Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D1083380	02/27/2019
Name of Provider or Supplier	**Street Address, City, State**	
Atlanta Family Physicians Pc	3424 Flat Shoals Road, Decatur, GA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on February 27, 2019. The laboratory was found not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. An Immediate Jeopardy was identified due to the laboratory's inability to have a qualified Laboratory Director and Technical Consultant for a moderate complexity laboratory. The following deficiencies were cited:
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's proficiency testing records, lack of quality assessment activity, and staff interview the laboratory failed to monitor and evaluate the overall quality of the laboratory. Identified problems were not corrected by laboratory staff. (Refer to: D5209, D5211, D5217, D5291 and D5293)
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

	This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the testing personnel (TP), the laboratory failed to establish a written policy to determine employee competency for all test performed in the laboratory from May 2017 through February 2019. The findings include: 1. A review of testing personnel records revealed that the laboratory failed to perform a competency assessment with the six criteria required by CMS for the specialties of Chemistry and Toxicology from May 2017 through February 2019. 2. The laboratory failed to have a written policy and procedure to assess competency based on the position responsibilities on an initial, semi-annual, and annual basis. 3. The laboratory did not have a written policy for assessing employee competency for the tests performed in the laboratory. 4. An interview with TP #1 (CMS 209), in the laboratory, on February 27, 2019, at 11:30 AM confirmed that the laboratory did not perform a competency assessment on TP #1.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of proficiency test (PT) records and interview with the testing personnel (TP), the laboratory failed to review and evaluate the results of the American Proficiency Institute (API) proficiency test for the specialty of Chemistry from December 2017 through February 2019. The findings include: 1. A review of PT records for API revealed that attestation and performance review statements for Chemistry were not signed and reviewed by the Laboratory Director from December 2017 through February 2019. 2. The Laboratory Director and testing personnel must attest that PT samples were performed according to the guidelines set forth by the PT provider. 3. TP #1 confirmed on 02/27/19, at 10:30 AM, in the laboratory, that the Laboratory Director failed to review and sign the PT attestation and performance review statements for the specialty of Chemistry.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency test (PT) records and interview with the testing personnel, the laboratory failed to ensure that at least twice annually the laboratory verified the accuracy of Medica EasyRA toxicology drug screen test. The findings include: 1. Review of the laboratory's records revealed that there was no documentation of peer review or proficiency testing results for Medica EasyRA toxicology drug screen panel from June 2018 through February 2019. 2. Testing personnel #1 confirmed on 02/27/19, at 10:45 AM, in the laboratory that the laboratory failed to verify accuracy of their Toxicology drug screen test.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT

	CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the office manager, the laboratory failed to follow their written quality assessment (QA) to monitor, assess, and correct problems in the general laboratory system for quality assessment from May 2017 through February 2019. 1. The laboratory's current written quality assessment policy does not encompass all facets of the laboratory's technical and non-technical functions. The laboratory failed to follow their own QA policy regarding proficiency test review, competency assessment review, and overall QA of the laboratory. 2. The laboratory failed to have a QA policy addressing patient confidentially, specimen accept/reject criteria, sample identification, complaints, and corrective actions. 3. Testing personnel #1 confirmed on February 27, 2019, at 11:15 AM, in the laboratory, that the laboratory did not follow their own QA policy.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual (SOP), quality assurance (QA) policy, and interview with the testing personnel the laboratory failed to ensure and verify an ongoing assessment to evaluate, monitor, and when indicated, correct problems identified in the laboratory. Th findings include: 1. Review of QA records revealed that the laboratory's current QA policy does not indicate the necessary steps to be taken to identify and correct problems, nor efforts to prevent recurrences and necessary procedures to prevent reoccurrence of problems in the laboratory. Corrective actions are being performed in the laboratory but are not documented. 2. The testing personnel confirmed on 02/27/19, at 10:30 AM, in the laboratory, that the laboratory is performing corrective actions but not documenting them. TP#1 also confirmed that the QA policy does not adequately assess and identify problems in the laboratory.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and

	rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedure manual (SOP) and interview with the testing personnel, the laboratory failed to have a written procedure and policy for specimen acceptance and rejection of patient urine and blood specimens for all test performed in the laboratory. The findings include: 1. A review of the SOP revealed that the laboratory failed to have a written procedure and policy for specimen acceptance and rejection for urine and blood patient samples from May 2017 through February 2019. 2. An interview with testing personnel (# 1 on CMS form 209) on 2/27 /2019, at 2:30 PM, confirmed that the laboratory did not have a written procedure and policy for specimen acceptance and rejection of patient urine and blood specimens.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual (SOP) and interview with testing personnel, the laboratory failed to have a written procedure manual that monitors and evaluates the overall quality of the analytic systems within the laboratory. The findings include: 1. A review of the laboratory's SOP revealed there was no procedure or policy for preparation of patient samples, calibrators, corrective actions, calibration verification procedures, reportable ranges, control procedures and reference intervals for all test performed in the laboratory from May 2017 through February 2019. 2. An interview with Testing Personnel #1 (CMS 209) on 2/27/19 at 1: 00 PM, in the laboratory, confirmed that the laboratory's SOP failed to evaluate and monitor the overall analytic system of the laboratory.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it

	can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of laboratory records and an interview with testing personel, the laboratory failed to meet analytic system requirements for their Toxicology drug test panel. The findings include: 1. The laboratory failed to provide statistically significant data that validated the accuracy, precision, analytical specificity, and analytical sensitivity for the Toxicology drug test panel. The laboratory had no records for the validation or calibration data for the Medica EasyRA Clinical Chemistry Analyzer. The facility began using the instrument in June of 2018. 2. An interview with Testing Personnel #1 on 2/27/19, at 1:00 PM, in the laboratory, confirmed that the laboratory failed to meet specifications for accuracy, precision, analytical specificity, analytical sensitivity, reportable range, and reference interval (normal range) for their Toxicology drug test panel.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, and interview with testing personnel (TP) #1, the laboratory failed to establish, perform, and document a maintenance and function check protocol that ensures the performance of the instruments, which is necessary for accurate and reliable test results for their Toxicology and Chemistry test panels. The findings include: 1. A review of the laboratory documentation revealed there was no documentation of maintenance or function checks for the Medica EasyRA Chemistry analyzer or the FastPackip analyzer from May 2017 through February 2019. 2. The laboratory failed to establish a written protocol that entails the maintenance of all non-waived instruments in the laboratory. 3. An interview with Testing Personnel #1 on 2/27/19 at 1:00 PM in the laboratory confirmed that the laboratory failed to perform maintenance and function checks for all non-waived instruments in the laboratory.
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 review of laboratory records and interview with the laboratory personnel, the laboratory director did not provide overall management and direction in accordance with 493.1407 resulting in Immediate Jeopardy. The Laboratory Director (LD) failed to meet CMS qualification requirements for LD, failed to employ a qualified Technical Consultant (TC), failed to monitor and evaluate the overall quality of the general laboratory system and failed to ensure and quality assessment (QA) program was maintained appropriately. (Refer to: D6003, D6018, D6021, D6024, D6031, D6032) This condition level deficiency contributed to the Immediate Jeopardy determination.
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 review of personnel documentation and an interview with the Office Manager, the laboratory director (LD) failed to meet the qualification requirements during the time of January 2018 through February 2019. The findings include: 1. A review of personnel records revealed the LD did not have the required laboratory

	training for a moderate complexity laboratory, no record of the 20 hours of continuing medical education credit hours in laboratory practice, and no documentation of previous experience directing or supervising a non-waived laboratory. 2. An interview with the LD on 2/27/19, at 2:30 PM, in the LD's office confirmed that the laboratory director did not meet the CMS qualification requirements for Moderate Complexity Laboratory Director.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency test (PT) records and interview with the testing personnel, the laboratory director failed to ensure that at least twice annually the laboratory verified the accuracy of Medica EasyRA toxicology drug screen test. The findings include: 1. Review of the laboratory's records revealed that there was no documentation of peer review or proficiency testing results for Medica EasyRA toxicology drug screen panel from June 2018 through February 2019. 2. The testing personnel confirmed on 02/27/19, at 10:45 AM, in the laboratory, that the laboratory failed to verify accuracy of their Toxicology drug screen test.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of proficiency test (PT) records and interview with the testing personnel, the laboratory director (LD) failed to review and evaluate the results of the American Proficiency Institute (API) proficiency test for Chemistry from December 2017 through February 2019. The findings include: 1. A review of PT records for API revealed that attestation and performance review statements for Chemistry were not signed and reviewed by the Laboratory Director for the specialty of Chemistry for Event 2 & 3 of 2017 and Events 1, 2 & 3 of 2018. 2. The Laboratory Director and testing personnel must attest that PT samples were performed accordingly to the guidelines set forth by the PT provider. 3. The testing personnel confirmed on 02/27

	/19, at 10:30 AM in the laboratory, that the Laboratory Director failed to review and sign the PT attestation and performance review statements for the specialty of Chemistry.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the office manager, the laboratory director failed to ensure the laboratory personnel followed their written quality assessment (QA) to monitor, assess, and correct problems in the general laboratory system for quality assessment in from May 2017 through February 2019. The findings include: 1. The laboratory's current written quality assessment policy does not encompass all facets of the laboratory's technical and non-technical functions. The laboratory failed to follow their own QA policy regarding proficiency test review, competency assessment review and overall QA of the laboratory. 2. The laboratory failed to have a QA that addresses patient confidentially, specimen accept /reject criteria and identification, complaint and corrective actions. 3. Testing personnel #1 confirmed on February 27, 2019, in the laboratory, that the laboratory did not follow their own QA policy.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual (SOP), quality assurance (QA) policy and interview with the testing personnel, the laboratory director failed to ensure and verify an ongoing assessment to evaluate, monitor, and when indicated, correct problems identified in the lab. Findings include: 1. Review of QA records revealed that the laboratory's current QA policy does not indicate the necessary steps to take to identify and correct problems, nor efforts to prevent recurrences and necessary procedures to prevent reoccurrence of problems in the laboratory. Corrective actions are being performed in the laboratory but are not documented. 2. The Laboratory Director failed to ensure that remedial actions were documented by testing personnel for all test performed in the laboratory. 2. The testing personnel confirmed on 02/27 /19, at 10:30 AM, in the laboratory, that the laboratory is performing corrective

	actions but not documenting it. TP#1 also confirmed that the QA policy does not adequately assess and identify problems in the laboratory.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual (SOP) and interview with testing personnel, the laboratory director failed to have a written procedure manual that monitors and evaluates the overall quality of the analytic systems within the laboratory. The findings include: 1. A review of the laboratory's SOP revealed there was no procedure or policy for preparation of patient samples, calibrators, corrective actions, calibration verification procedures, reportable ranges, control procedures, and reference intervals for all test performed in the laboratory from May 2017 through February 2019. 2. The Laboratory Director failed to provide written adequate policies and procedures for the analytic systems of the laboratory. 3. An interview with Testing Personnel #1 (CMS 209) on 2/27/19, at 1:00PM, in the laboratory, confirmed that the laboratory's SOP failed to evaluate and monitor the overall analytic system of the laboratory.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 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. This CONDITION is not met as evidenced by: Based on review of personell records and an interview with the Laboratory Director (LD), the laboratory failed to fill the position of Technical Consultant (TC) who meets the CMS qualification requirements. -Refer to D6034 This condition level deficiency contributed to the Immediate Jeopardy determination.
D6034	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

	This STANDARD is not met as evidenced by: Based on review of personnel records and an interview with the Laboratory Director (LD), the laboratory director failed to have an individual that meets the requirements of Technical Consultant (TC) for a CLIA moderate complexity facility. The findings include: 1. A review of personnel records revealed the LD did not have the required 1 year laboratory training and previous laboratory experience performing Toxicology or Chemistry testing to perform in the capacity of Technical Consultant. 2. The Laboratory Director failed to have an indivalual that meets the CMS qualification requirements for TC. 3. An interview with the LD on 2/27/19 , at 2:30 PM, in the LD's office, confirmed that the laboratory director did not meet the CMS qualification requirements for Technical Consultant Moderate Complexity.