

Influenza A(H1N1)pdm09 <u>cell culture-derived</u> ¹ candidate vaccine viruses or <u>recombinant</u> vaccine antigen(s) for development and production of vaccines for use in the 2022 southern hemisphere influenza season

Human influenza virus isolation using a certified cell line (e.g. MDCK 33016 PF³, NIID-MDCK¹) 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.

24 September 2021

Cell culture-based candidate vaccine viruses (ccCVVs), antigenically-like A/Wisconsin/588/2019 (MDCK-SIAT derived) - Accession number (GISAID): EPI_ISL_404460

ccCVV	Candidate Vaccine Virus	Type of virus or reassortant	Certified cell line used for isolation and propagation	Developing institute	Passage level available	Available from
A/Delaware/55/2019	Wild type virus	Wild type virus	MDCK 33016 PF	CDC, USA	P2-P3	CDC, USA
A/Washington/23/2020	Wild type virus	Wild type virus	MDCK 33016 PF	CDC, USA	P2-P3	CDC, USA
A/Washington/19/2020	Wild type virus	Wild type virus	MDCK 33016 PF	CDC, USA	P2-P3	CDC, USA
CVR-45 (A/Delaware/55/2019)	Cell reassortant	Cell reassortant	MDCK 33016 PF	Seqirus, Australia	P2/D6	Seqirus, Australia

For recombinant vaccine antigen(s), it is recommended that the protein sequence(s) closely matches the sequence of A/Wisconsin/588/2019 (MDCK-SIAT derived).

^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/Seqirus

^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/

 $^{{\}color{blue} {\underline{\textit{2}}} \ https://www.who.int/publications/m/item/recommended-composition-of-influenza-virus-vaccines-for-use-in-the-2022-southern-hemisphere-influenza-season}$

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

Institutes contact details for candidate vaccine virus orders/information:

CDC, USA: Bin Zhou, nmb7@cdc.gov (Subject: CVV request)

Reference antigens (freeze dried)

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	Parent virus	Starting m	naterials	Ref Ag Lot	Unitage	Available
		Candidate vaccine virus	Egg or cell	Egg or cell number		from
	A/Delaware/55/2019	Wild type virus	cell	H1-Ag-2017	109	CBER/FDA, USA
	A/Washington/19/2020	Wild type virus	cell	H1-Ag-2106	64	CBER/FDA, USA
	A/Wisconsin/588/2019		Recombinant HA	H1-Ag-2102	53	CBER/FDA, USA

Sheep antisera

Purified HA	Order Lot number	Available from	
Parent virus	arent virus Egg or cell		
A/Victoria/2570/2019 - like	Egg	AS443	TGA, Australia
		H1-Ab-2109	CBER/FDA, USA

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

CBER: CBERshippingrequests@fda.hhs.gov **TGA:** influenza.reagents@health.gov.au

For other candidate vaccine viruses and potency testing reagents, please go to https://www.who.int/teams/global-influenza-programme/vaccines/who-recommendations/candidate-vaccine-viruses For general enquiries, please contact gisrs-whohq@who.int