

Product Data

Product Name: IMPROVACUTER[®] 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
684090242	EDTA.K2	16×100mm	9ml	Safety Cap	Powder	PET	transparent	lavender	50/1000
684950242	EDTA.K2	16×100mm	8.5ml	Safety Cap	Powder	PET	transparent	lavender	50/1000
684081242	EDTA.K ₂	16x100mm	8ml	Safety Cap	Liquid	PET	transparent	lavender	50/1000
684080242	EDTA.K ₂	16x100mm	8ml	Safety Cap	Powder	PET	transparent	lavender	50/1000
683061242	EDTA.K ₂	13×100mm	6ml	Safety Cap	Liquid	PET	transparent	lavender	100/1000
683060242	EDTA.K ₂	13×100mm	6ml	Safety Cap	Powder	PET	transparent	lavender	100/1000
683051242	EDTA.K ₂	13×100mm	5ml	Safety Cap	Liquid	PET	transparent	lavender	100/1000
683050242	EDTA.K ₂	13×100mm	5ml	Safety Cap	Powder	PET	transparent	lavender	100/1000
683041242	EDTA.K ₂	13×100mm	4ml	Safety Cap	Liquid	PET	transparent	lavender	100/1000
683040242	EDTA.K ₂	13×100mm	4ml	Safety Cap	Powder	PET	transparent	lavender	100/1000
683031242	EDTA.K ₂	13×100mm	3ml	Safety Cap	Liquid	PET	transparent	lavender	100/1000
683030242	EDTA.K ₂	13×100mm	3ml	Safety Cap	Powder	PET	transparent	lavender	100/1000
682041242	EDTA.K ₂	13×75mm	4ml	Safety Cap	Liquid	PET	transparent	lavender	100/1000
682040242	EDTA.K ₂	13×75mm	4ml	Safety Cap	Powder	PET	transparent	lavender	100/1000
682031242	EDTA.K ₂	13×75mm	3ml	Safety Cap	Liquid	PET	transparent	lavender	100/1000
682030242	EDTA.K ₂	13×75mm	3ml	Safety Cap	Powder	PET	transparent	lavender	100/1000
682021242	EDTA.K ₂	13×75mm	2ml	Safety Cap	Liquid	PET	transparent	lavender	100/1000
682020242	EDTA.K ₂	13×75mm	2ml	Safety Cap	Powder	PET	transparent	lavender	100/1000
682011242	EDTA.K ₂	13×75mm	1ml	Safety Cap	Liquid	PET	transparent	lavender	100/1000
682010242	EDTA.K ₂	13×75mm	1ml	Safety Cap	Powder	PET	transparent	lavender	100/1000
684090202	EDTA.K2	16×100mm	9ml	Safety Cap	Powder	PET	Paper	lavender	50/1000
684950202	EDTA.K2	16×100mm	8.5ml	Safety Cap	Powder	PET	Paper	lavender	50/1000
684081202	EDTA.K ₂	16x100mm	8ml	Safety Cap	Liquid	PET	Paper	lavender	50/1000
684080202	EDTA.K ₂	16x100mm	8ml	Safety Cap	Powder	PET	Paper	lavender	50/1000
683061202	EDTA.K ₂	13×100mm	6ml	Safety Cap	Liquid	PET	Paper	lavender	100/1000
683060202	EDTA.K ₂	13×100mm	6ml	Safety Cap	Powder	PET	Paper	lavender	100/1000
683051202	EDTA.K ₂	13×100mm	5ml	Safety Cap	Liquid	PET	Paper	lavender	100/1000
683050202	EDTA.K ₂	13×100mm	5ml	Safety Cap	Powder	PET	Paper	lavender	100/1000
683041202	EDTA.K ₂	13×100mm	4ml	Safety Cap	Liquid	PET	Paper	lavender	100/1000
683040202	EDTA.K ₂	13×100mm	4ml	Safety Cap	Powder	PET	Paper	lavender	100/1000
683031202	EDTA.K ₂	13×100mm	3ml	Safety Cap	Liquid	PET	Paper	lavender	100/1000
683030202	EDTA.K ₂	13×100mm	3ml	Safety Cap	Powder	PET	Paper	lavender	100/1000
682041202	EDTA.K ₂	13×75mm	4ml	Safety Cap	Liquid	PET	Paper	lavender	100/1000
682040202	EDTA.K ₂	13×75mm	4ml	Safety Cap	Powder	PET	Paper	lavender	100/1000
682031202	EDTA.K ₂	13×75mm	3ml	Safety Cap	Liquid	PET	Paper	lavender	100/1000
682030202	EDTA.K ₂	13×75mm	3ml	Safety Cap	Powder	PET	Paper	lavender	100/1000
682021202	EDTA.K ₂	13×75mm	2ml	Safety Cap	Liquid	PET	Paper	lavender	100/1000
682020202	EDTA.K ₂	13×75mm	2ml	Safety Cap	Powder	PET	Paper	lavender	100/1000
682011202	EDTA.K ₂	13×75mm	1ml	Safety Cap	Liquid	PET	Paper	lavender	100/1000
682010202	EDTA.K ₂	13×75mm	1ml	Safety Cap	Powder	PET	Paper	lavender	100/1000

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

Subject and application

The interior of the tube wall is coated with EDTA.K2. The tube is also available with a liquid EDTA solution. The EDTA binds calcium ions thus blocking the coagulation cascade. IMPROVACUTER® EDTA Tubes can be used in direct sampling analyzers without actually being opened. Blood smearing should be done within 3 hours after blood collection. IMPROVACUTER® EDTA Tubes are used for testing whole blood in the clinical laboratory. IMPROVACUTER® EDTA.K2 Tubes may be used for routine immunohematology testing i.e. red cell grouping, Rh typing and antibody screens, and viral marker testing in screening laboratories. IMPROVACUTER® EDTA.K2 Tubes are used for testing plasma in molecular diagnostics. The performance characteristics of this device have not been established in general. Users must validate use of product for their specific molecular diagnostic assay.

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: EDTA.K2

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

Centrifugation

Whole blood tubes do not require centrifugation.

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

 陽普醫療 <small>IMPROVE MEDICAL</small>	Product Technical Data EDTA.K2 Tube	Document No	
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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