Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0698104	08/21/2018
Name of Provider or Supplier	**Street Address, City, State**	
Mountain Region Family Practice	142 Meade Ave, Nickelsville, 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 announced CLIA initial survey was conducted at the Mountain Region Family Practice on August 21, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: A. Based on interviews, the review of the hematology analyzer operator's guide, and the laboratory's policy and procedure manual, the laboratory did not have documentation of a written policy that defined how testing personnel will review and report the patient Complete Blood Counts (CBC) test results, to include interpretation of instrument test code/flags for the CBC parameters at the time of survey on August 21, 2018. (Refer to D6030) Findings include: 1. The inspector asked TP A how she/he would assay a complete blood count (CBC) patient sample and review results from the instrument for flag codes. TP A replied, "I really didn't have good training. I had to go to Kingsport for additional training. I am told one thing then another for the CBC flags." 2. Review of the Beckman Coulter AcT Diff 2 analyzer operator's manual revealed the following statement: "Test code/flag (M, 1, 2, or 3)- Indicates differential parameters failed the internal regional size distributional criteria at one specific region (1, 2, 3, 4) or multiple regions (M). Suggested action is to verify results according to laboratory's protocol." 3. Review of the laboratory's policy and procedure manual revealed that the laboratory did not have documentation of a written policy that defined how testing personnel would report patients' CBC test results that presented

	with instrument flags. The inspector requested to review a written policy. The policy was not available for review. 4. An interview with the laboratory director at approximately at 11:40 AM confirmed that the laboratory did not have a written policy that defined how testing personnel would review and report the patient CBC test results, to include interpretation of instrument test code/flags for the CBC parameters at the time of survey on August 21, 2018. B. Based on the review of the laboratory's policy, tour of the laboratory, patient report and interviews, testing personnel (TP) A did not follow the established written policy for reviewing and recording urine sediment examinations at the date of survey on August 21, 2018. See attached personnel code sheet. (Refer to D6030) Findings include: 1. Review of the laboratory's policy for urinalysis (signed by the lab director on July 13, 2017) revealed the following statements: "XII. Interpretation of Urinary Sediment- the elements of urine sediment should be quantitated as follows by counting and averaging at least ten high power fields. WBC and RBC- report range based on average of ten high power fields. 100+, 200+ or packed field- may be used when WBC or RBC cover the entire high power field. Other elements report as follows: Rare- 1 element in 3 or more fields, Occasional- 0-2 elements/hpf, few- 3-5 elements/hpf, several- 5-15 elements /hpf (>20 for bacteria), and many- half the field or more filled with elements." 2. A tour of the laboratory revealed a taped document on the wall next to the Nikon Eclipse E200 microscope that provided the following information (the document was not signed by the lab director): "Microscopic report as follows: WBC/RBC: 0-2, 2-5, 5-10- 10-20, 20-50, 50-100, Too Numerous to Count (TNTC), Bacteria/mucous/yeast, amorphous: trace, 1+, 2+, 3+, 4+, Casts- 0-2, 2-5, 5-10, >10, Squamous Epi's- 0-5, 5-10, >10, Transitional and Renal Tubular Epi's- 0-5, 5-10, >10, Trichomonas- 0-5, >5" 3. During an interview with TP A at approximately 10:40 AM, the inspector asked if she/he understood the elements for urine microscopy and reporting results. TP A replied: "No, not really". 4. The inspector pulled a random urine microscopy for specimen number 221805. TP A hand-wrote on the Clinitek urine printout "trace of bacteria". The final patient report from the Medcom laboratory information system (LIS) reported the bacteria as "a lot". The inspector asked TP A why she/he initially wrote trace of bacteria on the print out then changed the answer to "a lot" in the Medcom LIS. She/he replied: "I don't know. I get told one thing then another." 5. An interview with the laboratory director at approximately at 11:40 AM confirmed that TP A did not follow the established written policy for reviewing and recording urine sediment examinations at the date of survey on August 21, 2018.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on the review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), initial training competency assessments, patient report, quality assurance (QA) policy, and interviews, the laboratory director failed to ensure: 1) that testing personnel (TP) A was trained and demonstrated competency for hematology analyzer and urine sediment examinations prior to reporting patients (Refer to D6030, part A) and 2) documentation of a competency assessment for testing personnel (TP) B for 2018 (Refer to D6030, part B).

D6030

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:
A. Based on the review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), initial training competency assessments, patient report, quality assurance (QA) policy, and interviews, the laboratory director failed to ensure that testing personnel (TP) A was trained and demonstrated competency for patient testing with the Beckman Coulter AcT Diff 2 hematology analyzer and urine sediment examinations prior to reporting patients on May 18, 2018. Findings include: 1. Review of the CMS 209 Laboratory Personnel Report form revealed that TP A performs patient testing. Initial training competency assessments for TP A revealed procedures for pre-analytic, analytic and post-analytic processes for waived testing signed by TP B as observer on May 18, 2018, lab manager A on May 18, 2018 and laboratory director on July 12, 2018. There was no documentation for initial training and competency assessments for hematology analyzer and urine sediment examinations. (See attached personnel code sheet.) The inspector was presented with a hand-written paper that indicated 9 urine sediment examinations were examined by TP A and signed by lab manager A. The hand-written paper did not include documentation of review of the policy and procedures, to include sample preparation and reporting results, nor did it include the 6 elements of competency. 2. An interview with TP A at approximately 10:40 AM, the inspector asked if TP A if she/he understood the elements for urine microscopy and reporting results. TP A replied: "No, not really". The inspector pulled a random urine microscopy for specimen number 221805. TP A hand-wrote on the Clinitex urine printout "trace of bacteria". The final patient report from the Medcom laboratory information system (LIS) reported the bacteria as "a lot". The inspector asked TP A why she/he initially wrote trace of bacteria on the print out then changed the answer to "a lot" in the Medcom LIS. She/he replied: "I don't know. I get told one thing then another." The inspector asked TP A how she/he would assay a complete blood count (CBC) patient sample and review results from the instrument for flag codes. TP A replied: "I really didn't have good training. I had to go to Kingsport for additional training. I am told one thing then another for the CBC flags". The inspector requested documentation of the additional training. It was not available for review. 3. Review of the QA policy (signed by the lab director on August 31, 2016) revealed the following statements: "Personnel Competency- this laboratory will ensure that all testing personnel are properly trained and are competent prior to testing patient samples. As least annually, the laboratory director and/or technical consultant will review the performance of each employee working in the laboratory to assure employee competency. This includes employees responsible for specimen collection and processing (if different from the testing personnel) and the technical consultant if

	applicable. The written result of the review will be filled in the individual's personnel filed. The director will ensure the laboratory personnel are provided with retraining or continuing education if indicated. Competency check-off will include annual review of the procedure manual by the employee. Any new or revised procedure are reviewed by the employee." The inspector requested to review additional training records. There was no documentation available for review. 4. An interview with the laboratory director at approximately 11: 40 AM confirmed that TP A did not have documented training or competency for performing testing with the Beckman Coulter AcT Diff 2 hematology analyzer and urine sediment examinations prior to reporting patients. B. Based on the review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), competency assessments, quality assurance (QA) policy, and interviews, the laboratory director failed to provide documentation of a competency assessment for testing personnel (TP) B for the hematology and urine sediment examination procedures performed on-site at the date of survey on August 21, 2018. Findings include: 1. Review of the CMS 209 Laboratory Personnel Report form revealed that TP B performs patient testing. TP B did not have competency assessment documentation available for review for the test procedures performed on-site by the laboratory director. (See attached testing personnel code sheet.) Interviews with TP A and the laboratory director revealed that TP B also works at an affiliated site and provided coverage at the Nickesville site during the transition of testing personnel in April and May 2018. 2. Review of the QA policy (signed by the lab director on August 31, 2016) revealed the following statements: "Personnel Competency- this laboratory will ensure that all testing personnel are properly trained and are competent prior to testing patient samples. As least annually, the laboratory director and/or technical consultant will review the performance of each employee working in the laboratory to assure employee competency. This includes employees responsible for specimen collection and processing (if different from the testing personnel) and the technical consultant if applicable. The written result of the review will be filled in the individual's personnel filed. The director will ensure the laboratory personnel are provided with retraining or continuing education if indicated. Competency check-off will include annual review of the procedure manual by the employee. Any new or revised procedure are reviewed by the employee." 3. An interview with the laboratory director at approximately 11:40 AM confirmed that TP B did not have documentation of a competency assessment for the hematology and urine sediment examination procedures performed on-site.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the Center for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), available testing personnel records, and interviews with the primary testing personnel and laboratory director, the laboratory failed to provide documentation of the highest level of education for one (1) of two (2) laboratory testing personnel performing patient testing at the date of survey on August 21, 2018. (Refer to D 6065).
D6065	TESTING PERSONNEL QUALIFICATIONS

	CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the Center for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), available testing personnel records, and interviews, the laboratory failed to provide documentation of the highest level of education for one (1) of two (2) laboratory testing personnel performing patient testing at the date of survey on August 21, 2018. Findings include: 1. Review of the CMS 209 Laboratory Personnel Report Form revealed that testing personnel (TP) A and B performs patient testing. 2. Review of TP records revealed that there was no documentation of the highest level of education for TP A. The laboratory could not produce the documents for review when requested by the inspector. 3. An interview with the laboratory director and TP A at approximately 11:45 AM confirmed that the laboratory did not have documentation of the highest level of education for TP A at the date of survey on August 21, 2018.