TECHNICAL INFORMATION SHEET

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

Product Catalogue Number: 368815

Product Description

Single use, evacuated, sterile blood collection tubes containing a clot activator coating intended for the primary containment and preservation of specimens for the purposes of in-vitro diagnostic examination. Used to obtain a serum 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:	Silica (Clot Activator)
Separator:	None
Closure material (cap):	Polymer (low density Polyethylene resin)
Closure material (stopper):	Bromobutyl Elastomer
Closure colour:	Red
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):	42386
Material Safety Data Sheet (MSDS):	VS8020032
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):	0.031809

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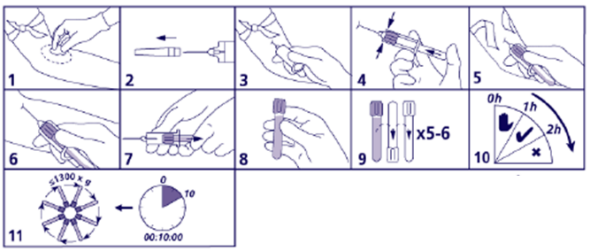
Labelling Information

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

Instructions For Use



Sample Storage & Stability

After an aliqout of serum is separated from the clot:[1,2]
≤ 8h: store sample at 22ºC
> 8h and ≤ 48h: store sample at +4ºC
> 48h: store sample at -20ºC
Stability depends on the analyte (see specific analyte).[2,3]

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. Wilson JM, Leonard KS and Posey YF., "Evaluation of Plastic Blood Collection Tubes for Therapeutic Drug Monitoring". Clin Chem Suppl. September 2002; 48(6): A43.
3. Chance J. "Choosing the Right Specimen for Blood Testing". Clinical Laboratory News. July 2001; 18-20.
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. BD White Paper VS7593. "A Comparison of BD Vacutainer® Serum Plus Tubes with BD Vacutainer® Serum Glass Tubes for Ischemia Modified Albumin (IMA®)". 2006.
6. BD White Paper VS7276. "A Comparison of BD Vacutainer® Serum Plus Tubes with BD Vacutainer® Serum Glass Tubes for Six Infectious Disease Markers". 2006.
7. BD White Paper VS7344. "A Comparison of Adjusted BD Vacutainer® Serum Plus Tubes to BD Vacutainer® Serum Glass Tubes for Total T3 on the DPC Immulite® Analyzer". 2005.
8. BD White Paper VS7273. "A Comparative Evaluation of BD Vacutainer® Serum Plus Tubes and BD Vacutainer® Serum Glass Tubes for ToRCH Immunoassays". 2005.
9. BD White Paper VS7266. "A Multi-site Evaluation of BD Vacutainer® Serum Plus tubes for Immunohematology Parameters". 2004.
10. BD White Paper VS7253. "A Comparative Evaluation of BD Vacutainer® Serum Plus Tubes with BD Vacutainer® Serum Glass Tubes for Select Cardiac Markers". 2004.
11. BD White Paper VS7033. "Evaluation of BD Vacutainer™ Serum Plus Plastic Tubes Compared with BD Vacutainer™ Serum Glass Tubes for Routine Chemistry Analytes". 2003.
12. BD White Paper VS5419: "Summary Report of a Comparison of BD Vacutainer™ Plain Serum Tubes (Glass versus PLUS Plastic) for Therapeutic Drug Monitoring". 2003.

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.