

# **Certificate of Analysis**

Product Name rAAV2

Vector information ssAAV-CMV-EGFP-WPRE-SV40pA

Batch Number PTB006-GTPD-DS230804-01

Specification $50\mu$ I/VialProduction date2023-08-04Storage ConditionStore at -80 °CExpiration Date2024-08-03

Storage Buffer Virus formulated in 10mM Tris buffer supplemented with 100mM sodium citrate

and 0.001% poloxamer 188 (pH8.0)

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

#### **Titer Determination**

The titer was determined by the quantitative PCR (qPCR) method. Viral DNA was extracted from viral particles.

The EGFP sequence of AAV2 was used as a target to quantify the amount of viral genome.

Specification: >10<sup>13</sup> vg/ml Result: 1.44x10<sup>13</sup> vg/ml

# **Virus Purity**

Viral purity was determined by SDS-PAGE followed by silver staining.

Specification: >80% Pure Result: 92.20%

# **Full Capsid Ratio**

The full capsid ratio was determined by the AUC method.

Specification: >70% Result: 90.11%

### **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

#### **Endotoxin**

Endotoxin was determined by LAL

Specification: <10 EU/ml Result: < 2EU/ml



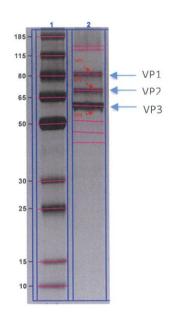


Figure 1. SDS-PAGE picture (lane1: marker, lane2: sample)



Reporter	tothy	Reviewer	in my	Auditor	3 MARIE
Date	2023-09-01	Date	2023-09-04	Date	2015. v9. 04