



FOR THE COLLECTION OF HUMAN BONE MARROW AND IMMEDIATE STABILIZATION OF INTRACELLULAR RNA

For Research Use Only

Not for use in diagnostic procedures

To be used only in conjunction with the PAXgene Bone Marrow RNA Kit (30) (Cat. No. 764133)

I. Intended Use

The PAXgene Bone Marrow RNA System consists of a bone marrow collection tube (PAXgene Bone Marrow RNA Tube) and nucleic acid preparation kit (PAXgene Bone Marrow RNA Kit). It is intended for the collection, storage, and transport of human bone marrow and stabilization of intracellular RNA in a closed tube and subsequent isolation and purification of total RNA.

Product Features

PAXgene Bone Marrow RNA Tube	2.0 ml • 16 x 125 mm	11.1 ml additive	Sterile
764114	Plus • BD Hemogard™	50 tubes/case	RUO

For Research Use Only. Not For Use In Diagnostic Procedures. No claim or representation is intended to provide information for the diagnosis, prevention, or treatment of a disease. The performance characteristics of this product have not been fully established.

Do Not Use For Blood Collection.

II. Summary and Explanation

The aspiration and collection of whole bone marrow is the first step in many molecular assays used to study intracellular RNA. A major challenge in this type of testing is the instability of intracellular RNA, which rapidly degrades within hours after bone marrow aspiration. Furthermore, the expression of certain species of RNA, through the process of gene induction, increases in vitro after bone marrow collection. Both in vitro RNA degradation and gene induction can lead to an under- or overestimation of in vivo gene transcript number.

PAXgene Bone Marrow RNA Tubes contain an additive that stabilizes the in vivo gene transcription profile by reducing in vitro RNA degradation and minimizing gene induction. When used in conjunction with the PAXgene Bone Marrow RNA Kit, the PAXgene Bone Marrow RNA Tube provides stabilization and purification of intracellular RNA for accurate detection and quantification of gene transcripts.

III. Specimen Collection and Preparation for Analysis

- 1. Label PAXgene Bone Marrow RNA Tube appropriately with subject identification.
- Aspirate bone marrow using standard medical practices. Collect the bone marrow in a syringe with a standard anticoagulant (not supplied).
- 3. Remove the needle from the syringe used to collect bone marrow. Remove the BD Hemogard Closure from the PAXgene Bone Marrow RNA Tube as stated in Section VII. Add 2.0 ml bone marrow to the labeled PAXgene Bone Marrow RNA Tube as soon as possible after bone marrow aspiration. Use the gradations on the syringe to measure the amount of bone marrow. Alternatively, transfer the bone marrow to a secondary tube and pipet 2.0 ml bone marrow into the PAXgene Bone Marrow RNA Tube.

Note: Use of greater than 2.0 ml will interfere with the stabilization properties of the PAXgene Bone Marrow RNA Tube, leading to reduced RNA yields and degraded RNA. Use of less than 2.0 ml can lead to incorrect analytical results or poor product performance.

Note: The bone marrow sample is subject to RNA degradation and changes in gene expression until the bone marrow is transferred into the PAXgene Bone Marrow RNA Tube. To reduce changes of transcript levels that occur within minutes of aspiration, reduce as much as possible the time between bone marrow aspiration and transfer to the PAXgene Bone Marrow RNA Tube.

- 4. Close the PAXgene Bone Marrow RNA Tube with the original BD Hemogard Closure as stated in Section VIII. To close the tube, replace closure over tube. Next, twist and push down firmly until stopper is fully reseated. Complete reinsertion of the stopper is necessary for the closure to remain securely on the tube and prevent leakage during handling.
- Immediately after bone marrow transfer and recapping, secure closure with thumb while holding tube in one hand, and mix the tube contents vigorously by powerfully inverting the PAXgene Bone Marrow RNA Tube 8–10 times.

Note: For sufficient RNA stabilization, it is important to mix bone marrow and tube solution completely. Some anticoagulants (e.g. lithium heparin) are known to complicate efficient mixing if tubes are only gently inverted.

- 6. Store the PAXgene Bone Marrow RNA Tube upright at room temperature (18–25°C) for a minimum of 2 hours before processing or transferring to refrigerator (2–8°C) or freezer (–20°C). Bone Marrow samples filled in PAXgene Bone Marrow RNA Tubes are stable at room temperature (18–25°C), refrigerated (2–8°C), or frozen (–20°C /–70°C).
 - Stand the PAXgene Bone Marrow RNA Tubes upright in a wire rack. Do not use a polystyrene foam tray as this may cause tubes to crack during freezing.
 - If PAXgene Bone Marrow RNA Tubes are to be stored at temperatures lower than -20°C, freeze them first for 24 hours at -20°C, then transfer them to -70°C.
 - Frozen PAXgene Bone Marrow RNA Tubes are subject to breakage upon impact. To reduce the risk of breakage during transport, frozen tubes should be treated in the same manner as glass tubes. Users must validate their own freezing and shipping protocol for PAXgene Bone Marrow RNA Tubes.

Note: Currently available data shows stabilization of intracellular RNA for 13 months at -20°C. For more information from ongoing studies evaluating stability for longer time periods or at other temperatures, please contact QIAGEN Technical Services (techservice-eu@qiagen.com).

Procedure for Specimen Preparation for Analysis

Bone marrow samples must be processed according to the instructions provided with the PAXgene Bone Marrow RNA Kit (Cat. No. 764133).

IV. Limitations of System

- The PAXgene Bone Marrow RNA System (Tube and RNA Preparation Kit) is for research use only, the use of this product for diagnostic procedures and patient management is strictly prohibited. Neither the clinical utility nor the performance of the PAXgene Bone Marrow RNA Tube and Kit as part of an in vitro diagnostic procedure have been established.
- Bone marrow samples obtained with the PAXgene Bone Marrow RNA Tube should be prepared only with the PAXgene Bone Marrow RNA Kit (Cat. No. 764133).
- Over-filling or under-filling of tubes will result in an incorrect bone marrow-to-additive ratio and may lead to incorrect analytic results or poor product performance.
- Endotoxin not controlled. Bone marrow and bone marrow components collected and processed in the tube are not intended for infusion or introduction into the human body.

V. Warnings and Precautions

- 1. Contents of this tube may cause irritation to eyes, respiratory system and skin.
 - After inhalation, supply fresh air, and seek medical advice in case of complaints.
 - After skin contact, immediately wash with water and soap and rinse thoroughly.
 - After eye contact, rinse immediately with plenty of water for at least 15 minutes and seek medical advice.
 - After swallowing, immediately seek medical advice.
- Practice Universal Precautions. Use gloves, gowns, eye protection, other personal protective equipment, and engineering controls to protect from bone marrow splatter, bone marrow leakage, and potential exposure to blood borne pathogens.
- 3. Handle all biologic samples and bone marrow aspiration devices (e.g., syringes or other collection devices) according to the policies and procedures of your facility. Obtain appropriate medical attention in the event of any exposure to biologic samples (for example, through a puncture injury), since they may transmit viral hepatitis, HIV, or other infectious diseases. Utilize any built-in used-needle protector, if the aspiration device provides one. PreAnalytiX does not recommend re-shielding used needles; however, the policies and procedures of your facility may differ and must always be followed.
- 4. Discard all bone marrow collection tubes and accessories in biohazard containers approved for disposal.
- 5. Do not draw blood using the PAXgene Bone Marrow RNA Tube.
- 6. Do not reuse PAXgene Bone Marrow RNA Tubes.
- 7. Do not transfer a sample from a syringe to a tube through the stopper.
- 8. Excessive centrifugation speed (over 10,000 RCF) may cause PAXgene Bone Marrow RNA Tube breakage, exposure to bone marrow and possible injury.

VI. Storage

Store the unused PAXgene Bone Marrow RNA Tubes at 4-25°C.

VII. Instructions for Removal of BD Hemogard Closure

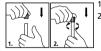


 Grasp the PAXgene Bone Marrow RNA Tube with one hand, placing the thumb under the BD Hemogard Closure (for added stability, place arm on solid

surface). With the other hand, twist the BD Hemogard Closure while simultaneously pushing up with the thumb of the other hand ONLY UNTIL THE TUBE STOPPER IS LOOSENED.

- 2. Move thumb away before lifting closure. DO NOT use thumb to push closure off tube. Caution: If the tube contains blood, an exposure hazard exists. To help prevent injury during closure removal, it is important that the thumb used to push upward on the closure is removed from contact with the tube as soon as the BD Hemogard Closure is loosened.
- Lift closure off tube. In the unlikely event of the plastic shield separating from the rubber stopper, DO NOT REASSEMBLE CLOSURE. Carefully remove rubber stopper from tube.

VIII. Instructions for Reinsertion of BD Hemogard Closure



1. Replace closure over tube.

Twist and push down firmly until stopper is fully reseated. Complete reinsertion of the stopper is necessary for the closure to remain securely on the tube during handling.

IX. Technical Assistance

If you have any questions regarding the PAXgene Bone Marrow RNA System, contact one of the QIAGEN Technical Services Departments listed in the OIAGEN – Customer Service section.

X. Ordering Information

PAXgene Products

PAXgene Bone Marrow RNA Tubes (50) / 764114

Contents: 50 Bone Marrow Collection Tubes.

Use in conjunction with the PAXgene Bone Marrow RNA Kit (30).

PAXgene Bone Marrow RNA Kit (30) / 764133

Content: 30 PAXgene RNA Spin Columns, 30 PAXgene Shredder Spin Columns, Processing Tubes, RNase-free DNase-I, RNase-free Reagents and Buffers.

Use in conjunction with the PAXgene Bone Marrow RNA Tubes (50).

QIAGEN – Customer Service

Australia Orders: 1.800.243.800 Technical: 1.800.243.066 Fax: 03.9840.9888

Austria

Orders: 0800.28.10.10 Technical: 0800.28.10.11 Fax: 0800.28.10.19

Belgium Orders: 0800.79612 Technical: 0800.79556 Fax: 0800.79611

Canada

Orders: 800.572.9613 Technical: 800.DNA.PREP (800.362.7737) Fax: 800.713.5951

China Orders: 86.21.3865.3865 Technical: 800.988.0325 Fax: 86.21.3865.3965

Denmark Orders: 80.885945 Technical: 80.885942 Fax: 80.885944

Finland Orders: 0800.914416 Technical: 0800.914413 Fax: 0800.914415

France Orders: 01.60.920.926 Technical: 01.60.920.930 Fax: 01.60.920.925

Germany Orders: 02103.29.12000 Technical: 02103.29.12400 Fax: 02103.29.22000

Hong Kong Orders: 800.933.965 Technical: 800.930.425 Fax: 800.930.439 Ireland Orders: 1800.555.049 Technical: 1800.555.061 Fax: 1800.555.048

Italy Orders: 800.789.544 Technical: 800.787.980 Fax: 02.334304.826

Japan Orders: 03.6890.7300 Technical: 03.6890.7300 Fax: 03.5547.0818

Korea (South) Orders: 080.000.7146 Technical: 080.000.7145 Fax: 02.2626.5703

Luxembourg Orders: 8002.2076 Technical: 8002.2067 Fax: 8002.2073

Mexico Orders: 01.800.7742.639 Technical: 01.800.7742.436 Fax: 01.800.1122.330

The Netherlands Orders: 0800.0229592 Technical: 0800.0229602 Fax: 0800.0229593

Norway Orders: 800.18859 Technical: 800.18712 Fax: 800.18817

Singapore Orders: 1800.742.4362 Technical: 1800.742.4368 Fax: 65.6854.8184

Spain Orders: 91.630.7050 Technical: 91.630.7050 Fax: 91.630.5145

Sweden

Orders: 020.790282 Technical: 020.798328 Fax: 020.790582

Switzerland

Orders: 055.254.22.11 Technical: 055.254.22.12 Fax: 055.254.22.13

BD - Customer Service

Argentina, Uruguay and Paraguay Orders: 0800.444.5523 E-mail: crc_argentina@bd.com

Australia

Orders: 1.800.656.100 Fax: 1.800.656.110 E-mail: bd anz@bd.com

Austria

Orders: 43.1.706.36.60 Fax: 43.1.706.36.60-11 Email: customerservice.vac.ga@europe.bd.com

Belgium

Orders: 32.53.720.556 Fax: 32.53.720.549 Orders: orders.be@europe.bd.com

Brazil

Orders: 0800.055.56.54 E-mail: consultoria_vacutainer@bd.com

Canada

Orders: 800.268.5430 Fax: 800.565.0897 E-mail: custsvccan@bd.com

Central and Eastern Europe (CEE)

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UK

Orders: 01293.422.911 Technical: 01293.422.999 Fax: 01293.422.922

USA

Orders: 800.426.8157 Technical: 800.DNA.PREP (800.362.7737) Fax: 800.718.2056

Slovakia: info_slovakia@europe.bd.com Slovenia: info_slovenia@europe.bd.com Technical: bd_service_poland@bd.com

Denmark

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Orders: 358.9.88.70.780 Fax: 358.9.88.70.7816 Orders: tilaukset.fi@europe.bd.com Technical: bdsuomi@europe.bd.com

France

Orders: 33.476.68.36.93 Fax: 33.476.68.36.93 Orders: commandesfr@europe.bd.com E-mail: serviceclientbdf@europe.bd.com Technical: vacutainerfr@bd.com

Germany Orders: 49.6221.305.553

Fax: 49.6221.305.379 Email: customerservice.vac.ga@europe.bd.com

Italy

Orders: 39.02.48.240.500 Technical: 39.335.424.388 Fax: 39.02.40.91.80.11 E-mail: ordini.it@europe.bd.com

Middle East & Africa (EMA) Orders: 971.4.3379525 Fax: 971.4.03379551 E-mail: EMA PAS@bd.com The Netherlands Orders: 31.20.582.94.20 Fax: 31.20.582.94.21 Orders: orders.nl@europe.bd.com

New Zealand Orders: 0800.572.468 Fax: 0800.572.469 E-mail: nz_customerservice@bd.com

Norway (Puls Handicare) Orders: 47.23.32.30.00 Fax: 47.23.32.30.99 E-mail: kundeservice@puls-norge.no

Spain, Portugal and Andorra

Orders: 34.91.848.8104 Technical: 34.902.27.17.27 Fax: 34.91.828.81.48 E-mail: info.spain@europe.bd.com

Symbol and Mark Key



Batch Code



Catalog Number



Contains sufficient for <n> tests



Manufacturer



Method of Sterilization Using Irradiation



Temperature Limitation

Recyclable

Use By

Sweden Orders: 46.8.775.51.60 Fax: 46.8.775.51.95 Orders: order.se@europe.bd.com Technical: bdsweden@europe.bd.com

Switzerland

Orders: 41.61.485.22.22 Fax: 41.61.485.22.00 E-mail: infoch@europe.bd.com

UK

Orders: 44.1.865.781.666 Fax: 44.1.865.717.313 E-mail: bduk_customerservice@europe.bd.com

USA

Orders: 888.237.2762 Technical: 800.631.0174 Fax: 800.847.2220 Technical: www.bd.com/vacutainer/contact



H315 – Causes skin irritation. H317 – May cause an allergic skin reaction.



H318 – Causes serious eye damage.



H411 – Toxic to aquatic life with long last effects.

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