Description

PET sterile plastic blood collection tube Ø 13x100 mm with gel and coagulation clot activator
Blood draw: 5 ml



REF 10176

Dimensions and specifications:

Tubes in PET polyethylene terephthalate transparent, shockproof

Raw material:	**Polyethylene Terephtalate**
Diameter:	**13 mm (external tube),**
Height:	**100 mm**

Stopper and safety cap REPOSITIONABLE

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

Vacuum:	**5 ml**

REFERENCE CODES AND COLOR CAPS

CODE	CAP COLOR	CODE	CAP COLOR	CODE	CAP COLOR
10020 ***RED***		**10094** *TRANSPARENT RED*		**10104** *BEIGE*	
10118 *YELLOW*		**10176** *OCHRE*		**10344** *ORANGE*	
10140 *WHITE*		**10182** *BLACK*		**10188** *PINK*	
10261 *FUCHSIA*		**10150** *BLUE*		**10228** *BLU ELETTRICO*	
10214 *AZZURRO*		**10315** *TRASPARENTE*		**10244** *MARRONE*	

10313 *TERREA DI SIENA*		

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

							
Blu elettrico	Azzurro	Azzurro trasparente	Blu	Arancio	Giallo ocra	Giallo	Beige
							
Terra di Siena	Marron	Trasparente	Bianco	Grigio	Nero	Verde	Verde scuro
							
Verde acqua	Viola	Viola trasparente	Fucsia	Rosa	Rosso	Rosso trasparente	

Shelf life

SHELF LIFE: 18 (eighteen) months from manufacturing date

Additives

CLOT ACTIVATOR.

Micronized silica coating. It helps the blood coagulation in order to obtain the serum by centrifuging it 20-30 min. after the collection.

Immediately after collecting the test shake the tube inverting it slowly at least 6 – 8 times.
Replace the test tube vertically on the tube-stand.
Wait for 20-30 (till the serum shows spontaneously on the upper part of the tube).
Centrifuge it as indicated below.

GEL in quantity of approximately 0,9 mg

The new generation of gel separator used by VACUTEST KIMA is composed by a mix of polymers that have a specific predetermined weight.

It is highly thixotropic and it does not interfere with subsequent.

These specifications, associated to the particular modalities of distribution within the test tube and complete sterilization makes it particularly proper to its function of separator agent between serum/clotting and plasma/other blood containing elements.

The gel is perfectly placed at the bottom of the test tube and stays stable if storage indications are correctly observed (see "storage and preservation").

After centrifugation the gel sets itself between the parts that should separate creating a cylindrical barrier , perfectly and permanently adherent to the surface of test tube.

Speed centrifugation (expressed in G = relative centrifugation force) might vary within a wide margin 1600-2000 g (these speeds refers to centrifuges of radius 20 cm a 2500-3000 rpm) **referring to centrifuges with swinging wings.**
Minimum suggested centrifugation time is 10'.
In case of a centrifuge with fixed wing is suggested to increase the centrifugation time to 15'.
Separation remains constant even when the test tubes after centrifugation, are stored at temperatures below a 0°C and after that placed in room temperatures for further analysis.

Sterilization:

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

Raw material certifications:

All raw materials used are non-toxic, food and medical certified, as per European and FDA (USA) directives.

Packing:

Rack	Inner Box	Shipping case
Rack in plastic of 50 pcs	**100 pcs (2 racks of 50 pcs)** Each box is printed with: Company name " Vacutest Plast", address, size of tubes, CE marking, sterilization, storage and user's directions. Each box is labeled with: Sealing label, additional label with code, cap colour, content description, drawing volume, lot and expiry (year and month). Each box contains direction of use.	**500 pcs (5 boxes of 100 pcs)** Each box is printed with: Company name " Vacutest Plast", address, size of tubes, Ce marking, sterilization, storage and user's directions. Each box is labeled with: Sealing label, additional label with code, cap colour, content description, drawing volume, lot and expiry (year and month). Each box contains direction of use in various languages.

Labels on tubes:

Stocked label – white 40x20 mm, printed in 3 colous. Label bearing: company name "Vacutest Plast", EMO, CE marking, Sterile Interior R, Lot, Expiry (year and month), REF (code of tube), additive description and concentration, volume draw + other variable data + usage symbols

Destination of use:

Tubes are used to take blood collection samples for subsequent chemical-clinical serum determinations, molecular testing, infectious disease testing.

This product has to be used by professionally qualified personnel.

Suggested centrifugation speed

After collecting the venous blood , mix the tube slowly at least 6 – 8 times, wait 30', centrifuge it at a velocity between 1600-2000 g.
(consult the nomograph to set RPM rotation speed)

Compatibility with analytical instruments:

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

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.

Disposal modality:

Before the use the products have to be consider not hazardous material: CER 18 01 07 "chemical substances different from 18 01 08*".
After the use become waste potentially infected that have to collect and disposed applying all particular precautions to avoid infections: CER 18 01 03.

Quality system applied during manufacturing and reference standards:

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

UNI EN ISO 13485:2016, 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) .

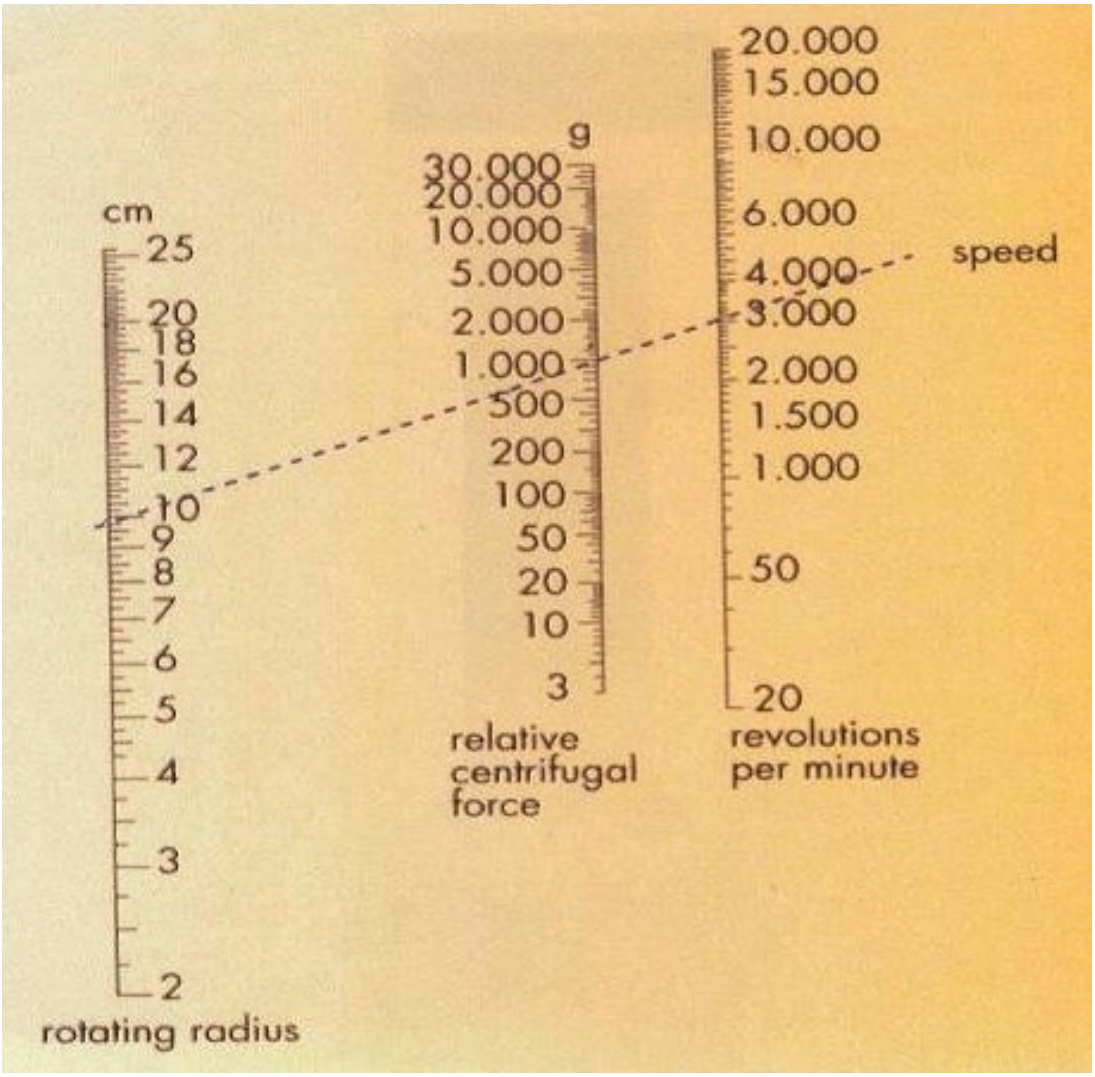
UNI CEI EN ISO 15223-1 symbols to be used on medical devices labels (ex UNI CEI EN 980:2009)

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.

NOMOGRAPH


cm
25
20
18
16
14
12
10
9
8
7
6
5
4
3
2
rotating radius
g
30.000
20.000
10.000
5.000
2.000
1.000
500
200
100
50
20
10
3
relative centrifugal force
20.000
15.000
10.000
6.000
4.000
3.000
2.000
1.500
1.000
50
20
revolutions per minute
speed