

# Influenza A(H1N1)pdm09 <u>cell culture-derived</u> <sup>1</sup> 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<sup>a</sup>, NIID-MDCK<sup>b</sup>) 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 recommendation<sup>2</sup>. **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 country<sup>3</sup>. 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/Wisconsin/588/2019

ccCVV	Candidate Vaccine Virus		Certified cell line used for isolation and propagation	Developing institute	Passage level available	Available from
A/Delaware/55/2019	Wild type virus		MDCK 33016 PF	CDC, USA	P2 – P3	CDC, USA

#### Institutes contact details for candidate vaccine virus orders/information:

CDC, USA: Bin Zhou, <a href="mailto:nmb7@cdc.gov">nmb7@cdc.gov</a> (Subject: CVV request)

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

**CBER:** CBERshippingrequests@fda.hhs.gov

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

NIID: flu-vaccine@nih.go.jp

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

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

<sup>&</sup>lt;sup>a</sup> 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

<sup>&</sup>lt;sup>b</sup> Derived from MDCK cell line developed by the National Institute of Infectious Diseases (NIID), Japan

<sup>&</sup>lt;sup>1</sup> For egg-derived candidate vaccine viruses and reference reagents please see <a href="https://www.who.int/influenza/vaccines/virus/candidates\_reagents/home/en/2">https://www.who.int/influenza/vaccines/virus/recommendations/2021</a> south/en/

<sup>&</sup>lt;sup>3</sup> http://www.who.int/immunization standards/national regulatory authorities/offices/en/