

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  49D2049329	<b>(X3) Date Survey Completed</b>  10/16/2018
<b>Name of Provider or Supplier</b>  Primary And Urgent Care	<b>Street Address, City, State</b>  10009 Southpoint Parkway, Fredericksburg, VA	
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>D0000</b>	An announced CLIA recertification survey was conducted at Primary and Urgent Care on October 16, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows:
<b>D5781</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, proficiency testing (PT) records and interviews, the laboratory failed to review and document corrective actions taken when PT results were less than one hundred percent (100%) for three (3) of twelve (12) PT events from October 2016 to October 2018. The findings include: 1. Review of the laboratory's policy and procedure manual revealed a policy, "Quality Assessment", which stated: "Review Proficiency Testing results every quarter for any result less than 100% and perform corrective Action accordingly." 2. Review of the PT records revealed the following events where the PT results were less than 100%: 2018 Cardiac Event 1 CK=80%, 2018 Hematology/Coagulation Event 1 RBC=80%, 2018 Hematology/Coagulation Event 2 Cell ID=80%, a total of 3 events less than 100%. The inspector requested to review corrective actions taken by the laboratory for the</p>

above-specified events with PT results less than 100%. No documentation was available for review. 3. An interview with the Testing Personnel A on October 16, 2018 at approximately 11:00 AM, confirmed the laboratory failed to review and document corrective actions for the PT events specified above.