YOUR RELIABLE BIOSAFETY PARTNER, WE BRING NEAR-BY SERVICE CLOSER TO YOU

Biosafety Testing for Lentivirus-based Gene Modified Cell Therapy

In recent years, cell and gene therapy (CGT) has exhibited great potential in the fields of malignant tumors, genetic diseases, chronic degenerative diseases, and other conditions. Several CGT products (such as KYMRIAH in Novartis and YESCARTA in Gilead) have been successfully marketed.

Recombinant lentiviral vector (LV) is able to transduce the target gene into both dividing and non-dividing cells efficiently, thus it is widely used in immune cell therapeutical products. In the cell therapy process, the components such as recombinant plasmid/lentivirus/modified cells are required to be manufactured in GMP-grade environment to keep the stable and consistent quality.

BRC Biotechnology (Shanghai) Co., Ltd. is committed to providing professional compliance biosafety testing service, assay development services and testing products for cell & gene therapy, antibodies, vaccines, nucleic acid drugs and other biological products. As your reliable biotech-service partner on the way to success, we are committed to providing world-class the biosafety services for you.

- Safety - Comprehensive Solutions for biosafety testing
- Efficiency – Automatic process empowering testing capabilities
- Compliance - Meet the requirements of different regulatory systems
- Scientific - Rigorous customization solution capability

Technology Roadmap	Test Article	Identity	Microbiology Contaminations	Adventitious Virus Screen	Endogenous Retroviruses Screen	Specific Species Viruses*	Replication Competent Lentivirus**	Insertion Site Analysis***
Banking	HEK293T MCB	●	●	●	●	●		
	HEK293T WCB	●	●	●				
USP	HEK293T EOPC	●	●	●	●	●	●	
	MPDCB	●	●	●	●	●		
Clarification	Lentivirus UBH	●	●	●	●		●	
Polish	Lentivirus DS	●	●				●	
Final Fill	Lentivirus DP	●	●					
Transduction	Modified Cell Product	●	🚀			🚀	🚀	●

* High-risk human pathogens. If there is a risk of exposure to porcine and bovine components, it is necessary to test for porcine and bovine viruses in accordance with regulatory and submission requirements.

** Susceptible cell co-culture method for detection. Cell products can be tested rapidly based on risk analysis. For details, please contact BRC Biotechnology experts.

*** Analysis of integration sites based on next generation sequencing, including safety risk analysis in clinical tracking.

🚀 Rapid detection method.

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Biosafety Testing for Retrovirus-based Gene Modified Cell Therapy

Gamma-Retroviruses are widely used in CAR-T products and other clinical products. The first successful clinical trial for gene therapy used of Murine Leukemia Virus (MLV) as a gene transfer vector to treat children with X-linked Severe Combined Immunodeficiency (SCID-X1). Currently, out of the 9 cell therapy products on the market, 3 of them were using Gamma-retroviruses as the gene transfer vector. The production of gamma-retroviruses requires an appropriate packaging cell line, such as the PG13 stable cell line (which stably expresses the Gag, Pol, and Env proteins required for retroviral packaging), to facilitate the production of high-titer viruses. We will develop a comprehensive biosafety control strategy based on rigorous analysis of your specific product and process.

* High-risk human pathogens. If there is a risk of exposure to porcine and bovine components, it is necessary to test for porcine and bovine viruses in accordance with regulatory and submission requirements.

** Susceptible cell co-culture method for detection. Cell products can be tested rapidly based on risk analysis. For details, please contact BRC Biotechnology experts.

*** Analysis of integration sites based on next generation sequencing, including safety risk analysis in clinical tracking.

Rapid detection method.

Reference

ChP	• 2020 Part Three: Preparation and Quality Control of Animal Cell Substrates for the Production and Testing of Biopharmaceuticals. • 2020 Part Three: General Monographs for Human Gene Therapy.
USP	• USP 1046 Cell-Based Advanced Therapies and Tissue-Based Products • USP 1047 Gene Therapy Products • USP 1050 Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin
EP	• 2010 5.14 Gene transfer medicinal products for human use: Retroviridae-derived vectors for human use.
FDA	• 1998 Guidance for Human Somatic Cell Therapy and Gene Therapy • 2010 US Characterization and Qualification of Cell Substrates and Other Biological Materials Used in the Production of Viral Vaccines for Infectious Disease Indications • 2020 Testing of Retroviral Vector-Based Human Gene Therapy Products for Replication Competent Retrovirus During Product Manufacture and Patient Follow-up • 2020 Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs) Guidance for Industry • 2022 Considerations for the Development of Chimeric Antigen Receptor (CAR) T Cell Products; Draft Guidance for Industry
WHO	• 2010 WHO Recommendations for the evaluation of animal cell cultures as substrates for the manufacture of biological medicinal products and for the characterization of cell banks. TRS 978, Annex 3
ICH	• ICH Q5A (R1) Viral Safety evaluation of biotechnology products derived from cell lines of human or animal origin • ICH Q5D Derivation and Characterization of Cell Substrates Used for Production of Biotechnological /Biological Products

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