

Certificate of Analysis

Product Name	Lentiviral Vector (Lentivirus)
Batch Number	R2332-VVPD-230814-100
Specification	0.1ml/Vial x 10 Vials
Production date	2023-08-14
Storage Condition	Store at -80°C
Expiration Date	2024-08-13
Storage Buffer	Virus formulated in X-vivo15+2%SR

The product is functionally tested for optimum performance using the following tests:

Titer Determination	
The titer was determined by "p24 ELISA" method. p24 antigen was captured by anti-p24 coated microtiter wells and sandwiched with biotinylated secondary anti-p24 antibody. Subsequently, a streptavidin-HRP conjugate and a substrate were added to produce visible color in the solution. Color intensity was measured spectrophotometrically to indicate the level of p24 in the sample. The transduction titer of the sample was approximate calculated according to the formula $1 \text{ ng P24} = 1.25E + 07 \text{ LPs} = 1.25E + 05 \text{ TU}$.	
Specification: >1E+9 TU/ml	Result: 7.82E+8 TU/ml
Transduction Test	
HEK293 cells were infected with viral samples, and visualized under fluorescent microscope.	
Specification: Positive	Result: Pass
Endotoxin	
Endotoxin was determined by LAL	
Specification: <10 EU/ml	Result: < 2EU/ml
Sterility Test	
Bacteria and fungi were detected by rapid sterility test. The virus sample was inoculated into a culture medium 5 days and detected by BD BACTEC FX40 to detect bacterial and fungal growth.	
Specification: Negative	Result: Pass
Mycoplasma Test	
Through a DNA extraction kit, the mycoplasma DNA in the sample was purified, and the sample was amplified and detected by the qPCR method. Whether there was mycoplasma contamination in the sample was determined by qPCR.	
Specification: Negative	Result: Pass



Reporter	<i>Kathy</i>	Reviewer	<i>[Signature]</i>	Auditor	<i>[Signature]</i>
Date	2023-09-01	Date	2023-09-04	Date	2023-09-04