

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0219053	(X3) Date Survey Completed 02/06/2020
Name of Provider or Supplier Pediatric Center Llc,The	Street Address, City, State 5900 Waterloo Rd Suite 110, Columbia, MD	
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 record review and interview with the laboratory staff, the laboratory did not establish written policies and procedures for assessing the testing personnel as defined in subpart M- CFR 493.1413(b)(8) through (9). Findings: 1. The laboratory's written procedure manual did not include all the required elements for evaluating the competency of the testing personnel and assuring that they maintain their competency to perform test procedures and report test results promptly, accurately, and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to: direct observations of routine patient test performance, including patient preparation, if applicable; specimen handling, processing and testing; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and assessment of problem solving skills; and evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. 2. The laboratory's "Training Checklist" form was used to perform competency assessments. The form had not been updated after the laboratory began using the Cell-Dyn Emerald for hematology testing and referred to the "QBC" analyzer used previously; and 3. The "Training Checklist" form did not include all 6 required elements for evaluating the competency of testing personnel. 4. A review of</p>

competency assessment records showed that 9 of 9 testing personnel reviewed had been evaluated using the outdated "Training Checklist." 5. During an interview on 1/23/2020 at 12:15 PM, the laboratory staff confirmed that the policies and procedure manual did not include a written training program along with updated worksheets for the documentation of the training of the testing personnel and medical assistants who perform pre-analytical and analytical preparation.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

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 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 standard operating procedure manual (SOPM) review and interview with the laboratory staff, the laboratory did not ensure that there was an approved policy for how to run hematology quality control (QC) or the corrective actions to take when QC is out of range. Findings: 1. During a tour of the laboratory at 9:15 AM, it was observed that a page from the "Cell-Dyn Emerald Operator's Manual," "Principles of Operation," "Section 3-White Cell Flags" was posted on the cabinet above the hematology analyzer. Laboratory staff stated that this was the guide that testing personnel used when running hematology QC. 2. A review of the SOPM showed that the page from the operator's manual posted above the hematology analyzer was not included in the approved SOPM and that there were no other procedures for how and when to run hematology QC, how to determine if QC is acceptable before running patient specimens, what corrective actions to take when QC is out of range, or how to document corrective actions taken. 3. During an interview on 1/23/20 at 12:15 PM, the laboratory staff confirmed that the laboratory's SOPM did not include procedures for running hematology QC.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)

-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on calibration record review and interview with laboratory staff, the laboratory failed to ensure that calibrations for the hematology instrument were verified at least once every 6 months. Findings: 1. A review of calibration records from January, 2018 to January, 2020 for the Cell-Dyn Emerald hematology analyzer showed that calibration verifications were performed 10/9/18, 7/15/19, and 1/15/20. 2. During an interview on 1/23/20 at 10:40 AM, the laboratory staff stated that there had been a large turnover of laboratory staff and confirmed that calibration verifications had not been performed at least every 6 months.

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.

This STANDARD is not met as evidenced by:

The laboratory director (LD) acting as technical consultant (TC) did not ensure that the testing personnel performing hematology testing were evaluated for competency using the 6 competency assessment criteria. Cross-refer to D5209