

Instruction for Use

VLP-RNA

Virus-Like-Particles RNA

For general laboratory use.

For *in vitro* use only.

REF

G07008-96



96



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1 Intended Use

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

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

2 Principles of VLP-RNA

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

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

IMPORTANT NOTE: The VLP-RNA have no assigned values. The gerbion reference assays, used for the qualification of the VLP-RNA generate values between Ct 28 and Ct 32. The actual VLP-RNA 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 VLP-RNA using their laboratory's nucleic acid extraction system and real time PCR equipment.

3 Package Contents

VLP-RNA is designed for 96 reactions.

Table 1: Components of VLP-RNA.

Label	Cat. No.	Content
VLP-RNA	G07008	2 x 240 µl

4 Equipment and Reagents to be Supplied by User

- RNA 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

VLP-RNA 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 VLP-RNA must be utilised by qualified personnel only.
- Good Laboratory Practice (GLP) has to be applied.
- VLP-RNA 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 VLP-RNA 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 VLP-RNA 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 VLP-RNA must then be treated in the same manner to that required by the laboratory for routine specimens.

Add 5 µl of VLP-RNA to the respective amount of a clinical specimen used for RNA 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

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