

368832 - BD Vacutainer® Urine Analysis Preservative Tube

Intended Use

Single use, evacuated, sterile urine collection tubes with urine preservative, intended for the collection and primary containment and preservation of urine specimens derived from the human body for the purpose of in-vitro diagnostic examination. 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 and Certificates: ISO 13485, MD 19.2137
Country of Origin: USA
Certification Body: NSAI
Authorised Representative: Becton Dickinson and Company
Belliver Industrial Estate
Belliver Way, Roborough
Plymouth, PL6 7BP UK

Sterilisation

Method: Gamma Irradiation, Co-60
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 IVD

Product Specification

Tube Material: Polyethylene Terephthalate
Tube Size (mm): 16 x 100
Draw Volume (mL): 8
Fill Line Indicator: Yes
Additive: Sodium Propionate / Ethyl Paraben / Chlorhexidine
Closure Material (cap): Polymer (Polyethylene)
Closure Material (stopper): Chlorobutyl Elastomer
Closure Colour: Yellow
Product Storage: Do not expose to direct sunlight
Store product between 4°C and 25°C
Label type: Paper
Shelf life: 18 months
GMDN: 57924 – Evacuated urine specimen container IVD, ethyl paraben/sodium propionate/chlorhexidine
MSDS: Not Available
Does the product contain: Latex (NRL) - No
Dry Natural Rubber (DNR) - No
Phthalates - No

Materials of Animal Origin - No

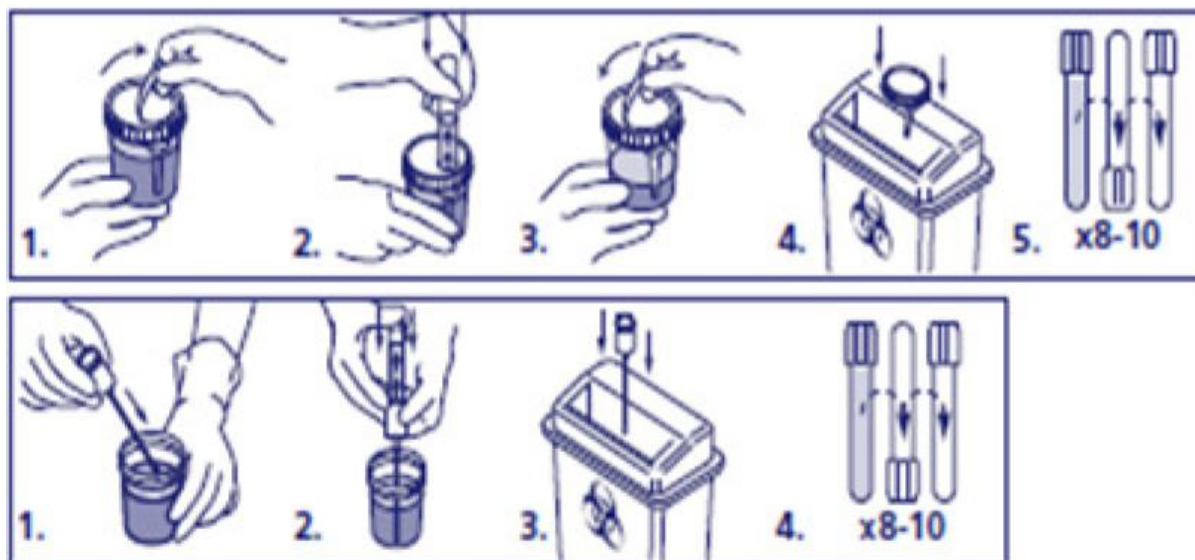
Packaging Specifications

100 unit packaging material: Expanded Polystyrene (EPS) / Polyolefin film
1000 unit packaging material: Cardboard

Labelling Information

	Unit Pack	Shelf Pack	Case Pack
Company name and manufacturers address	*	*	*
Product catalogue number (PCN)	*	*	*
Sterile symbol showing method of sterilisation	*	*	*
Colour coding	*	*	*
CE marking and 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), qty, expiry, lot number			*
Product name and short description	*	*	*
EU Authorised Representative	*	*	*

Instructions for Use



Sample Storage and Stability

In general, urine samples can be stored:

- 2 hours after collection at room temperature
- 24hours if immediately refrigerated between 2 to 8°C after collection

BD has data that supports stability in the urine culture & sensitivity tube for up to 48 hours at room temperature.

Sample should be transported from cup into tube as quickly as possible and mixed.