

# HCP-ELISA characterization and coverage

Do your HCP-ELISAs cover all critical Host Cell Proteins?

## Choose the best ELISA for your biologic

Traditionally, HCP-ELISA coverage has been evaluated by spot counting in 2D-PAGE and Western blotting, which is inaccurate and difficult to reproduce. The ELISA-MS™ analysis uses immunocapture in the ELISA plate format and LC-MS for protein identification. It provides detailed and accurate information about each HCP in your process and product, plus the coverage % of your HCP-ELISA assay - reducing the risk of project delays due to problematic HCPs.

Different results with 2 ELISAs due to poor specificity and low coverage?



## Compare ELISAs and document HCP coverage

Characterize coverage percentage, identify covered vs. uncovered HCPs, - including high-risk HCPs - and select the best fit ELISA for your product.

## Bridging studies

Characterize changes in ELISA reagents or methods implemented during development and lead to inconsistent result.

## Troubleshoot ELISAs

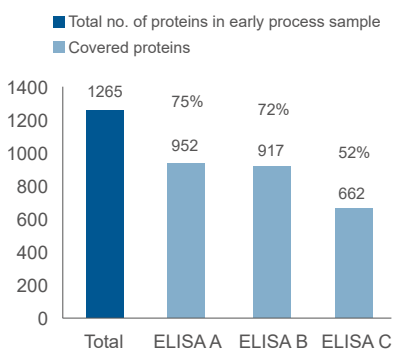
Investigate issues with antibody/drug substance cross-reactivity, insufficient specificity, incorrect standards for the calibration curve, etc.

## Example of results

3 ELISA kits were used on an early process sample in which 1265 HCPs were identified by LC-MS. 952 of them were covered by ELISA A, 917 by ELISA B, and 662 by ELISA C, corresponding to coverages of 75%, 72%, 52%.

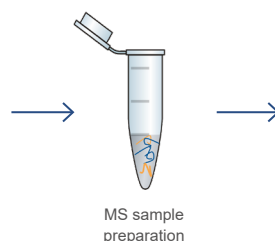
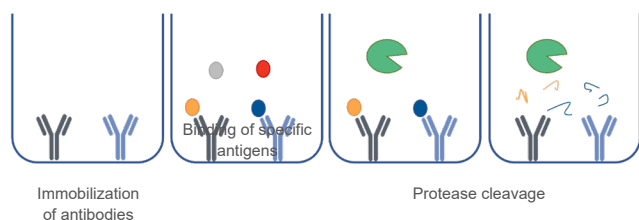
The lists were compared to the top 10 HCPs identified by LC-MS in the purified drug substance. ELISA A showed the best coverage of the early process sample (75%) and the most abundant HCPs in the drug substance (9 of 10).

### HCP coverage of 3 ELISA kits on early process sample



### Specific coverage of HCPs in drug substance

	ELISA A	ELISA B	ELISA C
Oxidoreductase A	+	+	+
Protein B	+	+	-
C Reductase	+	+	+
Cyclohydrolase D	+	-	+
Regulation protein E	+	-	-
Heat shock protein F	+	+	-
Protein G	-	+	-
Dehydrogenase H	+	+	+
Protein I	+	+	+
Chaperone J	+	+	+
<b>Specific coverage</b>	<b>9/10</b>	<b>8/10</b>	<b>6/10</b>



LC-MS analysis

## Principles of ELISA-MS™

The method is based on immunocapture using ELISA antibodies immobilized in a plate combined with LC-MS protein identification and quantification.

## What customers say

"Using the Alphalyse ELLISA-MS™ method for ELISA selection, we estimate savings of approximately \$1M and, likely, one year of development time."

SAVARA Aps, Denmark  
Lars Skriver - Senior Science Officer

## Why work with us?

- 20+ years of experience helping biotech companies in Europe and USA
- 500+ MS-based HCP projects makes us the World's most experienced lab



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