Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D0929179	09/24/2020
Name of Provider or Supplier	**Street Address, City, State**	
Mountain After Hours Clinic	1908 North Main St Ste 120, Hazard, KY	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on staff interview and complete blood count (CBC) policy review on 09/24 /2020, the laboratory failed to include: reference intervals for patient results, criteria for reporting abnormal or panic values, corrective action procedure for when quality control is out of acceptable range, and procedure for when analyzer is out of service. The findings include: 1. Policy review conducted on 09/24/2020, revealed the laboratory did not have all the necessary procedural requirements for the policy regarding CBC testing on the Abbott Cell-Dyn Emerald hematology analyzer. 2. Interview with the laboratory staff on 09/24/2020 at 11:00 AM confirmed that the

	laboratory did not have a system in place to ensure that all the policies and procedures contained all the information needed to perform and report the test.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of Hematology proficiency testing results from the American Proficiency Institute (API) testing agency and staff interview on 09/24/2020, the laboratory director failed to ensure proficiency testing results were reviewed by staff for five (5) out of five (5) testing events in 2019 and 2020. Findings include: 1. There was no evidence of review of hematology proficiency testing results from API for three (3) testing events in 2019. 2. There was no evidence of review of hematology proficiency testing results from API for two (2) testing events in 2020. 3. An interview with the laboratory staff on 09/24/2020 at 10:30 AM revealed the laboratory failed to have a system in place to ensure proficiency testing results received from API were reviewed by the laboratory director and appropriate staff to evaluate the laboratory's performance.