



*Excellence in Pathology and Laboratory Services*

## ***Test Update***

*From Your Laboratory Service Provider, PathGroup*

### **Hepatitis C Virus Genotyping**

**September 21, 2007**

#### **OVERVIEW**

PathGroup is now performing HCV Genotyping in our laboratory. PathGroup has validated a HCV genotyping assay using Invader™ technology which utilizes cleavase enzyme followed by FRET detection to determine genotype. HCV genotyping is an important predictor of treatment response, duration of therapy and dosage used for treating HCV infections.

Since April 2007 PathGroup has been offering polymerase chain reaction (PCR) based assays for the diagnosis of Hepatitis C Viral (HCV) infections. PathGroup validated a HCV RNA assay using TaqMan® Technology from Roche Molecular Systems. This technology is considered to be one of the most sensitive and advanced technologies available to diagnose Hepatitis C infection with a broad dynamic detection range of 25 IU/mL through 10 million IU/mL. This assay is offered as both qualitative and quantitative, since different uses may apply in diagnosis and monitoring the treatment of HCV infection.

HCV infection is one of the most common causes of chronic liver disease, accounting for 60-70% of all chronic hepatitis. Cirrhosis resulting from HCV has become the leading cause of liver transplantation in the United States today and is responsible for an estimated 8,000-10,000 deaths annually. HCV infected patients who develop cirrhosis are at increased risk of developing hepatocellular carcinoma. However, most individuals infected with HCV typically remain asymptomatic with minor liver enzyme elevations. This provides little evidence of disease progression which usually results in chronic hepatitis, a state of ongoing inflammation in the liver. Immunoassays (EIA, RIBA) detect antibodies related to current and/or past HCV infection, but cannot discriminate between the two. Detection of HCV RNA in plasma or serum by PCR is an important tool to confirm the diagnosis of Hepatitis C infection.

#### **CLINICAL UTILITY**

**Test Code: HCVQL (HCV RNA by PCR Qualitative)**

**CPT Code: 87521**

- ⌘ Detection and confirmation of an initial diagnosis of HCV
- ⌘ Distinguish active from resolved infections
- ⌘ To assess response to therapy

**Test Code: HCVRI. (HCV RNA by PCR Quantitative -Viral Load)**



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**Test Code: HCVQG (HCV RNA by PCR Quantitative –Reflexing to Genotyping )**

**CPT Code: 87522 and 87902**

✉ Viral loads in excess of 120 IU/mL are reflexed to the genotype assay to determine type.

**Specimen Collection:** 2 EDTA plasma tubes (purple/lavender top tube) or 2 ACD tubes (yellow top tube)  
Specimen(s) must be centrifuged upon collection and the plasma transferred into plastic (screw top) tube(s) and frozen within 4 hours of collection. Minimum volume 1mL.

**Alternate Collection:** Plasma preparation tubes or PPT-K<sup>2</sup> EDTA (white cap) tubes.  
Specimen(s) should be spun down within 2 hours. This tube contains separating gel that separates blood cells from plasma and can be frozen without splitting or aliquoting. Freeze the tube(s) immediately after centrifuging.

**NOTE:** Although serum is an acceptable specimen, the HCV RNA results may be lower than those from plasma; therefore plasma is preferred for this assay. If serum is submitted, collect specimen in an SST (serum separator tube).

The specimen should be spun, separated (aliquot) and frozen within 4 hours.

Shipping and Handling: All specimens should be transported frozen on dry ice provided by PathGroup.

**Reference Range:** HCV RNA Qualitative - Not Detected  
HCV RNA Quantitative – Linear Dynamic range: 25 IU/mL through 10 million IU/mL

Turnaround Time: 1-7 days. Testing will initially be performed each Wednesday.

If you have any questions, please contact our Client Services Department at 615-562-9300 or toll-free 888-474-5227.

References:

1. Chou PP, Hepatitis C Virus Epidemiology, Diagnosis and Patient Management. Labmedicine, Vol. 38, No2 (85-90), February 2007.
2. Carey, W. Tests and screening strategies for the diagnosis of hepatitis C. Cleveland Clinic Journal of Medicine, Vol. 70, Sup.4 (S7-S13), September, 2003.
3. Coleman, WB and Tsongalis, GJ, editors (2006). Molecular Diagnostics for the Clinical Laboratorian-Second Edition. Humana Press, 999 Riverview Drive, Suite 208, Totowa, NJ 07512. p. 253.
4. Cobas Ampliprep/Cobas Amplicor HCV test version 2.0 (package insert). 2006. Roche Molecular.
5. Cobas Amplicor™ hepatitis C Virus test, version 2.0 (package insert). April 2003. Roche Molecular.