Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2051885	07/16/2021
Name of Provider or Supplier	**Street Address, City, State**	
Wellstar Urgent Care Atlanta	3730 Carmia Drive, Sw, Suite 110, 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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on July 16, 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:
D5485	CONTROL PROCEDURES CFR(s): 493.1256(h) If control materials are not available, the laboratory must have an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be documented. This STANDARD is not met as evidenced by: Based on Chemistry Quality Control (QC) data review and staff interviews, the laboratory failed to perform QC on the Abbott I-Stat Chemistry analyzer, thereby failing to meet the laboratory's established (SOP) guidelines. Findings include: 1.) Quality Control documents review revealed NO (QC) data available at the time of survey during the month of June 2021. 2.) Interviews with the laboratory coordinator, office manager and TP #1(CMS 209) in the review room on 07/16/2021 at approximately 12:35 pm confirmed NO Chemistry (QC) was done in June 2021 due to lack of supplies.
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 review of the employee competency assessments, and staff interview, the laboratory failed to provide Initial training documents for Testing Personnel (TP) rotating in the laboratory. Findings: 1. Review of the employee competency assessment records revealed, there was no documentation of initial training or 6 months evaluations for TPs #1 - 4 (CMS 209) from December 2020 to July 2021. 2. Interviews with the laboratory coordinator, Office Manager and TP #1 (CMS 209) on 07/16/2021 at approximately 12:40 pm in the review room, confirmed there were no initial training or 6 months review documents for the aformentioned Testing Personnel during the time of survey.
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 American Proficiency Testing 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 (API) (PT) records for 2021 revealed the laboratory director or Technical Consultant (TC) did not review results for 2021 Events #s 1 & 2. 2. An interview with the laboratory coordinator on 07/16/2021 at approximately 12:30 pm in the review room, confirmed results did not reviewed by the LD or TC.