



1 Scheme of SPR-Assay for nADA determination @ Fraunhofer IME / Sorwe Mojtahed Poor

2 nADA standard curve @ Fraunhofer IME / Sorwe Mojtahed Poor

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IMMUNOGENICITY TESTS

In view of the increasing number of approved biologicals, the focus is also on the associated immunogenicity. Immunogenicity comprises the formation of anti-drug antibodies (ADA) that are able to influence pharmacokinetics and pharmacodynamics of the therapeutics. This leads to a high need to determine parameters altered by immunogenicity such as biological concentration, ADA and neutralizing ADA (nADA) levels. Regulatory agencies recommend a multitiered testing system, including a screening and a confirmatory assay. Therefore two assay systems for the determination of immunogenicity parameters have been established. It is also important to exclude that co-medication and serum proteins (i.e. rheumatoid factor) do not interact with the assay system, so for the establishing of immunogenicity assays, patient serum is used. The assays can be customized.

Biological determination

- Assay using surface plasmon resonance (SPR) technology

- Assay based on enzyme linked immunosorbent assay (ELISA) technology

ADA and nADA determination

- Assay using SPR technology
- Assay based on ELISA technology

Complexed nADA determination

- Complex dissociation by pH alteration and detection of nADA by ELISA

In vivo nADA are free or bound to the biological. Therefore besides the free nADA also the complexed nADA are of interest.

Reference

Mojtahed Poor S. et al. Development and validation of assays for assessment of immunogenicity of biologic therapy as exemplified by ustekinumab. Clin Exp Immunol. (2019); 17. doi: 10.1111/cei.13261