Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2119508	01/09/2019
Name of Provider or Supplier	**Street Address, City, State**	
Qc Wellness	7500 Us Hwy 72 West, Madison, 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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of the 2017 Beckman Coulter AcT diff 2 Hematology analyzer calibration records and an interview with Testing Personnel #1, the laboratory failed to ensure the November 2017 calibrator was used before its expiration date. This was observed on one of one 2017 calibrations reviewed. The findings include: 1. A review of records for the AcT diff 2 Hematology analyzer, revealed a calibration was performed on 11/28/2017, using S-CAL Calibrator lot number 4728 with an expiry date of 11/11/2017. A note on the 11/28/2017 calibration records indicated the Laboratory Director had discovered the use of the expired calibrator and had written "used expired calibrator". 2. During an interview on 1/10/2019 at 4:40 PM, the surveyor reviewed and confirmed the above noted findings with Testing Personnel #1. .
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 Beckman Coulter AcT diff 2 Hematology analyzer Operator's Manual, calibration records, and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to follow the laboratory's policy in the performance frequency of calibrations in 2017. The findings include: 1. A review of the Beckman Coulter AcT diff 2 Hematology analyzer Operator's Guide on page 5-1 revealed the following written instructions from the Technical Consultant dated "2/4 /2017", "Calibration must be performed at least every six months". 2. A review of the Hematology records revealed the following: A) Installation (including a calibration and other validation data) on 1/11/2017 B) 11/28/2017: Documentation of a calibration performed with an expired calibrator (Lot number 4728; Expiry 11/11 /2017) (Refer to D5417.) C) 05/31/2018: Documentation of a valid calibration performed sixteen months after installation 3. During an interview on 1/10/2019 at 4: 40 PM, the surveyor asked if the laboratory had performed a valid calibration of the AcT diff 2 the latter half of 2017. TP #1 stated she thought they had performed a calibration in May 2017 (however the laboratory did not provide any documentation). The surveyor reviewed the available calibration records with TP #1, who confirmed the 11/28/2017 was performed with an expired calibrator (and thus, invalid). The first valid calibration was performed on 5/31/2018 (sixteen months after installation). TP #1 further confirmed the Hematology analyzer calibration should be performed every six month. .
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of the calibration verification (C/V) records for the Beckman

	Coulter AU480 Chemistry analyzer and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to perform calibration verifications every six months in 2017. The findings include: 1. A review of the records for the Beckman Coulter AU480 Chemistry analyzer revealed all analytes except C-Reactive Protein were calibrated with one- or two-calibrator kits. Analytes calibrated with less than three calibrators must have a calibration verification (C/V) performed every six months. 2. A review of the Chemistry records for the Beckman Coulter AU480 revealed the analyzer was installed in April 2017, and a C/V was performed on 2/27 /2018, approximately ten months after the installation. 3. During an interview on 1/10 /2018 at 6:05 PM, TP #1 was asked if the laboratory had performed a C/V on the AU480 for analytes with less than three calibrators the latter half of 2017. TP #1 stated, "No, they did not". Thus the above findings were confirmed. SURVEYOR ID #32558 Licensure and Certification Surveyor