



February 2008

Hepatitis C Virus (HCV) RNA and Genotype Testing and Interpretation - Update

To Health Care Providers

For Hepatitis C RNA testing, the Ontario Public Health Laboratory (OPHL) has replaced the Cobas Amplicor Qualitative and Quantitative HCV RNA assays with the new Roche Taqman Real Time HCV RNA PCR assay. The linear range of the new Roche Taqman HCV RNA assay is 15 IU/ml to 10 E+8 IU/ml. For comparison, the previously used Roche Cobas Amplicor quantitative HCV RNA assay has a linear range of 600 IU/ml to 10 E+6 IU/ml.

For Hepatitis C Genotype testing, OPHL has replaced the AutoLipa HCV Genotype assay with the Invader® HCV Genotype assay. The Invader® HCV Genotype assay is a research use only assay that provides rapid differentiation of HCV genotypes 1 to 6 based on sequence variation within the HCV 5' non-coding region. The precision of the Invader® HCV Genotype assay is 99.9%.

1. Hepatitis C RNA Testing

Clinical Utility

Quantitation of HCV RNA by PCR is used to measure viremia in anti-HCV positive individuals who are on treatment or who are being considered for treatment. Detection of HCV RNA can also be used to assess active HCV infection in immuno-compromised anti-HCV negative individuals.

Specimen Requirements

A minimum of 2.5 ml of frozen serum or plasma is required to perform the Roche Taqman HCV RNA assay. Samples received with less than 2.5 ml will be rejected. All requests for HCV RNA testing must include a completed OPHL Test Requisition Form and a Laboratory Information Form, (F-C-HE-036) available at:

<http://www.health.gov.on.ca/english/providers/pub/labs/specimen.html>.

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Results Interpretation

The following table is a guide to aid in the interpretation of HCV RNA results:

HCV RNA Result	Interpretation	Comments
Detected	Hepatitis C RNA detected, >15 IU/ml	Viral Load will be provided
Detected	Hepatitis C RNA detected, <15 IU/ml	The result for HCV RNA is below the linear range of the assay and thus the exact value cannot be calculated
Not Detected	No detectable Hepatitis C RNA	Refer to comments on laboratory report if follow-up testing is required

2. Hepatitis C Genotype

Clinical Utility

Genotyping of HCV is useful in evaluating the likelihood of response to currently available antiviral therapy. Patients with HCV genotypes 2 or 3 generally respond better to therapy and typically require approximately 24 weeks of treatment. Patients with HCV genotypes 1 and 4 to 6 may require up to 48 weeks of treatment. HCV genotypes are sufficient for treatment evaluation; HCV subtypes are not required.

Specimen Requirements

No additional sample is required. The first pre-treatment (i.e. baseline) sample submitted for HCV RNA is automatically used to perform HCV genotyping.

For Further Information

- Refer to the Specimen Collection Guide at www.health.gov.on.ca/english/providers/pub/labs/specimen.html
- Hepatitis Laboratory at (416) 235-5737
- OPHL HELPLINE at 1-800-640-7221