TECHNICAL INFORMATION SHEET
PAXgene® Blood RNA Tube
For *In Vitro* Diagnostics Use
Product Catalogue Number: 762165

BD
BD Diagnostics
Preanalytical Systems

Intended Use

Single-use, evacuated, sterile blood collection tubes intended for the collection, storage and transport of blood and the stabilization of intracellular RNA. For the subsequent isolation and purification of intracellular RNA from the whole blood for molecular diagnostic testing. These products are intended for use by healthcare professionals.

Manufacturing Information

(Legal) Manufacturer	PreAnalytiX GmbH Feldbachstrasse Hombrechtikon, Switzerland CH-8634
Standards & Certificate Numbers	ISO 13485:2003, MD19.2137
Country of origin	UK
Certification body	NSAI (0050)

Sterilisation

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

Relevant Product Standards & Guidelines

Standards:	ISO 6710:1995, EN14820:2004
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 Use IVD

Product Specification

Tube material:	Polyethylene Terephthalate (PET)	**Label type:**	Paper
Tube size (mm):	16 x 100	**Shelf-life:**	18 months
Draw volume (mL):	2.5	**Global medical device nomenclature (GMDN)**	Not Currently Available
Fill line indicator:	No		
Additives:	6.9 mL of Proprietary RNA stabilisation additive	**Material Safety Data Sheet (MSDS)**	VS60342
Closure material (cap):	Polymer (low density polypropylene resin)	**Does product contain?**	
Closure material (stopper):	Butyl Rubber	**Latex (NRL):**	No
Closure colour:	Transparent shield with red stopper	**Dry Natural Rubber (DNR):**	No
Product Storage:	☼ Do not expose to direct sunlight	**Phthalates:**	Yes (stopper)
	🌡 Store product between 4° and 25°C	**Material of animal origin:**	No

Packaging Specifications

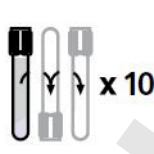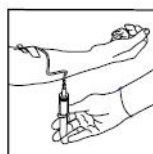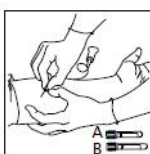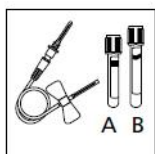|			
100 unit pack weight (kg):	0.97	**100 unit packaging material:**	Expanded Polystyrene (EPS) / Polyolefin film
100 unit pack volume (m³):	0.005133		
100 unit pack dimensions LxHxW (mm):	292 x 178 x 95		

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	•	•

Instructions for Use

Sample Storage & Stability

Stability will dependant upon the application and takes effect as soon as the blood is mixed with the additive[1,2]

RNA will be stable in PAXgene tubes for:[2,3]

- 3 days at room temperature

- 5 days at 4°C

- 50 months at -20°C as well as -70°C

(see further reading).

References

1. Lynne Rainen, Uwe Oelmueller, Stewart Jurgensen, Ralf Wyrich, Cynthia Ballas, Jim Schram, Chris Herdman, Danute Bankaitis-Davis, Nancy Nicholls, David Trollinger, and Victor Tryon. Stabilization of mRNA Expression in Whole Blood Samples. Clin. Chem., Nov 2002; 48: 1883 - 1890.

2. Guenther et al., Performance Evaluation Study of the PAXgene Blood RNA System with Regulatory Compliance, www.preanalytix.com access 25/11/2010

3. In Situ Stability of RNA in Blood Samples Stored at –20°C and –70°C in PAXgene Blood RNA Tubes; Guenther et al., ISBER, 2009

Further Reading

1. Gene expression as peripheral biomarkers for sporadic Alzheimer's disease. E Grunblatt, J Bartl, S Zehetmayer, TM Ringel, P Bauer, P Riederer, and CP Jacob. J Alzheimers Dis, Mar 2009; 16(3): 627-34

2. Differential expression of toll-like receptor genes: sepsis compared with sterile inflammation 1 day before sepsis diagnosis. ME Lissauer, SB Johnson, GV Bochicchio, CJ Feild, AS Cross, JD Hasday, CC Whiteford, WA Nussbaumer, M Towns, and TM Scalea. Shock, Mar 2009; 31(3): 238-44

3. Autoimmune Transcriptional Profiles in Early Rheumatoid Arthritis Peripheral Blood Cells. Nancy J Olsen, John Ligon, and Laurie S Davis. J. Immunol., Apr 2009; 182: 49.12.

4. Development of a blood based breast cancer test for Indian population. D Tobin, K Bårdsen, T Lindahl, M Kauczynska, D Punia, Y Kumar, C Desai, C Shroff, A Børresen-Dale, and P Sharma Cancer Res., Jan 2009; 69: 5013.

5. SCG3 Transcript in Peripheral Blood Is a Prognostic Biomarker for REST-Deficient Small Cell Lung Cancer. Adrian C. Moss, Gregory M. Jacobson, Lauren E. Walker, Neil W. Blake, Ernie Marshall, and Judy M. Coulson. Clin. Cancer Res., Jan 2009; 15: 274 - 283.

6. R. W. Ross, D. Bankaitis-Davis, L. Siconolfi, L. Katz, K. Storm, J. Magidson, K. Wassmann, and W. K. Oh. Sensitivity and specificity of a whole-blood RNA transcript-based diagnostic test for the diagnosis of prostate cancer (CaP) compared with prostate-specific antigen (PSA) alone. ASCO Meeting Abstracts, May 2009; 27: 5052.

7. K Vartanian, R Slottke, T Johnstone, A Casale, SR Planck, D Choi, JR Smith, JT Rosenbaum, and CA Harrington. Gene expression profiling of whole blood: comparison of target preparation methods for accurate and reproducible microarray analysis. BMC Genomics, Jan 2009; 10: 2.

8. S Debey-Pascher, D Eggle, and JL Schultze. RNA stabilization of peripheral blood and profiling by bead chip analysis. Methods Mol Biol, Jan 2009; 496: 175-210.

9. Effect of hypoxia on circulating levels of retina-specific messenger RNA in type 2 diabetes mellitus. A Wong, S Merritt, AN Butt, A Williams, and R Swaminathan. Ann N Y Acad Sci, Aug 2008; 1137: 243-52.

10. Gene expression measurements in the context of epidemiological studies. C Bieli, R Frei, V Schickinger, J Steinle, C Bommer, S Loeliger, C Braun-Fahrlander, E von Mutius, G Pershagen, and R Lauener Allergy, Dec 2008; 63(12): 1633-6.

11. ED Carrol, F Salway, SD Pepper, E Saunders, LA Mankhambo, WE Ollier, CA Hart, and P Day. Successful downstream application of the Paxgene Blood RNA system from small blood samples in paediatric patients for quantitative PCR analysis. BMC Immunol, Jan 2007; 8: 20.

12. An international study to standardize the detection and quantitation of BCR-ABL transcripts from stabilized peripheral blood preparations by quantitative RT-PCR. Martin C. Müller, Giuseppe Saglio, Feng Lin, Heike Pfeifer, Richard D. Press, Raymond R. Tubbs, Peter Paschka, Enrico Gottardi, Steven G. O'Brien, Oliver G. Ottmann, Hubertus Stockinger, Lothar Wieczorek, Kirsten Merx, Heiko König, Uwe Schwindel, Rüdiger Hehlmann, and Andreas Hochhaus. Haematologica, Jul 2007; 92: 970 - 973.

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.