| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number<br><br>49D0227482 | (X3) Date Survey Completed<br><br>12/05/2022 |
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| **Name of Provider or Supplier**<br><br>Pediatric Center One Colonial Place | **Street Address, City, State**<br><br>10571 Telegraph Road - Suite 110, Glen Allen, 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 |
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| **D0000** | An announced CLIA recertification survey was conducted at Pediatric Center-One Colonial Place on December 5, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The inspector noted that the laboratory performs COVID-19 testing and was in compliance with the applicable COVID-19 reporting requirements. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows and includes a Condition under 42 CFR part 493 CLIA Regulation: D5400 -42 CFR. 493.1250 Analytic Systems. |
| **D5400** | ANALYTIC SYSTEMS<br>CFR(s): 493.1250<br><br>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.<br><br>This CONDITION is not met as evidenced by:<br>Based on a review of manufacturer's operations manual, hematology analyzer maintenance records, procedures, instrument calibration records, lack of documentation, and an interview, the laboratory failed to: 1. document performance of twice annual Abbott Emerald hematology instrument syringe piston preventative maintenance as required during the twenty-three months reviewed (timeframe January 2021 to December 5, 2022). See D5429; and 2. perform Complete Blood Count calibration procedures for patient testing on the Emerald analyzer every six months, according to their procedure, during calendar year 2021. See D5437 *REPEAT DEFICIENCY. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS |

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| | CFR(s): 493.1254(a)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of manufacturer's operations manual, hematology analyzer maintenance records, lack of documentation, and an interview, the laboratory failed to document performance of twice annual Abbott Emerald hematology instrument syringe piston preventative maintenance as required during the twenty-three months reviewed (timeframe January 2021 to December 5, 2022). Findings include: 1. Review of the laboratory's hematology procedures revealed an Abbott Emerald Operations Manual with manufacturer's instructions to "perform Lubricating Syringe Pistons maintenance procedure twice annually" (under heading: Preventative Maintenance: Semi-Annual). 2. Review of the laboratory's available Emerald analyzer's maintenance logs from January 2021 to 12/05/22 revealed semi annual syringe piston maintenance was documented once (dated 5/14/21). 3. The inspector requested to review documentation of additional semi annual maintenance for the Abbott Emerald analyzer in calendar year 2021 and year to date in 2022. No additional records were available for review. 4. An exit interview with the Lead Laboratory/Floor Nurse on 12/05/22 at approximately 1:30 PM confirmed the above findings. |
| **D5437** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of procedures, instrument calibration records, lack of documentation, and an interview, the laboratory failed to perform Complete Blood Count (CBC) calibration procedures for patient testing on the Abbott Emerald analyzer every six months, according to their procedure, during calendar year 2021. *REPEAT DEFICIENCY Findings include: 1. Review of the laboratory's procedure manual revealed a Hematology Calibration policy that outlined to calibrate CBC testing at a frequency of every six months. The policy stated: "Calibration is a procedure that confirms the accuracy and precision of the Emerald equipment and is performed every six months or more frequently as needed." 2. Review of the laboratory's 2021 Abbott Emerald instrument calibration documentation revealed one calibration record dated 03/25/21. 3. The inspector requested to review additional calibration records for the Abbott Emerald analyzer in calendar year 2021. No additional calibration |

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| | documentation was available for review. 4. An exit interview with the Lead Laboratory/Floor Nurse on 12/05/22 at approximately 1:30 PM confirmed the above findings. |