

## Availability of a candidate reassortant vaccine virus for the novel influenza A (H1N1) vaccine development

27 May 2009

### NIBRG-121

A candidate reassortant vaccine virus (NIBRG-121) has been developed, using reverse genetics technology, 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, including safety testing in ferrets, 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-121 reassortant virus meets the specifications in the recent WHO recommendation on viruses to be used in vaccine development.<sup>1</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-121 reassortant virus is available for distribution to manufacturers under certain biocontainment conditions.<sup>2</sup> Institutions, companies and other parties interested in developing vaccines to the novel variant influenza A (H1N1) virus, 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: [enquiries@nibsc.hpa.org.uk](mailto:enquiries@nibsc.hpa.org.uk) or [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)

The WHO Global Influenza Surveillance Network closely monitors the antigenic and genetic evolution of emerging and circulating human influenza viruses. Countries are encouraged to share with WHO both their specimens/isolates for inclusion in the WHO influenza vaccine virus selection and development process, and other activities of public health importance.

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

The candidate reassortant vaccine virus contains infectious materials and should be handled only in appropriate containment facilities (until completion of the above-mentioned safety tests, it is recommended to use biosafety level 2 plus [BSL-2 plus] facilities with biosafety level 3 [BSL-3] practices<sup>3</sup> using fully trained and competent staff in accordance with national safety guidelines. Further guidance will be provided to recipient laboratories when the safety tests have been completed. If, as expected, attenuation is demonstrated, vaccine production may proceed at BSL-2 enhanced level, as described in WHO Technical Report Series No. 941.<sup>4</sup> Recipient laboratories must accept full responsibility for the use and disposal of all materials.

<sup>1</sup> <http://www.who.int/csr/disease/swineflu/guidance/laboratory/en/index.html>

<sup>2</sup> <http://www.who.int/biologicals/publications/trs/areas/vaccines/influenza/en/index.html>

<sup>3</sup> <http://www.who.int/csr/resources/publications/swineflu/LaboratoryHumanspecimensinfluenza/en/index.html>

<sup>4</sup> [http://whqlibdoc.who.int/trs/WHO\\_TRS\\_941.pdf](http://whqlibdoc.who.int/trs/WHO_TRS_941.pdf)