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# ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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**INSIDE:**



**2007 #35** **September 21, 2007**

## FDA Approves Rapid Bacterial Detection Device for Platelets

The Food and Drug Administration has cleared for marketing the first rapid test to detect bacterial contamination in blood platelets prior to transfusion. The Platelet Pan Genera Detection (PGD) Test System, manufactured by Verax Biomedical Inc. of Worcester, Mass., is a disposable test strip device for use in a hospital transfusion setting. It is not a release test but can supplement current quality control testing methods for platelets collected with an automated instrument.

> **The package insert notes that "Users considering such release should first consult [the Center for Biologics Education and Research] for the appropriate clinical studies. [The performance of the PGD] to detect bacteria in whole blood-derived platelets or non-leukocyte reduced platelets is not known... [T]esting alone should not be used to extend the shelf life of platelets."**

Two studies supported the determination of substantial equivalence of the Platelet PGD Test system to BacT/ALERT testing and demonstrated the value of the PGD Test system as an adjunct QC test following culture testing, FDA said in a summary report. Testing at 72 hours using the PGD Test System was found to be substantially equivalent to testing by BacT/ALERT at 24 and 48 hours post collection. The PDG Test System was able to detect bacterial contamination when an early culture was unable to detect bacteria due to sampling errors.

> **"I am excited about the potential of this new test."**
>
> ***– Kevin Land, MD, Bonfils Blood Center***

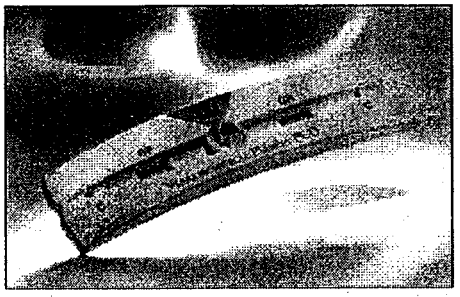
A 500uL platelet sample is insert in a sample well, and in about 20 minutes, a pink colored bar will appear in one of the two windows if either Gram-positive or Gram-negative bacteria are detected. Procedural controls at each end of the test cartridge change from yellow to blue violet when the appropriate volume of sample has been added to the cartridge and the test has run to completion.

"The clearance of a rapid test is a significant step in the detection of bacterial contamination of platelets for transfusion," said Jesse L. Goodman, MD, director of FDA's Center for Biologics Evaluation and Research.

(continued on page 2)

Rapid Platelet Test (continued from page 1)

Patients who are transfused with platelets contaminated with bacteria are at risk of developing a serious and potentially life-threatening infection of the blood stream. Bacterial contamination of platelets is the leading infectious cause of transfusion-related patient fatalities. The risk of a patient receiving a transfusion contaminated with bacteria is 1 in 5,000 – far greater than the risk of transmitting the hepatitis C virus (1 in 1.6 million) or HIV (1 in 1.9 million), the FDA said in a press release.



To reduce the risk of transfusing contaminated platelets, blood centers do culture-based testing of platelet samples 24 hours after the donation. The culture is read in the next 24 hours (within 48 hours of the donation), and contaminated units are discarded. However, the number of bacteria present at the time of culture may be so low that bacteria is not detected due to sampling limitations. Blood community professionals agreed that the test is more of a transfusion-end product but that it is better than other non-culture-based methods used by some blood centers and transfusion centers.

Kevin Land, MD, chief scientific and medical officer at Denver-based Bonfils Blood Center, told the *ABC Newsletter* that because the device is licensed to supplement current methodologies, "I don't see this test being widely implemented at this time due to the additional cost and time."

But, he added, "I am excited about the potential of this new test as it delays sampling of the product until it is being issued. The longer the delay prior to sampling, the more sensitive it should be to the presence of bacteria in the platelet component, even if the limit of detection is higher than current methodologies. It should definitely be an improvement over surrogate tests such as swirling and dipstick methods. Hopefully, the time between sampling and reading will decrease as the technology matures, as it likely represents a barrier to widespread use at this time."

Although the test system is less sensitive than standard cultures, testing is done later in storage when bacteria, if present, have multiplied, and thus are easier to detect, the FDA notes.

A prototype Platelet PGD test was tested against numerous bacterial species implicated in transfusion reactions. In an in-house study, Verax detected four contaminated platelet units in a mixed population of 7,889 apheresis and whole blood derived platelets. All four units were confirmed as contaminated by culture testing. (Sources: FDA press release, 9/18/07; Verax Web site) ♦

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医薬品　研究報告　調査報告書

| 識別番号・報告回数 | | | 報告日 | 第一報入手日<br>2008年1月15日 | 新医薬品等の区分<br>該当なし | 総合機構処理欄 |
|---|---|---|---|---|---|---|
| 一般的名称 | 別紙のとおり | | 研究報告の公表状況 | Xinhua News Agency, China View.<br>2008-01-10 | 公表国<br>中国 | |
| 販売名（企業名） | 別紙のとおり | | | | | |

| 研究報告の概要 | 使用上の注意記載状況・その他参考事項等 |
|---|---|
| 問題点：2007年12月に中国で発生した鳥インフルエンザ感染患者は、感染患者から感染した可能性があることが明らかになった。しかし、ウイルスがヒトからヒトへ感染するタイプに変異した確証はない。<br><br>2008年1月10日、中国衛生当局は、2007年12月に江蘇省南京で発生した52歳男性の鳥インフルエンザ感染患者は、患者であった息子との濃厚な接触により感染したものであり、ウイルスの変異は認められていないことを明らかにした。<br>24歳の彼の息子は、2007年11月24日にH5N1型鳥インフルエンザに感染し、発熱、悪寒、その他の症状を発症した。同27日に下葉肺炎と診断され入院したが、2007年12月2日に死亡した。その後、男性の父親が、息子が死亡した翌日の12月3日に下葉肺炎と診断され入院した。H5N1型鳥インフルエンザウイルスに感染していることが判明したが、この父親は回復した。疫学調査により、この父親は息子との濃厚接触を通じて感染したことが分かった。<br>中国当局は、息子に感染したウイルスが家禽由来であり、変異がないことを確認していた。しかし、息子と父親、いずれにもヒトへの主な感染ルートである死亡した家禽との接触がないため、この息子がどのようにして感染したかは判明していない。地元当局は、2人の男性と密接な接触があった83人を厳重な監視下においていたが、これまで異常を示すものは1人もなかった。これで2003年以降の中国国内での鳥インフルエンザ感染事例は27例となり、うち17人が死亡している。<br>WHOは、鳥インフルエンザウイルスは、条件が整えば、感染力が増しヒト-ヒト感染を生じやすくなる可能性があると警告していた。このような変異は世界的大流行につながる。しかし、今回の事例では、ある患者からもう1人の患者へ疾患が伝播したことは明らかだが、ヒト-ヒト感染流行を生じる様な感染力は有していなかった。 | 記載なし |

| 報告企業の意見 | 今後の対応 |
|---|---|
| 別紙のとおり | 日本での流行の可能性を視野に入れ、今後とも関連情報の収集に努め、本剤の安全性の確保を図っていきたい。 |

MedDRA10.1

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別紙

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| 一般的名称 | ①人血清アルブミン、②人血清アルブミン、③人血清アルブミン*、④人免役グロブリン、⑤乾燥ペプシン処理人免疫グロブリン、⑥乾燥スルホ化人免疫グロブリン、⑦乾燥スルホ化人免疫グロブリン*、⑧乾燥濃縮人活性化プロテインC、⑨乾燥濃縮人血液凝固第Ⅷ因子、⑩乾燥濃縮人血液凝固第Ⅸ因子、⑪乾燥抗破傷風人免疫グロブリン、⑫抗HBs人免疫グロブリン、⑬トロンビン、⑭フィブリノゲン加第ⅩⅢ因子、⑮乾燥濃縮人アンチトロンビンⅢ、⑯ヒスタミン加人免疫グロブリン製剤、⑰人血清アルブミン*、⑱人血清アルブミン*、⑲乾燥ペプシン処理人免役グロブリン*、⑳乾燥人血液凝固第Ⅸ因子複合体*、㉑乾燥濃縮人アンチトロンビンⅢ |
| 販売名(企業名) | ①献血アルブミン20“化血研”、②献血アルブミン25“化血研”、③人血清アルブミン“化血研”*、④“化血研”ガンマーグロブリン、⑤献血静注グロブリン“化血研”、⑥献血ベニロンーⅠ、⑦ベニロン*、⑧注射用アナクトC2,500単位、⑨コンファクトF、⑩ノバクトM、⑪テタノセーラ、⑫ヘパトセーラ、⑬トロンビン“化血研”、⑭ボルヒール、⑮アンスロビンP、⑯ヒスタグロビン、⑰アルブミン20%化血研*、⑱アルブミン5%化血研*、⑲静注グロブリン*、⑳ノバクトF*、㉑アンスロビンP1500注射用 |
| 報告企業の意見 | 鳥インフルエンザウイルスは、オルソミクソウイルス科のA型インフルエンザウイルス属に分類される。ウイルス粒子は70～120nmの球形または多形性で、8本の分節状マイナス一本鎖RNAを核酸として有する。エンベロープの表面に赤血球凝集素(HA)とノイラミダーゼ(NA)のスパイクを持ち、その抗原性により16種類のHA亜型および9種類のNA亜型に分類される。H5亜型とH7亜型の鳥インフルエンザウイルスの中には、家禽に高い致死率を示す高病原性のウイルスが存在する。現在、アジア中心に高病原性のH5N1亜型による鳥インフルエンザが拡がっており、鳥からヒトだけでなく、ヒトからヒトへの感染事例も報告されている。<br>弊所の血漿分画製剤の製造工程には、冷エタノール分画工程、ウイルス除去膜ろ過工程あるいは加熱工程等の原理の異なるウイルス除去及び不活化工程が存在しているので、ウイルスクリアランスが期待される。<br>各製造工程のウイルス除去・不活化効果は、「血漿分画製剤のウイルスに対する安全性確保に関するガイドライン（医薬発第1047号、平成11年8月30日)」に従い、ウシウイルス性下痢ウイルス（BVDV)、仮性狂犬病ウイルス（PRV)、ブタパルボウイルス（PPV)、A型肝炎ウイルス（HAV）または脳心筋炎ウイルス（EMCV）をモデルウイルスとして、ウイルスプロセスバリデーションを実施し、評価を行っている。今回報告した鳥インフルエンザウイルスは、エンベロープの有無、核酸の種類等からモデルウイルスとしてはBVDVが該当すると考えられるが、上記バリデーションの結果から、BVDVの除去・不活化効果を有することを確認している。<br>また、これまでに当該製剤による鳥インフルエンザウイルス感染の報告例は無い。<br>以上の点から、当該製剤は鳥インフルエンザウイルスに対する安全性を確保していると考える。 |

*現在製造を行っていない

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HEALTH

# China's latest human case of bird flu infected through close contact with ill son

www.chinaview.cn 2008-01-10 12:05:53



BEIJING, Jan. 10 (Xinhua) -- Health authorities confirmed here on Thursday that the latest human case of bird flu in the eastern province of Jiangsu, which involved a 52-year-old father, came from close contact with his infected son and not a viral mutation.

The World Health Organization has warned that the virus that causes the illness -- if given sufficient opportunity -- would mutate into a form that is highly infectious and easily transmissible from person to person. Such a change could start a global outbreak.

However, this case -- although it involved the disease apparently passing from one person to another -- does not exactly fit the profile of an infectious human-to-human outbreak, and it has remained something of a puzzle.

"It has no biological features for human-to-human transmission," said Mao Qun'an, Health Ministry spokesman. An epidemiological investigation showed the father was infected through close contact with his son, he said.

The cases took place in the provincial capital, Nanjing. The son, 24, and the first to be infected, died on Dec. 2. The father was later confirmed to be infected with the H5N1 virus, which causes bird flu.

At the time, the ministry said experts had found that the virus that infected the son had originated with poultry and had not mutated. But it remained unclear how the son was infected in the first place, as neither man had any known contact with dead poultry -- the primary known source of the ailment for humans.

The young man, surnamed Lu, developed fever, chills and other symptoms on Nov. 24 and was hospitalized on Nov. 27 after being diagnosed with lower left lobe pneumonia. His father developed a fever and was hospitalized for lower lobe pneumonia on Dec. 3, the day after his son's death.

"The father has recovered," Mao said, adding that the cases have been effectively contained.

Local authorities had kept 83 people who had close contact with either man under close observation but none had shown unusual symptoms so far, according to the ministry.

The case of the Lu family, although unusual, is not the only one of its kind. Reuters reported last month that a similar case occurred in Pakistan.

The latest cases bring the number of confirmed human infections of bird flu in China to 27 since 2003, with 17 deaths.

A human-use bird flu vaccine has been in the second phase of clinical tests in Beijing by the Beijing-based vaccine producer Sinovac Biotech and the Chinese Center for Disease Control and Prevention.

Next ▶▶

Editor: An Lu

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It has proved "safe" and "effective" in the test, said Sinovac Biotech in late last month.

The major index of the vaccine all reached international standard and performed well in human body. None of the test takers were found with serious negative reaction, which proved that the vaccine was safe, it said.

Bird flu, or Avian influenza, is a contagious disease of animal origin caused by viruses that normally infect only birds and, less commonly, pigs.

China's Ministry of Agriculture said in early December that the possibilities of regional bird flu outbreaks were "very high" in the winter and coming spring.

Xinjiang in northwest China has reported an outbreak of bird flu since late December, leading to the death of more than 35,000 poultry.

The local government said the situation has been under control and no human infection has been found yet.

Previous

Editor: An Lu