

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2066463	(X3) Date Survey Completed 09/21/2020
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 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 D2017 - 42 C.F.R. 493.807 Condition: Reinstatement of laboratories performing nonwaived testing after failure to participate 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:</p>

Based on a desk review of proficiency testing records obtained from the CMS (Center 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 3 of 5 testing events (2019 first and third event and 2020 second event). (refer to D2121)

D2017

REINSTATEMENT OF NONWAIVED LABORATORIES
CFR(s): 493.807(a)(b)

(a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before CMS will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test. (b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate.

This CONDITION 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 failed to successfully participate in the specialty of Hematology/coagulation for the analyte White Blood Cell Differential (WBC Diff) in 3 of 5 events between 2019 and 2020 resulting in a non-initial PT failure. Refer to D2121, D2130 The laboratory must demonstrate sustained satisfactory performance ($\geq 80\%$) on two consecutive testing events for reinstatement.

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 review of the CMS (Center for Medicare and Medicaid Services) national database and verified by proficiency testing report, American Proficiency Institute records (API), the laboratory failed to attain a score of at least 80 percent for 1 of 6 regulated analytes White Blood Cell Differential (WBC Diff) in 3 of 5 events in 2019 and 2020. The findings included: 1. Review of the national database report for the WBC differential for 2019 first and third event and 2020 second event, the laboratory failed to attain a score of at least 80 percent on the following analytes: White Blood Cell Differential 2019 First Event - 67 percent 2019 Third Event - 0 percent 2020

	<p>Second Event - 67 percent 2. Review of the American Proficiency Institute proficiency result records for WBC differential for 2019 first and third event and 2020 second event, the laboratory failed to attain a score of at least 80 percent on the following analytes: White Blood Cell Differential 2019 First Event - 67 percent 2019 Third Event - 0 percent 200 Second Event - 67 percent</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, the laboratory failed to achieve satisfactory performance of at least 80% for the same analyte in three out of five testing events from 2019 first and third event and 2020 second event in the specialty of Hematology for the regulated analyte White Blood Cell Differential (WBC Diff). The findings included: 1. Review of the national database report for the WBC differential, the laboratory scores for 2019 first and third event and 2020 second event, the laboratory failed to attain a score of at least 80 percent for WBC Diff: 2019 Hematology - 1st Event WBC Diff- 67 % 2019 Hematology - 3rd Event WBC Diff - 0 % 2020 Hematology- 2nd Event WBC Diff - 67% 2. A review of the API testing records for WBC differential, the laboratory scores for 2019 first and third event and 2020 second event, the laboratory failed to attain a score of at least 80 percent for WBC Diff 2019 Hematology - 1st Event WBC Diff - 67 % Granulocytes - 60% Monocytes - 60% 2019 Hematology - 3rd Event WBC Diff - 0 % Granulocytes - 0 % Lymphocytes - 0% Monocytes - 0% 2020 Hematology- 2nd Event WBC Diff - score of 67% . Monocyte - 40% 3. A score of less than 80 percent is unsatisfactory performance. 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>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 D6016.</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</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)(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 successful participation in a HHS approved proficiency testing program for the analyte WBC Differential in 2019 and 2020. (refer to D2121, D2130)