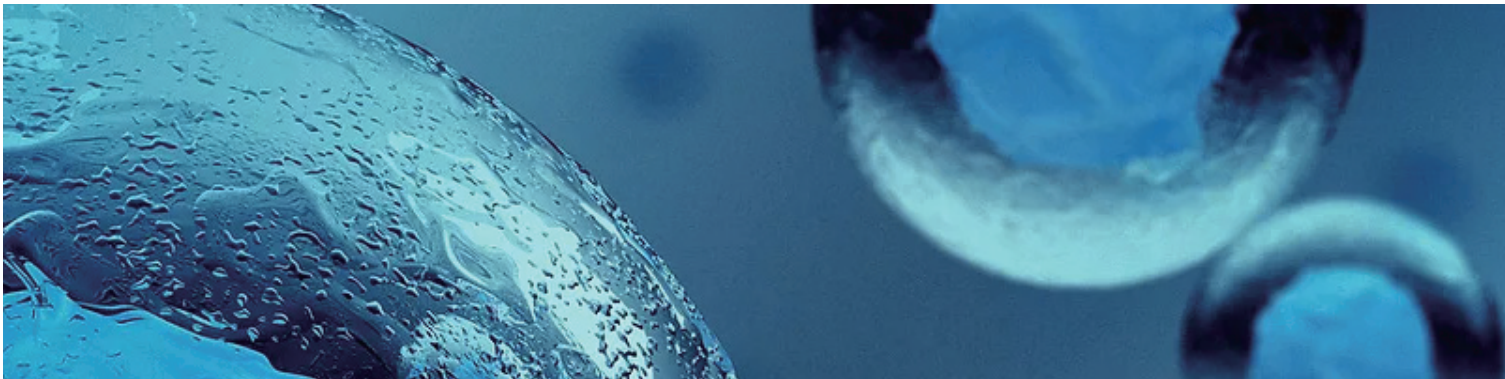


## ADVANCED mRNA-LNP PLATFORM

# Power of IVT-produced highly stable mRNA + microfluidics LNP encapsulation

### Leveraging High-Efficiency Encapsulation for mRNA Delivery

uBriGene's unique mRNA/LNP platform combines the power of proprietary high-efficiency mRNA IVT with the advanced microfluidic technology. The resulted mRNA is encapsulated in lipid nanoparticles (LNPs) at high yield and purity. Our innovative processes result in superior encapsulation efficiency that consistently exceeds 90%.



### Precision and Purity in mRNA Synthesis

uBriGene's proprietary IVT technology sets new standards in the synthesis of mRNA:

- Optimized IVT processes for high mRNA:DNA mass ratio of 200:1
- mRNA concentrations up to 10  $\mu\text{g}/\mu\text{L}$
- Rigorous purification to achieve highly pure final product purity.
- Ensures seamless transition from development to commercial scale production.

The mRNA-LNP we produce has the following characteristics:



Good batch consistency



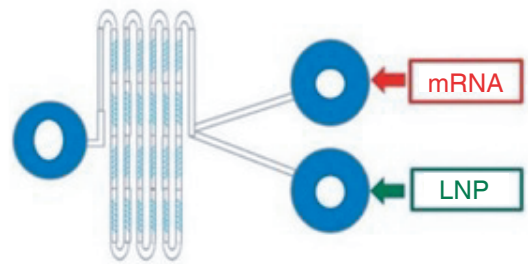
Controllable particle size (within 50-200nm)



Packaging efficiency above 80%



Can provide mg-g level mRNA products



Microfluidics mRNA-LNP packaging

## Harnessing Microfluidics for Enhanced mRNA-LNP Formulation

### LEVERAGING CUTTING-EDGE MICROFLUIDIC TECHNOLOGY TO OVERCOME THE CORE CHALLENGES OF mRNA THERAPY DEVELOPMENT

#### *High Yield, Purity, and Encapsulation Rate*

uBriGene's microfluidic technology addresses these obstacles while providing tailored solutions for each challenge:

- **Stabilized mRNA:** Our LNPs encapsulate and shield mRNA from nuclease activity.
- **Targeted Delivery Systems:** LNPs are designed to deliver mRNA payloads directly into the cytoplasm to enhance the translational process.
- **Endosomal Release:** We engineer LNPs to facilitate efficient endosomal escape which is critical for mRNA functionality.
- **Reduced Immunogenicity:** Our mRNA constructs are optimized for reduced immunogenicity



These advantages culminate in a robust mRNA-LNP platform capable of delivering therapeutic molecules precisely and efficiently to target cells.

#### Benefits of microfluidics based LNP manufacturing.

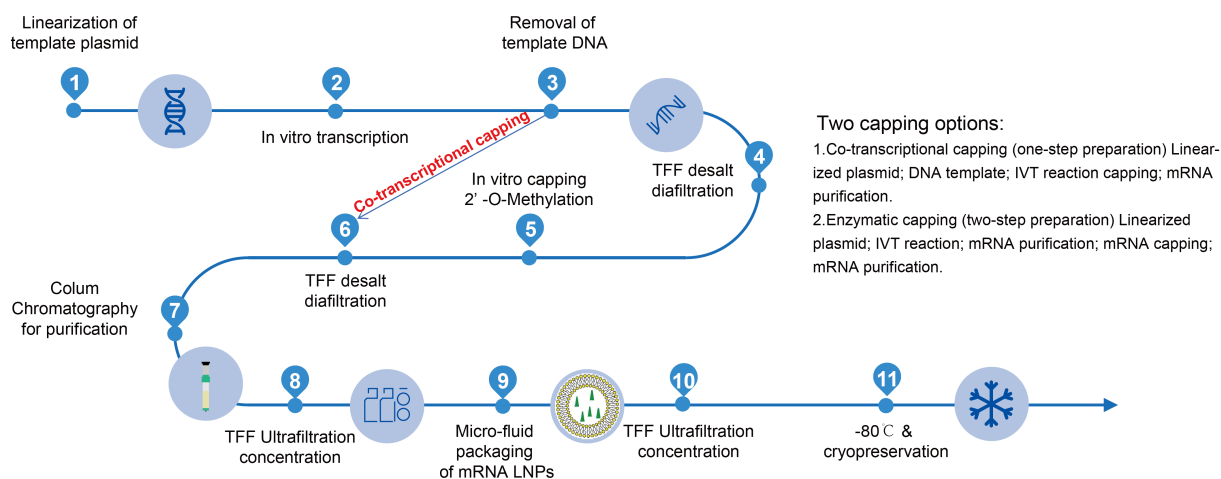
1. Fully enclosed encapsulation
2. Robust and consistent mRNA-LNP production
3. High encapsulation ratio (>90%)

# Your Pathway to Excellence in mRNA

uBriGene's streamlined process for mRNA synthesis and LNP encapsulation is at the forefront of mRNA therapeutic development. Our process (Figure 1) ensures that each phase is optimized for efficiency and effectiveness:

- **DNA Template for mRNA IVT Optimization:** To ensure high yield and stable mRNA, we screened and selected the optimal promoter, transcription initiation sequence, 5' UTR, 3' UTR, polyA (100-120 bp)
- **In Vitro Transcription (IVT):** Our IVT process leverages proprietary enzymes and optimal conditions to produce mRNA with high fidelity.
- **mRNA Purification:** Post-synthesis, mRNA is refined to eliminate impurities and unincorporated components using advanced techniques.
- **LNP Formulation:** Using sophisticated microfluidic technology, purified mRNA is encapsulated into LNPs, allowing precise control over their size, composition, and morphology.
- **Encapsulation Efficiency:** Our encapsulation process is finely tuned to maximize efficiency.
- **LNP Characterization:** Each LNP batch is rigorously tested to ensure size uniformity and encapsulation efficiency.

Figure 1. mRNA synthesis and LNP encapsulation process flow



LNPs = Lipid Nano-particles

# Leading with Innovation, Excelling in Quality

## RIGOROUS QUALITY CONTROL: THE uBriGene STANDARD

uBriGene presents a rigorous, data-driven quality control paradigm. Our QC matrix, reflecting encapsulation efficiency and nucleic acid integrity, aligns with stringent regulatory requirements. These metrics are not only markers of fidelity but also indicators of our commitment to reproducibility and scalability in mRNA therapeutic production.

	QC item	QC method
Quantity	mRNA purity	OD260/OD280
Identification	Capping efficiency	CE
	Length of Poly(A) tail	CE
Purity	Incomplete RNA test	HPLC
	dsDNA	ELISA
	RNA polymerase residual test	ELISA
	DNA template residual test	Fluorescence stain method
	T7-RNA polymerase residual test	ELISA
	DNase 1 residual test	ELISA
	RNase Inhibitor Residue test	ELISA
Safety	Sterility test	Direct culture method
	Bacteria endotoxin	Gel-clot method



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