

Residual Protein Liberase Kit

Complete manufacturing solutions for improved product safety

Enzymes used in cell therapy manufacturing — during cell preparation or for the modification and activation of products — pose safety risks and must therefore be removed before final product release. Conventional methods used to ascertain the presence of enzymes are based on measuring enzyme activity, which fails to detect inactivated proteins that can still be immunogenic.

To enhance product safety, Roche CustomBiotech has introduced high-performance kits based on ELISA technology to reliably detect complete and fragmented enzymes, independent of activity.

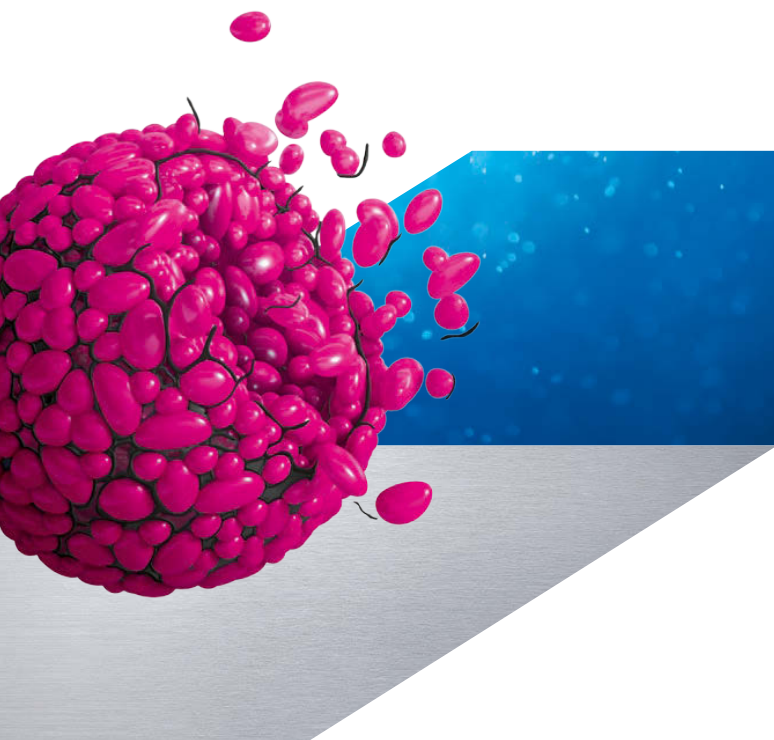
The **Residual Protein Liberase Kit** includes high-affinity polyclonal antibodies that detect the presence of enzyme with high sensitivity and in a broad range of sample matrices and types. Combining these kits with Roche animal-free, GMP-grade enzymes augments production efficiency, from the use of high-activity enzymes to timely verification of their clearance.

Benefit from:

- **Increased safety** of your products due to accurate detection of enzymes and enzyme fragments in process samples and final biopharmaceutical products.
- More **accurate control** due to activity-independent detection.

Residual Protein Liberase Kit features:

- **High specificity**
Antibodies raised specifically against Roche Liberase enzyme blends.
- **High sensitivity**
Limit of detection 0.1 ng/ml.
- **Reliability**
High lot-to-lot consistency of kit reagents, leading to reproducible results.
- **Convenience**
All-inclusive reagent kits with pre-coated plates, controls, and standards.
- **Fast turnaround time**
Time-to-result: 2 – 2.5 hours.



Test characteristics for Liberase detection*

	Specification	Typical performance
Sensitivity	≤0.1 ng/ml	approx. 0.005 ng/ml
Measuring range	0.1 – 5 ng/ml	
Precision	≤15%	<5%
Accuracy (vs. weight)	≤25%	<10%
Specificity	Roche Liberase Blends; Collagenases I and II from <i>Clostridium histolyticum</i> , thermolysin from <i>Bacillus thermoproteolyticus</i> , and fragments*	
Assay time (h:min)	2 – 2:30 total assay time	
Test format	96 reactions can be split into 2 runs	

*Compatibility with enzyme formulations from other suppliers must be verified.

Ordering information

Product	Catalog number
Residual Protein Liberase Kit** (96 reactions)	07 758 693 001
Related Products***	
Liberase MNP – S (35 mg)	05 578 566 001
Liberase MNP – S GMP Grade (5 mg)	06 297 790 001
Liberase MTF C/T GMP Grade (2 x 500 mg)	05 339 880 001
Additional Quality Control or In-Process Manufacturing Kits**	
Residual Protein Trypsin Kit (96 reactions)	07 568 975 001
Residual DNA <i>E. coli</i> Kit (96 reactions)	07 728 735 001
Residual DNA CHO Kit (96 reactions)	07 427 689 001
MycotoOL Mycoplasma Real-Time PCR Kit (160 PCR reactions)	06 495 605 001
ViroTOOL MVM PCR Detection Kit (30 PCR reactions)	06 479 359 001
MycotoOL PCR Mycoplasma Detection Kit including controls and standard (1 Kit for testing of 10 samples) Consists of 2 subkits:	05 200 709 001
MycotoOL Mycoplasma Detection Prep Kit	05 184 592 001
MycotoOL Mycoplasma Detection Amplification Kit	05 184 240 001

Reference *Data derived from Roche R&D.

Regulatory disclaimer **For use in quality control/ manufacturing process only. ***Blended proteolytic enzyme for tissue dissociation. For further processing only.

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