

Whether you're advancing a vaccine, gene therapy, CAR T-cell therapy, or an immunomodulating biologic, understanding cellular immunity is critical to evaluating mechanism of action, durability of response, patient variability, and overall therapeutic effectiveness. We design and deliver fit-for-purpose ELISpot assays to evaluate cellular immune responses in both nonclinical and clinical programs.

Our expertise encompasses immuno-oncology, vaccines, infectious diseases, autoimmune and inflammatory disorders, as well as cell and gene therapies. We develop, optimize, and validate assays that align with your protocols and regulatory requirements, ensuring the generation of sensitive and reproducible data. This applies even to low-volume or complex biological samples, supporting informed and risk-aware development decisions.

Using our validated **ELISpot/FluoroSpot platform**, our scientists:

- Design and execute sensitive ELISpot assays to quantify antigen-specific T and B cell responses across a wide range of therapeutic areas.
- Simultaneously evaluate multiply immune markers while maximizing data from limited samples by applying multiplex FluoroSpot assays.
- Implement functional immune assays that focus on cytokine secretion as a biologically meaningful readout of immune activation.
- Generate high-quality immunogenicity data that supports key development decisions, including dose selection and risk mitigation, and that strengthens regulatory submissions (e.g., IND/BLA).
- Develop and run regulatory-aligned workflows to support GLP studies, and exploratory or secondary clinical endpoints.

Our experts ensure consistent, reproducible results across all phases, helping you effectively scale your program and successfully prepare for regulatory submission.

Broad Therapeutic Applicability

Supports immune monitoring across:

- Vaccines and infectious diseases
- Immuno-oncology
- Autoimmune and inflammatory disorders
- Gene therapy (AAV, LV, mRNA, cell therapies)

Multi-Species and Matrix Support

- Human
- Nonhuman Primate (NHP)
- Mouse
- Rat
- Pig

Assays can be fit-for-purpose validated to support secondary clinical endpoints.

Advanced Immune Monitoring for Regulated Studies

S6 Flex M2 Analyzer

- 4-color ELISpot/FluoroSpot reader
- Supports work in a regulated environment
 - 21 CFR Part 11 compliant system
 - IQ/OQ/PQ and immunocompliance packages
 - Full audit trails for traceable, audit-ready data

High Throughput and Scalable Performance

- 96-well plate module
- Assays on PBMCs or splenocytes
- Quantification of T and B cell responses (antigen-specific or total)
- Multiplexing capabilities with FluoroSpot Analyzer

Supports exploratory profiling to large-cohort clinical studies.

FDA-Aligned Immune Monitoring

Early-Phase Cell and Gene Therapy

Validated ELISpot/FluoroSpot assays to assess cellular immune responses, providing decision-enabling data for immunogenicity risk and regulatory strategy.

CAR T-Cell Guidance

Validated ELISpot/FluoroSpot assays to assess immunogenicity against CAR constructs and co-expressed transgenes, supporting clinical outcome optimization and regulatory strategy.

Method Development and Pre-Validation Preparations

- Early planning: peptide design, purity, aliquots, final peptide, and DMSO concentrations
- Sample strategy: blood volume, isolation method, storage/shipping conditions, aliquots
- Priority planning for experimental conditions when working with limited cell numbers
- Method development: kit selection, positive control selection, peptide pools, cell density, stimulation conditions

Quality Assurance Commitment

- SOP-controlled workflows
- Trained, qualified personnel
- 21 CFR Part 11-compliant data systems
- Full deviation, investigations, CAPA procedures
- Internal auditing and instrument qualification
- ALCOA+ data integrity principles

Method Validation

- Precision, LOD, specificity, stability, linearity, robustness
- 6 healthy donors and disease population, if applicable
- Recommended for secondary clinical endpoints
- Follows current industry practices for ELISpot

Outcome: Defensible, inspection-ready, regulatory-compliant immune monitoring data.