Lyme Disease – Statement

Februrary 25 ,2011

Lyme disease is an illness caused by bacteria spread through the bite of certain types of ticks that are prevalent in many regions across Canada. Lyme disease can be serious, but is treatable.

When someone shows symptoms of Lyme disease and might have been exposed to the ticks that carry it, guidelines recommend that physicians treat the illness, even if it has not been confirmed with laboratory testing.

When a lab test is ordered by a physician, a blood sample from the patient is sent to the provincial or territorial lab for testing. The provincial/territorial labs will often send any positive test results to the Public Health Agency of Canada's National Microbiology Laboratory (NML) in Winnipeg for confirmatory testing.

This testing at the NML involves a two-step process, which includes a screening step (Elisa test) followed by a confirmatory step (Western blot test). This is internationally recognized as the gold standard for Lyme disease testing.

In November 2009, the NML began solely using an automated Western blot test because it promised even more reliable results.

However, in January 2011, while performing an extensive quality control analysis of its Lyme disease testing methods, the NML discovered that 24 test results out of more than 1,557 samples tested for Lyme disease were incorrect. As a result, 24 patients in five provinces received false-negative test results for Lyme disease. All attending physicians of the 24 patients have been notified.

The Public Health Agency of Canada has and continues to work with the five affected provinces to ensure that physicians and their patients are notified of the revised test results so that patients can get appropriate treatment, if any is required.

The Public Health Agency of Canada continues to investigate the cause of these false-negative test results.

In the meantime, the Public Health Agency of Canada has taken the following measures:

- a comprehensive quality assurance review of the testing process at the NML;
- close consultations with the manufacturer of the test kit associated with the incorrect results, to examine the kit and its instructions for use and to fix any identified problems;
- enhanced training for lab technicians that conduct the testing;
- for greater assurance, over the next six months, the NML will use the manual test and the new automated test side by side when conducting testing for Lyme disease; and
- to confirm our corrective action plan, the NML is exploring an external review of the test and the testing process.

All laboratory tests have a margin of error, which is why physicians are encouraged to follow the recommended treatment guidelines and treat patients they suspect may have Lyme disease with antibiotics, even without the results of lab tests.

If you require further information please email ticks@phac-aspc.gc.ca.

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