

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2130192	(X3) Date Survey Completed 09/21/2020
Name of Provider or Supplier Grace Er	Street Address, City, State 1851 Pearland Parkway, Pearland, 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 CMS (Center for Medicare Services) 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 conditions not met were: D2016- 42 C.F.R. 493.803 Condition: Successful participation in a proficiency testing program 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 desk review of proficiency testing records obtained from the CMS (Center</p>

	<p>for Medicare Services) national database and verified with the proficiency testing company, American Proficiency Institute (API), it was determined the laboratory had not successfully participated in a proficiency testing program approved by HHS, 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 analytes White Blood Cell Differential (WBC DIFF) for 2 of 3 events. (refer to D2121)</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 desk review of proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with the laboratory's American Proficiency Institute (API) proficiency test results, it was revealed the laboratory failed to attain a score of at least 80% for 1 of 6 regulated analytes (WBC Diff) in the specialty of Hematology for 2 of 3 events in 2019 and 2020. Findings include: 1. Review of the CMS national database proficiency testing report for 2109 third events and 2020 second event, the laboratory failed to attain at least 80% for WBC Diff: WBC Diff 2019 - Third event: 0 % 2020 - Second Event: 0% 2. Review of API proficiency records for the 2019 third event and 2020 second revealed the laboratory failed to attain a score of at least 80 percent on the following analytes: WBC Diff 2019 - Third event: 0 % 2020 - Second Event: 0%</p>
<p>D2122</p>	<p>HEMATOLOGY CFR(s): 493.851(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the CMS national database and American Proficiency Institute (API) proficiency testing records, the laboratory failed to attain an overall testing event score of at least 80 % for each event which constitutes unsatisfactory performance in 1of 3 events for 2019. Findings were: 1. Review of the CMS national database revealed the laboratory received "0" for Hematology for third testing event in 2019. 2019- Third event Hematology - 0% 2. Review of the laboratory API test records revealed the laboratory received "0" for the specialty of Hematology for third testing event in 2019. 2019 Third event Hematology - 0%</p>
<p>D2123</p>	<p>HEMATOLOGY CFR(s): 493.851(c)</p> <p>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</p>

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 review of the CMS national database and 2019 and 2020 American Proficiency Institute (API) proficiency testing records, the laboratory failed to participate in the specialty of hematology for 2019 third testing event. Findings were:
1. Review of the CMS national database revealed the laboratory received "0" for all the analytes in hematology for the third testing event in 2019. 2019 Third event WBC - 0% RBC - 0% HGB - 0% HCT - 0% PLT - 0% WBC Diff - 0%
2. Review of the laboratory API test records revealed the laboratory received "0" for Failure to Participate for all analytes in hematology for third testing event in 2019. 2019 Third event WBC - 0% RBC - 0% HGB - 0% HCT - 0% PLT - 0% WBC Diff - 0%

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 proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with records from American Proficiency Institute (API), the laboratory did not successfully participate in the specialty of Hematology/Coagulation for the analytes Cell ID or WBC Diff in 2 of 3 events between 2019 and 2020. The findings included: 1. Review of the CMS national database revealed the laboratory received "0" for Cell ID or WBC Diff for the following test events: 2019 - Third event: 0 percent 2020 - Second event: 0 percent
2. Review of the API testing records from 2019 and 2020 revealed the laboratory received "0" for the Cell ID or WBC Diff for the following test events: 2019 - Third event: 0 percent 2020 - Second event: 0 percent
Score of less than 80 percent are unsatisfactory performance. Unsatisfactory performance on two (2) consecutive events or two out of three (2 out of 3) events is unsuccessful performance.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 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 proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with the laboratory's American Proficiency Institute (API) proficiency test results, it was revealed that the laboratory director failed to provide overall management and direction of the laboratory services. (Refer to D6016)

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 a HHS approved proficiency testing program. (refer to D2121, D2130)