

# Exact Sciences LBgard® Blood Tubes

## INSTRUCTIONS FOR USE

REF 100426

### INTENDED USE

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

### REAGENTS

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

### WARNINGS

1. For Investigational Use Only. The performance characteristics of this product have not been established.
2. For IVD Performance Evaluation Only.
3. Store LBgard Blood Tubes away from sunlight.
4. Practice Universal Precautions when handling this product.
5. Avoid skin contact with the LBgard Blood Tube reagent.
6. Do not use LBgard Blood Tubes for the collection of materials intended for injection into patients.

### 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. Underfilling will result in an incorrect blood-to-reagent ratio and may lead to poor product performance or incorrect analytical results.

### STORAGE AND STABILITY

#### Prior to blood collection:

1. LBgard Blood Tubes should be stored between 4°C and 25°C.
2. Avoid direct exposure to sunlight.

#### Post-blood collection:

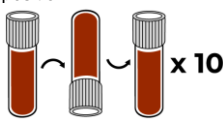
1. Whole blood specimen storage and stability:

	Cell free DNA	Genomic DNA	Circulating Tumor Cells	White Blood Cells
<b>Stability</b>	7 days	7 days	4 days	4 days
<b>Storage</b>	18 to 25°C	4 to 25°C	18 to 25°C	18 to 25°C

### INSTRUCTIONS FOR USE

#### A. Sample Collection

1. LBgard Blood Tubes should be filled in the draw order outlined in CLSI GP41, 7th Edition<sup>1</sup>, 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 a winged blood collection set is used for venipuncture and 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.
  - Place the subject's arm in a downward position.
  - During blood collection, hold the tube below the donor's arm in a vertical position with the cap in the uppermost position.
  - Release the tourniquet as soon as blood starts to flow into the tube.
  - Ensure the blood tube reagent does not contact the cap or the end of the needle during venipuncture.
2. Completely fill the LBgard Blood Tubes by venipuncture according to CLSI GP41, 7th Edition. Avoid possible backflow of chemical additives from the tube as follows:
  - 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.



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

**NOTE: Specimens may be processed per assay instructions, independently validated laboratory protocols, or per the procedures below, which are recommended to maximize plasma yield (see Table 1).**

LBL-10598 Rev. 3

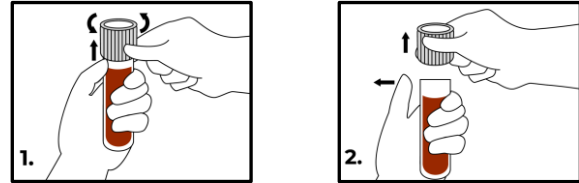
### B. Recommended Procedure for Cell Free DNA (cfDNA) Extraction

1. To separate plasma, spin whole blood at 1,900 RCF for 25 minutes at room temperature.
2. Transfer the top plasma layer to a new 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.
5. Isolate cell-free DNA from the plasma per extraction kit manufacturer's instructions.

### C. Recommended Procedure for Genomic DNA (gDNA) Extraction

1. Spin whole blood at 1,900 RCF for 25 minutes at room temperature.
2. Remove the top plasma layer.
3. Remove the buffy coat layer and transfer to a new conical tube (not provided).
4. Isolate gDNA from the buffy coat per extraction kit manufacturer's instructions.

### REMOVAL OF LBGARD BLOOD TUBE CAP



1. Grasp the tube with one hand while also placing the thumb of that hand under the cap. With the opposite hand, twist the cap while simultaneously pushing up on the cap with the thumb of the other hand.
2. Once the cap disengages, move thumb away from the tube and then remove the cap.

### PRELIMINARY STUDY RESULTS

**Table 1. Impact of centrifugation parameters on plasma yield.**

Condition	Mean Plasma Volume (mL, per tube)
1,900 RCF for 10 min with brake	3.8
1,900 RCF for 10 min without brake	4.2
1,900 RCF for 25 min with brake	4.7
1,900 RCF for 25 min without brake	4.7

### LIMITATIONS

1. For single use only.
2. The volume of blood drawn per LBgard Blood Tube should be 8.5 mL, but this may vary with altitude, temperature, barometric pressure, tube age, venous pressure, and filling technique.

### REFERENCES

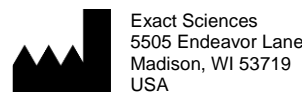
1. Clinical and Laboratory Standards Institute, GP41 Collection of Diagnostic Venous Blood Specimens, Seventh Edition.

### GLOSSARY OF SYMBOLS

Manufacturer	Date of Manufacture	REF	Part Number
Consult Instructions for Use	LOT	Batch Number	Temperature Limitation
STERILE R	Sterile	Keep Away From Sunlight	Do Not Reuse
For IVD Performance Evaluation Only			
Glossary of symbols may contain symbols not used in the labeling of this product.			

### Trademarks

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