Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D1062908	05/19/2021
Name of Provider or Supplier	**Street Address, City, State**	
Wellstar Urgent Care Of Cooper Lake	4480 North Cooper Lake Se Suite 100, Smyrna, 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 19, 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:
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. 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 that Proficiency Test (PT) samples were tested in the same manner as patient specimens in the specialty of Hematology (0760). Findings include: 1. Review of the API attestation statements revealed the samples in the specialty of Hematology (0760) for PT were not run the same as the patient specimens, for Event 3 of 2020 and Event 1 of 2021. Testing personnel (TP)#6 (CMS 209) and TP#10 (CMS-209) each performed all the PT samples and signed the API attestation statement document. 2. During an interview with the Quality Improvement Coordinator on May 19, 2021 at approximately 3:00 PM, confirmed the PT was not run the same as the patient specimens for Event 3 of 2020 and Event 1 of 2021.
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 6/20/19, 1/6/20, and 7/21/20, but has not been performed to date. (Due date = January 2021) 2. Interview with the QIC on May 19, 2021 at approximately 2:15 PM in the breakroom, confirmed the calibration has not been completed to date.
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. The 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 May 19, 2021 at approximately 4:00 PM, confirmed the laboratory failed to run QC every 8 hours for hematology testing as required.