BIOMEDICINE

Focus on Raw Material Development
and Provide High-quality Service!

mRNA Medicine Raw Material Enzyme And Quality & Safety Analysis Of Biological Products

Zhuhai Biori Biotechnology Co.,Ltd

About us

Zhuhai Biori Biotechnology Co., Ltd. was established in 2012. It is a National high-tech enterprise, a national specialized and new "Little Giant" enterprise, the Molecular Diagnostic Enzyme Engineering Technology Research Center of Guangdong Province, and Unicorn enterprise in Zhuhai. In recent years, with the rapid development of the company, Biori has actively laid out research on mRNA drug raw materials in the field of biopharmaceuticals based on a sound R&D platform and rich development experience. It has now developed multiple high-quality RNA transcription-related raw materials enzymes, including T7 RNA polymerase, inorganic pyrophosphatase, and RNase inhibitor. At the same time, enzymes such as vaccinia capping enzyme, 2'-O-Methyltransferase , and E. coli Poly(A) Polymerase have also been developed. For the above-mentioned enzyme raw materials, a GMP-level quality attribute inspection plan has been established, which can provide clients with stable and compliant, high-yield mRNA drug production raw materials.

Biori has developed a series of products based on magnetic bead extraction and real-time fluorescence quantitative PCR technology, including Mycoplasma DNA detection reagent kit, branch Bacillus DNA detection reagent kit, CHO residual DNA detection reagent kit, E. coli residual DNA detection reagent kit, Vero residual DNA detection reagent kit, B. subtilis residual DNA detection reagent kit, HEK293 residual DNA detection reagent kit, automated extraction equipment and supporting reagents. These products can provide professional overall solutions for the quality and safety analysis of bioproducts.

Focusing on raw material development and providing quality services, Biori will adhere to the concept of integrity and responsibility, enterprising innovation, and strive to develop upstream core technologies to contribute to the supply of upstream raw materials for China's biopharmaceuticals!

CONTENTS

01/ mRNA Pharmaceutical Raw Material Enzyme

Product Name	Specs	Part Number
T7RNAPolymerase, 50U/μL	5KU	BP-E01-5K
T7RNAPolymerase, 50U/μL	50KU	BP-E01-50K
T7RNAPolymerase, 50U/μL	500KU	BP-E01-500K
RNaseInhibitor, 40U/μL	40KU	BP-E02-40K
Inorganic pyrophosphatase, 0 . 1U/μL	10U	BP-E03-10
Inorganic pyrophosphatase, 0 . 1U/μL	100U	BP-E03-100
Inorganic pyrophosphatase, 0 . 1U/μL	1000U	BP-E03-1K
DNaseI,2U/μL	1KU	BP-E04-1K
VacciniaCappingEnzyme,10U/μL	1KU	BP-E05-1K
VacciniaCappingEnzyme,10U/μL	10KU	BP-E05-10K
VacciniaCappingEnzyme,10U/μL	100KU	BP-E05-100K
2'-O-Methyltransferase ,10U/μL	1KU	BP-E06-1K
2'-O-Methyltransferase ,10U/μL	10KU	BP-E06-10K
2'-O-Methyltransferase ,10U/μL	100KU	BP-E06-10OK
E. coli Poly(A) Polymerase,5U/μL	100U	BP-E07-100
RibonucleaseR, 20U/μL	1KU	BP-E08-1K
RibonucleaseR, 20U/μL	10KU	BP-E08-10K
RibonucleaseR, 20U/μL	100KU	BP-E08-100K
T7 high-efficiency transcription reagent kit	50T	BP-01-50
T7 high-efficiency transcription reagent kit (with pUTP)	50T	BP-02-50
T7 high-efficiency transcription reagent kit (with N1- Me- pUTP)	50T	BP-03-50
mRNA capping reagent kit	50T	BP-04-50
Pre-treatment kit for mRNA capping rate detection	3T	BP-QN80-3T
ATP(100mM)	100mM	BP-AS01-100
GTP(100mM)	100mM	BP-AS02-100
CTP(100mM)	100mM	BP-AS03-100
UTP(100mM)	100mM	BP-AS04-100
N1- Me- pUTP(100mM)	100mM	BP-AS07-100
pUTP(100mM)	100mM	BP-AS05-100
SAM(32mM)	32mM	BP-AS06-32

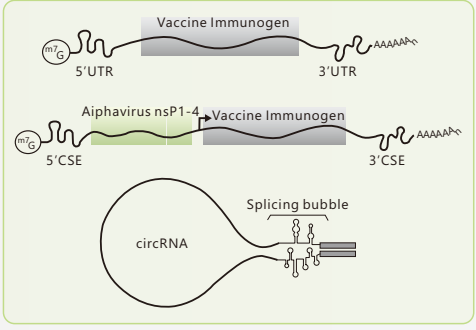
Dedicated to the development of raw material enzyme products

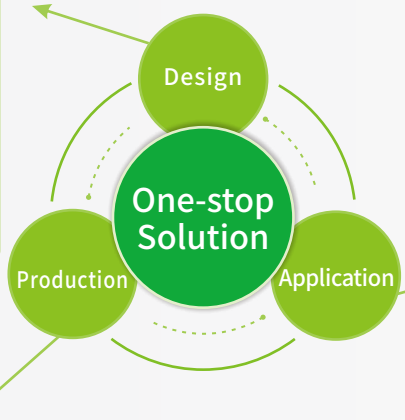
Strive to solve customer's issues in the application of raw material enzymes

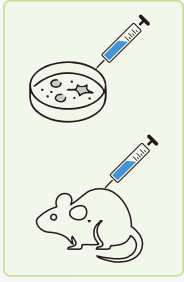
Facilitate the research and production of mRNA-based drug products

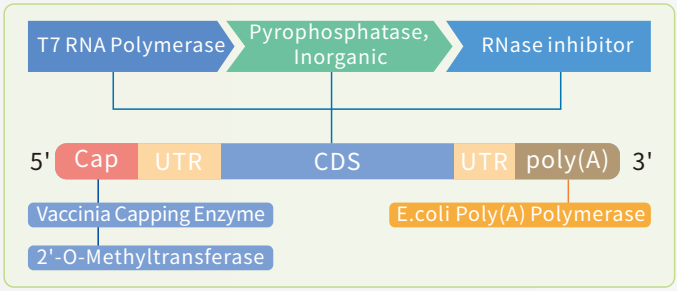
Founded in 2012, Biori Biotechnology has over ten years of experience in the development and application of raw material enzymes. In recent years, with the rapid development of the biopharmaceutical field, Biori has actively positioned itself in the development of mRNA drug raw material enzymes. Leveraging its comprehensive research and development platform and expertise, Biori adheres to high-quality standards and is dedicated to producing GMP-grade core raw material enzyme products for mRNA drugs (please refer to the product catalog for details). Our goal is to ensure the high-quality and stable supply of upstream raw materials for the biopharmaceutical industry.

Dedicated in raw materials supplying and offers a complete solution from design, production, to application.









T7 RNA Polymerase

The T7 promoter is the most efficient promoter in nature for transcription. Based on this, Biori has successfully developed T7 RNA polymerase specifically designed for the T7 promoter. It exhibits superior purity and enzyme activity compared to competing products. When combined with a transcription reaction buffer optimized through extensive processes, T7 RNA polymerase can accurately and efficiently recognize the T7 promoter region (5'-TAATACGACTCACTATAG-3') within a DNA sequence containing the T7 promoter . Starting from the 'G' in this region, it utilizes substrate NTPs to transcribe the downstream DNA sequence into single-stranded RNA with high efficiency and stability.

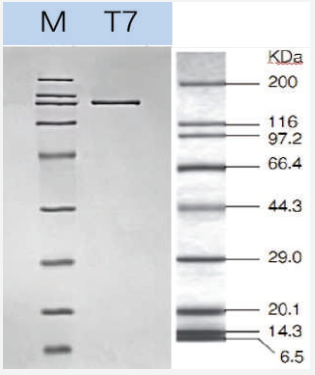
Quality Control

- The solution is clear and transparent, without any visible foreign particles
- Protein purity≥99%
- No DNase or RNase activity
- No Exonuclease or Endonuclease Activity

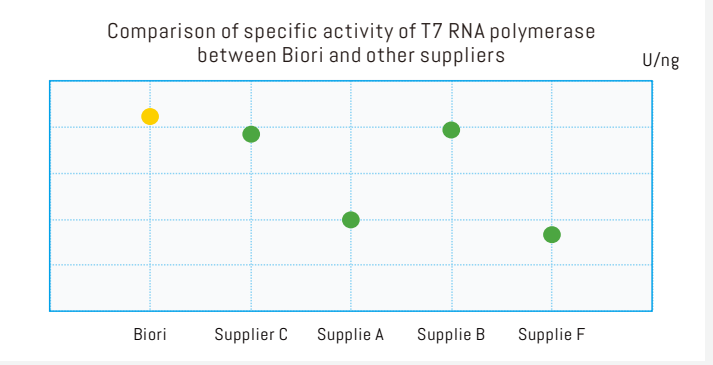
Product Features

- High Purity
- High Activity
- High Stability
- Strong Template Adaptability

Biori offers high purity and high activity T7 RNA polymerase

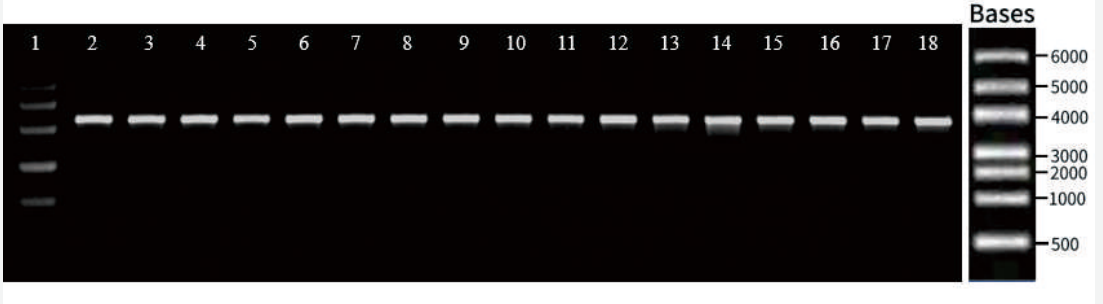


- The purity of T7 RNA polymerase produced by Biori is greater than 99%



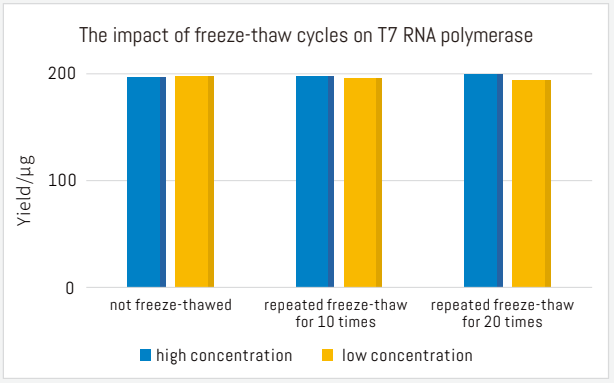
- The activity of T7 RNA polymerase from Biori is significantly superior to other suppliers)

The transcription product of Biori's T7 RNA polymerase

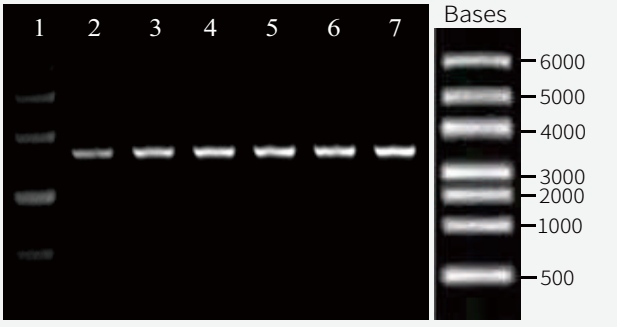


1. RNA ladder
2-18. Biori T7RNA polymerase transcript product

Biori's T7 RNA polymerase is not affected by repeated freeze-thaw cycles in terms of product quality and transcription yield.

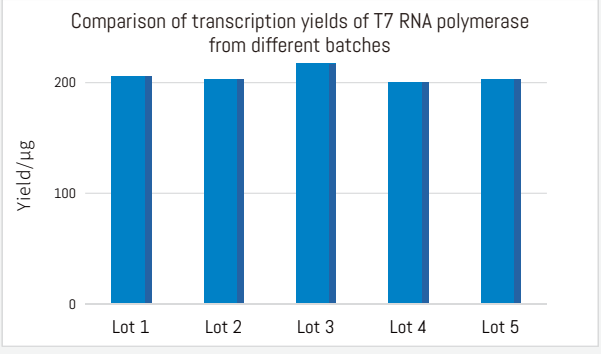


- The transcription yield is not significantly affected by the number of freeze-thaw cycles

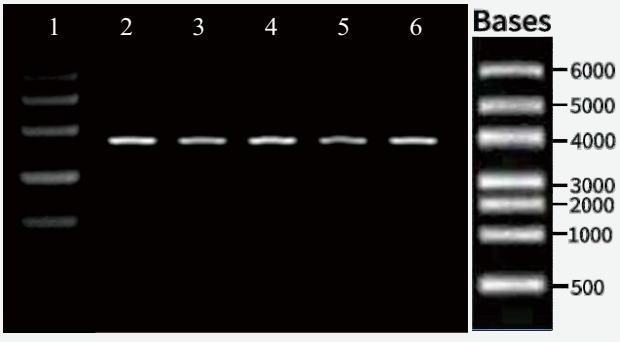


1. RNA ladder
2. Transcription verification at high concentration without freeze-thawing
3. Transcription verification at high concentration with repeated freeze-thaw cycles for 10 times
4. Transcription verification at high concentration with repeated freeze-thaw cycles for 20 times
5. Transcription verification at low concentration without freeze-thawing
6. Transcription verification at low concentration with repeated freeze-thaw cycles for 10 times
7. Transcription verification at low concentration with repeated freeze-thaw cycles for 20 times

Biori's T7 RNA polymerase exhibits minor inter-batch variability in terms of stability

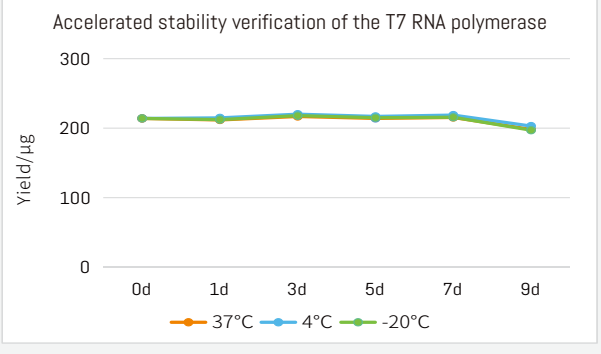


- The transcription yield differences of T7 RNA polymerase from different batches are small, and they remain relatively consistent

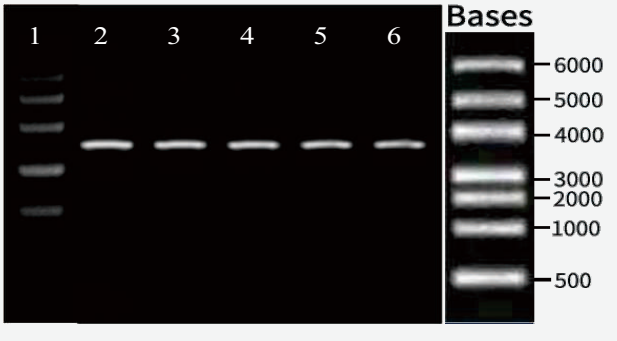


1. RNA ladder
2. Lot 1 transcription product
3. Lot 2 transcription product
4. Lot 3 transcription product
5. Lot 4 transcription product
6. Lot 5 transcription product

Biori's T7 RNA polymerase demonstrates excellent performance in accelerated stability testing

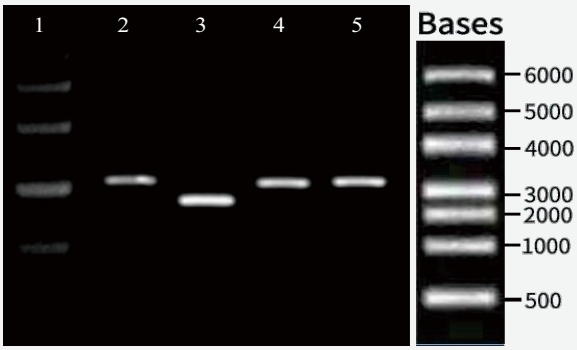


- The transcription yield of T7 RNA polymerase from different batches remains relatively constant after accelerated stability testing at 37°C for 9 days, consistent with the results obtained at -20°C

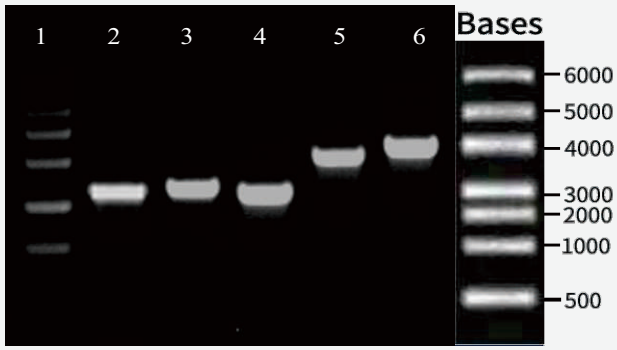


1. RNA ladder
2. The transcription product after 1 day of acceleration
3. The transcription product after 3 days of acceleration
4. The transcription product after 5 days of acceleration
5. The transcription product after 7 days of acceleration
6. The transcription product after 9 days of acceleration

Biori's T7 RNA polymerase exhibits excellent template adaptability.



1. RNAladder
2. 30% GC template
3. 45% GC template
4. 50% GC template
5. 60% GC template



1. RNAladder
2-6. Transcription products of different lengths DNA templa

Product Info

Product Name	Specs	Part Number
T7 RNA Polymerase (50 U/μL)	5KU	BP-E01-5K
	50KU	BP-E01-50K
	500KU	BP-E01-500K

RNase Inhibitor

Rnase Inhibitor, obtained through recombinant expression (referred to as RI in the text), is a highly purified recombinant RNA enzyme inhibitor. It can bind to RNA enzymes in a 1:1 ratio through non-covalent high-affinity interactions, thereby inhibiting the activity of RNase A, RNase B, and RNase C, while not affecting the activity of RNase H and S1 Nuclease. This product does not inhibit Phage RNA Polymerases (SP6, T7, or T3), Taq, AMV, MMLV, etc., and it exhibits stronger antioxidant capacity, maintaining stability under low concentration of DTT. It is suitable for excluding RNA enzyme contamination during mRNA in vitro transcription processes.

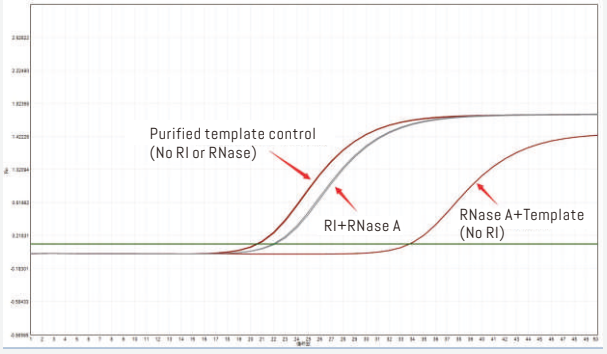
Quality Control

- The solution is clear and transparent, without any visible foreign particles
- Protein purity≥99%
- No DNase or RNase activity
- No Exonuclease or Endonuclease Activity

Product Info

Product Name	Specs	Part Number
RNase Inhibitor(40U/μL)	40KU	BP-E02-40K

Using RNA as the template, qPCR was conducted to verify the protective effect of RNase Inhibitor on the RNA template.



- Purified template control group (No RI or RNaseA)
  Rnase A Control group (No RI with R NaseA)
  Experimental group (with RI with R NaseA)

  After qPCR validation, it has been confirmed that RNase Inhibitor can effectively protect RNA and prevent RNase A from degrading the RNA template

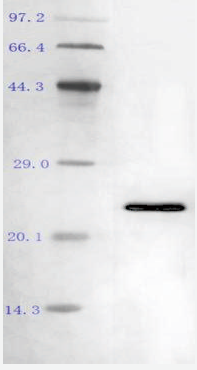
Inorganic Pyrophosphatase

This product is an E. coli recombinant expression and purification of inorganic pyrophosphatase. It catalyzes the hydrolysis of inorganic pyrophosphate to generate orthophosphate. In the process of in vitro transcription, inorganic pyrophosphatase hydrolyzes the accumulated inorganic pyrophosphate, preventing its inhibition on the reaction system. This helps shift the reaction equilibrium towards the production of the desired products. In molecular biology, it is applied in in vitro transcription reactions to significantly enhance RNA yield.

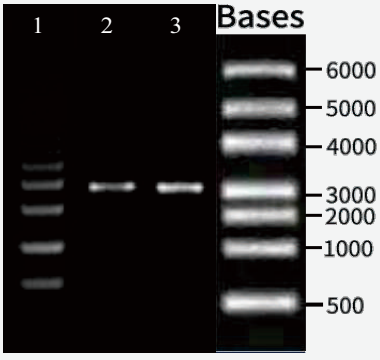
Quality Control

- The solution is clear and transparent, without any visible foreign particles
- Protein purity≥99%
- No DNase or RNase activity
- No Exonuclease or Endonuclease Activity

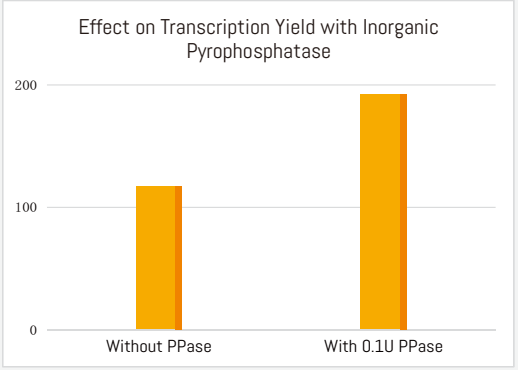
SDS-PAGE Validation **Product validation**



- The PPase was validated by SDS-PAGE, and the purity was determined to be greater than 99%. The product exhibits excellent purity.



1. R NAladde r
2. T7 transcription without P Pase
3. T7 transcription with 0 . 1 UP Pase



- 0.1 UBiori's self-produced PPase significantly enhances transcription yield.

Product Info

Product Name	Specs	Part Number
Inorganic Pyrophosphatase (0 . 1U/μL)	10U	BP-E03-10
	100U	BP-E03-100
	1000U	BP-E03-1K

T7 High-yield Transcription Kit

Based on a comprehensive range of mRNA synthesis enzyme raw materials, Biori has developed the T7 High-Efficiency Transcription Kit (Catalog Number: BP-01-50) optimized for different templates and nucleotide types. By using this kit, customers can obtain a large quantity of RNA through short-term in vitro transcription, with over 200 μg of product obtained from 1 μg of template input. Additionally, the kit allows for the transcription of mRNA with cap structures by incorporating Cap 0 or Cap 1 or similar cap structure analogs into the reaction substrates.

Product Features

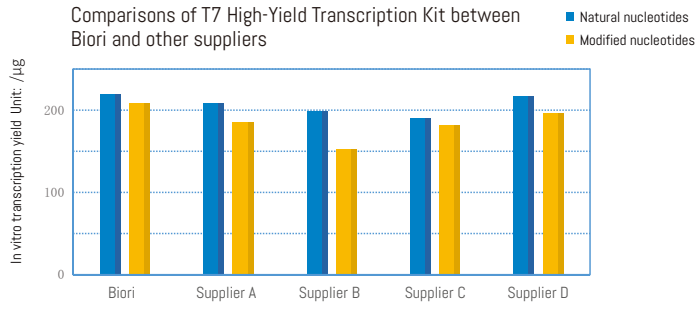
- Convenient and efficient, single-component, with space for optimization
- High transcription yield
- Low dsRNA residual
- High purity of transcription products

Product Info

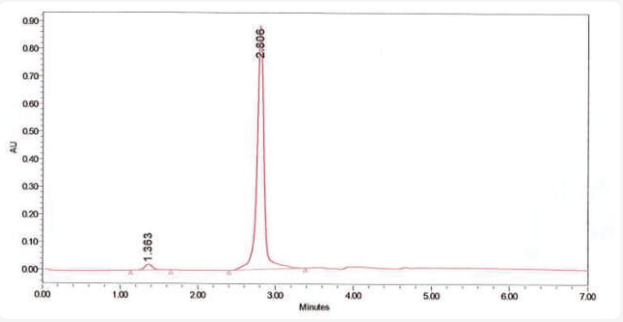
Product Name	Specs	Part Number
T7 High-yield Transcription Kit	50T	BP-01-50
T7 High-yield Transcription Kit (with N1- Me- Putp)	50T	BP-02-50
T7 High-yield Transcription Kit (with Putp)	50T	BP-03-50

M. ssRNAladder6000
1. Transcription product A from the T7 High-Yield Transcription Kit
2. Transcription product B from the T7 High-Yield Transcription Kit
3. The product of the T7 High-Yield Transcription Kit (pUTP)
4. The product of the T7 High-Yield Transcription Kit (N1-Me-pUTP)

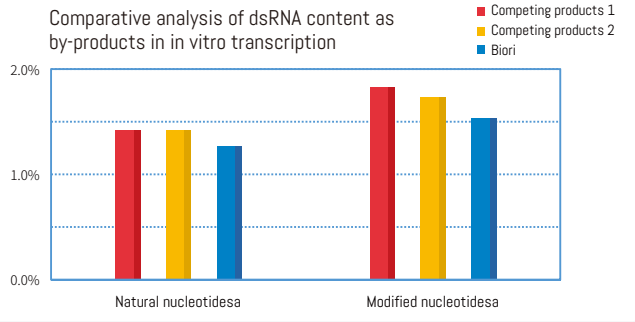
- The transcription products from the T7 High-Yield Transcription Kit display a single band on gel electrophoresis, indicating high purity.



- The T7 High-Yield Transcription Kit has advantage in transcription yield compared to competing products



- The transcription product of the T7 High-Yield Transcription Kit exhibit a purity of >98.5% as shown by HPLC analysis.



- The T7 High-Yield Transcription Kit exhibits lower yields of dsRNA as by-products compared to competing products.

Vaccinia Capping Enzyme

The capped structure at the 5' of mature mRNA, known as the m7GPPPN structure or methylguanosine cap, not only protects mRNA from RNase degradation and prolongs its half-life but also enhances its stability during translation, splicing, and nuclear export processes. The Vaccinia capping enzyme (VCE) developed by Biori integrates the necessary activities of mRNA triphosphatase, guanylyltransferase, and guanine-N7 methyltransferase, using S-adenosylmethionine (SAM) as the methyl donor. It directly adds the m7G cap structure to the 5' of mRNA. This cap structure is closely related to the stability, transport, and translation of mRNA, significantly improving the stability and translational efficiency of mRNA used for cellular validation and in vivo expression.

Quality Control

- The solution is clear and transparent, without any visible foreign particles
- Protein purity≥99%
- No DNase or RNase activity
- No Exonuclease or Endonuclease Activity

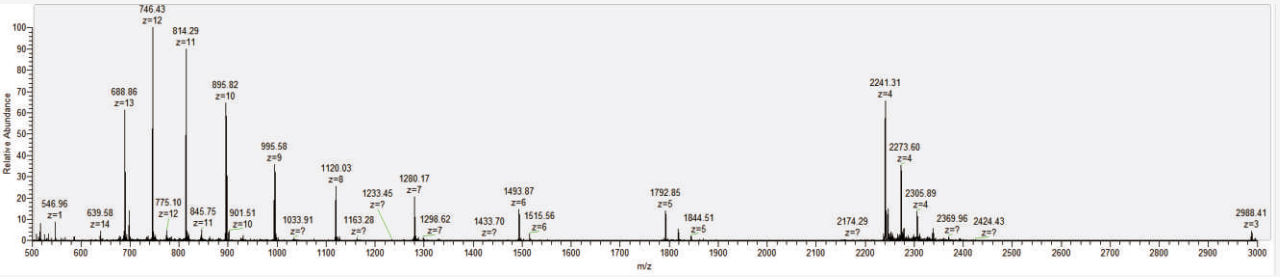
Product Features

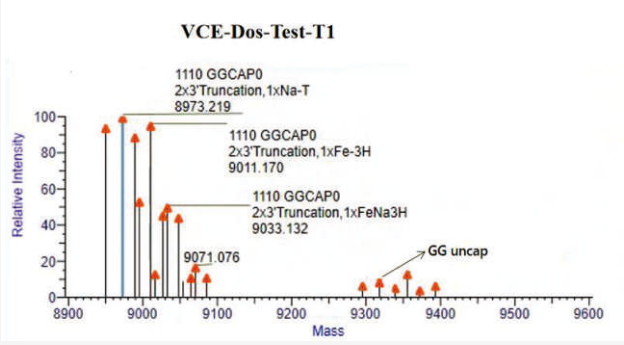
- High Purity
- High capping efficiency

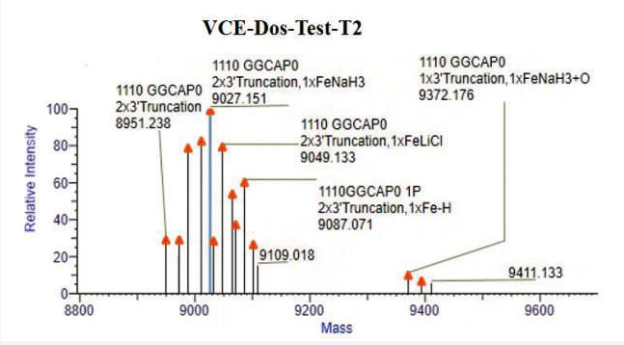
Product Info

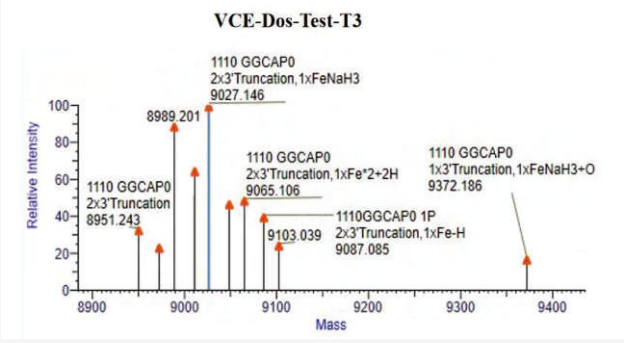
Product Name	Specs	Part Number
Vaccinia Capping Enzyme (10U/μL)	1KU	BP-E05-1K
	10KU	BP-E05-10K
	100KU	BP-E05-100K

The precise calibration of the dosage of Vaccinia capping enzyme can be achieved by utilizing liquid chromatography-mass spectrometry (LC-MS) based on the capping efficiency data.









2'-O-Methyltransferase

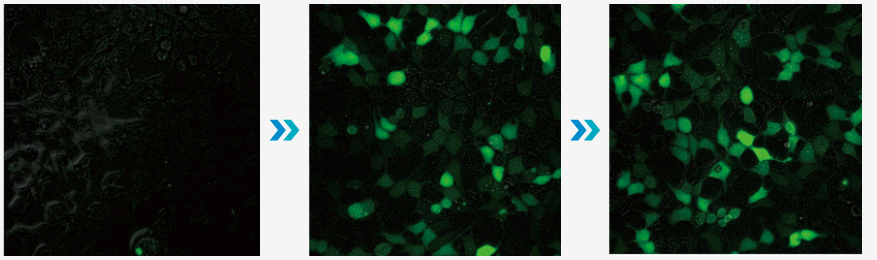
2'-O-Methyltransferase (2OM) is a methyltransferase enzyme encoded by the Vaccinia virus DNA, which is expressed in recombinant E. coli. It is responsible for converting the Cap0 cap structure into a Cap1 cap structure.

This enzyme utilizes S-Adenosylmethionine (SAM) as the methyl donor and adds a methyl group at the 2'-O position of the first nucleotide adjacent to the cap structure (Cap0) on RNA, resulting in mRNA with a Cap1 structure. This modification further reduces the immunogenicity of mRNA itself and enhances the expression level of encoded proteins after transfection.

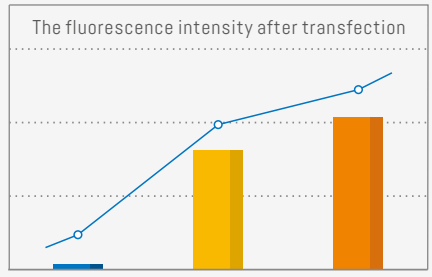
Quality Control

- The solution is clear and transparent, without any visible foreign particles
- Protein purity≥99%
- No DNase or RNase activity
- No Exonuclease or Endonuclease Activity

The results of GFP RNA transfection were analyzed by confocal microscopy



GFP before capping | VCE after capping cap0 | VCE+20M after capping cap1



Product Info

Product Name	Specs	Part Number
2'-O-Methyltransferase(10U/μL)	1KU	BP-E06-1K
	10KU	BP-E06-10K
	100KU	BP-E06-100K

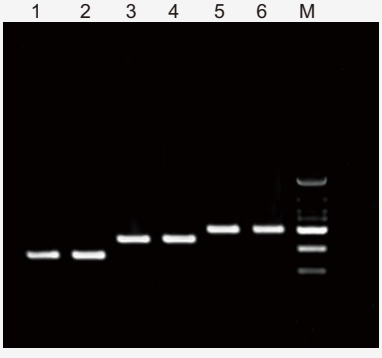
E. coli Poly(A) Polymerase

E. coli Poly(A) Polymerase is an enzyme that can add a poly(A) tail to the 3' end of an RNA molecule. It catalyzes the addition of adenosine monophosphate (AMP) units to the RNA molecule, creating a stable poly(A) tail. This enzyme is commonly used in mRNA production processes to generate mRNA molecules with a poly(A) tail, which enhances mRNA stability, transport, and translation efficiency.

For certain applications or specific processes, post-transcriptional tailing of mRNA may be required. In such cases, where template-independent tailing is desired, Biori offers an E. coli Poly(A) Polymerase. This enzyme can catalyze the sequential addition of ATP as AMP units to the 3' end of RNA, resulting in the addition of a poly(A) tail ranging from 20 to 200 adenine bases. The enzyme exhibits high tailing efficiency, and by controlling the enzyme's usage, one can achieve different lengths of poly(A) tails, thereby enhancing mRNA stability and translation efficiency.

Quality Control

- The solution is clear and transparent, without any visible foreign particles
- Protein purity≥99%
- No DNase or RNase activity
- No Exonuclease or Endonuclease Activity



Agarose gel electrophoresis verification

Lane1-2: Control (before tailing)
Lane3-4: 5U EPA tailing (2 parallel groups)
Lane5-6: 10U EPA tailing (2 parallel groups)

- After agarose gel verification, the tailing process resulted in controllable length of the tail, and the tailed products were complete with good reproducibility

Product Info

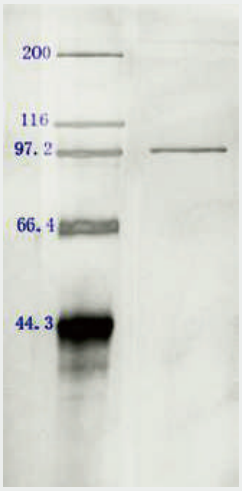
Product Name	Specs	Part Number
E. coli Poly(A) Polymerase (5U/μL)	100U	BP-E07-100

RNase R

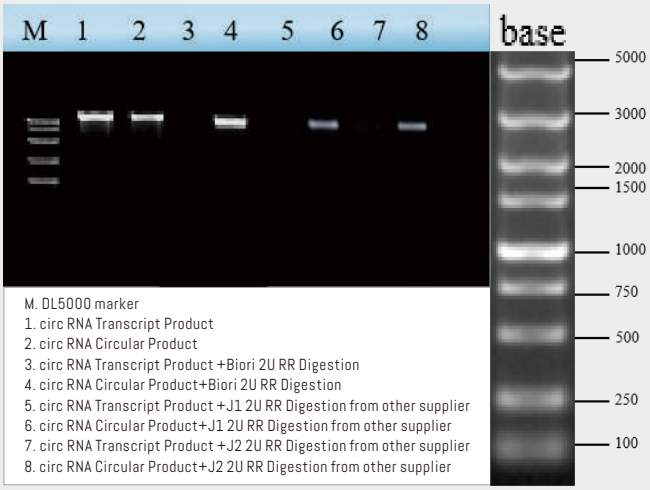
Rnase R (Ribonuclease R) is a Mg^{2+}-dependent ribonuclease that belongs to the RNR superfamily and is derived from E. coli. It cleaves linear RNA from the 3' to 5' direction, completely hydrolyzing it into dinucleotides and trinucleotides. It is not sensitive to circular RNA or double-stranded RNA and can be used for the production of specialized RNA structures such as circular RNA (circRNA), lariat RNA, double-stranded RNA with less than 7 nucleotides overhang at the 3' end, and complex structured tRNA. RNase R is commonly used in gene expression and alternative splicing studies to digest linear RNA and enrich circRNA or lariat RNA.

Quality Control

- Clear and transparent solution, no any visible foreign particles
- Protein purity≥99%
- No Endonuclease Activity



- The RNase R provided by Biori has a purity greater than 99%.



- Compared to other suppliers, Biori's RNase R exhibits higher enzymatic efficiency and stronger specificity towards linear RNA.

Product Info

Product Name	Specs	Part Number
RNase R (20U/μL)	1KU	BP-E08-1K
	10KU	BP-E08-10K
	100KU	BP-E08-100K

02/ Quality & Safety Analysis Of Biological Products

More new product kits are on the way...

Mycoplasma DNA Detection Kit

Mycobacterium DNA Detection Kit

Minute Virus of Mice (MMV) Detection Kit

CHO Cell Residual DNA Detection Kit

Vero Cell Residual DNA Detection Kit

Pichia Pastoris Residual DNA Detection Kit

E.coli Residual DNA Detection Kit

HEK293 Residual DNA Detection Kit

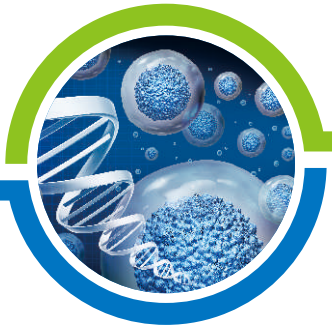
NS0&SP2/0 Residual DNA Detection Kit

Human Residual DNA Detection Kit

Hela Residual DNA Detection Kit

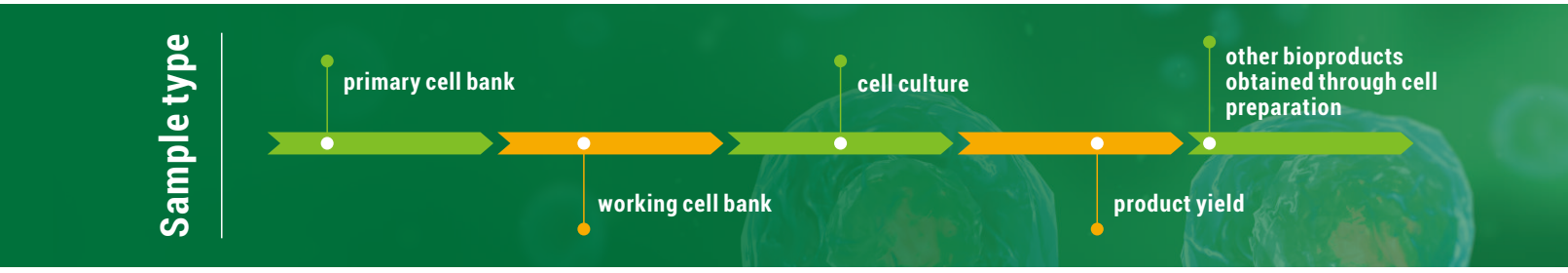
Nucleic Acid Extraction Kit (Magnetic Bead Method)

* This series of kits has undergone comprehensive method validation in accordance with relevant regulations, guidelines, and other documents. Performance validation reports can be provided upon request.



Mycoplasma DNA Detection Kit

Traditional methods for detecting Mycoplasma require at least 28 days of cultivation to reach a conclusion, which is time-consuming. The EP guidelines state that if the sensitivity of NAT (Nucleic Acid Testing) can achieve the same level as the classical cultivation method, while maintaining good robustness and specificity, NAT can be used as an alternative to classical cultivation for Mycoplasma testing. The qPCR (quantitative Polymerase Chain Reaction) assay kit provides a very fast and user-friendly solution, suitable for Mycoplasma control in laboratories or production lines.



Product Advantages

Simple Operation

Single-tube PCR reagents allow the direct addition of extracted nucleic acid into the PCR reaction without the need for multiple component mixing; 2 lsample can also Be taken for direct amplification.

Rapid Detection

Short testing time, with the entire test completed within 1.5 hours.

Internal QC System

Introduction of internal quality control (internal standard) and positive controls (PC) effectively prevents the occurrence of false-negative and false-positive results, thereby improving the quality of the testing.

Prevention of Contamination

The UDG (Uracil-DNA Glycosylase) enzyme contamination prevention system is adopted to effectively prevent amplification product contamination.

High Sensitivity

The detection limit reaches 5 CFU/mL, fully complying with the requirements of EP 2.6.7 regulations.

Strong Applicability

Compatible with multiple PCR instruments, no additional equipment required. It has been validated with various matrix sample types, and different sample matrices do not affect the detection sensitivity. It is especially suitable for high-concentration cell samples.

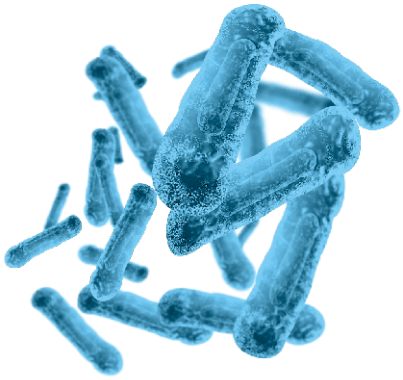
Excellent Specificity

The optimized TaqMan probe targeting the 16S rRNA gene of over 100 Mycoplasma species exhibits high specificity. It has been validated against more than 30 structurally similar organisms and commonly used cell lines, demonstrating no cross-reactivity with the Mycoplasma detection reagents.

Mycobacterium DNA Detection Kit

The conventional method for Mycobacterium testing is through cultivation, which is time-consuming and cannot meet the testing requirements for short-shelf-life bioproducts. Multiple countries have recommended the development of rapid microbiological testing methods to replace traditional cultivation methods and have issued corresponding guidelines.

This detection kit is based on fluorescent quantitative PCR method. It is designed with primers and probes targeting conserved sequences of Mycobacterium for qualitative detection of Mycobacterium DNA in various bioproducts and pharmaceutical intermediates, semi-finished products, and finished products. This kit, used in conjunction with Biori nucleic acid extraction or purification kits, can detect Mycobacterium as low as 10 CFU in as fast as 1.5 hours.



Product Advantages

Simple Operation

Single-tube PCR reagents allow the direct addition of extracted nucleic acid into the PCR reaction without the need for multiple component mixing.

Rapid Detection

Short testing time, with the entire test completed in as fast as 1.5 hours.

Internal QC System

The introduction of internal quality control (internal standard) allows monitoring of the entire process of extraction and amplification, thereby improving the quality of the testing.

Prevention of Contamination

The UDG (Uracil-DNA Glycosylase) enzyme contamination prevention system is adopted to effectively prevent amplification product contamination.

High Sensitivity

The detection limit is as low as 10 CFU.

Strong Applicability

Compatible with multiple PCR instruments, no additional equipment required.

Excellent Specificity

Covers nearly 200 species of Mycobacterium, exhibiting high specificity and inclusiveness. It shows no cross-reactivity with more than 30 bacteria, fungi, and commonly used cell lines such as Escherichia coli, Bacillus subtilis, and VERO.

Professional

We strictly follow the pharmacopoeial requirements for performance validation and can provide a complete set of performance evaluation data.

CHO Residual DNA Detection Kit

This testing kit is based on fluorescent quantitative PCR method. It is designed with primers and probes targeting the conserved sequences of CHO (Chinese hamster ovary) cells. It is used in combination with ready-to-use quantitative reference standards for the quantitative detection of residual CHO cell DNA in various bioproducts, pharmaceutical intermediates, and finished products.

This kit is used in conjunction with Biori nucleic acid extraction or purification kits, and it can detect fg-level (femtogram) residual CHO cell DNA in as fast as 1.5 hours.

Product Advantages

Biori CHO residual DNA detection kit (PCR-fluorescent probe method) has advantages such as high sensitivity, simple operation, and good precision. It assists in the quality control of bioproducts.

Simple Operation

Single-tube PCR reagents allow the direct addition of extracted nucleic acid into the PCR reaction without the need for multiple component mixing, making it convenient and fast.

Rapid Detection

Short testing time, with the entire test completed in as fast as 1.5 hours.

Internal QC System

The introduction of internal quality control (internal standard) allows monitoring of the entire process of extraction and amplification, thereby improving the quality of the testing.

Prevention of Contamination

The adoption of UDG (Uracil-DNA Glycosylase) contamination prevention system effectively prevents amplification product contamination.

High Precision and Sensitivity

The coefficient of variation (CV) for 0.5 fg/μL is less than 20%, and for the mid to high range, the CV is less than 10%. The quantification limit is 0.5 fg/μL, and the detection limit is 0.125 fg/μL.

Strong Applicability

Compatible with multiple PCR instruments, no additional equipment required.

Excellent Specificity

No cross-reactivity observed with SP2/0 cells, VERO cells, Escherichia coli, Salmonella, hybridoma cells, Mycoplasma, and human genomic DNA.

Professional

We strictly conduct performance validation in accordance with pharmacopoeial requirements and can provide a complete set of performance evaluation data.

E.coli Residual DNA Detection Kit

The detection kit is based on fluorescent quantitative PCR method. It is designed with primers and probes targeting the conserved sequences of the E. coli genome. It is used in combination with ready-to-use E. coli DNA quantitative reference standards, establishing a rapid and highly sensitive real-time fluorescent quantitative PCR assay. It is used for the quantitative detection of E. coli host cell DNA in various bioproducts, pharmaceutical intermediates, and finished products.

This kit is used in conjunction with Biori nucleic acid extraction or purification kits, and it can detect fg-level (femtogram) residual E. coli DNA in as fast as 1.5 hours.

Product Advantages

Biori E.coli residual DNA detection kit (PCR-fluorescent probe method) has advantages such as high sensitivity, simple operation, and good precision, assisting in the quality control of biopharmaceutical products.

Simple Operation

Calibrators do not need to be diluted, and the finished products are assembled quickly and easily.

Convenient and Fast

It is easy to use for single-tube PCR reagent;
3-step operation to complete the PCR acid extraction.

Internal QC System

The introduction of internal quality control (internal standard) allows monitoring of the entire process of extraction and amplification, thereby improving the quality of the testing.

Prevention of Contamination

The adoption of UDG (Uracil-DNA Glycosylase) contamination prevention system effectively prevents amplification product contamination.

High Precision

The CV for 5 fg/μL is less than 20%, and for the mid to high range, the CV is less than 15%.

High Sensitivity

The detection limit can reach 1 fg/μL, and the quantification limit can reach 5 fg/μL, comparable to international leading standards.

Excellent Specificity

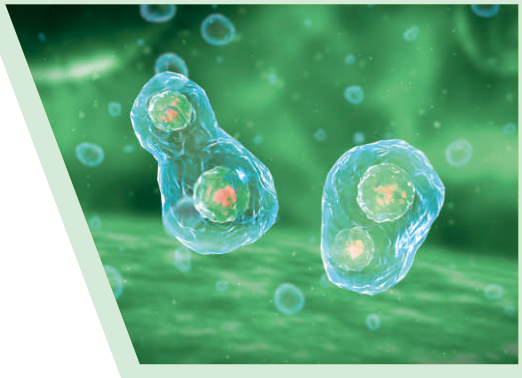
There is no cross-reactivity observed with common pathogens such as Lactobacillus acidophilus, Propionibacterium, HEK293, MDCK, BHK21, Vero, CHO, Bacillus, and human genomic DNA in the environment. It also does not produce any interference.

Professional

We strictly conduct performance validation in accordance with pharmacopoeial requirements and can provide a complete set of performance evaluation data.

Vero Residual DNA Detection Kit

This assay kit is based on fluorescence quantitative PCR method, designed with primers and probes targeting the conserved sequence of Vero cells. It is used in conjunction with ready-to-use Vero DNA quantification reference standards to quantitatively detect residual Vero cell DNA in various biopharmaceutical products at different stages of production. This assay kit is compatible with the nucleic acid extraction or purification kits provided by Biori, and it can detect fg-level residual Vero cell DNA in as fast as 1.5 hours.



Product Advantages

Biori's Vero Residual DNA Detection Kit (PCR-Fluorescent Probe Method) offers advantages such as high sensitivity, simple operation, and good precision, which is helpful for quality control of biopharmaceutical products.

Simple Operation

Calibration standards do not require dilution or assembly of the final product, making it convenient and quick. Single-tube detection allows for a short testing time, with the entire process completed in as fast as 1.5 hours. PCR reagents are convenient to use and easily accessible.

Rapid Detection

The testing time is short, and the entire process can be completed in as fast as 1.5 hours.

Internal QC System

The introduction of internal quality control (internal standard) allows for monitoring of the entire extraction and amplification process, ensuring high-quality detection.

Prevention of Contamination

The adoption of UDG (Uracil-DNA Glycosylase) contamination prevention system effectively prevents amplification product contamination. UDG is an enzyme that degrades uracil-containing DNA, including any potential carryover contamination from previous PCR reactions, minimizing the risk of false-positive results and ensuring accurate detection.

Precision and Sensitivity

The coefficient of variation (CV) for 0.3fg/μL is less than 20%, and for the medium to high values, it is less than 15%. The quantification limit is 0.3fg/μL. The detection limit is even lower at 0.03fg/μL.

Strong Applicability

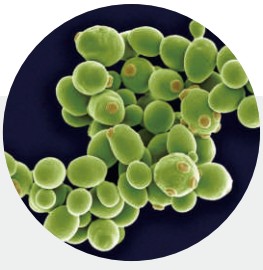
Compatible with multiple PCR instruments, no additional equipment needed.

Excellent Specificity

No cross-reactivity with SP2/0, CHO, HEK293, MDCK, BHK-21, hybridoma, human cells, and Bacillus subtilis.

Professional

We strictly conduct performance validation in accordance with pharmacopoeial requirements and can provide a complete set of performance evaluation data.



Pichia Pastoris Residual DNA Detection Kit

This kit is based on fluorescence quantitative PCR method. It is designed with primers and probes targeting the conserved sequences of Pichia pastoris. It is used in combination with ready-to-use quantitative reference standards for the quantitative detection of residual Pichia pastoris DNA in various biological and pharmaceutical products, including intermediates, semi-finished products, and finished products. It is compatible with the use of Biori nucleic acid extraction or purification kit II, and it can detect Pichia pastoris DNA residues at the fg level in as fast as 100 minutes.

Product Advantages

Biori's Pichia pastoris residual DNA detection kit (PCR-fluorescent probe method) has the advantages of high sensitivity, simple operation, and good precision, which contribute to the quality control of biopharmaceutical products.

Simple Operation

The one-tube PCR reagent is easy to use, allowing for convenient handling. The calibration standard does not require dilution, and the final product assembly is also convenient and quick.

Rapid Detection

The detection time is short, and the entire testing process can be completed in as fast as 100 minutes.

Internal QC System

By introducing internal quality control (internal standard), the extraction and amplification processes are monitored, thereby enhancing the overall testing quality.

Prevention of Contamination

The UDG contamination prevention system is used, which effectively prevents contamination from amplification products.

Precision and Sensitivity

Cv＜20% for 5fg/μL, CV＜15% for intermediate and high values; Quantification limit up to 5fg/μL, detection limit down to 2.5fg/μL.

Strong Applicability

Compatible with multiple PCR instruments, no additional equipment required.

Excellent Specificity

No cross-reactivity observed with BHK-21 cells, MDCK cells, HEK293 cells, SP2/0 cells, CHO cells, VERO cells, mycoplasma, and human genome.

Professional

We strictly conduct performance validation in accordance with pharmacopoeial requirements and can provide a complete set of performance evaluation data.

HEK293 Residual DNA Detection Kit

This kit is based on the fluorescence quantitative PCR method. It is designed with primers and probes targeting the conserved sequences of the HEK293 genome. With the included ready-to-use HEK293 DNA quantification reference, it establishes a fast and highly sensitive real-time fluorescence quantitative PCR assay. This kit is used for quantitative detection of HEK293 host cell DNA in intermediate, semi-finished, and finished products during the development of gene therapies, cell vaccines, and similar biopharmaceuticals. When used in conjunction with the Biori nucleic acid extraction or purification kit, it can detect residual HEK293 DNA at the fg level in as fast as 1.5 hours.

Product Advantages »»

The Biori HEK293 residual DNA detection kit (PCR-fluorescence probe method) offers several advantages such as excellent stability, simple operation, and high precision. It aids in the quality control of biopharmaceutical products.

Simple Operation

Ready-to-use calibration standards are provided, allowing for easy assembly without the need for dilution. They can be used directly as needed.

Convenient and Fast

Extraction only requires three steps, while amplification in a single tube is done in one step, making it convenient and easy to use.

Rapid Detection

The entire detection process can be completed in as fast as 1.5 hours.

Sensitivity

The CV for a concentration of 30fg/μL is less than 20%, and the CV for the mid-to-high range values is less than 15%.

Prevention of Contamination

The assay kit utilizes the UDG enzyme contamination prevention system, which effectively prevents contamination from amplification products.

Internal QC System

Internal quality control (internal standard) is introduced to monitor the entire process of extraction and amplification, ensuring improved testing quality.

Professional

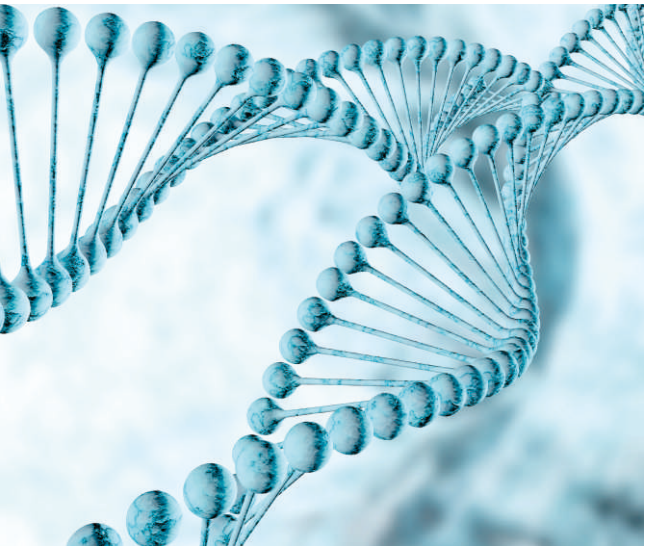
We strictly conduct performance validation in accordance with pharmacopoeial requirements and can provide a complete set of performance evaluation data.

Stable Result

The components of the assay kit are stable and reliable, ensuring good reproducibility of results.

Excellent Specificity

There is no cross-reactivity or interference observed with various microorganisms including Lactobacillus acidophilus, Streptococcus pneumoniae, E. coli, Staphylococcus aureus, Bacillus subtilis, CHO cells, BHK21 cells, and Pseudomonas aeruginosa.



NS0&SP2/0 Residual DNA Detection Kit

This kit is based on fluorescent quantitative PCR method, with primers and probes designed for the conserved sequences of NS0&SP2/0 cells. It is accompanied by ready-to-use quantitative reference standards and is used for quantifying the residual NS0&SP2/0 DNA in various biopharmaceutical products, including intermediates, semi-finished products, and finished products. When used in conjunction with Biori's nucleic acid extraction or purification kits, it can detect fg-level NS0&SP2/0 DNA residues in as fast as 90 minutes.

Product Advantages

The Biori NS0&SP2/0 Residual DNA Detection Kit (PCR-fluorescent probe method) offers advantages such as high sensitivity, easy operation, and good precision. It helps in the quality control of biopharmaceutical products.

Simple Operattion

One-tube PCR reagents are convenient to use, and the calibration solution does not require dilution. The kit is designed for easy and quick assembly of the final product, providing a convenient and efficient workflow.

Rapid Detection

The detection time is short, and the entire testing process can be completed in as fast as 90 minutes.

Internal QC System

The internal quality control (internal standard) is introduced to monitor the entire process of extraction and amplification, thereby improving the quality of the detection.

Prevention of Contamination

The UDG contamination prevention system is adopted to effectively prevent contamination from amplification products.

Precision and Sensitivity

Cv＜20% for 1.5fg/μL, CV＜15% for intermediate to high values; Quantification limit of 1.5fg/μL, detection limit of 0.3fg/μL.

High Applicability

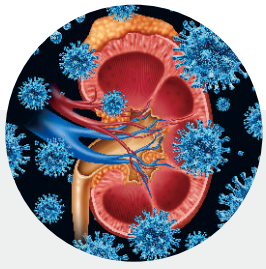
Compatible with multiple PCR instruments, no additional equipment required.

Excellent Specificity

No cross-reactivity observed with MDCK cells, CHO cells, VERO cells, human genome, HEK293 cells, BHK-21 cells, Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus, and Mycoplasma.

Professional

We strictly conduct performance validation in accordance with pharmacopoeial requirements and can provide a complete set of performance evaluation data.



Human Residual DNA Detection Kit

This kit is based on fluorescence quantitative PCR method. It is designed with primers and probes targeting the conserved sequences of the human host cell genome. It is accompanied by a ready-to-use Human DNA quantification reference standard. This kit establishes a fast and highly sensitive real-time fluorescence quantitative PCR assay for the quantitative detection of residual human host cell DNA in various bioproducts, including intermediate, semi-finished, and finished products. The kit can be used in conjunction with the nucleic acid extraction or purification kits from Biori Reagents. The detection time for fg-level human host cell DNA is as fast as 1.5 hours.

Product Advantages »»

The Biori Human Residual DNA Detection Kit (PCR-Fluorescence Probe Method) offers several advantages, including excellent stability, simple operation, and high precision. It is designed to assist in the quality control of biopharmaceutical products.

Simple Operation

Ready-to-use calibration standards, convenient product assembly, no need for dilution, and can be used immediately as needed.

Rapid Detection

The entire testing can be completed in as fast as 1.5 hours.

Internal QC System

The internal quality control (internal standard) is introduced to monitor the entire process of extraction and amplification, thereby improving the quality of the detection.

Prevention of Contamination

The UDG contamination prevention system is adopted to effectively prevent contamination from amplification products.

Convenient and Rapid

Extraction only requires three steps; single-tube amplification only requires one step, making it convenient to use.

Precision

The CV for samples of different concentrations is less than 15%.

Excellent Specificity

Does not cross-react with Streptococcus pneumoniae, E. coli, CHO cells, BHK21 cells, Staphylococcus aureus, Bacillus subtilis, Lactobacillus acidophilus, Pseudomonas aeruginosa, or any other organisms, nor does it produce any interference.

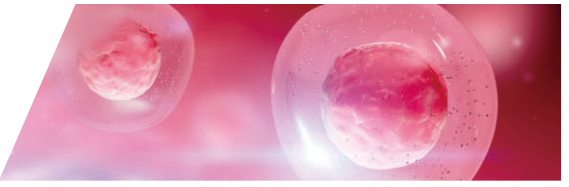
Stable Result

The components of the reagent kit are stable and reliable, providing excellent reproducibility of results.

Professional

We strictly conduct performance validation in accordance with pharmacopoeial requirements and can provide a complete set of performance evaluation data.

Hela Residual DNA Detection Kit



This kit is based on the fluorescence quantitative PCR method. It is designed with primers and probes targeting conserved sequences in the Hela cell genome. Together with a ready-to-use Hela cell DNA quantification reference standard, it establishes a rapid and highly sensitive real-time fluorescence quantitative PCR reagent kit. It is used for the quantitative detection of residual Hela cell DNA in various biological products, including intermediates, semi-finished products, and finished products. This reagent kit is compatible with the Biori nucleic acid extraction or purification reagent kit, enabling the detection of Hela cell host DNA at the femtogram level within a minimum of 1.5 hours.

Product Advantages

The Biori Hela Cell Residual DNA Detection Kit (PCR-Fluorescent Probe Method) offers several advantages, including good stability, easy operation, and excellent precision. It aids in quality control of biopharmaceutical products.

Simple Operation

Ready-to-use calibration standards, convenient product assembly, no need for dilution, and can be used immediately as needed.

Convenient and Rapid

Extraction only requires three steps, and single-tube amplification only requires one step, making it convenient to use.

Rapid Detection

The entire testing process can be completed in as little as 1.5 hours.

Precision

The CV for samples of different concentrations is consistently less than 15%.

Prevention of Contamination

By implementing the UDG enzyme contamination prevention system, it effectively prevents contamination of amplification products.

Internal QC System

The internal quality control (internal standard) is introduced to monitor the entire process of extraction and amplification, thereby improving the quality of the detection.

Excellent Specificity

There is no cross-reactivity with bacteria such as Lactobacillus acidophilus, Streptococcus pneumoniae, E. coli, Staphylococcus aureus, Bacillus subtilis, CHO cells, BHK21 cells, Pseudomonas aeruginosa, or any other organisms. Additionally, it does not produce any interference.

Stable Result

The reagent kit components are stable and reliable. This stability and reliability contribute to the excellent reproducibility of results.

Professional

We strictly conduct performance validation in accordance with pharmacopoeial requirements and can provide a complete set of performance evaluation data.

Magnetic Bead Method
Nucleic Acid Extraction And Purification Kit

Product principle »»

Utilize guanidine isothiocyanate to denature proteins, utilize proteinase K for protein degradation and digestion, and use a detergent to wash away impurities. Subsequently, employ the principle of nanoscale magnetic beads to adsorb nucleic acids. Through specialized magnetic rods, the magnetic beads are adsorbed, transferred, and released, enabling the extraction, enrichment, and purification of nucleic acids. The purified nucleic acids can be directly used for downstream nucleic acid detection.

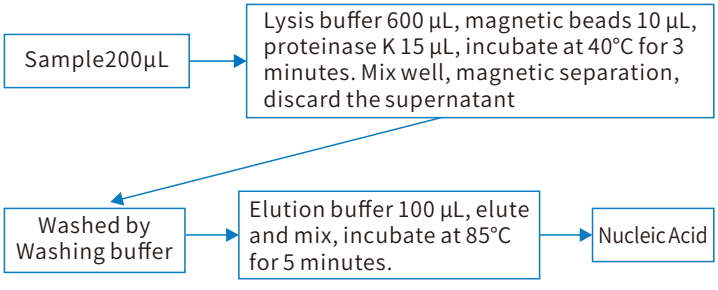
Product Applications »»

This product is used for the extraction, enrichment, and purification of nucleic acids from swabs, saliva, and various biological samples. The resulting nucleic acids can be used for routine molecular detection. It is compatible with high-throughput magnetic rod-based nucleic acid extraction instruments.

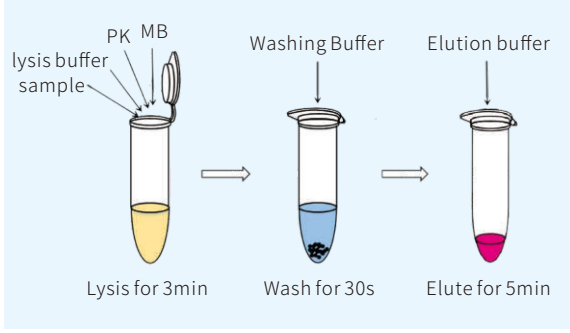
- The product provides a high yield of extracted nucleic acids with high purity, making it suitable for a wide range of applications, including quality control of biopharmaceuticals and disease detection.
- The reagent kit eliminates the need for the addition of volatile alcohols, ensuring a safer and more stable performance.

Product Components »»

The nucleic acid extraction and purification kit (magnetic bead method) consists of three components: magnetic bead suspension solution, lysis buffer, and proteinase K, as well as wash buffer and elution buffer. This composition allows for a simpler operation while ensuring a higher yield of nucleic acids.



● Steps for nucleic acid extraction



● Illustration of nucleic acid extraction

Product Advantages

Nucleic acid extraction can be completed with just three steps: lysis, washing, and elution, all performed at room temperature.

Easy to Operate

Intelligent extraction

Combined with a nucleic acid extraction instrument, it enables automated and high-throughput operations.

All components of the kit can be stored at room temperature.

Easy to Store

Hhigh recovery rate

The binding between the free magnetic beads and nucleic acids is stronger, resulting in higher specificity and purity of the extracted nucleic acids. Additionally, this leads to a higher recovery rate of nucleic acid extraction.

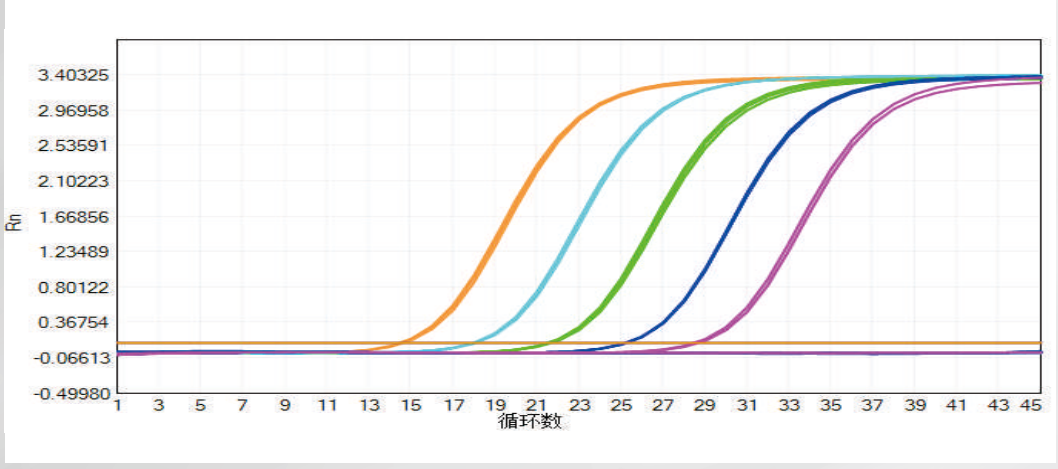
Nucleic acid extraction can be achieved within 10 minutes for a single batch.

Fast extraction

Safe and environ mentally friendly

Safe and Non-toxic:
The reagents do not contain toxic chemicals such as phenol or chloroform, fully aligning with modern environmental standards.

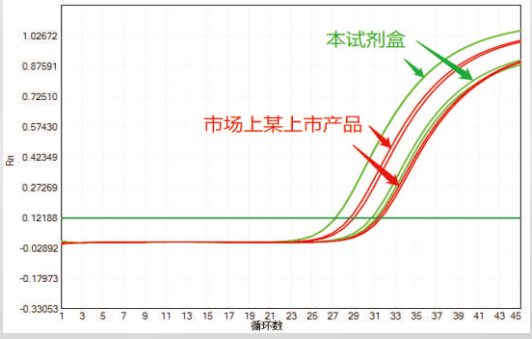
Low Sample Requirement:
Only a small amount of material is required to obtain a high concentration of nucleic acids.



▼ Good precision and linearity

Sample	Company A	Biori
Sample 1	31.58	30.69
Sample 1	31.33	31.14
Sample 2	29.02	27.22
Sample 2	28.60	27.24

▲ Comparing the results with commercially available products from Company A



Founded in March 2021, Zhuhai Biotech Instrumentation Co., Ltd. is an automation life science instrument and equipment supplier. The company has an experienced R&D team and has filed seven relevant product patents to date.

Biotech Instrumentation is strategically positioned in the fields of molecular diagnostics, immunology, and scientific instruments. With a proactive and innovative approach and a commitment to integrity and responsibility, Biotech Instrumentation is dedicated to providing high-quality product solutions to its customers and aims to be a leader in the Chinese manufacturing industry.

BTE-32 Automatic Nucleic Acid Extractor

Preprocessing system

Combining with Biori's magnetic bead nucleic acid extraction and purification kit, it assists in ensuring the quality and safety control of bioproducts.

Efficient operation

Nucleic acid extraction for 1-32 samples can be completed in as fast as 10 minutes, with a magnetic bead recovery rate of ⩾98%. The recovery rate can range from 70% to 130%.

Easy to use

Simplified operation steps with user-friendly function settings and detachable magnetic rods make it easier for maintenance and replacement, thus extending the instrument's lifespan.

High compatibility

Supports multiple nucleic acid extraction and purification reagents, and the program is programmable to be compatible with a variety of Biori's test kits for cell residual DNA, mycoplasma, and bacterial contamination, among others.

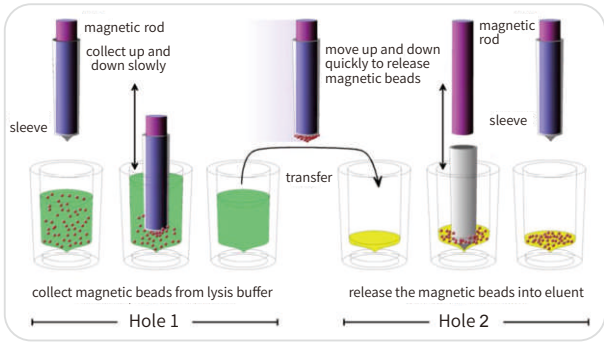
Stable resistance to contamination

Automatic lighting control for intelligent matching of disinfection/extraction status.
Intelligent negative pressure system to reduce the risk of cross-contamination.
Improve disinfection efficiency, and eliminate the occurrence of contamination.

BTE -32 Technical Principle / Device Parameters

Biori's fully automated nucleic acid extraction instrument utilizes magnetic bead separation technology. In this method, the magnetic beads are transferred between deep-well plates containing specific reagents. A disposable mixing sleeve is loaded onto the magnetic rod, and through the closing and separation of the magnetic rod and the mixing sleeve, the collection, release, and transfer of the magnetic beads are achieved.

By the specific recognition and efficient binding between the magnetic beads and nucleic acid molecules, combined with the outstanding performance of Biori's nucleic acid extraction and purification reagents, high-quality trace amounts of nucleic acid can be extracted from biological products. It can be well adapted to various detection kits, such as residual cell DNA, mycoplasma, and divergent bacteria, assisting in the quality control of biopharmaceutical products.



Schematic diagram of the technology principle

BTE-32 Technical Specifications	
Specifications	Parameter
Sample throughput	1~32
Process volume	20~1000μL
Bead recovery rate	⩾98%
Inter-pore uniformity	CV<3%
Rate of recovery	70%-130%
Extraction capacity	Class fg
Compatibility	Suitable for a variety of magnetic bead method nucleic acid extraction and purification reagents
Program management	Create, edit, save, delete, and more
Pollution control	Exhaust ventilate, ultraviolet disinfection function, self-cleaning
Consumables	Standard 96 deep-well plates and 8-link magnetic rod sleeves
Maximum output power	350W
Data storage	Built-in SD card; 255 groups of programs can be stored
Size(mm)	360×382×480
Weight	⩽20kg

Product Components

The magnetic bead-based nucleic acid extraction and purification kit consists of three components: magnetic bead suspension buffer, lysis buffer, and proteinase K, washing solution, and elution buffer. These components are designed to simplify the operation while ensuring higher nucleic acid yield.

* Please see related products on PAGE-24.

Nucleic acid extraction and purification reagent kit I

Nucleic acid extraction and purification reagent kit II

BTE-8 Automatic Nucleic Acid Extractor

NEW

High-efficiency operation
Operating 1-8 samples flexibly
Rotary mix, efficient and mute

Convenient operation
The consumables compartment ejects automatically

Hardcore system
High precision & high efficiency temperature control
80μl-3200μl huge operating volume

Intelligent design
Operation by one smart knob
Novel vertical design to save space

BTE -8 Technical principle / Equipment parameters

The Biotech BTE-8 8-channel fully automated nucleic acid extraction instrument utilizes magnetic bead separation technology. This method involves transferring magnetic beads between deep well plates containing specific reagents. A disposable mixing sleeve is loaded onto the magnetic rod, and the collection, release, and transfer of the magnetic beads are achieved through the closure and separation of the magnetic rod and the mixing sleeve.

By leveraging the specific recognition and high-efficiency binding between the magnetic beads and nucleic acid molecules, it is compatible with Biotech nucleic acid extraction reagents and Biori fluorescent quantitative PCR amplification reagents. This system enables the extraction of high-quality nucleic acid from various sample types such as saliva, swabs, dried blood spots, whole blood, serum/plasma, and animal/plant tissues. It finds wide applications in clinical disease diagnosis, blood transfusion safety, forensic identification, environmental microbial testing, food safety testing, molecular biology research, and other fields.

BTE-8 Technical Specifications	
Specifications	Parameter
Sample throughput	1~8
Process volume	80μL~1000uL(standard), 1000~3200μL
Product name	Automatic nucleic acid extraction instrument
Code	BTE-8
Inter-pore uniformity	CV＜3%
Rotate speed	Multi-position
Extracting time	8-20mins/time (typical value)
Illuminating system	Internal LED
Sterilization	Ultraviolet ray
Lysis/elution temperature	Room temperature~120°C
Maximum output power	90W
Power input	DC 24V
Size(mm)	170×360×356
Weight	＜7kg

Centrifugal Mixer

CM-8 / CM-8 Plus

Ingenious design

Exquisite appearance
drill-cut design high quality
Patent No.:202130389474.0

Graded locking
Smooth operation
Patent No.:202110698687.0
Small size and portable

Integrated pallet design
Good uniformity between tubes
Stable baseline in PCR

Intelligent actions

Compound knob
Patent No.:202121409450.8
Smart Halo
Easy-to-use with start/stop combo button

Low-noise operation
Polarization shutdown
Automatically operation and reliable

Inductive control
Open cover protection
Patent No.:202121406810.9
Smart and versatile

A new option to improve PCR hands-on efficiency and uniformity between tubes

CM -8 Test Report

Fm5071 lyophilized powder Test:HBV extraction template，75IU/T，8T(25μL)

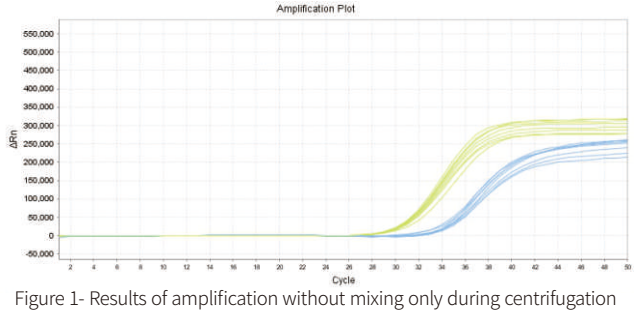


Figure 1- Results of amplification without mixing only during centrifugation

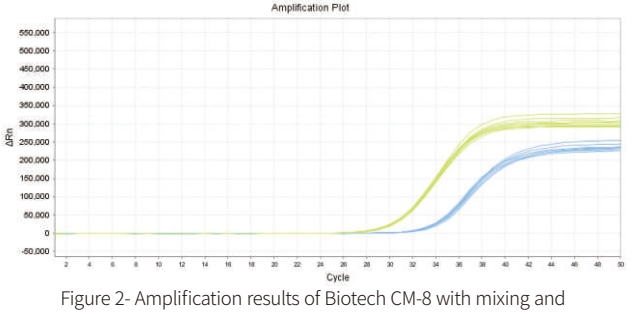


Figure 2- Amplification results of Biotech CM-8 with mixing and centrifugation (10 cycles)

CM-8 Technical Specifications	
Specifications	Parameter
Centrifugation RPM	1500-4000rpm
Minimum Speed Regulation	100rpm
Operating mode	Centrifugal and mix
Mixing Intensity Level	Strong, medium and soft
Rotor Capacity	8-strip tubes
Lock Mode of Rotor	Quick-release knob
Lock Force	Multilevel adjustment
Procedural memory	Yes
Program Cycle	1-999
Open cover protection	Induction Type
Abnormal vibration Halting	Yes
Input	AC 100～240V, 1.4A, 50/60HZ
Maximum input power	60W
Size(mm)	218mm×234mm×136mm
Weight	≦1.5kg

CM-8 Plus Technical Specifications	
Specifications	Parameter
Centrifugation RPM	1500-4000rpm
Minimum Speed Regulation	100rpm
Operating mode	Centrifugal, mix, Centrifugal and mix
Mixing Intensity Level	Strong, medium and soft
Rotor Capacity	8-strip tubes, 1.5/2mL Centrifuge tube
Lock Mode of Rotor	Quick-release knob
Lock Force	Multilevel adjustment
Procedural memory	Yes
Program Cycle	1-999
Open cover protection	Induction Type
Abnormal vibration Halting	Yes
Input	AC 100～240V, 1.4A, 50/60HZ
Maximum input power	60W
Size(mm)	218mm×234mm×136mm
Weight	≦1.5kg

PCR Raw Materials

Stable Accurate Fast

- Hot-start Taq Polymerase • Premix
- MMLV • Tth • UNG • dNTP
- Acetylated BSA
- Single Chain Binding Protein

Isothermal amplification

Hot Start Version Lyophilized

- LAMP
- RT-LAMP

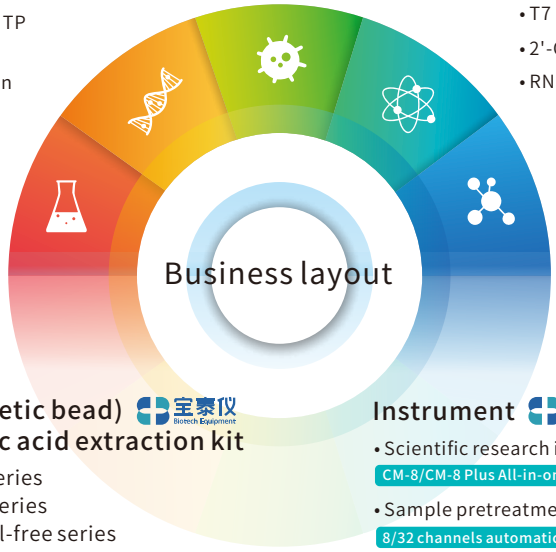
mRNA Medicine Raw Material Enzyme NEW

- T7 RNA Polymerase • Vaccinia Capping Enzyme
- 2'-O-Methyltransferase • E.coli Poly(A) Polymerase
- RNase R

Molecular diagnostic POCT raw materials

Lyophilized Fast Resistance to inhibitor
Compatible with UNG+dUTP

- Lyophilized enzyme
- Premix
- Direct, fast PCR raw materials



Quality and safety control of biological products NEW

Simple operation Fast detection
High sensitivity Good repeatability

- CHO • *E.coli* • Vero • HEK293
- Mycoplasma • Pichia
- Automatic extraction instrument and reagent

(magnetic bead) Nucleic acid extraction kit

- Virus series
- Swab series
- Alcohol-free series
- Free Nucleic Acid Extraction

Instrument

- Scientific research instrument

CM-8/CM-8 Plus All-in-one Centrifugal Mixer

- Sample pretreatment

8/32 channels automatic nucleic acid extractor
Disposable virus sampling tube

Enterprise vision

Create excellence, Guard Life

Enterprise values

Honest and responsible,
enterprising and innovative

Official website

LinkedIn

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