

TECHNICAL INFORMATION SHEET

BD Vacutainer® Lithium Heparin Plasma Plus Tube with BD Hemogard™ Safety Closure



Product Catalogue Number: **368884**

Product Description

Single use, evacuated, sterile blood collection tubes containing Lithium Heparin intended for the primary containment and preservation of specimens for the purposes of in-vitro diagnostic examination. Used to obtain a 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 75
Draw volume (mL):	4
Additives:	Spray Dried Lithium Heparin (17 IU/mL)
Separator:	None
Closure material (cap):	Polymer (low density Polyethylene resin)
Closure material (stopper):	Bromobutyl Elastomer
Closure colour:	Dark Green
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):	47589
Material Safety Data Sheet (MSDS):	VS8020015
Fill line indicator:	Yes



Materials

Latex (NRL):	No
Dry Natural Rubber (DNR):	No
Phthalates:	No
Material of animal origin:	Lithium Heparin: Porcine Origin

Packaging Specifications

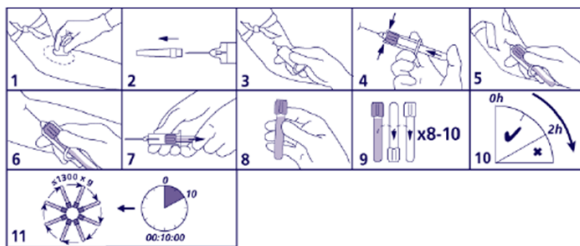
100 unit pack weight (kg):	0.6	100 unit packaging material:	Expanded Polystyrene (EPS) / Polyolefin film
100 unit pack volume (m ³):	0.002380	100 unit packaging weight (kg):	0.02
100 unit pack dimensions LxHxW (mm):	180 x 87 x 152	100 unit packaging volume (m ³):	0.000680
1000 unit pack weight (kg):	6.34	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

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, 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.
- Giavarina D, Fortunato A, Barzon E, Church S, Bérubé J, Green S and Siffiati G. "Evaluation of BD Vacutainer® PST™ II Tubes for a Wide Range of Immunoassays". Clin Chem Lab Med. 2009; 47(2): 237-41.
- Chance J, Bérubé J, Vandersmissen M, Blanckaert N. "Evaluation of the BD Vacutainer® PST™ II Tube for Special Chemistry Analytes". Clin Chem Lab Med, 2009; 47(3): 358-61.
- Nosanchuk JS, Stull R and Keefner R. "The Effects of Substitution of Plasma for Serum on Chemistry Stat Turnaround Time". Lab Med. July 1991; 22(7): 465-9.
- Harr R, Bond L and Trumbull D. "A Comparison of Results for Serum versus Heparinized Plasma for 30 Common Analytes". Lab Med. July 1987; 18(7): 449-55.
- BD White Paper VS7597-OUS: "A Comparative Evaluation of BD Vacutainer® PST™ II Tubes with BD Vacutainer® Lithium Heparin Plus and BD Vacutainer® Serum Plus Tubes for Selected Hormones, Therapeutic Drugs, Tumor Markers and Other Chemistry Analytes". 2008.
- BD White Paper VS7174: "Comparison of BD Vacutainer® Lithium Heparin Plus Tubes with BD Vacutainer® Lithium Heparin Glass Tubes for Routine Chemistry Analytes". 2004.

Sample Storage & Stability

After an aliquot of plasma is separated from the sedimented cells:^{1,2}
 ≤ 8h: store sample at 22°C
 > 8h and ≤ 48h: store sample at +4°C
 > 48h: store sample at -20°C
 Stability depends on the analyte (see specific analyte).^{2,3}

References

- Clinical and Laboratory Standards Institute (CLSI; formerly NCCLS): Procedures for the Handling and Processing of Blood Specimens; Approved Guideline (4th Edition). Document H18-A4. Wayne, PA, USA: 2010.
- 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.
- Tietz NW. Clinical Guide to Laboratory Tests (4th Edition). W.B. Saunders, USA: 2006.