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To: Michigan Local Health Department Medical Directors, Epidemiologists, and Communicable Disease Investigators

From: MDCH Zoonotic and Special Projects Section

Date: May 27, 2014

Re: *Borrelia* Genus Culture Laboratory Reports

The Michigan Department of Community Health (MDCH) has been receiving an increasing number of laboratory results reporting positive blood cultures for *Borrelia* genus in Michigan patients, performed by Advanced Laboratory Services, 501 Elmwood Ave., Sharon Hill, Pennsylvania. This methodology is the topic of a recently published MMWR article, “Concerns Regarding a New Culture Method for *Borrelia burgdorferi* Not Approved for the Diagnosis of Lyme Disease”.<sup>1</sup> This memo is to provide guidance to Michigan Local Health Departments in how to use this laboratory information when determining if a patient’s illness meets the surveillance case definition for a probable or confirmed case of Lyme disease.

This culture test<sup>2</sup> is in a category of in-house “laboratory-developed tests”, and has not been reviewed by FDA because it is not meant to be used outside the laboratory in which it was developed. It’s clinical sensitivity and specificity has not been evaluated or validated by independent laboratories. Preliminary studies<sup>3</sup> found that false positivity due to laboratory contamination of patient samples could not be ruled out and that further validation of the proposed novel culture method is required. Until this test has undergone independent verification and/or FDA approval, it cannot be used to fulfill the laboratory criteria of “Positive culture for *B. burgdorferi*” that is part of the CSTE surveillance case definition for Lyme disease.

These patients can still be evaluated using the other standard laboratory and/or case classification components of the [case definition for Lyme disease](#). MDCH has developed a flowchart for public health investigators to use when following up on reported cases of Lyme disease which can be accessed at [www.michigan.gov/cdinfo](http://www.michigan.gov/cdinfo) under the topic of Lyme disease. Please contact one of the MDCH epidemiologists at 517-335-8165 if you have additional questions or concerns.

<sup>1</sup>Morbidity and Mortality Weekly Report. April 18, 2014: 63(15); 333-333.

<sup>2</sup> Sapi *et al.* Improved culture conditions for the growth and detection of *Borrelia* from human serum. Int J Med Sci. 2013, 10 (4):362-376.

<sup>3</sup> Johnson *et al.* Assessment of new culture method for detection of *Borrelia* species from serum of Lyme disease patients. J Clin Micro. 2014, 52(3): 721-724