# TECHNICAL INFORMATION SHEET

# BD Microtainer® PST™ LH Amber Blood Collection Tubes



Product Catalogue Number: 365988

## **Product Description**

BD Microtainer® Blood Collection Tubes are non sterile, single use in vitro diagnostic medical devices. They are intended to be used by trained healthcare professionals for the collection, containment and transport of human capillary blood specimens and the subsequent separation of serum or plasma by centrifugation for in vitro diagnostic testing.

BD Microtainer® Blood Collection Tubes contain a Lithium Heparin (LH) additive to anticoagulate the specified volume of capillary blood.

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BD Microtainer® PST™ Blood Collection Tubes have a separator gel at the tube bottom. The density of this material causes it to move upward during centrifugation to the plasma cell interface, where it forms a barrier separating plasma from cells

BD Microtainer® PST™ Amber Blood Collection Tubes significantly reduce light transmission and are used when protection is required for light sensitive analytes.

### Manufacturing Information

(Legal) Manufacturer: Becton, Dickinson and Company, 1 Becton Drive, Franklin Lakes, NJ 07417, USA

Standards & Certificate

EN ISO 13485, MD19,2137

Country of origin: USA NSAI (0050) Certification body: Notified Body: N/A

EU Authorised Representative: Becton Dickinson Ireland Ltd. Donore Road, Drogheda Co. Louth, A92 YW26 Ireland

#### Sterilisation

Method: Not sterile

# Compliance

Directive: In Vitro Diagnostic Medical Device Regulation (IVDR)

(EU) 2017/746

Classification: Class A non-sterile

# **Product Specification**

Polypropylene (PP) Amber

Tube size (mm): Maximum fill volume (mL):

Additives: Lithium Heparin: 0.2 - 1.0 mg/mL blood

Polvester Gel: 0.17 - 0.27a Separator:

Not Applicable Collector material:

High Density Polyethylene Resin (HDPE) Closure material (cap):

Closure material (stopper): N/A Closure colour: Mint Green

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):

Material Safety Data Sheet (MSDS): https://regdocs.bd.com/regdocs/sdsSearch

Fill line indicator (µL): 400 & 600 μL



#### Materials

200 unit packaging volume (m³):

Latex (NRL): No Dry Natural Rubber (DNR): No Phthalates:

Material of animal origin: i. Lithium Heparin: Porcine Origin. ii.

Gel barrier: Contains Component from

Bovine Origin.

# **Packaging Specifications**

50 unit pack weight (kg): 0.14 50 unit packaging material: Polyethylene

0.00095 0.01 50 unit pack volume (m3): 50 unit packaging weight (kg):

181 x 163 x 143

50 unit pack dimensions LxHxW (mm): 215 x 25 x 177 Not Available 50 unit packaging volume (m3): 0.69 Cardboard 200 unit pack weight (kg): 200 unit packaging material: 200 unit pack volume (m3): 200 unit packaging weight (kg): 0.126

Not Available

200 unit pack dimensions LxHxW (mm):

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### **Labelling Information**

All labelling complies with the requirements of the In Vitro Diagnostic Medical Device Regulation (IVDR) (EU) 2017/746 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	•		
Storage instructions	•		•
Quantity in package	•		•
Primary barcode (GS1-128) product identification	•		
Secondary barcode (GS1-128) quantity, expiry, lot number	•		
Product name & short description	•		•
Authorised Representative	•		•

### Instructions For Use

Please see eIFU (VDP40477) for further details on instructions for use, storage and references. https://eifu.bd.com/

# **Further Reading**

Not applicable

# Sample Storage & Stability

# References

Not applicable

