Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2171679	10/27/2020
Name of Provider or Supplier	**Street Address, City, State**	
Urgent Care For Children-Madison	8490 Hwy 72 West, Suite 100, Madison, 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
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on reviews of the Beckman Coulter AcT diff 2 Hematology analyzer calibration records, and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to follow the laboratory's policy in the performance frequency of calibrations in 2020. The findings include: 1. A review of the Beckman Coulter AcT diff 2 Hematology analyzer records revealed the following: A) Installation (including a calibration) on 9/23/2019 B) 8/27/2020: Documentation of a calibration performed eleven months after installation 2. During an interview on 10/27/2020 at 3:00 PM, the surveyor asked if the laboratory had performed a calibration of the AcT diff 2 in early 2020; TP #1 answered, "No". The surveyor then asked how often the analyzer should be calibrated; TP #1 answered, "Every six months". .
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the

	manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of quality control (QC) and patient records, and an interview with Testing Personnel #1, the laboratory failed to ensure at least two levels of Hematology QC were within acceptable ranges before patient testing began. This was noted on two days in the 2019 records. The findings include: 1. A review of the Beckman Coulter AcT diff 2 Hematology analyzer QC records revealed the following: A) 12/14/2019: Low and High QC were outside acceptable ranges. B) 12/15/2019: Normal and High QC were outside acceptable ranges. 2. During an interview on 10/27/2020 at 5:14 PM, Testing Personnel #1 confirmed the above noted findings. The surveyor then asked if patient CBC's (Complete Blood Counts) were performed on these dates. After a review of patient records, Testing Personnel #1 stated one patient CBC was performed each day on 12/14 and 12/15/2019. .
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 Beckman Coulter AcT diff 2 Hematology analyzer and an interview with Testing Personnel #1, 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 Beckman Coulter AcT diff 2 Hematology analyzer revealed the initial verification procedures for precision, accuracy and reportable ranges were performed on 9/23/2019 and 9/30 /2019. 2. A review of Hematology records revealed patient CBC (Complete Blood Count) testing on the analyzer began 10/19/2019, however the Laboratory Director did not document his review and approval of the validation until 10/12/2020 (nearly a year later). 3. During an interview on 10/27/2020 at 2:22 PM, Testing Personnel #1 reviewed and confirmed the above noted findings. SURVEYOR ID #32558 Licensure and Certification Surveyor