Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0860364	09/25/2019
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
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 review of the written procedure manual and interview with the laboratory director (LD), the laboratory did not follow the manufacturer ' s package insert for performing throat cultures with the Taxo A Disc. Findings: 1. The laboratory did not follow the Taxo A Disc package insert for performing throat cultures. 2. The laboratory was incubating patient throat cultures inoculated with the Taxo A Disc between 35-37 degrees Celsius for 24 to 48 hours. 3. The Taxo A Disc package insert states to incubate plates with the Taxo A Disc in ambient air at 35 to 37C for 18 to 24 hours. 4. The LD confirmed that the laboratory did not follow the Taxo A Disc package insert for performing throat cultures.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on review of the written procedure and interview with the laboratory director (LD), the laboratory did not establish an Individualized Quality Control Plan (IQCP) for performing throat culture testing. Findings: 1. The laboratory did not perform two levels quality control procedures with a positive and negative control organisms each day of patient testing. 2. The laboratory performs throat culture testing for Beta Hemolytic Strep A. 3. The laboratory performs QC once a week with the Taxo A Disc and the Strep Select Agar plate. 3. The laboratory did not perform an IQCP that included a risk assessment, quality control plan, and a quality assessment plan. 4. The LD confirmed that an IQCP was not performed.
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 written procedure manual and interview with the laboratory director (LD), the LD did not establish and maintain quality assessment (QA) programs for the overall quality of the laboratory. Findings: 1. The laboratory director did not establish programs for the preanalytic, analytic, and postanalytic phases of patient testing to ensure the overall quality of patient testing 2. The laboratory director did not perform QA procedures for "laboratory safety, personnel policies, proficiency testing, patient test management, and quality control". 3. Quality assessment procedures are needed for the preanalytic, analytic, and postanalytic phases of patient testing to ensure the overall quality of patient testing and laboratory services provided. 4. The LD confirmed that QA procedures were not performed.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with the testing

	person, the laboratory director did not specify in writing the duties and responsibilities of all persons involved in laboratory testing. Findings: The laboratory director did not have written duties and responsibilities for all personnel involved in the preanalytic, analytic, and postanalytic phases when performing bacteriology patient testing.
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 training and competency procedures and interview with the laboratory director (LD) , the LD acting as the technical consultant (TC) did not perform competency procedures that included, direct observations, problem solving skills, proficiency testing, maintenance and function checks, preventative maintenance, and reporting patient test results. Findings: 1. The LD acting as the TC did not have training and competency procedures for testing personal performing bacteriology testing. 2. The LD stated that competency procedures that included direct observations, problem solving skills, proficiency testing, maintenance and function checks, preventative maintenance, and reporting patient test results was not performed.