*12 May 2009*

*This supplement has been prepared to present scientific and technical news items that may be of more interest to technical personnel at RDT&E activities and the labs, or the medics rather than the broader readership of the basic CB Daily. Due to the nature of the material, the articles, if available online, are usually only available through subscription services thus making specific links generally unavailable. Thus, usually only the bibliographic citation is available for use by an activity's technical library.*

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## *Chem-Bio News – Pandemic Influenza Edition #60*


**1. A NESTED REAL-TIME PCR ASSAY HAS AN INCREASED SENSITIVITY SUITABLE FOR DETECTION OF VIRUSES IN AEROSOL STUDIES:** *"A two-step, nested real-time PCR assay was developed for MS2 bacteriophage, and for influenza A and B, parainfluenza 1 and human respiratory syncytial virus."*

**2. COOKING UP MILLIONS OF VIRUSES FOR A NEW VACCINE:** : *"Federal health officials have not yet decided whether to call for a swine flu vaccine, but they say it is important to be ready for quick production of millions of doses."*

**3. NIGERIA OBTAINS WHO CERTIFICATION TO DIAGNOSE 'SWINE FLU':** *"THE Asokoro District Hospital, National Influenza Diagnostic Laboratory in Abuja has been identified as a diagnostic center for Influenza A (H1N1) infection in humans."*

**4. THE ROLE OF LAW IN PANDEMIC INFLUENZA PREPAREDNESS IN EUROPE:** *"The porous nature of borders between EU states, and of their borders with other non-EU states, limits the extent to which states are able to protect their populations in a disease pandemic."*

**5. ANTIBODY RECOGNITION OF A HIGHLY CONSERVED INFLUENZA VIRUS EPITOPE:** *"The CR6261 epitope identified here should accelerate the design and implementation of improved vaccines that can elicit CR6261-like antibodies, as well as antibody-based therapies for the treatment of influenza."*

**6. FDA APPROVES NEW INFLUENZA VACCINE PRODUCTION FACILITY:** *"The facility is approved for seasonal influenza vaccine production and could be used for the production of vaccine against the new 2009 H1N1 influenza strain."*

**7. EU AGENCY CALLS FOR EXTENDED TAMIFLU SHELF LIFE:** *"Europe's drug watchdog on Friday recommended that the shelf life of Roche's Tamiflu should be extended to seven years from five years due to the outbreak of the new H1N1 virus."*

**8. SWINE FLU: EARLY FINDINGS ABOUT PANDEMIC POTENTIAL REPORTED IN NEW STUDY:** *"The data so far is very consistent with what researchers would expect to find in the early stages of a pandemic."*


# CB Daily Report

## *Chem-Bio News*

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**A NESTED REAL-TIME PCR ASSAY HAS AN INCREASED SENSITIVITY SUITABLE FOR DETECTION OF VIRUSES IN AEROSOL STUDIES**
Virus Weekly
May 12, 2009

"A two-step, nested real-time PCR assay was developed for MS2 bacteriophage, and for influenza A and

B, parainfluenza 1 and human respiratory syncytial virus. Outer primer pairs were designed to nest each existing real-time PCR assay. The sensitivities of the nested real-time PCR assays were compared to those of existing real-time PCR assays. Both assays were applied in an aerosol study to compare their detection limits in air samples. The nested real-time PCR assays were found to be several logs more sensitive than the real-time PCR assays, with lower levels of virus detected at lower Ct values. The nested real-time PCR assay successfully detected MS2 in air samples, whereas the real-time assay did not. AND IMPACT OF THE STUDY: The sensitive assays for respiratory viruses will permit further research using air samples from naturally generated virus aerosols."

The full article can be found at: (P. Perrott, et. al., "A nested real-time PCR assay has an increased sensitivity suitable for detection of viruses in aerosol studies". Journal of Applied Microbiology, 2009;106(5):1438-47). Link not available.
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**COOKING UP MILLIONS OF VIRUSES FOR A NEW VACCINE**
New York Times on HSToday.com
May 06, 2009

"Federal health officials have not yet decided whether to call for a swine flu vaccine, but they say it is important to be ready for quick production of millions of doses. Because the virus is new, some people may need two shots to build immunity. The vaccine would probably be separate from seasonal flu vaccine, meaning a total of three shots might be recommended for certain people.

Creating the seed stock is an essential first step for any vaccine. So the CDC has sent samples of the new strain to about 10 other government and academic laboratories in this country, Australia, Britain, Hungary and Russia. For the past five years, Dr. Bucher's laboratory has provided seed stock for one of the virus strains included in the seasonal flu vaccine used all over the world.

"Our job is to make it grow really well," she said. "We're good at this."

One of the group's strengths has been in developing a "high-yield donor," meaning an influenza virus that grows well in eggs and that, when injected into eggs along with a new strain like H1N1, will swap some of its genes with the new strain. An array of new viruses results, and the researchers can sort through it to pick ones that have donor genes inside the ball-shaped viral particles, so they will grow well in eggs, but that will retain the new strain's traits on the outside — enabling the vaccine to spark immunity when injected into people."

The full article can be found at: http://www.hstoday.us/content/view/8402/243/
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**NIGERIA OBTAINS WHO CERTIFICATION TO DIAGNOSE 'SWINE FLU'**
By Sola Ogundipe
Vanguard
May 05, 2009

"THE Asokoro District Hospital, National Influenza Diagnostic Laboratory in Abuja has been identified as a diagnostic center for Influenza A (H1N1) infection in humans. This development is based on the listing of Nigeria by the World Health Organisation as one of the countries capable of diagnosing the Influenza A(H1N1) infection in humans. The nation got the listing based on the global health body's approval of countries with Polymerase Chain Reactor (PCR) capacity in place to diagnose the pathogen."

"Amongst these requirements are a score of 100 per cent in the last two or more WHO external quality assurance programme panels (EQAP2) or a score of 100 per cent in the last EQAP panel and a history of consistent correct results for earlier panels."

The full article can be found at: http://www.vanguardngr.com/content/view/35051/80/
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**THE ROLE OF LAW IN PANDEMIC INFLUENZA PREPAREDNESS IN EUROPE**
Biotech Week
May 13, 2009

"The European Union (EU) is composed of 27 states with widely varying histories, economies, cultures, legal systems, medical systems and approaches to the balance between public good and Private right. The individual nation states within Europe are signatories to the International Health Regulations 2005, but the capacity of states to undertake measures to control communicable disease is constrained by their obligations to comply with EU law."

"Some but not all states are signatories to the Schengen Agreement that Provides further constraints on disease control measures. The porous nature of borders between EU states, and of their borders with other non-EU states, limits the extent to which states are able to protect their populations in a disease pandemic."

The full article can be found at: (R. Martin, et. al., "The role of law in pandemic influenza preparedness in Europe". Public Health, 2009;123(3):247-254). Link not available.
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**ANTIBODY RECOGNITION OF A HIGHLY CONSERVED INFLUENZA VIRUS EPITOPE**
Health Risk Factor Week
May 12, 2009

"High-affinity antibodies against a conserved epitope could provide immunity to the diverse influenza subtypes and protection against future pandemic viruses."

"Cocrystal structures were determined at 2.2 and 2.7 angstrom resolutions for broadly neutralizing human antibody CR6261 Fab in complexes with the major surface antigen (hemagglutinin, HA) from viruses responsible for the 1918 H1N1 influenza pandemic and a recent lethal case of H5N1 avian influenza. In contrast to other structurally characterized influenza antibodies, CR6261 recognizes a highly conserved helical region in the membrane-proximal stem of HA1 and HA2. The antibody neutralizes the virus by blocking conformational rearrangements associated with membrane fusion."

"The CR6261 epitope identified here should accelerate the design and implementation of improved vaccines that can elicit CR6261-like antibodies, as well as antibody-based therapies for the treatment of influenza."

The full article can be found at: (D.C. Ekiert, et. al., "Antibody Recognition of a Highly Conserved Influenza Virus Epitope". Science, 2009;324(5924):246-251). Link not available.
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**FDA APPROVES NEW INFLUENZA VACCINE PRODUCTION FACILITY**
US Food and Drug Administration News Release
May 7, 2009

"The U.S. Food and Drug Administration (FDA) today announced that it has approved a new manufacturing facility used to produce influenza virus vaccines. The facility is approved for seasonal influenza vaccine production and could be used for the production of vaccine against the new 2009

H1N1 influenza strain.

As part of its overall pandemic influenza preparedness efforts, the FDA meets with vaccine manufacturers to guide the efficient establishment of influenza vaccine facilities that comply with agency requirements. The agency promptly reviews applications and manufacturing supplements that could increase both the number of manufacturers and the overall supply of vaccine.

The facility, located in the United States, is owned and operated by sanofi pasteur, which manufactures Fluzone Influenza Virus Vaccine. This new facility will greatly increase sanofi pasteur's production capability.

"This approval represents an important step towards increasing the availability of influenza vaccines," said Karen Midthun, M.D., the FDA's acting director of the Center for Biologics Evaluation and Research.

"Increased manufacturing capacity for influenza vaccine is critical to our preparedness for an influenza pandemic," said Jesse Goodman, M.D., M.P.H., the FDA's acting chief scientist and deputy commissioner for scientific and medical programs. "This action also enhances the ability to produce and provide vaccines to protect the public from seasonal influenza, still estimated to cause more than 30,000 deaths per year. Thanks to strategic investments by the federal government and proactive efforts and engagement by the FDA and the vaccine industry, our nation's preparedness has come a long way over the last five years."

The FDA has interacted with the company throughout the regulatory process to help ensure compliance with applicable requirements.

The bulk manufacturing facility will be used for the production of Fluzone, sanofi pasteur's egg-based influenza vaccine.

Sanofi Pasteur is located in Swiftwater, Pa."

The full article can be found at: http://www.fda.gov/bbs/topics/NEWS/2009/NEW02008.html
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**EU AGENCY CALLS FOR EXTENDED TAMIFLU SHELF LIFE**
By Michael Kahn
Reuters
May 08, 2009

"Europe's drug watchdog on Friday recommended that the shelf life of Roche's Tamiflu should be extended to seven years from five years due to the outbreak of the new H1N1 virus."

"The watchdog also called for tablets already on the market to be used for up to two more years after their current five-year expiry date during a declared pandemic and recommended wider use of both Relenza and Tamiflu.

"Patients who have Tamiflu capsules that have recently expired should not dispose of them because they might be needed during a novel influenza A/H1N1 pandemic," the London-based agency said.

It also issued guidance that in a declared pandemic children under the age of one should receive Tamiflu because the benefits would outweigh the risks."

The full article can be found at: http://uk.reuters.com/article/UKNews1/idUKTRE5472JL20090508
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**SWINE FLU: EARLY FINDINGS ABOUT PANDEMIC POTENTIAL REPORTED IN NEW STUDY**
EurekAlert!
May 11, 2009

" * The data so far is very consistent with what researchers would expect to find in the early stages of a pandemic.

* The researchers' best estimate is that in Mexico, influenza A (H1N1) is fatal in around 4 in 1,000 cases, which would make this strain of influenza as lethal as the one found in the 1957 pandemic. The researchers stress that healthcare has greatly improved in most countries since 1957 and the world is now better prepared.

* The epidemic of influenza A (H1N1) is thought to have started in Mexico on 15 February 2009. The data suggests that by the end of April, around 23,000 people were infected with the virus in Mexico and 91 of these died as a result of infection. However, the figures are uncertain – for example, some mild cases may have gone unreported. The numbers infected could be as low as 6,000 people or as high as 32,000 people.

* The uncertainty around the numbers of people who have been infected with influenza A (H1N1) in Mexico means that the case fatality ratio (CFR) of 0.4% (4 deaths per 1000) cannot be definitely established. The CFR is in the range of 0.3% to 1.5%, but at this stage the researchers believe that 0.4% is the most likely.

* For every person infected, it is likely that there will be between 1.2 and 1.6 secondary cases. This is high compared to normal seasonal influenza, where around 10-15 percent of the population are likely to become infected. However, it is lower than would be expected for pandemic influenza, where 20-30 percent of the population are likely to become infected.

* In an outbreak in an isolated village called La Gloria, Mexico, children were twice as likely to become infected as adults, with 61% of those aged under 15 becoming infected, compared with 29% of those over 15. This may suggest that adults have some degree of immunity against infection, because of having been previously infected with a related strain of influenza, or it may mean that children are more susceptible to infection because they interact much more closely together, for example in school, than adults."

The full article can be found at: http://www.eurekalert.org/pub_releases/2009-05/icl-sfe051109.php
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**Steve Tesko:** Steve.Tesko@anser.org

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