Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0262290	05/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Adventhealth Medical Group Family Medicine	109 Hospital Drive, Calhoun, 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 May 21, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) document review and staff interviews, the laboratory failed to retain attestation statements for 3 testing events of 2018. Findings include: 1. Review of PT documents revealed the lab did not retain the attestation statements for 2018 Hematology event #3, Potassium Hydroxide (KOH) event #2, or Parasitology (Wet Prep) event #1. 2. Interviews with the clinical supervisor and laboratory advisor on 5/21/19 in the clinical supervisor's office at 11:45 AM confirmed the lack of aforementioned attestation statements.
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 Proficiency Testing (PT) document review and staff interviews, the laboratory failed to review and evaluate the results obtained on proficiency testing performed for 1 testing event of 2018 in 2 sub-specialities. Findings include: 1. Review of 2018 PT results revealed the lab did not document review of the results received for mycology or parasitology for the 2018 testing event #1. 2. Interviews with the clinical supervisor and laboratory advisor on 5/21/19 in the clinical supervisor's office at 11:45 AM confirmed the lack of aforementioned reviews.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on Proficiency Testing (PT) document review and staff interviews, the laboratory failed to document corrective actions for the results obtained on proficiency testing performed for 2 testing events of 2018 in 4 sub-specialities. Findings include: 1. Review of 2018 PT results revealed the lab did not document corrective actions of the results received for hematology 2018 event #1 (score 88%), urine sediment 2018 event #3 (score 50%), mycology (score 0%) or parasitology (score 0%) 2018 testing event #3. 2. Interviews with the clinical supervisor and laboratory advisor on 5/21/19 in the clinical supervisor's office at 11:45 AM confirmed the lack of aforementioned corrective actions.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on policy and procedure (SOP) review and staff interviews, the laboratory failed to have a written procedure for all tests, assays, and examinations performed by the laboratory. Findings include: 1. Review of the SOP revealed the lack of written procedures for potassium hydroxide (KOH), wet prep, Quality Assurance (QA), and how to proceed during a downtime. 2. Interviews with the clinical supervisor and laboratory advisor on 5/21/19 in the clinical supervisor's office at 10:30 AM confirmed the lack of aforementioned procedures.
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 procedure manual (SOP) and staff interviews, the procedure manual failed to include the required components for all procedures/testing performed by the lab. Findings include: 1. Review of the SOP revealed the procedure manual failed to include the critical values for complete blood counts (CBC) or reference intervals for all procedures/testing performed by the lab. 2. Interviews with the clinical supervisor and laboratory advisor on 5/21/19 in the clinical supervisor's office at 10:33 AM confirmed the lack of aforementioned required procedure components.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on quality control (QC) document review and staff interview, the lab failed to monitor over time the accuracy and precision of test performance in hematology. Findings include: 1. Review of hematology QC documents revealed no long term monitoring was done (Levy-Jennings) for the time period of September 2017 to April 2019. 2. Interviews with the clinical supervisor and laboratory advisor on 5/21/19 in the clinical supervisor's office at 12:26 PM confirmed the lack of aforementioned long term monitoring .
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)

	Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on log sheet and quality control (QC) document review and staff interview, the laboratory failed to perform QC on all procedures. Findings include: 1. Review of QC documents and log sheets revealed the lab did not perform QC for Mycology - Potassium Hydroxide (KOH) or parasitology - Saline Wet Preps. 2. Interview with the laboratory advisor on 5/21/19 in the clinical supervisor's office at 11:20 AM confirmed the lack of the aforementioned QC.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on lab report review and staff interviews, the laboratory failed to include all the required information on the in-house laboratory test reports. Findings include: 1. Review of in-house test reports (#601518 and #295069) revealed the lack of reference range for each component or the units of measurement. 2. Interviews with the clinical supervisor and laboratory advisor on 5/21/19 in the clinical supervisor's office at 10: 33 AM confirmed the lack of aforementioned required information on the test reports.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by:

	Based on review of the laboratory policy and procedure manual (SOP) and staff interviews, the laboratory director (LD) failed to specify, in writing the duties and responsibilities of each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of laboratory testing. Findings include: 1. SOP review revealed the LD failed to specify in writing the duties and responsibilities of each person engaged in the performance of all phases of laboratory testing. 2. Interviews with the clinical supervisor and the lab advisor in the clinical supervisor's office on 5/21/19 at 10:30 AM confirmed the SOP did not contain a duties and responsibilities policy and procedure.
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 documents and staff interviews, the laboratory failed to employ a qualified person to fulfill the position of Technical Consultant (TC). Findings include: 1. Review of the personnel documents revealed the personnel #11 (CMS 209 form) listed as the TC did not have the documented requirements of training or experience. 2. Interviews with the clinical supervisor and the lab advisor in the clinical supervisor's office on 5/21/19 at 10:30 AM confirmed the lack of documented training or experience as TC for Personnel #11 (CMS 209).