

## Appendix 1 (as supplied by the authors): Hepatitis C testing at provincial/territorial labs: environmental scan

### OBJECTIVE

The objective of this environmental scan was to obtain information about the tests and testing sequences used to diagnose HCV infection in Canada.

### METHODS

Given that provincial and territorial (P/T) laboratories would be expected to perform a majority of HCV testing (and nearly all HCV genotyping), I focused on HCV testing performed by the P/T laboratories. I first performed a grey literature search of all P/T laboratory websites, as well as websites from reputable HCV-related non-profit organization such as CATIE.

Next, to supplement the grey literature search, I contacted each P/T laboratory by email and/or telephone and asked to speak to the person most directly responsible for HCV testing. I asked the following 6 questions for each P/T laboratory:

*The Canadian Task Force on Preventive Health Care (CTFPHC) is currently working on a guideline re: screening for hepatitis C in primary care. To help with this process, we would like more information about how each of the provincial labs conducts testing for hepatitis C.*

*Could you please provide us with the following information:*

- 1) What is the initial test for hepatitis C used by your laboratory (e.g., ELISA)?*
- 2) What is the confirmatory test for hepatitis C used by your laboratory (e.g., PCR)?*
- 3) Are other tests done routinely (other than viral load)?*
- 4) Is the confirmatory test applied to all specimens that are positive on the initial test automatically?*
- 5) Is additional specimen collection required in order to apply the confirmatory test?*
- 6) When is the ordering physician notified of the test result (i.e., after the initial test, or only after the confirmatory test)?*

For ambiguous answers, I obtained clarification by email or telephone as needed. Data collection for this environmental scan took place from February 25 to March 2, 2016.

### RESULTS

The grey literature search identified useful but potentially outdated information about each province's HCV testing on the CATIE website (<http://www.catie.ca/en/practical-guides/hepc-in-depth/testing/testing-your-region>). A search of individual P/T laboratory websites similarly identified some useful but potentially outdated information (Table 1). Information identified through the grey literature search was verified and supplemented by surveying each P/T laboratory (Table 1).

**Initial screening test**

9 provinces and 1 territory performed the initial screening test for HCV locally; 3 referred it to other P/T labs (NU, PE, YT). For the initial HCV screening test, 6/10 laboratories used a CMIA (AB, MB, NB, NL, NS, ON), 3/10 used a CLIA (BC, NT, SK), and 1/10 used an MEIA (QC).

**Confirmatory testing**

9 provinces performed confirmatory testing for HCV locally; 4 referred it to other P/T laboratories (NT, NU, PE, YT). For the confirmatory HCV test, 6/9 laboratories used an immunoassay (AB, BC, MB, ON, QC, SK), and 3/9 used PCR (NB, NL, NS).

**Testing sequence**

In all P/T laboratories, the confirmatory test is usually performed on the same blood specimen as the initial test, provided that the specimen is sufficient; the patient is not typically required to provide an additional blood specimen for the confirmatory test to be applied. Some laboratories release the results of the initial test to the ordering physician immediately, whereas others wait until the confirmatory test result is available.

**DISCUSSION**

This rapid environmental scan revealed that a large majority of P/T laboratories use immunoassays for both their initial screening test and their confirmatory test for HCV. The initial screening tests for HCV included CMIA, CLIA, and MEIA; ELISA was not used by any P/T laboratory as an initial screening test. Only a small minority of P/T laboratories use PCR as their confirmatory test for HCV.

A limitation of this study is that not all testing for HCV is done by the P/T laboratories; this study did not ascertain the tests used by non-P/T (typically, commercial) laboratories. This study does not account for the use of 'rapid tests' (based on finger prick blood) that may be conducted in some healthcare settings; however, in Canada, 'rapid tests' would typically be used to reach high-risk and/or vulnerable populations, and not the general population targeted by the CTFPHC clinical practice guideline.

Table 1. Hepatitis C testing by provincial labs: results from the environmental scan

Province/territory	First test	Second test	Third test	Notification of ordering physician	Testing site (laboratory)	Information source
Alberta (AB)	Architect Anti-HCV CMIA	BioRad Monolisa HCV Ag-Ab ULTRA Assay (EIA)	We do not currently have a reflex to viral load testing, although for first time positives and for indeterminate results (i.e. when 1/2 EIAs are positive), we recommend to the physician that they send in a sample for viral load testing.	The result is reported after the confirmatory EIA is completed.	Most Hep C tests in Alberta are sent to the Provincial Laboratory of Public Health (ProvLab).	Carmen L Charlton Clinical Microbiologist Provincial Laboratory of Public Health (ProvLab) (responded by email on 2016-02-25)
British Columbia (BC)	Advia Centaur HCV CLIA	Architect Anti-HCV CMIA	For all seropositive or equivocal samples we automatically request a new sample to be drawn in an EDTA blood for HCV RNA testing.	After the confirmatory (second) test, which is done automatically if the initial test is positives or equivocal.	Most Hep C tests in British Columbia are sent to the BC Centre for Disease Control (BCCDC).	Mel Krajden BC Public Health Microbiology & Reference Laboratory (responded by email on 2016-02-28)
Manitoba (MB)	Architect Anti-HCV CMIA	Chiron RIBA HCV test 3.0	COBAS AmpliPrep/COBAS AMPLICOR HCV test		Most Hep C tests in Manitoba are sent to the Cadham Provincial Lab.	CATIE, 2010. <a href="http://www.catie.ca/en/practical-guides/hepc-in-depth/testing/testing-your-region/manitoba">http://www.catie.ca/en/practical-guides/hepc-in-depth/testing/testing-your-region/manitoba</a>  No response was obtained from the Cadham Provincial Laboratory.

Province/territory	First test	Second test	Third test	Notification of ordering physician	Testing site (laboratory)	Information source
New Brunswick (NB)	Architect Anti-HCV CMIA	COBAS AmpliPrep/COBAS AMPLICOR HCV test	INNO-LIA HCV Score v2	Depends on the hospital policy. All tests are run automatically if the sample is sufficient.	<i>"Les tests de dépistage sont faits dans les 7 hôpitaux régionaux du NB. Nous utilisons tous le même test de dépistage. Les tests supplémentaires référés à mon laboratoire, qui sert de laboratoire provincial en la matière."</i>	Richard Garceau Microbiology Laboratory at George Dumont Hospital (responded by email 2016-02-29)
Newfoundland & Labrador (NL)	Architect Anti-HCV CMIA	Roche Diagnostics. Cobas Amplicor (PCR); if reactive anti-HCV (auto-reflex testing by laboratory)	If PCR is negative, then INNO-LIA HCV test		All Hep C tests in the province are sent to the Public Health Laboratory in St. John's.	Newfoundland and Labrador Public Health Laboratory  Testing algorithm on lab website (2012): <a href="http://publichealthlab.ca/wp-content/uploads/2012/10/Hepatitis-Algorithm.pdf">http://publichealthlab.ca/wp-content/uploads/2012/10/Hepatitis-Algorithm.pdf</a> and <a href="http://publichealthlab.ca/service/anti-hcv-anti-hepatitis-c-virus-antibodies/">http://publichealthlab.ca/service/anti-hcv-anti-hepatitis-c-virus-antibodies/</a>
Northwest Territories (NT)	VITROS Anti-HCV CLIA	See AB	See AB	See AB	Hep C antibody tests from Yellowknife HSS area are sent to the Stanton Territorial Hospital in Yellowknife. All other Health authorities in the Northwest Territories send their Hep C antibody tests directly to Alberta.	CATIE, 2010. <a href="http://www.catie.ca/en/practical-guides/hepc-in-depth/testing/testing-your-region/northwest-territories">http://www.catie.ca/en/practical-guides/hepc-in-depth/testing/testing-your-region/northwest-territories</a>

Province/territory	First test	Second test	Third test	Notification of ordering physician	Testing site (laboratory)	Information source
Nova Scotia (NS)	Architect Anti-HCV CMIA	Roche Taqman HCV viral load assay. We do not ask for a second specimen for confirmation.	If the Viral load assay is negative we perform an InnoLia immunoblot assay to see if the positive screen was due to a previous infection that has resolved or a false positive screening result. These are reflexively added.	We release the result as a screening test only and highlight that a confirmatory test is to follow.	Most Hep C tests in Nova Scotia are sent to the Queen Elizabeth II Health Sciences Centre in Halifax.	Dr Todd F. Hatchette Chief, Division of Microbiology Department of Pathology and Laboratory Medicine Nova Scotia Health Authority (responded by email on 2016-02-25)
Nunavut (NU)	See AB	See AB	See AB	See AB	Most Hep C tests in Nunavut are sent to the Provincial Laboratory of Public Health (ProvLab) in Alberta	CATIE, 2010. <a href="http://www.catie.ca/en/practical-guides/hepc-in-depth/testing/testing-your-region/nunavut">http://www.catie.ca/en/practical-guides/hepc-in-depth/testing/testing-your-region/nunavut</a>
Ontario (ON)	Architect Anti-HCV CMIA	Advia Centaur HCV CLIA	For reactive (positive) or inconclusive anti-HCV results, submission of a 2.5 mL frozen serum or frozen plasma is recommended for HCV RNA viral load (Roche Assay) +/- HCV genotyping (Abbott Assay)	CMIA and CLIA results are reported together, turnaround time is up to 5 days	Most Hep C tests in Ontario are sent to the Public Health Ontario Laboratory (PHOL).	Public Health Ontario Laboratory (PHOL) Jocelyn Maregmen Supplemental Virology (responded by email on 2016-02-25)
Prince Edward Island (PE)	See NS	See NS	See NS	See NS	All Hep C tests in Prince Edward Island are sent to the lab at the Queen Elizabeth II Health Sciences Centre in Halifax, Nova Scotia	CATIE, 2010. <a href="http://www.catie.ca/en/practical-guides/hepc-in-depth/testing/testing-your-region/prince-edward-island">http://www.catie.ca/en/practical-guides/hepc-in-depth/testing/testing-your-region/prince-edward-island</a>

Province/territory	First test	Second test	Third test	Notification of ordering physician	Testing site (laboratory)	Information source
Quebec (QC)	AxSym Anti-HCV MEIA	Chiron RIBA HCV test 3.0	COBAS AmpliPrep/COBAS AMPLICOR HCV test (PCR)		Most Hep C tests in Québec are sent to Le Laboratoire de Santé Publique du Québec (LSPQ).	CATIE, 2010. <a href="http://www.catie.ca/en/practical-guides/hepc-in-depth/testing/testing-your-region/quebec">http://www.catie.ca/en/practical-guides/hepc-in-depth/testing/testing-your-region/quebec</a>  No response was obtained from the Laboratoire de sante publique du Québec (LSPQ)
Saskatchewan (SK)	Advia Centaur anti-HCV CLIA	Architect HCV-Ag CMIA	if the Architect HCV-Ag CMIA is negative then a INNO-LIA HCV Score test is run	Only after the confirmatory test	Most Hep C tests in the province are sent to the Saskatchewan Disease Control Laboratory in Regina.	Jim Putz, Saskatchewan Disease Control Laboratory (responded by email 2016-02-26)
Yukon (YT)	See BC	See BC	See BC	See BC	Most Hep C tests in Yukon are sent to the BCCDC Provincial Lab in British Columbia	CATIE, 2010. <a href="http://www.catie.ca/en/practical-guides/hepc-in-depth/testing/testing-your-region/yukon">http://www.catie.ca/en/practical-guides/hepc-in-depth/testing/testing-your-region/yukon</a>

CLIA: chemiluminescent immunoassay; CMIA: chemiluminescent microparticle immunoassay; MEIA: microparticle enzyme immunoassay; ELISA : enzyme-linked immunosorbent assay; RIBA : recombinant immunoblot assay; PCR: polymerase chain reaction