

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  49D0881952	<b>(X3) Date Survey Completed</b>  09/19/2023
<b>Name of Provider or Supplier</b>  Smith Mountain Lake Family Practice Pc	<b>Street Address, City, State</b>  70 Westwind Road, Moneta, 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 unannounced CLIA off-site proficiency testing desk review of Smith Mountain Lake Family Practice was conducted on 09/19/23 by a Medical Facilities Inspector of the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The laboratory was not in compliance with the following Conditions under 42 CFR part 493 CLIA Regulations: D2000 - 42 C.F.R. 493.801 Condition- Enrollment and Testing of Samples.
<b>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on a review of proficiency testing (PT) records, lack of documentation, and interview, the laboratory failed to enroll in a PT program for White Blood Cell Count (WBC), Red Blood Cell Count (RBC), Hemoglobin (HGB), Hematocrit (HCT), Platelet Count (PLT), and Cell Identification (Cell ID) from January 2023 up to date of survey on 09/19/23. Findings include: 1. Review of the CASPER PT Failure to Re-Enroll 0164S Report revealed lack of re-enrollment with a PT company for the WBC, RBC, HGB, HCT, PLT and Cell ID analytes for 2023. Review of the CASPER Individual Laboratory Profile 0155D Report revealed lack of documentation of scores reported to CMS for the specified analytes as of 09/19/23. 2. An interview with the</p>

technical consultant on 09/19/23 at 09:25 AM revealed that the laboratory had previously been enrolled in with the American Academy of Family Physicians for the year 2022. They stated that "significant changes had occurred within the office over the last year and that they didn't realize that proficiency testing had not been sent." The technical consultant confirmed findings.