TECHNICAL INFORMATION SHEET

BD Vacutainer® CPT™ Cell Preparation Tube

BD Diagnostics
Preanalytical Systems

Product Catalogue Number: **362781**

TIS362781, CF, 23 05 14, 01

Intended Use

Single use, evacuated, sterile blood collection tubes containing buffered sodium citrate anticoagulant, liquid density media and an inert gel barrier intended for the collection of whole blood and the subsequent separation of mononuclear blood cells for the purposes of in-vitro diagnostic examination. The tube can be used as a transport device for the separated cell fraction. 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, MD19.2137
Country of origin	USA
Certification body	NSAI
EU Authorised Representative	Becton, Dickinson and Company Belliver Industrial Estate Belliver Way Roborough, Plymouth, PL6 7BP, UK.

Sterilisation

Method:	Heat Sterilised
SAL:	10^{-6}
Standards applied:	EN ISO 11134

Relevant Product Standards & Guidelines

Standards:	ISO 6710, EN14820
Guidelines:	Clinical and Laboratory Standards Institute (CLSI; Formerly NCCLS): Tubes and Additives for Venous Blood Specimen Collection. Approved Guideline - Fifth Edition. Document H1 -A5. Wayne, PA, USA, 2003

Compliance

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

Product Specification

Tube material:	Glass
Tube size (mm):	13 x 100
Draw volume (mL):	4
Fill line indicator:	No
Additives:	0.45 mL 0.1M Buffered Sodium Citrate, 1 mL buffered Liquid Density Media (LDM), Polyester Gel
Closure material (stopper):	Butyl Rubber
Closure colour:	Blue/Black
Product Storage:	Do not expose to direct sunlight Store product between 18° and 25°C

Label type:	Mylar
Shelf-life:	12 months
Global medical device nomenclature (GMDN)	Not Currently Available
Material Safety Data Sheet (MSDS)	VS60315
Does product contain?	
Latex (NRL):	No
Dry Natural Rubber (DNR):	No
Phthalates:	No
Material of animal origin:	Gel barrier: Contains Component from Bovine Origin.

Packaging Specifications

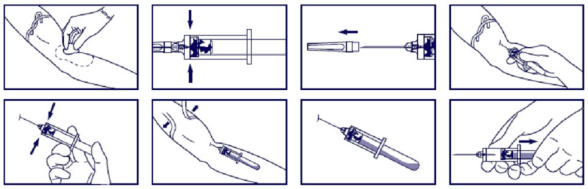
60 unit pack weight (kg):	1.09
60 unit pack volume (m^3):	0.002370
60 unit pack dimensions LxHxW (mm):	178 x 114 x133
60 unit packaging material:	Cardboard Carton with Cardboard Dividers
60 unit packaging weight (kg):	0.18

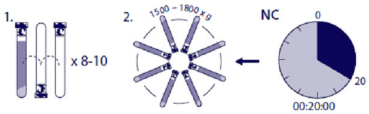
Labelling Information

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
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) qty, expiry, lot number		•
Product name & short description	•	•
EU Authorised Representative		•

Instructions for Use





Sample Storage & Stability

Isolated Peripheral Blood Mononuclear Cells (PBMC) will be stable in BD CPT for 24 hours at room temperature, depending on the downstream application.[1,2]

References

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2. Weinberg A, Betensky RA, Zhang L and Ray G. "Effect of Shipment, Storage, Anticoagulant and Cell Separation on Lymphocyte Proliferation Assays for Human Immunodeficiency Virus-Infected Patients". Clin Diagn Lab Immunol. 1998; 5: 804 – 807.

Further Reading

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3. Barousse MM, van Der Pol BJ, Fortenberry D, Orr D and Fidel PL. "Vaginal Yeast Colonisation, Prevalence of Vaginitis and Associated Local Immunity in Adolescents". Sex Transm Infect. Feb 2004; 80: 48 - 53.

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8. Diggle CP, Bentley J and Kiltie AE. "Development of a Rapid, Small-Scale DNA Repair Assay for Use on Clinical Samples". Nucleic Acids Res. Aug 2003; 31: 83.

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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.

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