

## Influenza B Victoria lineage <u>cell culture-derived</u><sup>1</sup> candidate vaccine viruses 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 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) 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.

## 23 February 2024

Cell culture-based candidate vaccine viruses (ccCVVs), antigenically like B/Austria/1359417/2021 (MDCK derived) - Accession number (GISAID): EPI\_ISL\_983345

ccCVV	Certified cell line used for isolation and propagation	Developing institute	Passage level available	Available from
B/Connecticut/01/2021		CDC, USA	P2	CDC, USA
B/Singapore/WUH4618/2021	MDCK 33016 PF	VIDRL, Australia	P2	VIDRL, Australia

For recombinant vaccine antigen(s), it is recommended that the protein sequence(s) closely matches the sequence of B/Austria/1359417/2021 (MDCK-SIAT cell-derived).

Institutes contact details for candidate vaccine virus orders/information:

**CDC:** pdx1@cdc.gov (Subject: CVV request)

VIDRL: whoflu@influenzacentre.org

<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

Reference antigens (freeze-dried)

	Starting materials		Dof Aglat	Unitodo	Available
Parent virus	Candidate vaccine virus	Egg or cell	Ref Ag Lot number	Unitage (µg HA/ml)	Available from
B/Singapore/WUH4618/2021	Wild type virus	cell	B(v)-Ag-2115	63	CBER/FDA, USA
			23/268	48	MHRA, UK
B/Austria/1359417/2021		recombinant	B(v)-Ag-2207	60	CBER/FDA,
			B(v)-Ag-2306	50	USA

## Sheep antisera

Purified HA from		Ouden Let mount hou	Available from	
Parent virus	Egg or Cell	Order Lot number	Available from	
B/Austria/1359417/2021-like	Egg	B(v)-Ab-2202	CBER/FDA, USA	
		B(v)-Ab-2308	CBER/FDA, USA	
		22/228	MHRA, UK	
		AS446-1	TCA Australia	
		AS452	TGA, Australia	

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

**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:** influenza.reagents@health.gov.au

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 <a href="mailto:gisrs-whohq@who.int">gisrs-whohq@who.int</a>