

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D0623807	(X3) Date Survey Completed 11/09/2020
Name of Provider or Supplier Pediatric Associates Of The Northwest	Street Address, City, State 2701 Nw Vaughn Street Ste 360, Portland, 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
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 written testing personnel training and competency records, the laboratory failed to ensure all testing personnel (TP) performing Bilirubin, Hematology and Microbiology assays were trained and assessed for competency. Findings include: 1. Six (6) new Medical Assistants (MA's) were hired since the last survey dated 09/24/2018. Six (6) out of six (6) lack any written documentation of initial training for the Bilirubin assay on the Reichert Bilirubinometer or the Emerald Cell Dyne Complete Blood Count (CBC) Hematology analyzer. 2. Three (3) out of six (6) of the new MA's also had no written record of a six (6) or twelve (12) month competency on the Reichert Bilirubinometer or the Emerald Cell Dyne Complete Blood Count (CBC) Hematology analyzer. . 3. Two (2) out of six (6) of the new MA's had written competencies for the CBC analyzer documented as yearly competency assessment on 10/08/2020 but were new employees as of July 2020. 4. Two (2) of the long term MA's (employees for more than two (2) years) had no written yearly competency assessment for the CBC manual differential procedure for 2018 and 2019. 5. Two (2) out of two (2) of the TP performing Microbiology testing had no written competency assessment for 2019 and 2020. 6. There was no written competency assessments for the Technical Consultant (TC) on assays for the Reichert Bilirubinometer or the Emerald Cell Dyne Complete Blood Count (CBC) Hematology analyzer or the Technical Supervisor (TS) performing Microbiology assays for 2019 or 2020.</p>
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

Based on review of proficiency testing (PT) results and records in Microbiology and discussion with staff during survey 11/09/2020, the laboratory failed to review unsatisfactory performance in PT for three (3) events. Findings include: 1. For Microbiology PT event #3 in 2019, the identification of a gram negative rod organism was graded unacceptable. No corrective action (CA) or written documentation by the Technical Supervisor (TS) or Laboratory Director (LD) could be produced during survey. 2. For Microbiology PT event #1 in 2020, the identification of a gram negative rod organism was graded unacceptable. No corrective action (CA) or written documentation by the TS or LD could be produced during survey. 3. For Microbiology PT event #2 in 2020, the susceptibility of the antibiotic Tetracycline was graded unacceptable. No corrective action (CA) or written documentation by the TS or LD could be produced during survey. 4. Staff confirmed during interview 11/09/2020 at approximately 1 pm that no written documentation for the unacceptable PT performance could be produced.