

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D1019005	(X3) Date Survey Completed 07/02/2019
Name of Provider or Supplier Pediatric Partners Of Northern Virginia, Pc	Street Address, City, State 4211 Fairfax Corner East Avenue - Suite 225, Fairfax, VA	
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
D0000	An announced CLIA recertification survey was conducted at Pediatric Partners of Northern Virginia, PC on July 2, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies are as follows:
D2020	<p>BACTERIOLOGY CFR(s): 493.823(a)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records and an interview with Testing Personnel D (TP D), the laboratory failed to attain a score of at least eighty (80) percent (%) of acceptable responses for one (1) of six (6) Bacteriology-Throat Culture events reviewed from October 2017 until July 2019. Findings include: 1. Review of the laboratory's PT records for Medical Laboratory Evaluations (MLE) events 2017 M2, 2017 M3, 2018 M1, 2018 M2, 2018 M3 and 2019 M1 (a total of 6 events reviewed) revealed a score of 50% for Bacteriology Throat Culture in MLE event 2017 M3. 2. In an exit interview with TP D at approximately 11:45 AM, TP D confirmed the findings.</p>
D2026	<p>BACTERIOLOGY CFR(s): 493.823(d)</p> <p>(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) Remedial action must be taken and documented, and the documentation must be</p>

maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's procedure manual, proficiency testing (PT) records, and interview with Testing Personnel D, the laboratory failed to follow established policies to review unsatisfactory test results and discuss with involved staff for one (1) unsatisfactory scored event out of six (6) Bacteriology-Throat Culture PT events reviewed from October 2017 until July 2019. Findings include: 1. Review of the laboratory's policy and procedure manual revealed a policy, "Quality Assurance Pediatric Partners of Northern Virginia", which stated "2. A single unsatisfactory test results for throat will be reviewed by all laboratory personnel, with potential errors being discussed with all involved staff. 3. The effectiveness of any interventions will be assessed in the following round of testing." 2. Review of the laboratory's PT records from October 2017 until July 2019, a total of six (6) events, revealed no evidence of review and discussion with involved staff for the 2017 M3 Bacteriology-Throat Culture scored as 50%. The surveyor requested documentation of the review and discussion. The laboratory provided no documentation. 3. In an exit interview with the Testing Personnel D at approximately 11:45 AM, TP D confirmed the findings.

D5415

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

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on a tour of the laboratory, review of the manufacturer's package insert (PI) and interview with Testing Personnel D (TP D), the laboratory failed to ensure three (3) of three (3) hematology quality control (QC) materials were not used beyond the manufacturer's opened-vial expiration date from June 12, 2019 until the date of the survey on July 2, 2019. Findings include: 1. A tour of the laboratory on 7/2/19 at approximately 9:15 AM revealed the laboratory utilizes the Cell Dyn 18 Plus Hematology QC materials. The surveyor observed 3 QC vials (lot number 9126 low, normal and high expiration date 8/23/19) with the hand-written dates of 6/4/19. In an interview at approximately 9:30 AM, TP D stated the date written on the vials was the date when the QC was first used. 2. Review of the Cell Dyn 18 Plus package insert revealed the following statement: "8 Consecutive Day Open-Tube Stability." 3. In an exit interview with TP D at approximately 11:45 AM, TP D confirmed the findings.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
 Based on a review of Abbott Cell Dyn Emerald manufacturer's operations manual, maintenance records, and an interview with Testing Personnel D, the laboratory failed to perform and document Abbott Emerald hematology instrument monthly and semi-annual maintenance procedures for twenty (20) of twenty (20) months reviewed. Findings include: 1. Review of the Abbott Emerald Operations Manual revealed maintenance instructions that stated: "Monthly Maintenance-Cleaning the system with bleach solution is to be performed monthly using 3.6 percent (%) hypochlorite (bleach) solution"; "Semi-annual Maintenance-For optimal operation, the syringe pistons are to be lubricated every six months". 2. Review of the laboratory's Emerald hematology maintenance logs revealed no documentation of performance of the monthly and semi-annual maintenance from November 2017 to July 2019. The surveyor requested documentation of the required monthly and semi-annual maintenance procedures. TP D stated, "We have never performed the semi-annual maintenance. Our field service representative may have performed it with the preventative maintenance." The laboratory provided no documentation of the monthly and semi-annual maintenance. 3. In an exit interview with TP D at approximately 11:45 AM, the findings were confirmed.

D5437

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

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:
 Based on the review Abbott Cell Dyn Emerald operator's manual, calibration records, and an interview with Testing Personnel D (TP D), the laboratory failed to follow the manufacturer's instructions for performing calibration procedures on the Abbott Cell Dyn Emerald hematology analyzer every six months from July 2018 until July 2019. Findings include: 1. Review of the manufacturer operator's manual for the Abbott Cell Dyn Emerald analyzer revealed the following statements: "Section 6- When to Calibrate-Criteria should be established for calibration verification. Calibration verification criteria include: When indicated by Quality Control data, after major maintenance and service procedures, at least every 6 months and as directed by the regulatory agencies governing the laboratory." 2. Review of calibration documents revealed calibration performed on February 15, 2018, July 31, 2018 and June 25, 2019. The surveyor requested additional documentation of the Emerald's calibration. The laboratory provided no further calibration documentation for review. 3. In an exit interview with TP D at approximately 11:45 AM, TP D confirmed the findings.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(4)(iii)

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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on a review of proficiency testing (PT) records and interview with TP D, the laboratory director (LD) failed to document evaluation of and corrective action for unacceptable Bacteriology-Throat Culture results for one (1) of six (6) scored PT events reviewed from October 2017 until July 2019. Findings include: 1. Review of the laboratory's Medical Laboratory Evaluation (MLE) PT documentation from October 2017 until July 2019, a total of 6 scored events, revealed no evidence of the evaluation of and corrective action for 2017 MLE M3 Throat Culture with a score of 50%. The surveyor requested to review documentation that the LD evaluated corrective action for PT event 2017 MLE M3. The laboratory provided no documentation for review. 2. In an exit interview with TP D at approximately 11:45 AM, TP D confirmed the findings.