CND CODE: W050101010201

PRODUCT DESCRIPTION

Sterile PET vacuum tube) Ø 13x75 mm "IN" with 0,2 ml of Buffered Sodium Citrate solution at 3,2% (0,109 M)
Vacuum: 1,8 ml
Nominal value: 2 ml
Anticoagulant solution: 0,2 ml



Photo cod. 14074

Dimensions and specifications:

Tubes in Polyethylene terephthalate(PET), transparent, shockproof.
It is indicated for all the cases of drawing at reduced volume.
The particular inner configuration of Vacutest "IN" increases the inner level of the liquid corresponding to a standard drawing.
The strengthened thickness of the wall increases the preservation of the inner vacuum.

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

Stopper and repositionable Safety Cap

Pierceable butyl rubber stopper.	PET safety cap against splashes and aerosol. Safety grip surface of 20 mm, to protect operators

VACUUM: 1,8 ml

SHELF LIFE: 12 (twelve) months from manufacturing date

REFERENCE CODES AND CAP COLORS

REFERENCE CODES	*CAP COLORS*	CAP IMAGES
14074	**TRANSLUCENT LIGHT BLUE**	
140740	**LIGHT BLUE**	

ADDITIVE

0,2 ml of Buffered Sodium Citrate at 3,2% (0,109 M)

DESTINATION OF USE

They are used for blood samples collection for further coagulation test on plasma.
Anticoagulant/blood rate = 1:9.
Filling at 2 ml
This product has to be used by professionally qualified personnel.

RECOMMENDED USE

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Mixing indications: Immediately after blood collection, gently invert the sample 4 – 5 times;
Minimum time before centrifugation: none;
Maximum time before centrifugation: 2-4 hours after the collection, depending on the test

Centrifugation speed: 2000-2500g for 15-20 minutes at 20-25 °C. Use proper centrifugation speed and time enough to guarantee a plasma poor on platelets.
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 speed in RPM.

Sample preservation (plasma separated from blood cells): preservation time and temperature may vary depending on the test.

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
Plastic 50-position 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. 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).	**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 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: 10,50 Kg - Volume 0,028 m³

STERILIZATION

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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: 2006 sterilization of sanitary products- radiation- Part 1

COMPATIBILITY WITH ANALYTICAL INSTRUMENTS

No incompatibility with instruments currently present in the market have been reported. Users must check the compatibility of the external tubes sizes with the sizes requested by the instrument in use in the specific 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 9001:2008, ICIM certificate no. 4264/2 issued by ICIM S.p.a. on 18/01/2013;
UNI EN ISO 13485 : 2012 ICIM certificate no. 4265/2 issued by ICIM S.p.a. on 18/01/2013;

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) .

EN 375 In Vitro Diagnostic Devices – Labels requirements and products information related to the used reagents for IVD products for professional use.
UNI CEI EN ISO 15223-1:2012 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

