

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0261345	<b>(X3) Date Survey Completed</b>  01/16/2018
<b>Name of Provider or Supplier</b>  Gainesville Internal Medicine	<b>Street Address, City, State</b>  667 Lanier Park Dr, Gainesville, GA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on January 16, 2018. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780 An immediate jeopardy situation was identified due to the laboratory's inability to demonstrate compliance with personnel qualifications. The following deficiencies were cited:
<b>D3011</b>	<p><b>FACILITIES</b> CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory failed to observe safety procedures to ensure protection from physical, biochemical, and electrical hazards as required. Findings include: 1. Observation during the tour of the laboratory and adjoining hallways on 1/16/18 at approximately 12:15 p.m. revealed fire extinguisher #999318 and fire extinguisher #999308 were last serviced on 12/18/13. 2. An interview with the office manager in a medical office on 1/16/18 at approximately 2:00 p.m. confirmed the service dates for the aforementioned fire extinguishers.</p>
<b>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p>

This STANDARD is not met as evidenced by:  
Based on observation and staff interview, the laboratory failed to perform and document maintenance of laboratory equipment as required by the manufacturer. Findings include: 1. Observation during the laboratory tour on 1/16/18 at approximately 1215 p.m. revealed the Quest Diagnostic centrifuge in the urinalysis area did not have a calibration sticker nor was there any calibration documentation for this centrifuge. 2. Observation during the laboratory tour on 1/16/18 at approximately 12:15 p.m. revealed Labcorp centrifuge #1 in the chemistry area was last calibrated on 5/01/08, and Labcorp centrifuge #2 in the chemistry area was last calibrated on 6/16 /15. 3. An interview with Staff #1 (CMS 209) on 1/16/18 at approximately 12:15 p.m. in the laboratory confirmed the calibration dates for the aforementioned centrifuges.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**  
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:  
Based on personnel document review and staff interview, the laboratory director (LD) was unqualified to perform the duties/responsibilities of LD. Findings include: Refer to D6003, D6007, D6015, D6019, D6033, D6035, D6053, and 6102.

**D6003**

**LABORATORY DIRECTOR QUALIFICATIONS**  
CFR(s): 493.1405 AND 493.1406

The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the Laboratory is located; and (b)(2)(ii) Have had laboratory training or experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; or (b)(2)(ii)(B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in 493.1407; or (b)(2)(ii)(C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and (b)(3)(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or (b)(3)(ii) Have had at least one year experience directing or

supervising non-waived laboratory testing; (b)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; (b)(4)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and (b)(4)(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or (b)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and (b)(5)(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing; (b)(6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under 493.1406; or (b)(7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which the laboratory is located. Laboratory director qualifications on or before February 28, 1992 The laboratory director must be qualified to manage and direct the laboratory personnel and test performance. (a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and (b) The laboratory director must: (b)(1) Be a physician certified in anatomical or clinical pathology (or both) by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (b)(2) Be a physician who: (b)(2)(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or (b)(2)(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or (b)(2)(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification; or (b)(2)(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for certification; (b)(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and (b)(4)(i) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties; or (b)(4)(ii) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, either: (b)(5)(i) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or (b)(5)(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or (b)(6) Qualify under State law to direct the laboratory in the State in which the laboratory is located. Note: The January 1, 1968 date for meeting the 12 months' laboratory direction requirement in paragraph (b)(5) of this section may be

extended 1 year for each year of full-time laboratory experience obtained before January 1, 1958 required by State law for a laboratory director license. An exception to the July 1, 1971 qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975 and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications.

This STANDARD is not met as evidenced by:  
Based on personnel document review and staff interview, the laboratory director (LD) was unqualified to perform the duties/responsibilities of LD due to lack of required documentation submission to the state agency. Findings include: 1. LD document review revealed the LD was unqualified to perform the duties/responsibilities of LD due to lack of required documentation submission to the state agency. 2. An interview with the LD in a medical office on 1/16/18 at approximately 12:30 p.m. confirmed the required LD documents had not been submitted to the state agency.

**D6007**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(1)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:  
Based on review of linearity documents and staff interview, the lab director (LD) failed to review and review the studies performed on the FRENDO Immunoassay analyzer. Findings include: 1. Review of the FRENDO analyzer linearity studies performed 1/19/17 revealed the LD did not review or approve the studies on Thyroid Stimulating Hormone (TSH) and Prostatic Specific Assay (PSA). 2. . An interview with Staff #1 (CMS 209) on 1/16/18 at approximately 1 PM. in the side medical office confirmed the LD did not review/approve the aforementioned studies.

**D6015**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:  
Based on review of proficiency testing (PT) records and staff interview, the laboratory director failed to ensure the laboratory's enrollment in PT for all non-waived testing

	<p>performed. Findings include: 1. Review of PT records reveals the laboratory failed to enroll in PT for the sub-specialty of parasitology for the years 2016 and 2017. 2. An interview with Staff #1 (CMS 209) on 1/16/18 at approximately 11:30 AM in the medical office confirmed the lab was not enrolled for the parasitology PT during 2016 and 2017.</p>
<p><b>D6019</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(iv)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Proficiency Testing (PT) records and staff interview, the laboratory director (LD) failed to review and approve corrective actions for failed PT. Findings include: 1. Review of PT records for 2016 revealed the laboratory received a score of 0% on Creatine Kinase (CK) for Event MLE- M2 for "failure to participate". 2. Interview with TP # 1 (CMS 209 form) on January 16, 2018 at approximately 12 PM, confirmed results were not reported to the PT agency, which resulted in a score of 0% and the LD failed to review and approve the corrective action.</p>
<p><b>D6033</b></p>	<p><b>TECHNICAL CONSULTANT-MODERATE COMPEXITY</b> CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on personnel document review and staff interview, the technical consultant /laboratory director (TC/LD) was unqualified to perform the duties/responsibilities of TC/LD due to lack of required laboratory training and experience. Findings include: Refer to D6035</p>
<p><b>D6035</b></p>	<p><b>TECHNICAL CONSULTANT QUALIFICATIONS</b> CFR(s): 493.1411</p> <p>(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State</p>

in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:  
 Based on personnel document review and staff interview, the technical consultant /laboratory director (TC/LD) was unqualified to perform the duties/responsibilities of TC/LD due to lack of required laboratory training and experience. Findings include; 1. TC/LD document review revealed the TC/LD was unqualified to perform the duties /responsibilities of TC/LD due to lack of required laboratory training and experience. 2. An interview with the TC/LD in a medical office area on 1/16/18 at approximately 12:30 p.m. confirmed the TC/LD did not have the required laboratory training and experience to perform the duties/responsibilities of TC/LD.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
 CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:  
 Based on testing personnel (TP) document review and staff interview, the technical consultant/laboratory director (TC/LD) failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least semi-annually during the first year of laboratory testing of patient specimens. Findings include: 1. TP document review revealed the TC/LD failed to perform a six-month evaluation of Staff #1 (CMS 209) in 2016. 2. An interview in a medical office on 1/16 /18 at approximately 11:30 a.m. confirmed the TC/LD did not perform a six-month competency on Staff #1 (CMS 209) in 2016.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on testing personnel (TP) document review and staff interview, the technical consultant/laboratory director (TC/LD) failed to evaluate and document the performance of TP responsible for moderate complexity testing at least annually after the first year. Findings include: 1. TP document review revealed the TC/LD failed to perform an annual competency for Staff #1 (CMS 209) for 2016 and 2017. 2. An interview with Staff #1 (CMS 209) in a medical office on 1/16/18 at approximately 11:30 a.m. confirmed the TC/LD failed to perform an annual competency on Staff #1 (CMS 209) for 2016 and 2017.

**D6102**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on testing personnel (TP) document review and staff interview, the laboratory director (LD) failed to ensure that all TP receive appropriate training for the type and complexity of the laboratory services offered. Findings include: 1. TP document review revealed the LD failed to ensure Staff #1 (CMS 209) received appropriate training for the type and complexity of the services offered. 2. An interview with Staff #1 (CMS 209) in a medical office on 1/16/18 at approximately 11:30 a.m. confirmed the LD failed to ensure Staff #1 (CMS 209) received proper training prior to performing the type and complexity of the laboratory services offered.