Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2009563	10/23/2018
Name of Provider or Supplier	**Street Address, City, State**	
Seib Wellness Center Lab	101 South Union Street, Montgomery, 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of the temperature logs, a lack of documentation of humidity, a review of the reference manual for the Beckman Coulter Act Diff 2, and an interview with the Technical Consultant, the surveyor determined the laboratory failed to monitor and document humidity. The Act Diff 2 reference manual indicated a certain humidity range (20 - 80 percent) for optimal performance of the instrument, used for Complete Blood Count (CBC) testing. This affected the survey review period from 4 /25/17 until 10/23/18. The findings include: 1. A review of the temperature logs revealed no documentation of humidity. 2. When asked what were the humidity requirements for the Act Diff 2, the Technical Consultant (TC) and the surveyor reviewed the instrument's reference manual. The manual revealed the optimal humidity range for operation of the instrument was 20 - 80 % (percent), without condensation. 3. In an interview on 10/23/18 at 12:41 PM, the TC confirmed the laboratory had not monitored the humidity for the survey period reviewed.
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 calibration and quality control (QC) records for the Act Diff 2, an interview with the Technical Consultant (TC), and a review of the reference manual for the instrument, the surveyor determined the laboratory failed to verify the calibration performed on 2/09/18. This affected one of three calibrations reviewed by the surveyor. The findings include: 1. A review of the calibration records for the Act Diff 2 revealed the instrument was calibrated in the PM on 2/09/18. However there was no quality control testing documented after the calibration was performed. 2. The surveyor reviewed the QC and calibration records for 2/09/18 to verify the time of day the quality controls were tested, and if the controls were tested. The review revealed the QC for 2/09/18 was tested in the AM, between 8:50 AM - 9:00 AM, but had not been tested after the calibration. 3. In an interview on 10/23/18 at 12:27 PM, the surveyor asked the TC to review the records to determine if the staff ran quality control after the calibration had been performed. The TC reviewed the calibration and QC records and confirmed there was no documentation of QC after the calibration. 4. A revive of the reference manual for the instrument revealed the manufacturer's instructions to verify the calibration by running the 4C Plus Cell controls.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a review of the personnel and proficiency testing records, a review of a policy and procedure in development, and an interview with the technical consultant and testing personnel, the surveyor determined the Laboratory Director failed to ensure laboratory testing personnel (TP) presented with the appropriate educational credentials, prior to allowing the personnel to test patients' specimens. This affected five of thirteen testing personnel. The Laboratory Director further failed to ensure each employee received appropriate training to perform moderate complexity testing, prior to testing patient specimens. This affected at least two testing personnel of the current thirteen. The findings include: 1. A review of the personnel records revealed no educational documents or verification of education for the following testing

	peronnel: TP #5, #7, #11 #13 and #14. 2. Further review of the personnel records revealed ten of the thirteen testing personnel had initial training documented for August - October of 2018. TP #5 was trained in August, and TP #7, #11, #13 and #15 received training in 10/19/18, without verification of their education. 3. In an interview at 10:04 - 10:19 AM on 10/23/18, the Technical Consultant (TC) verified no educational credentials were included in the records/files for TP #5, 7, #11, #13 and #14. 4. During an interview at 10:42 AM, TP #10, a previously qualified and trained laboratory testing personnel, stated TP #1, whose initial training was documented on 8 /21/18, did not perform CBCs (Complete Blood Counts). However the TC, who started her employment in August of 2018, stated TP #1 did perform CBCs, because she was present when the testing personnel performed CBC testing on a patient specimen. TP #6 had initial training documented on 9/20/18. According to TP #10, TP #6 was performing CBC testing on patient specimens prior to September of 2018. The TC stated she performed and documented the initial training (9/20/18) for TP #6 and for the others, because there was no documented training records in the employees' files. Further review of the proficiency testing records for Hematology revealed TP #6 performed testing Event #2, 2018 CBC testing, also prior to the initial training documentation for this personnel. TP #8 had initial training documented on 8/08/18. TP #10 stated the personnel began CBC testing of patient specimens in 2017. 5. At 11: 00 AM on 10/23/18, the surveyor inquired of the TC the laboratory's policy and procedure on personnel training and competency evaluations. The TC (who started employment in August of 2018) stated she was currently working to develop the policy and procedure, and provided the "Quality Management" plan (not signed by the Laboratory Director), which included the following bullet-point: "...Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of services offered, and have demonstrated that they can perform all tests reliable to provide and report accurate results." Patricia Watson, BS, MT (ASCP) Licensure and Certification Supervisor