Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2083752	(X3) Date Survey Completed 02/06/2019
Name of Provider or Supplier Wellstar Urgent Care East Cobb Health Park	**Street Address, City, State** 3747 Roswell Road, Suite 107, Marietta, 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 06, 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:
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. Findings include: 1. Review of QC documents revealed the lab failed to monitor QC via Levey-Jennings charts to detect errors over time. 2. Interview with the Technical Consult (CMS 209 form) on 2/6/19 in the practice manager's office at approximately 11:18 AM, confirmed the lab was not performing long term monitoring of hematology QC.
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10)

	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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: Based on review of personnel documents and staff interview, the lab director (LD) failed to ensure all testing personnel (TP) obtained appropriate education prior to testing patients' specimens. Findings include: 1. Review of personnel documents revealed staff #11 and #13 (CMS 209 form) did not have documented minimum education to perform the lab testing. 2. Interview with the technical consultant (CMS 209 form) on 2/6/19 at approximately 10:30 in the practice manager's office, confirmed the missing documents of education for the aforementioned staff.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) 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 review of personnel documents and staff interview, the lab director (LD) failed to ensure all testing personnel (TP) received appropriate training prior to testing patients' specimens. Findings include: 1. Review of personnel documents revealed staff #3, 9, and 10 (CMS 209 form) did not have documented training to perform the lab testing. 2. Interview with the technical consultant (CMS 209 form) on 2/6/19 at approximately 10:30 in the practice manager's office, confirmed the missing documents of training for the aforementioned staff.
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on review of temperature and relative humidity (RH) charts, the laboratory testing personnel (TP) failed to follow established policy and procedures. Findings include: 1. Review of temperature charts revealed the TP failed to record lab

	refrigerator temperatures: 2 of 31 days in May 2018, 3 of 30 days in June 2018, 4 of 31 days in August 2018, 5 of 30 days in September 2018, and 3 of 30 days in November 2018. 2. Review of temperature charts revealed the TP failed to record lab room temperatures: 3 of 31 days in August 2018, 2 of 30 days in September 2018, 3 of 31 days in October 2018, and 2 of 30 days in November 2018. 3. Review of RH charts revealed the TP failed to record lab RH: 3 of 31 days in August 2018, 3 of 30 days in September 2018, 5 of 31 days in October 2018, and 2 of 30 days in November 2018. 4. Interview with the technical consultant (CMS 209 form) on 2/6/19 at approximately 11:30 in the practice manager's office, confirmed the aforementioned missing temperature and RH.