Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2136367	09/16/2020
Name of Provider or Supplier	**Street Address, City, State**	
Med 360 Urgent Care	1700 Hwy 78 East, Jasper, AL	

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
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of the installation and validation documentation for the Horiba ABX Micros ES Hematology analyzer and interviews with Testing Personnel #2 and the General Supervisor, the surveyor determined the Laboratory Director failed to document (as indicated by signature and date) his review and approval of the initial validation procedures for precision, accuracy and reportable ranges, as verifying the manufacturer's performance specifications for the analyzer, before patient testing began. The findings include: 1. A review of the installation and validation records for the Horiba ABX Micros ES Hematology analyzer revealed no documentation of review and approval by the Laboratory Director (as indicated by a signature and date) on the initial verification procedures for precision and reportable ranges performed on 10/7/2019, and the correlation studies for accuracy performed in November 2019. (These studies were printed by the General Supervisor on the day of the survey.) 2. A review of Hematology records revealed patient CBC (Complete Blood Count) testing on the analyzer began 10/21/2019. 3. During an interview and review of these records on 9/16/2020 at 11:10 AM, Testing Personnel #2 and the General Supervisor confirmed the previous Laboratory Director had failed to document his review before the analyzer was utilized for patient CBC testing. SURVEYOR ID#32558 Licensure and Certification Surveyor