Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0673481	10/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Valley Medical Clinic	7812 Gateway East Boulevard Suite 230, El Paso, 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: 10/16/2018 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 analyte Cholesterol, Total. 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 review of American Proficiency Institute (API) records and CMS-155 proficiency report, the laboratory failed to attain a satisfactory score of at least 80 percent of acceptable responses for the following analytes in subspecialty of routine chemistry for the second and third events of 2018: 1. 2018 - 2nd event - API score of 60 percent for Cholesterol, Total and 2018 3rd event API score of 40 percent for Cholesterol, Total Scores of less than 80 percent are unsatisfactory performance. Two consecutive scores of less than 80 percent is unsuccessful performance; Refer o D2096. 2. 2018 - 2nd event API score of 40 percent for Sodium 3. 2018 - 3rd event - API score of 20 percent for Calcium 4. 2018 - 3rd event - API score of 40 percent for Albumin 5. 2018 - 3rd event - API score of 40 percent for alanine aminotransferase (ALT) 6. 2018 - 3rd event - API score of 0 (zero) percent for Total Protein
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: 10/16/2018 Based on review of American Proficiency Institute (API) records and CMS-155 proficiency report, the laboratory failed to attain a satisfactory score of at least 80 percent of acceptable responses for Cholesterol, Total in the subspecialty of routine chemistry for the second and third events of 2018: The findings included: 1. 2018 - 2nd event - API score of 60 percent for Cholesterol, Total and 2018 3rd event API score of 40 percent for Cholesterol, Total Scores of less than 80 percent are unsatisfactory performance. Two consecutive scores of less than 80 percent is unsuccessful performance.
D6003	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1405 AND 493.1406 The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) 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; and (b)(2)(ii) Have had laboratory training or experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-

waived laboratory testing; or (b)(2)(ii)(B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in 493.1407; or (b)(2)(ii)(C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and (b)(3)(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or (b)(3)(ii) Have had at least one year experience directing or supervising non-waived laboratory testing; (b)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; (b)(4)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and (b)(4)(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or (b)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and (b)(5)(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing; (b)(6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under 493.1406; or (b)(7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which the laboratory is located. Laboratory director qualifications on or before February 28, 1992 The laboratory director must be qualified to manage and direct the laboratory personnel and test performance. (a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and (b) The laboratory director must: (b)(1) Be a physician certified in anatomical or clinical pathology (or both) by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (b)(2) Be a physician who: (b)(2)(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or (b)(2)(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or (b)(2)(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification; or (b)(2)(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for certification; (b)(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and (b)(4)(i) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties; or (b)(4)(ii) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, either: (b)(5)(i) Was a physician and subsequent to graduation had at

	least 4 years of pertinent full-time laboratory experience; (b)(5)(ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or (b)(5)(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or (b)(6) Qualify under State law to direct the laboratory in the State in which the laboratory is located. Note: The January 1, 1968 date for meeting the 12 months' laboratory direction requirement in paragraph (b)(5) of this section may be extended 1 year for each year of full-time laboratory experience obtained before January 1, 1958 required by State law for a laboratory director license. An exception to the July 1, 1971 qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975 and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications. This STANDARD is not met as evidenced by: 09/24/2018 Based on review of patient test records, personnel credentials, and interview with facility personnel, the laboratory failed to have a qualified laboratory director between March 29, 2018 and July 25, 2018. The findings included: 1. On 4/23 /2018 at 18:40 hours, facility personnel notified the State agency that the laboratory director had passed away. The email stated the following: " Thank you in advance for your time and also I regret to inform you that {previous lab director name redacted} has passed away." 2. In an interview at 12:08 hours on 9/24/2018 in the laboratory, the Technical Consultant confirmed the laboratory director had passed on March 29, 2018. 3. Based on a review of the credentials submitted on 8/10/2018, the current laboratory director met the requirements at 493.1405(b)(2)(ii)(B). The current laboratory director passed the 20 hours of medical education credit hours in laboratory practice commensurate with the director responsibilities on 7/25/2018. On 8/17/2018, the laboratory administrator submitted a CMS-116 to change the laboratory director to the current laboratory director effective 8/8/2018. 4. Based on patient records reviewed on 9/24/2018 in the laboratory, the laboratory performed patient testing between March 29, 2018 and July 25, 2018. This time period is between the death of the previous laboratory director and the date the current laboratory director met the qualifications at 42 CFR 493.1405. 5. In an interview with the Technical Consultant on 9/24/2018 at 13:18 hours in the laboratory, the Technical Consultant confirmed the laboratory had not ceased any patient testing until his involvement and assessment on August 29, 2018.
D8100	INSPECTION REQUIREMENTS CFR(s): 493.1771 Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. All CLIA-exempt laboratories must comply with the inspection requirements in 493.1773 and 493.1780, when applicable. This CONDITION is not met as evidenced by: Based on review of the Plans of Corrections submitted by the laboratory following the

	survey conducted on 03/07/2018, the laboratory failed to provide an acceptable plan of correction to maintain compliance with CLIA regulations (refer to D8103).
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: 9/24/2018 Based on review of the Plans of Corrections submitted by the laboratory between May 2018 and August 2018, the laboratory failed to maintain compliance with CLIA regulations by submitting an acceptable Plan of Corrections following the survey conducted on March 7, 2018. The findings included: 1. Based on a routine recertification inspection conducted on March 7, 2018, the laboratory was determined to not be in compliance with Conditions of Participation in the CLIA program. On May 8, 2018, the CMS Regional Office sent the CMS-2567 survey findings, enforcement letter E18-113, and instructions for providing an acceptable plan of correction. 2. The laboratory submitted a portion of a plan of correction on 5/13/2018. The submitted document did not address all deficiencies and was unacceptable. The laboratory submitted a portion of a plan of correction on 06/06/2018. The submitted document did not address all deficiencies and was unacceptable. The laboratory submitted a portion of a plan of correction on 07/24/2018. The submitted document did not address all deficiencies and was unacceptable. The laboratory submitted a portion of a plan of correction on 07/30/2018. The submitted document did not address all deficiencies and was unacceptable. The laboratory submitted a portion of a plan of correction on 08/17/2018. The submitted document did not address all deficiencies and was unacceptable. An allegation of compliance was submitted by the Technical Consultant on 09/04/2018. The allegation of compliance did not address all deficiencies. 3. In an interview at 12:07 hours on 9/24/2018 in the laboratory, the Technical Consultant stated that he had not yet addressed the plan of correction.