

# HCP ELISA COVERAGE ANALYSIS

**CHOOSE THE BEST  
ELISA FOR YOUR  
BIOLOGIC!**



## DOES YOUR HCP ELISA COVER ALL CRITICAL HOST CELL PROTEINS?

Traditionally, the quality of an HCP ELISA is evaluated by spot counting in 2D-PAGE and Western blotting. This method is inaccurate and difficult to reproduce. Alphalyse Coverage Analysis uses immunocapture in the ELISA plate and LC-MS/MS protein identification.

It provides detailed and accurate information about each HCP, plus the specificity and coverage of the HCP ELISA for your process and product - a knowledge that helps you reduce the risk of project delays due to problematic HCPs.

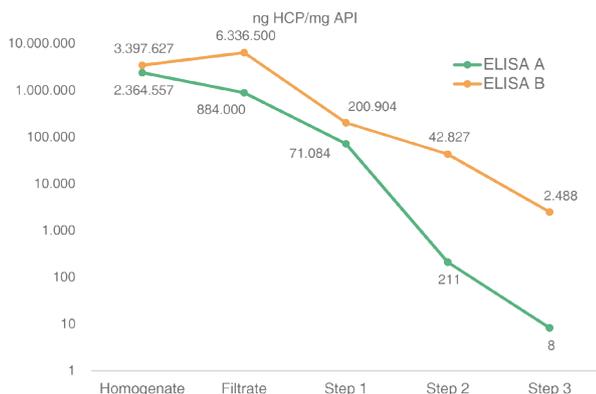
### Evaluate HCP ELISAs

Compare ELISA antibodies to select the most suitable for your product and process.

### Validate your HCP ELISA

Get the coverage for individual HCPs in your process, and in the pure drug substance. For both commercial and process specific HCP ELISAs.

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



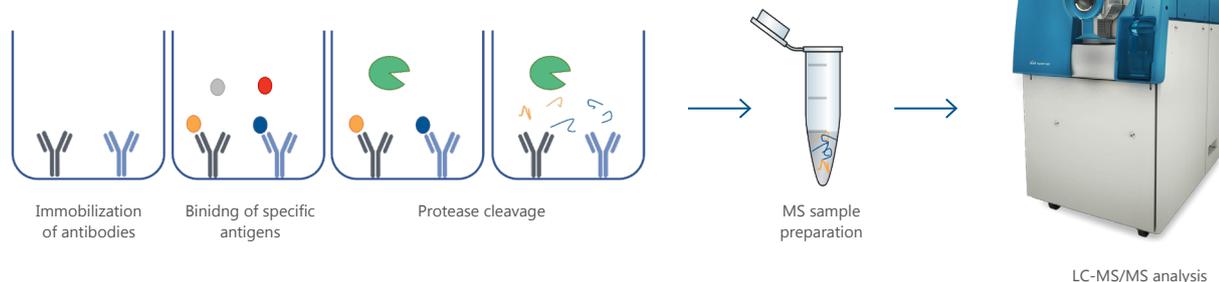
## ADVANTAGES

- ✓ **FAST** - No need for a null-cell line. Can be applied directly to your samples.
- ✓ **ROBUST** - Reproducible data is obtained by microflow LC-MS/MS.
- ✓ **DETAILED** - You get a list of individual HCPs including pI, MW, and accession number, for risk assessment.

# PRINCIPLES OF THE ALPHALYSE COVERAGE ANALYSIS



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



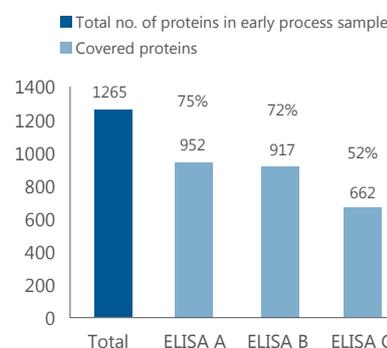
## Results from Alphalyse Coverage Analysis

The coverage of three commercial HCP ELISAs was evaluated with an early process sample in which 1265 proteins were identified. Of these, 952 proteins were covered by ELISA A, 917 proteins by ELISA B, and 662 proteins by ELISA C, corresponding to coverages of 75%, 72%, 52% (see figure on the right).

The lists were compared to the top 10 HCPs identified in the purified drug substance (see the table below).

In conclusion, ELISA A showed the best coverage of both the process sample (75%) and the drug substance (9 of the 10 most abundant HCPs).

HCP coverage of 3 commercial ELISAs of 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>

## WHAT CUSTOMERS SAY

*"Using the Alphalyse LC-MS/MS Coverage method for HCP-ELISA selection, we estimate savings of approximately \$1M and, likely, one year of development time."*

SAVARA Aps, Horsholm, Denmark

## WHY WORK WITH US ?



- 15+ years of experience helping biotech & pharma companies in Europe & USA.
- Analysis is tailored to your requirements.
- 75+ HCP analysis projects by mass spectrometry - making us the world's most experienced lab.



## CONTACT US

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