

Instructions for Use

REF CE-71001-002

INTENDED USE

The LBgard Blood Tube is intended for the collection, stabilization, transport and storage of whole blood samples. This product is FOR EXPORT ONLY, not to be sold in the United States.

SUMMARY AND PRINCIPLES

LBgard Blood Tubes are direct-draw blood collection tubes pre-filled with a proprietary, formaldehyde-free reagent that stabilizes cells and cell-free DNA (cfDNA) in whole blood, preserving biological analytes for downstream applications. LBgard Blood Tubes also prevent the release of cellular components that can interfere with analysis, such as cellular genomic DNA and products from hemolysis.

Samples collected in LBgard Blood Tubes, when stored at 4°C - 37°C, are stabilized for downstream circulating tumor DNA and cell-free DNA applications for up to 14 days. Samples collected in LBgard Blood Tubes, when stored at ambient temperature up to 30°C, are stabilized for downstream nucleated cell (circulating tumor cells and white blood cells) applications for up to 4 days.

REAGENTS

LBgard Blood Tubes contain an anticoagulant and a formaldehyde-free preserving agent in a liquid medium.

PRECAUTIONS

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

CAUTION

1. Blood is considered a biohazard and should be treated in accordance with federal, state, and local regulations. Contents of this tube may cause irritation to eyes, respiratory system and skin. Avoid all contact with skin and mucous membranes.
2. In case of skin contact, immediately wash with soap and water, rinse thoroughly, and seek medical advice.
3. In case of eye contact, rinse immediately with plenty of water for at least 15 minutes and seek medical advice.
4. 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 LBgard 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.

Post-blood collection:

	Sample Type	
	DNA	Nucleated Cells
Analyte	Circulating tumor DNA; Cell-free DNA	White blood cells; Circulating tumor cells
Storage Temperature	4-37°C	Ambient-30°C
Stability	14 days	4 days

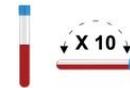
INDICATIONS OF PRODUCT DETERIORATION

1. Turbidity/precipitate visible in reagent prior to blood draw.
2. Collection tubes do not maintain vacuum during blood draw.

INSTRUCTIONS FOR USE

A. Sample Collection

1. LBgard Blood Tubes should be filled in the draw order outlined in CLSI H3-A6¹; after EDTA tubes and before glycolytic inhibitor tubes. If a heparin tube precedes LBgard Blood Tubes in the draw order, it is recommended that a non-additive or EDTA tube be drawn as a waste tube before collection in LBgard Blood Tubes. If an LBgard Blood Tube is the first tube drawn, it is recommended that a waste tube be partially drawn first to eliminate air/dead space from the tubing.
2. Completely fill the LBgard Blood Tubes by venipuncture according to CLSI H3-A6¹. Avoid possible backflow of chemical additives from the tube as follows:
 - 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. Ensure that tube additives do not contact stopper or end of needle during venipuncture.
3. Ensure that the blood has stopped flowing into the tube before removing the tube from the holder.
4. Immediately after blood draw, gently invert the LBgard Blood Tube ten times.



5. Refer to Storage and Stability section for storage of LBgard Blood Tubes following sample collection.

B. Recommended Procedure for cfDNA Extraction

1. To separate plasma, spin whole blood at 1,900 rcf for 10 minutes.
2. Transfer the top plasma layer to an empty conical tube (not provided), carefully avoiding the buffy coat and red blood cell layers.
3. Spin the extracted plasma at 4,500 rcf for 15 minutes.
4. Transfer the plasma to an empty conical tube, avoiding any remaining pelleted cells. Repeat steps 3 and 4 if desired.
5. Isolate cfDNA from plasma per extraction kit manufacturer instructions.

LIMITATIONS

1. For single use only.
2. The volume of blood drawn should be 8.5mL per LBgard Blood Tube but may vary with altitude, temperature, barometric pressure, tube age, venous pressure, and filling technique.
3. Under-filling will result in an incorrect blood to preserving agent ratio and may lead to incorrect analytical results or poor product performance

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.

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 to 25°C)	Do Not Re-use	Sterile

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

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LBgard® Blood Tubes Internet IFU Directions

Instructions for use can be obtained via the internet at <http://biomatrica.com/lbgard-blood.php>, by calling the following phone number: 00 1 858 550 0308, or by calling your local supplier.

Gebrauchsanweisung kann über das Internet unter <http://biomatrica.com/lbgard-blood.php>, telefonisch unter der Telefonnummer: 00 1 858 550 0308, oder von Ihrem Lieferanten anrufen.

Mode d'emploi peuvent être obtenues via Internet à <http://biomatrica.com/lbgard-blood.php>, en appelant le numéro suivant de telephone: 00 1 858 550 0308, ou en appelant votre fournisseur local.

Instrucciones de uso se pueden obtener a través de Internet en <http://biomatrica.com/lbgard-blood.php>, llamando al siguiente número de teléfono: 00 1 858 550 0308, o llamando a su proveedor local.

Istruzioni per l'uso possono essere ottenuti via internet al <http://biomatrica.com/lbgard-blood.php>, chiamando il seguente numero di telefono: 00 1 858 550 0308, o chiamando il fornitore locale.