



Quality Control And Detection Solution For Cell Therapy

Cell therapy innovation inspired.

BlueKit[®]

Powered by  Hillgene

01 Detection Kits for Plasmid 5

HG-HCP002	<i>E.coli</i> HCP ELISA Detection Kit
HG-ED001	<i>E.coli</i> Residual DNA Detection Kit (qPCR)
HG-ER001	<i>E.coli</i> Residual Total RNA Detection Kit (RT-PCR)
HG-KA001	Kanamycin ELISA Detection Kit

02 Detection Kits for Lentivirus 10

HG-CL100	Host Cell Residual DNA Sample Preprocessing Kit(Magnetic Bead Method)
HG-P001L	Lentivirus Titer p24 ELISA Detection Kit
HG-HCP001	293T HCP ELISA Detection Kit
HG-HD001	Human Residual DNA Detection Kit (qPCR)
HG-HR001	Human Residual RNA Detection Kit (RT-PCR)
HG-HF001	Human Residual DNA Fragment Analysis Detection Kit (qPCR)
HG-EA001	E1A&SV40LTA Residual DNA Detection Kit (Multiplex qPCR)
HG-BE001	Benzonase Nuclease ELISA Detection Kit
HG-ZL001	Plasmid Residual DNA Detection Kit (qPCR)
HG-BS001	BSA ELISA Detection Kit
HG-TR001	Trypsin ELISA Detection Kit
HG-BC001	BCA Rapid Protein Quantitative Detection Kit

03 Detection Kits for Cell 24

HG-NA100	Blood/Tissue/Cell Genomic DNA Extraction Kit
HG-CA001	CAR/TCR Gene Copy Number Detection Kit (Multiplex qPCR)
HG-BA001	BaEV Gene Copy Number Detection Kit (qPCR)
HG-RC001	RCL(VSVG) Gene Copy Number Detection Kit (qPCR)
HG-ZY001	Mycoplasma DNA Detection Kit (qPCR)-ZY001
HG-CL200	Mycoplasma DNA Sample Preprocessing Kit (Magnetic Bead Method)
HG-ZY002	Mycoplasma DNA Detection Kit (qPCR)-ZY002
HG-HC001	CRS Cytokine Multiplex ELISA Detection Kit
HG-P001	HIV-1 p24 ELISA Detection Kit
HG-IL002	Cell Residual Human IL-2 ELISA Detection Kit
HG-IL007	Cell Residual Human IL-7 ELISA Detection Kit
HG-IL015	Cell Residual Human IL-15 ELISA Detection Kit
HG-IL021	Cell Residual Human IL-21 ELISA Detection Kit
HG-IF001	Human IFN- γ ELISA Detection Kit

04 Detection Kits for mRNA 41

HG-DI001	DNase I ELISA Detection Kit
HG-RI001	RNase Inhibitor ELISA Detection Kit
HG-TP001	T7 RNA Polymerase ELISA Detection Kit
HG-DS001	dsRNA ELISA Detection Kit

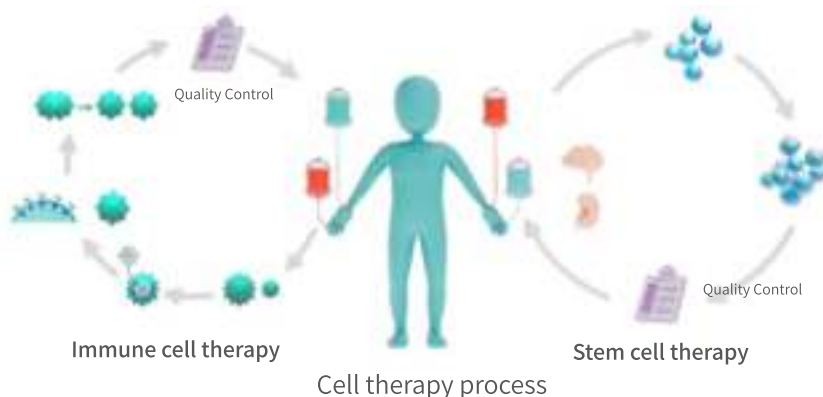
05 Detection Kits for Antibodies/vaccines 46

HG-CH001	CHO Residual DNA Detection Kit (qPCR)
HG-VE001	Vero Residual DNA Detection Kit (qPCR)

Quality Control And Detection Solution For Cell Therapy

Cell Therapy

The production process of cellular drugs represented by CAR-T involves three different objects: plasmid, virus and cell. Their culture, purification, detection and other processes are different, which has high requirements for the quality control of cellular drugs. In the process of cell drug production, it is necessary to detect impurities, safety, content/potency, identification/physical chemistry and other indicators. In response to the requirements of cell drug production and quality release, Hillgene has developed a kit to detect biological residues and biological functions in the production process of cell drugs, helping to control the quality of cell drug production.



CAR-T Quality Control Detection Kit

Plasmid

- E. coli* HCP ELISA Detection Kit
- E. coli* Residual DNA Detection Kit (qPCR)
- E. coli* Residual Total RNA Detection Kit (RT-PCR)
- Kanamycin ELISA Detection Kit

Lentivirus

- Host Cell Residual DNA Sample Preprocessing Kit
- Lentivirus Titer p24 ELISA Detection Kit
- 293T HCP ELISA Detection Kit
- Human Residual DNA Detection Kit (qPCR)
- Human Residual RNA Detection Kit (RT-PCR)
- Human Residual DNA Fragment Analysis Detection Kit (qPCR)
- E1A&SV40LTA Residual DNA Detection Kit (Multiplex qPCR)
- Benzonase Nuclease ELISA Detection Kit
- Plasmid Residual DNA Detection Kit (qPCR)
- BSA ELISA Detection Kit
- Trypsin ELISA Detection Kit
- BCA Rapid Protein Quantitative Detection Kit

Cell

- Blood/Tissue/Cell Genomic DNA Extraction Kit
- CAR/TCR Gene Copy Number Detection Kit (Multiplex qPCR)
- BaEV Gene Copy Number Detection Kit (qPCR)
- RCL(VSVG) Gene Copy Number Detection Kit (qPCR)
- Mycoplasma DNA Detection Kit (qPCR)-ZY001
- Mycoplasma DNA Sample Preprocessing Kit
- Mycoplasma DNA Detection Kit (qPCR)-ZY002
- CRS Cytokine Multiplex ELISA Detection Kit
- HIV-1 p24 ELISA Detection Kit
- Cell Residual Human IL-2 ELISA Detection Kit
- Cell Residual Human IL-7 ELISA Detection Kit
- Cell Residual Human IL-15 ELISA Detection Kit
- Cell Residual Human IL-21 ELISA Detection Kit
- Human IFN- γ ELISA Detection Kit

CAR-NK Quality Control Detection Kit

Plasmid

E.coli HCP ELISA Detection Kit
E.coli Residual DNA Detection Kit (qPCR)
E.coli Residual Total RNA Detection Kit (RT-PCR)
 Kanamycin ELISA Detection Kit

Lentivirus

Host Cell Residual DNA Sample Preprocessing Kit
 Lentivirus Titer p24 ELISA Detection Kit
 293T HCP ELISA Detection Kit
 Human Residual DNA Detection Kit (qPCR)
 Human Residual RNA Detection Kit (RT-PCR)
 Human Residual DNA Fragment Analysis Detection Kit (qPCR)
 E1A&SV40LTA Residual DNA Detection Kit (Multiplex qPCR)
 Benzonase Nuclease ELISA Detection Kit
 Plasmid Residual DNA Detection Kit (qPCR)
 BSA ELISA Detection Kit
 Trypsin ELISA Detection Kit
 BCA Rapid Protein Quantitative Detection Kit

Cell

Blood/Tissue/Cell Genomic DNA Extraction Kit
 CAR/TCR Gene Copy Number Detection Kit (Multiplex qPCR)
 Mycoplasma DNA Detection Kit (qPCR)-ZY001
 Mycoplasma DNA Sample Preprocessing Kit
 Mycoplasma DNA Detection Kit (qPCR)-ZY002
 CRS Cytokine Multiplex ELISA Detection Kit
 HIV-1 p24 ELISA Detection Kit
 Cell Residual Human IL-2 ELISA Detection Kit
 Cell Residual Human IL-7 ELISA Detection Kit
 Cell Residual Human IL-15 ELISA Detection Kit
 Cell Residual Human IL-21 ELISA Detection Kit
 Human IFN- γ ELISA Detection Kit



TCR-T Quality Control Detection Kit

Plasmid

E.coli HCP ELISA Detection Kit
E.coli Residual DNA Detection Kit (qPCR)
E.coli Residual Total RNA Detection Kit (RT-PCR)
 Kanamycin ELISA Detection Kit

Lentivirus

Host Cell Residual DNA Sample Preprocessing Kit
 Lentivirus Titer p24 ELISA Detection Kit
 293T HCP ELISA Detection Kit
 Human Residual DNA Detection Kit (qPCR)
 Human Residual RNA Detection Kit (RT-PCR)
 Human Residual DNA Fragment Analysis Detection Kit
 E1A&SV40LTA Residual DNA Detection Kit
 Benzonase Nuclease ELISA Detection Kit
 Plasmid Residual DNA Detection Kit (qPCR)
 BSA ELISA Detection Kit
 Trypsin ELISA Detection Kit
 BCA Rapid Protein Quantitative Detection Kit

Cell

Blood/Tissue/Cell Genomic DNA Extraction Kit
 CAR/TCR Gene Copy Number Detection Kit (Multiplex qPCR)
 BaEV Gene Copy Number Detection Kit (qPCR)
 RCL(VSVG) Gene Copy Number Detection Kit (qPCR)
 Mycoplasma DNA Detection Kit (qPCR)-ZY001
 Mycoplasma DNA Sample Preprocessing Kit
 Mycoplasma DNA Detection Kit (qPCR)-ZY002
 CRS Cytokine Multiplex ELISA Detection Kit
 HIV-1 p24 ELISA Detection Kit
 Cell Residual Human IL-2 ELISA Detection Kit
 Cell Residual Human IL-7 ELISA Detection Kit
 Cell Residual Human IL-15 ELISA Detection Kit
 Cell Residual Human IL-21 ELISA Detection Kit
 Human IFN- γ ELISA Detection Kit



01 Detection Kits for Plasmid

E.coli HCP ELISA Detection Kit

E.coli Residual DNA Detection Kit (qPCR)

E.coli Residual Total RNA Detection Kit (RT-PCR)

Kanamycin ELISA Detection Kit

E.coli HCP ELISA Detection Kit

Overview

Cat.No. HG-HCP002

This kit is designed for the quantitative detection of HCP (host cell protein) content in biopharmaceuticals expressed on *E.coli* by using a double-antibody sandwich method.

This kit can be used to detect all components of HCP (host cell protein) in *E.coli*.

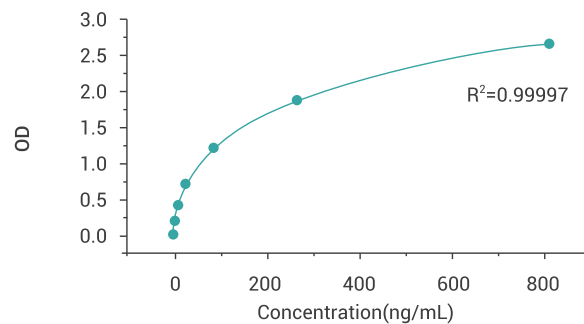
Specification

Assay range: 3.3-810ng/mL

Limit of quantitation: 3.3ng/mL

Precision: CV% ≤ 10%, RE% ≤ ±15%

Standard curve



Datasheet

Concentration of standard (ng/mL)	OD value1	OD value2	Mean value
810	2.659	2.658	2.659
270	1.902	1.908	1.905
90	1.213	1.194	1.204
30	0.720	0.723	0.722
10	0.408	0.41	0.409
3.3	0.228	0.231	0.230
0	0.047	0.050	0.049

E.coli Residual DNA Detection Kit (qPCR)

Overview

Cat.No. HG-ED001

This kit is designed for the quantitative detection of E.coli host cell DNA in intermediates, semi-finished products and finished products of various biological products.

This kit adopts the principle of Taqman probe to quantitatively detect E.coli residual DNA in samples. The kit is a rapid, specific and reliable device, with the minimum detection limit reaching fg level.

Specification

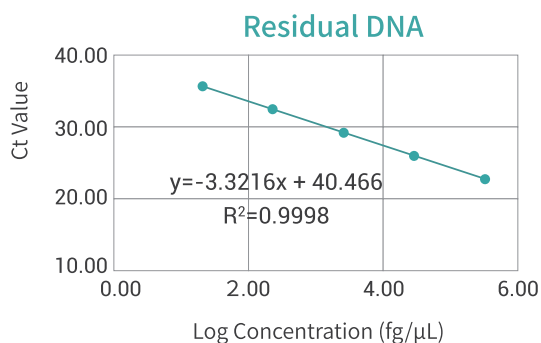
Assay range: $3.00 \times 10^1 \sim 3.00 \times 10^5$ fg/ μ L

Limit of quantitation: 3.00×10^1 fg/ μ L

Limit of detection: 3.00 fg/ μ L

Precision: CV% \leq 15%

Standard curve



Datasheet

Concentration (fg/ μ L)	Log Concentration	Ct Value(1)	Ct Value(2)	Ct Value(3)	Ct Mean Value	Recovery rate
3.00E+05	5.48	22.30	22.33	22.32	22.32	97%
3.00E+04	4.48	25.51	25.43	25.49	25.48	108%
3.00E+03	3.48	29.09	28.89	28.90	28.96	97%
3.00E+02	2.48	32.38	32.30	32.72	32.32	95%
3.00E+01	1.48	35.52	35.28	35.72	35.51	104%
Amplification efficiency						100.01%

E.coli Residual Total RNA Detection Kit (RT-PCR)

Overview

Cat.No. HG-ER001

This kit is designed for the quantitative detection of residual E.coli total RNA in various biological products to improve control quality of nucleic acid.

This kit adopts the principle of the RT-PCR fluorescent probe, combining reverse transcription PCR technology and fluorescent probe method, to realize one-step quantitative detection.

Specification

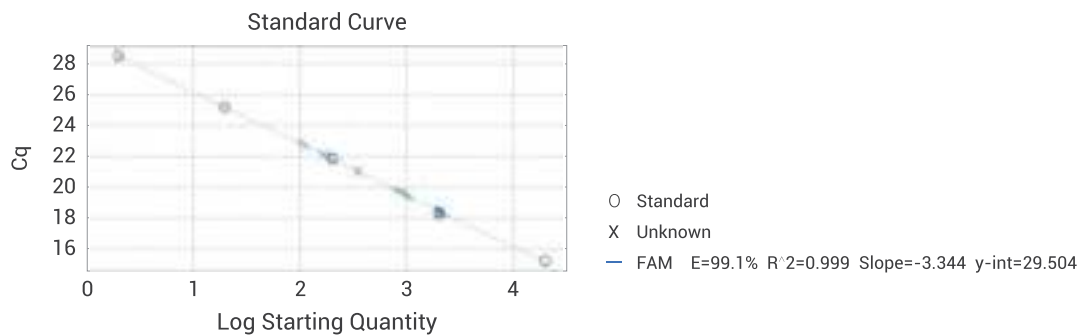
Assay range: 2.00~2.00 × 10⁴ fg/μL

Limit of quantitation: 2.00 fg/μL

Limit of detection: 0.50 fg/μL

Precision: CV% ≤ 15%

Standard curve



Datasheet

Concentration (fg/μL)	Log ₁₀ Concentration	Ct Value(1)	Ct Value(2)	Ct Value(3)	Ct Mean Value	Recovery rate
2.00E+04	4.30	15.30	15.23	15.21	15.24	0.30%
2.00E+03	3.30	18.39	18.28	18.18	18.28	0.56%
2.00E+02	2.30	21.86	21.82	21.78	21.82	0.18%
2.00E+01	1.30	25.22	25.22	25.09	25.18	0.31%
2.00E+00	0.30	28.55	28.58	28.43	28.52	0.29%
Amplification efficiency						99.1%

Kanamycin ELISA Detection Kit

Overview

Cat.No. HG-KA001

BlueKit® series Kanamycin ELISA Detection Kit is a specialized kit for quantitative detection of residual kanamycin content in drug substance, intermediates, and drug products of cell and gene therapy drugs.

Specification

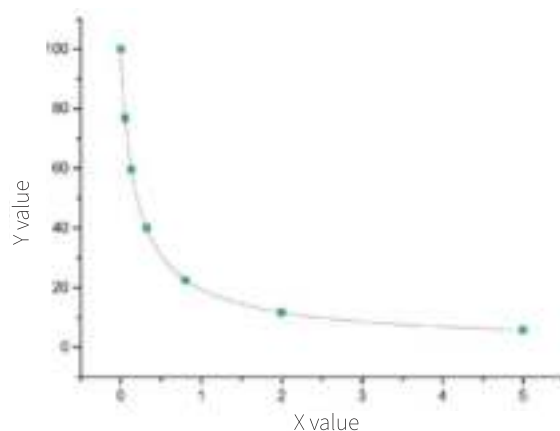
Assay range: 0.05~5.00 ng/mL

Limit of quantitation: 0.05 ng/mL

Limit of detection: 0.05 ng/mL

Precision: CV% ≤ 10%, RE% ≤ ±15%

Standard curve



Datasheet

Standard Curve (ng/mL)	Percent Absorbance (%)
5	5.9
2	11.66
0.8	22.42
0.32	40.05
0.128	59.63
0.0512	76.89
0	100.00

02 Detection Kits for Lentivirus

Host Cell Residual DNA Sample Preprocessing Kit

Lentivirus Titer p24 ELISA Detection Kit

293T HCP ELISA Detection Kit

Human Residual DNA Detection Kit (qPCR)

Human Residual RNA Detection Kit (RT-PCR)

Human Residual DNA Fragment Analysis Detection Kit (qPCR)

E1A&SV40LTA Residual DNA Detection Kit (Multiplex qPCR)

Benzonase Nuclease ELISA Detection Kit

Plasmid Residual DNA Detection Kit (qPCR)

BSA ELISA Detection Kit

Trypsin ELISA Detection Kit

BCA Rapid Protein Quantitative Detection Kit

Host Cell Residual DNA Sample Preprocessing Kit (Magnetic Bead Method)

Overview

Cat.No. HG-CL100

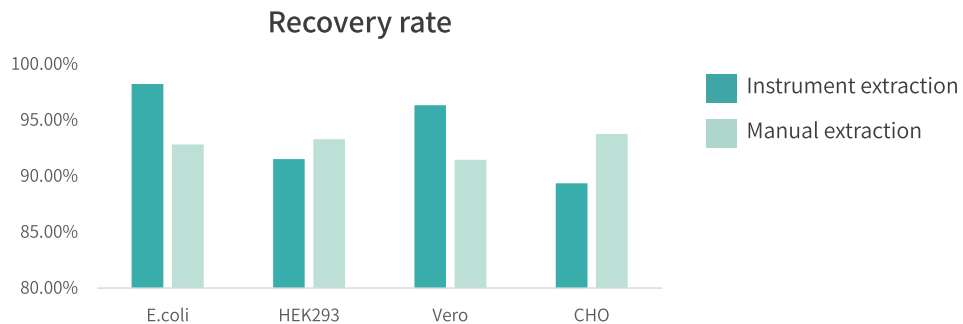
The residual DNA of host cells in biological products has many risks such as tumorigenicity and infectivity, so the accurate quantitative detection of trace amounts of residual DNA is particularly important. Pretreatment is the process of extracting and purifying trace amounts of DNA in biological products from complex sample matrices. An effective and stable pretreatment method is the basis for ensuring accurate detection of residual DNA detection and other rapid nucleic acid detection methods. BlueKit® Host Cell Residual DNA Sample Preprocessing Kit can meet both manual extraction and machine extraction methods. Manual extraction is accurate and sensitive, and it is efficient and convenient to use with a fully automatic nucleic acid extractor.

Specification

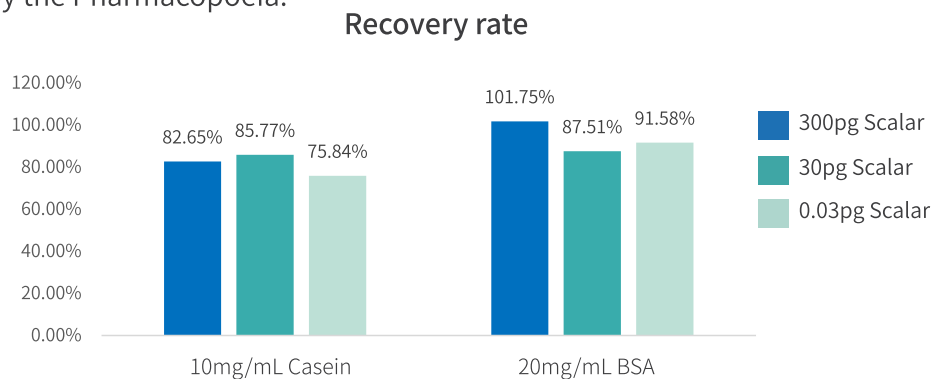
Detection sensitivity: 0.03pg/μL

Recovery rate: 70%~130%

Data



Manual extraction and instrument extraction were performed on DNA samples of different host types, and the final sample recovery rates were 70% to 130%, which were better than the 50% to 150% required by the Pharmacopoeia.



The two sample matrices (PBS+10mg/mL BSA and PBS+10mg/mL casein) were added with a total of 0.03pg, 3pg, and 300pg of CHO gDNA reference substance for pretreatment, and the final recovery of the standard addition was 70 %~130%.

Lentivirus Titer p24 ELISA Detection Kit

Overview

Cat.No. HG-P001L

This product uses a double antibody sandwich method to detect HIV 1 p24 protein in samples. A monoclonal antibody specific to HIV 1 p24 antigen is coated on a microplate, and the standard or test sample is added into the reaction well. At the same time, the anti HIV 1 p24 secondary antibody is added and incubated at room temperature to form the antibody antigen secondary antibody complex. The unconjugated compounds are removed by washing and protein content in the sample is indicated by the intensity of TMB color development.

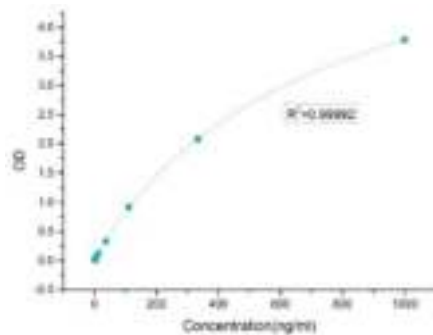
Specification

Assay range: 1.37-1000 ng/mL

Detection sensitivity: 0.35 ng/mL

Precision: CV% \leq 10%, RE% \leq \pm 15%

Standard curve



Datasheet

Concentration of standard (ng/mL)	OD value1	OD value2	Mean value
1000.00	3.8020	3.7780	3.790
333.33	2.1020	2.0660	2.084
111.11	0.9526	0.9072	0.930
37.04	0.3212	0.3512	0.336
12.35	0.1222	0.1243	0.123
4.12	0.0403	0.0459	0.043
1.37	0.0174	0.0177	0.018
0.00	0.0059	0.0058	0.006

293T HCP ELISA Detection Kit

Overview

Cat.No. HG-HCP001

This kit is designed for the quantitative detection of HCP (host cell protein) content in biopharmaceuticals expressed on 293T cells by using a double-antibody sandwich method.

This kit can be used to detect all components of HCP (host cell protein) in 293T cell.

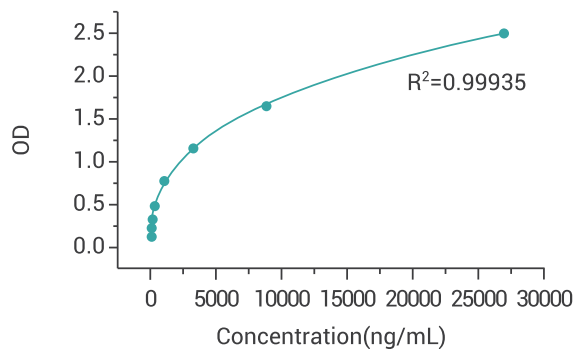
Specification

Assay range: 37-27000 ng/mL

Limit of quantitation: 37ng/mL

Precision: CV% \leq 10%, RE% \leq \pm 15%

Standard curve



Datasheet

Concentration of standard (ng/mL)	OD value1	OD value2	Mean value
27000	2.507	2.494	2.5005
9000	1.618	1.625	1.6215
3000	1.176	1.181	1.1785
1000	0.773	0.77	0.7715
333	0.496	0.475	0.4855
111	0.289	0.285	0.287
37	0.205	0.195	0.2
0	0.14	0.137	0.1385

Human Residual DNA Detection Kit (qPCR)

Overview

Cat.No. HG-HD001

This kit is designed for the quantitative detection of the Human host cell DNA in intermediate, semi-finished and finished products of various biological products.

This kit adopts the principle of the Taqman probe to quantitatively detect Human residual DNA in samples. The kit is a rapid, specific and reliable device, with the minimum detection limit reaching fg level.

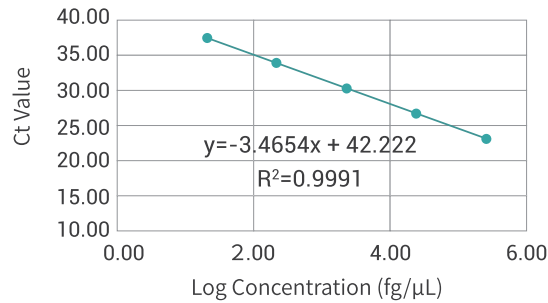
Specification

Assay range: $3.00 \times 10^1 \sim 3.00 \times 10^5 \text{ fg}/\mu\text{L}$

Limit of quantitation: $3.00 \times 10^1 \text{ fg}/\mu\text{L}$

Precision: $\text{CV}\% \leq 15\%$

Standard curve



Datasheet

Concentration (fg/μL)	Log Concentration	Ct Value(1)	Ct Value(2)	Ct Value(3)	Ct Mean Value	Recovery rate
3.00E+05	5.48	23.52	23.37	23.39	23.43	88%
3.00E+04	4.48	26.64	26.55	26.45	26.54	111%
3.00E+03	3.48	30.16	30.07	30.06	30.09	105%
3.00E+02	2.48	33.75	33.33	33.52	33.53	107%
3.00E+01	1.48	38.3	36.49	36.90	37.26	90%
Amplification efficiency						94.34%

Human Residual RNA Detection Kit (RT-PCR)

Overview

Cat.No. HG-HR001

This kit is designed for the quantitative detection of residual Human total RNA in various biological products to improve control quality of nucleic acid.

This kit adopts the principle of the RT-PCR fluorescent probe, combining reverse transcription PCR technology and fluorescent probe method, to realize one-step quantitative detection.

Specification

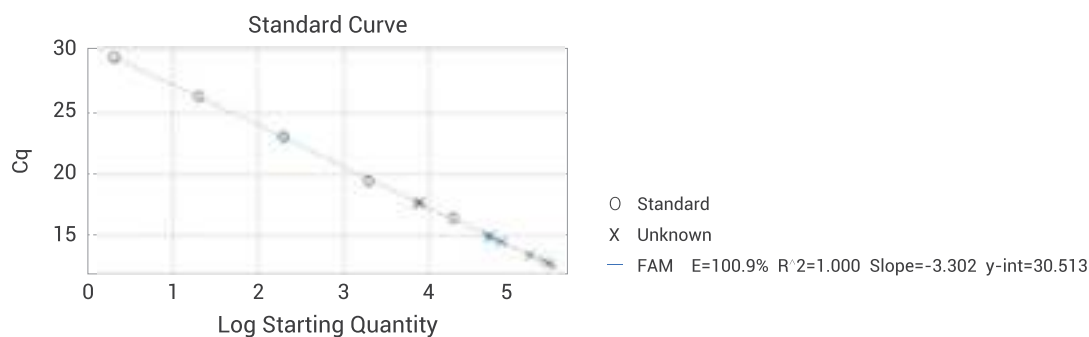
Assay range: 2.00~2.00×10⁴ fg/μL

Limit of quantitation: 2.00 fg/μL

Limit of detection: 0.50 fg/μL

Precision: CV% ≤ 15%

Standard curve



Datasheet

Concentration (fg/μL)	Log Concentration	Ct Value(1)	Ct Value(2)	Ct Value(3)	Ct Mean Value	Recovery rate
2.00E+04	4.30	16.45	16.37	16.36	16.39	0.30%
2.00E+03	3.30	19.41	19.51	19.44	19.46	0.26%
2.00E+02	2.30	23.03	22.83	22.98	22.95	0.45%
2.00E+01	1.30	26.31	26.33	26.26	26.30	0.12%
2.00E+00	0.30	29.53	29.48	29.42	29.48	0.19%
Amplification efficiency						100.9%

Human Residual DNA Fragment Analysis Detection Kit (qPCR)

Overview

Cat.No. HG-HF001

This kit is designed for the quantitative detection of the size distribution of Human residual host cell DNA fragments in intermediates, semi-finished and finished products of various biological products.

This kit adopts the principle of PCR fluorescent probe method to quantitatively detect the size distribution of human residual host cell DNA fragments in the sample. The kit features three different amplified fragments (99 bp, 200 bp and 307 bp), and the Human DNA quantification reference is used to make standard curves for different amplified fragments respectively, and the fragment distribution of Human residual DNA in the sample is analyzed through the ratio of different sizes of fragments.

This kit is a rapid, specific and reliable device, with the minimum detection limit reaching fg level.

Specification

Assay range: $3.00 \times 10^1 \sim 3.00 \times 10^5$ fg/ μ L

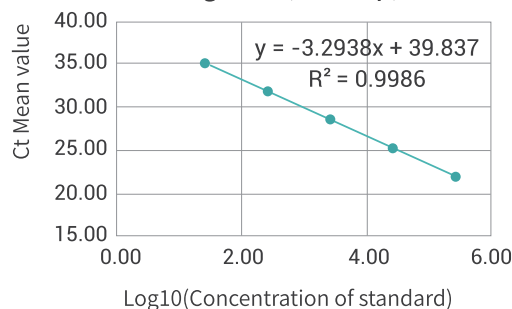
Limit of quantitation: 3.00×10^1 fg/ μ L

Precision: CV% \leq 15%

Residual DNA fragment (\geq 99bp) Detection

Standard		Ct Value		Ct-IPC value	
Concentration (fg/ μ L)	Log10 (Concentration)	Ct Value	Mean value	Ct-IPC value	Mean value
3.00E+05	5.48	21.66	21.66	22.96	22.80
3.00E+04	4.48	25.06	25.06	22.67	
3.00E+03	3.48	28.61	28.61	22.81	
3.00E+02	2.48	31.85	31.85	22.70	
3.00E+01	1.48	34.74	34.74	22.86	
			Amplification efficiency	101.19%	

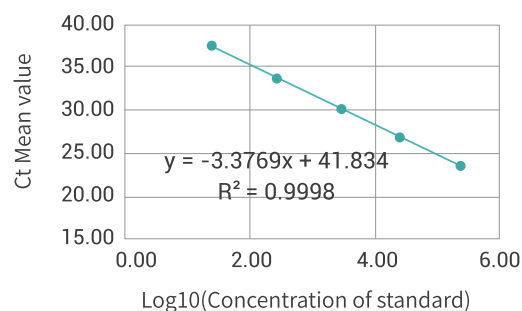
Residual DNA fragment (\geq 99bp) Standard curve



Residual DNA fragment (≥ 200bp) Detection

Standard		Ct Value		Ct-IPC value	
Concentration (fg/μL)	Log10 (Concentration)	Ct Value	Mean value	Ct-IPC value	Mean value
3.00E+05	5.48	23.23	23.23	23.09	23.06
3.00E+04	4.48	26.80	26.80	23.08	
3.00E+03	3.48	30.16	30.16	22.99	
3.00E+02	2.48	33.49	33.49	23.13	
3.00E+01	1.48	36.77	36.77	23.00	
			Amplification efficiency	97.76%	

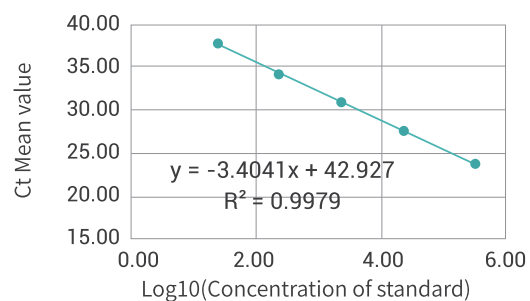
Residual DNA fragment (≥ 200bp) Standard curve



Residual DNA fragment (≥ 307bp) Detection

Standard		Ct Value		Ct-IPC value	
Concentration (fg/μL)	Log10 (Concentration)	Ct Value	Mean value	Ct-IPC value	Mean value
3.00E+05	5.48	23.98	23.98	23.00	22.99
3.00E+04	4.48	27.98	27.98	22.99	
3.00E+03	3.48	31.31	31.31	23.04	
3.00E+02	2.48	34.40	34.40	22.88	
3.00E+01	1.48	37.79	37.79	23.02	
			Amplification efficiency	96.68%	

Residual DNA fragment (≥ 307bp) Standard curve



E1A&SV40LTA Residual DNA Detection Kit (Multiplex qPCR)

Overview

Cat.No. HG-EA001

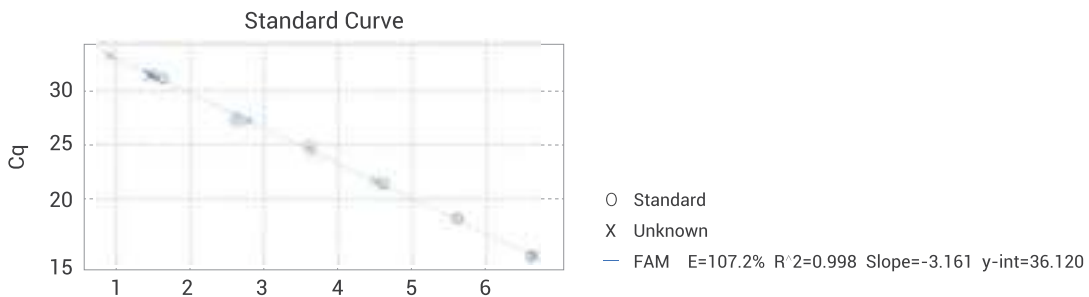
This kit is designed for the rapid and specific detection of residual E1A&SV40LTA DNA derived from host cell (e.g., HEK293T cell) in biological products.

This kit adopts the fluorescent probe method and multiplex PCR method. The kit is a rapid, specific and reliable device, with the minimum detection limit reaching 40copies/μL.

Specification

- Assay range:** $4 \times 10^1 \sim 4 \times 10^6$ copies/μL
- Limit of quantitation:** 4×10^1 copies/μL
- Precision:** CV% $\leq 15\%$

Standard curve



Datasheet

Concentration (copies/μL)	Log10 Concentration	Ct Value(1)	Ct Value(2)	Ct Value(3)	Ct Mean Value	CV
4.00E+06	6.60	15.15	15.14	15.04	15.11	0.40%
4.00E+05	5.60	18.51	18.63	18.40	18.51	0.63%
4.00E+04	4.60	21.66	21.70	21.71	21.69	0.12%
4.00E+03	3.60	25.04	24.51	25.11	24.89	1.32%
4.00E+02	2.60	27.48	27.75	27.25	27.49	0.91%
4.00E+01	1.60	31.30	31.18	31.17	31.22	0.24%
Amplification efficiency						107.2%

Benzonase Nuclease ELISA Detection Kit

Overview

Cat.No. HG-BE001

This kit is designed for the quantitative detection of residual nuclease content in intermediates, semi-finished products and finished products of various biological products by using a double-antibody sandwich method.

Specification

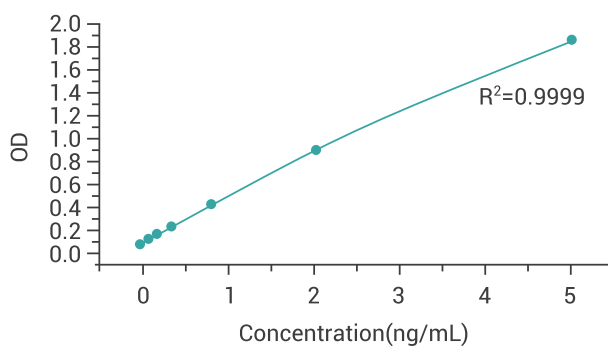
Assay range: 0.05-5ng/mL

Limit of quantitation: 0.05ng/mL

Limit of detection: 0.05ng/mL

Precision: CV% \leq 10%, RE% \leq \pm 15%

Standard curve



Datasheet

Concentration of standard (ng/mL)	OD value1	OD value2	Mean value
5	1.925	1.774	1.849
2	0.917	0.865	0.891
0.8	0.447	0.441	0.444
0.32	0.228	0.209	0.218
0.128	0.146	0.137	0.141
0.0512	0.114	0.107	0.110
0	0.090	0.091	0.091

Plasmid Residual DNA Detection Kit (qPCR)

Overview

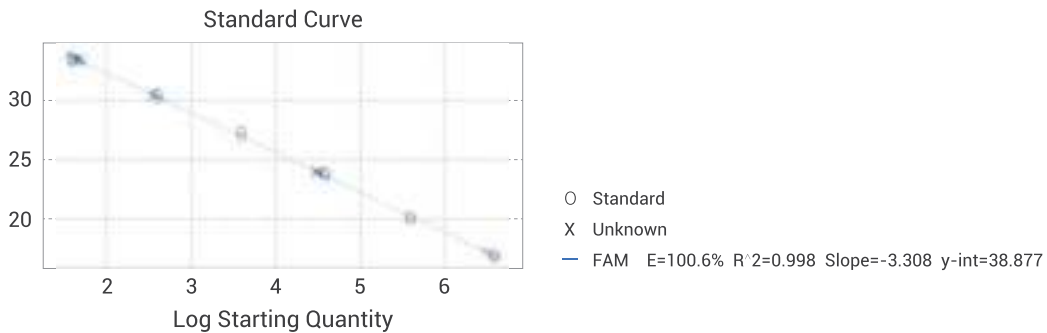
Cat.No. HG-ZL001

This kit is designed for the quantitative detection of residual plasmid DNA in intermediates, semi-finished products and finished products of various biological products. Plasmid DNA content in samples (e.g., lentivirus, adenovirus) is detected by analyzing the consensus sequence. This kit uses TaqMan fluorescence probe principle, with strong specificity, high sensitivity and reliable performance.

Specification

- Assay range:** $4 \times 10^1 \sim 4 \times 10^6$ copies/ μ L
- Limit of quantitation:** 4×10^1 copies/ μ L
- Precision:** CV% \leq 15%

Standard curve



Datasheet

Concentration (copies/ μ L)	Log10 Concentration	Ct Value(1)	Ct Value(2)	Ct Value(3)	Ct Mean Value	CV
4.00E+06	6.60	16.76	17.14	17.07	16.99	1.18%
4.00E+05	5.60	19.93	20.32	20.20	20.15	1.01%
4.00E+04	4.60	23.59	23.99	23.85	23.81	0.85%
4.00E+03	3.60	26.90	27.34	27.37	27.20	0.97%
4.00E+02	2.60	30.09	30.54	30.41	30.35	0.76%
4.00E+01	1.60	33.27	33.20	33.57	33.35	0.60%
Amplification efficiency						100.6%

BSA ELISA Detection Kit

Overview

Cat.No. HG-BS001

This kit is designed for the quantitative detection of residual BSA content in intermediates, semi-finished products and finished products of various biological products by using a double-antibody sandwich method.

Specification

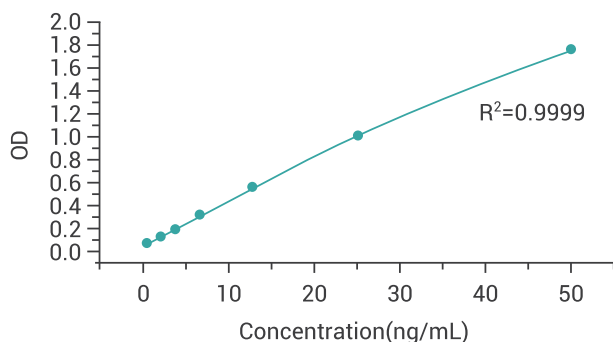
Assay range: 1.56-50 ng/mL

Limit of quantitation: 1.56 ng/mL

Limit of detection: 0.5ng/mL

Precision: CV% \leq 10%, RE% \leq \pm 15%

Standard curve



Datasheet

Concentration of standard (ng/mL)	OD value1	OD value2	Mean value
50	1.775	1.803	1.789
25	1.091	0.995	1.043
12.5	0.571	0.591	0.581
6.25	0.324	0.308	0.316
3.125	0.193	0.179	0.186
1.56	0.132	0.127	0.130
0	0.072	0.088	0.080

Trypsin ELISA Detection Kit

Overview

Cat.No. HG-TR001

This kit is designed for the quantitative detection of residual Trypsin content in intermediates, semi-finished products and finished products of various biological products by using a double-antibody sandwich method.

Specification

Assay range: 0.039~2.5 ng/mL

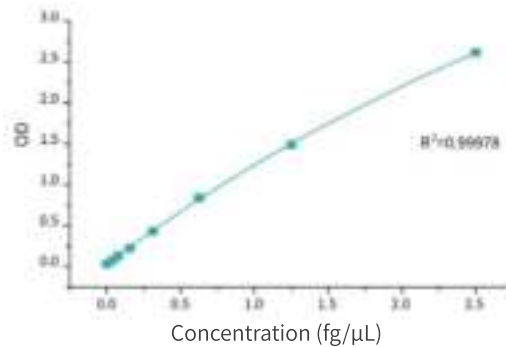
Limit of detection: 0.003ng/mL

Limit of quantitation: 0.039ng/mL

Precision: CV% ≤ 10%

Recovery rate: 80%~120%

Standard curve



Datasheet

Concentration of standard (ng/mL)	OD value1	OD value2	Mean value
2.5	2.6273	2.6046	2.61595
1.25	1.5106	1.4703	1.49045
0.625	0.8347	0.8452	0.83995
0.3125	0.4358	0.4291	0.43245
0.156	0.2306	0.2232	0.2269
0.078	0.1307	0.1334	0.13205
0.039	0.0809	0.0765	0.0787
0	0.0325	0.0336	0.03305

BCA Rapid Protein Quantitative Detection Kit

Overview

Cat.No. HG-BC001

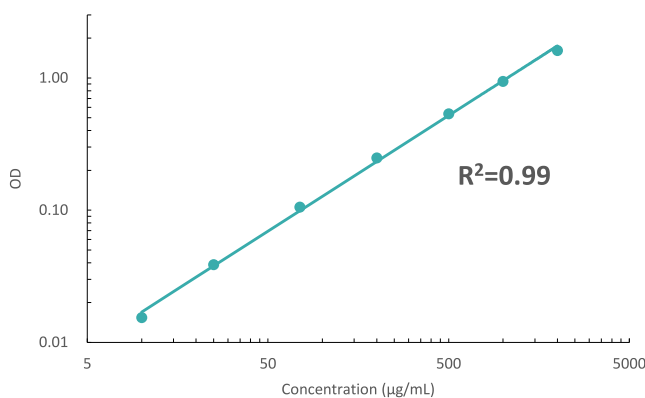
BCA Rapid Protein Quantitative Detection Kit in the BlueKit® series has the characteristics of high sensitivity, stable results, and simple operation. The principle of this kit is that Cu^{2+} is reduced by protein to Cu^{+} under alkaline conditions, and then Cu^{+} and BCA interact to form a purple reaction complex, showing a strong absorbance at 562 nm, and presenting a good linear relationship with protein concentration.

Specification

Assay range: 10~2000 $\mu\text{g}/\text{mL}$

Limit of detection: 0.39 $\mu\text{g}/\text{mL}$

Standard curve



Datasheet

Concentration of standard (ng/mL)	OD value1	OD value2	Mean value
0.00	0.1039	0.1039	0.1039
10	0.1196	0.1190	0.1193
25	0.1424	0.1430	0.1427
75	0.2098	0.2094	0.2096
200	0.3519	0.3540	0.3530
500	0.6408	0.6380	0.6394
1000	1.0423	1.0500	1.0462
2000	1.7229	1.7210	1.7220

03 Detection Kits for Cell

Blood/Tissue/Cell Genomic DNA Extraction Kit

CAR/TCR Gene Copy Number Detection Kit (Multiplex qPCR)

BaEV Gene Copy Number Detection Kit (qPCR)

RCL(VSVG) Gene Copy Number Detection Kit (qPCR)

Mycoplasma DNA Detection Kit (qPCR)-ZY001

Mycoplasma DNA Sample Preprocessing Kit (Magnetic Bead Method)

Mycoplasma DNA Detection Kit (qPCR)-ZY002

CRS Cytokine Multiplex ELISA Detection Kit

HIV-1 p24 ELISA Detection Kit

Cell Residual Human IL-2 ELISA Detection Kit

Cell Residual Human IL-7 ELISA Detection Kit

Cell Residual Human IL-15 ELISA Detection Kit

Cell Residual Human IL-21 ELISA Detection Kit

Human IFN- γ ELISA Detection Kit

Blood/Tissue/Cell Genomic DNA Extraction Kit (Magnetic bead method)

Overview

Cat.No. HG-NA100

This kit is designed for the simple and efficient extraction of genome. This kit can be applied to extract a small quantity of samples manually and perform in a high-throughput scale automatically.

Genomic DNA Extracted by this kit can be used to detect host cell DNA in some experiments.

Applications

Shows higher yield and higher purity compared to competing products.



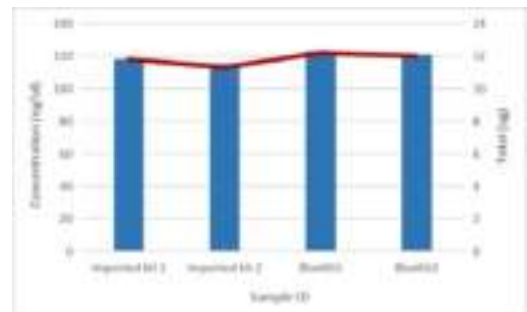
Electrophoresis in 1% agarose gels

Strip No.1&2: Blood/Tissue/Cell Genomic DNA Extraction Kit (Magnetic bead method)

Strip No.3&4: Imported Kit

Results show that genomic fragments extracted using the Bluekit® kit are as complete as those using imported kits.

Extract genomic DNA from two blood samples respectively with the imported kit and the Bluekit® kit, and then detect the concentration with Nanodrop. Results show that the the Bluekit® kit has 5-10% yield more than the imported kit.



	ng/μL	Total(μg)	260/280	260/230
Sample 1	108.72	10.87	1.80	2.13
	112.72	11.27	1.79	2.09
Sample 2	106.56	10.66	1.80	2.10
	106.95	10.70	1.79	2.07

CAR/TCR Gene Copy Number Detection Kit (Multiplex qPCR)

Overview

Cat.No. HG-CA001

This kit is designed for the quantitative detection of CAR gene copy number in the genome of CAR-T/TCR-T cells prepared by using HIV-1 lentiviral vector technology.

This kit adopts the fluorescent probe method and multiplex PCR method to detect the DNA sequence related to integration or expression function on the transfer plasmid and the reference gene (RFG) in human cells, and the CAR gene copy number/cell in the sample can be calculated. The kit is a rapid, specific and reliable device.

Specification

Assay range: $3.00 \times 10^1 \sim 3.00 \times 10^6$ copies/ μ L

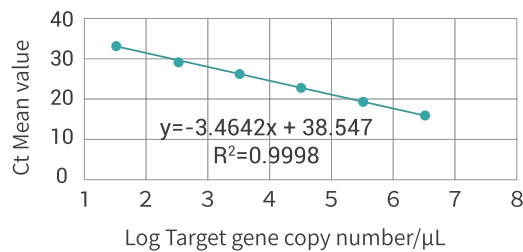
Limit of quantitation: 30 copies/ μ L

Limit of detection: 15 copies/ μ L

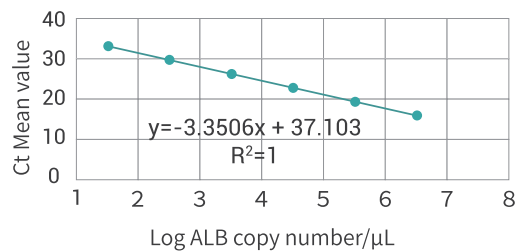
Precision: CV% \leq 15%

Standard curve

Target gene copy number Standard curve



RFG gene copy number Standard curve



Datasheet

Copies/ μ L	Log Copies	Target gene copy number Standard curve					RFG gene copy number Standard curve				
		Ct Value(1)	Ct Value(2)	Ct Value(3)	Ct Mean Value	CV	Ct Value(1)	Ct Value(2)	Ct Value(3)	Ct Mean Value	Recovery rate
3.00E+06	6.48	16.14	16.29	16.21	16.21	93.33%	15.39	15.48	15.42	15.43	97.93%
3.00E+05	5.48	19.27	19.61	19.43	19.43	109.50%	18.67	18.79	18.71	18.72	101.97%
3.00E+04	4.48	23.00	23.04	23.01	23.01	101.34%	22.09	22.12	22.03	22.08	101.49%
3.00E+03	3.48	26.42	26.53	26.54	26.54	100.21%	25.43	25.46	25.45	25.45	100.45%
3.00E+02	2.48	30.10	30.00	30.06	30.06	94.34%	28.85	28.80	28.88	28.84	97.50%
3.00E+01	1.48	33.41	33.50	33.27	33.27	102.29%	32.25	32.18	32.00	32.14	100.80%
Amplification efficiency						94.4%	Amplification efficiency				98.82%

BaEV Gene Copy Number Detection Kit (qPCR)

Overview

Cat.No. HG-BA001

The BaEV Gene Copy Number Detection Kit is a specialized kit for quantitative detection of BaEV gene copy number.

This kit quantitatively detects the copy number of BaEV gene in the sample based on the fluorescence probe method. This kit is rapid, specific and reliable in performance.

Specification

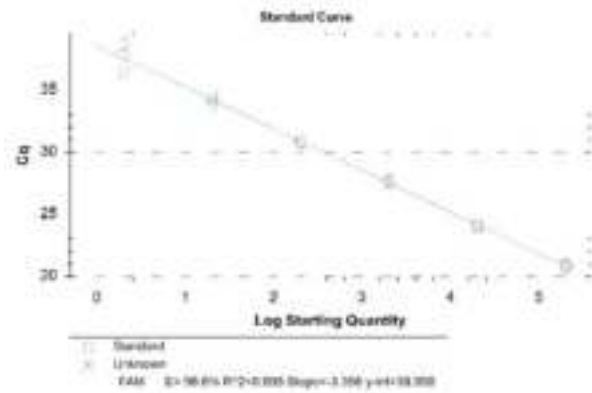
Assay range: $2.00 \times 10^1 \sim 2.00 \times 10^6$ copies/ μ L

Limit of quantitation: 20 copies/ μ L

Limit of detection: 2 copies/ μ L

Precision: CV% \leq 15%

Standard curve



Datasheet

Concentration (copies/ μ L)	Log10 Concentration	Ct Value(1)	Ct Value(2)	Ct Value(3)	Ct Mean Value	CV
2.00E+05	5.30	20.86	21.01	20.74	20.87	0.64%
2.00E+04	4.30	24.05	24.17	23.83	24.02	0.71%
2.00E+03	3.30	27.81	27.50	27.56	27.62	0.60%
2.00E+02	2.30	30.95	30.80	30.73	30.83	0.36%
2.00E+01	1.30	34.24	34.42	33.79	34.15	0.96%
2.00E+00	0.30	37.41	37.81	37.72	37.64	0.55%
Amplification efficiency						99.60%

RCL(VSVG) Gene Copy Number Detection Kit (qPCR)

Overview

Cat.No. HG-RC001

This kit is designed for the quantitative detection of RCL gene copy number in the genome of CAR-T cells prepared by using HIV-1 lentiviral vector technology.

This kit adopts the fluorescent probe method and multiplex PCR method to detect the DNA sequence related to integration or expression function on the transfer plasmid, and the VSVG gene copy number in the sample can be calculated. The kit is a rapid, specific and reliable device.

Specification

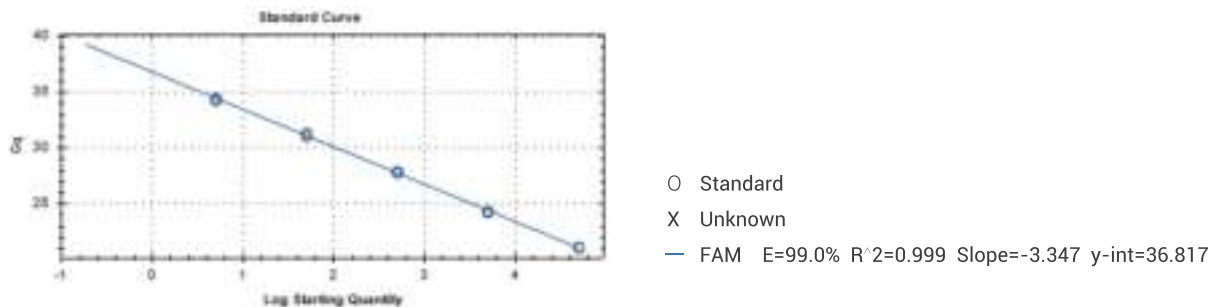
Assay range: $1.00 \times 10^1 \sim 1.00 \times 10^5$ copies/ μ L

Limit of quantitation: 8 copies/ μ L

Limit of detection: 1 copies/ μ L

Precision: CV% \leq 15%

Standard curve



Datasheet

Concentration (copies/ μ L)	Log10 Concentration	Ct Value(1)	Ct Value(2)	Ct Value(3)	Ct Mean Value	CV
1.00E+05	5.00	20.27	20.16	20.13	20.18	0.36%
1.00E+04	4.00	23.35	23.21	23.27	23.28	0.32%
1.00E+03	3.00	26.93	26.85	26.96	26.91	0.21%
1.00E+02	2.00	30.31	30.31	30.20	30.27	0.21%
1.00E+01	1.00	33.54	33.30	33.19	33.34	0.53%
Amplification efficiency						99.60%

Mycoplasma DNA Detection Kit (qPCR)-ZY001

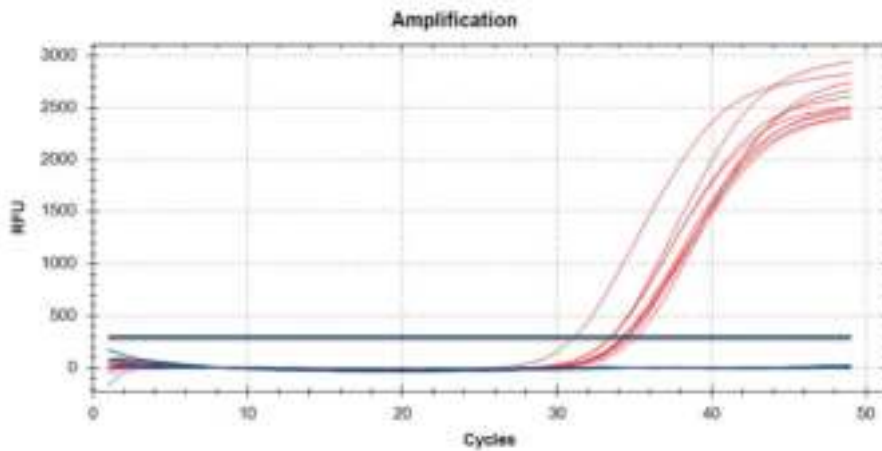
Overview

Cat.No. HG-ZY001

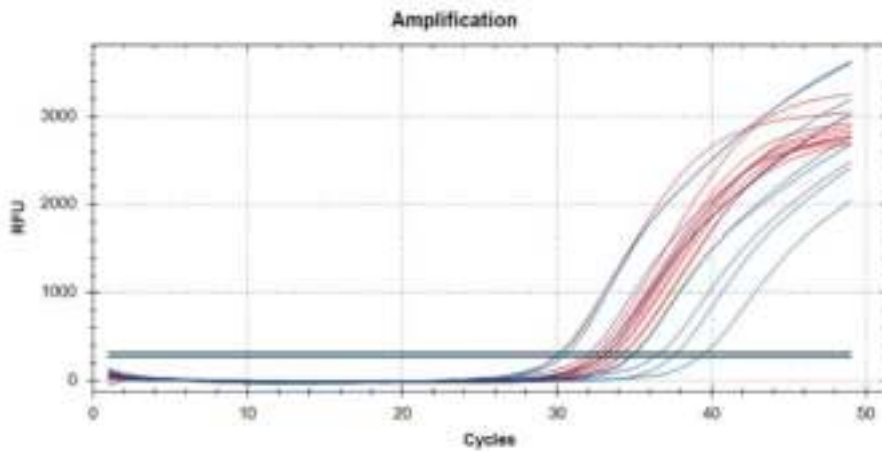
This kit is designed for the detection of mycoplasma contamination in master cell bank, working cell bank, cells for clinical use and biological products. This kit conforms to relevant regulations about mycoplasma testing in EP2.6.7 and JP XVI.

This kit adopts the qPCR-fluorescent probe method. The kit is a rapid, specific and reliable device and can finish the detection within 2 hours.

Test curve



Negative



Positive

— FAM
— HEX

Datasheet

	FAM(CT Value)		HEX(CT Value)	
	Negative	Positive	Negative	Positive
1	NA	31.72	34.45	32.62
2	NA	33.05	31.08	33.12
3	NA	36.32	33.43	33.45
4	NA	30.01	34.56	30.02
5	NA	30.37	35.05	33.55
6	NA	34.68	34.22	34.19
7	NA	34.83	34.35	32.63
8	NA	39.23	34.12	32.58
9	NA	32.95	33.39	34.07
10	NA	37.44	33.41	32.24

Results of 10 mycoplasma standards				Results of 3 relevant bacteria		
Strain	Positive/Total	Strain	Positive/Total	L.acidophilus	S.pneumoniae	Clos. acetobutyleum
M. orale	24/24	M. synoviae	24/24	Negative	Negative	Negative
M. gallisepticum	23/24	M. arginini	23/24			
A. laidlawii	24/24	M. hyorhinis	24/24			
M. fermentans	23/24	Spiroplasma citri	24/24			
M. pneumonia	24/24	M. salivarium	24/24			

Mycoplasma DNA Sample Preprocessing Kit (Magnetic Bead Method)

Overview

Cat.No. HG-CL200

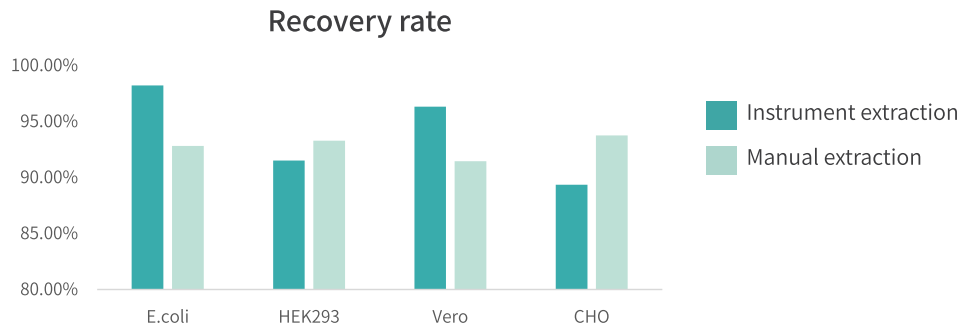
The kit is used for pre-processing of biological product samples to accurately extract residual DNAs of host cells in various biological products. The kit is applicable to various matrix buffers to effectively extract and purify trace amounts of DNAs. It can be used together with mycoplasma DNA detection kit manufactured by Hillgene.

Specification

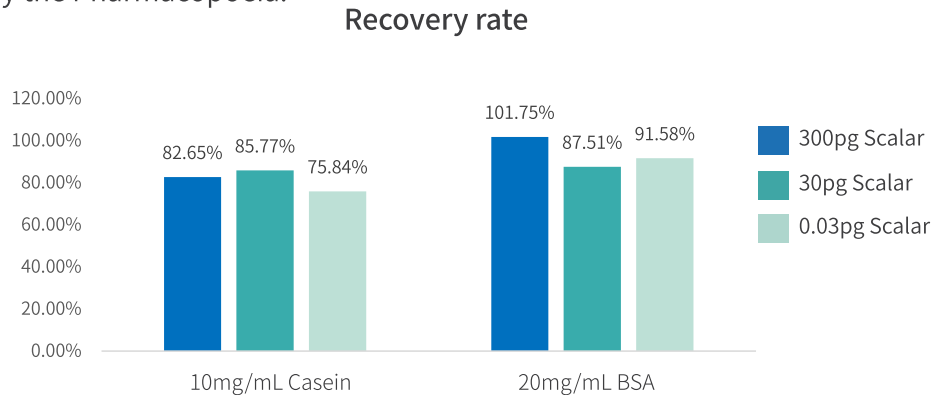
Detection sensitivity: 0.03pg/ μ L

Recovery rate: 70%~130%

Data



Manual extraction and instrument extraction were performed on DNA samples of different host types, and the final sample recovery rates were 70% to 130%, which were better than the 50% to 150% required by the Pharmacopoeia.



The two sample matrices (PBS+10mg/mL BSA and PBS+10mg/mL casein) were added with a total of 0.03pg, 3pg, and 300pg of CHO gDNA reference substance for pretreatment, and the final recovery of the standard addition was 70 %~130%.

Mycoplasma DNA Detection Kit (qPCR)-ZY002

Overview

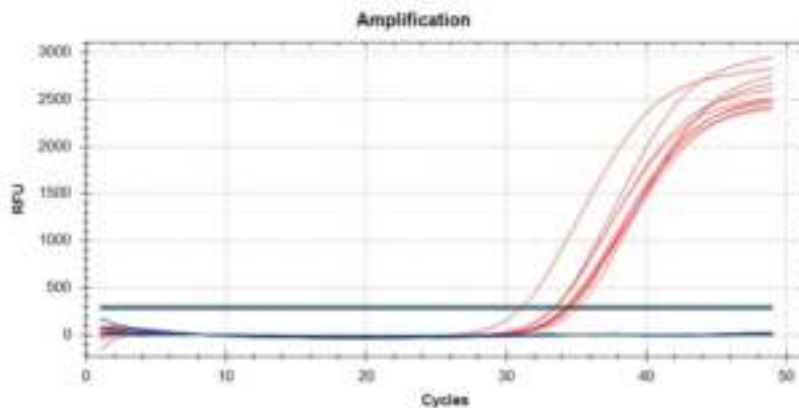
Cat.No. HG-ZY002

The kit is used to qualitatively detect the presence of mycoplasma contamination in master cell banks, working cell banks, virus seed lots, control cells, and cells for clinical therapy.

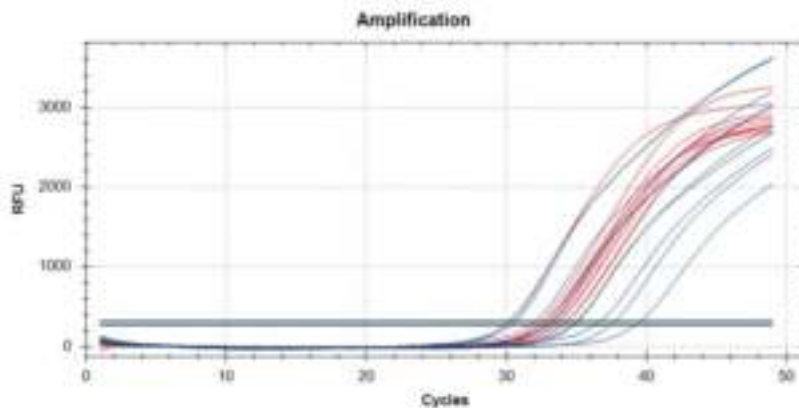
The kit uses qPCR-fluorescent probe technology to verify with reference to mycoplasma detection-related requirements in EP2.6.7 and JPXVII. It can cover more than 100 mycoplasmas and has no cross reaction with closely related strains. The detection is rapid which can be completed within 2 hours, with strong specificity.

Specification

50 Reactions.



Negative



Positive

— FAM
— Cy5

Datasheet

	FAM(CT Value)		HEX(CT Value)	
	Negative	Positive	Negative	Positive
1	NA	32.65	33.26	32.48
2	NA	34.26	32.29	33.23
3	NA	35.32	35.46	34.67
4	NA	31.51	34.79	31.68
5	NA	30.54	35.25	35.91
6	NA	34.97	33.57	34.20
7	NA	34.32	34.35	33.26
8	NA	38.45	35.87	35.54
9	NA	33.67	33.24	33.12
10	NA	37.41	33.41	32.24

Results of 10 mycoplasma standards				Results of 3 relevant bacteria		
Strain	Positive/Total	Strain	Positive/Total	L.acidophilus	S.pneumoniae	Clos. acetobutyleum
M. orale	24/24	M. synoviae	24/24	Negative	Negative	Negative
M. gallisepticum	23/24	M. arginini	23/24			
A. laidlawii	24/24	M. hyorhinis	24/24			
M. fermentans	23/24	Spiroplasma citri	24/24			
M. pneumonia	24/24	M. salivarium	24/24			

CRS Cytokine Multiplex ELISA Detection Kit

Overview

Cat.No. HG-HC001

The kit is an Enzyme Immunoassay kit for the semi-quantification of Human CART-T / CRS (Cytokine Release Syndrome) Cytokine (IL2, IL6, IL10, IFN gamma) in serum, plasma and cell culture supernatants.

Specification

Assay range:

IL2: 15.625-500 pg/mL

IL6: 31.25-1000 pg/mL

IL10: 15.625-500 pg/mL

IFN- γ : 15.625-500 pg/mL

Limit of quantitation:

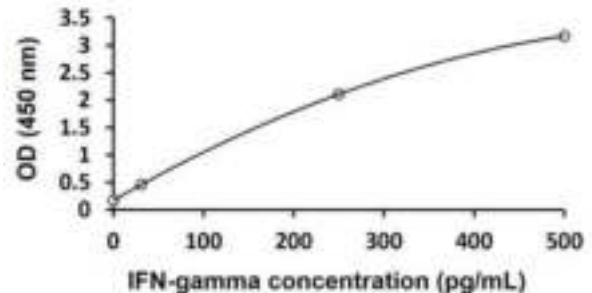
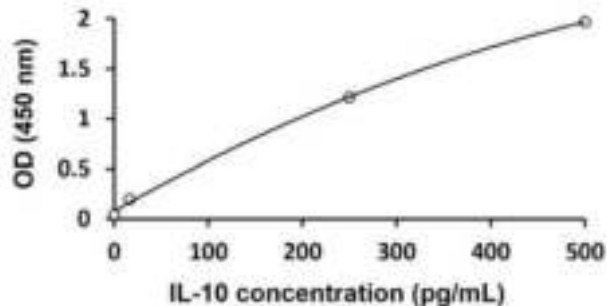
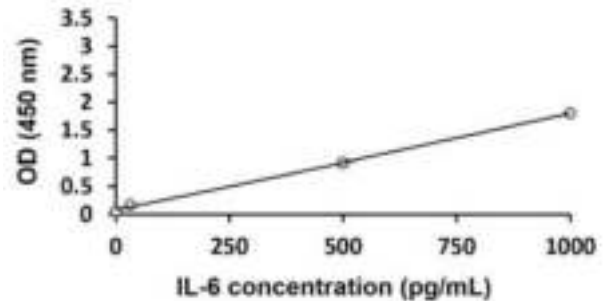
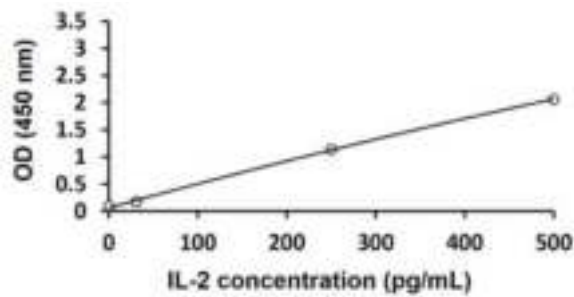
IL2: 15.625 pg/mL

IL6: 31.25 pg/mL

IL10: 15.625 pg/mL

IFN- γ : 15.625 pg/mL

Standard curve



HIV-1 p24 ELISA Detection Kit

Overview

Cat.No. HG-P001

This kit is designed for the quantitative detection of p24 protein content by using a double-antibody sandwich method, suitable to detect residual p24 protein content in any HIV-1 lentivirus product.

Specification

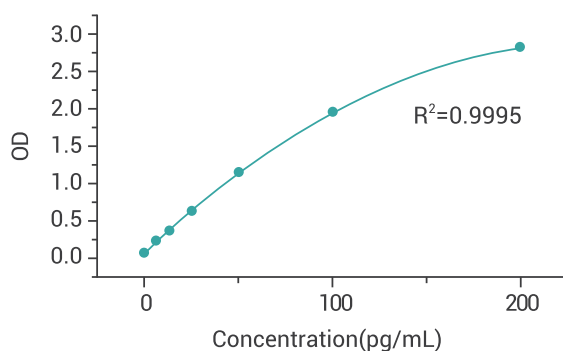
Assay range: 6.25-200pg/mL

Limit of quantitation: 6.25pg/mL

Limit of detection: 3.125pg/mL

Precision: CV% \leq 10%, RE% \leq \pm 15%

Standard curve



Datasheet

Concentration of standard (pg/mL)	OD value1	OD value2	Mean value
200	2.846	2.841	2.844
100	1.965	1.979	1.972
50	1.110	1.189	1.150
25	0.636	0.582	0.609
12.5	0.362	0.338	0.350
6.25	0.213	0.204	0.209
0	0.061	0.059	0.060

Cell Residual Human IL-2 ELISA Detection Kit

Overview

Cat.No. HG-IL002

BlueKit® series cell residual human IL-2 ELISA detection kits use the double-antibody sandwich method to detect IL-2 protein in samples. IL-2 specific monoclonal antibodies are coated on microwell plates, and standards or samples to be tested are added to the reaction wells. Samples were added anti-IL-2 secondary antibody at the same time, and incubated at room temperature to form antibody-antigen-secondary antibody complexes. Wash to remove unbound matter, and the protein content in the sample is indicated by the degree of TMB color development.

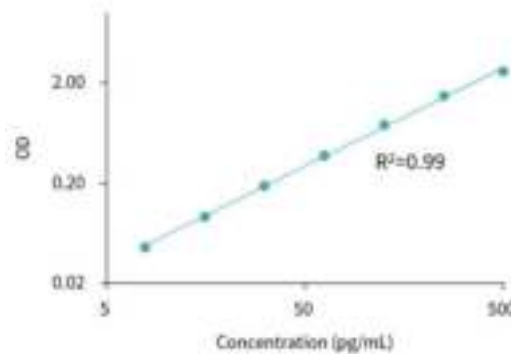
Specification

Assay range: 7.81-500pg/mL

Detection sensitivity: 0.13pg/mL

Precision: CV% ≤ 10%, RE% ≤ ±15%

Standard curve



Datasheet

Concentration of standard (pg/mL)	OD value1	OD value2	Mean value
0.00	0.0214	0.0215	0.0215
7.81	0.0674	0.0665	0.0670
15.63	0.1140	0.1154	0.1147
31.25	0.2154	0.2062	0.2108
62.50	0.4035	0.3916	0.3976
125.00	0.7904	0.7754	0.7829
250.00	1.5240	1.4780	1.5010
500.00	2.6660	2.5960	2.6310

Cell Residual Human IL-7 ELISA Detection Kit

Overview

Cat.No. HG-IL007

BlueKit® series cell residual human IL-7 ELISA detection kits use the double-antibody sandwich method to detect IL-7 protein in samples. IL-7 specific monoclonal antibodies are coated on microwell plates, and standards or samples to be tested are added to the reaction wells. Samples were added anti-IL-7 secondary antibody at the same time, and incubated at room temperature to form antibody-antigen-secondary antibody complexes. Wash to remove unbound matter, and the protein content in the sample is indicated by the degree of TMB color development.

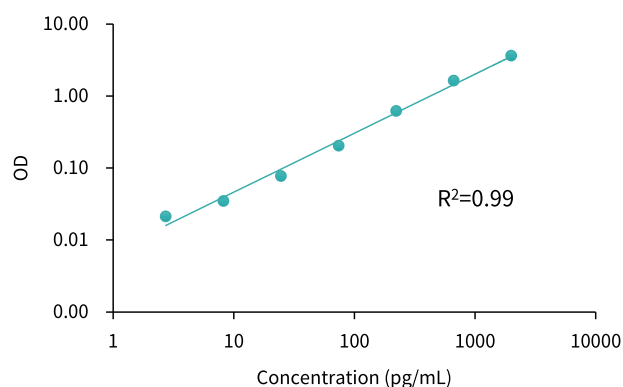
Specification

Assay range: 2.74-2000pg/mL

Detection sensitivity: 0.62pg/mL

Precision: CV% ≤ 10%, RE% ≤ ±15%

Standard curve



Datasheet

Concentration of standard (pg/mL)	OD value1	OD value2	Mean value
0.00	0.0139	0.0144	0.0142
2.74	0.0221	0.0202	0.0212
8.23	0.0347	0.0347	0.0347
24.69	0.0817	0.0730	0.0774
74.07	0.2122	0.1976	0.2049
222.22	0.6447	0.5979	0.6213
666.67	1.6810	1.5880	1.6345
2000.00	3.7070	3.5910	3.6490

Cell Residual Human IL-15 ELISA Detection Kit

Overview

Cat.No. HG-IL015

BlueKit® series cell residual human IL-15 ELISA detection kits use the double-antibody sandwich method to detect IL-15 protein in samples. IL-15 specific monoclonal antibodies are coated on microwell plates, and standards or samples to be tested are added to the reaction wells. Samples were added anti-IL-15 secondary antibody at the same time, and incubated at room temperature to form antibody-antigen-secondary antibody complexes. Wash to remove unbound matter, and the protein content in the sample is indicated by the degree of TMB color development.

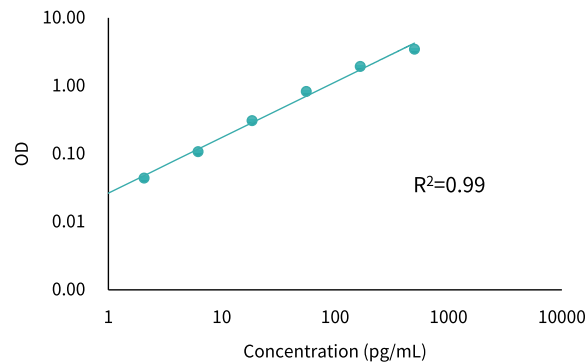
Specification

Assay range: 0.69-500pg/mL

Detection sensitivity: 0.14pg/mL

Precision: CV% ≤ 10%, RE% ≤ ±15%

Standard curve



Datasheet

Concentration of standard (pg/mL)	OD value1	OD value2	Mean value
0.00	0.0090	0.0090	0.0090
0.69	0.0201	0.0190	0.0196
2.06	0.0460	0.0419	0.0440
6.17	0.1111	0.1045	0.1078
18.52	0.3220	0.2937	0.3079
55.56	0.8509	0.8028	0.8269
166.67	2.0501	1.8177	1.9339
500.00	3.5230	3.4139	3.4685

Cell Residual Human IL-21 ELISA Detection Kit

Overview

Cat.No. HG-IL021

BlueKit® series cell residual human IL-21 ELISA detection kits use the double-antibody sandwich method to detect IL-21 protein in samples. IL-21 specific monoclonal antibodies are coated on microwell plates, and standards or samples to be tested are added to the reaction wells. Samples were added anti-IL-21 secondary antibody at the same time, and incubated at room temperature to form antibody-antigen-secondary antibody complexes. Wash to remove unbound matter, and the protein content in the sample is indicated by the degree of TMB color development.

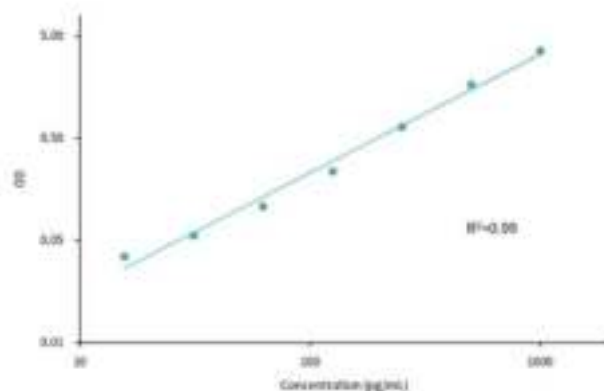
Specification

Assay range: 15.63-1000pg/mL

Detection sensitivity: 1.34pg/mL

Precision: CV% ≤ 10%, RE% ≤ ±15%

Standard curve



Datasheet

Concentration of standard (pg/mL)	OD value1	OD value2	Mean value
1000.00	3.5504	3.6410	3.596
500.00	1.6473	1.7458	1.697
250.00	0.6417	0.6588	0.650
125.00	0.2261	0.2519	0.239
62.50	0.1038	0.1112	0.108
31.25	0.0529	0.0596	0.056
15.63	0.0339	0.0363	0.035
0.00	0.0173	0.0152	0.016

Human IFN- γ ELISA Detection Kit

Overview

Cat.No. HG-IF001

BlueKit® series human IFN- γ ELISA detection kits use the double-antibody sandwich method to detect IFN- γ protein in samples. IFN- γ specific monoclonal antibodies are coated on microwell plates, and standard products or samples to be tested are added to the reaction wells. Samples were added with anti-IFN- γ secondary antibody and incubated at room temperature to form antibody-antigen-secondary antibody complexes. Wash to remove unbound matter, and the protein content in the sample is indicated by the degree of TMB color development.

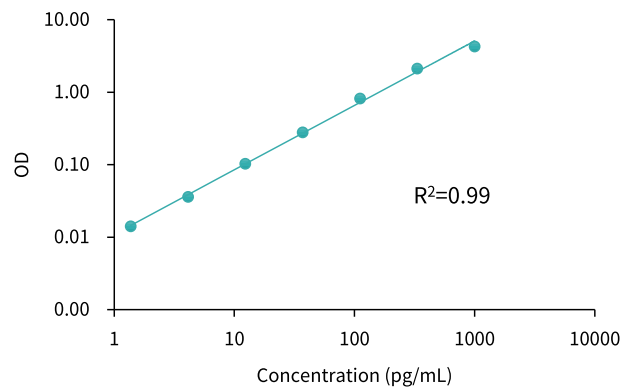
Specification

Assay range: 1.37-1000pg/mL

Detection sensitivity: 0.36pg/mL

Precision: CV% \leq 10%, RE% \leq \pm 15%

Standard curve



Datasheet

Concentration of standard (pg/mL)	OD value1	OD value2	Mean value
0.00	0.0098	0.0106	0.0102
1.37	0.0124	0.0160	0.0142
4.12	0.0382	0.0340	0.0361
12.35	0.1072	0.0989	0.1031
37.04	0.2915	0.2705	0.2810
111.11	0.8112	0.8352	0.8232
333.33	2.0721	2.1701	2.1211
1000.00	4.1920	4.3700	4.2810

04 Detection Kits for mRNA

DNase I ELISA Detection Kit

RNase Inhibitor ELISA Detection Kit

T7 RNA Polymerase ELISA Detection Kit

dsRNA ELISA Detection Kit

DNase I ELISA Detection Kit

Overview

Cat.No. HG-DI001

This kit is designed for the quantitative detection of residual Dnase I content added in RNA pharmaceuticals processes by using a double-antibody sandwich method.

Specification

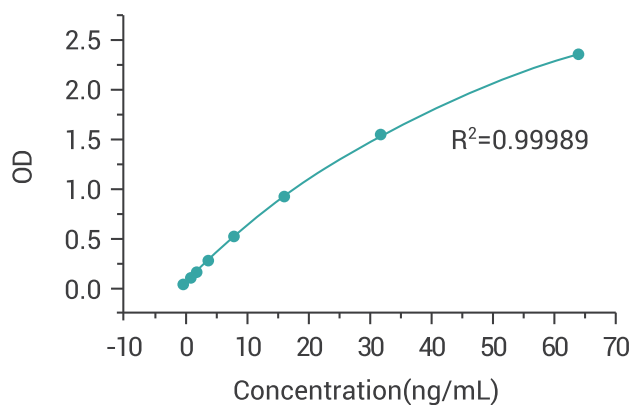
Assay range: 1-64 ng/mL

Limit of quantitation: 1 ng/mL

Limit of detection: 0.5 ng/mL

Precision: CV% \leq 10%, RE% \leq \pm 15%

Standard curve



Datasheet

Concentration of standard (ng/mL)	OD value1	OD value2	Mean value
64	2.373	2.347	2.360
32	1.520	1.546	1.533
16	0.933	0.934	0.9335
8	0.518	0.536	0.527
4	0.259	0.291	0.275
2	0.166	0.168	0.167
1	0.115	0.109	0.112
0	0.057	0.049	0.053

RNase Inhibitor ELISA Detection Kit

Overview

Cat.No. HG-RI001

This kit is designed for the quantitative detection of residual RNase Inhibitor content added in RNA pharmaceuticals processes by using a double-antibody sandwich method.

Specification

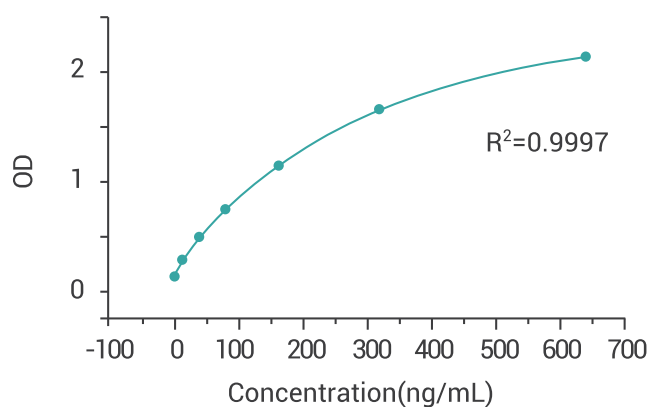
Assay range: 20-640 ng/mL

Limit of quantitation: 20 ng/mL

Limit of detection: 5 ng/mL

Precision: CV% \leq 10%, RE% \leq \pm 15%

Standard curve



Datasheet

Concentration of standard (ng/mL)	OD value1	OD value2	Mean value
640	2.213	2.110	2.162
320	1.661	1.641	1.651
160	1.181	1.143	1.162
80	0.743	0.755	0.749
40	0.486	0.478	0.482
20	0.298	0.292	0.295
0	0.151	0.15	0.151

T7 RNA Polymerase ELISA Detection Kit

Overview

Cat.No. HG-TP001

This kit is designed for the quantitative detection of residual T7 RNA Polymerase content added in RNA pharmaceuticals processes by using a double-antibody sandwich method.

Specification

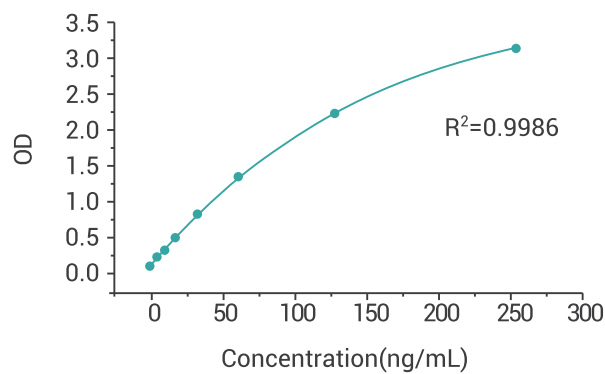
Assay range: 4-256 ng/mL

Limit of quantitation: 4 ng/mL

Limit of detection: 2 ng/mL

Precision: CV% ≤ 10%, RE% ≤ ±15%

Standard curve



Datasheet

Concentration of standard (ng/mL)	OD value1	OD value2	Mean value
256	3.109	3.183	3.146
128	2.281	2.213	2.247
64	1.411	1.394	1.4025
32	0.787	0.845	0.816
16	0.463	0.447	0.455
8	0.299	0.307	0.303
4	0.235	0.235	0.235
0	0.141	0.133	0.137

dsRNA ELISA Detection Kit

Overview

Cat.No. HG-DS001

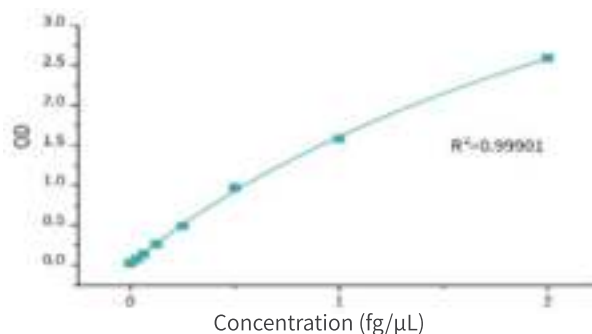
This dsRNA ELISA detection kits of BlueKit® series use a double antibody sandwich method to quantitatively detect the content of double stranded RNA (dsRNA) in samples. The detected dsRNA is 60 bp or more in length, and is not related to its nucleic acid sequence.

Specification

Standard type	Assay range (pg/μL)	Limit of quantitation (pg/μL)	Limit of detection (pg/μL)	Recovery rate	CV%
No modification	0.0156-0.5	0.0156	0.001	80-120%	≤ 10%
N1-Me-pUTP modified	0.0312-1	0.0312	0.001	80-120%	≤ 10%
pUTP modified	0.0156-0.5	0.0156	0.001	80-120%	≤ 10%
5-OMe-UTP modified	0.0625-1	0.0625	0.01	80-120%	≤ 10%

*Range of linearity: Coefficient of determination > 0.99

Standard curve



Datasheet

Concentration of standard (pg/μL)	OD value1	OD value2	Mean value
2	2.8412	2.7362	2.7887
1	1.8725	1.9135	1.8930
0.5	1.0863	1.1207	1.1035
0.25	0.623	0.6055	0.6143
0.125	0.3388	0.3292	0.3340
0.0625	0.1947	0.1885	0.1916
0.0312	0.1192	0.1247	0.1220
0	0.0567	0.0518	0.0543

05 Detection Kits for Antibodies/vaccines

CHO Residual DNA Detection Kit (qPCR)

Vero Residual DNA Detection Kit (qPCR)

CHO Residual DNA Detection Kit (qPCR)

Overview

Cat.No. HG-CH001

This kit is designed for the quantitative detection of residual CHO DNA content in intermediates, semi-finished products and finished products of various biological products.

This kit adopts the principle of the Taqman probe to quantitatively detect CHO residual DNA in samples. The kit is a rapid, specific and reliable device, with the minimum detection limit reaching fg level.

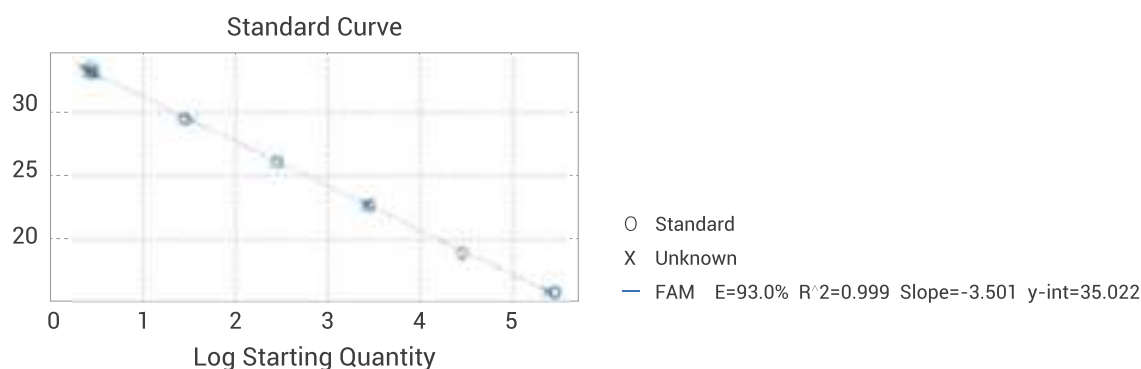
Specification

Assay range: 3.00~3.00x10⁵fg/μL

Limit of quantitation: 3fg/μL

Precision: CV% ≤ 15%

Standard curve



Datasheet

Concentration (fg/μL)	Log10 Concentration	Ct Value(1)	Ct Value(2)	Ct Value(3)	Ct Mean Value	CV
3.00E+05	5.48	15.94	16.08	16.12	16.05	0.59%
3.00E+04	4.48	19.10	19.16	19.17	19.14	0.18%
3.00E+03	3.48	22.72	22.89	22.95	22.86	0.51%
3.00E+02	2.48	26.26	26.38	26.30	26.31	0.23%
3.00E+01	1.48	29.61	29.70	29.79	29.70	0.30%
3.00E+00	0.48	33.88	33.28	33.43	33.53	0.93%
Amplification efficiency						93.0%

Vero Residual DNA Detection Kit (qPCR)

Overview

Cat.No. HG-VE001

This kit is designed for the quantitative detection of residual Vero host cell DNA in intermediates, semi-finished products and finished products of various biological products.

This kit adopts the principle of Taqman probe to quantitatively detect residual Vero DNA in samples. The kit is a rapid, specific and reliable device, with the minimum detection limit reaching fg level.

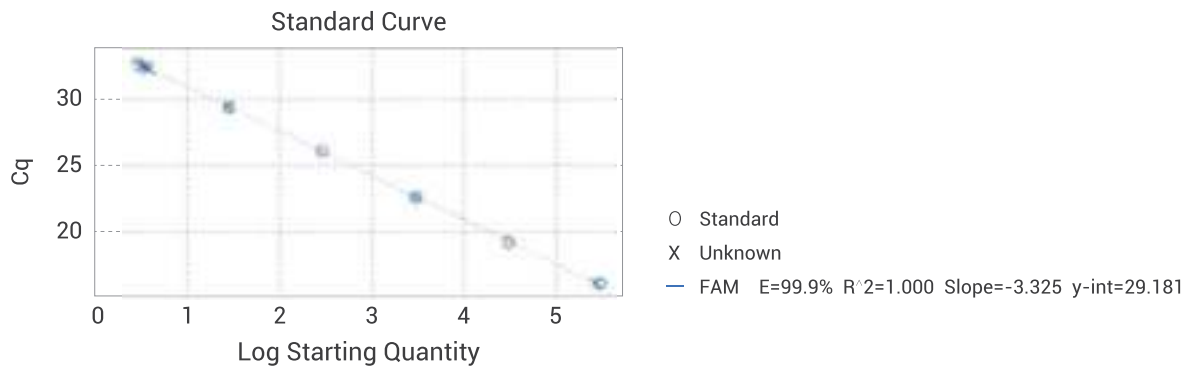
Specification

Assay range: 3.00~3.00x10⁵fg/μL

Limit of Quantitation: 3fg/μL

Precision: CV% ≤ 15%

Standard curve



Datasheet

Concentration (fg/μL)	Log10 Concentration	Ct Value(1)	Ct Value(2)	Ct Value(3)	Ct Mean Value	CV
3.00E+05	5.48	11.07	10.99	11.15	11.07	0.72%
3.00E+04	4.48	14.09	14.18	14.31	14.20	0.78%
3.00E+03	3.48	17.68	17.46	17.64	17.59	0.65%
3.00E+02	2.48	20.76	21.07	21.03	20.95	0.80%
3.00E+01	1.48	24.32	24.19	24.22	24.24	0.29%
3.00E+00	0.48	27.84	27.55	27.54	27.64	0.61%
Amplification efficiency						99.9%

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