CND CODE: W050101010201

PRODUCT DESCRIPTION

Sterile PET vacuum tubes Ø 13x75 mm with LITHIUM HEPARIN (17 I.U. / ml of blood) Drawing: 4 ml



REF. 12010

Dimensions and specifications:

Tubes in Polyethylene terephthalate (PET) transparent, shockproof.

Material: Diameter: Height:	Polyethylene terephthalate; 13 mm (external tube size); 75 mm

Cap and repositionable Safety Cap

Pierceable butyl rubber stopper.	PE safety cap against splashes and aerosol. Safety grip surface of 20 mm, to protect end-user.

VACUUM: 4 ml

SHELF LIFE: 18 (eighteen) months from manufacturing date

REFERENCE CODES AND CAP COLORS

REFERENCE CODES	CAP COLOR	CAP IMAGE
12010	GREEN	
12032	PINK	
12042	WHITE	
12015	BROWN	

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12041	RUSTY	

ADDITIVE

Lithium Heparin

Anticoagulant of organic origin, with anti-prothrombotic and antithrombotic action.
It is considered a natural anticoagulant because of its low level presence in blood and tissues.
It acts preventing conversion of pro-thrombin to thrombin and of fibrinogen to fibrin.
It is the anticoagulant less interfering with chemical dosages and it does not modify erythrocytes volume.
It is present in the tubes with a concentration corresponding to 17 I.U. / ml of blood (17 USP units) approx.
The dose is refers to CLSI (NCCLS) protocol "Tubes and additives for venous blood specimen collection; approved standard - fifth edition".

DESTINATION OF USE

Tubes are used for blood collection and following clinical-chemical tests on plasma.
This product has to be used by professionally qualified personnel.

RECOMMENDED USE

Mixing indications: Immediately after blood collection, gently invert the sample 6 – 8 times;
Minimum time before centrifugation: none;
Maximum time before centrifugation: 2 hours after collection.

Centrifugation speed: at 1300g for 10 minutes at 20-25 °C.
Conversion formula: $g=1{,}118x10^{-5}x\ R\ x\ S^2$ (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 RPM speed.

Sample preservation: for plasma separated from blood cells, see the 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 made 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 colours. 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	EXTERNAL BOX

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Plastic 50 places-rack	**100 pcs (2 racks of 50 pcs)** 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.	**1000 pcs (10 boxes of 100 pcs)** Each box is printed with: brand name "Vacutest Plast", manufacturer name and address, size of tubes, CE mark, sterilization, storage and user's directions.
	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).	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.

SIZE OF PACKAGING

Weight: 7,4 Kg - Volume 0,028 m^3

STERILIZATION

By irradiation as per 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 tge 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, latex free for medical and alimentary uses certified, according to the European and FDA (USA) directives.

QUALITY SYSTEM APPLIED DURING MANUFACTURING AND REFERENCE STANDARDS

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UNI EN ISO 9001:2015, ICIM certificate no. 4264/5/D issued by ICIM S.p.a.;
UNI EN ISO 13485:2016, ICIM certificate no. 4265/5/D 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.

NOMOGRAPH

