Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0860364	12/22/2023
Name of Provider or Supplier	**Street Address, City, State**	
Pediatrics At Chartley Pa	210 Business Center Drive, Reisterstown, MD	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the laboratory director (LD), the laboratory failed to attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. Findings: 1. Records for three PT events were reviewed. 2. Records for PT events D1-C 2022 and D1-B 2023 included the attestation form with the names of the testing personnel (TP) typed into the form, but not signed by the TP who performed the PT. 3. Event D1-A 2023 was performed and evaluated after the PT provider's deadline. A signed attestation form was not included in the PT records. 4. During the survey on 12/15/2023 at 11:15 AM, the LD confirmed that the attestation forms were not signed by the TP performing the PT.
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 review of temperature logs and interview with the laboratory director (LD), the laboratory failed to ensure refrigerator temperature logs were maintained for at

	least 2 years. Findings: 1. The laboratory stored culture plates and Taxo A discs in the refrigerator designated "Private." 2. Temperature logs for the "Private" refrigerator were reviewed from 05/2022 through 11/2023. 3. Temperature logs for the "Private" refrigerator were missing from 10/2023 and 05/2022-09/2022. 4. During the survey on 12/15/2023 at 11:15 AM, the LD confirmed that at the time of the survey, temperature logs for the "Private" refrigerator could not be located for 10/2023 and 05/2022-09 /2022.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the procedure, review of the group A Streptococcus (GAS) patient log, and interview with the laboratory director (LD), the laboratory failed to consistently record test results in the patient testing log. Findings; 1. The laboratory performed rapid and culture testing to screen throat specimens for GAS. 2. The testing procedure stated to "Perform Rapid Strep test per package insert. If the Rapid Strep Test is negative, inoculate a blood agar plate for culture" and to "Record the information in the lab log and in the patient's chart." 3. The log included columns for the "Date", "Patient Name", "D. O. B. [date of birth]", "Rapid Result", "MA [medical assistant] Initials", "Throat Culture Y/N", "24 / HR Culture" (culture result after 24 hours), and "Documented in chart". 4. When a throat culture was performed, a result of "+" was entered for positive and "-" was entered for negative. 5. Log entries for 219 patients from 02/03/2023-04/19/2023 and 06/15/2023-11/02/2023 were reviewed. 6. For 9 patients, the log recorded "N" in the "Throat Culture Y/N" column indicating that a throat culture was not performed and a "-" in the "24 / HR Culture" column. 7. For 2 patients, the log recorded a "-" in the "Throat Culture Y/N' column and a "-" in the "24 / HR Culture" column. 8. For 11 patients, the log recorded a "Y" in the "Throat Culture Y/N" column indicating that a throat culture was performed and the "24 / HR Culture" column was left blank with no culture result recorded. 9. During the survey on 12/15/2023 at 11:15 AM, the LD confirmed that the patient testing log was not completed in a consistent manner.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the laboratory

	director (LD), the LD failed to ensure the PT results evaluations were signed as reviewed. Findings: 1. Records for three PT events were reviewed. 2. The results evaluations for two of the three PT events (D1-C 2022 and D1-B 2023) were not signed as reviewed by the LD or designee. 3. During the survey on 12/15/2023 at 11: 15 PM, the LD confirmed that PT results evaluations were not signed as reviewed in two of three PT events.
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 Quality Assessment (QA) procedure and interview with the laboratory director (LD), the LD failed to ensure QA checklists were performed on a triannual basis as stated in the procedure. Findings: 1. The QA procedure stated "Monthly Quality Assessment Checklist - Laboratory director will review checklist and use results to guide corrective action" with an addendum that stated "Monthly quality Assessment checklist frequency is changed to every 4 months (August, December, April)." 2. The QA checklist included sections for General Laboratory Systems, Preanalytical Systems, Analytical Systems, and Postanalytical Systems. 3. The QA checklists from 08/2022-08/2023 were reviewed. 4. The QA checklist from 04 /2023 was not available at the time of the survey and the QA checklist from 12/2022 did not have the Analytical and Postanalytical Systems sections completed. 5. During the survey on 12/15/2023 at 11:15 AM, the LD confirmed that the QA checklist from 04/2023 was not available at the time of the survey.