Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2056204	01/31/2020
Name of Provider or Supplier	**Street Address, City, State**	
Crescent Medical Center Lancaster	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
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: Revisit 01/30 -01/31/2020 NEW DEFICIENCY Based on review of Centers for Medicare and Medicaid (CMS) and API proficiency testing records for 2019, it was revealed 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 Immunohematology/Compatibility Testing. Refer to D2181
D2173	COMPATIBILITY TESTING

	CFR(s): 493.863(a) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Revisit 01/30 -01/31/2020 NEW DEFICIENCY Based on a review of Centers for Medicare and Medicaid (CMS) and API proficiency testing records for 2019, it was revealed the laboratory failed to attain an overall compatibility testing event score of at least 100% (2019-3rd Event) for Immunohematology/Compatibility Testing which constitutes unsatisfactory performance. Findings included 1. Review of the CMS 0155 report revealed the following results: API 2019 - 3rd Event laboratory received an unsatisfactory score of 60% for Immunohematology/Compatibility Testing. 2. Review of the laboratory's API proficiency testing records revealed the following results: API 2019 - 3rd Event laboratory received an unsatisfactory score of 60% for Immunohematology/Compatibility Testing.
D2181	COMPATIBILITY TESTING CFR(s): 493.863(e) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Revisit 01/30 -01/31/2020 NEW DEFICIENCY Based on a review of Centers for Medicare and Medicaid (CMS) and API proficiency testing records from 2019 (1st, 2nd, and 3rd Events), it was revealed that the laboratory failed to achieve satisfactory performance for the same analyte in two consecutive testing events or two out of three consecutive testing events. The laboratory failed to achieve satisfactory performance (100 %) in the specialty of Immunohematology for Compatibility Testing for 2 of 3 consecutive testing events. Two out of three unsatisfactory scores results in unsuccessful PT performance. Findings included: 1. Review of the CMS 0155 report revealed the following results: API 2019 - 1st Event laboratory received an unsatisfactory score of 0% for Immunohematology/Compatibility Testing. API 2019 - 3rd Event laboratory received an unsatisfactory score of 60% for Immunohematology /Compatibility Testing. 2. Review of the laboratory's API proficiency testing records revealed the following results: API 2019 - 1st Event laboratory received an unsatisfactory score of 0% for Immunohematology/Compatibility Testing. API 2019 - 3rd Event laboratory received an unsatisfactory score of 60% for Immunohematology /Compatibility Testing.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Revisit 01/30/2020 - 01/31/2020 New deficiency. Based on review of CMS 155 report

	and proficiency testing records, the laboratory director failed to ensure the PT samples were tested as required under subpart H of this part. The laboratory failed to achieve satisfactory performance for the same analyte in two consecutive testing events or two out of three consecutive testing events. Refer to D2181.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Revisit 01/30/2020-01/31/2020 New Condition-Level Deficiency. Based on review of the CMS 209 form, personnel records, and in interview with staff, the laboratory failed to ensure all individuals met qualification requirements. The laboratory failed to ensure 1 of 5 newly hired individuals met one of the requirements to perform high complexity testing. Refer to D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such

training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Revisit 01/30/2020-01/31/2020 New Deficiency. Based on review of the CMS 209 form, personnel records, and in interview with staff, the laboratory failed to ensure 1 of 5 newly hired individuals met one of the requirements to perform high complexity testing. Findings included: 1. Review of the CMS 209 form provided onsite 01/31/2020 included 5 newly hired individuals who were to perform high complexity. 2. Review of testing person - 3 (TP-3) personnel records included documentation of "...U. S. equivalent of senior high school graduation and ninety-three semester units of undergraduate coursework." The high school diploma was obtained in November /December 1983. TP-3 records did not include, in addition to a high school diploma obtained before September 1, 1997, documentation required in 493.1489 (b)(5)(i) - (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; TP-3 did not have all required documentation to perform high complexity testing (immunohematology and hematology). 3. During the exit interview on 01/31/2020 at 12:45 pm, all attendees confirmed not all documentation was available to qualify TP-3 for performing high complexity testing.