Public Health Ontario | Santé publique Ontario

Labstract – November 2017

Lyme Disease Serology Update- Implementation of VlsE1/pepC10 IgM/IgG *Borrelia* assay

Audience

Health Care Providers, public health unit personnel, specimen collection centres

Overview

Effective November 27, 2017:

- Public Health Ontario (PHO) is changing the C6 peptide *Borrelia burgdorferi* (Lyme) IgM/IgG ELISA to a VlsE1/pepC10 *Borrelia* (Lyme) IgM/IgG ELISA.
- The assay change is a result of a competitive procurement and technical evaluation at PHO on Health Canada approved Lyme Disease IgM/IgG ELISA. Based on evaluation and comparison of assays, the performance characteristics of the new assay will not have an impact on detecting *B. burgdorferi* antibodies and results will be reported the same way (Reactive, Non-reactive, Indeterminate).

Lyme Serology Algorithm

PHO will continue to use a two-tier test method as recommended by the Canadian Public Health Laboratory Network[1]. This will consist of a *Borrelia* VlsE1/pepC10 *Borrelia* (Lyme) IgM/IgG ELISA. If the ELISA is reactive or indeterminate, PHO will perform Western Blot to detect *Borellia burgdorferi* IgM and IgG antibodies.

The diagnosis of Lyme disease is made based on a person's exposure to blacklegged ticks, with compatible signs and symptoms of Lyme disease. The laboratory testing results are used to confirm clinical suspicion of Lyme disease. In patients with early localized disease, serological testing is not recommended because at this stage the ability of serology to detect infection is poor as the immune response has not fully matured. These patients are diagnosed clinically and should be managed appropriately regardless of serological results.

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As infection progresses and the immune system responds to the infection, patients develop sufficient antibodies. Thus during the later stages of disease (i.e., early disseminated Lyme disease, and late disseminated Lyme disease), serological testing becomes useful in confirming a *B. burgdorferi* infection.

European Lyme Disease (*Borrelia afzelii and Borrelia garinii)*

European Lyme testing must be **specifically requested** on the PHO General Test Requisition and you must **indicate all relevant clinical information** and **travel history** of the patient. Specimens are forwarded to the National Microbiology Lab (NML) in Winnipeg for European Lyme testing as the VlsE1/pepC10 *Borrelia* (Lyme) IgM/IgG ELISA has not been currently validated to detect antibodies for European Lyme disease.

Specimen type and requisition requirements

Specimen type and volume for ELISA and western blot:

- Submit clotted whole blood or,
- Serum separator tubes (SST) with the gel sediment or,
- Minimum 1 ml of serum

  Note: Haemolysed, icteric, lipemic or microbially contaminated sera are not recommended for testing and should be avoided if possible

Requisition requirements:

Complete all fields of the PHO General Test Requisition: include, the patient's full name, date of birth, Health Card Number (must match the specimen label), physician name and address, and,

- Enter *Borrelia burgdorferi* or Lyme disease under 'Test description' on the PHO General Test Requisition. If European Lyme disease testing is required:
  - Enter European Lyme disease
- Date of onset
- Date of collection
- Clinical signs and symptoms
- Travel history
- Exposure (e.g. tick bite)

The following specimens will not be tested for Lyme disease by ELISA or western blot:

- Plasma
- CSF (please contact PHO for further information)

Turnaround time (TAT)

- Non-reactive results are available within 7 days
- Reactive or indeterminate results are available within 14 days
- European Lyme requests are referred to NML, Winnipeg and are available within 21 days

References

1. Public Health Laboratory Network. *The laboratory diagnosis of Lyme borreliosis: Guidelines from the Canadian Public Health Laboratory Network.* Can J Infect Dis Med Microbiol. 2007; 18(2):145-8.

For further information

- Visit PHO's Lyme disease webpage at www.publichealthontario.ca/en/BrowseByTopic/InfectiousDiseases/Pages/IDLandingPages/Lyme-Disease.aspx
- Contact the PHOL Customer Service Centre at 416-235-6556 or 1-877-604-4567 (toll-free), or by email at CustomerServiceCentre@oahpp.ca
- For PHOL specimen collection information and previous Labstracts, refer to wwww.publichealthontario.ca/Labs
- The current version of the PHOL General Test Requisition and other forms are available at www.publichealthontario.ca/requisitions
- To subscribe to future Labstracts, email labstracts@oahpp.ca
- To register for Autofax and receive laboratory reports by fax directly from our laboratory information system as soon as they are released, contact the PHOL Customer Service Centre.