

TECHNICAL INFORMATION SHEET

BD Microtainer[®] SST[™] with Microgard[™] Closure



Product Catalogue Number: **365968**

Intended Use

Single use, non-sterile capillary blood collection tube, 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, 1 Becton Drive, Franklin Lakes, NJ 07417, USA
Standards & Certificate Numbers:	EN ISO 13485:2012, MD19.2137, CE 252.191
Country of origin:	USA
Certification body:	NSAI (0050)
Notified Body:	NSAI (0050)
EU Authorised Representative:	BD Switzerland Sarl, Terre Bonne Park - A4, Route de Crassier 17, 1262 Eysins, Switzerland

Sterilisation

Method:	Not sterile
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Compliance

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

Product Specification

Tube material:	Polypropylene (PP)
Tube size (mm):	10 x 45
Maximum fill volume (mL):	0.6
Additives:	Silica: 0.10 – 2.56 mg/mL blood
Separator:	Polyester Gel: 0.90 – 3.50 g
Collector material:	Not Applicable
Closure material (cap):	High Density Polyethylene Resin (HDPE)
Closure material (stopper):	N/A
Closure colour:	Gold
Product Storage:	Do not expose to direct sunlight Store product at less than 25°C
Label type:	None
Shelf-life:	15 months
Global medical device nomenclature (GMDN):	58138
Material Safety Data Sheet (MSDS):	VS60313-11
Fill line indicator (µL):	400 & 600 µL



Materials

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

Packaging Specifications

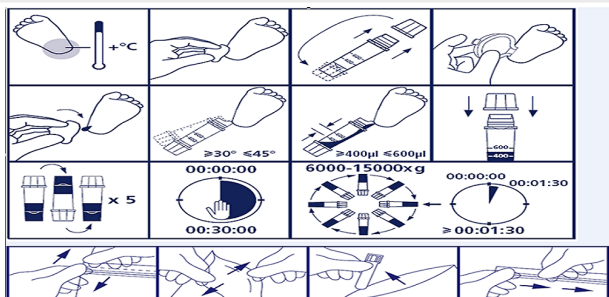
50 unit pack weight (kg):	0.1587	50 unit packaging material:	Polyethylene
50 unit pack volume (m ³):	0.000950	50 unit packaging weight (kg):	0.01
50 unit pack dimensions LxHxW (mm):	215 x 25 x 177	50 unit packaging volume (m ³):	Not Available
200 unit pack weight (kg):	0.69	200 unit packaging material:	Cardboard
200 unit pack volume (m ³):	0.004000	200 unit packaging weight (kg):	0.126
200 unit pack dimensions LxHxW (mm):	177 x 143 x 158	200 unit packaging volume (m ³):	Not Available

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)		•	•
Colour Coding	•	•	•
CE marking		•	•
Single use symbols		•	•
Lot number	•	•	•
Expiry date	•	•	•
Instructions for Use (pictorials)		•	
Draw Volume	•		
Storage instructions		•	•
Quantity in package		•	•
Secondary barcode (GS1-128) quantity, expiry, lot number			•
Product name & short description	•	•	•
Authorised Representative		•	•

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.
- Clinical and Laboratory Standards Institute (CLSI; formerly NCCLS). Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens Samples: Approved Standard (6th Edition). Document: H04-A6. Wayne, PA, USA: 2008.
- BD White Paper VS7353: "A Comparison of Adjusted BD Microtainer Serum Tubes and Adjusted BD Microtainer SST Tubes for Total T3 on the DPC Immulite 1000 Analyzer and TSH on the Abbott AxSYM Analyzer". 2007.
- BD White Paper VS5866: "Comparison of BD Microtainer™ SST™ Tubes with BD Microgard™ Closure and the BD Microtainer™ SST™ Tubes with FloTop Collector for Visual Hemolysis, Clotting Time and Chemistry Analytes". 2001.

Sample Storage & Stability

Stability depends on the analyte (see specific analyte).^{1,2}

References

- 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.