

Availability of two new candidate reassortant vaccine viruses for pandemic (H1N1) 2009 virus vaccine development

14 September 2009

X-181 and X-181A

Two new candidate reassortant vaccine viruses (X-181 and X-181A) were developed by New York Medical College, USA, using conventional reassortment technology. Both have a 5:3 gene constellation with three genes (PB1, HA and NA) obtained from A/California/07/2009 (H1N1)v and the remaining five genes originating from A/PR/8/1934. The PR/8 genes were provided by reassorting NYMC X-157 with A/California/07/2009 (H1N1)v.

Full characterization of two reassortant viruses has been conducted by the WHO Collaborating Centre for Surveillance, Epidemiology and Control of Influenza in the Centers for Disease Control and Prevention (CDC), Atlanta, USA. Antigenic and genetic analyses completed so far indicate that the X-181 and X-181A reassortant viruses meet the specifications in the recent WHO recommendation on viruses to be used in vaccine development.¹

The Genbank accession numbers for HA, NA and PB1 genes of these reassortants are as follows:

A/CALIFORNIA/07/2009 X-181 PB1 (GQ906800) A/CALIFORNIA/07/2009 X-181 HA (GQ906801) A/CALIFORNIA/07/2009 X-181 NA (GQ906802) A/CALIFORNIA/07/2009 X-181A PB1 (GQ906803) A/CALIFORNIA/07/2009 X-181A HA (GQ906804) A/CALIFORNIA/07/2009 X-181A NA (GQ906805)

The X-181 and X-181A reassortant viruses are available for distribution to manufacturers, institutions, companies and other parties interested in developing vaccines to the pandemic (H1N1) 2009 virus. Those who wish to receive these candidate reassortant vaccine viruses should contact either the WHO Global Influenza Programme at GISN@who.int or at the address below:

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 $^{{}^{1}\}underline{\text{http://www.who.int/csr/resources/publications/swineflu/vaccine}} \ \ \underline{\text{recommendations/en/index.html}}$

Biocontainment requirements for handling the candidate reassortant vaccine virus

The candidate reassortant vaccine viruses X-181 and X-181A contain infectious materials and should be handled only in appropriate containment facilities. As these reassortant candidate vaccine viruses have a 5:3 gene constellation² similar to donor viruses previously tested in ferrets with satisfactory results³ and with expected gene sequences, ferret safety testing for the reassortant vaccine virus X-181 and X-181A may not be required. Vaccine production using these candidate reassortant viruses may proceed at BSL-2 enhanced level using fully trained and competent staff in accordance with national safety guidelines, as described in WHO Technical Report Series No. 941.⁴ Recipient laboratories must accept full responsibility for the use and disposal of all materials.

² The reassortant virus has the HA, NA and PB1 genes from the mentioned A/California/7/2009 (H1N1) v and five internal genes (M, NS, NP, PA, and PB2) from A/Puerto Rico/8/1934 virus.

http://www.who.int/csr/resources/publications/swineflu/biocontainment/en/index.html

http://www.who.int/biologicals/publications/trs/areas/vaccines/influenza/H1N1 vaccine production biosafety SHOC.27May2009.pdf