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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 01D2009563 | (X3) Date Survey Completed 04/27/2023 |
| 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 |
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| D2007 | <p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on a review of WLSH (Wisconsin State Laboratory of Hygiene) Proficiency Testing (PT) records and an interview with the Technical Consultant, the laboratory failed to ensure PT samples were tested: (A) by personnel who routinely performed the patient testing, (B) during hours of operation when patients CBC's (Complete Blood Counts) were run. This was noted on two of four 2022-2023 survey events. The findings include: 1. A review of the 2022-2023 WLSH PT records revealed the following: A) 2022-Event #2: The Technical Consultant signed the attestation statement as the testing personnel; instrument printouts documented the PT was performed on 6/11/2022 from 1732 to 1745 (5:32 to 5:44 PM). B) 2022-Event #3: Instrument printouts documented the PT was performed on 9/24/2022 from 1703 to 1716 (5:03 to 5:16 PM). 2. A review of the hours of operation on the laboratory's CMS-116 (CLIA Application for Certification) revealed the clinic/laboratory hours were 8:00 AM to 5:00 PM. 3. During an interview on 4/27/2023 at 10:05 AM the surveyor reviewed and confirmed the above findings with the Technical Consultant, who also confirmed she did not do patient testing. The Consultant stated she had run the PT because 2022-Event #2 had been assigned to a testing personnel who was no longer working at the clinic. However, the surveyor noted there are a total of eight testing personnel on the CMS-116 (Laboratory Personnel Report) who routinely ran patient CBC's (Complete Blood Counts). .</p> |
| D5407 | <p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> |

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on a review of Hematology records, a review of the User's Manual for the new Beckman Coulter (B-C) DxH 520 Hematology analyzer, and an interview with the Technical Consultant, the Laboratory Director failed to review, sign and date approval of the procedures before the Testing Personnel began using the instrument for patient testing. This affected procedures in use for one of one new instruments performing moderate-complexity tests. The findings include: 1. A review of Hematology records revealed the validation records for the B-C DxH 520, installed 12/28/2022. Patient CBC (Complete Blood Count) testing began on 12/30/2022. 2. A review of the "Instructions for Use DxH 520" Manual revealed no documentation of the Laboratory Director's review and approval (as indicated by a signature and date) of the procedures in use by the testing personnel. 3. During an interview on 4/27/2023 at 12:10 PM, the surveyor reviewed CLIA requirements, and confirmed the above noted findings with the Technical Consultant. .

D6013

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(ii)

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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:

Based on a review of the installation and validation records for the Beckman Coulter (B-C) DxH 520 Hematology analyzer, and an interview with the Technical Consultant, the Laboratory Director failed to document review and approval of the procedures as verification of the manufacturer's performance specifications before patient testing began. This affected one of one new instruments performing moderate-complexity tests. The findings include: 1. A review of the validation records for the B-C DxH 520 revealed no documentation (signature and date) of the Laboratory Director's review and approval of the procedures verifying the manufacturer's performance specifications. Patient CBC (Complete Blood Count) testing began on 12/30/2022. 2. During an interview on 4/27/2023 at 10:35 AM, the surveyor reviewed the records with the Technical Consultant, and confirmed the above noted findings. SURVEYOR ID#32558 Licensure and Certification Surveyor