Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D2156283	11/03/2023
Name of Provider or Supplier	**Street Address, City, State**	
Afc Urgent Care Castle Rock	5700 New Abbey Lane, Suite D-300, Castle Rock, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on the deficiencies cited herein, the laboratory failed to enroll in a CMS approved Proficiency Testing (PT) program for the specialty of hematology since testing began in July of 2023. The laboratory performs approximately 1,800 hematology tests annually (Refer to D2001).
D2001	ENROLLMENT CFR(s): 493.801(a)(1)(2)(i) The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS; This STANDARD is not met as evidenced by:

	Based on an onsite records review, and interview with the laboratory director (LD), the laboratory failed to enroll in a CMS approved Proficiency Testing (PT) program for the specialty of hematology since testing began in July of 2023. The laboratory performs approximately 1,800 hematology tests annually. Findings include: 1. Based on an onsite records review, it was revealed that the laboratory failed to enroll in a CMS approved PT program for the following analytes in hematology since testing began in July of 2023: Cell ID or White Blood Cell Differential Red Blood Cell count Hematocrit (non-waived) Hemoglobin (non-waived) White Blood Cell count Platelets 2. Based on an interview with the LD on November 3, 2023, at approximately 10:00 AM, confirmed that the laboratory failed to enroll in a CMS approved PT program for hematology since testing began in July of 2023.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of the laboratories policies and procedures manual, and an interview with the Laboratory Director (LD), the laboratory failed to establish policies or procedures to evaluate competency of Clinical Consultants (CC), Technical Consultants (TC), or testing personnel (TP), since testing began in July of 2023. The laboratory performs approximately 1,800 tests annually. Findings include: 1. Based on a review of the laboratory's policies and procedures manual, it was revealed that the laboratory failed to establish a written policy or procedure to evaluate the competency of CC, TC, or TP employed by the laboratory. 2. Based on an interview with the LD on November 3, 2023, at approximately 10:30 AM, confirmed that the laboratory failed to establish a written policy or procedure to evaluate the competency of CC, TC, or TP employed by the laboratory.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) 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. This STANDARD is not met as evidenced by: Based on an onsite records review, and an interview with the laboratory director (LD), the laboratory failed to document instrument maintenance for their Medonics M hematology analyzer as specified by the manufacturer since testing began in July of 2023. The laboratory performs approximately 1,800 hematology tests annually. Findings include: 1. Based on an onsite records review, it was revealed that the laboratory failed to document the instrument maintenance for their Medonic M series hematology analyzer as specified by the manufacturer. 2. Based on an interview with the LD, on November 3, 2023, at approximately 09:50 AM, confirmed that the laboratory failed to document the instrument maintenance for their Medonic M series hematology analyzer as specified by the manufacturer.