NeoVac

LNP 2.0 platform for RNA Technology

INSTRUCTIONS FOR USE (IFU)
LipTx™ FORMULATION KIT

Document No.: IFU-NVFK Revision: 1.0 Effective Date: JUL/2026

1 Introduction

Before unpacking and using these products, all users must read this document in its entirety and follow applicable laboratory safety procedures. This instruction contains information that is important for the safe handling, unpacking, storage, and preparation of the LipTx™ Formulation Kit.

Typical application:

- In vitro RNA such as messenger RNA (mRNA), self-amplified RNA (saRNA), circular RNA (circRNA) and small interfering RNA (siRNA) delivery studies
- In vivo RNA delivery studies
- mRNA, saRNA, circRNA and siRNA delivery
- CRISPR/Cas gene editing applications
- Formulation optimization and lipid screening studies

1.1 Description

The LipTx™ Formulation Kit is a research-use-only product designed for the preparation and evaluation of lipid nanoparticle (LNP) formulations for RNA delivery applications.

The kit contains a pre-optimized lipid formulation system comprising an ionizable lipid, helper lipid, stabilizer, and cholesterol for the formulation of messenger RNA (mRNA), self-amplified RNA (saRNA), circular RNA (circRNA), small interfering RNA (siRNA), micro-RNA (miRNA), guide RNA (gRNA) and other nucleic acid payloads.

1.2 Safety information

Refer to the applicable Material Safety Data Sheet (MSDS) supplied with the product. Appropriate laboratory personal protective equipment (PPE) should be worn at all times.

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2 Product Specification

Product	Volume	Concentration
LipTx™ Formulation Kit	2 mL	25 mM
LipTx™ Formulation Kit	5 mL	25 mM
LipTx™ Formulation Kit	10 mL	25 mM

2.1 Kit composition

Components: **LipTx™ Ionizable lipid**, Helper lipid, Cholesterol and PEG-lipid.

2.2 Shelf life and Storage

12 months when stored at –80°C in a properly closed container and handled according to the instructions. Avoid repeated freeze-thaw cycles.

3 Material Required But Not Provided

3.1 List of equipment

- Microfluidic mixing device
- Heating block or oven capable of heating to 50°C
- Oven, capable of heating to 37°C
- UV spectrometer
- Vortex mixer
- Fluorescent plate reader for RiboGreen assay

3.2 List of consumables

- mRNA of interest
- Formulation buffer - 50mM Citrate buffer pH 4.5
- 10mM Tris (tris(hydroxymethyl)aminomethane) buffer pH 7.4

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- Refrigerated centrifuge and swing bucket
- Bead bath or heat block for thawing kit components
- Conical centrifuge tubes: 15 and 50 mL
- 0.5 to 2 mL RNase free Eppendorf tubes
- Disposable syringe: 1, 3, 5, or 10 mL
- Micropipettes and RNase free pipette tips: 10, 20, 200 and 1000 µL
- Blunt needles
- Syringe filters: 13 mm, 0.2 µm, polyethersulfone (PES)
- Amicon 30 kDa molecular weight cut off (MWCO) centrifugal filters, 15 mL or
- 3 mL dialysis tubes with 8-14 kDa cut off filters
- Molecular grade water (RNase/DNase and endotoxin-free)
- 70% isopropanol or ethanol
- RNase decontamination solution
- RiboGreen Assay materials:
    - Quant-iT RiboGreen Assay Kit
    - Triton X-100
    - 96-well black bottom plates
    - 1X phosphate buffered saline (PBS), without calcium and magnesium

4 Reagent Preparation

4.1 Reconstitution procedure (RNA Cargo Preparation)

Retrieve the RNA aliquot and thaw on ice. Determine RNA concentration using UV spectrophotometry and prepare 1 mg/mL stock solution by adding nuclease free water.

4.2 Preparation of aqueous phase

- Take the required amount of mRNA from 1 mg/mL stock solution and add remaining amount (please see below table) of 50 mM citrate buffer pH4.5 made with RNAse free water
- Mix gently by pipetting.
- Keep the prepared mRNA solution in pH 4.5 citrate buffer on ice until formulation.

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4.3 Preparation of organic phase

Thaw the lipid mix at RT for 5 minutes then place in a bead bath or heat block at 50˚C. After thawing, keep the lipid mix at room temperature in the biological safety cabinet until use. Keep the vial closed to prevent evaporation. Vortex the lipid mix tube to ensure homogeneity.

5 Formulation Protocol

For a 2 mL LNP preparation, transfer 500 µL of the lipid mixture into a 1 mL syringe and 1.5 mL of mRNA in citrate buffer (pH 4.5) into a 3 mL syringe. Connect both syringes to the microfluidic mixing device and inject the solutions at a total flow rate e.g. of 12 mL/min. Dialyze the resultant LNPs against 10 mM Tris buffer (pH 7.4). Replace the dialysis buffer every 12 hours and repeat the buffer exchange twice.

Table for the calculations:

Total LNP volume (mL)	Lipid Mix (mL)	mRNA amount (mL)	Volume of citrate buffer (mL)
1.2	0.3	0.17	0.75
2.0	0.5	0.27	1.25
6.0	1.5	0.80	4.50

5.1 Mixing parameters

Total flow rate: 12 mL/min

Ratio: 3:1 (Citrate buffer: ethanol)

Start waste: 0.1 mL

End waste: 0.1 mL

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Recommended starting conditions for formulation development.

Parameter	Recommended Value
Total Lipid Concentration	25 mM
Lipid to RNA Ratio	Recommended 6:1 (can be varied based on customer requirement)
Flow Rate Ratio	3:1 (Citrate buffer: ethanol)
Buffer	10 mM Tris pH 7.4

5.2 Critical steps / Recommendations

- Ensure all lipids are completely dissolved in ethanol to obtain a clear, homogeneous solution.
- Filter the lipid solution through a 0.22 µm PTFE filter before use.
- Ensure the mRNA is fully dissolved and free of particulates and keep the mRNA solution on ice until use.
- Prepare the lipid and aqueous phases at the required concentrations to achieve the desired final formulation.
- Use the validated flow rate ratio (FRR) and total flow rate (TFR).
- Complete the buffer exchange according to the mentioned procedure

6 Troubleshooting Guide

6.1 Documentation

- Certificate of Analysis (CoA)
- Material Safety Data Sheet (MSDS)
- Product Data Sheet (PDS).

6.2 Legal and Ordering information

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This product is supplied for research and development use only. NOT FOR CLINICAL USE.

6.3 Disclaimer

NeoVac products are supplied For Research Use Only (RUO) and are not intended for use in humans or animals for therapeutic, diagnostic, or clinical purposes.

These products are intended solely for laboratory research by qualified personnel using appropriate laboratory practices and in accordance with the applicable Instructions for Use (IFU), Material Safety Data Sheet (MSDS), and all relevant product documentation. Users are solely responsible for determining the suitability of the product for their intended research application and for ensuring compliance with all applicable laws, regulations, and institutional requirements.

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6.4 Contact and Technical support

info@neovac.co.uk