

INTERPRETING HCV SEROLOGY AND PCR RESULTS IN DIAGNOSTIC HCV TESTING

RECOMMENDED WORDING FOR NSW LABORATORIES WHEN REPORTING HCV DIAGNOSTIC TEST RESULTS

THIS DOCUMENT HAS BEEN ENDORSED BY: Australasian Society for HIV Medicine, Australasian Society for Infectious Diseases, NRL, Hepatitis NSW, Australian Liver Association, Australasian Hepatology Association, RCPA Quality Assurance Programs Pty Ltd, Royal College of Pathologists of Australasia.



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This document has been developed as a concise source of standardised, currently available information to inform those laboratories performing hepatitis C testing for diagnosis in NSW about the recommended wording to use when reporting results to health professionals. The advice in this document is a guide only and is considered correct as of February 2015.

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GLOSSARY

HCV:	Hepatitis C virus
IA:	Immunoassay
PCR:	Polymerase chain reaction

1.0 THE AIM OF THIS DOCUMENT

The aim of this document is to be a guideline and resource for laboratories performing hepatitis C testing for diagnosis in NSW in providing comments that are useful to clinicians. It is not intended to cover interpretation of testing performed for therapeutic monitoring purposes.

The actual testing and reporting strategies used in each laboratory remain under the direction of the pathologists. It is understood that if followed, not all of the recommendations contained in the comments will be adequately funded by the current Medicare rebate scheme. However, like the National HCV Testing Policy 2012 v1.1 (<http://testingportal.ashm.org.au/hcv>), this document aims to promote best practice hepatitis C testing and reporting to improve diagnosis of hepatitis C infection and improve the understanding and interpretation of hepatitis C serology by requesting doctors.

The National HCV Testing Policy recommends that all specimens that are HCV reactive in an HCV screening immunoassay (IA) are confirmed by a second IA to distinguish true reactivity from false reactivity. The comments in sections 2 and 3 of this document assume this recommendation is followed. Further, supplemental testing for HCV viral RNA using PCR is recommended to confirm HCV diagnosis or current HCV infection.

The following laboratory workflow for HCV testing has been assumed in the preparation of this guidance:

- It is recognised that the first specimen a laboratory receives will be for serology and therefore could be either inappropriate for, or handled inappropriately for PCR;
- PCR is necessary for determining infection status following reactive serology;
- Specimen recollection is most likely to be necessary for those individuals requiring PCR;
- It is possible that laboratories will not review and / or refer to an individual's serology results when reporting PCR results.

Some immunoassays' instructions for use (IFU) specify an equivocal range. In immunoassays used in Australia, this range never includes values greater than the immunoassay cut-off. Therefore, in this guidance, "equivocal" refers to results that fall below the immunoassay cut-off and within the range specified by IFU that define an equivocal range.

Serological testing for HCV can include combination immunoassays that detect both HCV antibody (Ab) and antigen (Ag). Further, an immunoassay that detects HCV antigen alone is available for use as a supplemental test. Results from combination assays were considered in developing this guidance, even though their use in Australia is limited. Similarly, the HCV Ag test is not widely used instead of HCV PCR to determine current infection.

How to use this resource

The comments in the "Recommended wording for pathology report" column **should** be included in the reporting of results.

The comments in the "Additional considerations / options" columns have been provided for your consideration and are optional but may be useful to include in some situations.

The inclusion of comments directing clients to the Hepatitis Infoline as indicated is highly recommended.

Interpretation of HCV test results is complex and should be considered in light of patient history and presentation. Medical practitioners are strongly encouraged to consult a specialist microbiologist if they are not clear on any aspect of the HCV test results they receive.

2.0 RECOMMENDATIONS FOR REPORTING FOLLOWING HCV SEROLOGY

Scenario	IA*1	IA2	Recommended wording for pathology report	Additional considerations / options
2.1	Negative	Not tested	<p>No serological evidence of HCV infection.</p> <p>If recent exposure is suspected, recommend repeat testing at 3 and 6 months post exposure.</p> <p>Medical Practitioners are encouraged to contact their specialist microbiologist if they are not sure on any aspect of the HCV results.</p>	For further information, direct client to Hepatitis Infoline on 1800 803 990.
2.2	Reactive	Reactive	<p>HCV reactivity has been detected in two assays.</p> <p>The presence of HCV antibodies does not distinguish between acute, past (resolved) or chronic infection.</p> <p>Alternatively, simultaneously occurring non-specific (i.e. false positive) reactivity in two assays is possible but uncommon.</p> <p>Recommend HCV PCR.</p> <p>This result has been notified to the NSW Department of Health.</p> <p>Medical Practitioners are encouraged to contact their specialist microbiologist if they are not sure on any aspect of the HCV results.</p>	For further information about viral hepatitis diagnosis, management, treatment, referral and support, direct client to Hepatitis Infoline on 1800 803 990.
2.3	Reactive	Negative / Equivocal	<p>HCV serology is indeterminate.</p> <p>In the absence of risk factors, the reactivity is likely to be non-specific (i.e. false positive).</p> <p>If risk factors are present, the results may indicate early seroconversion.</p> <p>Recommend HCV PCR.</p> <p>Medical Practitioners are encouraged to contact their specialist microbiologist if they are not sure on any aspect of the HCV results.</p>	<ul style="list-style-type: none"> Repeat testing for anti-HCV could be undertaken in 4-6 weeks to exclude seroconversion. For further information, direct client to Hepatitis Infoline on 1800 803 990.
2.4	Equivocal	Negative / Equivocal	<p>HCV serology is inconclusive.</p> <p>In the absence of risk factors, the equivocal reactivity is likely to be non-specific.</p> <p>If risk factors are present, the results may indicate early seroconversion.</p> <p>Recommend HCV PCR.</p> <p>Medical Practitioners are encouraged to contact their specialist microbiologist if they are not sure on any aspect of the HCV results.</p>	<ul style="list-style-type: none"> Repeat testing for anti-HCV could be undertaken in 4-6 weeks to exclude seroconversion. For further information, direct client to Hepatitis Infoline on 1800 803 990.

*IA = Immunoassay

3.0 RECOMMENDATIONS FOR REPORTING FOLLOWING QUALITATIVE HCV PCR

Scenario	PCR	Recommended wording for pathology report	Additional considerations / options
3.1	Positive	<p>HCV RNA detected.</p> <p>Results consistent with current HCV infection.</p> <p>Recommend that this result is reviewed in the context of serology results, where available, to confirm correlation.</p> <p>This result has been notified to the NSW Department of Health.</p> <p>Medical Practitioners are encouraged to contact their specialist microbiologist if they are not sure on any aspect of the HCV results.</p>	<ul style="list-style-type: none"> • If this result were known to be a first time positive, best practice would be to repeat the PCR on a second specimen to confirm. However a second PCR would not be rebatable under 12 months. • Chronic HCV is curable in the majority of people using a 3-12 month course of combination antiviral therapy. If the patient is interested in accessing HCV treatment, perform LFTs and an HCV genotype test and refer to a HCV treatment service. • For further information about viral hepatitis diagnosis, management, treatment, referral and support, direct client to Hepatitis Infoline on 1800 803 990.
3.2	Negative	<p>HCV RNA not detected.</p> <p>No evidence of current HCV infection.</p> <p>If HCV antibody has been detected in one or more immunoassays, the HCV negative RNA result most likely indicates past (resolved) infection or non-specific (i.e. false positive) reactivity in the immunoassay(s).</p> <p>A further specimen for HCV PCR is recommended after 12 months.</p> <p>Medical Practitioners are encouraged to contact their specialist microbiologist if they are not sure on any aspect of the HCV results.</p>	<ul style="list-style-type: none"> • If a repeat PCR on a second specimen is performed in < 12 months, it would not be Medicare rebatable. • For further information, direct client to Hepatitis Infoline on 1800 803 990.