

Propelling cell and gene therapies from concept to commercialization

Our commitment to next-generation manufacturers:
high-quality, well-characterized raw materials

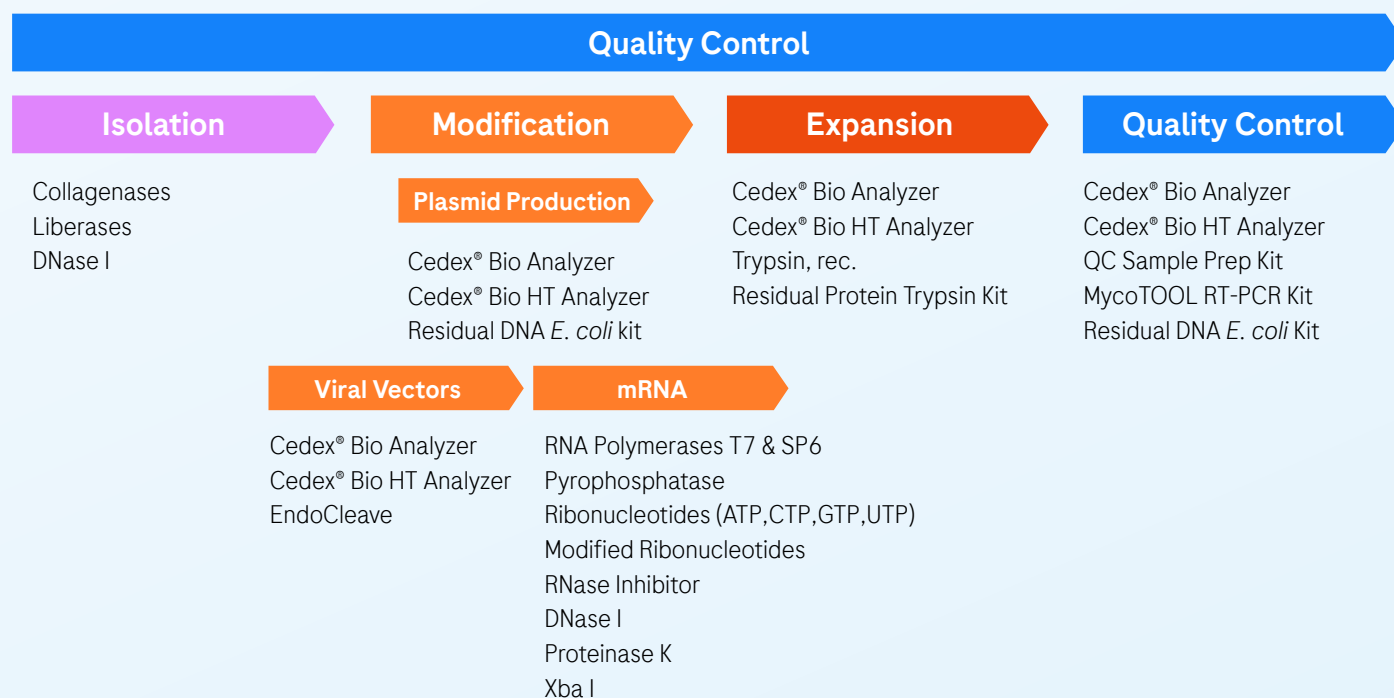


Advancing healthcare with tailored solutions

Roche CustomBiotech is your dedicated partner in manufacturing cell and gene therapies

Cell and gene therapies have the potential to revolutionize healthcare by offering unprecedented treatment possibilities.* At Roche CustomBiotech, we understand the technical complexity involved in implementing transformative advanced therapy medicinal products (ATMPs). Our commitment is to be your dedicated partner in providing tailored solutions for manufacturing advanced therapeutics. By utilizing precisely defined and scalable raw materials, coupled with robust quality

control solutions, we support manufacturing efficiency and compliance with regulatory requirements. Located in our state-of-the-art biotechnology facility in Penzberg, Germany, we combine the expertise of pharma and diagnostics with decades of experience in producing high-quality raw materials. Join us in advancing cell and gene therapies from cell isolation to quality control release testing.



*Chancellor D et al. 2023. Mol Ther. 2023;31(12):3376-3388

Regulatory disclaimers are listed on the respective product page on custombiotech.roche.com

High-quality enzymes for cell isolation and clarification

Maximize yields of viable cells with our DNase I and Collagenases



High-purity enzymes with well-characterized performance parameters are essential for safe and efficient cell isolation from diverse tissue sources. Collagenases play a crucial role in breaking down collagen and liberating cells from tissues, enabling maximum cell yield.

Our Liberase portfolio contains products with a precise blend of Collagenase I and II, together with an additional neutral protease - Thermolysin. This mixture is especially suitable for the dissociation of a broad range of tissue types, where high purity of the enzyme blend is necessary for high cell yield and viability.

Furthermore, DNase I allows the elimination of interfering DNA, ensuring optimal downstream applications in cell and gene therapy. Roche CustomBiotech is your reliable partner to provide these enzymes for high cell yield and viability.

Collagenase I Collagenase II Collagenase I/II DNase I

- Manufactured in GMP Grade and under ISO 13485:2016 quality standards
- Exhibit high lot-to-lot consistency for reproducible results
- Reduce risk of contamination and animal disease transmission
- Benefit from documentation supporting regulatory submissions

Liberase MNP-S Liberase MNP-S, GMP Grade Liberase T-Flex, Research Grade Liberase MTF C/T, GMP Grade

- Maximum cell yield, viability and functionality
- Manufactured free of mammalian- or avian-derived raw materials
- High experimental reproducibility
- Flexible enzyme portfolio

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Raw materials for mRNA therapeutics

Leverage our expertise with GMP Grade and fit-for-purpose mRNA reagents



At Roche CustomBiotech, we strive to enhance our mRNA raw materials portfolio to meet the evolving needs of cell and gene therapy developers and manufacturers. Our materials support innovative drug development, including CAR-T cell therapy, which harnesses the patient's immune cells to target and eliminate cancer cells.

Additionally, our mRNA raw materials are crucial for CRISPR/Cas9 applications, which enable precise genetic editing for personalized therapies targeting genetic diseases.

RNA Polymerases T7 & SP6

Pyrophosphatase

Ribonucleotides (ATP, CTP, GTP, UTP)

Modified Ribonucleotides

RNase inhibitor

DNase I

Proteinase K

Restriction endonuclease Xba I

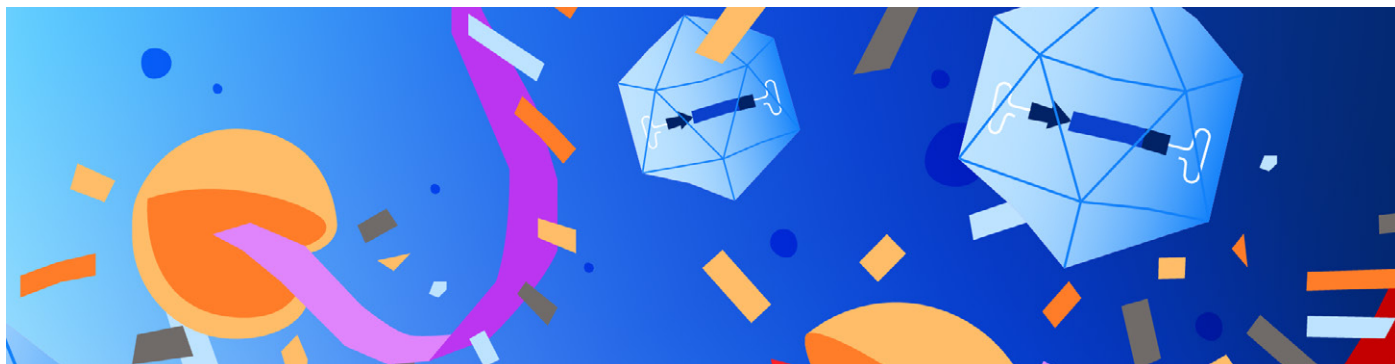


- Manufactured in GMP Grade and under ISO 13485:2016 quality standards
- Animal-origin-free
- Antibiotic-free (entirely antibiotics free or β -lactam antibiotics-free)
- Tested for critical impurities, like endotoxin, bioburden, heavy metals, host-cell DNA and protein
- Highly consistent from lot-to-lot
- Available in the scale and quality for biopharma manufacturing purposes
- Supplied with documentation supporting regulatory submissions

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Spotlight on EndoCleave

Elevate your viral vector manufacturing



Quality Control

Isolation

Modification

Expansion

Quality Control

EndoCleave is an endonuclease from *Serratia marcescens* produced in *E. coli*. Cleaving a wide range of DNA and RNA substrates, the product is designed for use during downstream processing of viral vectors (such as AAV), oncolytic viruses and viral vaccines to digest the nucleic acids in the harvest, while retaining viral integrity.

EndoCleave is particularly convenient, enabling seamless integration into existing workflows. It offers a cost-effective solution with GMP Grade quality, representing a significant step forward in helping make cell and gene therapy more accessible.

EndoCleave rec., GMP Grade

- Manufactured in GMP Grade and under ISO 13485:2016 quality standards
- Animal-origin-free production
- Antibiotic-free process
- Supplied with documentation supporting regulatory submissions
- Extended impurity testing

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High-quality enzymes for gentle cell detachment after culture expansion

Gain certainty with Trypsin, rec., GMP Grade



Fast, effective, yet gentle detachment of cells is vital for scaling manufacturing of cell and gene therapies. Trypsin, a serine protease, efficiently facilitates cell detachment by cleaving peptide bonds, enabling rapid separation of cells from culture surfaces. This is particularly important in processes like viral vector and CAR-T cell production, based on adherent HEK cells. Simultaneously, the final product must be safeguarded against variability or contamination introduced by raw materials like enzymes.

Trypsin, rec., GMP Grade

- Gentle cell detachment leads to increased viable cell recovery
- Stringent GMP specifications provide lot-to-lot consistency and reproducible quality
- Supplied with documentation supporting regulatory submissions

Residual Protein Trypsin Kit

- Establish in-process and final quality controls based on highly sensitive and reliable testing with the Residual Protein Trypsin Kit
- Robust removal of the added detaching enzyme is ensured for further downstream processing

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Comprehensive solutions for reliable in-process control

Take control of your cell and gene therapy bioprocess with Cedex® Analyzers



In the development of cell and gene therapies, effective bio-process control is crucial for a seamless transition to commercialization. Close monitoring of culture conditions ensures consistency, quality, and predictable outcomes. Implementing validated commercial technologies overcomes the challenge of diverse starting materials and processes, including autologous and allogeneic approaches. This minimizes risks, while conserving resources for safe and effective therapies. In addition, in process control during the viral vector production in gene therapy is essential for managing the scalability of therapies.

Cedex® Bio Analyzer **Cedex® Bio HT Analyzer**

- Proven data reliability
- Options for an automated workflow integration
- Broad and expandable test menu
- Accurate determination of substrate and metabolite levels in low-volume samples of cell cultures



For use in quality control/manufacturing process only.

Cedex[®] assay menu

Powerful, flexible and comprehensive cell culture profiling



Culture control for mammalian cells & bacteria

Substrates	Metabolites	Products
Ala-Gln (GlutaMAX)	Acetate	Ig Fab (human)
Arabinose	Ammonia	IgG (human)
Asparagine	Formate	Mouse IgG
Aspartate	Lactate	Optical Density (biomass)
Calcium	LDH	Total Protein
Cholesterol	Osmolality calc.	
Ethanol	Urea	
Galactose		
Glucose		
Glutamate		
Glutamine		
Glycerol		
Iron		
Magnesium		
Methanol		
Nitrate		
Phosphate		
Potassium		
Pyruvate		
Sodium		
Sucrose		

Additional assays are in development. Visit custombiotech.roche.com/cedex for updates.

For use in quality control/manufacturing process only.

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Rapid and reliable quality control kits

Deliver constant product quality with proven ready-to-use control solutions

Quality Control

Isolation

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Quality Control

Fast, sensitive and reliable analytical quality control is of growing importance for cell and gene therapy development. Since mycoplasma contamination evidently affects cell cultures, testing for mycoplasmas has increasingly become regulated by authorities. Fast and reliable mycoplasma detection is crucial in manufacturing workflows to ensure the quality and safety of cell-based medicinal products to patients.

Additionally, the residual DNA *E. coli* kit is a vital tool for quality control. This kit enables the accurate quantification of residual host cell DNA, thereby further enhancing the overall reliability of the plasmid production process.

MycoTOOL Mycoplasma Real-Time PCR Kit

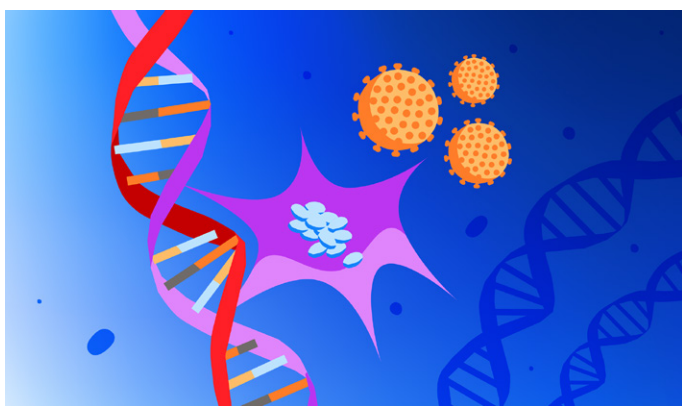
- Process control in cell and gene therapy development
- Fast and reliable mycoplasma detection
- Enables quality and safety of cell-based medicinal products
- Utilization of nucleic acid amplification techniques (NAT) and highly specific probes to detect over 150 cultivable and non-cultivable mollicute species
- Validation of the kit according to Ph. Eur. 2.6.7 NAT guidelines
- Efficiency through small sample size and a significantly shorter time frame for testing

Residual DNA *E. coli* Kit

- Vital tool for quality control
- Accurate quantification of residual host cell DNA
- Enhancing the overall reliability of the plasmid production process

QC Sample Preparation Kit

- Designed for use with the MycoTOOL Mycoplasma Real-Time PCR Kit
- Compatible with the Residual DNA *E. coli* Kit
- Fast and efficient sample preparation for PCR tests through optimized extraction protocols



CustomBiotech cell & gene therapy raw materials portfolio

Isolation

DNase I, rec., GMP Grade, AOF	320 mL 200 kU	09 852 093 103 09 873 562 001
Collagenase I, GMP Grade	custom fill	05 172 969 103
Collagenase II, GMP Grade	custom fill	05 172 942 103
Collagenase I/II, GMP Grade	1 bottle	05 349 907 103
Liberase MNP-S, 0.2 µm filtered, lyo.	35 mg	05 578 566 001
Liberase MNP-S, GMP Grade, 0.2 µm filtered, lyo.	5 mg	06 297 790 001
Liberase T-Flex, Research Grade, 0.2 µm filtered, lyo.	1 kit	05 989 132 001
Liberase MTF C/T, GMP Grade, 0.2 µm filtered, lyo.	1 kit	05 339 880 001

Modification

T7 RNA Polymerase, rec., GMP Grade, AOF	10 mL (ca. 10 mg)	08 140 669 103
SP6 RNA Polymerase, rec., GMP Grade AOF	25 mL (ca. 50 mg)	09 959 513 103
Pyrophosphatase, rec., GMP Grade, AOF	20 mL (ca. 40 mg)	08 140 677 103
ATP, 100 mM, pH 8.3, GMP Grade, AOF	100 mL	09 744 363 103
CTP, 100 mM, pH 8.3, GMP Grade, AOF	100 mL	09 745 092 103
GTP, 100 mM, pH 8.3, GMP Grade, AOF	100 mL	09 745 173 103
UTP, 100 mM, pH 8.3, GMP Grade, AOF	100 mL	09 745 343 103
N1-Methyl-Pseudo-UTP, GMP Grade, AOF	100 mL 1.0 mL	09 744 878 103 09 744 762 103
Pseudo-UTP, AOF	100 mL 1.0 mL	09 754 334 103 09 538 798 103

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Modification

RNase Inhibitor, rec., GMP Grade, AOF	100 kU 2 MU	09 537 643 103 09 537 589 103
DNase I, rec., GMP Grade, AOF	320 mL 200 kU	09 852 093 103 09 873 562 001
Proteinase K, GMP Grade	850 mL	03 654 672 103
Restriction endonuclease Xba I, rec., AOF	5 mL (50 kU) 25 mL (250 kU)	09 520 848 101 09 520 848 103
EndoCleave, rec., GMP Grade, AOF	100 kU 500 kU 5000 kU	10 360 500 103 10 360 364 103 10 360 321 103

Expansion

Trypsin, rec., GMP Grade	3.5 MU 1 g = 0.23 MU	03 358 658 103 06 369 880 103
Residual Protein Trypsin Kit	1 kit (96 reactions)	07 568 975 001

Quality Control

Cedex® Bio Analyzer*	1 instrument with software and accessories	06 395 554 001
Cedex® Bio HT Analyzer*	1 instrument with software and accessories	06 608 116 001
QC Sample Preparation Kit	1 kit	08 146 829 001
MycotoOL Mycoplasma Real-Time PCR Kit	1 kit (160 PCR reactions)	06 495 605 001
Residual DNA <i>E. coli</i> Kit	96 reactions	07 728 735 001

*Depending on the application, several system reagents and test-specific kits are required.

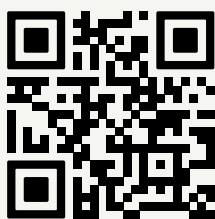


Discover the full potential of our cell and gene therapy solutions – scan the code to explore our comprehensive portfolio

Regulatory disclaimers are listed on the respective product page on custombiotech.roche.com

We supply your next step

About us - discover Roche CustomBiotech



Scan the code to learn more about how high-quality raw materials can power your growth



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Published by

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