

Middle East Respiratory Syndrome Coronavirus (MERS-CoV), EMC/2012, Irradiated Infected Cell Lysate

Catalog No. NR-50549

Product Description: A crude preparation of Vero E6 cells infected with MERS-CoV, EMC/2012 was gamma irradiated (5 x 10⁶ RADs) on dry ice.

Lot^{1,2}: 70003285

Manufacturing Date: 29MAR2017

TEST	SPECIFICATIONS	RESULTS
Pre-Inactivation Titer by TCID₅₀ Assay in Vero E6 cells³⁻⁵	Report results	8.9 x 10 ⁵ TCID ₅₀ per mL
Pre-Inactivation Sterility (21-day incubation) Harpo's HTYE broth ⁶ , 37°C and 26°C, aerobic Trypticase soy broth, 37°C and 26°C, aerobic Sabouraud broth, 37°C and 26°C, aerobic Blood agar, 37°C, aerobic Blood agar, 37°C, anaerobic Thioglycollate broth, 37°C, anaerobic DMEM with 10% FBS, 37°C and 5% CO ₂	No growth No growth No growth No growth No growth No growth No growth	No growth No growth No growth No growth No growth No growth No growth
Pre-Inactivation Mycoplasma Contamination Agar and broth culture (14-day incubation at 37°C) DNA detection by PCR of extracted Test Article nucleic	None detected None detected	None detected None detected
Pre-Inactivation Amplification of MERS-CoV Sequence by RT-PCR	~ 1100 base pair amplicon	~ 1100 base pair amplicon
Pre-Inactivation Sequencing of Species-Specific Region (~ 1160 nucleotides)	≥ 98% identity with MERs-CoV, EMC/2012 (GenBank: JX869059)	100% identity with MERs-CoV, EMC/2012 (GenBank: JX869059)
Viral Genome Copy Number by Droplet Digital RT-PCR⁷	Report results	2.7 x 10 ⁶ genome copies/μL
Virus Inactivation Cell culture safety test for residual virus ⁸ NR-50549 was inoculated on Vero E6 cells and evaluated for cytopathic effect and presence of viral RNA by real-time PCR after serial passage ⁹	No recovered virus No viable virus detected	No recovered virus No viable virus detected

¹BEI Resources NRC-44260 lot 70002772 was the source material for the irradiated antigen.

²All tests were completed post-inactivation unless specified as pre-inactivation tests.

³Vero E6 cells (ATCC® CRL-1586™)

⁴The Tissue Culture Infectious Dose 50% (TCID₅₀) endpoint is the 50% infectious endpoint in cell culture. The TCID₅₀ 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% (LD₅₀) is expected to kill half of the animals exposed. A reciprocal of the dilution required to yield the TCID₅₀ provides a measure of the titer (or infectivity) of a virus preparation.

⁵Assay plate was incubated 5 days at 28°C and 5% CO₂

⁶Atlas, Ronald M. *Handbook of Microbiological Media*. 3rd ed. Ed. Lawrence C. Parks. Boca Raton: CRC Press, 2004, p. 798.

⁷ddPCR data was obtained post-vial from 9 replicates on the BioRad QX200 Droplet Digital PCR (ddPCR™) System

⁸Performed at University of Texas Medical Branch, Galveston, Texas, USA

⁹The inactivated virus preparation was plated on Vero E6 cells and incubated for 14 days at 37°C and 5% CO₂; cell lysate and supernatant from these cultures was passaged on fresh monolayers of Vero E6 cells and again incubated for 14 days at 37°C and 5% CO₂.

/Heather Couch/

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29 NOV 2018

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