

Propelling cell and gene therapies from concept to commercialization

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

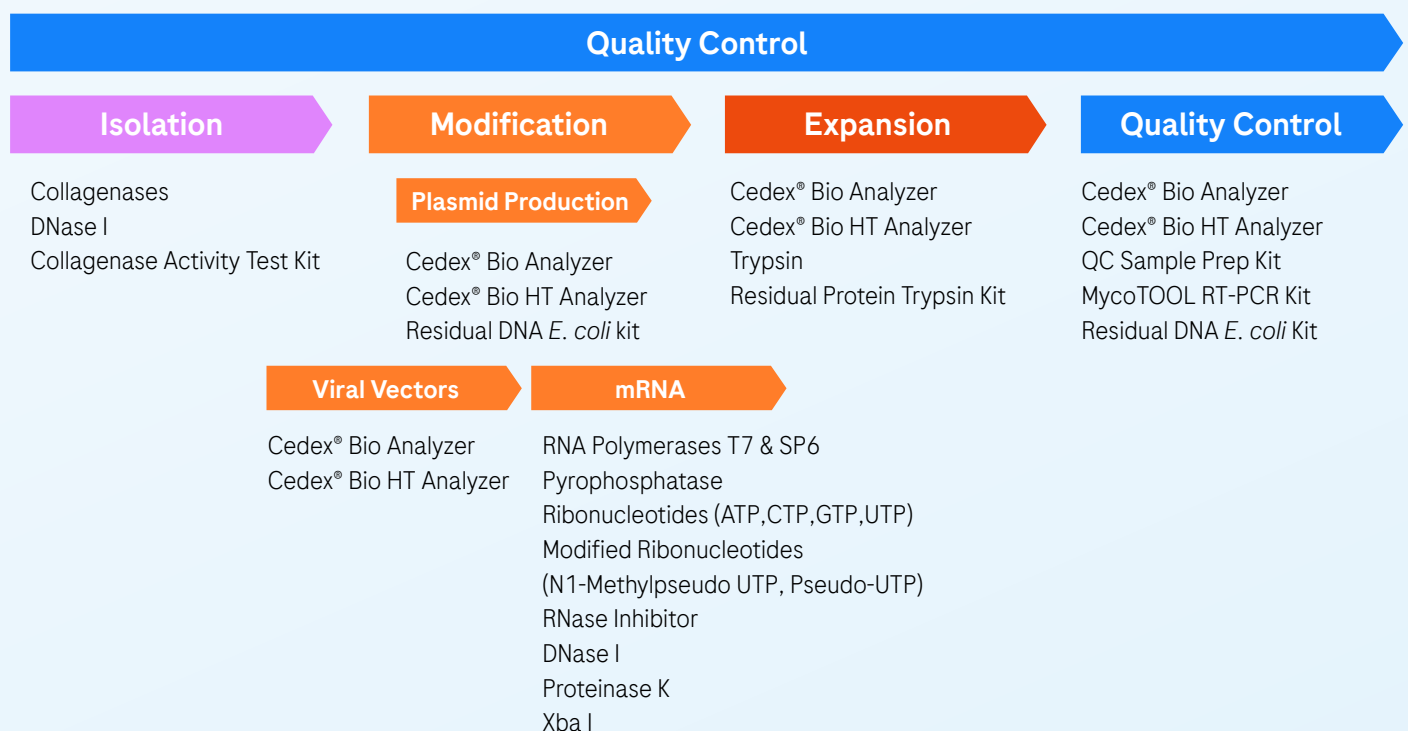


Advancing healthcare with tailored solutions

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 while ensuring 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 and warranty limitations on product level are listed on page 9 - 11.

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. 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

- Ensure high cell viability
- Exhibit high lot-to-lot consistency for reproducible results
- Reduce risk of contamination and animal disease transmission
- Benefit from documentation supporting regulatory submissions

Collagenase Activity Test Kit

- Detect enzymatic activity of collagenases
- Rely on reproducible results due to included calibration standards and the kit's high lot-to-lot consistency

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 (N1-Methylpseudo UTP, Pseudo-UTP)
RNase inhibitor
DNase I
Proteinase K
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

Regulatory disclaimers and warranty limitations on product level are listed on page 9 - 11.

High-quality enzymes for gentle cell detachment after culture expansion

Gain certainty with GMP Grade and recombinant Trypsin



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.

Recombinant Trypsin

- Gentle cell detachment leads to maximum viable cell recovery
- Stringent GMP specifications help ensure 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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Complete solutions for reliable in-process control

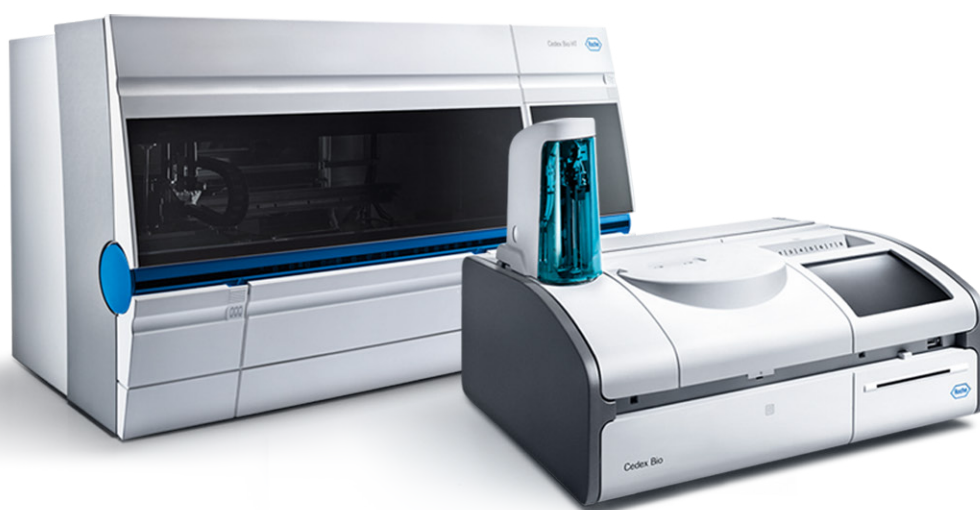
Take control of your cell and gene therapy bioprocess with Cedex® Analyzers



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 safer and more effective therapies. In addition, in process control during the viral vector production in gene therapy is essential for managing the scalability of therapies and achieving desired therapeutic outcomes.

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



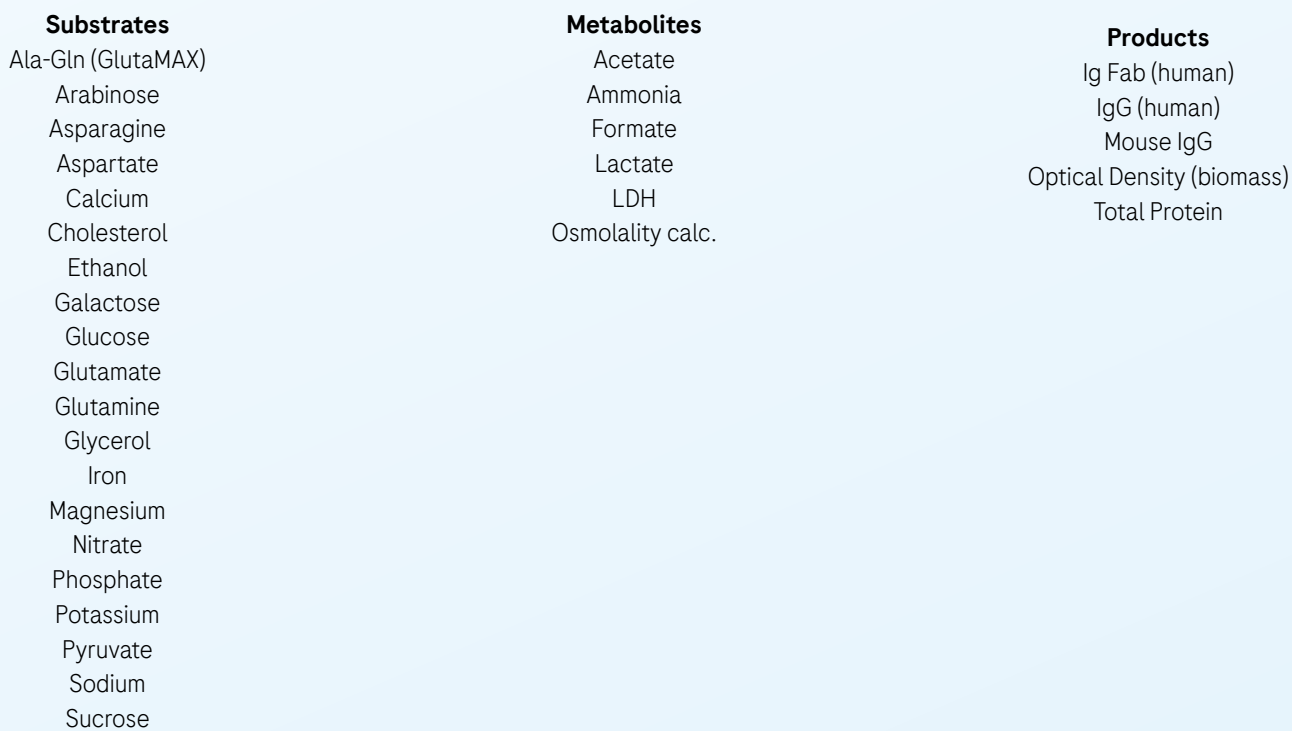
For use in quality control/manufacturing process only.

Cedex[®] assay menu

Powerful, flexible and comprehensive cell culture profiling



Culture control for mammalian cells & bacteria



Additional assays are in development. Visit custombiotech.roche.com/cedex for updates.
For use in quality control/manufacturing process only.

Rapid and reliable quality control kits

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

Quality Control

Isolation

Modification

Expansion

Quality Control

Fast, sensitive and reliable analytical quality control is of growing importance for development of 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
- Ensure 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 Prep Kit

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

Regulatory disclaimers and warranty limitations on product level are listed on page 9 - 11.

We supply your next step

About us - discover Roche CustomBiotech

As part of global biotechnology company Roche we are a leading supplier of innovative, high-quality raw materials and solutions to forward-thinking biopharma and diagnostics businesses.

Based in one of Europe's largest and most productive biotechnology centres, at the Roche site Penzberg, Germany, we provide access to tailored solutions that meet the highest standards in quality, safety and regulatory requirements: from ISO-certified quality management to GMP, animal-free and antibiotic-free production of excipients, raw materials, kits and bioprocessing instruments.

Our goal is to support our customers as they develop and manufacture valuable new products and services and deliver better healthcare outcomes.



Please scan to discover more
about CustomBiotech



CustomBiotech cell & gene therapy raw materials portfolio

Isolation

DNase I, rec., GMP Grade, AOF ¹	320 mL 200 kU	09 852 093 103 09 873 562 001
Collagenase I ²	custom fill	05 172 969 103
Collagenase II ²	custom fill	05 172 942 103
Collagenase I/II ⁴	1 bottle	05 349 907 103
Collagenase Activity Test Kit ³	96 reactions	08 074 461 001

Modification

T7 RNA Polymerase, rec., GMP Grade, AOF ²	10 mL (ca. 10 mg)	08 140 669 103
SP6 RNA Polymerase, GMP Grade AOF ¹	25 mL (ca. 50 mg)	09 959 513 103
Pyrophosphatase, rec., GMP Grade, AOF ²	20 mL (ca. 40 mg)	08 140 677 103
ATP, 100 mM, pH 8.3, GMP Grade, AOF ¹	100 mL	09 744 363 103
CTP, 100 mM, pH 8.3, GMP Grade, AOF ¹	100 mL	09 745 092 103
GTP, 100 mM, pH 8.3, GMP Grade, AOF ¹	100 mL	09 745 173 103
UTP, 100 mM, pH 8.3, GMP Grade, AOF ¹	100 mL	09 745 343 103
N1-Methyl-Pseudo-UTP, GMP Grade, AOF ²	100 mL 0.1 mL	09 744 878 103 09 744 762 103
Pseudo-UTP, AOF ²	100 mL 0.1 mL	09 754 334 103 09 538 798 103
RNase Inhibitor, rec., GMP Grade, AOF ²	100 kU 2 MU	09 537 643 103 09 537 589 103
DNase I, rec., GMP Grade, AOF ¹	320 mL 200 kU	09 852 093 103 09 873 562 001
Proteinase K, PCR Grade ²	850 mL	03 654 672 103
Xba I, AOF ²	5 mL (50 kU) 25 mL (250 kU)	09 520 848 101 09 520 848 103

Expansion

Trypsin, rec., GMP Grade ²	3.5 MU 1 g = 0.23 MU	03 358 658 103 06 369 880 103
Residual Protein Trypsin Kit ⁵	1 kit (96 reactions)	07 568 975 001

Quality Control

Cedex® Bio Analyzer* ³	1 instrument with software and accessories	06 395 554 001
Cedex® Bio HT Analyzer* ³	1 instrument with software and accessories	06 608 116 001
QC Sample Preparation Kit ³	1 kit	08 146 829 001
MycoTOOL Mycoplasma Real-Time PCR Kit ³	1 kit (160 PCR reactions)	06 495 605 001
Residual DNA <i>E. coli</i> Kit ³	96 reactions	05 196 132 103

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



Please scan to see the entire portfolio

Regulatory disclaimer

¹ For further processing into medical devices, IVD and pharmaceutical products only.

Warranty limitation applies:

It is the sole responsibility of the customer to determine the suitability of all raw materials, products and components in order to ensure that the final end-use product is safe for its end use; performs or functions as intended; and complies with all applicable legal and regulatory requirements. Roche makes no representations or warranties of any kind regarding the Product, express or implied, other than those expressly set forth in the terms and conditions of sale (if any), and disclaims all implied or statutory warranties including warranty of merchantability and fitness for a particular purpose.

² For further processing only.

³ For use in quality control/manufacturing process only.

⁴ Blended proteolytic enzyme for tissue dissociation. For further processing only.

⁵ For quality control/manufacturing of IVD/medical devices/pharmaceutical products only.

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