Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0669731	09/16/2022
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Place Llc	2800 S Seacrest Blvd Ste 150, Boynton Beach, FL	

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	An announced CLIA recertification survey was conducted at Pediatric Place LLC on 08/29/2022 to 09/16/2022. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D2000 Enrollment and Testing of Samples 493.801 D5400 Analytic Systems 493.1250 D6000 Moderate Complexity Laboratory Director 493.1403
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 College of American Pathologist (CAP) proficiency testing and interview with Testing Person #A the laboratory failed to enroll in proficiency testing for Hematology in 2021 and 2020. Findings Included: Review of CAP proficiency testing revealed no proficiency testing for Complete Blood Count (CBC) being performed on the QBC autoread plus Hematology analyzer in 2021 and 2022. Interview on 08/29/2022 at 1:20 PM Testing Person #A confirmed that the laboratory was not enrolled in proficiency testing for CBC testing in 2021 and 2022.
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 record review, observation, and interview the Laboratory failed to plate Throat cultures per their policy on 4 out of 4 patient samples observed on 08/29/2022. Findings Included: Review of Throat culture policy (signed by the Laboratory Director on 06/07/2022) revealed that throat cultures should be streaked across the top 1/3 of the Strep agar plate with "the cotton tip specimen" then "put oil lamp and sterilize the wire loop flame time till loop red". With the wire loop, streak through the original streak on the right 1/3 of the Strep agar plate, then streak through the bottom 1 /3 of the Strep agar plate. Observation of the laboratory on 08/29/2022 at 1:00 PM revealed 3 Strep agar plates that had break in the agar in the middle of the plate. On plate 1 there were 2 Patients plated with a streak across 1/3 of the plate for each patient. Growth could be observed growing across the break in the plate from one Patient to the other Patient. Plates 2 and 3 each had a break in the agar and 1 Patient on 1/3 streak on each plate. Interview on 08/29/2022 at 1:00 PM Testing Person #A confirmed that the staff made the break in the Strep agar plates to plate 2 Patients on one plate and the policy for plating was not being followed.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation, record review, and interview the Laboratory failed to perform maintenance on the QBC Hematology analyzer (See D5429), failed to run 2 levels of controls every day of patient testing (See D5447), used expired Strep agar plates (See D5417), and failed to perform visual inspection on agar plates (See D5477).
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation, record review, and interview the Laboratory used a Strep Agar plate that was expired for 1 Patient. Findings Included: Observations of the

	Laboratory on 08/29/2022 at 1:00 PM revealed Strep agar plated (Lot # 145157P) that expired on 08/24/2022. There was a Patient #1 that was observed to be plated on the expired Strep agar plate. The Patient #1's final report was pulled to reveal that the Strep agar plate was set up on 08/25/2022 and resulted out on 08/26/2022. Interview on 08/26/2022 at 3:00 PM Testing Person #A confirmed that an expired Strep agar plate was used on Patient #1.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory failed to perform maintenance on the QBC Autoread Plus Hematology analyzer in 2021 and 2022. Findings Included: Review of the "QBC Autoread Plus Operator's /Service Manual" revealed that "The rotor of the QBC Capillary Centrifuge is designed to spin at 12,000 +- 80 rpm. At least every 6 months or after any adjustments or repairs, check the rotor speed with a non-contact strobe tachometer to assure that speed is sufficient to produce visibly distinct and differentiated cell layers in the QBC tube." "The electronic timer of the Centrifuge is designed to be accurate to 300 +- 15 s. Check the timer for accuracy against a reliable stopwatch or quartz timer at least every 3 months". There was no documentation of the QBC centrifuge rpm or timer checks done in 2021 or 2022. Interview on 08/29/2022 at 1:20 PM Testing Person #A confirmed that the service provider no longer performed maintenance on the QBC Autoread Plus Hematology analyzer and that it did not get performed in 2021 or 2022.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview the Laboratory failed to run 2 levels of controls each day of testing for 2 out of 2 years (2021-2022) reviewed for CBC (Complete Blood Count), Urine cultures, and Throat cultures. Findings included: The Laboratory was performing CBCs on a QBC Autoread Plus. There were no Quality Control (QC) records available for review. Interview on 08/29/2022 at 1:20 PM the Testing Person #A confirmed that no QC was being performed in 2021 and 2022. There were 28 CBC tests reported in 2021 and 42 in 2022. The Laboratory was performing Urine cultures on Uricult Urine Paddles. There were no QC records available for review. Interview on 08/29/2022 at 1:20 PM the Testing Person #A confirmed that no QC was being performed in 2021 and 2022. There were 18 Urine cultures reported in 2021 and 26 in 2022. The Laboratory was performing Throat cultures on Strep plates. There were no QC records available for review. Interview on 08/29/2022 at 1:20 PM the Testing

	Person #A confirmed that no QC was being performed in 2021 and 2022 on the Strep plates, only on the Taxo discs weekly. There were 320 Throat cultures reported in 2021 and 260 in 2022.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview the Laboratory failed to document the physical characteristics of each batch of Uricult urine cultures for 2 out of 2 (2020-2022) years reviewed. This is a repeat deficiency from the 06/22/2020 recertification survey. Findings Included: Review of quality control (QC) records from 06/2020 to 08/2022 revealed no visual inspection of the physical characteristics of the Uricult urine cultures. Review of the plan of correction (signed by the Laboratory Director on 06/30/2020) from the 06/22/2020 recertification survey revealed that "Upon opening a new uricult box the Medical Assistant that open the box is responsible for performing a negative and positive control. Visually inspect uricult vials for damage. Documenting date of when new uricult box is open. Writing down the lot number, expiration date and condition of uricult along with their initials." Interview on 08/29/2022 at 3:00 PM Testing Person #A confirmed that the visual inspections were not being documented.
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 observation, record review, and interview the Laboratory Director failed to ensure a Quality Control plan was effective (See D6020) and failed to ensure the Laboratory had a Quality Assurance plan (See D6021).
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: Based on observation, record review, and interview the Laboratory Director failed to perform maintenance on the QBC Hematology analyzer (See D5429), failed to run 2 levels of controls every day of patient testing (See D5447), used expired Strep agar plates (See D5417), and failed to perform visual inspection on agar plates (See D5477).
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 record review and interview the Laboratory Director failed to follow their policy to maintain a QA (Quality Assurance) program for 2 out of 2 (2020-2022) years reviewed. Findings Included: Review of "Monthly Quality Assurance Checklist" revealed that there were no QA checklists completed from 06/2020 to 08/2022. Interview on 09/07/2022 at 1:52 PM the Laboratory Director confirmed that there were no QA checklists being completed.