Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0860364	05/12/2022
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
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 microbiology proficiency testing (PT) records and interview with the laboratory director (LD), the laboratory failed to ensure that the all PT records were being saved; the testing person who performed the test documented the results in the same manner as the patients; the attestation worksheets were being printed and saved; and the records were maintained for two years as required. Findings: 1. The PT records from the 2021 through the first event of 2022 (7 events) were reviewed. 2. The PT records showed that six of the seven events did not include a copy of the completed PT worksheet showing the results submitted to the PT agency. 3. The PT records showed that the attestation worksheets for six of the seven events were not signed by the laboratory director or the designee. 4. The patient logs showed that the PT samples were recorded along with the patients on one of seven events. 5. During the survey on 05/12/2022 at 2:15 PM, the LD confirmed that the PT records were not available and maintained for required two years.
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: A. Based on review of the Individualized Quality Control Plan (IQCP) and interview with the laboratory director (LD), the LD did not ensure that the IQCP included supporting data and quality control (QC) frequency and remedial actions to be taken for failures as part of the risk assessment. Findings: 1. The IQCP did not include the supporting data for making the assessment, e.g., package insert, documentation of successful proficiency testing results and documentation of successful quality control results. The IQCP did not include policies and procedures for QC frequency and remedial actions to be taken when there is a QC failure. 2. During the survey on 05/12 /2022 at 2:15 PM, the LD confirmed that the IQCP did not have supporting documentation and QC requirements. B. Based on review on the quality assurance (QA) procedure, monthly QA logs and interview with the LD, the LD did not ensure that the monthly QA reviews were performed as required. Findings: 1. The QA procedure requires monthly reviews to be performed and documented. 2. Review of the monthly QA worksheets from January 2020 through April 2022 showed that the monthly QA review was performed and documented 7 of 28 months. The monthly QA reviews that were performed showed that one of seven were signed and dated by the LD. 3. During the survey on 05/12/2022 at 2:15 PM, the LD confirmed that the monthly QA procedure had not been performed as required and the monthly QA reviews had not been signed and dated by the LD.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of the standard operating procedure manual (SOPM) and interview with the laboratory director (LD), the LD failed to provide approved policies and procedures for handling, performing, recording and maintaining all required records proficiency testing (PT) records. Findings: 1. The PT records from the 2021 through the first event of 2022 (7 events) were reviewed. The PT records were not being maintained as required. Cross refer to Tag D2015. 2. Review of the SOPM showed that there were no written policies and procedures handling, performing, recording and maintaining all required records PT records. 3. During the survey on 05/12/2022

	at 2:15 PM, the LD confirmed that there were not written instructions for maintaining the required PT records to ensure that they were available for review at the time of the recertification survey.