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/](https://www.cms.gov/CLIA/). Additional information is available at [www.COLA.org](http://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*. 

Galaxy Diagnostics, Inc. | 7020 Kit Creek Rd, Suite 130 | Research Triangle Park, NC 27709 | t 919-313-9672 | f 919-287-2476 | www.galaxydx.com
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* were evaluated 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.
This certificate makes known that
Galaxy Diagnostics, Inc.
has met all criteria for
Laboratory Accreditation
COLA ID #: 23168
06/20/2017
This certificate expires two years from this date

Chairman, Board of Directors

Chief Executive Officer
CENTERS FOR MEDICARE & MEDICAID SERVICES
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS
CERTIFICATE OF ACCREDITATION

LABORATORY NAME AND ADDRESS
GALAXY DIAGNOSTICS, INC
7020 KIT CREEK ROAD, SUITE 270
RESEARCH TRIANGLE PARK, NC 27709

CLIA ID NUMBER
34D2027997

EFFECTIVE DATE
01/11/2016

EXPIRATION DATE
01/10/2018

LABORATORY DIRECTOR
SUSAN M ORTON Ph.D.

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures. This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

Karen W. Dyer
Acting Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

<table>
<thead>
<tr>
<th>LAB CERTIFICATION (CODE)</th>
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</thead>
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<td>09/28/2013</td>
<td>PARASITOLOGY (130)</td>
<td>02/17/2015</td>
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<tr>
<td>GENERAL IMMUNOLOGY (220)</td>
<td>09/28/2013</td>
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FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR YOUR STATE AGENCY’S ADDRESS AND PHONE NUMBER. PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.
State of California Department of Public Health

CLINICAL LABORATORY LICENSE

In accordance with the provisions of Chapter 3, Division 2 of the Business and Professions Code, the persons named below are hereby issued a license authorizing operation of a clinical laboratory at the indicated address or other site(s) on file with the department.

GALAXY DIAGNOSTICS, INC.
7020 KIT CREEK RD., #130, P.O. BOX 14346
RESEARCH TRIANGLE PARK NC 27707

OWNER(S): GALAXY DIAGNOSTICS, INC. ET AL

DIRECTOR(S): ORTON SUSAN PHD MAGGI RICARDO MOZAYENI BOB MD

Lab ID Number: COS 00800375
Effective Date: July 22, 2016
Valid Until: July 21, 2017
CLIA Number: 34D2027997

Robert J. Thomas, Chief
Laboratory Field Services
State of Florida
AGENCY FOR HEALTH CARE ADMINISTRATION
DIVISION OF HEALTH QUALITY ASSURANCE
CLINICAL LABORATORY
Licensed

This is to confirm that GALAXY DIAGNOSTICS INC has complied with Chapter 483, Part I, Florida Statutes, and with Chapter 59A-7, Florida Administrative Code, and is authorized to operate the following laboratory in the specialties or subspecialties of:

Bacteriology, General Immunology, Parasitology

GALAXY DIAGNOSTICS INC
7020 Kit Creek Rd Ste 130
Research Triangle Pk, NC 27709

EFFECTIVE DATE: 03/20/2016
EXPIRATION DATE: 03/19/2018

Deputy Secretary, Division of Health Quality Assurance
MARYLAND
DEPARTMENT OF HEALTH AND MENTAL HYGIENE
OFFICE OF HEALTH CARE QUALITY
SPRING GROVE CENTER
BLAND BRYANT BUILDING
55 WADE AVENUE
CATONSVILLE, MD 21228-4663

MEDICAL LABORATORY PERMIT

NUMBER: 1828   EFFECTIVE PERIOD: 07/01/2017 - 06/30/2019

Pursuant to the provisions of TITLE 17, subtitle 2, Health-General Article § 17-201 et seq.,
Annotated Code of Maryland, this permit is issued to:

GALAXY DIAGNOSTICS INC
7020 KIT CREEK ROAD SUITE 130
RESEARCH TRIANGLE PA, NC 27709

Director: Dr SUSAN ORTON
Owner: AMANDA ELAN, PHD

For the performance of Medical Laboratory Tests in the following disciplines:

Microbiology:
Bacteriology
Immunology:
General Immunology
Molecular Biology:
PCR Amplifications

CONTROL: 67607

Patricia Tomsko, May, M.D.
Director

Falsification of a license shall subject the perpetrator to criminal prosecution and the imposition of civil fines.
Pursuant to the act of September 26, 1951, P.L. 1539 as amended, a Permit to operate a Clinical Laboratory is hereby granted to:

Laboratory Identification Number: 32300

Name and Director of Laboratory:

GALAXY DIAGNOSTICS, INC.
LESLIE A. WOLF
7020 KIT CREEK ROAD, SUITE 130
PO BOX 14346
RESEARCH TRIANGLE PARK, NC 27709

Owner:

EDWARD B BREITSCHWENDT

ISSUE DATE: August 15, 2016
DATE EXPIRES: August 15, 2017

AUTHORIZED CATEGORIES/TESTS:
BACTERIOLOGY
NON-SYPHILIS SEROLOGY
PARASITOLOGY

Karen M. Murphy Ph.D. RN
Secretary of Health

DISPLAY THIS CERTIFICATE PROMINENTLY
This permit is subject to revocation, suspension, or limitation for violation of the Act or the Regulations promulgated thereunder.
CENTERS FOR MEDICARE & MEDICAID SERVICES
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS
CERTIFICATE OF ACCREDITATION

LABORATORY NAME AND ADDRESS
GENEWIZ, LLC
115 CORPORATE BLVD
SOUTH PLAINFIELD, NJ 07080

CLIA ID NUMBER
31D2038673

EFFECTIVE DATE
11/28/2016

EXPIRATION DATE
11/27/2018

LABORATORY DIRECTOR
JAMES J DERMOODY Ph.D.

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures. This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

Karen W. Dyer
Acting Director
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<tr>
<td>ROUTINE CHEMISTRY (310)</td>
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