

TECHNICAL INFORMATION SHEET

BD Vacutainer® ACD (B) Tube with BD Hemogard™ Safety Closure



Product Catalogue Number: **367756**

Product Description

Single-use, evacuated, sterile blood collection tubes containing trisodium citrate with citric acid and dextrose (solution B) intended for the primary containment and preservation of specimens for the purposes of in-vitro diagnostic examination. Used to obtain a whole blood or a plasma sample. These products are intended for use by healthcare professionals.

Manufacturing Information

(Legal) 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:	Becton Dickinson Ireland Ltd., Donore Road, Drogheda, Co. Louth, A92 YW26, Ireland

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

Regulation:	European In Vitro Diagnostic Medical Device Regulation 2017/746
Classification:	A Sterile

Product Specification

Tube material:	Glass
Tube size (mm):	13 x 100
Draw volume (mL):	6
Additives:	1 mL ACD Solution B (1.89 mg/mL Trisodium Citrate, 0.69 mg/mL Citric acid, 2.1 mg/mL Dextrose, 0.029 mg/mL Potassium Sorbate)
Separator:	None
Closure material (cap):	Polymer (low density Polyethylene resin)
Closure material (stopper):	Bromobutyl Elastomer
Closure colour:	Yellow
Product Storage:	Do not expose to direct sunlight Store product between 4° and 25°C
Label type:	Paper
Shelf-life:	18 months
Global medical device nomenclature (GMDN):	42370
Material Safety Data Sheet (MSDS):	VS8020033
Fill line indicator:	No



Materials

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

Packaging Specifications

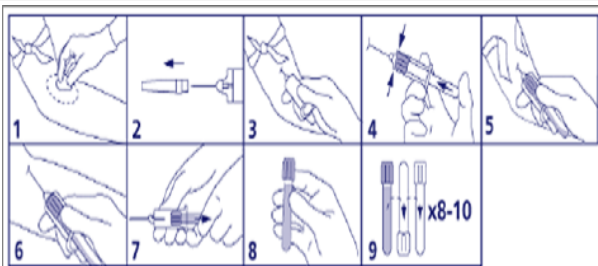
100 unit pack weight (kg):	1.13	100 unit packaging material:	Expanded Polystyrene (EPS) / Polyolefin film
100 unit pack volume (m ³):	0.003064	100 unit packaging weight (kg):	0.02
100 unit pack dimensions LxHxW (mm):	180 x 112 x 152	100 unit packaging volume (m ³):	0.000680
1000 unit pack weight (kg):	11.71	1000 unit packaging material:	Cardboard
1000 unit pack volume (m ³):	0.032323	1000 unit packaging weight (kg):	0.36
1000 unit pack dimensions LxHxW (mm):	560 x 355 x 215	1000 unit packaging volume (m ³):	0.031809

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) quantity, expiry, lot number			•
Product name & short description	•	•	•

Instructions For Use



Further Reading

- Guder WG, Narayanan S, Wissner 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.
- Han W, Liu J.H, Wang T.J, Li R, Ouyang X.L, Li X.J et al. "Measuring the Shelf Life of CPDA and ACD Whole Blood Stored at Above 4 Degrees C in Vitro". Transfusion. 2004; 12(1): 95-7.
- Kuritzkes D.R et al. "Performance Characteristics of the TRUGENE HIV-1 Genotyping Kit and the Opengene DNA Sequencing System". J Clin Microbiol. 2003; 41(4): 1594-99.
- Branum E, Cummins L, Bartilson M, Hopper M, Pruett S, O'Brien J.F. "Effect of Two Anticoagulants on Leukocyte Yield and Function and on Lysosomal Enzyme Activity". Clin Chem. 1998; 34(1): 110-113.
- Dickover R, Herman S, Saddiq K, Wafer D, Dillon M and Bryson Y. "Optimization of Specimen-Handling Procedures for Accurate Quantitation of Levels of Human Immunodeficiency Virus RNA in Plasma by Reverse Transcriptase PCR". J Clin Microbiol. 1998; 36(4): 1070-73.
- Kolberg J and Nordhagen R. "An Evaluation of Some Factors Affecting the Detection of Blood Group Antibodies by Automated Methods". Transfusion. 1975; 15(4): 334-9.

Sample Storage & Stability

Samples drawn in the BD Vacutainer® ACD tube are stable after collection up to 48 hours at room temperature if the plasma is separated from the cells within 6 hours of blood draw (see further reading).¹
Stability depends on the analyte (see specific analyte).

References

- Tietz NW. Clinical Guide to Laboratory Tests (4th Edition). W.B. Saunders, USA: 2006.