TECHNICAL INFORMATION SHEET

BD Vacutainer® K_2EDTA Plus Tube with BD Hemogard™ Safety Closure

Product Catalogue Number: 367864

Product Description

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

Manufacturing Information

Manufacturer:	Becton, Dickinson and Company Belliver Industrial Estate Belliver Way Roborough, Plymouth, PL6 7BP, UK.
Standards & Certificate Numbers:	ISO 13485:2003 & EN ISO 13485:2012, MD 613320, ISO 14001:2004, EMS 37154
Country of origin:	UK
Certification body:	BSI UK (0086)
Notified Body:	N/A
EU Authorised Representative:	BD Switzerland Sarl, Terre Bonne Park - A4, Route de Crassier 17, 1262 Eysins, Switzerland

Sterilisation

Method:	Gamma Irradiation, Co-60
SAL:	10^{-6}
Standards applied:	EN ISO 11137

Product Standards & Guidelines

Standards:	ISO 6710:1995, EN14820
Guidelines:	Clinical and Laboratory Standards Institute (CLSI; Formerly NCCLS): Tubes and Additives for Venous Blood Specimen Collection; Approved Guideline (6th Edition). Document GP39-A6. Wayne, PA, USA, 2010.

Compliance

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

Product Specification

Tube material:	Polyethylene Terephthalate (PET)
Tube size (mm):	13 x 100
Draw volume (mL):	6
Additives:	1.8mg/mL Spray Dried K_2EDTA
Separator:	None
Closure material (cap):	Polymer (low density Polyethylene resin)
Closure material (stopper):	Bromobutyl Elastomer
Closure colour:	Lavender
Product Storage:	Do not expose to direct sunlight Store product between 4° and 25°C
Label type:	Paper
Shelf-life:	17 months
Global medical device nomenclature (GMDN):	43865
Material Safety Data Sheet (MSDS):	VS8020004
Fill line indicator:	Yes



Materials

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

Packaging Specifications

100 unit pack weight (kg):	0.74	100 unit packaging material:	Expanded Polystyrene (EPS) / Polyolefin film
100 unit pack volume (m^3):	0.003064	100 unit packaging weight (kg):	0.02
100 unit pack dimensions LxHxW (mm):	180 x 112 x 152	100 unit packaging volume (m^3):	0.000680
1000 unit pack weight (kg):	7.74	1000 unit packaging material:	Cardboard
1000 unit pack volume (m^3):	0.030538	1000 unit packaging weight (kg):	0.36
1000 unit pack dimensions LxHxW (mm):	555 x 304 x 181	1000 unit packaging volume (m^3):	0.31809

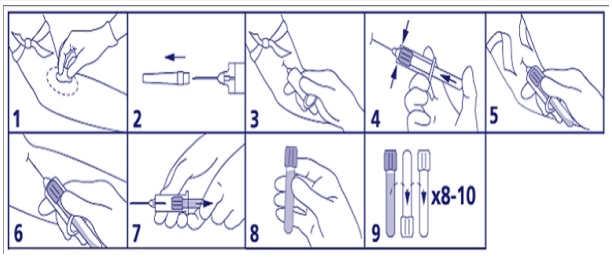
Product Catalogue Number: **367864**

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)	•	•	•
Sterile symbol showing method of sterilisation	•	•	•
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	•	•	•

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. Van Cott E, Lewandrowski K, Patel S, Grzybek D, Patel H, Fletcher S and Kratz A. "Comparison of Glass K3EDTA versus Plastic K2EDTA Blood-Drawing Tubes for Complete Blood Counts, Reticulocyte Counts and White Blood Cell Differentials". Lab Hematol. 2003; 9:10-14.
3. Landry M, Garner R and Ferguson D. "Use of Plastic Vacutainer® Tubes for Quantification of Human Immunodeficiency Virus Type 1 in Blood Specimens". J Clin Microbiol. Jan 2001; 39(1): 354- 56
4. Anderson DR, Wiseman J, MacLeod J, Burton E and Zayed E. "Evaluation of Polyethylene Terephthalate for ABO and Rh Typing and Alloantibody Screening". Transfusion. June 2000; 40: 669-72.
5. Phillips J, Coiner J, Smith E, Becker D and Leong J. "Performance of K2EDTA vs. K3EDTA Collected Blood Specimens on Various Haematology Analyzers". Lab Hematol. 1998; 4: 17-20.
6. Faynor SM and Robinson R. "Suitability of Plastic Collection Tubes for Cyclosporine Measurements". Clin Chem. 1998; 44: 2220-2221.
7. Brunson D, Smith D, Bak A, Sheridan B and Muncer DL. "Comparing Hematology Anticoagulants: K2EDTA and K3EDTA". Lab Hematol. 1995; 1: 112-119.
8. 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.
9. BD White Paper VS7279: "A Comparison of BD Vacutainer® K2EDTA Plus Tubes with BD Vacutainer® K3EDTA Glass Tubes for Six Infectious Disease Markers". 2006.
10. BD White Paper VS7081: "Evaluation of BD Vacutainer® K2EDTA Plus Tubes and BD Vacutainer® K3EDTA Glass Tubes for CBC, WCB Differential Counts and Reticulocyte Counts on the Coulter® Gen-S™ Hematology Analyzer". 2004.

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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