

Certificate of Analysis for NR-53880

Flucelvax® Quadrivalent Influenza Vaccine, 2019/2020 Season (0.5 mL Syringe)

Catalog No. NR-53880

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

Product Description:

Flucelvax® Quadrivalent Influenza Vaccine, 2019/2020 Season is an inactivated influenza virus vaccine prepared from four strains of influenza viruses propagated in Madin-Darby Canine Kidney (MDCK) cells. This vaccine preparation is being released <u>for research use only</u> and not for human use. Vaccines produced for the 2019-2020 season are now past their expiration dates (EXP. 26JUN2020). All quality control testing completed and provided by Seqirus, Inc.

Lot: 261204 Manufacturing Date: 2019

TEST	SPECIFICATIONS	RESULTS
Appearance	Report results	Slightly opalescent liquid
Hemagglutinin Content		
A/Idaho/07/2018 (H1N1)	15 μg	15 µg
A/Indiana/08/2018 (H3N2)	15 μg	15 µg
B/Iowa/06/2017 (B Victoria lineage)	15 μg	15 µg
B/Singapore/INFTT-16-0610/2016 (B Yamagata lineage)	15 μg	15 μg
Hemagglutinin Concentration		
A/Idaho/07/2018 (H1N1)	30 μg per mL	30 μg per mL
A/Indiana/08/2018 (H3N2)	30 μg per mL	30 μg per mL
B/Iowa/06/2017 (B Victoria lineage)	30 μg per mL	30 μg per mL
B/Singapore/INFTT-16-0610/2016 (B Yamagata lineage)	30 μg per mL	30 μg per mL
Residual Components		
MDCK protein	≤ 25.2 µg	≤ 25.2 µg
Protein other than hemagglutinin	≤ 240 µg	≤ 240 µg
MDCK cell DNA	≤ 10 ng	≤ 10 ng
β-propiolactone	< 0.5 µg	< 0.5 µg
Polysorbate 80	≤ 1500 μg	≤ 1500 µg
Cetyltrimethylammonium bromide	≤ 18 µg	≤ 18 µg

/Heather Couch/

Heather Couch 11 DEC 2020

Program 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 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.

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You are authorized to use this product for research use only. It is not intended for human use.

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