Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0270243	03/01/2024
Name of Provider or Supplier	**Street Address, City, State**	
Professional Park Pediatrics Pa	1881 Professional Park Cir Ste 80, Tallahassee, 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 on - site announced CLIA recertification survey was conducted at Professional Park Pediatrics on 02/23/24-03/01/24. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on the laboratory Proficiency Testing procedure review and interview it was determined the Laboratory failed to rotate American Proficiency Institute (API) testing proficiency samples through all laboratory testing personnel for 2 of 2 years (2022-2023). Findings include: The laboratory Proficiency Testing (PT) procedure signed by the Laboratory Director 7/12/2004, stated samples were to be tested using the same personnel and methods as patient testing. The CMS-209 Laboratory Personnel Report, signed by the Laboratory Director 2/22/2024, listed 14 Testing Personnel (TP # A, B , C, D, E, F, G, H, I, J, L, M, and N). The Technical Consultant, who is listed as TP #B, stated 2/23/24 at 11:55 a.m. proficiency testing was not rotated through all testing personnel and that she performed all PT samples for 2022-2023.
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 American Proficiency Institute (API) Proficiency Testing (PT) records and interview it was determined the laboratory failed to maintain a copy of attestation statements, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for 2 of 2 years (2022-2023) reviewed. Findings include: The API PT records for 2022-2023 did not include signed attestation statements. The Technical Consultant confirmed 2/23/2024 at 11:55 a.m., the lab did not have signed attestation statements for proficiency testing performed in 2022-2023.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on observation of patient specimens and interview, the laboratory failed to ensure positive identification and optimum integrity of patient's specimens from the time of collection or receipt of the specimen through completion of testing and reporting of results for 4 of 5 patient specimens in the laboratory at the time of the survey. Findings include: 1. Observation on 2/23/24 at 10:20 a.m., patient urine specimens 3 of 4 were labeled with first name only and 1 of 1 throat swab was not labeled at all. 2. On 2/23/24 at 10:20 a.m., the Technical Consultant stated patient samples were to be labeled with first name and time. The Technical Consultant confirmed the 1 of 1 throat swab was not labeled with any identifier and the 3 of 4 urine samples were not labeled according to the laboratory procedure.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on record review and interview with the Technical Consultant, the laboratory failed to ensure testing was performed following the manufacturer's instructions for 4

	of 4 daily Urine and Throat culture logs reviewed. Findings include: 1. The laboratory used Hardy Diagnostics media. The manufacturer's instructions state "incubate plates for 18-24 hours. 2. Reviewed patient logs dated 09/30/22, 12/29/22, 12/20/23, and 07 /13/23 failed to indicate how long urine cultures and throat cultures were incubated before being read. 3. The Technical Consultant stated on 02/23/24 at 12:20 p.m. inoculated patient cultures for urine and throat were incubated overnight and read the following morning. The Technical Consultant confirmed there was no method to monitor inoculated plates prior to interpretation to ensure they were incubated for 18-24 hours.
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 the Throat and Urine culture media received 8/17/2022-11/29/2023. Findings include: The laboratory performed throat cultures using Blood Agar and urine cultures using TSA 5% Sheep Blood/MacConkey Agar Bi-Plate. The laboratory media Quality Control Log sheets for media received 8/17/2022-11/29/2023 did not indicate which media type was being checked or if it was acceptable. The Technical Consultant stated 2/23/2024 at 11:55 a.m., the visual check of media was performed but there was no documentation of which media or if it was acceptable.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on record review and interview with the Technical Consultant, the Laboratory failed to identify of the personnel who performed the testing for 4 of 4 patients reviewed. Findings include: 1. A random review of 4 patient test reports dated 12/29 /22, 09/30/22, 12/20/23, and 07/13/23 (for patients #1-4 respectively) did not have any indication who performed the testing. 2. The Technical Consultant on 2/23/24 at 12:20 p.m.,confirmed there was no method in place to identify the person who performed the testing.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of College of American Pathologist (CAP) and American Proficiency Institute (API) proficiency records and interview it was determined the laboratory director failed to ensure the laboratory was enrolled in a proficiency testing program for Microbiology testing performed for 1 of 2 years (2022-2023) reviewed. Findings include: The Laboratory was enrolled in CAP in 2022 and API in 2023 and 2024. Review of API proficiency records for 2023 did not include any records for the first event for Group A Strep Antigen, Susceptibility Testing, Throat culture, Urine Colony Count or Urine Identification.. There were no records for Susceptibility Testing for the 2nd testing event in 2023. The Technical Consultant confirmed on 02 /23/2024 at 11:55 a.m., the laboratory failed to enroll with a proficiency program for 2023 until after the first event deadline had passed.