BIORI BIOTECH

BIOLOGICAL PRODUCTS

QUALITY CONTROL ANALYSIS

IMPURITIES AND SAFETY

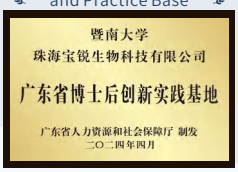
PURSUING EXCELLENCE IN QUALITY
PROVIDING PROMPT AND THOROUGH SERVICE

CORPORATE HONORS ACCREDITATIONS

ational Level Specialized, Refined, Differentiated, and Innovative Little Giant Enterprise

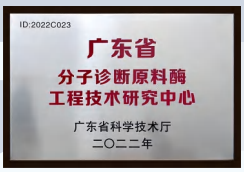
National High-Tech Enterprise

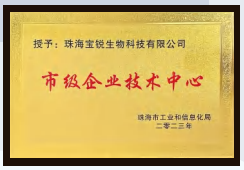
Postdoctoral Innovation and Practice Base



ISO 13485:2016

ISO 9001:2015

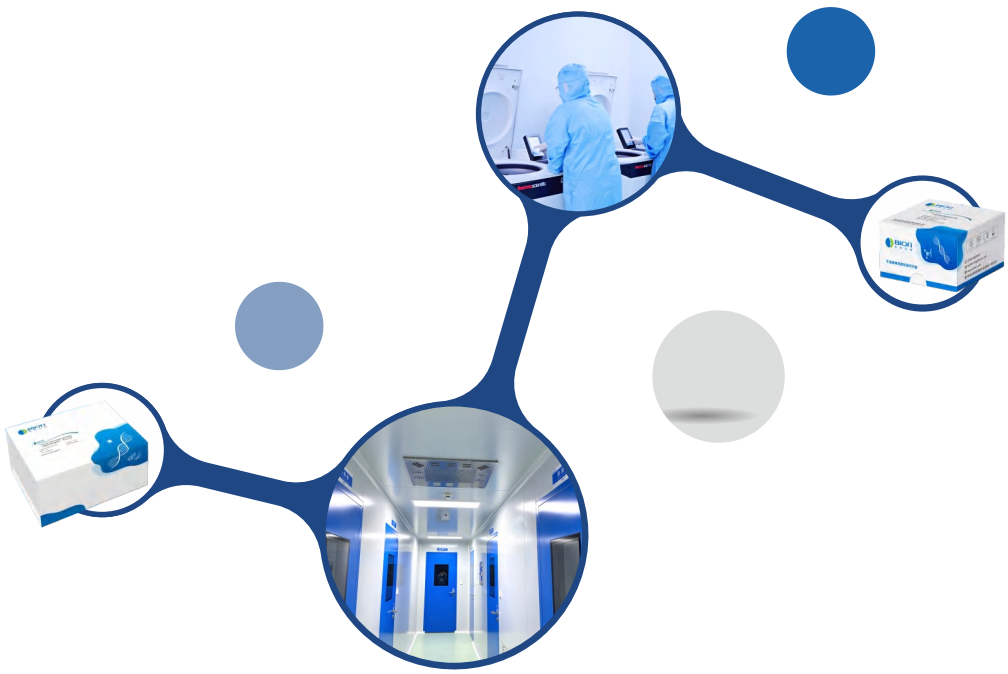




Molecular Diagnostic Raw Materials Technology Center of Guangdong Province

Municipal Enterprise Technology Center

COMPANY PROFILE



Zhuhai Biori Biotechnology Co.,Ltd

Founded in 2012, Zhuhai Biori Biotechnology Co., Ltd. provides biological raw materials and reagent solutions for life science research, in vitro diagnostics (IVD), and biopharmaceutical applications. The company builds on established capabilities in protein engineering, recombinant expression, process development, and application-focused research to support both research and industrial customers worldwide.

Biori operates under ISO 13485 and ISO 9001 certified quality management systems and maintains GMP and GMP-grade manufacturing facilities to ensure consistent quality and reliable supply. With a long-term focus on innovation and quality, Biori aims to support customer success, foster sustainable team growth, and contribute to the advancement of life science and healthcare technologies.

Web：www.biori.com

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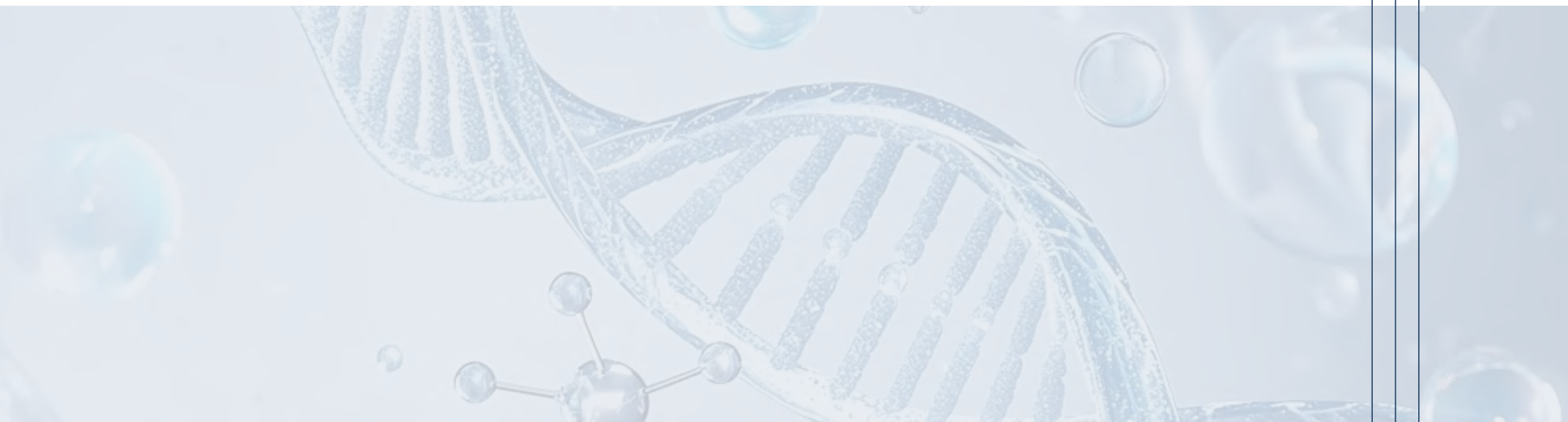


Cell & Gene Therapy

Plasmid Stage

ELISA (One-Step Method)

- *E.coli* Host Cell Protein ELISA Kit

PCR (Fluorescent Probe Method)

- *E.coli* Residual Host Cell DNA Detection Kit
- *E.coli* Total Residual RNA Detection Kit
- Plasmid DNA (Kanamycin Resistance Gene) Residual Detection Kit
- Plasmid DNA Residual Detection Kit

PCR (Fluorescent Probe Method)

- Mycoplasma DNA Detection Kit
- Spiroplasma DNA Detection Kit
- Fungal DNA Detection Kit
- Bacterial DNA Detection Kit
- Mycobacterium DNA Detection Kit

- BR-32PH Automated Nucleic Acid Extraction System

Viral Vector Stage

ELISA (One-Step Method)

- HEK293 Host Cell Protein ELISA Kit

PCR (Fluorescent Probe Method)

- HEK293 Residual Host Cell DNA Detection Kit
- HEK293 Residual Host Cell DNA Fragment Analysis Kit
- HEK293 Total Residual RNA Detection Kit
- E1A Residual DNA Detection Kit
- E1A & SV40LTA Residual DNA Detection Kit
- RCR Gene Copy Number Detection Kit
- RCL Gene Copy Number Detection Kit

PCR (Fluorescent Probe Method)

- Hansenula (Pichia) Residual Host Cell DNA Detection Kit
- HeLa Residual Host Cell DNA Detection Kit
- HeLa Residual Host Cell DNA Fragment Analysis Kit
- HeLa Total Residual RNA Detection Kit
- HPV18 E6/E7 Residual DNA Fragment Analysis Kit
- Human Residual Host Cell DNA Detection Kit
- Human Residual Host Cell DNA Fragment Analysis Kit
- Human Total Residual RNA Detection Kit

Cell Stage

qPCR (Fluorescent Probe Method)

- Sf Rhabdovirus Nucleic Acid Detection Kit
- Sf9 & AcNPV Residual DNA Detection Kit
- Hi5 & AcNPV Residual DNA Detection Kit
- E1B Residual DNA Detection Kit
- rcAAV-2/N Detection Kit
- rcAAV-5/N Detection Kit

ELISA

- BSA ELISA Kit

qPCR (Fluorescent Probe Method)

- Mycoplasma DNA Detection Kit
- Spiroplasma DNA Detection Kit
- Fungal DNA Detection Kit
- Bacterial DNA Detection Kit
- Mycobacterium DNA Detection Kit

- BR-32PH Automated Nucleic Acid Extraction System

qPCR (Fluorescent Probe Method)

- CAR/TCR Gene Copy Number Detection Kit

qPCR (Fluorescent Probe Method)

- Bovine Viral Panel (BVDV/REO3/BPIV3/BPV3/BAV3) Nucleic Acid Detection Kit
- Porcine Parvovirus (PPV) Nucleic Acid Detection Kit
- Torque Teno Sus Virus (TTSuV) Nucleic Acid Detection Kit
- Porcine Circovirus (PCV) Nucleic Acid Detection Kit
- Mouse Minute Virus (MMV) Detection Kit
- Mouse Adenovirus (MAV) Nucleic Acid Detection Kit
- Pneumonia Virus of Mice (PVM) Nucleic Acid Detection Kit
- Murine Retrovirus (MRV) Nucleic Acid Detection Kit
- Minute Virus of Mice (MVM) Nucleic Acid Detection Kit
- Sendai Virus (SeV) Nucleic Acid Detection Kit
- Lymphocytic Choriomeningitis Virus (LCMV) Nucleic Acid Detection Kit
- EHFV Nucleic Acid Detection Kit

qPCR (Fluorescent Probe Method)

- Reovirus Type 3 (REO-3) Nucleic Acid Detection Kit
- Murine Leukemia Virus (MuLV) Nucleic Acid Detection Kit
- Mouse Minute Virus (MMV) Detection Kit
- Pseudorabies Virus (PRV) Nucleic Acid Detection Kit
- Sindbis Virus (SINV) Nucleic Acid Detection Kit
- Encephalomyocarditis Virus (EMCV) Nucleic Acid Detection Kit
- Porcine Parvovirus (PPV) Nucleic Acid Detection Kit

qPCR (Fluorescent Probe Method)

- Mycoplasma DNA Detection Kit
- Fungal DNA Detection Kit
- Bacterial DNA Detection Kit
- Mycobacterium DNA Detection Kit

- BR-32PH Automated Nucleic Acid Extraction System

Antibodies & Recombinant Proteins

- CHO Host Cell Protein ELISA Kit ELISA (One-Step Method)
- HEK293 Host Cell Protein ELISA Kit ELISA (One-Step Method)
- E.coli Host Cell Protein ELISA Kit ELISA (One-Step Method)
- CHO Residual Host Cell DNA Detection Kit qPCR (Fluorescent Probe Method)
- HEK293 Residual Host Cell DNA Detection Kit qPCR (Fluorescent Probe Method)
- *E.coli* Residual Host Cell DNA Detection Kit qPCR (Fluorescent Probe Method)
- Ns0 & SP2/0 Residual Host Cell DNA Detection Kit qPCR (Fluorescent Probe Method)
- Saccharomyces cerevisiae Residual Host Cell DNA Detection Kit qPCR (Fluorescent Probe Method)
- Hansenula (Pichia) Residual Host Cell DNA Detection Kit qPCR (Fluorescent Probe Method)
- HeLa Residual Host Cell DNA Detection Kit qPCR (Fluorescent Probe Method)
- Human Residual Host Cell DNA Detection Kit qPCR (Fluorescent Probe Method)

- BSA ELISA Kit ELISA
- Protein A ELISA Kit ELISA

qPCR (Fluorescent Probe Method)

- Reovirus Type 3 (REO-3) Nucleic Acid Detection Kit
- Murine Leukemia Virus (MuLV) Nucleic Acid Detection Kit
- Mouse Minute Virus (MMV) Nucleic Acid Detection Kit
- Pseudorabies Virus (PRV) Nucleic Acid Detection Kit
- Sindbis Virus (SINV) Nucleic Acid Detection Kit
- Encephalomyocarditis Virus (EMCV) Nucleic Acid Detection Kit
- Porcine Parvovirus (PPV) Nucleic Acid Detection Kit

» For more products, please visit www.biori-en.com

qPCR (Fluorescent Probe Method)

- Mycoplasma DNA qPCR Detection Kit
- Fungal DNA qPCR Detection Kit
- Bacterial DNA qPCR Detection Kit
- Mycobacterium DNA qPCR Detection Kit

- BR-32PH Automated Nucleic Acid Extraction System

Vaccines

ELISA (One-Step Method)

- MDCK Host Cell Protein ELISA Kit
- CHO Host Cell Protein ELISA Kit

qPCR (Fluorescent Probe Method)

- MDCK Residual Host Cell DNA Detection Kit
- Pichia pastoris Residual Host Cell DNA Detection Kit
- Vero Residual Host Cell DNA Detection Kit
- CHO Residual Host Cell DNA Detection Kit
- Hi5 & AcNPV Residual DNA Detection Kit
- Saccharomyces cerevisiae Residual Host Cell DNA Detection Kit
- Hansenula (Pichia) Residual Host Cell DNA Detection Kit
- Human Residual Host Cell DNA Detection Kit

- BSA ELISA Kit ELISA

qPCR (Fluorescent Probe Method)

- Reovirus Type 3 (REO-3) Nucleic Acid qPCR Detection Kit
- Murine Leukemia Virus (MuLV) Nucleic Acid qPCR Detection Kit
- Mouse Minute Virus (MMV) Nucleic Acid qPCR Detection Kit
- Pseudorabies Virus (PRV) Nucleic Acid qPCR Detection Kit
- Sindbis Virus (SINV) Nucleic Acid qPCR Detection Kit
- Encephalomyocarditis Virus (EMCV) Nucleic Acid qPCR Detection Kit
- Porcine Parvovirus (PPV) Nucleic Acid qPCR Detection Kit

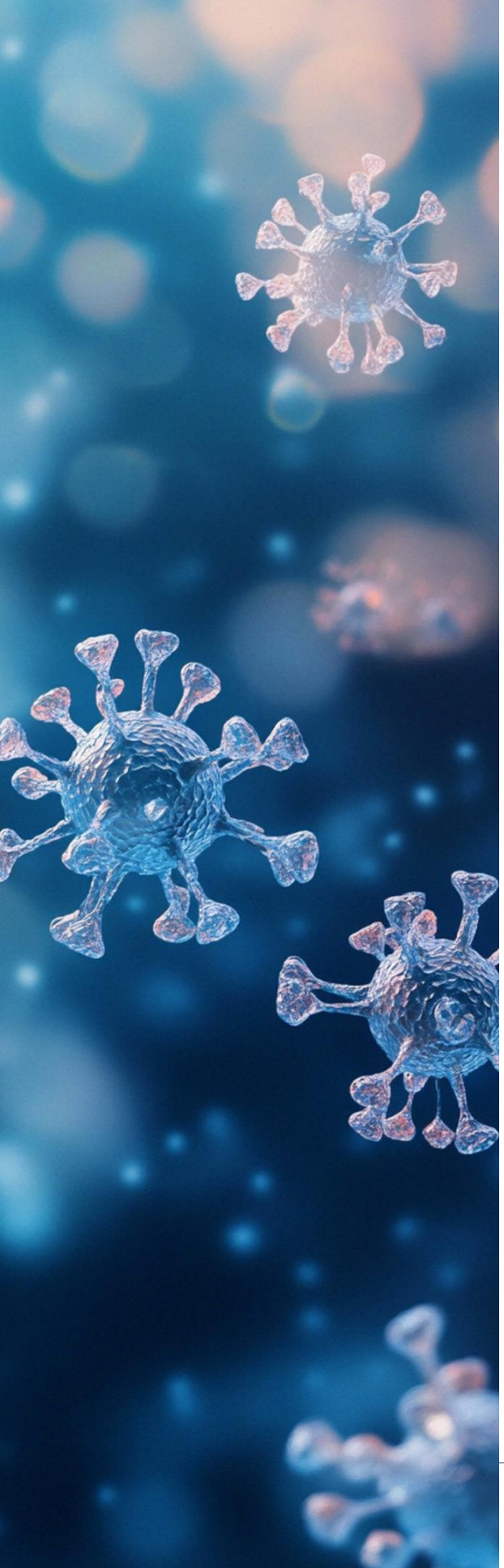
qPCR (Fluorescent Probe Method)

- Mycoplasma DNA qPCR Detection Kit
- Fungal DNA qPCR Detection Kit
- Bacterial DNA qPCR Detection Kit
- Mycobacterium DNA qPCR Detection Kit

- BR-32PH Automated Nucleic Acid Extraction System

mRNA

- E.coli Host Cell Protein ELISA Kit ELISA (One-Step Method)
- E.coli Residual Host Cell DNA Detection Kit qPCR (Fluorescent Probe Method)
- E.coli Total Residual RNA qPCR Detection Kit qPCR (Fluorescent Probe Method)
- RNA Ladder 6000
- RNA ladder 12000
- RNA Ladder 1000
- mRNA Capping Efficiency Pretreatment Kit
- mRNA Capping Efficiency Pretreatment Kit (2.0)
- Poly(A) Tail Length Distribution Pretreatment Kit
- Residual dsRNA Quantification Kit
- Residual RNase Quantification Kit
- Residual DNase Quantification Kit
- T7 RNA Polymerase ELISA Kit ELISA (One-Step Method)
- DNase I ELISA Kit ELISA (One-Step Method)



Adventitious Agent Testing

Mycoplasma Testing

Sterility Testing

Adventitious Virus Testing

- Bovine Virus Testing
- Porcine Virus Testing
- Murine Virus Testing
- Insect Virus Testing

Rapid Testing

Fast turnaround—complete workflow in as little as 1.5 hours

Easy Operation

Single-tube PCR format, no reagent premixing required

Internal Control (IC) System

Built-in internal control (IC) to enhance testing quality and reliability

Contamination Prevention

UDG-based carryover prevention to minimize amplicon

High Performance & Compliance-Ready

Performance verified in accordance with pharmacopeias and regulatory requirements; high sensitivity and robust stability, with complete validation documentation available

Broad Compatibility

Compatible with a wide range of domestic and international qPCR instruments—no additional equipment required

01 Mycoplasma Testing

Mycoplasma DNA qPCR Detection Kit

qPCR (Fluorescent Probe Method)

Cat. No. BP-QN08-50 BP-QN22-50

This kit is based on real-time fluorescent qPCR and targets conserved mycoplasma sequences with optimized primers and probes. When used with Biori' s nucleic acid extraction/purification kits (magnetic bead-based), it enables rapid qualitative detection of mycoplasma in production raw materials, cell banks, viral seeds, viral or cell harvests, and cell therapy products.

Fully validated for limit of detection, specificity, and robustness in compliance with EP 2.6.7 mycoplasma testing requirements. Detects down to 5 CFU/mL (or the equivalent genome copies recommended by relevant guidelines). Coverage includes mycoplasma strains required by USP, JP, WHO, and ChP.

Coverage
Detects 200+ mycoplasma species

Limit of Detection (LoD)
5 CFU/mL

Key Benefits

Precision
Intermediate precision (Ct), CV ⩽ 5%

Specificity
Tested against structural analogs, closely related microorganisms, and commonly used cell lines; no cross-reactivity observed with this mycoplasma qPCR assay.

Kit Performance Summary

Validation Summary and Conclusions for the Mycoplasma qPCR Detection Kit

Performance	Validation Parameter	Results
Limit of Detection (LoD)	LoD with mycoplasma strains	For 10 pharmacopeia-required mycoplasma strains at 5 CFU/mL, 24 replicates were tested per strain; detection rate >95%.
Specificity	Matrix Interference	Tested 8 sample matrices and DNA dilution buffers; no mycoplasma was detected (no interference).
	Cross-reactivity	Tested rDNA from 27 structural analogs, closely related species, and common cell lines; no mycoplasma detected (no cross-reactivity).
Robustness	Freeze–Thaw Stability	Withstood 10 freeze–thaw cycles with no impact on kit performance.
	Instrument Compatibility	Compatible with a broad range of domestic and international qPCR instruments.
Coverage	Mycoplasma DNA Coverage	Database alignment based on mycoplasma 16S rRNA sequences supports coverage of 200+ Mollicutes species.

Note: Data shown are for reference only. Please refer to the validation report for the specific catalog number for detailed performance specifications.

Data Results

Limit of Detection (LoD) (refer to the validation report for details)

For 10 commonly tested mycoplasma reference strains (5 CFU/mL), 24 independent extractions and tests were performed, generating 24 data points. Each run included NCS and NTC controls.

Strain Information & Sensitivity Verification

Strain	Cell Suspension Concentration	Detection Rate
Acholeplasma laidlawii	5 CFU/mL	24/24
Mycoplasma fermentans	5 CFU/mL	24/24
Mycoplasma hyorhinis	5 CFU/mL	24/24
Mycoplasma orale	5 CFU/mL	24/24
Mycoplasma pneumoniae	5 CFU/mL	24/24
Mycoplasma gallisepticum	5 CFU/mL	24/24
Mycoplasma synoviae	5 CFU/mL	24/24
Mycoplasma arginini	5 CFU/mL	24/24
Spiroplasma citri	5 CFU/mL	24/24
Mycoplasma salivarium	5 CFU/mL	24/24

Results

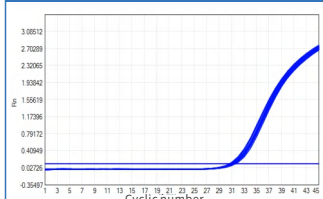
NCS and NTC passed. All 24 tests at 5 CFU/mL for each strain were positive, meeting the acceptance criterion of ⩾23 positives out of 24 tests.

For Mycoplasma orale at 5 CFU/mL, testing was conducted in three runs with 8 replicates per run. Overall results met the criterion of ⩾23 positives out of 24 tests. Data below show one representative run.

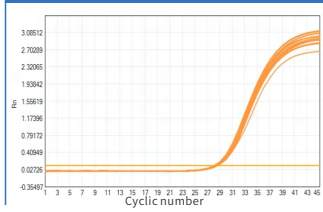
Mycoplasma orale Test Results (Kit Performance)

	Mycoplasma		Internal Control (IC)		Result Interpretation
Replicate 1	31.15	31.10	28.19	28.26	Positive
Replicate 2	31.56	31.32	28.19	28.50	Positive
Replicate 3	30.76	30.58	28.90	28.08	Positive
Replicate 4	31.17	31.13	28.61	28.19	Positive
Replicate 5	31.38	31.35	28.65	28.04	Positive
Replicate 6	31.04	31.18	28.23	28.10	Positive
Replicate 7	30.74	31.23	28.22	28.34	Positive
Replicate 8	31.16	31.19	28.17	28.19	Positive
NCS	NoCt	NoCt	28.19	28.41	Pass
NTC	NoCt	NoCt	28.36	28.47	Pass
PC	26.93	26.72	28.48	28.25	Pass

Mycoplasma Amplification Curve



Internal Control (IC) Amplification Curve



Related Products

Product Name	Cat. No.
Mycoplasma Decontamination Spray	BP-QN288
Cell Sample Pretreatment Kit	BP-QN110-100

Spiroplasma DNA qPCR Detection Kit

qPCR (Fluorescent Probe Method)

Cat. No. BP-QN299-50

This kit is based on real-time fluorescent qPCR and targets conserved Spiroplasma sequences with optimized primers and probes. When used with Biori' s nucleic acid extraction/purification kits (magnetic bead-based), it enables rapid qualitative testing for Spiroplasma contamination in production raw materials, cell banks, viral seeds, viral or cell harvests, and cell therapy products.

Fully validated for limit of detection, specificity, and robustness in accordance with EP 2.6.7 mycoplasma testing requirements, with sensitivity down to 10 CFU/mL (or equivalent genome copies recommended by applicable guidelines).

When used with Biori extraction/purification kits, the workflow can be completed in as little as 1.5 hours.

Coverage
Detects 40+ Spiroplasma species

Limit of Detection (LoD)
10 CFU/mL

Key Benefits

Precision
Intermediate precision (Ct), CV ⩽ 5%

Specificity
Tested against structural analogs, closely related microorganisms, and commonly used cell lines; no cross-reactivity observed.

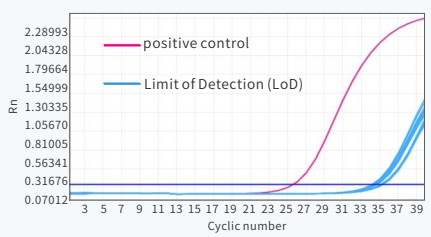
Kit Performance Summary

Performance Summary: Spiroplasma DNA qPCR Detection Kit (Fluorescent Probe qPCR)

Performance	Validation Parameter	Results
Limit of Detection (LoD)	Nucleic Acid Verification	Tested Spiroplasma samples at 10 CFU/mL with 24 replicates; detection rate ⩾95%.
Specificity	Cross-reactivity	Evaluated nucleic acids from common cell lines and microorganisms; no cross-reactivity observed.
	Matrix Interference	Tested 6 common sample matrices; no interference observed.
Robustness	Operator-to-Operator	Consistent results across different operators.
	Instrument Compatibility	Compatible with a broad range of domestic and international qPCR instruments.
	Freeze–Thaw Stability	Withstood 10 freeze–thaw cycles without affecting results.
Precision	Intra-batch Precision	Ct value CV ⩽5%
	Intermediate Precision	Ct value CV ⩽5%
	Total Imprecision	Ct value CV ⩽5%

Limit of Detection (LoD)

LoD Summary: Spiroplasma DNA qPCR Detection Kit



Related Products

Nucleic Acid Extraction/Purification Kit (Magnetic Bead-Based)
Cat. No. BP-QN01-100

Mycoplasma Decontamination Spray
Cat. No. BP-QN288

Cell Sample Pretreatment Kit
Cat. No. BP-QN110-100

02 Microbial Contamination Testing

Fungal DNA qPCR Detection Kit

qPCR (Fluorescent Probe Method)

Cat. No. BP-QN78-50

This kit uses fluorescent probe-based qPCR with primers and probes designed for conserved regions of the fungal 18S gene to qualitatively test for fungal DNA in samples. When used with Biori's Bacteria & Fungi Nucleic Acid Extraction/Purification Kit, results can be obtained in as little as 1.5 hours.

Key Benefits

Easy Workflow
No specialized equipment required for sample preparation; processing can be completed in ~20 minutes.

Coverage
Covers >92% of fungal species, matching DNA subtype sequences for ~5,000 known fungi.

Precision
Intermediate precision (Ct), CV ⩽ 5%

Specificity
No cross-reactivity with commonly used cell lines and bacteria.

Sensitivity
⩽100 CFU (10 CFU/reaction)

Kit Performance Summary

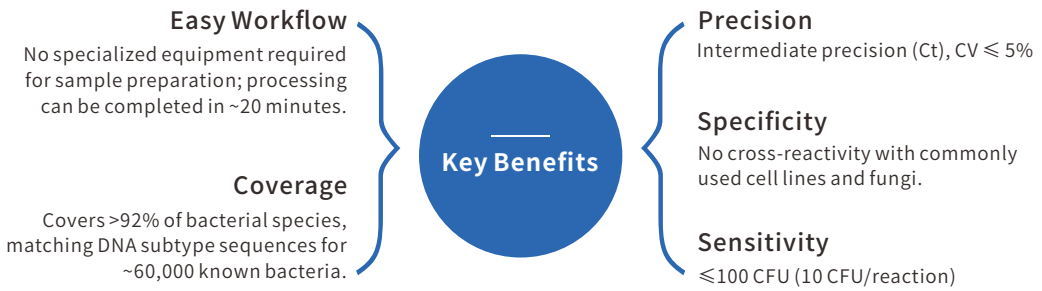
Performance Summary: Fungal DNA qPCR Detection Kit

Performance	Validation Parameter	Results
Limit of Detection (LoD)	Fungal Reference Strain Verification	Two pharmacopeia-required fungal reference strains at 100 CFU were tested with 24 replicates each; detection rate >95%.
Specificity	Cross-reactivity	Tested DNA from 11 common cell lines and bacteria; no cross-reactivity observed.
	Matrix Interference	Tested 8 common sample matrices; no interference observed.
Robustness	Operator-to-Operator	Consistent results across different operators.
	Instrument Compatibility	Compatible with a broad range of domestic and international qPCR instruments.
	Freeze–Thaw Stability	Withstood 10 freeze–thaw cycles without affecting results.
Precision	Intra-batch Precision	Ct value CV ⩽5%
	Intermediate Precision	Ct value CV ⩽5%
	Total Imprecision	Ct value CV ⩽5%
Coverage	Sequence Database Analysis	Database alignment analysis: 9,258 fungal 18S sequences in the database, with 8,485 matched sequences, yielding ~92% sequence coverage.

Bacterial DNA qPCR Detection Kit qPCR (Fluorescent Probe Method)

Cat. No. BP-QN99-50

This kit uses fluorescent probe-based qPCR with primers and probes designed for bacterial 16S gene regions to qualitatively test for bacterial DNA in samples. When used with Biori's Bacteria & Fungi Nucleic Acid Extraction/Purification Kit, sample extraction and testing can be completed in as little as 1.5 hours.



Kit Performance Summary

Performance Summary: Bacterial DNA qPCR Detection Kit

Performance	Validation Parameter	Results
Limit of Detection (LoD)	Bacterial Reference Strain Verification	Nine pharmacopeia-required bacterial reference strains at 100 CFU were tested with 24 replicates each; detection rate >95%.
Specificity	Cross-reactivity	Tested DNA from 11 common cell lines and fungi; no cross-reactivity observed.
	Matrix Interference	Tested 8 common sample matrices; no interference observed.
Robustness	Operator-to-Operator	Consistent results across different operators.
	Instrument Compatibility	Compatible with a broad range of domestic and international qPCR instruments.
	Freeze–Thaw Stability	Withstood 10 freeze–thaw cycles without affecting results.
Precision	Intra-batch Precision	Ct value CV ⩽5%
	Intermediate Precision	Ct value CV ⩽5%
	Total Imprecision	Ct value CV ⩽5%
Coverage	Sequence Database Analysis	Database alignment analysis: ~318,200 classified bacterial 16S sequences in the database, with ~291,800 matched sequences, yielding ~92% sequence coverage.

Adventitious Agent Testing

qPCR (Fluorescent Probe Method)

Product Name	Cat. No.
Mycoplasma Testing	
Mycoplasma DNA qPCR Detection Kit	BP-QN08-50 BP-QN22-50
Spiroplasma DNA qPCR Detection Kit	BP-QN299-50
Sterility Testing	
Fungal DNA qPCR Detection Kit	BP-QN78-50
Bacterial DNA qPCR Detection Kit	BP-QN99-50
Adventitious Virus Testing	
Mycobacterium DNA qPCR Detection Kit	BP-QN15-50
Bovine Virus Testing	
Bovine Virus (BVDV/REO3/BPIV3/BPV3/BAV3) Nucleic Acid qPCR Detection Kit	BP-QN32-50
Porcine Virus Testing	
Porcine Parvovirus (PPV) Nucleic Acid qPCR Detection Kit	BP-QN136-50
Torque Teno Sus Virus (TTSuV) Nucleic Acid qPCR Detection Kit	BP-QN137-50
Porcine Circovirus (PCV) Nucleic Acid qPCR Detection Kit	BP-QN25-50
Rodent Virus Testing	
Mouse Minute Virus (MMV) qPCR Detection Kit	BP-QN121-50
Mouse Adenovirus (MAV) Nucleic Acid qPCR Detection Kit	BP-QN202-50
Pneumonia Virus of Mice (PVM) Nucleic Acid qPCR Detection Kit	BP-QN203-50
Murine Retrovirus (MRV) Nucleic Acid qPCR Detection Kit	BP-QN205-50
Minute Virus of Mice (MVM) Nucleic Acid qPCR Detection Kit	BP-QN206-50
Insect Virus Testing	
Sf Rhabdovirus qPCR Detection Kit	BP-QN17-50

Genetic Stability Testing

Exogenous Gene Copy Number Testing

Replication-Competent Virus (RCV) Testing

Rapid Testing

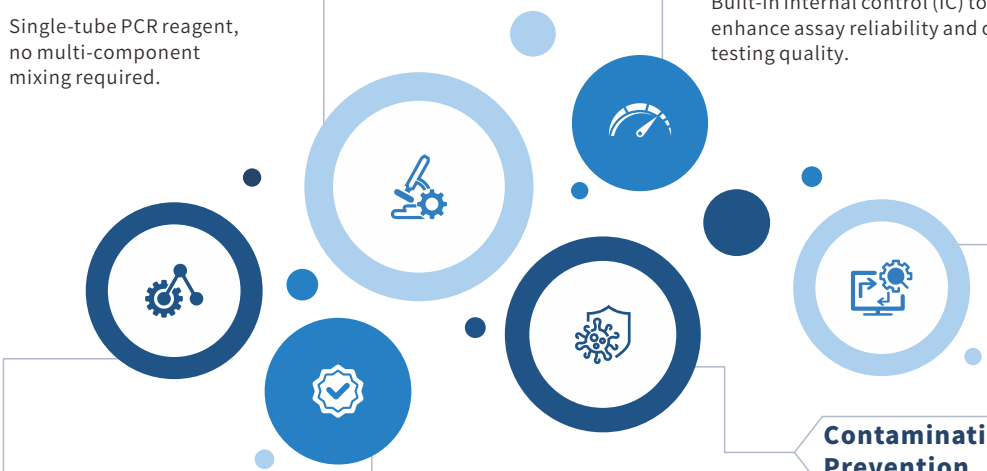
Short turnaround time, complete testing workflow in as fast as 1.5 hours.

Easy Operation

Single-tube PCR reagent, no multi-component mixing required.

Internal Control (IC) System

Built-in internal control (IC) to enhance assay reliability and overall testing quality.



Contamination Prevention

UDG-based carryover prevention to minimize amplicon contamination.

High Performance & Compliance-Ready

Performance validated in accordance with pharmacopeial and regulatory requirements, delivering high sensitivity and robust stability. Recovery: 70–130%. Complete performance evaluation documentation available.

Convenient & Fast

Ready-to-use calibrators—no dilution required, take-and-run convenience.

01 Transgene Copy Number Testing

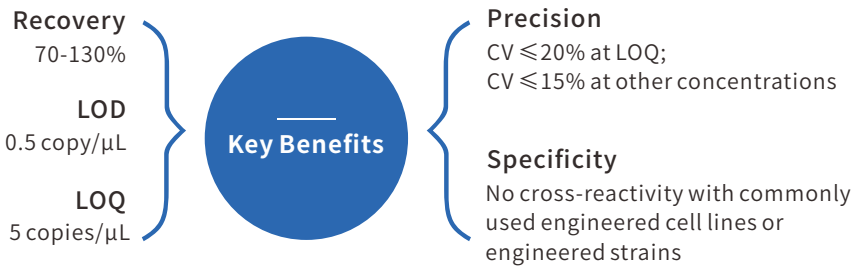
CAR/TCR Gene Copy Number Quantification qPCR Kit

Cat. No. BP-QN29-100

qPCR (Fluorescent Probe Method)

This kit uses probe–based qPCR and is designed with primers/probes targeting DNA sequences associated with vector integration/expression, together with a human single-copy reference gene (Single Copy Gene, SCG). It enables quantification of the average target gene copy number per cell in tested samples.

Optimized for use with Biori nucleic acid extraction or purification kits to enable a fast and reliable testing workflow.



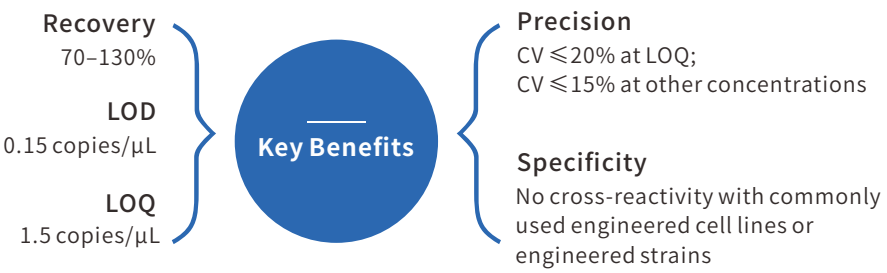
Replication-Competent Lentivirus (RCL) Quantification qPCR Kit

Cat. No. BP-QN29-100

qPCR (Fluorescent Probe Method)

This kit uses probe–based qPCR with primers/probes targeting the VSV-G gene, enabling quantification of replication-competent lentivirus (RCL) copy number in cell therapy and gene therapy products.

Optimized for use with Biori nucleic acid extraction or purification kits to enable a fast and reliable testing workflow.



Genetic Stability Testing

qPCR (Fluorescent Probe Method)

Product Name	Cat. No.
Transgene Copy Number Testing	
CAR/TCR Gene Copy Number Detection Kit	BP-QN29-100
RCL Gene Copy Number Detection Kit	BP-QN10-100
RCR Gene Copy Number Detection Kit	BP-QN14-100
Replication-Competent Virus Testing	
Replication-Competent AAV (rcAAV-2/N) Detection Kit	BP-QN28-100
Replication-Competent AAV (rcAAV-5/N) Detection Kit	BP-QN19-100

Residual Host Cell DNA Testing

Rapid Turnaround

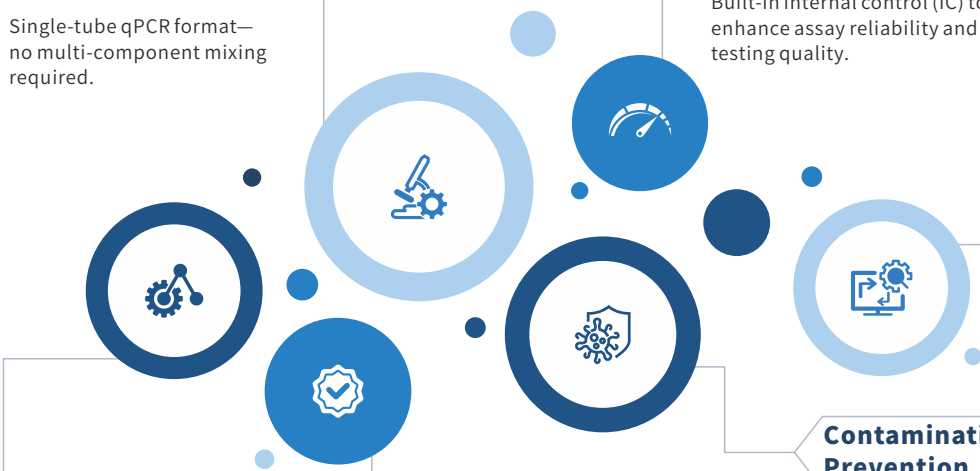
Short assay time—complete workflow in as little as 1.5 hours.

Easy Workflow

Single-tube qPCR format—no multi-component mixing required.

Internal Control (IC) System

Built-in internal control (IC) to enhance assay reliability and overall testing quality.



Contamination Prevention

UDG-based carryover prevention to minimize amplicon contamination.

High Performance & Compliance-Ready

Performance validated per pharmacopeial and regulatory requirements, delivering high sensitivity and robust stability with 70–130% recovery; full validation documentation available.

Convenient & Fast

Ready-to-use standards—no dilution required; use directly when needed.

E.coli Residual Host Cell DNA Detection Kit

Cat. No. BP-QN24-100

qPCR (Fluorescent Probe Method)

This kit uses fluorescent probe–based qPCR. Primers and probes are designed against conserved E. coli sequences and paired with ready-to-use calibrators for quantitative measurement of residual E. coli DNA in intermediates, in-process samples, and final drug/biological products.

When used with Biori nucleic acid extraction or purification kits, the assay can be completed in as little as 1.5 hours.

Key Benefits

Recovery
70-130%

Sensitivity
LoQ: 5 fg/μL; LoD: 1 fg/μL

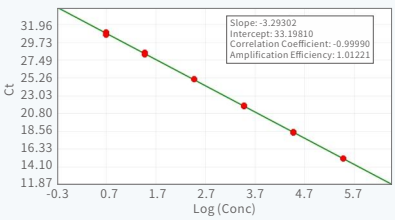
Precision
CV ⩽ 20% at LoQ
CV ⩽ 15% at mid–high concentrations

Specificity
Specific detection of residual *E.coli* DNA with no cross-reactivity to common engineered cells or engineered microorganisms.

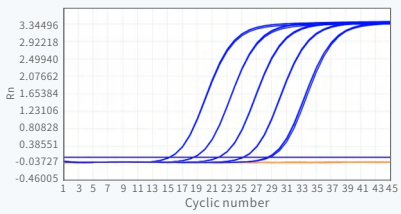
Traceability
Standard curve is calibrated using national E.coli DNA reference standards for accurate and reliable quantification.

Data

Linear range: 5 fg/μL–300 pg/μL; Amplification efficiency: 101.2%; $R^2 > 0.99$



Calibrator Amplification Curves



Related Products

Product Name	Cat. No.
E.coli Residual DNA Calibrator	BP-QN158
Nucleic Acid Extraction/Purification Kit II (Magnetic Beads)	BP-QN11-100
Nucleic Acid Extraction/Purification Kit III (Magnetic Beads)	BP-QN36-100

HEK293 Residual Host Cell DNA Fragment Analysis Detection Kit

qPCR (Fluorescent Probe Method)

Cat. No. BP-QN60-100

This kit uses fluorescent probe–based qPCR. Primers and probes are designed against conserved HEK293 sequences to quantitatively measure residual HEK293 DNA fragments in intermediates, in-process samples, and final biological products.

When used with Biori nucleic acid extraction or purification kits, the assay can be completed in as little as ~2 hours.

Key Benefits

Recovery
70-130%

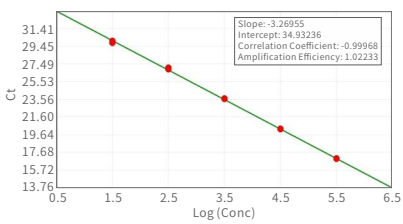
Precision
CV ⩽ 30% at LoQ;
CV ⩽ 15% at mid–high concentrations

Sensitivity
LoQ: 30 fg/μL

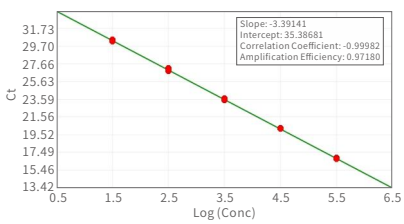
Specificity
Specific detection of residual HEK293 DNA fragments with no cross-reactivity to common engineered cells or engineered microorganisms.

Data

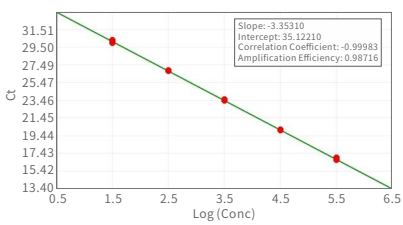
Linear range (all four fragments): 30 fg/μL–300 pg/μL; Amplification efficiency: 90%–110%; $R^2 > 0.99$



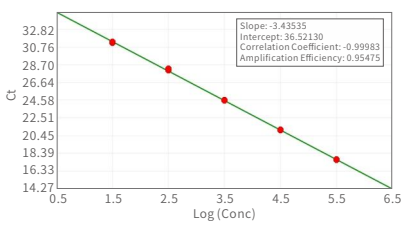
HEK293 Fragment (66 bp) Standard Curve



HEK293 Fragment (177 bp) Standard Curve

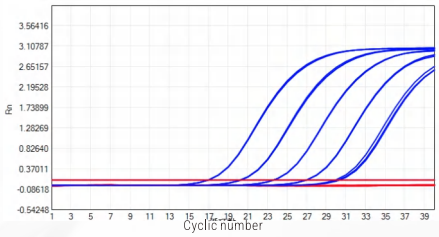


HEK293 Fragment (200 bp) Standard Curve

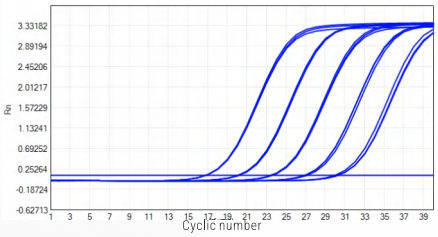


HEK293 Fragment (528 bp) Standard Curve

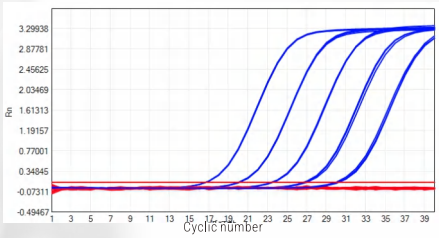
Linear range: All four fragments show a linear range of 30 fg/μL–300 pg/μL;
Amplification efficiency: 90%–110%; $R^2 > 0.99$



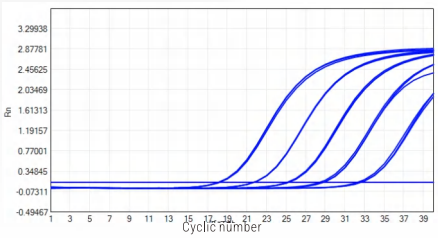
HEK293 Fragment (66 bp) Calibrator Amplification Plot



HEK293 Fragment (177 bp) Calibrator Amplification Plot



HEK293 Fragment (200 bp) Calibrator Amplification Plot



HEK293 Fragment (528 bp) Calibrator Amplification Plot

Related Products

Product Name	Cat. No.
DNA Sample Pretreatment Kit	BP-QN80-100
Nucleic Acid Extraction/Purification Kit II (Magnetic Beads)	BP-QN11-100
Nucleic Acid Extraction/Purification Kit III (Magnetic Beads)	BP-QN36-100

Residual Host Cell DNA Testing

qPCR (Fluorescent Probe Method)

Product Name	Cat. No.
E. coli Residual Host Cell DNA Detection Kit	BP-QN29-100
CHO Residual Host Cell DNA Detection Kit	BP-QN06-100 BP-QN88-100
Human Residual Host Cell DNA Detection Kit	BP-QN14-100
Pichia pastoris Residual Host Cell DNA Detection Kit	BP-QN10-100
Vero Residual Host Cell DNA Detection Kit	BP-QN14-100
HEK293 Residual Host Cell DNA Detection Kit	BP-QN10-100
HeLa Residual Host Cell DNA Detection Kit	BP-QN14-100
Ns0 & SP2/0 Residual Host Cell DNA Detection Kit	BP-QN10-100
E1A Residual DNA Detection Kit	BP-QN14-100
E1B Residual DNA Detection Kit	BP-QN10-100
E1A & SV40 Large T Antigen (SV40LT) Residual DNA Detection Kit	BP-QN14-100
Hi5 & AcNPV Residual DNA Detection Kit	BP-QN10-100
Saccharomyces cerevisiae Residual Host Cell DNA Detection Kit	BP-QN14-100
Hansenula (Yeast) Residual Host Cell DNA Detection Kit	BP-QN10-100
MDCK Residual Host Cell DNA Detection Kit	BP-QN14-100
Sf9 & AcNPV Residual DNA Detection Kit	BP-QN10-100
Plasmid DNA (Kanamycin Resistance Gene) Residual DNA Detection Kit	BP-QN14-100
Plasmid DNA Residual DNA Detection Kit	BP-QN66-100 BP-QN120-100

Cell Species Identification

Product Portfolio

qPCR (Fluorescent Probe Method)

Product Name	Cat. No.
Cell Species Identification Kit	BP-QN44-50

Rapid Testing

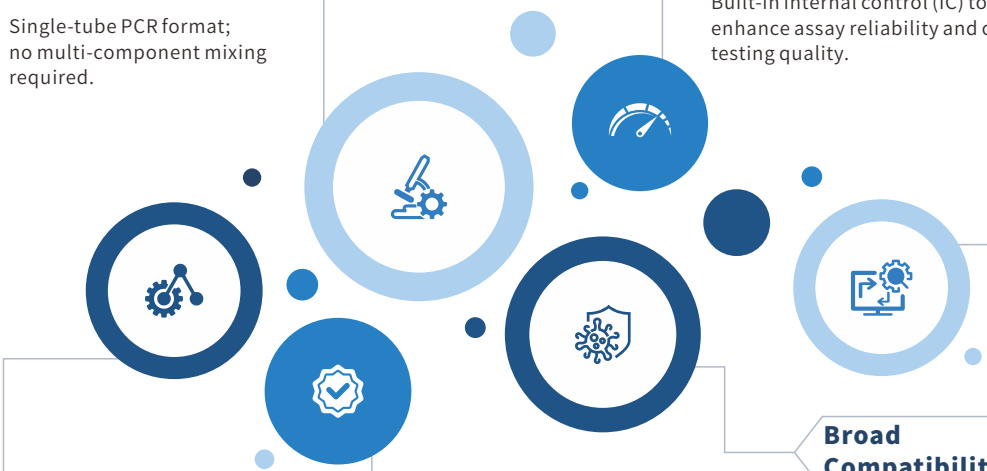
Short turnaround time—complete workflow in as fast as 1.5 hours.

Easy Workflow

Single-tube PCR format; no multi-component mixing required.

Internal Control (IC) System

Built-in internal control (IC) to enhance assay reliability and overall testing quality.



Broad Compatibility

Compatible with a wide range of domestic and imported PCR instruments—no additional equipment needed.

High Performance & Compliance-Ready

Performance validated in line with pharmacopeial and regulatory requirements, offering high sensitivity and robust stability, with complete performance evaluation documentation available.

Convenient & Efficient

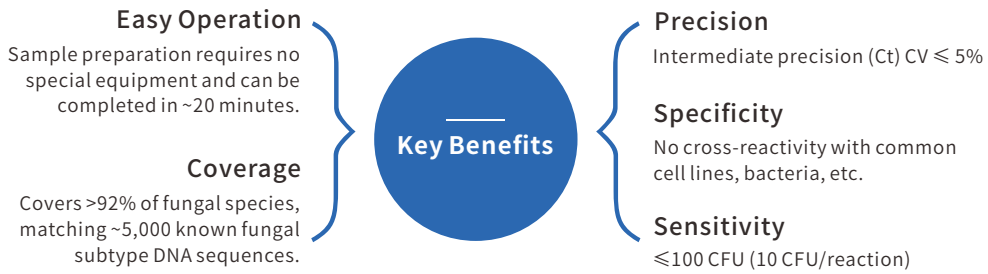
Ready-to-use calibrators—no dilution required; use on demand.

Cell Species Identification Kit qPCR (Fluorescent Probe Method)

Cat. No. BP-QN44-50

This kit is based on real-time fluorescent quantitative PCR. Primers and probes are designed against conserved sequences of commonly used cell lines in biopharmaceutical manufacturing. Target genes are amplified and fluorescence signals are used for cell species identification and cross-contamination testing.

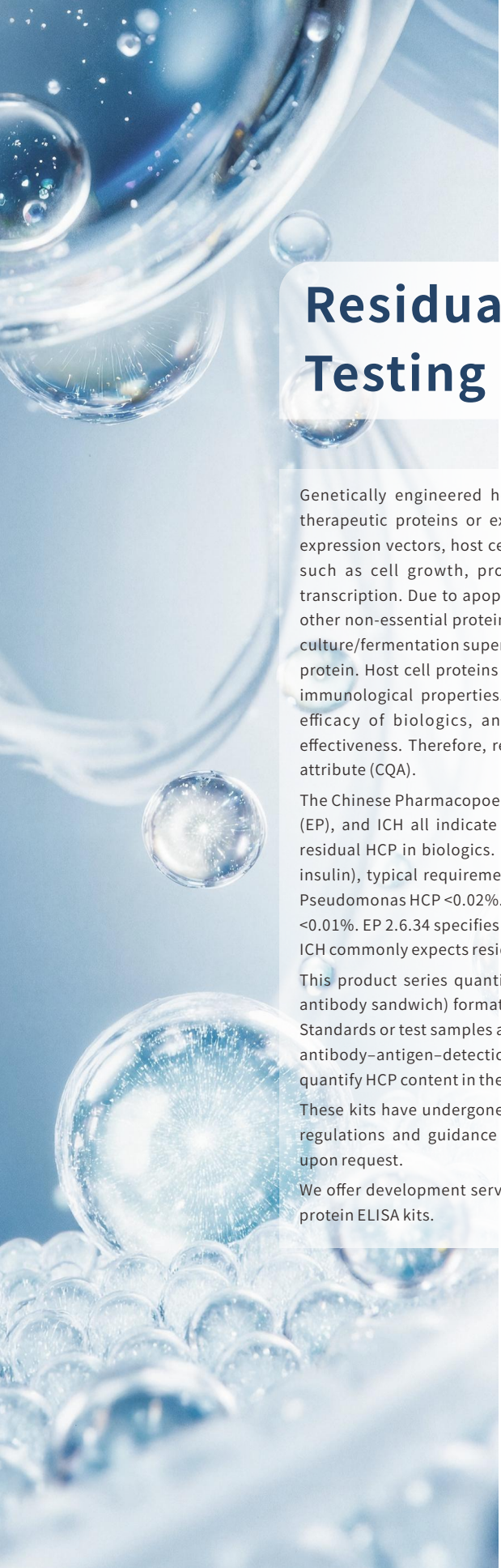
When used with Biori nucleic acid extraction or purification kits, cell species identification and cross-contamination testing can be completed in as fast as 1.5 hours.



Performance Summary

Validation Overview and Conclusions

Performance	Validation Parameter	Results
Limit of Detection (LoD)	LoD across 10 cell types	LoD as low as 10 cells; cross-contamination detection limit down to 0.1% or lower.
Specificity	Matrix Interference	No interference observed across seven matrices (RPMI 1640, DMEM, CHO culture medium, 10% premium FBS, 100% premium FBS, D-PBS, and DNA dilution buffer).
	Cross-reactivity	Tested 13 non-target species DNAs (Pichia pastoris, Sf9, E. coli, Staphylococcus epidermidis, Mycoplasma pneumoniae, Mycobacterium ranae, Streptococcus pneumoniae, Staphylococcus aureus, Staphylococcus intermedius, Propionibacterium spp., Pseudomonas aeruginosa, Monascus spp., Lactobacillus acidophilus). No cross-reactivity was observed.
Robustness	Freeze–Thaw Stability	Withstands 10 freeze–thaw cycles with no impact on performance.
	Instrument Compatibility	Compatible with multiple domestic and imported PCR instruments.



Residual Host Cell Protein Testing

Genetically engineered host cells can be used to intentionally produce recombinant therapeutic proteins or express vectors. During production of recombinant proteins or expression vectors, host cells also generate proteins involved in normal cellular functions, such as cell growth, proliferation, survival, and protein synthesis related to gene transcription. Due to apoptosis, cell death, and cell lysis, in addition to the target protein, other non-essential proteins may be released together with the target product or enter the culture/fermentation supernatant after cell disruption, resulting in a mixture with the target protein. Host cell proteins (HCPs) are complex mixtures with diverse physicochemical and immunological properties. Their potential immunogenicity, impact on the stability and efficacy of biologics, and possible adverse effects may affect product safety and effectiveness. Therefore, residual HCP content in biologics is considered a critical quality attribute (CQA).

The Chinese Pharmacopoeia, United States Pharmacopeia (USP), European Pharmacopoeia (EP), and ICH all indicate that robust methods are required to strictly monitor and test residual HCP in biologics. In the Chinese Pharmacopoeia (except for growth hormone and insulin), typical requirements include E. coli HCP <0.1%, CHO and yeast HCP <0.05%, and Pseudomonas HCP <0.02%. The referenced method is generally ELISA. USP typically requires <0.01%. EP 2.6.34 specifies that HCP content in biologics should be <0.1%. For HCP as a CQA, ICH commonly expects residual HCP to be <0.01%.

This product series quantifies residual HCP in samples using a sandwich ELISA (double-antibody sandwich) format. Anti-HCP capture antibodies are coated onto microplate wells. Standards or test samples are added, followed by an anti-HCP detection antibody to form an antibody–antigen–detection antibody complex. A colorimetric reaction is then used to quantify HCP content in the test samples.

These kits have undergone comprehensive method validation in accordance with relevant regulations and guidance documents, and performance validation reports are available upon request.

We offer development services for platform-specific and process-specific residual host cell protein ELISA kits.

Product Assurance

Backed by in-house ISO 9001 and ISO 13485 quality systems; audit-ready; fast lead time; strong kit stability.

High Sensitivity

Limit of Quantitation (LOQ) down to the ng/mL level.

High Specificity

Verified with no cross-reactivity to HCP from other cell lines.

Fast & Convenient

Most kits can be completed within 2 hours. One-step workflow saves time and effort; gradient-diluted standard working solutions and ready-to-use reagent working solutions are provided.

Regulatory Compliance

Designed in accordance with USP <1132> and Ph. Eur. 2.6.34; comprehensively validated per the Chinese Pharmacopoeia, USP, and ICH requirements.

Product Portfolio

Product Name	Cat. No.
ELISA	
E.coli Host Cell Protein ELISA Kit	BP-QP-E001-96
CHO Host Cell Protein ELISA Kit	BP-QP-C002-96
ELISA (One-Step Method)	
E.coli Host Cell Protein ELISA Kit	BP-QP-E011-96
CHO Host Cell Protein ELISA Kit	BP-QP-C012-96
HEK293 Host Cell Protein ELISA Kit	BP-QP-H005-96
MDCK Host Cell Protein ELISA Kit	BP-QP-M006-96

CHO Host Cell Protein ELISA Kit

ELISA (One-Step Method)

Cat. No. BP-QN60-100

CHO cells are widely used mammalian cell lines for commercial production of therapeutic proteins. During manufacturing, residual host cell proteins (HCP) may remain in the final product and potentially trigger immune responses, affecting safety and efficacy. Therefore, residual CHO HCP levels should be monitored and controlled.

Recommended Applications

Quantitative measurement of HCP in biologics expressed/expanded in CHO cells (e.g., recombinant proteins, antibodies, vaccines). Suitable for HCP monitoring during process development and for QC lot release testing.

Key Benefits

Regulatory Compliance

Designed in accordance with USP <1132> and Ph. Eur. 2.6.34; comprehensively validated per the Chinese Pharmacopoeia, USP, and ICH requirements.

Precision

Intra-plate CV ⩽ 10%;
inter-plate CV ⩽ 15%.

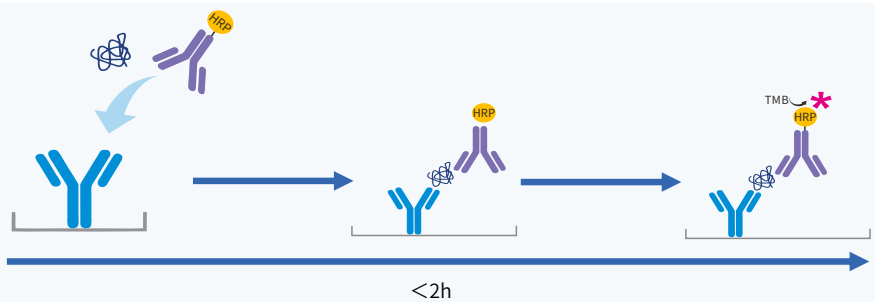
Specificity

No cross-reactivity with E. coli or Pichia pastoris host cell proteins.

Kit Stability

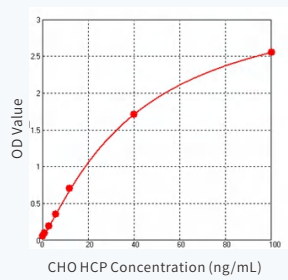
Stable components for convenient shipping and long-term storage.

Assay Principle



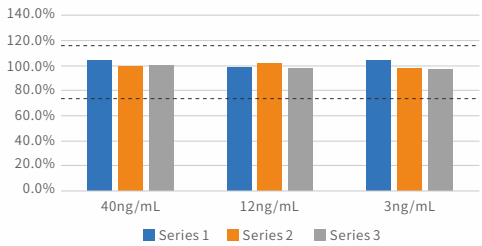
Typical Standard Curve

CHO HCP Concentration (ng/mL)	OD Value
100	2.5530
40	1.7089
12	0.7008
6	0.3501
3	0.1929
1	0.0963
0	0.0585



- Data are for reference only. Actual results may vary.

Accuracy



- Within the linear range (high/medium/low levels), the recovery of measured concentrations is 80–120%.

Repeatability

Theoretical Concentration (ng/mL)	40	12	3
No. of Tests	6	6	6
Mean Measured Concentration (ng/mL)	39.40	12.24	2.96
Concentration CV (%)	1.8	2.4	2.9

- Within the linear range (high/medium/low levels), repeatability CV is <10% (three runs).

Inter-batch Precision

Theoretical Concentration (ng/mL)	40	12	3
No. of Batches	3	3	3
Mean Measured Concentration (ng/mL)	40.0	11.94	3.21
Concentration CV (%)	1.5	2.7	8.9

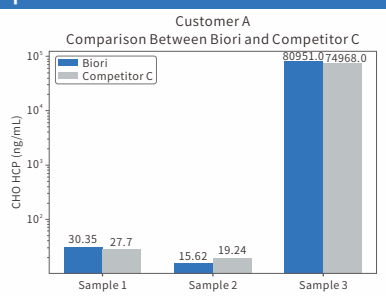
- Within the linear range (high/medium/low levels), inter-batch precision across three batches shows CV ⩽15%.

Specificity

Sample	*E. coli* Host Cell Protein (HCP)			Pichia pastoris Host Cell Protein (HCP)		
Sample Concentration (μg/mL)	1			1		
Spike Level (ng/mL)	0	1	3	0	1	3
Measured Concentration (ng/mL)	9.4×10^{-2}	0.944	2.944	7.9×10^{-2}	0.905	3.065
Recovery (%)	/	94.4	98.1	/	90.5	102.2

- No cross-reactivity is observed with up to 1 μg/mL of E. coli and Pichia pastoris HCP.

Comparison Data



- Results are consistent with Competitor C.

Process Validation and Residual Testing

Biopharmaceutical products are closely linked to manufacturing processes. Process control and validation studies are required throughout production to establish the optimal process. Residual process-related impurities are often unavoidable and may pose potential clinical safety risks, threatening patient safety. Biopharmaceutical manufacturing involves relatively complex processes, and therefore requires evaluation of multiple parameters and residual impurities.

This product series mainly covers process validation products, as well as kits for testing various process-related impurities generated during biopharmaceutical manufacturing beyond residual HCD and HCP.

Product Assurance

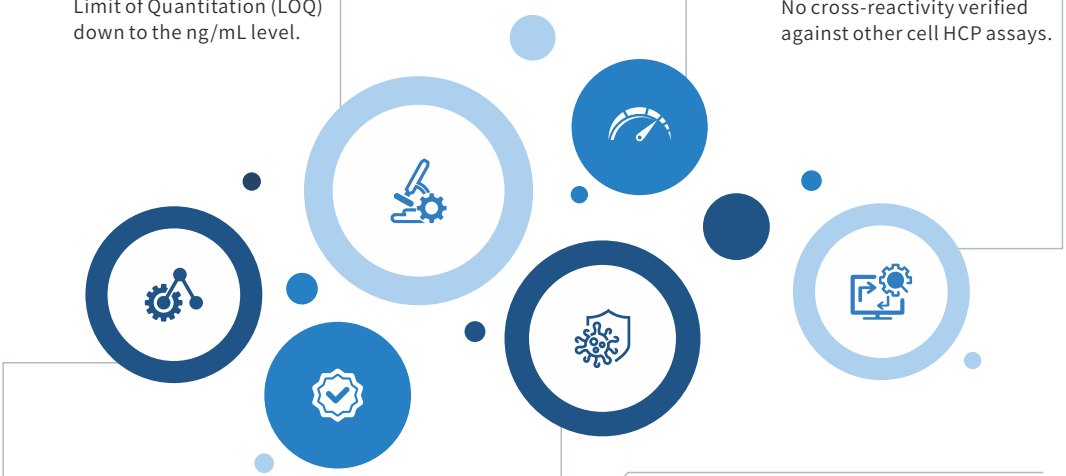
Backed by in-house ISO 9001 and ISO 13485 quality systems; audit-ready; fast lead time; strong kit stability.

High Sensitivity

Limit of Quantitation (LOQ) down to the ng/mL level.

High Specificity

No cross-reactivity verified against other cell HCP assays.



Fast & Convenient

Most kits can be completed within 2 hours. One-step workflow for time- and labor-saving operation; supplied with serially diluted standard working solutions and ready-to-use reagent working solutions

Regulatory Compliance

Designed in accordance with USP <1132> and EP 2.6.34; comprehensively validated per ChP, USP, and ICH

Process Validation and Residual Testing

Product Name	Cat. No.
BSA ELISA Kit ELISA (One-Step Method)	BP-QP-T003-96
RNA Ladder 1000	BP-QN14-100
RNA Ladder 6000	BP-QN10-100
RNA ladder 12000	BP-QN14-100
mRNA Capping Efficiency Test Sample Preparation Kit	BP-QN10-100
mRNA Capping Efficiency Test Sample Preparation Kit (2.0)	BP-QN14-100
Poly(A) Tail Length Distribution Test Sample Preparation Kit	BP-QN10-100
Residual dsRNA Quantification Kit	BP-QN14-100
Residual RNase Quantification Kit	BP-QN10-100
Residual DNase Quantification Kit	BP-QN14-100
T7 RNA Polymerase ELISA Kit ELISA (One-Step Method)	BP-QN10-100
Dnase I ELISA Kit ELISA (One-Step Method)	BP-QN14-100
Rnase Inhibitor ELISA Kit ELISA (One-Step Method)	BP-QN10-100

Nucleic Acid Testing Reagents & Instruments

Nucleic Acid Extraction Reagents

Amplification & Detection Reagents

Extraction Instruments & Accessories

Nucleic Acid Testing Reagents & Instruments

Product Name	Cat. No.
Nucleic Acid Extraction Reagents	
Nucleic Acid Extraction/Purification Kit (Magnetic Bead Method)-V1	BP-QN01-100 / BP-QN01-48
Nucleic Acid Extraction/Purification Kit (Magnetic Bead Method)-V2	BP-QN11-100 / BP-QN11-48
Nucleic Acid Extraction/Purification Kit (Magnetic Bead Method)-V3	BP-QN36-100 / BP-QN36-48
Bacteria & Fungi Nucleic Acid Extraction/Purification Kit (Magnetic Bead Method)-V1	BP-QN188-100
Nucleic Acid & Nuclease Decontamination Reagent-V1	BP-QN99-50
DNA Removal Kit-V1	BP-QN65-100
DNA Cell Sample Pre-treatment Kit-V1	BP-QN80-100
RNA Cell Sample Pre-treatment Kit-V1	BP-QN81-100
Rnase Inhibitor-V1	BP-QN48
Amplification & Detection Reagents	
2× qPCR Premix (Probe)-V1	BP-QN86
2× qRT-PCR Premix (Probe)-V1	BP-QN87
5× dPCR Premix (Probe) -V1	BP-QN58
5× RT-dPCR Premix (Probe)-V1	BP-QN59
2× qPCR Premix-V1	BP-QN70
2× qRT-PCR Premix-V1	BP-QN71
DNA Dilution Buffer-V1	BP-QN20
RNA Dilution Buffer-V1	BP-QN38
Extraction Instruments & Accessories	
BR-32PH Fully Automated Nucleic Acid Extraction System-V1	BR-32 PH
Centrifuge Mixer-V1	CM-8 / CM-8 Plus
Magnetic Rack-V1	BP-QN45
8-Rod Magnetic Sleeve Set-V1	BP-QN41
96-Well Deep-Well Plate-V1	BP-QN42
Reagent Cartridge Strips-V1	BP-QN61
Mixing Sleeve Set-V1	BP-QN62

Corporate Mission

Protecting Life and Health, Creating a Better Life

Corporate Vision

Leader in the Life Sciences Field

Core Values

Integrity, Responsibility, Proactiveness, Innovation

Pursuing Excellence in Quality Providing Prompt and Thorough Service

Product Inquiry

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BRE-BP-1-202601