

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0081613	(X3) Date Survey Completed 08/08/2024
Name of Provider or Supplier Pediatric Associates Of Fall River	Street Address, City, State 851 Middle Street, Fall River, MA	
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on the College of American Pathologists (CAP) proficiency testing (PT) record review and confirmed through an interview with the Laboratory Supervisor (LS) and Laboratory Director (LD), the laboratory did not enroll in PT for complete blood count (CBC) testing in the specialty of Hematology. Findings include: 1. Record review on 8/7/2024 of the laboratory's CASPER Report 0096D, CLIA Application and Survey Summary Report revealed there were no scores reported to CMS in 2023 and 2024 to date for the regulated Hematology analytes white blood cell differential, red blood cell count, white blood cell count, hemoglobin, hematocrit and platelets. 2. Record review on 8/7/2024 of the laboratory's 2023 and 2024 to date PT records revealed the laboratory did not have PT records for the analytes in #1 above. 3. Record review on 8/7/2024 of the laboratory's CBC volume report revealed the laboratory was performing CBC testing until 3/12/2024. 4. Staff interview with the LS and LD on 8/7/2024 at 12:15 PM confirmed the laboratory was performing CBC testing in 2023 and up until 3/12/2024 and was not enrolled in PT. The LS stated, CBC testing was temporarily stopped as of 3/13/2024 because the laboratory has purchased a new CBC analyzer and the old analyzer is unreliable. 5. The laboratory performs 1,428 tests annually in the specialty of Hematology.</p>

<p>D2006</p>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to test proficiency testing (PT) samples in the same manner as patient samples by testing personnel who routinely perform the testing in the subspecialty of Bacteriology. This is a repeat deficiency cited at the 11/15/2022 survey. Findings include: 1. Record review on 8/7/2024 of the laboratory's College of American Pathologists (CAP) 2023 PT Bacteriology Survey D attestation sheets record revealed 4 of of 13 bacteriology TP who perform throat cultures did not participate in PT in 2023. 2. Staff interview on 8/7/2024 at 12:15 PM with the laboratory supervisor and laboratory director confirmed the above findings. 3. The laboratory performs 2,577 throat cultures annually in the subspecialty of bacteriology.</p>
<p>D6019</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)</p> <p>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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the College of American Pathologists (CAP) proficiency testing (PT) results and confirmed through an interview with the laboratory director (LD), the LD failed to ensure that an approved corrective action plan was followed when PT results were found to be unacceptable as evidenced by the following: 1. Record review on 8/7/2024 of the laboratory's 2023 CAP PT results revealed: a. The laboratory received a score of 93% for Virology Nucleic Acid Amp, Respiratory LTD 2023 Event 2. b. The CAP result sheet with the unacceptable result was signed as reviewed by the LD on 9/11/2023. c. The LD failed to investigate or document corrective action for the above unacceptable PT score. 2. Staff interview with the LD on 8/7/2024 at 12:15 PM confirmed the above findings. 3. The laboratory performs 6,807 tests annually in the specialty of Microbiology.</p>
<p>D6021</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of</p>

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 record review and confirmed through an interview with the laboratory director (LD), the LD failed to ensure a quality assurance program was established and maintained to assure the quality of laboratory services provided. 1. Record review on 8/7/2024 of the laboratory's procedure manual revealed the procedure manual did not have written policies to monitor and evaluate the ongoing and overall quality of the total testing process (pre-analytic, analytic, postanalytic). 2. Staff interview on 8/7/2024 at 12:15 PM with the LD confirmed the above findings. 3. The laboratory performs 8,235 tests annually.