Consultation Document

Hepatitis C Virus Testing

Proposed Changes

Labtests, 37-43 Carbine Road, Mt Wellington Auckland 1060
P O Box 12049, Penrose, Auckland 1642
(09) 574 7399 **www.labtests.co.nz**

Auckland City Hospital Building 31, Gate 4, Grafton Road, P.O. Box 110031, Grafton 1148
0800 522 7587 +64 9 307 3995 **www.labplus.co.nz**

Contents

1. BACKGROUND

It is thought that up to 1.2% of the NZ population is sero-positive for hepatitis C virus (HCV). Following infection, some people will clear the virus spontaneously although the majority become chronically infected. Diagnosis of HCV consists of serological screening for HCV antibodies followed by molecular confirmation of persistent viral replication. The presence of antibodies does not necessarily imply active infection; for this the molecular test for HCV RNA must be performed.

There are a number of issues around HCV testing:

1.1. Testing is somewhat ad hoc

1.1.1. It is required for immigration purposes regardless of risk factors

1.1.2. It is often done in response to raised γGT and ALP without elevation in ALT (the relevant liver test marker for hepatitis)

1.1.3. Some practitioners are inappropriately requesting HCV testing as part of a routine sexual health screen (HCV is rarely a sexually transmitted infection, and almost exclusively among men who have sex with men).

1.2. Although the antibody tests have good specificity, most positive results in a low prevalence setting will be false positives. We see a number of low-level positive antibody results in the community laboratory and these almost always negative for HCV RNA – i.e. either false positives or cleared infection.

1.3. The confirmatory testing (HCV RNA) is expensive.

2. WHO SHOULD BE TESTED FOR HCV INFECTION?

- Patients who have a history of intravenous drug use
- Patients who have a history of spending time in jail
- Patients who have had a tattoo or body piercing using unsterile equipment
- Patients who received blood transfusion or blood products prior to 1992
- Patients born to a mother who is/was chronically infected with HCV
- Patients who have received medical care in a high-risk country (South East Asia, China, Eastern Europe (including Russia), or the Middle East)

3. PROPOSED CHANGES

3.1. The laboratory will review all positive HCV antibody tests

3.2. All first-time antibody positive patients will have reflex HCV RNA test, with the exception of the low level antibody reactors which will follow the pathway below.

1.3.1. Specimens with low level positive results will be tested on another assay and reported as positive only if consistently positive

1.3.2. Consistently positive low level specimens will have HCV RNA tested if the patient is not already known to be infected

1.4. HCV RNA testing will only be performed as above or when requested by hepatologist/infectious diseases/specialist nurse

In other words, blood samples received from Primary Care requesting Hepatitis C antibody testing will undergo **reflex testing** for Hepatitis C RNA where appropriate. Primary care clinicians will no longer need to request HCV RNA testing.

These changes should result in patients getting more accurate results (and fewer patients will get false positive results). They will also prevent unnecessary HCV RNA testing.

4. CONSULTATION PROCESS

4.1. What are we consulting on?

We are consulting on restricting HCV RNA testing in primary care.

4.2. Who Is being consulted?

Stakeholder consultation will be with the following groups:

- Primary care referrers
- PHOs
- Public and private gastroenterology and hepatology specialists
- The hepatitis foundation
- DHB chief medical officers
- Specialist hepatitis nurses

4.3. Consultation Timeline

Consultation document	Friday 18th March 2016
Feedback	Until 5pm Friday 8th April 2016
Decision and announcement	Friday 15th April 2016

5. HOW TO GIVE FEEDBACK

Please give feedback before 5pm on Friday 8th April 2016 to:

Dr Arlo Upton

Clinical Microbiologist and Medical Director, Labtests and Northland Pathology Laboratory

Arlo.upton@labtests.co.nz

Dr Kitty Croxson
Clinical Virologist, ADHB
kittyc@adhb.govt.nz

6. DECISION

The decision will be made available on the Labtests and LabPLUS websites, and those giving feedback will also be informed of the decision by email.