Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0262297	01/09/2019
Name of Provider or Supplier	**Street Address, City, State**	
Adventhealth Medical Group Family Medicine	824 Gi Maddox Parkway, Chatsworth, 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 January 9, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiency was cited:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory failed to ensure the PT samples were examined by testing personnel (TP) who routinely perform laboratory tests as required. Findings include: 1. American Proficiency Institute (API) PT document review revealed the second and third Hematology PT events for 2017 and all 3 Hematology PT events for 2018 were performed by the Staff #3 (CMS 209). 2. An interview with Staff #3 (CMS 209) in a medical office on 1/9/2019 at approximately 3:15 p.m. confirmed the aforementioned PT events were performed by the same TP.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

	This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory director (LD) failed to attest to the routine integration of PT samples into the patient workload as required. Findings include: 1. American Proficiency Institute (API) PT document review revealed there was no attestation statement available at the time of survey for the 2017 Hematology third event. 2. An interview with Staff #3 (CMS 209) on 1/09/2019 in a medical office at approximately 3:15 p.m. confirmed there was no attestation statement for the 2017 Hematology third PT event.
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 policy and procedure manual (SOP) and staff interview, the laboratory failed to establish a competency policy for testing personnel (TP). Findings include: 1. SOP review revealed the laboratory failed to establish a policy and policy for performing initial, six-month, and annual TP competencies. 2. An interview with Staff #3 (CMS 209) in a medical office on 1/9/2019 at approximately 3:15 p.m. confirmed there was not a competency policy in the laboratory SOP.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on instrument maintenance document review and staff interview, the laboratory failed to perform and document function checks as required. Findings include: 1. Coulter AcT Diff 2 hematology analyzer maintenance document review revealed the laboratory was unable to produce 2017 instrument maintenance documents at the time of survey. 2. An interview with Staff #3 (CMS 209) in a medical office on 1/9/19 at approximately 3:15 p.m. confirmed the aforementioned maintenance documents were not available at the time of survey.
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 hematology document review and staff interview, the laboratory failed to establish control procedures to monitor the accuracy and precision of the complete analytic process as required. Findings include: 1. Hematology document review revealed there were no Levey-Jennings charts for 2017 and 2018 for the Sysmex. 3. An interview with Staff #3 (CMS 209) in a medical office on 1/09/2019 at approximately 3:15 p.m. confirmed there were no Levey-Jennings charts for 2017 and 2018.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review and staff interview, the laboratory director (LD) failed to designate qualified testing personnel (TP) to perform TP competencies. Findings include: 1. TP competency document review revealed the LD designated unqualified TP to perform TP competencies due to lack of educational qualifications. 2. An interview with Staff #3 (CMS 209) in a medical office on 1/9/19 at approximately 3:15 p.m. confirmed all TP competencies were performed by unqualified TP.
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) documents and staff interview, the laboratory director (LD) failed to review PT reports as required. Findings include: 1. American Proficiency Institute (API) PT report review revealed the LD failed to

	review the third 2017 Hematology event. 2. An interview with Staff #3 (CMS 209) in a medical office on 1/92019 at approximately 3:15 p.m. confirmed the LD did not review the aforementioned PT event report.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on review of quality control (QC) documents, instrument maintenance logs, and eyewash logs the laboratory director/technical consultant (LD/TCP) failed to perform a review as required. Findings include: 1. Review of QC documents, instrument maintenance logs, and eyewash logs revealed the LD/TC failed to perform required reviews for 2017 and 2018. 2. An interview with Staff #3 (CMS 209) in a medical office on 1/9/2019 at approximately 3:15 p.m. confirmed the aforementioned lack of LD/TC review.