TECHNICAL INFORMATION SHEET

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

Product Catalogue Number: 368817

Intended Use

Single use, evacuated, sterile blood collection tubes with labelling for crossmatch use 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

(Legal) Manufacturer
Becton, Dickinson and Company
Belliver Industrial Estate
Belliver Way
Roborough, Plymouth, PL6 7BP, UK.

Standards & Certificate Numbers
ISO 14001, EMS37154
ISO 13485, FM78169

Country of origin
UK

Certification body
BSI

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
Fill line indicator: Yes
Additives: Spray Dried Clot Activator
Closure material (cap): Polymer (low density Polyethylene resin)
Closure material (stopper): Bromobutyl Elastomer
Closure colour: Pink
Product storage: Do not expose to direct sunlight
Store product between 4º and 25ºC

Label type: Crossmatch
Shelf-life: 17 months
Global medical device nomenclature (GMDN): 42386
Material Safety Data Sheet (MSDS): VS8020032

Packaging Specifications

100 unit pack weight (kg): 0.73
100 unit pack volume (m³): 0.003064
100 unit pack dimensions LxHxW (mm): 180 x 112 x 152
1000 unit pack weight (kg): 7.64
1000 unit pack volume (m³): 0.030538
1000 unit pack dimensions LxHxW (mm): 555 x 304 x 181

Sterilisation

Method: Gamma Irradiation, Co-60
SAL: 10
Standards applied: EN ISO 11137

Relevant Product Standards & Guidelines

Standards: ISO 6710, EN14620

This tube has been designed to enable tube differentiation in laboratories and therefore does not follow the established colour code, described in ISO 6710, which is used by BD for the majority of our tube product portfolio. If ordering this tube, it is important to ensure that the appropriate staff in your organization are aware of these differences. Using the wrong tube for any given test may result in analytical error.


Does product contain?
- Latex (NRL): No
- Dry Natural Rubber (DNR): No
- Phthalates: No
- Material of animal origin: No

These products are supplied as a result of a standard order. The above guidelines should be followed.

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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.

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Further Reading


Sample Storage & Stability

After serum is separated from the clot: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


Whenever changing any manufacturer's blood collection tube type, size, handling, processing or storage conditions for a particular laboratory assay, the laboratory personnel should review the tube manufacturer's data and their own data to establish/verify the reference range for a specific instrument/reagent system. Based on such information, the laboratory can then decide if a change is appropriate.