AMPLICOR™ Hepatitis C Virus (HCV) Test, version 2.0 (v2.0) P000010

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 and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name:	AMPLICOR ™ Hepatitis C Virus (HCV) Test, version 2.0 (v2.0)
Manufacturer:	Roche Molecular Systems, Inc
Address:	4300 Hacienda Dr, Pleasanton CA 94588-2722
Approval Date:	July 5, 2001
Approval Letter:	http://www.fda.gov/cdrh/pdf/p000010a.pdf

What is it? The AMPLICOR™ HCV Test, v2.0 is a laboratory test for determining whether a person is actively infected with hepatitis C virus (HCV). HCV chronically infects several million Americans and causes hepatitis C and other liver diseases in many people.

How does it work? The AMPLICOR™ HCV Test, v2.0 takes genetic material from inside viruses in the patient's blood and uses enzymes to produce enough HCV genetic material for detection in the laboratory.

When is it used ? The AMPLICOR™ HCV Test, v2.0 is used for patients who are suspected to be actively infected with HCV because they have liver disease and their blood contains antibodies to HCV. The test will determine whether they are actively infected or not.

What will it accomplish? A **positive** AMPLICOR ™ HCV Test, v2.0 result indicates that HCV is reproducing itself in the liver and is thus evidence of active HCV infection. However, a negative test result does not rule out the possibility of active HCV infection.

When should it not be used? The AMPLICOR ™HCV Test, v2.0 should not be used:

- On patients who do not have antibodies to HCV.
- As the sole test for determining whether a patient is actively infected with HCV. (All AMPLICOR™ HCV Test, v2.0 results should be interpreted along with additional clinical and

laboratory findings.)

- For distinguishing between acute infection (less than six months duration) and chronic infection,
- For determining whether a patient has liver disease,
- For screening blood, plasma, or tissue donors, or
- To eliminate the possibility of active HCV infection. (Caution should be used when interpreting a **negative** AMPLICOR™ HCV Test, v2.0 result.)

Additional information: Summary of Safety and Effectiveness and labeling are available at: http://www.fda.gov/cdrh/pdf/p000010.html

Other:

- http://odp.od.nih.gov/consensus/cons/105/105_intro.htm (Published as: National Institutes of Health Consensus Development Conference Panel statement: management of hepatitis C. Hepatology 1997;26:2S-10S.**)
- http://www.cdc.gov/mmwr/PDF/rr/rr4719.pdf (Published as: Centers for Disease Control and Prevention. Recommendations for prevention and control of hepatitis C virus [HCV] infection and HCV-related chronic disease. MMWR Morb Mortal Wkly Rep 1998; 47 [No. RR-19]:1-54**)
- http://www.fda.gov/fdac/features/2001/401_hepc.html (Published as: Bren L. Hepatitis C: An Update. FDA Consumer 35:24-29, 2001. Article contains additional web links to National Digestive Diseases Information Clearinghouse, Hepatitis Foundation International, and American Liver Foundation.**)

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