

LBgard™ Blood Tubes - Instructions for Use

INTENDED USE

The LBgard Blood Tube is intended for the collection and storage of whole blood samples. **This product is for Research Use Only and has not been cleared by the U.S. Food and Drug Administration for In Vitro Diagnostic use. This product is NOT intended for use in diagnostic procedures.**

SUMMARY AND PRINCIPLES

The 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 DNA applications (for example, circulating tumor DNA characterization and Noninvasive Prenatal Testing, NIPT) for up to 14 days. Samples collected in LBgard Blood Tubes, when stored at ambient temperature to 30°C, are stabilized for downstream circulating tumor cell applications (cell recovery and protein characterization) 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 Research Use Only. Not for use in diagnostic procedures.
2. Do not use tubes after expiration date.
3. Do not freeze samples collected in tubes.
4. Avoid skin contact with LBgard preserving reagent.
5. Avoid excessive centrifugation speed (>4000 x g) to prevent tube breakage, exposure to blood and possible injury.
6. Do not use tubes for the collection of materials intended for injection into patients.
7. Overfilling/underfilling will result in an incorrect blood-to-preserving reagent ratio and may affect analytical results/product performance.

CAUTION

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

1. Blood is considered a biohazard and should be treated in accordance with federal, state, and local regulations. Avoid all contact with skin and mucous membranes.
2. Refer to SDS in case of accidental ingestion or skin/mucous membrane contact. All SDS information is available at www.biomatrica.com.

STORAGE & STABILITY

Before 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.

After blood collection:

	Sample Type	
	DNA	Nucleated Cells
Analyte	Circulating tumor DNA; Cell-free DNA	White blood cells; Circulating tumor cells
Stability	14 days	4 days
Storage Temperature	4-37°C	18-30°C

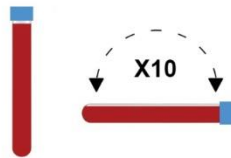
INDICATIONS OF PRODUCT DETERIORATION

1. Turbidity/precipitate visible in reagent prior to blood draw.
2. Contact Biomatrica at 1-866-379-6879 if signs of product deterioration occur.

INSTRUCTIONS FOR USE

A. Procedure for Specimen Collection

1. Collect blood by venipuncture according to CLSI H3-A6¹. Follow recommendation for order of draw outlined in CLSI H3-A6¹. LBgard Blood Tubes should be drawn 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 Collection 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. Because LBgard Blood Tubes contain a chemical preservative, it is important to avoid possible backflow. To prevent backflow during blood collection: (a) place the patient's arm in a downward position; (b) hold tube in vertical orientation below donor's arm; (c) release tourniquet as soon as blood begins to collect in tube; (d) ensure that tube reagent does not touch stopper or end of needle.
3. Fill tubes completely.
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 LBgard Blood Tube ten times.



6. Refer to Storage & Stability section for recommended temperature ranges post-draw.

B. Recommended Procedure for cfDNA Extraction

1. To separate plasma, spin whole blood at 1900 x g 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 4500 x g for 15 minutes.
4. Transfer the plasma to an empty conical tube, avoiding any remaining pelleted cells. Repeat steps 3 and 4 an additional time if desired.
5. Isolate cfDNA from plasma per kit manufacturer instructions.

NOTES

1. Because the volume of LBgard preserving reagent is small, no dilution factor correction is necessary for blood samples.
2. For single use only.
3. Underfilling (drawing less than 4 mL of blood into LBgard Blood Tubes) results in an incorrect blood-to-preserving reagent ratio and may affect analytical results/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, via phone at 1-866-379-6879, or via fax at 1-858-678-0597.

GLOSSARY OF HARMONIZED SYMBOLS

REF Catalog Number	LOT Batch code	Hazard	Use By	STERILE R Sterile
Keep Away From Sunlight	Manufacturer	Consult Instructions For Use	4°C - 25°C Temperature Limitation	Do Not Re-Use

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