

Influenza A(H3N2) lineage <u>cell culture-derived</u> candidate vaccine viruses <sup>1</sup> or <u>recombinant</u> vaccine antigen(s) for development and production of vaccines for use in the 2024-2025 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.

# 23 February 2024 (updated 26 May 2024)

Cell culture-based candidate vaccine viruses (ccCVVs) antigenically like A/Massachusetts/18/2022 (MDCK SIAT cell-derived) - Accession number (GISAID): EPI ISL 16968012

(GISAID). LI 1_13L_10300012							
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/Sydney/1304/2022	Wild type virus		MDCK 33016PF	VIDRL, Australia	P2	VIDRL, Australia	
	Wild type virus			CDC, USA	P2	CDC, USA	
A/California/123/2022	CVR-178	Cell reassortant		Seqirus, Australia	QMC1/QMC6	Seqirus, Australia	
A/California/45/2023	Wild type virus		MDCK 33016PF	CDC, USA	P2	CDC, USA	

For recombinant vaccine antigen(s), it is recommended that the protein sequence(s) closely matches the sequence of A/Massachusetts/18/2022 (MDCK-SIAT cell-derived).

<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/teams/global-influenza-programme/vaccines/who-recommendations/candidate-vaccine-viruses/">https://www.who.int/teams/global-influenza-programme/vaccines/who-recommendations/candidate-vaccine-viruses/</a>

<sup>&</sup>lt;sup>2</sup> https://www.who.int/teams/global-influenza-programme/vaccines/who-recommendations

<sup>&</sup>lt;sup>3</sup> https://www.who.int/initiatives/who-listed-authority-reg-authorities

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

**CDC**: nmb7@cdc.gov (Subject: CVV request)

**Seqirus:** <u>brad.dickson@seqirus.com</u> **VIDRL:** whoflu@influenzacentre.org

# Reference antigens (freeze-dried)

	Starting m	naterials	Ref Ag Lot	Unitage	Available
Parent virus	Candidate egg or cell		number	(µg HA/ml)	from
A/Sydney/1304/2022	Wild type virus	Cell	H3-Ag-2312	102	CBER/FDA,
A/Massachusetts/18/2022		Recombinant HA	H3-Ag-2405*	49	USA

<sup>\*</sup>New reagents shown in blue

## **Sheep Antisera**

<u></u>						
Purified HA from	222 24 2211	Ouder Let work or	Available from			
Parent virus	egg or cell	Order Lot number				
A/Thailand/8/2022 - like		H3-Ab-2315	CBER/FDA, USA			
	Egg	23/222	MHRA, UK			
		AS450	TGA, Australia			

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

CBER: CBERshippingrequests@fda.hhs.gov

MHRA: <a href="mailto:standards@nibsc.org">standards@nibsc.org</a> or <a href="mailto:enquiries@nibsc.org">enquiries@nibsc.org</a>

NIID: flu-vaccine@nih.go.jp

TGA: <a href="mailto:influenza.reagents@tga.gov.au">influenza.reagents@tga.gov.au</a>

For other candidate vaccine viruses and potency testing reagents, please go to <a href="https://www.who.int/teams/global-influenza-programme/vaccines/who-recommendations/candidate-vaccine-viruses">https://www.who.int/teams/global-influenza-programme/vaccines/who-recommendations/candidate-vaccine-viruses</a>

For general enquiries, please contact gisrs-whohq@who.int