Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0933840	06/20/2023
Name of Provider or Supplier	**Street Address, City, State**	
Clinica Santa Maria	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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of proficiency testing records and confirmed in staff interview, the laboratory failed to provide signed proficiency testing attestation statements for 10 of 10 proficiency testing events in 2023. Findings included: 1. A review of the laboratory's American Association of Bioanalysts (AAB) proficiency testing records revealed the following testing events were submitted in 2023 : a) Chemistry Module b) Endocrinology 1 c) Glycohemoglobin d) Lipid Profile e) Blood Bank 1 f) Chlamydia/GC/Streptococcus B Antigen Screen g) Hematology with 3-Part Differential h) Rubella i) Syphilis Serology j) Viral Markers 2. The laboratory was asked to provide proficiency testing attestation statements signed by the testing personnel and by the laboratory director or designee. No documentation was provided. 3. In an interview on 06/20/2023 at 1030 hours in the laboratory, after review of the proficiency testing records, Technical Consultant 1 (as listed on the CMS Form 209) confirmed the above findings. Word Key: GC = Neisseria gonorrhoeae CMS = Centers for Medicare and Medicaid Services.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a)

	A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on direct observation, a review of laboratory record, a review of BD Max procedure, and confirmed in staff interview, the laboratory failed to provide an approved procedure for 1 of 1 FDA approved, non-modified assays. Findings included: 1. During a tour of the laboratory conducted on 06/20/2023 at 0905 hours, one BD Max (serial number 1599) was observed by the surveyor. 2. A review of laboratory records for the BD Max instrument indicated a new method verification study was performed on 10/21/2022 for the "CT/GC/TV assay". 3. The laboratory was asked to provide an updated procedure for the new method BD Max CT/GC/VT assay. No procedure was provided. 4. In an interview on 06/20/2023 at 1400 in the laboratory, after review of the above records, the Technical Consultant #1 (as listed on the CMS Form 209) confirmed the findings. Word key : BD = Becton Dickinson CT = Chlamydia trachomatis GC = Neisseria gonorrhoeae TV = Trichomonas vaginalis
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Cobas Folate III assay, surveyor observation, review of patient test records June 15, 2023 - June 19, 2023, and staff interview, it was revealed the laboratory failed to test samples within the manufacturer's required timeframe. The findings include: 1. A review of the manufacturer's instructions for the Cobas Folate III assay (2015-02, V 9.0 English) under the section titled "Specimen collection and preparation" revealed: "Serum: Stable for 2 hours at 20 - 25C, 2 days at 2 - 8C, 4 weeks at -20C." 2. Surveyor observation on 06/20/2023 at 1200 hours identified the following patient serum samples in a test tube rack on the counter in the laboratory awaiting Folate testing to be performed: Specimen ID: 23061513 Specimen ID: 23061608 Specimen ID: 23061614 Specimen ID: 23061904 Specimen ID: 23061915 3. An interview with testing personnel number 1 (as listed on Form CMS 209) on 06/20/2023 at 1400 hours revealed samples for Folate testing were tested twice a week. Samples were stored in the refrigerator at 2 - 8C until testing could be performed. She stated the samples had been on the counter since 11:30 am waiting to warm to room temperature. 4. A review of patient test records for the identified samples revealed the following collection dates: a)Specimen ID: 23061513 Collected 06/15/2023 4 days stored at 2 - 8C. > 2 hours at 20 - 25C the day of testing. b) Specimen ID: 23061608 Collected 06/16/2023 3 days stored at 2 - 8C. > 2 hours at 20 - 25C the day of testing. c) Specimen ID: 23061614 Collected 06/16/2023 4 days stored at 2 - 8C. > 2 hours at 20 - 25C the day of testing. d) Specimen ID: 23061904 Collected 06/19/2023 > 2 hours at 20 - 25C the day of testing. e) Specimen ID: 23061915 Collected 06/19/2023 > 2 hours at 20 - 25C the day of testing. 5. An interview with testing personnel number 1 (as listed on Form

	CMS 209) on 06/20/2023 at 1410 hours in the laboratory - after her review of the records- confirmed the findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the laboratory's test menu, the laboratory's verification studies for the BD Max analyzer performed in 2022, review of the laboratory's test volumes, and confirmed in staff interview, the laboratory failed to provide documentation of performing required studies for 4 of 4 non-modified FDA-approved assays. The findings included: 1. A review of the laboratory's test menu revealed the laboratory performed the following patient testing assays performed on the BD Max (serial number 1599): a) Chlamydia trachomatis b) Neisseria gonorrhoeae c) Trichomonas vaginalis d) Bacterial vaginosis panel 2. The laboratory was asked to provide documentation of performing precision studies as part of the BD Max verification study accepted by the Technical Consultant (as listed on the CMS Form 209) on 10/21/2022. No documentation was provided. 3. A review of the laboratory's annual test volume for the BD Max revealed 10,788 tests are performed. 4. In an interview on 06/20/2023 at 1340 hours in the laboratory, after review of the above records, Technical Consultant 1 (as listed on the CMS Form 209) confirmed the above findings.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on direct observation, a review of laboratory procedure, and confirmed in staff interview, the laboratory failed to provide maintenance records for 1 of 1 centrifuges (2021 - 2023). Findings included: 1. During a tour of the laboratory conducted on 06/20/2023 at 0905 hours, one Sero 12 centrifuge (serial number 210514AA423) was observed by the surveyor. 2. A review of the laboratory procedure titled "Centrifuge Operations and Calibration" (reviewed by the laboratory director on 04-17-2023) stated the following maintenance requirements: "Weekly: External and internal surfaces of each centrifuge must be cleaned using 10% bleach solution. Document on appropriate department disinfection schedule. Semi-annually: 1) Check and record

	RPMs. 2) Check power cord for fraying. 3) Check latch. 4) Omitted from procedure. 5) Check timer (see Timer Calibration SOP). 6) Document on Centrifuge Calibration and Maintenance Schedule." 3. The laboratory was asked to provide documentation of centrifuge maintenance records for 2021 - 2023. No documentation was provided. 4. In an interview on 06/20/2023 at 1440 hours in the laboratory, after review of the above records, Testing Personnel #2 (as listed on the CMS Form 209) confirmed the findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of manufacturer's inserts, laboratory records, laboratory test volume and confirmed in staff interview, the laboratory failed to meet the Emerald Cell-Dyn calibration verification acceptability requirements for 4 of 4 events (December 2021 - April 2023). Findings included: 1. A review of Cell-Dyn 18 Plus Calibrator package inserts revealed the following criteria: a) Lot 1319C, Expiration Date 2021-12-29 WBC 109/L Assay Value = 8.5; Tolerance Limits 0.3 RBC 1012/L Assay Value = 4.23; Tolerance Limits 0.10 HGB g/dL Assay Value = 11.5; Tolerance Limits 0.2 PLT 109/L Assay Value = 207; Tolerance Limits 15 b) Lot 2150C, Expiration Date 2022-07-13 RBC 1012/L Assay Value = 4.13; Tolerance Limits 0.10 c) Lot 2262C, Expiration Date 2022-11-02 RBC 1012/L Assay Value = 4.20; Tolerance Limits 0.10 HGB g/dL Assay Value = 11.0; Tolerance Limits 0.2 d) Lot 3093C, Expiration Date 2023-05-17 HGB g/dL Assay Value = 11.1; Tolerance Limits 0.2 2. A review of laboratory records titled "Calibration Verification Worksheet" revealed the following results: a) Date 12/15/2021, Calibrator Lot 1319C, Expiration Date 12/29/2021 Documented WBC Mean Value = 8.5. The provided data's WBC Mean Value = 8.1 (Difference = -0.4) Documented RBC Mean Value = 4.25; The provided data's RBC Mean Value = 4.01 (Difference = -0.22) Documented HGB Mean Value = 11.5; The provided data's HGB Mean Value = 11.1 (Difference = -0.4) Documented PLT Mean Value = 210; The provided data's PLT Mean Value = 181 (Difference = -26) The mean value results exceeded the tolerance limits specified

	in the manufacturer's insert. b) Date 06/27/2022, Calibrator Lot 2150C, Expiration Date 07/13/2022 Documented RBC Mean Value = 4.23; The provided data's RBC Mean Value = 4.24 (Difference = +0.11) The mean value result exceeded the tolerance limit specified in the manufacturer's insert. c) Date 10/11/2022, Calibrator Lot 2262C, Expiration Date 11/02/2022 Documented RBC Mean Value = 4.30; The provided data's RBC Mean Value = 4.39 (Difference = +0.19) Documented HGB Mean Value = 11.3; The provided data's HGB Mean Value = 11.3 (Difference = +0.3) The mean value results exceeded the tolerance limits specified in the manufacturer's insert. d) Date 04/25/2023, Calibrator Lot 3093C, Expiration Date 05/17/2023 Documented HGB Mean Value = 10.9; The provided data's HGB Mean Value = 10.7 (Difference = -0.4) The mean value result exceeded the tolerance limit specified in the manufacturer's insert. 3. A review of the laboratory test volume revealed an annual volume of 16,926 tests. 4. In an interview on 06/20/2023 at 1340 hours in the laboratory, after review of the above records, the Technical Consultant #1 (as listed on the CMS Form 209) confirmed the findings. Word Key: WBC = White blood cell RBC = Red blood cell HGB = Hemoglobin MCV = Mean corpuscular volume PLT = Platelet L = Liter g/dL = grams per deciliter fL = Femtoliters