Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2101461	09/25/2019
Name of Provider or Supplier	**Street Address, City, State**	
Central Alabama Urgent Care	27 Midway Plaza Suite B, Dora, 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
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 reviews of the Horiba ABx Micros 60 calibration guide, calibration and quality control records, and interviews with Testing Personnel #1 and the Laboratory Director, the surveyor determined the laboratory: (1) failed to follow the manufacturer's instructions to verify calibrations by running quality controls (QC) for one out of four calibrations of the Hematology analyzer performed in 2017 - 2019 (refer to D5437), and (2) failed to implement effective corrective actions to ensure patient Complete Blood Counts (CBC's) were performed only on days when at least two levels of quality controls (QC) were within acceptable ranges; patient CBC's were performed and results were released on seven days between May and September 2019) when QC was outside acceptable limits (refer to D5481 and 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 reviews of the Horiba ABx Micros 60 calibration guide, calibration and quality control records, and an interview with Testing Personnel, the surveyor determined the laboratory failed to follow the manufacturer's instructions to verify calibrations by running quality controls (QC) for one out of four calibrations of the Hematology analyzer performed in 2017 - 2019. The findings include: 1. A review of calibration records for the Horiba Micros 60 revealed the instrument was calibrated on 12/27/2017 at 1:25 PM. 2. A review of the monthly cumulative QC records revealed three levels of QC were run on this date at 12:43 - 12:47 PM (before the calibration). 3. A review of the manufacturer's instruction in the "M60 Calibration Guide when using Lite DM" revealed as the final steps under the calibration section, "...15. Run QC as normal. ...". 4. During the exit summation on 9/25/2019 at 4:30 PM, the surveyor reviewed the above findings with Testing Personnel #1 and the Laboratory Director (on the phone). Testing Personnel #1 reviewed the calibration date and time, printed the QC results for 12/27/2019, and confirmed the QC was run before the calibration. .
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (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) records for the Horiba ABx Micros 60 Hematology analyzer and an interview with Testing Personnel #1, the laboratory failed to ensure at least two levels of QC were within acceptable range before performing patient testing and releasing results. The findings include: 1. A review of the QC records for the Horiba ABx Micros 60 Hematology analyzer revealed no QC was run on 5/13/2019. 2. During an interview on 9/25/2019 at 2:30 PM, the surveyor reviewed the above noted findings, and asked Testing Personnel #1 if patient CBC's (Complete Blood Counts) were performed on 5/13/2019. Testing Personnel #1 checked her records and stated four patients CBC's were performed on that date, and further stated the laboratory had not previously noticed the QC outages, so no corrective action had been performed for the patients. .
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 the Horiba ABx Micros 60 Hematology records, and interviews with Testing Personnel #1 and the Laboratory Director, the surveyor determined the laboratory failed to implement effective corrective actions to ensure patient Complete Blood Counts (CBC's) were performed only on days when at least two levels of quality controls (QC) were within acceptable ranges. The findings include: 1. A review of the Hematology and Quality Assurance (QA) records revealed the Horiba ABx Micros 60 had an extended period of downtime from 11/28/2018 through 5/7 /2019. A notation in the 2019 QA records specified a new service agreement with Horiba was in effect on 3/11/2019, and a Horiba "Validation Test Report" documented the 5/7/2019 service; patient testing resumed on this date. 2. However, a review of the Horiba ABx Micros 60 QC records revealed six days when the testing personnel (the previous "Laboratory Manager") ran patients CBCs without performing any QC, as follows: A) 5/09/19--No QC run; one patient CBC performed B) 5/10/19--No QC run; four patient CBCs performed C) 5/12/19--No QC run; one patient CBC performed D) 5/13/19--No QC run; four patient CBCs performed E) 5/19/19--No QC run; three patient CBCs performed F) 6/05/19--No QC run; four patient CBCs performed 3. A further review of the QC data in May and June revealed the testing personnel continued to have difficulties obtaining acceptable QC results, however there was no documentation the Technical Consultant was informed or Horiba Service was requested. Two out three or all three levels of QC were out on the following dates 5/22, 5/24, 5/25, 5/26, 6/1, and 6/8/2019; the testing personnel had not performed any patient CBCs on these dates. 4. A review of QA documentation for May and June 2019 revealed a note specifying the "Laboratory Manager" had been trained by the Horiba technician, however she had failed to train other testing personnel, and failed to run QC or ensure QC was in range "most of May"; this was signed by the Technical Consultant on 7/29/2019. During an interview on 9/25/2019 at 2:30 PM, TP #1 confirmed she had written this note, and further stated the previous "Lab Manager" was terminated on 6/10/2019. The laboratory had documented corrective action; all patient CBCs on the above cited dates (except 5/13/2019--refer to D5447) had been printed and signed by one of the CRNP (Certified Registered Nurse Practitioner), the practice provider. TP #1 (a Medical Laboratory Technician) stated she had notified the Laboratory Director in early June when she discovered the problem, and TP #1 was placed in charge of the lab. 5. The surveyor accepted the explanation of the problems documented in May and June 2019. To verify the problems had been rectified, the surveyor continued to review QC data for the latter half of June, July and August 2019. Two out of three levels of QC were in range for this period, though the surveyor noted more than half the time at least one level of QC was outside acceptable ranges. 6. However, a review of September 2019 QC revealed on 9/1/2019 patient samples were tested when two out of three levels of QC were out of range; seven patient CBC's were performed. Corrective action was the laboratory had printed the patient CBCs, and the CRNP had signed the reports. 7. During an interview with TP #1 on 9/25/2019 at 3:30 PM, the surveyor expressed serious concerns about problems in the laboratory, noting seven days in the last four months when patient CBC's were run when QC was outside acceptable limits. The surveyor also noted the difficulties in running the daily QC might indicate a problem with the analyzer, yet there was no documentation Horiba was called for additional service until 9/23/2019, two days before the survey. (The Horiba Service Report was provided by TP #1). 8. During the exit summation on 9/25/2019 at 4:30 PM, these concerns were reviewed with TP #1

	and with the Laboratory Director via conference call. The surveyor reviewed the serious concerns concerning lack of acceptable QC on seven days of patient CBC testing; all events occurred after an extended downtime for the analyzer. The surveyor then asked the Director if she or the Technical Consultant had checked the status of the testing in May or June 2019 after the analyzer was again operational. The Director stated yes, the Technical Consultant had visited in May; TP #1 provided a "Memo" dated 5/20/2019 from the Technical Consultant. 9. A review of the "Memo" revealed the Technical Consultant reviewed the July 2018 - October 2018 records. The Memo does not specify any review of May 2019 QC records and ensuing problems, or when his on-site visit actually occurred. 10. At the conclusion of the exit interview at approximately 4:55 PM, the surveyor explained the Laboratory Director and Technical Consultant needed to closely monitor this laboratory, and implement additional corrective actions to ensure patient testing was performed only on days when at least two levels of QC were within acceptable limits. .
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of the Horiba ABx Micros 60 Hematology records, and interviews with Testing Personnel #1 and the Laboratory Director, the surveyor determined the Technical Consultant failed to adequately fulfill his responsibilities to provide effective technical and scientific oversight of the laboratory when the Hematology analyzer was in use again by the Testing Personnel after a period of extended downtime. Refer to D6036. .
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on a review of the Horiba ABx Micros 60 Hematology records, and interviews with Testing Personnel #1 and the Laboratory Director, the surveyor determined the Technical Consultant failed to adequately fulfill his responsibilities to provide effective technical and scientific oversight of the laboratory when the Hematology analyzer was in use again by the Testing Personnel after a period of extended downtime. The findings include: 1. A review of laboratory processes revealed the Technical Consultant had failed to provide effective technical and scientific oversight in the following areas: A) Failure to ensure testing personnel follow the manufacturer's instructions to verify calibrations by running quality controls (QC) for one out of four calibrations of the Hematology analyzer performed in 2017 - 2019 (refer to D5437), and A) Failure to ensure patient Complete Blood Counts (CBC's) were performed only on days when at least two levels of quality controls (QC) were within acceptable ranges; patient CBC's were performed and results were released on seven days between May and September 2019) when QC was outside acceptable

	limits (refer to D5447 and D5793). The laboratory was unable to provide evidence the Technical Consultant was monitoring the status of testing in May and June 2019 when the analyzer was again operational, after an extended downtime from 11/28/2018 - 5/7 /2019. 2. These concerns were discussed with Testing Personnel #1 and the Laboratory Director (via conference call) during the exit summation on 9/25/2019 from 4:30 - 4:55 PM. SURVEYOR ID#32558 Licensure and Certification Surveyor