

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0311095	(X3) Date Survey Completed 02/03/2020
Name of Provider or Supplier Mountain Region Family Medicine, Pc	Street Address, City, State 444 Clinchfield Street, Suite 2300, Kingsport, TN	
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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: ===== Based on review of 2018 and 2019 Proficiency Testing (PT) attestation sheets and upon interview with the MLT Supervisor, it was determined the laboratory director failed to sign the attestation sheets for Chemistry, Hematology and Clinical Microscopy for the two year period. The findings include: 1. The laboratory director failed to sign the PT attestation sheets for 2018 and 2019 for Chemistry, Hematology and Clinical Microscopy. 2. An interview at approximately 3:00 p.m. on 1/27/2020 with the MLT Supervisor confirmed the laboratory director had not signed the attestation sheets for the two year period. =====</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: ===== Based on observation of Chemistry</p>

and Hematology control materials at 9:30 a.m. on January 27, 2020 and an interview with the Medical Laboratory Technician (MLT) Supervisor, it was determined the laboratory failed to document open date expiration dates for the Chemistry and CBC controls in use. The findings include: 1. Observation at 9:30 a.m. on January 27, 2020 of control materials in use for Chemistry and CBC testing revealed no open dates or expiration dates documented. 2. An interview at 9:30 a.m. on January 27, 2020, with the MLT Supervisor, confirmed the Chemistry and CBC control materials that were in use, did not have open dates or expirations dates documented.

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D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

===== Based on Quality Assessment (QA) policy stating the Laboratory Director is to review the analytic systems monthly, lack of CBC Quality Control (QC) reviews from October 2018 to December 2019 and an interview with the MLT Supervisor, it was determined the Laboratory Director failed to follow QA policy for monthly CBC QC reviews since October 2018. The findings include: 1. The Quality Assessment policy states the Laboratory Director is to review analytic systems monthly. 2. There was no documentation of CBC QC reviews from October 2018 to December 2019. 3. An interview at approximately 3:00 p.m. on January 27, 2020 with the MLT Supervisor confirmed the Laboratory Director had not reviewed the CBC quality controls since October 2018.

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D6015

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)

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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

===== Based on lack of documentation for Proficiency Testing (PT) order confirmation for 2020 for Chemistry, Hematology and Clinical Microscopy and an interview with the MLT Supervisor, it was determined the laboratory director failed to ensure that Proficiency Testing for 2020 had been re-ordered. The findings include: 1. There was no PT order confirmation for 2020 for testing performed to include Chemistry, Hematology and Clinical Microscopy. 2. An interview at approximately 3:00 p.m. on January 27, 2020 with the MLT Supervisor confirmed the laboratory failed to re-order the Proficiency Testing for 2020.

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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 lack of training and semi-annual competency documentation for Medical Laboratory Technician #1, hire date 10/29/2018, and an interview with the MLT Supervisor, it was determined the Technical Consultant failed to document training and semi-annual competency performance for Chemistry, Hematology, KOH (Potassium Hydroxide) and Wet Prep Analysis testing since hire date. The findings include: 1. No training and/or semi-annual competencies documented for MLT #1 for performing Chemistry, Hematology, KOH and Wet Prep Analysis testing since hire date of 10/29/2018. 2. An interview with the MLT Supervisor at approximately 3:00 p.m. on January 27, 2020 confirmed there was no documentation of training and/or semi-annual competency for MLT #1 since hire date 10/29/2018.

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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 lack of annual competency documentation for Medical Laboratory Technician (MLT) number 1 and MLT number 3 and Medical Technologist (MT) number 4 and an interview with the MLT Supervisor, it was determined the Technical Consultant failed to document annual competency performance for Chemistry, Hematology, KOH (Potassium Hydroxide) and Wet Prep Analysis testing for 2019. The findings include: 1. The Technical Consultant failed to document annual competencies for MLT's number 1 and 3 and MT number 4, for performance of Chemistry, Hematology, KOH and Wet Prep Analysis testing for 2019. 2. An interview with the MLT Supervisor at approximately 3:00 p.m. on January 27, 2020 confirmed that 2019 annual competencies had not been documented.

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