

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2079996	(X3) Date Survey Completed 06/17/2022
Name of Provider or Supplier Pediatric Associates	Street Address, City, State 10710 Fl 54 Ste 108, Trinity, FL	
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
D0000	An announced CLIA recertification survey was conducted at Pediatric Associates of Tampa Bay LLC on 06/17/22. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D6033 - 42 CFR 493.1409: Laboratories performing moderate complexity testing; technical consultant
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with Testing Personnel #D, the laboratory failed to have documentation of competency assessments for one (#D) out of three (#B, #C, and #D) Testing Personnel for two out of two years reviewed (2020-2022). Findings Included: Review of the CMS 209, Laboratory Personnel Report, signed by the Laboratory Director on 06/17/22 revealed three Testing Personnel (#B, #C, and #D). Review of the policy titled "LAB 101 Laboratory Director's Responsibilities/Job Description/Delegation signed by the Laboratory Director on 10/15/21 revealed "11. Monitoring personnel in all phases (pre-analytic, analytic and post-analytic) of testing to assure the ongoing competency of all individuals who perform testing, including completed 6 month competency and annul [sic] competency documents." Review of Testing Personnel #D's file revealed no competency records were present. On 06/17 /22 at 12:50 PM, Testing Personnel #D stated she performed testing when the laboratory was short staffed. Testing Personnel #D confirmed the laboratory had not performed competency assessments on her.</p>
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY

CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

Based on record review and interview, the laboratory failed to have a qualified Technical Consultant in the Specialty of Hematology and Subspecialties of Bacteriology and Routine Chemistry from 09/24/21 to 06/17/22 with an annual estimated test volume of 2,750 (See D6034).

D6034

TECHNICAL CONSULTANT QUALIFICATIONS

CFR(s): 493.1411

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to have a qualified Technical Consultant to provide technical oversight of the testing process from 09/24/21 to 06/17/22. Findings Included: Record review of the CMS 209, Laboratory Personnel Report, signed by the Laboratory Director on 06/17/2022 revealed the Laboratory Director also functioned as the Technical Consultant for moderate complexity testing in the Specialty of Hematology and Subspecialties of Bacteriology and Routine Chemistry. Review of the CMS-116, Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, signed by the Laboratory Director on 6/17/22 revealed the estimated annual test volume for Hematology was 2400, Bacteriology was 150, and Routine Chemistry was 200 for a total estimated test volume of 2,750. Review of Laboratory Director's personnel records revealed she became the Laboratory Director on 9/24/21. Review of the Laboratory Director's Curriculum Vitae (CV) and additional education/training records revealed no evidence of 1 year of laboratory training. Record review of the laboratory's policy titled "LAB 101 Laboratory Director's Responsibilities/Job Description/Delegation" revised 12/16/19 revealed "The Laboratory Director is responsible for the overall operation and administration of the laboratory...The Lab Director is also the Technical Consultant..." On 06/17/22 at 12:45 PM, the Diagnostics Services Director stated she did not know that the Laboratory Director needed 1 year of laboratory training to become the Technical Consultant.