

iLite[®] GM-CSF

ASSAY READY CELLS

The *iLite* GM-CSF Assay Ready Cells can be used for the quantification GM-CSF activity, GM-CSF inhibitor activity, and for determination of neutralizing antibodies in either buffer systems or human serum.

The growth factor GM-CSF has shown to be a key player in inflammation. As such, the inhibition of GM-CSF provides an attractive approach for the treatment of inflammatory and autoimmune diseases. In addition, GM-CSF's immunostimulatory activities can also be used to enhance the immune response when needed, such as accelerating leukocyte recovery after bone marrow transplants or in cancer therapies.

iLite GM-CSF Assay Ready Cells are based on a genetically engineered reporter gene cell line responsive to GM-CSF by specific and proportional expression of Firefly Luciferase. Normalization of cell counts and serum matrix effects is obtained by a second reporter gene, a Renilla Luciferase reporter gene construct, under the control of a constitutive promoter.

As a functional assay, *iLite* GM-CSF Assay Ready Cells can be used to determine the activity of GM-CSF, or of GM-CSF inhibitors, as well as neutralizing antibodies, all using the same assay set-up.

- Can be used for assaying both drug potency and immunogenicity
- Highly sensitive (pg/mL)
- Large dynamic range
- Fold induction >10x



GM-CSF Assay Ready Cells are stored at -80°C and conveniently thawed in a water bath before use - no culturing required.

iLite[®] GM-CSF Assay Ready Cells	
Product code	BM4050
Format	Assay Ready Cells
Related Products	BM3044 <i>iLite[®]</i> TNF-alpha Assay Ready Cells BM3049 <i>iLite[®]</i> Type I IFN Assay Ready Cells BM4012 <i>iLite[®]</i> IL-12 Assay Ready Cells BM4023 <i>iLite[®]</i> IL-23 Assay Ready Cells
Application	The <i>iLite</i> GM-CSF Assay Ready Cells can be used for the quantification GM-CSF activity, GM-CSF inhibitor activity, and for determination of neutralizing antibodies against such either in buffer systems or human serum. <ul style="list-style-type: none"> • Quantification of GM-CSF activity using <i>iLite</i> GM-CSF Assay Ready Cells • Determination of GM-CSF neutralizing activity using <i>iLite</i> GM-CSF Assay Ready Cells
Incubation time	Drug Assays 5 hours NAb Assays 30 min +5 hours
Detection system	Luminescence
Availability	Research Use Only (RUO)*

**These products are intended for professional research use only. The data and results originating from using the products, should not be used either in diagnostic procedures or in human therapeutic applications.*

In accepting delivery of iLite[®] Assay Ready Cells the recipient agrees not to sub-culture these cells, attempt to sub-culture them or to give them to a third party, and recipient is only to use them directly in assays. The iLite[®] cell-based products are covered by patents which are the property of Svar Life Science AB and any attempt to reproduce the delivered iLite[®] Assay Ready Cells would constitute an infringement.

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iLite[®] Technology

UTILITY & BENEFITS

iLite technology is based upon a reporter gene assay format, modified and adapted for applications during the whole drug development continuum as well as for monitoring of biological drugs. *iLite* cell lines can be developed for any biopharmaceutical target and assays for drug potency, i.e. drug activity and immunogenicity (neutralizing antibodies, NAb) can easily be set-up using the same cell line.

The *iLite* technology eliminates many of the limitations of conventional cell-based assays:

- The cells are delivered as assay ready frozen cells allowing cell-based assays to be carried out without the need for cell culture or the maintenance of cells continuously in the laboratory.
- This allows for significant cost reductions and increases the applicability of cell-based assays to routine use as potency or neutralization assays.

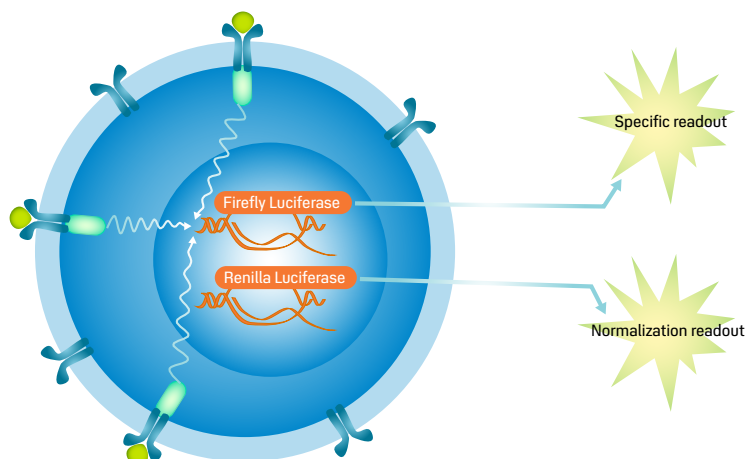
The cell lines are engineered by use of target specific reporter gene constructs. By using host cell lines engineered not to respond to other factors that signal through the specific pathway, a specific and precise assay can be engineered. The read-out is light emission as measured by a standard luminometer.

Assay precision

- Assay precision is optimized by engineering cells to express Firefly luciferase under the control of a drug responsive promoter and Renilla luciferase under the control of a constitutive promoter.
- This allows both luciferases to be assayed sequentially in the same well of an assay plate, and drug-induced luciferase activity to be normalized relative to Renilla expression.
- Serum matrix effects are thereby eliminated and assay results independent of cell number.

Pathway specificity

- Assay sensitivity is enhanced by up-regulating drug-target expression.
- Assay selectivity is increased by the use of novel synthetic chimeric transcription factors.



Features	Benefits
<i>iLite</i> reporter gene cells delivered as ready to use frozen cells . Same day results (from 2 hour).	Fast and convenient use
Potency and neutralizing antibody assays using a single reporter gene cell line.	Two assays using a single reporter gene cell line
Direct comparisons between biosimilars and originator/innovator drugs in one single <i>iLite</i> assay .	Standardization and economy of costs
Unrivalled specificity to distinguish between structurally related drugs that share common or related signal transduction pathways.	
A single assay for structurally diverse drugs in the same class (such as TNF-alpha antagonists).	
Normalization gene , expressing Renilla Luciferase, allows normalization for matrix effect as well as cell counts.	Eliminates matrix effect