



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

Catalog No. 764114

# For Research Use Only

Not for use in diagnostic procedures

To be used only in conjunction with the PAXgene™ Bone Marrow RNA Kit (Cat. No. 764133) for the isolation and purification of intracellular RNA from the PAXgene™ Bone Marrow RNA Tube

#### 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 Plus

764114

BD Hemogard™ • 11.1 mL additive

50 tubes/case

For Research Use Only. Not For Use In Diagnostic Procedures. 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<sup>™</sup> 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<sup>™</sup> Bone Marrow RNA Kit, the PAXgene<sup>™</sup> Bone Marrow RNA Tube provides stabilization and purification of intracellular RNA for accurate detection and quantification of gene transcripts.

#### III. Warnings

- 1. Contents of this tube are irritating to eyes, respiratory system and skin.
  - If inhaled, supply fresh air: consult doctor in case of complaints.
  - If skin contact occurs, immediately wash with water and soap and rinse thoroughly.
  - If eye contact occurs, rinse opened eye for fifteen minutes under running water, then consult a doctor.
  - If swallowed, immediately call a doctor.
- 2. 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 (AIDS), or other infectious diseases. Utilize any built-in needle protector, if the aspiration device provides one. PreAnalytiX does not recommend reshielding used needles, however, the policies and procedures of your facility may differ and must always be followed.
- 3. Discard all bone marrow collection devices in biohazard containers approved for disposal.
- 4. Do not draw blood using the PAXgene™ Bone Marrow RNA Tube.
- 5. Do not reuse PAXgene™ Bone Marrow RNA Tubes.
- 6. Do not transfer a sample from a syringe to a tube through the stopper.

#### IV. Specimen Collection and Preparation for Analysis

- 1. Label PAXgene™ Bone Marrow RNA Tube appropriately with patient identification.
- 2. 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 VIII. 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<sup>™</sup> 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 IX. 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.
- 5. 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 18 25 °C, 2 8 °C, -20 °C, or -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 h 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).

# V. Limitations of System

- The use of the PAXgene<sup>™</sup> Bone Marrow RNA System (Tube and RNA Preparation Kit) is restricted to research use only, and therefore the use of this product for diagnostic procedures and patient management is strictly prohibited. Neither the clinical utility nor the performance of the PAXgene<sup>™</sup> Bone Marrow RNA Tube and Kit as part of an *in vitro* diagnostic procedure have been established.
- 2. 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).
- 3. 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.

#### **VI. Precautions**

- 1. 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 bloodborne pathogens.
- 2. 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 (AIDS), or other infectious diseases. Utilize any built-in needle protector, if the aspiration device provides one. PreAnalytiX does not recommend reshielding used needles. However, the policies and procedures of your facility may differ and must always be followed.
- 3. Discard all bone marrow collection tubes in biohazard containers approved for their disposal.
- 4. Do not re-use PAXgene™ Bone Marrow RNA Tubes.
- 5. Excessive centrifugation speed (over 10,000 RCF) may cause PAXgene™ Bone Marrow RNA Tube breakage, exposure to bone marrow and possible injury.
- 6. Do not transfer a sample from a syringe to a tube through the stopper.
- 7. Do not draw blood using the PAXgene™ Bone Marrow RNA Tube.

# VII. Storage

1. Store the unused PAXgene™ Bone Marrow RNA Tubes at 4 °C to 25 °C.

# VIII. Instructions for Removal of BD Hemogard™ Closure

- 1. 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 first 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 bone marrow, an exposure hazard exists. To help prevent injury during closure removal, it is important that the thumb used to push upward on the closure be removed from contact with the tube as soon as the BD Hemogard™ closure is loosened.
- 3. 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.

# IX. Instructions for Reinsertion of BD Hemogard™ Closure

- 1. Replace closure over tube.
- 2. 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.

The PAXgene™ Bone Marrow RNA Tube is made in the UK by BD for PreAnalytiX GmbH. PAXgene and PreAnalytiX are trademarks of PreAnalytiX Gmbh; BD Hemogard is a trademark of Becton, Dickinson and Company.

U.S. Patent Nos. 4,741,446, 4,991,104, 6,602,718, 6,617,170, and 6,821,789.

#### **ORDERING INFORMATION**

PAXgene™ Products	Contents
PAXgene™ Bone Marrow RNA Tubes (50) 764114	50 Bone Marrow Collection Tubes. Use in conjunction with the PAXgene™ Bone Marrow RNA Kit (30).
PAXgene™ Bone Marrow RNA Kit (30) 764133	30 PAXgene <sup>™</sup> RNA Spin Columns, 30 PAXgene <sup>™</sup> Shredder Spin Columns, Processing Tubes, RNase-free DNase-I, RNase-free Reagents and Buffers. Use in conjunction with the PAXgene <sup>™</sup> Bone Marrow RNA Tubes (50).

# PAXgene™ Bone Marrow RNA Tubes are distributed by QIAGEN for PreAnalytiX

Location	<b>Customer Service</b>	Fax	Technical Service
Australia	03-9840-9800	03-9840-9888	1-800-243-066
Austria	0800/28-10-10	0800/28-10-19	0800/28-10-11
Belgium	0800-79612	0800-79611	0800-79556
Canada	800-572-9613	800-713-5951	800-DNA-PREP (800-362-7737)
China	021-51345678	021-51342500	021-51345678
Denmark	80-885945	80-885944	80-885942
Finland	0800-914416	0800-914415	0800-914413
France	01-60-920-926	01-60-920-925	01-60-920-930
Germany	02103-29-12000	02103-29-22000	02103-29-12400
Hong Kong	800-933-965	800-930-439	800-930-425
Ireland	1800 555 049	1800 555 048	1800 555 061
Italy	02-33430411	02-33430426	800 787980
Japan	03-5547-0811	03-5547-0818	03-5547-0811
Luxembourg	8002-2076	8002-2073	8002-2067
The Netherlands	0800-0229592	0800-0229593	0800-0229602
Norway	800-18859	800-18817	800-18712
South Korea	1544-7145	1544-7146	1544-7145
Sweden	020-790282	020-790582	020-798328
Switzerland	055-254-22-11	055-254-22-13	055-254-22-12
UK	01293-422-911	01293-422-922	01293-422-999
USA	800-426-8157	800-718-2056	800-DNA-PREP (800-362-7737)

For other countries not listed here, please contact your local QIAGEN distributor, see www.PreAnalytiX.com, or call +49-2103-29-16600.

### Symbol & Mark Key

Symbol & Wark Key		0
REF – Catalog number	② – Do not reuse	– Temperature limitation
LOT – Batch code	– Manufacturer	- Consult instructions for use
- Dangerous for environment	∑ – Contains sufficient for <n> tests</n>	STERILE R - Method of sterilization using irradiation
- Irritant	- Recyclable USA	∠ – Use by

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