48 hours	> 48 hours

### STORAGE AND PRESERVATION

Storage and preservation of the tubes for long periods have to be at a temperature between +5 and +25°C, in a dry place. Tubes have to be stored in vertical position with cap upwards as indicated on each case.

### TUBE LABEL

Adhesive paper label for specific medical use – size 40x20 mm, printed in 3 colors. Label bearing: brand name, REF code, additive, volume of draw, lot and expiry date, symbols (Sterile R, IVD, CE and single use), level, cap color identification, , manufacturer name.

### PACKAGING

RACK	INNER BOX	SHIPPING CASE
<b>Plastic 50-places rack</b>	<p><b>100 pcs (2 racks of 50 pcs)</b></p> <p>Each box is printed with: brand name, manufacturer name and address, size, CE mark, sterilization, storage and user's directions, origin and single use indication.</p> <p>Each box is labeled with a multilingual sealing label, and an additional label with code, cap color, description, drawing volume, lot and expiry (year and month).</p>	<p><b>1000 pcs (10 boxes of 100 pcs)</b></p> <p>Each box is printed with: brand name "Vacutest Plast", manufacturer name and address, size of tubes, CE mark, sterilization, storage and user's directions.</p> <p>Each box is labeled with manufacturer named and address, brand name "Vacutest plast", CE and IVD symbols and relative CE directive, description, size and volume, ref, single use, origin and storage indications, manufacturing and expiry dates, lot and quantity, operator initials and day, cap color, bar code with EAN13 indications, description in multilingual, Sterilization indication and sterilization sticker.</p>

### SIZE OF PACKAGING

Weight: 8,9 Kg – Volume 0,036 m<sup>3</sup>

### STERILIZATION

Vacutest Kima S.r.l. Via dell'Industria, 12 35020 Arzergrande (PD) <b>Technical Sheet</b>		K2 Edta tubes 6 ml	PAGE 3 OF 4
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By irradiation with a sterility assurance level (SAL) in the order of 10-6 as and following directives:

UNI EN 556-1 requirements for sterile medical devices,  
UNI EN ISO 11737-2 microbiological method- sterility tests made during the validation of a sterilization process ,  
UNI EN ISO 11137-1 sterilization of sanitary products- radiation- Part 1

**COMPATIBILITY WITH ANALYTICAL INSTRUMENTS**

No report of incompatibility with instruments currently present in the market.  
The users must check the compatibility of the external tubes dimensions with those required by the instrument in use at the laboratory.

**DISPOSAL MODALITY**

Before use the tubes have to be considered not hazardous material to be disposed according to Italian law 156/06 and following amendments.  
After use, they become potentially infected waste which have to be collected and disposed applying all particular cares to avoid infections: CER 18 01 03.

**RAW MATERIAL CERTIFICATIONS**

All raw materials used are non toxic, for medical and alimentary use certified, according to the European and FDA (USA) directives.

**QUALITY SYSTEM APPLIED DURING MANUFACTURING AND REFERENCE STANDARDS**

UNI EN ISO 9001:2015, ICIM certificate no. 4264/5 issued by ICIM S.p.a. ;  
UNI EN ISO 13485:2021, ICIM certificate no. 4265/5 issued by ICIM S.p.a.

CE: quality guarantee system through the CE Declaration of Conformity issue after preparation of technical files available for competent authorities, and according to CE 98/79/CE Directive (Italian legislative decree 08/09/2000 No.332) .

UNI CEI EN ISO 15223-1 symbols to be used on medical devices labels (ex UNI CEI EN 980:2009)

UNI EN 1041 Information given by the manufacturer with medical devices.

UNI EN 14971 – Risk management application on medical devices.

UNI EN 14820 and ISO 6710 – disposable containers for venous blood collection.

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**NOMOGRAPH**

