

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2009563	(X3) Date Survey Completed 05/28/2021
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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on a review of scores for the WSLH (Wisconsin State Laboratory of Hygiene) proficiency testing (PT) on the CMS (Centers for Medicare and Medicaid) CASPER reports, and an interview with the Technical Consultant, the surveyor determined the laboratory failed to satisfactorily perform on RBC (Red Blood Cell) in Hematology proficiency testing on two consecutive testing events, 2020-Event #3 and 2021-Event #1. These failures resulted in an initial unsuccessful performance on RBC proficiency testing. The findings include: 1. A review of the CASPER Report 0155D (Individual Laboratory Profile) revealed the laboratory scored zero percent (0 %) for RBC in Hematology (Complete Blood Count [CBC] testing) for 2020-Event #3 and, a score of</p>

60 % for RBC on 2021-Event #1. These two consecutive failures resulted in an initial unsuccessful performance on RBC proficiency testing. 2. During an interview on 5/24 /2021 at 10:40 AM, the Technical Consultant confirmed the laboratory had failed to perform and submit the results for the 2020-Event #3 survey within the timeframe prescribed by the PT provider, and had received a score of 0 % for the event (including RBC); the laboratory had performed patient CBC testing during this period, and WSLH was not provided with a valid reason for failing to perform the PT. The Technical Consultant further confirmed the laboratory received a failing score of 60 % for RBC on the 2021-Event #1 survey. .

D2123

HEMATOLOGY
CFR(s): 493.851(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:
Based on a review of scores for the WSLH (Wisconsin State Laboratory of Hygiene) proficiency testing (PT) on the CMS (Centers for Medicare and Medicaid) CASPER reports, and an interview with the Technical Consultant, the surveyor determined the laboratory failed to submit the results for the 2020-Event #3 survey within the timeframe prescribed by the PT provider. The findings include: 1. A review of the CASPER Report 0155D (Individual Laboratory Profile) revealed the laboratory scored zero percent (0 %) for Hematology (Complete Blood Count [CBC] testing) on the 2020-Event #3 survey. 2. During an interview on 5/24/2021 at 10:40 AM, the Technical Consultant confirmed the laboratory had failed to perform and submit the results for the 2020-Event #3 survey within the timeframe prescribed by the PT provider, and had received scores of 0 %; the laboratory had performed patient CBC (Complete Blood Count) testing during this period, and WSLH was not provided with a valid reason for failing to perform the PT. .

D2130

HEMATOLOGY
CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on a review of scores for the WSLH (Wisconsin State Laboratory of Hygiene) proficiency testing (PT) on the CMS (Centers for Medicare and Medicaid) CASPER reports, and an interview with the Technical Consultant, the surveyor determined the laboratory failed to satisfactorily perform on RBC (Red Blood Cell) in Hematology proficiency testing on two consecutive testing events, 2020-Event #3 and 2021-Event #1. These failures resulted in an initial unsuccessful performance on RBC proficiency

testing. The findings include: 1. Refer to D2016. SURVEYOR ID# 32558 Licensure and Certification Surveyor

D6017

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:
Based on a review of scores for the WSLH (Wisconsin State Laboratory of Hygiene) proficiency testing (PT) on the CMS (Centers for Medicare and Medicaid) CASPER reports, and an interview with the Technical Consultant, the surveyor determined the Laboratory Director failed to ensure the laboratory submitted results for the 2020-Event #3 survey within the timeframe prescribed by the PT provider. The findings include: 1. Refer to D 2123. SURVEYOR ID# 32558 Licensure and Certification Surveyor