Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2062129	03/24/2021
Name of Provider or Supplier	**Street Address, City, State**	
Wellstar Urgent Care At Kennestone Hospital	780 Church Street Ne, Suite 1110, 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 March 24, 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:
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and interview with Clinical Coordinator, the laboratory failed to establish written instructions for sending specimens to an outside reference laboratory for testing. The findings include: 1. The laboratory's procedure manual did not include a written policy and procedure (to include collection, preservation, storage, transport, testing schedule times, and how to obtain additional assistance) for staff to follow when sending specimens to reference laboratories (LabCorp, Quest, and Wellstar Health System). 2. During an interview on March 24, 2021 at 1:20 PM, the Clinical Coordinator confirmed that the laboratory did not have a written policy and procedure for staff to follow when sending specimens to a reference laboratory.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d)

	Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on the laboratory procedure manual review and an interview with the Clinical Coordinator, the laboratory failed to ensure that testing procedures were updated and approved by the laboratory director(LD) before use. The findings include: 1. The laboratory changed from a non-waived iStat chemistry(analyte) to a waived method on June 29, 2020. 2. Review of the laboratory's policy and procedure manual reveals that the laboratory did not update the testing procedure from waived to non-waived or get the LD approval prior to implementation. 3. During an interview on March 24, 2021 at 1:40 PM, the Clinical Coordinator confirmed that the laboratory failed to update changes in their procedure manual and seek LD approval from October 2018 through March 2021.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on the lab report review and staff interview, the laboratory failed to include all the required information on the in-house laboratory test reports. Findings include: 1. The final test report for an in-house iStat chemistry test did not include the address where testing was performed. 2. During an interview on March 24, 2021 at 1:30 PM, the Practice Manager confirmed that the address where testing was performed was not included on the final report.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on the laboratory procedure manual review and an interview with the Practice Manager, the Laboratory Director(LD) failed to ensure the changes to the procedure manual were reviewed, updated, and approved before use (see D5407). The findings include: 1. Review of the laboratory's procedure manual revealed that the LD failed to

	ensure that the procedure change for (analyte) Chemistry testing on the iStat was reviewed, updated, and signed prior to use. 2. During an interview on March 24, 2021 at 2:00 PM, the Practice Manager confirmed that the LD failed to review and sign the updated chemistry testing procedure.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on laboratory record review and a staff interview, the laboratory failed to present education documentation for a testing personnel(TP). The Findings include: 1. Documentation of minimum educational requirements(high school diploma) for TP #3 (CMS-209 form) was not available for review on the day of the survey. 2. During an interview on March 24, 2021 at 2:30 PM, the Practice Manager confirmed that the TP #3's high school diploma was not present during the time of the survey.