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Product Data

Product Name: IMPROVACUTER® Clot Activator Tube

Item Code and specification and package information:

Catalog Number	Items	Tube Size	Volume	Closure Type	Additive State	Tube material	Label	Color	Pack/Carton Qty
613070242	Clot Activator	13×100mm	7ml	Safety Cap	/	PET	Transparent	Red	100/1000
613060242	Clot Activator	13×100mm	6ml	Safety Cap	/	PET	Transparent	Red	100/1000
613050242	Clot Activator	13×100mm	5ml	Safety Cap	/	PET	Transparent	Red	100/1000
613040242	Clot Activator	13×100mm	4ml	Safety Cap	/	PET	Transparent	Red	100/1000
612040242	Clot Activator	13×75mm	4ml	Safety Cap	/	PET	Transparent	Red	100/1000
612030242	Clot Activator	13×75mm	3ml	Safety Cap	/	PET	Transparent	Red	100/1000
612020242	Clot Activator	13×75mm	2ml	Safety Cap	/	PET	Transparent	Red	100/1000
614080242	Clot Activator	16×100mm	8ml	Safety Cap	/	PET	Transparent	Red	50/1000
614090242	Clot Activator	16×100mm	9ml	Safety Cap	/	PET	Transparent	Red	50/1000
614950242	Clot Activator	16×100mm	9.5ml	Safety Cap	/	PET	Transparent	Red	50/1000
613070202	Clot Activator	13×100mm	7ml	Safety Cap	/	PET	Paper	Red	100/1000
613060202	Clot Activator	13×100mm	6ml	Safety Cap	/	PET	Paper	Red	100/1000
613050202	Clot Activator	13×100mm	5ml	Safety Cap	/	PET	Paper	Red	100/1000
613040202	Clot Activator	13×100mm	4ml	Safety Cap	/	PET	Paper	Red	100/1000
612040202	Clot Activator	13×75mm	4ml	Safety Cap	/	PET	Paper	Red	100/1000
612030202	Clot Activator	13×75mm	3ml	Safety Cap	/	PET	Paper	Red	100/1000
612020202	Clot Activator	13×75mm	2ml	Safety Cap	/	PET	Paper	Red	100/1000
614080202	Clot Activator	16×100mm	8ml	Safety Cap	/	PET	Paper	Red	50/1000
614090202	Clot Activator	16×100mm	9ml	Safety Cap	/	PET	Paper	Red	50/1000
614950202	Clot Activator	16×100mm	9.5ml	Safety Cap	/	PET	Paper	Red	50/1000

Note: the specification is not limited to the above table. Refer to product list for full specification.

Subject and application


IMPROVACUTER® Clot Activator Tubes are coated with silicone and micronized silica particles to accelerate clotting. Particles in the white or brownish film on the interior surface activate clotting when tubes are mixed 5-8 times by inversion.

See Limitations of System, Cautions and Warnings, Specimen Collection and Handling, Analytic Equivalency Sections.

This product has to be used by professionally qualified personnel.

Product photo



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Composition and raw material:

Tubing:

- Tubing material: polyethylene terephthalate (PET)
- Diameter and height: 13mmx75mm, 13x100mm, 16x100mm

Safety cap:

- Raw material: Safety cap against aerosol, in polyethylene
- Color: Red

Rubber stopper:

- Raw material: Butyl rubber

Additive: Clot activator

Raw material certifications

All raw materials used are non toxic, food and medical certified, as per European directives.

Shelf life

18 (eighteen) months for PET tubes from manufacturing date

Storage

Storage tubes at 4-25°C (39-77°F) , unless there is other notice on the package or label. All liquid preservatives and anticoagulants are clear and colorless. Do not use if they are discolored or contain precipitates. Clot activator may be white or brownish; fluoride and fluoride/oxalate may be pale pink. Do not use if color has changed. EDTA or clot activator spray coated additives may have a brownish appearance; this does not affect the performance of the EDTA additive or clot activator. Do not use tubes after their expiration date. Tubes expire on the last day of the month and year indicated.

Sterilization

Shipping Information

Normal shipping; Normal dry container

Sterilization

By irradiation as per European Union directives:

UNI EN 552, UNI EN 556-1 ISO, 11137 , UNI EN ISO 11737-2

Clotting Instructions

Allow blood to clot thoroughly before centrifugation. The recommended minimum clotting time for IMPROVACUTER® Clot Activator Tube is 30 minutes. Tubes with clot activator should be inverted 5-8 times.

Minimum Clotting Time Recommendations (Room Temperatures)

Product	Time(min)
Clot Activator Tube	30

Centrifugation




















Do not centrifuge glass tubes at forces above 2200 RCF in a horizontal head (swinging bucket) centrifuge as breakage may occur. Glass tubes may break if centrifuged above 1300 RCF in fixed angle centrifuge heads. Always use appropriate carriers or inserts. Use of tubes with cracks or chips or excessive centrifugation speed may cause tube breakage, with release of sample, droplets, and an aerosol into the centrifuge bowl. Release of these potentially hazardous materials can be avoided by using specially designed sealed containers in which tubes are held during centrifugation. Centrifuge carriers and inserts should be of the size specific to the tubes used. Use of carriers too large or too small for the tube may result in breakage.

The following table gives recommended centrifuge RCF and time using a horizontal head (swinging bucket) centrifuge:

Centrifugation RCF and Time Recommendations		
Product	RCF (g)	Time (min)
Clot Activator Tubes	1500-2200	10

Information on the label and symbols

Symbol and Mark Key

 Single Use	 In Vitro Diagnostic Medical Device	 Date of Manufacture
 Expiry Date	 Temperature Limitation	REF Catalog Number
 Batch Code	 Lower Limit of Temperature	 Consult Instructions for Use
 Sterile	 Upper Limit of Temperature	 Biological Risk
 This End Up	 Method of Sterilization (Irradiation)	 Fragile, Handle with Care
 Manufacturer	 Authorized Representative	 Keep Away from Sunlight
 Recyclable	 Caution, Consult Accompanying Documents	

ISO/EN Standards

ISO 6710 “Single-use containers for venous blood specimen collection”

EN 14820 “Single-use containers for human venous blood specimen collection”

ISO 11137 “Sterilization of health care products – Requirements for validation and routine control – Radiation sterilization”

Clinical and Laboratory Standards Institute (CLSI)



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GP39-A6 Tubes and Additives for Venous and Capillary Blood Specimen Collection; Approved Standard - Sixth Edition

GP34-A Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection; Approved Guideline

GP41-A6 Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Sixth Edition

GP44-A4 Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline—Fourth Edition.

H21-A5 Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays; Approved Guideline—Fifth Edition