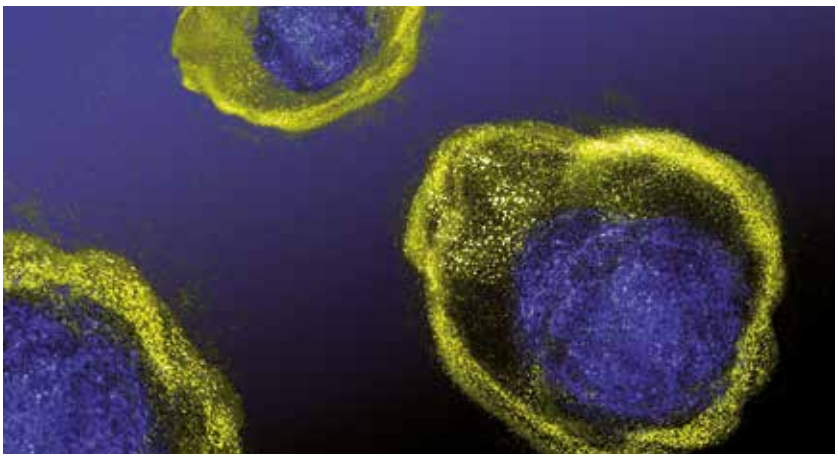

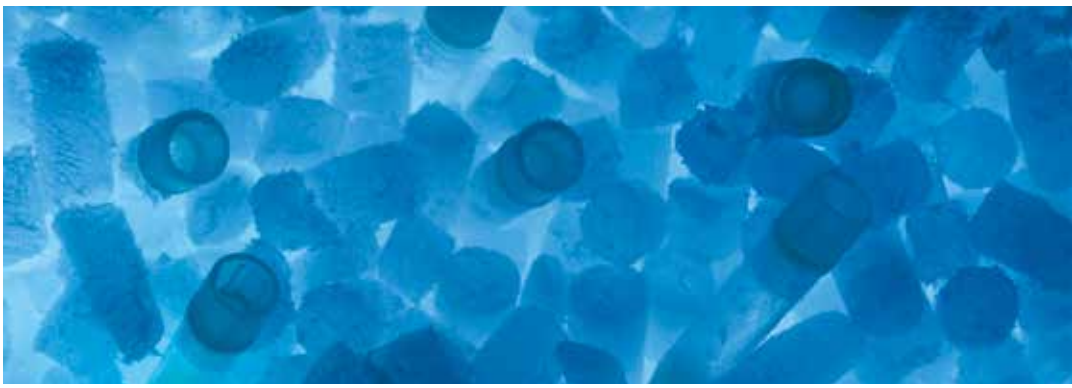

Discuss your project with our scientists today
- let's develop the future of life science together!

Doc No: S-162-GB00, Nov. 2024

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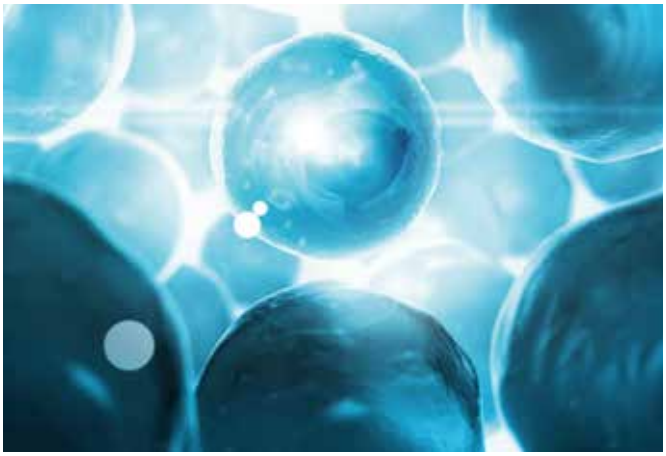
SVAR

Answers in Life Science

CELL-BASED SOLUTIONS

BRINGING BIOLOGICAL RELEVANCE TO YOUR DRUG DEVELOPMENT



Reporter Gene Assay Solutions

iLite® Technology

EXPLORE THE WORLD OF

CELL-BASED REPORTER GENE ASSAYS

UNLOCKING SCIENTIFIC DISCOVERY

Cell-based reporter gene assays have transformed biomedical research and drug development.

These cutting-edge tools provide real-time insights into cellular mechanisms and gene expression, offering accurate, in vivo-like conditions that lead to reliable, translatable results.

These assays are powerful tools for dissecting complex cellular processes, evaluating mechanisms of action, and assessing treatment effects. They are essential for determining the biological activity, potency, and manufacturing quality of biotherapeutic products, thereby accelerating the drug discovery process.

WHAT IT'S USED FOR

Used by pharma companies, CROs, and clinical laboratories with applications both within drug development and patient monitoring:

- Drug candidate screening
- Assessment of drug potency (incl. regulated lot release)
- Detection of neutralizing antibodies (NAbs)
- Therapeutic drug monitoring in patients

OUR SUITE OF CELL-BASED SOLUTIONS

Functional Bioassays
A range of different reporter cell lines allowing to detect and quantify Biopharmaceutical-induced biological functions.

Fc Effector Bioassays
Effector cells that measure the effect of antibodies and other biologics that specifically bind and activate Fc receptors.

T-Cell Activation Bioassays
CD3-expressing cells that measure the efficacy of antibodies to elicit T-cell activation through CD3 interactions.

AAV Antibody Assessment
A dual cell-based assay platform with AAV producing packaging cells and AAV responsive reporter cells to assess neutralizing antibodies against AAV serotypes.

CDC Bioassays
An assay platform based on a complement-competent target cell line that allows assessment of antibody-mediated complement-dependent cytotoxicity.

Target cells
Homologous target cells with a controlled antigen expression (+) or depletion (-) that enable screening for antibody-induced effector functions.

Custom cell-based development services
A wide range of custom services to support drug development programs from discovery to lot release.

CELLS ENGINEERED FOR YOU

As experts in cell engineering and advanced cell-based assay development, we provide a proprietary platform, the advanced *iLite*® technology, and tailored services based on this technology.

The technology empowers you to navigate complex hurdles with confidence and propels advancements in your drug development journey. When standard solutions fall short, we specialize in developing reliable cell-based assays to meet our customer's testing and assessment needs.

SENSITIVITY & SPECIFICITY

Strong signals with minimal pathway crosstalk

iLite cells are engineered to meet the highest standards of sensitivity, fold activation, and dynamic range. Their high performance is the result of advanced cell line development strategies, such as overexpressing or invalidating key proteins in the signaling cascade, using chimeric transcription factors, and implementing synthetic reporter gene promoters.

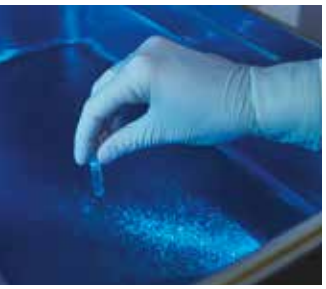
These techniques minimize pathway crosstalk and enhance the specificity, resulting in a reporter gene system with unparalleled sensitivity and specificity, making it a powerful tool for research needs.

ASSAY READY FORMAT

Fast, easy, and reproducible results

iLite cells are delivered as Assay Ready Cells and stored at -80°C. There is no need for cell culturing and continuous maintenance of cells – just thaw and dilute before use in the assay.

Besides significant reductions in the amount of labor required and assay turnaround times, the assay-ready cell format also gives superior assay reproducibility in comparison to cells in culture, since all cells are cryopreserved at the same passage number.



Designed to streamline your experimental processes, accelerate your discoveries, and elevate your research outcomes.

ASSAY PRECISION

Reproducibility & Accuracy

While traditional cell-based assays often have high variability, *iLite* bioassays consistently show better repeatability and intermediate precision, with high sample accuracy.

This accuracy provides the biological relevance of cell-based assays with the ease and precision of ligand-binding assays.

NORMALIZATION GENE

Ideal for accurate normalization

A second reporter gene is constitutively expressed by *iLite* cells, and its activity is assessed in the same wells as the specific pathway-induced reporter gene expression.

This allows for compensation for differences in cell numbers and matrix effects. This feature allows for normalization of the results, further improving assay consistency.

CUSTOMIZATION POSSIBILITIES

- Cell-based solutions adapted to your needs

As every project is different and every development process has its hurdles to overcome, our custom cell-based development services enable us to offer versatile assay solutions to pharma, biotech, and CRO customers, as well as to our partners within diagnostics, tailored to your specific needs.

Get all the benefits of *iLite* cells, such as assay-ready cells and normalization capabilities for your target of choice.

ASSAY PRINCIPLES & APPLICATIONS

iLITE® BIOASSAYS

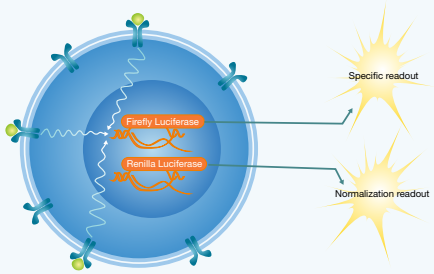
The powerful *iLite*® technology combines the simplicity and robustness of a ligand binding assay with the flexibility of a reporter gene format, offering a seamless, high-performance solution throughout the entire drug development process.

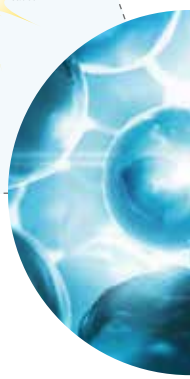
The technology supports sensitive measurement of drug potency, detection of neutralizing antibodies (NAbs), and comprehensive immunogenicity evaluation, and it can be customized for virtually any pharmaceutical target.

FUNCTIONAL BIOASSAYS

iLite® functional bioassays employ a single cell line engineered to contain a reporter gene producing a measurable signal (luciferase) in response to target interactions. By utilizing the existing intra-cellular signaling system, the biological relevance of the assay is maintained.

Unique features like normalization possibilities and chimeric transcription factors ensure high target specificity and a superior signal-to-noise ratio. An additional reporter gene serves as an internal control, eliminating the need for cell counting and enhancing the accuracy of your results.





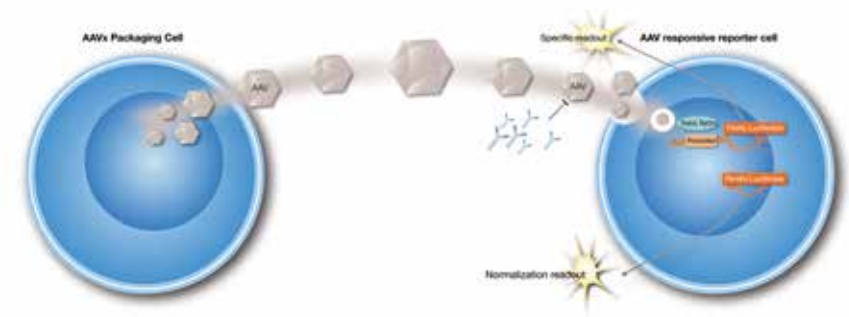
AAV-BASED GENE THERAPY IMMUNOGENICITY BIOASSAYS

iLite® AAV NAb platform is a two-cell line setup used for neutralizing AAV antibody assessment.

The different *iLite* packaging cells produce AAV vector serotypes, and the AAV Responsive Reporter cells trigger the expression of Firefly luciferase in response to AAV transduction. This AAV transduction correlates directly with the produced readout and is easily measurable by a standard luminometer.

The flexibility and adaptability of *iLite* technology in this platform means that the AAV-packaging cells can be easily adapted to produce any vector of choice. It ifunctions as a essential tool in the assessment of recombinant next-gen vectors, offering flexibility for hybrid, chimeric, or semi-synthetic capsids.

- Customizable for any capsid
- Direct readout of vector transduction
- Adaptable for various vector types and next-gen vectors

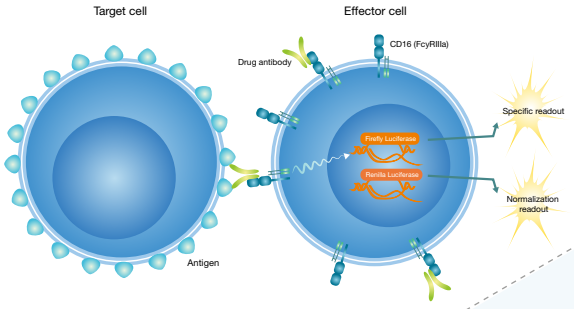


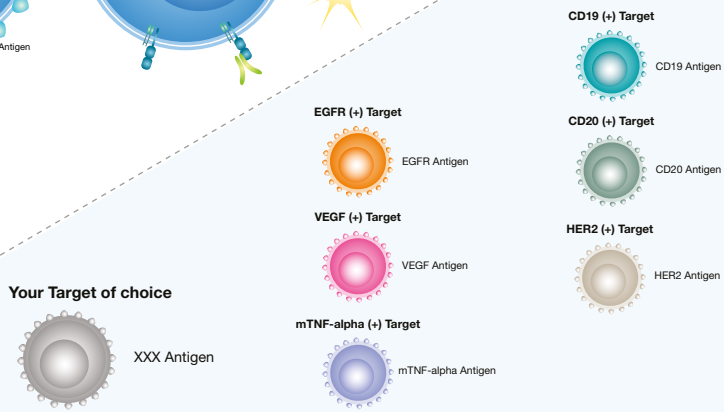
FC EFFECTOR BIOASSAYS

iLite® Fc Effector bioassays are a two-cell line setup that determines antibody-receptor binding activity and Fc-mediated immune effector functions.

By using engineered effector cells that mimic natural Fc signal transduction pathways and homologous target cells with controlled antigen expression, accurate measurement of Fc effects of antibodies and biologics is achieved.

- Assess ADCC and ADCP in vitro with ease
- Determination of antibody-receptor binding activity & mechanism of action

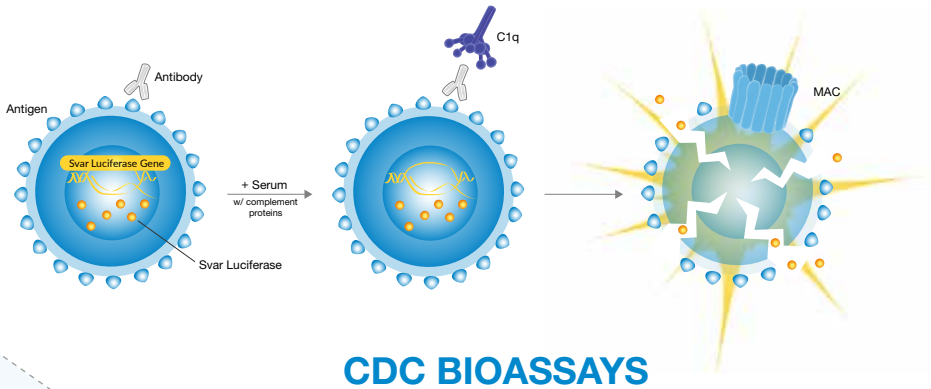




TARGET CELLS

Homologous target cells with controlled antigen expression (+) or depletion (-).

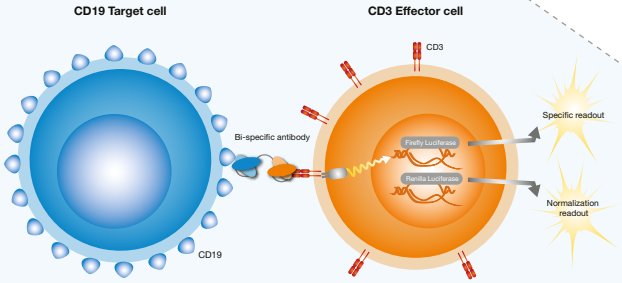
- Allow differences in activity to be determined with precision and specificity
- Compare activity across antibody variants
- Detect unwanted activity from antibody



CDC BIOASSAYS

iLite® CDC platform is based on a combined target and effector cell, with nucleus arrested luciferase, used for assessment of anti-bodies eliciting Complement-Dependent Cytotoxicity (CDC).

- Only signal upon actual cell lysis
- Assay Ready Cell expressing CD20, CD38, CD52
- Enhanced stability with proprietary Svar LUC luciferase



T-CELL ACTIVATION BIOASSAYS

iLite® T-cell activation platform is a two-cell line setup with an engineered effector cell that closely resembles the natural expression of the TCR/CD3 complex.

- Designed for evaluating CD3-mediated T-cell activation
- Ideal for discovery and development of novel biologics such as CD3 engaging bispecific antibodies

A VERSATILE TOOL FOR THE WHOLE DRUG DEVELOPMENT PROCESS

DISCOVERY

We help you find and validate your target

- Target validation and lead optimization
- Analyze what signaling pathway is being activated
- Understand the biological mechanism of action
- Identify potential targets in biologically relevant settings

PRE-CLINICAL PHASE

We help evaluate efficacy of your lead compound

- Initial activity & Potency testing
- Provide invaluable information about the therapeutic mechanism of action (MOA)

CMC & MANUFACTURING

We ensure quality of products & high manufacturing process standards

- Robust cell based potency assays that can consistently measure the product's biological activity and be included in lot release assays

COMPREHENSIVE CELL-BASED SOLUTIONS

Your Partner in Drug Discovery and Development

These assays provide a single tool for all stages of drug development, from early compound screening, and potency testing to neutralizing antibodies (NAB) assessment.

Biological drugs often have multiple functional domains interacting with various molecules. Before release, they require extensive tests for function, efficiency, and safety.

Cell-based assays are essential in regulatory settings for cytotoxicity testing, determining biological activity (potency), understanding the mechanism of action (MOA), conducting early proof-of-principle studies, and assessing immunogenicity to check if patient-produced antibodies neutralize the drug.

CLINICAL PHASE

We help ensure safety, efficacy and compliance

- Evaluation of safety, identification of immunogenicity, and related adverse effects, etc.
- Detect the presence of neutralizing antibody titers in human serum with high reproducibility, with the added benefit of compensating for serum matrix effects by normalization

COMMERCIAL PHASE

We provide solutions for long-term drug and patient monitoring

- Monitor long-term efficacy, risk, and safety
- Assessment of drug immunogenicity by measuring the development of neutralizing antibodies
- Potency assays for lot release, in-process, and stability testing to monitor potency over the product's shelf life