TECHNICAL INFORMATION SHEET

BD Vacutainer® SST™ II Advance Plus Tube with BD Hemogard™ Safety Closure

Product Catalogue Number: 367953

Intended Use

Single use, evacuated, sterile blood collection tubes containing an inert gel barrier and a clot activator coating intended for the primary containment and preservation of specimens for the purposes of in-vitro diagnostic examination. Used to obtain and separate a serum 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:	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):	16 x 100
Draw volume (mL):	8.5
Additives:	Silica (Clot Activator)
Separator type:	Acrylic Based Gel
Closure material (cap):	Polymer (Polypropylene)
Closure material (stopper):	Chlorobutyl Elastomer
Closure colour:	Gold
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):	41128
Material Safety Data Sheet (MSDS):	VS8020006
Fill line indicator:	Yes

Materials

Latex (NRL):	No
Dry Natural Rubber (DNR):	No
Phthalates:	No
Material of animal origin:	Gel barrier: Contains Component from Bovine Origin.

Packaging Specifications

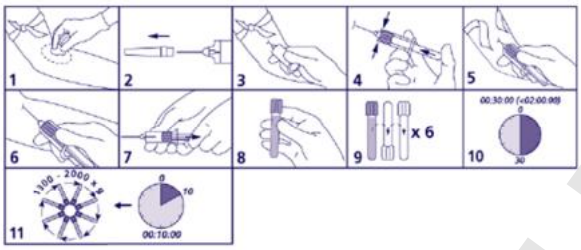
100 unit pack weight (kg):	1.12	100 unit packaging material:	Expanded Polystyrene (EPS) / Polyolefin film
100 unit pack volume (m^3):	0.004057	100 unit packaging weight (kg):	0.02
100 unit pack dimensions LxHxW (mm):	207 x 112 x 175	100 unit packaging volume (m^3):	0.001040
1000 unit pack weight (kg):	11.54	1000 unit packaging material:	Cardboard
1000 unit pack volume (m^3):	0.042742	1000 unit packaging weight (kg):	0.427
1000 unit pack dimensions LxHxW (mm):	560 x 355 x 215	1000 unit packaging volume (m^3):	0.041671

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



Sample Storage & Stability

In general serum can be stored on the gel barrier after centrifugation for up to 48 hours at 4°C (see further reading).[1,2]
BD internal studies suggest stability of 23 routine chemistry analytes for up to 24h at room temperature and 144h at 2-8°C (see further reading).
BD internal studies suggest stability of 13 drugs from 5 different classes for 48h at 25°C and up to 7 days at 4°C (see further reading).
Stability depends on the analyte (see specific analyte).[2,3]

References

1. 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.
2. 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.
3. Tietz NW. Clinical Guide to Laboratory Tests (4th Edition). W.B. Saunders, USA: 2006.

Further Reading

1. van den Ouweland JMW, Church S. "High Total Protein Impairs Appropriate Gel Barrier Formation in BD Vacutainer Blood Collection Tubes". Clin Chem. 2007; 53(2): 364-5.
2. Mensel B, Wenzel U, Roser M, Lüdemann J, Nauck M. "Considerably Reduced Centrifugation Time Without Increased Hemolysis: Evaluation of the New BD Vacutainer® SST™ II Advance". Clin Chem. 2007; 53(4): 794-5.
3. Smets E and Dijkstra-Lagemaat J. "Influence of Blood Collection in Plastic vs Glass Evacuated Serum-Separator Tubes on Hormone and Tumour Marker Levels". Clin Chem Lab Med, 2004; 42(4): 435-9.
4. Spiritus T, Zaman Z and Desmet W. "Iodinated Contrast Media Interfere with Gel Barrier Formation in Plasma and Serum Separator Tubes". Clin Chem. 2003; 49(7): 1187-9.
5. Bakker J, Hackeng C, Church S, Dieijen-Visser M and Beckers O. "An Evaluation of the Integrity of BD Vacutainer® SST™ II and Analyte Stability when Subject to Freezing at -20°C". EUREGIO Congress of Clinical Chemistry and Laboratory Medicine: Aachen, Germany, Oct 2003.
6. Bush V, Janu M, Bathur F, Wells A and Dasgupta A. "Comparison of BD Vacutainer® SST™ Plus Tubes with BD SST™ II Plus Tubes for Common Analytes". Clinica Chimica Acta. April 2001; 306(1-2): 139-43.
7. Bush V, Blennerhasset J, Well A and Dasgupta A. "Stability of Therapeutic Drugs in Serum Collected in Vacutainer Serum Separator Tubes Containing a New Gel (SST II)". Ther Drug Monit. June 2001; 23(3).
8. BD White Paper VS7278-OUS: "A Comparison of BD Vacutainer® SST™ II Advance Tubes with BD Vacutainer® Serum Glass Tubes for Six Infectious Disease Markers". 2006.
9. BD White Paper VS7351: "A Comparison of Adjusted BD Vacutainer® SST™ II Advance Tubes with BD Vacutainer® Serum Glass Tubes for Cortisol, Total T3, Total T4 and TSH on the DPC Immulite® 1000 Analyzer". 2005.
10. BD White Paper VS7050: "Therapeutic Drug Compatibility in BD Vacutainer® SST™ II Plus Tubes". 2004.
11. BD White Paper VS7249: "A Comparative Evaluation of BD Vacutainer® SST™ II Advance Tubes with BD Vacutainer® SST™ Glass Tubes for Select Cardiac Markers". 2004.
12. BD White Paper VS7228: "Performance of BD Vacutainer® SST™ II Advance Tubes at Four and Five Minute Centrifugation Times". 2004.
13. BD White Paper VS7051: "Performance of BD Vacutainer® SST™ II Plus Tubes for Special Chemistry Testing". 2004.
14. BD White Paper VS5780: "Comparison of BD Vacutainer™ SST™ Plus Tubes with SST™ II Plus Tubes Common Analytes on the Toshiba/Abbott Aeroset". 2001.
15. BD White Paper VS5824: "Gel Barrier Stability Comparison of BD Vacutainer® SST™ II Plus, SST™ Plus and SST™ Plus Transport Tubes in Post Centrifugation Transport". 2001.