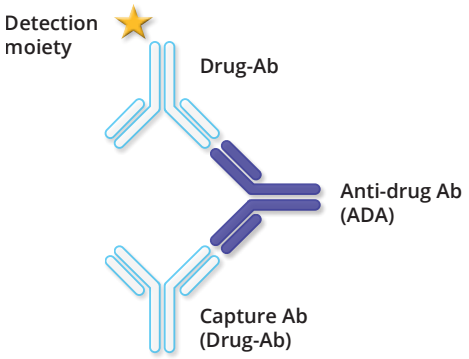
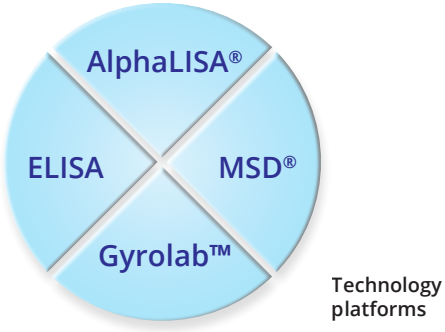
Bridging assay configuration for detection of ADAs





Immunogenicity assessment – choice of an appropriate platform is crucial

The most common technology to evaluate ADA response is the enzyme-linked immunosorbent assay (ELISA) by the bridging assay format. The new immunoassay platforms at IBR Inc., AlphaLISA®, MSD® and Gyrolab™, widen the choice and offer considerable advantages in terms of sensitivity, accuracy, robustness, reduced assay time and sample consumption, better drug- and target tolerance, dynamic range and detection of low affinity ADAs. Selection of the most appropriate technology is the most crucial parameter and must be carefully evaluated prior to assay validation and subsequent analysis of clinical samples.

Development of Biologics: Our Experience – Your Track to Success

IBR Inc. is a Swiss GxP-compliant contract research organization founded in 1998. With a focus on bioanalytical services for therapeutic antibodies, biologics, antibody-drug conjugates and vaccines, IBR Inc. is covering the bioanalytical needs from pre-clinical and clinical development to manufacturing. Beside a broad panel of classical bioanalytical methods, IBR Inc. offers advanced technologies including Alpha technology, TR-FRET, MSD ECL, Gyrolab™, flow cytometry, multiplex cytometric bead array and quantitative PCR.
The IBR Inc. team has vast experience with primary cells, transformed cell lines and transfected reporter-gene cell systems as well as longstanding expertise on 2D and 3D cell based assays. IBR Inc. supports your studies from assay development to assay validation and sample measurement.

Immunoassay platforms

The **ELISA** is the most commonly used assay to evaluate ADA response. Bridging format assays show high target tolerance even in the absence of target depletion.
The **Gyrolab™** ADA solution provides an automated nanoliter-scale method with or without acid pre-treatment and uses dedicated Gyrolab™ ADA software designed for 21 CFR part 11 compliance. The technology is especially suitable for studies with small sample volumes.
The **Meso Scale Discovery® (MSD)** platform allows multiplex assay formats and offers rapid development of MSD bridging immunogenicity assays with a homogeneous solution phase incubation step where only one wash step is required.
The **AlphaLISA®** platform is a proximity-based homogeneous assay that relies on energy transfer between donor and acceptor beads with a high signal amplification. Sensitivity of ADA detection can be achieved on the ng/ml scale. Drug tolerance is high at µg/ml concentrations of free drug.

IBR Inc. Services

Platform selection

Carefully selecting the appropriate platform can improve success. IBR Inc. invites you to discuss your requirements with its scientific experts, ensuring the proper choice of technology platform (ELISA, AlphaLISA®, Gyrolab™ or MSD®) as well as sample pre-treatment strategies, tailored to your specific needs.

Immunogenicity assay setup and optimization

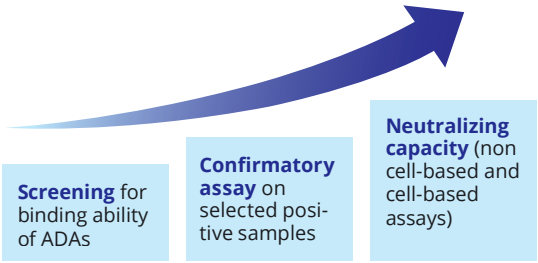
IBR Inc. develops immunogenicity assays in direct or bridging format. During the assay development, sample pre-treatment strategies to reach an appropriate target and drug tolerance are carefully evaluated. Acid dissociation, target depletion and ECL-based PandA method are some of the strategies that might be employed. Neutralizing capacity can be evaluated by non cell-based or cell-based assays, depending on the particular mechanism of action of the specific drug.

Assay validation

Analysis of clinical trial samples must be performed using appropriately validated methods with adequate acceptance criteria. IBR Inc. assay validation is conducted following regulatory requirements and validation guidelines EMEA/CHMP/EWP/192217/2009, ICH Q2 (R1) and USP Chapter 1033.

Clinical sample measurement

Analysis of clinical trial samples for the assessment of the immunogenic potential, is done by a tiered approach, following the regulatory guidelines EMEA/CHMP/BMWP/14327/2006.



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