

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D0960104	<b>(X3) Date Survey Completed</b>  03/23/2022
<b>Name of Provider or Supplier</b>  Pediatric Associates Of Dearborn	<b>Street Address, City, State</b>  2331 Monroe St, Dearborn, MI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:                      . Based on observation and interview with Testing Personnel #1 (TP1), the laboratory failed to retain all abnormal, out of range quality control records for at least two years for 2 (March 2020 to March 2022) of 2 years. Findings include; 1. The surveyor observed a sticky note taped on the laboratory's Beckman Coulter Act Diff hematology analyzer stating, "If control is abnormal please delete it and rerun" on 3/23 /22 at 9:07 am. 2. An interview on 3/23/22 at 9:09 am with TP1 revealed controls that are not in range are deleted and the information is not retained.</p>
<b>D6033</b>	<p><b>TECHNICAL CONSULTANT-MODERATE COMPEXITY</b> CFR(s): 493.1409</p> <p>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.</p> <p>This CONDITION is not met as evidenced by:                      . Based on record review and interview with Testing Personnel #1, the laboratory failed to ensure Testing Personnel #1, performing the duties of a Technical Consultant, met the qualification requirements at 493.1411. Findings include: 1. The laboratory failed to ensure the personnel performing the Technical Consultant duty of performing testing personnel competency assessments were qualified. Refer to</p>

D6035. \*\*\*This is a repeated Condition-Level deficiency from the 2/12/20 recertification survey\*\*\*

**D6035**

**TECHNICAL CONSULTANT QUALIFICATIONS**  
CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

. Based on record review and interview with Testing Personnel #1, the laboratory failed to ensure personnel performing the Technical Consultant duty of performing testing personnel competency assessments was qualified for 1 (Testing Personnel #1) of 4 testing personnel listed on the CMS-209 form. Findings include: 1. A review of the laboratory's personnel competency records revealed Testing Personnel #1 had performed a competency assessment for Testing Personnel #2 on 3/15/22. 2. A review of the qualifications for Testing Personnel #1 revealed they did not meet the qualification requirements to perform Technical Consultant responsibilities. 3. A review of the laboratory's "Quality Assurance Plan" revealed a section stating, "At least annually, the laboratory director and/or technical consultant will review the performance of each staff member working in the lab to assure employee competency, The written result of the review will be filed in the individual's personnel file." 4. An interview with Testing Personnel #1 on 3/23/22 at 9:34 am confirmed Testing

Personnel #1 had performed the competency assessment for Testing Personnel #2 and did not meet the qualification requirements to be a Technical Consultant. .

**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 record review and interview with Testing Personnel #1 (TP1), the Technical Consultant failed to evaluate the performance at least semiannually in the first year of employment for 1 (Testing Personnel #3) of 4 testing personnel on the CMS-209 form. Findings include: 1. A review of the laboratory's personnel records revealed Testing Personnel #3 was hired on 10/20/20 and had competency assessments performed on 10/22/20 and 10/5/21. 2. A review of the laboratory's "Competency Requirements" revealed a section stating, "Regulation 493.1413 b (9) refers to the frequency of the competency evaluations. Evaluating and documenting the performance of individuals responsible for moderate complex testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually." 3. An interview on 3/23/22 at 11:18 am with TP1 confirmed the Technical Consultant did not assess the competency of Testing Personnel #3 at least semiannually during the first year of patient specimen testing.