

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 44D0951827	<b>(X3) Date Survey Completed</b> 01/07/2020
<b>Name of Provider or Supplier</b> Mountain Region Family Medicine	<b>Street Address, City, State</b> 1242 West Shipley Ferry Road, Kingsport, TN	
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>D5401</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: ===== Based on lack of written procedures for Complete Blood Counts (CBC) and manual differentials and upon interview with the Primary Laboratory person, it was determined the laboratory failed to present written procedures on 1/7/2020 for CBC and manual differential testing for 2018-2019. The findings include: 1. There were no written procedures available for review for CBC's and manual differential testing. 2. An interview at approximately 1:00pm on January 7, 2020, with the Primary Laboratory person, confirmed there were no written procedures available for CBC and maunal differential testing for 2018-2019. =====</p>
<b>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: ===== Based on review of CBC (Complete Blood Count) instrument maintenance requirements, review of maintenance logs for</p>

2019 and interview with the Primary Laboratory person, determined the laboratory failed to document CBC instrument maintenance since installation of new CBC analyzer January 2019. The findings include: 1. Review of the CBC analyzer maintenance requires daily, weekly and PRN (as needed) maintenance to be performed. 2. No maintenance was documented for CBC analyzer since installation in January 2019. 3. Interview with Primary Laboratory person at approximately 1:00 p. m. January 7, 2020 confirmed that maintenance for the CBC analyzer had not been documented since installation of new CBC analyzer January 2019.

=====

**D6021**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:  
===== Based on review of the Laboratory's Quality Assessment (QA) for Complete Blood Counts (CBCs), CBC Calibrations, and Internal Quality Assessment Program (IQAP), lack of Laboratory Director review of QC and QA for 2019, and an interview with the Primary Laboratory Person, determined the Laboratory Director did not ensure quality of laboratory services was maintained for 2019. The findings include: 1. There was no documentation of Laboratory Director review of quality assessment which includes, CBC Quality Control, CBC Calibrations, and CBC IQAP, since implementation of the new CBC analyzer in January 2019. 2. An interview with the Primary Laboratory Person at approximately 1:00 p.m. January 7, 2020 confirmed there was no documentation of Laboratory Director review of the quality controls or quality assessment records to ensure the quality of the laboratory services were maintained since new CBC analyzer in January 2019. =====

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:  
\_\_\_\_\_ Based on a review of the laboratory's employee competency evaluations and upon interview with the Primary Laboratory Person, determined the Technical Consultant failed to perform and document a semi-annual competency evaluation for testing personnel #2 who began laboratory testing December of 2018 The findings include: 1. A review of the laboratory's semi-annual competency evaluation results were not available for testing personnel # 2 who began CBC testing in December of 2018. 2. An interview with the Primary Laboratory Person at approximately 1:00p.m. on January 7, 2020 confirmed that semi-annual

competency evaluation was not documented for testing personnel #2 since hire date in December 2018. \_\_\_\_\_

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

===== Based on a review of the laboratory's employee competency evaluations and upon interview with the Primary Laboratory Person, determined the Technical Consultant failed to perform and document annual competency evaluations for testing personnel #1 for 2018 and 2019. The findings include: 1. A review of employee competency evaluations for testing personnel #1 disclosed no annual competency evaluations documented for 2018 and 2019. 2. Interview with Primary Laboratory Person at approximately 1:00pm on January 7,2020 confirmed the Technical Consultant failed to perform and document annual competency evaluations for testing personnel #1 for the 2 year period.  
=====