

# Residual Protein Trypsin Kit

## Complete manufacturing solutions for improved product safety

Trypsin used in a biopharmaceutical manufacturing process – during cell preparation or for the modification and activation of products – must be completely removed before final product release. Other methods used to detect trypsin are based on measuring its enzymatic activity, failing to detect inactive protein fragments which still can be immunogenic.

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

The **Residual Protein Trypsin Kit** includes high-affinity polyclonal antibodies that detect the presence of trypsin protein 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:

- **Sensitive** detection of enzymes and enzyme fragments in process samples and final biopharmaceutical products to increase product safety.
- **Reliable 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 is 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  | <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)    | 2:00 to 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., GMP Grade (expressed in <i>Pichia pastoris</i> , 1 g = 0.23 MU) | 06 369 880 103 |
| Trypsin, rec., GMP Grade (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 disclaimers, warranty limitations and legal notes**  
are listed on the respective product page on [custombiotech.roche.com](https://custombiotech.roche.com)

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