Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2171687	03/15/2022
Name of Provider or Supplier	**Street Address, City, State**	
Urgent Care For Children - Vestavia	520 Montgomery Hwy, Vestavia, 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
D0000	A recertification survey was conducted on 3/15/2022 at Urgent Care for Children. Based on a review of the Horiba Micros 60 (Hematology analyzer) calibration records, Quality Control (QC) records, User Manual, control package insert, patient result logs, and an interview with the Laboratory Manager, the laboratory failed to monitor and evaluate the quality of the calibration and quality control being performed on the Horiba Micros 60 analyzer and to ensure a properly working analyzer. Due to the potential for serious injury or death when it is unknown if the analyzer is properly working, the surveyor called an Immediate Jeopardy (IJ) on 3/15 /2022 at 1:00 PM. [Refer to D5400, D5437, D5481, and D5785.] The surveyor provided the IJ template to the Laboratory Manager, and received a voluntary statement, on 3/15/2022 at 2:30 PM, to suspend testing on the Horiba Micros 60 analyzer, until analytic processes are remediated.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of American Academy of Family Physicians (AAFP) Proficiency Testing (PT) records and an interview with the Laboratory Manager, the laboratory failed to retain all proficiency testing records for at least 2 years. This was noted for three out of six testing events. The findings include: 1. A review of AAFP PT records revealed 2020 - A, 2020 - B, and 2020 - C Events could not be located during the survey. 2. During an interview on 03/15/2022 at 10:25 AM, the Laboratory Manager confirmed the 2020 PT Binder could not be located.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)

	The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of American Academy of Family Physicians (AAFP) Proficiency Testing (PT) records and an interview with the Laboratory Manager, the laboratory failed to provide evidence of review and evaluation of PT results. This was noted five out six testing events. The findings include: 1. A review of AAFP PT records revealed the laboratory failed to retain the 2020 PT records (events A, B, and C). For 2021 - A and 2021 - B events the laboratory failed to provide evidence of review and evaluation of the PT results. 2. During an interview on 3/15/2022 at 10:51 AM, the Laboratory Manager confirmed the 2020 PT Binder could not be located. Also, she confirmed the two events in 2021 did not have documentation of review and evaluation of PT results.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of the Horiba Micros 60 (Hematology analyzer) calibration records, Quality Control (QC) records, User Manual, control package insert, patient result logs, and an interview with the Laboratory Manager, the laboratory failed to monitor and evaluate the quality of the calibration and QC being performed on the Horiba Micros 60 analyzer and to ensure a properly working analyzer. From September 2020 to January 2022, the laboratory performed 6 patient Complete Blood Counts (CBC). Due to the evidence of this condition, an Immediate Jeopardy (IJ) was called on 03/15/2022 at 1:00 PM. An adverse outcome resulting in serious injury, harm, or death to patients is likely to occur if the following laboratory failures are not corrected: a) failure to follow the manufacturer's instructions to verify the calibration by running acceptable QC (refer to D5437). b) failure to ensure QC was acceptable before reporting patient test results (refer to D5481). c) failure to document corrective action taken when the refrigerator which stored the Horiba controls was outside of the acceptable limits (refer to D5785). d) failure to implement and document corrective action when QCs were outside of the acceptable range (refer to D5793).
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 a review of the Horiba Micros 60 (Hematology analyzer) calibration records, User Manual, patient result logs, and an interview with the Laboratory Manager, the laboratory failed to follow the manufacturer's instructions to verify the calibration by running Quality Control (QC). This was noted one out of three calibration records reviewed from 2020 - 2022. The findings include: 1. A review of Horiba Micros 60 calibration records revealed on 1/12/2022 the staff performed the calibration. The staff did not perform QC until 1/15/2022, and all three levels were outside the acceptable ranges. From 1/15/2022 to 02/21/2022, for 20 days all three levels of QC were outside the acceptable ranges. 2. A review of Horiba Micros 60 User manual revealed under 2.2.7 Verify Calibration "...4. Run Quality Control and verify that all 3 levels of control results are within their specified ranges. Verify that all control parameter results are without Flags (H, L, *, $, and ! for HGB)." 3. A review of patient result log revealed on 01/27/2022 a patient Complete Blood Count (CBC) was performed and reported, although there was no acceptable QC performed. 4. During an interview on 3/15/2022 at 12:00 PM, the Laboratory Manager confirmed the QC had not been acceptable for all three levels since the calibration was performed on 01/12/2022. Also, the Laboratory Manager confirmed one patient CBC was performed and resulted during this time period.
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 the Horiba Micros 60 (Hematology analyzer) Quality Control (QC) records, User Manual, patient result logs, and an interview with the Laboratory Manager, the laboratory failed to ensure QC was acceptable before reporting patient test results. This was noted two days out of twelve days reviewed. The findings include: 1. A review of QC records for the Horiba Micros 60 revealed on 9/11/2020 and 01/27/2022 all three levels (low, normal, and high) were unacceptable. 2. A review of the Horiba Micros 60 User Manual revealed under 2. Daily Quality Control and Calibration verification "Before analyzing any patient blood samples, it is recommended that the Operator performs Quality Control analysis on 3 levels of Control Blood Material (Low, Normal, and High), to verify that the ABX Micros 60 is performing within the specified ranges of the Quality control material..." 3. A review of the patient result logs revealed one patient was run on 9/11/2020 and one patient was run on 01/27/2022, when QCs were outside of acceptable range. 4. During an interview on 3/15/2022 at 2:20 PM, the Laboratory Manager confirmed all three levels of QC were unacceptable and patient testing was performed on the above noted days.
D5785	CORRECTIVE ACTIONS

	CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on a review of temperature records, Horiba Minotrol 16 Tri-Level control package insert, and an interview with the Laboratory Manager, the laboratory failed to document corrective action taken when the refrigerator which stored the Horiba controls was outside of the acceptable limits (2 - 8 degrees Celsius or 35.6 - 46.4 degrees Fahrenheit) . This was noted for 7 months out of 24 months reviewed by the surveyor. The findings include: 1. A review of temperature records revealed refrigerator temperatures were below 35.6 degrees Fahrenheit [temperatures were recorded as low as 29.1 degrees Fahrenheit (which is below freezing)] with no corrective action documented for the following months: a) June 2021 for 4 days b) July 2021 for 8 days c) August 2021 for 17 days d) September 2021 for 20 days e) October 2021 for 26 days f) November 2021 for 13 days g) December 2021 for 20 days 2. A review of the Horiba Minotrol 16 Tri-Level control package insert revealed under 5. Stability and storage "Store the tubes vertically in their original package at 2 to 8 degrees Celsius (35.6 - 46.4 degrees Fahrenheit) when not in use. DO NOT FREEZE..." 3. During an interview on 3/15/ 2022 at 2:12 PM, the Laboratory Manager confirmed the above findings.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of Quality Assessment (QA) records, Quality Control (QC) records for the Horiba Micros 60 (hematology analyzer), and an interview with the Laboratory Manager, the laboratory failed to implement and document corrective action when QCs were outside of the acceptable range. This was noted for two out of three months QA records reviewed by the surveyor. The findings include: 1. A review of QA records revealed the monthly checklist for January 2021 and February 2021 had yes check for "Was any QC out of range? If so what documentation was provided for solution". No documentation was provided as a solution of the out of range QC, the laboratory failed to implement and document for the failed QC. 2. A review of QC records for the Horiba Micros 60 revealed from 1/15/2022 to 2/21/2022 all three levels (low, normal, and high) of QC were outside of the acceptable range. 3. During an interview on 3/15/2022 at 2:00 PM, the Laboratory Manager confirmed the QA was marked as yes for QC being out of range, but no corrective action was provided.