Public Health Ontario | Santé publique Ontario

Labstract – March 2018

Hepatitis C Virus (HCV) Antibody Testing - Change in Supplemental Assay

Audience

Healthcare providers, public health unit personnel, specimen collection centres

Overview

Effective March 2018:

- Public Health Ontario's laboratory (PHOL) is changing the supplemental hepatitis C virus (HCV) antibody assay system that it currently uses (ADVIA Centaur® CP Immunoassay System) to the Ortho Clinical Diagnostics VITROS ® 3600 Immunodiagnostic System.
- The assay change is the result of a competitive procurement and technical evaluation. There will be no change in reporting of results.

HCV Antibody Serology Algorithm

PHOL uses a two-tier algorithm to test for HCV antibody as recommended by the American Association for the Study of Liver Diseases (AASLD) guidelines, consisting of an initial HCV antibody screen using the Abbott Architect® i4000sr and i2000sr immunoassay systems.

If the screen result on the Architect system is non-reactive, then no further testing is performed and the final interpretation is reported as "No evidence of Anti-HCV Antibody".

If the screen result is reactive, PHOL will perform HCV antibody supplemental testing using the VITROS® 3600 system for confirmation. For further information on HCV antibody test results and interpretation refer to the table below.

Patients with evidence of HCV antibody (both screen and supplemental results reactive) should have a new sample submitted for molecular testing for HCV RNA. The results of this RNA test will determine their infection status and help guide their clinical management. Further information regarding the interpretation of HCV antibody test results is available in LAB-SD-034 Hepatitis C – Anti HCV Positive Results, Next Steps.

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Patients whose samples have inconclusive results for HCV antibody (screen results reactive and supplemental results non-reactive) should have additional blood specimens submitted for both HCV RNA testing as well as repeat HCV antibody testing (please refer to the table below).

HCV RNA testing and specimen collection is available in the following Labstracts: LAB-SD-033 Hepatitis C Virus (HCV) RNA and Genotype Testing and Interpretation and LAB-SD-123 Hepatitis C Virus (RNA) detection in Dried Blood Spots (DBS).

Specimen type and requisition requirements

Specimen type and volume required for HCV antibody testing:

- Clotted whole blood (at least 2 mL) or,
- Serum separator tubes(SST) (at least 2 mL) or,
- Serum or plasma (at least 1 mL)
- Refer to the Hepatitis C – Diagnostic Serology Test Information Sheet for more information on specimen requirements.

Note: Hemolysed, icteric, lipemic or microbially contaminated sera or plasma are inappropriate for testing and should be avoided

Requisition requirements:

- Complete all fields of the PHO General Test Requisition including the patient's full name, date of birth, Health Card Number (must match the specimen label), as well as the physician name, address, and telephone number
- In the 'Hepatitis Serology' section of the PHO General Test Requisition, check either 'Acute infection' or 'Chronic infection', and 'Hepatitis C'.
- For more information or if multiple hepatitis viruses are required, refer to PHOL's Labstract entitled 'Viral Hepatitis Serologic Testing – Changes to Test Ordering, Algorithm and Reporting' available at publichealthontario.ca/labstracts

Turnaround time (TAT)

- Specimens interpreted as 'No evidence of Anti-HCV Antibody' (HCV antibody screen non-reactive) are available and reported within 3 days
- Specimens interpreted as 'Evidence of Anti-HCV Antibody' or 'Inconclusive result for Anti-HCV Antibody' are available and reported within 6 days

HCV Antibody Test Results, Interpretations, and Follow-up Testing

HCV Antibody Screen Test Result	HCV Antibody Supplemental Test Result	Overall Interpretation	Recommended Follow-up
Non-reactive	Not performed	No evidence of Anti-HCV Antibody	Patients with recent exposures may have non-reactive serology if they are in the process of seroconverting or immunocompromised[1]. Follow-up testing for HCV antibody is recommended if exposure to HCV occurred within the past 6 months[2].
Indeterminate or Reactive	Non-Reactive or Indeterminate	Inconclusive result for Anti-HCV Antibody	If not already submitted, submit the following: i) A sample for HCV RNA testing. This requires a minimum of 2.5 ml frozen serum or frozen plasma, separated within 6 hours of collection **AND** ii) A new sample for repeat HCV antibody testing. If the HCV RNA test result is 'target not detected', additional follow-up serologic testing is required (collected at least 6-8 weeks after the initial serology result). Follow-up testing for patients found repeatedly inconclusive for Anti-HCV Antibody can be discussed with a microbiologist.
Reactive	Reactive	Evidence of Anti-HCV Antibody	A sample for HCV RNA testing. This requires a minimum of 2.5 mL frozen serum or frozen plasma, separated within 6 hours of collection.

Footnotes:

[1] Immunocompromised individuals may not demonstrate an HCV antibody response when infected with hepatitis C virus. If hepatitis C is suspected in an immunocompromised individual, HCV RNA should be ordered even if the anti-HCV is negative. A reason for testing HCV RNA for patients with no evidence of Hepatitis C antibody must be provided on the requisition.

[2] Submit a serum sample for a repeat HCV antibody test at least 6-8 weeks following the last potential exposure, and again 6 months following the latest exposure if the initial follow-up specimen is negative.

For further information

- Contact the PHOL Customer Service Centre at 416-235-6556 or 1-877-604-4567 (toll-free), or by email at CustomerServiceCentre@oahpp.ca
- For PHOL specimen collection information and previous Labstracts, refer to wwww.publichealthontario.ca/Labs
- The current version of the PHOL General Test Requisition and other forms are available at www.publichealthontario.ca/requisitions
- PHO laboratory's Test Information Sheets are available at www.publichealthontario.ca/test_directory
- To subscribe to future Labstracts, register on our website.
- To register for Autofax and receive laboratory reports by fax directly from our laboratory information system as soon as they are released, contact the PHOL Customer Service Centre.