

April 18, 2014

Advanced Laboratory Services Statement

Advanced Laboratory Services designs and administers diagnostic tests for the purpose of supporting the medical community with reliable data. We continue to have strong confidence in the quality of the results of our culture test for detecting the presence of *Borrelia* in patients.

The *Borrelia* culture test offers potentially valuable information to the medical community and to the patients whom we serve. Existing serological tests are capable of only indirect detection of *Borrelia*, have limited sensitivity and are susceptible to generating false positives. Our culture test is intended to directly detect the presence or absence of *Borrelia*.

The results of our research was published in January 2013. In August a paper written by a researcher affiliated with the CDC, but not representing the official position of the CDC, asserted that the findings in the initial journal may be consistent with laboratory contamination. We want to be clear no one from the CDC or any of its researchers including the author who criticized our test had ever visited our lab or received specimens from us.

We are committed to continuously evaluate the results of our own research and adding to the body of scientific data. Along those lines, an independent researcher has written an article that will be published in the May issue of the same journal discrediting the August article by the CDC researcher.

We continue to undertake more extensive research and additional validation studies to address all issues to confirm the scientifically sound method of our process.

Recently, news reports have printed inaccurate statements from the CDC researcher's article concluding our test was contaminated, which is not correct.

Advanced Laboratory Services is regulated by the Centers for Medicare & Medicaid Services in accordance with the Clinical Laboratory Improvement Amendments (CLIA) and the Pennsylvania Department of Health. Pennsylvania Department of Health officials have inspected our laboratory on more than one occasion and examined the validation data for our *Borrelia* culture test.

Senior Staff of Advanced Laboratory Services