

Influenza A(H3N2) lineage <u>cell culture-derived</u>¹ candidate vaccine viruses for development and production of vaccines for use in the 2018-2019 northern hemisphere influenza season

Human influenza virus isolation using a certified cell line (eg MDCK 33016 PF^a, NIID-MDCK^b) 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) as indicated. Unless otherwise noted these ccCVVs have passed two-way haemagglutination inhibition (HI) 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 appropriate national or regional control authorities regarding the suitability of these ccCVVs for influenza vaccine production.

22 February 2018

Cell culture-based candidate vaccine viruses (ccCVVs) (Antigenically like A/SINGAPORE/INFIMH-16-0019/2016)

ccCVV	Certified cell line used for isolation and propagation	Developing institute	Passage level available	Available From
A/North Carolina/04/2016	MDCK 33016 PF	CDC, USA	P2/P3	CDC, USA
A/Canberra/7/2016	MDCK 33016 PF	VIDRL, Australia	P2	VIDRL, Australia

Institutes contact details for candidate vaccine viruses orders/information:

CDC: dwentworth@cdc.gov (Subject: CVV request)

VIDRL: whoflu@influenzacentre.org

The list of all WHO Collaborating Centres (CCs) and WHO Essential Regulatory Laboratories (ERLs) for influenza can be found on the WHO web site at

http://www.who.int/influenza/gisrs_laboratory/collaborating_centres/

^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

http://www.who.int/influenza/vaccines/virus/recommendations/2018 19 north/

³ http://www.who.int/immunization_standards/national_regulatory_authorities_offices/en/

Reference antigens (freeze-dried) for use with vaccines produced using ccCVV – To be updated

Parent virus	Starting materials		Ref Ag		
	Candidate vaccine virus	Certified Cell line	Lot number	Unitage (μgHA/ml)	Available from

Sheep antisera to ccCVV derived antigen – To be updated

Purified HA from	Purified HA from		
Parent virus	Certified Cell line	Order Lot number	Available From

ERLs contact details for reagents orders/information:

CBER: fda.gov/cber

NIBSC: <u>standards@nibsc.org</u> or <u>enquiries@nibsc.org</u>

NIID: flu-vaccine@nih.go.jp

TGA: influenza.reagents@tga.gov.au

For other candidate vaccine viruses and potency testing reagents, please go to http://www.who.int/influenza/vaccines/virus/candidates reagents/home/en/

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