

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 2023-2024 northern 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.

25 February 2023 (last updated 22 September 2023)

Cell culture-based candidate vaccine viruses (ccCVVs), antigenically-like A/Wisconsin/67/2022 (MDCK SIAT cell-derived) - Accession number (GISAID):EPI ISL 15928563

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/Georgia/12/2022	Wild type virus		MDCK 33016	CDC, USA	P2-P3	CDC, USA
	CVR-167	Cell reassortant	PF PF	Seqirus	QMC1/QMC 6	VIDRL, Australia
A/West Virginia/30/2022	Wild type virus		MDCK 33016	CDC, USA	P2-P3	CDC, USA
	CVR-159	Cell reassortant	PF PF	Seqirus	QMC1/QMC 6	VIDRL, Australia

For recombinant vaccine antigen(s), it is recommended that the protein sequence(s) closely matches the sequence of A/Wisconsin/67/2022 (MDCK SIAT cell-derived).

Institutes contact details for candidate vaccine virus orders/information:

^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/teams/global-influenza-programme/vaccines/who-recommendations
https://www.who.int/teams/global-influenza-programme/vaccines/who-recommendations

³ https://www.who.int/initiatives/who-listed-authority-reg-authorities

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

VIDRL: whoflu@influenzacentre.org

Reference antigens (freeze dried)

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	Starting materials		Ref Ag Lot	Unitage	
Parent virus	Candidate vaccine virus	Egg or cell	number	(µg HA/ml)	Available from
A/Georgia/12/2022	CVR-167	Cell	H1-Ag-2307	85	
A/West Virginia/30/2022		Recombinant HA	H1-Ag-2304	50	CBER/FDA, USA

Sheep antisera

Purified HA fro	om	Order let number	Available from	
Parent virus	Egg or cell	Order lot number		
A/Victoria/4897/2022-like	Egg	AS451-1*	TGA, Australia	
		23/100	MHRA, UK	
		2023AH1-1*	NIID, Japan	
A/Sydney/5/2021		H1-Ab-2214 [†]	CBER/FDA, USA	

^{*}New reagents shown in blue

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

CBERshippingrequests@fda.hhs.gov

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

NIID: <u>flu-vaccine@nih.go.jp</u>

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

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

[†]This antiserum should be used with CBER reference antigens only