

## Influenza B Yamagata 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 2022 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) 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.

## 24 September 2021

Cell culture-based candidate vaccine viruses (ccCVVs) (antigenically like B/Phuket/3073/2013 (MDCK-SIAT derived) - Accession number (GISAID): EPI\_ISL\_161843

ccCVV	Certified cell line used for isolation and propagation	Developing institute	Passage level available	Available from
B/Singapore/INFTT-16- 0610/2016	MDCK 33016 PF	VIDRL, Australia	P2	VIDRL, Australia
B/Singapore/INFKK-16- 0569/2016	MDCK 33016 PF	VIDRL, Australia	P2	VIDRL, Australia
B/Brisbane/9/2014	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/Phuket/3073/2013 (MDCK-SIAT derived).

Institutes contact details for candidate vaccine virus orders/information:

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/Seqirus

<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> <a href="https://www.who.int/publications/m/item/recommended-composition-of-influenza-virus-vaccines-for-use-in-the-2022-southern-hemisphere-influenza-season">https://www.who.int/publications/m/item/recommended-composition-of-influenza-virus-vaccines-for-use-in-the-2022-southern-hemisphere-influenza-season</a>

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

Reference antigens (freeze-dried)

	Starting materials		Dof Ag lot	Unitogo	Available
Parent virus	Candidate vaccine virus	Egg or cell	Ref Ag lot number	Unitage (μg HA/ml)	from
B/Phuket/3073/2013		Recombinant HA	B(y)-Ag-2001	44	CBER/FDA, USA
B/Utah/9/2014	Wild type	Cell	B(y)-Ag-1501	56	CBER/FDA, USA
	Wild type		15/100	40	NIBSC, UK
B/Singapore/INFTT- 16-0610/2016	Wild type	Cell	B(y)-Ag-1709	94	CBER/FDA, USA
	Wild type		B(y)-Ag-2103	45	CBER/FDA, USA
	Wild type		19/308	73	NIBSC, UK

## Sheep antisera

Purified HA from		Order Lot number	Available from	
Parent virus	Egg or Cell	Order Lot number	Available from	
		B(y)-Ab-1808	CBER/FDA, USA	
D /DL   L   /2072 /2042	<b>5</b>	19/322	NIBSC, UK	
B/Phuket/3073/2013	Egg	2017BY-1	NIID, Japan	
		AS425	TCA Australia	
		AS434	TGA, Australia	
D/M/seessin /1 /2010 /DV 41 A)	Гаа	AS402/AS402-1	TCA Australia	
B/Wisconsin/1/2010 (BX-41A)	Egg	AS426	TGA, Australia	

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

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="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