Quality Assurance Statement

Revised June 14, 2017

Galaxy Diagnostics, Inc. provides highly sensitive, enhanced detection of *Bartonella* species infection using optimized detection methods for culture, PCR, and serology. Galaxy Diagnostics, Inc. runs diagnostic assays for both Animal Health and Human Health under strict quality control testing standards in a **COLA accredited CLIA laboratory** (COLA 23168; CLIA 34D2027997; PDH 32300; DHMH 1828; AHCA 800026370; COS 800375).

We follow exemplary laboratory practices regarding personnel qualifications and experience, facility and equipment maintenance, and protocol validation as defined by federal regulations governing laboratory testing for human health in the United States (Clinical Laboratory Improvement Amendment, 1998, 2002). For more information on laboratory standards, please see the Centers for Medicare/Medicare Services website - https://www.cms.gov/CLIA/. Additional information is available at www.COLA.org.

Personnel

Our Laboratory Director is a CLIA-qualified High Complexity Laboratory Director, with a PhD in Immunology, a BS in Medical Technology, MS in Biology, and ten years of experience directing high complexity clinical laboratories. Our Medical Advisors include experts in diagnosis and treatment of bartonelloses and other hard to diagnose infections (DVM for Animal Health and MD for Human Health). Our minimum educational standard for laboratory personnel is a BA/BS in biological science and all personnel are formally trained on our Standard Operating Procedures, Blood-borne Pathogens/Laboratory Safety, and Quality Assurance Procedures regarding sample handling, processing, and reporting.

Facilities & Equipment

Our laboratory and equipment are maintained according to COLA/CLIA standards, including temperature monitoring, routine calibration of instruments and equipment, and the use of biosafety cabinets for culture and PCR hoods for pre- and post-PCR processing. Human and animal samples are processed in separate incubators, separate PCR runs, and stored in separate freezers.

Protocol Validation

Our test methods are classified as "validated in house" following standards set by CLIA regulations and other best practice standards in molecular microbiology and immunology: (1) Ongoing documentation of internal or inter-laboratory performance using known reference standards for the species and/or diagnostic specimens of interest; (2) publication of novel methods in a peer-reviewed journals with sufficient documentation to establish diagnostic performance and interpretation of results; and (3) documentation of internal or inter-laboratory comparison to an accepted methodology or protocol.

In order to pre-enrich samples for *Bartonella* species, we use a novel enrichment media called *Bartonella* alpha-Proteobacteria Growth Medium (BAPGM), developed and described in the literature by researchers with an established expertise in the field of bartonelloses at North Carolina State University College of Veterinary Medicine. BAPGM serves as the foundation for a novel testing platform which combines enrichment culture with pre- and post-culture PCR processes. This novel test platform provides enhanced detection of *Bartonella* DNA missed by standard PCR detection methods and is currently the most effective means of *Bartonella* DNA detection offered anywhere in the world. Quality assurance for culture is verified with each test run by consistent use of both positive and negative control samples. Positive PCR results from clinical samples are further characterized and confirmed by DNA sequencing.

The purpose of indirect immunofluorescence assay (IFA) testing for Bartonellosis is to determine the presence or absence of antibodies to certain *Bartonella* species in human serum. Clinically, measured antibody levels are generally considered to be indicative of an individual's immune status regarding a specific pathogen. The presence of antibodies can indicate that a patient has been exposed to a particular species of *Bartonella*.

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In order to establish the performance of IFA testing in detecting human IgG levels, we assessed test accuracy, precision, analytical sensitivity and specificity. The Galaxy Diagnostics IFA serologic assays for *B. henselae* and *B. quintana* wereevaluated based on these criteria and the assay has been approved as a useful tool for identifying patient exposure to *B. henselae* and *B. quintana*. Additionally, our IFA test demonstrated limited cross-reactivity to *Anaplasma phagocytophilum*, *Borrelia*, *Ehrlichia*, *Rickettsia* and *Coxiella burnetii*.

Quality assurance for PCR and serology are verified with each testing run by consistent use of positive and negative control samples. Cultured *Bartonella* organisms are used for culture positive standards, and quantified *Bartonella* DNA is used for PCR positive standards. When not available, DNA from naturally-infected animals may be used for PCR controls after verification by sequencing. Serological testing for animal health is currently outsourced to the Vector-borne Disease Diagnostics Laboratory at NC State University College of Veterinary Medicine.

For questions, please contact Dr. Susan Orton at 919-313-9672 or email us at contact@galaxydx.com.