BIOSYSTEMS Acro

Comprehensive Quality Control Solutions for Biologics

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As biologics continue to expand in types and therapeutic applications, robust quality control has become critical to ensuring their safety and efficacy. By leveraging global pharmacopoeia standards and regulatory guidelines, ACROBiosystems has developed comprehensive quality control solutions that cover both safety indicators and process-related residuals. Our platforms are designed to enhance detection efficiency, support regulatory compliance, and accelerate the development and commercialization of biologic products.

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SAFENSURE™ Safety Testing Solution

Endotoxin Detection Platform | Mycoplasma Detection Platform

Endotoxin, mycoplasma, and sterility testing are vital components of biologics quality control, playing a key role in ensuring regulatory compliance and patient safety.

Endotoxin, commonly present in manufacturing environments, can cause pyrogenic reactions and reduce drug efficacy. Recombinant Factor C assay provides a sensitive, animal-free detection method using fluorescence readouts. For mycoplasma and sterility testing, nucleic acid amplification technologies have become the preferred choice, offering rapid, real-time detection to monitor contamination and support fast release of cell and gene therapies. Compared to traditional microbial culture methods that can take up to 14 days, qPCR-based mycoplasma and sterility test significantly shorten turnaround time, improve efficiency, and lower contamination risk. These advanced testing strategies are aligned with global regulatory standards and play a critical role in maintaining aseptic processes, protecting patients, and enhancing product competitiveness.

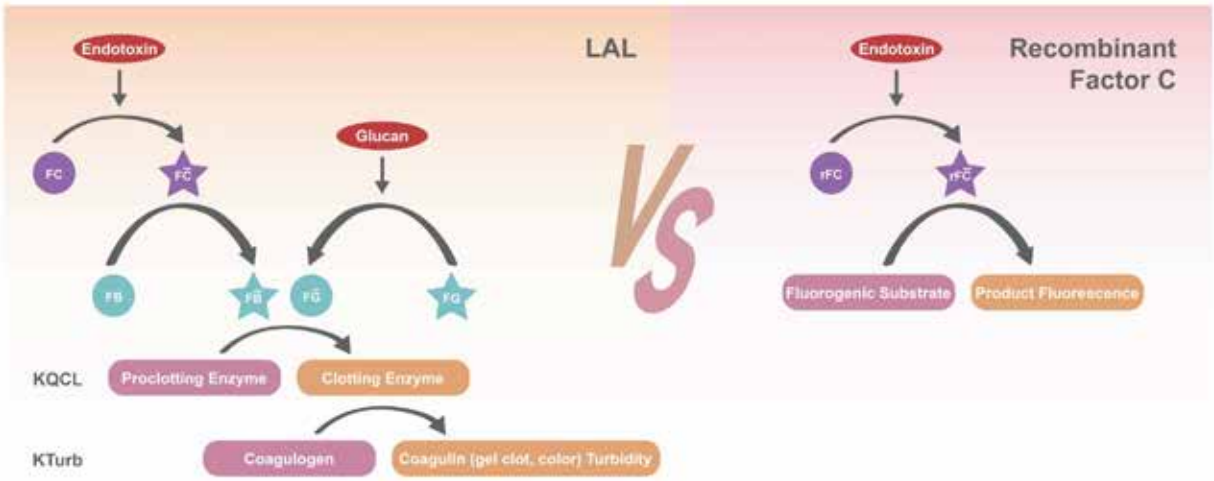
ACROBiosystems provides a comprehensive portfolio of safety testing solutions tailored for biopharmaceutical manufacturing. Developed in accordance with international pharmacopoeias and biologics guidelines, our kits cover endotoxin, mycoplasma, and sterility detection—empowering manufacturers to meet evolving quality demands with confidence.

Endotoxin Detection Platform

- Recombinant Factor C Endotoxin Detection Kit

Factor C, originally derived from the amebocyte lysate of horseshoe crabs, has long been used in endotoxin detection due to its ability to specifically bind endotoxins and activate the coagulation cascade. However, with increasing restrictions in global pharmacopeias and concerns over the sustainability of horseshoe crab populations, recombinant Factor C (rFC) has emerged as a reliable alternative.

The **Recombinant Factor C Endotoxin Detection Kit (Cat. No. RES-A056)** utilizes genetically engineered rFC to bind and respond to endotoxins. Upon activation by endotoxin, rFC hydrolyzes a fluorogenic substrate, generating a fluorescent signal that is directly proportional to the endotoxin concentration. Compared to traditional LAL-based methods, this assay offers enhanced stability, improved accuracy, and eliminates interference from Factor G–mediated pathways, ensuring more reliable and reproducible endotoxin detection results.



The left panel illustrates the mechanism of the traditional LAL-based endotoxin detection method, while the right panel shows the mechanism of the recombinant Factor C (rFC) assay. rFC exhibit high specificity for endotoxin, binding to it and triggering a downstream reaction pathway that cleaves a fluorogenic substrate. By measuring the signal from the cleaved substrate and comparing it to a standard curve, the endotoxin concentration can be accurately quantified.

Product Advantage

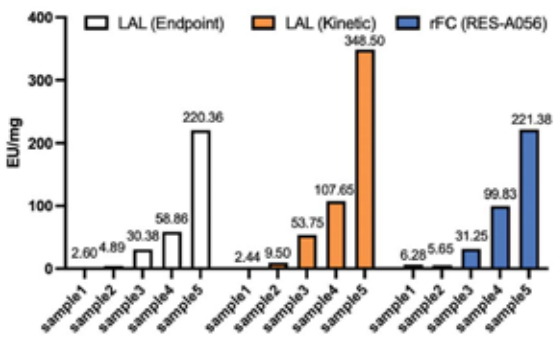
- Comparable to LAL method - Endpoint fluorescent assay, comparable to other chromogenic quantitative LAL methods.
- High specificity - Unlike LAL Assay, as Factor G is absent from the rFC test kit, false-positive results due to β-glucan activation are not expected to occur.
- Accuracy - Traceability of endotoxin standards in the kit against USP Standard (Catalog No: 1235503).
- Fast time to results - 2 hours.
- High sensitivity - Sensitivity range from 0.005-5 EU/mL.
- Extensive validation – Verification on multiplex biological products, kinds of microplate readers and various buffer systems, comprehensive validation of specificity, sensitivity, precision, accuracy, applicability, and other aspects according to the parameters listed in the EUROPEAN PHARMACOPOEIA 11.0 and USP <1225>.
- USP<86> has officially included the recombinant factor C assay.
- Sustainable resource - Get rid of dependence on animal derived reagents, reduce dependence on horseshoe crab resources and fishing pressure and realize long-term supply.
- Good inter batch consistency - Batch consistency of products is guaranteed due to the use of genetic recombination technology for production.

Product List

Cat. No.	Description	Size
RES-A056	Recombinant Factor C Endotoxin Detection Kit	48 / 96 Tests

Validation Data

- High sensitivity, endotoxin detection results comparable to traditional LAL methods

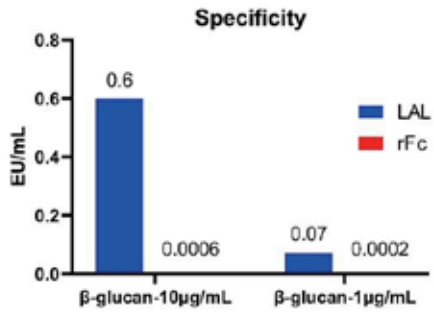


Different methods were used to detect endotoxin residues in five samples, and the values of this rFC method and LAL method were at the same level.

Sample	Endotoxin limit	LAL (Endpoint)	LAL (Kinetic)	rFC (RES-A056)
Recombinant Human Interferon α-1b	10EU/mL	＜0.02EU/mL	＜0.01EU/mL	＜0.16EU/mL
Human insulin injection	32EU/mL	＜0.02EU/mL	＜0.01EU/mL	＜0.02EU/mL
CelThera™ GMP T Cell Expansion Medium (ACROBiosystems, Cat.No. GMP-CM3101)	10EU/mL	＜0.02EU/mL	＜0.01EU/mL	0.005EU/mL
RPMI 1640 Medium (Hyclone, Cat.No. SH30809.01)	10EU/mL	＜0.02EU/mL	＜0.01EU/mL	＜0.01EU/mL
DMEM Medium (Basalmedia, Cat.No. L120KJ)	10EU/mL	＜0.02EU/mL	＜0.01EU/mL	0.009EU/mL

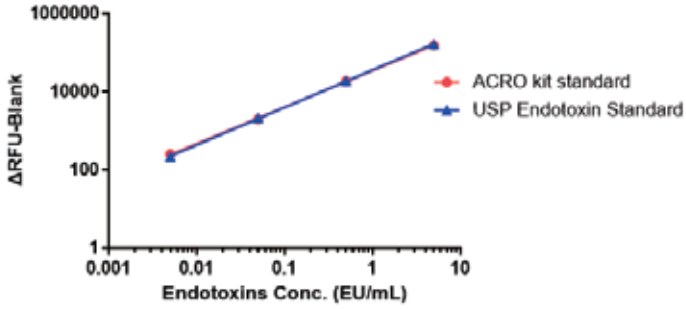
The kit is applicable in endotoxin detection of injectable drugs and some medium, such as Recombinant Human Interferon α-1b, Human insulin injection and different mediums. The results of the rFC method of this kit are compared with those of LAL method.

- High specificity, effectively eliminating false positives caused by β-glucan interference



The rFC method was employed to detect endotoxin residues in β-glucan at concentrations of 10μg/mL and 1μg/mL. No non-specific signals were detected. In contrast, the dynamic chromogenic method used for β-glucan detection resulted in the detection of endotoxin and non-specific signals. This indicates that rFC does not react with β-glucan, demonstrating the good specificity of the rFC method.

- Standard Traceability, endotoxin standards are traceable to the USP standard



Using Endotoxin (USP, Cat. No. U1235503) as the standard, the recovery rate of ACRO Kit standard is in the range of 80%-120% , which meets the requirements.

- Excellent buffer compatibility, validated across various buffer systems

Matrix	Recovery	Dilution Factor
1M NaCl	140%	16
20mM $CaCl_2$	82%	8
20mM $MgCl_2$	98%	4
1M Sodium acetate, pH5.0	73%	16
50mM Sodium acetate, pH3.5	74%	20
100mM Tris, pH10.9	113%	80
100mM Glycine, pH3.5	109%	16
1×PBS, pH7.5	102%	40
1×PBS, pH6.0	91%	20
50 mM Tris,100 mM Glycine,225 mM Arginine, 150 mM NaCl,0.005% Tween 80, pH7.5 with 11% Trehalose	81%	4
50 mM Tris,100 mM Glycine,25 mM Arginine, 150 mM NaCl, pH7.5 with 0.01% Tween80 with 11%Trehalose	88%	16
Essential 8™ Flex Basal Medium (Thermofisher, Cat. No. A2858501)	74%	4
mTeSR™ Plus (Stemcell, Cat. No. 100-0276)	82%	32
CelThera™ GMP T Cell Expansion Medium (ACROBiosystems, Cat. No. GMP-CM3101)	93%	4
RPMI 1640 Medium (Hyclone, Cat. No. SH30809.01)	109%	8
DMEM Medium (Basalmedia, Cat. No. L120KJ)	104%	8
CTS™ OpTmizer™ T-Cell Expansion SFM, no phenol red, bottle format (Gibco, Cat. No. A3705001)	91%	16
12.5 mM Histidine Buffer, pH6.5	88%	4
Keytruda Formulation (1.55 mg/mL L-histidine, 0.2mg/mL polysorbate 80, 70mg/mL sucrose in water, pH5.2-5.8)	76%	64
Hemlibra Formulation (26.1 mg/mL L-arginine, 3.1 mg/mL L-histidine, 0.5mg/mL poloxamer 188, adjusted to pH 6.0 with L-asparticacid)	100%	4
30%DMSO	99%	16
HSA (25mg/mL)	73%	64
Toripalimab (40mg/mL)	83%	40
Multiple Electrolytes Injection (Baxter)	96%	4
100%FBS	109%	10

We have conducted interference effect test about different ionic strengths, pH buffers, and medium, the kit has excellent buffer compatibility. For specific buffers or medium, it is recommended that you verify recovery to determine the minimum dilution ratio.

FAQ on Endotoxin Detection

1. Is the recombinant Factor C (rFC) method recognized by pharmacopeias and accepted for endotoxin release testing?

Yes. Several major pharmacopeias have recognized the rFC method as an alternative for bacterial endotoxin testing.

- **European Pharmacopoeia:** Europe has been a leader in developing rFC testing standards. In 2015, the European Pharmacopoeia recognized rFC as an alternative method. By 2017, work began on the development of this method, and in January 2021, Chapter 2.6.32 was officially released, outlining bacterial endotoxin testing using rFC. This method is now widely adopted across Europe, and in 2020, rFC-based endotoxin testing was approved for drug release.
- **United States Pharmacopeia (USP):** The research and standardization of rFC testing are ongoing in the United States. A 2018 draft included rFC as an accepted alternative method, with further revisions made to the standards. On July 26, 2024, the USP Microbiology Expert Committee approved Chapter <86>: Bacterial Endotoxin Testing, which permits the use of rFC for endotoxin testing. The final text will be published in November 2024 and official in May 2025.
- **Japanese Pharmacopoeia:** Japan has been actively conducting related research. Its expert committee-initiated discussions on developing a bacterial endotoxin testing method using rFC and conducted comparative studies between horseshoe crab reagents and rFC. The relevant section, <G4 - 4 - 180>, outlines procedures and considerations for endotoxin testing with recombinant protein reagents.
- **Chinese Pharmacopoeia:** China has focused on rFC methods since 2012. In 2016, the Chinese Pharmacopoeia Committee launched systematic method validation and applicability studies. The 2020 edition of the Chinese Pharmacopoeia included rFC as a supplementary method in the 9251 bacterial endotoxin test guidelines. In 2024, two drafts of the "9251 Bacterial Endotoxin Test Guidelines" were published, clarifying this method as a supplementary approach for endotoxin testing. Additionally, the January 2025 cell therapy product manufacturing guidelines specified that rFC could be used for endotoxin testing in safety assessments.

2. Can plastic tubes be used instead of depyrogenated glass tubes for endotoxin testing?

The use of plastic tubes is not recommended. Endotoxins may adsorb onto plastic surfaces, regardless of the tube's sterility level, which can lead to inaccurate test results. It is strongly advised to use depyrogenated glass tubes appropriate for endotoxin testing, based on the volume and testing requirements.

3. Is a specific brand of instrument required for recombinant Factor C endotoxin testing?

The recombinant Factor C endotoxin assay is compatible with any fluorescence microplate reader equipped with an excitation wavelength of 380 nm and an emission wavelength of 440 nm. Prior to testing, it is important to verify the performance of the instrument to ensure reliable results.

4. How to Calculate the Maximum Valid Dilution (MVD) of a Sample?

High concentrations of sample components, interfering substances, or unsuitable pH levels may affect the accuracy of endotoxin detection. To reduce such interference, it is recommended to dilute samples with high-concentration components appropriately. If the sample pH is not within the acceptable range, adjustments should be made as outlined below. When dilution does not eliminate the interference, the sample buffer system should be replaced with an endotoxin-free buffer until the interference is resolved. If the recovery rate falls outside the acceptable range of 50%–200%, dilution can be used to reduce or eliminate interference. The sample dilution factor must remain within the Maximum Valid Dilution (MVD). MVD Calculation Formula:

MVD = (Endotoxin Limit × Sample Concentration) / λ

λ refers to the lowest point on the standard curve of the assay (e.g., 0.005 EU/mL).
Example Calculation: If the endotoxin limit is 10 EU/mg, the sample concentration is 10 mg/mL, and λ is 0.005 EU/mL, then: MVD = (10 EU/mg × 10 mg/mL) / 0.005 EU/mL = 20,000

Ensure that the units used for both endotoxin limit and sample concentration are compatible. Refer to the conversion table below for guidance.

Concentration Unit	Group 1	Group 2	Group 3	Group 4
Endotoxin limit unit	EU/mg	EU/U	EU/dose	EU/mL
Sample concentration unit	mg/mL	U/mL	dose/m	ml/mL

5. How should the endotoxin standard be reconstituted?

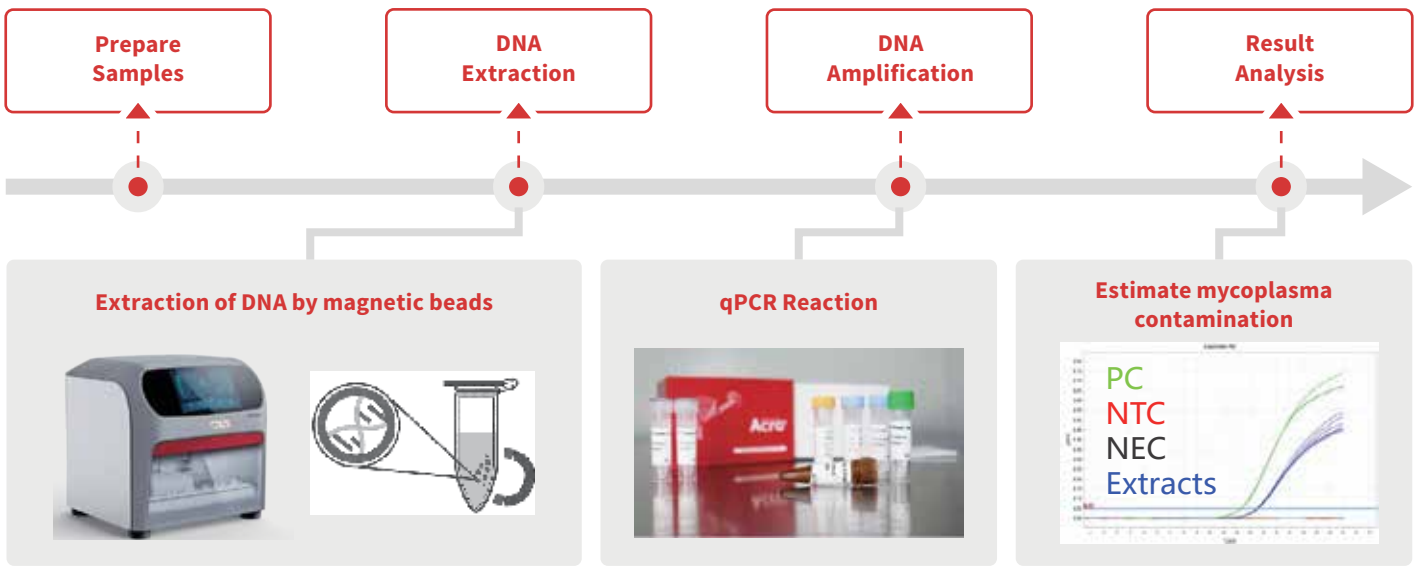
Please refer to the Certificate of Analysis (COA) for the specific batch. The COA can be downloaded at: *https://www.acrobiosystems.com/A655-Certificate-of-Analysis-Download-navigator.html*. Reconstitute the standard by adding the specified volume of endotoxin-free water as instructed in the COA.

Mycoplasma Detection Platform

- Mycoplasma DNA Sample Preparation Kit & Mycoplasma Rapid Detection Kit

During the manufacturing of biological products—including cell isolation, modification, and expansion—mycoplasma contamination poses a potential risk to patient safety. To ensure the safety of the final product, mycoplasma must be completely excluded during release testing. To accelerate both in-process monitoring and batch release, ACROBiosystems offers a comprehensive mycoplasma detection solution, including Mycoplasma DNA Sample Preparation Kits and Mycoplasma Rapid Detection Kits, developed to meet the requirements of European Pharmacopoeia Chapter 2.6.7.

The Mycoplasma Rapid Detection Kit enables sensitive and reliable detection of mycoplasma contamination in biologics, meeting or exceeding regulatory guidelines of 10 CFU/mL. Unlike traditional culture-based methods, which are time-consuming, this assay simplifies the detection workflow and delivers results in under 3 hours, significantly enhancing testing efficiency.



Product Advantage

- Broad Coverage: Detects over 250 species of Mycoplasma and Spiroplasma, including all species listed in the Chinese, European, U.S., and Japanese Pharmacopoeias.
- High Specificity: Features multiplex primers and probes targeting mycoplasma-specific 16S rRNA, with no cross-reactivity to closely related non-mycoplasma genera such as Clostridium, Lactobacillus, or Streptococcus.
- High Sensitivity: Fully meets or exceeds regulatory requirements with a detection limit of 10 CFU/mL.
- Strong Compatibility: Suitable for complex matrices, including high cell density samples (10^7 cells/mL), 10% DMSO, and T/NK cell culture media.
- User-Friendly: Single-well assay design with built-in UNG, positive control, and internal control; total workflow time is only 3 hours.
- Comparable Results: Delivers results consistent with traditional culture-based methods.
- Third-Party Validated: Includes validation reports from Eurofins third-party labs using both culture and indicator cell methods.

Product List

Cat. No.	Description	Size
OPA-E101	Mycoplasma DNA Sample Preparation Kit (Magnetic beads)	50 Prep
OPA-S102	Mycoplasma Rapid Detection Kit (qPCR)	50 Tests
OPA-R013	96 V-Bottom Deep-well Plate	1 box
OPA-R014	8-Strip V-Bottom Tip Comb	1 box

Validation Data

- Broad Coverage: Detects over 250 species of Mycoplasma and Spiroplasma

Number of Mollicutes detected with a Database match	
Genus	No.
Mycoplasma	>200
Acholeplasma	14
Spiroplasma	25
Ureaplasma	7

- High Sensitivity: Meets regulatory guideline standards with a detection limit of 10 CFU/mL

ID	Mycoplasma Species	Compendia requirements (CFU/mL)	Result	Limit (CFU/mL)
1	Mycoplasma orale	10	24/24	1
2	Mycoplasma pneumoniae	10	24/24	0.1
3	Mycoplasma hyorhinis	10	24/24	1
4	Mycoplasma salivarium	10	24/24	1
5	Mycoplasma fermentans	10	24/24	1
6	Mycoplasma synoviae	10	24/24	1
7	Mycoplasma gallisepticum	10	24/24	1
8	Mycoplasma arginini	10	24/24	1
9	Acholeplasma laidlawii	10	24/24	0.1
10	Spiroplasma citri	10	24/24	0.1

24 tests were performed on each of the 10 mycoplasma standards (10 CFU/mL), all of which results were positive and met or exceeded the requirements of EP 2.6.7 (10 CFU/mL).

- High Specificity: Unaffected by unrelated cell types or microbial strains

Unrelated strain/ Cell line	Ct Value		Result
Streptococcus pneumoniae	Undetermined	Undetermined	0/2
Lactobacillus acidophilus	Undetermined	Undetermined	0/2
Staphylococcus epidermidis	Undetermined	Undetermined	0/2
Clostridium sporogenes	Undetermined	Undetermined	0/2
Clostridium acetobutylicum	Undetermined	Undetermined	0/2
CHO (10^6 cells/mL)	Undetermined	Undetermined	0/2
HEK293 (10^6 cells/mL)	Undetermined	Undetermined	0/2
T cell (10^7 cells/mL)	Undetermined	Undetermined	0/2
Pichia pastoris	Undetermined	Undetermined	0/2
E.coli	Undetermined	Undetermined	0/2

Two common cell lines and four unrelated strains were extracted and tested. All were negative which indicates that the kit's mycoplasma detection is not affected by unrelated cells/strains.

- Excellent Compatibility and Robust Performance: Suitable for diverse sample types and complex testing conditions

Verification items	Content
qPCR Device comparability	ABI 7500/7500 Fast Real-Time PCR System ABI QuantStudio® 5 Bio-Rad CFX96 Real-Time PCR System Roche Light Cycler 480 II
High cell density Background	CHO (10^6, 10^7 cells/mL) HEK293 (10^6, 10^7 cells/mL)
Sample matrix	OPM-AM103 medium CHO media + CHO Cell (10^7 cells/mL) Gibco CD CHO Medium (1x) Gibco FreeStyle CHO T17 DMEM FBS DMEM+10%FBS DMEM+10%FBS+10 ug/mL Puro DMEM+10%FBS+50 ug/mL Zeo DMEM+10%FBS+500 ug/mL G418 10% DMSO 50 mg/mL HSA

The kit was also suitable for the following conditions, and all test results were negative, indicated that these conditions do not interfere with the detection of mycoplasma.

- High-quality assurance with superior performance compared to other competing products

Brand	ACRO	Competitor T	Competitor S	Competitor R
Type of PCR	TaqMan® based qPCR Assay	TaqMan® based qPCR Assay	TaqMan® based qPCR Assay	TaqMan® based qPCR Assay
Target DNA Probe	520 nm (FAM™ channel)	520 nm (FAM™ channel)	520 nm (FAM™ channel)	520 nm (FAM™ channel)
Internal Control DNA Probe	554 nm (VIC™ channel)	546 nm (NED™ channel)	612 nm (ROX™ channel)	554 nm (VIC™ channel) (recovery control)
Fluorescence dyes	FAM™ and VIC™	FAM™ and NED™	FAM™ and ROX™	FAM™ and VIC™
Time	2 hours 45minutes	4-5 hours	4 hours	4-5 hours
Internal/Recovery Control in one well	Yes	Yes	Yes	No
UNG in kit	Yes	No	No	Yes
Extraction Automation	Yes	Yes	No	Yes
EP 2.6.7 compliance	Yes	Yes	Yes	Yes

FAQ on Mycoplasma Detection

1. At which stages of biologics manufacturing are mycoplasma testing required?

According to pharmacopeial guidelines, mycoplasma testing is required for the master cell bank, working cell bank, viral seed stock, control cells, and clinical-grade therapeutic cells. For viral vaccines, both the virus harvest fluid and bulk harvest must also be tested for mycoplasma using culture-based methods. If necessary, indicator cell assays may be used to screen culture media for contamination.

2. What are the advantages and disadvantages of the culture method and the indicator cell culture method for mycoplasma detection?

Culture Method:

- **Advantages:** Considered the gold standard for mycoplasma detection, this method is well-established and offers high sensitivity.
- **Disadvantages:** It has a long turnaround time, typically 28 days—and involves the use of live positive control strains, which may increase the risk of contamination.

Indicator Cell Culture Method:

- **Advantages:** Slightly shorter detection time compared to the traditional culture method, usually around 21 days.
- **Disadvantages:** Lower sensitivity, and similar to the culture method, the use of positive controls can still pose a contamination risk.

3. What are the advantages of nucleic acid testing (NAT) for mycoplasma detection?

- **Rapid Results:** Detection can be completed within a few hours.
- **High Sensitivity:** Eliminates the need for live positive control strains, reducing the risk of contamination, and enables the detection of low concentrations of mycoplasma.

Meanwhile, it is important to note that due to the diversity and biological variability of mycoplasma species, the entire testing system must be properly validated.

4. How should mycoplasma detection results be interpreted?

Once the quality control (QC) results meet the acceptance criteria, sample results can be analyzed. Using the Mycoplasma Rapid Detection Kit (qPCR) as an example:

- **FAM Signal:** Indicates the presence of mycoplasma nucleic acid.
  If the FAM Ct value is < 35, the result is positive, indicating the sample is contaminated with mycoplasma. If the FAM Ct value is > 35, the result is negative, indicating no mycoplasma contamination.
- **VIC Signal:** Serves as an internal control. VIC Ct value < 35 indicates no PCR inhibition. VIC Ct value > 35 suggests the presence of PCR inhibitors, and extraction or amplification conditions may need to be optimized.

5. How should sample inhibition be addressed in mycoplasma detection?

To mitigate PCR inhibition during mycoplasma testing, consider the following strategies:

- **Pre-treatment Before Nucleic Acid Extraction:** Dilute the sample, centrifuge and collect the supernatant
- **Reduce Cell Count:** Use fewer cells, ideally less than 10^6 cells per 200 µL
- **Extend Proteinase K Treatment Time:** Increase the digestion time during the extraction step to improve lysis efficiency
  Post-Lysis Centrifugation: After cell lysis, centrifuge immediately to remove cell debris and prevent magnetic bead aggregation

6. How can sample contamination be prevented during mycoplasma testing?

Preventing cross-contamination during sample pre-processing is essential for accurate mycoplasma detection. The following steps and precautions should be taken:

(1) Sample Collection and Transportation

Use Sterile Containers: Ensure that sample containers are sterile and maintain aseptic techniques during sample collection.

Avoid Sample Mixing: Keep different samples strictly separated. Label each sample clearly to ensure traceability.

Transport Conditions: Transport samples to the laboratory as soon as possible. Maintain appropriate temperature conditions (e.g., 2–8°C) to prevent mycoplasma growth or degradation.

(2) Laboratory Preparation

Clean Work Areas: Before sample handling, thoroughly clean benchtops, equipment, and tools. Disinfects using 70% ethanol or other appropriate disinfectants.

Use Sterile Reagents and Supplies: Ensure that all reagents and consumables (e.g., centrifuge tubes, pipettes, and tips) are sterile and properly disinfected before use.

Work Area Separation: Physically separate different steps of the workflow—sample preparation, nucleic acid extraction, and PCR setup—into distinct work areas to minimize cross-contamination. For example, designate separate zones for sample handling, nucleic acid extraction, and PCR reactions.

(3) Sample Handling

Wear Protective Equipment: Personnel should wear appropriate PPE such as disposable gloves, lab coats, masks, and safety goggles. Gloves should be changed between handling different samples.

Avoid Aerosol Contamination: Minimize vigorous mixing or shaking of samples to reduce the risk of aerosol formation. Use sealed centrifuge buckets when centrifugation is required.

Apply Aseptic Techniques: Follow strict aseptic practices for all procedures, including the use of sterile pipettes and filter tips, and avoid any direct contact between samples and the external environment.

(4) Nucleic Acid Extraction

Use Sterile Reagents and Consumables: All reagents and consumables used for nucleic acid extraction must be sterile and appropriately disinfected before use.

Prevent Cross-Contamination Between Samples: Use dedicated reagents and consumables (e.g., disposable pipette tips and centrifuge tubes) for each sample to avoid cross-use.

Include Internal Controls (ICs): Add internal controls during the extraction process to monitor for potential inhibitors or contamination.

(5) PCR Reaction Setup

Use Sterile Materials: Ensure all PCR reagents and consumables are sterile and disinfected before use.

Avoid Cross-Contamination Between Samples: Prepare PCR reactions using separate tubes and reagents for each sample. Use disposable pipette tips and reaction tubes.

Apply Aseptic Techniques: Follow aseptic procedures when adding samples and reagents to avoid environmental exposure.

(6) Waste Disposal

Properly Dispose of Waste: All used consumables and sample materials must be handled in accordance with biosafety regulations to prevent lab contamination.

Use Dedicated Waste Containers: Discard used items into designated biohazard waste containers and ensure they are disinfected appropriately.

(7) Routine Monitoring and Validation

Monitor Lab Environment Regularly: Perform routine microbiological monitoring to verify the cleanliness and sterility of the laboratory environment.

Validate Workflow Procedures: Regularly validate sample handling and testing workflows to ensure accuracy and reliability. For example, perform tests using known positive and negative control samples.

7. How to prevent or minimize DNA aerosol contamination?

What is DNA aerosol?

DNA aerosol refers to liquid droplets that carry free, submicroscopic DNA particles suspended in the air. These aerosols are typically generated during laboratory procedures and can linger in the surrounding air or workspace. Due to their microscopic size, these DNA-carrying droplets can remain airborne for extended periods.

Since DNA aerosols contain exogenous DNA fragments, their presence can lead to non-specific amplification in PCR reactions—ultimately resulting in false-positive outcomes and compromising experimental accuracy.

Common sources of DNA aerosol contamination include:

- Leaving used pipette tips, microcentrifuge tubes (EP tubes), or gloves inside a biosafety cabinet.
- Performing frequent DNA-related experiments in the same workspace without proper cleaning protocols.
- Improper pipetting techniques, such as repeatedly pressing the plunger during mixing or dilution steps.

For instance, when diluting high-concentration DNA samples, aerosols can be easily generated. The airflow within a biosafety cabinet can spread these aerosols into the surrounding air. Additionally, unnecessary repetitive pipetting during mixing can significantly increase aerosol formation.

How to Prevent DNA Aerosol Contamination?

To minimize the risk of DNA aerosol contamination during nucleic acid extraction, PCR, or other genetic procedures, ACROBiosystems' Molecular R&D Platform has established a standardized set of SOPs in accordance with international guidelines for nucleic acid handling laboratories. These protocols are designed to help researchers reduce the risk of contamination throughout the entire workflow.

1. Laboratory Layout Recommendations

To minimize the risk of contamination from nucleic acids or amplification products during extraction, dilution, and qPCR procedures, it is strongly recommended to physically separate work areas. An ideal PCR laboratory should include a Reagent Preparation Room (a DNA-free zone), a Sample Extraction Room, and an Amplification Room. Alternatively, at minimum, two clearly defined areas should be maintained: a Clean Room (negative area) for reagent preparation and a Contaminated Room (positive area) for sample extraction and amplification. Additionally, proper airflow control and pressure differentials between rooms should be implemented to further reduce the risk of cross-contamination.

2. Nucleic Acid Decontamination Procedures

(1) General Lab Decontamination: Nucleic acid decontamination reagents should be used to thoroughly clean all operational surfaces in the laboratory. Spray the inside of the biosafety cabinet, including the work surface, front panel, and both side walls; if the surface can be lifted, also clean the underside and the back panel. Additional areas to be sprayed include benchtops, the external surfaces of pipettes, centrifuge racks, magnetic stands, refrigerator handles, and any other commonly touched surfaces within the lab environment. Allow the decontamination reagent to sit for 10–15 minutes, then wipe all treated areas with lint-free wipes soaked in 70% ethanol to effectively remove any residue.

(2) Pipette Decontamination: Spray pipettes thoroughly with 70% ethanol, focusing on the nozzle area where the pipette connects with tips. Ensure the area is rinsed well, then dry using lint-free wipes and allow to dry completely to avoid residual buildup.

(3) Centrifuge Rack Cleaning: Spray the racks with 70% ethanol and soak them in purified water for at least 20 minutes. Rinse thoroughly with clean water and air dry before reuse.

(4) Floor Cleaning: Use purified water or tap water and a clean mop to wipe down the lab floors. Mop heads should be cleaned immediately after use. Alternatively, the floor can be disinfected using 10% sodium hypochlorite, followed by mopping with water to remove any residual chlorine.

(5) UV Sterilization: Once cleaning is complete, perform UV disinfection of the entire lab space for 15–30 minutes. This should be done at least once per week. After UV treatment, run the ventilation system for 10–30 minutes to ensure proper air circulation and particle removal.

(6) Laboratory Waste Disposal: Dispose of lab waste promptly. Securely seal waste bags and place them in designated disposal areas for centralized treatment. This applies to general molecular laboratories and not to HCD-specific testing labs.

(7) Routine Nucleic Acid Contamination Monitoring: It is recommended to conduct monthly environmental monitoring in each experimental area and biosafety cabinet. Use an 8-strip PCR tube, add 10 µL of nuclease-free water to each well, leave the tube open in the target area for 1–2 hours, then add the appropriate PCR mix and perform qPCR. Select primers based on the nucleic acid targets most used in your lab to detect potential airborne DNA contamination effectively.

3. Daily Laboratory Cleaning Procedures

(1) Biosafety Cabinet: After completing nucleic acid-related experiments, the biosafety cabinet must be cleaned on the same day using a nucleic acid decontamination reagent. Thoroughly spray the work surface, front panel, and side walls, allow the reagent to react for 10–15 minutes, then wipe down with 70% ethanol. After cleaning, perform UV disinfection inside the cabinet for 15–30 minutes.

(2) Pipettes: All pipettes used during the day should be cleaned with a nucleic acid decontamination reagent. Allow the reagent to sit for 10–15 minutes, then wipe thoroughly with 70% ethanol.

(3) Lab Tools and Consumables: Items such as centrifuge tube racks, PCR tube racks, and magnetic stands used during the day should be sprayed with 70% ethanol, soaked in purified water for approximately 20 minutes, rinsed thoroughly with purified water, and left to air dry.

(4) Workbenches: All benchtops in the lab should be cleaned with a nucleic acid decontamination reagent at the end of each day. Allow the reagent to sit for 10–15 minutes, then wipe clean with 70% ethanol.

(5) Floor Cleaning: Laboratory floors should be cleaned at least once a week using water or an appropriate disinfectant, followed by mopping with clean water.

resDetect™ CMC Process Residual Detection Solution

| Nucleic Acid Residuals | Enzyme Residuals | Cell Culture Materials Residuals | Other Residuals

Biopharmaceutical process residue detection is a quality control methodology used to quantify the number of residues generated throughout the biological manufacturing process. The production of biologics such as cell and gene therapies, therapeutic antibodies, and vaccines involves the use of biological materials. As such, residues with a biological origin such as host cell DNA, affinity chromatography ligands, culture medium additives, and other substances may be introduced. It is crucial to remove and quantitatively control these introduced residues during the production process for drug/vaccine manufacturing, as residual contaminants can severely impact the safety and efficacy of the final product.

resDetect™ is our brand of reagent kits designed to follow international legal and regulatory requirements and guidelines for the detection of residual components. These kits cover various applications related to process-related residue detection for biopharmaceuticals, including cell and gene therapies (CGT), antibody drugs, mRNA-based therapeutics, vaccines, and more. resDetect™ offers comprehensive solutions for process residue detection and includes reagent kits for the detection of residual components such as host cell DNA, affinity ligand, tool enzymes, cytokines, and more.

Stable and Relable —— Stringent batch testing and release, with inter-batch differences less than 15%

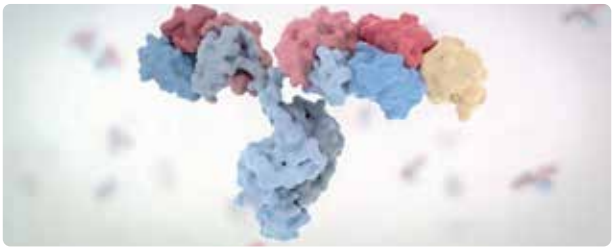
Regulatory Compliance —— Complaitn with standards and regulations of international regulatony agencies.

Global Supply —— Product delivery in 1-3 days, worldwide

Comprehensive Validation —— Referencing guidelines including ICH Q2(R2) and ChP 9101

Cell therapy process residue quality control

Gene therapy process residue quality control



Therapeutic antibodies process residue quality control

mRNA-based therapeutics process residue quality control

Nucleic Acid Residue Detection

During the production of various bioproducts such as cell/gene therapy drugs, therapeutic antibodies, vaccines, etc., the residual nucleic acids can impact the quality of the final product. Residual DNA from various host cells (Residual DNA, resDNA), plasmid DNA residue, and other nucleic acid residues pose potential carcinogenic and infectious safety concerns. To ensure the safety and efficacy of related products, regulatory agencies in various countries have imposed strict limits on the amount of nucleic acid residues in bioproducts.

We have various nucleic acid residue detection kits, including host cell residue detection kits, plasmid DNA residue detection kits, risk element residue detection kits, and more.

- resDetect™ Host Cell Residual DNA Detection Kit

- Host cell DNA types: CHO, E. coli, HEK293, HEK293T, Vero, Pichia pastoris.
- High sensitivity: Accurate quantification of residual host cell DNA at femtogram levels.
- High consistency: Consistent performance across different DNA fragment sizes.
- High specificity: No cross-reactivity with unrelated DNA, minimizing false positive detection.
- Manufactured under ISO 13485/9001 Quality Management Systems: High-Quality Host Cell Residual DNA Sample Preparation and Detection Kits.
- Rigorous quality management system; comprehensive validation: References to ICH Q2(R2) guidelines with thorough validation reports.

Product List

Cat. No	Extraction kit	Application
OPA-R005	resDetect™ resDNA Sample Preparation Kit (Magnetic Beads)	/
OPA-R023	resDetect™ resDNA Sample Preparation Prefilled Kit (Magnetic Beads)	/
Cat. No	**Host cell DNA quantitative kit**	**Application**
OPA-O002	resDetect™ *E. coli* resDNA Quantitative Kit	Recombinant protein, plasmid expression
OPA-R004	resDetect™ CHO resDNA Quantitation Kit	Antibody production
OPA-R007	resDetect™ E1A & SV40LTA resDNA Quantitation Kit (qPCR)	CAR-T
OPA-R008	resDetect™ E1A resDNA Quantitation Kit (qPCR)	CAR-T
OPA-R009	resDetect™ Plasmid resDNA Quantitation Kit (qPCR)	Plasmid

Cat. No	Extraction kit	Application
OPA-R024	resDetect™ resDNA Sample Preparation Kit II (Magnetic Beads)	/
Cat. No	**Host cell DNA quantitative kit**	**Application**
OPA-R006	resDetect™ HEK293 resDNA Quantitation Kit (qPCR)	CAR-T
OPA-R010	resDetect™ HEK293T resDNA Quantitation Kit (qPCR)	CAR-T
OPA-R017	resDetect™ *Pichia pastoris* resDNA Quantiation Kit (qPCR)	Protein production by Pichia pastoris
OPA-R018	resDetect™ Vero resDNA Quantitation Kit (qPCR)	Vaccine

resDetect™ *E.coli* resDNA Quantitation Kit

Escherichia coli is a key host in biopharmaceutical production, widely used for plasmid amplification in viral vector and IVT workflows, as well as for manufacturing recombinant proteins like insulin. Its rapid growth, simple cultivation, and well-characterized genetics enable high-yield, cost-effective expression, making it a preferred platform for producing a broad range of biologics. However, residual host cell DNA from *E. coli* can negatively affect both downstream purification and product safety. It may clog filters, disrupt chromatography, or trigger immune responses in patients. Additionally, the risk of horizontal gene transfer underscores the need for strict monitoring and removal to ensure safety, consistency, and regulatory compliance.

Product Advantages

High sensitivity for optimal product safety

LLOD (1 fg/μL) for detection of residual host cell DNA

High specificity

No cross-reactivity with unrelated DNA

Fully validation

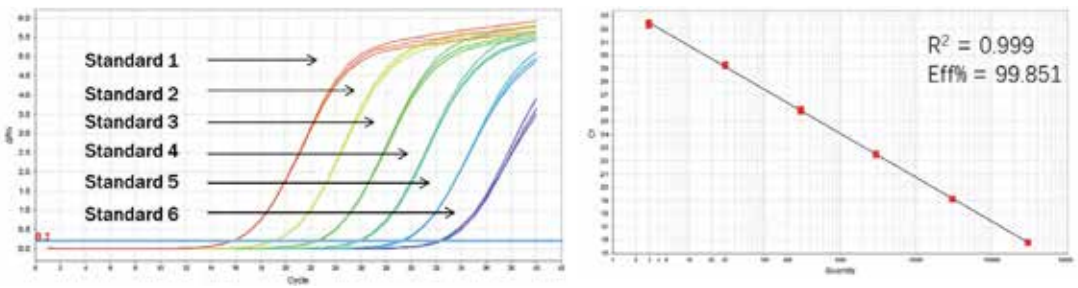
Analytical procedures validated according to ICH Q2(R2) guidelines

High quality

This kit is manufactured in alignment with the ISO 13485 standard

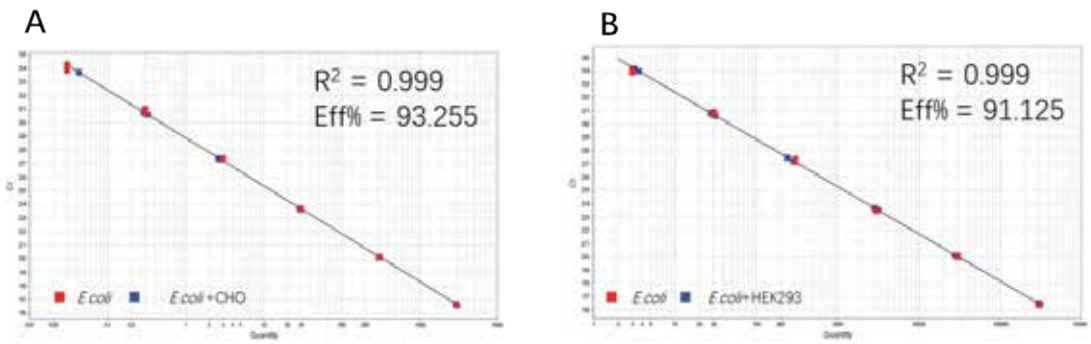
Validation Data

- High Sensitivity



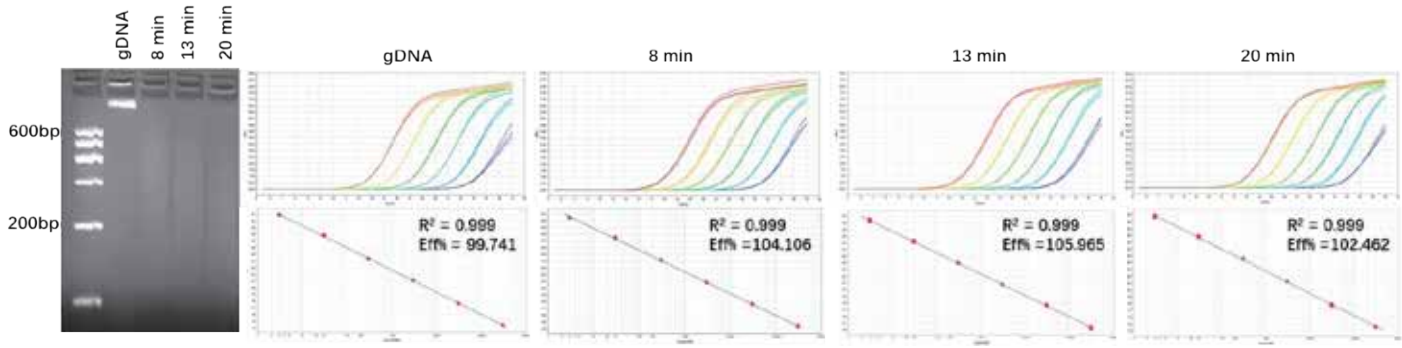
High sensitivity and broad dynamic range using the E. coli residual DNA quantitative Kit. (A) Typical analysis results obtained with Standard 1 (300 pg/μL) to 6 (3 fg/μL). (B) The standard curve of the 10-fold dilution series. PCR efficiency should be 90-110%.

- High Specificity: No cross-reactivity with unrelated DNA



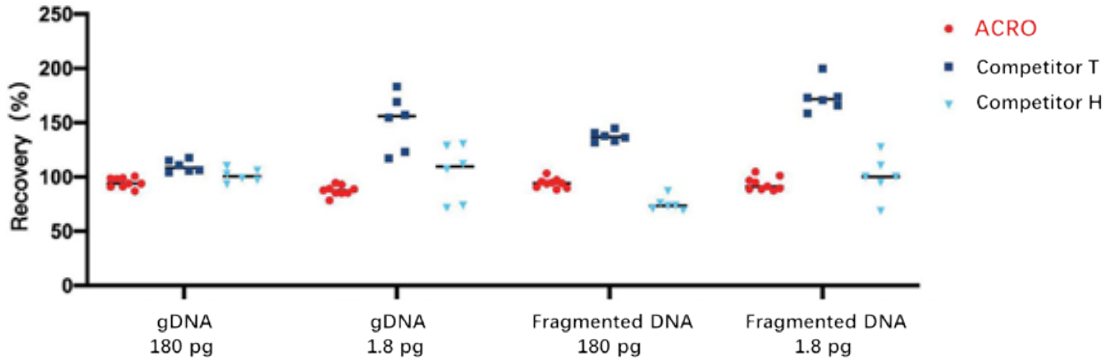
Assay specificity. Standard curves generated using 10-fold serial dilution of E.coli genomic DNA (included in the kit).

- High Consistency: Reliable performance across DNA fragments of varying sizes



Consistent quantitation across a broad range of fragment sizes. Standard curves were generated using a 10-fold serial dilution of gDNA and fragmented DNA. Fragmented DNA was generated by sonicating total CHO genomic DNA (8min, 13min, 20min).

- Recovery Rate Verified



Validation of the recoveries of four different E. coli DNA samples (gDNA 180 pg, gDNA 1.8 pg, fragmented DNA 180 pg, fragmented DNA 1.8 pg) showed recoveries between 90-100% for ACRO products.

resDetect™ CHO resDNA Quantitation Kit

CHO (Chinese Hamster Ovary) cells play a key role in antibody production. They can be genetically engineered to express high levels of recombinant antibodies. Once antibody genes are inserted into their genome and cultured under optimal conditions, CHO cells efficiently transcribe and translate the target proteins. They also carry out essential post-translational modifications, such as glycosylation, which affect antibody folding, solubility, stability, binding affinity, effector function, and immunogenicity. With a stable genetic background, CHO cells enable consistent and scalable antibody production in large-scale bioreactors, ensuring a reliable supply for therapeutic and research use.

However, residual host cell DNA in antibody drugs poses safety concerns. It may integrate into the human genome, leading to insertional mutagenesis and potential cancer risk. It can also trigger immune responses, such as inflammation or allergic reactions. If viral vector-related sequences are present, they may cause unexpected toxicity. As a result, pharmacopoeias in many countries have established strict limits on residual CHO DNA levels in biopharmaceuticals.

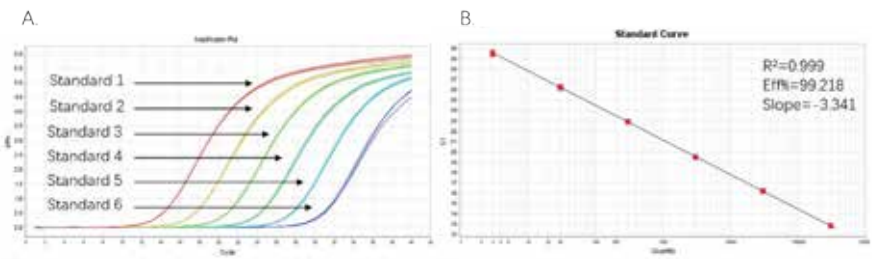
To address this, ACROBiosystems offers highly sensitive and specific reagents for the extraction and detection of residual CHO DNA, helping ensure the safety and quality of antibody drugs.

Product Advantages

- ☑ High sensitivity for optimal product safety: LLOD (3 fg/μL) for detection of residual host cell DNA
- ☑ High specificity: No cross-reactivity with unrelated DNA
- ☑ Validation: Analytical procedures validated according to ICH Q2(R2) guidelines
- ☑ Exceptional performance in challenging matrices: Demonstrates strong tolerance to high-protein, acidic, and alkaline backgrounds
- ☑ High quality: This kit is manufactured in alignment with the ISO 13485 standard
- ☑ Proven performance: Independently verified by a third-party laboratory (Eurofins)

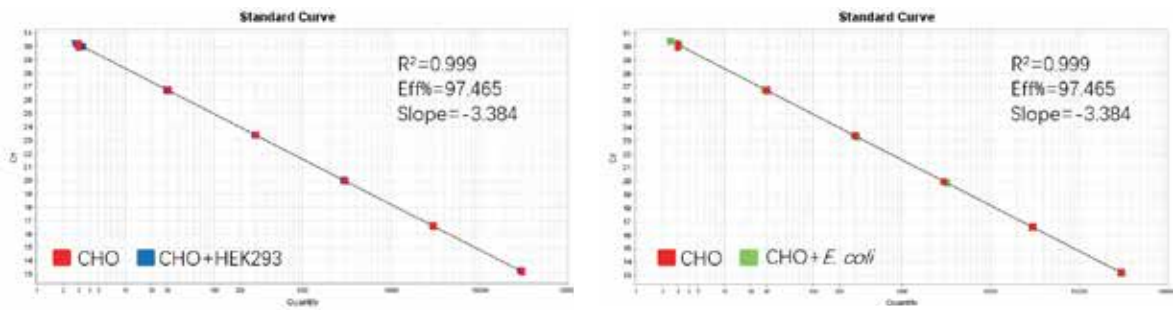
Validation Data

- High sensitivity: Limit of detection (LLOD) for residual host cell DNA is 3 fg/μL



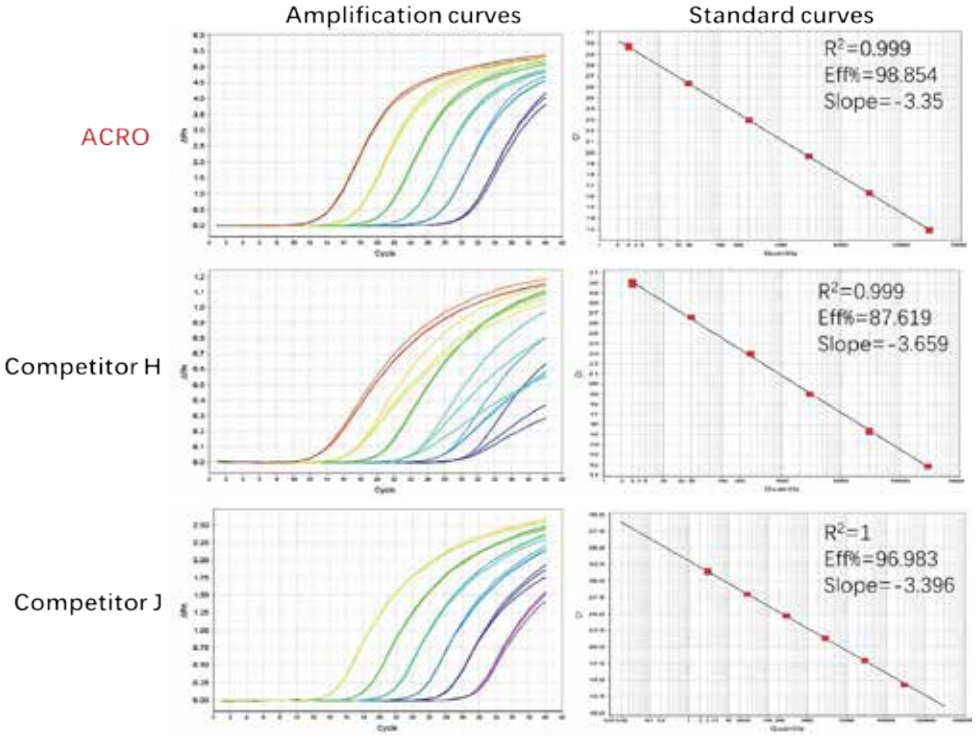
High sensitivity and broad dynamic range using the CHO resDNA Quantitation Kit. (A) Typical analysis results obtained with Standard 1 (300 pg/μL) to 6 (3 fg/μL). (B) The standard curve of the 10-fold dilution series. PCR efficiency should be 90-110%.

- High Specificity: No cross-reactivity with unrelated DNA



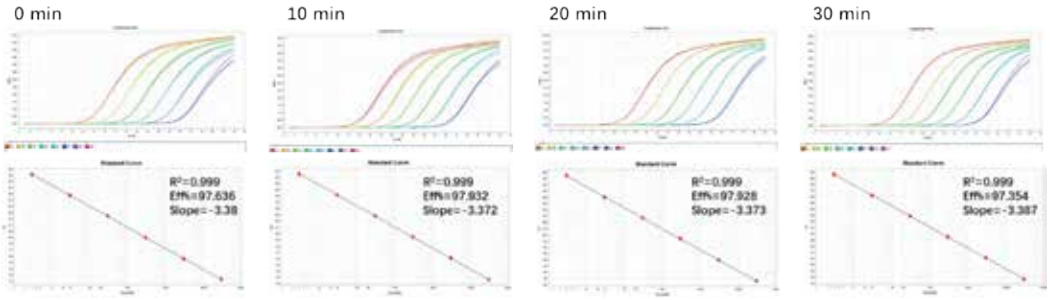
Assay specificity. Standard curves generated using 10-fold serial dilution of CHO genomic DNA (included in the kit).

- Standard curve validated: Enables more efficient and consistent detection of low concentrationsof residual CHO host cell DNA



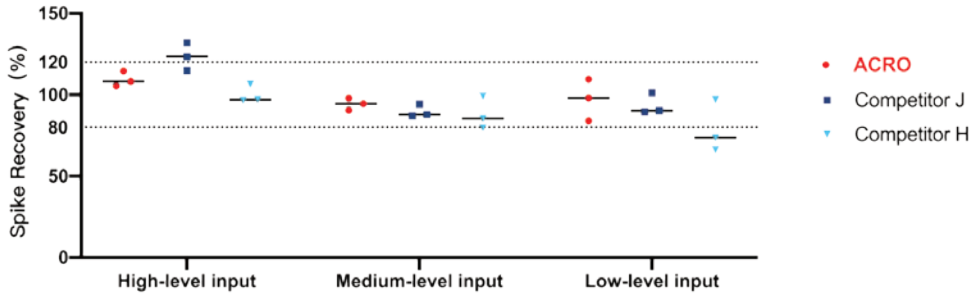
ACRO and competitor J The amplification efficiency of the standard curve is close to 100%, The Amplification efficiency of competitor H the standard curve is less than 90%。

- High Consistency: Reliable performance across DNA fragments of varying sizes



Consistent quantitation across a broad range of fragment sizes. Standard curves were generated using a 10-fold serial dilution of gDNA and fragmented DNA. Fragmented DNA was generated by sonicating total CHO genomic DNA (10min, 20min, 30min).

- Recovery Rate Verified



The recovery of CHO DNA samples spiked at 3 spike levels (High, Medium, Low) was validated and showed recoveries between 90-110% for ACRO products.

Practical Application

During the purification process development, HCD testing of intermediates and final product solutions is necessary to ensure process optimization. The process parameters are adjusted based on the HCD residue levels. However, complex matrices (such as intermediates in low or high pH buffers, and high-protein final product solutions) can affect HCD detection results.

In simulated samples containing high-protein matrices (up to 150 mg/mL) and varying pH ranges ($3.0 \leq pH \leq 10.0$), the resDetect™ kit can directly extract and detect HCD. The spiked recovery rate should be between 50-150%. Experimental results show that all spiked recoveries fall within the 98-120% range, as detailed in the table below.

Sample matrix	CHO HCD spike-in	Ct Value	Detection	Recovery rate
150 mg/ml protein	300pg	20.02	297.88 pg	99.29%
	300fg	30/15	295 fg	98.18%
	0	No Ct	-	-
pH 3.0 PBS	300pg	19.94	314.84 pg	104.95%
	300fg	30.17	291 fg	96.88%
	0	38.34	1 fg (below LLOQ)	-
pH 10.0 PBS	300pg	19.85	336.81 pg	112.27%
	300fg	29.85	363 fg	121.04%
	0	No Ct	-	-
PC	300pg	19.77	354.04 pg	118.01%

resDetect™ HEK293/HEK293T resDNA Quantitation Kit

Residual host cell DNA refers to DNA fragments from the host organism left behind during biological processes such as the production of a biopharmaceutical product or the cultivation of a cell line. This residual DNA can potentially contaminate the final product and affect its safety and efficacy. In biopharmaceutical production, regulatory agencies such as the FDA and EMA have set limits on the acceptable levels of residual host cell DNA in the final product. These limits vary depending on the product type and route of administration. Residual host cell DNA quantitative kits are designed to ensure the final product is safe for human use.

Product Advantages

High sensitivity for optimal product safety

LLOD (15 fg/μL) for detecting residual host cell DNA

High specificity

No cross-reactivity with unrelated DNA

Validation

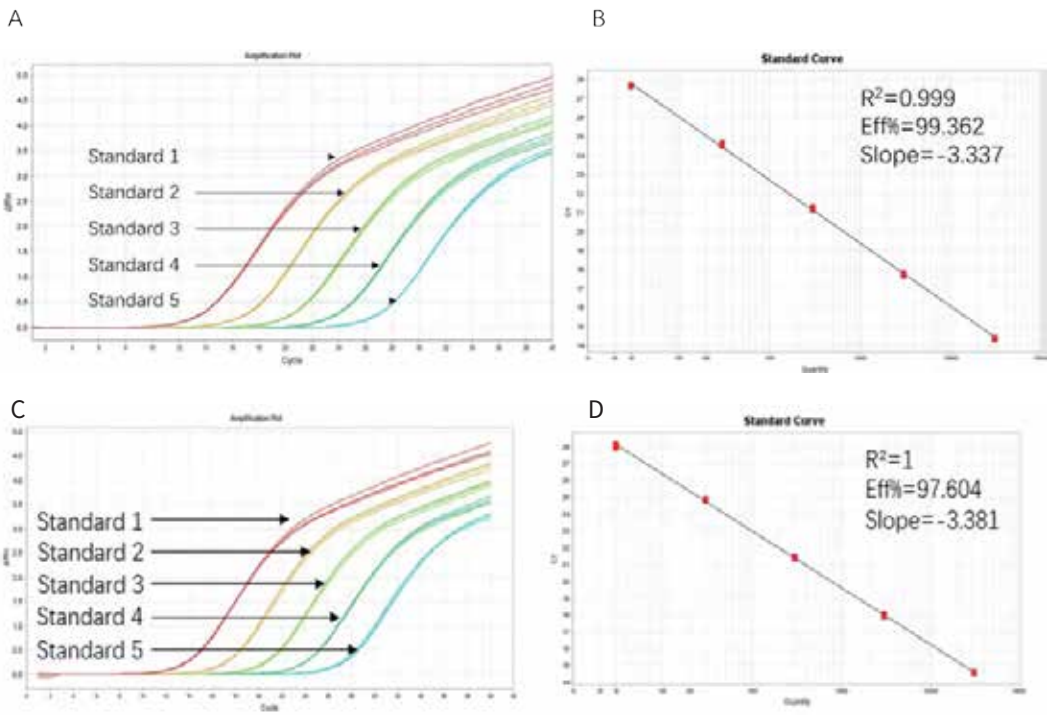
ICH Q2(R2) validation of analytical procedures

High quality

This kit is manufactured in alignment with the ISO 13485 standard

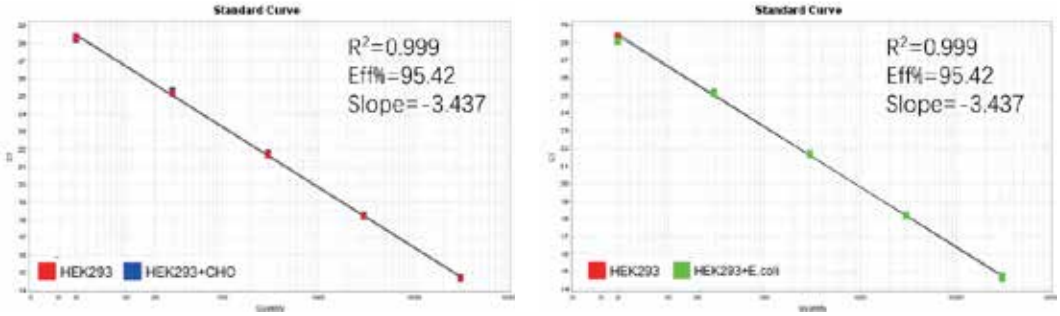
Validation Data

- High-sensitivity quantitative detection of HEK293/HEK293T residual DNA



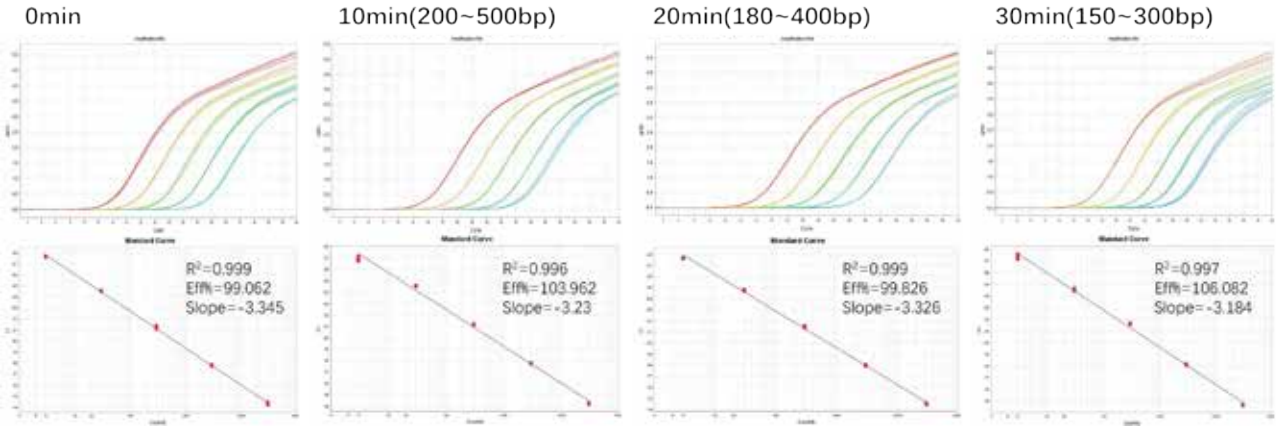
Both the HEK293 resDNA Quantitation Kit (A, B) and the HEK293T resDNA Quantitation Kit (C, D) offer high sensitivity and a broad dynamic range. (A, C) Typical analysis results were obtained with Standard 1 (300 pg/μL) to 5 (30 fg/μL). (B, D) The standard curve of the 10-fold dilution series shows that the PCR efficiency should be 90-110%.

- High Specificity: No cross-reactivity with unrelated DNA



Assay specificity. Standard curves generated using 10-fold serial dilution of HEK293 genomic DNA (included in the kit) in the presence of CHO DNA and E. coli DNA.

- High Consistency: Reliable performance across DNA fragments of varying sizes



Consistent quantitation across a broad range of fragment sizes. Standard curves were generated using a 10-fold serial dilution of gDNA and fragmented DNA. Fragmented DNA was generated by sonicating total HEK293 genomic DNA (10min, 20min, 30min).

resDetect™ *Pichia pastoris* resDNA Quantitation Kit

Pichia pastoris is highly valuable in the pharmaceutical industry. It is used for recombinant protein production, offering high-level expression and proper post-translational modifications, such as glycosylation, for therapeutic proteins. It also serves as a platform for vaccine production by expressing viral antigens. Due to its widespread use, detecting Pichia pastoris host cell DNA residues in pharmaceutical preparations is crucial. Residual DNA can trigger immune responses in patients or potentially cause insertional mutagenesis, affecting drug safety and efficacy. Therefore, monitoring this residue is essential to ensuring the quality and safety of pharmaceutical products.

Product Advantages

High sensitivity for optimal product safety

LLOD (1 fg/μL) for detecting residual host cell DNA

High specificity

No cross-reactivity with unrelated DNA

Validation

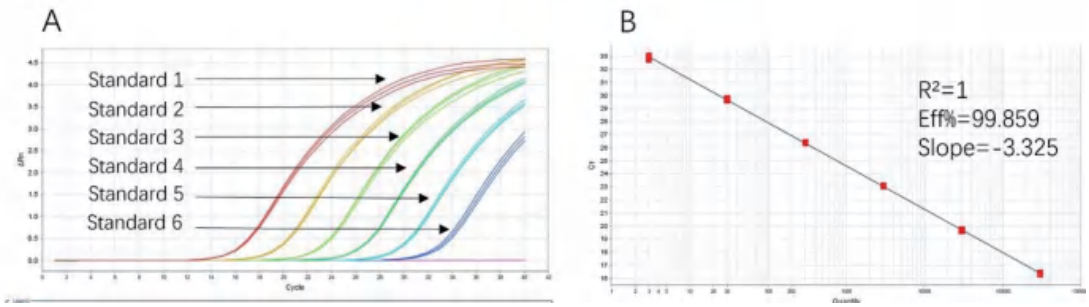
ICH Q2(R2) validation of analytical procedures

High quality

This kit is manufactured in alignment with the ISO 13485 standard

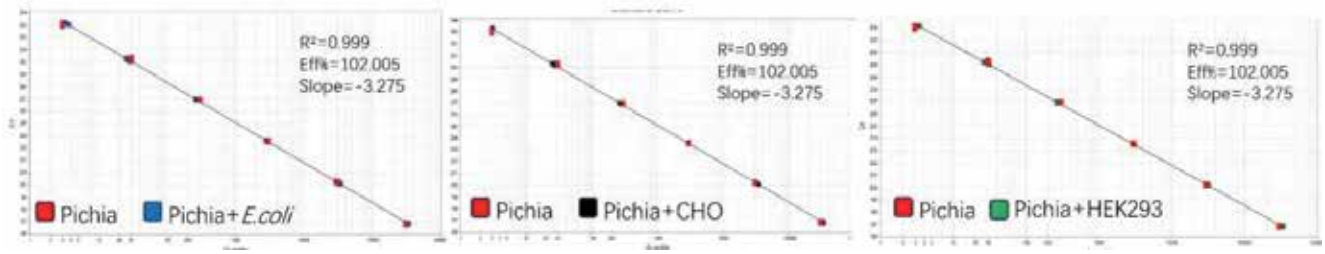
Validation Data

- High-sensitivity quantitative detection of Pichia pastoris residual DNA



High sensitivity and broad dynamic range using the Pichia pastoris resDNA Quantitation Kit. (A) Typical analysis results obtained with Standard 1 (300 pg/μL) to 6 (3 fg/μL). (B) The standard curve of the 10-fold dilution series. PCR efficiency should be 90-110%.

- High Specificity: No cross-reactivity with unrelated DNA



Assay specificity. Standard curves generated using 10-fold serial dilution of Pichia pastoris genomic DNA (included in the kit) in the presence of DNA (CHO, E. coli and HEK293).

resDetect™ Vero resDNA Quantitation Kit

Vero cells, derived from African green monkey kidney epithelial cells, are highly significant in the pharmaceutical industry. In vaccine production, they are widely used as host cells for cultivating viruses such as those for influenza, rabies, and polio vaccines. Their large-scale cultivation enables efficient production of high-titer virus stocks. Beyond vaccine production, Vero cells play a vital role in vaccine development research, where they are used to test the efficacy and safety of new vaccine candidates and to study virus-host cell interactions for optimizing manufacturing processes.

Regarding safety, as Vero cells are a continuous cell line that may show carcinogenic potential after multiple passages, their residual DNA in vaccines poses risks such as insertional mutagenesis. Therefore, strict regulations are in place. The WHO and FDA recommend that residual DNA in vaccine products not exceed 10 ng/dose, while the FDA sets a limit of ≤ 100 pg/dose for biopharmaceuticals. Multinational Pharmacopoeia specifies limits for different Vero cell-based vaccines, ensuring vaccine safety and protecting recipients' health.

Product Advantages

High sensitivity for optimal product safety

LLOD (1 fg/μL) for detecting residual host cell DNA

High specificity

No cross-reactivity with unrelated DNA

Validation

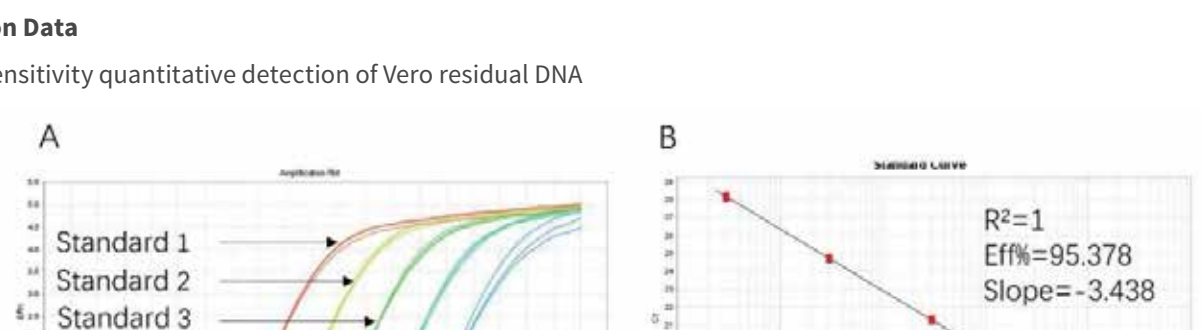
ICH Q2(R2) validation of analytical procedures

High quality

This kit is manufactured in alignment with the ISO 13485 standard

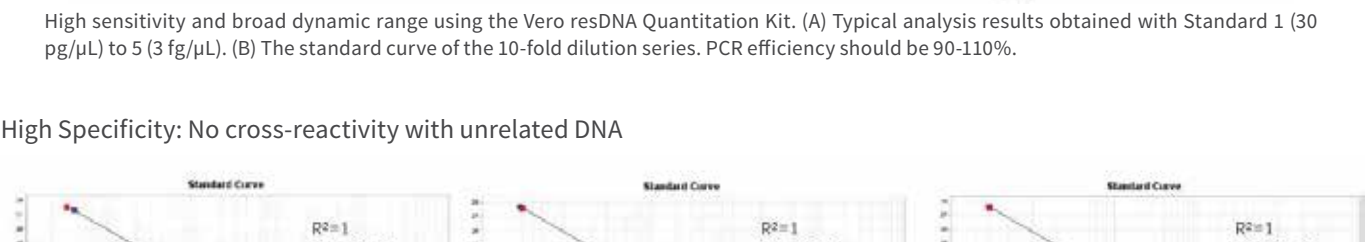
Validation Data

- High-sensitivity quantitative detection of Vero residual DNA



High sensitivity and broad dynamic range using the Vero resDNA Quantitation Kit. (A) Typical analysis results obtained with Standard 1 (30 pg/μL) to 5 (3 fg/μL). (B) The standard curve of the 10-fold dilution series. PCR efficiency should be 90-110%.

- High Specificity: No cross-reactivity with unrelated DNA



Assay specificity. Standard curves generated using 10-fold serial dilution of Pichia pastoris genomic DNA (included in the kit) in the presence of DNA (E. coli, CHO, and Pichia).

- resDetect™ Viral Oncogenes Residual DNA Detection Kit

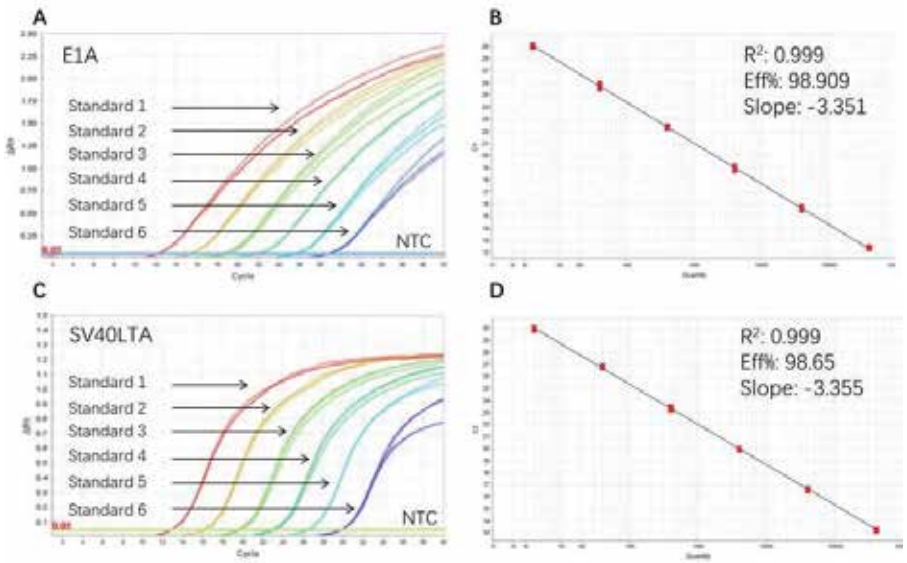
Designed specifically to quantify residual E1A and SV40LTA DNA in biopharmaceutical production (cells, viruses, etc.), this kit is based on a real-time quantitative PCR (qPCR) method. It can rapidly and reliably detect the content of residual DNA, with a quantitative lower limit of 40 copies/μL. Typically, all operations can be completed within 4 hours. It can be used in conjunction with the resDNA Sample Preparation Kit (Magnetic Bead Method) (Catalog Number: OPA-R005) for DNA extraction to achieve optimal detection performance.

Product list

Cat. No.	Product Description
OPA-R008	resDetect™ E1A & SV40LTA resDNA Quantitation Kit (qPCR)
OPA-R007	resDetect™ E1A resDNA Quantitation Kit (qPCR)

Validation Data

- High Sensitivity



High sensitivity and broad dynamic range using the E1A&SV40LTA resDNA Quantitative Kit. (A) Typical analysis results of obtained with E1A DNA Control Standard 1 (4×10^6 copies/μL) to 6 (4×10 copies/μL). (B) The standard curve of the E1A DNA Control 10-fold dilution series. PCR efficiency should be 90-110%. (C) Typical analysis results of obtained with SV40LTA DNA Control Standard 1 (4×10^6 copies/μL) to 6 (4×10 copies/μL). (D) The standard curve of the SV40LTA DNA control 10-fold dilution series. PCR efficiency should be 90-110%.

- High Specificity

Unrelated DNA	Mean (copies/μL)	
	E1A	SV40LTA
E. coli DNA	0.99	1.52
CHO DNA	Undetermined	Undetermined
Vero DNA	Undetermined	Undetermined
Pichia pastoris DNA	Undetermined	Undetermined
MDCK DNA	1.76	1.26

To evaluate the specificity of assay using E1A&SV40LTA resDNA Quantitation Kit, no template samples spiked with unrelated DNA were tested. Results shown in the following Table. Unrelated DNA (CHO, Vero, Pichia pastoris) were not detected in assay, and the values of E. coli and MDCK were outside the range of standard curve (4×10^6 copies/μL to 4×10 copies/μL).

Samples (copies/μL)	Mean (copies/μL)		Recovery (%)	
	E1A	SV40LTA	E1A	SV40LTA
$4x10^6$	$3.94x10^6$	$3.64x10^6$	98.4	90.93
$4x10^4$	$4.00x10^4$	$3.40x10^6$	99.89	84.98
4x10	3.52x10	3.14x10	87.97	78.57

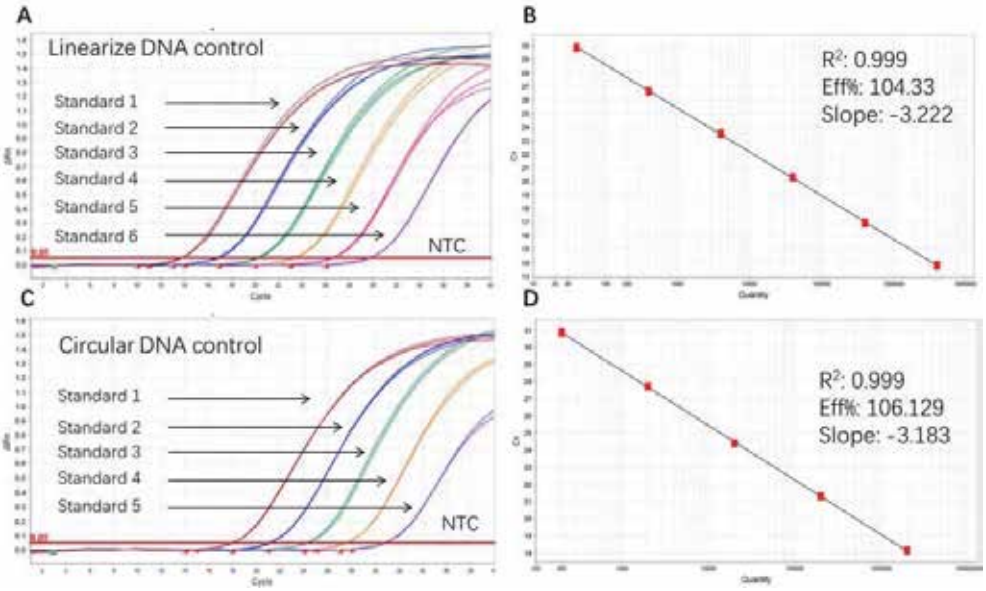
To evaluate the recovery of assay using E1A&SV40LTA resDNA Quantitation Kit, three different concentrations of DNA samples were tested. Results shown in the following Table. All samples had recoveries between 78%-100%.

- resDetect™ Plasmid DNA Residual Detection Kit

ACROBiosystems' resDetect™ Plasmid DNA Residual Detection Kit enables quantitative detection of residual plasmid DNA in various bioproducts, including intermediates, semi-finished products, and finished products.

Product Data

- High Sensitivity



High sensitivity and broad dynamic range using the Plasmid resDNA Quantitation Kit. (A) Typical analysis results of obtained with Linearize DNA control Standard 1 (4×10^6 copies/μL) to 6 (4×10 copies/μL). (B) The standard curve of the Linearize DNA control 10-fold dilution series. PCR efficiency should be 90-110%. (C) Typical analysis results of obtained with Circular DNA control Standard 1 (2×10^6 copies/μL) to 5 (2×10^2 copies/μL). (D) The standard curve of the Circular DNA control 10-fold dilution series. PCR efficiency should be 90-110%.

- High Specificity

Linearize Samples (copies/μL)	Mean (copies/μL)	Recovery (%)
	Plasmid	Plasmid
$4x10^6$	$4.34x10^6$	108.61
$4x10^4$	$4.33x10^4$	108.22
4x10	3.76x10	94.07

Circular Samples (copies/μL)	Mean (copies/μL)	Recovery (%)
	Plasmid	Plasmid
$2x10^6$	$1.88x10^6$	93.86
$2x10^4$	$1.71x10^4$	85.40
$2x10^2$	$1.87x10^2$	93.35

To evaluate the recovery of assay using Plasmid resDNA Quantitation Kit, three different concentrations of DNA samples were tested. Results shown in the following Table. All samples had recoveries between 80%-110%.

Unrelated DNA	Mean (copies/μL)
	Plasmid
E. coli DNA	5.08
CHO DNA	0.88
Vero DNA	0.99
Pichia pastoris DNA	2.8
MDCK DNA	23.86

To evaluate the specificity of assay using Plasmid resDNA Quantitation Kit, no template samples spiked with unrelated DNA were tested. Results shown in the following Table. Unrelated DNA (HEK293, CHO, Vero, Pichia pastoris, and MDCK) were detected in assay, however the values of Mean were outside the range of standard curve (4×10^6 copies/μL to 4×10 copies/μL).

FAQ on Nucleic Acid Residuals Detection

1. Crystals have formed in Buffer LA from the DNA Extraction Kit. How should this be handled?

Crystallization typically occurs due to low storage temperatures causing components to precipitate. To resolve this, incubate Buffer LA in a 37°C water bath for 10–20 minutes. If the crystals do not fully dissolve, the temperature can be raised to 50°C until the solution becomes completely clear. To minimize crystallization, avoid storing the buffer at temperatures around 20°C. Once dissolved, the crystals do not affect the performance or downstream applications of the reagent.

2. What are the recommended speed and duration for brief centrifugation steps?

For brief centrifugation (also known as pulse spin), a recommended speed is 3000–6000 rpm for 5–10 seconds. This step is typically used during the Host Cell DNA Residual Detection Kit workflow.

3. How should the purified DNA samples be stored?

It is recommended to perform qPCR within 24 hours after DNA extraction. For short-term storage, keep the samples at 2–8°C. For long-term storage, store the DNA at –20°C to preserve stability.

4. What should I do if magnetic bead residues are present in the eluted DNA solution?

Residual beads may result from insufficient magnetic separation or accidental aspiration of beads. To address this, perform a brief centrifugation (3000–6000 rpm for 10–15 seconds), then place the tube on a magnetic rack for 2–5 minutes. Carefully aspirate the supernatant without disturbing the beads.

5. What are the possible causes of low spike-in recovery rates, and how can they be improved?

Several factors may lead to low recovery rates. Below are the most common causes along with recommended solutions:

(1) Anhydrous ethanol not added to Wash Buffers WA and WB

Ensure that anhydrous ethanol is added to Wash Buffers WA and WB prior to use, as specified in the instructions. Confirm this step by checking the appropriate box on the reagent label.

(2) Reduced activity of Proteinase K, resulting in incomplete DNA elution

Proteinase K must be stored at 2–8°C to preserve its enzymatic activity. Decreased activity may lead to inefficient DNA release during elution.

(3) Over-drying of magnetic beads, hindering DNA elution

Magnetic beads should not be over-dried after washing. Excessive drying may prevent effective elution of DNA. In high-temperature, low-humidity, or high-airflow environments (e.g., inside biosafety cabinets), limit drying time to 2–5 minutes. In cooler or more humid conditions, drying should not exceed approximately 5 minutes. Under adequate lighting, check the beads: proceed with elution when the bead surface appears matte (non-glossy). If the surface appears ochre (earthy yellow), the beads may be over-dried, which can negatively affect recovery.

(4) Magnetic beads adhering to the tube wall during elution, leading to insufficient mixing

After adding the elution buffer, vortex or gently flick the tube to dislodge beads from the wall and ensure thorough mixing. If beads remain stuck to the tube wall, incubate the tube in a 70°C water bath for 2 minutes and then vortex again to achieve complete elution.

(5) Reduced magnetic bead binding capacity

Before use, mix the magnetic bead suspension thoroughly and aliquot in small portions as needed. Do not freeze the beads, as this can reduce their binding efficiency.

(6) Magnetic bead loss during wash steps

If beads are collecting near the bottom of the tube, gently tap or flick the tube to move them toward the side wall. This helps minimize bead loss and ensures more consistent recovery during washing.

6. What are the possible causes of significant Ct variation between replicates in the standard curve or sample wells, and how can this be improved?

Common causes include:

- Occasional pipetting errors
- Inadequate mixing of the stock standard solution or serial dilutions
- Insufficient mixing prior to sample loading
- Large variability in DNA extraction between samples

Recommendations for improvement:

Before performing serial dilutions of the standard stock solution and each dilution level, be sure to vortex thoroughly for at least 30 seconds, followed by a brief centrifugation (pulse spin) to collect the liquid. Ensure all pipetting and dilution steps are performed accurately and consistently, with adequate mixing throughout. These practices help improve assay reproducibility and reduce variability in Ct values.

7. How is spike-in recovery rate calculated?
Elution volume note:

Elution volume note: For optimal nucleic acid recovery, it is recommended to elute with 100 µL of elution buffer when using the resDetect™ Host Cell DNA Residual Detection Kit.

Calculation example (based on mass in pg):

Spike-in Recovery Rate (%) =

(Measured amount after spike-in (pg/sample)−Measured value of unspiked sample (pg/sample))÷Theoretical spike−in amount (pg/sample) × 100%

Where:

Measured amount after spike-in = Measured ERC concentration (pg/µL) × Elution volume (µL)

Measured amount in unspiked sample = Sample concentration (pg/µL) × Elution volume (µL)

Theoretical spike-in amount = Theoretical spike-in concentration (pg/µL) × Volume added before extraction (µL)

8. What are the main causes of high concentration values in the negative extraction control (NEC/NEG) or abnormal NTC results, and how can they be addressed?

- **Main causes:**

(1) Contamination during the experimental process: Contaminants may be introduced during DNA extraction or PCR setup.

(2) Environmental contamination: Nucleic acids or aerosolized PCR products in the lab environment may interfere with results.

- **Recommended solutions:**

(1) Control contamination during the process:

(1.1) It is recommended to run NEC as a standalone control using 100µL of 1× PBS as the extraction input.

(1.2) If the NEC result is below the lowest point of the standard curve, it can be considered qualified.

(2) Control environmental contamination:

(2.1) Regularly clean the lab environment, including work surfaces, pipettes, and equipment.

(2.2) Use low-retention, filter-equipped pipette tips.

(2.3) Clean the workspace before and after each experiment. Implement zoned operations where possible: DNA extraction should be performed in a biosafety cabinet, PCR setup should be done in a separate, dedicated area, qPCR amplification must be conducted in an area isolated from both DNA extraction and PCR setup zones. To avoid contamination, do not open tubes after amplification.

(3) Alternative solution for limited workspace:

(3.1) If your lab setup does not allow for strictly separated zones, we recommend using Automated Nucleic Acid Extraction System to reduce the risk of contamination caused by manual handling.

9. What are the common causes of abnormal amplification curves (non-sigmoidal) and how can they be optimized?

(1) Low DNA purity:
If DNA purity is suspected to be an issue, perform serial dilutions of the sample (e.g., 2×, 5×, 10×, or 100×) and re-run the qPCR assay to improve amplification performance.

(2) Air bubbles:
Before running the assay, check each qPCR reaction well for air bubbles. If bubbles are present, gently tap the tube or plate to remove them, or perform a brief centrifugation (pulse spin) to eliminate bubbles before placing the plate into the instrument.

(3) Instrument voltage issues:
To prevent voltage-related interference, use a voltage stabilizer with the qPCR machine, or contact the instrument provider for inspection and maintenance.

Enzyme Residue Detection

In the production processes of biologics such as cell/gene therapies and vaccines, monitoring enzyme residues from raw materials and tools is essential to ensure product quality and safety. Enzyme residues are key indicators of drug quality. ACROBiosystems offers a range of nucleases residue detection kits, including T7 RNA polymerase and pyrophosphatase residue detection kits, to effectively address your enzyme residue detection needs.

Product List

Cat. No	Description	Size
CAS-C001	resDetect™ Cas9 (CRISPR Associated Protein 9) ELISA Kit (Residue Testing)	96 Tests
CRS-A031	resDetect™ GENIUS™ Nuclease ELISA Kit (Residue Testing)	96 Tests
RES-A054	resDetect™ Salt Active GENIUS™ Nuclease ELISA Kit (Residue Testing)	96 Tests
RES-A005	resDetect™ Pyrophosphatase ELISA Kit (Residue Testing)	96 Tests
RES-A018	resDetect™ T7 RNA Polymerase ELISA Kit (Residue Testing)	96 Tests
ASE-A001	RNase Activity Assay Kit (Fluorescence)	96/480 Test
ASE-A002	DNase Activity Assay Kit (Fluorescence)	96/480 Test

- resDetect™ Cas9 Residual Detection Kit

CRISPR-associated protein 9 (Cas9) is widely used in cell and gene therapy (CGT) manufacturing due to its precision in genome editing. Cas9 enables targeted modifications, such as gene knockouts, insertions, or corrections, which are crucial for developing therapies for genetic disorders, cancers, and other diseases. In CGT production, Cas9 is typically delivered into cells using viral vectors, electroporation, or lipid nanoparticles to ensure efficient genome editing.

However, residual Cas9 protein and its genetic material must be carefully monitored and quantified post-editing. Residual Cas9 poses potential risks, including off-target effects, prolonged immune responses, or disruptions to cellular function. Regulatory agencies require strict quality control measures to ensure CGT product safety and efficacy. Detection methods, such as ELISA, are used to assess Cas9 clearance levels before final product release. Effective removal and verification of Cas9 residues are essential to minimize safety concerns and ensure the therapeutic success of gene-edited products.

Product Advantages

High sensitivity

< 0.781 ng/mL for detecting residual Cas9

High specificity

No cross-reactivity with unrelated enzymes

Excellent consistency

Consistent performance across batches and groups

Validation

ICH Q2(R2) validation of analytical procedures

Validation Data

- High Specificity: No Cross-Reactivity with Unrelated Enzymes

Enzyme				
Cap-2'-O-Methyltransferase	T7 RNA Polymerase	Nuclease	Cas12a	Pyrophosphatase

This kit can detect both natural and recombinant Cas9. The factors listed below were specifically tested, and no significant cross-reactivity was observed.

- Robust Matrix Tolerance

Additive	Tolerated concentration
Cell culture medium (DMEM)	50%
Cell culture medium (1640)	50%
DMSO	1%
HSA	5%

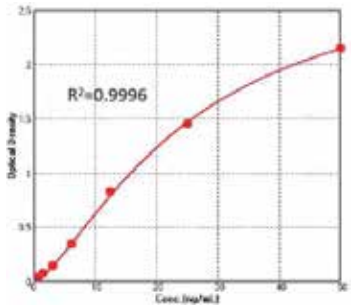
Verify potential matrix effects by adding different levels of Cell culture medium, DMSO and HSA to the diluted buffer.

- Excellent Recovery Rate

Sample (n=3)	Average % Recovery	Range %
High	90.4	88.2-92.6
Middle	100.5	94.6-106.6
LOW	103.6	95.3-119.2

Three Cas9 nuclease with different concentrations were tested to calculate the recovery rate.

- Standard Curve



For each experiment, a standard curve needs to be set for each micro-plate, and the specific OD value may vary depending on different laboratories, testers, or equipment. The following example data is for reference only.

- Dilution Linearity

Dilution	Parameter	Cell culture medium (DE)	Cell culture medium(1640)
1:2	Average Recovery (%)	102.6	93.6
	Range (%)	100.1 - 105.0	86.5 - 104.4
1:4	Average Recovery (%)	104.9	102.5
	Range (%)	101.0 - 109.8	101.9 - 102.9
1:8	Average Recovery (%)	102.5	107.4
	Range (%)	99.9-106.4	100.3 - 110.7
1:16	Average Recovery (%)	100	110.7
	Range (%)	96.3-105.5	101.4 - 117.3

To assess the linearity of the assay, samples spiked with high concentrations of Cas9 nuclease were serially diluted with calibrator diluent to produce samples with values within the dynamic range of the assay.

- resDetect™ GENIUS™ Salt Active/Nuclease Residual Detection Kit

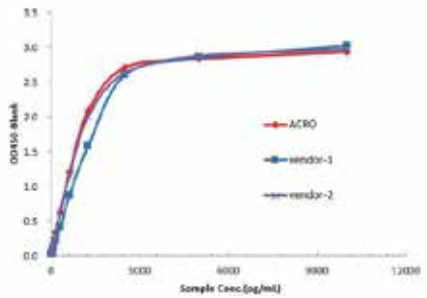
During the nuclease treatment of biopharmaceuticals, trace amounts of nuclease residues may be introduced. As nucleases are exogenous substances, these residual traces can affect the subsequent application of the biopharmaceuticals and may potentially lead to toxicity or immune reactions. Therefore, precise detection of nuclease residues is a critical requirement to ensure the activity and safety of the related biopharmaceuticals.

Product Advantages

- ☑ High Sensitivity: Sensitivity up to 25 pg/mL, enabling precise quantification of trace nuclease residues in culture medium supernatant
- ☑ Strong Compatibility: Compatible with several commercially available nuclease products, in addition to ACRO's nuclease
- ☑ Stable Performance: Excellent batch-to-batch and within-batch precision, with a coefficient of variation (CV) <10%
- ☑ Raw materials are sourced in-house, ensuring high production capacity and short lead times
- ☑ High Specificity: No cross-reactivity with non-related enzymes, ensuring accurate results
- ☑ Exceptional Consistency: Outstanding consistency both within and between batches
- ☑ ICH Q2(R2) Compliance: Meets ICH Q2(R2) analytical method validation standards

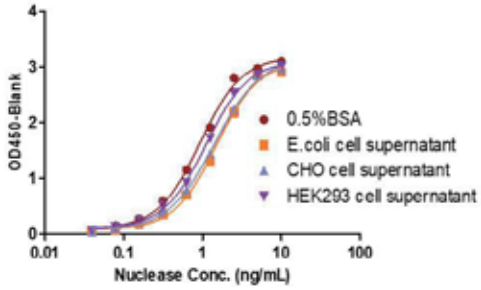
Validation Data

- High Sensitivity



GENIUS™ Nuclease ELISA Kit (Residue Testing) (Cat. No. CRS-A016) can detect the nuclease from different manufacturers with similar sensitivity.

- Robust Matrix Tolerance



GENIUS™ Nuclease ELISA Kit (Residue Testing) (Cat. No. CRS-A016) can detect the nuclease from different manufacturers with similar sensitivity.

- resDetect™ Pyrophosphatase Residual Detection Kit

Pyrophosphatase plays a critical role in the In Vitro Transcription (IVT) process. During the IVT reaction, pyrophosphate is generated, and its accumulation can inhibit the reaction. Pyrophosphatase hydrolyzes pyrophosphate into two phosphate molecules, thereby removing excess pyrophosphate from the reaction and alleviating its inhibitory effect on the IVT process. This enables the reaction to proceed in the direction of RNA production, ultimately enhancing RNA yield.

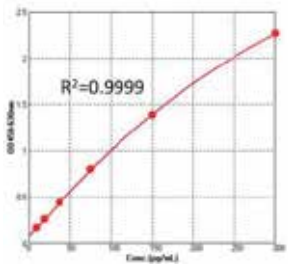
However, trace residues of pyrophosphatase may have an impact on the subsequent application of biological products and could potentially trigger toxic reactions or immune responses. Therefore, accurately detecting residual pyrophosphatase is essential to ensure the activity and safety of the related biological products.

Product Advantages

- ☑ High Sensitivity: Sensitivity as low as 9.38 pg/mL, enabling precise quantification of trace residual pyrophosphatase
- ☑ Stable Performance: Excellent batch-to-batch and within-batch precision, with a coefficient of variation (CV) <10%
- ☑ Raw materials are sourced in-house, ensuring high production capacity and short lead times
- ☑ High Specificity: No cross-reactivity with non-related enzymes, ensuring accurate results
- ☑ Exceptional Consistency: Outstanding consistency both within and between batches
- ☑ ICH Q2(R2) Compliance: Complies with ICH Q2(R2) analytical method validation standards

Validation Data

- Standard Curve



For each experiment, a standard curve needs to be set for each micro-plate, and the specific OD value may vary depending on different laboratories, testers, or equipment. The following example data is for reference only.

- Excellent Recovery Rate

Sample (n=3)	Average % Recovery	Range %
High	104.1	98.3-110.8
Middle	106.7	96.7-112.7
LOW	95.4	85.2-103.3

Three Pyrophosphatase with different concentrations were tested to calculate the recovery rate.

- resDetect™ T7 RNA polymerase Residual Detection Kit

T7 RNA Polymerase plays a crucial role in the In Vitro Transcription (IVT) process, where it synthesizes large amounts of mRNA using a DNA template. However, during downstream purification, it is essential to remove T7 RNA polymerase to ensure the stability and efficacy of the final product. According to relevant guidelines issued by the CDE, stringent quality control must be applied throughout the entire production process, including the detection and analysis of potential impurities, to ensure the quality and safety of the final product.

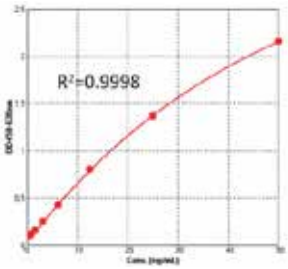
The resDetect™ T7 RNA Polymerase Residual Detection Kit offers broad detection range, high sensitivity, and excellent precision, supporting your CMC (Chemistry, Manufacturing, and Controls) process control for enzyme residue detection.

Product Advantages

- ☑ High Sensitivity: Sensitivity as low as 0.78 pg/mL.
- ☑ Strong Compatibility: Compatible with both wild-type T7 RNA polymerase and commercially available modified T7 RNA polymerase.
- ☑ Stable Performance: Excellent batch-to-batch and within-batch precision, with a coefficient of variation (CV) <10%.
- ☑ Raw materials are sourced in-house, ensuring high production capacity and short lead times.
- ☑ High Specificity: No cross-reactivity with non-related enzymes, ensuring accurate detection.
- ☑ Exceptional Consistency: Outstanding consistency both within and between batches.
- ☑ ICH Q2(R2) Compliance: Meets ICH Q2(R2) analytical method validation standards.

Validation Data

- Standard Curve



For each experiment, a standard curve needs to be set for each micro-plate, and the specific OD value may vary depending on different laboratories, testers, or equipment. The following example data is for reference only.

- Stable Performance: Excellent batch-to-batch and within-batch precision, with a coefficient of variation (CV) <10%

	Intra-Assay Statistics			Inter-Assay Statistics		
Sample	1	2	3	1	2	3
n	20	20	20	3	3	3
Mean(ng/mL)	36.606	12.845	1.779	37.457	13.009	1.801
SD	2.255	0.383	3.9%	6.0%	5.0%	2.4%
CV(%)	6.2%	3.0%	3.9%	6.0%	5.0%	2.4%

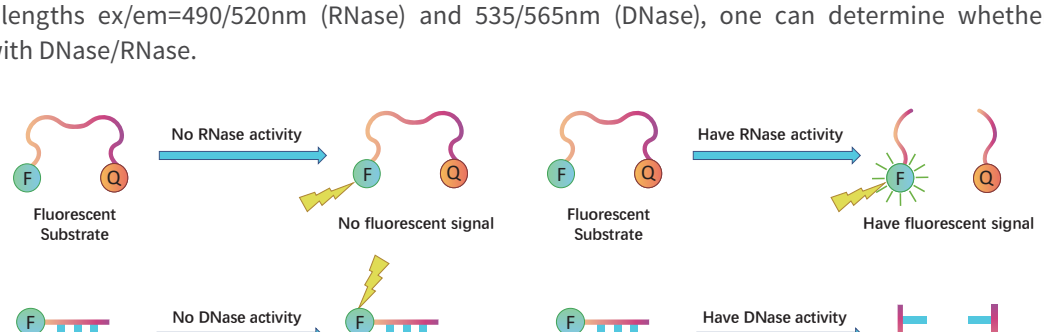
Three samples of known concentration were tested twenty times on one plate to assess intra/inter-assay precision, Intra-Assay/Inter-Assay Precision CV<10%.

- resDetect™ DNase Activity Assay Kit & RNase Activity Assay Kit

Through rigorous methodological validation, we have independently developed DNase and RNase residue detection kits based on the fluorescence probe method. These kits can be used to determine whether the environment, consumables, raw materials, etc., are contaminated with DNase and RNase. They are designed to detect the residual levels of DNase and RNase in bioproducts, enabling the development of appropriate clearance solutions to meet research and production needs.

Detection Principle

Fluorescence probe-based DNase and RNase residual activity detection relies on fluorescence-labeled RNA and DNA substrates. When the sample does not contain RNase and DNase activity, the substrate remains stable, and the fluorescent and quenching moieties are close together. Due to the principle of fluorescence resonance energy transfer, no fluorescence signal is generated. When the sample contains RNase and DNase activity, the substrate degrades, causing the fluorescent and quenching moieties to move away from each other, resulting in an gradually enhanced fluorescence signal. The rate of increase in fluorescence signal is positively correlated with the quantity and activity of the enzymes. Using a fluorescence microplate reader at wavelengths ex/em=490/520nm (RNase) and 535/565nm (DNase), one can determine whether the sample is contaminated with DNase/RNase.



Product Advantages

- Designed based on the principle of enzyme activity, suitable for detecting residual RNase or DNase of various types
- High sensitivity, with a detection limit as low as $3.9*10^{-5}$U (DNase)/0.03pg (RNase)
- Strict quality control, ensuring sensitivity, inter-batch/intra-batch variation, accuracy, freeze-thaw stability, etc
- Comprehensive method validation in accordance with ICH Q2(R2) guidelines
- Simple and fast to use, with the ability to complete testing for over 80 samples within 30 minutes
- Verified recovery rate, eliminating interference from glycerol stabilizers in the original enzyme
- Can be used in combination, allowing simultaneous detection of RNase or DNase residue without interference

Product List

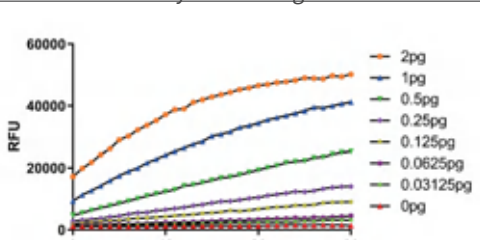
Cat. No.	Product Description
ASE-A001	RNase Activity Assay Kit (Fluorescence)
ASE-A002	DNase Activity Assay Kit (Fluorescence)

Validation Data

Cut-off Criteria: Using the enzyme-linked immunosorbent assay (ELISA) method, if the fluorescence ratio between the test sample and the negative control sample is <2, it is determined as no residual DNase/RNase. Otherwise, if the ratio is ≥2, it is determined as having residual DNase/RNase.

- RNase Activity Assay Kit (Fluorescence) (ASE-A001)

The validated sensitivity of this reagent can reach 0.03125pg



Add 90 µL of the working RNase Substrate solution to each 96-well plate, and add 10µL of RNase A standards (0-200pg/mL*10µL / well = 0-2pg/well), incubate the plate in the fluorometer (BMG CLARIOstar) collecting real-time data at 1 minute intervals for 30 minutes at 37°C using the settings described in this section. The RNase Activity Assay can be evaluated in rigorous kinetic terms using real-time data.

The intra-assay variability of RNase Activity Assay Kit (Fluorescence) (Cat. NO. ASE-A001) is less than 10%, inter-assay variability is less than 15%, and the precision meets standards set in regulatory guidelines

Intra-Assay Statistics

Sample	1	2	3	4	5	6	7
Number of Replicate	8	8	8	8	8	8	8
Mean RFU	3506	5964	9831	16862	27758	41779	56643
Standard Deviation	130	192	291	532	180	783	412
Coefficient of Variation (%)	3.7	3.4	3.0	3.2	0.6	1.9	0.7

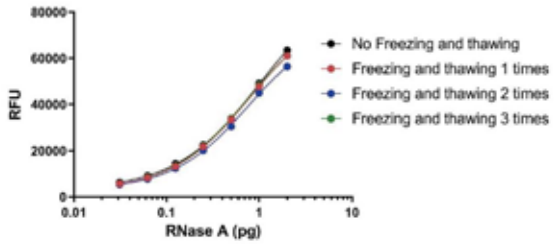
Inter-Assay Statistics

Sample	1	2	3	4	5	6	7
Number of Replicate	8	8	8	8	8	8	8
Mean RFU	3858	6132	10530	17609	28071	41161	53533
Standard Deviation	579	769	1495	2307	3341	4203	4249
Coefficient of Variation (%)	15	12.5	14.2	13.1	11.9	10.2	7.9

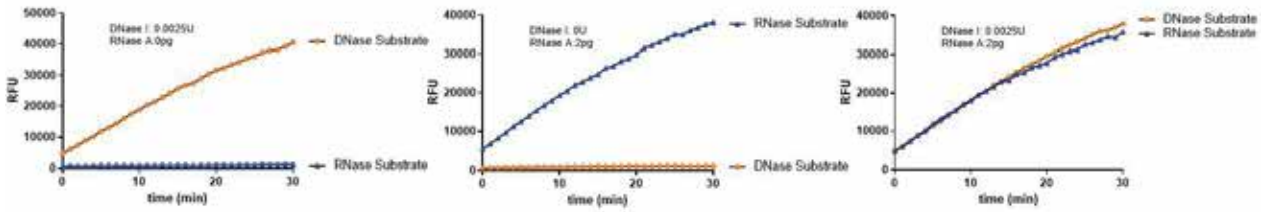
Verified, the recovery rate of RNase Activity Assay Kit (Fluorescence) (Cat. No. ASE-A001) is within the range of 80% to 120%

	System	5.5 µg/mL of Pyrophosphatase (n=2)		1% of (50mM Tris-HCl and 50% Glycerol) (n=2)		2 µg/mL Thermostable Inorganic Pyrophosphatase(n=2)		1×Reaction Buffer (n=2)	
Sample	weight. (pg)	Calculated weight. (pg)	Ave%RE	Calculated weight. (pg)	Ave%RE	Calculated weight. (pg)	Ave%RE	Calculated weight. (pg)	Ave%RE
Sample 1	1.5	1.4252	95	1.3319	89	1.3375	89	1.4193	95
Sample 2	0.2	0.1691	85	0.1669	83	0.1683	84	0.1839	92
Sample 3	0.05	0.0437	87	0.0461	92	0.0442	88	0.0472	94

After three freeze-thaw cycles of the probe, the performance meets the requirements, and there is no decrease in sensitivity. The CV is less than 10%.

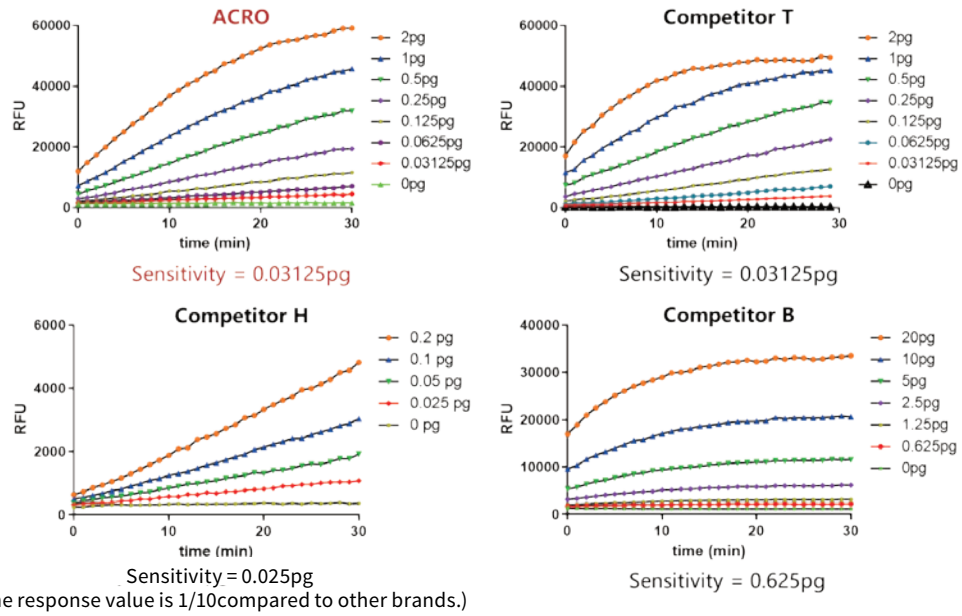


No cross-interference: Verified using RNase Activity Assay Kit (Fluorescence) (Cat. No. ASE-A001) and DNase Activity Assay Kit (Fluorescence) (Cat. No. ASE-A002) to detect the residual nucleases in the same sample, and no cross-interference was observed.



Competitor Evaluation Data

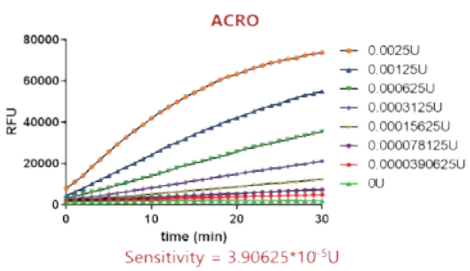
The sensitivity of this kit can reach 0.03125pg, comparable to the performance of the imported brand Competitor T, and superior to most other brands on the market.



(The response value is 1/10compared to other brands.)

- DNase Activity Assay Kit (Fluorescence) (ASE-A002)

The validated sensitivity of this reagent can reach 3.90625*10^{-5}U.



Add 90 µL of the working DNase Substrate solution to each 96-well plate, and add 10 µL of DNase I standards (0.00000390625-0.00025 U/µL*10µL/well = 0.0000390625-0.0025U/well), incubate the plate in the fluorometer (BMG CLARIOstar) collecting real-time data at 1 minute intervals for 30 minutes at 37°C using the settings described in this section. The DNase Activity Assay can be evaluated in rigorous kinetic terms using real-time data.

The intra-assay variability of DNase Activity Assay Kit (Fluorescence) (Cat. NO. ASE-A002) is less than 10%, inter-assay variability is less than 15%, and the precision meets standards set in regulatory guidelines.

Intra-Assay Statistics

Sample	1	2	3	4	5	6	7
Number of Replicate	8	8	8	8	8	8	8
Mean RFU	2703	4170	6804	11847	19904	32163	45024
Standard Deviation	30	87	182	340	538	455	713
Coefficient of Variation (%)	1.1	2.1	2.7	2.9	2.7	1.4	1.6

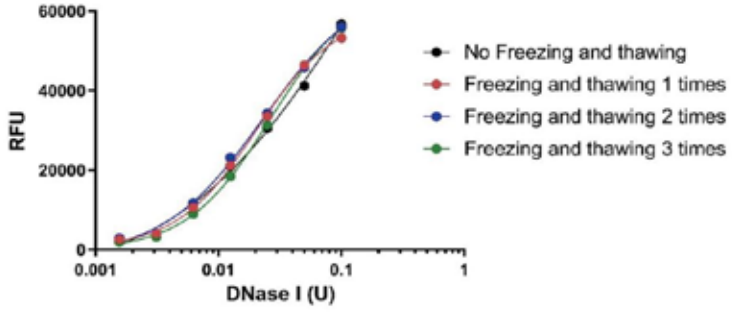
Inter-Assay Statistics

Sample	**1**	**2**	**3**	**4**	**5**	**6**	**7**
Number of Replicate	8	8	8	8	8	8	8
Mean RFU	2987	4711	8021	13914	23835	37728	51370
Standard Deviation	291	504	1025	1879	3323	5016	6482
Coefficient of Variation (%)	9.8	10.7	12.8	13.5	13.9	13.3	12.6

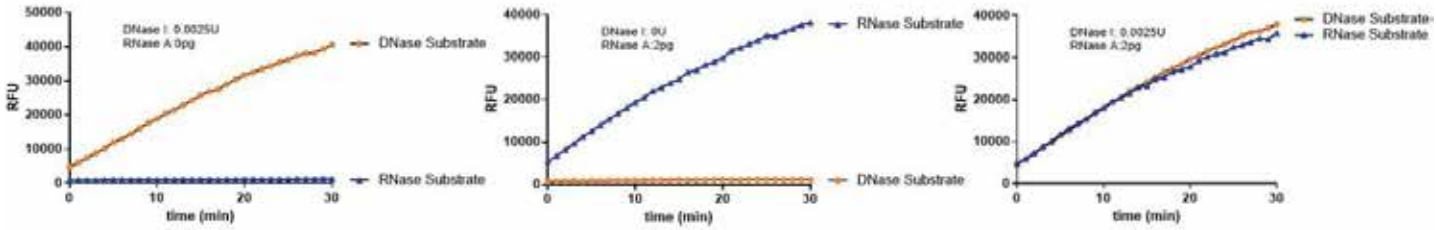
Verified, the recovery rate of DNase Activity Assay Kit (Fluorescence) (Cat. No. ASE-A002) is within the range of 80% to 120%.

	System	**55 μg/mL of Pyrophosphatase (n=2)**		**20 μg/mL Thermostable Inorganic Pyrophosphatase (n=2)**		**10% of (50mM Tris-HCl and 50% Glycerol) (n=2)**		**1×Reaction Buffer (n=2)**	
Sample	Enzyme activity. (U)	Calculated Enzyme activity. (U)	Ave%RE	Calculated Enzyme activity. (U)	Ave%RE	Calculated Enzyme activity. (U)	Ave%RE	Calculated Enzyme activity. (U)	Ave%RE
Sample 1	0.002	0.002132	107	0.00201	100	0.002013	101	0.002183	109
Sample 2	0.0005	0.000534	107	0.000491	98	0.000502	100	0.000565	113
Sample 3	0.0001	0.000110	110	0.000101	101	0.000105	105	0.000118	118

After three freeze-thaw cycles of the probe, the performance meets the requirements, and there is no decrease in sensitivity. The CV is less than 10%.

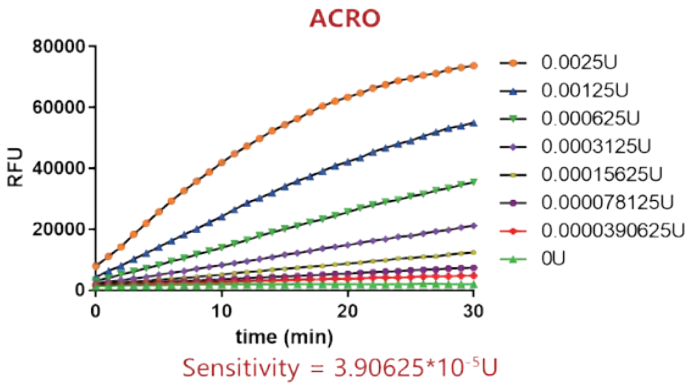


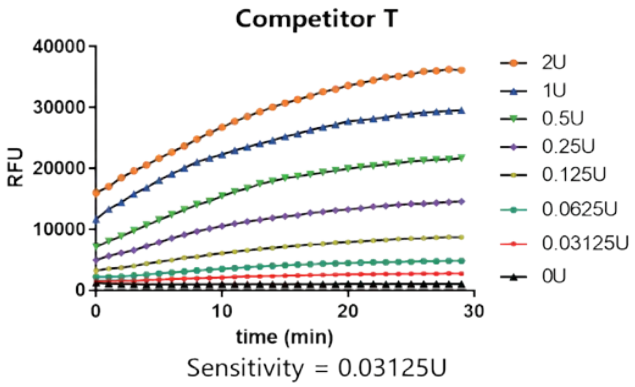
No cross-interference: Verified using RNase Activity Assay Kit (Fluorescence) (Cat. No. ASE-A001) and DNase Activity Assay Kit (Fluorescence) (Cat. No. ASE-A002) to detect the residual nucleases in the same sample, and no cross-interference was observed.

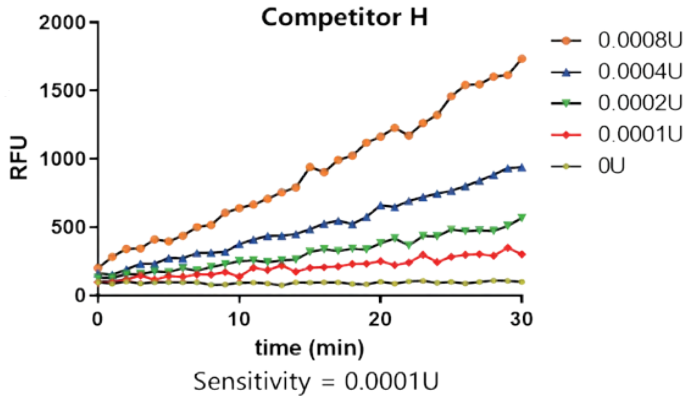


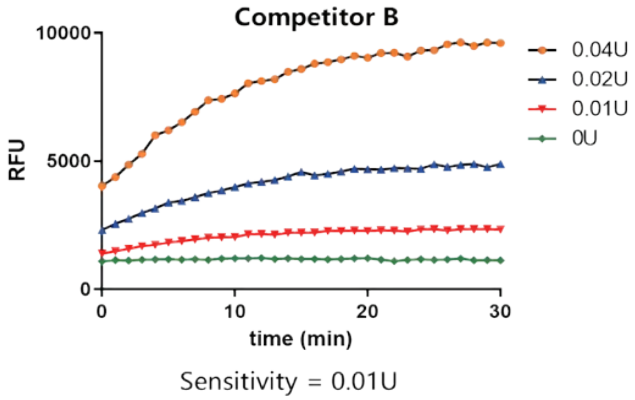
Competitor Evaluation Data

The sensitivity of this kit can reach 3.90625*10^{-5}U, comparable to the performance of the imported brand Competitor T, and superior to most other brands on the market.









Cell Culture Supplement Residue Detection

In the production of certain drugs, culture medium additives such as IL-2/IL-15/IL-7 cytokines, antibiotics, and BSA are often used. Regulations clearly state that the residues of these additives must be assessed and controlled. For example, USP<1043> recommends that developers establish procedures and analytical methods for the removal of raw materials and excipients (AM) early in the development process. Developing appropriate residue detection methods ensures the consistency of CGT products and processes, characterizes the final CGT product, and minimizes potential negative impacts on product quality, clinical efficacy, and safety.

We offer a series of highly sensitive process residue detection kits, including cytokine residue detection kits, antibiotic residue detection kits, BSA residue detection kits, etc.

- resDetect™ Cytokine/Antibody Residue Detection Kit

In the production process of immune cell therapy products, culture medium supplements such as GMP-grade IL-2, IL-15, IL-7, and IL-21, among others, are essential reagents for the proliferation and differentiation of immune cells such as T/NK cells. They are key raw materials for the production of immune cell therapy drugs. However, to ensure the safety of the final product, it is necessary to control the residual amounts of these culture additives.

Product List

- Cytokine

Cat.No.	Description	Match to
CRS-A003	resDetect™ Human Interleukin-2 (IL-2) ELISA Kit (Residue Testing)	GMP-L02H14 / GMP Human IL-2 Protein
CRS-A004	resDetect™ Human Interleukin-4 (IL-4) ELISA Kit (Residue Testing)	GMP-L04H26 / GMP Human IL-4 Protein
CRS-A005	resDetect™ Human Interleukin-6 (IL-6) ELISA Kit (Residue Testing)	GMP-L06H27 / GMP Human IL-6 Protein
CRS-A008	resDetect™ Human Interleukin-10 (IL-10) ELISA Kit (Residue Testing)	GMP-L10H25 / GMP Human IL-10 Protein
CRS-A010	resDetect™ Human Interleukin-21 (IL-21) ELISA Kit (Residue Testing)	GMP-L21H25 / GMP Human IL-21 Protein
CRS-A012	resDetect™ Human Interleukin-1 beta (IL-1 beta) ELISA Kit (Residue Testing)	GMP-ILBH25 / GMP Human IL-1 beta Protein
CRS-A024	resDetect™ Human Interleukin-15 (IL-15) ELISA Kit (Residue Testing)	GMP-L15H13 / GMP Human IL-15 Protein
RES-A099	resDetect™ Human Interleukin-18 (IL-18) ELISA kit (Residue Testing)	GMP-L18H16 / GMP Human IL-18 Protein
RES-A010	resDetect™ IL-3 ELISA Kit (Residue Testing)	GMP-L03H18 / GMP Human IL-3 Protein
RES-A027	resDetect™ Human Tumor Necrosis Factor Alpha (TNF-α) ELISA Kit (Residue Testing)	GMP-TNAH23 / GMP Human TNF-alpha Protein
RES-A028	resDetect™ Human Interferon-γ(IFN-γ) ELISA Kit (Residue Testing)	GMP-IFGH24 / GMP Human IFN-gamma Protein
RES-A055	resDetect™ Human Interleukin-7 (IL-7) ELISA Kit (Residue Testing)	GMP-L07H24 / GMP Human IL-7 Protein

- Growth Factor

Cat.No.	Description	Match to
RES-A006	resDetect™ Human SCF ELISA Kit (Residue Testing)	GMP-SCFH25 / GMP Human SCF Protein
RES-A007	resDetect™ Human FLT3L ELISA Kit (Residue Testing)	GMP-FLLH28 / GMP Human Flt-3 Ligand Protein
RES-A009	resDetect™ Human FGF2 ELISA Kit (Residue Testing)	GMP-FGCH17 / GMP Human FGF basic Protein
RES-A034	resDetect™ Human TPO ELISA Kit (Residue Testing)	GMP-THNH25 / GMP Human Thrombopoietin Protein

- Antibody and Ligand

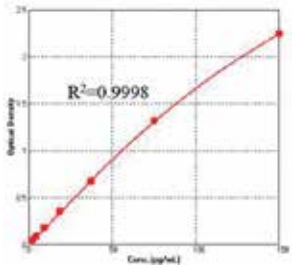
Cat.No.	Description	Match to
CRS-A014	resDetect™ Anti-CD28 Antibody ELISA Kit	GMP-MC2824 / GMP Monoclonal Anti-Human CD28 Antibody
RES-A022	resDetect™ Biotinylated Human DLL4 ELISA Kit (Residue Testing)	GMP-DL4H27 / GMP Human DLL4 Protein, Fc Tag (Flagship)
RES-A031	resDetect™ Human CD5 ELISA Kit (Residue Testing)	
CRS-A008	resDetect™ Human 4-1BB Ligand ELISA Kit (Residue Testing)	GMP-41LH26 / GMP Human 4-1BB Ligand Protein, Fc Tag
CRS-A010	resDetect™ Anti-CD3 Antibody Indirect ELISA Kit (Residue Testing)	GMP-MC0323 / GMP Monoclonal Anti-Human CD3 Antibody (OKT3)
CRS-A012	resDetect™ 4-1BB antibody ELISA Kit (Residue Testing)	GMP-M41B35 / Monoclonal Anti-Human 4-1BB Antibody

- Extracellular Matrix

Cat.No.	Description	Match to
RES-A040	resDetect™ Human Laminin 521 ELISA Kit (Residue Testing)	GMP-LA5H24 / GMP Human Laminin 521 Protein
RES-A096	resDetect™ Human Laminin 511 ELISA Kit (Residue Testing)	GMP-LA1H25 / GMP Human Laminin 511 Protein
RES-A101	resDetect™ VCAM Fc Tag ELISA Kit (Residue Testing)	GMP-VC1H25 / GMP Human VCAM-1 Protein, Fc Tag
RES-A103	resDetect™ Vitronectin ELISA Kit (Residue Testing)	GMP-VINH19 / GMP Human Truncated Vitronectin
RES-A108	resDetect™ Human Fibronectin quantitative ELISA Kit	GMP-FINH18 / GMP Recombinant Human Fibronectin fragment

Validation Data

- Sample Data



For each experiment, a standard curve needs to be set for each micro-plate, and the specific OD value may vary depending on different laboratories, testers, or equipments. The following example data is for reference only (CRS-A024) .

- Dilution Linearity

Dilution	Parameter	Cell culture medium (DMEM)	Serum	Citrate plasma
1:2	Average Recovery (%)	102.6	91.9	96.4
	Range (%)	97.2-108.2	84.5-99.8	88.8-103.9
1:4	Average Recovery (%)	111.1	92.8	92.6
	Range (%)	93.0 - 104.0	84.9-103.0	81.2-99.9
1:8	Average Recovery (%)	103.7	97.3	95.9
	Range (%)	100.7-108.4	88.8-107.2	88.3-101.0
1:16	Average Recovery (%)	114.7	93.3	99.2
	Range (%)	108.8-117.7	81.4-105.8	91.1-107.0

- Intra-Assay Statistics

Sample	1	2	3
Number of Replicate	20	20	20
Mean(pg/mL)	95.805	27.934	8.718
SD	5.227	1.629	0.669
CV(%)	5.5	5.8	7.7

Three samples of known concentration were tested twenty times on one plate to assess intra-assay precision, Intra-Assay Precision CV<10%.

- Inter-Assay Statistics

Sample	1	2	3
Number of Replicate	3	3	3
Mean(pg/mL)	93.999	28.455	9.573
SD	5.629	1.900	0.783
CV(%)	6.0	6.7	8.2

Three samples of known concentration were tested in three separate assays to assess inter-assay precision, Inter-Assay Precision CV<10%.

- Recovery

Sample Type	Average % Recovery	Range %
Serum(n=5)	86.3%	80.9-97.7%

Three parts of blank serum were added with different concentrations of human IL-15, and the serum without human IL-15 was used as background to calculate the recovery rate. The range of the recovery rate is 80.9-97.7%, and the average recovery is 86.3%.

Each cytokine/antibody residue detection kit undergoes strict quality control and is equipped with complete validation data. Above is an example of the resDetec™ Human Interleukin-15 (IL-15) ELISA Kit (Residue Testing). For validation data of other residue detection kits, please scan the QR code for more information.

- resDetect™ BSA Residue Detection Kit

In the production and quality control of biopharmaceuticals, controlling residual levels of bovine serum albumin (BSA) is a critical step to ensure product safety and quality. Leveraging its proprietary development platform, ACROBiosystems has launched a ready-to-use BSA ELISA Kit (Cat. No. RES-A098) based on a one-step sandwich ELISA format. This kit employs a double-antibody sandwich enzyme-linked immunosorbent assay combined with a horseradish peroxidase (HRP)-based signal amplification system, enabling rapid and sensitive detection of BSA residues in various samples.

Product List

Cat.No.	Description	Size
RES-A098	resDetect™ BSA ELISA Kit (USP Calibrated)	96 Tests

Product Advantages

- **One-Step Sandwich ELISA:** Simplified protocol with results available in just 1.5 hours
- **Traceability: The BSA standard included in the kit is traceable to the USP reference standard (1076192)**
- **Buffer Compatibility: Highly compatible with commonly used buffers to ensure stable and reliable results**
- **High Specificity:** Demonstrates excellent specificity for BSA detection across a wide range of sample types, including human serum, equine serum, human serum albumin, rabbit serum, MDCK cells, HEK293 cells, CHO cells, and T cells
- **Wide Detection Range:** Broad and accurate detection range from 0.5 ng/mL to 40.5 ng/mL

Product Data

- High Specificity: No cross-reactivity observed across a variety of sample types

Sample	1% Human serum			2.5% Mouse serum			Human Serum Albumin (1.25mg/mL)			10% Rabbit serum		
Added BSA Conc. (ng/mL)	30	5	0	30	5	0	30	5	0	30	5	0
Mean(pg/mL)	25.805	4.239	0	24.319	4.369	0.327	26.009	4.535	0.056	35.252	5.995	0.3
SD	86	85.9	/	80	87.4	/	86.5	89.6	/	107.4	119.3	/

High, medium and low concentrations of BSA were added to Human serum (v/v 1%), Mouse serum (v/v 2.5%), Human Serum Albumin (1.25mg/mL) and Rabbit serum (v/v 10%), the recovery rate of BSA was used as the specific validation index.

Sample	MDCK			HEK293			CHO			T-lymphocyte			Vero		
Cells.Con. cells/mL	2×10^6			3.5×10^6			4.32×10^6			2.15×10^6			3×10^6		
Dilution Factor	2			2			2			2			2		
Added BSA Conc. (ng/mL)	30	5	0	30	5	0	30	5	0	30	5	0	30	5	0
Mean(ng/mL)	32.519	4.778	0	31.566	6.622	0.447	28.970	4.836	0.196	31.509	4.862	0	28.502	4.306	0
Recovery(%)	108.4%	95.6%	/	103.7%	123.5%	/	95.9%	92.8%	/	105.0%	97.2%	/	95.0%	86.1%	/

High, medium and low concentrations of BSA were added to MDCK Cell, HEK293 Cell, CHO Cell , T Cell and VERO Cell, the recovery rate of BSA was used as the specific validation index.

- High Compatibility: Suitable for use with a wide range of commonly used buffers

Additive	1×PBS	50 mM Tris	DMSO	Multiple Electrolytes Injection	Glucose	Dextran	Fish gelatin	DMEM
Tolerated concentration	100%	100%	100%	100%	100%	100%	100%	100%

Verify potential matrix effects by adding different levels of specific buffers to the sample buffer. For specific buffers, it is recommended that you verify recovery to determine the optimal dilution ratio.

- Excellent Dilution Linearity: Delivers consistent recovery rates and reliable performance across serial dilutions

Dilution	Parameter	Cell culture medium (DMEM)	Cell culture medium(MEM)	Serum
1:2	Average Recovery (%)	97.4	94.2	116.2
	Range (%)	89.6 - 111.8	94.5 - 104.1	110.8 - 123.9
1:4	Average Recovery (%)	98.4	102.3	114.7
	Range (%)	93.0 - 104.0	93.1 - 123.0	112.8 - 117.3
1:8	Average Recovery (%)	96.6	103.9	115.4
	Range (%)	93.4-103.6	96.9 - 108.5	109.6 - 120.4
1:16	Average Recovery (%)	96	104.3	113.2
	Range (%)	92.8-99.9	93.4 - 112.4	111.9 - 115.1

To assess the linearity of the assay, samples spiked with high concentrations of BSA were serially diluted with calibrator diluent to produce samples with values within the dynamic range of the assay.

- resDetect™ Antibiotic Residue Detection Kit

ACROBiosystems, through rigorous methodological validation, has independently developed the resDetect™ Kanamycin ELISA Kit and resDetect™ Gentamicin ELISA Kit. The calibration standards for these kits trace back to regulatory standards (Kanamycin 130556; Gentamicin 130326). They are suitable for the quantitative determination of residual antibiotics in plasmid DNA raw materials and proteins for cell and gene therapy (CGT), vaccines, and other biopharmaceuticals.

Product Advantages

High specificity

No cross-reactivity with ampicillin, tetracycline, and chloramphenicol

Convenient and efficient

Simple operation, using a one-step method, results can be obtained in just 1 hour and 20 minutes

Excellent performance

Good linearity of the standard curve, high accuracy, and good repeatability

Good stability

Small batch-to-batch variation, long shelf life

Product List

Cat.No.	Description	Size
RES-A004	resDetect™ Kanamycin ELISA Kit	96 Tests
RES-A078	resDetect™ Kanamycin ELISA Kit	96 Tests
RES-A025	resDetect™ Gentamicin ELISA Kit	96 Tests
RES-A079	resDetect™ Gentamicin ELISA Kit (high sensitivity)	96 Tests

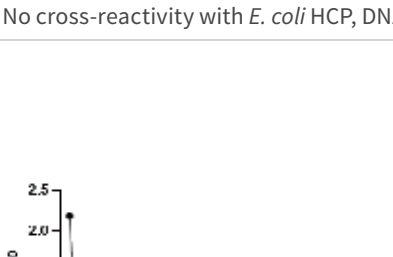
Product Performance

Cat.No.	RES-A004	RES-A025
Detection Range	0.5~40.5ng/mL	0.25~8ng/mL
Recovery	70%~130%	70%~130%
Precision	<15%	<15%
Specificity	No cross-reactivity with ampicillin, tetracycline, chloramphenicol; No cross-reactivity with *E. coli* HCP, DNA	No cross-reactivity with ampicillin, tetracycline, chloramphenicol; No cross-reactivity with *E. coli* HCP, DNA

- Standard Curve

- *resDetect™ Kanamycin ELISA Kit*

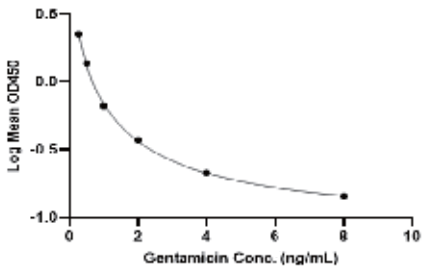
Standard Conc. (ng/mL)	OD450-1	OD450-2	OD450-3
40.5	0.203	0.185	0.194
13.5	0.352	0.345	0.349
4.5	0.643	0.635	0.639
1.5	1.258	1.207	1.233
0.5	2.195	2.165	2.18



For each experiment, a standard curve needs to be set for each micro-plate, and the specific OD value may vary depending on different laboratories, testers, or equipments. The following example data is for reference only.

- *resDetect™ Gentamicin ELISA Kit*

Standard Conc. (ng/mL)	OD450-1	OD450-2	OD450-3
8	0.133	0.153	0.143
4	0.202	0.222	0.212
2	0.354	0.388	0.371
1	0.625	0.794	0.665
0.5	1.287	1.443	1.365
0.25	2.233	2.271	2.247



Serial dilutions of gentamicin (from 8 ng/mL to 0.25 ng/mL) was added into gentamicin: anti-gentamicin binding reactions. The assay was performed according to the protocol dscribed below. Background was subtracted from data points prior to log transformation and curve fitting.

- High Specificity

- *resDetect™ Kanamycin ELISA Kit*

Validated results showed no significant cross-reactivity when separately adding 500µg/mL ampicillin, tetracycline, and chloramphenicol in the sample diluent. Additionally, when adding 2000ng/mL E. coli host protein, 200ng/mL E. coli host DNA, and 50ng/µL plasmid DNA in the diluent, the recovery rates for all three samples were between 70-130%.

Cross-reactivity

Cross Reactant	Cross-reactivity
Kanamycin (500 µg/mL)	100%
Ampicillin (500 µg/mL)	<1%
Tetracycline (500 µg/mL)	<1%
Chloramphenicol (500 µg/mL)	<1%

Interference

Interference Factor	*E.coli* HCP Conc. (2000 ng/mL)			*E.coli* HCD Conc. (200 ng/ml)			Plasmid DNA Conc. (50 ng/µL)		
Sample Conc.(ng/mL)	30	4.5	1	30	4.5	1	30	4.5	4.5
Detected Sample Conc. (ng/mL)	27.79	5.47	1.17	32.42	4.83	1.22	39.59	6.23	1.34
Recovery Rate (%)	92	116	117	108	107	122	130	118	127

- ***resDetect™ Gentamicin ELISA Kit***

Validated results showed no significant cross-reactivity when separately adding 500μg/mL ampicillin, tetracycline, and chloramphenicol in the sample diluent. Additionally, when adding 2000 ng/mL E. coli host protein, 200 ng/mL E. coli host DNA, and 100ng/μL plasmid DNA in the diluent, the recovery rates for all three samples were between 70-130%.

Cross-reactivity

Cross Reactant	Cross-reactivity
Kanamycin (500 μg/mL)	100%
Ampicillin (500 μg/mL)	<1%
Tetracycline (500 μg/mL)	<1%
Chloramphenicol (500 μg/mL)	<1%

Interference

Interference Factor	E.coli HCP Conc. (2000 ng/mL)			E.coli HCD Conc. (200 ng/ml)			Plasmid DNA Conc. (50 ng/μL)		
Sample Conc.(ng/mL)	5	2	0.5	5	2	0.5	5	2	0.5
Detected Sample Conc. (ng/mL)	4.57	2	0.4	5.09	2.2	0.58	6.06	2.4	0.62
Recovery Rate (%)	91	100	80	102	110	116	121	120	125

Other Residue Detection

- resDetect™ Affinity Ligand Residue Detection Kit

To support CMC-related research and quality control in drug development and manufacturing, ACROBiosystems has independently developed the resDetect™ Affinity Ligand ELISA Kits based on a rigorously validated double-antibody sandwich ELISA platform. These kits are designed for the sensitive and specific detection of residual affinity ligands—including native or structurally conserved forms of Protein A, Protein L, VH3, and Protein G—in intermediate or final antibody and Fc-fusion protein drug products. The resDetect™ series meets the requirements of pharmaceutical companies for quantitative residual analysis, helping to optimize purification processes and accelerate the path to market for biologic drugs.

Product List

Cat.No.	Description	Size
RES-A024	resDetect™ Universal Protein A Quick ELISA kit	96 Tests
RES-A029	resDetect™ Universal Protein A Quick ELISA Kit (Boiling-free)	96 Tests
RES-A026	resDetect™ Protein L ELISA Kit	96 Tests
RES-A059	resDetect™ VH3 ELISA Kit	96 Tests

resDetect™ Universal Protein A Quick ELISA kit

Product Performance

- Applicability

This kit includes three different types of Protein A standards: Recombinant Protein A Standard, Alkali-Tolerant Recombinant Protein A Standard, and MaXtar® ARPA ligand Protein A Standard (Bio-Link Co.). For the detection of ligand residues in different Protein A affinity chromatography resins, the recommended standards are as follows:

Resin	Standard
MabSelect SuRe™	Alkali-Tolerant Recombinant Protein A Standard
MaXtar® ARPA ligand	MaXtar® ARPA ligand Protein A Standard (Bio-Link Co.)
Alkali-Tolerant Protein A Resin 1 (Manufacturer B)	Alkali-Tolerant Recombinant Protein A Standard
Alkali-Tolerant Protein A Resin 2 (Manufacturer D)	Alkali-Tolerant Recombinant Protein A Standard
Alkali-Tolerant Protein A Resin 3 (Manufacturer N)	Alkali-Tolerant Recombinant Protein A Standard
native & rprotein A	Recombinant Protein A Standard

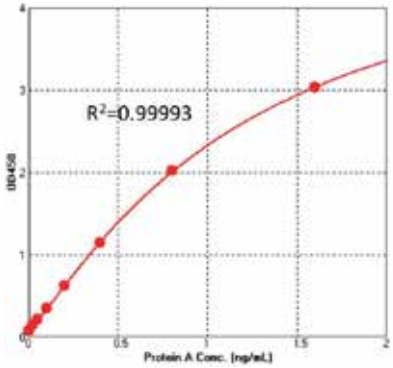
ACROBiosystems' Protein A Residue Detection Kit has excellent recovery rates (80-120%). In addition to MabSelect SuRe™ and MaXtar® ARPA ligand, three alkali-tolerant affinity media commonly used in the market were also tested. The data shows ideal recovery rates and compatibility, demonstrating excellent versatility.

Ligand / Competitor	ACRO	Competitor C	Competitor P
Natural and Recombinant Protein A	93-106%	125-329%	68-103%
MabSelect SuRe™ Protein A	89-106%	106-148%	105-158%
MaXtar® ARPA ligand Protein A (Bio-Link Co.)	91-112%	146-186%	93-127%
Alkali-Tolerant Protein A Resin 1 (Manufacturer B)	90-101%	176-213%	131-170%
Alkali-Tolerant Protein A Resin 2 (Manufacturer D)	96-105%	83-118%	57-121%
Alkali-Tolerant Protein A Resin 3 (Manufacturer N)	96-121%	122-164%	96-154%

- Sample Data

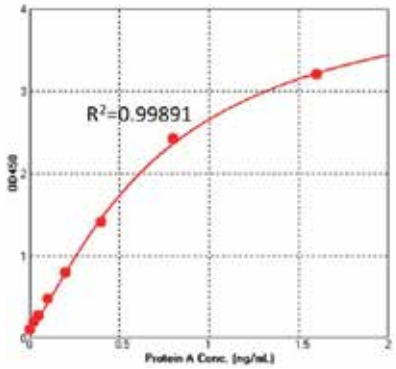
Recognition and detection of various Protein A structures, including native or structurally conserved recombinant Protein A, as well as various alkali-resistant Protein A ligands commonly used in bioprocess manufacturing applications, such as MabSelect SuRe™, MaXtar® ARPA ligand, etc.

Standard Num.	Concentration	OD450nm
Standard 7	1.6 ng/mL	3.032
Standard 6	0.8 ng/mL	2.017
Standard 5	0.4 ng/mL	1.144
Standard 4	0.2 ng/mL	0.624
Standard 3	0.1 ng/mL	0.342
Standard 2	0.05 ng/mL	0.205
Standard 1	0.025 ng/mL	0.143
Standard 0	0 ng/mL	0.076



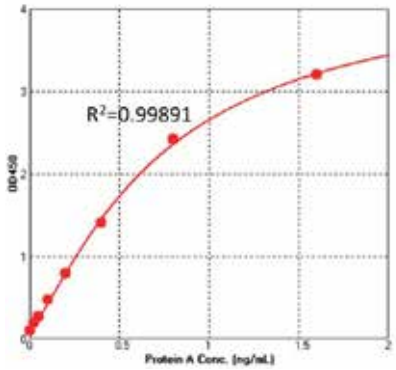
The standard curve is generated by diluting the ACRO self-produced high-purity, high-sensitivity ***recombinant Protein A*** series and fitting the data using a 4-parameter logistic (4-PL) model. The detection range is from 25 to 1600 pg/mL, with an R^2 value of up to 0.99.

Standard Num.	Concentration	OD450nm
Standard 7	1.6 ng/mL	3.197
Standard 6	0.8 ng/mL	2.415
Standard 5	0.4 ng/mL	1.4
Standard 4	0.2 ng/mL	0.795
Standard 3	0.1 ng/mL	0.474
Standard 2	0.05 ng/mL	0.267
Standard 1	0.025 ng/mL	0.182
Standard 0	0 ng/mL	0.092



The standard curve is generated by diluting the ACRO self-produced high-purity, high-sensitivity ***alkali-tolerant recombinant Protein A*** series and fitting the data using a 4-parameter logistic (4-PL) model. The detection range is from 25 to 1600 pg/mL, with an R^2 value of up to 0.99.

Standard Num.	Concentration	OD450nm
Standard 7	1.6 ng/mL	2.945
Standard 6	0.8 ng/mL	2.052
Standard 5	0.4 ng/mL	1.194
Standard 4	0.2 ng/mL	0.635
Standard 3	0.1 ng/mL	0.358
Standard 2	0.05 ng/mL	0.212
Standard 1	0.025 ng/mL	0.14
Standard 0	0 ng/mL	0.068

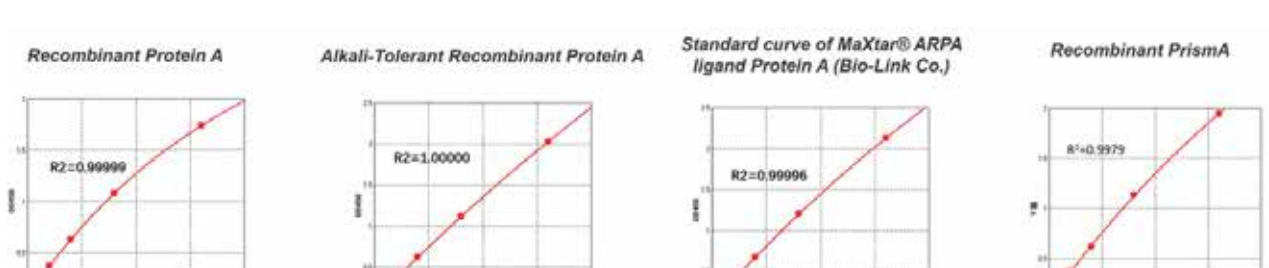


The standard curve is generated by diluting the high-purity, high-sensitivity ***MaXtar® ARPA ligand Protein A*** series self-produced by Bio-Link, and fitting the data using a 4-parameter logistic (4-PL) model. The detection range is from 25 to 1600 pg/mL, with an R2 value of up to 0.99.

resDetect™ Universal Protein A Quick ELISA Kit (Boiling-free)

- Broad Applicability: Compatible with various forms and variants of Protein A

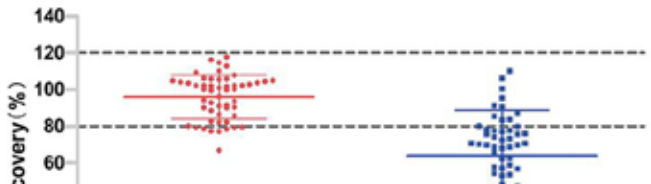
Includes four different types of standards, covering the majority of commercially available Protein A and variant affinity chromatography resins for residual detection.



The minimum detectable concentration of different forms of protein A are 40 pg/mL. The minimum detectable concentration was determined by adding twice standard deviations to the mean optical density value of twenty zero standard replicates and calculating the corresponding concentration.

- High Recovery Rate

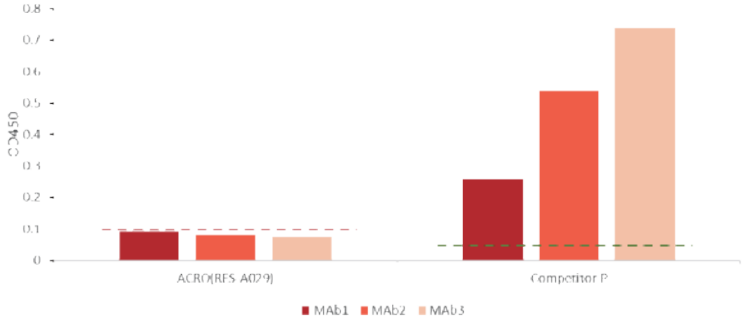
Addresses the common issue of low recovery in detecting Protein A from non-native antibody drug structures. ACROBiosystems has optimized the dissociation process between antibody drugs and Protein A in samples, significantly improving recovery rates.



Total 53 samples were tested by ACRO and Competitor C kits simultaneously. 45 samples tested by ACRO (Cat. NO. RES-A029) kit fell into the acceptable recovery range (80-120%), and only 11 samples tested by competitor C kit fell into the acceptable recovery range.

- Ultra-Low Non-Specific Binding

Demonstrates excellent specificity for Protein A detection with no non-specific signals, outperforming comparable products on the market.



3 monoclonal antibody samples which not contain Protein A were tested by ACRO and Competitor P kits simultaneously. All 3 testing results tested by ACRO kit were below LOD (blank+2SD, red line), meanwhile, all 3 testing results tested by Competitor P kit were far beyond the LOD (blank+2SD, green line). Those data show there are non-specific binding of Competitor P kit.

- resDetect™ dsRNA Residue Detection Kit

During the *in vitro* transcription (IVT) process of mRNA production, in addition to the target mRNA, double-stranded RNA (dsRNA) by-products may also be generated. To ensure the quality and safety of IVT-derived mRNA products, strict monitoring and control of dsRNA residues is essential.

ACROBiosystems has independently developed a high-performance **dsRNA Residual Detection ELISA Kit** (Cat. No. RES-A092), offering high sensitivity, excellent specificity, and outstanding lot-to-lot consistency. This kit is particularly well-suited for the trace-level detection of dsRNA in quality control of mRNA-based biopharmaceuticals.

Product Advantages

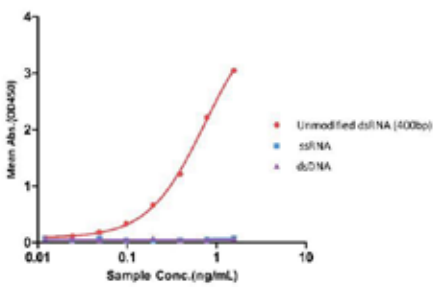
- **High Sensitivity:** Capable of detecting dsRNA as low as 8.988 pg/mL, making it ideal for trace-level dsRNA detection in mRNA product quality control
- **High Specificity:** Specifically recognizes dsRNA with no cross-reactivity to ssRNA or dsDNA, ensuring accurate and reliable results
- **Broad Applicability:** Detects dsRNA fragments over 40 bp in length and covers a wide range of modification types, suitable for various testing scenarios
- **High Precision and Accuracy:** Demonstrates excellent intra- and inter-assay consistency. Accurate recovery rates at high, medium, and low concentrations ensure the reliability of test results
- **Flexible Use:** A variety of dsRNA standards is available—including 5-OMe-UTP dsRNA, N1-Me-pUTP dsRNA, and pUTP dsRNA—to support flexible selection and application

Product List

Cat.No.	dsRNA Standard	Size
RES092-C09	5-0Me-UTP dsRNA (400bp) Standard	10 μg
RES092-C10	N1-Me-pUTP dsRNA (400bp)	10 μg
RES092-C11	pUTP dsRNA (400bp) Standard	10 μg
RES092-C12	Unmodified dsRNA (142bp)	10 μg

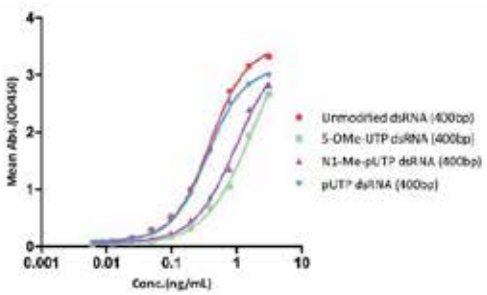
Validation Highlights

- High Specificity: Exclusively detects dsRNAwith no cross-reactivity to ssRNA or dsDNA



The kit has been tested to specifically identify dsRNA, and does not identify ssRNA, dsDNA.

- Broad Applicability: Effectively identifies dsRNA of various lengths and modification types



The kit can detect the dsRNA from different modifications.

- High Precision and Accuracy: Excellent lot-to-lot and within-lot consistency with accurate recovery across concentration ranges

Sample	1	2	3
Number of Replicate	10	10	10
Mean(pg/mL)	661.110	164.505	66.802
SD	40.762	8.868	3.295
CV(%)	6.2	5.4	4.9

Three samples of known concentration were tested ten times on one plate to assess intra-assay precision.

Sample	1	2	3
Number of Replicate	3	3	3
Mean(pg/mL)	659.921	163.056	65.590
SD	13.344	4.376	2.396
CV(%)	2.0	2.7	3.7

Three samples of known concentration were tested ten times on one plate to assess intra-assay precision.

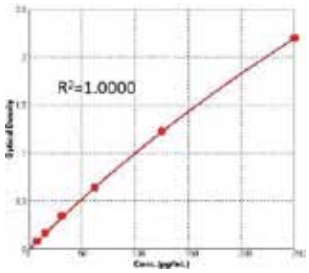
Sample (n=5)	Average % Recovery	Range %
High	105.5	94.6-113.8
Middle	95.7	88.5-100.3
Low	95.6	84.1-109.0

Three samples with different concentrations were tested to calculate the recovery rate.

- resDetect™ HIV-1 P24 Residue Detection Kit

The HIV-1 P24 Residual Detection ELISA Kit (Cat. No. RES-A050) is based on a sandwich ELISA principle and is designed for the quantitative detection of HIV-1 p24, a key component of lentiviral vectors used in CAR-T cell production. This kit is suitable for use during drug development and CMC quality control processes, helping to ensure the safety and quality of CAR-T cell products.

Validation Data



For each experiment, a standard curve needs to be set for each micro-plate, and the specific OD value may vary depending on different laboratories, testers, or equipments. The following example data is for reference only.

- Recovery

Five different concentrations of HIV-1 p24 were added to the cell culture supernatant, and the cell culture supernatant without HIV-1 p24 was used as the background to calculate the recovery rate.

Sample Type	Range %
HEK293 cell culture supernatant (n=5)	88.6-93.0%
T cell culture supernatant (n=5)	88.0-97.1%

- Linearity

To assess the linearity of the assay, samples spiked with high concentrations of HIV-1 p24 were serially diluted with calibrator diluent to produce samples with values within the dynamic range of the assay.

Dilution	Parameter	Cell culture medium (DMEM)	Cell culture medium(1640)
1:2	**Average Recovery (%)**	98.1	89.1
	Range (%)	89.6 - 110.7	84.2 - 93.2
1:4	**Average Recovery (%)**	93.9	90.8
	Range (%)	91.9 - 96.0	87.3 - 96.5
1:8	**Average Recovery (%)**	93.8	89.9
	Range (%)	87.9-101.9	85.9 - 95.0
1:16	**Average Recovery (%)**	97.7	95.4
	Range (%)	87.7-106.5	89.7 - 101.9

Note: *The example data is for reference only*

- Interfering Substances

Verify potential matrix effects by adding different levels of cell culture medium to the diluted buffer.

Additive	Tolerated concentration
DMEM	50%
1640	50%

FAQ on ELISA Detection

1. What causes weak or no signal in an ELISA assay, and how can it be resolved?

Possible causes:

- Reagents not equilibrated to room temperature
- Expired reagents
- Capture antibody not properly coated onto the plate
- Insufficient concentration of detection antibody
- Scratching the wells during pipetting or washing
- Incorrect wavelength used for signal reading

Recommended solutions:

Allow all reagents to equilibrate at room temperature for 15–20 minutes before use. Check the expiration date of all reagents. Ensure proper coating and blocking of the capture antibody. Dilute the detection antibody according to the recommended ratio. Avoid scratching the wells during pipetting and washing. Use the recommended wavelength for ELISA plate reading.

2. What causes high background signal in an ELISA assay, and how can it be reduced?

Possible causes include insufficient washing, exposure of the substrate to light, over-incubation, or incorrect preparation of the standard curve dilution buffer.

Suggestions to reduce background:

Use sufficient wash buffer and follow the recommended washing procedure. Store the substrate away from light. Adhere strictly to the recommended incubation times. Verify the accuracy of pipetting and the preparation of all dilutions.

3. What causes a poor standard curve in an ELISA assay, and how can it be improved?

Possible causes:

- Incorrect preparation of the dilution buffer
- Capture antibody not properly coated onto the plate
- Inadequate washing
- Inconsistent incubation temperatures

Optimization tips:

Ensure accuracy in pipetting techniques and concentration calculations. Use ELISA-specific plates instead of tissue culture plates. Increase the soaking time during wash steps. Maintain consistent and uniform incubation temperatures throughout the assay.

4. What causes inconsistent replicate data in an ELISA assay, and how can it be improved?

Possible causes include insufficient washing, not using sealing film during incubation, reusing sealing film, or inaccurate pipetting.

Recommendations:

- Perform thorough washing according to standard operating procedures
- Use a new sealing film for each incubation
- Check the accuracy of pipettes and ensure proper pipetting technique

5. What causes edge effects in an ELISA assay, and how can they be avoided?

Edge effects may be caused by uneven incubation temperatures, evaporation of liquid in the outer wells, or stacking of plates during incubation. **Preventive measures** include sealing the plate with a sealing film during incubation, avoiding stacking of plates, and ensuring uniform temperature distribution inside the incubator.

6. What should be noted when pipetting in an ELISA assay?

- Use pipettes within the volume range recommended by the manufacturer.
- Ensure that pipette tips are securely attached to avoid air leakage or bubble formation.
- Change tips when handling different reagents or samples to prevent cross-contamination.

7. What should be noted during washing steps in an ELISA assay?

- Add at least 300 µL of wash buffer to each well.
- After washing, invert the plate and gently tap it to remove residual liquid.
- Ensure that all remaining liquid is completely removed from the wells.

- Overview of ELISA: Principles and Common Types

◦ **The Principle of the ELISA Assay**

ELISA (Enzyme-Linked Immunosorbent Assay) is an immunoassay technique based on the specific interaction between antigens and antibodies, combined with an enzyme-catalyzed colorimetric reaction. It is widely used for the quantitative detection of specific proteins, antibodies, or other target molecules in biological samples.

The core principles of ELISA consist of two main components:

1. Specific Antigen–Antibody Binding

An antigen is a molecule that can trigger an immune response and specifically bind to an antibody. Antibodies are immunoglobulins produced by the immune system in response to antigens and have the ability to selectively recognize and bind to them. ELISA utilizes this high-affinity interaction to accurately capture and detect target molecules in the sample.

2. Enzyme-Catalyzed Color Development

To enable visual detection, enzymes such as horseradish peroxidase (HRP) or alkaline phosphatase (AP) are conjugated to either the antigen or antibody. Upon addition of a chromogenic substrate, the enzyme reacts with the substrate to produce a measurable color change. The intensity of the color is directly proportional to the concentration of the target analyte. A commonly used substrate is TMB (3,3',5,5'-tetramethylbenzidine), which produces a blue or yellow color in the presence of HRP. The absorbance is then measured at a specific wavelength using a microplate reader to determine the analyte concentration.

◦ **Common Types of ELISA**

1. Sandwich ELISA

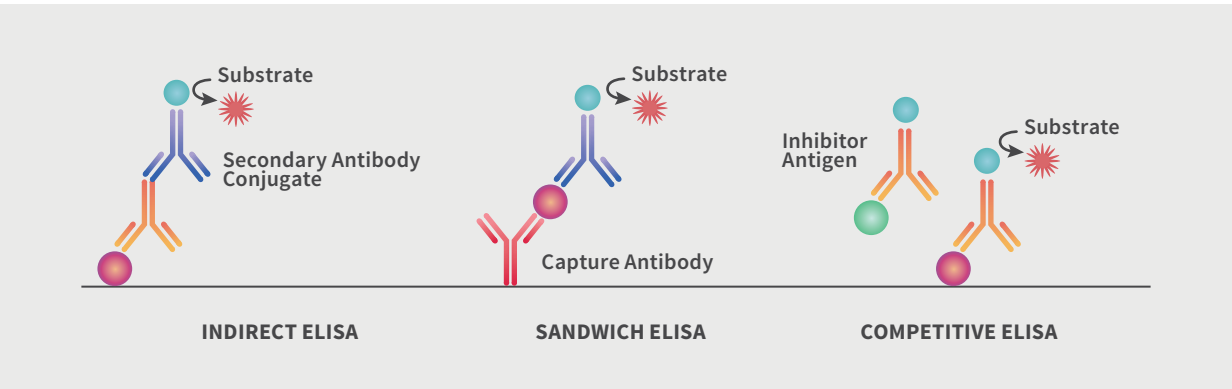
Sandwich ELISA is commonly used for detecting large molecular antigens. A capture antibody specific to the target antigen is first immobilized on a solid surface, such as a 96-well plate. The sample containing the antigen is then added, and the antigen binds specifically to the capture antibody. Next, an enzyme-labeled detection antibody is introduced, which binds to a different epitope on the same antigen, forming a “capture antibody–antigen–enzyme-labeled detection antibody” complex. After substrate is added, the enzyme catalyzes a colorimetric reaction. The color intensity is directly proportional to the antigen concentration in the sample—the deeper the color, the higher the antigen concentration.

2. Indirect ELISA

Indirect ELISA is primarily used for antibody detection. The antigen is first coated onto a solid surface. When the sample is added, any specific antibodies present will bind to the immobilized antigen. A secondary antibody, labeled with an enzyme and specific to the primary antibody, is then added. After substrate addition, a color change occurs due to enzymatic reaction, and the color intensity correlates with the amount of antibody in the sample.

3. Competitive ELISA

Competitive ELISA is suitable for detecting small molecule antigens or haptens, which typically lack sufficient epitopes for sandwich assays. In this format, a limited amount of enzyme-labeled antibody competes to bind with either the solid-phase antigen or the free antigen in the sample. The higher the concentration of antigen in the sample, the less labeled antibody will bind to the solid-phase antigen. As a result, color development after substrate addition is inversely proportional to the antigen concentration in the sample—the higher the antigen level, the weaker the color signal.



Automated Nucleic Acid Extraction System(Cat. NO. OPE-32S)

Automated Sample Preprocessing
Reduces errors, minimizes operation time, and enhances extraction efficiency

Extract up to 32 Samples in a Single Operation
Increases sample processing capacity and extraction efficiency, meeting high-throughput demands

Principle

The Automated Nucleic Acid Extraction System utilizes magnetic bead technology to provide automated DNA sample preparation. Efficient magnetic bead collection and transfer ensure thorough washing, effective elution, and rapid processing, resulting in reliable high recovery rates and consistent performance across a variety of complex samples. The Automated Nucleic Acid Extraction System is designed to work with DNA extraction kits and supports a range of qPCR detection kits, offering a comprehensive solution to meet the drug quality control requirements throughout the entire production process.

Product Features

- Reduces errors and minimizes hands-on time
- Automated sample preprocessing
- Capable of extracting up to 32 samples simultaneously in a single run
- Optimized solution for the SAFENSURE™ and resDetect™ sample preparation kits
- Stable and reliable data
- Customizable operation programs
- UV lamp for disinfection and sterilization
- Audit management system

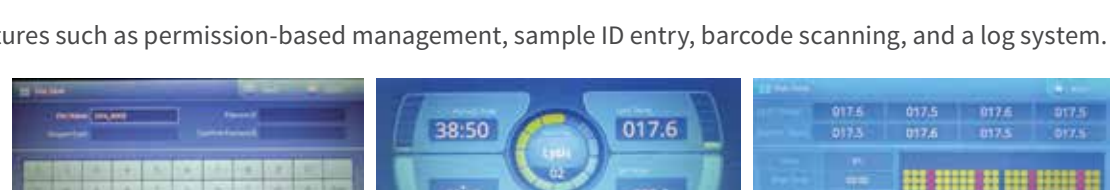
Technical Specifications

Automated Nucleic Acid Extraction System	
Cat. No.	OPE-32S
Samples Per Run	32
Magnetic Rod (Fixed)	4x8
Sample Volume Range	20-1000 µl
Magnetic Bead Collection Efficiency	>98%
Optimal Magnetic Bead Size	0.2-1.0 µm
Size	430x395x435 mm(LxWxH)
Weight	32.5 Kg

Provides 3Q verification for the instrument and extended warranty services.

Audit Trail Version

Includes features such as permission-based management, sample ID entry, barcode scanning, and a log system.



The instrument is compatible with various magnetic bead-based reagent kits and comes with built-in resDetect™ sample preparation protocol.

Type	Cat. No.	Description
Sample Preparation Kits	OPA-R005	resDetect™ resDNA Sample Preparation Kit (Magnetic Beads)
	OPA-R024	resDetect™ resDNA Sample Preparation Kit II (Magnetic Beads)
	OPA-E101	Mycoplasma DNA Sample Preparation Kit (Magnetic beads)

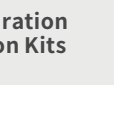
Scan the QR code below to learn more

Automated Nucleic Acid Extraction System

Host DNA Preparation and Detection Kits

Mycoplasma Preparation and Rapid Detection Kits

For inquiries about the Automated Nucleic Acid Preprocessing System or technical support, please scan the QR code to contact us.



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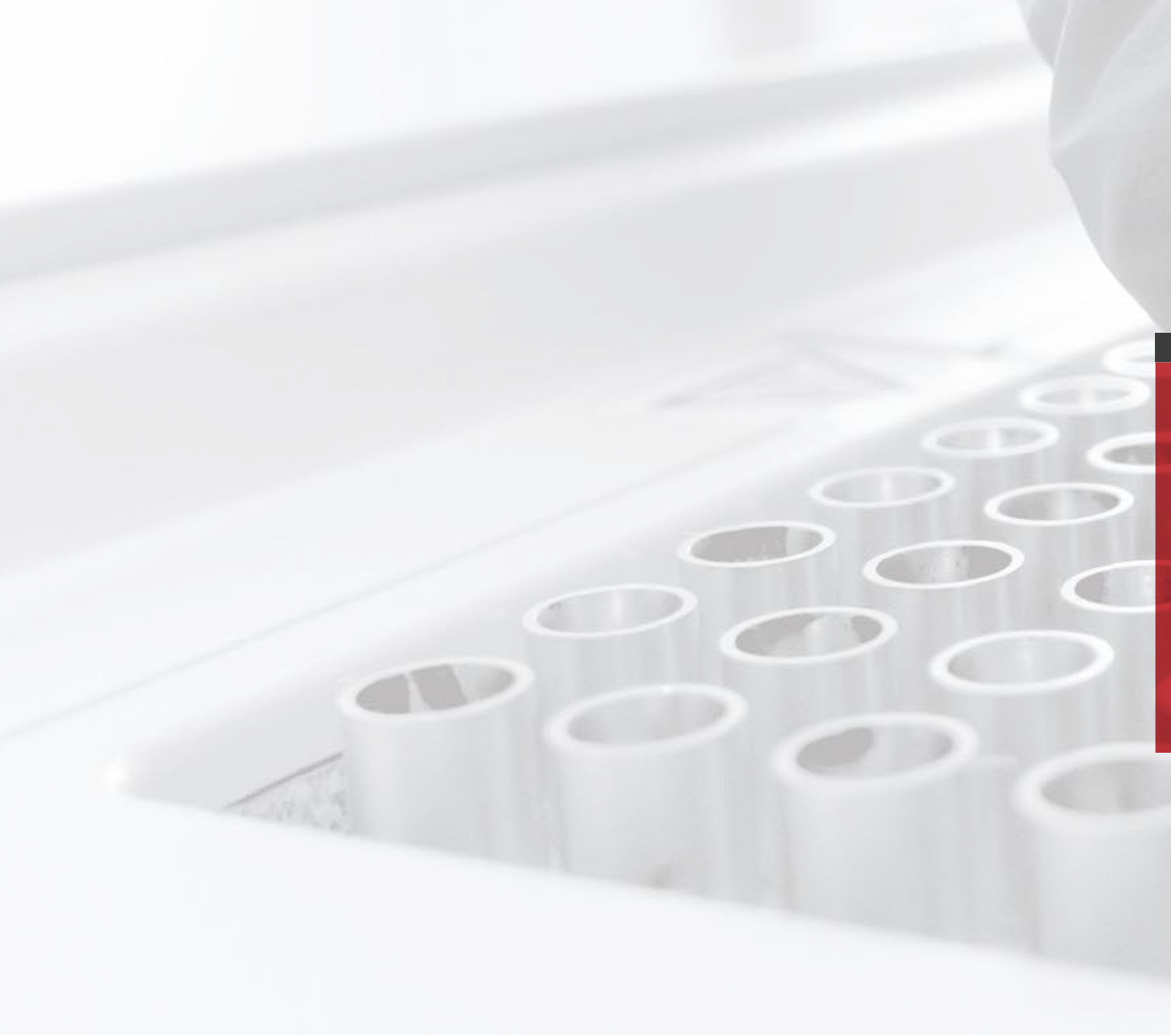

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