

Consumer Information on: Abbott RealTime HCV - P100017

U.S. Food & Drug Administration

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness Data (SSED) and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: Abbott RealTime HCV, Abbott RealTime HCV Amplification Reagent Kit, Abbott RealTime HCV Control Kit, Abbott RealTime HCV Calibrator Kit, and optional UNG Uracil-N-Glycosylase (UNG) for use in conjunction with Abbott RealTime HCV

PMA Applicant: Abbott Molecular Inc.

Address: 1300 E. Touhy Avenue, Des Plaines, IL 60018

Approval Date: May 17, 2011

Approval Letter: http://www.accessdata.fda.gov/cdrh_docs/pdf10/p100017a.pdf

[1]

What is it? The Abbott RealTime HCV assay is a laboratory test that measures the amount of hepatitis C viral RNA in the blood of an individual infected with the [hepatitis C virus \(HCV\)](#) [2]. Viral RNA (ribonucleic acid) is the genetic material from the hepatitis C virus. The individual's hepatitis C viral RNA load is measured before beginning treatment and during treatment to predict and assess an individual's response to the treatment. This test is used with the Abbott *m2000sp* and *m2000rt* automated instruments. The results from the Abbott RealTime HCV test must be interpreted within the context of all other relevant clinical and laboratory findings.

How does it work? A sample of a patient's blood is obtained and sent to a clinical laboratory. Nucleic acid (RNA) is separated from the cells in the blood sample and mixed with assay reagents using the automated Abbott *m2000sp* system. The resulting mixture is put into the *m2000rt* analyzer. The *m2000rt* analyzer calculates the amount of HCV DNA in the patient's blood based on the amount of produced light measured by the analyzer after completion of the reaction. Measurement of the amount of HCV RNA in the blood, together with clinical information and other laboratory blood tests, is used by physicians help determine an individual's response to treatment.

When is it used? This test is used together with other laboratory results and clinical information to evaluate the treatment of an individual infected with the hepatitis C virus.

What will it accomplish? Test results help predict an individual's response to treatment and aid in the management of patients with HCV infection undergoing anti-viral therapy.

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When should it not be used? This lab test should not be used if it is not ordered by a physician. The assay should not be used to determine if a person is infected with the hepatitis C virus. It should not be used to screen blood or blood products for transfusion.

Additional information : [Summary of Safety and Effectiveness and labeling](#) [3] will be available online.

Other Resources:

- [Centers for Disease Control and Prevention \(CDC\) - Hepatitis C Information for the Public](#) [4]

[SOURCE](#) [5]

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<http://www.mdtmag.com/news/2011/05/consumer-information-abbott-realtime-hcv-p100017>

Links:

[1] http://www.accessdata.fda.gov/cdrh_docs/pdf10/p100017a.pdf

[2] <http://www.nlm.nih.gov/medlineplus/hepatitisc.html>

[3] <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=p100017>

[4] <http://www.cdc.gov/hepatitis/c/>

[5] <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm256063.htm>