

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2066463	(X3) Date Survey Completed 01/28/2020
Name of Provider or Supplier Grace Er	Street Address, City, State 10900 Gulf Freeway, #B102, Houston, 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>

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) and Red Blood Cell Count (RBC). Refer to D2130.

D2121

HEMATOLOGY
CFR(s): 493.851(a)

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.

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 each analyte in the specialty of Hematology. Findings include: 1. A review of the laboratory's American Proficiency Institute (API) proficiency test results for 2019 Hematology/Coagulation - 1st Event revealed the laboratory received an unacceptable score of 67% for the analyte White Blood Cell Differential (WBC DIFF). 2. A review of the laboratory's American Proficiency Institute (API) proficiency test results for 2019 Hematology/Coagulation - 1st Event revealed the laboratory received an unacceptable score of 20% for the analyte Red Blood Cell Count (RBC)

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 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 participate in 1 of 3 testing events for 2019, resulting in unsatisfactory scores for all analytes in the specialty of Hematology. Findings include: 1. 2019 Hematology/Coagulation - 3rd Event unacceptable score of 0% for the analyte Cell I.D. or WBC DIFF. 2. 2019 Hematology/Coagulation - 3rd Event unacceptable score of 0% for the analyte RBC. 3. 2019 Hematology/Coagulation - 3rd Event unacceptable score of 0% for the analyte HCT. 4. 2019 Hematology/Coagulation - 3rd Event unacceptable score of 0% for the analyte HGB. 5. 2019 Hematology/Coagulation - 3rd Event

	<p>unacceptable score of 0% for the analyte WBC. 6. 2019 Hematology/Coagulation - 3rd Event unacceptable score of 0% for the analyte PLATELETS. Key: Cell I.D.= Cell Identification WBC DIFF= White Blood Cell Differential RBC= Red Blood Cell HCT= Hematocrit HGB= Hemoglobin WBC= White Blood Cell</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 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 achieve satisfactory performance of at least 80% for the same analyte in two out of three consecutive testing events in the specialty of Hematology for the analytes White Blood Cell Differential (WBC DIFF) and Red Blood Cell Count (RBC). Findings include: WBC DIFF: 1. 2019 Hematology/Coagulation - 1st Event unacceptable score of 67%. 2. 2019 Hematology/Coagulation - 3rd Event unacceptable score of 0% -failure to participate. RBC: 1. 2019 Hematology /Coagulation - 1st Event unacceptable score of 20%. 2. 2019 Hematology/Coagulation - 3rd Event unacceptable score of 0% -failure to participate.</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 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>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 D6018.</p>
<p>D6018</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</p> <p>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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p> <p>This STANDARD is not met as evidenced by:</p>

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 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, D2123, D2130.