

## Availability of a new candidate reassortant vaccine virus for pandemic (H1N1) 2009 virus vaccine development

6 August 2009

### NIBRG-121xp

A new candidate reassortant vaccine virus (NIBRG-121xp) has been developed by extended egg passage of the reverse genetics technology derived reassortant NIBRG-121<sup>1</sup> originally developed from an A/California/7/2009(H1N1)v virus by the National Institute for Biological Standards and Control (NIBSC), Potters Bar, Hertfordshire, United Kingdom.

The full characterization of this reassortant virus is currently being conducted by the NIBSC and the WHO Collaborating Centre for Reference and Research on Influenza, National Institute for Medical Research, Mill Hill, London, United Kingdom. Antigenic and genetic analyses completed so far indicate that the NIBRG-121xp reassortant virus meets the specifications in the recent WHO recommendation on viruses to be used in vaccine development.<sup>2</sup>

The haemagglutinin (HA) and neuraminidase (NA) sequences of the A/California/7/2009(H1N1)v virus can be found on the public web site of GenBank via the following links:

#### HA sequence

[http://www.ncbi.nlm.nih.gov/nuccore/227977171?ordinalpos=1&itool=EntrezSystem2.PEntrez.Sequence.Sequence\\_ResultsPanel.Sequence\\_RVDocSum](http://www.ncbi.nlm.nih.gov/nuccore/227977171?ordinalpos=1&itool=EntrezSystem2.PEntrez.Sequence.Sequence_ResultsPanel.Sequence_RVDocSum)

#### NA sequence

[http://www.ncbi.nlm.nih.gov/nuccore/229396468?ordinalpos=1&itool=EntrezSystem2.PEntrez.Sequence.Sequence\\_ResultsPanel.Sequence\\_RVDocSum](http://www.ncbi.nlm.nih.gov/nuccore/229396468?ordinalpos=1&itool=EntrezSystem2.PEntrez.Sequence.Sequence_ResultsPanel.Sequence_RVDocSum)

The NIBRG-121xp candidate reassortant vaccine virus is available for distribution to manufacturers, institutions, companies and other parties interested in developing vaccines for the pandemic (H1N1) 2009 virus. Those who wish to receive this candidate reassortant vaccine virus should contact either the WHO Global Influenza Programme at [GISN@who.int](mailto:GISN@who.int) or at the address below:

Division of Virology  
National Institute for Biological Standards and Control  
Blanche Lane, South Mimms, Potters Bar  
Hertfordshire, EN6 3QG, United Kingdom  
E-mail: [standards@nibsc.hpa.org.uk](mailto:standards@nibsc.hpa.org.uk)  
[http://www.nibsc.ac.uk/flu\\_site/viruses\\_reagents.html](http://www.nibsc.ac.uk/flu_site/viruses_reagents.html)

### Biocontainment requirements for handling the candidate reassortant vaccine virus

The candidate reassortant vaccine virus NIBRG-121xp contains infectious materials and should be handled only in appropriate containment facilities. As this candidate reassortant vaccine virus have 6:2 gene

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<sup>1</sup> [http://www.who.int/csr/resources/publications/swineflu/candidates\\_nibrg121/en/index.html](http://www.who.int/csr/resources/publications/swineflu/candidates_nibrg121/en/index.html)

<sup>2</sup> [http://www.who.int/csr/resources/publications/swineflu/vaccine\\_recommendations/en/index.html](http://www.who.int/csr/resources/publications/swineflu/vaccine_recommendations/en/index.html)

constellation,<sup>3</sup> similar to donor viruses previously tested in ferrets with satisfactory results<sup>4,5</sup> and with expected gene sequences, ferret safety testing for the candidate reassortant vaccine virus NIBRG-121xp is not required. Vaccine production using this candidate reassortant vaccine virus may proceed at BSL-2 enhanced levels using fully trained and competent staff in accordance with national safety guidelines, as described in WHO's Technical Report Series No. 941.<sup>6</sup> Recipient laboratories must accept full responsibility for the use and disposal of all materials.

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<sup>3</sup> The reassortant virus possess the HA and NA from the mentioned A/California/7/2009 (H1N1)v-like viruses and six internal genes (M, NS, NP, PA, PB1 and PB2) from A/Puerto Rico/8/1934(H1N1) virus

<sup>4</sup> <http://www.who.int/csr/resources/publications/swineflu/biocontainment/en/index.html>

<sup>5</sup> [http://www.who.int/csr/resources/publications/swineflu/ivr\\_153/en/index.html](http://www.who.int/csr/resources/publications/swineflu/ivr_153/en/index.html)

<sup>6</sup> [http://www.who.int/biologicals/publications/trs/areas/vaccines/influenza/H1N1\\_vaccine\\_production\\_biosafety\\_SHOC.27May2009.pdf](http://www.who.int/biologicals/publications/trs/areas/vaccines/influenza/H1N1_vaccine_production_biosafety_SHOC.27May2009.pdf)