

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2009563	(X3) Date Survey Completed 05/29/2025
Name of Provider or Supplier Seib Wellness Center Lab	Street Address, City, State 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	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on reviews of the Temperature Control Log (TCL), the Beckman Coulter (BC) DxH 520 Instruction For Use (IFU) manual and an interview with the Technical Consultant (TC), the laboratory failed to ensure the room temperature for the DxH 520 analyzer was within the manufacturer's acceptable ranges. The room temperature was noted out of acceptable limits for 35 days of the 14 months in the 2024-2025 review period. The findings include: 1. A review of the TCL revealed the room temperature was out of the manufacturer's acceptable limits for the following days: A) January-April 2024; 19 days, B) December 2024; 7 days E) January-February 2025; 9 days 2. A review of the BC DxH 520 IFU manual revealed on page 1-7 the manufacturer's required operational temperature of 18-32 degrees Celsius. 3. During the exit conference with the TC and Director on 05-29-2025 at 1:42 PM, the TC confirmed the above findings.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency</p>

specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on reviews of the Hematology maintenance logs, the Beckman Coulter (BC) DxH 520 In-Lab Training Guide and an interview with the Technical Consultant (TC), the laboratory failed to document the monthly maintenance for 5 of the 23 months reviewed, and the annual maintenance in 2023 and 2024. The findings include: 1. A review of the maintenance logs for the BC DxH 520 revealed the following: A) No evidence of monthly maintenance, as follows: a) May and August 2023 b) January and September 2024 c) March 2025 B) No evidence of annual maintenance for 2023 or 2024. 2. A review of the BC DxH 520 In-Lab Training Guide revealed a Cleaning and Replacement Procedure Log Sheet with the following maintenance requirements. A) Monthly or every 1,000 cycles (Bleach Cycle) B) Monthly (Cleaning the WBC Bath Filter) C) Yearly (Lubricating Pistons) D) Yearly or every 18,000 cycles (Replace Rinsing Head O-Ring) 3. During the exit conference with the TC and Director on 05-29-2025 at 1:42 PM, TC confirmed the above findings.

D5441

CONTROL PROCEDURES

CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.

This STANDARD is not met as evidenced by:

Based on a review of the Hematology Quality Control (QC) records and an interview with the Technical Consultant (TC), the laboratory had missing documentation of the mechanism utilized to monitor for shifts and trends of test performance over time. This was noted for six of the twelve months in 2024 and one of three months in 2025. The findings include: 1. A review of the Hematology QC records revealed the following months in 2024-2025 had no evidence of Levey Jennings charts or peer group comparison data: a) 2024: July, August, September, October, November, and December, b) 2025: January. 2. During the exit conference with the TC and Director on 05-29-2025 at 1:42 PM, TC confirmed the above findings.

D6064

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(a)

Each individual performing moderate complexity testing must-- (a) possess a current license issued by the State in which the laboratory is located, if such licensing is required; and

This STANDARD is not met as evidenced by:

Based on a review of the personnel records and an interview with the Technical Consultant (TC), the TC failed to ensure competency assessments for Testing Personnel (TP) performing moderate complexity testing included the six CLIA minimal regulatory requirements. The surveyor noted six of the six requirements were missing on the semi-annual and annual competencies. The findings include: 1. A review of the 2023-2025 personnel records revealed TP competency assessments for the Hematology specialty had no documentation of the six CLIA minimal regulatory requirements which are as follows: (1) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing, and testing. (2) Monitoring the recording and reporting of test results. (3) Review of intermediate test results of worksheets, quality control records, proficiency testing results, and preventive maintenance results. (4) Direct observation of performance of instrument maintenance and function checks. (5) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. (6) Assessment of problem-solving skills. 2. The TC confirmed the above findings during the exit conference with the TC and Director on 05-29-2025 at 1:42 PM.