Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0884136	02/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
Wellstar Pediatric Adolescent Center - Austell	1810 Mulkey Road Suite 201, Austell, 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 February 9, 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:
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of quality assurance (QA) records and staff interview, the lab failed to document QA monitors per the written policies and procedures (SOP). Findings include: 1. Review of QA records of 2019 and 2020 revealed QA monitors were not performed in 2019 and 2020. 2. Interview with the Quality Improvement Coordinator on 02/09/2021 at approximately 11:30 AM in the breakroom, confirmed the QA monitors were not documented for the aforementioned dates.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: Based on review of the laboratory records and staff interview, the laboratory director failed to ensure that the quality assessment(QA) program is maintained to identify failures in quality. Findings include: 1. Review of the laboratory's QA records revealed the lack of documentation of QA monitors for 2019and 2020. 2. Interview with the Quality Improvement Coordinator on 02/09/2021 at approximately 11:30 AM in the breakroom, confirmed the QA monitors were not documented for the aforementioned dates.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) documents and staff interview , the lab director failed to ensure all personnel have the appropriate training prior to testing patients' specimens. Findings include: 1. Review of the TP personnel file documents reveals staff #6 (CMS 209) did not have documented training for the testing performed. 2. Interview with the Quality Improvement Coordinator on 02/09/2021 at approximately 11:30 AM in the breakroom, confirmed the aforementioned TP did not have documented initial training.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) documents and staff interview , the technical consultant failed to perform annual competency on all testing personnel. Findings include: 1. Review of the TP personnel file documents reveals staff #1 (CMS 209) and staff #4 (CMS 209) did not have annual competency performed in 2019. 2. Interview with the Quality Improvement Coordinator on 02/09/2021 at approximately 11:30 AM in the breakroom, confirmed the aforementioned TP did not have documented competency performed in 2019.