

June 2019

Re: **Increase in hepatitis A IgM antibody indeterminate and reactive results**

Dear Health Care Provider:

You are receiving this letter because your patient has been tested for hepatitis A IgM antibody at Public Health Ontario (PHO) Laboratory and was indeterminate or identified as low level reactive.

PHO Laboratory has observed an increased number of indeterminate and low level reactive hepatitis A IgM results. It is suspected that this is due to a slight reduction in specificity of the assay causing a proportion of non-reactive specimens to become indeterminate or low level reactive. This observation has been corroborated by another Canadian provincial laboratory that utilizes the same hepatitis A IgM assay. PHOL has reviewed its available testing data, and confirmed an increase in indeterminate results since November 2018, along with an increase in reactive results since a new test lot was introduced in late April 2019. Further analysis indicates that among reactive specimens, the increase is mainly in low level reactive specimens.

Indeterminate or low level hepatitis A IgM results should be interpreted cautiously taking into account the clinical signs, symptoms and history of the patient, including recent hepatitis A vaccination. **If acute hepatitis A infection was suspected at the time the initial specimen was drawn, and is still considered a likely possibility, a repeat serology specimen should be submitted if not done already.** Guidelines for interpreting repeat testing results in such patients are as follows:

- Patients with acute hepatitis A infection should have a changing (either rising or falling) hepatitis A IgM antibody level on retesting if the first specimen collected at the time of acute symptoms was either indeterminate or low level reactive.
- All reactive hepatitis A IgM specimens are forwarded to The National Microbiology Laboratory (NML) for genotyping. Any specimen successfully genotyped would be consistent with acute/recent hepatitis A infection. However, the inability to obtain a genotype does not necessarily imply a false reactive IgM antibody result, as viremia does not persist as long as IgM antibody, which may persist for months or longer.

At present, the magnitude of the problem appears to be relatively small, with test specificity remaining well within expected parameters at over 99%. PHO Laboratory will continue to monitor data and provide this letter for all low level reactive and indeterminate hepatitis A IgM results until the issue is resolved. We are working with the manufacturer to determine the cause of this issue and to find an appropriate solution. Once the problem is resolved, PHO Laboratory will no longer append this explanatory letter to indeterminate and low level reactive hepatitis A IgM antibody reports.

The PHO document, "QUESTIONS AND ANSWERS: Public Health Management of Hepatitis A" also provides guidance on dealing with potential false-reactive hepatitis A IgM results (see question 6). This resource, along with further information on hepatitis A serology testing, can be accessed at [publichealthontario.ca](http://publichealthontario.ca).

If you wish to discuss your patient's results with a microbiologist, please contact PHOL's Customer Service Centre at 416-235-6556 or 1-877-604-4567 (toll free), or by email at **[CustomerServiceCentre@oahpp.ca](mailto:CustomerServiceCentre@oahpp.ca)**.

Sincerely,

A handwritten signature in black ink, appearing to read 'Vanessa Allen', with a long, sweeping flourish extending to the right.

Vanessa Allen MD, MPH  
Chief, Medical Microbiology  
Public Health Ontario Laboratory  
Public Health Ontario