

 Product Technical Data Gel & EDTA.K2 Tube	Document No	
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Product Data

Product Name: IMPROVACUTER® Gel & EDTA.K2 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
722350242	Gel & K2EDTA	13×75mm	3.5ml	Safety Cap	K2EDTA: Powder	PET	transparent	lavender	100/1000
723040242	Gel & K2EDTA	13×100mm	4ml	Safety Cap	K2EDTA: Powder	PET	transparent	lavender	100/1000
723050242	Gel & K2EDTA	13×100mm	5ml	Safety Cap	K2EDTA: Powder	PET	transparent	lavender	100/1000
723060242	Gel & K2EDTA	13×100mm	6ml	Safety Cap	K2EDTA: Powder	PET	transparent	lavender	100/1000
724080242	Gel & K2EDTA	16x100mm	8ml	Safety Cap	K2EDTA: Powder	PET	transparent	lavender	50/1000
722350202	Gel & K2EDTA	13×75mm	3.5ml	Safety Cap	K2EDTA: Powder	PET	paper	lavender	100/1000
723040202	Gel & K2EDTA	13×100mm	4ml	Safety Cap	K2EDTA: Powder	PET	paper	lavender	100/1000
723050202	Gel & K2EDTA	13×100mm	5ml	Safety Cap	K2EDTA: Powder	PET	paper	lavender	100/1000
723060202	Gel & K2EDTA	13×100mm	6ml	Safety Cap	K2EDTA: Powder	PET	paper	lavender	100/1000
724080202	Gel & K2EDTA	16x100mm	8ml	Safety Cap	K2EDTA: Powder	PET	paper	lavender	50/1000

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

Subject and application

IMPROVACUTER® Gel & EDTA.K2 Tubes are used for testing plasma in molecular diagnostics and viral load detection. IMPROVACUTER® Gel & EDTA.K2 is a single use tube used to collect, transport, separate and process venous blood specimens to obtain plasma for virus load determination or preparation of undiluted plasma specimens for molecular diagnostic test or where undiluted plasma is required. Whole blood is collected and barrier gel forms a barrier separating plasma from cellular components of the blood after centrifugation.

Gel & EDTA.K2 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)
- Diameter and height: 13mmx75mm, 13x100mm, 16x100mm

Safety cap:

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

Rubber stopper:

- Raw material: Butyl rubber

Additive: Gel & EDTA.K2

Raw material certifications

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

Shelf life

12 (twelve) 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

Centrifugation




















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 & EDTA.K2 Tubes	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 -



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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