| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number**<br><br>45D0933840 | **(X3) Date Survey Completed**<br><br>10/29/2019 |
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| **Name of Provider or Supplier**<br><br>Clinica Santa Maria | **Street Address, City, State**<br><br>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 |
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| **D0000** | Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately. |
| **D2006** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)<br><br>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.<br><br>This STANDARD is not met as evidenced by:<br>Review of the laboratory's American Association of Bioanalysts (AAB) proficiency testing records from 2018 and 2019, manufacturer's instructions for Macro-Vue RPR test, laboratory PT policy, review of patient records and staff interview, it was revealed the laboratory failed to test proficiency samples in the same manner it tested |

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| | patient samples. The findings were: 1. A review of the laboratory's AAB proficiency testing records from 2018 (events 1,2 and 3), 2019 (events 1 and 2) revealed RPR testing for syphilis were not tested as patient samples. Q1 2018 Spec 1 Reactive, not quantitated Spec 3 Reactive, not quantitated Spec 4 Reactive, not quantitated Date tested: 03/02/2018 Q2 2018 Spec 1 Reactive, not quantitated Spec 2 Reactive, not quantitated Spec 3 Reactive, not quantitated Date tested: 05/22/2018 Q3 2018 Spec 3 Reactive, not quantitated Spec 4 Reactive, not quantitated Spec 5 Reactive, not quantitated Date tested:10/18/2018 Q1 2019 Spec 1 Reactive, not quantitated Spec 3 Reactive, not quantitated Spec 4 Reactive, not quantitated Date tested: 02/07/2019 Q2 2019 Spec 1 Reactive, not quantitated Spec 2 Reactive, not quantitated Spec 4 Reactive, not quantitated Date tested: 05/16/2019 2. Review of laboratory policy titled, "MACRO-VUE RPR CARD TEST" no signature or date of approval by the laboratory director under, "Quality Control" it stated, "Controls with established patterns of graded reactivity are included in each days (sic) testing to confirm optimal reactivity of the antigen." 3. A review of the laboratory's Proficiency Testing policy under "Testing" stated "Process all survey specimens, as closely as possible, in the same manner as patient samples. "approved and signed April 08, 2019 by the laboratory director. 4. Review of patient final reports from June 2019 to October 2019 found the following patient results were titered when only qualitative quality control was performed (see patient alias list): Alias List Patient 1 Test Date: 06-19-2019 Result: Reactive 1:4 Alias List Patient 2 Test Date: 07-30-19 Result: Reactive 1:16 Alias List Patient 3 Test Date: 08-28-2019 Result: Reactive 1:4 Alias List Patient 4 Test Date: 10-17-2019 Result: Reactive 1:4 4. During an interview with the technical consultant on October 29, 2019 at 1044 hours in the laboratory she confirmed the findings. She revealed that positive PT RPR samples were not titered as a patient result. Key: RPR - Rapid Plasma Reagin PT - Proficiency Testing CMS - Centers for Medicare and Medicaid Services |
| **D5405** | PROCEDURE MANUAL<br>CFR(s): 493.1251(c)<br><br>Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the manufacturer's instructions for the Cell- Dyn 1800 hematology analyzer, review of patient test records from October 7 to October 15, 2019, and staff interview, the laboratory failed to have a written protocol for each step of the hematology testing process not provided by the Cell-Dyn 1800 User's Manual including procedures for handling flagged results on patient complete blood counts (CBC) results. The findings were: 1.A review of the manufacturer's instructions for the Cell-Dyn 1800 hematology analyzer (9140390 D) under the section titled "System-Initiated Messages and Data Flags" revealed, "Instructions for interpreting all flags, numeric and histogram data must be incorporated into your laboratory's procedure manual and use to determine the need for further action and/or review of results." LYM R0 or RM LRI URI LYM R1 LYM R2 MID R2 or RM MID R3 or RM GRAN R3 or RM GRAN R4 or RM 2. The laboratory's procedures had not provided the laboratory with a protocol for handling flags on the patient CBC results. 3. A review of patient test records from October 07 to October 15, 2019 revealed 4 patient test results with flags on the CBC (complete blood count) final results. Date tested |

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| | Specimen ID Flag 10/07/19 19100720 R2 10/11/19 19101103 R0 10/11/19 19101106 R2 10/15/19 19101116 R2 4. An interview with technical consultant on October 29, 2019 at 12:50 hours in the laboratory revealed the laboratory did not have a procedure to address the flags. This confirmed the findings. Key: LYM - Lymphocyte MID - Mid Range GRAN - Granulocyte |
| **D5407** | PROCEDURE MANUAL<br>CFR(s): 493.1251(d)<br><br>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor observations, review of laboratory policy, and confirmed in interview of facility personnel, it was revealed that the laboratory's policy for RPRs did not reflect its current laboratory practice. The findings were: 1. A surveyor observation made in the laboratory on October 29, 2019 revealed the kit in use in the laboratory is the ImPact RPR (Document 5453 IN-DB1C-07 November, 2015). 2. Review of laboratory policy (not signed or approved by the current laboratory director) revealed the procedure in their manual is for "Macro-Vue RPR Card Test" 3. An interview with the technical consultant on October 29, 2019 at 12:55 hours in the laboratory confirmed the findings the policy did not match their current practice. Key: RPR - Rapid Plasma Reagin |
| **D5449** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(ii)(g)<br><br>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of manufacturer's instructions, quality control records, patient records and confirmed in interview of facility personnel, the laboratory failed to include a negative external control each day of patient testing for the BD Affirm VPIII. NOTE: The laboratory did not develop an IQCP (Individualized Quality Control Plan) to modify the frequency of quality control testing. The laboratory was required to perform two levels of external quality control with each day of patient testing. The findings were: 1. Review of the BD Affirm VPIII, "Quality Control" stated "Quality control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's quality control procedures. It is recommended that the user refer to pertinent CLSI guidance and CLIA regulations for appropriate Quality Control practices." 2. Review of the laboratory's quality control records from October 7, 2019 to October 28, 2019 revealed that the laboratory failed to include a negative external quality control on the following days of patient testing: 10-07-2019 10-09-2019 10-11-2019 10-14-2019 10-16-2019 10-18-2019 10-21-2019 10-23-2019 10-25-2019 10-28-2019 3. Review of patient logs from October 7, 2019 to October 28, 2019 revealed 67 patients were tested on days when no negative external quality control had been |

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| | performed. (see patient alias list) 4. The findings were confirmed in interview of the technical supervisor (as listed on CMS form 209) on October 29, 2019 at 15:30 hours in the laboratory. Key: CMS - Centers for Medicare and Medicaid Services BD - Becton Dickinson CLSI - Clinical and Laboratory Standards Institute CLIA - Clinical Laboratory Improvement Amendments |
| **D5451** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(iii)(g)<br><br>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed.<br><br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policy, review of manufacturer's instructions, patient final results, and confirmed in interview of facility personnel, the laboratory failed to perform quality control titers on each day of patient testing when patient results were titered. The findings were: 1. Review of the laboratory's policy titled, "MACRO-VUE RPR CARD TEST" no laboratory director approval date, under, "Quality Control" it stated, "Controls with established patterns of graded reactivity are included in each days testing to confirm optimal reactivity of the antigen." Note: This is not the current kit in use (cross refer to D5407). The policy did not include instructions on how to perform quality control titers. However, in regards to patient reporting under, "REPORTING RESULTS" it stated, "ALL REACTIVE RESULTS should be confirmed by retesting the specimens using the quantitative procedure. (see package insert)." 2. Review of the manufacturer's instructions for IMPACT RPR (Rapid Plasma Reagin) (IN-060C3-07) under "Titration (Quantitative" Quantitative Test" it listed the following: Undiluted Reactive 1:2 Reactive 1:4 Reactive 1:8 Nonreactive 1: 16 Nonreactive 3. Review of patient final reports from June 2019 to October 2019 found the following patient results were titered when only qualitative quality control was performed (see patient alias list): Alias List Patient 1 Test Date: 06-19-2019 Result: Reactive 1:4 Alias List Patient 2 Test Date: 07-30-19 Result: Reactive 1:16 Alias List Patient 3 Test Date: 08-28-2019 Result: Reactive 1:4 Alias List Patient 4 Test Date: 10-17-2019 Result: Reactive 1:4 4. An interview with the technical consultant on October 29, 2019 at 09:42 hours in the laboratory confirmed the findings. She confirmed that the laboratory performs quantitative titers on patients but not controls. |
| **D6020** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. |

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| | This STANDARD is not met as evidenced by:<br>A review of manufacturer's instructions, review of quality control records, review of patient records revealed that the laboratory director failed to ensure that quality control programs were established and maintained. (refer to D5449 and D5451) |
| **D6042** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(4)<br><br>(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of manufacturer's instructions, review of quality control records, review of patient records and staff interview, it was revealed that the technical consultant failed to ensure an appropriate quality control program was maintained throughout the testing process (refer to D5449 and D5451). |