

Host Cell Protein Quantitation and Analysis

Detection and assessment of Host Cell Proteins (HCPs) are critical for ensuring the quality and safety of protein-based biologics. HCPs comprise a highly heterogeneous population of residual proteins that may persist in drug substances and downstream purification intermediates. Due to their potential impact on product quality and clinical safety, comprehensive HCP characterization and monitoring are essential throughout biopharmaceutical development and manufacturing.

To effectively address the diverse and complex nature of HCPs, SHENTEK® employs robust method development strategies and complementary, orthogonal analytical technologies to achieve sensitive and comprehensive detection and characterization of a broad range of residual HCPs, supporting process optimization, purification efficiency, and consistent product quality.

SHENTEK® offers a variety of HCP detection and analysis service platforms:

- ☑ HCP assay and analysis platform [ELISA, LC-MS, 2D with different staining]
- ☑ HCP coverage assessment platform [IMBS®-2D, IMBS®-MS]
- ☑ Anti-HCP polyclonal antibody preparation platform
- ☑ Customized HCP ELISA kit development platform



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Not for diagnostic or therapeutic use.

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HCP Assay and Analysis Service Platform (ELISA, LC-MS and 2D with different staining)

- ✓ Process-specific SHENTEK® HCP ELISA kits to ensure accurate and specific detection;
- ✓ Traceability system for HCP ELISA standards to ensure assay accuracy and reliability;
- ✓ Process-specific and high-risk HCP analysis, as well as lot-to-lot comparison for preclinical and clinical trial lots;
- ✓ Identification of high-risk HCPs using orthogonal methods to address the limitations of HCP ELISA during bioprocess development.

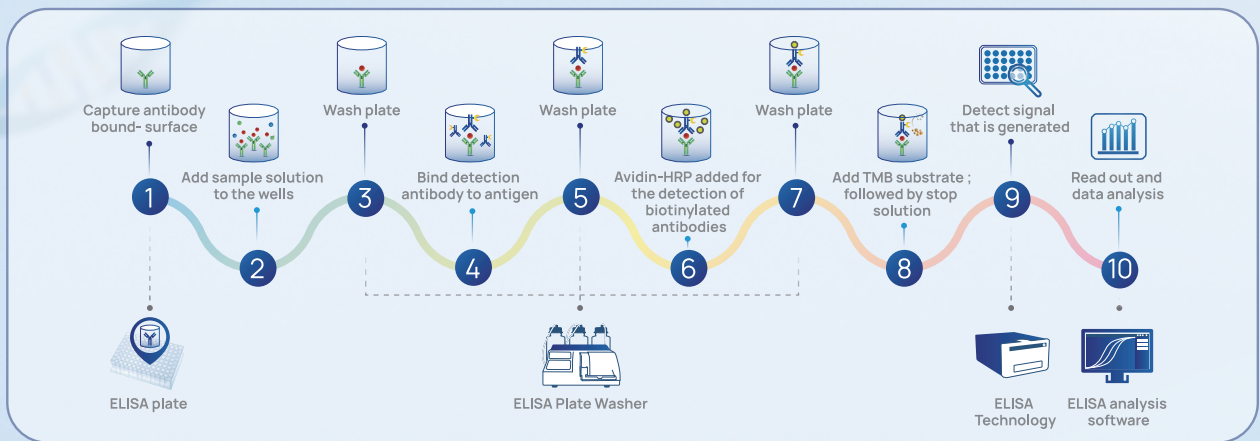


Figure 1 Standard Method for HCP Monitoring - Sandwich ELISA Workflow

2

HCP Coverage Assessment Platform (IMBS®-2D, IMBS®-MS)

- ✓ Antigen-specific antibody immunoaffinity-purification based proprietary IMBS® (Immunomagnetic Bead Separation) technology for rapid & specific HCP immunogen isolation;
- ✓ Orthogonal proteomic methods of 2D & LC-MS to illustrate antibody coverage of HCPs with increased sensitivity and accuracy;
- ✓ Antibody coverage analysis on the early process samples or mock samples to select suitable ELISA for the specific bioprocess;

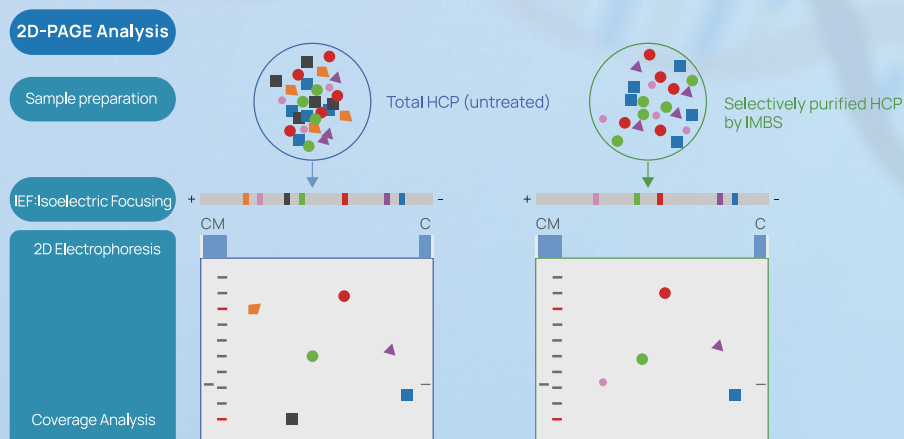


Figure 2 IMBS®-2D HCP-antibody Coverage Analysis

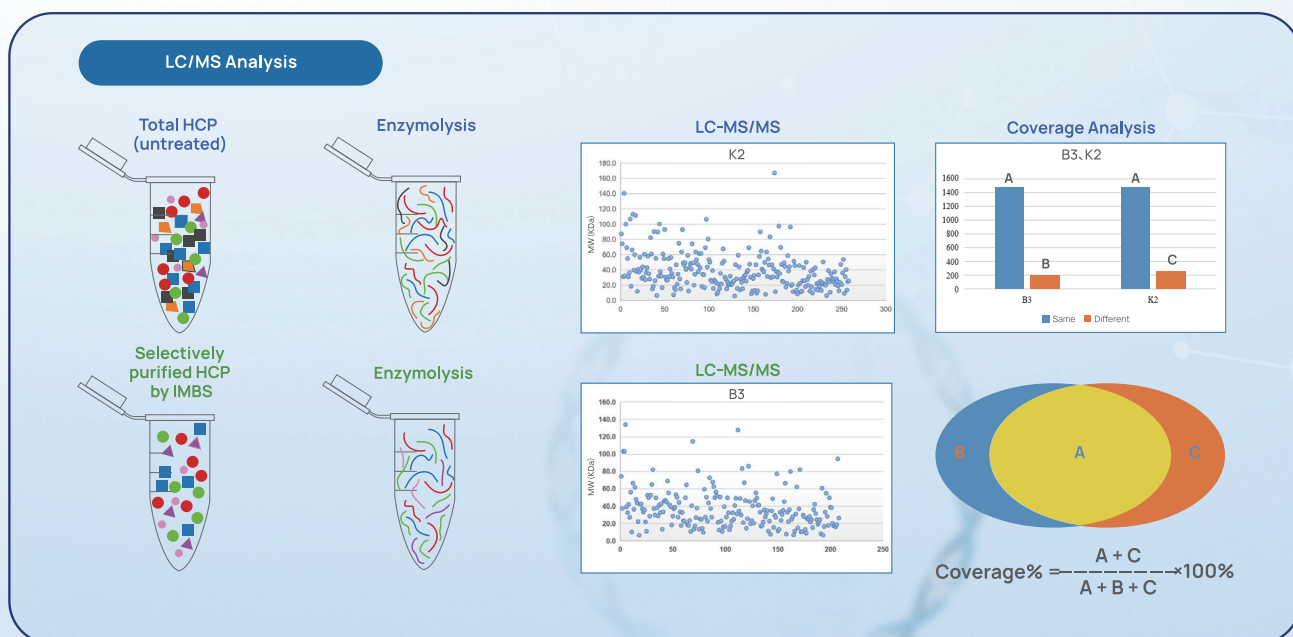


Figure 3 IMBS®-LC/MS HCP-antibody Coverage Analysis

3

Anti-HCP Polyclonal Antibody Preparation Platform

- ✓ Effective immunization strategies and antibody preparation for different antigen groups;
- ✓ Characterization and quality control of antibodies to maximize quality, coverage, and speed;
- ✓ Antibody generation, purification and screening with optimized processes;
- ✓ Standard practice of HCP reference traceability to ensure the reliability of immunoassays;

Strategy of multi-level immunization

Immunogen treatment in specific orientations

Cross-species



Low molecule weight protein

Low immunogenicity protein

Non-immunogenic proteins

Figure 4 HCP Antigen Preparation and Immunization for Capture Antibody Generation

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Customized HCP ELISA Kit Development Platform:

- ✓ Comprehensive studies of residual HCP (rHCP) standards to achieve excellent coverage and specificity;
- ✓ Standard practice of HCP reference traceability to ensure the reliability of immunoassays;
- ✓ Effective and intensive antigen and antibody preparation strategies for robust immune response and high-quality polyclonal antibodies;
- ✓ Compliance with ISO13485 quality system to guarantee the high-quality HCP ELISA kit development;

SHENTEK® Customized HCP ELISA Kit Development Workflow

- 1 Assay Standard Preparation**
Comprehensive studies (concentration, composition, stability, traceability, etc.) and production
- 2 Antibody Preparation**
Effective immunization strategies, and antibody generation & coverage evaluation
- 3 Kit Development**
Assay set-up and product specification setting
- 4 Production Validation**
Pilot scale test and process scale-up validation
- 5 Assay Performance Evaluation**
Assay validation & method transfer studies

SHENTEK® Comprehensive and Customized Residual Host Cell Protein (rHCP) Analysis Service Platforms

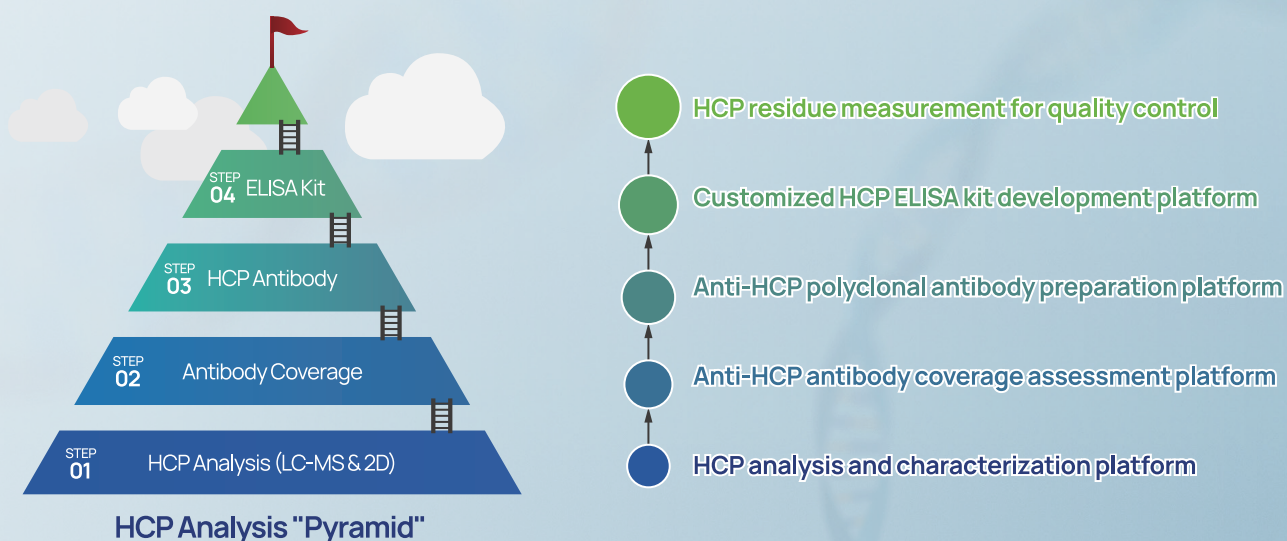


Figure 5 SHENTEK® Residual Host Cell Protein Analysis Service Platforms

SHENTEK® has established a robust and efficient platform for HCP antigen and anti-HCP antibody development, preparation and characterization. The platform provides customized process- or platform-specific HCP reference standards and diverse anti-HCP antibodies, supporting the rapid assay development and reliable, consistent supply of high-quality HCP ELISA kits.