Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0933840	(X3) Date Survey Completed 01/29/2018
Name of Provider or Supplier Clinica Santa Maria	**Street Address, City, State** 3855 Southmost Road, Brownsville, 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, American Association of Bioanalysts (AAB). 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 laboratories performing moderate complexity testing; laboratory director
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 that the laboratory has 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 chemistry for the analyte Uric Acid (refer to D2096) and speciality General Immunology for the analyte Hepatitis B Antigen (refer to D2084).
D2072	SYPHILIS SEROLOGY CFR(s): 493.835(d) (1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of CMS form 155 and AAB records found the laboratory failed to attain a score of at least 80% acceptable responses for each analyte in the speciality of serology. Findings: 1. AAB 2017 - 3rd event laboratory received an un satisfactory score of 0 % for Syphilis Serology.
D2075	GENERAL IMMUNOLOGY CFR(s): 493.837(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 upon a review of the CMS 155 report and AAB proficiency testing records, it was revealed that the laboratory failed to attain a score of 80% for Rubella resulting in unsatisfactory analyte performance. Findings: 1. AAB 2017 - 2nd event, laboratory received a score of 0 % for HBS AG (hepatitis B surface antigen). 2. AAB 2017 - 2nd event laboratory received a score 60 % for HBE AG (hepatitis B antigen). 3. AAB 2017 - 3rd event laboratory received a score 0 % for HBE AG (hepatitis B antigen).
D2076	GENERAL IMMUNOLOGY CFR(s): 493.837(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of CMS form 155 and AAB records found that the laboratory failed to attain an overall score of at least 80% for each testing event in the specialty of general immunology. Findings: 1. API 2017 - 2nd event lab received a score of 65% for the general immunology testing event. 2. API 2017 - 3rd event lab received a score of 70% for the general immunology testing event.

D2084	GENERAL IMMUNOLOGY CFR(s): 493.837(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 desk review of proficiency testing records, it was determined the laboratory failed to achieve satisfactory performance (80 % or greater) for the same analyte in the specialty of immunology in two consecutive testing events or two out of three consecutive testing events. Two out of three unsatisfactory scores results in unsuccessful PT performance. 1. AAB 2017 - 2nd event laboratory received an unsatisfactory score 60 % for HBE AG (hepatitis B antigen). 2. AAB 2017 - 3rd event laboratory received an unsatisfactory score 0 % for HBE AG (hepatitis B antigen).
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 155 and AAB records found that the laboratory failed to attain a score of at least 80% of acceptable responses for each analyte in the subspecialty of chemistry for the analyte uric acid. Findings: 1. API 2017-1st event the laboratory received an unsatisfactory score of 0% for uric acid. 2. API 2017-2nd event the laboratory received an unsatisfactory score of 0% for uric acid.
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 desk review of AAB proficiency testing records, it was determined that laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte in two out of three consecutive testing events. The laboratory failed to achieve satisfactory performance in the specialty of chemistry for the analyte uric acid. Two out of three unsatisfactory scores results in unsuccessful PT performance. Findings: 1. API 2017-1st event the laboratory received an unsatisfactory score of 0% for uric acid. 2. API 2017-2nd event the laboratory received an unsatisfactory score of 0% for uric acid.
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 and D2084).