

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0232253	(X3) Date Survey Completed 05/04/2020
Name of Provider or Supplier Mountain Region Family Medicine	Street Address, City, State 390 Kane Street, Gate City, 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 unannounced CLIA off-site proficiency testing desk review of Mountain Region Family Medicine was conducted on May 4, 2020 by a Medical Facilities Inspector of the Virginia Department of Health's Office of Licensure and Certification. The laboratory was inspected under 42 CFR Part 493 CLIA regulations. Specific deficiencies cited are as follows:
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on the off-site desk review of proficiency (PT) testing scores for the second event in 2019 and the first event in 2020, the review of the CASPER 0153D Unsuccessful PT report, and telephone interview with the primary testing personnel,</p>

the laboratory failed to achieved satisfactory performance of at least 80% for two out of three events for the White Blood Cell Differential (WBC Diff) parameter, in which the laboratory received scores of 16% and 8% respectively, resulting in unsuccessful performance (Cross Reference D 2130).

D2130

HEMATOLOGY
CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on the off-site desk review proficiency testing (PT) scores for the second event in 2019 and the first event in 2020, the CASPER 0153D Unsuccessful PT report and a telephone interview with the primary testing personnel, the laboratory failed to achieve satisfactory performance of at least 80% for two out of three events for the White Blood Cell Differential (WBC Diff) parameter, in which the laboratory received scores of 16% and 8% respectively, resulting in unsuccessful performance. Findings include: 1. Review of the Medical Laboratory Evaluation (MLE) hematology PT scores and the CASPER 0153D Unsuccessful PT report revealed the following scores: 2019 2nd event WBC Diff- 16% 2020 1st event WBC Diff- 8% The laboratory received an unsuccessful MLE PT score for the above listed analyte. 2. An telephone interview with the primary testing personnel on May 4, 2020 at approximately 9:45 AM confirmed the findings.