Certificate of Analysis for NR-53911

Whole Cell Antigen, SARS-Related Coronavirus 2, Isolate USA-WA1/2020 with Uninfected Control Vero E6 Cells with High Expression of Angiotensin-Converting Enzyme 2, Gamma-Irradiated

Catalog No. NR-53911

Product Description:

NR-53911 consists of crude preparation of cell lysate and supernatant from uninfected *Cercopithecus aethiops* kidney epithelial cells with high expression of angiotensin-converting enzyme 2 (Vero E6-heACE2) and cells infected with severe acute respiratory syndrome-related coronavirus 2 (SARS-CoV-2), isolate USA-WA1/2020. These lysates were gamma-irradiated (5×10^6 RADs) on dry ice, followed by sonication.

The starting material for NR-53910 was produced by infecting VE6-heACE2 in Eagle's Minimum Essential Medium (ATCC® 30-2003™) supplemented with 2% fetal bovine serum (ATCC® 30-2020™) for 5 days at 37°C with 5% CO_2. Titer of the pre-inactivation material was 1.2×10^6 $TCID_{50}$ per mL by $TCID_{50}$ assay in Vero E6-heACE2 cells, determined by cytopathic effect in 5 days at 37°C with 5% CO_2, and sterility of the preparation was confirmed.[1,2]

Table 1: SARS-CoV-2 Whole Cell Antigen Kit Components

COMPONENT NUMBER	DESCRIPTION	LOT NUMBER	DATE OF MANUFACTURE
NR-53909	Gamma-irradiated uninfected Vero E6-heACE2 cell lysate control	70041014	07JAN2021
NR-53910	Gamma-irradiated SARS-CoV-2, isolate USA-WA1/2020 infected Vero E6-heACE2 cell lysate	70041015	07JAN2021

Table 2: Gamma-Irradiated SARS-CoV-2, isolate USA-WA1/2020 infected Vero E6-heACE2 Cell Lysate (NR-53910)

TEST	SPECIFICATIONS	RESULTS
Virus Inactivation 10% of total bulk gamma-irradiated preparation inoculated on Vero E6 cells and evaluated for cytopathic effect and expression of viral antigen by indirect immunofluorescence assay[2,3]	No viable virus detected	No viable virus detected

[1]The Tissue Culture Infectious Dose 50% ($TCID_{50}$) is the 50% infectious endpoint in cell culture. The $TCID_{50}$ is the dilution of virus that under the conditions of the assay can be expected to infect 50% of the culture vessels inoculated, just as a Lethal Dose 50% (LD_{50}) is expected to kill half of the animals exposed. A reciprocal of the dilution required to yield the $TCID_{50}$ provides a measure of the titer (or infectivity) of a virus preparation.

[2]Performed at University of Texas Medical Branch, Galveston, Texas, USA

[3]The gamma-irradiated virus preparation was plated on Vero E6-heACE2 cells and incubated for 14 days at 37°C and 5% CO_2; cell lysate and supernatant from these cultures were blind passaged on fresh monolayers of Vero E6-heACE2 cells and again incubated for 14 days at 37°C and 5% CO_2.

/Heather Couch/
Heather Couch 18 JUN 2021
Program Manager or designee, ATCC Federal Solutions

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www.beiresources.org
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