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Product Data

Product Name: IMPROVACUTER® Gel & Heparin 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
742030242	Gel & LH	13×75mm	3ml	Safety Cap	LH: Powder	PET	transparent	Green	100/1000
742040242	Gel & LH	13×75mm	4ml	Safety Cap	LH: Powder	PET	transparent	Green	100/1000
742030202	Gel & LH	13×75mm	3ml	Safety Cap	LH: Powder	PET	paper	Green	100/1000
742040202	Gel & LH	13×75mm	4ml	Safety Cap	LH: Powder	PET	paper	Green	100/1000
742350202	Gel & LH	13×75mm	3.5ml	Safety Cap	LH: Powder	PET	paper	Green	100/1000
743040242	Gel & LH	13×100mm	4ml	Safety Cap	LH: Powder	PET	transparent	Green	100/1000
743050242	Gel & LH	13×100mm	5ml	Safety Cap	LH: Powder	PET	transparent	Green	100/1000
744080242	Gel & LH	16×100mm	8ml	Safety Cap	LH: Powder	PET	transparent	Green	50/1000
744850242	Gel & LH	16×100mm	8.5ml	Safety Cap	LH: Powder	PET	transparent	Green	50/1000
743040202	Gel & LH	13×100mm	4ml	Safety Cap	LH: Powder	PET	paper	Green	100/1000
743050202	Gel & LH	13×100mm	5ml	Safety Cap	LH: Powder	PET	paper	Green	100/1000
744080202	Gel & LH	16×100mm	8ml	Safety Cap	LH: Powder	PET	paper	Green	50/1000
744850202	Gel & LH	16×100mm	8.5ml	Safety Cap	LH: Powder	PET	paper	Green	50/1000
752350242	Gel & NH	13×75mm	3.5ml	Safety Cap	NH: Powder	PET	transparent	Green	100/1000
753040242	Gel & NH	13×100mm	4ml	Safety Cap	NH: Powder	PET	transparent	Green	100/1000
753050242	Gel & NH	13×100mm	5ml	Safety Cap	NH: Powder	PET	transparent	Green	100/1000
754850242	Gel & NH	16×100mm	8.5ml	Safety Cap	NH: Powder	PET	transparent	Green	50/1000
752350202	Gel & NH	13×75mm	3.5ml	Safety Cap	NH: Powder	PET	paper	Green	100/1000
753040202	Gel & NH	13×100mm	4ml	Safety Cap	NH: Powder	PET	paper	Green	100/1000
753050202	Gel & NH	13×100mm	5ml	Safety Cap	NH: Powder	PET	paper	Green	100/1000
754850202	Gel & NH	16×100mm	8.5ml	Safety Cap	NH: Powder	PET	paper	Green	50/1000

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

Subject and application

IMPROVACUTER® Plasma Tubes with Lithium Heparin and Gel contain a barrier gel in the tube bottom. The density of this material causes it to move upward during centrifugation to the plasma-cell inter face, where it forms a barrier separating plasma from cells. Plasma may be aspirated directly from the collection tube, eliminating the need for transfer to another container.

Gel & Heparin Tubes with blood should be inverted 5-8 times.

This product has to be used by professionally qualified personnel.

Product photo



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: Green

Rubber stopper:

- Raw material: Butyl rubber

Additive: Gel & Lithium Heparin / Gel & Sodium Heparin

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,
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

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 & Heparin Tubes (Plasma Tubes with gel)	1500-1800	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)

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



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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