



## Validation of an ELISA method for the detection of anti-host cell antibodies in human serum

### Aim of the study

Biopharmaceutical products may contain host cell derived protein impurities at low levels. A method for the detection of antibodies to HCP in human serum of patients treated with recombinant drug protein was validated for immunogenicity assessment.

### Analyte

Anti-host cell antibodies.

### Methodology

The ELISA method consists in a direct ELISA using antigen-coated microwell plates, while the detection system is a mixture of commercial HRP conjugated antibodies. Positive samples are confirmed by titration and specificity tests. The ELISA method was tested for sensitivity, specificity, intra- and inter-run accuracy and precision, and for inter-operator variability using spiked quality control samples.

**System** Human serum

**Therapeutic area** Reproductive Medicine

**Development stage** Preclinical

**Customer** Large pharmaceutical company

### Results

The ELISA method for detection in human serum of antibodies against host cell proteins of a recombinant protein produced in serum free medium was demonstrated to be accurate, precise, capable to confirm positive samples and sensitive and selective for the antigen.

### Advantage of the methodology

Anti-host cell antibodies can activate immunogenic reactions in treated patients. Here, an accurate, precise and selective ELISA method was validated to detect the presence of these antibodies in patient serum.

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