Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0257747	03/01/2022
Name of Provider or Supplier	**Street Address, City, State**	
Gwinnett Pediatric Partners	4120 Five Forks Trickum Road, Suite 102, Lilburn, 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 1, 2022. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following Condition and Standard deficiencies were cited:
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the College of American Pathologist (CAP) Proficiency Testing (PT) documents, and staff interview, the laboratory was not performing the PT samples in the same manner as patient samples. Reference: D2006, D2015
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally

	require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on document review of the College of American Pathologist (CAP) Proficiency Testing (PT) documents for 2020, 2021 and 2022, in the Specialty of Hematology, the laboratory was not performing the testing on the PT samples in the same manner as the patient samples. Findings: 1. Review of the CAP PT attestation statements for Hematology for 2020, 2021, and 2022 showed the following: 2020 - Event A- there were six signatures on the attestation statement, with no PTspecimens assigned to personnel for testing - Event B- there were two signatures on the attestation statement, with no PT specimens assigned to personnel for testing - Event C - there was not an attestation statement available 2021 - Event A - there were four signatures on the attestation statement, with no PT specimens assigned to personnel for testing - Event B - there were five signatures on the attestation statement, with no PT specimens assigned to personnel for testing - Event C - there were three signatures on the attestation statement, with no PT specimens assigned to personnel for testing 2022 - Event A - there were six signatures on the attestation statement, with no specimens assigned to personnel 2. A phone interview with staff # 2(CMS 209 form), who was currently working at one of the other Gwinett Pediatric Partner offices. confirmed they were testing the samples in duplicate so all testing personnel could participate in PT performance. 3. Interview with staff #1(CMS 209 form) and the Office Manager, on March 1, 2022 at approximately 1pm in the breakroom, confirmed the above aforementioned statements.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of the College of American Pathologist (CAP) Proficiency Testing (PT) documents, and staff interview, the laboratory failed to retain all instrument printouts that were created during sampling of the PT specimens, in 2020, 2021, and 2022. Findings: 1. A review of the CAP PT documents confirmed that there was only one set of instrument printouts available, although samples were run several times, as shown on review of the attestation statements. 2. Interview with staff #1, (CMS 209 form) and the office manager, on March 1, 2022, at approximately 1:10 pm, in the breakroom confirmed the above afforementioned statement.

D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on document review and staff interview, the laboratory was not retaining the instrument printouts from the Horiba Hematology analyzer (Horiba) for a minimum of two years. Findings: 1. The laboratory was not retaining the instrument printouts from the Horiba. A review of the College of American Pathologist (CAP) Proficiency Testing (PT) documents for 2020, 2021, and 2022, confirmed that there was only one copy of the PT results retained although the samples were ran several times. 2. Observation of laboratory documents confirmed that the laboratory utilized the Horiba printout and manually entered the results into the Electronic Medical Record (EMR), discarding the instrument printout. 3. Interview with staff #1 (CMS 209 form) and the office manager, on March 1, 2022, at approximately 1:25pm in the conference room confirmed the aforementioned statements.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the College of American Pathologist (CAP). Proficiency Testing documents (PT), Testing personnel (TP) training and competency documents, the Laboratory Director (LD) failed to provide overall management and direction as required. Reference: D6046, D6065
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the Testing Personnel (TP) Competency documents, and staff interview, the Laboratory Director (LD) , acting as the Technical Consultant (TC), failed to provide training and competency documents for all TP staff for the years 2020, and 2021. Findings: 1. Review of the TP documents showed the following: TP #1 (CMS 209 form) - no competency documents to review TP #2 (CMS 209 form) - competencies for 2020, and 2021 TP #3 (CMS 209 form) - competencies for 2020, and a 6 month competency for 2021, no annual competency in 2021 TP #4 (CMS 209

	form) - no training documentation TP #5 (CMS 209 form) - an initial training in 2022 3. Interview with staff #1 and thre office manager on March 1, 2022, at approximately 1:30 pm, in the break room confirmed the above mentioned statement.
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 review of Personnel Files for all testing personnel (TP) and staff interview, the laboratory failed to provide educational documents. Findings: 1. Review of the Personnel files for the five TP, listed on the CMS-209 personnel report, no educational records were available to review. 2. Interview with staff #1 (CMS 209 form) and the office manager, on March 1, 2022, at approximately 1:30 pm, in the break room, confirmed the above aforementioned statement.