

	<b>Product Technical Data</b> <b>Gel &amp; Clot Activator Tube</b>	Document No	
		Page	1/4
		Version	A/2

## Product Data

**Product Name: IMPROVACUTER® Gel & 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
623060242	Gel & clot Activator	13×100mm	6ml	Safety Cap	/	PET	transparent	Gold	100/1000
623050242	Gel & clot Activator	13×100mm	5ml	Safety Cap	/	PET	transparent	Gold	100/1000
623040242	Gel & clot Activator	13×100mm	4ml	Safety Cap	/	PET	transparent	Gold	100/1000
623030242	Gel & clot Activator	13×100mm	3ml	Safety Cap	/	PET	transparent	Gold	100/1000
622030242	Gel & clot Activator	13×75mm	3ml	Safety Cap	/	PET	transparent	Gold	100/1000
622350242	Gel & clot Activator	13×75mm	3.5ml	Safety Cap	/	PET	transparent	Gold	100/1000
624070242	Gel & clot Activator	16×100mm	7ml	Safety Cap	/	PET	transparent	Gold	50/1000
624080242	Gel & clot Activator	16×100mm	8ml	Safety Cap	/	PET	transparent	Gold	50/1000
624850242	Gel & clot Activator	16×100mm	8.5ml	Safety Cap	/	PET	transparent	Gold	50/1000
623060202	Gel & clot Activator	13×100mm	6ml	Safety Cap	/	PET	paper	Gold	100/1000
623050202	Gel & clot Activator	13×100mm	5ml	Safety Cap	/	PET	paper	Gold	100/1000
623040202	Gel & clot Activator	13×100mm	4ml	Safety Cap	/	PET	paper	Gold	100/1000
623030202	Gel & clot Activator	13×100mm	3ml	Safety Cap	/	PET	paper	Gold	100/1000
622030202	Gel & clot Activator	13×75mm	3ml	Safety Cap	/	PET	paper	Gold	100/1000
622350202	Gel & clot Activator	13×75mm	3.5ml	Safety Cap	/	PET	paper	Gold	100/1000
624070202	Gel & clot Activator	16×100mm	7ml	Safety Cap	/	PET	paper	Gold	50/1000
624080202	Gel & clot Activator	16×100mm	8ml	Safety Cap	/	PET	paper	Gold	50/1000
624850202	Gel & clot Activator	16×100mm	8.5ml	Safety Cap	/	PET	paper	Gold	50/1000

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

## Subject and application

The clot activator sprayed on the inner wall of tube can accelerate clotting. Particles in the white or brownish film on the interior surface activate clotting when tubes are mixed 5-8 times by inversion. The tube contains a gel barrier polymer at the tube bottom. The density of this material causes it to move up ward during centrifugation to the serum-clot interface, where it forms a barrier separating serum from the clot. Serum may be aspirated directly from the collection tube, eliminating the need to transfer to another container.

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

## Product photo



	<b>Product Technical Data</b> <b>Gel &amp; Clot Activator Tube</b>	Document No	
		Page	2/4
		Version	A/2

## Composition and raw material:

Tubing:

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

Safety cap:

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

Rubber stopper:

- Raw material: Butyl rubber

Additive: Gel and clot activator

## Raw material certifications

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

## Shelf life

- 18 (eighteen) months for PET tubes from manufacturing date,
- 24 (twenty-four) months for Glass 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® Gel & Clot Activator Tube is 30 minutes. Tubes with clot activator or/and gel should be inverted 5-8 times.

	<b>Product Technical Data</b> <b>Gel &amp; Clot Activator Tube</b>	Document No	
		Page	3/4
		Version	A/2

Minimum Clotting Time Recommendations(Room Temperatures)	
Product	Time(min)
Gel & 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 )
Gel & Clot Activator Tubes	1800-2200	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	<b>REF</b> 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)

	<b>Product Technical Data</b> <b>Gel &amp;Clot Activator Tube</b>	Document No	
		Page	4/4
		Version	A/2

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