

Instruction for Use

BLP-DNA

Bacteria Like Particles

For general laboratory use.

For *in vitro* use only.

REF

G07013-96

G07013-960



96

960



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1 Intended Use

Bacteria-Like Particles DNA (BLP-DNA) are for extraction control purposes of bacterial DNA and intended to help laboratories to control the quality of nucleic acid extraction from e.g. clinical samples by spiking the BLP-DNA into the sample before starting the respective extraction protocol. BLP-DNA is intended to be used as patient-side extraction control in combination with gerbion real time PCR kits. After amplification extracted DNA is identified in the VIC/JOE/HEX channel or 498-580 detection channel of the Roche LightCycler 480 II, respectively. The Control DNA of the respective kits can be substituted by BLP-DNA.

The BLP-DNA can also be used to support laboratory staff training in molecular assays from extraction phase through amplification to detection.

2 Principles of BLP-DNA

The BLP-DNA are suitable for use with the majority of commercial nucleic acid extraction kits. They can also be used to support the training and monitoring of new operators in line with laboratories quality management requirements.

The target concentration of BLP-DNA have been assigned to cover the dynamic range of the Internal Control System of gerbion real time PCR kits and are consistent within each lot and across batches.

The Internal Control Systems of gerbion real time PCR kits are designed to detect inhibitors or insufficient extraction of nucleic acids in the respective sample.

IMPORTANT NOTE: The BLP-DNA have no assigned values. The gerbion reference assays, used for the qualification of the BLP-DNA generate values between Ct 28 and Ct 32. The actual BLP-DNA Ct values may vary from those reported and are dependent on the real time PCR machine and the nucleic acid extraction used.

It is the responsibility of the end user to establish their own target results for BLP-DNA using their laboratory's nucleic acid extraction system and real time PCR equipment.

3 Package Contents

BLP-DNA is designed for 96 or 960 reactions respectively.

Table 1: Components of BLP-DNA.

Label	Content	
	96	960
BLP-DNA	2 x 240 µl	4 x 1200 µl

4 Equipment and Reagents to be Supplied by User

- DNA isolation kit (e.g. **NukEx Pure** RNA/DNA, gerbion Cat. No. G05004) or **NukEx** Nucleic Acid Release Reagent (gerbion Cat. No. G01013)
- Sterile microtubes
- Pipets (adjustable volume)
- Sterile pipet tips with filter
- Table centrifuge
- Vortexer
- Real time PCR instrument
- Optical PCR reaction tubes with lid
- Optional: Liquid handling system for automation

5 Transport, Storage and Stability

BLP-DNA is shipped on dry ice. All components must be stored at -18°C in the dark immediately after receipt. Do not use reagents after the date of expiry printed on the package.

For convenience, opened reagents can be stored at +2-8°C for up to 6 months. Protect kit components from direct sunlight during the complete test run.

6 General Information

6.1 Important Notes

- The BLP-DNA must be utilised by qualified personnel only.
- Good Laboratory Practice (GLP) has to be applied.
- BLP-DNA must always be regarded as potentially infectious material and all equipment used has to be treated as potentially contaminated.

6.2 Precautions

- Do not let reagents touch your skin, eyes, or mucous membranes. If contact does occur, wash the affected area immediately with large amounts of water; otherwise, the reagent may cause burns. If you spill the reagent, dilute the spill with water before wiping it up.
- Never store or use reagents near human or animal food.
- Always wear gloves and follow standard safety precautions when handling these reagents.

6.3 Handling Requirements

- Exercise the normal precautions required for handling all laboratory reagents.
- Do not pool reagents from different lots or from different bottles of the same lot. Immediately after usage, close all bottles in order to avoid leakage, varying buffer concentrations or buffer conditions. After first opening store all bottles in an upright position.
- Do not use BLP-DNA after its expiration date.
- Use only calibrated pipettes.

6.4 Laboratory Procedures

- All sourced material and all resulting waste should be considered potentially infectious. Thoroughly clean and disinfect all work surfaces with disinfectants recommended by the local authorities.
- Do not eat, drink or smoke in the laboratory work area.
- Do not pipette by mouth.
- Wear protective disposable gloves, laboratory coats and eye protection when handling specimens and kit reagents.
- Avoid microbial and nuclease contamination of reagents when removing aliquots from reagent bottles.
- The use of sterile disposable pipettes is recommended.
- Wash hands thoroughly after handling samples and test reagents.

6.5 Waste Handling

- Dispose of unused reagents and waste should occur in accordance with country, federal state and local regulations.
- Material Safety Data Sheets (MSDS) are available upon request from gerbion.

7 Procedure

The BLP-DNA must be thawed at room temperature.










Vortex briefly and spin down at 12,000 RPM for a few seconds before opening the sample tube.

The BLP-DNA must then be treated in the same manner to that required by the laboratory for routine specimens.

Add 5 µl of BLP-DNA to the respective amount of a clinical specimen used for DNA extraction, mix vigorously and perform nucleic acid extraction according to the manufacturer´s instructions.

For technical queries please contact info@gerbion.com

8 Abbreviations and Symbols

DNA	Desoxy Ribonucleic Acid		Catalog number
PCR	Polymerase Chain Reaction		Contains sufficient for <n> test
	BLP-DNA		Upper limit of temperature
			Manufacturer
			Use by YYYY-MM-DD
			Batch code
			Content
			Consult instructions for use