Influenza A(H1N1)pdm09 cell culture-derived\(^1\) candidate vaccine viruses for development and production of vaccines for use in the 2019 southern hemisphere influenza season

Human influenza virus isolation using a certified cell line (eg MDCK 33016 PF, 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 recommendation\(^2\). **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\(^3\). Manufacturers should consult appropriate national or regional control authorities regarding the suitability of these ccCVVs for influenza vaccine production.

\(a\) Derived from MDCK cell line approved for use for human vaccine manufacture in compliance with Ph. Eur. general chapter 5.2.3 by Novartis/Seqirus

\(b\) Derived from MDCK cell line developed by the National Institute of Infectious Diseases (NIID), Japan

09 January 2019

Cell culture-based candidate vaccine viruses (ccCVVs) (Antigenically-like A/MICHIGAN/45/2015)

<table>
<thead>
<tr>
<th>ccCVV</th>
<th>Certified cell line used for isolation and propagation</th>
<th>Developing institute</th>
<th>Passage level available</th>
<th>Available From</th>
</tr>
</thead>
<tbody>
<tr>
<td>A/SINGAPORE/TT1384/2016</td>
<td>MDCK 33016 PF</td>
<td>VIDRL, Australia</td>
<td>P2</td>
<td>CDC, USA VIDRL, Australia</td>
</tr>
</tbody>
</table>

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/

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\(^1\) For egg-derived candidate vaccine viruses and reference reagents please see

https://www.who.int/influenza/vaccines/virus/candidates_reagents/summary_a_h1n1pdm09_cvv_egg_sh19.pdf?ua=1

\(^2\) https://www.who.int/influenza/vaccines/virus/recommendations/2019_south/en/

\(^3\) http://www.who.int/immunization_standards/national_regulatory_authorities/offices/en/
ERLs contact details for reagents orders/information:

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