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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 49D1010005 | (X3) Date Survey Completed 04/09/2019 |
| Name of Provider or Supplier Primary And Urgent Care | Street Address, City, State 231 Garrisonville Road, Stafford, 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 Primary and Urgent Care on April 9, 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: |
| D5437 | <p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, hematology calibration records, and an interview with Testing Personnel D (TP D), the laboratory failed to document calibration procedures every six (6) months for Complete Blood Count (CBC) testing according to their policy in 2018. Findings include: 1. Review of the laboratory's procedure manual revealed a procedure, "Medonic M-Series Hematology Analyzer", which stated: "Calibration must be performed upon setup of the instrument and then a minimum of every 6 months." 2. Review of the hematology's 2017, 2018 and 2019 calibration records revealed two (2) CBC calibrations were documented in 2017 (06/22/17 and 9/21/17), one (1) CBC calibration documented in 2018 (8/30/18) and one (1) CBC calibration documented in 2019 (3/11/19). The surveyor requested to</p> |

review additional calibration records for 2018. The laboratory provided no documentation to review. 3. In an exit interview at approximately 12:45 PM, TP D confirmed the findings.