

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D0213550	<b>(X3) Date Survey Completed</b>  01/23/2019
<b>Name of Provider or Supplier</b>  Pediatric Associates Of Mont Co	<b>Street Address, City, State</b>  12520 Prosperity Drive Ste 350, Silver Spring, MD	
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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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:                      A. Based on review of competency assessment records for laboratory (lab) staff and interview with the technical consultant, the lab director did not perform competency assessments for the technical consultant. Findings: 1. The competency assessments records for 2017 and 2018 did not include competency checks for the technical consultant; and 2. The technical consultant, during interview on the day of survey stated that the director did not perform competency checks for the duties she performs as technical consultant. B. Based on review of competency assessment records for laboratory (lab) staff and interview with the technical consultant, the lab did not ensure that all elements of the competency assessment for staff performing throat culture testing (reading selective strep agar plates) were performed. Findings: 1. Records show that only the proficiency testing was evaluated as the competency check for medical staff interpreting throat culture plates for presence or absence of Group A beta strep; 2. Lab staff were not evaluated by methods of observation, record review and problem solving as part of the competency check; and 3. The technical consultant, during interview in the morning of the day of survey stated that the staff performing the throat culture testing were only evaluated by proficiency testing.</p>
<b>D5441</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The</p>

laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and interview, the hematology lab did not have written quality control procedures to ensure accurate and reliable testing. Findings: 1. The technical consultant stated during interview on the day of the survey that the hematology quality control result(s) can be accepted if result(s) for two of the three quality control reagents fall within the manufacturers published range and that the lab did not take into account whether or not the third failed quality control result(s) exceeded three standard deviations from the mean of the published value or was unacceptable on consecutive days of testing; 2. The laboratory did not have written procedures instructing staff to not accept quality control results that are greater than 3 standard deviations (as given by the manufacturer) from the mean even though the other two quality control reagents fall within the manufacturers stated range; 3. The lab did not have written procedures instructing staff to not accept quality control results when a control result exceeds the manufacturers stated range on consecutive days of testing; 4. The laboratory accepted quality control results when one of the three hematology control results did not meet the manufacture's allowable range and that result was also greater than 3 standard deviations away from the mean value as given by the manufacturer; 5. On July 21, 2017 the normal result for the white blood cell count control was 7.0 [x10(3) microliters], the lab accepted this result even though it was greater than 4 standard deviations from the allowable mean, using the manufacturers statistics (the control reagent manufacturer limits for the normal WBC count are 8.2 to 9.6); 6. On July 5, 2017 the normal result for the white blood cell count control was 7.9 [x10(3) microliters], the lab accepted this result even though it was greater than 3 standard deviations from the allowable mean, using the manufacturers statistics (the control reagent manufacturer limits for the normal WBC count are 8.2 to 9.6); 7. On February 13, 2017 the normal result for the platelet count control was 284 and 269 [x10(6) microliters], the lab accepted the results (control was tested in duplicate) even though both values were greater than 3 standard deviations from the allowable mean, using the manufacturers statistics (the control reagent manufacturer limits for the normal RBC count are 168 to 248); 8. On January 30, 2017 the normal result for the platelet count control was 269 [x10(6) microliters], the lab accepted the result (control was tested in duplicate) even though it was greater than 3 standard deviations from the allowable mean, using the manufacturers statistics (the control reagent manufacturer limits for the normal RBC count are 168 to 248); and 9. The result of the high level quality control reagent for white blood cell count failed to meet the manufacturers stated range on 4/14/17 when the control also failed on the previous day of testing (4/7 /17).

**D5445**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--

(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

A. Based on record review, the lab did not perform quality control procedures and check strep select agar plates upon receipt. Findings: 1. The laboratory written quality control policy for selective strep agar (SSA) states that the agar plates will be documented upon receipt and the media characteristics will be documented to ensure media is not substandard quality; and 2. SSA plates with the lot numbers 1709502 (expiration date: 7/12/17) and 1703905 (expiration date: 5/17/17) were not reported in the receipt records and did not have their characteristics evaluated upon receipt.

**D5469**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(10)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and interview, the lab did not verify that hematology quality control reagents provide results that agree with the manufacturers stated statistical performance (parallel quality control checks). Findings: 1. The lab did not have written procedures for verifying the performance of hematology quality control reagents prior to use and in parallel with the current reagents to be replaced; 2. The lab did not have quality control records showing that parallel quality control checks were performed prior to use of new control reagents; and 3. These findings were confirmed with the technical consultant during interview on the day of survey.