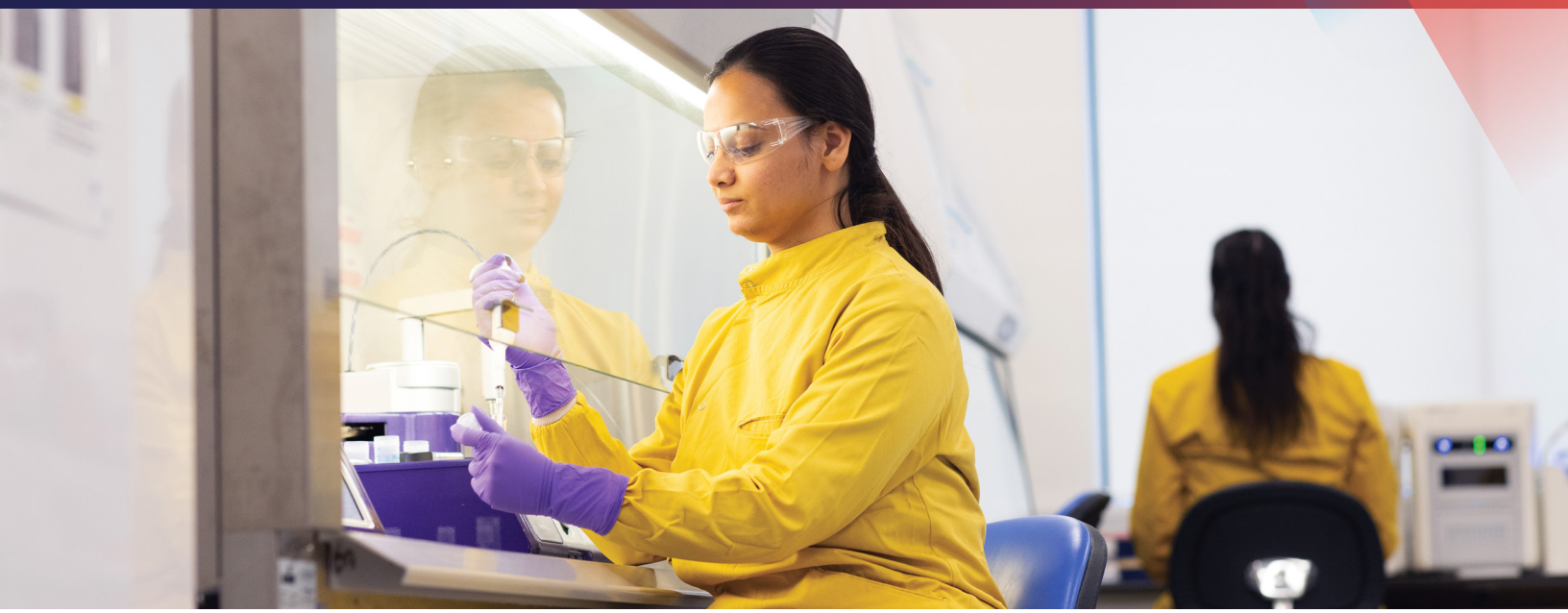
ABZENA

Advanced Immunogenicity Assessments



Immunogenicity assessments play a critical role in the development of biotherapeutics, as unintended immune responses can severely compromise the safety and efficacy of treatments. These immune-mediated reactions may lead to adverse patient outcomes, reduce therapeutic benefits, and result in significant delays or failures in the clinic. Addressing immunogenicity early in the development process minimizes costly setbacks, accelerates time to market, and enhances a therapeutic program's overall success.

At Abzena, we recognize the importance of immunogenicity testing in biotherapeutic development and provide a comprehensive suite of solutions that address these challenges. Our extensive experience and innovative approaches ensure that your therapeutic candidates are thoroughly assessed for immunogenic potential, facilitating smoother regulatory pathways and enhancing clinical outcomes.

Immunogenicity Assays

Abzena provides a robust suite of immunogenicity assays, meticulously designed to meet the technical demands of biological development. Our advanced methods and state-of-the-art technologies ensure precise and reliable assessments of immunogenic risks.

Whole Molecule Risk Assessment

Our comprehensive approach includes:

- **EpiScreen® 2.0 Time Course Assay:** This assay measures T-cell responses over time to evaluate the immunogenic potential of therapeutic candidates. Utilizing multi-parametric flow cytometry, it assesses multiple T-cell activation and proliferation markers, providing a detailed immune response profile.
- **EpiScreen® 2.0 DC: T Cell Assay:** Specifically designed for therapeutics with immunomodulatory effects, this assay assesses T-cell proliferation and activation following antigen presentation by monocyte-derived dendritic cells to isolated T cells.
- **Cytokine Release Assay:** This assay monitors cytokine profiles to predict potential immune responses and assess the risk of cytokine storm. High-throughput Luminex analysis simultaneously quantifies multiple cytokines with high sensitivity and specificity, enabling detailed immune profiling.

‘Hot Spot’ Identification

Identifying and mitigating immunogenic “hot spots” within therapeutic molecules is crucial for reducing immunogenicity risks. Our advanced techniques include:

- **MAPPs Assay (MHC-associated Peptide Proteomics):** This assay identifies peptides presented on MHC molecules, pinpointing potential immunogenic epitopes within therapeutic proteins. By using specific antibodies to isolate MHC-peptide complexes from sample treated donors, it ensures efficient capture of relevant epitopes. Combining immunoprecipitation with high-resolution LC-MS/MS enables precise identification and quantification of presented peptides, facilitating accurate and detailed epitope mapping.
- **T Cell Epitope Mapping:** Providing comprehensive mapping of T-cell epitopes, this technique identifies immunogenic regions within your molecule by utilizing overlapping peptide libraries to identify peptide regions that stimulate T-cells.
- **iTope AI:** Leveraging machine learning, iTope AI predicts immunogenic epitopes with high accuracy, streamlining the immunogenicity assessment process. It integrates deep learning models trained on extensive epitope and MHC binding datasets to predict potential immunogenic regions with high precision. The high-throughput screening capabilities enable rapid identification of immunogenic epitopes and prioritization for experimental validation, thereby accelerating the development timeline.

Custom Solutions

Abzena delivers tailored immunogenicity testing solutions supported by our decades of expertise and advanced instrumentation.

- **Expertise in Immune Cell Isolation:** Proficient in isolating peripheral blood mononuclear cells (PBMCs) from sources including leukopaks, we ensure high yield, purity and viability for downstream assays. Further cell isolations can be performed via automated magnetic bead-based separation using RoboSep technology. Donors are selected to ensure broad HLA-diversity to provide confidence that results from our EpiScreen® 2.0 assays are representative of the human population.
- **Advanced Instrumentation:** Equipped with state-of-the-art flow cytometers capable of multi-parametric analysis, our high-throughput flow cytometry facilitates detailed cell population profiling, enabling comprehensive immune response characterization. Our multiplex cytokine analyzers, including platforms such as Luminex and FluoroSpot, provide comprehensive cytokine profiling, allowing simultaneous detection of multiple immune mediators with high sensitivity and specificity.
- **Collaborative Expertise:** Engaging immunologists, protein engineers, and analytics experts, our cross-functional teams enhance assay development, antibody humanization, and developability. This multidisciplinary approach ensures a comprehensive understanding of immunogenicity profiles. Our integrated project workflows facilitate seamless communication and data sharing across teams, ensuring cohesive and efficient project execution from assay development to data analysis, optimizing project timelines and outcomes.

Summary

Abzena’s immunogenicity testing services are designed to identify and mitigate immunogenicity risks early in the biotherapeutic development process. Our advanced assays, continuous innovation, and deep technical expertise provide critical insights that enhance the safety and efficacy of your therapeutic candidates. By proactively addressing immunogenicity risks, we help you navigate regulatory requirements efficiently and accelerate your path to market success.

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Reach out to Abzena today to discuss how our specialized immunogenicity testing services can support your therapeutic development.

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