Next-gen HCV test, 4/13:86

Roche has received FDA approval for its Cobas AmpliPrep/Cobas TaqMan HCV test, v2.0. The next-generation viral load test is for use in the management of patients with chronic hepatitis C virus infection. The test provides a novel dual-probe approach, for an extra layer of protection in detecting and quantifying the virus and is designed to accurately determine the amount of HCV RNA to assess a patient's response to antiviral therapy.

The test is intended to be used in conjunction with clinical and laboratory markers of infection. It is an in vitro nucleic acid amplification test for the quantitation of HCV RNA genotypes 1 to 6 in human EDTA plasma or serum. It can be used to predict the probability of sustained virologic response early during a course of antiviral therapy and to assess viral response to antiviral treatment, as measured by changes of HCV RNA levels.

The real-time polymerase chain reaction-based HCV test is for use on Roche's Cobas AmpliPrep/Cobas TaqMan platform.

Roche Diagnostics, 317-521-2000