TECHNICAL INFORMATION SHEET

BD Vacutainer® CPT™ Cell Preparation Tube

BD Diagnostics
Preanalytical Systems

Product Catalogue Number: **362782**

TIS362782, 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):	16 x 125
Draw volume (mL):	8
Fill line indicator:	No
Additives:	1.0 mL 0.1M Buffered Sodium Citrate, 2 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)	42585
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

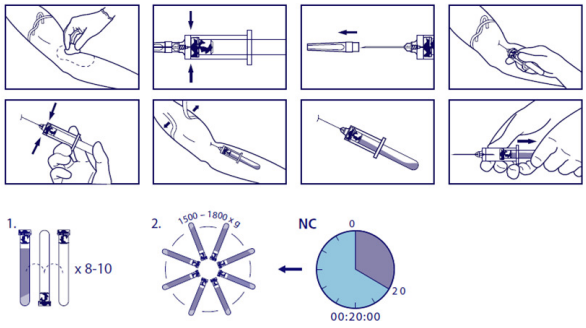
60 unit pack weight (kg):	1.72
60 unit pack volume (m^3):	0.003840
60 unit pack dimensions LxHxW (mm):	190 x 127 x 159
60 unit packaging material:	Cardboard Carton with Cardboard Dividers
60 unit packaging weight (kg):	0.25

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

1. Schlenke P, Klüter H, Müller-Steinhardt M, Hammers H-J, Borchert K and Bein G. "Evaluation of a Novel Mononuclear Cell Isolation Procedure for Serological HLA Typing". Clin Diagn Lab Immunol. 1998; 5: 808 - 813.

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

1. Williamson ED, Flick-Smith HC, LeButt C, Rowland CA, Jones SM, Waters EL, Gwyther RJ, Miller J, Packer PJ and Irving M. "Human Immune Response to a Plague Vaccine Comprising Recombinant F1 and V Antigens". Infect Immun, Jun 2005; 73: 3598 -

2. Pruvost A, Negredo E, Benech H, Theodoro F, Puig J, Grau E, García E, Moltó J, Grassi J, Clotet B. "Measurement of Intracellular Didanosine and Tenofovir Phosphorylated Metabolites and Possible Interaction of the Two Drugs in Human Immunodeficiency Virus-Infected Patients". Antimicrob Agents Chemother. May 2005; 49: 1907 - 1914.

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.

4. Azoulay S, Nevers M-C, Créminon C, Heripret L, Durant J, Dellamonica P, GrassiJ, Guedj R and Duval D. "Sensitive Enzyme Immunoassay for Measuring Plasma and Intracellular Nevirapine Levels in Human Immunodeficiency Virus-Infected Patients". Antimicrob Agents Chemother. Jan 2004; 48: 104 - 109.

5. Tautenhahn A, Brüne B and von Knethen A. "Activation-induced PPAR Expression Sensitizes Primary Human T Cells Toward Apoptosis". J Leukoc Biol. May 2003; 73: 665 - 672.

6. Beijer L, Thorn J and Rylander R. "Mould Exposure at Home Relates to Inflammatory Markers in Blood". Eur Respir J. Feb 2003; 21: 317 - 322.

7. Jian Xu, Rudolf Lucas, Marcus Schuchmann, Simone Kühnle, Thomas Meergans, Ana P. Barreiros, Ansgar W. Lohse, Gerd Otto and Albrecht Wendel. "GM-CSF Restores Innate, But Not Adaptive, Immune Responses in Glucocorticoid-Immunosuppressed Human Blood In Vitro". J Immunol., Jul 2003; 171: 938 - 947.

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.

9. Cohen SJ, Ho L, Ranganathan S, Abbruzzese JL, Alpaugh KR, Beard M, Lewis NL, McLaughlin S, Rogatko A, Perez-Ruixo JJ, Thistle AM, Verhaeghe T, Wang H, Weiner L, Wright J, Hudes GR, Meropol NJ. "Phase II and Pharmacodynamic Study of the Farnesyltransferase Inhibitor R115777 as Initial Therapy in Patients With Metastatic Pancreatic Adenocarcinoma". J Clin Oncol. Apr 2003; 21: 1301 - 1306.

10. Peralba J, deGraffenried L, Friedrichs W, Fulcher L, Grünwald V, Weiss G, Hidalgo M. "Pharmacodynamic Evaluation of CCI-779, an Inhibitor of mTOR, in Cancer Patients". Clin Cancer Res. Aug 2003; 9: 2887 - 2892.

11. Bosma AJ, Weigelt B, Lambrechts AC, Astrid J. Bosma, Britta Weigelt, A. Caro Lambrechts, Verhagen OJHM, Pruntel R, Hart AAM, Rodenhuis S and van 't Veer L. "Detection of Circulating Breast Tumor Cells by Differential Expression of Marker Genes". Clin Cancer Res., Jun 2002; 8: 1871 - 1877.

12. McDaid HM, Mani Sridhar, Shen HJ, Muggia F, Sonnichsen D and Horwitz S. "Validation of the Pharmacodynamics of BMS-247550, an Analogue of Epothilone B, during a Phase I Clinical Study". Clin Cancer Res. Jul 2002; 8: 2035 - 2043.

13. van Epps HL, Terajima M, Mustonen J, Arstila TP, Corey EA, Vaheri A and Ennis FA. Heather L. "Long -lived Memory T Lymphocyte Responses After Hantavirus Infection". J Exp Med. Sep 2002; 196: 579 - 588.

14. Kaur A, Yang J, Hempel D, Gritz L, Mazzara G, McClure H, Johnson RP. "Identification of Multiple Simian Immunodeficiency Virus (SIV)-Specific CTL Epitopes in Sooty Mangabeys with Natural and Experimentally Acquired SIV Infection". J Immunol. Jan 2000; 164: 934 - 943.

15. Ennis RD, Katz AE, de Vries GM, Heitjan DF, O'Toole KM, Rubin M, Buttyan R, Benson MC and Schiff PB. "Detection of Circulating Prostate Carcinoma Cells via an Enhanced Reverse Transcriptase-Polymerase Chain Reaction Assay in Patients with Early Stage Prostate Carcinoma. Independence from other pretreatment characteristics". Cancer. Jun 1997; 79(12): 2402-8.

BD Diagnostics
Preanalytical Systems
The Danby Building
Edmund Halley Road
Oxford Science Park
Oxford, OX4 4DQ, UK
Tel: +44 (0)1865 748844
Fax: +44 (0)1865 781528
www.bd.com
bdukvacutainer@europe.com

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.