Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1047729	07/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Pediatricare Associates	901 Route 23, Pompton Plains, NJ	

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 surveyor review of the Proficiency Testing (PT) records and interview with the Testing Supervisor (TS), the laboratory failed to have the work records for all of the American Associates of Bioanlalysts (AAB) PT events for Throat Culture in the calendar years of 2023, 2022 and 2021. The findings include: 1. There were no work records for Throat Culture AAB PT events M1-2023, Q3-2022, Q2-2022, Q1-2022, Q3-2021 and Q2-2021 2. The TS confirmed on 7/13/23 at 10:35 AM work records were not available for the above listed PT events for review.
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 surveyor review of the Quality Control (QC) records and interview with the Technical Supevisor (TS) the laboratory failed to retain Certificates of Analysis (COA) for Selective Strep Agar (SSA) media from 12/22/21 to the date of the survey. The TS confirmed on 7/13/23 at 10:00 am that the COA for SSA media were not retained.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records and interview with the Testing Supervisor (TS) the laboratory failed to follow its policies and procedures for assessing the competency of Testing Personnel (TP) who perform Bacteriology for the calendar years of 2022 and 2023. The findings include: 1. The laboratory failed to use all the required elements applicable to Bacteriology for assessing the competency of TP. The laboratory did not use: a) #2. Monitoring the recording and reporting of test results; b) #3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; c) #4. Direct observations of performance of instrument maintenance and function checks; d) #5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and e) #6. Assessment of problem solving skills. 2. 3 out of 3 TP did not have the above listed elements on their CA for Bacteriology for the calendar year 2022. 3. 7 out of 7 TP did not have the above listed elements on their CA for Bacteriology for the calendar year 2023. 2. The TS confirmed on 7/13/23 at 10:30am the laboratory failed to follow the CA procedures for the calendar years 2022 and 2023.
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: A) Based on surveyor review of the Procedure Manual (PM) and interview with Technical Supervisor (TS), the laboratory failed to have procedures for Throat Culture testing from 5/1/2010 to the date of survey. The findings include: 1. The procedure for "Strep Plate- Selective Strep plates" did not indicate an incubation time or incubation temperature for innoculated Selective Strep Agar (SSA) media. 2. The TS confirmed on 7/13/23 at 10:30 am that the above mentioned elements were not indicated in the the procedure for "Strep Plate- Selective Strep plates."

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 surveyor review of the Quality Control (QC) records and interview with the Technical Supervisor (TS), the laboratory failed to check each new lot number and shipment of Selective Strep Agar (SSA) media for it ability to inhibit specific organisms from 11/30/16 to the date of the survey. The TS confirmed on 7/13/23 at 11:30 am the laboratory did not perform the above metioned QC on SSA media.
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 the surveyor review of the Quality Assurance (QA) policy and interview with the Techincal Consultant (TC), the Laboratory Director (LD) to failed ensure that the QA program was maintained from 9/26/19 to the date of survey. The finding includes: 1. The QA program states "the laboratory must have an ongoing mechanism to evaluate the effectiveness of its policies and procedures for assuring employee competence." 2. The LD failed to ensure employee competencey assessment procedures were followed in the calendar years of 2022 and 2023. 3. The TC confirmed on 7/13/23 at 11:20 am that the LD did not maintain the QA program.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Technical Supervisor (TS), the Laboratory Director failed to ensure that the laboratory maintained a QC program from 11/30/16 to the date of the survey. The findings include: 1. The LD failed to ensure the laboratory checked each new lot number and

	shipment of Selective Strep Agar (SSA) media for its ability to inhibit specific organisms. 2. The TC confirmed on 713/23 at 10:30 am the LD did not ensure the QC program was maintained.