Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2056204	(X3) Date Survey Completed 08/07/2020
Name of Provider or Supplier Crescent Medical Center Lancaster	**Street Address, City, State** 2600 West Pleasant Run Road, Lancaster, 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 (Centers for Medicare and Medicaid Services) national database and verified with the proficiency testing company, American Proficiency Institute (API). 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: 493.803 Successful participation in a proficiency testing program 493.1403 Laboratory Director, Moderate Complexity
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by:

	Based on a desk review of proficiency testing records, 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 Routine Chemistry for the pO2 blood gas analyte. Refer to D2096.
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(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 proficiency testing desk review of CMS form 0155 and American Proficiency Institute (API) records, the laboratory failed to attain a satisfactory score of at least 80% acceptable responses for each analyte in the specialty of Routine Chemistry for the pO2 blood gas analyte. Findings included: 1. Review of the CMS 0155 report revealed the following results: Routine Chemistry 2020 - 1st Event laboratory received an unsatisfactory score of 60% for pO2 blood gas analyte. Routine Chemistry 2020 - 2nd Event laboratory received an unsatisfactory score of 60% for pO2 blood gas analyte. 2. A proficiency desk review from American Proficiency Institute (API) 2020 proficiency testing records confirmed the laboratory received the following results: API Chemistry Core 2020 - 1st Event laboratory received an unsatisfactory score of 60% for pO2 blood gas analyte. API Chemistry Core 2020 - 2nd Event laboratory received an unsatisfactory score of 60% for pO2 blood gas analyte.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing 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 (PT) records from 2020 (1st Event and 2nd Event), it was revealed that the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte in two consecutive testing events or two out of three consecutive testing events in the specialty of Routine Chemistry for the Chloride analyte. Two consecutive unsatisfactory scores result in unsuccessful PT performance. Findings included: 1. Review of the CMS 0155 report revealed the following results: Routine Chemistry 2020 - 1st Event laboratory received an unsatisfactory score of 60% for pO2 blood gas analyte. Routine Chemistry 2020 - 2nd Event laboratory received an unsatisfactory score of 60% for pO2 blood gas analyte. 2. A proficiency desk review of the American Proficiency Institute (API) 2020 proficiency testing records confirmed the laboratory received the following results: API Chemistry Core 2020 - 1st Event laboratory received an unsatisfactory score of 60% for pO2 blood gas analyte. API Chemistry Core 2020 - 2nd Event laboratory received an unsatisfactory score of 60% for pO2 blood gas analyte.
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 laboratory proficiency testing performance 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 D2096