Certificate of Analysis for NR-59622

Center for Biologics Evaluation and Research Next Generation Sequencing Virus Reagents

Catalog No. NR-59622

Product Description:

NR-59622 consists of a 5-member panel of virus preparations. With the availability of the 1st WHO International Reference Panel for Adventitious Virus Detection (BEI Catalog No. NR-59630), the 5-member panel has been discontinued as WHO Reference Reagents and will continue to be provided to support the development of NGS for adventitious virus detection. [1,2] Viruses should be used directly without amplification or propagation.

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

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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)[5,6,7,8,9]	≥ 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.

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[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 replication associated protein.
[7]ddPCR samples contain virus genomes and may have residual mRNAs.
[8]Residual bovine bosavirus sequences were detected by NGS analysis.
[9]Host cell genome copy number is 1.54 × 10^6 genome copies/mL.

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)[5,6,7,8,9]	≥ 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.
[8]Residual bovine bosavirus sequences were detected by NGS analysis.
[9]Host cell genome copy number is 5.49 × 10^5 genome copies/mL.

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)[5,6,7,8]	≥ 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.
[8]Host cell genome copy number is 3.8 × 10^5 genome copies/mL.

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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)[5,6,7,8,9]	≥ 1 × 10^{10} genome copies/mL	1.0 × 10^9 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]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]Host cell genome copy number is 2.06 × 10^5 genome copies/mL.
[9]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)[5,6,7,8,9,10]	≥ 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 iNST bottle (anaerobic) at 32°C, 14-day incubation	 No growth No growth	 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]Residual bovine bosavirus sequences were detected by NGS analysis.
[9]Host cell genome copy number is 2.46 × 10^5 genome copies/mL.
[10]The genome copy number for HHV-4, strain B95-8 is below the current specifications but does not negatively impact the final product.

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

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/Sonia Bjorum Brower/
Sonia Bjorum Brower 09 AUG 2024
Technical Manager or designee, ATCC Federal Solutions

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