BLOOD COLLECTION TUBES TECHNICAL DATA SHEET

VACUSERA® K2E/K2EDTA and K2E/K2EDTA&Gel Blood Collection Tubes

Ref No	GMDN Code	Draw Vol (ml)	Label Type	Additive	Size Tube (mm)	Color	Cap Color
234601	43865	1	Paper	K2EDTA	13x75	Lavender	
234602	43865	2	Paper	K2EDTA			
234603	43865	3	Paper	K2EDTA			
234604	43865	4	Paper	K2EDTA			
234605	43865	4.5	Paper	K2EDTA			
434601	43865	1	Transparent	K2EDTA			
434602	43865	2	Transparent	K2EDTA			
434603	43865	3	Transparent	K2EDTA			
434604	43865	4	Transparent	K2EDTA			
434605	43865	4.5	Transparent	K2EDTA			
234623	47587	3	Paper	K2EDTA + GEL			
434623	47587	3	Transparent	K2EDTA + GEL			
235606	43865	6	Paper	K2EDTA	13x100		
435606	43865	6	Transparent	K2EDTA			
235625	47587	5	Paper	K2EDTA + GEL			
435625	47587	5	Transparent	K2EDTA + GEL			
236609	43865	9	Paper	K2EDTA	16x100		
436609	43865	9	Transparent	K2EDTA			
236628	47587	8	Paper	K2EDTA + GEL			
436628	47587	8	Transparent	K2EDTA + GEL			

DİSERA TIBBİ MALZEME LOJİSTİK SANAYİ VE TİCARET A.Ş.
GAZİEMİR VD. : 301 053 3601 Tic.Sic.No : Merkez 123171 K - 10769 Mersis No : 0301053360100013
Merkez : Karabağlar Mah. 5758 Sk. No:4 H/11 - Karabağlar / İZMİR Tel : +90 (0232) 264 66 68 info@disera.com.tr
Fabrika : İbni Melek Mah. Tosbi Yol 5 Sk. No: 46 Tire / İZMİR Faks : +90 (0232) 264 84 00 www.disera.com.tr

Ref No	GMDN Code	Draw Vol (ml)	Label Type	Additive	Size Tube (mm)	Color	Cap Color
234602DLL	43865	2	Paper	K2EDTA	13x75	Light Lavender	
234603DL	43865	3	Paper	K2EDTA	13x75	Lavender	
234604DML	43865	4	Paper	K2EDTA	13x75	Dark Lavender	
235606DL	43865	6	Paper	K2EDTA	13x100	Lavender	
236609DL	43865	9	Paper	K2EDTA	16x100	Lavender	
235625DH	43865	5	Paper	K2EDTA + GEL	13x100	White	

1. Intended Use:

K2 EDTA Tubes are used for testing whole blood in haematology. VACUSERA® EDTA Tubes may be used for routine immunohematology testing (i.e. red cell grouping), Rh typing and antibody screens, viral marker testing in screening laboratories. The interior of the tube wall is coated with EDTA K2. The EDTA binds calcium ions thus blocking the coagulation cascade. Blood smearing should be done within 3 hours after blood collection. Tubes are used for testing whole blood in the clinical haematology laboratory within 24 hours at room temperature. VACUSERA® EDTA K2/Gel Tubes are used for testing plasma in molecular diagnostics and viral load detection.

2. Information About The Manufacturer

Manufacturer: Disera Tıbbi Malzeme Lojistik Sanayi ve Ticaret A.Ş
Country of Origin: Turkey
EN ISO 13485:2016 Cert. n 31723701 Released by Szutest

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3. Applicable Standards

No	EXPLANATION OF STANDARD
1	EN ISO 13485:2016 Medical devices — Quality Management Systems — Requirements for Regulatory Purposes
2	EN ISO 15223-1:2021 Medical Devices — Symbols to be Used with Information to be Supplied by The Manufacturer — Part 1: General Requirements
3	EN ISO 20417:2021 Medical Devices - Information to be Supplied by the Manufacturer
4	EN ISO 14971:2019 Medical Devices — Application of Risk Management to Medical Devices
5	EN 62366-1:2015 Medical Devices - Part 1: Application of Usability Engineering to Medical Devices
6	EN ISO 11137-1:2015 Sterilization of Health Care Products - Radiation - Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices
7	EN ISO 11137-2:2015 Sterilization of Health Care Products — Radiation — Part 2: Establishing the Sterilization Dose
8	EN ISO 11137-3:2017 Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development, validation and routine control
9	EN ISO 11737-1:2018 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products
10	EN ISO 11737-2:2020 Sterilization of Health Care Products — Microbiological Methods — Part 2: Tests of Sterility Performed in The Definition, Validation and Maintenance of a Sterilization Process
11	ASTM F 1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices
12	EN ISO 6710 :2017 Single-Use Containers for Human Venous Blood Specimen Collection

13	EN 556-1:2001 Sterilization of medical devices - Requirements for medical devices to be designated "Sterile" - Part 1: Requirements for terminally sterilised medical devices
14	EN ISO 14644-1:2015 Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
15	EN ISO 14644-2:2015 Cleanrooms And Associated Controlled Environments — Part 2: Monitoring to Provide Evidence of Cleanroom Performance Related to Air Cleanliness by Particle Concentration
16	EN ISO 14644-3:2019 Cleanrooms And Associated Controlled Environments — Part 3: Test Methods
17	98/79/EC Directive of In vitro diagnostic medical devices
18	EN 13612: 2002 Performance evaluation of in vitro diagnostic medical devices
19	EN ISO 18113 -1 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling)

4. Product Specifications

Tube material:	Polyethylene teraphthalate (PET)
Cap material (outer shield):	Polymer (low density polyethylene resin)
Rubber material (inner cap):	Bromobutyl elastomers
Additives:	EDTA K2 and EDTA K2EDTA + GEL (1.2 - 2mg EDTA per milliliter of blood)
Additive Filling Form(K2EDTA)	Pulvarized
Gel Specification	Acrylic gel
Fill indicator:	Yes
Expiry (months):	18 months
Storage conditions:	Do not expose to direct sunlight. Store between +4 and 35 ° C.

5. Physical Properties

a) Raw Materials:

Tubes are made from PET (polyethylene terephthalate) material. They should be colorless and transparent.

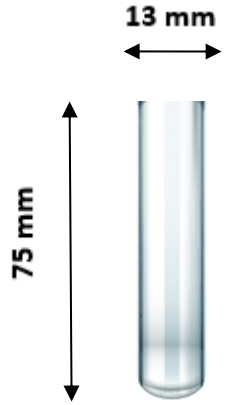
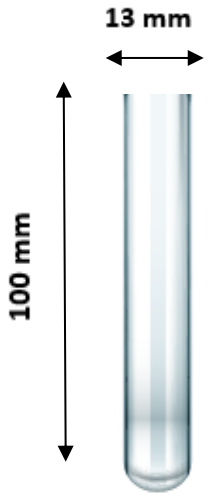
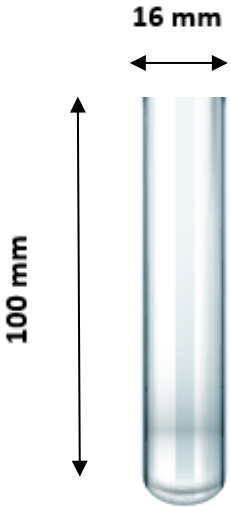
Tube caps are made from PE (polyethylene) material. Their colors may differ according to the additive that the tube contains.

Rubber stoppers are made from butyl elastomers.

All components are latex-free.

b) Dimensions

There are three different types of PET tubes according to their dimensions

13 x 75 mm PET Tube	13 x 100 mm PET Tube	16 x 100 mm PET Tube
		

There are PE caps with two different diameters (13mm & 16mm) that could fit into these PET tubes.

Accordingly, there are stoppers with 13 mm and 16 mm diameter that could fit in these PE caps and PET tubes.

All detailed dimensions are represented in the technical drawings.

6. Packaging

100 pieces of VACUSERA® Blood Collection Tubes are lined up in a styrofoam and wrapped with a shrink film. Each of these packages is called as rack. 12 racks are placed in a carton box and each box contains 1200 tubes.

Outer box dimensions for 13x75mm tubes: 36.0 X 53.5 X 18.5 mm
Outer box dimensions for 13x100mm tubes: 36.0 X 53.5 X 24.0 mm
Outer box dimensions for 16x100mm tubes: 38.0 X 56.5 X 24.0 mm

7. Sterilization

VACUSERA® Blood Collection Tubes are placed in the market as sterile. Products are sterilized using radiation sterilization. Sterilization process shall be validated.
Internamente sterility: SAL 10^{-6} (SAL= sterility assurance level) Standards: EN ISO 11137-2:2015; EN 556:2001/AC:2006

8. Label Information

	Tube Label	Rack Label	Carton Label
Company name and address of the manufacturer	+	+	+
Ref No (Product Code)	+	+	+
Lot No	+	+	+
Sterile (symbol) and method of sterilization	+	+	+
CE mark and single use			

Symbols on the label	Description of the Symbols	Tube Label	Rack Label	Box Label
Fill volume		+	+	✓
REF	Reference Number			
Expiration Date		+	+	
Product name and short description		✓ +	✓ +	✓
LOT	Batch Code	+	+	
Instructions for use (pictograms)		✓ +	✓ +	✓
Use by		-		
Quantity per package		✓ +	✓ +	✓
Single Use		-		
Storage instructions		+	✓ +	✓
	Keep away from sunlight			
Primary barcode		- +	+	
STERILE R	Radiation Sterilization	✓	✓	✓
Secondary barcode		- +	+	
Sterile indicator			✓	✓
	See the Instruction for Use	-	+	

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IVD	In Vitro Diagnostic Device	✓	✓	✓
	Temperature Limits		✓	✓
CE	CE symbol	✓	✓	✓

9. Instructions For Use

For more detailed information and usage instructions, please check the IFU document.

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