ProBioGen
Intelligent Biopharmaceutical Solutions

Lenti.RiGHT® – Your Shortcut to Successful Lentivirus Manufacturing

This lentivirus (LV) production platform is based on HEK293 packaging cells stably transfected with all necessary viral components. It enables an inducible, scalable and efficient production of high-titer lentiviral particles for gene transfer applications.

Lentivirus Packaging Cell Lines as New Platinum Standard for LV Production

Lentiviral vectors dominate the modification of the CAR-T cells. Lentivirus production is also the main cost-driver for CAR-T cell based gene therapy.

The production of the lentiviruses is typically based on transient transfection where 4 GMP-grade bacterial plasmids have to be manufactured and co-introduced at bioreactor scale. The whole process is complex, not very robust and difficult to scale.

Our Lenti.RiGHT® platform is a new standard for efficient large-scale lentivirus production for CAR-T manufacturing. It allows for compatible timelines to standard transient transfection strategy with more security for commercialization of the product.

Features

- Based on ProBioGens HEK293 with superior growth properties in chemically defined medium (no animal components) in suspension that enables easy scale-up
- Unique packaging cell clone with activatable gag-pol, rev and VSV-G genes located in best suited genomic spots
- Production directly upon transfection of the transfer vector containing your gene of interest, in stable pools or—with best performance and competitive timeline—in a clonal producer cell line
- Built using the transposase system DirectedLuck®
- No lentivirus release prior to induction

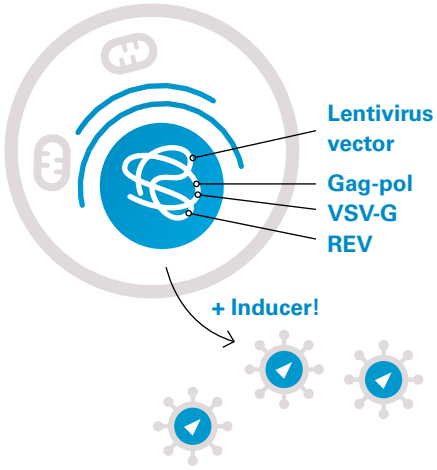

Fig 1: ProBioGen's lentivirus producer cell lines

Benefits of Lenti.RiGHT® as Lentivirus Production Platform

Robust and stable

- Proven cell line stability
- Robust growth without lentivirus release
- Straightforward scale-up and purification

Efficient and costsaving

- No transfection reagents required
- No GMP-grade plasmids required

GMP ready

- GMP qualified starter cell bank
- Modification/single cell cloning w/o o animal components
- Fully documented history

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ProBioGen's Comprehensive Path to Lentiviral Vectors

We offer various packages. Depending on your capabilties, you can choose from the options below. We can produce the virus as starting material for cell therapy and/or a Lentivirus as drug product.

A) Three Ways to Produce Lentivirus Vectors

1. **Transient transfection** – Transfection of universal or customized lentiviral plasmids into suspension HEK293 cells
2. **Usage of Lenti.RiGHT® Packaging Cells** – Transient transfection of a single plasmid (lentiviral transfer vector with gene of interest [GOI]) to produce your Lentiviral Vector
3. **Usage of Lenti.RiGHT® Producer Cells** – Stable transfection of the lentiviral transfer vector with GOI in combinantion with DirectedLuck® transposase follwed by generation of cell clones capable to produce highest titer LV just by adding the inducer

B) Integrated Manufacturing of Lentiviral Vectors

- **Process Development (DSP/DSP)**
  Process development in respect of the route of drug administration
- **GMP Manufacturing**
  Manufacturing of drug substance and drug product fulfilling requirements specified in EU GMP Annex1

  Robust upstream processing up to 200L scale stirred tank

  Platform purification process
- **Analytics, Bioassay & Quality Control**

  Total LV particles

  Transducing LV particles

  Expression of gene product

  Host cell DNA

  Host cell protein

  Replication comp. LV
- **Fill & Finish**

  Aseptic filling line in the same production facility as drug substance manufacturing

  Inhouse formulation buffer and diluent production

  Aseptic filling of drug product or diluent in volumes of 1–20 mL under GMP conditions

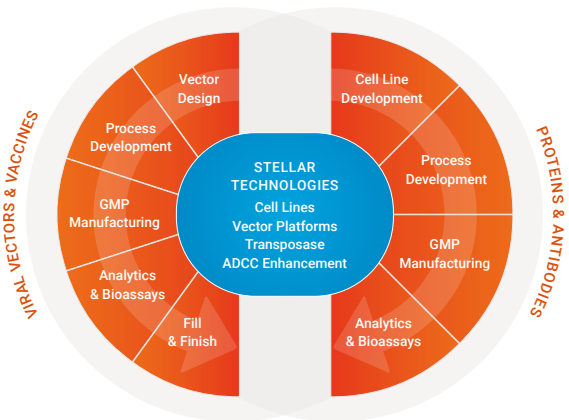
  Storage capacities for BSL 2 drug substance and drug product

  QP Release

Your One-Stop CDMO Expert for Biologics and Advanced Therapies

ProBioGen is a Berlin-based specialist for developing and manufacturing biopharmaceutical active ingredients, viral vectors and vaccines with applying proprietary technologies to improve product quality and features.

Combining both state-of-the-art development services, together with intelligent product-specific technologies yields biologics with optimized properties. Rapid and integrated cell line and process development, comprehensive analytical development and GMP-compliant manufacturing is performed by a highly skilled and experienced team.



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