

One-stop solution for mRNA

Synthgene Biotech focuses on mRNA vaccine/drug raw materials, strictly adhering to GMP quality management system. It provides core raw materials for mRNA in vitro synthesis, including cap analogs, modified nucleotides, and NTPs, and also offers custom-synthesized raw materials.

Synthgene Biotech possesses a comprehensive mRNA technology platform, providing a wide range of services from sequence design and optimization, plasmid construction, linearized template preparation, IVT, mRNA purification and quality control, LNP encapsulation, and mRNA-LNP detection, capable of delivering end-to-end full-process mRNA CRO services.

1 HiSignal® Sequence Design

2 HiSynth® Nucleic Acid Chemistry Platform

3 HiTrans® In Vitro Transcription and Encapsulation Platform

4 HiSignal® Detection Platform

Detailed Service Content

CMC Director Personal Supervision
Direct Communication and Project Initiation

Group-Based Work
Independent Full-Process Management
Project Manager Responsibility System

Project Progression
1. Sequence Design Optimization
2. Plasmid Construction and Linearized Template Preparation
3. mRNA Preparation
4. LNP Encapsulation
5. mRNA/LNP Quality Control

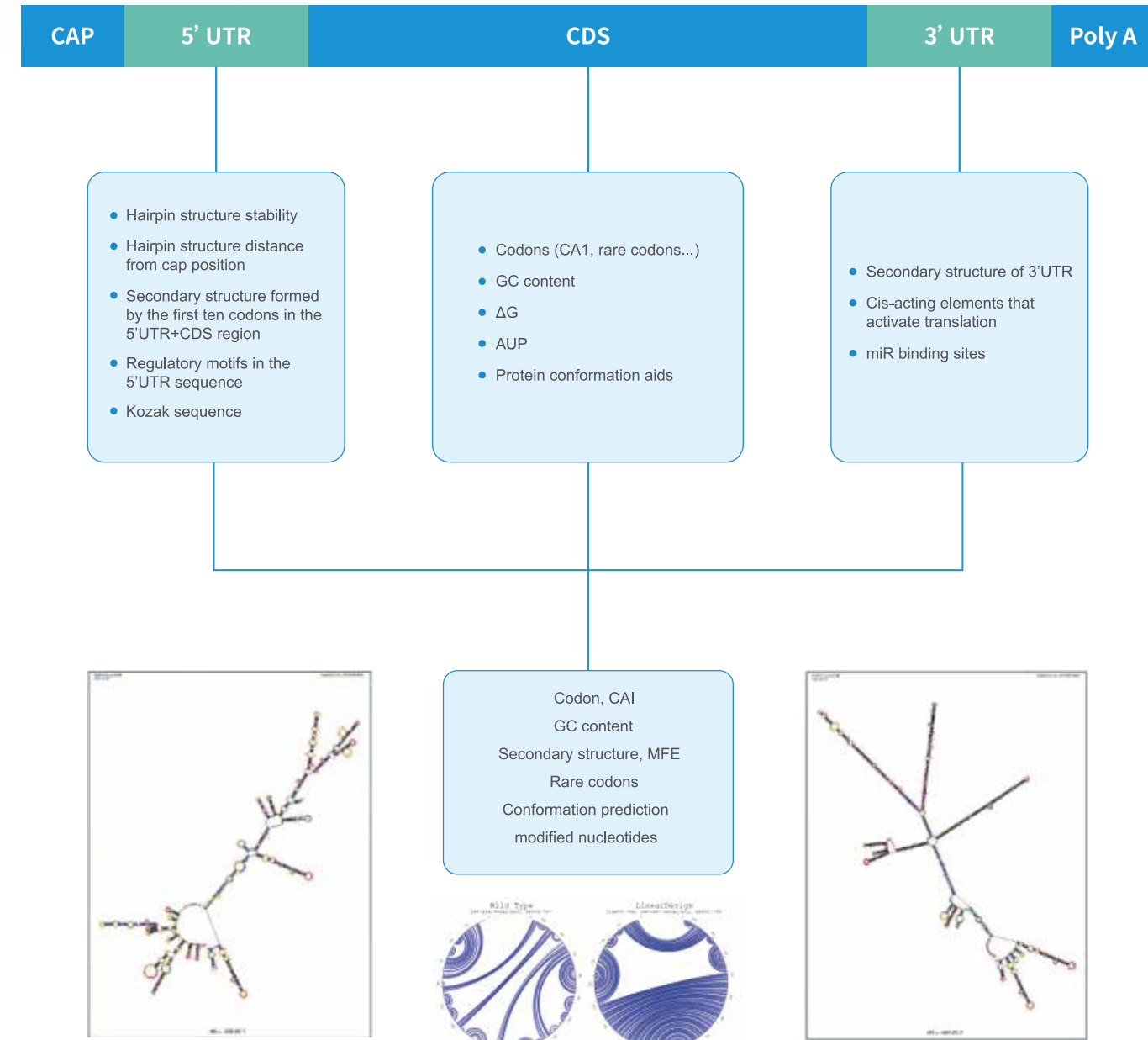
Regular Email Reports
Contactless Communication of Project Details
Welcome Engaging Discussions

Long-Term After-Sales Response
Project Manager Full-Process Tracking

SYNTHGENE CRO 1 — Sequence Design and Optimization

Different mRNA sequences exhibit significant differences in immunogenicity, stability, and expression capacity. Therefore, it is necessary to design and optimize mRNA sequences with suitable immunogenicity, good stability, and stronger expression capacity based on protein sequences. This includes designing and optimizing cap structures, 5'UTR sequences, CDS sequences, 3'UTR sequences, Poly A, nucleotides, etc.

Synthgene Biotech can provide advanced and professional sequence design and optimization services.



SYNTHGENE CRO 2 — mRNA Preparation

Based on its mature technical accumulation, Synthgene Biotech can supply various tool mRNA products, and also provide customized mRNA preparation services to comprehensively meet the different experimental and project needs of different customers!

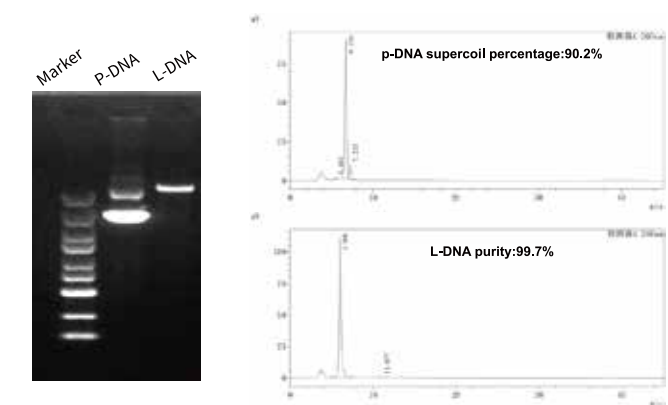
Tool mRNA

Product Name	Catalog Number	Specifications
HiSignal® eGFP mRNA (5' CAP)	11001-CAP	1mg/5mg/10mg
HiSignal® Fluc mRNA (5' CAP)	11002-CAP	1mg/5mg/10mg
HiSignal® Fluc-eGFP mRNA(5' CAP)	11003-CAP	1mg/5mg/10mg
HiSignal® mCherry mRNA (5' CAP)	11004-CAP	1mg/5mg/10mg
HiSignal® Cas9 mRNA (5' CAP)	11005-CAP	1mg/5mg/10mg
HiSignal® OVA mRNA (5' CAP)	11006-CAP	1mg/5mg/10mg
HiSignal® eGFP mRNA with N1-Me-pUTP (5' CAP)	11011-CAP	1mg/5mg/10mg
HiSignal® Fluc mRNA with N1-Me-pUTP (5' CAP)	11012-CAP	1mg/5mg/10mg
HiSignal® Fluc-eGFP mRNA with N1-Me-pUTP (5' CAP)	11013-CAP	1mg/5mg/10mg
HiSignal® mCherry mRNA with N1-Me-pUTP (5' CAP)	11014-CAP	1mg/5mg/10mg
HiSignal® Cas9 mRNA with N1-Me-pUTP (5' CAP)	11015-CAP	1mg/5mg/10mg
HiSignal® OVA mRNA with N1-Me-pUTP (5' CAP)	11016-CAP	1mg/5mg/10mg

High-quality service data sharing (taking the preparation of Fluc-eGFP mRNA as an example)

1. Plasmid and linearized template purity data

With a supercoil ratio exceeding 90%, the plasmid is considered a high-quality plasmid. The Synthgene Biotech template plasmid has a 90.2% supercoil ratio, and after linearization, the template purity reaches 99.7%!



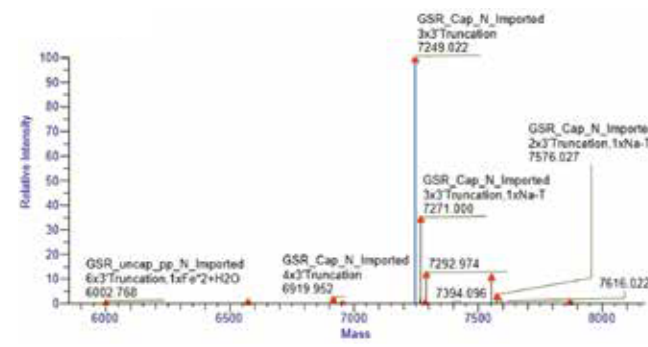
2. Integrity Data

With a supercoil ratio exceeding 90%, the plasmid is considered a high-quality plasmid. The Synthgene Biotech template plasmid has a 90.2% supercoil ratio, and after linearization, the template purity reaches 99.7%!



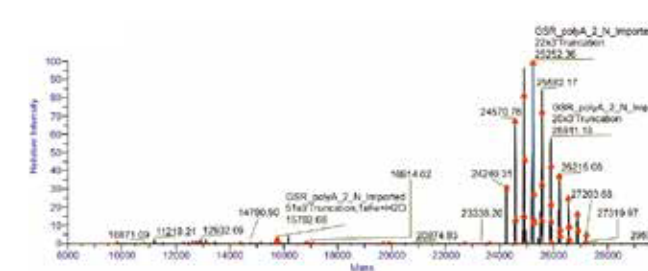
3. Capping efficiency data

The capping efficiency of Fluc-eGFP mRNA, as detected by LC-MS, was as high as 99.5%.



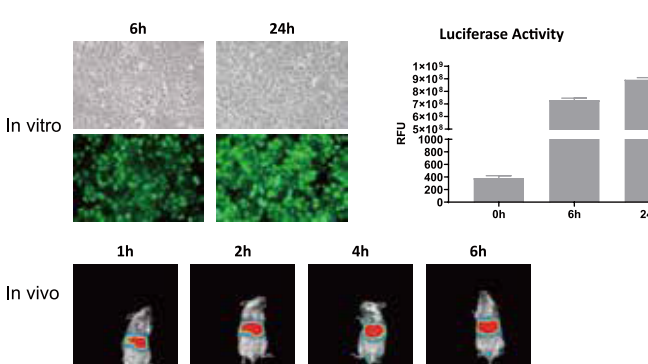
4. Poly(A) distribution data

LC-MS analysis of the Poly A length of Fluc-eGFP mRNA showed that the first tail segment was 31 Å long and the second tail segment was 74-83 Å long, which was in line with expectations.



5. Bioactivity data

Fluc-eGFP mRNA was transfected in vivo and in vitro, respectively. The results showed that not only could eGFP and Luciferase be highly expressed in cells, but protein expression could also be achieved in vivo.



Service Tenet:

We value timeliness, yet we hold authenticity in higher regard.
We adhere to standards, while we are flexible and prompt.

Synthgene Biotechnology Co., Ltd.



Senior CMC experts for pre-sales: conducting communication and evaluation. Dedicated project managers for in-sales: providing full-process attentive tracking of progress. 24/7 online support for after-sales: addressing queries promptly.

Our experienced mRNA team, equipped with advanced experimental equipment, provides rapid response and rigorous quality assurance to meet the diverse delivery needs of our clients.

Available in selectable scales, from mg to g levels of mRNA/LNP.

Multiple quality control tests o comprehensively ensure the quality of mRNA products.

We offer end-to-end services from sequence design and optimization to mRNA products, providing one-stop solutions to mRNA preparation challenges!

We can provide customized solutions based on your specific requirements, thus addressing your R&D needs!

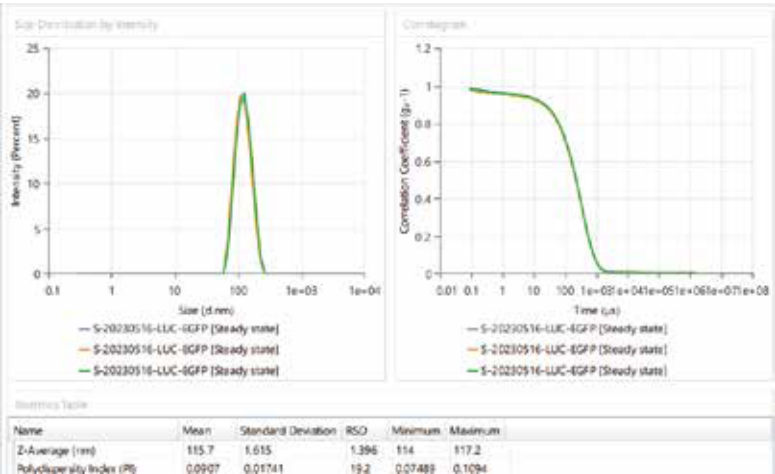
SYNTHGENE CRO 3—— LNP encapsulation

For mRNA vaccines to function effectively in vivo, not only does the antigen sequence need to be optimized, but a delivery system capable of overcoming challenges such as extracellular barriers, endosome escape, and intra-cellular immunity is also required. Lipid nanoparticle (LNP) delivery systems are currently the most widely used. Synthgene Biotech formulates applicable formulations using lipids from marketed vaccines (SM102, ALC0315) and self-developed novel lipids, providing advanced LNP delivery system preparation services.

High-Quality Product Data Sharing
(Taking SM102 Encapsulated Fluc-eGFP mRNA as an Example)

1. Nanoparticle Size Data

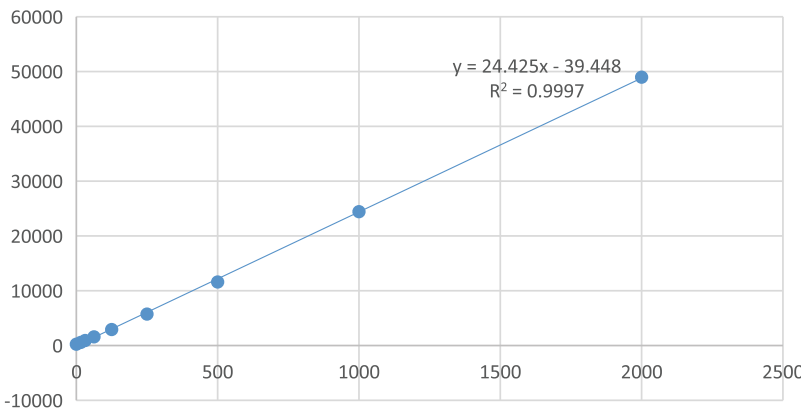
The particle size of SM102-encapsulated Fluc-eGFP mRNA-LNP is 115.7 nm, and the PDI is 0.09.



2. Encapsulation Efficiency Data

mRNA encapsulation efficiency is greater than 95%.
This methodology has been validated and can detect concentrations as low as 1 ng/ml.

Encapsulation ratio calculation standard curve



SYNTHGENE CRO 4—— mRNA & LNP Detection

In April 2023, the United States Pharmacopeia (USP) released the "mRNA Vaccine Quality Analysis Methods - Draft Guideline" (Second Edition). The second version starts from the entire life cycle of mRNA vaccines and conducts multi-dimensional evaluations to ensure their safety, efficacy, and product quality.

Synthgene Biotech, referencing the USP draft, has developed a complete mRNA & LNP testing system.

mRNA testing service		mRNA-LNP testing service	
Test Items	Test Methods	Test Items	Test Methods
Appearance	Visual inspection method	Appearance	Visual inspection method
pH	ChP 0631	pH	ChP 0631
mRNA sequence identification	RT-PCR	Osmotic pressure	ChP 0632
mRNA concentration	UV	mRNA sequence identification	RT-PCR
mRNA integrity	CGE/Agarose gel electrophoresis	LNP component identification and quantification	HPLC-CAD
mRNA purity (fragments)	RP-HPLC	mRNA integrity	CGE/SEC
mRNA purity (aggregates)	SEC-HPLC	mRNA purity (fragments)	RP-HPLC
Capping efficiency	LC-MS	mRNA purity (aggregates)	SEC-HPLC
Poly A tail distribution	LC-MS	Encapsulated mRNA content/encapsulation efficiency	RiboGreen assay
dsRNA	ELISA method	Lipid content	HPLC-CAD
DNA residue	qPCR method	Particle size and dispersibility (PDI)	DLS
Protein residue	Nano Orange/ELISA method	Zeta potential	Electrophoresis light scattering
Plasmid purity	HPLC	Insoluble microparticle examination	Microscopic counting method/optical obliteration method
Linearized plasmid purity	HPLC/CGE	Residual solvent examination	USP<467>, ChP 0861
Nucleotide and cap analogue residue	HPLC	Endotoxin	Gel method/dynamic colorimetric method
Endotoxin	Gel method/dynamic colorimetric method	Bioactivity	Flow cytometry/ELISA/WB

mRNA & LNP detection platform demonstration



SYNTHGENE
CRO Services

- ▶ CRO 1—Sequence Design and Optimization
- ▶ CRO 2—mRNA Preparation
- ▶ CRO 3—LNP Encapsulation
- ▶ CRO 4—mRNA & LNP Detection

Add : Building 7, Zone C, Yixing Medicinal Valley, South of Science and Technology Avenue, Gaocheng Town, Yixing City, Jiangsu Province, China
Web : www.synthgene-bio.com
Tel : +86(025)83696681
E-mail : sales@syngenebio.com
After-sales service : service@syngenebio.com

Synthgene Biotechnology Co., Ltd.