Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2183212	02/03/2021
Name of Provider or Supplier	**Street Address, City, State**	
Wellstar Dekalb Avenue Pc And Walk-In Clinic	670 Dekalb Avenue, Ne, Suite 106, Atlanta, 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	Based on a CLIA recertification survey performed on February 3, 2021, this facility was found to not be in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on Hematology quality control (QC) document review and staff interview, the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems as required. Findings include: For details refer to D5441 and D5469
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 policy and procedure manual (SOP) and staff interview, the laboratory failed to establish a policy and procedure for the course of action to take if a test system becomes inoperable as required.. Findings include: 1. SOP review revealed the lack of a policy and procedure for patient testing if the Beckman Coulter DxH 520 (hematology analyzer) or the iStat Chem 8 (chemistry analyzer) were inoperable. 2. SOP review revealed the lack of a policy and procedure for panic or alert values. 3. An interview with the Quality Improvement Coordinator (QIC) in the consult room on 2/3/2021 at approximately 2:30 p.m. confirmed the lack of the aforementioned policies and procedures.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory failed to define criteria for proper storage of specimens as required. Findings include: 1. SOP review revealed the lack of a policy and procedure for specimen storage. 2. An interview with the Quality Improvement Coordinator (QIC) in the consult room on 2/3/2021 at approximately 2:30 p.m. confirmed the lack of the aforementioned policy and procedure.
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 quality control (QC) document review and staff interview, the laboratory failed to monitor over time the accuracy and precision of test performance as required. Findings include: 1. Beckman Coulter DxH500 (hematology analyzer) quality control (QC) document review revealed the lack of Levey-Jennings charts for 2020 (August through December) and 2021 thus far. 2. An interview with the Quality Improvement Coordinator on 2/3/2021 in the consult room at approximately 11:45 a. m. confirmed the lack of Levey-Jennings charts for the aforementioned time periods.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (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 define establish reference ranges for each batch and lot number of control materials as required. Findings include: 1. Beckman Coulter DxH 520 (hematology analyzer) quality control (QC) document review revealed the lack of parallel study documentation at the time of survey to establish reference ranges for Hematology Abnormal Low, Normal, and Abnormal High controls for the following: Between Abnormal Low (Lot #352011411), Normal (Lot #362011412), Abnormal High (Lot #372011413) and Abnormal Low (Lot #352011811), Normal (Lot #362011812), Abnormal High (Lot #372011813) in 2020 Between Abnormal Low (Lot #352011811), Normal (Lot #362011812), Abnormal High (Lot #372011813), and Abnormal Low (Lot #352011911), Normal (Lot #362011912), Abnormal High (Lot #372011913) in 2021 2. An interview on 2/3/2021 in a consult room on 2/3/2021 with the Quality Improvement Coordinator at approximately 3:00 p.m. confirmed parallel studies were not performed to establish reference ranges in 2020 and 2021.
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 Hematology quality control (QC) document review, testing personnel (TP) document review, and staff interview, the laboratory director (LD) failed to provide overall managment and direction of the laboratory as required. Findings include: For details refer to D6004, D6044, D6073, D6074,
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 delegate technical consultant (TC) responsibilities to qualified TP as required. Findings include: 1. TP document review revealed the following initial training competencies were performed by unqualified TP due to lack of laboratory experience: 2020 -- Staff #1 (CMS 209) and Staff #2 (CMS 209); 2021 -- Staff #3 (CMS 209) and Staff #4 (CMS 209). 2. An interview with Staff #5 (CMS 209) in the consult room on 2/3/2021 at approximately 11:00 confirmed the aforementioned TP competencies were performed by unqualified TP due to lack of laboratory experience.
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 Hematology quality control (QC) document review, patient test result review, and staff interview, the technical consultant (TC) failed to fulfill TC responsibilities as required. Findings include: For details refer to D6044, D6073, D6074
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;

	This STANDARD is not met as evidenced by: Based on Hematology quality control (QC) document review and staff interview, the technical consultant (TC) failed to ensure patient test results are not reported until all corrective actions have been taken as required. Findings include: 1. Review of Hematology QC document review and patient test reports revealed patient results were reported when QC was out of range for the following dates: August, 2020 -- 1 out of 31 days; October, 2020 -- 1 out of 31 days; December, 2020 -- 1 out of 31 days; January, 2021 -- 1 out of 31 days. 2. An interview with the Quality Improvement Coordinator in a consult room on 2/3/2021 at approximately 3:15 p.m. confirmed patient test results were reported when Hematology QC was out of range for the aforementioned time periods
D6073	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(4) Each individual performing moderate complexity testing must follow the laboratory's established corrective action policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual, review of quality control (QC) documents, and staff interview, testing personnel (TP) performing moderate complexity testing failed to follow the laboratory's established corrective action policies and procedures as required. Findings include: 1. SOP review revealed TP are required to investigate results that do not fall within established ranges, take corrective action, and document corrective action taken. 2. Beckman Coulter DxH 520 (Hematology analyzer) document review revealed Hematology controls (Abnormal Low #352011411, Normal (#362011412), Abnormal High (#372011413) were out of range for the following time periods with no corrective action: August -- All 3 controls were out 1 out of 31 days. 3. Beckman Coulter DxH 520 (Hematology analyzer) document review revealed Hematology controls (Abnormal Low #352011811, Normal (#362011812), Abnormal High (#372011813) were out of range for the following time periods with no corrective action: October, 2020 : All three levels of control (Abnormal Low, Normal, Abnormal High) were out of acceptable range for 1 out of 31 days December, 2020: Controls were out of range for 20 out of 31 days; All three levels of control (Abnormal Low, Normal, Abnormal High) were out of acceptable range for 5 out of 31 days January, 2021: Controls were out of range for 2 out of 14 days. 4. Beckman Coulter DxH 520 (Hematology analyzer) document review revealed Hematology controls (Abnormal Low #352011911, Normal (#362011912), Abnormal High (#372011913) were out of range for the following time periods with no corrective action: January, 2021: Controls were out of range for 3 out of 7 days; All three levels of control were out of range for 1 out of 7 days. 5. An interview with the Quality Improvement Coordinator on 2/3/2021 in the consult room at approximately 3:00 p.m. confirmed corrective action was not performed for the aforementioned Hematology controls.
D6074	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(5) Each individual performing moderate complexity testing must be capable of

	identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director. This STANDARD is not met as evidenced by: Based on Hematology Quality Control (QC) document review, patient report review, and staff interview, testing personnel (TP) failed to identify problems that may adversely affect reporting of test results as required. Findings include: 1. Review of Hematology QC document review and patient test reports revealed patient results were reported when QC was out of range for the following dates: August, 2020 -- 1 out of 31 days; October, 2020 -- 1 out of 31 days; December, 2020 -- 1 out of 31 days; January, 2021 -- 1 out of 31 days. 2. An interview with the Quality Improvement Coordinator in a consult room on 2/3/2021 at approximately 3:15 p.m. confirmed patient test results were reported when Hematology QC was out of range for the aforementioned time periods.