TECHNICAL INFORMATION SHEET

BD Vacutainer® Plus C&S Boric Acid Sodium Borate/Formate with BD Hemogard™ Safety Closure

Product Catalogue Number: 364958

Product Description

Single use, evacuated, sterile urine collection tubes, intended for the collection and transport of urine samples derived from the human body for bacteriological culture and sensitivity testing. These products are intended for use by healthcare professionals.

Manufacturing Information

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:	Gamma Irradiation, Co-60
SAL:	10^{-6}
Standards applied:	EN ISO 11137

Product Standards & Guidelines

Standards:	EN14254

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 75
Draw volume (mL):	4
Additives:	Boric Acid 2.63 mg/mL / Sodium Borate 2.08 mg/mL / Sodium Formate 1.65 mg/mL
Separator:	None
Closure material (cap):	Polymer (low density Polyethylene resin)
Closure material (stopper):	Bromobutyl Elastomer
Closure colour:	Olive Green
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):	58151
Material Safety Data Sheet (MSDS):	VS61004
Fill line indicator:	Yes



Materials

Latex (NRL):	No
Dry Natural Rubber (DNR):	No
Phthalates:	No
Material of animal origin:	No

Packaging Specifications

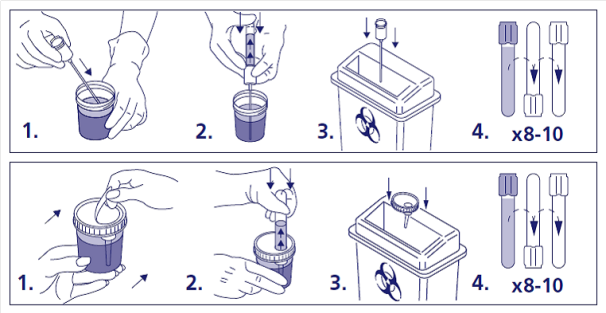
100 unit pack weight (kg):	0.59	100 unit packaging material:	Expanded Polystyrene (EPS) / Polyolefin film
100 unit pack volume (m^3):	0.002380	100 unit packaging weight (kg):	0.02
100 unit pack dimensions LxHxW (mm):	180 x 87 x 152	100 unit packaging volume (m^3):	0.000405
1000 unit pack weight (kg):	5.92	1000 unit packaging material:	Cardboard
1000 unit pack volume (m^3):	0.024650	1000 unit packaging weight (kg):	0.298
1000 unit pack dimensions LxHxW (mm):	435 x 308 x 184	1000 unit packaging volume (m^3):	0.024645

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	•	•	•
Authorised Representative		•	•

Instructions For Use



Further Reading

1. Kouri T, Vuotari L, Pohjavaara S and Laippala P. "Preservation of Urine for Flow Cytometric and Visual Microscopic Testing". Clin Chem. Jun 2002; 48: 900 - 905.
2. BD White Paper VS7099: "Evaluation of BD Vacutainer® Urine Culture & Sensitivity PLUS Tube vs. BD Vacutainer® Urine Culture & Sensitivity Glass Tube for Microbiological Testing - Patient Urine". 2003.
3. BD White Paper VS7097: "Evaluation of BD Vacutainer™ Urine Culture & Sensitivity PLUS Tube vs. Refrigerated BD Vacutainer™ Non-Additive PLUS Tube for Microbiological Testing - Seeded Urine". 2003.

Sample Storage & Stability

In general, urine samples for bacteriological culture without stabilisers can be stored for:
2 hours after collection at room temperature[1,2]
24 hours if immediately refrigerated between 2 to 8°C after collection[2,3]
BD has data that supports stability in the urine culture & sensitivity tube for up to 48 hours at room temperature (see further reading).

References

1. Clinical and Laboratory Standards Institute (CLSI; formerly NCCLS): Urinalysis. Approved Guideline (3rd Edition). Document GP16-A3. Wayne, PA, USA: 2009.
2. ECLM European Urinalysis Group. "European Urinalysis Guidelines". Scand J Clin Lab Invest Suppl. 2000; 231(1), 1-86.
3. 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.

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