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Lab Director: Leslie Douglas, PhD, HCLD(MD), ABB

Patient: Berenson, MD, Les (11/26/52)

Provider: **Les Berenson, MD** Test ID: 51866

<u>Sample Collected</u> <u>Sample Received</u> <u>Sample Tested</u> <u>Test Reported</u>

Sample type: **Urine** Test performed by: L. Douglas

This test utilizes the polymerase chain reaction (PCR) technology to detect the presence of targeted microbial DNA for the causative agent of Lyme disease and common tick-transmitted co-infections. Sensitivity of the test is 1 to 10 microbes with a specificity exceeding  $5 \times 10^{18}$ .

# The √highlighted microbes were detected in the submitted sample:

Borrelia burgdorferi F7

✓B. burgdorferi Osp A-IND

✓B. burgdorferi Osp B-IND

B. burgdorferi Osp C

Babesia microti

Babesia divergens

✓ Babesia duncani-IND

✓ Bartonella bacilliformis-IND

Bartonella henselae

Bartonella quintana

Borrelia miyamotoi

✓ Borrelia recurrentis-NPS

✓ Ehrlichia chaffeensis-IND

Anaplasma phagocytophilium

NONE

Interpretation of Results Disclaimer: DNA Connexions is not a clinical diagnostic laboratory and cannot provide a diagnosis for disease and/or subsequent treatment. These results are from DNA PCR testing, and indicate the presence of disease-causing agents known to be transferred by ticks. A positive result indicates the presence of DNA from B. burgdorferi and/or other tick-transmitted organisms. A negative result only indicates the absence of detectable targeted organismal DNA in the submitted specimen. The information is supplied as a courtesy to health care providers to aide in an overall assessment. This information alone should not be used to diagnose and/or treat a health problem or disease. All reported results are intended for research purposes only and consultation with a qualified health care provider is required.

#### **Interpretation of Results**

#### **Positive**

A Positive result is indicated by the organism or gene being highlighted in yellow.

When our species-specific primer sets are designed, the expected size of the amplification product (in base pairs) is known. As every patient sample, every positive control, and every negative control are run in duplicate, when a sample produces an amplification product of the expected size on either, or both, of the assay runs, it is scored as a 'positive'.

### **Non-Predicted Size (NPS)**

A NPS result is indicated by the organism or gene being highlighted in yellow, followed by NPS.

When we see an aberrantly sized amplification product, we consider the following: These microbial genomes are small, on the order of a million bp, and tend to reproduce quickly. If a mutation occurs within the genome, something non-deleterious to the organism, the mutation will then be perpetuated in subsequent generations. If this mutation occurs in our target amplification region, the size of the subsequent amplification product will change (small or larger). The product size differential could possibly be due to mutation, degraded DNA, mutation of species, unspecified subspecies, etc. We have found that the NPS are more commonly detected in individuals with long-term infections. To be scored as an NPS, the product needs to be visualized on both runs of the sample. It is at the discretion of a qualified medical provider to interpret NPS results.

## **Indeterminate (IND)**

An Indeterminate result is indicated by the organism or gene being highlighted in yellow, followed by IND.

An Indeterminant result indicates that an amplification product was produced for a particular organism on the panel. However, the amplification product was not the expected size and was only present on one test run of the sample. The explanation for this is the same as the NPS, however the aberrant amplification product was only present on one test run. It is at the discretion of a qualified medical provider to interpret IND results.