

CND code: W050301020102

DESCRIPTION

Cylindrical sterile PET plastic collection tube (polyethylene terephthalate) Ø 13x75 mm for urine without additive
Vacuum: 4 ml



REF 14900

Dimensions and specifications

Tubes in PET (polyethylene terephthalate) transparent, shockproof.

Material: polyethylene terephthalate;
Diameter: 13 mm external size of the tube;
Height: 175 mm

Stopper and re-positionable Safety Cap

Butyl rubber stopper, black.. Safety cap against aerosol, in polyethylene.
Safety grip surface of 20 mm, to protect end-user

Predetermined vacuum : 4 ml

SHELF LIFE: 18 (eighteen) months from manufacturing date

REFERENCE CODES AND CAP COLOURS

REFERENCE CODE	CAP IMAGE	REFERENCE CODE	CAP IMAGE	REFERENCE CODE	CAP IMAGE
14900 YELLOW		14905 RED		14906 BEIGE	

OTHER COLOURS ARE ALSO AVAILABLE, BASED ON THE FOLLOWING TABLE:

							
Electric blue <i>Blu elettrico</i>	Light blue <i>Azzurro</i>	Translucent light blue <i>Azzurro trasparente</i>	Dark blue <i>Blu</i>	Orange <i>Arancio</i>	Gold <i>Giallo ocra</i>	Yellow <i>Giallo</i>	Beige <i>Beige</i>
							
Rusty <i>Terra di Siena</i>	Brown <i>Marrone</i>	Translucent <i>Trasparente</i>	White <i>Bianco</i>	Grey <i>Grigio</i>	Black <i>Nero</i>	Green <i>Verde</i>	Dark green <i>Verde scuro</i>
							
Light green <i>Verde acqua</i>	Lavender <i>Viola</i>	Translucent lavender <i>Viola trasparente</i>	Fuchsia <i>Fucsia</i>	Pink <i>Rosa</i>	Red <i>Rosso</i>	Translucent red <i>Rosso trasparente</i>	Olive green <i>Verde oliva</i>

ADDITIVE

CND code: W050301020102

NONE

Destination of use:

Usable for biological liquids sample collection.

This product has to be used by professionally qualified personnel.

RECOMENDED USE

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

Minimum time before centrifugation: none

Maximum time before centrifugation: at 2-8 °C within 24 hours

Centrifugation speed: 400 g for 5 minutes

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: after the centrifugation see the following table:

Storage temperatures	Up to 24 °C	at 2-4 °C
Maximum preservation time	≤ 2 hours	≤24 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 dry place. Tubes have to be stored in vertical position with cap on upper side 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), PHT/DEHP Free ,level, cap color identification, manufacturer name.

PACKAGING

RACK	INNER BOX	SHIPPING CASE
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CND code: W050301020102

Plastic 50 places rack	100 pcs (2 racks of 50 pcs)	1000 pcs (10 boxes of 100 pcs)
	<p>Each box is printed with: brand name, manufacturer name and address, size, CE mark, sterilization mark, storage and user's directions, origin and single use indication and number of pieces contained in one box.</p> <p>Each box is labeled with a multilingual sealing label, and an additional label with code, cap color, description, drawing volume, lot and expiration date (year-month-day), PHT/DEHP Free, bar code. Each box contain the instruction for use for the tubes.</p>	<p>Each box is printed with: manufacturer name and address, size of tubes, CE mark, sterilization, storage and user's directions, number of pcs inside of the box.</p> <p>Each box is labeled with manufacturer named and address, multilingual description, brand name "Vacutest plast", CE mark, 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, PHT/DEHP Free, bar code description in multilingual, Sterilization indication and sterilization sticker.</p>

SIZE OF PACKAGING

Weight ,5Kg – Volume 0,028 m³

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: 2006 sterilization of sanitary products- radiation- Part 1

COMPATIBILITY WITH ANALYTICAL INSTRUMENTS :

No incompatibility with instruments actually present in the market have been reported.
The users must check the compatibility of the external tubes sizes with the sizes requested by the instrument in use in the specific laboratory.

DISPOSAL METHODS :

For the correct disposal please refer to the national and local regulation concerning sanitary waste in force in the using country

Disposal BEFORE use (example: expired or deteriorated):

Classification: special waste comparable to domestic waste CER 15 01 02 or 20 01 39

Disposal AFTER use:

Classification: hazardous special waste CER 18 01 03* or 18 02 02*

RAW MATERIAL CERTIFICATIONS:

All raw materials and materials employed are non-toxic, for certified alimentary and medical uses, according to European legislation and FDA (USA) in force.

All the components of the system, at the current date and on the basis of the technical documentation provided by the manufacturers of the raw materials we use and on the basis of the production process implemented, the products offered are LATEX-FREE and Phtalates free "PHT/DEHP FREE".

Vacutest Kima S.r.l. Via dell'Industria, 12 35020 Arzergrande (PD) Technical sheet		PAGINA 4 DI 4 REVISIONE 2	DATA 07/06/2023
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**QUALITY SYSTEM APPLIED DURING MANUFACTURING
AND REFERENCE STANDARDS :**

- UNI EN ISO 9001:2015, ICIM certificate no. 4264 issued by ICIM S.p.a. current issue;
- UNI EN ISO 13485:2016, ICIM certificate no. 4265 issued by ICIM S.p.a. current issue.
- 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 ISO 6710 (Ex ISO 14820) – Disposable containers for the collection of venous blood samples