

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D0622078	(X3) Date Survey Completed 10/12/2020
Name of Provider or Supplier Pediatric Associates Of The Northwest	Street Address, City, State 7150 Sw Dartmouth Street, Tigard, OR	
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 review of Proficiency Testing (PT) documents provided for review during survey and discussion with the Technical Consultant (TC), the laboratory failed to ensure PT samples were rotated among testing personnel (TP). Findings include: 1. Upon review of the PT documentation for all three (3) events in 2020, the laboratory failed to rotate the PT events with different TP. 2. One TP out of seven (7) performed all three (3) PT events in 2020. 3. An interview with the TC on 10/12/20 at approximately 1200 confirmed this.</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 review of Proficiency Testing (PT) documents for 2018, 2019, and 2020, the laboratory failed to ensure the attestation form was signed by the Laboratory Director (LD) each time PT was performed and submitted. Findings include: 1. Seven (7) PT events were examined during survey, three (3) for 2020, three (3) for 2019 and one (1) for 2018. Three (3) out of seven (7) had no attestation form signed and available for</p>

	<p>review during survey 10/12/2020. 2. An interview with the TC on 10/12/20 at approximately 1200 confirmed this.</p>
<p>D3011</p>	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on review of safety records and interview with one Testing Personnel (TP), the laboratory failed to ensure the eyewash equipment was tested weekly according to laboratory policy. Findings include: 1. Upon review of the written records for checking the eye wash weekly, it was noted that the eye wash had not been checked by TP since the first week of September 2020, creating a possible safety hazard if it was inoperable. 2. The one TP interviewed during survey 10/12/2020 confirmed it had not been done.</p>
<p>D5200</p>	<p>GENERAL LABORATORY SYSTEMS CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of the quarterly Quality Assurance (QA) policy and QA records available for review during survey, the Technical Consultant (TC) failed to follow the laboratory's policy for quarterly QA review. Findings include: 1. The written policy for performing quarterly QA assessment submitted as a part of their plan of correction (POC) after survey 08/07/2018 has not been followed. This policy includes personnel competency, complaints, proficiency testing and chart review. 2. The TC confirmed during interview 10/12/2020 at approximately 1100 that he had not followed the revised quarterly QA policy submitted with the POC for deficiencies from survey on 08/07/2018. 3. When asked for written documentation of quarterly QA records for 2019 and 2020, only two (2) documents could be produced for 2019 and 2020. One from 06/06/2019 and one from 01/02/2020. 4. The written QA document from 01/02/2020 was conducted and signed by one of the testing personnel (TP) not qualified to assess items on the QA checklist document including written documentation of training and competency of other TP and monitoring of their QA program for compliance. 5. This is a repeat deficiency. 6. See Dtag 5209 and 5291.</p>
<p>D5209</p>	<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,</p>

consultant competency.

This STANDARD is not met as evidenced by:

Based upon the lack of written personnel training and competency records and discussion with the Technical Consultant (TC), no written documentation of training and competency of testing personnel (TP) and TC could be produced for 2019 and 2020. Findings include: 1. No written personnel training or competency records as stated in the Quality Assurance checklist for seven (7) TP could be produced for 2019 and 2020. 2. No written competency records for the TC could be produced for 2019 and 2020.

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on review of written Quality Assurance (QA) records and discussion with the Technical Consultant (TC), the laboratory failed to follow the revised policy on quarterly QA reports and assessments submitted with the Plan of Correction 08/21 /2018. Findings include: 1. For the year 2019 and 2020, there are only two written quarterly QA documents/checklists available for review, dated 06/06/2019 and 01/02 /2020. 2. This is a repeat citation.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on written records and interview with one Testing Personnel (TP) during survey 10/12/2020, the laboratory failed to ensure the policy for manually recording refrigerator and freezer daily temperatures was being followed. Findings include: 1. Review of the first half of October 2020 (eight (8) out of eight (8) clinical days) the refrigerator and freezer temperatures had no written entries. 2. . The TP interviewed during survey 10/12/2020 confirmed it had not been done "because they were too busy". She was the TP assigned to this duty for the month of October 2020 on a wall chart in the lab area.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on the lack of testing personnel (TP) education, training and competency records and interview with the Technical Consultant (TC), the Laboratory Director (LD) failed to ensure all TP had the required educational documents on file and initial training, 6 month competencies and 12 month competencies. Additionally, no written competency assessment for the TC could be produced during survey 10/12/2020. Findings include: 1. There were no diplomas or transcripts available for review for the five (5) new TP during survey 10/12/2020. 2. No initial training, 6 month competencies or 12 month competencies could be produced for five (5) new testing personnel (TP) during survey 10/12/2020. 3. The TC confirmed there were no written training or competency records for the five (5) new TP since last survey during interview 10/12/2020. 4. There were no written annual competency assessments for the two (2) long term TP for review during survey 10/12/2020. 5. The TC confirmed there were no written competency assessments for the two (2) long term personnel since the last survey 08/07/2018. 6. This is a repeat citation, see D6046.

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 review of Technical Consultant (TC) written records and discussion with TC during interview throughout the survey 10/12/2020, the TC failed to fulfill the responsibilities as described in 493.1409. Findings include: 1. No diplomas or transcripts for five new (5) testing personnel (TP) hired since the last survey 08/07 /2018 could be produced. 2. No documentation of initial training, 6 month competencies or 12 month competencies for the first year of employment could be produced for these five (5) TP. 3. No annual competencies for two (2) long term TP could be produced for 2019 or 2020. 4. During an interview with the TC 10/12/2020, the TC said "the TP train each other". 5. See D2007, D2009, D5209,D5291 and D6046

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

	<p>This STANDARD is not met as evidenced by: Based on review of written training and competency records for testing personnel performing moderate complexity testing, the Technical Consultant (TC) failed to fulfill his responsibilities. Findings include: 1. No written competency records for seven (7) out of seven (7) testing personnel (TP) since last survey 08/07/2018 could be produced during survey 10/12/2020. 2. The TC confirmed during survey 10/12/2020 that he had not performed competency assessment since the last survey 08/07/2018.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on the lack of written records for training and competency assessment of testing personnel (TP) and technical consultant (TC) competency assessment, quality assurance (QA) activities, proficiency testing (PT), safety with eye wash checks, recording of refrigerator and freezer temperatures and interview with the TC during survey, the Laboratory Director failed to fulfill his responsibilities. Findings include: 1. See D2007, D2009, D3011, D5209, D5291, D5413, D6029</p>
<p>D6094</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on review of written Quality Assurance (QA) policy and QA records produced for review during survey 10/12/2020, the Laboratory Director (LD) failed to ensure the quarterly QA policy was followed and documented for three (3) quarters in 2019 and two (2) quarters in 2020. Findings include: 1. See D5200, D5209, D5291 2. This is a repeat deficiency.</p>