Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2151731	01/31/2019
Name of Provider or Supplier	**Street Address, City, State**	
Urgent Care For Children-Trussville	117 N Chalkville Road, Trussville, 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
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of the laboratory specimen collection policy (faxed to the CLIA office), a review of quality assurance (QA) records, and interviews with Testing Personnel (TP) #1, the facility failed to ensure procedures in use assured positive patient identification. The findings include: 1. During the initial tour of the laboratory and a review of pre-analytic processes with TP #1 on 1/31/2019 at approximately 9:35 AM, the surveyor determined the current practices in use have the potential for misidentification of the patient's test results. TP #1 explained the current procedure of performing a CBC (Complete Blood Count) as follows: (A) Testing Personnel entered the patient's date of birth (as the specimen identifier) in the Hematology analyzer; (B) proceeded to the patient's room to collect the specimen, labeling it with the DOB only, and (C) then returned to the laboratory to run the test; the patient's name was hand-written on the CBC after the results printed out. The laboratory failed to address the potential for misidentification if a second testing personnel also had to perform a CBC before the first testing personnel returned. 2. The laboratory further failed to ensure procedures for pre-analytic processes were available to the testing personnel and the surveyor during the survey. [The surveyor requested these procedures; however, the "Specimen Collection Policy", which specified two unique identifiers should be utilized, was not available for review until it was faxed to the CLIA office on 1/31 /2019 at 4:45 PM.] 3. Refer to D5203. .

D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on a review of the laboratory specimen collection policy (faxed to the CLIA office), a review of quality assurance (QA) records, and interviews with Testing Personnel (TP) #1, the facility failed to ensure procedures in use assured positive patient identification. The findings include: 1. During the entrance interview and tour of the laboratory on 1/31/2019 at approximately 9:35 AM, TP #1 was asked about the pre-analytic processes. TP #1 explained tests are ordered in the e-Clinical electronic medical record, and testing personnel entered the date of birth (DOB) as the patient's identifying number in the Hematology analyzer. Then the testing personnel go to the patient's room, collect the sample, and return to the laboratory to run the CBC (Complete Blood Count). 2. As the interview continued on 1/31/2019, the surveyor asked about the potential for misidentification if a second testing personnel also had to perform a CBC before the first testing personnel returned. [A review of the Form CMS-209 listed eight moderate complexity testing personnel.] TP #1 answered she did not think this could happen because the laboratory does not perform many CBC's yet. When asked how the CBC samples are labeled, TP #1 stated they used the DOB. 3. A review of the "Policy and Procedure" manual revealed information about the waived procedures only. The laboratory also used the Operator's Guide for the Beckman Coulter AcT diff 2 analyzer as their Hematology procedure manual. During an interview on 1/31/2019 at 1:10 PM, the surveyor asked TP #1 if the laboratory had a specimen collection procedure. TP #1 stated, yes, because all testing personnel received a copy of the policy during training. However, the facility did not provide a copy of the policy during the survey. 4. A review of quality assurance (QA) documentation revealed an occurrence where the laboratory's QA reviewer discovered three days in September 2019 when testing personnel failed to enter the correct DOB for the individual patients. The same DOB was used for all patients during the three day period. There was no documentation of the corrective action taken after this incident was discovered. 5. During the exit summation on 1/31/2019 at 1:55 PM, the surveyor discussed the concern of ensuring the correct DOB was entered in the instrument at the time the CBC was run for accurate patient identification. The surveyor also stated the laboratory had failed to provide the requested procedure for their pre-analytic processes. 6. On 1/31/2019 at 4:45 PM laboratory faxed the "Specimen Collection Policy" (along with other requested information) to the CLIA office. A review of the procedure revealed, "...A. All specimens must be labeled with two unique identifiers in the presence of the patient. This identification must be maintained through all phases of testing...". TP #1 had stated only the DOB was used for specimen identification, and the unique identifier was not always maintained through the testing phase (as documented in QA records). Thus the above noted findings were confirmed. .
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 installation and validation documentation for the Beckman Coulter AcT diff 2 Hematology analyzer, and interviews with Testing Personnel (TP) #1, TP #2 and Technical Consultant (TC) #1, the surveyor determined the laboratory failed to ensure the initial installation procedures proved verification of precision and accuracy as per manufacturer's performance specifications before patient testing began on 9/15/2018. The findings include: 1. A review of the documentation of the installation procedures for the Beckman Coulter AcT diff 2 Hematology analyzer revealed the Coulter technical representative calibrated the instrument on 9/13/2018. A review of the calibration procedures in Section 5 of the Operator's Guide revealed "Reproducibility" (Precision) should be performed during the calibration procedure, however the laboratory had no record this was performed. 2. A further review of the installation records revealed Coulter LIN-C Linearity controls (a five level kit) were used (times six runs) to establish reportable range on 9/14/2018. Information for each of the five parameters was hand-written on a chart, and the instrument printouts of the raw data was retained in the binder. Graphs of the assay values for WBC (White Blood Cell), RBC (Red Blood Cell), Hemoglobin and Platelets were printed to show linearity; each of the four graphs were initialed by the Technical Consultant and the Laboratory Director. However there was no date of approval documented to ensure the data was reviewed/approved before patient testing began. The surveyor futher noted values for the MCV (Mean Corpuscular Volume) were included in the instrument printouts of the raw data, however there was no analysis of the data for MCV. (Note: MCV is a measured parameter on the Complete Blood Count; precision, accuracy and reportable range must be evaluated to ensure the accurary the the RBC indices.) 3. In a phone interview with Technical Consultant (TC) #1 on 1/31/2019 at 12:24 PM, the surveyor asked how the laboratory had established precision and accuracy during the installation of the AcT diff 2; TC #1 stated she had seen the Reproducibility report, and that accuracy was established by running controls. The TC stated TP #1 and #2 had this information. 4. During an on-site interview on 1/31/2019 at 12:40 PM, TP #1 and #2 were asked when patient testing on the Beckman Coulter AcT diff 2 Hematology analyzer began. TP #1 reviewed the records, and stated "9/15 /2018". When asked if Reproducibility was performed when the analyzer was installed, the testing personnel searched their records and provided a Reproducibility study dated 7/25/2018. [The surveyor determined the 7/25/2018 Reproducibility was performed during the off-site factory calibration.] The laboratory had no documentation of verification of Reproducibility/Precision performed during the on-site installation. 5. As the interview continued on 1/31/2019 the surveyor then reviewed with TP #1 and #2, Coulter's Performance Specifications for WBC, RBC, Hemoglobin, MCV (Mean Corpuscular Volume) and Platelets (on pages 4-4 and 4-5 in the manufacturer's "Basic Concepts of QC" [Quality Control] binder). The surveyor then asked how the studies the laboratory performed verified the 95% Confidence levels for accuracy as established by the manufacturer in the Performance Specifications. The surveyor also asked if accuracy and reportable range had been established for MCV. TP #1 and #2 were unable to provide any additional information or data. Thus the above noted findings were confirmed. .

D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on reviews of the laboratory specimen collection policy (faxed to the CLIA office because it was not provided during the survey), a review of installation and validation documentation for the Beckman Coulter AcT diff 2 Hematology analyzer, a review of quality assurance records, and interviews with Testing Personnel #1, #2 and the Technical Consultant, the Laboratory Director: (1) failed to ensure procedures in use by the testing personnel assured positive patient identification. (2) and failed to ensure the initial installation procedures proved verification of precision, accuracy and reportable range for all measured CBC (Complete Blood Count) parameters as per manufacturer's performance specifications before patient testing began on 9/15/2018. (Refer to D6007.) .
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on reviews of the laboratory specimen collection policy (faxed to the CLIA office because it was not provided during the survey), a review of installation and validation documentation for the Beckman Coulter AcT diff 2 Hematology analyzer, a review of quality assurance records, and interviews with Testing Personnel #1, #2 and the Technical Consultant, the Laboratory Director: (1) failed to ensure procedures in use by the testing personnel assured positive patient identification. (Refer to D5203.) (2) and failed to ensure the initial installation procedures proved verification of precision, accuracy and reportable range for all measured CBC (Complete Blood Count) parameters as per manufacturer's performance specifications before patient testing began on 9/15/2018. (Refer to D5421.)
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

	This STANDARD is not met as evidenced by: Based on a review of installation and validation documentation for the Beckman Coulter AcT diff 2 Hematology analyzer, and interviews with Testing Personnel #1 and #2 and Technical Consultant #1, the surveyor determined the Technical Consultants failed to ensure the initial installation procedures proved verification of precision and accuracy as per manufacturer's performance specifications before patient testing began on 9/15/2018. The findings include: 1. Refer to D5421. SURVEYOR ID #32558 Licensure and Certification Surveyor