

## Hepatitis C Virus

Molecular assays are key components in the management of hepatitis C virus (HCV) infection, from diagnosis to documenting resolved infection.

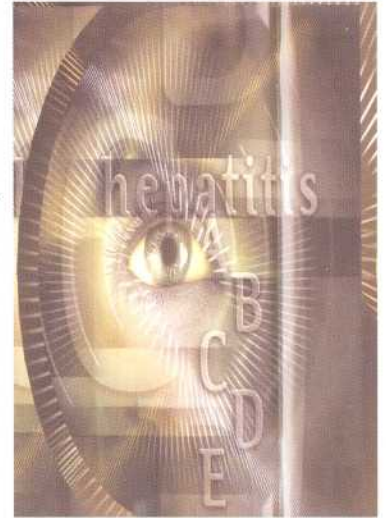
**QUALITATIVE HCV RNA ASSAYS** determine whether or not HCV is present in blood. They can be used to confirm positive enzyme immunoassay (EIA) results and to document resolved or persistent infection during and after treatment.

**QUANTITATIVE HCV RNA ASSAYS** can also be used to

confirm EIA results and document persistent infection, but have several advantages that make them preferable to qualitative assays for patients who receive treatment.<sup>1</sup> First, measurement of pretreatment viral load helps predict the likelihood of sustained response: a high baseline viral load indicates a poor prognosis. Serial measurement of viral load also provides information about the degree of virologic response during treatment.

**GENOTYPIC ASSAYS** identify the type and subtype of

HCV because type 1 HCV responds to therapy less favorably than other types and typically requires a longer course of treatment, genotyping can help determine the optimal duration of therapy and predict the likelihood of sustained virologic response to therapy. The line-probe assay can provide genotype information in samples with viral levels as low as 600 IU/mL and its results correlate well with those of sequencing-based assays.



### Hepatitis C Viral RNA, Qualitative PCR

**Purposes:** Early diagnosis of acute infection; resolve indeterminate RIBA results; distinguish current from past infection; and demonstrate resolution of infection.

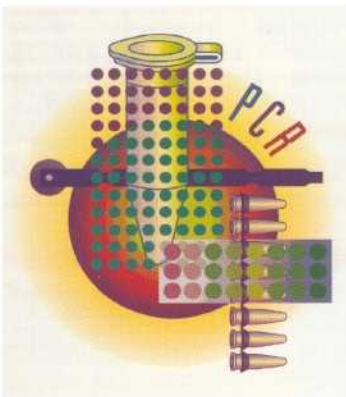
The qualitative HCV RNA test detects the presence of hepatitis C virus (HCV) circulating in the blood. It is used to confirm HCV diagnosis following a positive or indeterminate antibody test result. It differentiates between resolved and

active infection and may be useful for detecting acute infection prior to seroconversion. It is especially useful for confirming diagnosis in people with indeterminate HCV immunoblot (RIBA) results, as well as in immunosuppressed or immunoincompetent individuals.

Following 24 weeks of interferon/ribavirin therapy, virologic response is assessed using HCV RNA. If HCV RNA is still detectable,

therapy can be stopped since the likelihood of a favorable response is low. Therapy can also be stopped when HCV RNA is undetectable and the patient is infected with a type 2 or 3 virus. In patients with undetectable HCV RNA and other genotypes, however, continuation of therapy for another 24 weeks increases the chance of sustained therapeutic response. Long-term cure is probable when HCV RNA is still undetectable six months

after the end of treatment. A "detected" result indicates the presence of HCV RNA and is consistent with active infection (acute or chronic). A "not detected" result, on the other hand, is suggestive of the absence of detectable HCV RNA. Six months following cessation of antiviral therapy, a repeatedly negative test suggests clearance of the virus and recovery from the infection.



### Hepatitis C Viral RNA, Quantitative PCR

**Purposes:** Predict response to antiviral therapy; determine duration of treatment; and differentiate lack of therapeutic response from partial response.

The HCV RNA test measures the level of hepatitis C virus (HCV) circulating in blood. Although this level does not correlate with severity of disease, it does correlate with the

likelihood of response to antiviral therapy. Patients with a low baseline HCV RNA level (<2 million copies/mL) are more likely to achieve eradication of the virus with treatment.

During or after therapy, rising or sustained HCV RNA levels indicate a lack of therapeutic response. A partial response is indicated by a drop in viral level at least one-third of a log.

In HCV type 1b infections with a high viral load, lack of a one-log decrease after 4 weeks of treatment may predict treatment failure. At the end of treatment and afterwards, an undetectable level suggests a favorable therapeutic response.