Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D2219564	02/07/2023
Name of Provider or Supplier	**Street Address, City, State**	
Afc Urgent Care - Saddle Rock	7460 S Gartrell Rd, Aurora, CO	

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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) results, Quality Assurance (QA) policy, Technical Consultant interview and Lab Director interview the laboratory failed to maintain a copy of the attestation statement and test reports from the Medonic M-Series hematology analyzer used to analyze the CBC PT material sent by Medical Laboratory Evaluation (MLE) for the 2022 Event 3. Findings: 1. The laboratory QA manual states that all PT records will be retained for two years. 2. The laboratory QA manual states that the Lab Director and Testing Personnel will sign the attestation statement. 3. Review of PT results on February 7, 2023 at 11:00 am that were sent by MLE for the 2022 Event 3 revealed that only the final score sheet was retained by the laboratory. 4. The Laboratory Director and Technical Consultant confirmed that the instrument test records and attestation statement was not retained as specified in the laboratory's QA policy.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)

	The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) results, Quality Assurance (QA) policy, and Lab Director interview the laboratory failed to document any review or evaluation of the CBC PT material sent by the Medical Laboratory Evaluation (MLE) for the 2022 Event 3. Findings: 1. The laboratory QA manual states that the Lab Director will review all PT results and will sign the PT provider score sheets provided to the laboratory. 2. The laboratory QA manual states that the Lab Director will investigate any PT failures. 3. Review of PT results on February 7, 2023 at 11:00 am that were sent by MLE for the 2022 Event 3 revealed that the score sheet provided to the laboratory was not signed by the Lab Director. 4. Review of PT results on February 7, 2023 at 11:00 am that were sent by MLE for the 2022 Event 3 revealed that one of the WBC results was not acceptable resulting in a score of 80% for that analyte. 5. No documentation existed that an investigation as to why that WBC analyte was unacceptable. 6. The Laboratory Director confirmed that the PT score sheet was not signed and that an investigation into the cause of the unacceptable WBC result was performed as specified in the laboratory's QA policy.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on review of the approved Cell Blood Count (CBC) procedure and Technical Consultant interview, the laboratory failed to include all of the procedural requirements in the Medonic M-Series 3 part differential procedure that was not included by the manufacturer. Findings: 1. The laboratory has adopted the manufacturer's Standard Operating Procedure (SOP) to perform CBC's with a 3 part differential using the Medonic M-Series instrument. 2. Review of the manufacturer's SOP on February 7, 2023 at 12:00 pm revealed that it is missing the following criteria; - Critical or panic values. - Process for entering results into the laboratory's Electronic Medical Record (EMR) system. - Actions to take if the test system is inoperable. 3. The Technical Consultant confirmed on February 7, 2023 at 12:00 pm the CBC SOP failed to include all of the items required.