Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2137187	08/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
Urgent Care For Children-280	500 Cahaba Park Circle Ste 100, Birmingham, 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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of AAFP (American Academy of Family Physicians) proficiency testing records and an interview with Testing Personnel (TP) #1, who is also a provider, and the Technical Consultant (since June of 2019), the surveyor determined the laboratory failed to implement and document corrective actions for a Lymphocyte [WBC (White Blood Cell) Differential] Count which was scored less than one hundred percent (%) by AAFP. This affected Event 2018 C, one of five testing events reviewed by the surveyor. The findings include: 1. A review of the proficiency testing records for Hematology, Event 2018 C, revealed the laboratory scored 80 % for the Lymphocytes, due to the results of specimen HD15 being unacceptable. The overall score for the WBC Differential was 93 %. 2. The laboratory did not implement and document corrective actions for the above noted score of less than one hundred percent. 3. During the exit interview on 8/14/2019 at 12:50 PM, the surveyor asked TP #1 and the Technical Consultant to review the records. TP #1 reviewed the results for Event 2018 C and confirmed the Lymphocyte score of 80 % was missed, during the initial review of the proficiency testing results.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)

	(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the temperature and humidity logs, policies and procedures, Beckman Coulter's packing slip for the S-Cal (calibrator material), and an interview with Testing Personnel (TP) #1 and the Technical Consultant (TC), the surveyor determined the laboratory failed to implement and document corrective actions when the refrigerator temperatures were found outside acceptable limits. This affected at least eight days in 2018. The findings include: 1. A review of the temperature /humidity logs revealed the laboratory had established an acceptable refrigerator temperature equal to 34 - 40 degrees Fahrenheit. 2. A review of Beckman Coulter's packing slip for the S-Cal calibrator for the Act Diff 2 revealed the calibrator should be stored at 2 -8 degrees Celsius, which converts to 35.6- 46.4 degrees Fahrenheit (the laboratory documented 34 -40 degrees was acceptable). 3. A review of the temperature logs revealed the laboratory documented temperature of 32 - 33 degrees Fahrenheit on 2/19/2018, April 16 and 24, and May 5, 13, 18, 24 and 29 of 2018. 4. During an interview on 8/14/2019 at 12:50 PM, the surveyor discussed the established temperature ranges with the TC and TP #1. The surveyor discussed the correct conversion to Fahrenheit of the refrigerator temperature, which should be maintained at 2 - 8 degrees Celsius (35.6 - 46.4 degrees Fahrenheit).
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of the quality control (QC) and quality assurance (QA) records, temperature logs, proficiency testing records, policies and procedures, manufacturer's package inserts, and an interview with Testing Personnel (TP) #1 and the Technical Consultant (TC), the surveyor determined the laboratory failed to implement a quality assurance program sufficient to identify errors, resolve problems, and document corrective actions, when necessary. This affected quality control testing, temperature monitoring, and proficiency testing practices for the survey review period, extending from January 2018 - day of the survey. The findings include: 1. A review of the Hematology QC records for CBC (Complete Blood Count) testing revealed the laboratory did not have at least two levels of acceptable quality control on 4/4/2018, when staff tested five patient samples and reported the results. The low level of QC was the only acceptable level of three levels tested. Within the quality assurance activities, the laboratory documented five patient CBC were tested on 4/4/2018, when QC was found to be unacceptable. The laboratory documented the Laboratory Director should review the patient reports. The surveyor reviewed the quality assurance documentation, which revealed five patient test reports (instrument printouts), performed on 4/4/2018, which were initialed on the bottom by the laboratory director, who was not always the practioner of the patient. The laboratory

	failed to document corrective actions sufficient to determined how the deficiency affected the patients and how the patients were remediated. The laboratory failed to document corrective actions sufficient to ensure the problem of testing patients without appropriate and acceptable quality control did not reoccur. 2. On 1/15/2019, all three levels of QC were outside of the acceptable ranges. The laboratory staff tested three patient CBC specimens and reported the results. Within the quality assurance activities, the laboratory documented the Laboratory Director should review the patients' reports. The laboratory failed to document corrective actions sufficient to determined how the deficiency affected the patients and how the patients were remediated. The laboratory failed to document corrective actions sufficient to ensure the problem of testing patients without appropriate and acceptable quality control did not reoccur. 3. A review of the temperature logs revealed the laboratory had established an acceptable refrigerator temperature equal to 34 - 40 degrees Fahrenheit. The room temperature was measured in degrees Fahrenheit, which the laboratory had established as acceptable at 68 -77 degrees and then changed to 59 - 90 degrees Fahrenheit, without explanation. A review of Beckman Coulter's packing slip for the S-Cal calibrator for the Act Diff 2 revealed the calibrator should be stored at 2 -8 degrees Celsius, which converts to 35.6- 46.4 degrees Fahrenheit (the laboratory documented 34 -40 degrees was acceptable). The acceptable operating temperature for the Act Diff 2, as indicated in the policy and procedure manual, is 20 - 25 degrees Celsius, which is 68 - 77 degrees Fahrenheit. During an interview on 8/14/2019 at 12: 50 PM, the surveyor discussed the established temperature ranges with the TC and TP #1. The surveyor asked how, when and why the room temperature acceptability changed to 59 -90 degrees, when the operating temperature for the instrument is 68 -77 degrees Fahrenheit. The staff could not explain the change. The surveyor also discussed the correct conversion to Fahrenheit of the refrigerator temperature, which should be maintained at 2 - 8 degrees Celsius (35.6 - 46.4 degrees Fahrenheit). 4. A review of the proficiency testing records revealed the laboratory scored 60 percent (%) for Lymphocytes (White Blood Cell Differential) for Event AAFP (American Academy of Family Physicians) 2018 A. As corrective actions, the laboratory documented the specimens #1 and #4 were repeated, however found still to be unacceptable. The laboratory failed to document corrective actions sufficient to ensure the problem with testing was resolved and did not reoccur. 5. The laboratory repeated a missed specimen (MCV = 80 %) for Event 2018 B multiple times; and the result was still unacceptable. The laboratory failed to document corrective actions sufficient to ensure the problem with testing was resolved and did not reoccur. During an interview on 8/14/2019 at 12:50 PM, the surveyor discussed the proficiency testing with the TC and TP #1. The PT (Proficiency Testing) provider sent a second group of specimens to the laboratory, due to the initial batch was the incorrect samples. TP #1 documented the error was due to a bad specimen, due to a delayed shipment. However, TP #1 stated the specimens were within the expiration dates, and no problems with the shipment were noted/documented. .
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of the personnel records and an interview with Testing Personnel

	(TP) #1 and the Technical Consultant (TC), the surveyor determined the TC failed to assess the competency of TP #1 and #3 on an annual basis. This affected two of four testing personnel, who perform moderate complexity testing. The findings include: 1. A review of the personnel records revealed TP #1 was initially trained on 11/28/17. The testing personnel's semiannual competency assessment was performed on 4/18 /18; however the annual competency was not done until May 1, 2019. 2. TP #3 was initially trained on 5/14/18. The semiannual competency assessment for this personnel was performed on 11/14/18. The TC has not yet performed an annual competency assessment for TP #3, who has been performing moderate-complexity testing for greater than one year. 3. During an interview on 8/14/2019 at 12:50 PM, the surveyor asked TP #1 and the TC to review the personnel records. The TC and TP #1 reviewed the records and confirmed the above noted findings.