

Instructions for Use (IFU)

INTENDED USE

RNAgard Blood Tubes are intended for the collection and preservation of cellular RNA in whole blood for up to 14 days at room temperature.

SUMMARY AND PRINCIPLES

RNAgard Blood Tubes are direct-draw blood collection tubes pre-filled with a proprietary reagent that preserves cellular RNA in whole blood until purification and downstream analysis can be completed. High RNA quality and yield with unaltered gene expression are obtained for use in a wide range of downstream molecular diagnostic applications.

REAGENTS

RNAgard Blood Tubes contain 6.65mL of RNA stabilization reagent.

PRECAUTIONS

1. For In Vitro Diagnostics Use.
2. Store RNAgard Blood Tubes away from sunlight.
3. Practice Universal Precautions when handling this product.
4. Avoid skin contact with RNAgard Blood Reagent.
5. Avoid excessive centrifugation speed (over 10,000 RCP) to prevent tube breakage and exposure to blood and possible injury.
6. Do not use RNAgard Blood Tubes for the collection of material intended for injection into patients.
7. Do not use RNAgard Blood Tubes after the expiration date printed on the tube label.

CAUTION

Contents of this tube may cause irritation to eyes, respiratory system and skin.

1. If accidental inhalation occurs, supply fresh air, and seek medical advice in case of complaints.
2. In case of skin contact, immediately wash with water and soap, and rinse thoroughly.
3. In case of eye contact, rinse immediately with plenty of water for at least 15 minutes and seek medical advice.
4. If accidental swallowing occurs, immediately seek medical advice.
5. Refer to SDS in case of accidental ingestion or skin contact. All SDS information is available at http://biomatrica.com/support_sds.php.

STORAGE & STABILITY

Prior to blood collection:

1. Store RNAgard Blood Tubes between 4°C and 25°C until the end of shelf life marked by the expiration date.
2. Avoid direct exposure to sunlight.
3. Equilibrate the RNAgard Blood Tubes to room temperature (18-25°C) for at least 2 hours prior to blood collection.

Post-blood collection:

1. Store at room temperature (18-25°C) for up to 14 days.
2. Store at 2-8°C for up to 1 month.
3. For longer storage periods see Procedure for Freezing & Thawing Specimens.

INDICATIONS OF PRODUCT DETERIORATION

1. Preservative solution becomes yellow.
2. Collection tubes do not maintain vacuum during blood draw.

INSTRUCTIONS FOR USE

A. Procedure for Specimen Collection

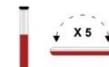
1. Ensure that the RNAgard Blood Tube is equilibrated to room temperature (18°C - 25°C) for at least 2 hours prior to blood collection.
2. RNAgard Blood Tubes should be the last tubes drawn. If the RNAgard Blood Tube is the only tube to be drawn, blood should be drawn into a "Discard Tube" prior to drawing blood into the RNAgard Blood Tube.
3. Collect 2.5mL of blood by venipuncture according to CLSI H3-A6¹ following techniques to prevent possible backflow:

Prevention of Backflow – Since RNAgard Blood Tubes contain a chemical additive, it is important to avoid possible backflow from the tubes, with the possibility of adverse donor reactions. To guard against backflow, observe the following precautions:

- a. Place the subject's arm in a downward position.
 - b. Hold tube in vertical position, below the donor's arm during blood collection.
 - c. Release tourniquet as soon as blood starts to flow into tube.
 - d. Make sure tube additives do not touch stopper or end of the needle during venipuncture.
4. Ensure that the blood has stopped flowing into the tube before

removing the tube from the holder.

5. Immediately after blood draw, gently invert the RNAgard Blood Tube at least five times.



6. Refer to Storage and Stability for storage of RNAgard Blood Tubes following sample collection.

B. Procedure for Freezing and Thawing Specimens Collected in RNAgard Blood Tubes

Freezing

1. Freeze RNAgard Blood Tubes upright in a wire rack. Avoid Styrofoam[®] to prevent tubes from cracking.
2. For storage below -20°C, transfer specimens to cryovials, freeze them first at -20°C for 24 hours and then transfer to -70°C or -80°C.

Thawing

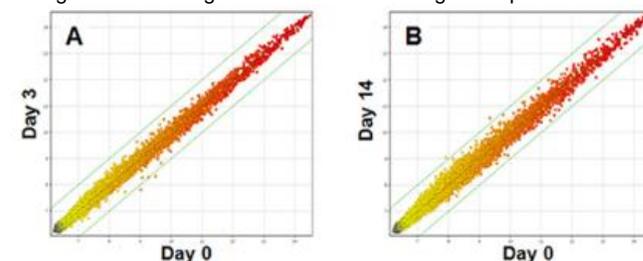
1. Thaw RNAgard Blood Tubes at room temperature (18-25°C) for at least 2 hours. Longer equilibration to room temperature before proceeding to RNA purification result in higher RNA yields.
2. Gently invert the thawed tubes five times.

C. Procedure for Specimen Preparation for Analysis

It is recommended that RNA purification be performed using the RNAgard[®] Blood RNA Purification Kit (Cat. No. CE-12000-001). Other commercially available RNA purification systems are also compatible with the RNAgard Blood Tubes using the RNAgard[®] Blood Precipitation Buffer, sold separately (Cat. No. CE-12180-001). For precipitation and purification procedures, please reference the Resources tab at www.biomatrica.com/RNAgardblood_tube.php.

EXPECTED RESULTS

RNAgard Blood Reagent maintains accurate gene expression levels.



Analysis of gene expression profile of more than 47,000 transcripts, using the Illumina Human HT12 Bead Array after 3 and 14 days at room temperature in RNAgard Blood relative to day 0 reference samples.

LIMITATIONS

1. For single use only.
2. The quantity of blood drawn should be 2.5mL per RNAgard Blood Tube but may vary with altitude, ambient temperature, barometric pressure, tube age, venous pressure, and filling technique.
3. Under-filling will result in an incorrect blood to additive ratio and may lead to incorrect analytical results or poor product performance.
4. Not intended for plasma preparation as blood cells will be lysed.

REFERENCES

1. Clinical and Laboratory Standards Institute, H3-A6, Procedures for the collection of diagnostic blood specimens by venipuncture. Approved Standard - Sixth Edition.

ORDERING INFORMATION

Orders may be placed online at www.biomatrica.com, via email at orders@biomatrica.com, or through Biomatrica Customer Support at 00 1 858 550 0308 (International), or by calling your local supplier.

GLOSSARY OF HARMONIZED SYMBOLS

Authorized Representative in the European Community	Catalog Number	Batch Code	Hazard	Use By	In Vitro Device
Keep away from sunlight	Manufacturer	Consult instructions for use	Temperature Limitation 4°C - 28°C	Do Not Re-use	Contains sufficient reagent for n number of tests

Glossary of symbols may contain symbols not used in the labeling of this product

RNAgard® Blood Tubes Internet IFU Directions

Instructions for use can be obtained via the internet at http://biomatrica.com/rnagardblood_tube.php or by calling the following phone numbers: 00 1 858 550 0308 (International), or by calling your local supplier.

Die Gebrauchsanweisung kann über das Internet unter http://biomatrica.com/rnagardblood_tube.php oder telefonisch unter den Telefonnummern 00 1 858 550 0308 (International) erhalten werden oder telefonisch von Ihrem örtlichen Lieferanten.

Le mode d'emploi est accessible sur Internet http://biomatrica.com/rnagardblood_tube.php ou en appelant 00 1 858 550 0308 (Internationale), ou en appelant votre fournisseur local.

Las instrucciones de uso se pueden conseguir a través de Internet en http://biomatrica.com/rnagardblood_tube.php, o llamando al siguiente número de teléfono 00 1 858 550 0308 (Internacional), o llamando a su proveedor local.

È possibile ricevere le istruzioni per l'uso visitando il sito Web http://biomatrica.com/rnagardblood_tube.php, chiamando il numero di telefono 00 1 858 550 0308 (Internazionale) oppure contattando il proprio fornitore locale.