

February 2009

Hepatitis C Antibody - Change in Supplementary Testing, Interpretation, and Recommended Follow-up Testing

To Health Care Providers:

The Ontario Public Health Laboratories has replaced the Biorad and the INNO-LIA™ supplementary tests for Hepatitis C antibody with the Siemens anti-HCV assay. The Siemens anti-HCV assay is an in vitro diagnostic immunoassay that uses Direct Chemiluminescence (CLIA) technology for the qualitative detection of IgG antibodies to Hepatitis C virus in human serum or plasma.

The sensitivity and specificity of the assay is 99.9%.

Laboratories requesting confirmation of Hepatitis C antibody reactive results must include the following information on the Public Health Laboratory requisition:

- the anti-HCV screen result
- the screening test method

Interpretation of Hepatitis C Supplementary Testing

Table 1: Siemens anti-HCV Results and Recommended Follow-up Testing

anti-HCV Result	Interpretation	Recommended follow-up
Reactive	Evidence of Hepatitis C antibody	Patient should be assessed for possible treatment of Hepatitis C
Non-Reactive or Borderline	Inconclusive result for Hepatitis C antibody	Submit minimum 2.5 ml frozen serum, separated within 4 hours of collection for Hepatitis C RNA

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(Continued)

Table 2: Hepatitis C RNA Testing and Recommended Follow-up Testing

Hepatitis C RNA Result	Interpretation	Recommended follow-up
Detected	Hepatitis C RNA detected, >15 IU/ml (Note: Viral Load will be provided)	Patient should be assessed for possible treatment of Hepatitis C
Detected	Hepatitis C RNA detected, <15 IU/ml (Note: The result for HCV RNA is below the linear range of the assay and thus the exact value cannot be calculated)	Patient should be assessed for possible treatment of Hepatitis C
Not Detected	No Detectable Hepatitis C RNA	Submit minimum 2.5 ml frozen serum, separated within 4 hours of collection for Hepatitis C RNA in six months.

For Further Information:

- Hepatitis Laboratory at **416-235-5737**
- Specimen Collection Guide website: www.health.on.ca
- Ontario Agency for Health Protection and Promotion website: www.oahpp.ca
- Public Health Agency of Canada website: www.phac-aspc.gc.ca