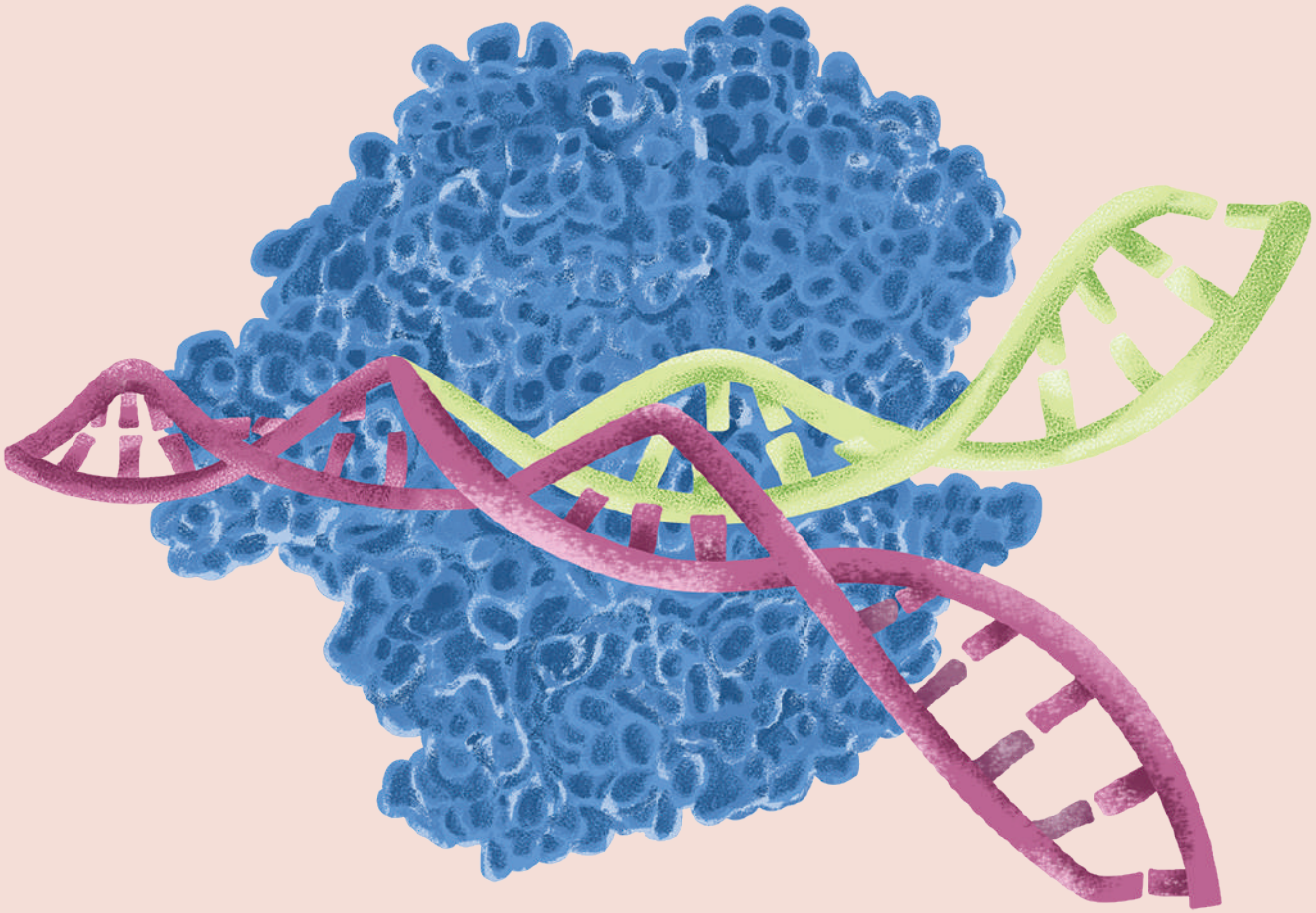
KACTUS

Gene Editing Enzymes

GMP-Grade & Research-Grade



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United States

GMP-Grade Cas9 Nuclease

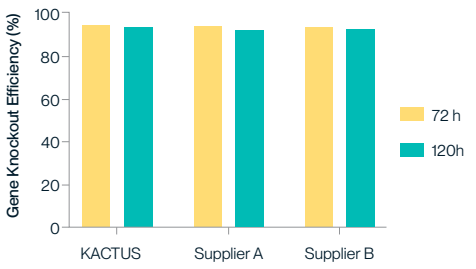
Catalog No. #GMP-CAS-EE109

KACTUS GMP-grade spCas9 is a top-performing CRISPR Cas9 protein, designed to achieve better ribonucleoprotein (RNP) editing efficiency. It is produced under cGMP conditions to meet the standards of Ancillary Materials for Cell, Gene, and Tissue-Based Products. It undergoes rigorous quality control to meet the needs of CGT development and clinical research.

Key Features:

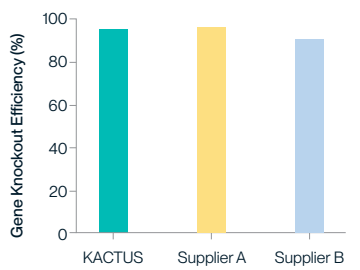
- **Wild-Type spCas9:** *Streptococcus pyogenes* Cas9 protein, engineered and expressed in *E. coli*
- **High Editing Efficiency:** Proven performance across multiple cell types, including primary T cells
- **Regulatory Support:** FDA DMF Type II filing to ease clinical applications
- **Streamlined Workflow:** Seamlessly transition from research-grade to GMP-grade

High Editing Activity



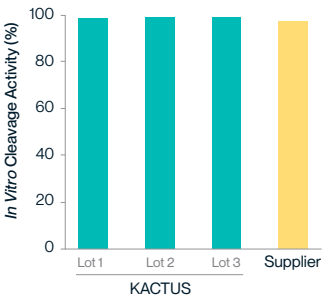
High Gene Knockout in Allogeneic CAR-T

Gene knockout was performed on CAR-T cells on genes related to GvHD and HvGR. KACTUS Cas9 nuclease and two leading suppliers were compared, with the gene knockout efficiency tested at 72h and 120h after electroporation. The performance of KACTUS Cas9 nuclease is comparable to that of leading suppliers.



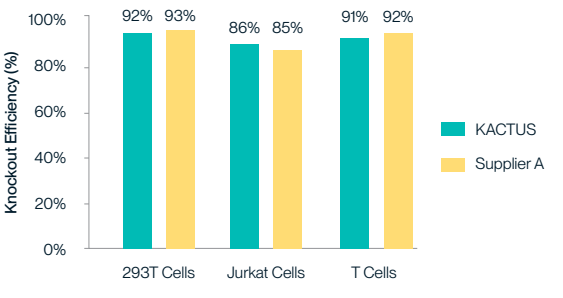
High Gene Knockout in HSCs

Gene knockout was performed on hematopoietic stem cells on genes related to β-thalassemia. KACTUS Cas9 nuclease and two leading suppliers were compared. The performance of KACTUS Cas9 nuclease is comparable to that of leading suppliers.



High *In Vitro* Cleavage Activity

KACTUS spCas9 activity is assessed using an *in vitro* cleavage assay. The results indicate that the activity exceeds 85% and is consistent across different batches.



High Editing Efficacy in Multiple Cell Types

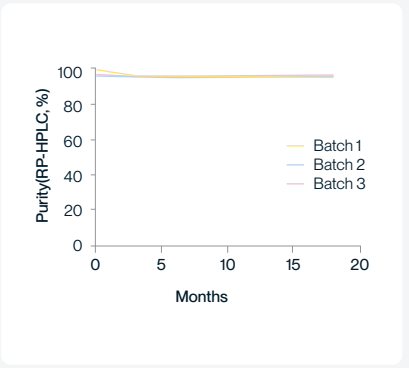
Gene knockout efficiency was analyzed in nucelofected 293T, Jurkat, and T cells using TIDE analysis. Results show > 85% editing efficacy across all three cell types, comparable to a leading supplier.

Quality Control Standards for GMP spCas9 Nuclease

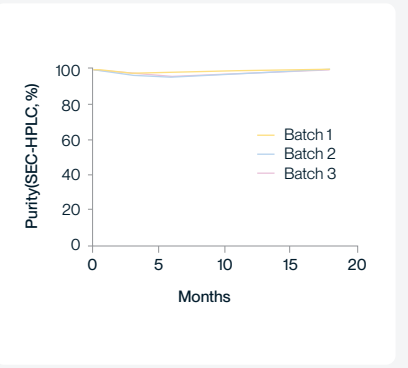
Catalog No. #GMP-CAS-EE109

Parameter		Acceptance Criteria
Appearance		Clear Liquid
Loading Amount		Not less than the amount of identification
Concentration		9.5-11.5mg/mL
Identification		Corresponding to Reference Standard
Purity	RP-HPLC	≥ 95.0%
	SEC-HPLC	Monomer ≥ 95.0%, Aggregates ≤ 5.0%
	NR-CE	≥ 85.0%
	R-CE	≥ 90.0%
Bacterial Endotoxin		≤10.0 EU/mg
Activity		≥85.0%
Residual DNase		Negative
Residual RNase		Negative
Residual Host Cell Protein		≤ 100.0 ng/mL
Residual Host Cell DNA		≤ 3.0 ng/mL
Sterility		No growth
Residual Nickel Salt		≤ 10.0 ppm
pH		7.4±0.5

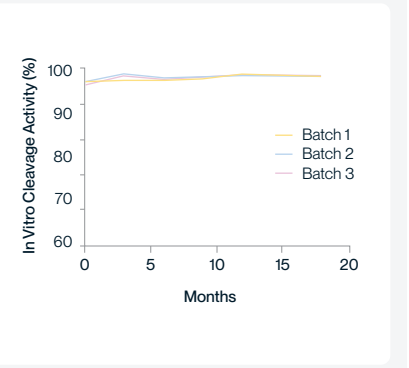
Stability testing



RP-HPLC



SEC-HPLC



In vitro cleavage activity

Long-term stability data (0-18 months) of three batches of GMP-Grade Cas9 nuclease (#GMP-CAS-EE109). As shown in the figure, RP-HPLC and SEC-HPLC are both higher than 95%, indicating that the purity of the product performs well within 18 months; In addition, the *in vitro* cleavage activity showed no obvious downward trend within 18 months, and the activity was stable.

Universal spCas9 Nuclease ELISA Kit (#CAS-MM00B)

KACTUS has carefully developed a highly sensitive spCas9 detection kit (#CAS-MM00B).

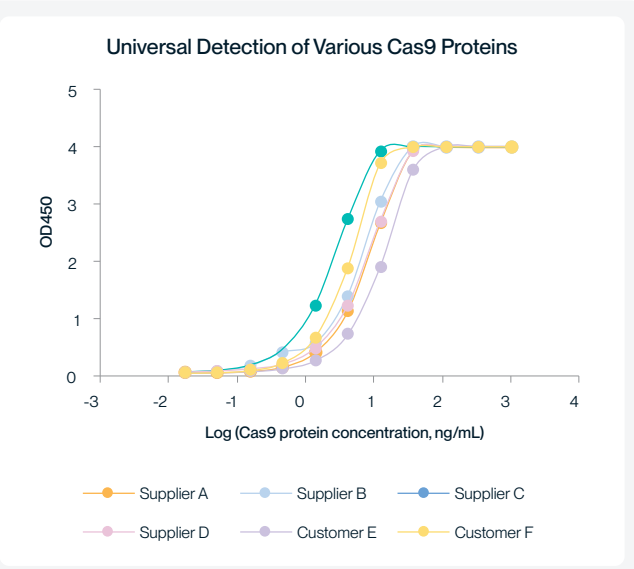
Applications:

- Detection of spCas9 protein residue
- Detection of spCas9 protein expression
- Universal spCas9 detection kit

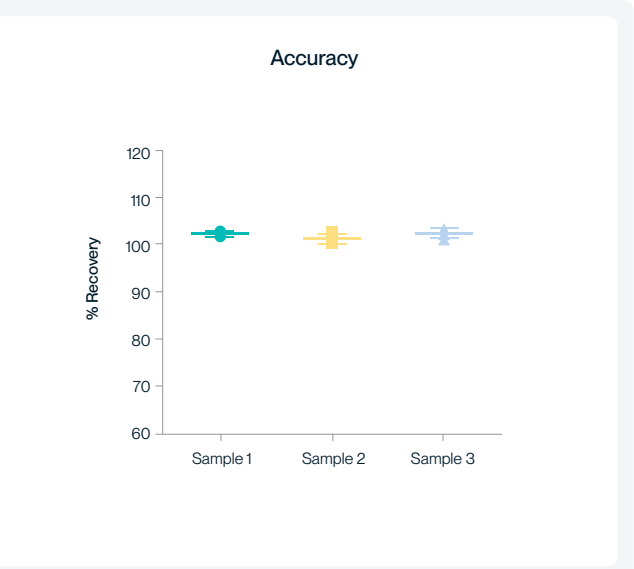
Performance Specifications:

Detection range:	Sensitivity:	Accuracy:
0.25 ng/mL – 16 ng/mL	0.125 ng/mL	CV <10%

Product Data



Detection of various suppliers Cas9 protein using KACTUS Cas9 ELISA Kit. The Cas9 products were serially diluted 3-fold from 1000ng/mL and tested following the KACTUS Cas9 ELISA kit procedure. Results show that the KACTUS Cas9 ELISA kit can be used for the quantification of various vendors' Cas9 protein. The sensitivity for other vendors was 0.2-0.4ng/mL, which is close to the sensitivity for KACTUS Cas9 protein (0.125ng/mL).



The recovery rates of three different concentrations of Cas9 nuclease samples in dilution buffer ranged from 80% to 120%, indicating that the kit has high accuracy in detecting Cas9 nuclease.

Consistency

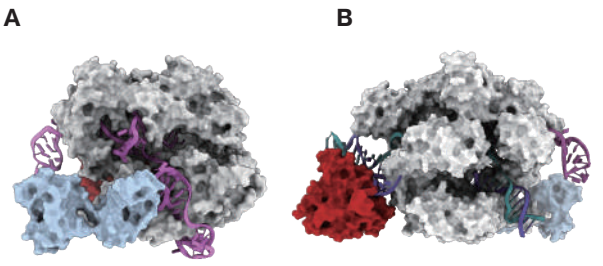
Sample Name	Batch	Number of Replicates	Average Detection Value M (ng/mL)	Coefficient of Variation CV (%)
1 (10ng/mL)	Batch 1	n=10	9.91	1.86%
	Batch 2	n=10	10.64	1.62%
	Batch 3	n=10	10.14	2.30%
2 (2.5ng/mL)	Batch 1	n=10	2.49	1.37%
	Batch 2	n=10	2.47	2.11%
	Batch 3	n=10	2.58	2.58%
3 (0.625ng/mL)	Batch 1	n=10	0.61	2.13%
	Batch 2	n=10	0.58	1.63%
	Batch 3	n=10	0.59	3.10%

A single batch of Cas9 ELISA kit was used to detect Cas9 protein samples with different concentrations. In addition, three batches of kits were tested to assess consistency and reliability.

AccuBase® Cytosine Base Editor

Engineered base editor to minimize off-target effects

AccuBase® is a cytosine DNA base editor engineered by Base Therapeutics and exclusively manufactured by KACTUS. It creatively embeds a deaminase inside the Cas protein to prevent random binding of deaminase to non-target sites, significantly reducing off-target occurrence while still maintaining high editing efficiency. KACTUS has successfully developed a GMP-grade manufacturing process for AccuBase® with high stability, purity, and activity.

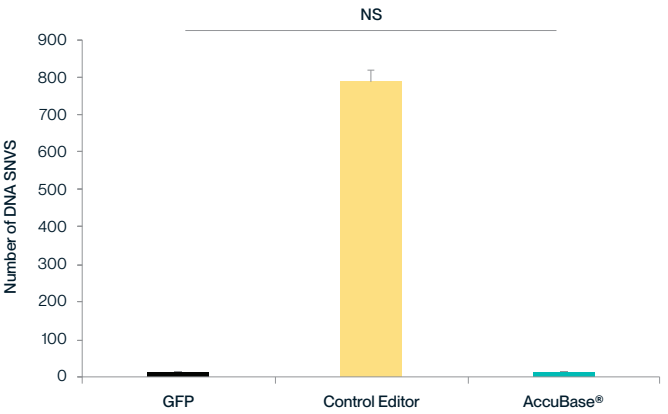


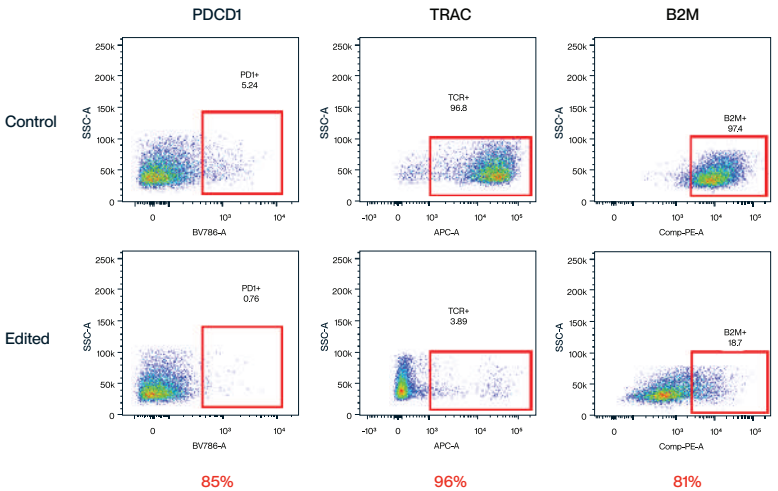
How AccuBase® Works

(A) After AccuBase® forms RNP with sgRNA, when it is not combined with the target DNA, the RNP is in a non-editing state. The deaminase is wrapped inside the Cas9 Nickase protein and will not act on any non-target DNA, greatly reducing risk of off-target effects.
(B) When AccuBase® RNP binds to the target DNA, the AccuBase® conformation changes, causing the deaminase domain to be exposed, effectively editing the bases within the 3-12 window range of the target site (the one far away from the PAM is the 1st position) .

Near-Zero Off-Target Effects

Measurement of off-target effects were analyzed by genome-wide off-target analysis by two-cell embryo injection (GOTI). By leveraging GOTI to measure off-target effects throughout the whole genome, it was shown that compared to the control base editor (with 700 SNVs detected), the number of SNVs obtained after editing with AccuBase® is similar to the negative control group (GFP), suggesting a near-to-zero off-target effect by AccuBase®.





FACS efficacy %
*FACS efficacy % = (positive control-KO group) / positive control *100%*

High Gene Editing Efficiency

AccuBase® RNP was electroporated into activated primary T cells. According to flow cytometry, AccuBase® can efficiently knock out PD1, B2M, and TRAC proteins on the membrane of activated primary T cells at the protein level. For PD1 and B2M, the knockout efficiency exceeded 80%, while the knockout efficiency of TRAC reached 96%.

Learn More

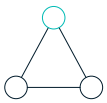
GMP Quality Management System

KACTUS has established a mature quality management system (QMS) and developed comprehensive regulatory documentation in accordance with pharmacuetical Good Manufacturing Practice (GMP) and ISO13485:2016 requirements. Our comprehensive documentation programs undergo continuous updates and improvements to ensure the effectiveness, appropriateness, and adequacy of our quality management system. Quality control is strictly managed at every production stage including raw and auxiliary material inspection, equipment validation, cell strain management, process development and optimization, analytical method development and validation, product packaging, and batch release testing.

KACTUS' quality testing system ensures batch consistency and long-term stability so that our products meet the stringent requirements of drug manufacturing. Our QMS and GMP facilities have passed audits and been recognized by various pharmaceutical companies. We have successfully assisted multiple clients in completing Investigational New Drug (IND) applications.

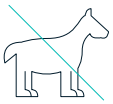
Cell Strain Control

Cell strains are strictly controlled, divided into Master Cell Bank (MCB) and Working Cell Bank (WCB).



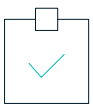
Analytical Method Verification

The analysis method is verified/confirmed by the system to ensure the validity and repeatability of the results.



Free from Animal- Derived Materials

The production process does not use raw and auxiliary materials containing animal sources, equipment, and facilities.

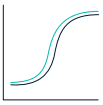


Quality Release Testing

Perform QC testing and release in all directions from central control samples, raw solutions, semi-finished products, and finished products.

Continuous Process Improvement

The process is continuously improved and optimized to become more rational, stable, and feasible.



Batch-to-Batch Consistency

Continuously monitor batch-to-batch differences to ensure batch-to-batch consistency.

Control of Production Variables

The key parameters in the production process are strictly controlled to ensure consistency of products between batches.

Stability Testing

Continuous research on product stability, including influencing factors, tests, accelerated tests, long-term stability studies.

State-of-the-art GMP Manufacturing Facility

KACTUS operates a large GMP-certified manufacturing facility complete with large-scale protein expression and purification systems.

500L Dosing and Cleaning In Place (CIP) System

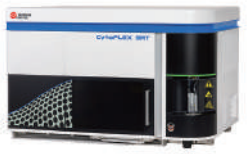
1000L Fermentation Tank

Aseptic filling

Chromatography System

Comprehensive Suite of Analytical Equipment

KACTUS has a comprehensive in-house portfolio of validated analytical equipment. Our verified analytical methods ensure accurate and reliable testing.



CytoFLEX SRT Flow Sorter

Biacore™ T200

1260 High-Performance Liquid Chromatograph

Multifunctional Microplate Reader

Capillary Electrophoresis Instrument

Ordering Information

Catalog #	Product Description	Available Sizes
CAS-EE109	CRISPR Cas9 Protein (Research-Grade)	100µg / 1mg
GMP-CAS-EE109	CRISPR Cas9 Protein (GMP-Grade)	3mg
CAS-MM00B	Cas9 ELISA Kit	96T
CAS-EE111	SpCas9 D10A Nickase	1mg
CAS-EE121	AsCas12a Nuclease	1mg
KD-0001	AccuBase® (Research-Grade)*	200µg / 500µg / 1mg
GMP-KD-0001	AccuBase® (GMP-Grade)*	1mg
ACB-EE00B	AccuBase® ELISA Kit	96T

*AccuBase® is the trade name for BS-EP1.

Request a Quote or More Information

Please contact support@kactusbio.us to request a quote or additional information for one of our gene editing enzymes or reagents. One of our team representatives would be happy to speak with you!

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