Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2171685	03/11/2020
Name of Provider or Supplier	**Street Address, City, State**	
Urgent Care For Children-Tuscaloosa	4700 Rice Mine Road Northeast, Tuscaloosa, 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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the installation and validation records for the Horiba ABx Micros 60 Hematology analyzer, and interviews with the Testing Personnel #1 and the Technical Consultant, the surveyor determined the laboratory failed to verify the manufacturer's performance specifications for accuracy and reportable range before patient testing began. The findings include: 1. During the entrance tour of the laboratory, Testing Personnel #1 listed CBC's (Complete Blood Counts) performed on the Horiba ABx Micros 60 Hematology analyzer as the only moderate complexity test, and stated patient testing began on 12/03/2019. 2. A review of the installation and validation records for the Horiba ABx Micros 60 Hematology analyzer revealed the Horiba technician calibrated the instrument, and validated precision on 12/02/2019, however there was no documentation of studies proving verification of accuracy and reportable ranges. 3. During an interview and review of these records on 3/11/2020 at 12:35 PM, the Technical Consultant confirmed a complete validation of the Micros 60 was not performed; Testing Personnel #1 stated she was given incorrect information after the installation, and was told the "Linearity" (which can be used to validate accuracy and reportable range) was not necessary. .
D5441	CONTROL PROCEDURES

	CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the quality control (QC) records for the Horiba ABx Micros 60 Hematology analyzer, and interviews with the Testing Personnel #1 and the Technical Consultant, the surveyor determined the laboratory failed to implement a mechanism to monitor for QC shifts and trends over time since use of the instrument began in December 2019. The findings include: 1. A review of the QC records for the the Horiba ABx Micros 60 Hematology analyzer, revealed cumulative printouts of the daily QC results from December 2019 thru March 2020, however the laboratory had no records documenting the monitoring of QC shifts and trends over time. (Examples include printing Levy-Jennings charts periodically or submitting data to a company's Interlaboratory Quality Assurance Program [IQAP]). Testing personnel began using the Micros 60 for patient testing in December 2019. 2. During an interview on 3/11 /2020 at 12:55 PM, the Technical Consultant confirmed the testing personnel had failed to print the Levy-Jennings charts with the cumulative QC reports. At 1:10 PM the surveyor asked Testing Personnel #1 if the laboratory submitted the QC results to an IQAP service as an alternative method of tracking shifts and trends; Testing Personnel #1 confirmed they did not. .
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 reviews of the installation and validation records for the the Horiba ABx Micros 60 Hematology analyzer, and interviews with the Technical Consultant, the surveyor determined the Laboratory Director failed to ensure validation procedures for accuracy and reportable ranges were completed and approved before testing personnel began using the instrument for patient testing in December 2019. The findings include: 1. A review of the Horiba ABx Micros 60 Hematology analyzer records revealed the instrument was calibrated and precision was verified on 12/02 /2019. The Laboratory Director had initialed these the documents, however he failed

	to indicate the date of his approval, and further failed to ensure complete validation procedures verifying the manufacturer's performance specifications for accuracy and reportable range were performed before the the Micros 60 was used for patient testing on 12/03/2019. 2. During an interview and review of these records on 3/11/2020 at 12: 35 PM, , the Technical Consultant confirmed the above noted findings. SURVEYOR ID# 32258 Licensure and Certification Surveyor