



About this edition:

With the publication of the new USP chapter <1132.1> in May 2025, LC-MS/MS has become an officially acknowledged technology for HCP analysis and the regulatory landscape changed.

For approval of a new biological drug substance, regulatory agencies are often no longer satisfied with ELISA data only and demand for orthogonal analyses.

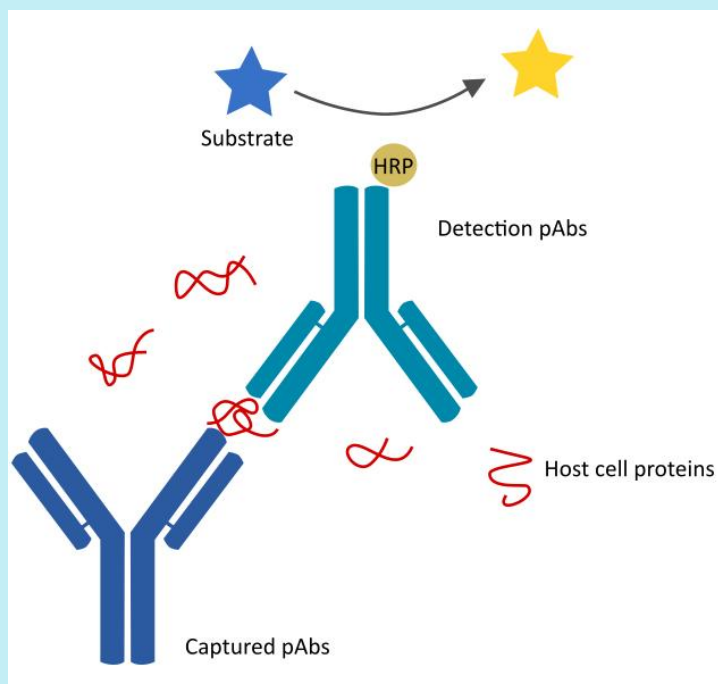
Thus, we dedicate our first Newsletter of 2026 to the two key technologies for host cell protein (HCP) monitoring in biopharmaceutical production: ELISA and LC-MS/MS. We present their features, highlight their advantages and the ability to complement each other.

A few words about the technologies

ELISA

Enzyme-linked immunosorbent assay (ELISA) is an established, validated and trusted technology for host cell protein (HCP) monitoring in biopharmaceutical production.

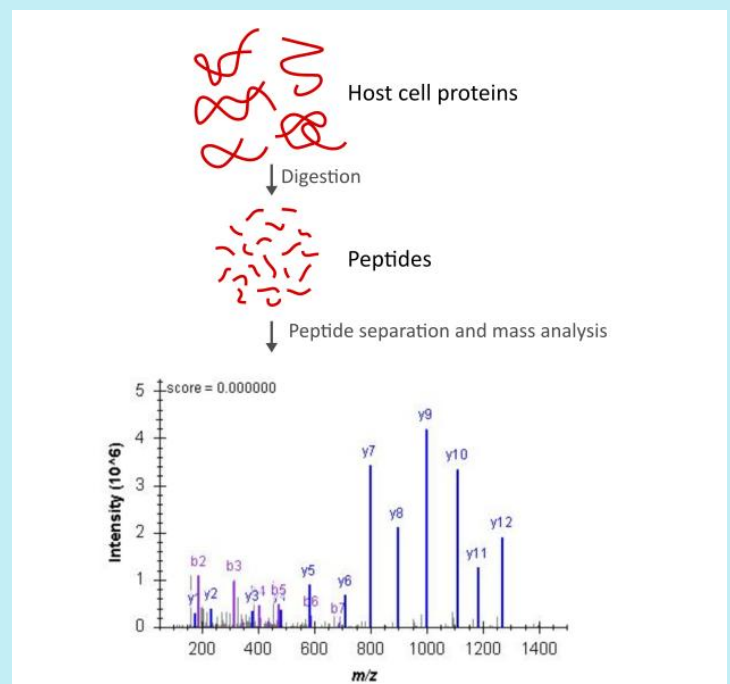
Captured polyclonal antibodies, raised against e. g. a mock cell line bind to remnant host cell proteins in the analyte sample. HCP detection and quantification is enabled with a second antibody that is coupled to an enzyme (e. g. Horseradish peroxidase), inducing measurable turnover of a substrate.



LC-MS/MS

Liquid chromatography-tandem mass spectrometry is a technology combining peptide separation using liquid chromatography and mass analysis.

After digestion of a proteinaceous sample with an appropriate protease (e. g. Trypsin), the peptides are physically separated, followed by ionization and mass analysis. The acquired spectral information is then used to identify the peptides based on a known spectral library.

















ELISA and LC-MS/MS – a perfect match for host cell protein analyses

Both technologies have their advantages and disadvantages.




Setting up a new ELISA is a time-consuming process. But once established, an ELISA enables fast and reproducible assessment of global HCP abundance and is ideally suited for routine HCP measurement in quality control and batch release testing. However, when reagents run out or expire, a new ELISA needs to be developed. And as the quality of the assay depends on the sensitivity and specificity of the raised antibodies, the results will diverge from the previous assay. It is also important to note that some critical proteins may be missed due to low immunogenicity.

Here LC-MS/MS closes the gap. For early production stages, for new organisms or if there is no ELISA available, LC-MS/MS is able to provide detailed information on the proteins present in a sample. The assay can be set up for any production organism in a matter of weeks. Though the turnaround time for a routine assay is longer than ELISA (approx. 1 week), LC-MS/MS provides valuable insight at early production stages and enables production optimization from start to finish. Being antibody-independent, LC-MS/MS provides supporting information for e. g. ELISA validation and transition from old to new assays.

	ELISA		LC-MS/MS	
Detection	Quantitative measurement of global HCP levels		Unbiased identification and quantification of individual proteins	
Development time	6-12 months		4-8 weeks	
Turnaround time per assay	≤ 2 days		≤ 1 week	
Life cycle	While reagents last		unlimited	
Antibody-dependance	Yes		No	
Skill requirements	Easy		High	
Equipment cost	Moderate		High	

Our offer:

PolyQuant provides comprehensive services and support for quantitative proteomics projects. We offer unbiased determination of HCPs in a biological sample as well as quantification of common and critical HCPs using our proprietary QconCAT technology. Our established LC-MS/MS and bioinformatics workflows provide you with tailored solutions for application in process development and quality control of recombinant proteins, vaccines, protein purifications etc.

-  Flexible services for every development stage
-  Tailored assay development for novel hosts
-  Targeted HCP quantification using our proprietary QconCAT technology

Are you planning to strengthen your HCP analysis workflows with LC-MS/MS? Our experts are [here](#) to talk to you. [More information.](#)



Other news:

We proudly present two new publications featuring QconCAT reference standards that were produced by PolyQuant.



FGF1 ameliorates hepatic steatosis through acute activation of the unfolded protein response and VLDL production

van Zutphen T, Struik D, Liu W, Liu S, Sermikli BP, Wolters JC, Verkade HJ, Atkins AR, Downes M, Evans RM, Jonker JW.

[JHEP Rep. 2025 Oct 30;8\(2\):101660.](#)

Aiming at identifying new candidates for therapeutic intervention of metabolic dysfunction-associated steatotic liver disease (MASLD), van Zutphen et al., studies the mechanism underlying the anti-steatotic properties of fibroblast growth factor (FGF) analogs. They evaluated liver physiology, ER stress and signalling through metabolic and proteomic analyses in human and rodent hepatocytes. Targeted proteomics using a QconCAT reference standard enabled them to determine absolute amounts of 8 apolipoproteins and to observe a significant increase of ApoB100, ApoC2 and ApoM concentrations in plasma following treatment with FGF1, indicating that FGF1 modulates apolipoprotein levels mainly at the post-translational level.

An LC-Immuno-MRM-MS Winterplex Method Development Framework for Respiratory Viral Screening

Van Puyvelde B, Dufrasne FE, Denayer S, Parys A, Van Mulders T, Van Hulle M, Deforce D, Barbezange C, De Cremer K, Van Gucht S, Vissers JP, Dhaenens M.

[Anal Chem. 2026 Feb 23](#)




Currently, RT-qPCR is the gold standard for clinical detection and diagnosis of viral infections. During the COVID-19 pandemic however, RT-qPCR reached its limits, highlighting a need for alternative, scalable detection methods.

To support pandemic preparedness, van Puyvelde et al. developed and validated a quantitative immuno-multiple reaction monitoring (iMRM) assay (“Winterplex”) for the simultaneous detection of influenza A, influenza B, RSV, and SARS-CoV-2 using a [QconCAT reference standard](#) providing two proteotypic peptides per virus. Their method was validated according to ISO standards for in vitro diagnostics and benchmarked against RT-qPCR.

Our ISO 9001:2015-certified products and services are also available through [Scientist.com](#).



We quantify your proteins

-  > 15 years of experience in quantitative proteomics
-  proprietary QconCAT technology for multiplex protein quantification
-  supported by experienced professionals at every project stage

