Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2083752	07/22/2021
Name of Provider or Supplier	**Street Address, City, State**	
Wellstar Urgent Care East Cobb Health Park	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 July 22, 2021. 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:
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 review of the American Proficiency Institute (API) records and interview with the Quality Improvement Coordinator(QIC), the lab director failed to ensure Proficiency Test (PT) samples were tested by testing personnel (TP) who routinely run patient samples in the specialty of Hematology (0760). Findings include: 1. Review of the API attestation statements reveals the PT samples in the specialty of Hematology (0760) were tested by TP#3 (CMS 209) for Event 3 of 2019, Events 1, 2, 3 of 2020, and Event 1 of 2021. Samples were not rotated among all TP. 2. Interview with the QIC on July 22, 2021 at approximately 3:30 PM, in the facility manager's office, confirmed the PT was run by TP#3 (CMS 209) for the aforementioned PT dates and events.
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 procedure manual (SOP) review, review of Proficiency Testing (PT) results, and staff interview, the laboratory failed to follow the SOP as written and approved for Proficiency Testing (PT) (#701.1). Findings include: 1. SOP review reveals the laboratory is not following written procedure for Proficiency Testing (#701.1). Forms 701B and 701C are to be completed as SOP indicates when an unsatisfactory, unacceptable, or unsuccessful PT result is investigated. 2. Review of American Proficiency Institute (API) PT 2021 event #1 results, reveals erythrocyte (RBC) count was unsuccessful with a score of 60%. Forms 701B nor 701C were available for review at the time of the survey. 3. Interview with the Quality Improvement Coordinator on 7/22/21 at approximately 4:30 PM in the facility manager's office, confirmed the SOP was not followed.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

	This STANDARD is not met as evidenced by: Based on calibration document review and interview with the Quality Improvement Coordinator(QIC), the lab failed to calibrate the AcT Diff II analyzer every six (6) months as required by the manufacturer. Findings include: 1. Review of calibration data revealed the AcT Diff II was calibrated on 3/12/19 and 5/20/21. 2. Interview with the QIC on July 22, 2021 at approximately 3:15 PM in the facility manager's office confirmed the calibration has not been calibrated per manufacturer instructions.
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 ACT Diff II 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 reveals the lack of long term QC monitoring (Levey-Jennings charts) from 2019, 2020, and 2021. 2. Interview with the Quality Improvement Coordinator on 7/22/21 at approximately 4:00 PM in the facility manager's office, confirmed the lack of a long term QC monitoring system.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (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 laboratory failed to run Quality Control(QC) every 8 hours as required for hematology testing. Findings include: 1. Quality control document review revealed the laboratory failed to run QC every 8 hours for hematology testing as required for 2019, 2020, and 2021. 2. Interview with the Quality Improvement Coordinator on July 22, 2021 at approximately 4:00 PM, confirmed the laboratory failed to run QC every 8 hours for hematology testing as required.
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 the laboratory's American Proficiency Institute (API) Proficiency Testing (PT) records and staff interview, the laboratory director (LD) failed to ensure PT results were reviewed upon receipt from the PT agency. Findings include: 1. Review of PT records for 2019, 2020, and 2021 reveals the LD or designee (TC) failed to review 2020 Event #1 upon receipt from the PT agency. 2. Interview with Quality Improvement Coordinator on July 22, 2021 at 4 PM confirmed 2020 event #1 results were not reviewed by the LD or designee.
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 testing personnel (TP) document review and staff interview, the laboratory director (LD) failed to ensure that prior to testing patient's samples, all TP have the appropriate education. Findings include: 1. TP document review revealed the LD failed to ensure the TP had the minimal educational document on Staff #12, #13, #15, and #16 (CMS 209) in 2019, 2020, and 2021. 2. An interview with the Quality Improvement Coordinator in the facility manager's office on 7/22/21 at approximately 3:30 p.m. confirmed the lack of educational documents on the aforementioned TP.
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 testing personnel (TP) document review and staff interview, the laboratory director (LD) failed to ensure that prior to testing patient's samples, all TP have the appropriate training. Findings include: 1. TP document review revealed the LD failed to ensure the TP had the appropriate training documented on 9 of 19 TP (CMS 209) in 2019, 2020 and/or 2021. 2. Interview with the Quality Improvement Coordinator in the facility manager's office on 7/22/21 at approximately 4:30 p.m. confirmed the lack of training documents on 9 of 19 TP (CMS 209).
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 review of testing personnel (TP) documents and staff interview, the technical consultant failed to perform semiannual competency on all testing personnel. Findings include: 1. Review of testing personnel (TP) competency documents reveals the lack of semiannual competency review for 4 of 19 TP (CMS 209) during the time period of 2019, 2020, or 2021. 2. Interview with the Quality Improvement Coordinator in the facility manager's office on 7/22/21 at approximately 4:30 p.m. confirmed the lack of trainig documents on 4 of 19 TP (CMS 209).
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 review of testing personnel(TP) documents and staff interview, the technical consultant failed to perform annual competency on all testing personnel. Findings include: 1. Review of testing personnel (TP) competency documents reveals the lack of annual competency review for 9 of 19 TP (CMS 209) during the time period of 2019, 2020, or 2021. 2. Interview with the Quality Improvement Coordinator in the facility manager's office on 7/22/21 at approximately 4:30 p.m. confirmed the lack of annual competency documents on 9 of 19 TP (CMS 209).