synexa | Life Sciences

Laboratory Solutions for Vaccine Clinical Trials

Introduction

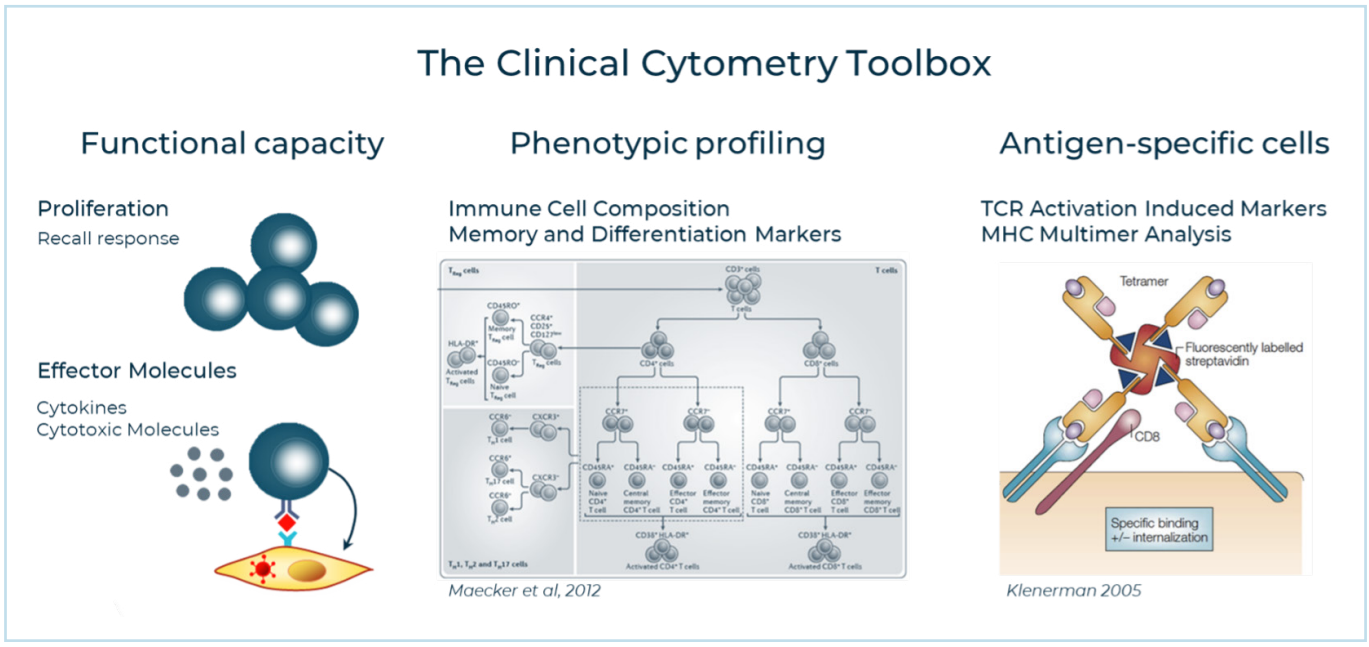
With years of experience and a multidisciplinary team of experts, Synexa Life Sciences is a leading provider of biomarker and bioanalytical solutions in the field of vaccines. We offer cutting-edge technologies to evaluate both cellular and humoral immune responses, and innovative approaches to accelerate vaccine development and ensure efficacy evaluations. We possess an in-depth understanding of immunology, molecular biology, and clinical research, enabling us to deliver comprehensive and reliable solutions that meet the highest scientific standards. We believe in fostering strong collaborations with our customers, working closely with them to achieve shared goals and drive scientific progress.

Our expertise

With a deep understanding of the complex immune system and its dynamic interactions, we provide comprehensive solutions to assess the efficacy and immunogenicity of vaccine candidates. Through techniques such as flow cytometry, MHC multimer analysis, and state-of-the-art immunoassays, we empower our customers to gain valuable insights into the immune response generated by vaccines. By leveraging our expertise, customers can make informed decisions and navigate the intricate landscape of vaccine development with confidence.

Our services

Synexa Life Sciences offers a comprehensive range of laboratory testing services tailored to meet the specific needs of vaccine developers. With a global presence, we are equipped to support vaccine clinical trials worldwide. We provide strategic guidance and scientific expertise throughout the vaccine development process, from translational studies to clinical trials and regulatory submissions. We are committed to delivering timely and cost-effective solutions, minimizing project timelines and optimizing resource allocation without compromising scientific integrity.



Analyzing Cellular Immune Responses in Vaccine Trials with Advanced Methods

Understanding the cellular immune response generated by vaccines is crucial for evaluating their efficacy and optimizing their development. At Synexa, we employ advanced methods to analyze vaccine-specific immune responses in vaccine trials, providing comprehensive insights into immune cell subsets and their functional properties. These methods offer a comprehensive assessment of immune cell populations, rare antigen-specific T cells, kinetics of T cell responses, and long-term immune memory. Our commitment to utilizing state-of-the-art technologies and adherence to stringent validation standards positions Synexa as a trusted provider in assessing and characterizing cellular immune responses in vaccine trials.

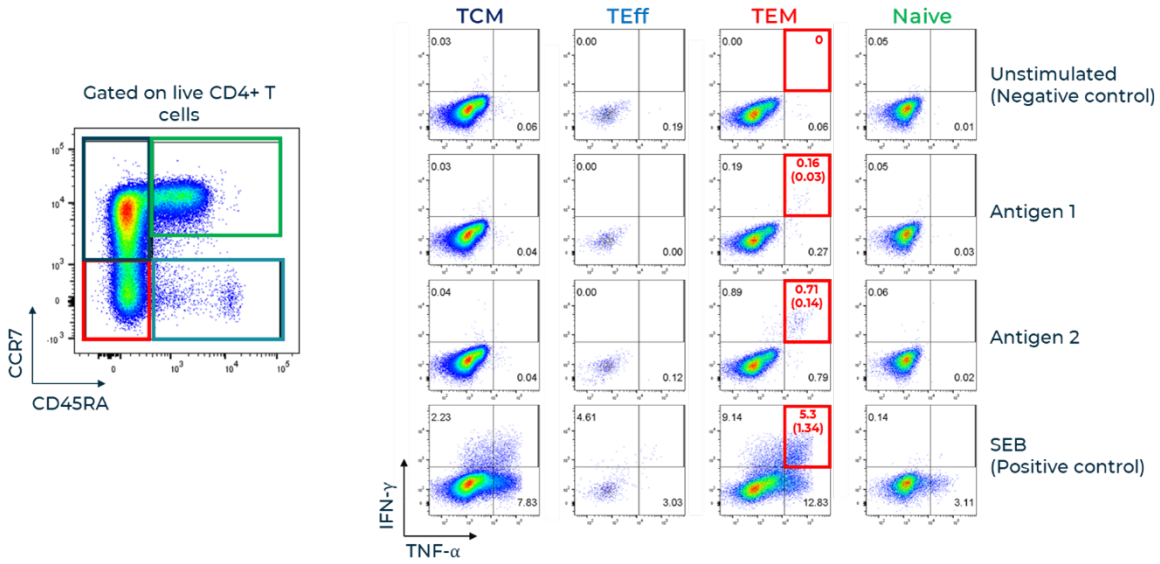
Immunophenotyping and Intra-cytoplasmic Cytokine Staining by Flow Cytometry

- Analyze and characterize vaccine-specific immune cells based on phenotypic markers, cytokine expression and activation induced markers to provide a comprehensive understanding of immune cell subsets and their functional properties.
- Extensive experience and portfolio of phenotypic and functional flow cytometry assays to assess responses against vaccine antigens.
- Up to 28-parameter flow cytometry panels.
- Fit-for-purpose validations according to the Clinical and Laboratory Standards Institute (CLSI) H62 Validation of Assays Performed by Flow Cytometry guidelines.

Long-term Culture Assays

- Long-term culture of PBMCs or whole blood in the presence of vaccine antigens with downstream quantification of proliferation, cytokines and/or gene expression changes.

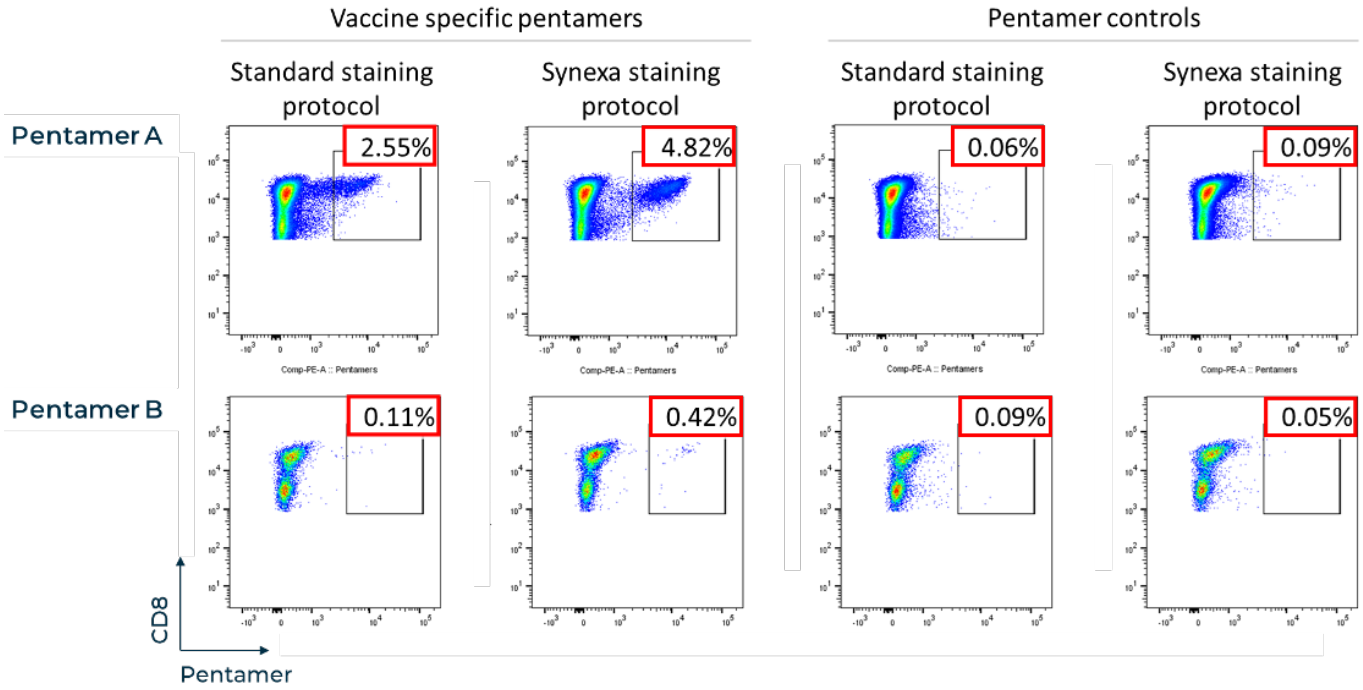
T Cell immunophenotyping and cytokine responses following stimulation of PBMC with vaccine-specific antigens



MHC Multimer Analysis

- Identify and enumerate rare antigen-specific T cell populations following vaccination, which might not be detectable using other methods.
- Monitor the kinetics of T cell responses over time to evaluate the duration and persistence of vaccine-specific immune responses.
- Synexa is a top performing member of the Immudex MHC Multimer Proficiency Panel.

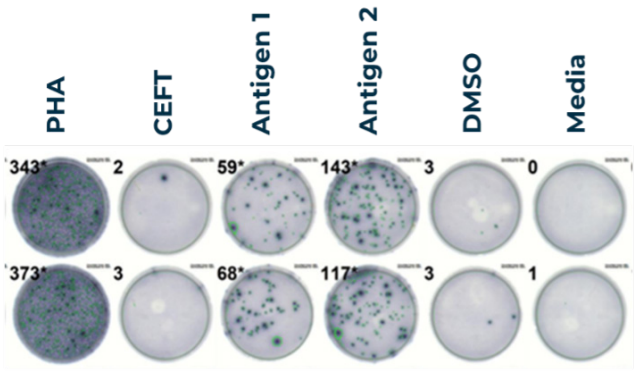
MHC Multimer Analysis: Detection of antigen specific vaccine responses using pentamers

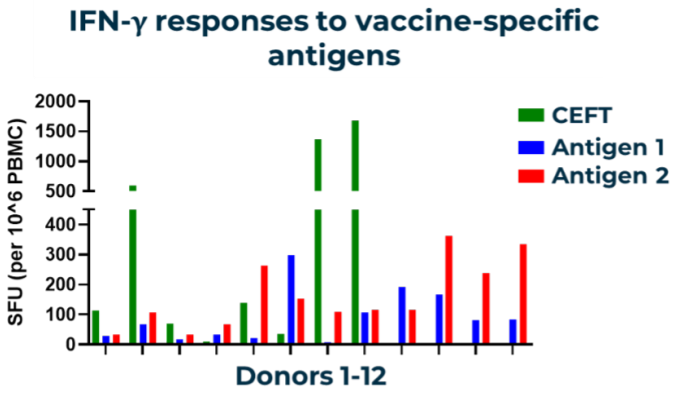


ELISpot

- Single or dual-color ELISpot immunostaining in response to a portfolio of vaccine antigens. Assays include negative, positive and CEF/T controls.
- Validation in accordance with Bioanalysis white papers on ELISpot assay validation.
- Synexa is a top performing member of the Immudex ELISpot Proficiency Panel.

Analysis of IFN-γ by ELISpot



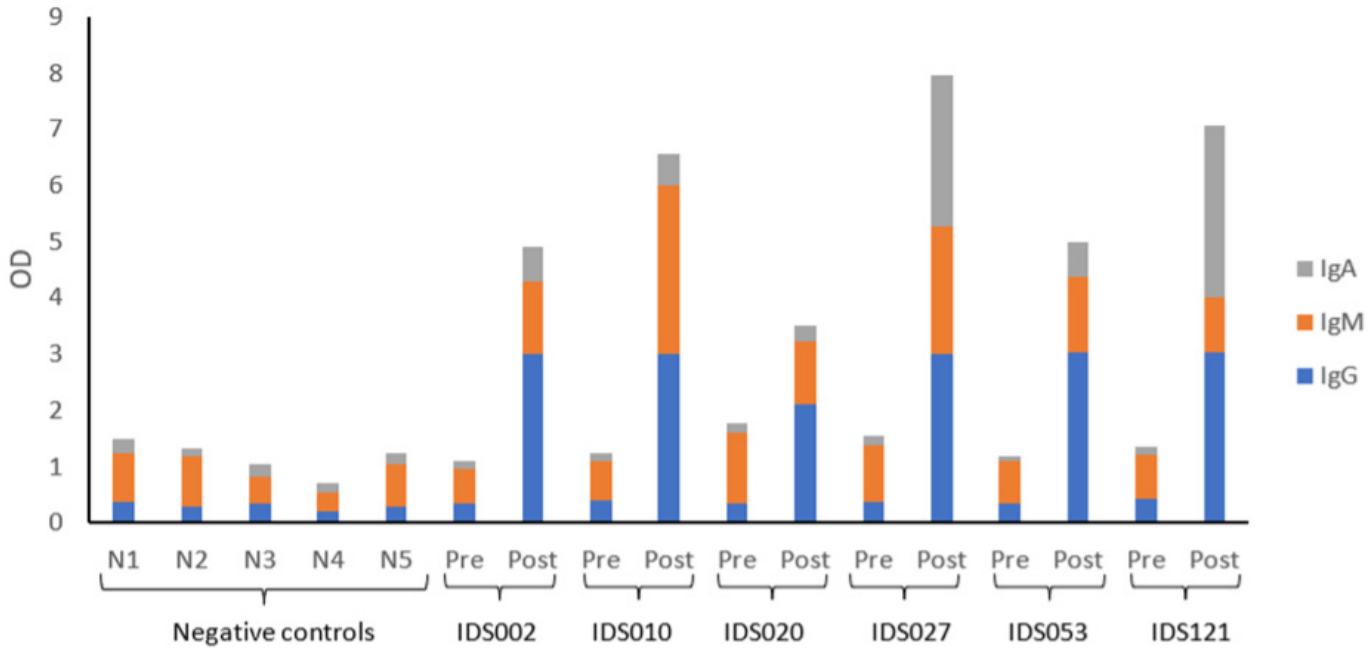


Analyzing Humoral Immune Responses in Vaccine Trials

The humoral immune response, characterized by the production of antibodies, plays a vital role in vaccine efficacy. At Synexa Life Sciences, we utilize advanced methods to analyze vaccine-specific humoral immune responses in vaccine trials. Our expertise includes single-plex or multiplex immunogenicity assays using platforms such as ELISA, MSD, Alphalisa, Gyros, and DELFIA.

- Assays permit semi-quantitative detection of antibodies raised against the specific vaccine target antigen.
- Assays are validated according to the relevant FDA and EMA guidelines.
- Depending on customer needs, assays can be developed using high-throuput methodology, permitting analysis of up to 160 samples in a single ELISA run.
- **Synexa has experience in detecting antigen-specific immune response in multiple matrix types including:**
  - Serum
  - Plasma
  - Saliva
  - Dried blood spots (DBS)

SARS-CoV-2 serological assay assessed antibody subtype-specific humoral response to vaccines against wildtype spike protein



Cumulative signals from SARS-CoV-2 spike-specific IgG, IgM and IgA antibody subtypes pre- and post- vaccination for individual donors

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