

TECHNICAL INFORMATION SHEET

BD Vacutainer® Urine Collection Cup



BD Diagnostics
Preanalytical Systems

Product Catalogue Number: **364941**

TIS364941, 10 10 10 AC

Intended Use

Single use sterile container intended for the collection and containment of urine. It is equipped with an integrated transfer device to enable transfer of urine from the collection cup into evacuated urine tubes. 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	ISO 13485:2003, MD19.2137
Country of origin	USA
Certification body	NSAI (0050)
EU Authorised Representative	Becton, Dickinson and Company Belliver Industrial Estate, Plymouth, Devon, PL6 7BP, UK

Sterilisation

Method:	Gamma Irradiation, Co-60
SAL:	10 ⁻⁶
Standards applied:	EN ISO 11137

Relevant Product Standards

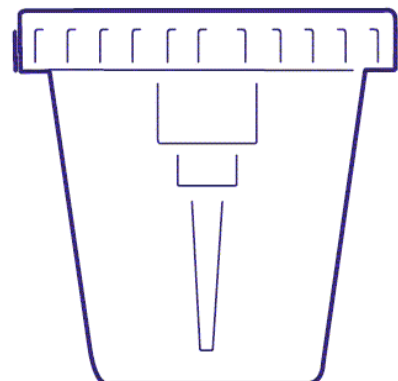
Standards:	EN14254:2004
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Compliance

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

Product Specification

Container Material:	Polypropylene
Lid Material:	Polyethelene
Cannula Material:	Stainless Steel (304 Grade)
Sleeve Material:	Synthetic Rubber
Capacity (ml):	120
Fill Indicator:	10mL graduations
Closure Colour:	Blue
Does product contain?	
Latex (NRL):	No
Dry Natural Rubber (DNR):	No
Phthalates:	No
Material of animal origin:	No



Product Storage:



Do not expose to direct sunlight

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	Case Pack
Company name & manufacturer address		•
Reference number	•	•
CE marking & single use symbols	•	•
Lot number	•	•
Instructions for use (pictorials)	•	
Draw Volume		
Colour coding	•	
Storage conditions		•
Quantity in package		•
Primary barcode (GS1-128) product identification		•
Secondary barcode (GS1-128) qty, expiry, lot number		•
Product name & short description		•
EU Authorised Representative		•

Packaging Specifications

200 unit pack weight (kg):	4.9	200 unit packaging material:	Plastic Bag and Cardboard
200 unit pack volume (m³):	0.045914	200 unit packaging weight (kg):	0.81
200 unit pack dimensions LxHxW (mm):	571 x 374 x 215	200 unit packaging volume (m³):	Not Available

Sample Storage & Stability

In general, urine samples can be stored:

- 2 hours from collection at room temperature^{1,2}
- 24 hours if immediately refrigerated between 2 to 8°C after collection^{2,3}

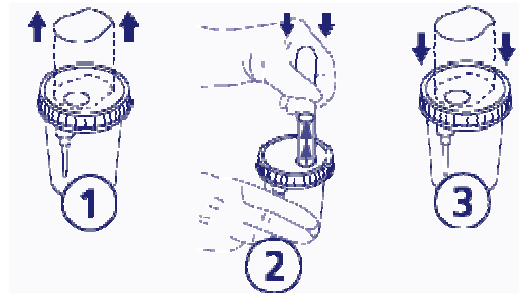
References

1. Clinical and Laboratory Standards Institute (CLSI; formerly NCCLS): Urinalysis and Collection, Transportation, and Preservation of Urine Specimens. Approved Guideline - Second Edition. Document GP16-A4. Wayne, PA, USA, 2001
2. ECLM European Urinalysis Group, European urinalysis guidelines. Scand J Clin Lab Invest Suppl. 2000;231:1-86.
3. Guder W.G. et al, Recommendations of the Working Group on Preanalytical Quality of the German Society for Clinical Chemistry and Laboratory Medicine, Quality of Diagnostic Samples, 3rd Edition, 2010

Further Reading

1. Guder W.G, Narayanan S, Wisser H. and Zawta B. Diagnostic Samples: From the Patient to the Laboratory. Fourth Edition. Darmstadt, Germany: Wiley-VCH; 2009

Instructions for Use



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