BIOSYSTEMS Acro

resDetect™ Manufacturing Process Residue Detection Solutions

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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 antibody drugs, cell and gene therapies (CGT), 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, host cell protein, host cell RNA, protein A, tool enzymes, cytokines, and more.

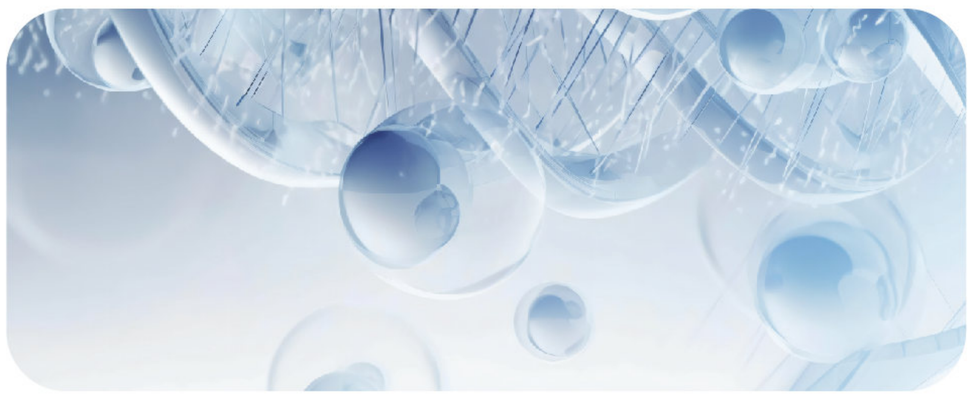
Stable and Reliable —— Stringent batch testing and release, with inter-batch differences less than 15%.

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

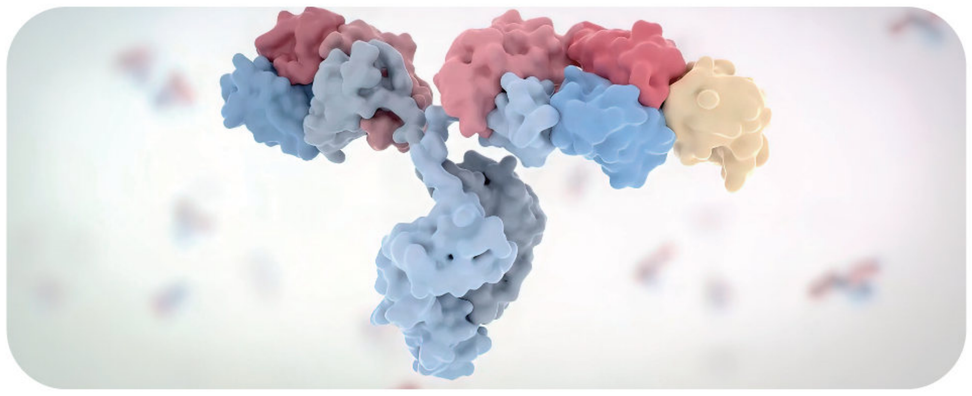
Global Supply —— Product delivery in 1-3 days, worldwide.

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

Biopharmaceutical CMC (Chemistry, Manufacturing, and Controls) residue quality control

Cell therapy process residue quality control

Host cell nucleic acid residue detection
Plasmid DNA residue detection
Viral oncogenes residue detection
Cytokine residue detection
Antibiotic residue detection
Enzyme residue detection
.....

Gene therapy process residue quality control

Host cell nucleic acid residue detection
Plasmid DNA residue detection
Viral oncogenes residue detection
Nuclease residue detection
Antibiotic residue detection
.....

Therapeutic antibodies process residue quality control

Affinity ligand residue detection
Host cell nucleic acid residue detection
.....

mRNA-based therapeutics process residue quality control

Host cell residual nucleic acid detection
Enzyme residue detection
dsRNA residue detection
.....

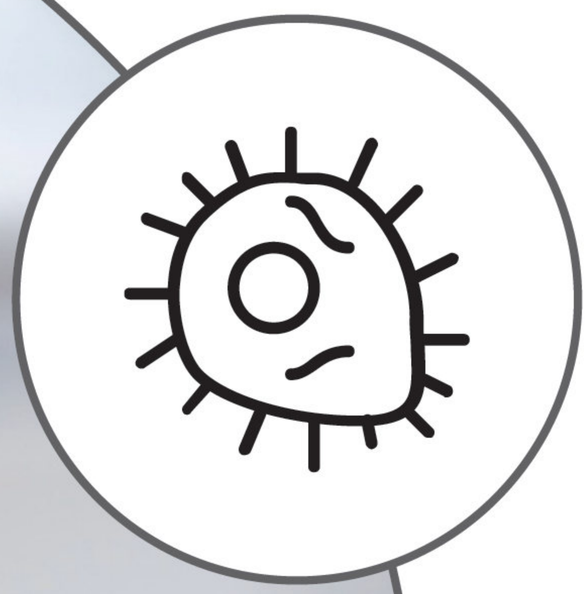
Types of Residues in CMC Process Quality Control

p04 Nucleic Acid Residue

Host Cell Residual Nucleic Acid Detection

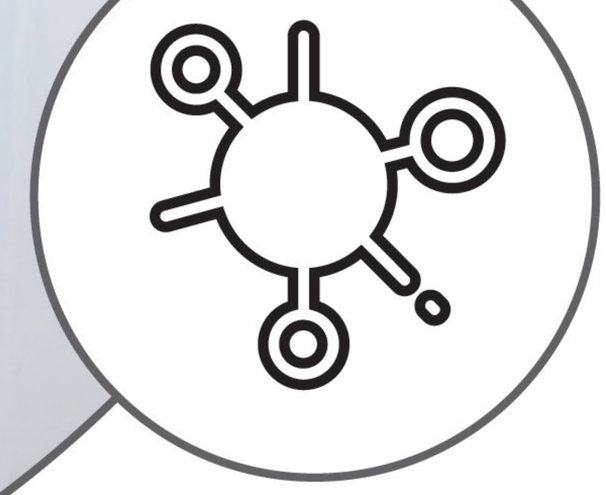
Plasmid DNA Residue Detection

Viral Oncogenes Residue Detection



p09 Affinity Ligand Residue

Protein A Residue Detection

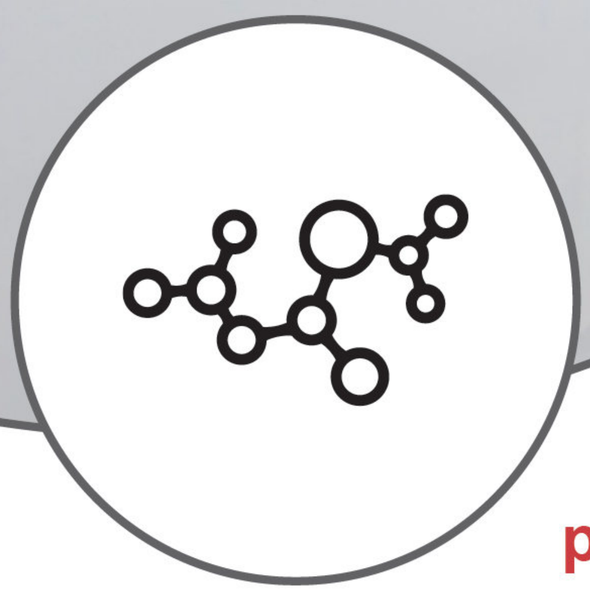


p12 Process Additive Residue

Cytokine Residue Detection

Antibiotic Residue Detection

Enzyme Residue Detection



p18 Other Residues

DNAse Residue Detection

RNAse Residue Detection

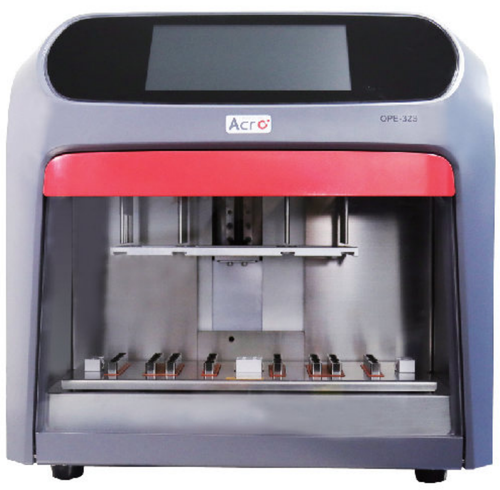
01

Nucleic Acid Residue

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.

Automatic Nucleic Acid Extraction System



- ☑ Purify up to 32 samples within 40 minutes.
- ☑ Equipped with door opening protection and UV disinfection measures to prevent contamination.
- ☑ Permanent magnetic bars with dynamically adjustable amplitude, ensuring residue-free and wall-free extraction.
- ☑ Precision automation operation, high extraction efficiency, stable results, and small inter-hole difference.
- ☑ Compatible with various magnetic bead-based nucleic acid extraction reagent kits.
- ☑ 3Q certification, audit tracking version (customizable).

The fully automated nucleic acid pretreatment system is a magnetic bead-based automated DNA sample processing system. Paired with our sample preparation reagent kits, it can reliably, efficiently, and automatically extract residual DNA from samples.

resDetect™ Host Cell Residual DNA Detection Kit

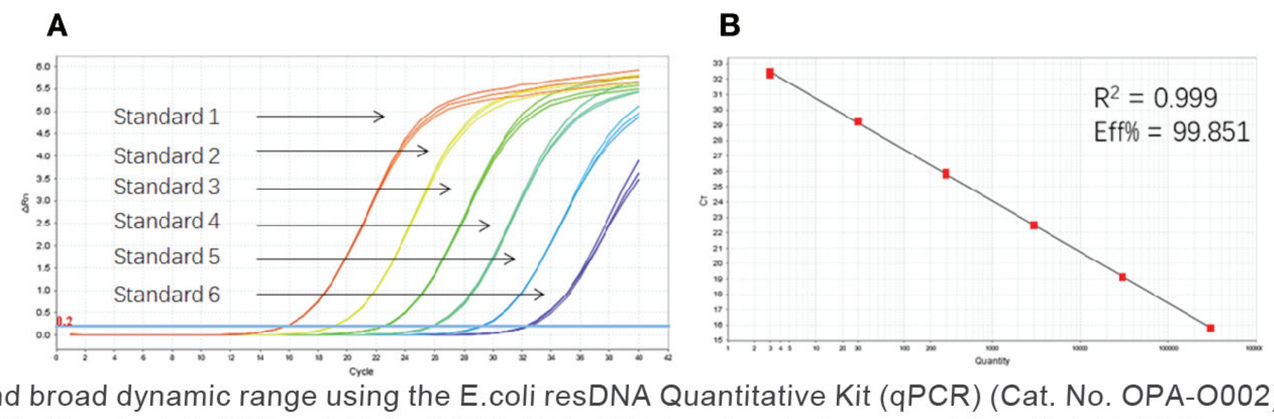
- ☑ Host cell DNA types: HEK293, *E. coli*, CHO, etc.
- ☑ High sensitivity: Developed based on quantitative PCR methods, with a Limit of Detection (LOD) reaching 1 fg/μL.
- ☑ High consistency: Consistent performance across different DNA fragment sizes.
- ☑ High specificity: No cross-reactivity with unrelated DNA, minimizing false positive detection.
- ☑ Manufactured under GMP-like facility and strictly adheres to an ISO13485:2016, ISO9001:2015 quality management system.
- ☑ Rigorous quality management system; comprehensive validation: References to ICH Q2(R2) guidelines with thorough validation reports.

Product List

Cat. No.	Product Description
OPE-32S	resDetect™ Automated Nucleic Acid Extraction System
OPA-R005	resDetect™ resDNA Sample Preparation Kit (Magnetic Beads)
OPA-O002	resDetect™ *E. coli* resDNA Quantitative Kit (qPCR)
OPA-R004	resDetect™ CHO resDNA Quantitation Kit (qPCR)
OPA-R006	resDetect™ HEK293 resDNA Quantitation Kit (qPCR)
OPA-R010	resDetect™ HEK293T resDNA Quantitation Kit (qPCR)
OPA-R009	resDetect™ Plasmid resDNA Quantitation Kit (qPCR)

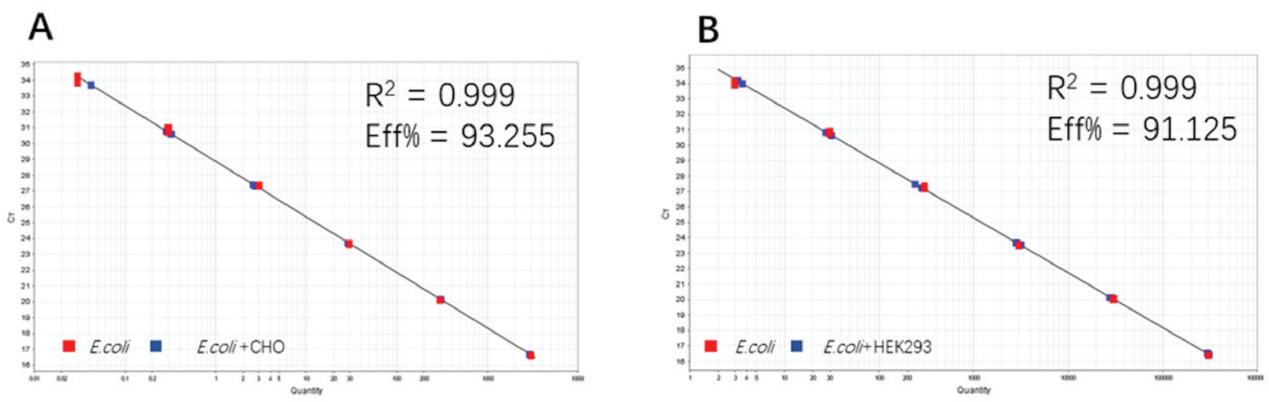
Product Data

High Sensitivity: Limit of Detection (LLOD) reaches 1 fg/μL



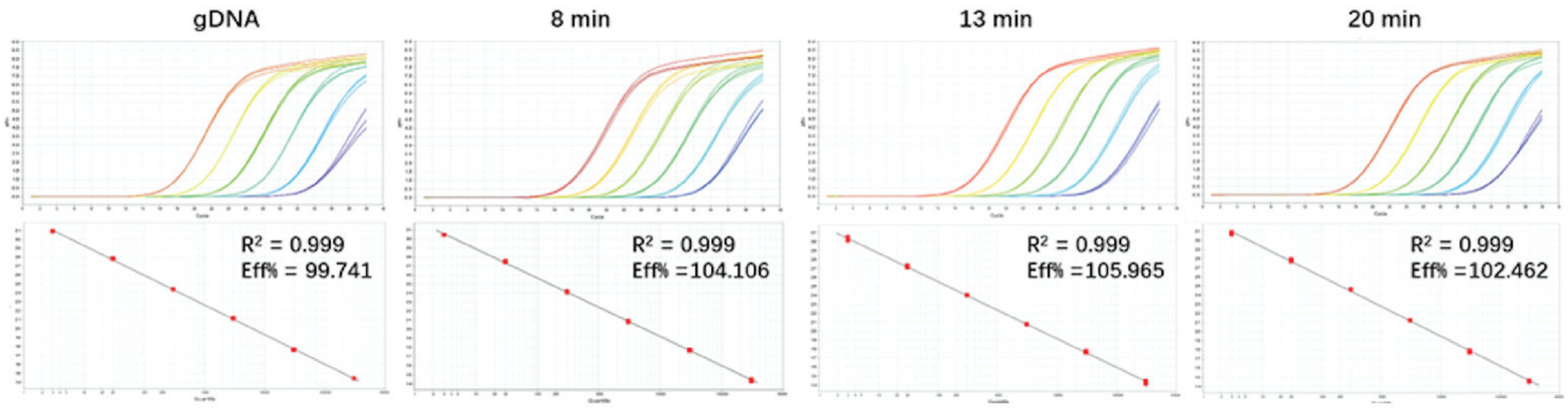
High sensitivity and broad dynamic range using the E.coli resDNA Quantitative Kit (qPCR) (Cat. No. OPA-O002). (A) Typical analysis results obtained with Standard 1 (300 pg/μL) to 6 (3 fg/μL). (B) The standard curve of the 10-fold dilution series. PCR efficiency should be 90-110%.

▶ High Specificity: No cross-reactivity with unrelated DNA



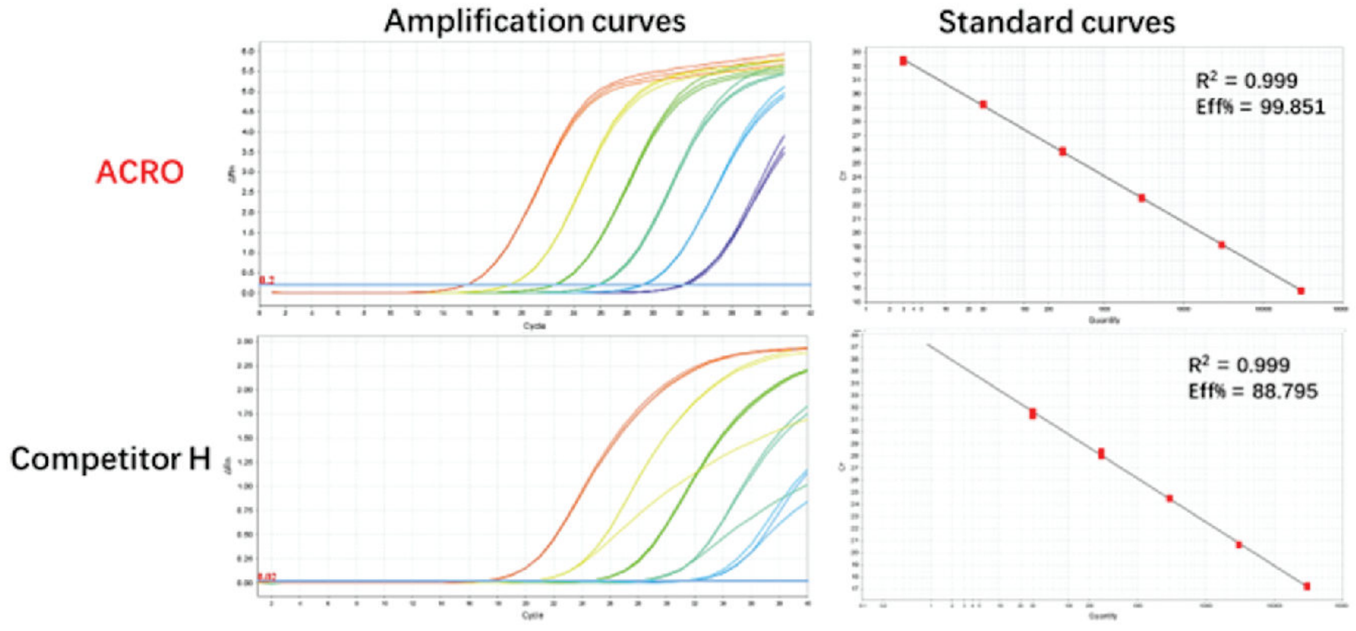
Assay specificity. Standard curves generated using 10-fold serial dilution of *E. coli* genomic DNA (included in the kit).

▶ High Consistency: Maintains consistent performance across different DNA fragment 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 *E. coli* genomic DNA (8min, 13min, 20min). Fragmentation of the DNA was confirmed by agarose gel analysis.

▶ Competitive Comparison Data



The amplification efficiency of standard curve (ACRO) is close to 100%, while the amplification efficiency of standard curve (Competitor H) is less than 90%. Better performances can be observed based on the standard curves from each kit.

resDetect™ Viral Oncogenes Residual DNA Detection Kit

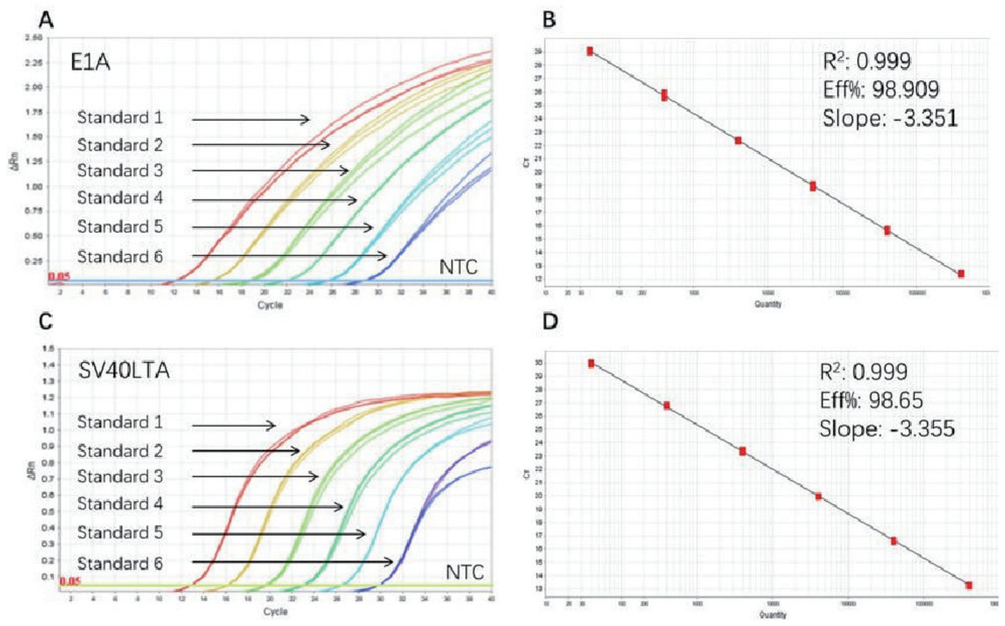
Designed specifically to quantify residual E1A and SV40LTA DNA in biopharmaceutical production (cells, viruses, etc.), this kit is based on a real-time quantitative PCR (qPCR) method. It can rapidly and reliably detect the content of residual DNA, with a quantitative lower limit of 40 copies/μL. Typically, 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 resDNA Quantitation Kit (qPCR)
OPA-R007	resDetect™ E1A & SV40LTA resDNA Quantitation Kit (qPCR)

Product 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) A standard curve of the E1A DNA Control 10-fold dilution series. PCR efficiency should be within 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 using E1A&SV40LTA resDNA Quantitation Kit, 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
$4x10^4$	$4.00x10^4$	$3.40x10^4$	99.89	84.98
4x10	3.52x10	3.14x10	87.97	78.57

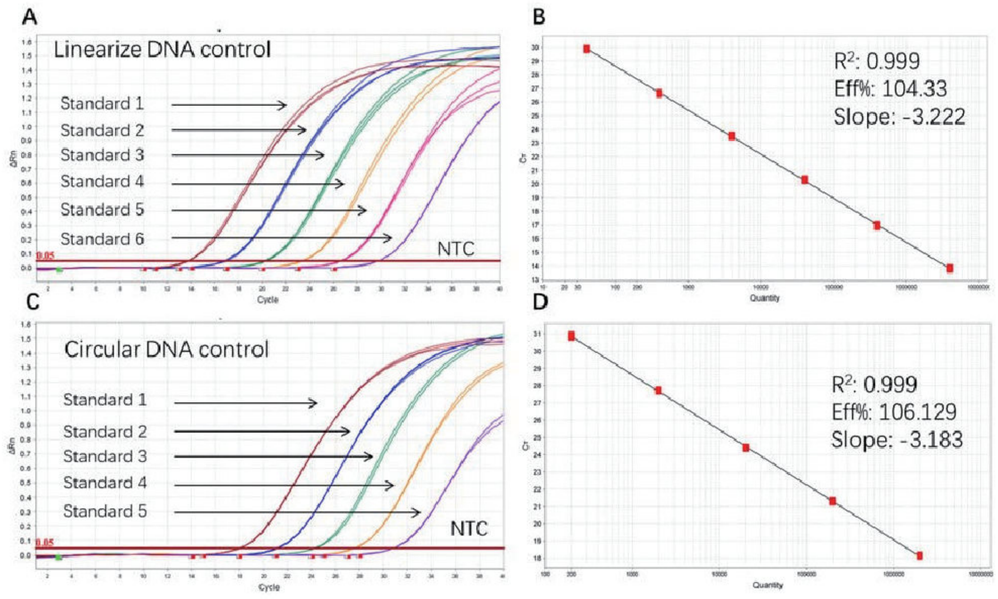
To evaluate the recovery of assay using E1A&SV40LTA resDNA Quantitation Kit, three different concentrations of DNA samples were tested. Results shown in the following Table. All samples had recoveries between 78%-100%.

resDetect™ Plasmid DNA Residual Detection Kit

ACROBiosystems' resDetect™ Plasmid DNA Residual Detection Kit (Catalog Number: OPA-R009) 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 using linearized 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 (2×106 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

Unrelated DNA	Mean (copies/µL)
	Plasmid
HEK293 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).

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%.

02

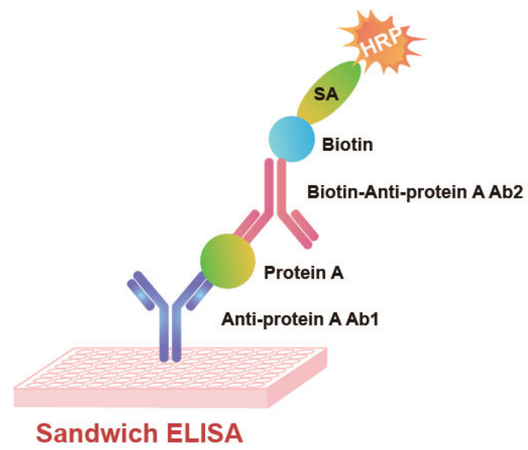
Affinity Ligand Residue Detection

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™ Universal Protein A Quick ELISA kit

ACROBiosystems' resDetect™ Universal Protein A Quick ELISA kit (Catalog Number: RES-A024) was developed to support drug CMC production and quality control-related research. Through rigorous methodological validation, this kit is based on sandwich enzyme-linked immunosorbent assay (sandwich ELISA). It can be used to determine the presence of native or structurally conserved recombinant Protein A in intermediate as well as final products of antibodies and Fc fusion protein drug formulations. It also detects the dissociation of various alkali-resistant recombinant Protein A ligands commonly used in bioprocess manufacturing applications, such as MabSelect SuRe™ and MaXtar® ARPA ligand. The kit meets the needs of pharmaceutical companies for residual quantitative analysis and optimization of relevant drug purification processes, thereby expediting the process of bringing biopharmaceuticals to market.



Application

The kit is developed for the detection of natural or structurally conserved recombinant forms of Protein A and alkaline-resistant Protein A variants, such as MabSelect SuRe™ , MaXtar® ARPA ligand (Bio-Link Co.), etc. in bioprocess manufacturing applications.

Features

- ☑ Universal - Suitable for detection of natural or structurally conserved recombinant forms of Protein A and alkaline-resistant Protein A variants, such as MabSelect SuRe™ and other ligands
- ☑ Fast time to results - less than 2 hours
- ☑ Accuracy - Tracebility of Protein A standards against BSA China National Standard (NIFDC code: 140619) with validated pharmacopoeia quantitation methodology
- ☑ Extensive validation - Validation Report (ICH compliant) available on request
- ☑ High sensitivity - Sensitivity < 20 pg/mL of recombinant Protein A and MabSelect™ SuRe Protein A or other Protein A ligands
- ☑ High IgG tolerance - Accurately quantify protein A in up to 10 mg/mL antibody
- ☑ Excellent buffer compatibility

Product Data

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	Standards
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

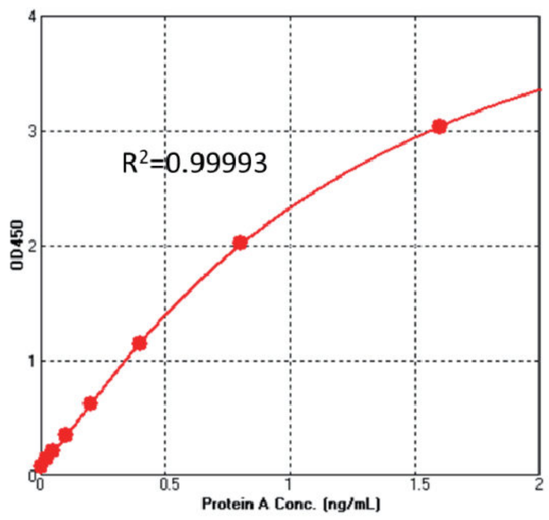
★ ACROBiosystems' Protein A Residue Detection Kit has excellent recovery rates (80-120%). In addition to MabSelect SuRe™ and MaXtar® ARPA ligand, three alkali-tolerant affinity media commonly used in the market were also tested. The data shows ideal recovery rates and compatibility, demonstrating excellent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

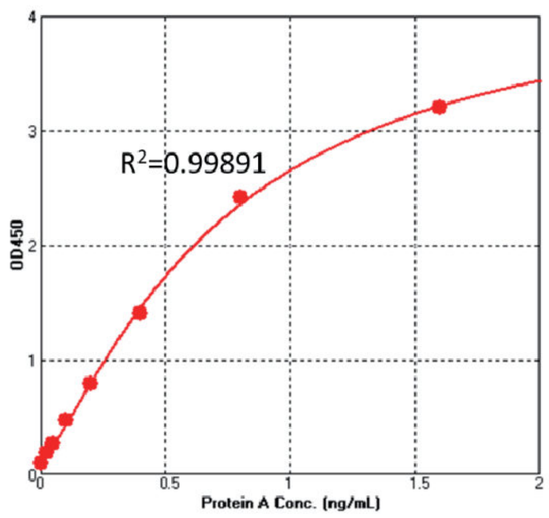
★ Recognition and detection of various Protein A structures, including native or structurally conserved recombinant Protein A, as well as various alkali-resistant Protein A ligands commonly used in bioprocess manufacturing applications, such as MabSelect SuRe™, MaXtar® ARPA ligand, etc.

Standard Num.	Concentration	OD_{450nm}
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



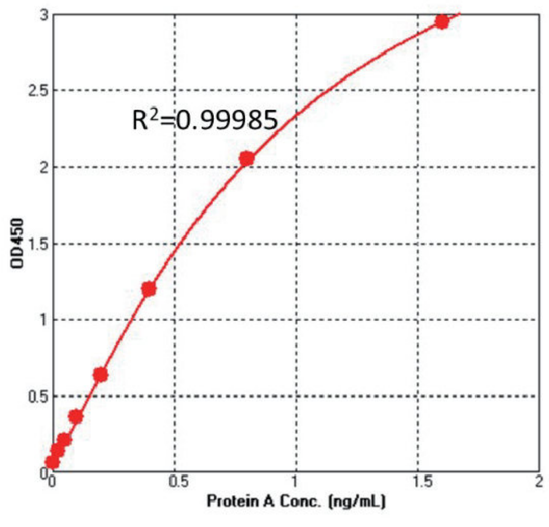
The standard curve is generated by diluting the ACRO self-produced high-purity, high-sensitivity recombinant Protein A series and fitting the data using a 4-parameter logistic (4-PL) model. The detection range is from 25 to 1600 pg/mL, with an R2 value of up to 0.99.

Standard Num.	Concentration	OD_{450nm}
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	OD_{450nm}
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 R^2 value of up to 0.99.

03

Cell Culture Supplement Residue Detection

In some drug manufacturing processes, substances such as culture medium supplements IL-2/IL-15/IL-7 cytokines, broad-spectrum nucleases, antibiotics, etc., are added. Relevant regulations have explicitly specified the need to assess and control the residues of these process additives stating, " Developing appropriate residuals specifications and detection methods ensures CGT product and process consistency, allows characterization of the final CGT product, and reduces negative effects 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, broad-spectrum nuclease 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.

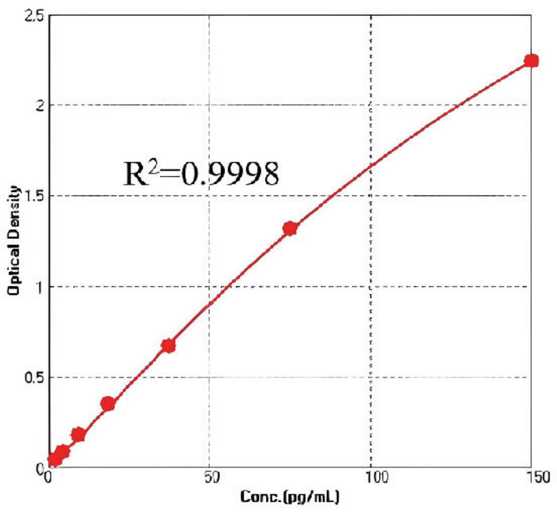
Hot Products list

Cat. No.	Product Description
CRS-A024	resDetect™ Human Interleukin-15 (IL-15) ELISA Kit (Residue Testing)
CRS-A025	resDetect™ Human Interleukin-7 (IL-7) ELISA Kit (Residue Testing)
CRS-A003	resDetect™ Human Interleukin-2 (IL-2) ELISA Kit (Residue Testing)
CRS-A005	resDetect™ Human Interleukin-6 (IL-6) ELISA Kit (Residue Testing)
CRS-A010	resDetect™ Human Interleukin-21 (IL-21) ELISA Kit (Residue Testing)
CRS-A014	resDetect™ Anti-CD28 Antibody ELISA Kit
CRS-A015	resDetect™ Anti-CD3 Antibody ELISA Kit

Learn more information

Product 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

		Cell culture medium	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 (%)	103.7	97.3	95.9
	Range (%)	100.7-108.4	88.8-107.2	88.3-101.0
1:8	Average Recovery (%)	111.1	92.8	92.6
	Range (%)	100.7-117.2	84.9-103.0	81.2-99.9
1:16	Average Recovery (%)	114.7	93.3	99.2
	Range (%)	108.8-117.7	81.4-105.8	91.1-107.0

To assess the linearity of the assay, samples spiked with high concentrations of human IL-15 were serially diluted with calibrator diluent to produce samples with values within the dynamic range of the assay.

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%.

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.

Features

- ☑ 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	96T
RES-A025	resDetect™ Gentamicin ELISA Kit	96T

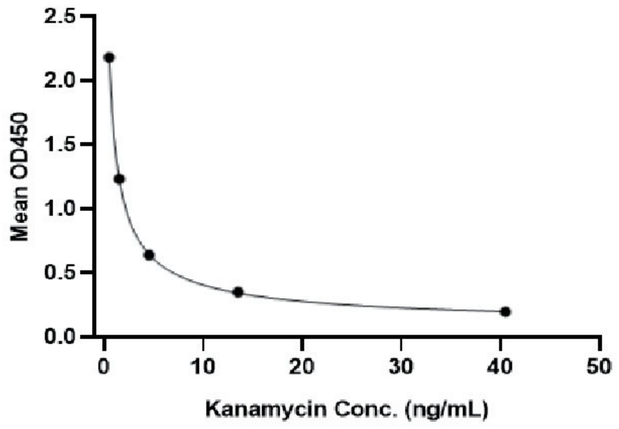
■ Features

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

★ RES-A004

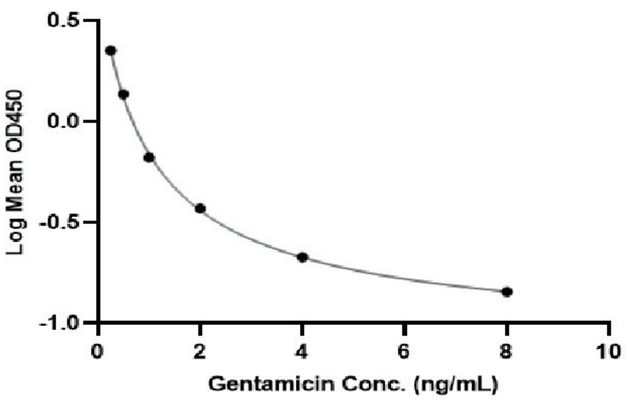
Standard Conc. (ng/mL)	OD450-1	OD450-2	Average
40.5	0.203	0.185	0.194
13.5	0.352	0.345	0.349
4.5	0.643	0.635	0.639
1.5	1.258	1.207	1.233
0.5	2.195	2.165	2.18



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.

★ RES-A025

Standard Conc. (ng/mL)	OD450-1	OD450-2	Average
8	0.133	0.153	0.143
4	0.202	0.222	0.212
2	0.354	0.388	0.371
1	0.625	0.704	0.665
0.5	1.287	1.443	1.365
0.25	2.223	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.

▶ 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 (500ug/mL)	100%
Ampicillin (500ug/mL)	＜1%
Tetracycline (500ug/mL)	＜1%
Chloramphenicol (500ug/mL)	＜1%

Interference

Interference Factor	E.coli HCP Conc. (2000ng/mL)			E.coli HCD Conc. (200ng/ml)			Plasmid DNA Conc. (50ng/μL)		
Sample Conc.(ng/mL)	30	4.5	1	30	4.5	1	30	4.5	1
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 2000ng/mL *E. coli* host protein, 200ng/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
Gentamicin (500ug/mL)	100%
Ampicillin (500ug/mL)	＜1%
Tetracycline (500ug/mL)	＜1%
Chloramphenicol (500ug/mL)	＜1%

Interference

Cross Reactant	E.coli HCP Conc. (2000ng/mL)			E.coli HCD Conc. (200ng/mL)			Plasmid DNA Conc. (100ng/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

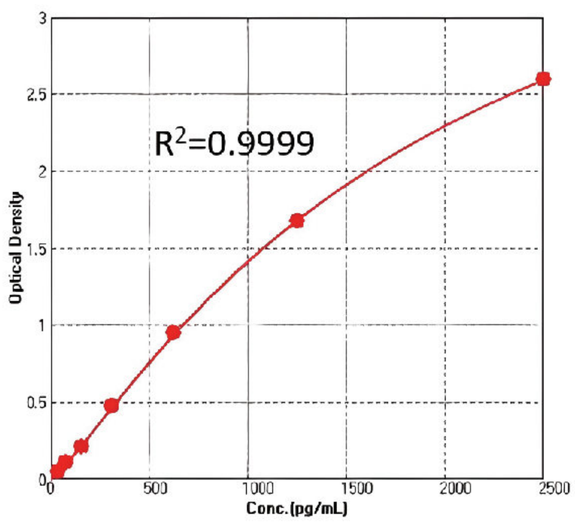
resDetect™ GENIUS™Nuclease ELISA Kit

In the process of treating bioproducts with nucleases, trace amounts of nucleases may remain. Since the broad-spectrum nuclease is classified as a contaminant, these trace residues impact on the subsequent application of bioproducts and may cause toxicity or immune reactions. Therefore, precise detection of nuclease residue is a crucial factor in ensuring the activity and safety of related bioproducts. Our GENIUS™Nuclease ELISA Kit (Catalog number: CRS-A016), a highly sensitive and specific assay for the accurate detection of broad-spectrum nuclease residue, addressing your concerns regarding nuclease residue.

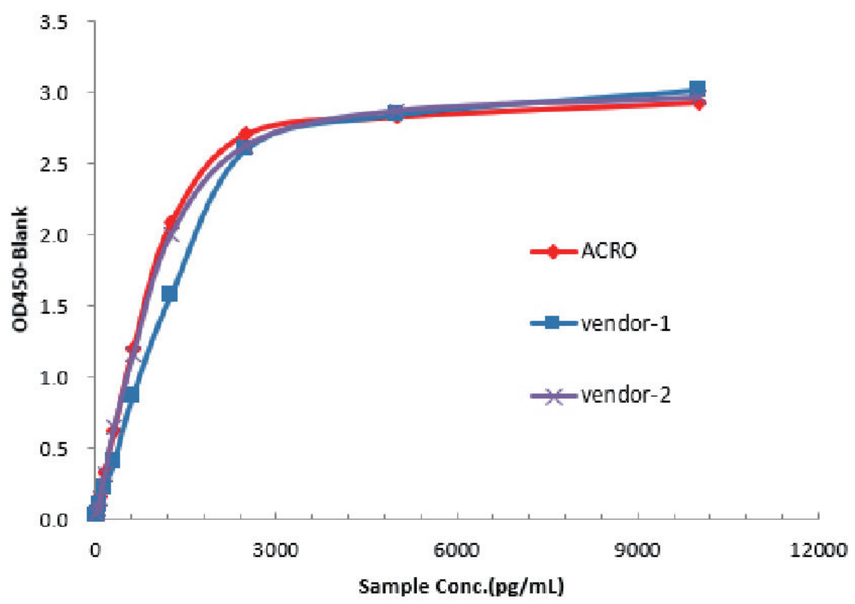
■ Features

- ☑ High sensitivity up to 2.733pg/mL, allowing precise quantification of trace residues of nucleases in culture medium supernatants.
- ☑ Strong adaptability, compatible not only with ACRO's own broad-spectrum nuclease but also with many enzyme products on the market.
- ☑ Stable product performance, with intra- and inter-batch precision below 10%.
- ☑ Complete methodological validation reports are available for free.
- ☑ Self-produced raw materials, high production yield, and short delivery time.

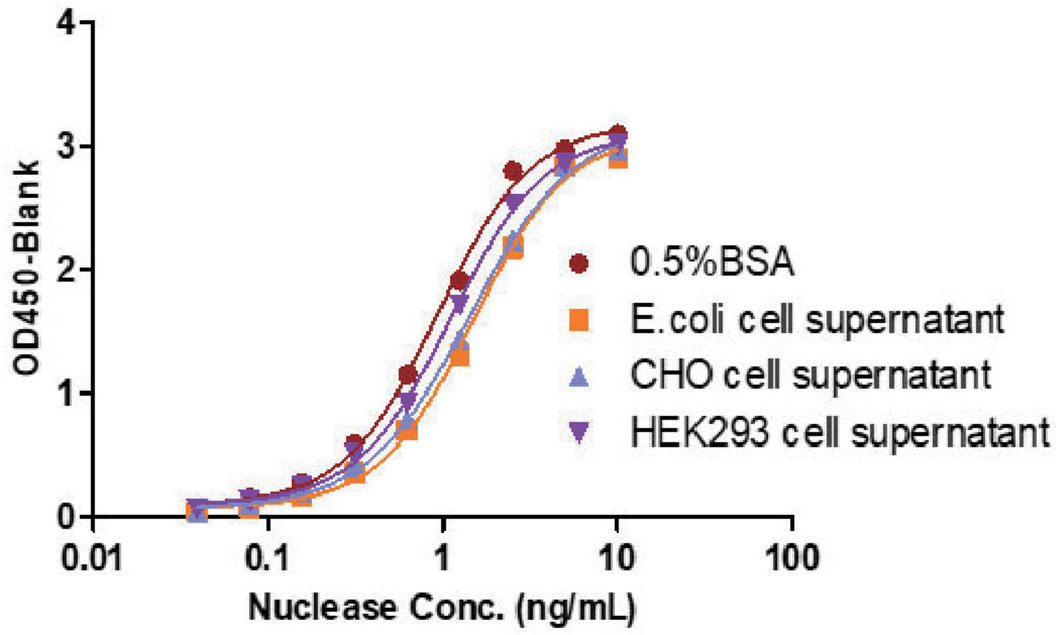
Data



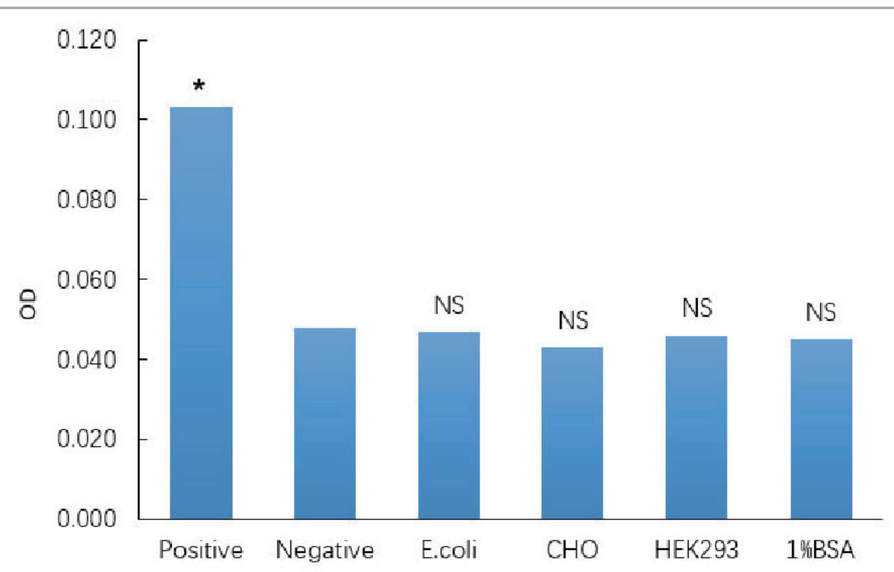
For each experiment, a standard curve needs to be set for each micro-plate, and the specific OD value may vary depending on different laboratories, testers, or equipments. The following example data is for reference only.



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



GENIUS™ Nuclease ELISA Kit (Residue Testing) (Cat. No. CRS-A016) can detect the nuclease in different culture supernatant with similar curve and sensitivity.



GENIUS™ Nuclease ELISA Kit (Residue Testing) (Cat. No. CRS-A016) can detect the nuclease from different culture supernatant and was free from the matrix effects. *means a significant difference compared with the negative, NS means no significant difference with the negative.

04

Other Residue Detection

DNase Activity Assay Kit (Fluorescence)

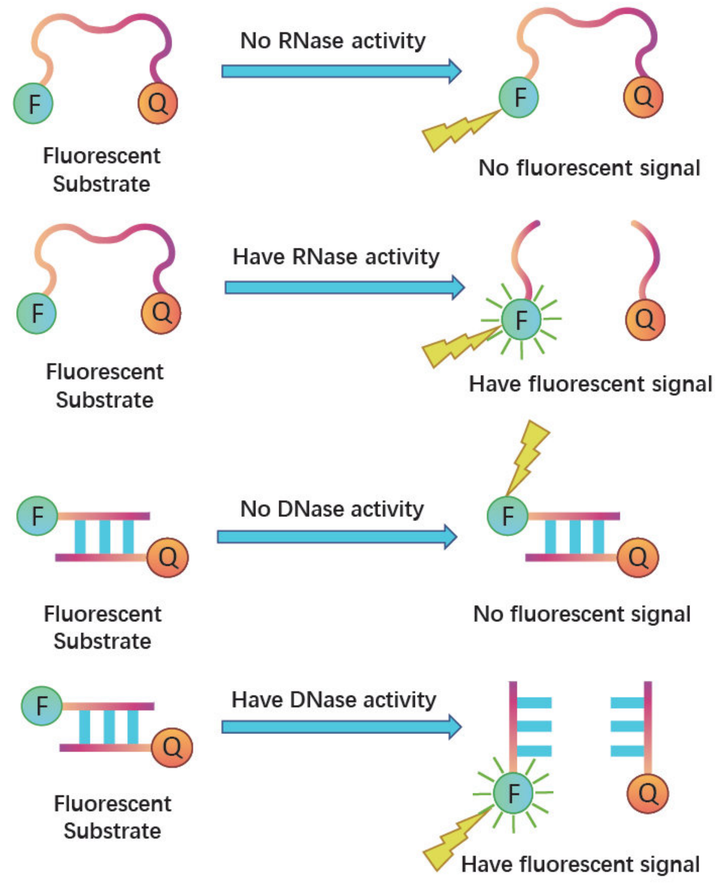
RNase Activity Assay Kit (Fluorescence)

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.



■ Features

- ☑ 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*10-5U (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

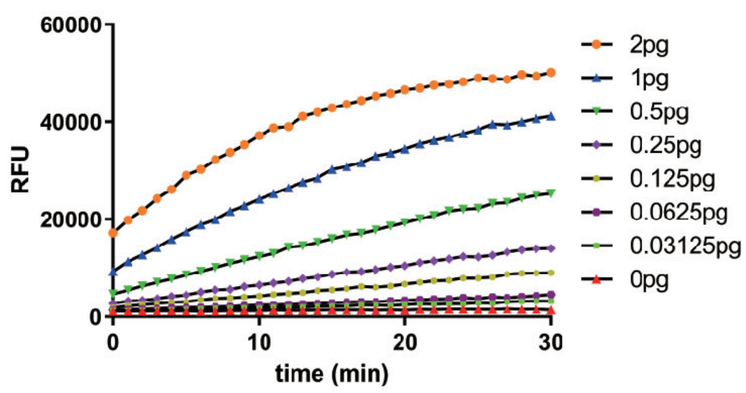
Cat. No.	Product Description
ASE-A001	RNase Activity Assay Kit (Fluorescence)
ASE-A002	DNase Activity Assay Kit (Fluorescence)

■ Product 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 10 μL 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 (96)	3.7	3.4	3.0	3.2	0.6	1.9	0.7

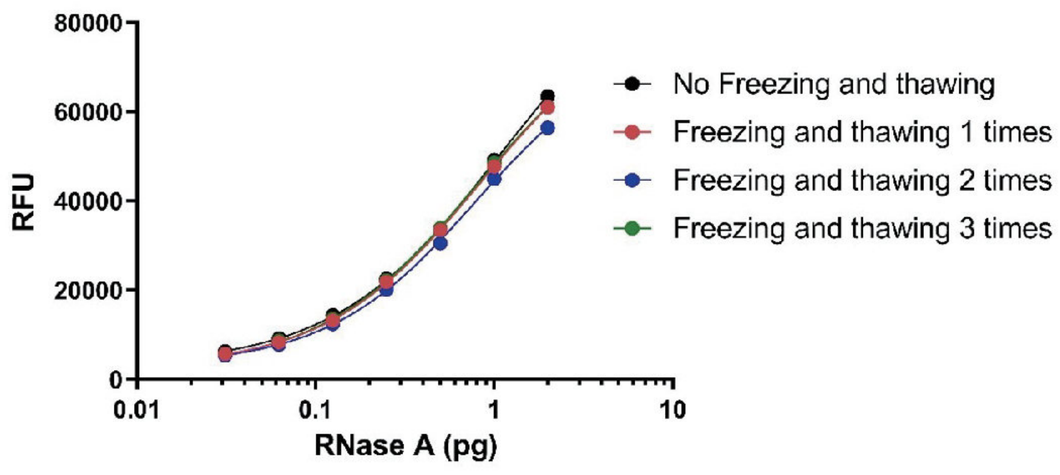
Inter-Assay Statistics

Sample	1	2	3	4	5	6	7
Number of Replicate	8	8	8	8	8	8	8
Mean RFU	3858	6132	10503	17609	28071	41161	53533
Standard Deviation	579	769	1495	2307	3341	4203	4249
Coefficient of Variation (96)	15	12.5	14.2	13.1	11.9	10.2	7.9

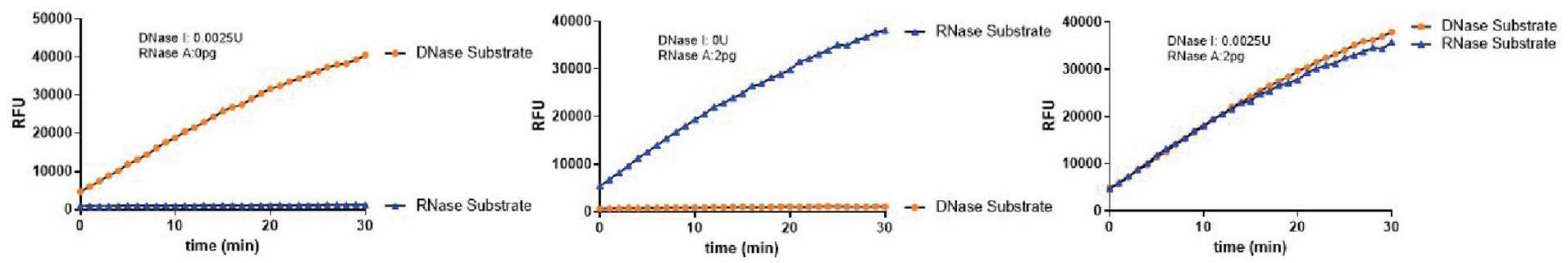
★ Verified, the recovery rate of RNase Activity Assay Kit (Fluorescence) (Cat. No. ASE-A001) is within the range of 80% to 120%.

	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%.



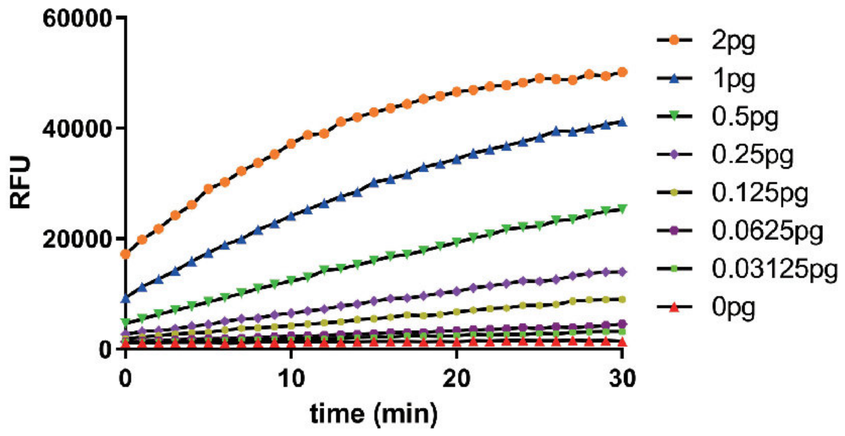
★ No cross-interference: Verified using DNase Activity Assay Kit (Fluorescence) (Cat. No. ASE-A002) and RNase Activity Assay Kit (Fluorescence) (Cat. No. ASE-A001) to detect the residual nucleases in the same sample, and no cross-interference was observed.



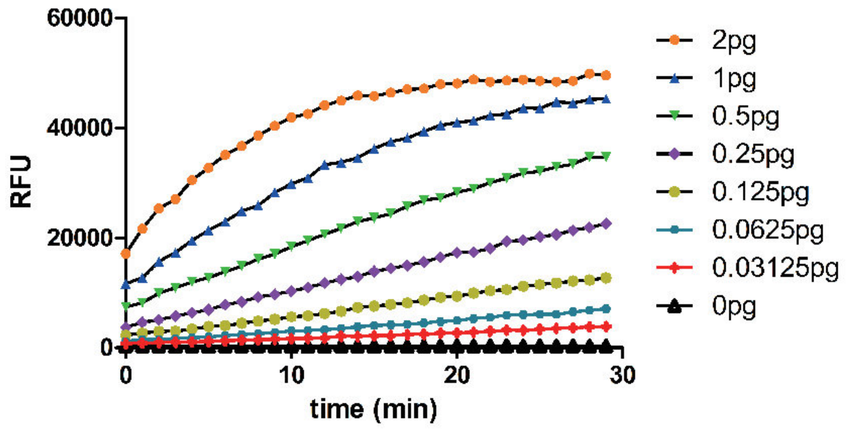
▶ Competitor Evaluation Data

★ 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.

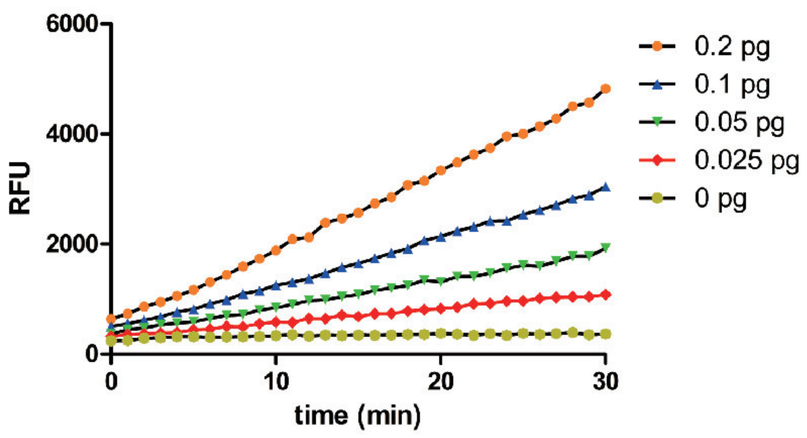
ACRO



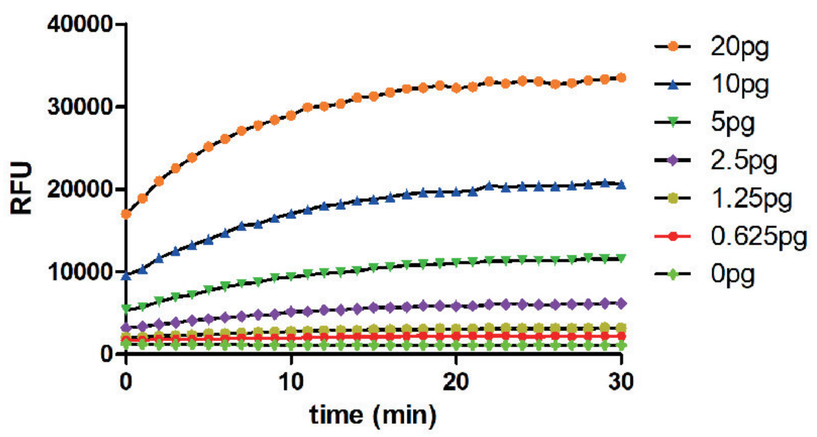
Competitor T



Competitor H



Competitor B



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