

Residual Protein Trypsin Kit

Complete manufacturing solutions for improved product safety

Enzymes used in biopharmaceutical 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 Trypsin Kit** includes high-affinity polyclonal antibodies that detect the presence of enzymes with high sensitivity and in a broad range of sample matrices and types. Combining these kits with Roche animal-free, GMPgrade enzymes augments production efficiency, from the use of high-activity enzymes to timely verification of their clearance.

Benefit from:

- **Accurate** detection of enzymes and enzyme fragments in process samples and final biopharmaceutical products to increase product safety.
- **Precise control** due to activity-independent detection.

Residual Protein Trypsin Kit features:

- **High specificity**
Antibodies raised specifically against Roche Trypsin, rec., GMP Grade.
- **High sensitivity**
Limit of detection 0.5 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 Trypsin detection*

	Specification	Typical performance
Sensitivity	≤0.5 ng/ml	approx. 0.5 ng/ml
Measuring range	0.5 – 50 ng/ml	
Precision	≤15%	<4%
Accuracy (vs. weight)	≤25%	<10%
Specificity	Trypsin, rec., expressed in <i>Pichia pastoris</i> *	
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 Trypsin Kit** (96 reactions)	07 568 975 001
Related products***	
Trypsin, rec., expressed in <i>Pichia pastoris</i> (1 g = 0.23 MU)	06 369 880 103
Trypsin, rec., expressed in <i>Pichia pastoris</i> (3.5 MU)	03 358 658 103
Additional quality control/in-process manufacturing kits	
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
QC Sample Preparation Kit****	08 146 829 001

Regulatory Disclaimer

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For further processing only. *For use in quality control/manufacturing process only.

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Published by

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