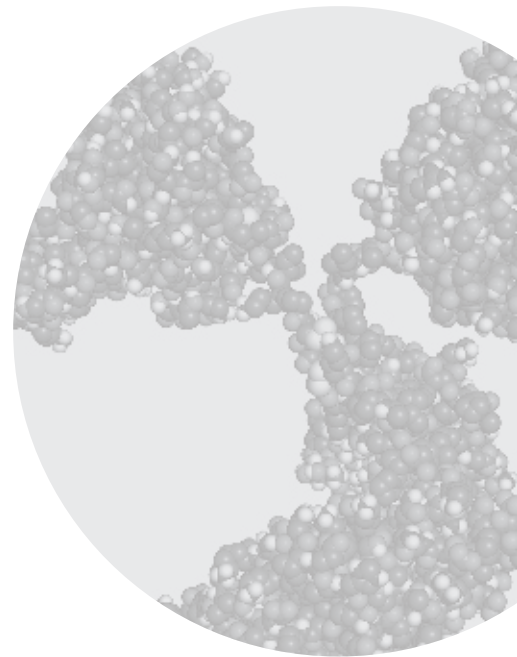




**KYMOS**  
BIOTECH

# Biologics

## Bioanalysis and immunogenicity



# BIOANALYSIS FOR PK AND PD STUDIES

**Immunological techniques** are the Gold Standard for the quantitation of large proteins in biological fluids although nowadays important advances in the use of the LC-MS/MS are being done. KYMOS has capabilities to perform development, validation and sample analysis of immunoassays with three different platforms depending on the drug characteristics:

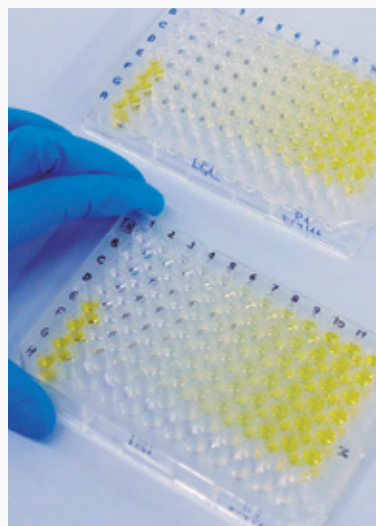
- **ELISA:** direct, sandwich, bridge or competitive using different detection techniques such as colorimetric, fluorescence or time resolved fluorescence
- **Electrochemiluminescence (ECLA)** by Meso Scale Discovery (MSD®)
- **Radioimmunoassay (RIA)** using  $^{125}$  radiotracers

**Mass Spectrometry** methods may be also used, especially during the development phases and for special cases. KYMOS capabilities cover:

- **LC-MS/MS** with triple quadrupole and QToF mass spectrometers to measure the intact proteins and peptides (up to 8-9 KD) or tryptic digested using selected diagnostic peptides for all size proteins
- **ICP-MS** for bioanalysis of metals and metalloproteins

Both Immunological and Mass Spectrometric methods are currently applied to the levels determination of recombinant and biomarker endogenous proteins.

Protein levels can be treated to obtain the pharmacokinetic parameters using the conveniently validated Phoenix® WinNonlin® software package.



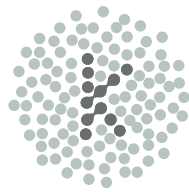
# IMMUNOGENICITY

Biologics may have a high potential to induce immune response which can impact on pharmacokinetics, efficacy, cross-reactivity and side effects. Due to these potential impacts on efficacy and safety, immunogenicity has become a key issue for health authorities. KYMOS provides services covering the different development phases:

- **Assays to determine binding Anti-Drug Antibodies (ADA)**
  - **Screening** assays for the detection of positive samples
  - **Confirmatory** assays for ruling out false positive results
  - **Isotyping** assays to determine the ADA isotypes
  - **Titration** assays to quantify the immune response
- **Neutralizing** assays to assess the drug function inhibition capabilities of the ADA using specific cell assays
- **Cellular immune response** using suitable cell-based assays

**ELISA, ECLA** and **RIA** platforms are available at KYMOS for these studies. In addition, KYMOS may provide label-free interaction studies using **Surface Plasma Resonance** technology (Biacore®)





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