




BIOLOGICAL PRODUCTS

QUALITY CONTROL ANALYSIS

IMPURITIES AND SAFETY

A large, faded background image of a robotic arm, likely used in a laboratory or manufacturing setting, extending from the bottom left towards the center of the page.

PURSuing EXCELLENCE IN QUALITY
PROVIDING PROMPT AND THOROUGH SERVICE



CORPORATE HONORS ACCREDITATIONS

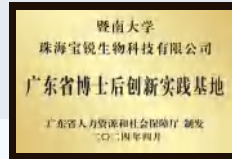
(National Level Specialized,
Refined, Differentiated, and
Innovative Little Giant Enterprise)



(National High-Tech Enterprise)



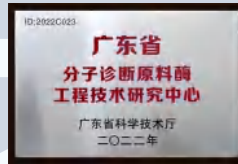
(Postdoctoral Innovation
and Practice Base)



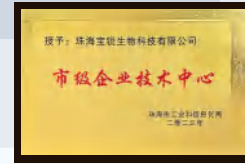
(ISO 13485:2016)



(ISO 9001:2015)



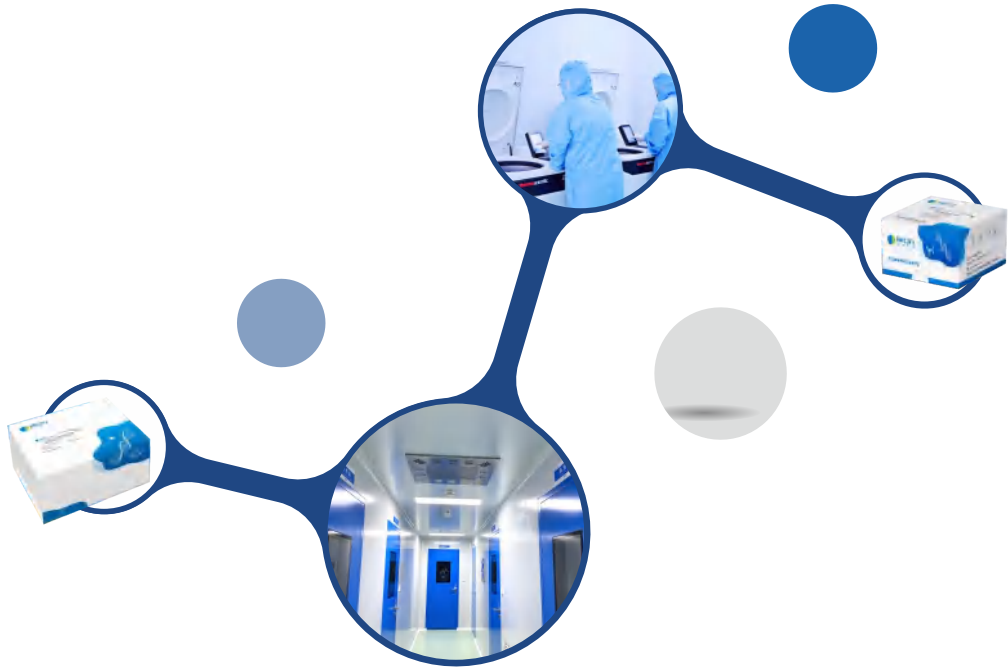
(Molecular Diagnostic Raw
Materials Technology Center
of Guangdong Province)



(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.



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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

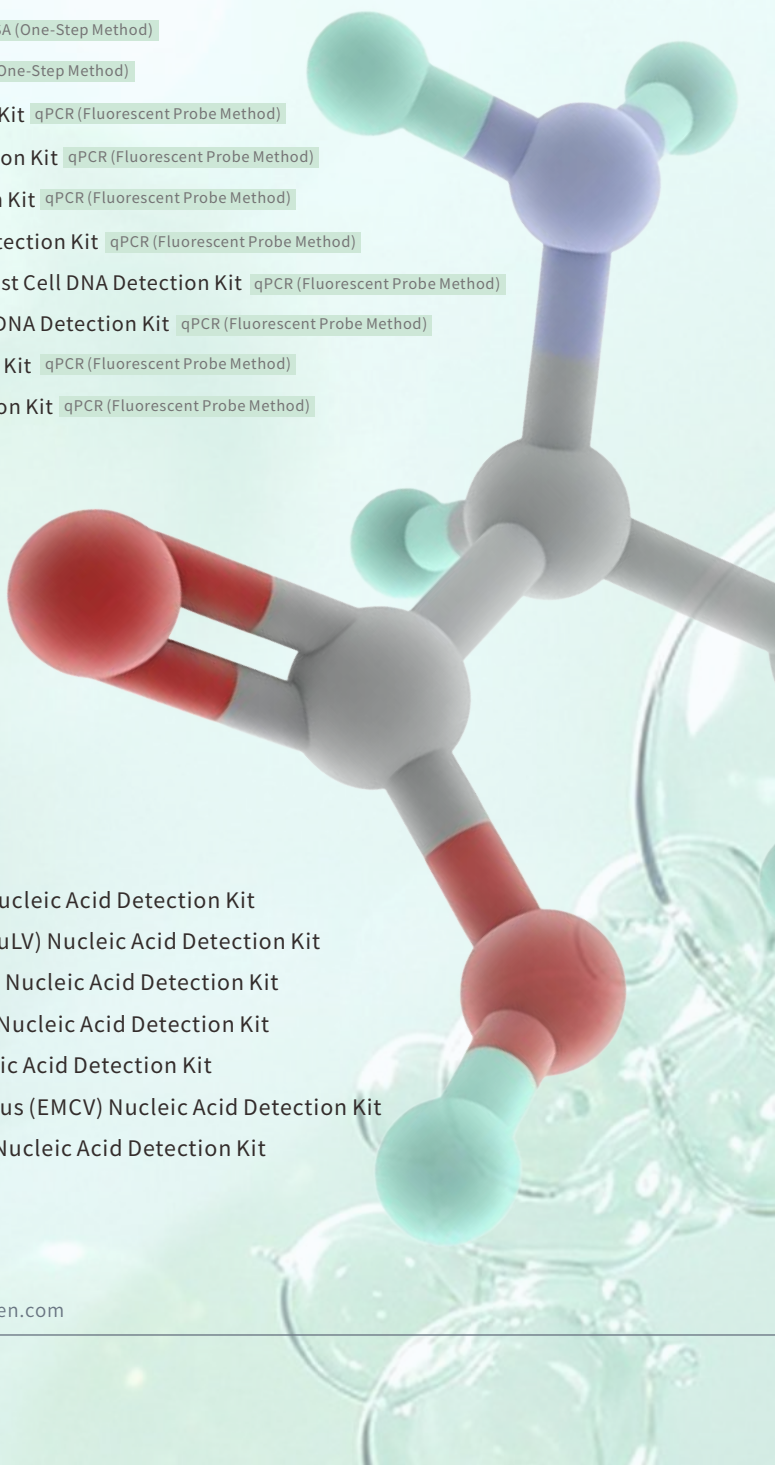
Antibodies & Recombinant Proteins

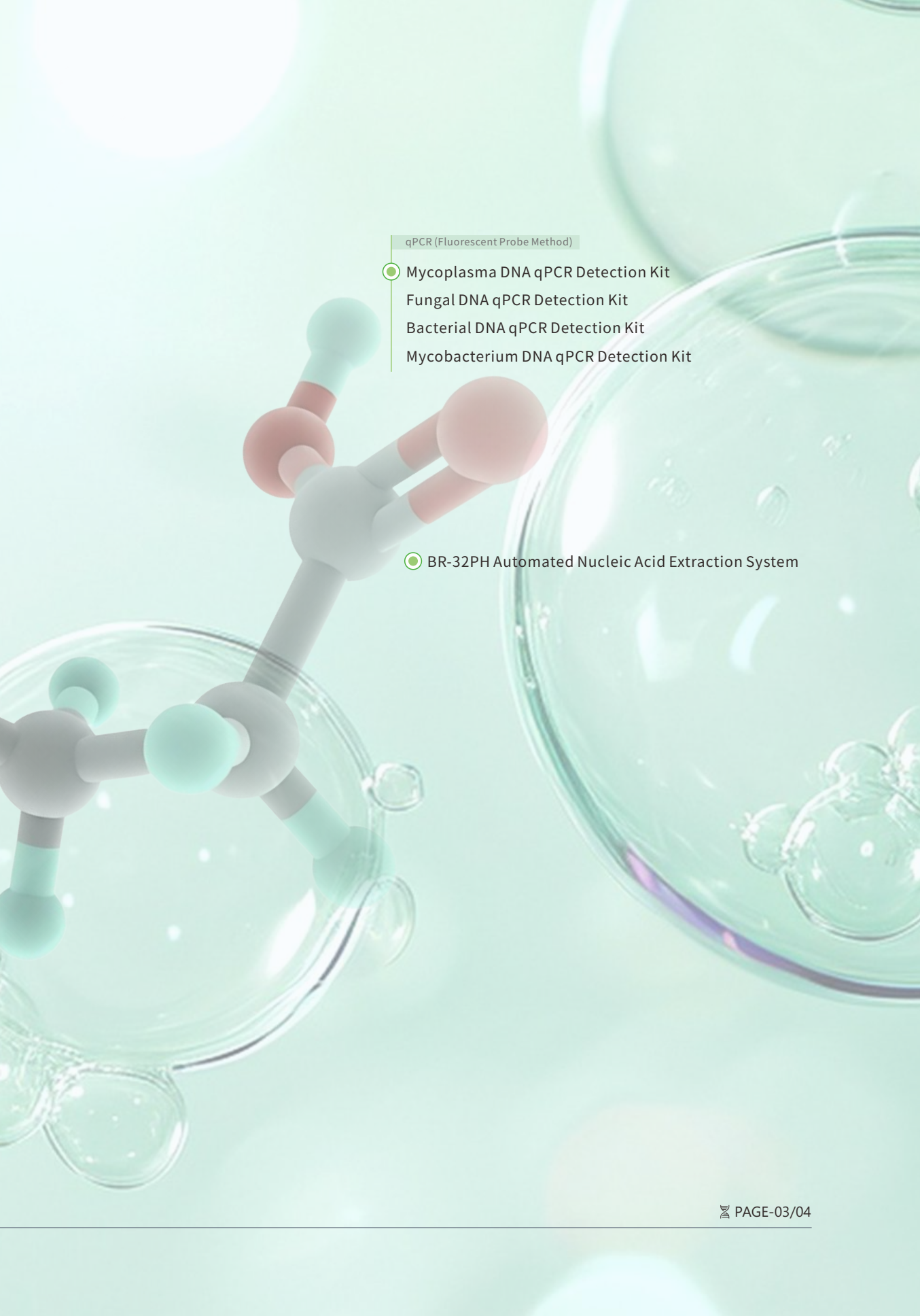
- CHO Host Cell Protein ELISA Kit ELISA (One-Step Method)
- HEK293 Host Cell Protein ELISA Kit ELISA (One-Step Method)
- E.coli Host Cell Protein ELISA Kit ELISA (One-Step Method)
- CHO Residual Host Cell DNA Detection Kit qPCR (Fluorescent Probe Method)
- HEK293 Residual Host Cell DNA Detection Kit 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





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)

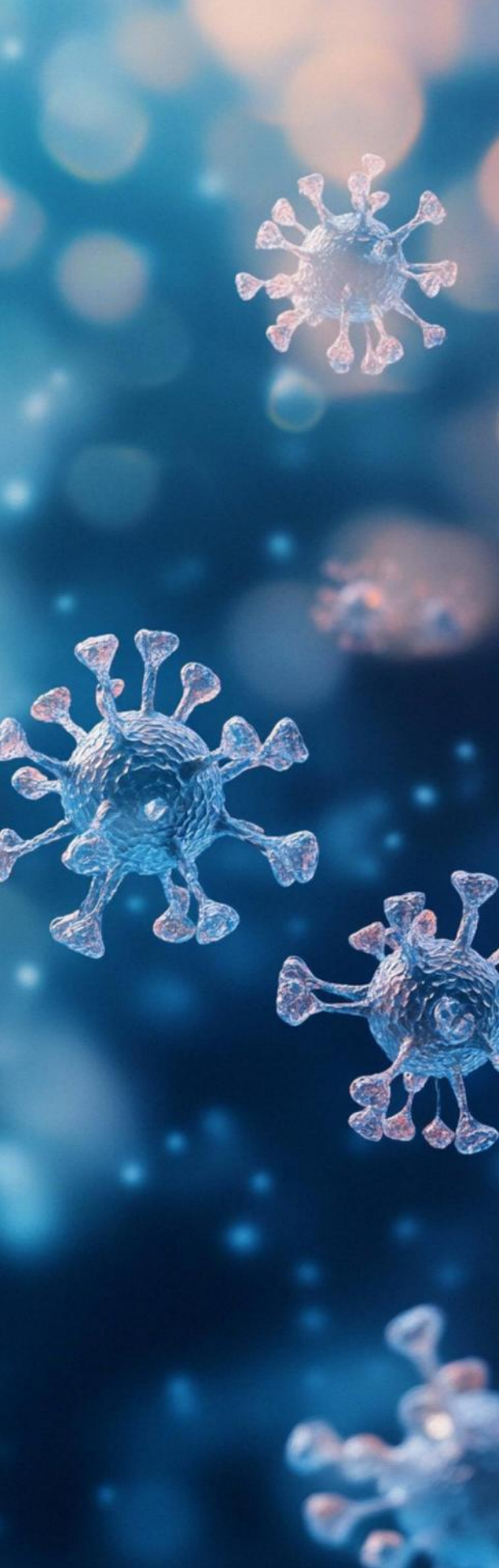
- Mycoplasma DNA qPCR Detection Kit
- Fungal DNA qPCR Detection Kit
- Bacterial DNA qPCR Detection Kit
- Mycobacterium DNA qPCR Detection Kit

- 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)



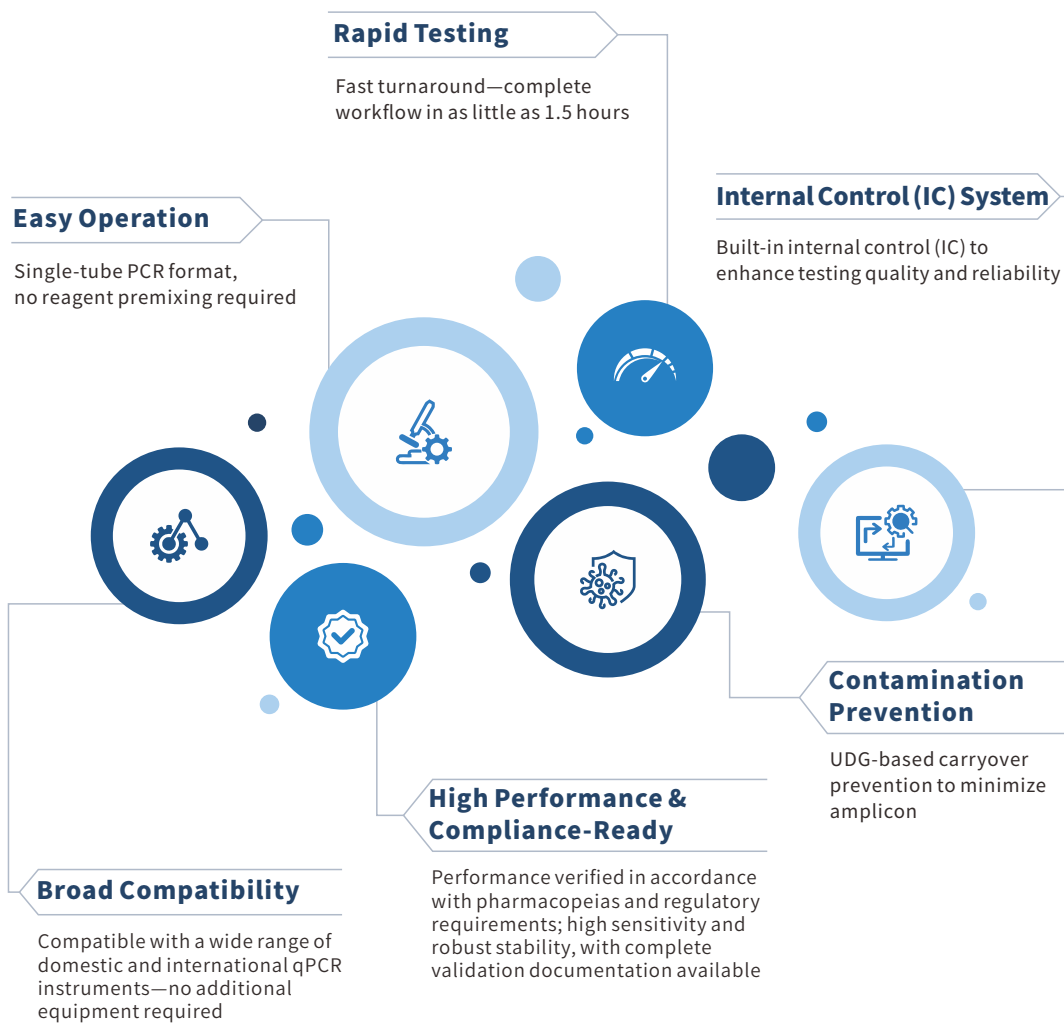
Adventitious Agent Testing

Mycoplasma Testing

Sterility Testing

Adventitious Virus Testing

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



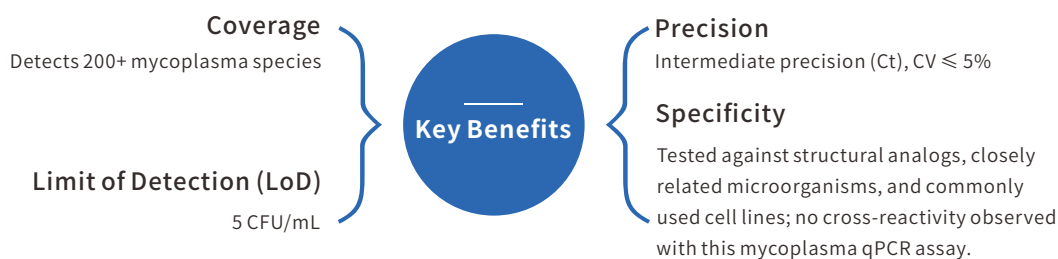
01 Mycoplasma Testing

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.



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.

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

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 hyorhinitis	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

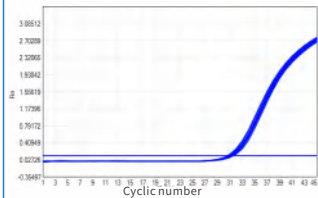
NCS and NTC passed. All 24 tests at 5 CFU/mL for each strain were positive, meeting the acceptance criterion of ≥ 23 positives out of 24 tests.

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.

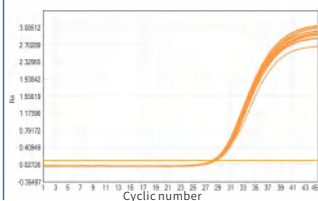
Mycoplasma orale Test Results (Kit Performance)

	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

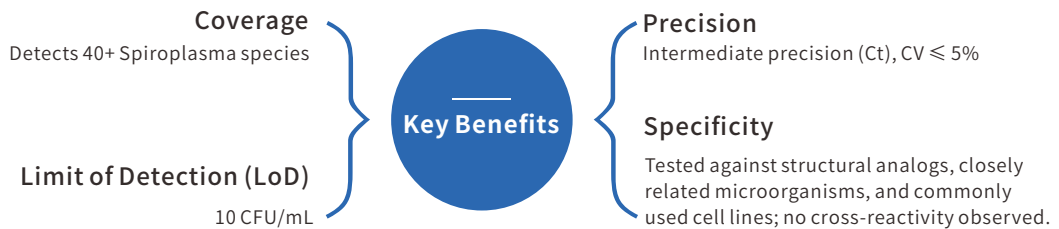
Spiroplasma DNA qPCR Detection Kit qPCR (Fluorescent Probe Method)

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.



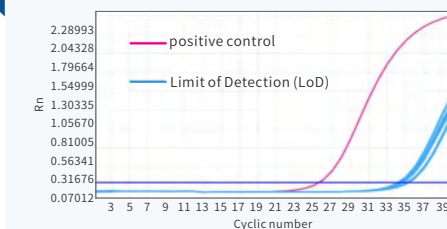
Kit Performance Summary

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

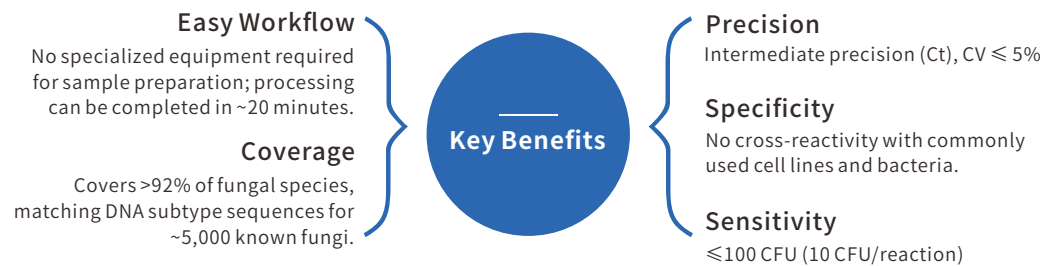
» For more products, please visit www.biori-en.com

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.



Kit Performance Summary

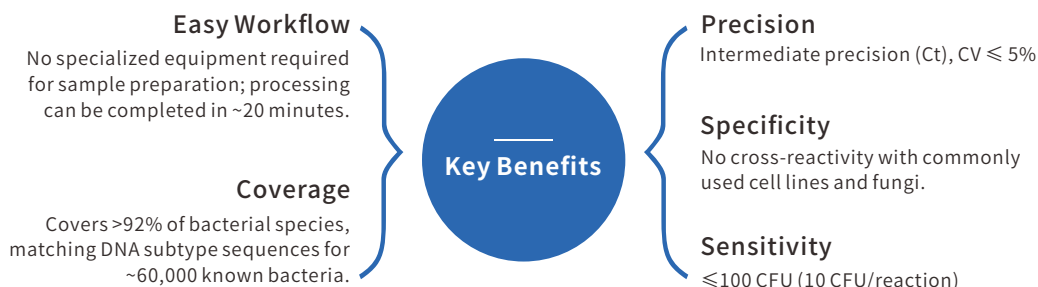
Performance Summary: Fungal DNA qPCR Detection Kit

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**



01 Transgene Copy Number Testing

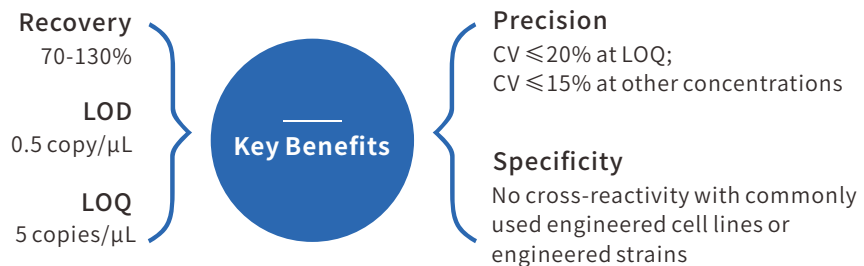
CAR/TCR Gene Copy Number Quantification qPCR Kit

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.



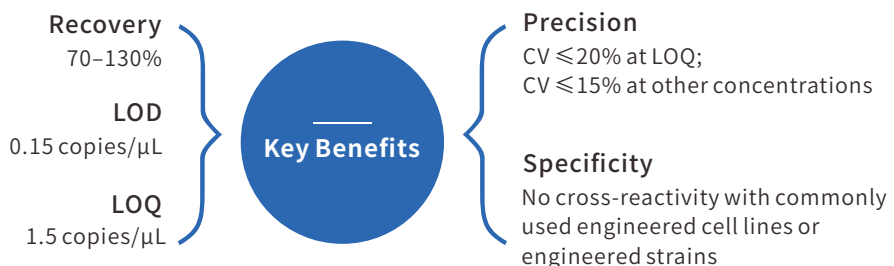
Replication-Competent Lentivirus (RCL) Quantification qPCR Kit

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.
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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

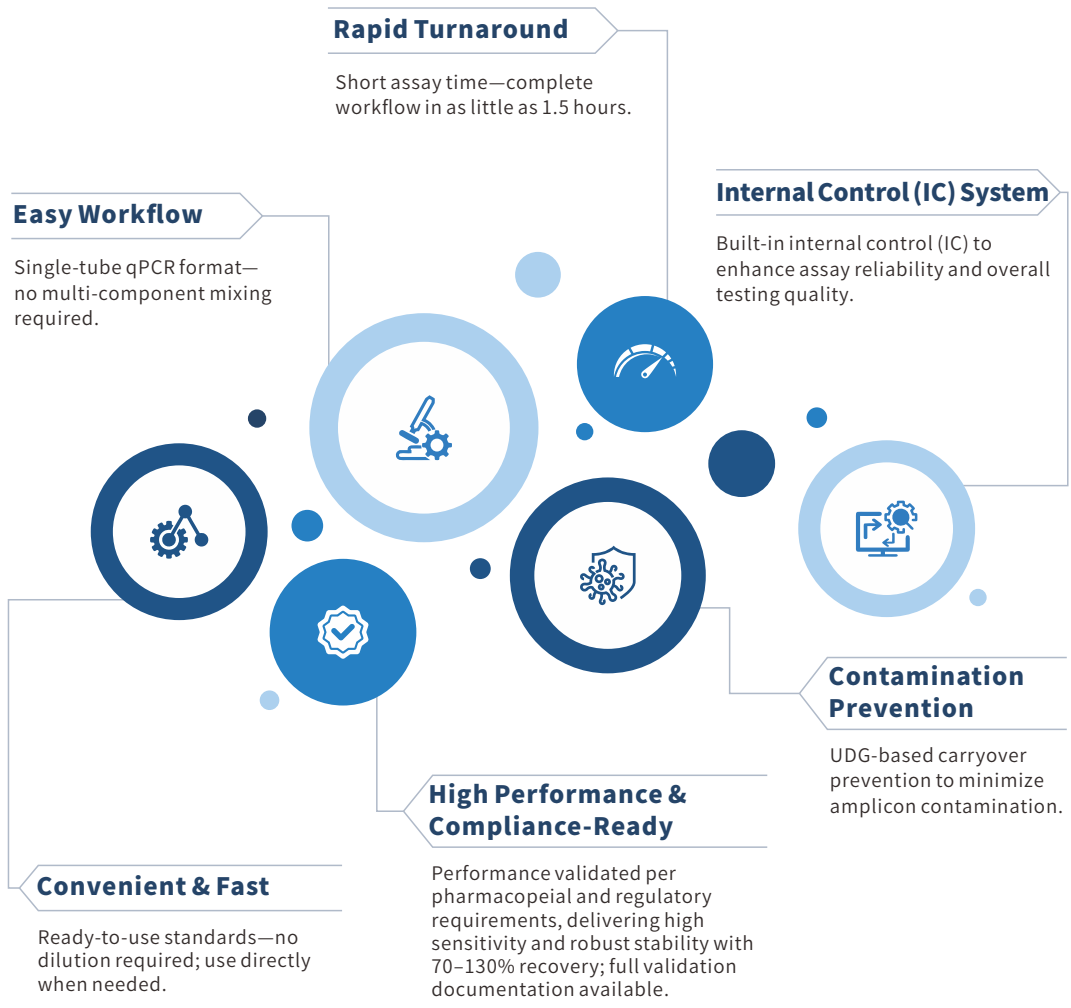
Replication-Competent AAV (rcAAV-2/N) Detection Kit	BP-QN28-100
Replication-Competent AAV (rcAAV-5/N) Detection Kit	BP-QN19-100





Residual Host Cell DNA Testing

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



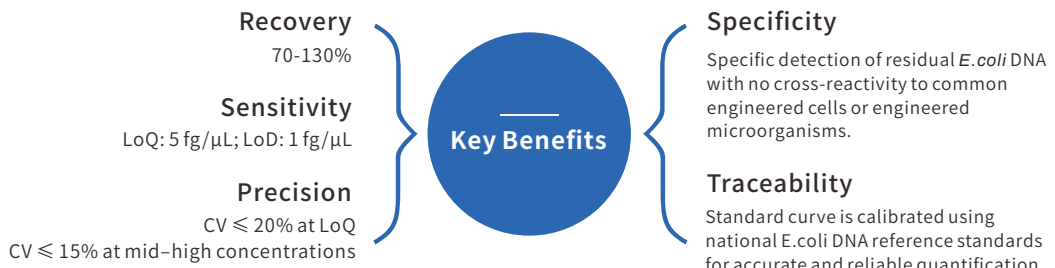
E.coli Residual Host Cell DNA Detection Kit

Cat. No. **BP-QN24-100**

qPCR (Fluorescent Probe Method)

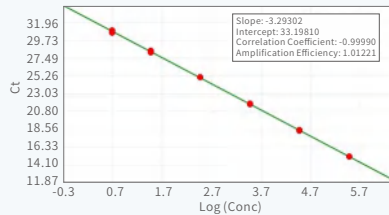
This kit uses fluorescent probe-based qPCR. Primers and probes are designed against conserved E. coli sequences and paired with ready-to-use calibrators for quantitative measurement of residual E. coli DNA in intermediates, in-process samples, and final drug/biological products.

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

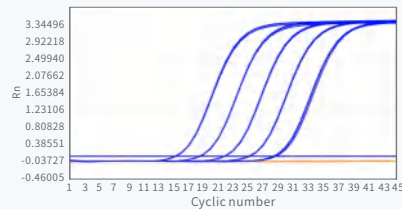


Data

Linear range: 5 fg/μL–300 pg/μL; Amplification efficiency: 101.2%; R² > 0.99



Calibrator Amplification Curves



Related Products

Product Name	Cat. No.
<i>E. coli</i> 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

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

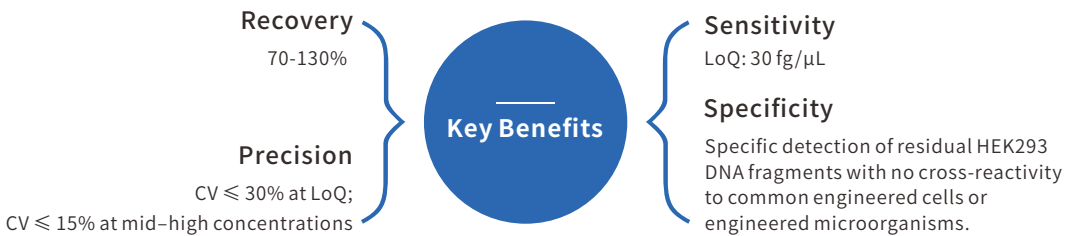
HEK293 Residual Host Cell DNA Fragment Analysis Detection Kit

qPCR (Fluorescent Probe Method)

Cat. No. **BP-QN60-100**

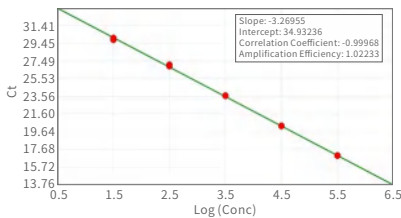
This kit uses fluorescent probe-based qPCR. Primers and probes are designed against conserved HEK293 sequences to quantitatively measure residual HEK293 DNA fragments in intermediates, in-process samples, and final biological products.

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

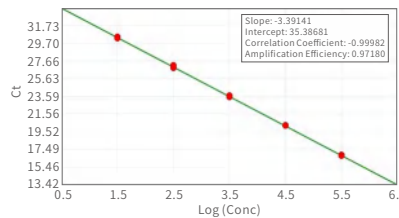


Data

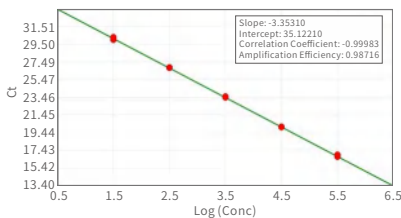
Linear range (all four fragments): 30 fg/μL–300 pg/μL; Amplification efficiency: 90%–110%; R² > 0.99



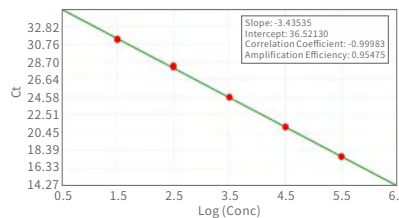
HEK293 Fragment (66 bp) Standard Curve



HEK293 Fragment (177 bp) Standard Curve

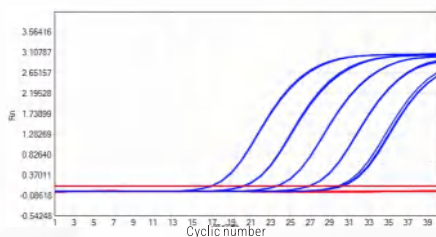


HEK293 Fragment (200 bp) Standard Curve

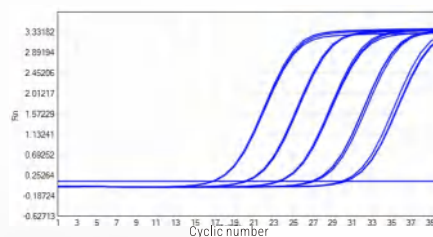


HEK293 Fragment (528 bp) Standard Curve

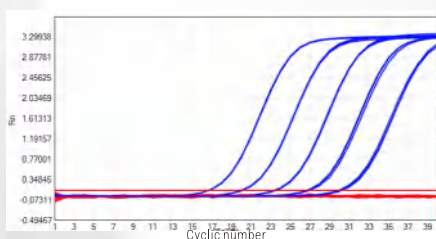
Linear range: All four fragments show a linear range of 30 fg/μL–300 pg/μL;
 Amplification efficiency: 90%–110%; $R^2 > 0.99$



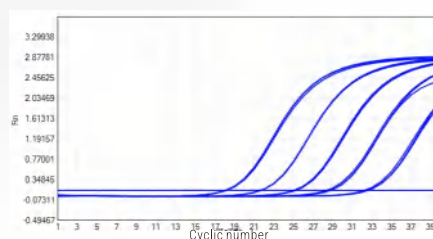
HEK293 Fragment (66 bp) Calibrator Amplification Plot



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.
<i>E. coli</i> Residual Host Cell DNA Detection Kit	BP-QN24-100
CHO Residual Host Cell DNA Detection Kit	BP-QN06-100 BP-QN88-100
Human Residual Host Cell DNA Detection Kit	BP-QN54-100
<i>Pichia pastoris</i> Residual Host Cell DNA Detection Kit	BP-QN18-100
Vero Residual Host Cell DNA Detection Kit	BP-QN31-100
HEK293 Residual Host Cell DNA Detection Kit	BP-QN09-100
HeLa Residual Host Cell DNA Detection Kit	BP-QN13-100
Ns0 & SP2/0 Residual Host Cell DNA Detection Kit	BP-QN37-100
E1A Residual DNA Detection Kit	BP-QN02-100
E1B Residual DNA Detection Kit	BP-QN04-100
E1A & SV40 Large T Antigen (SV40LT) Residual DNA Detection Kit	BP-QN16-100
Hi5 & AcNPV Residual DNA Detection Kit	BP-QN23-100
<i>Saccharomyces cerevisiae</i> Residual Host Cell DNA Detection Kit	BP-QN63-100
<i>Hansenula</i> (Yeast) Residual Host Cell DNA Detection Kit	BP-QN90-100
MDCK Residual Host Cell DNA Detection Kit	BP-QN161-100
Sf9 & AcNPV Residual DNA Detection Kit	BP-QN21-100
Plasmid DNA (Kanamycin Resistance Gene) Residual DNA Detection Kit	BP-QN05-100
Plasmid DNA Residual DNA Detection Kit	BP-QN66-100 BP-QN120-100

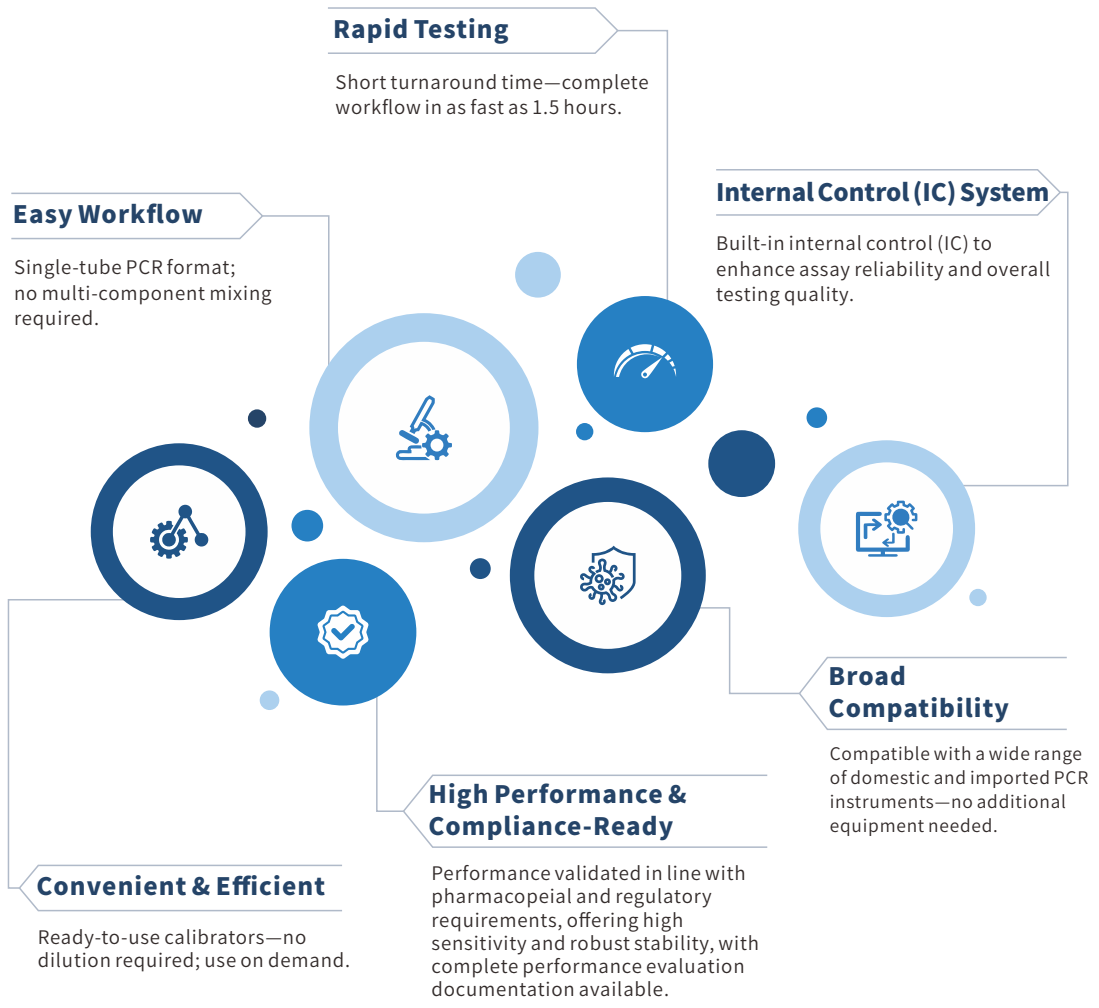


Cell Species Identification

Product Portfolio

qPCR (Fluorescent Probe Method)

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



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.
	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).
Specificity	Cross-reactivity	Tested 13 non-target species DNAs (<i>Pichia pastoris</i> , Sf9, <i>E. coli</i> , <i>Staphylococcus epidermidis</i> , <i>Mycoplasma pneumoniae</i> , <i>Mycobacterium ranae</i> , <i>Streptococcus pneumoniae</i> , <i>Staphylococcus aureus</i> , <i>Staphylococcus intermedius</i> , <i>Propionibacterium</i> spp., <i>Pseudomonas aeruginosa</i> , <i>Monascus</i> spp., <i>Lactobacillus acidophilus</i>). 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 Portfolio

Product Name	Cat. No.
	ELISA
<i>E. coli</i> Host Cell Protein ELISA Kit	BP-QP-E001-96
CHO Host Cell Protein ELISA Kit	BP-QP-C002-96
	ELISA (One-Step Method)
<i>E. coli</i> 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

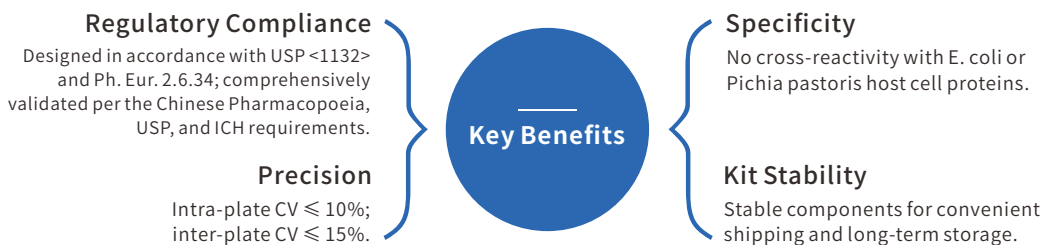
CHO Host Cell Protein ELISA Kit ELISA (One-Step Method)

Cat. No. BP-QN60-100

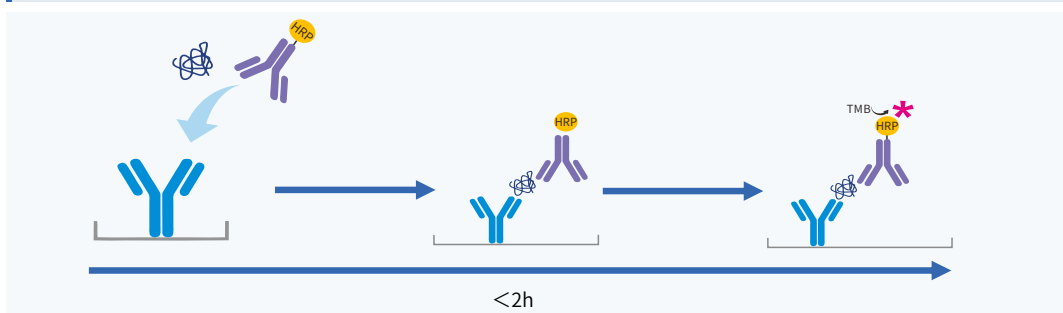
CHO cells are widely used mammalian cell lines for commercial production of therapeutic proteins. During manufacturing, residual host cell proteins (HCP) may remain in the final product and potentially trigger immune responses, affecting safety and efficacy. Therefore, residual CHO HCP levels should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

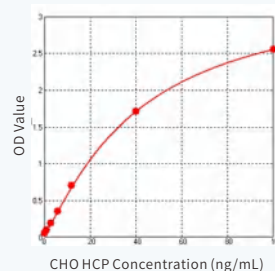


Assay Principle



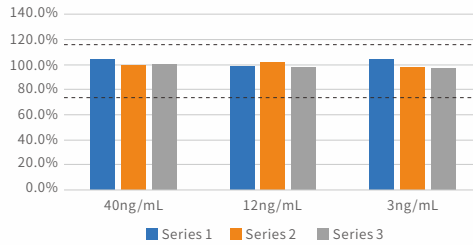
Typical Standard Curve

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

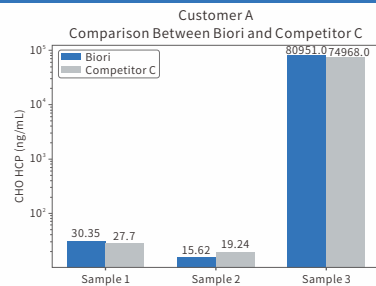
- Within the linear range (high/medium/low levels), inter-batch precision across three batches shows CV ≤15%.

Specificity

Sample	<i>E. coli</i> Host Cell Protein (HCP)			<i>Pichia pastoris</i> Host Cell Protein (HCP)		
	1			1		
Sample Concentration (µg/mL)	1					
Spike Level (ng/mL)	0	1	3	0	1	3
Measured Concentration (ng/mL)	9.4×10^{-3}	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.



Process Validation and Residual Testing

Product Name	Cat. No.
BSA ELISA Kit <small>ELISA (One-Step Method)</small>	BP-QP-T003-96
RNA Ladder 1000	BP-20-50
RNA Ladder 6000	BP-10-50
RNA ladder 12000	BP-15-50
mRNA Capping Efficiency Test Sample Preparation Kit	BP-05-10
mRNA Capping Efficiency Test Sample Preparation Kit (2.0)	BP-12-10
Poly(A) Tail Length Distribution Test Sample Preparation Kit	BP-11-10
Residual dsRNA Quantification Kit	BP-18-96
Residual RNase Quantification Kit	BP-06-100
Residual DNase Quantification Kit	BP-16-100
T7 RNA Polymerase ELISA Kit <small>ELISA (One-Step Method)</small>	BP-QP-T009-96
Dnase I ELISA Kit <small>ELISA (One-Step Method)</small>	BP-QP-D013-96
Rnase Inhibitor ELISA Kit <small>ELISA (One-Step Method)</small>	BP-QP-R014-96



Nucleic Acid Testing Reagents & Instruments

Nucleic Acid Extraction Reagents

Amplification & Detection Reagents

Extraction Instruments & Accessories

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

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 BP-QN188-48
Nucleic Acid & Nuclease Decontamination Reagent-V1	BP-QN281
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



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Protecting Life and Health, Creating a Better Life



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Leader in the Life Sciences Field



Core Values

Integrity, Responsibility, Proactiveness, Innovation



Pursuing Excellence in Quality Providing Prompt and Thorough Service



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