

Influenza A(H3N2) lineage <u>cell culture-derived</u>¹ candidate vaccine viruses for development and production of vaccines for use in the 2021 southern hemisphere influenza season

Human influenza virus isolation using a certified cell line (e.g. MDCK 33016 PF^a, NIID-MDCK^b) has been performed by WHO Collaborating Centres (CCs) of the WHO Global Influenza Surveillance and Response System (GISRS). The WHO CCs also perform antigenic and genetic analysis on the cell cultured Candidate Vaccine Viruses (ccCVVs). Unless otherwise specified, these ccCVVs have passed two-way haemagglutination inhibition (HI) or virus neutralization (VN) tests against the cell culture propagated prototype viruses matching the WHO recommendation². **No other testing (including adventitious agents) has been performed** on these ccCVVs by the WHO CCs. National or regional control authorities generally approve the manufacture, composition and formulation of influenza vaccines used in each country³. Manufacturers should consult relevant national or regional control authorities regarding the suitability of using these ccCVVs for influenza vaccine production.

25 September 2020

Cell culture-based candidate vaccine viruses (ccCVVs) (antigenically like A/Hong Kong/45/2019)

ccCVV	Certified cell line used for isolation and propagation	Developing institute	Passage level available	Available From
A/DELAWARE/39/2019	MDCK 33016 PF	CDC, USA	P1 or P2	CDC, USA
A/MINNESOTA/41/2019	MDCK 33016 PF	CDC, USA	P1 or P2	CDC, USA

Institutes contact details for candidate vaccine viruses orders/information:

CDC, USA: <u>nmb7@cdc.gov</u> (Subject: CVV request)

Contact details of WHO Essential Regulatory Laboratories for reagents orders/information:

CBER/FDA: CBERshippingrequests@fda.hhs.gov

NIBSC: standards@nibsc.org or enquiries@nibsc.org

NIID: flu-vaccine@nih.go.jp

TGA: <u>influenza.reagents@tga.gov.au</u>

For other candidate vaccine viruses and potency testing reagents, please go to http://www.who.int/influenza/vaccines/virus/candidates reagents/home/en/
For general enquiries, please contact gisrs-whohq@who.int

^a Derived from MDCK cell line approved for use for human vaccine manufacture in compliance with Ph. Eur. general chapter 5.2.3 by Novartis/Segirus

^b Derived from MDCK cell line developed by the National Institute of Infectious Diseases (NIID), Japan

¹ For egg-derived candidate vaccine viruses and reference reagents please see https://www.who.int/influenza/vaccines/virus/candidates_reagents/home/en/

² https://www.who.int/influenza/vaccines/virus/recommendations/2021 south/en/

³ http://www.who.int/immunization standards/national regulatory authorities/offices/en/