TECHNICAL INFORMATION SHEET

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

Product Catalogue Number: **368861**

TIS368861, AC, 10 10 10, 01

BD Diagnostics
Preanalytical Systems

Intended Use

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

(Legal) Manufacturer	Becton, Dickinson and Company Belliver Industrial Estate, Plymouth, Devon, PL6 7BP, UK
Standards & Certificate Numbers	ISO 14001:2004, EMS37154 ISO 13485:2003, FM79169
Country of origin	UK or USA
Certification body	BSI (0086)

Sterilisation

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

Relevant Product Standards & Guidelines

Standards:	ISO 6710:1995, EN14820:2004
Guidelines:	Clinical and Laboratory Standards Institute (CLSI; Formerly NCCLS): Tubes and Additives for Venous Blood Specimen Collection. Approved Guideline - Fifth Edition. Document H1-A5. Wayne, PA, USA, 2003

Compliance

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

Product Specification

Tube material:	Polyethylene Terephthalate (PET)
Tube size (mm):	13 x 75
Draw volume (mL):	4
Fill line indicator:	Yes
Additives:	1.8mg/mL Spray Dried K_2EDTA
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:	16 months
Global medical device nomenclature (GMDN)	43865
Material Safety Data Sheet (MSDS)	VS8020004
Does product contain?	
Latex (NRL):	No
Dry Natural Rubber (DNR):	No
Phthalates:	No
Material of animal origin:	No

Packaging Specifications

100 unit pack weight (kg):	0.62	**100 unit packaging material:**	Expanded Polystyrene (EPS) / Polyolefin film
100 unit pack volume (m^3):	0.002380	**100 unit packaging weight (kg):**	0.02
100 unit pack dimensions LxHxW (mm):	180 x 87 x 152	**100 unit packaging volume (m^3):**	0.000680
1000 unit pack weight (kg):	6.54	**1000 unit packaging material:**	Cardboard
1000 unit pack volume (m^3):	0.023660	**1000 unit packaging weight (kg):**	0.298
1000 unit pack dimensions LxHxW (mm):	430 x 304 x 181	**1000 unit packaging volume (m^3):**	0.024645

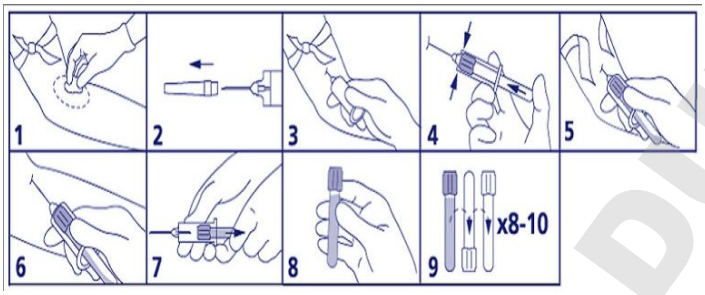
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Labelling Information

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		•	•
Primary barcode (GS1-128) product identification		•	•
Secondary barcode (GS1-128) qty, expiry, lot number			•
Product name & short description	•	•	•

Instructions for Use



Sample Storage & Stability

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

References

1. Guder W.G. et all, Recommendations of the Working Group on Preanalytical Quality of the German Society for Clinical Chemistry and Laboratory Medicine, Quality of Diagnostic Samples, 3rd Edition, 2010

2. Tietz N.W Ed, Clinical Guide to Laboratory Tests - Fourth Edition. W.B. Saunders, USA: 2006

Further Reading

1. Guder W.G, Narayanan S, Wisser H. and Zawta B. Diagnostic Samples: From the Patient to the Laboratory. Fourth 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. Laboratory Hematology. 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. Journal of Clinical Microbiology. 2001 January; p. 354- 56

4. Anderson D.R, Wiseman J, MacLeod J, Burton E, and Zayed E. Evaluation of Polyethylene Terephthalate for ABO and Rh Typing and Alloantibody Screening. Transfusion. 2000 June; 40: 669-72

5. Phillips J, Coiner J, Smith E, Becker D, Leong J. Performance of K2EDTA vs. K3EDTA collected blood specimens on various haematology analyzers. Laboratory Hematology 1998; 4: 17-20

6. Faynor S.M, Robinson R. Suitability of Plastic Collection Tubes for Cyclosporine Measurements. Clinical Chemistry 1998;44:2220-2221

7. Brunson D, Smith D, Bak A, Sheridan B, Muncer DL. Comparing hematology anticoagulants: K2EDTA and K3EDTA. Laboratory Hematology 1995; 1:112-119 International Society for Laboratory Hematology

8. International Council for Standardization in Haematology: Recommendation for measurement of erythrocyte sedimentation rate of human blood – Am. J. Clin. Pathol. 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

Whenever changing any manufacturer's blood collection tube type, size, handling, processing or storage conditions for a particular laboratory assay, the laboratory personnel should review the tube manufacturer's data and their own data to establish/verify the reference range for a specific instrument/reagent system. Based on such information, the laboratory can then decide if a change is appropriate.

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