

LBgard Blood Tubes

INSTRUCTIONS FOR USE

REF 100373

INTENDED USE

LBgard Blood Tubes are intended for the collection, stabilization, transport, and storage of whole blood samples.

For Research Use Only. Not for Use in Diagnostic Procedures.

SUMMARY AND PRINCIPLES

LBgard Blood Tubes are sterile, plastic direct-draw blood collection tubes pre-filled with a proprietary reagent that stabilizes whole blood and prevents the release of contaminating cellular genomic DNA, supporting downstream applications using cell-free DNA (cfDNA).

Samples collected in LBgard Blood Tubes are stable for 7 days when stored or shipped between 4°C and 25°C, with transient excursions of 37°C for up to 24 hours. The performance of LBgard Blood Tubes to stabilize whole blood samples remains consistent over the shelf life of the tube.

REAGENTS

LBgard Blood Tubes contain an anticoagulant and a proprietary preservative agent in a liquid medium.

WARNINGS

1. For research use only. Not for use in diagnostic procedures.
2. Store LBgard Blood Tubes away from sunlight.
3. Practice Universal Precautions when handling this product.
4. Avoid skin contact with the LBgard Blood Tube 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.

PRECAUTIONS

1. Blood is considered a biohazard and should be treated in accordance with federal, state, and local regulations.
2. The LBgard Blood Tube reagent may cause irritation to eyes, respiratory system and skin. Avoid all contact with skin and mucous membranes.
3. In case of skin contact, immediately wash with soap and water, rinse thoroughly, and seek medical attention.
4. In case of eye contact, rinse immediately with plenty of water for at least 15 minutes and seek medical attention.
5. Refer to the SDS in case of accidental ingestion or skin contact. All SDS information is available at www.ExactSciences.com/LBgardTubes.

STORAGE AND STABILITY

Prior to blood collection:

1. LBgard Blood Tubes are stable through their expiration date when stored between 4°C and 25°C.
2. Avoid direct exposure to sunlight.

Post-blood collection:

Whole blood samples collected in LBgard Blood Tubes are stable for 7 days when stored or shipped between 4°C and 25°C, with transient excursions of 37°C for up to 24 hours. The performance of LBgard Blood Tubes to stabilize whole blood samples remains consistent over the shelf life of the tube.

	SAMPLE TYPE
Analyte	Cell-free DNA
Storage Temperature	4 - 25°C with transient excursions of 37°C for up to 24 hours
Stability	7 days

INDICATIONS OF PRODUCT DETERIORATION

1. Turbidity/precipitate visible in the blood reagent prior to blood draw.
2. LBgard Blood Tubes do not maintain vacuum during blood draw.

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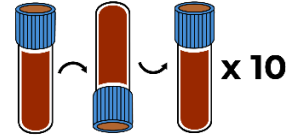
A. Sample Collection

1. LBgard Blood Tubes should be filled in the draw order outlined in CLSIGP41, 7th ed¹. 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 GP41, 7th ed.1. Avoid possible backflow of chemical additives from the tube as follows:

- a. Place the subject's arm in a downward position.
- b. Hold the tube in a vertical position with the stopper uppermost, below the donor's arm during blood collection.
- c. Release the tourniquet as soon as blood starts to flow into the tube.
- d. Ensure that the blood tube reagent does not contact the stopper or the non-patient end of the needle during venipuncture.

3. Continue blood collection until the vacuum is exhausted and blood has stopped flowing into the tube before removing the tube from the holder. The black draw line on the LBgard Blood Tube label represents an 8.5 mL blood draw volume.
4. Immediately after the blood draw, gently invert the LBgard Blood Tube ten times to ensure adequate mixing of the blood and the reagent. One complete inversion is defined as turning the filled tube upside-down, then returning it to an upright position.



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

A. Recommended Procedure for Cell Free DNA 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 cell-free DNA from the 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-reagent ratio and may lead to incorrect analytical results or poor product performance.

REFERENCES

1. Clinical and Laboratory Standards Institute, GP41 Collection of Diagnostic Venous Blood Specimens, Seventh Edition.

ADDITIONAL INFORMATION

Technical support is available via email at techsupport@biomatrica.com.

Glossary of Symbols

REF Catalog Number	LOT Batch Number	Hazard	Use By	STERILE R Sterile
Do Not Re-use	Manufacturer	Consult Instructions for use	IVD In Vitro Device	4°C - 25°C Temperature Limitation
Keep Away from Sunlight		EC REP Authorized Representative in the European Community		Glossary of symbols may contain symbols not used in the labeling of this product

Trademarks

LBgard is a trademark of Biomatrix a wholly owned subsidiary of Exact Sciences Corporation. Exact Sciences is a trademark of Exact Sciences Corporation. All other trademarks are the properties of their respective owners.

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