Certificate of Analysis for NR-59622

Center for Biologics Evaluation and Research Virus Next Generation Sequencing Reference Reagents

Catalog No. NR-59622

Product Description:

NR-59622 consists of a 5-member panel of viral preparations identified by the World Health Organization (WHO) as standards for high-throughput sequencing. These preparations are intended for next generation sequencing (NGS) studies for method establishment, verification, qualification and validation. Viruses should be used directly and not grown or amplified before use.

Lot: 70064122 **Assembly Date: OCT 2023**

BEI Resources is committed to ensuring digital accessibility for people with disabilities. This Certificate of Analysis contains complex tables and may not be fully accessible. Please let us know if you encounter accessibility barriers and a fully accessible document will be provided: E-mail: Contact@BEIResources.org. We try to respond to feedback within 24 hours.

Table 1: Kit Components

COMPONENT NUMBER	DESCRIPTION	HOST CELL LINE	LOT NUMBER	MANUFACTURING DATE
SC-VR-6000P™	Custom preparation of porcine circovirus type 1	PK(15) porcine kidney cells (ATCC® CCL-33™)	63856605	08DEC2015
SC-VR-6001P™	Custom preparation of mammalian orthoreovirus type 1, strain Lang	LLC-MK2 derivative Rhesus monkey kidney cells (ATCC® CCL-7.1™)	63633442	28JUL2015
SC-VR-6002P™	Custom preparation of feline leukemia virus, strain Thielen	FL74-UCD-1 cat lymphoblast cells (ATCC® CRL-8012™)	63856597	18APR2016
SC-VR-6003P™	Custom preparation of human respiratory syncytial virus, strain A2	HEp-2 cells (ATCC® CCL-23™)	63633439	14JUL2015
SC-VR-6004P™	Custom preparation of Epstein-Barr virus (HHV-4), strain B95-8	B95-8 Leukocyte Marmoset culture (ATCC® CRL-1612™)	63633440	03SEP2015

Table 2: Custom preparation of porcine circovirus type 1 (SC-VR-6000P™)[1,2,3]

Test / Method	Specification	Result
Titer (Post-vial)[4,5]	≥ 1×10^6 $TCID_{50}$/mL	1.2×10^7 $TCID_{50}$/mL
Genome Copy Number by ddPCR (Post-vial)[5,6,7]	≥ 1×10^{10} genome copies/mL	2.7×10^{11} genome copies/mL
Test for Mycoplasma Contamination DNA detection by PCR of test article nucleic acid [Universal Mycoplasma Detection Kit (ATCC® 30-1012K™)]	None detected	None detected
Sterility Test (BacT/ALERT 3D) iAST bottle (aerobic) at 32°C, 14-day incubation iNST bottle (anaerobic) at 32°C, 14-day incubation	 No growth No growth	 No growth No growth

[1]Porcine circovirus type 1 (PCV1) was grown in PK(15) porcine kidney cells (ATCC® CCL-33™) at 37°C with 5% CO_2. PK(15) cells are known to contain porcine endogenous retrovirus [Pol. J. Microbiol. (2012), 61: 211-215. PubMed: 29334069].
[2]Preparation was vialed in 10 mM Tris-HCl, 135 mM NaCl, 0.5% BSA and 5% trehalose and may contain residual cellular nucleic acids.
[3]Stability testing of the genome copy number and titer completed in 2018 and 2022 shows that the material maintains these characteristics when stored at -80°C.
[4]16 days in ST cells (ATCC® CRL-1746™) at 37°C with 5% CO_2, as determined by endpoint PCR with PCV1 specific primers.
[5]Test result from April 2018.

BEI Resources
www.beiresources.org
E-mail: contact@beiresources.org
Tel: 800-359-7370
Fax: 703-365-2898

[6]ddPCR data was obtained post-vial from 9 replicates on the BioRad QX200 Droplet Digital PCR (ddPCR™) System; gene assayed was replication associated protein.
[7]ddPCR samples contain virus genomes and may have residual mRNAs.

Table 3: Custom preparation of mammalian orthoreovirus type 1, strain Lang (SC-VR-6001P™)[1,2,3]

Test / Method	Specification	Result
Titer (Post-vial)[4,5]	≥ 1 × 10^6 $TCID_{50}$/mL	1.1 × 10^{10} $TCID_{50}$/mL
Genome Copy Number by ddPCR (Post-vial)[5,6,7]	≥ 1 × 10^{10} genome copies/mL	1.4 × 10^{10} genome copies/mL
Test for Mycoplasma Contamination DNA detection by PCR of test article nucleic acid [Universal Mycoplasma Detection Kit (ATCC® 30-1012K™)]	None detected	None detected
Sterility Test (BacT/ALERT 3D) iAST bottle (aerobic) at 32°C, 14-day incubation iNST bottle (anaerobic) at 32°C, 14-day incubation	 No growth No growth	 No growth No growth

[1]Mammalian orthoreovirus (MRV) type 1, strain Lang, was grown in LLC-MK2 derivative Rhesus monkey kidney cells (ATCC® CCL-7.1™) at 37°C with 5% CO_2 and humidity.
[2]Preparation was vialed in 10 mM Tris-HCl, 135 mM NaCl, 0.5% BSA and 5% trehalose and may contain residual cellular DNA.
[3]Stability testing of the genome copy number and titer completed in 2018 and 2022 shows that the material maintains these characteristics when stored at -80°C.
[4]9 days on LLC-MK2 cells (ATCC® CCL-7.1™) at 37°C with 5% CO_2 and humidity, as determined by CPE.
[5]Test result from April 2018.
[6]ddPCR data was obtained post-vial from 9 replicates on the BioRad QX200 Droplet Digital PCR (ddPCR™) System; gene assayed was L2.
[7]ddPCR samples contain virus genomes and may have residual mRNAs.

Table 4: Custom preparation of feline leukemia virus, strain Thielen (SC-VR-6002P™)[1,2,3]

Test / Method	Specification	Result
Titer (Post-vial)[4,5]	≥ 1 × 10^6 $TCID_{50}$/mL	2.3 × 10^7 $TCID_{50}$/mL
Genome Copy Number by ddPCR (Post-vial)[5,6,7]	≥ 1 × 10^{10} genome copies/mL	5.3 × 10^{10} genome copies/mL
Test for Mycoplasma Contamination DNA detection by PCR of test article nucleic acid [Universal Mycoplasma Detection Kit (ATCC® 30-1012K™)]	None detected	None detected
Sterility Test (BacT/ALERT 3D) iAST bottle (aerobic) at 32°C, 14-day incubation iNST bottle (anaerobic) at 32°C, 14-day incubation	 No growth No growth	 No growth No growth

[1]Feline leukemia virus (FLV), strain Thielen, was grown in FL74-UCD-1 cat lymphoblast cells (ATCC® CRL-8012™) at 36°C.
[2]Preparation was vialed in 10 mM Tris-HCl, 135 mM NaCl, 0.5% BSA and 5% trehalose and may contain residual cellular nucleic acids.
[3]Stability testing of the genome copy number and titer completed in 2018 and 2022 shows that the material maintains these characteristics when stored at -80°C.
[4]7 days in MYA-1 cells (ATCC® CRL-2417™) at 37°C with 5% CO_2 and humidity, as determined by endpoint PCR with FLV specific primers.
[5]Test result from August 2018.
[6]ddPCR data was obtained post-vial from 9 replicates on the BioRad QX200 Droplet Digital PCR (ddPCR™) System; gene assayed was protease.
[7]ddPCR samples contain virus genomes and may have residual mRNAs.

Table 5: Custom preparation of human respiratory syncytial virus, strain A2 (SC-VR-6003P™)[1,2,3]

Test / Method	Specification	Result
Titer (Post-vial)[4,5]	≥ 1 × 10^6 $TCID_{50}$/mL	1.1 × 10^6 $TCID_{50}$/mL
Genome Copy Number by ddPCR (Post-vial)[5,6,7,8]	≥ 1 × 10^{10} genome copies/mL	1.0 × 10^9 genome copies/mL

BEI Resources
www.beiresources.org

E-mail: contact@beiresources.org
Tel: 800-359-7370
Fax: 703-365-2898

Test / Method	Specification	Result
Test for Mycoplasma Contamination		
DNA detection by PCR of test article nucleic acid [Universal Mycoplasma Detection Kit (ATCC® 30-1012K™)]	None detected	None detected
Sterility Test (BacT/ALERT 3D)		
iAST bottle (aerobic) at 32°C, 14-day incubation	No growth	No growth
iNST bottle (anaerobic) at 32°C, 14-day incubation	No growth	No growth

[1]Human respiratory syncytial virus (hRSV), strain A2, was grown in HEp-2 cells (ATCC® CCL-23™) at 37°C with 5% CO_2 and humidity.
[2]Preparation was vialed in 10 mM Tris-HCl, 135 mM NaCl, 0.5% BSA and 5% trehalose and may contain residual cellular nucleic acids.
[3]Stability testing of the genome copy number and titer completed in 2018 and 2022 shows that the material maintains these characteristics when stored at -80°C.
[4]8 days in HEp-2 cells (ATCC® CCL-23™) at 37°C with 5% CO_2 and humidity, as determined by Immunofluorescence Light Diagnostics™ Respiratory Syncytial Virus FITC Reagent (Millipore catalog # 5022).
[5]Test result from April 2018.
[6]ddPCR data was obtained post-vial from 9 replicates on the BioRad QX200 Droplet Digital PCR (ddPCR™) System; gene assayed was N protein.
[7]ddPCR samples contain virus genomes and may have residual mRNAs.
[8]The genome copy number for hRSV, strain A2 is below the current specifications but does not negatively impact the final product.

Table 6: Custom preparation of Epstein-Barr virus (HHV-4), strain B95-8 (SC-VR-6004P™)[1,2,3]

Test / Method	Specification	Result
Titer (Post-vial)[4,5]	≥ 1 × 10^6 $TCID_{50}$/mL	1.1 × 10^7 $TCID_{50}$/mL
Genome Copy Number by ddPCR (Post-vial)[5,6,7,8]	≥ 1 × 10^{10} genome copies/mL	3.7 × 10^8 genome copies/mL
Test for Mycoplasma Contamination		
DNA detection by PCR of test article nucleic acid [Universal Mycoplasma Detection Kit (ATCC® 30-1012K™)]	None detected	None detected
Sterility Test (BacT/ALERT 3D)		
iAST bottle (aerobic) at 32°C, 14-day incubation	No growth	No growth
iNST bottle (anaerobic) at 32°C, 14-day incubation	No growth	No growth

[1]Epstein-Barr virus [human herpes virus 4 (HHV-4)], strain B95-8, was isolated from B95-8 Leukocyte Marmoset culture (ATCC® CRL-1612™) grown at 37°C with humidity with 5% CO_2. The B95-8 marmoset cell line is known to contain squirrel monkey retrovirus [Virology. (1995), 209: 374-383. PubMed: 7778272].
[2]Preparation was vialed in 10 mM Tris-HCl, 135 mM NaCl, 0.5% BSA and 5% trehalose and may contain residual cellular nucleic acids.
[3]Stability testing of the genome copy number and titer completed in 2018 and 2022 shows that the material maintains these characteristics when stored at -80°C.
[4]60 days in irradiated human lung fibroblast cells (ATCC® 55-X™) at 37°C with 5% CO_2 and humidity, as determined by transformation.
[5]Test result from May/June 2018.
[6]ddPCR data was obtained post-vial from 9 replicates on the BioRad QX200 Droplet Digital PCR (ddPCR™) System; gene assayed was EBER1 noncoding RNA.
[7]ddPCR samples contain virus genomes and may have residual mRNAs.
[8]The genome copy number for HHV-4, strain B95-8 is below the current specifications but does not negatively impact the final product.

/Sonia Bjorum Brower/
Sonia Bjorum Brower 01 DEC 2023
Technical Manager or designee, ATCC Federal Solutions

ATCC®, on behalf of BEI Resources, hereby represents and warrants that the material provided under this certificate has been subjected by ATCC® and the contributor to the tests and procedures specified and that the results described, along with any other data provided in this certificate, are true and accurate to the best of ATCC®'s knowledge.

ATCC® is a trademark of the American Type Culture Collection.
You are authorized to use this product for research use only. It is not intended for human use.

Support Provided by NIAID

BEI Resources
www.beiresources.org
E-mail: contact@beiresources.org
Tel: 800-359-7370
Fax: 703-365-2898