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Roche wins FDA approval for Elecsys anti-HCV test

By AMANDA PEDERSEN
***Medical Device Daily* Senior Staff Writer**

Roche Diagnostics (Indianapolis) said the FDA has granted premarket approval for its Elecsys Antibody to hepatitis C virus (anti-HCV) assay.

The Elecsys Anti-HCV assay is an in-vitro diagnostic test for the qualitative detection of total antibodies to hepatitis C virus in human serum or plasma.

Alan Garrett, group manager for the reagent marketing division at Roche Diagnostics, told *Medical Device Daily* that the assay will help physicians diagnose hepatits C in patients who show signs and symptoms, or are considered high risk for the virus. He said the assay is important to Roche because the company is trying to increase its infectious diseases menu, and this will help clinicians minimize the number of instruments they need to be able to run all their

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EuroPCR 2010

Volcano expanding platform for cardiologists to see-and-treat

By JOHN BROSKY
***Medical Device Daily* European Editor**

PARIS – Putting eyeballs on the catheters that snake through clogged arteries creates a critical advantage in advancing treatment of vascular disease.

Intravascular ultrasound (IVUS) provided the first inside views of plaque and stents, once the cardiologist operating the catheter learned how to read the snowy images.

Software enhancements have since added more intuitive views with color coding that highlights plaque formations.

Clinical trials have demonstrated IVUS can characterize five different forms of plaque and help predict the likelihood of a heart attack.

At EuroPCR, **LightLab Imaging** (Westford,

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Washington roundup

Dexcom: FDA flip-flopped on wire fracture device reports

By MARK McCARTY
***Medical Device Daily* Washington Editor**

A steady state of regulatory affairs is what industry pleads for in its interactions with FDA, but the recipient of a recent warning letter stated on a conference call that a steady state is not what it witnessed in its interactions with the agency. FDA penned **DexCom** (San Diego), maker of glucose monitoring systems, a May 21 warning letter for failure to file medical device reports in connection with fractures in sensor wires used in its glucose monitors, but the firm's president/CEO, Terry Gregg, asserts that his company had communicated with the agency regarding the fractures as early as 2006, but that FDA had no problem with the lack of MDRs for these events until this year.

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Report from Europe

Concentric gets expanded CE mark for its DAC catheters

A *Medical Device Daily* Staff Report

Concentric Medical (Mountain View, California), a developer of devices for clot removal in ischemic stroke patients, reported an expanded indication for the full line of DAC neurovascular catheters. The CE mark was granted, allowing the DAC family of distal access catheters to be used for the removal/aspiration of fresh, soft emboli and thrombi from vessels in the arterial system, including the neurovasculature.

Now, the full range of DAC catheters may be utilized for aspirating and removing thrombus from the neurovasculature. The DAC catheters continue to be first-in-class for providing distal access and support in tortuous anatomy commonly encountered in stroke and other

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Elecsys

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patient results.

"For us this is a test that allows us to help our customers to consolidate testing, its really important to us because it gives us that increasing breadth in infectious diseases," Garrett said.

Roche received approvals for the anti-HCV test on three platforms: the stand-alone cobas e 411 analyzer for low-volume testing; and the cobas e 601 and Modular Analytics E 170 analyzers, which are modules of consolidated immunoassay/clinical chemistry systems for mid-volume and high-volume testing, respectively.

"We cover from the smallest laboratory needs to the largst laboratory need so we have instruments that cover what we call low-volume laboratories, mid-volume laboratories, and high-volume laboratories," Garrett explained.

He said the anti-HCV assay will also be a beneficial diagnostic tool in the hospital setting.

"It's a disease that, in a lot of cases, is silent; you don't know that you have it without a blood test, so folks that are high risk may not show signs or symptoms [but still carry the virus]," Garrett said.

The clinical results of the assay is "very comparable," to others on the market, he said, but the benefit of the Elecsys Anti-HCV assay is its speed. The test only takes 18 minutes to produce results, Garrett said.

The test is designed for use with Roche's electrochemiluminescence (ECL) technology, the company noted.

Roche acquired the patent estate of the ECL technology in 2007 when it bought **BioVeris** (Gaithersburg, Maryland) for about $600 million. That purchase, Roche said at the time, allowed it to expand its immunochemistry business from human diagnostics into new segments such as life science research, patient self-testing, veterinary testing, drug discovery, drug development and clinical trials (*Medical Device Daily*, April 5, 2007).

Assay results, in conjunction with other laboratory results and clinical information, may be used to aid in the presumptive diagnosis of HCV infection in persons with signs and symptoms of hepatitis and in persons at risk for hepatitis C infection. The test does not determine the state of infection or associated disease, Garrett said.

Roche said it received FDA 510(k) clearance for another immunoassay in its infectious disease portfolio, Rubella IgM, in April for the qualitative determination of immunoglobulin M antibodies to rubella virus in human serum and plasma. The test is indicated as an aid in the presumptive diagnosis of acute or recent rubella infection, particularly in women of childbearing age.

The Elecsys anti-HCV assay is anticipated to ship in July, Roche said.

Hepatitis C virus, first identified in 1989, is the most common cause of posttransfusion and community-acquired non-A, non-B hepatitis worldwide, Roche noted. Infection with HCV frequently leads to chronic hepatitis and cirrhosis, and is associated with the development of hepatocellular carcinoma, according to the company. Hepatitis C is primarily transmitted through contaminated blood and blood products and to a lower extent by human body secretions. ■

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