| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number**<br><br>45D0933840 | **(X3) Date Survey Completed**<br><br>09/22/2021 |
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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** | The laboratory was surveyed and found to be in compliance with the conditions of participation found in the CLIA regulations at 42 CFR 493 and recertification is recommended. |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's verification studies, review of patient test records and staff interview, it was revealed the laboratory failed to have documentation of verifying patient normal ranges for 1 of 1 patient normal range used for testing CBCs (complete blood count). The findings included: 1. A review of the laboratory's verification studies revealed the laboratory failed to have documentation of verifying patient normal ranges for females on CBCs: WBC 4.6 - 10.8 Lymphocytes (% and absolute) 10.0 - 50.0 0.6 - 3.4 Mids (% and absolute) 0.1 -24.0 0.0 - 1.8 Granulocytes (% and absolute) 37.0 - 80.0 2.0 - 6.9 RBC 4.04 - 5.48 HGB 12.2 - 16.2 HCT 36.0 - 46.0 MCV 80.0 - 97.0 MCH 26.0 - 32.0 MCHC 32.0 - 36.0 RDW 11.5 - 14.5 Platelets 140 - 440 MPV 0.0 - 99.8 2. Review of patient records revealed the listed CBC ranges were in use for females. 3. The laboratory was asked to provide documentation of verifying the patient normal ranges currently in use. No documentation was provided. 4. An interview with the technical consultant on 09/22/2021 at 14:30 hours in the laboratory - after her review of the records- confirmed the findings. |

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| **D5807** | TEST REPORT<br>CFR(s): 493.1291(d)<br><br>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of patient records and confirmed in interview of facility personnel, the laboratory failed to ensure patient normal ranges were available to the ordering provider. The findings included: 1. Review of patient records for the following tests revealed patient normal values were listed as follows: Antibody Screen Positive /Negative RPR Reactive/Non-Reactive Rubella Reactive/Non-Reactive HIV 1/HIV2 Antibody Negative/Positive Chlamydia Trachomitis Positive/Negative Neisseria Gonorrhoeae Positive/Negative 2. In an interview with the Technical Consultant on 09-23-2021 at 14:30 hours in the laboratory, she was asked if a positive HIV and a reactive RPR was normal. She stated, "No." This confirmed the findings. |