

EU gives green light for while-you-wait hepatitis B test

May 18 2010

An inexpensive new test for the detection of Hepatitis B virus has been given regulatory approval for use in the European Union. The test, developed with support from the Wellcome Trust, delivers accurate results while-you-wait, enabling doctors to take immediate action on health decisions.

Hepatitis B virus (HBV) is highly infectious - one hundred times more infectious than HIV - and is endemic in many parts of the world. In the UK alone, one in a thousand people are infected and in China and Africa, as many as one in six people carry the virus.

The virus is spread through contact with infected blood or other [body fluids](#) including [sexual contact](#). Although the infection rarely kills, it can cause serious health problems and places a tremendous strain on healthcare resources.

The new Hepatitis B Rapid Test, developed with a Strategic Translation Award from the Wellcome Trust, uses a dipstick technology to deliver an accurate diagnosis on-site within half an hour and can be used with minimal training. Current methods of diagnosis require sending patient samples away to laboratories for analysis by skilled technicians using expensive machinery, taking days to weeks to obtain the results.

Professor Baruch S. Blumberg, who was awarded the Nobel Prize for Medicine for the discovery of the [Hepatitis B Virus](#) and the invention of the HBV vaccine said: "Approval of the new Hepatitis B Rapid Test is

positive news for the estimated 400 million HBV carriers worldwide. Studies have shown that anti-viral treatment can significantly decrease the risk of death from diseases linked to HBV infection, but most of the HBV carriers and patients in the world remain unidentified."

"Being able to identify carriers, initiate immediate treatment of appropriate candidates, and vaccinate family members and close contacts, has the potential to greatly accelerate the program to control HBV infection and spread."

"HBV infection and the diseases related to it are solvable problems. The Hepatitis B Rapid Test developed by Diagnostics for the Real World can make a significant contribution to the solution."

Dr Helen Lee from Diagnostics for the Real World, who led the development of the test said: "Our test is simple, quick, inexpensive and can survive very hot conditions for many months - all vital factors when you are working in poorer parts of the world".

The new test is expected to make a vital impact in helping to curb the spread of disease. The fast turnaround means that doctors will be able to screen pregnant mothers and take steps to prevent them from passing the virus to their unborn baby. And the ability to screen donors before they give blood will help to cut transmission through infected transfusions.

Ted Bianco, Director of Technology Transfer at the Wellcome Trust said "We are extremely pleased that the product is able to meet the exacting standards required by the EU regulatory agencies. The news marks a significant milestone on the road to getting affordable diagnostic tools into the developing world".

The group have already launched a [rapid test](#) for Chlamydia that is currently sold within the EU and many other countries around the world.

Other tests in the pipeline include rapid tests for the detection of HIV and influenza.

Charles Gore, president of the World Hepatitis Alliance, commented: "I am happy this new test has been approved in the EU. Rapid, cheap and robust diagnostic tests are an important component in the battle to prevent and control [hepatitis B](#). This is a battle that is only now beginning to be given the priority it needs with, for the first time, a comprehensive WHO viral hepatitis resolution on the agenda for the World Health Assembly, which coincides with World Hepatitis Day on May 19th.'

Provided by Wellcome Trust

Citation: EU gives green light for while-you-wait hepatitis B test (2010, May 18) retrieved 25 April 2024 from <https://medicalxpress.com/news/2010-05-eu-green-while-you-wait-hepatitis.html>

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