

Vazyme Online

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Better Raw Material, Robust Research

Comprehensive Solutions for mRNA Vaccines/ Drugs

mRNA is currently recognized as a relatively safe drug carrier, which has a strong flexibility in the prevention and treatment of diseases. In addition to infectious disease vaccines including COVID-19, mRNA has also been identified and applied to a number of therapies, such as systemic secretion, cell therapy, tumor vaccines, intratumoral immuno-oncology therapy, local regenerative therapy, etc.

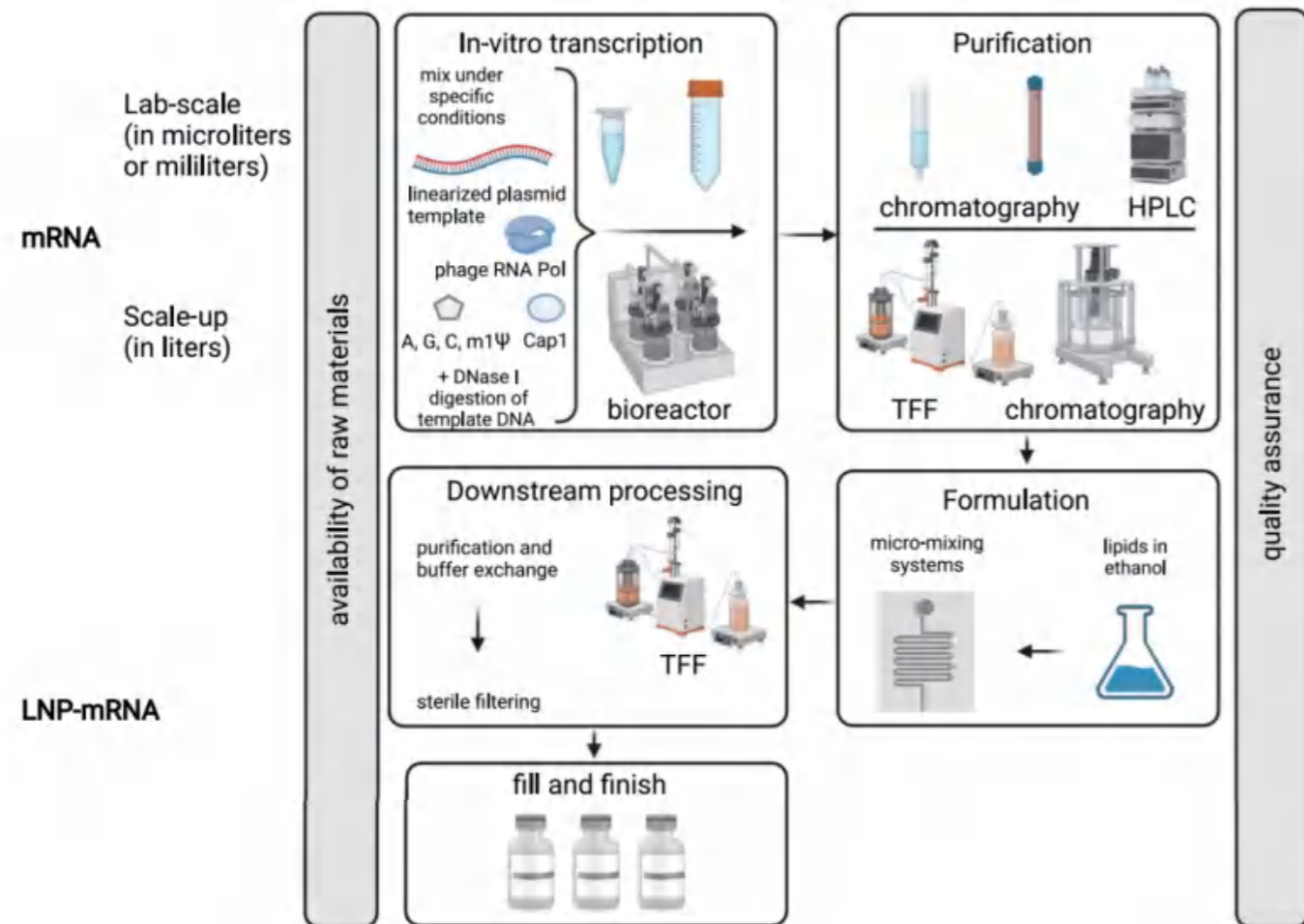
Vazyme has rich experience in research and development of enzyme raw materials and chemical raw materials, excellent product quality system and large-scale supply chain management experience guarantee, driven by two-wheel research on enzyme product quality and application scenarios. Vazyme will continue to supply GMP-grade tool enzymes and chemical raw materials with safety, high performance and controllable quality according to API standards, help the research and development and production of mRNA vaccines/drugs, and ensure the safety of customers' raw material supply chain.



Part I 01 Products



Part I 02
Services: 1 to 1 technical service



- 01 One-to-one technical service consultant
- 02 100+ Sequence system optimization services
- 03 Plasmid to mRNA process development services
- 04 Process development and analytical method development, validation and transfer

Part I 03
Quality management system

01 10,000 m² Class 100,000 cleanroom multifunctional GMP production workshop

- Based on ISO9001 quality management system, ISO14001 environmental management system, ISO45001 occupational health management system;
- The equipments are verified by URS, DQ, FAT SAT, 3Q and meet GMP requirements;
- 7 production lines ranging from 10-50-100-500-1000-5000 L fermentation scale;
- The production capacity reaches an annual production of 2 billion doses of mRNA vaccines.

02 1,000 m² Multifunctional QC inspection laboratory

- 200+ verified instruments and equipments
- 40+ self-developed analysis and detection methods
- 100+ confirmed pharmacopoeia physicochemical analysis methods



Part I 04 Quality Control of raw materials

01 Production without animal source

Fermentation

Raw materials are quality controlled **without adding** Bacterial peptone and penicillin

Purification

There is **no use** of Heparin chromatography during purification.

Formulation

The formula **does not contain** animal-derived BSA

02 Strict quality control

Impurity

- Endonuclease
- Exonuclease
- RNase
- Mycoplasma
- Endotoxin
- Microbial Count
- Exogenous DNA

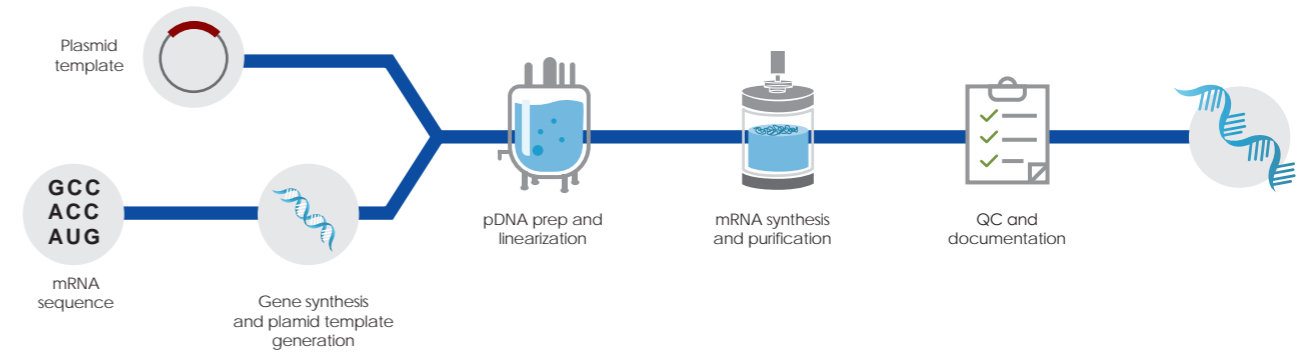
Control of components

- Activity: Quantitative analysis
- Protein Purity: SDS-PAGE; HPLC
- Concentration control

03 IND Application materials support

Basic data, quality data and research data, etc.

Part I 05 Production process of mRNA stock solution



01 Template preparation

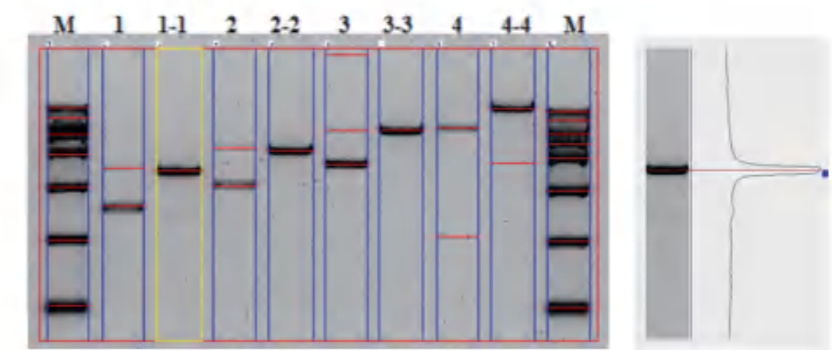
Product Name	Activity	Site of cleavage	Type	Characteristics
BspQ I	10 U/μl	5'.....GCTCTC(N).....3' 3'.....CGAGAAG(NNNN).....5'	Type IIS restriction enzyme	Cut out the clean Poly (A) tail
Bsa I	20 U/μl	5'.....GGTCTC(N).....3' 3'.....CCAGAG(NNNNN).....5'	Type IIS restriction enzyme	Cut out the clean Poly (A) tail
Xba I	15 U/μl	5'.....T↓CTAGA.....3' 3'.....AGATC↑T.....5'	Type IIS restriction enzyme	Get specific sticky ends

Features

- Efficient linearization
- Compatible with plasmids of different length
- Compatible with residues of different processes to meet the requirements of vaccine plasmid linearization

Data

System Research	
DMSO	✓
Glycerin	✓
pH	✓
Metal ion	✓
Temperature	✓
Reaction time	✓



M: 15000 DNA Marker
Before enzyme digestion: 1: 2958 bp; 2: 4416 bp; 3: 6468 bp; 4: 13985 bp
After enzyme digestion: 1-1: 2958 bp; 2-2: 4416 bp; 3-3: 6468 bp; 4-4: 13985 bp

02 In vitro transcription (IVT)

Available products: GMP level enzymes and chemical raw materials

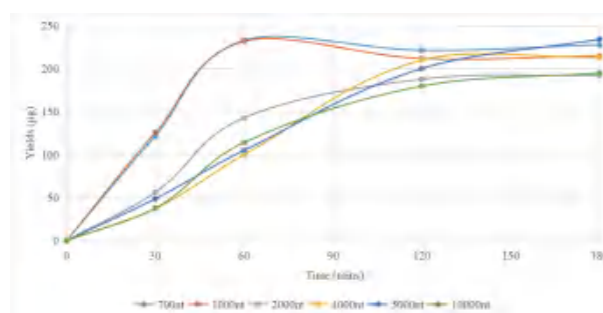
Product Name	Application
T7 RNA Polymerase (50 U/μl)/ (200 U/μl)	Specifically recognize the T7 promoter sequence, using it as a template and NTP as a substrate to synthesize RNA complementary to the ssDNA or dsDNA template strand downstream of the promoter
T7 Turbo RNA Polymerase(200 U/μl)	Compared with wild-type T7 RNA Polymerase, T7 Turbo RNA Polymerase effectively reduces the content of dsRNA, a by-product produced during transcription. While its co-transcription reaction product also has a higher capping rate
Murine RNase Inhibitor (40 U/μl)	Specifically inhibit the activity of RNase A, B, C, and protect mRNA in the large-scale production
Pyrophosphatase, Inorganic (yeast, 0.1 U/μl)	Hydrolyze the inorganic pyrophosphate produced in nucleic acid amplification, promote the reaction equilibrium to the product generation, increasing the amount of product
DNase I (1 U/μl)	Digest ssDNA and dsDNA

Available products: Rapid synthesis kits for scientific research and early stage R&D

Product Name	Specification	Application
T7 High Yield RNA Transcription Kit	50 rxns	Efficient mRNA synthesis, rapid construction of mRNA synthesis platform
T7 High Yield RNA Transcription Kit (N1 -Me-Pseudo UTP)	50 rxns	
EasyCap T7 Co-transcription Kit with CAG Trimer	50 rxns	

◆ T7 High Yield RNA Transcription Kit(N1 -Me-Pseudo UTP)

Data



- Compatible with 600~13000 nt RNA
- Integrity > 90%
- Production > 5 mg/ml
- Purity: A260/A280=1.8~2.0
- dsRNA as low as 0.1%

03 mRNA modification

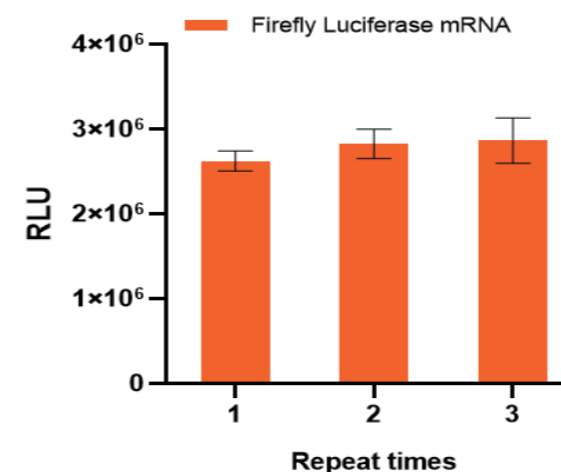
Available products:

Product Name	Process Route	Application
Vaccinia Capping Enzyme (10 U/μl)	Enzymatic capping	Ligation of the 7-methylguanine cap structure (m7Gppp) to the 5' end of the RNA (m7Gppp5'N), forming the Cap0 structure
mRNA Cap 2'-O-Methyltransferase (50 U/μl)	Enzymatic capping	Using SAM as a methyl donor to methylate and cap RNA, forming Cap1 structure
E.coli Poly (A) Polymerase	Enzymatic tailing	Catalyzing ATP to be sequentially incorporated into the 3' end of RNA in the form of AMP, and add polyadenosine tail to the 3' end of RNA

04 mRNA stock solution

Product Name	Application
EGFP mRNA (N1-Me-Pseudo,1 mg/ml)	Use as standards and in mRNA delivery, translation efficiency, cell viability, in vivo imaging, etc.
Firefly Luciferase mRNA (N1-Me-Pseudo,1 mg/ml)	Use as standards and in mRNA delivery, translation efficiency, cell viability, in vivo imaging, etc.

◆ Firefly Luciferase mRNA (N1-Me-Pseudo,1 mg/ml)



After 20h of HEK293T cell transfection, the cells were detected with Bio-Lite Luciferase Assay System (Vazyme # DD1201), and the signal value was read by the microplate reader

05 Quality control

Product Name	Detection Type
EasyAna dsRNA (Modified) Quantitative Detection Kit (ELISA) 2.0	Product related impurities-dsRNA
EasyAna Vaccinia Capping Enzyme Quantitative Detection Reagent (ELISA)	Process related impurities-Vaccinia Capping Enzyme
EasyAna 2'-O-Methyltransferase Quantitative Detection Kit (ELISA)	Product related impurities-Cap 2'-O-Methyltransferase
EasyAna T7 RNA Polymerase Quantitative Detection Kit (ELISA)	Product-related impurities- T7 RNA Polymerase
EasyAna DNase I Quantitative Detection Kit (ELISA)	Product-related impurities - DNase I
Murine RNase Inhibitor Antibody Pairs & Standards	Process related impurities-Murine RNase Inhibitor
Pyrophosphata-se, Inorgan Antibody Pairs & Standards	Product-related impurities - Pyrophosphata-se, Inorgan

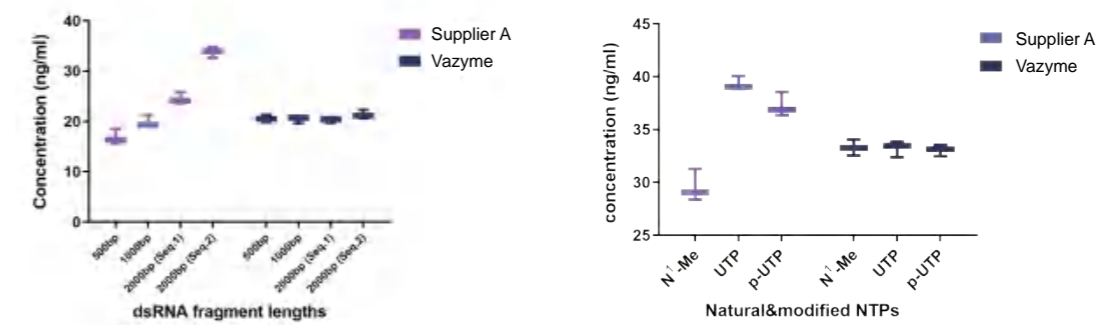
◆ EasyAna dsRNA (Modified) Quantitative Detection Kit (ELISA) 2.0

- Overcoming the stuck point of nucleic acid antibody screening, the antibodies are completely and independently developed and produced.
- Strict quality control measures are enforced to guarantee the traceability and consistency of raw materials, in order to meet the requirements of large-scale production.

Features

High analytical sensitivity	LOD < 10 pg/ml, LOQ = 47 pg/ml
High accuracy	The recovery accuracy of standard addition meets 80-120%
High precision	CV<15%, ensuring the repeatability of experimental results
High specificity	Only specifically recognizes dsRNA above 40 bp, and has no interference from other forms of nucleic acid or IVT tool enzymes

Data



Quantitative results for dsRNA standards of different sequences and lengths are consistent.

Part I 06

Product List

01 MRNA raw material products

Product Type	Product Name	Product No.
IVT	T7 Turbo RNA Polymerase(200 U/μl, GMP Grade)	GMP4120PB
	T7 High Yield RNA Transcription Kit	DD4201
	T7 High Yield RNA Transcription Kit(N1 -Me-Pseudo UTP)	DD4202
mRNA standard	EGFP mRNA (N1-Me-Pseudo, 1mg/ml)	DD4503
	Firefly Luciferase mRNA(N1-Me-Pseudo, 1mg/ml)	DD4511

02 mRNA residue detection series products

Product Type	Product Name	Product No.
dsRNA	EasyAna dsRNA (Modified) Quantitative Detection Kit (ELISA)2.0 Hot!	DD3509EN-01