Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D1056282	08/25/2022
Name of Provider or Supplier	**Street Address, City, State**	
Wellstar Outpatient Surgery Center	4300 University Parkway, Evans, 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 August 25, 2022 this facility was found to be in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on review of the Standard Operating Procedure (SOP) and staff interview, the laboratory failed to establish a safety procedure for the Eyewash. The Findings include: 1. SOP document review revealed that the laboratory failed to establish a safety procedure for the Eyewash in the laboratory. 2. During an interview with the Technical Consultant (CMS-209) on August 25, 2022, at approximately 2:45 PM, at the nurse's station, confirmed that the laboratory failed to establish a safety procedure for the Eyewash.
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual and interview with

	the Technical Consultant, the laboratory failed to have a policy and procedure in place for complaint investigations. The Finding include: 1. SOP document review revealed that the laboratory did not have a policy and procedure for complaint investigations, during the time of the survey. 2. An interview with Technical Consultant (CMS-209) on August 25, 2022 at approximately 2:30 PM, at the nurses station, confirmed that the laboratory did not have a SOP in place for complaint investigations.
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 general laboratory standard operating procedure manual (SOP) and staff interview, the laboratory failed to establish written instructions for sending specimens to an outside reference laboratory for testing. The findings include: 1. Review of the SOP revealed that the laboratory procedures did not include a written policy and procedure (to include collection, preservation, storage, transport, testing schedule times, or how to obtain additional assistance) for staff to follow when sending specimens to reference laboratory (Quest Diagnostics, LabCorp) 2. During an interview on August 25, 2022 with the Technical Consultant (TC) (CMS-209) at approximately 2:40PM, at the nurse's station, confirmed that the laboratory did not have a written policy and procedure for staff to follow when sending specimens to reference laboratories.
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 review of the Standard Operating Procedure(SOP) and staff interview, the laboratory failed to have procedures approved, signed, and dated by the current Laboratory Director(LD) before use. The Findings include: 1. SOP document review revealed the laboratory failed to have procedures approved, signed, and dated by the Laboratory Director (LD). 2. During an interview with the Techical Consultant(TC) (CMS-209) on August 25, 2022 at approximately 2:30 PM at the nurse's station, confirmed that the laboratory failed to have procedures approved, signed, and dated by the LD before use.
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 temperature document review and staff interview, the laboratory failed to monitor and document temperature records for the I-Stat testing area as required by the manufacturer's instructions. The Findings include: 1. Temperature document review revealed the laboratory did not monitor or document temperatures for 2021 and 2022, as required by the manufacturer's instructions. 2. During an interview with the Technical Consultant(CMS-209) on August 25, 2022 at approximately 2:35 PM, at the nurse's station, confirmed that temperatures were not being monitored and documented for the I-Stat testing area.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory director (LD) failed to establish a policy specifying in writing the duties and responsibilities of each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of laboratory testing. Findings include: 1. SOP review revealed the LD failed to have a job description and duties for testing personnel, during the time of the survey. 2. During an interview with the Technical Consultant(CMS-209) on August 28, 2022 at the nurse's station of the building at approximately 2:30 PM, confirmed the SOP did not contain duties and responsibilities policy and procedure.