



**CAPRION**  
ACCELERATING PRECISION MEDICINE



# HCP DETECT™ A BETTER SOLUTION TO IDENTIFY AND MONITOR HOST CELL PROTEINS

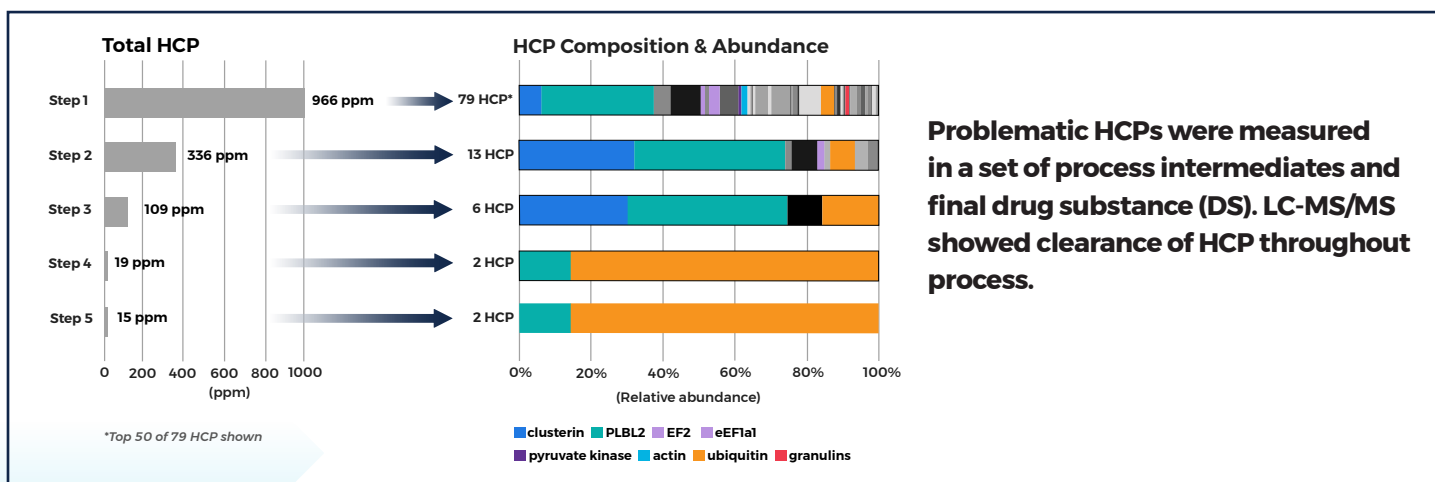
## ASSESS RISK AND IMPROVE BIOLOGIC MANUFACTURING

To ensure patient safety and product efficacy during manufacturing, regulatory authorities require testing of process-related host cell protein (HCP) impurities. HCPs are immunogenic, exhibit drug-modifying activity, and co-purify at high levels, which pose a safety risk. Caprion's solution, HCP Detect™, identifies and tracks all problematic HCPs to improve product purity and optimize process engineering.

## ENHANCING YOUR HCP ELISA DATA, WHILE ENSURING REGULATORY COMPLIANCE

To confirm and supplement HCP ELISA data, regulatory guidance recommends using new analytical technologies when appropriate to mitigate the risk of using a single method. Mass spectrometry-based assays are increasingly used as an orthogonal approach to obtain a list of all residual HCPs in a sample (including non-immunogenic or unknowns), and to track the levels of specific HCPs at all development phases.

**Dig deeper with a proven solution:** Caprion's robust orthogonal mass spectrometry-based assay technology delivers individual HCP identity and can track low-level specific HCPs at all development phases, providing you with reliable comprehensive data for regulatory submissions.



## AN IMPROVED PROCESS FOR OPTIMAL PRODUCT PURITY

To meet regulatory requirements, HCPs should be monitored through all development phases, ensuring the manufacturing process is controlled, reproducible, and able to yield drug substance (DS) or drug product (DP) that meets specifications. Caprion's HCP Detect™ provides insight at each step, reducing risk and putting you in control of your engineering process.

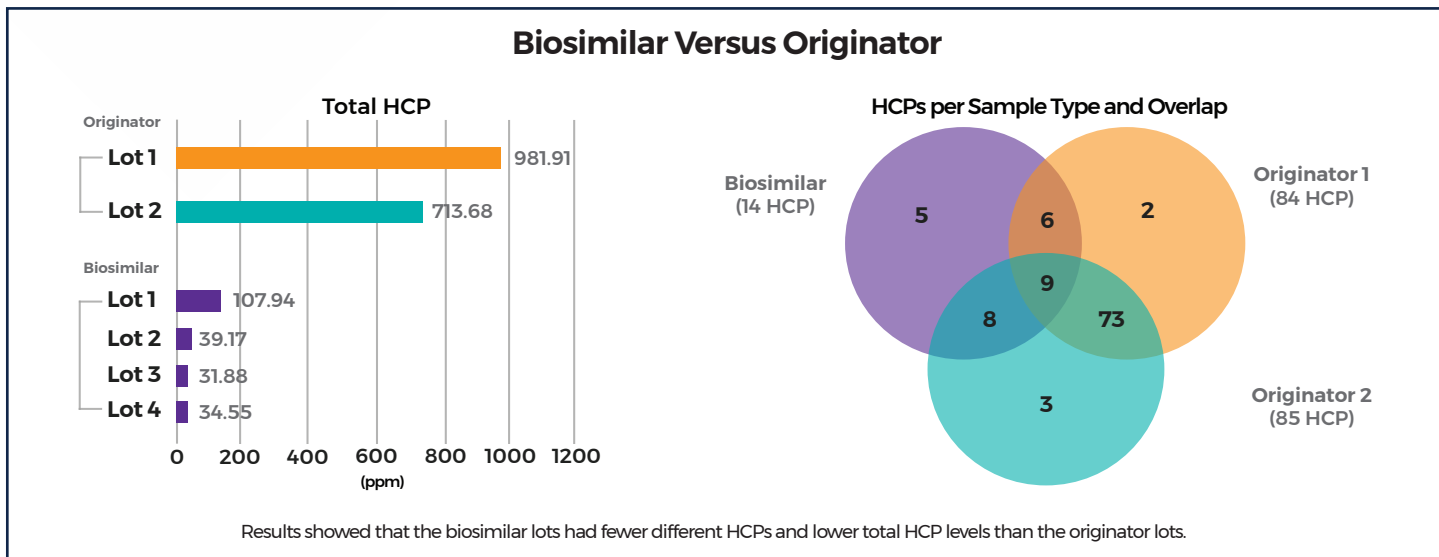
## MASS SPECTROMETRY: AT THE CENTER OF HCP DETECT

Caprion's HCP Detect™ uses proven, state-of-the-art mass spectrometry technology platforms to provide comprehensive, sensitive, and specific characterization of HCPs in the presence of DS or DP. Each HCP analysis is conducted using highly controlled, robust, and documented processes by experienced mass spectrometry scientists and a team of bioinformaticians. As the leader in proteomics and immune monitoring, Caprion's proven track record in mass spectrometry applied to biologics has no match.

## HCP IDENTIFICATION AND QUANTITATION USING NON-TARGETED LC-MS/MS

A comprehensive list of all HCPs and the abundance of each HCP

- ▼ Sensitivity down to ~1-10 ppm
- ▼ Direct measurement that does not require antibodies
- ▼ Custom process-specific database containing the entire host proteome for comprehensive protein identification
- ▼ No need for assay or reagent development



## HCP ABSOLUTE QUANTITATION USING TARGETED LC-MRM/MS

Highly multiplexed measurement of specific HCPs to confirm or to monitor levels

- ▼ Absolute quantitation ( $\leq 25$  HCPs) and/or relative quantitation ( $\leq 300$  HCPs) in a single assay
- ▼ Quick assay development based on target protein sequence(s)
- ▼ Sensitivity down to single digit ppm
- ▼ Stable isotope labeled peptide standards as reference material
- ▼ Assays can be fully validated as per regulatory requirements

## WHY CHOOSE CAPRION?

- ▼ Nearly 20 years of expertise in advanced mass spectrometry-based services on large molecules
- ▼ Leader in complex biomarker assay development, validation and deployment using mass spectrometry
- ▼ Superior science above all
- ▼ Proven data integrity and in-depth regulatory expertise
- ▼ Unwavering commitment to proactive partnership and open communication
- ▼ A commitment to highest quality standards

## ABOUT CAPRION BIOSCIENCES

Leading provider of specialized immunology and proteomics services to the biopharmaceutical industry with laboratory facilities located globally. Caprion offers proprietary multiparametric flow cytometry for monitoring of immune responses and mass spectrometry services for quantitative and robust measurement of protein biomarkers across the drug development life cycle.

FOR MORE INFORMATION  
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