

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2028521	(X3) Date Survey Completed 06/27/2019
Name of Provider or Supplier Pediatric Associates, Pc	Street Address, City, State 2863 Johnson Ferry Road, Suite 100, Marietta, GA	
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	A Clinical Laboratory Improvement Amendments (CLIA) Recertification survey was completed on June 27, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
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 review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory failed to establish and follow written policies and procedures to assess testing personnel (TP) competency. Findings include: 1. SOP review revealed there was not a six-procedure CLIA competency policy and procedure to assess TP competency (initial, six-month, and annual thereafter). 2. An interview with Staff #1 (CMS 209) in a conference room on 6/27/2019 at approximately 4:00 p.m. confirmed there was not a six-procedure CLIA competency policy in the laboratory SOP.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step</p>

performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
 Based on review of the policy and procedure manual (SOP) and staff interview, the laboratory failed to include required policies and procedures when applicable to laboratory testing. Findings include: 1. SOP review revealed there was not a policy and procedure for specimen storage and retention. 2. SOP review revealed there was not a policy and procedure for record retention. 3, An interview with Staff #1 (CMS 209) in a conference room on 6/27/2019 at approximately 4:00 p.m. confirmed the aforementioned policies and procedures were not in the laboratory SOP at the time of survey. REPEAT DEFICIENCY

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
 CFR(s): 493.1413(b)(9)

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.

This STANDARD is not met as evidenced by:
 Based on testing personnel (TP) document review and staff interview, the technical consultant/laboratory director (TC/LD) failed to perform a six-month TP competency as required. Findings include: 1. TP document review revealed the TC/LD failed to perform a six-month competency in 2018 on Staff #6 (CMS 209). 2. An interview with Staff #1 (CMS 209) on 6/27/2019 in a conference room at approximately 4:00 p. m. confirmed the lack of TP competency.

D6063

LABORATORY TESTING PERSONNEL
 CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:
 Based on review of testing personnel (TP) documentation and staff interview, the laboratory employed unqualified laboratory TP due to lack of education documentation Refer to D6065 for details.

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on review of testing personnel (TP) documentation and staff interview, the laboratory employed unqualified laboratory TP due to lack of education documentation. Findings include: 1. TP document review revealed Staff #6 (CMS 209) was unqualified to perform laboratory testing due to lack of education documentation 2. An interview with Staff #1 (CMS 209) in a conference room on 6/27 /2019 at approximately 4:00 p.m. confirmed the lack of education documentation for the aforementioned TP at the time of survey. REPEAT DEFICIENCY