

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2155580	(X3) Date Survey Completed 11/21/2024
Name of Provider or Supplier Pediatric Associates Of Mobile	Street Address, City, State 740 Museum Drive, Suite E, Mobile, AL	
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on a review of the API (American Proficiency Institute) Proficiency Testing (PT) records, and an interview with the Technical Consultant (TC) who is also the Testing Personnel (TP), the laboratory failed to ensure proficiency testing samples were rotated among all personnel who performed moderate complexity patient testing. This was noted on four out of seven Hematology events reviewed from 2022 to 2024. The findings include: 1. A review of API attestation statements revealed TP had performed the following Hematology PT events: a) 2023 Hematology 1st Event b) 2023 Hematology 2nd Event c) 2023 Hematology 3rd Event d) 2024 Hematology 1st Event 2. During an interview on 11-21-2024 at 1252 PM, TC confirmed the above findings.</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with the Technical Consultatnt (TC), the Testing</p>

	<p>Personnel (TP) and the Laboratory Director (LD) (or Designee) failed to sign the PT attestation statements for the specialty in Hematology. This was noted in two of the seven events reviewed from 2022 to 2024. The findings include: 1. A review of the API PT records revealed no signature by the TP or LD on attestation statements for the following surveys: a) 2022 Hematology 3rd Event was missing TP signature. b) 2024 Hematology 2nd Event was missing LD and TP signatures. 2. During an interview on 11-21-2024 at 12:52 PM, the TC confirmed the above findings.</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 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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Policies and Procedures and an interview with the Technical Consultant (TC), the Laboratory Director (LD) failed to establish and maintain a Quality Assurance Program (QAP) to assure the quality of laboratory services provided. This was noted from the implementation of the Policy and Procedure Manual on 7-11-2022, to the date of the current survey, 11-21-2024. The findings include: 1. A review of Policies and Procedures revealed no evidence of a QAP established and maintained for the laboratory patient testing services from 2022 to 2024. 2. During an interview on 11-21-2024 at 12:52 PM, the TC confirmed the above findings.</p>
<p>D6053</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the personnel records and an interview with Technical Consultant (TC), the TC failed to evaluate semi-annual competencies for Testing Personnel (TP) performing moderate complexity testing from 2022 to 2024. This was noted for four out of four testing personnel listed on the CMS-209 (Laboratory Personnel Report) submitted on the current survey date of 11-21-2024. The findings include: 1. A review of the personnel records revealed no evidence of evaluation by the Technical Consultant for the semi-annual competencies for four of the four TP listed on the current CMS-209 (Laboratory Personnel Report). 2. During an interview on 11-21-2024, at 10:30 AM, TC confirmed the above findings.</p>
<p>D6054</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the</p>

performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on a review of the personnel records and an interview with Technical Consultant (TC), the TC failed to evaluate annual competencies for Testing Personnel (TP) listed on the CMS-209 (Laboratory Personnel Report) and performing moderate complexity testing. The surveyor noted four out of four TP previously qualified since the date of the last survey, 6-9-2022 to the date of the current survey, 11-21-2024. The findings include: 1. A review of the personnel records revealed no evidence of evaluation by the Technical Consultant for annual competency assessments for four out of four TP listed on the CMS-209 (Laboratory Personnel Report). 2. During an interview on 11-21-2024, at 10:30 AM, TC confirmed the above findings.