

Certificate of Analysis for NR-52285

Genomic RNA from SARS-Related Coronavirus 2, Isolate USA-WA1/2020

Catalog No. NR-52285

This reagent is the property of the U.S. Government.

Product Description:

Genomic RNA was extracted from a preparation of cell lysate and supernatant from *Cercopithecus aethiops* kidney epithelial (Vero E6, ATCC[®] CRL-1586[™]) cells infected with SARS-related coronavirus 2 (SARS-CoV-2), isolate USA-WA1/2020, using QIAamp[®] Viral RNA Mini Kit (Qiagen 52904). The viral genomic RNA is in a background of cellular nucleic acid and carrier RNA.

Lot: 70035629 Manufacturing Date: 17MAR2020

TEST	SPECIFICATIONS	RESULTS
1231	SPECIFICATIONS	RESULTS
Functional Activity by RT-PCR Amplification ¹	~ 950 base pair amplicon	~ 950 base pair amplicon (Figure 1)
Sequencing of Species-Specific Region (~ 930 nucleotides) (~ 930 nucleotides)	≥ 98% identity with SARS-CoV-2, isolate USA-WA1/2020 (GenBank: MN985325.1) ≥ 98% identity with SARS-CoV-2, strain FDAARGOS_983 isolate USA-WA1/2020 (GenBank: MT246667.1)	100% identity with SARS-CoV-2, isolate USA-WA1/2020 (GenBank: MN985325.1) 100% identity with SARS-CoV-2, strain FDAARGOS_983 isolate USA-WA1/2020 (GenBank: MT246667.1)
Estimated Concentration (post-dilution) by RiboGreen® Measurement (Viral, Cellular and Carrier)²	Report results	47.5 ng per 100 μL (0.475 μg/mL)
Estimated Amount per Vial ²	Report results	47.5 ng
Genome Copy Number Using BioRad QX200 Droplet Digital PCR (ddPCR™) System (Post vial; 9 replicates)	Report results	1.84 × 10 ⁷ genome equivalents/mL
Virus Inactivation (14 Days, 2 Passages) 10% of total yield inoculated on Vero E6 cells and evaluated for cytopathic effect ³		
Passage 1	No viable virus detected	No viable virus detected
Passage 2	No viable virus detected	No viable virus detected
Virus Inactivation (14 Days, 2 Passages) 100% of total yield inoculated on Vero E6 cells and evaluated for cytopathic effect ³		
Passage 1	No viable virus detected	No viable virus detected
Passage 2	No viable virus detected	No viable virus detected

¹Amplified using iTaq™ Universal SYBR Green One-step Kit (Bio-Rad 172-5151) with 5 μL of NR-52285 in a 50 μL reaction

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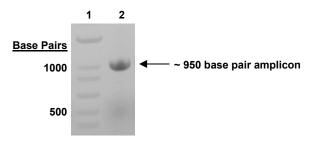
²Measurement is determined pre-vial prior to dilution due to the limit of detection of the quantification method

³Supernatant from both passages were tested for the presence of viral RNA by qPCR at the end of day 14 of Passage 2.



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Figure 1: Functional Activity of NR-52285 by RT-PCR Amplification



Lane 1: Invitrogen™ TrackIt™ 1 Kb Plus DNA Ladder Lane 2: PCR product from 1 µL of NR-52285

/Heather Couch/ Heather Couch

22 MAY 2020

Program Manager or designee, ATCC Federal Solutions

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