

Roche CustomBiotech Product Catalog for Biopharma Manufacturing



Roche CustomBiotech – We supply your next step

As partner and supplier for healthcare companies and manufacturers we streamline your operations, power your growth and assist you in delivering better healthcare for all.

Roche CustomBiotech has been a leader in supplying innovative, high-quality products to forward-thinking biopharma and diagnostics businesses for more than 50 years. As part of Roche we work with pioneering biopharma and diagnostic experts at one of Europe's largest and most productive biotechnology centers.

This is where Roche continually creates a wide range of drugs and diagnostics, including critical raw materials, ingredients, quality control kits and in-process analyzers.

Reliable access to these materials supports our customers in developing and manufacturing valuable new products and services, such as state-of-the-art mRNA-based vaccines, cell and gene therapies or molecular POC kits.



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Portfolio for Manufacturing of Biologics

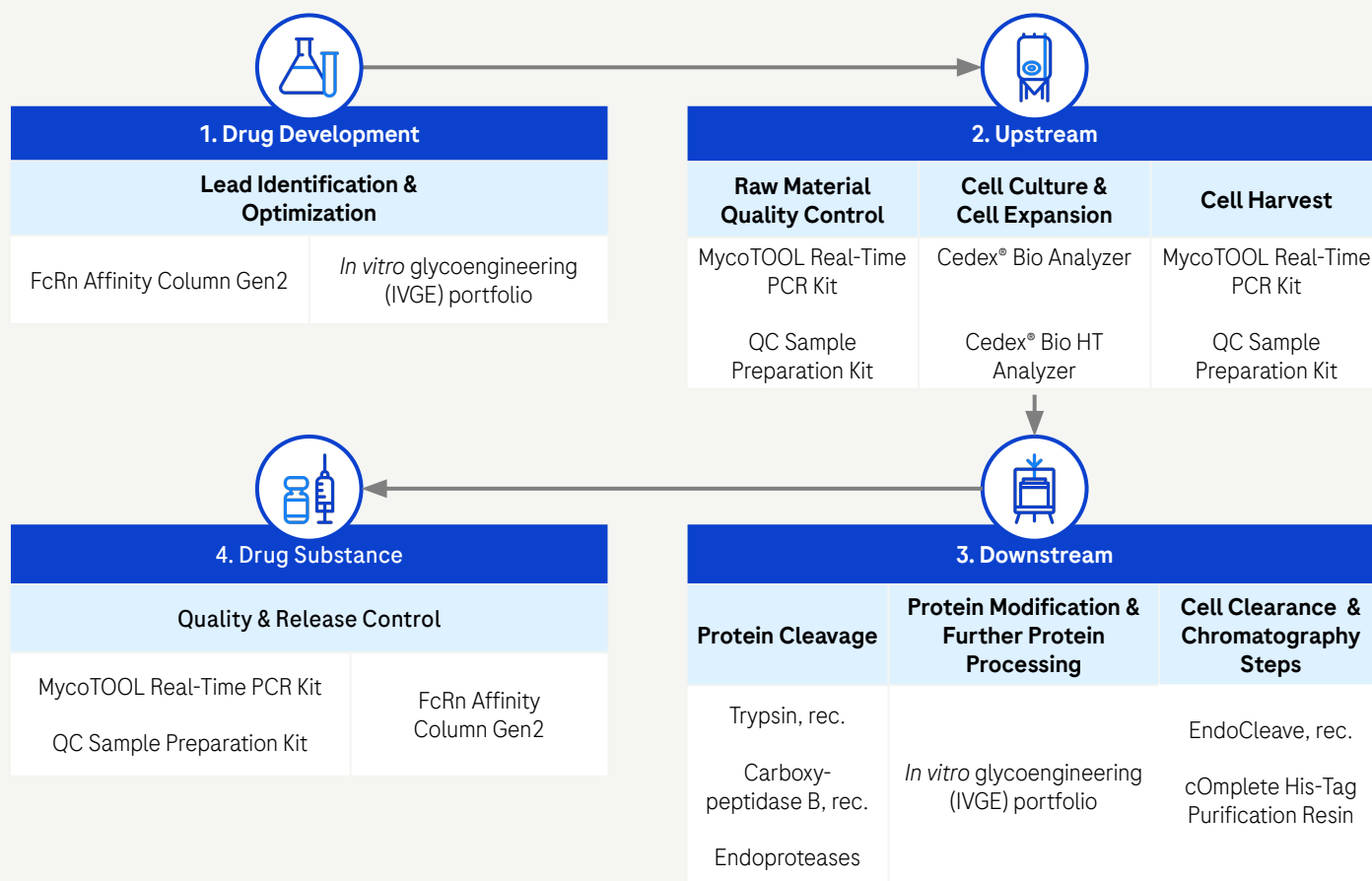
Biologics are an important drug class used in **oncology**, **anti-immunity**, and **chronic inflammatory diseases**. The drug therapy product's active substance is extracted or produced from a biological source.

Biologics include **monoclonal antibodies (mAbs)** and further therapeutic recombinant proteins.

The proteins are mainly produced by mammalian cells or bacteria.

With decades of experience in providing high quality raw materials, instruments and solutions for biotherapeutics manufacturers, we offer **proven solutions** for your unique process.

Discover Products for Your Biologics Workflow:



Discover more
about Biologics

Propelling advanced therapy medicinal products from concept to commercialization

Portfolio for Manufacturing of Cell & Gene Therapeutics

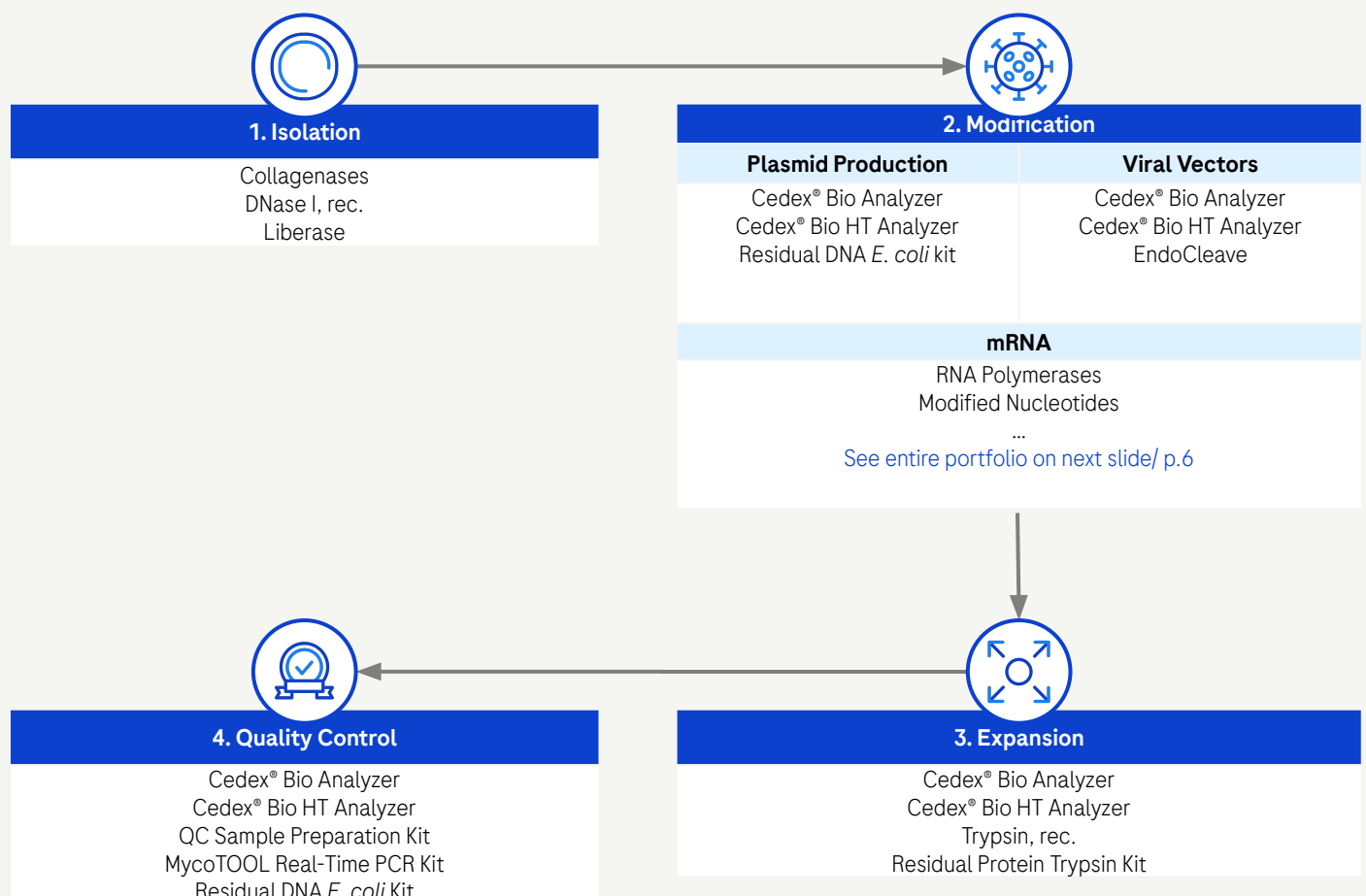
Cell and gene therapies have the potential to revolutionize healthcare by offering **unprecedented treatment possibilities**.* At Roche CustomBiotech, we understand the technical complexity involved in implementing transformative advanced therapy medicinal products (ATMPs).

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.



Discover more about solutions for CGT

Manufacturing Workflow Cell and Gene Therapeutics:



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



mRNA raw materials: a clear path to market

Portfolio for Manufacturing of mRNA Therapeutics

Design your mRNA manufacturing process with the **certainty of fit-for-purpose standards for raw materials**. Developed with a quality-by-design approach and based on customer requirements,

CustomBiotech mRNA raw materials align to industry specifications and are produced in the state-of-the-art facilities and quality infrastructure of Roche Pharmaceuticals and Diagnostics.

GMP Grade and fit-for-purpose mRNA materials



GMP Grade &
ISO 13465



Animal-origin-free (AOF)



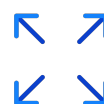
Antibiotic-free
(β-lactam-free)



Extended Impurity
testing

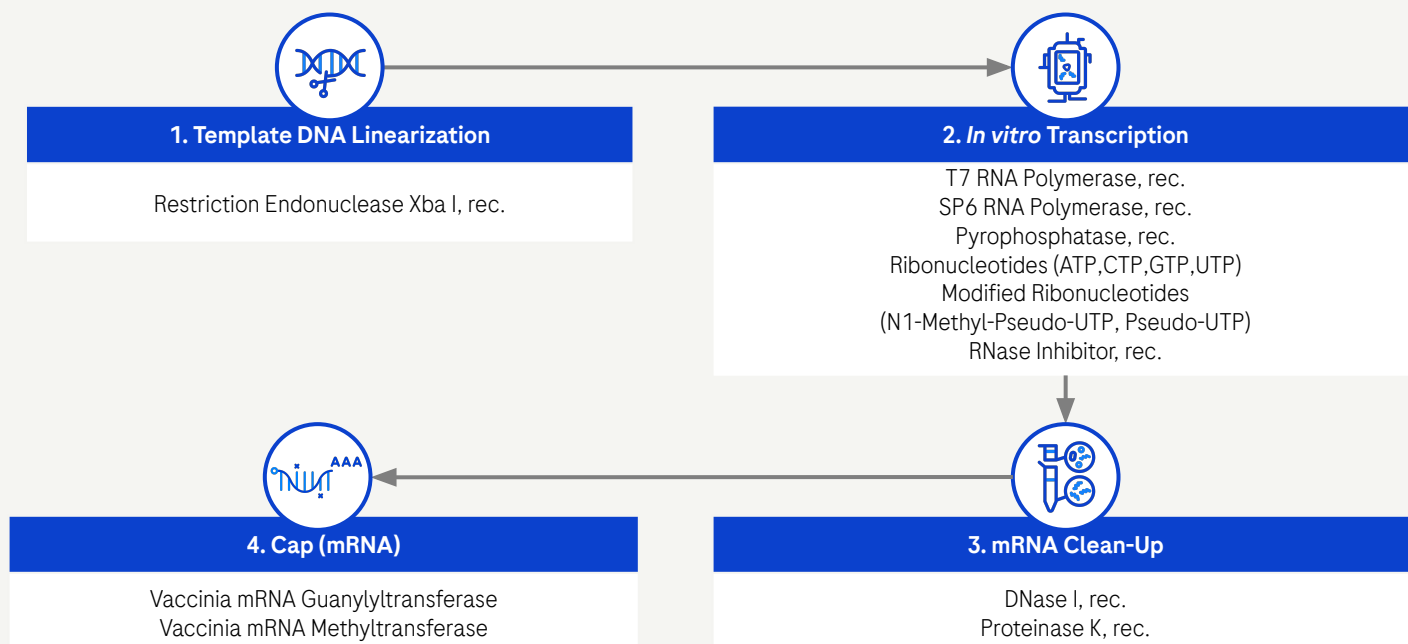


Extended quality
documentation



Scalability &
Consistency

mRNA Manufacturing Workflow and CustomBiotech Raw Materials:



Discover more about
reagents for mRNA
therapeutics



BioPharma Product List



Bioprocess Control

Cedex® Bio Analyzer & Accessories

Product Name	Catalog Number	Content
Cedex® Bio Analyzer	06395554001	1 instrument
Activator Bio	07766700001	4 x 9 mL
Adapter Cups	06455638001	30 adapters
Chimneys	06455646001	96 chimneys
Cleaner Acidic	06455590001	1000 mL
Cleaner Alkaline Bio	06689485001	8 x 21 mL
Deproteinizer Bio	06440517001	2 x 11 mL
Micro Cuvette Segments Bio	06455581001	1680 cuvettes
NaCl Diluent 9% Bio	06684700001	8 x 12 mL
Thermo Printer Paper	06455484001	5 rolls



Cedex® Bio Analyzer



Discover more about
Cedex® Analyzers

Bioprocess Control

Cedex® Bio HT Analyzer & Accessories

Product Name	Catalog Number	Content
Cedex® Bio HT Analyzer	06608116001	1 instrument
Accelerator, 100 mL	06609333001	100 mL
Activator Bio	07766700001	4 x 9 mL
Activator Bottle Set Bio HT	06613128001	50 bottles
Adapter Cups	06455638001	30 adapters
Cleaner Acidic	06455590001	1000 mL
Cleaner Alkaline Bio HT	06612369001	200 usages
Deproteinizer Bio HT	06664288001	6 x 21 mL
Kit Labels Multiwell Rack Cedex	10409347001	1 kit
Microcuvettes Bio HT	06609392001	20,000 cuvettes
NaCl Diluent 9%	06609406001	6 x 22 mL
Opening Tool Bio HT	07094345001	3 tools
Rack Multiwell Plate Cedex	10420618001	1 rack
Waste Container Bio HT	07094302001	20 containers



Cedex® Bio HT Analyzer



Discover more about
Cedex® Analyzers



Bioprocess Control

Cedex® Bio and Bio HT Assays Overview



Culture control for mammalian cells, bacteria, yeast & insect cells

Substrates

Ala-Gln (GlutaMAX)	Iron
Asparagine	Lactose
Aspartate	Magnesium
Calcium	Methanol
Cholesterol	Nitrate
Ethanol	Phosphate
Galactose	Potassium
Glucose	Pyruvate
Glutamate	Sodium
Glutamine	Sucrose
Glycerol	

Metabolites

Acetate
Ammonia
Formate
Lactate
LDH
Osmolality calc.
Urea

Product

Ig Fab (human)
IgG (human)
Mouse IgG
Optical Density (biomass)
Total Protein



Discover more about
Cedex® Analyzers

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



Cedex® Bio Analyzer Assays

Product Name	Catalog Number	Content (tests)
Acetate V2 Bio	07395442001	4 x 50 tests
Ala-Gln Bio	08056978001	4 x 50 tests
Asn/Asp Bio	09437312001	4 x 50 tests
Calcium Bio	07374623001	2 x 100 tests
Cholesterol Bio	07374577001	2 x 100 tests
Ethanol Bio	08055645001	4 x 50 tests
Formate Bio	07705590001	4 x 50 tests
Galactose/Arabinose Bio	08391599001	4 x 50 tests
Glucose Bio	06343732001	2 x 100 tests
Glutamate V2 Bio	07395582001	4 x 50 tests
Glutamine V2 Bio	07395655001	4 x 50 tests
Glycerol Bio	07374607001	4 x 50 tests
Ig Fab Bio	08881332001	4 x 50 tests
IgG Bio	06681743001	2 x 100 tests
Iron Bio	06990045001	2 x 50 tests
Lactate Bio	06343759001	4 x 50 tests
Lactose Bio	10387653001	4 x 100 tests
LDH Bio	06343767001	4 x 50 tests
Magnesium V2 Bio	09324542001	4 x 50 tests
Methanol Bio	08055688001	4 x 50 tests
Mouse IgG Bio	08377944001	4 x 50 tests
NH3 Bio	06343775001	2 x 100 tests
Nitrate Bio	09816364001	4 x 50 tests
OD Bio	07705620001	4 x 100 tests
Phosphate Bio	06990070001	4 x 50 tests
Potassium Bio	08881367001	4 x 50 tests
Pyruvate Bio	07395680001	4 x 50 tests
Sodium Bio	08881863001	4 x 50 tests
Sucrose Bio	07705557001	4 x 50 tests
Total Protein Bio	07374593001	2 x 100 tests
Urea Bio	10258829001	4 x 50 tests



**Discover more about
Cedex® Analyzers**

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respective product page on
custombiotech.roche.com



Cedex® Bio HT Analyzer Assays

Product Name	Catalog Number	Content (tests)
Acetate V2 Bio HT	07395485001	200 tests
Ala-Gln Bio HT	08056943001	200 tests
Asn/Asp Bio HT	09437339001	200 tests
Calcium Bio HT	06990100001	300 tests
Cholesterol Bio HT	07212763001	400 tests
Ethanol Bio HT	08055661001	100 tests
Formate Bio HT	07705603001	200 tests
Galactose/Arabinose Bio HT	08391629001	200 tests
Glucose Bio HT	06608418001	800 tests
Glutamate V2 Bio HT	07395566001	200 tests
Glutamine V2 Bio HT	07395612001	200 tests
Glycerol Bio HT	06990126001	250 tests
Ig Fab Bio HT	08881359001	200 tests
IgG Bio HT	06608540001	100 tests
Iron Bio HT	06990053001	200 tests
Lactate Bio HT	06608485001	100 tests
Lactose Bio HT	10387661001	400 tests
LDH Bio HT	06608493001	300 tests
Magnesium V2 Bio HT	09324569001	250 tests
Methanol Bio HT	08055718001	200 tests
Mouse IgG Bio HT	08377979001	200 tests
NH3 Bio HT	06608515001	150 tests
Nitrate Bio HT	09816356001	300 tests
OD Bio HT	07705654001	400 tests
Phosphate Bio HT	06990088001	250 tests
Potassium Bio HT	08881731001	165 tests
Pyruvate Bio HT	07299818001	200 tests
Sodium Bio HT	08881871001	200 tests
Sucrose Bio HT	07705565001	200 tests
Total Protein Bio HT	06990169001	300 tests
Urea Bio HT	10258845001	300 tests



**Discover more about
Cedex® Analyzers**

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custombiotech.roche.com



Cedex® Bio/Cedex® Bio HT Calibrators and Controls

Product Name	Catalog Number	Content (tests)
Calibrator A Bio	06682189001	6 x 1 mL
Calibrator B Bio	06682553001	6 x 0.5 mL
Calibrator C Bio	07020716001	6 x 1 mL
Calibrator D Bio	07368321001	6 x 1 mL
Calibrator E Bio	08083703001	6 x 0.5 mL
Calibrator F Bio	08377987001	6 x 1 mL
Calibrator K Bio	09336699001	6 x 1 mL
Calibrator M Bio	08083614001	6 x 0.5 mL
Control A Level 1 Bio	06682197001	6 x 1 mL
Control A Level 2 Bio	06682227001	6 x 1 mL
Control A Level 3 Bio	06682545001	6 x 1 mL
Control B Level 1 Bio	06682561001	6 x 0.5 mL
Control B Level 2 Bio	06682570001	6 x 0.5 mL
Control B Level 3 Bio	06682588001	6 x 0.5 mL
Control C Level 1 Bio	07020724001	6 x 1 mL
Control C Level 2 Bio	07020872001	6 x 1 mL
Control C Level 3 Bio	07020902001	6 x 1 mL
Control D Level 1 Bio	07368178001	6 x 1 mL
Control D Level 2 Bio	07368186001	6 x 1 mL
Control D Level 3 Bio	07368194001	6 x 1 mL
Control E Level 1 Bio	08083797001	6 x 0.5 mL
Control E Level 2 Bio	08083819001	6 x 0.5 mL
Control E Level 3 Bio	08083827001	6 x 0.5 mL
Control F Level 1 Bio	08377995001	6 x 1 mL
Control F Level 2 Bio	08378002001	6 x 1 mL
Control F Level 3 Bio	08378029001	6 x 1 mL
Control M Level 1 Bio	08083657001	6 x 0.5 mL
Control M Level 2 Bio	08083665001	6 x 0.5 mL
Control M Level 3 Bio	08083681001	6 x 0.5 mL
Control OD Level 1 Bio	07766637001	6 x 1 mL
Control OD Level 2 Bio	07766645001	6 x 1 mL
Control OD Level 3 Bio	07766670001	6 x 1 mL



**Discover more about
Cedex® Analyzers**

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Quality Control

Mycoplasma Testing

Product Name	Product Name Addition	Catalog Number	Pack Size
MycoTOOL Mycoplasma Real-Time PCR Kit	for real time PCR mycoplasma detection	06495605001	1 kit (160 PCR reactions)
MycoTOOL Mycoplasma Detection Amplification Kit	for endpoint PCR mycoplasma detection	05184240001	1 kit
MycoTOOL Control Plasmid	for use as positive control of mycoplasma detection	05196132103	10,000 ng
MycoTOOL Carrier DNA	for testing cell free samples for the absence of mycoplasma	05619424001	1 kit
QC Sample Preparation Kit	for preparation of cell culture samples before PCR/RT PCR detection of mycoplasma or residual DNA	08146829001	1 kit

Residual DNA & Protein Testing

Product Name	Product Name Addition	Catalog Number	Pack Size
Residual DNA CHO Kit	Kit for determination of residual DNA CHO	07427689001	1 kit
Residual DNA <i>E. coli</i> Kit	Kit for determination of residual DNA <i>E.coli</i>	07728735001	1 kit
Residual Protein Trypsin Kit	Kit for determination of trypsin	07568975001	1 kit
Residual Protein 2,6-Sialyltransferase	Kit for determination of 2,6-Sialyltransferase	08011478001	1 kit (96 reactions)
Residual Protein Galactosyltransferase	Kit for quantitative detection of β -1,4-Galactosyltransferase	08182990001	1 kit (96 reactions)



Discover more about
quality control solutions

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mRNA Raw Materials

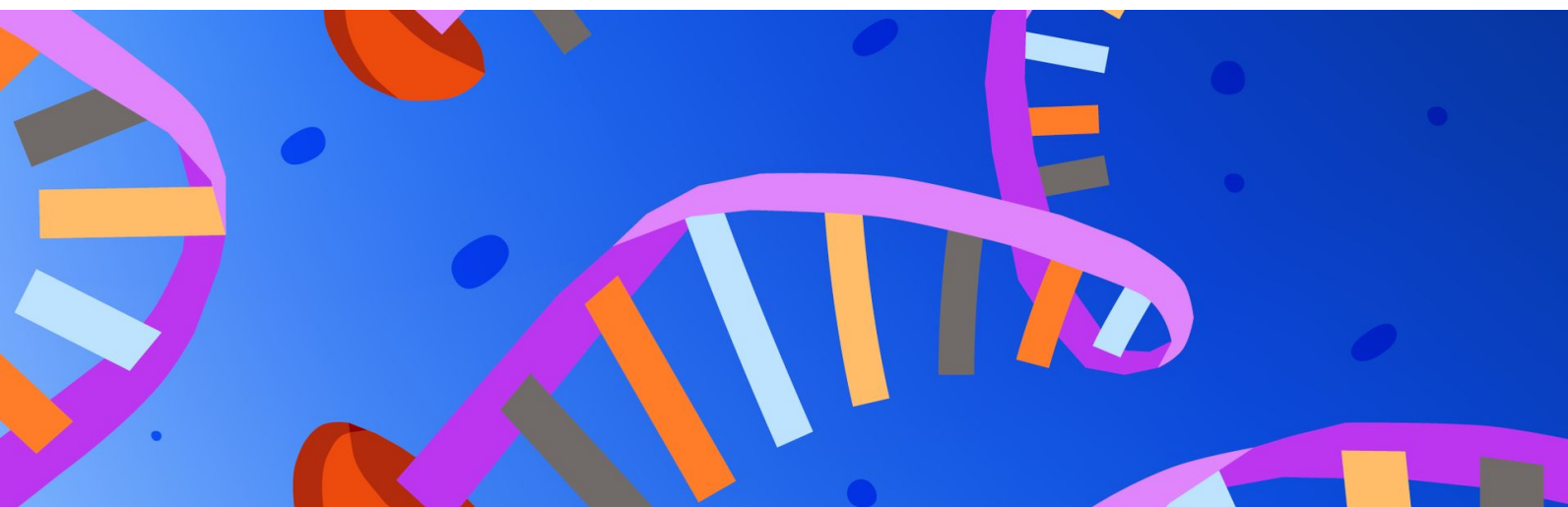
Proteins

Product Name	Product Name Addition	Catalog Number	Pack Size
T7 RNA Polymerase, rec., GMP Grade, AOF	from T7 bacteriophage, recombinant in <i>E.coli</i> , solution	08140669103	10 mL
Pyrophosphatase, rec., GMP Grade, AOF	from yeast, expressed in <i>E. coli</i> , solution	08140677103	20 mL
RNase Inhibitor, rec., GMP Grade, AOF	from rat lung, expressed in <i>E.coli</i> , solution	09537643103 09537589103	100 kU (2.5 mL) 2 MU (50 mL)
DNase I, rec., GMP Grade, AOF	from bovine pancreas, recombinant, expressed in <i>Pichia pastoris</i> , solution	09873562001 09852093103	200 kU 320 mL
Proteinase K, rec., PCR Grade, sol.	from <i>Titirachium album</i> , expr. in <i>Pichia pastoris</i> , solution	09753826103	please inquire
SP6 RNA Polymerase, rec., GMP Grade, AOF	from SP6 bacteriophage, recombinant in <i>E.coli</i> , solution	09959513103	25 mL
Restriction Endonuclease Xba I, rec., AOF	from <i>Xanthomonas campestris</i> pv. <i>Badrii</i> , expressed in <i>E. coli</i> , solution	09520848103 09520848101	250 kU (25 mL) 50 kU (5 mL)
Vaccinia mRNA Guanylyltransferase	from <i>vaccinia virus</i> , expressed in <i>E. coli</i> , solution	10642025101 10642025103	5 mL custom fill
Vaccinia mRNA Methyltransferase	from <i>vaccinia virus</i> , expressed in <i>E. coli</i> , solution	10267500101 10267500103	5 mL 70 mL



Discover more about mRNA raw materials

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mRNA Raw Materials

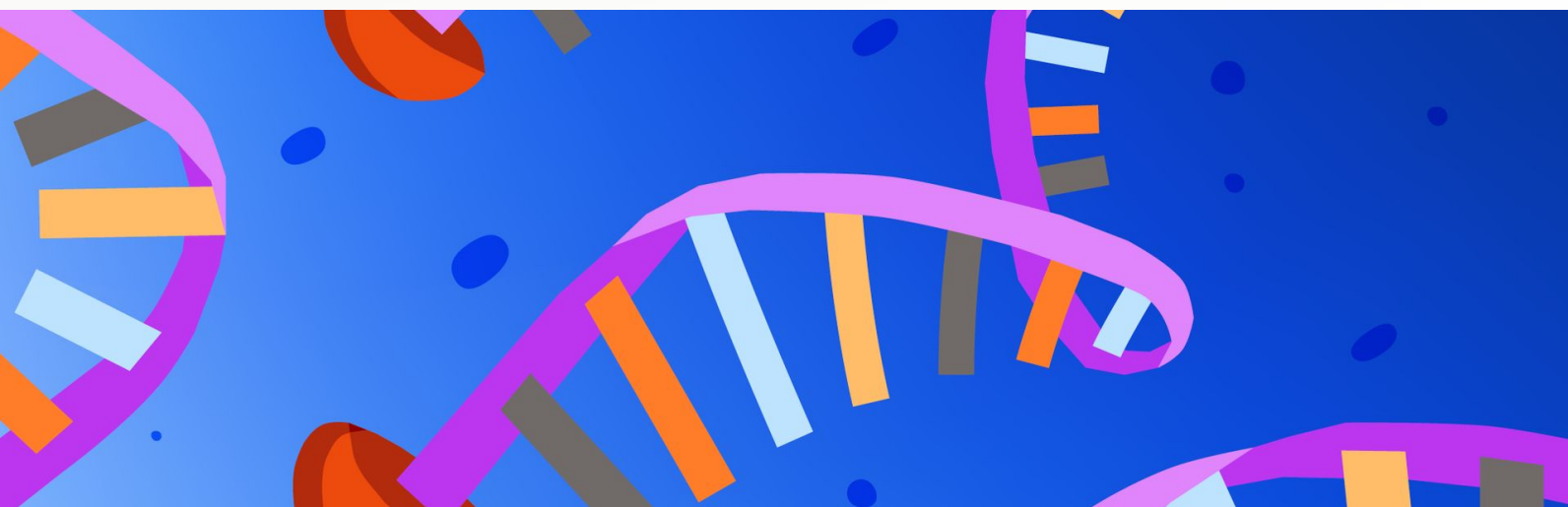
Nucleotides

Product Name	Product Name Addition	Catalog Number	Pack size
ATP, GMP Grade, AOF	sodium salt, 100 mM	09744363103	100 mL
ATP, GMP Grade, AOF	325 mM, pH 8.3	09744380103	500 mL
CTP, GMP Grade, AOF	sodium salt, 100 mM	09744410103	100 mL
CTP, GMP Grade, AOF	325 mM, pH 8.3	09745092103	100 mL
GTP, GMP Grade, AOF	sodium salt, 100 mM	09745106103	500 mL
GTP, GMP Grade, AOF	325 mM, pH 8.3	09745122103	100 mL
UTP, GMP Grade, AOF	sodium salt, 100 mM	09745173103	100 mL
UTP, GMP Grade, AOF	325 mM, pH 8.3	09745203103	500 mL
UTP, GMP Grade, AOF	sodium salt, 100 mM	09745220103	100 mL
UTP, GMP Grade, AOF	325 mM, pH 8.3	09745343103	100 mL
Pseudo-UTP, AOF	sodium salt, 100 mM, solution	09962646103	500 mL
Pseudo-UTP, AOF	325 mM, pH 8.3	09962689103	100 mL
Pseudo-UTP, AOF	sodium salt, 100 mM, solution	09538798103	1.0 mL
Pseudo-UTP, AOF	325 mM, pH 8.3	09754334103	100 mL
N1-Methyl-Pseudo-UTP, GMP Grade, AOF	sodium salt, 100 mM, solution	10490896103	100 mL



Discover more about
mRNA raw materials

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Endonucleases for Viral Vector Production

Endonuclease

Product Name	Product Name Addition	Catalog Number	Pack size
EndoCleave, rec., GMP Grade, AOF	from <i>Serratia marcescens</i> , recombinant, expressed in <i>E.coli</i> , solution	10360500103 10360364103 10360321103	100KU 500KU 5000KU

- **Broad-spectrum activity:**
Reliable degradation of both single-stranded and double-stranded DNA and RNA.
- **Protect Downstream Quality:**
Removes nucleic acids efficiently to prevent interference with your final product.
- **High Specificity:**
Preserves protein yield and integrity by **only** targeting nucleic acids¹.
- **Seamless Integration:**
Easily fits into your existing biopharmaceutical workflows
- **Speed Up Approval:**
Accelerate your timeline with our off-the-shelf regulatory documents



Discover more about
our Cell and Gene
Portfolio

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1) Data on file at Roche



Protease Portfolio

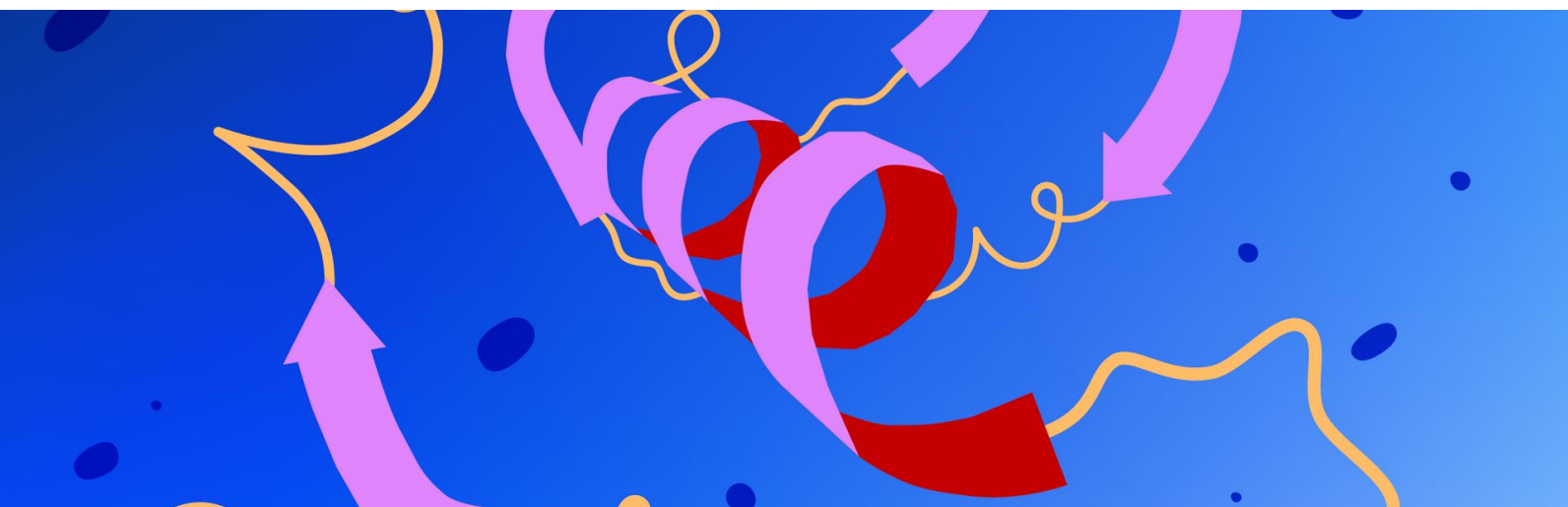
Endoproteases

Product Name	Product Name Addition	Catalog Number	Pack Size
Trypsin, rec., GMP Grade	expressed in <i>Pichia pastoris</i>	06369880103	PC (1g = 0.23 MU)
		03358658103	3.5 MU
Endoproteinase Glu-C	from <i>Staphylococcus aureus</i> V8, lyophilizate, salt-free	10787906103	50 µg
Proteinase K, rec., PCR Grade, sol.	from <i>Titirachium album</i> , expressed in <i>Pichia pastoris</i> , solution	03654672103	850 mL
Proteinase K, rec., PCR Grade, lyo.	from <i>Titirachium album</i> , expressed in <i>Pichia pastoris</i> , lyophilizate	03450384103	250 mg
		05963117103	5 g
Amino Acid Arylamidase	from Hog Kidney	10150754103	custom fill
Collagenase I, GMP Grade	liquid, mammalian free, from <i>Chlostridium histolyticum</i>	05172969103	custom fill
Collagenase I/II, GMP Grade	lyophilizate, mammalian free, from <i>Chlostridium histolyticum</i>	05349907103	1 bottle
Collagenase II, GMP Grade	liquid, mammalian free, from <i>Chlostridium histolyticum</i>	05172942103	custom fill



Discover more about proteases
for protein processing

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Protease Portfolio

Exoproteases

Product Name	Product Name Addition	Catalog Number	Pack Size
Carboxypeptidase B, rec., GMP Grade	from rat pancreas, expressed in <i>Pichia pastoris</i> , solution	03358682103	0.03 MU

Mix of Exo-and Endoproteases

Product Name	Product Name Addition	Catalog Number	Content (tests)
Pronase	from <i>Streptomyces griseus</i> , lyophilizate	10165913103	100 g

Related products/quality control

Product Name	Product Name Addition	Catalog Number	Content (tests)
Chromozym TRY	powder	10378496103	custom fill
Residual Protein Trypsin Kit	Kit for determination of trypsin	07568975001	1 kit

Protease inhibitors

Product Name	Product Name Addition	Catalog Number	Content (tests)
Aprotinin	from bovine lung, lyophilizate	10236632103	custom fill
Leupeptin	Ac-Leu-Leu-argininal x 1/2 H2SO4, synthetic	10528595103	custom fill



Discover more about proteases
for protein processing

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Columns and Resins

Product Name	Product Name Addition	Catalog Number	Pack Size
FcRn Affinity Column Gen2	prepacked column for affinity chromatography	09430857001	1 column
FcRn IgG Control	for functional control of the FcRn Affinity Column Gen 2	09494804001	1 mL
cOmplete His-Tag Purification Resin	pre-charged with Ni ²⁺ , ready-to-use	08778850001	800 mL, settled resin volume



Discover more about CustomBiotech

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In vitro Glycoengineering

Glycosyltransferases

Product Name	Product Name Addition	Catalog Number	Pack Size
α-2,3-Sialyltransferase, rec. EQ	human, expressed in HEK-293F, solution	07429916103	custom fill
α-2,6-Sialyltransferase, rec. EQ	human, expressed in CHO-K1 cells	08098174103	custom fill
β-1,4-Galactosyltransferase, rec. EQ	human, expressed in CHO-K1 cells	08098182103	custom fill

Activated Sugars

Product Name	Product Name Addition	Catalog Number	Pack Size
CMP-N-Acetylneuraminic Acid (CMP-NANA)	sodium salt, lyophilizate	05974003103	custom fill
UDP-Galactose animal-free	disodium salt, lyophilizate	07703562103	custom fill
UDP-N-Acetylgalactosamine	sodium salt, lyophilizate	06369855103	custom fill

Related Products

Product Name	Product Name Addition	Catalog Number	Pack Size
Alkaline Phosphatase, recombinant, highly active	from calf intestine, expressed in Pichia pastoris, solution	03137031103	custom fill
Residual Protein 2,6-Sialyltransferase	ELISA kit for determination of 2,6-Sialyltransferase	08011478001	1 kit (96 reactions)
Residual Protein Galactosyltransferase	ELISA kit for quantitative detection of β-1,4-Galactosyltransferase	08182990001	1 kit (96 reactions)



Discover more about
in vitro Glycoengineering

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Tissue Dissociation

Product Name	Product Name Addition	Catalog Number	Pack Size
Liberase MNP-S	0.2 µm filtered, lyophilizate	05578566001	35 mg
Liberase MNP-S GMP Grade	0.2 µm filtered, lyophilizate	06297790001	5 mg
Liberase MTF C/T, GMP Grade	0.2 µm filtered, lyophilizate	05339880001	1 kit
Liberase T-Flex, Research Grade	0.2 µm filtered, lyophilizate	05989132001	1 kit
Collagenase I, GMP Grade	liquid, mammalian free, from <i>Chlostridium histolyticum</i>	05172969103	custom fill
Collagenase I/II, GMP Grade	lyophilizate, mammalian free, from <i>Chlostridium histolyticum</i>	05349907103	1 bottle
Collagenase II, GMP Grade	liquid, mammalian free, from <i>Chlostridium histolyticum</i>	05172942103	custom fill



Discover more about products
for tissue dissociation

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Raw Materials BioPharma

Product Name	Product Name Addition	Catalog Number	Pack Size
Catalase	from <i>Corynebacterium glutamicum</i> , solution	11668153103	custom fill
NADH, Food Grade	disodium salt, lyophilizate	03277372103	1 kg
Glutathione, reduced form (GSH)	crystalline powder	10002801103	custom fill
Glutathione, oxidized form (GSSG)	crystalline powder	10151327103	custom fill



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CustomBiotech

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**Please contact your local
CustomBiotech representative**

Europe, Middle East, Africa, Latin America
mannheim.custombiotech@roche.com

United States
custombiotech.ussales@roche.com

Canada
custombiotech.can@roche.com

Asia Pacific
apac.custombiotech@roche.com