TECHNICAL INFORMATION SHEET

BD Vacutainer® Urine Collection Cup

Product Catalogue Number: 364941

Product Description

Single use specimen collection cup is used to collect and transfer urine, via an integrated transfer device, into an evacuated tube for transport and storage. The cup minimizes the risk of leaking and contamination, allows for the transfer of urine to one or more tubes without exposure to specimen, and eliminates the need for pouring.

Manufacturing Information

(Legal) Manufacturer:	Becton Dickinson and Company, 1 Becton Drive, Franklin Lakes, NJ 07417, USA
Standards & Certificate Numbers:	ISO 13485, MD 19.2137
Country of origin:	USA
Notified Body:	NSAI (0050)
Certification body:	NSAI (0050)
EU Authorised Representative:	BD Switzerland Sarl, Terre Bonne Park - A4, Route de Crassier 17, 1262 Eysins, Switzerland

Sterilisation

Method:	Gamma Irradiation
SAL:	10^{-6}
Standards applied:	EN ISO 11137

Compliance

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

Product Specification

Closure colour:	Blue
Product Storage:	Do not expose to direct sunlight
Shelf-life:	24 months
Global medical device nomenclature (GMDN):	47776
Lid Material:	Polyethelene
Cannula Material:	Stainless Steel (304 Grade)
Sleeve Material:	Synthetic Rubber
Capacity (mL):	120
Fill Indicator:	10 mL graduations



Materials

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

Packaging Specifications

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

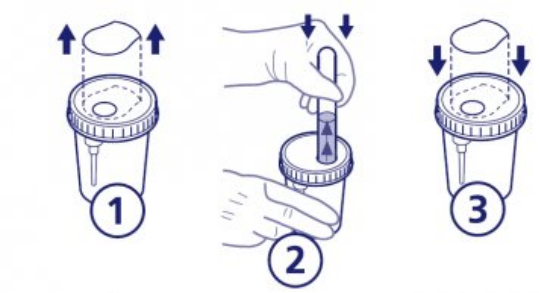
Product Catalogue Number: **364941**

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			•
Reference number	•		•
CE marking	•		•
Single use symbols	•		•
Lot number	•		•
Instructions for Use (pictorials)	•		
Colour Coding	•		
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



Sample Storage & Stability

In general, urine samples can be stored for:

- 2 hours from collection at room temperature [1,2]
- 24 hours if immediately refrigerated between 2 and 8°C after collection [2,3]

Further Reading

1. 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 (Fourth Edition). Darmstadt, Germany: Wiley-VCH; 2009.

References

1. Clinical and Laboratory Standards Institute (CLSI): Urinalysis and Collection, Transportation, and Preservation of Urine Specimens. Approved Guideline - Second Edition. Document GP16-A4. Wayne, PA, 2001
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 (Third Edition). Darmstadt, Germany: GIT, 2010.

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