

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0483827	(X3) Date Survey Completed 02/10/2021
Name of Provider or Supplier Freestone Medical Center	Street Address, City, State 125 Newman St, Fairfield, TX	
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
D0000	The following deficiencies are a result of a desk review of proficiency testing scores obtained from the national database and verified with the proficiency testing company. The facility was found to be out of compliance with the conditions of participation of the CLIA program The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director;
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 the CMS (Center for Medicare Services) national database and a</p>

	<p>proficiency desk review of the American Proficiency Institute (API) proficiency testing (PT) records from 2020, it was determined the laboratory has not successfully participated in a proficiency testing program, for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory did not successfully participate in the specialty of hematology for the analyte partial thromboplastin time (PTT) in 2 of 3 PT events in 2020. Refer to D2130</p>
<p>D2121</p>	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the CMS (Center for Medicare Services) national database and a proficiency desk review of the American Proficiency Institute (API) proficiency testing records from 2020, it was determined the laboratory failed to achieve satisfactory performance (at least 80%) in the specialty of hematology for the analyte PTT, for 2 of 3 consecutive testing events in 2020. Findings were: 1. A review of the CMS national proficiency testing database revealed the following scores for the analyte PTT for 2 of 3 consecutive testing events in 2020: 2020 API 2nd event PTT - 60 % 2020 API 3rd event PTT - 60% 2. A proficiency desk review of the API proficiency testing records from 2020 confirmed that the laboratory received the following scores for the analyte PTT for 2 of 3 testing events in 2020. 2020 API 2nd event PTT - 60 % 2020 API 3rd event PTT - 60%</p>
<p>D2130</p>	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the CMS (Center for Medicare Services) national database and a proficiency desk review of the American Proficiency Institute (API) proficiency testing records from 2020, it was determined the laboratory failed to achieve satisfactory performance (at least 80%) in the specialty of hematology for the analyte PTT for 2 of 3 consecutive testing events in 2020, resulting in an unsuccessful PT performance for PTT. Findings were: 1. A review of the CMS national proficiency testing database revealed the following scores for the analyte PTT for 2 of 3 consecutive testing events in 2020: 2020 API 2nd event PTT- 60 % 2020 API 3rd event PTT - 60% 2. A proficiency desk review of the API proficiency testing records from 2020 confirmed that the laboratory received the following scores for the analyte PTT for 2 of 3 testing events in 2020. 2020 API 2nd event PTT - 60 % 2020 API 3rd event PTT - 60% 3. Two out of three unsatisfactory scores of the same analyte result in unsuccessful PT performance.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.</p>

1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on a desk review of laboratory proficiency testing performance it was revealed that the laboratory director failed to provide overall management and direction of the laboratory services. Findings were: 1. A review of the laboratory proficiency testing results revealed that the laboratory director failed to ensure that the laboratory participated successfully. (refer to D6016) By not providing overall management and direction of the laboratory, the laboratory director could not ensure the accuracy or reliability of all laboratory services provided by the facility.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(i)

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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on a desk review of proficiency testing results it was revealed that the laboratory director failed to ensure the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation in an approved proficiency testing program. (refer to D2130)