TRANSGEN BIOTECH

CAR-T

CAR-T Immunotherapy Solutions

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CONTE

Lentiviral Packaging Solution

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SV40LTA and E1A Residual DNA Detection

Nuclease Residue Detection

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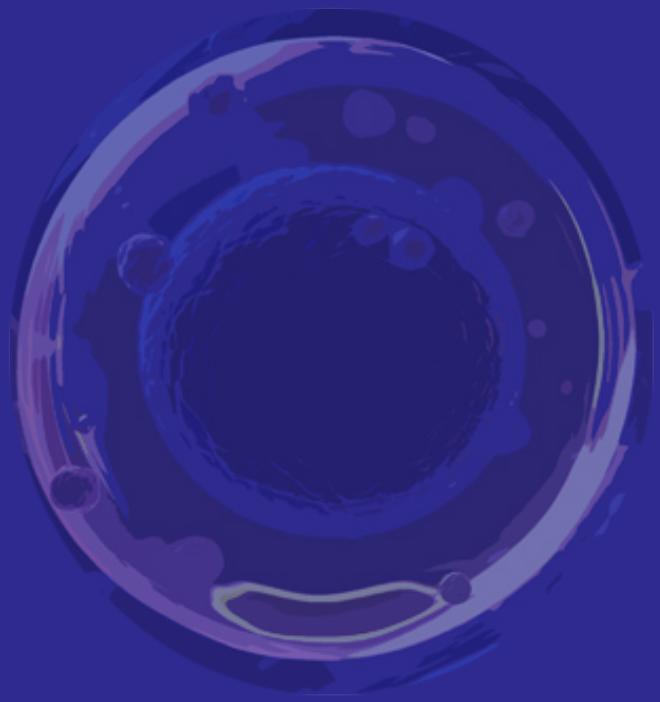
NTS



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CAR-T

In CAR T-cell therapies, T cells are taken from the patient's blood and are altered by adding the gene for the specific chimeric antigen receptor (CAR). This makes them CAR-T cells. These cells are then grown and multiplied in the lab. Once enough CAR-T cells have been made, they will be given back to the patient. Since the US FDA approved the launch of CAR-T therapy Kymriah (CTL019) in 2017, CAR-T therapy in global has continued to heat up. TransGen Biotech can provide lentivirus packaging and quality control, CAR-T cell expansion and quality control solutions to assist the development and production of CAR-T cell therapy.

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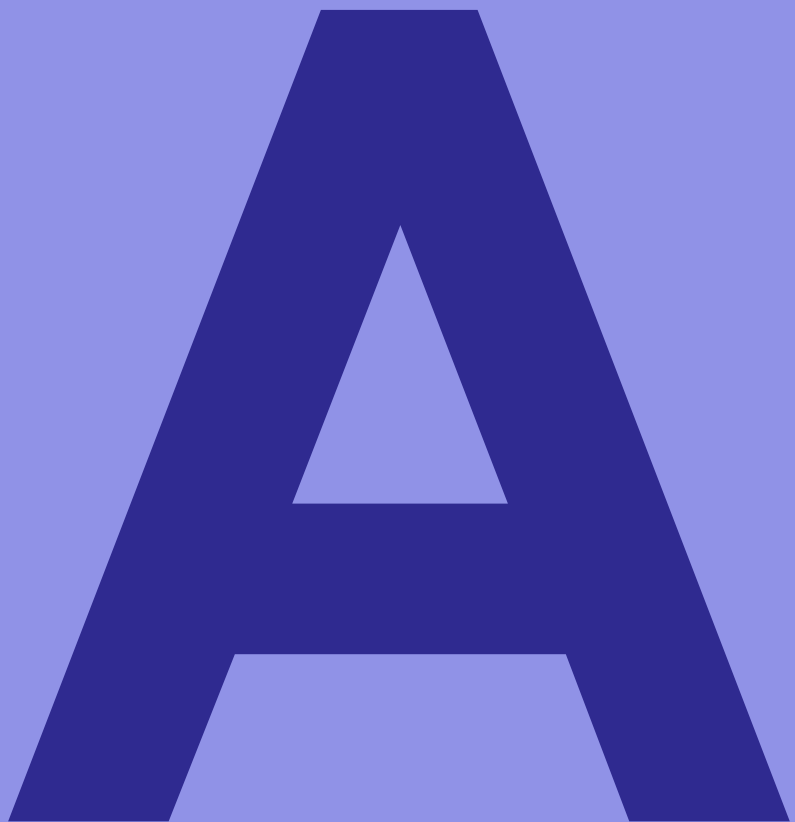

Lentiviral Packaging Solution

Lentiviral packaging is a key step in preparing CAR-T cells. Lentiviral vectors are the most frequently used tool to efficiently transfer and express CAR gene in T cells. TransGen Biotech provides lentiviral packaging plasmid extraction reagents, transfection reagent, universal nuclease, etc.

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Extraction of Lentiviral Packaging Plasmid

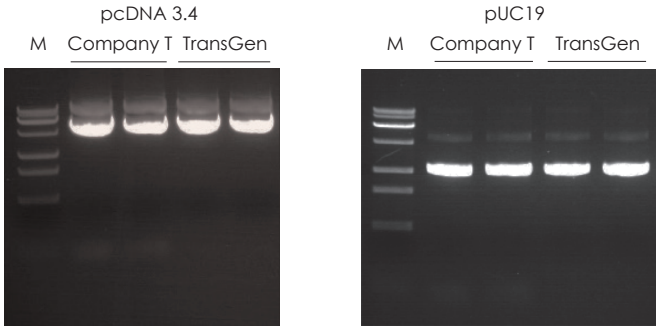
Endotoxin-free plasmids with high purity and concentration are the key to successful lentivirus packaging. TransGen Biotech provides plasmid DNA extraction reagents with simple operation, high yield, low endotoxin and can meet different experimental requirements.

EasyPure® EndoLow Plasmid MaxiPrep Kit (EM122)

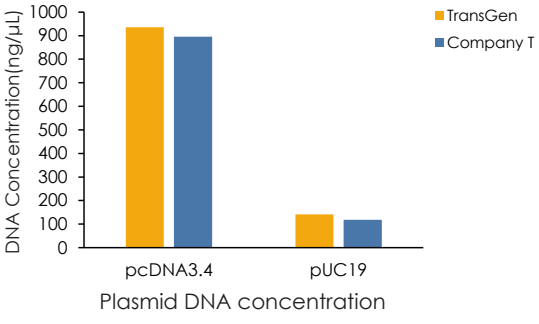
Features

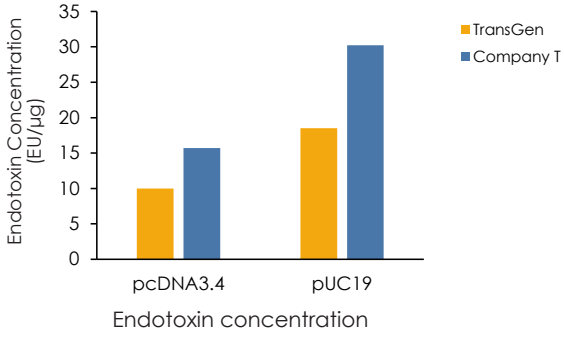
- Low endotoxin (<20 EU/μg, standard transfection): High-purity and transfection-grade plasmid DNA can be prepared.
- High yield (up to 4 mg nucleic acid load in the purification column).
- Wide range of applications: Low copy plasmids can be efficiently extracted.
- Simple and fast operation.

Data



M: *Trans*15K DNA Marker





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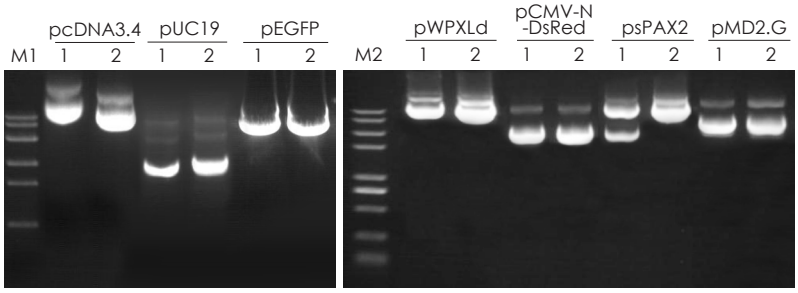
EasyPure® EndoFree Plasmid MaxiPrep Kit (EM123)

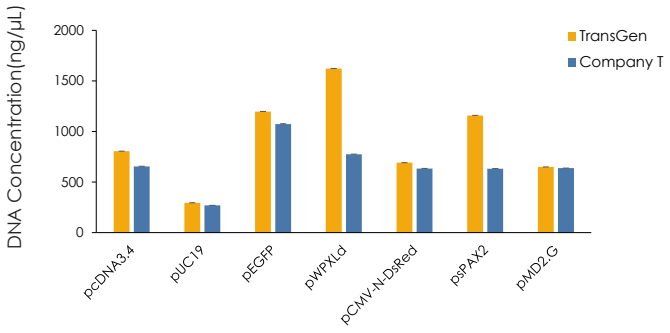
Features

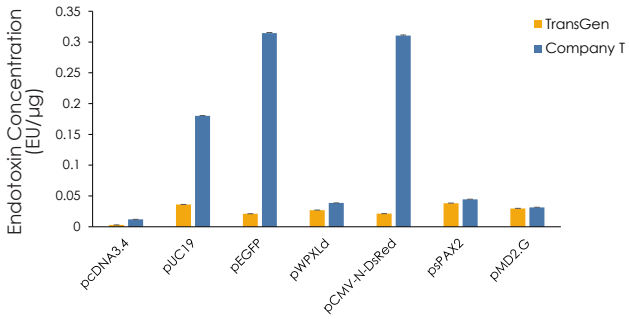
- Endotoxin-free (<0.1EU/μg, advanced transfection): High-purity plasmid DNA can be prepared.
- High yield (up to 4 mg nucleic acid load in the purification column).
- Wide range of applications: High copy and low copy plasmids can be efficiently extracted.
- Fast: The whole procedure can be performed in one hour.
- Transfection-grade: It is more suitable for mammalian cells transfection.
- Operational visualization: solution LB (blue) indicates whether the lysis and neutralization are complete through the change of color.

Data

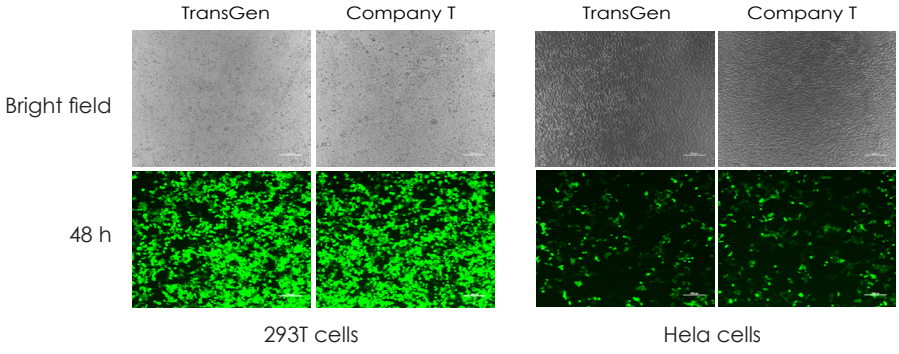


M1: *Trans*8K DNA Marker M2: *Trans*2K® Plus II DNA Marker 1:Company T 2:TransGen





Extracted plasmids for downstream transfection experiments



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PEI Transfection Reagent

Generating CAR-T cells using recombinant lentiviral vectors is a commonly used method for CAR-T cell modification. TransGen Biotech provides PEI transfection reagent with low cytotoxicity and high transfection efficiency, which can be used for efficient transfection of lentiviral vectors.

TransIntro® PEI Transfection Reagent (FT401)

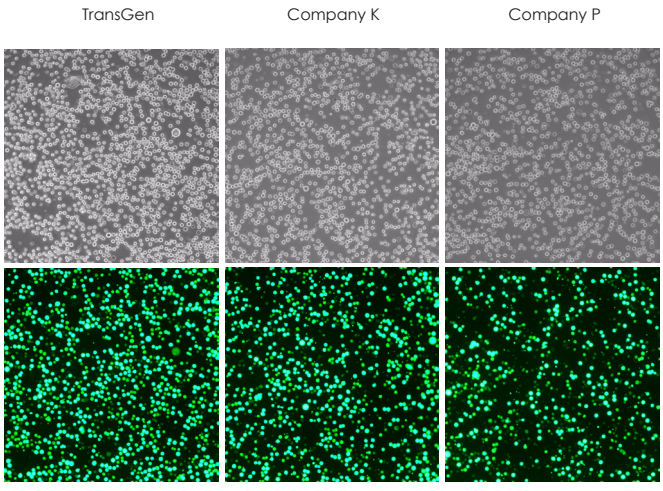
Features

- Wide application: Suitable for both transient and stable transfections of adherent or suspension cells such as HEK-293.
- High transfection efficiency: Suitable for high-efficiency transfection of plasmid DNA, HEK-293's transfection efficiency is more than 90%.
- Low cytotoxicity: Adherent cells has a good morphology after transfection, and the cell viability of suspended cells is more than 90% after 24 hours of transfection.
- Simple operation: No need to change the medium after transfection, tolerance with antibiotics and serum.
- Manufactured and managed under GMP standards.

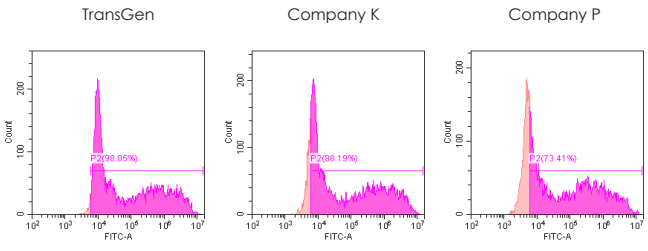
Data

Transfection efficiency is more than 90%, and cell viability is more than 90%.

Fluorescence signal was detected by fluorescence microscopy



Fluorescence rate was detected by flow cytometer



Brand	Fluorescence rate (%)
TransGen	98.05
Company K	88.19
Company P	73.41

Cell viability was measured by cell counter

Brand	Cell viability (%)
TransGen	95.43
Company K	95.58
Company P	92.50

Universal Nuclease

Nucleic acid residues (such as DNA from HEK293 cells and plasmids used for transfection) are generated during lentiviral packaging, which are potentially harmful and seriously affect the safety and efficacy of biologics. Therefore, the removal of nucleic acid residues is a critical step in the biologics manufacturing process. Universal Nuclease provided by TransGen Biotech has the advantages of xeno-free, antibiotics-free, endotoxin-free, high purity and high enzyme activity, which can degrade all forms of DNA and RNA to meet the needs of large-scale use from R&D to production.

Universal Nuclease (LN201)

DMF Number: MF037974

Features

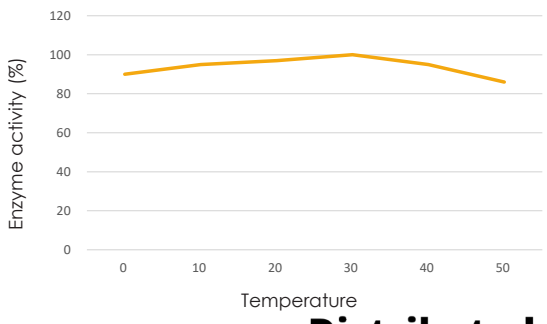
- Purity≥99%, specific activity≥1.0×10^6 U/mg.
- Compliant with pharmacopoeia requirements: xeno-free, no endotoxin.
- Produced under GMP conditions to meet the needs of large-scale use from R&D to production.
- Adaptable: High stability and strong tolerance. Maintain the its activity under the following tested conditions: 5 M Urea, 50 mM Guanidine HCl, 2% Triton X-100, 0.05% SDS, 1 mM EDTA, 5 mM PMSF. Compatible with a variety of cell lysates such as RIPA or containing a variety of ionic and nonionic detergents, reducing agents and protein extraction reagents.
- Wide range of applications: It degrades all forms of DNA and RNA and is widely used to remove nucleic acids from biological products.

Quality Control

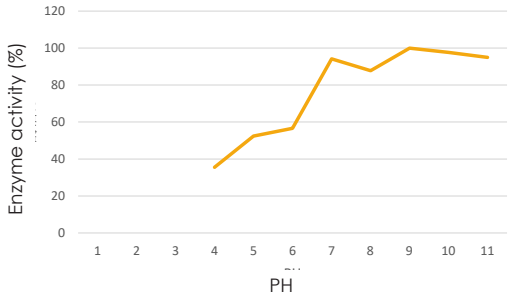
Item	Standard	Method
Appearance	Colorless and transparent	Visual inspection
Purity	≥99%	HPLC
Enzyme activity	≥250 U/μL	General substrate method
Specific activity	≥1.0×106 U/mg	Enzyme activity/ protein concentration
Bacterial residue	Not detectable	Culture method
Protease activity	Not detectable	General substrate method
Endotoxin content	<0.25 EU/1000 U	Gel clot
Host protein residue	≤10 ppm (μg/mL)	ELISA
Mycoplasma residue	Not detectable	Mycoplasma detection kit (qPCR method)
Pathogen detection （HCV/HBV/HIV）	Not detectable	PCR

Data

Universal Nuclease is active from temperature of 0-50°C.



Universal Nuclease is active in the PH of 7-11.



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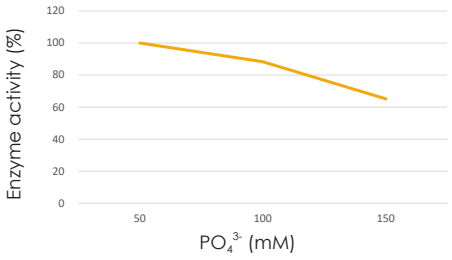
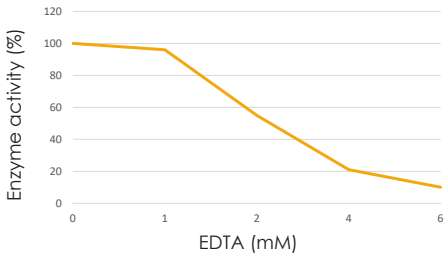
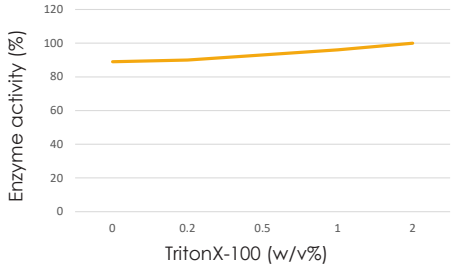
Universal Nuclease is active at PO_4^{3-} concentration of 150 mM



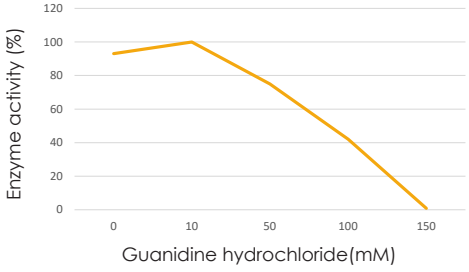
Universal Nuclease is active at EDTA concentration of 2 mM



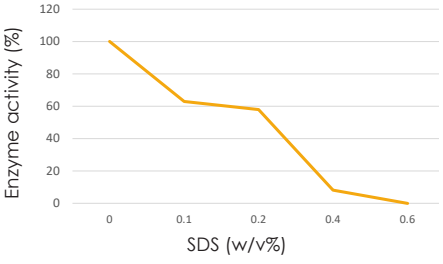
Universal Nuclease is active at 2% TritonX-100



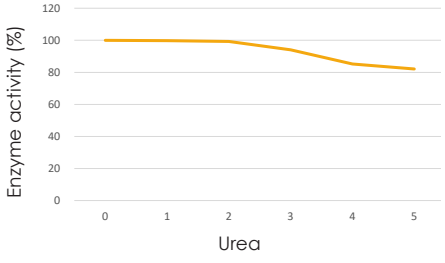
Universal Nuclease is active at guanidine hydrochloride concentration of 50 mM



Universal Nuclease is active at 0.2% SDS



Universal Nuclease is active at urea concentration of 5 mM



Recommended Conditions of Use

Condition Parameter	Optimum Conditions	Valid Conditions
Mg^{2+}	1~10 mM	1~20 mM
pH	6.0~9.0	4.0~11.0
Temperature	20~40℃	0~50℃
DTT	0~100 mM	＞0 mM
β-Mercaptoethanol	0~100 mM	＞0 mM
Monovalent Cations (eg. K^+, Na^+)	0~40 mM	0~150 mM
PO_4^{3-}	0~10 mM	0~100 mM

* Universal Nuclease activity is ≥90% under the optimum conditions, and the enzyme activity is ≥15% under valid conditions.

B

Lentivirus Packaging Quality Control Solution

In lentivirus packaging, universal nuclease residue detection and host residual DNA detection are required. After lentivirus packaging, the lentivirus titer, microorganisms, mycoplasma, etc. need to be detected. TransGen Biotech provides lentivirus titer detection by ELISA, mycoplasma detection, SV40LTA and E1A residual DNA detection, nuclease residue detection and other products.

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Lentivirus Titer Detection by ELISA

The relevant guidelines such as the "Key Points for Quality Control and Testing Research and Non-clinical Research of CAR-T Cell Therapy Products" and the "Technical Guidelines for Pharmaceutical Research and Evaluation of Gene Therapy Products" issued by National Institutes for Food and Drug Control and CDE clearly point out: The number of tiral particle is determined by measuring p24 content. ELISA detection kit for P24 provided by TransGen Biotech with wide detection range, high precision and high sensitivity, which can effectively detect lentiviral titer in quality control.

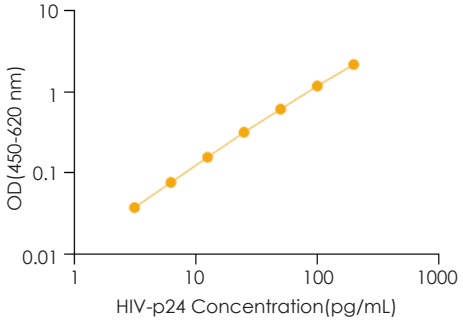
HIV-p24 ELISA Kit (NE107)

Features

- Wide detection range: 3.13~200 pg/mL.
- High accuracy: Recovery rate of 85 - 115%.
- High sensitivity: 1.0 pg/mL.
- High precision: CV% (intra-assay) <10%, CV% (inter-assay) <15%.

Data

Standard curve



Relative deviation ≤ 15%, sample recovery rate of 85%~115%.

Sample	1	2	3
Theoretical Concentration (pg/mL)	100	50	25
Average Detection Concentration (pg/mL)	94.6	46.8	21.9
Relative Deviation (%)	5.9	7.5	8.2
Recovery (%)	94.6	93.6	87.6

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CV% (inter-assay) ⩽ 15%

Sample	4	5	6
Theoretical Concentration (μg/mL)	9.5	0.33	0.21
Average Detection Concentration (μg/mL)	9.23	0.34	0.19
CV (%)	8.9	11.5	14.8

Unaffected by culture medium and buffer matrix

Sample	RPMI 1640+10% FBS				DMEM+10% FBS				PBS, pH7.4+10% FBS			
Standard Concentration (pg/mL)	0	25	50	100	0	25	50	100	0	25	50	100
Average Detection Concentration (pg/mL)	< 1	23.1	45.8	106.6	< 1	24.7	46.9	103.4	< 1	21.8	51.3	99.5
Relative Deviation (%)	—	92.6	97.7	102.8	—	94.5	103.9	98.2	—	93.9	95.1	100.5

Comparison of qRT-PCR and ELISA methods for the detection physical titer

The Number of Virus Particles (LP/mL) / Detection Method / Sample	ELISA	qRT-PCR
7	7.27×10^{7}	9.17×10^{7}
8	4.19×10^{7}	8.35×10^{7}
9	7.67×10^{7}	2.37×10^{7}
10	5.82×10^{7}	5.10×10^{7}
Result	The titers measured by both methods are within an order of magnitude (107), differing by 1 to 3.5 times.	

Comparison of ELISA detection of physical titer and qPCR detection of biological titer

Detection Method	ELISA	qPCR
The Number of Virus Particles (LP/mL)	1.71×10^{11}	—
Integration Efficiency (IU/mL)	—	2.91×10^{9}
Result	ELISA product: NE107 qPCR product: FV201 59 virus particles ≈ 1 IU.	

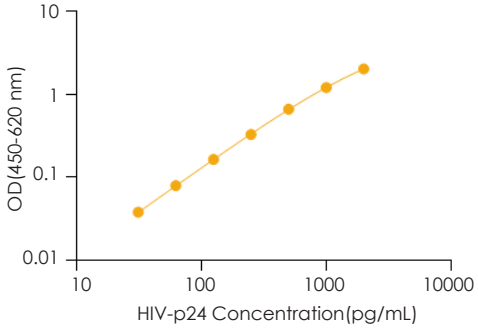
HIV-p24 ELISA Kit (One-step) (NE109)

Features

- Wide detection range: 31.3~2000 pg/mL.
- High accuracy: Recovery rate of 80 - 120%.
- High sensitivity: 10.0 pg/mL.
- High precision: CV% (intra-assay) ≤10%, CV% (inter-assay) ≤15%.
- Easy to use: Just add sample once, and the entire incubation time only takes 70 minutes.

Data

Standard curve



Relative deviation ≤ 15%, sample recovery rate of 80%~120%

Sample	1	2	3
Theoretical Concentration (pg/mL)	1500	400	100
Average Detection Concentration (pg/mL)	1375	437	87
Relative Deviation (%)	4.7	6.3	7.9
Recovery (%)	92%	109%	87%

CV% (inter-assay) ≤15%

Sample	4	5	6
Theoretical Concentration (ng/mL)	275	46	28
Average Detection Concentration (ng/mL)	256	49	32
CV (%)	6.8	9.1	11.6

Mycoplasma Detection

"In the considerations for pharmaceutical research and application materials for clinical trial of cell therapy products", it is pointed out that the quality standards for viral and cellular vectors should include mycoplasma, among others. Some species of mycoplasma are pathogenic to humans and animals, posing certain biosafety risks. Therefore, mycoplasma testing is a mandatory requirement stipulated by the biopharmaceutical industry. TransGen Biotech Biotech provides two types of mycoplasma detection reagents based on qPCR and luciferase methods, which are simple to operate, highly sensitive, and accurate.

TransDetect® qPCR Mycoplasma Detection Kit (FM321)

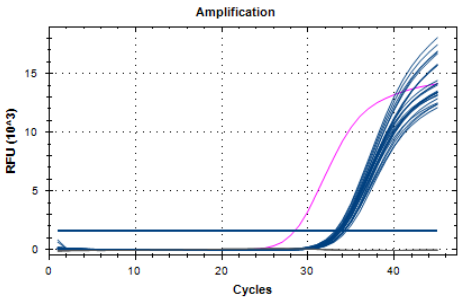
Features

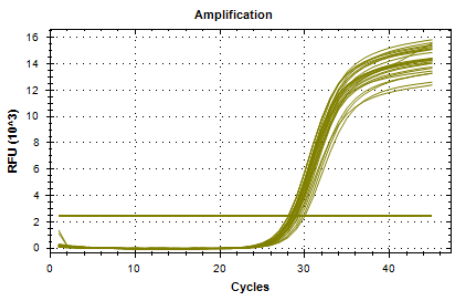
- Compliant with the requirements of nucleic acid amplification technology (NAT) for mycoplasma detection as stipulated in the European Pharmacopoeia (EP 2.6.7) and the Japanese Pharmacopoeia (JP G3).
- Wide coverage: Validated for the detection of 13 strains of mycoplasma and plasmid DNA, with database comparisons covering at least 129 species of mycoplasma DNA sequences.
- High sensitivity: Validated mycoplasma strains meet 95% detection requirements, with a detection limit of up to 10 CFU/mL; plasmid standards can reach 1 copy/μL.
- High specificity: No detection interference from commonly occurring bacteria or production cell genomes, among others.
- dUTP/UDG contamination prevention system: Effectively prevents contamination of PCR products, ensuring accurate data.
- High stability: Product can undergo at least 15 freeze-thaw cycles without significant impact on performance.
- Broad instrument compatibility: Compatible with mainstream qPCR instruments, ensuring consistent detection results.

Data

High sensitivity, detection limit is 10 CFU/mL

Mycoplasma Species	10 CFU/mL Detection Rate
Mycoplasma gallisepticum	24/24
Mycoplasma synoviae	24/24
Mycoplasma arginini	24/24
Spiroplasma citri	24/24
Mycoplasma fermentans	24/24
Acholeplasma laidlawii	24/24
Mycoplasma hyorhinis	24/24
Mycoplasma orale	24/24
Mycoplasma pneumoniae	24/24
Mycoplasma salivarium	24/24

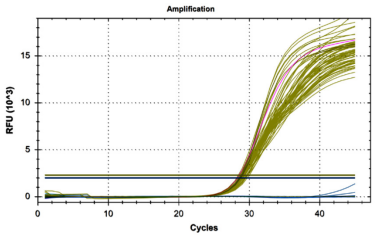




- 10 CFU/mL Fermentation-derived mycoplasma standards
- NTC, NSC (Negative sample extraction product)
- Positive control
- Internal reference

High specificity, no cross-reaction with non-mycoplasma species

Prokaryotic Species	Prokaryotic Species	Eukaryotic Species
Lactobacillus acidophilus	Escherichia coli	Pichia pastoris
Streptococcus pneumoniae	Mycobacterium smegmatis	Chinese Hamster Ovary
Streptococcus salivarius	Staphylococcus aureus	Sp2/0 cell (mouse)
Enterococcus faecalis	Rhodococcus erythropolis	293T cell
Bacillus subtilis	Micrococcus luteus	Sf9 cell (Spodoptera frugiperda)



- Internal reference signal from all samples
- Mycoplasma signal for each non-mycoplasma species
- Mycoplasma signal for positive controls

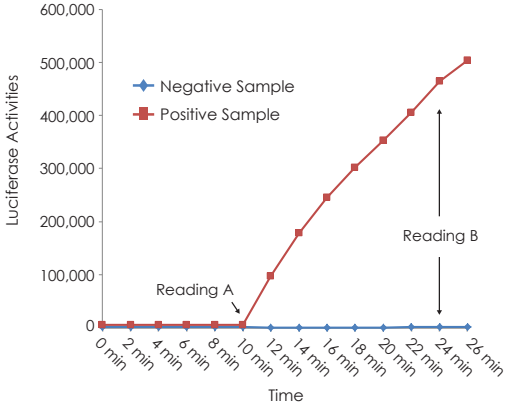
TransDetect® Luciferase Mycoplasma Detection Kit (FM301)

Features

- Detecting mycoplasma that are truly biologically active.
- Using fluorescence to detect mycoplasma contamination, with high accuracy.
- High sensitivity, easy operation, time-saving, only takes 25 minutes.

Data

High sensitivity, accurate detection of 1:125 diluted original sample



	TransGen	Company L
Original sample	+	+
1:5 dilution	+	+
1:25 dilution	+	+
1:125 dilution	+	+/-
1:625 dilution	+/-	-
1:3125 dilution	-	-
Negative control	-	-

+	Sample contaminated with mycoplasma
+/-	Need to repeat the test to confirm
-	Samples not contaminated with mycoplasma

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SV40LTA and E1A Residual DNA Detection

When using the 293 cell line for lentiviral packaging, residual 293 cell line DNA fragments will not only reduce the effectiveness of biological products, but also pose risks of infectivity and tumorigenicity. From the perspective of effectiveness requirements and safety of biological products, the detection of residual DNA in 293 cells is crucial.

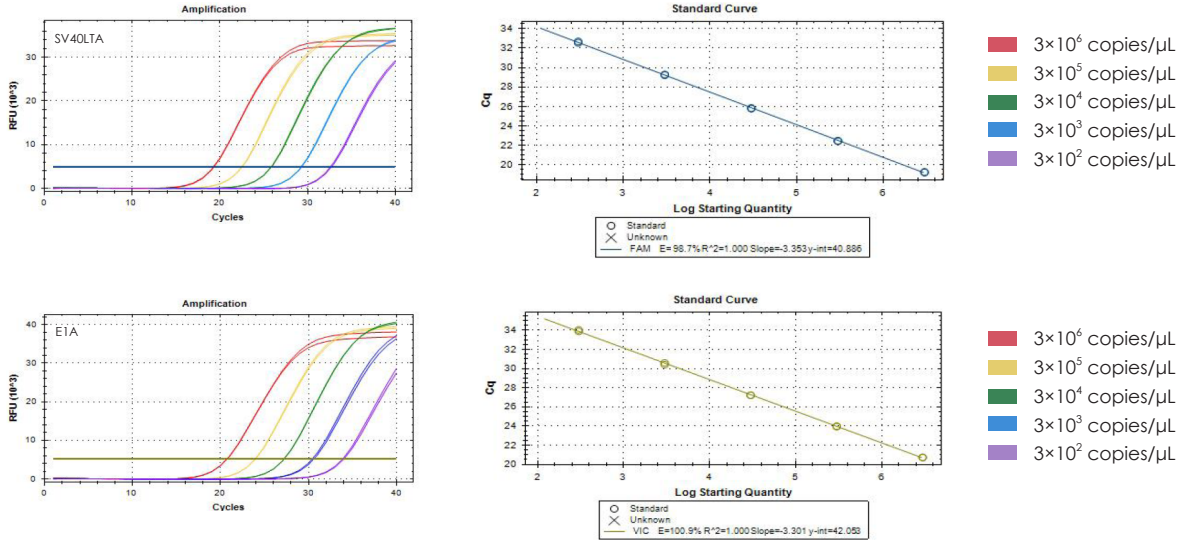
PerfectStart® SV40LTA & E1A DNA Quantification Kit (DH151)

Features

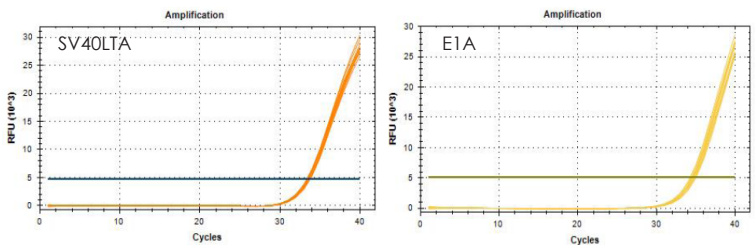
- 3 blocking antibodies, with high specificity, high sensitivity, high amplification efficiency and wide linear range.
- Specially optimized qPCR reaction buffer to provide higher extension speed, sensitivity and specificity.
- The use of UDG enzyme and dUTP can effectively prevent carry-over contamination of PCR products to ensure accurate data.
- High specificity: No cross-reaction with different cell lines.
- High accuracy: The DNA standard deviation is < 5%.
- Strong durability: DNA fragmentation will not affect the test results, compatible with a variety of qPCR instruments.
- High stability: Reagents have been tested for repeated freezing and thawing for 7 cycles, stored at 4°C, room temperature and 37°C for 8 days.

Data

Wide linear range(3×10^2 -3×10^6 copies/μL)



Limit of quantitation as low as 150 copies/μL



Limit of quantitation (150 copies/μL) amplification curve

Detection items	Concentration (copies/μl)	Average (copies/μl)	Standard deviation	CV
SV40LTA	300	320.17	25.42	7.93%
	150	151.68	11.71	7.72%
E1A	300	306.24	28.7	9.37%
	150	157.77	15.06	9.55%

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Detection of Nuclease Residue

After nuclease removes nucleic acid residues, it itself cannot remain as a recombinant protein. TransGen Biotech provides Universal Nuclease ELISA Kit for the detection and quantitative of nucleases.

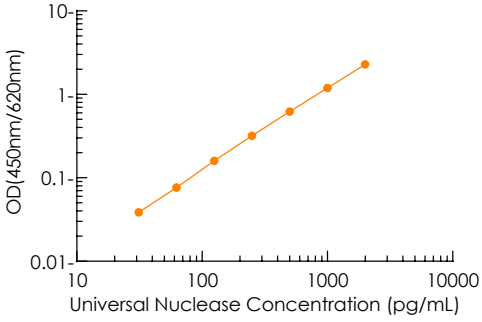
Universal Nuclease ELISA Kit (NE110)

Features

- High sensitivity and wide linear range: LOD is 7.97 pg/mL, linear range is 31.25~2000 pg/mL.
- High specificity and high accuracy: No non-specific binding to a variety of common samples, strong anti-interference ability.
- High stability: Good intra-batch and inter-batch precision.
- Good compatibility: Suitable for quantitative detection of various nucleases.

Data

Standard curve



Relative deviation ≤ 15%, sample recovery rate of 80%~120%

Sample	1	2	3
Theoretical Concentration (pg/mL)	2000	500	62.5
Average Detection Concentration (pg/mL)	1925.9	532	58.03
Relative Deviation (%)	7.55	2.45	10.8
Recovery (%)	96.3	106.4	92.8

CV% (inter-assay) ≤15%

Sample	5	6	7
Theoretical Concentration (pg/mL)	400	200	100
Average Detection Concentration (pg/mL)	380.3	178.4	80.1
CV (%)	5.6	6.2	8.8

CAR-T Cell Expansion Solution

CAR-T cell therapy involves using a patient's own immune T cells to attack cancer cells. The process includes collecting peripheral blood and isolating T cells, activating T cells, transfecting CAR molecules, culturing and expanding CAR-T cells in vitro, quality control of CAR-T cells and reinfusion of CAR-T cells. TransGen Biotech provides human peripheral blood lymphocyte separation solution, T cell serum-free medium, T cell activation reagent in vitro and other products to facilitate the development of CAR-T cell therapy.

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Human Peripheral Blood Lymphocyte Separation Solution

The isolation of human peripheral blood lymphocytes is the first step in the CAR-T cell production process. It is crucial to obtain lymphocytes with good shape, high viability and large number. TransGen Biotech offers peripheral blood lymphocyte separation solution with high separation efficiency and high cell viability, which has been classified as a Class I medical device by the National Medical Products Administration (NMPA), fully meeting customer needs.

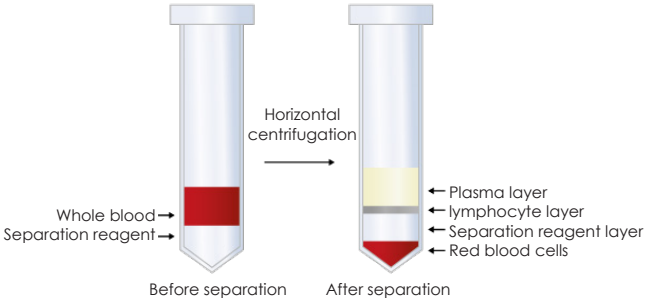
Human Peripheral Blood Lymphocyte Separation Solution (FB102)

Features

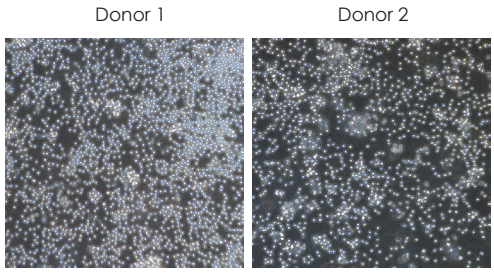
- The osmotic molarity of this solution is similar to that of human peripheral blood cells.
- The quantity of separated lymphocytes is greater than 1×106 cells/mL whole blood.
- The post-separation viability of lymphocytes > 95%.
- This product is ready-to-use, and the lymphocytes separated under sterile conditions can be used for in vitro culture and immunological assays.

Data

Separation diagram



The cell morphology is well preserved



The yield of cells is greater than 1×10^6 cells/mL whole blood, with a viability of over 95%.

Testing Parameters	Donor 1	Donor 2	Donor3	Donor 4	Donor 5
Number of cells harvested per mL of whole blood	1.51×10^6	1.78×10^6	1.12×10^6	1.33×10^6	1.5×10^6
Lymphocyte viability	98.22%	98.59%	97.08%	98.41%	99.28%

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T Cell Serum-Free Medium

China Food and Drug Administration (cFDA) issued the "Technical Guiding Principles for Research and Evaluation of Cell Therapy Products (Trial)", which gave clear instructions on whether serum can be used in cell culture processes: the use of serum from any source, including human serum, should be avoided as much as possible. If necessary, the applicant should provide sufficient research information to explain the necessity of using serum in the cell culture process. For reasons of safety, effectiveness, and quality control of cell therapy products, serum-free medium has become the first choice for cell culture. TransGen Biotech provides T cell serum-free medium and T cell activation reagent to support the rapid expansion and culture of T cells.

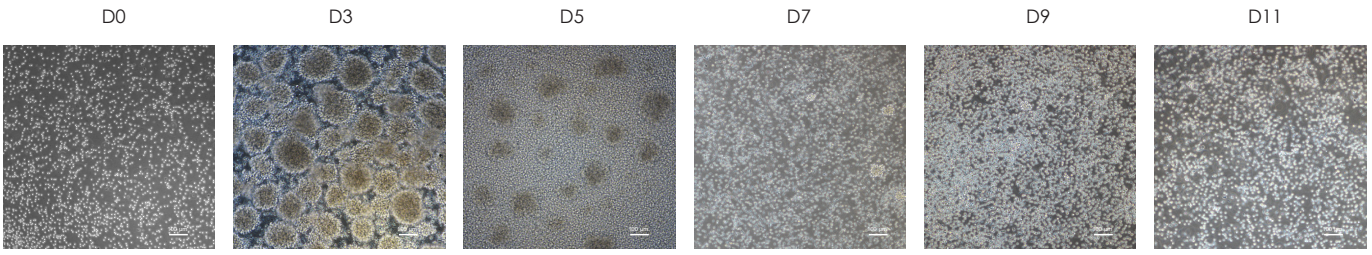
ArtMedia® Human T Cell Serum-Free Medium (MT101 (with phenol red)/MT102 (without phenol red))

Features

- Independent research and development.
- Serum-free, xeno-free and chemically defined.
- Supports rapid expansion and high-density culture of T cells.
- A variety of T cell activation methods (antibody soluble method, antibody coating method, antibody conjugated magnetic bead method) is optional.
- Produced and managed in accordance with GMP standards.

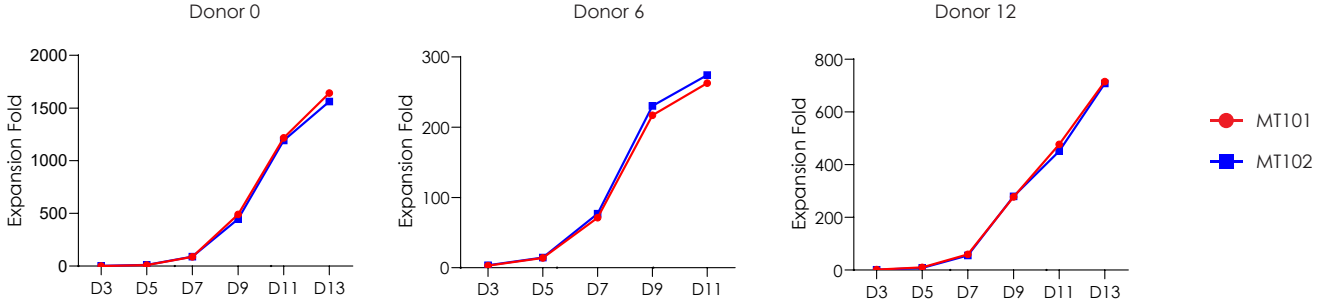
Data

Good cell morphology



Scale: 100 μm

Strong proliferation capability, with 200-2000 fold expansion in 11-13 days.



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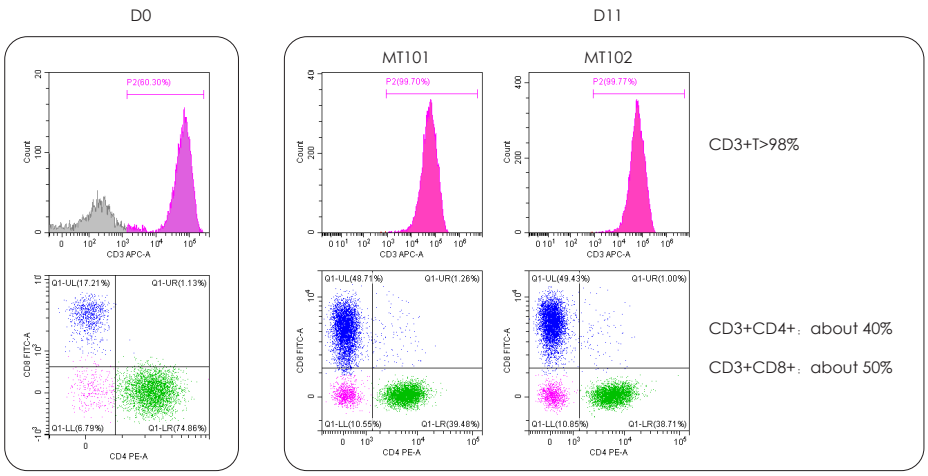
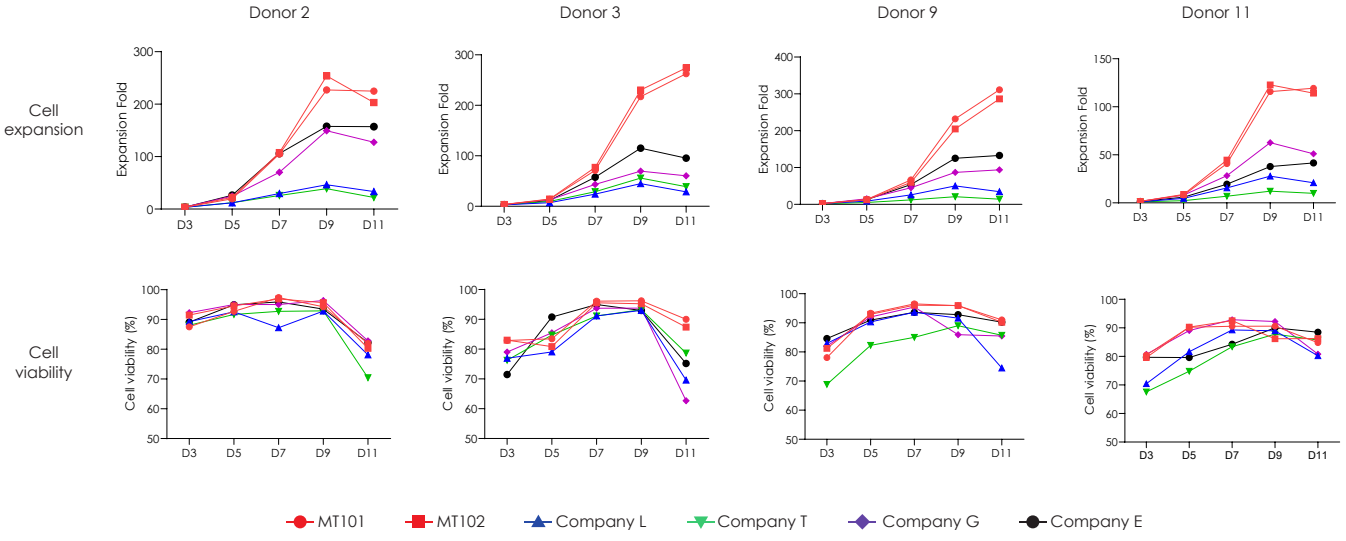
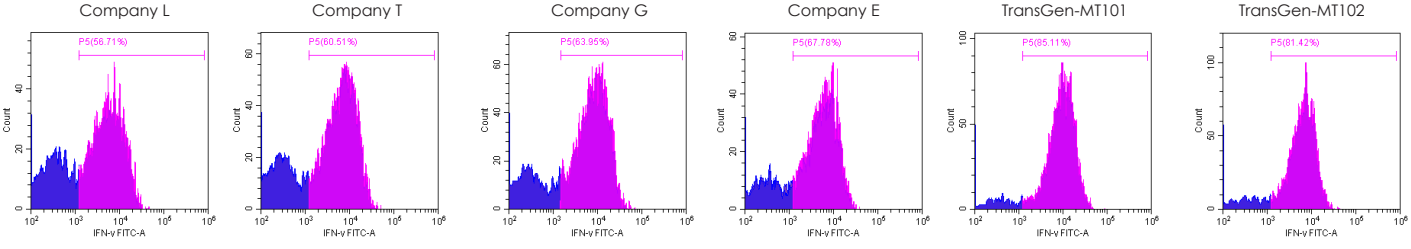
The proportion of CD3+ T cells is above 98%. Maintain the proportion of CD4+ and CD8+ T cells.



Strong proliferation capacity, high cell viability



Secrete more IFN-γ and have stronger tumor killing function



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Serum-Free Cell Cryopreservation Medium

Cells expanded in large quantities in vitro need to be frozen for long-term storage. Studies have shown that the quality of cryopreserved cells, the composition of the cryopreservation solutions, the freezing protocol, the freezing time and the thawing method, etc., will affect cell viability. TransGen Biotech provides a variety of serum-free cell cryopreservation solutions with high safety, high cell revival efficiency, simple operation, and meets the industrial needs of cell cryopreservation.

TransStem® Chemically Defined Xeno-free Cell Cryopreservation Medium-Protein Free (MC102)

Features

- Safety: Serum-free, xeno-free, protein-free, chemically defined.
- High efficiency: Significantly enhances cell revival rates, with revival rates exceeding 90% for mesenchymal stem cells.
- Stability: Does not affect the phenotype and growth status of stem cells, while maintaining their multipotency.
- Convenience: Ready-to-use product, no need for programmed cooling, can be directly transferred to liquid nitrogen for long-term storage after overnight storage at -80°C.
- Reliability: Suitable for the cryopreservation of various cells, including stem cells, immune cells, tumor cells, etc.

Differences from traditional serum-containing cell cryo-preservation solutions

Differences	Traditional serum-containing cell cryopreservation solution	Serum-free, protein-free cell cryopreservation solution (containing DMSO)
Serum	Yes	No
Protein	Yes	No
Clear chemical composition	Uncertain	Certain
Cooling program	Require	Not required
Cryopreservation solution preparation	Use immediately after preparation	Ready to use, store at 4℃
Revival rate	Normal	Outstanding (support high concentration cryopreservation)
Difference between batches	High	Low
Risk of carrying virus	Yes	No
Applicable to clinical research	No, containing animal serum and protein	Yes, clear chemical composition, no animal-derived substances, protein-free

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TransStem® Chemically Defined Xeno-free Cell Cryopreservation Medium III-DMSO Free, Protein Free (MC131) (Completely Using Pharmaceutical Grade Materials)

Features

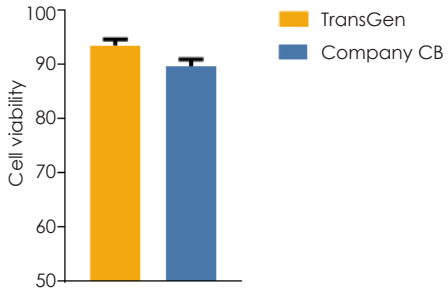
- Safety: Serum-free, xeno-free, protein-free, DMSO-free, clear chemical component, completely using pharmaceutical grade materials, with complete toxicity test.
- High efficiency: Effectively improves cell recovery viability, with over 90% recovery rate for most cells (including mesenchymal stem cells and immune cells).
- Stability: Does not affect stem cell phenotype and growth status, while maintaining stem cell pluripotency.
- Convenience: Ready-to-use product, no programmed cooling required, can be directly transferred to liquid nitrogen for long-term storage after overnight storage at -80°C.
- Reliability: Suitable for cryopreservation of various cells including stem cells, immune cells, tumor cells, and transformed cell lines.

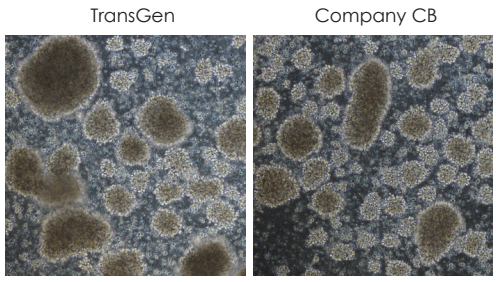
Data

Differences from traditional serum-containing cell cryopreservation solutions

Differences	Traditional serum-containing cell cryopreservation solution	Serum-free, protein-free, DMSO-free cell cryopreservation solution
Serum	Yes	No
Protein	Yes	No
DMSO	Yes	No
Clear chemical composition	Uncertain	Certain
Cooling program	Require	Not required
Cryo-preservation solution preparation	Use immediately after preparation	Ready to use, store at 4℃
Revival rate	Normal	Outstanding (support high concentration cryo-preservation)
Difference between batches	High	Extremely low
Risk of carrying virus	Yes	No
Apply for pharmaceutical excipients	Apply for pharmaceutical excipients	Apply for pharmaceutical excipients
Applicable to clinical research	No, containing animal serum and protein	Yes, clear chemical composition, xeno-free, protein-free

CD3+T cells cryopreservation





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T Cell Activation Reagent

It is the most widespread method for T cell activation and expansion in vitro that using CD3 and CD28 antibodies to stimulate T cells, relevant cell growth factors to activate T cells. TransGen Biotech provides CD3, CD28 monoclonal antibodies and IL-2 protein produced and managed according to GMP standards, with high performance, stable and cell-friendly.

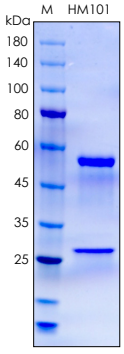
Features

- High purity (>98%).
- High activity and stability.
- Low endotoxin (<0.1 EU/μg).
- High safety: Produced by genetically engineered cell lines, serum-free and xeno-free.
- Pharmaceutical excipient grade packaging.

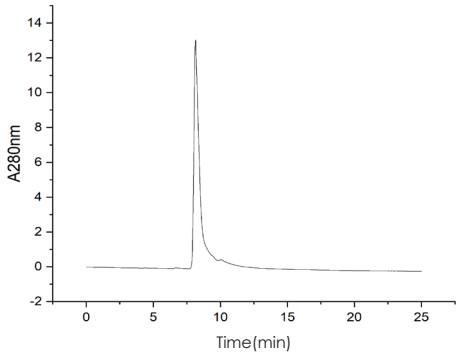
Anti-human CD3 mAb (HM101)

Data

Purity: >95% by SDS-PAGE



Purity: >95% by SEC-HPLC



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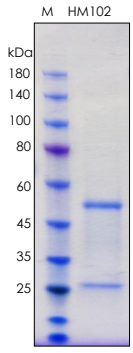
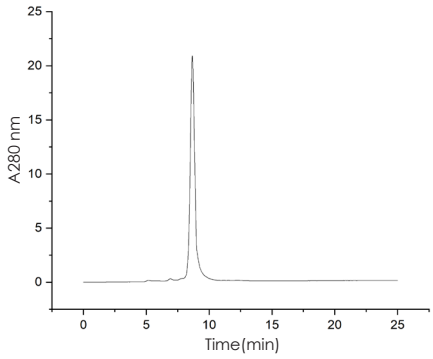
Anti-human CD28 mAb (HM102)

Data

Purity: >95% by SDS-PAGE



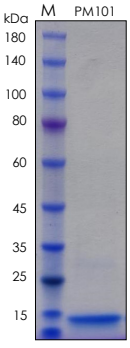
Purity: >95% by SEC-HPLC



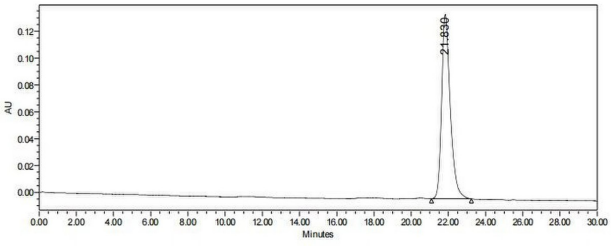
Recombinant Human IL-2 Protein (PM101)

Data

Purity: >98% by SDS-PAGE



Purity: >98% by SEC-HPLC



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D

CAR-T Cell Quality Control Solution

The quality of CAR-T cells directly determines the effectiveness of clinical therapy, hence rigorous testing is required before CAR-T cell infusion into patients. Quality assessment of CAR-T cells typically includes safety, purity, activity, and functionality testing. TransGen Biotech provides products for purity and cytotoxicity functional testing.

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CAR-T Cell Purity Detection (Subpopulation Ratio Detection)

Currently, most CAR-T cells are a heterogeneous population of T cells expressing CAR. Studies have shown that the therapeutic efficacy of CAR-T cells is related to the ratio, differentiation, activation, and functional status of T cell subpopulations (CD4+ or CD8+). Therefore, it is crucial to establish a more favorable cell composition and T cell phenotype during the production process.Flow cytometry is an important method for determining the composition of CAR-T cells, aiding in the selection of different ratios of T cell subpopulations to achieve more effective and personalized therapy. TransGen Biotech provides a variety of fluorescently labeled CD3, CD4, and CD8 flow cytometry antibodies, facilitating T cell subpopulation analysis.

Anti-Human CD3, FITC/PE/APC (HF151/HF152/HF154)

Anti-Human CD4, FITC/PE/APC (HF141/HF142/HF144)

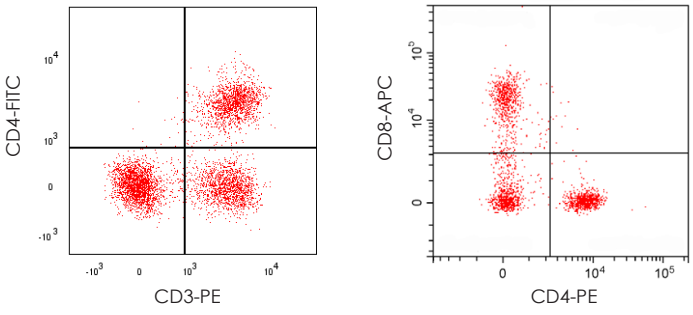
Anti-Human CD8a, FITC/PE/APC (HF161/HF162/HF164)

Features

- Monoclonal antibodies with strong specificity and high sensitivity.
- Directly conjugated primary antibodies, no need for self-conjugation, simple and time-saving.
- Direct binding to the target, unaffected by endogenous antibodies, reducing non-specific adsorption.
- Available in various fluorescent labels such as APC, PE, FITC, etc.
- Stable quality with good repeatability.

Data

PBMC stained with CD3/CD4/CD8 flow cytometry antibodies. Three groups of cells are distinguishable.



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CAR-T Cell Cytotoxicity Functional Detection

The proliferation activity and cytotoxicity of CAR-T cells are crucial factors in evaluating their therapeutic effectiveness. The proliferation activity allows CAR-T cells to exert sustained therapy, while cytotoxic activity enables CAR-T cells to rapidly target and kill tumor cells. TransGen biotech provides products such as cytokine ELISA detection, luciferase reporter gene activity detection, cell viability assays, cell proliferation, and toxicity assays, facilitating research on CAR-T cell cytotoxicity functionality.

ELISA Detection

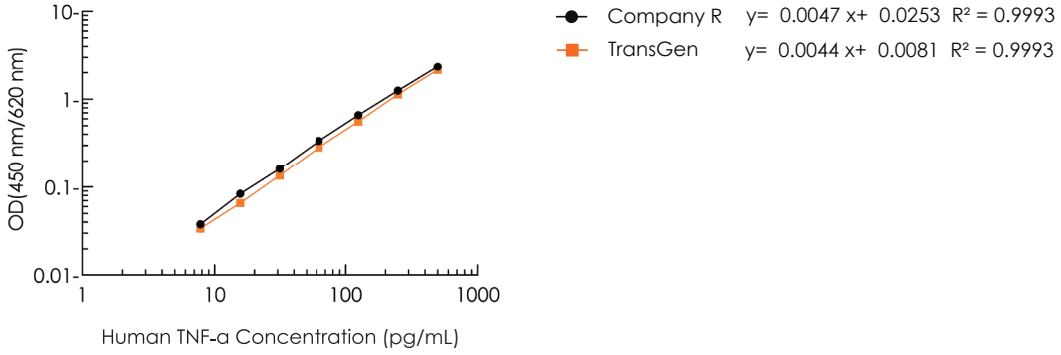
Human TNF-a ELISA Kit (NE104)

Features

- Utilizes high-affinity antibodies, ensuring strong specificity.
- High sensitivity (pg level) with a wide linear range.
- Pre-coated antibodies facilitates simple and convenient operation.

Data

Excellent linearity of standard curve



ELISA Series of Products

Product Name	Cat. No.	Specification	Sensitivity	Standard Curve Range	Sample Type	Sample Volume
Human IL-6 ELISA Kit (three steps)	NE101	96 T	2.7 pg/mL	7.81-500 pg/mL	Serum, Plasma, Cell Culture Supernatant	100 µL
Human IL-10 ELISA Kit (four steps)	NE102	96 T	3.5 pg/mL	7.81-500 pg/mL	Serum, Plasma	100 µL
Human IL-12 ELISA Kit (four steps)	NE103	96 T	2.0 pg/mL	4.69-300 pg/mL	Serum, Plasma	100 µL
Human TNF-a ELISA Kit (four steps)	NE104	96 T	3.0 pg/mL	7.81-500 pg/mL	Serum, Plasma, Cell Culture Supernatant	100 µL
Human GM-CSF ELISA Kit (three steps)	NE105	96 T	2.0 pg/mL	7.81-500 pg/mL	Serum, Plasma, Cell Culture Supernatant	100 µL
Human FGF basic ELISA Kit (four steps)	NE106	96 T	1.5 pg/mL	2.5-160 pg/mL	Serum, Plasma, Cell Culture Supernatant	100 µL
Human IL-1β ELISA Kit (three/four steps)	NE108	96 T	2.0 pg/mL	3.91-250 pg/mL	Serum, Plasma, Cell Culture Supernatant	100 µL

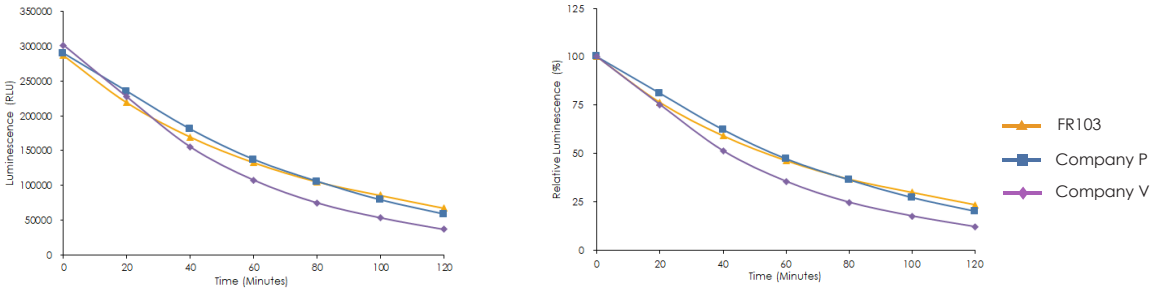
TransDetect® Bio-Luc Firefly Luciferase Reporter Assay Kit (FR103)

Features

- Simple operation: One-step procedure without requirement of washing or cell collection step.
- Strong stability: Up to 1 hour half-life.
- Rapid detection: All operations can be completed in 5-10 minutes.
- Pre-validation according to ICH guidelines: Parameters such as repeatability, accuracy, precision, linearity, specificity, etc., have been validated following ICH guidelines.

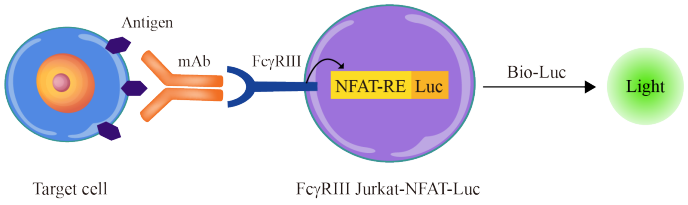
Data

Detection half-life for up to 1 hour.



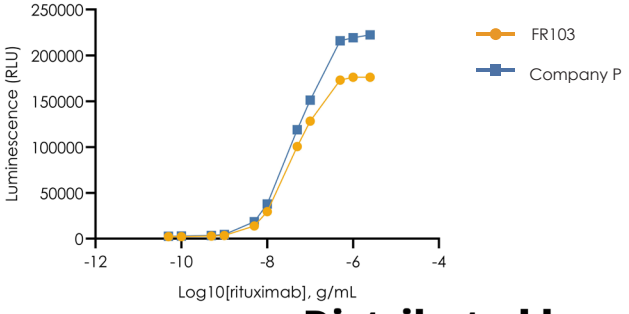
Application example: Antibody-dependent cell-cytotoxicity assay - ADCC

Schematic diagram of ADCC detection principle



Test result

After co-culturing FcγRIII Jurkat-NFAT-Luc (Effector Cell) with Raji (Target Cell) and employing TransGen FR103 and Company P products to detect the ADCC activity of Rituximab antibody drug. The results indicate that FR103 product is more suitable for ADCC activity detection.



Product / Indicator	FR103	Company P
Fold	109	121
EC50(μg/mL)	0.043	0.049
Half-Life(min)	83	71

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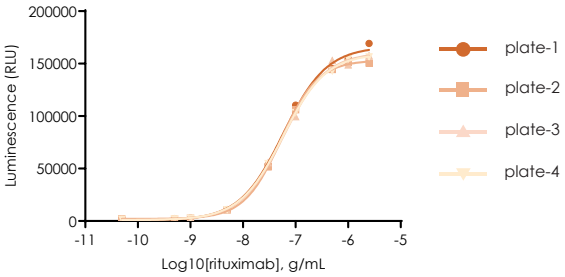
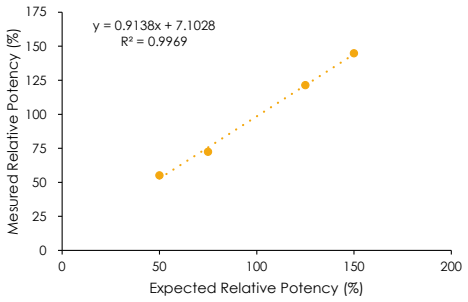
Pre-validation of ICH guidelines

According to the ICH guidelines, the Rituximab ADCC Bioassay model was utilized to validate the repeatability, linearity, precision and accuracy, specificity (Trastuzumab serving as the non-specific antibody) of FR103 in biological activity detection. The results indicate that all parameters are satisfactory.

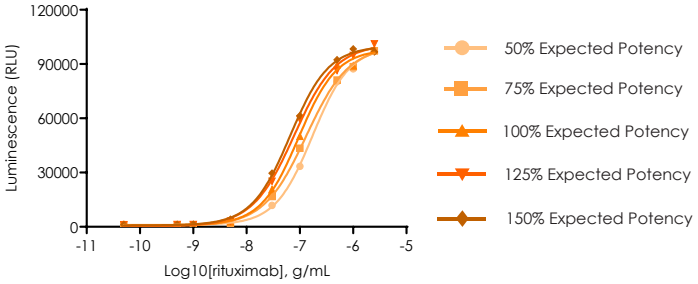
Repeatability



Linearity

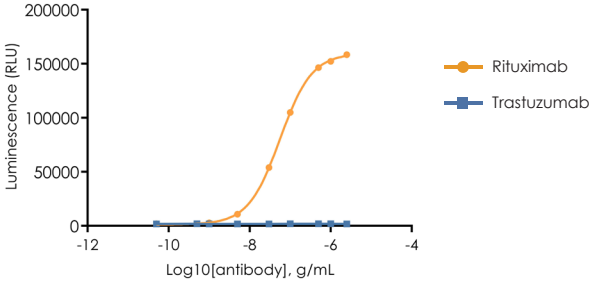


Precision and accuracy



	Expected Relative Potency (%)	Recovery Rate (%)	CV (%)
Accuracy	50	110.3	2.8
	75	96.6	8.8
	100	101.5	9.6
	125	97.2	5.7
	150	96.6	2.5
Intermediate Precision (CV %)	6.2		

Specificity



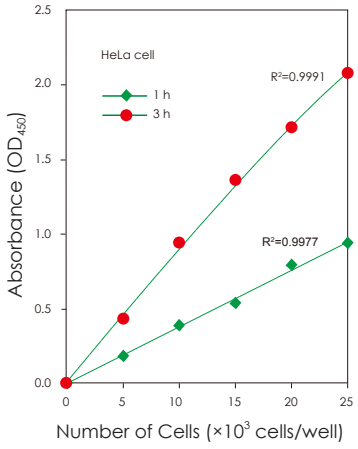
TransDetect® Cell Counting Kit (CCK) (FC101)

Features

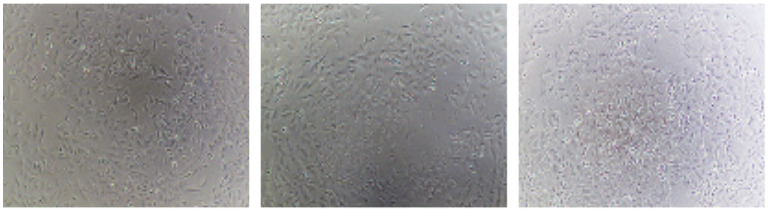
- Fast and sensitive.
- Low cytotoxicity.
- Wide linear range.
- Stable results, good repeatability.

Data

CCK sensitivity test



CCK exhibits low cytotoxicity towards cells



3 hours incubation | 6 hours incubation | 24 hours incubation

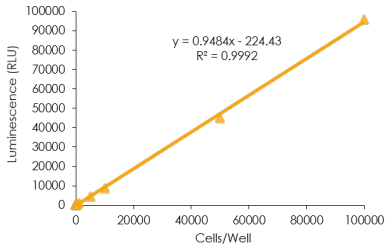
TransDetect® Luminescent Cell Viability Detection Kit (FC401)

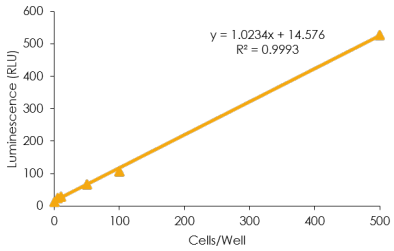
Features

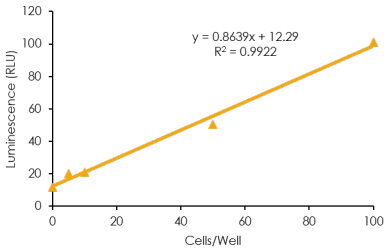
- Simple operation: Single-component. Lysis step can be completed in 10 minutes. Suitable for high-throughput detection.
- High sensitivity: Can detect as low as 5 cells.
- Good stability: Up to 3 hours half-life. Maintains good linearity even after 7 days of storage at room temperature.
- Wide linear Range: Shows excellent linearity from 5 to 100,000 cells.

Data

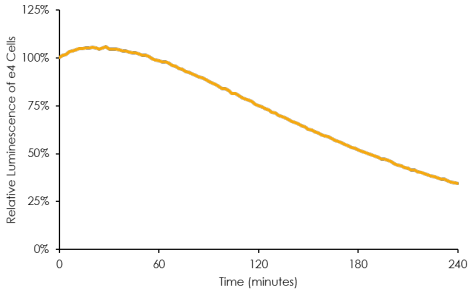
Wide linear range: capable of detecting 5-100,000 cells, with high sensitivity enabling detection of as few as 5 cells.





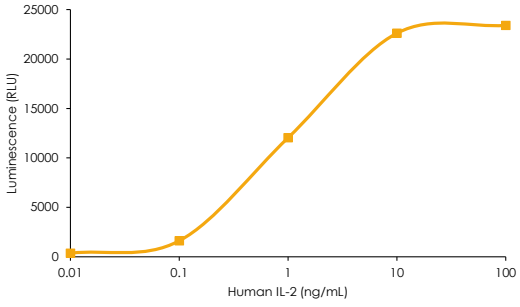


Stable performance with a half-life of up to 3 hours.

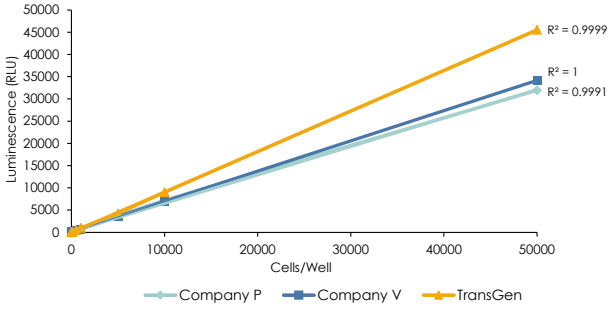


Application example - activity detection of cytokines

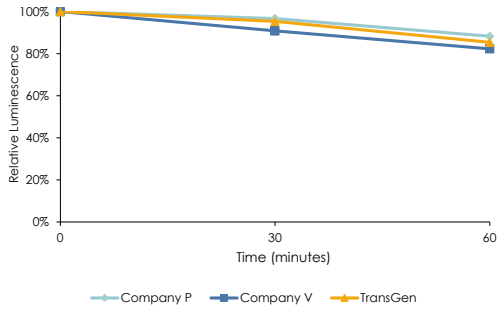
Using TransGen products to detect the biological activity of recombinant human IL-2. The proliferation of CTLL-2 cells was examined under stimulation with different concentrations of IL-2 (PM101).



Fluorescence values are higher within the range of 5-50,000 cells, showing excellent linearity.



Stable performance with a long half-life.



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Version 07-01-2025