TECHNICAL INFORMATION SHEET

BD Microtainer® EDTA Tube with Microgard™ Closure

Product Catalogue Number: 365975

Intended Use

Single use, non-sterile capillary blood collection tube, containing K_2EDTA intended for the primary containment and preservation of specimens for the purposes of in-vitro diagnostic examination. Used to obtain and separate a whole blood or EDTA plasma sample. These products are intended for use by healthcare professionals.

Manufacturing Information

(Legal) Manufacturer:	Becton, Dickinson and Company, 1 Becton Drive, Franklin Lakes, NJ 07417, USA
Standards & Certificate Numbers:	EN ISO 13485:2012, MD19.2137, CE 252.191
Country of origin:	USA
Certification body:	NSAI
EU Authorised Representative:	Becton, Dickinson and Company Belliver Industrial Estate Belliver Way Roborough, Plymouth, PL6 7BP, UK

Sterilisation

Method:	Not sterile

Compliance

Directive:	European In Vitro Diagnostic Medical Devices Directive 98/79/EC
Classification:	Non Annex II / General IVD

Product Specification

Tube material:	Polypropylene (PP)
Tube size (mm):	10 x 45
Maximum fill volume (mL):	0.5
Additives:	1 mg Spray Dried K_2EDTA 2.0 – 4.2 mg/mL blood
Separator:	None
Closure material (cap):	High Density Polyethylene Resin (HDPE)
Closure material (stopper):	N/A
Closure colour:	Lavender
Product Storage:	Do not expose to direct sunlight Store product at less than 25°C
Label type:	None
Shelf-life:	18 months
Global medical device nomenclature (GMDN):	Not Currently Available
Material Safety Data Sheet (MSDS):	VS60311-16
Fill line indicator (µL):	250 & 500



Materials

Latex (NRL):	No
Dry Natural Rubber (DNR):	No
Phthalates:	No
Material of animal origin:	No

Packaging Specifications

50 unit pack weight (kg):	0.153	50 unit packaging material:	Polyethylene
50 unit pack volume (m^3):	0.000950	50 unit packaging weight (kg):	0.01
50 unit pack dimensions LxHxW (mm):	215 x 25 x 177	50 unit packaging volume (m^3):	Not Available
200 unit pack weight (kg):	0.61	200 unit packaging material:	Cardboard
200 unit pack volume (m^3):	0.00428	200 unit packaging weight (kg):	0.126
200 unit pack dimensions LxHxW (mm):	177 x 158 x 153	200 unit packaging volume (m^3):	Not Available

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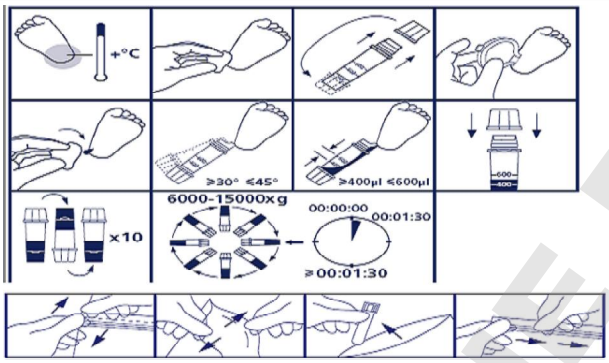
Product Catalogue Number: **365975**

Labelling Information

All labelling complies with the requirements of the European In Vitro Diagnostic Medical Devices Directive 98/79/EC and includes the CE marking.

	Unit Pack	Shelf Pack	Case Pack
Company name		•	•
Manufacturer address		•	•
Product Catalogue Number (PCN)		•	•
Colour Coding	•	•	•
CE marking		•	•
Single use symbols		•	•
Lot number	•	•	•
Expiry date	•	•	•
Instructions for Use (pictorials)		•	
Draw Volume	•		
Storage instructions		•	•
Quantity in package		•	•
Secondary barcode (GS1-128) quantity, expiry, lot number			•
Product name & short description	•	•	•
EU Authorised Representative		•	•

Instructions For Use



Sample Storage & Stability

Stability depends on the analyte (see specific analyte).[1,2]

Further Reading

1. Guder WG, Narayanan S, Wisser H and Zawta B. Samples: From the Patient to the Laboratory: the Impact of Preanalytical Variables on the Quality of Laboratory Results (4th Edition). Darmstadt, Germany: Wiley-VCH; 2009.
2. Clinical and Laboratory Standards Institute (CLSI; formerly NCCLS). Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens Samples: Approved Standard (6th Edition). Document: H04-A6. Wayne, PA, USA: 2008.
3. Daae L.N.W, Hallerud M and Halvorsen S. "A Comparison Between Haematological Parameters in 'Capillary' and Venous Blood Samples from Hospitalized Children Aged 3 Months to 14 Years". Scand J Clin Lab Invest. 1991, 51(7): 651-654.
4. Daae LNW, Halvorsen P, Mathisen PM and Mironska KA. "Comparison Between Haematological Parameters in 'Capillary' and Venous Blood from Healthy Adults". Scand J Clin Lab Invest. 1988, 48(7): 723-726.
5. International Council for Standardization in Haematology. "Recommendations of the International Council for Measurement of Erythrocyte Sedimentation Rate of Human Blood". Am J Clin Path. 1977, 68: 505-7.

References

1. Guder WG, et al. Recommendations of the Working Group on Preanalytical Quality of the German Society for Clinical Chemistry and Laboratory Medicine for Quality of Diagnostic Samples (3rd Edition), Darmstadt, Germany: GIT, 2010.
2. Tietz NW. Clinical Guide to Laboratory Tests (4th Edition). W.B. Saunders, USA: 2006.

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