

Host Cell Protein Quantitation and Analysis

Detection and evaluation of Host Cell Protein (HCP) is a critical quality attribute (CQA) in protein-based biologics manufacturing because HCPs are derived from expression host species, and represent a heterogeneous variety of different proteins that need to be quantified in the drug substance, and intermediates from the downstream purification process. HCPs carry potential clinical safety risks, and industry addresses this risk by diligent method development and the use of multiple and orthogonal technologies, to detect and evaluate the virtually unlimited variety of HCPs.

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

Huzhou Shenke Biotechnology Co., Ltd.



info@shentekbio.com

+1-908-822-3199/ +86-400-878-2189

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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;
- ✓ High-risk HCP identification by applying orthogonal methods to complement the limitations of HCP ELISA for bioprocess development.

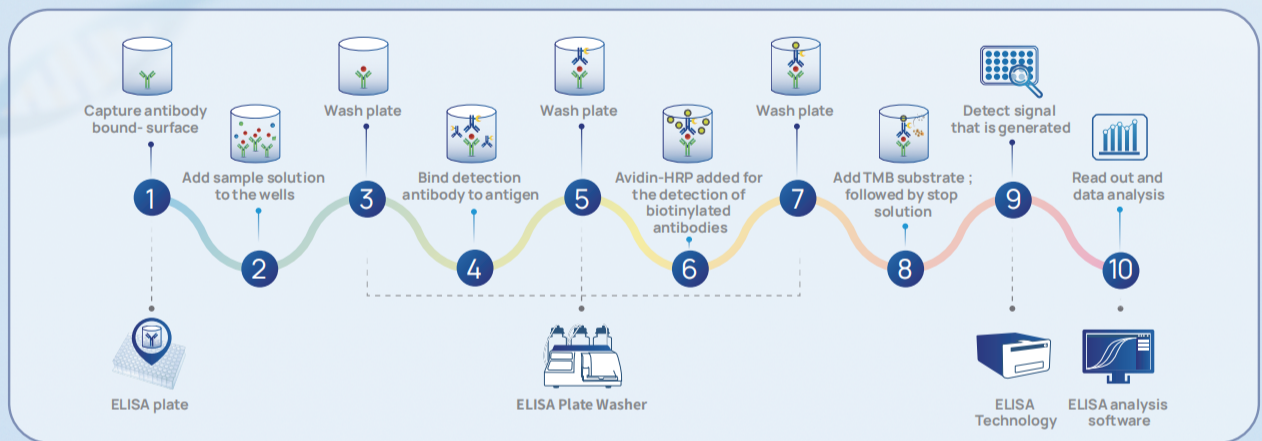


Figure 1 Standard Method for HCP Monitoring - Sandwich ELISA Workflow

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

- ✓ Proprietary IMBS (immunomagnetic bead separation) technology using antigen-specific antibody immunoaffinity-purification 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;

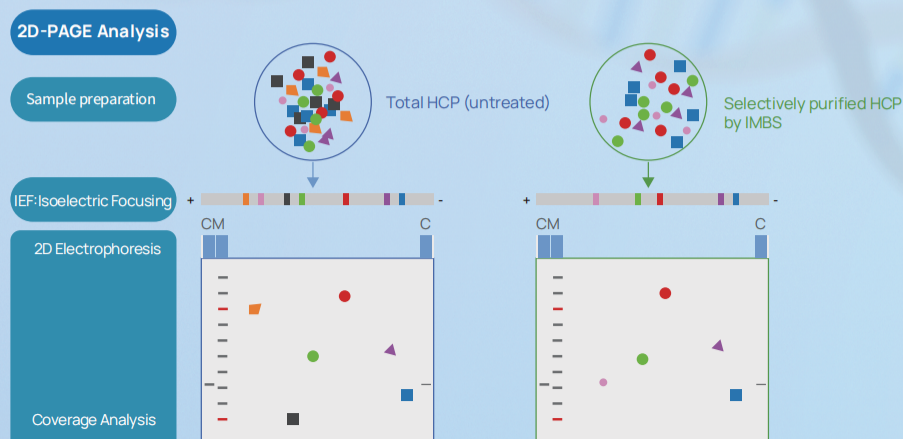


Figure 2 IMBS-2D HCP-antibody Coverage Analysis

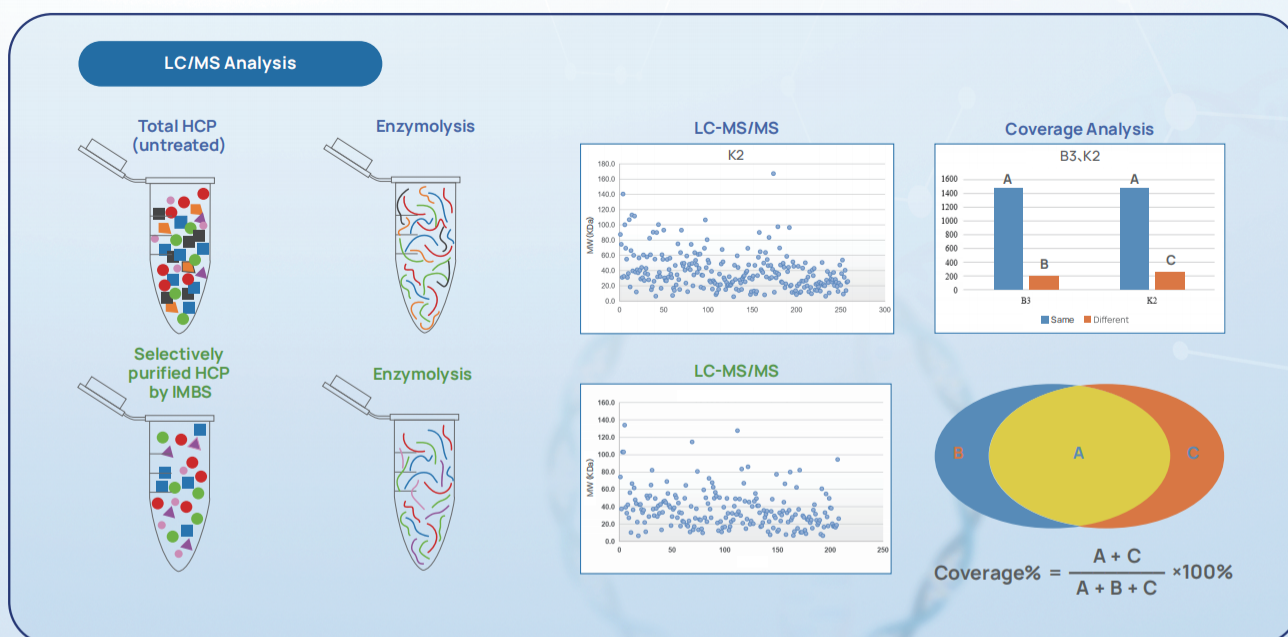


Figure 3 IMBS-LC/MS HCP-antibody Coverage Analysis

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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;



Figure 4 HCP Antigen Preparation and Immunization for Capture Antibody Production

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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 tier & coverage validation
- 3 Kit Development**
Assay set-up and product specification setting
- 4 Production Validation**
Pilot scale test and process scale-up validation
- 5 Method Transfer**
Assay validation & transfer test

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

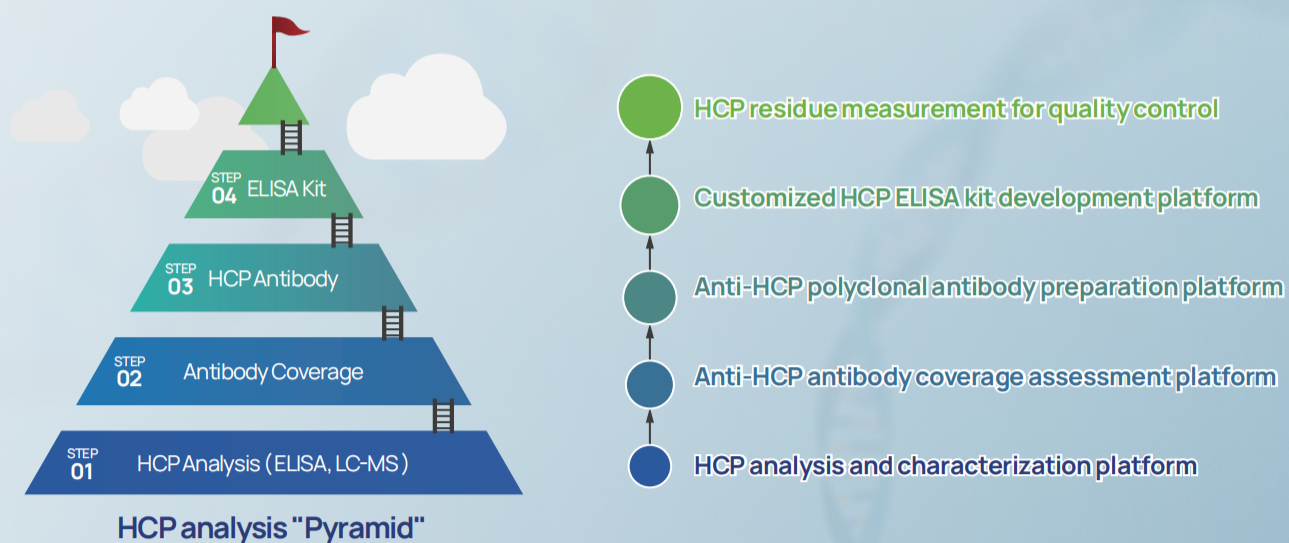


Figure 5 SHENTEK® Residual Host Cell Protein Analysis Service Platforms

SHENTEK® established a highly efficient HCP antigen and anti-HCP antibody preparation and analysis platform, which provides customized process- or platform-specific HCP reference standard and diverse antibodies, ensuring the efficient development and consistent supply of high-quality HCP ELISA kits.