| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 45D1042724 | 07/11/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Clinica Familiar San Jose Pa | 8030 N Fm 1015 Ste B, Mercedes, 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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| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policy, review of manufacturer's instructions, patient results, and confirmed in interview of facility personnel, the laboratory failed to have a policy to resolve abnormal CBC (complete blood count) flags. The findings were: 1. Review of laboratory's policy titled, "Policy for Abnormal Differentials" approved by the laboratory director on March 18, 2014 revealed the policy was written for the facility's previous analyzer. Therefore, the laboratory did not have a policy to instruct testing persons on how to resolve abnormal flags on CBC results. 2. Review of the manufacturer's instructions for the Sysmex XP-300 (Code No. AU553517, Revision: July 2017) under "8.3 Histogram flags" it stated, "WL: 1. Centrifuge sample and replace the plasma with equal volume of saline or CELLPACK and repeat analysis. 2) Check smear, etc." The table went on to list further flags, their probable cause, and correction (reference). 3. Random review of patient results from January 2019 to July 2019 found the following 10 of 10 patient reports that flags were not resolved prior to their release to the healthcare provider. Patient ID: 11-12-2013 Run Date: 05-06-2019 Flag: WL Patient ID: 07-21-2018 Run Date: 05-07-2019 Flag: WL Patient ID: 07-21-2019 Run Date: 05-07-2019 Flag: T2 Patient ID: 12072009 Run Date: 05-05-2019 Flag: WL Patient ID: 06-08-99 Run Date: 04-28-2019 Flag: WL Patient ID: 05-07-17 Run Date: 04-29-2019 Flag: WL Patient ID: 09-17-2006 Run Date: 02-05-2019 Flag: WL 4. Interview with the primary testing person on June 11, 2019 at 12:00 hours confirmed the findings. She revealed that she thought only "AG flags" needed to be verified. |

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| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor observation, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to monitor the room temperature where supplies were located. The findings were: 1. Surveyor observation on June 11, 2019 at 09:15 hours in the Triage Room revealed the following items available for use: Modified Amies Medium Lot 8EI0A Expiration: 2020-05-10 28 swabs a. Review of the manufacturer's instructions located on package labeling stated storage temperature as "4 - 25 degrees Celsius." Purple top Greiner pedi tubes Lot 18I4047 Expiration: 09-3-02020 63 tubes a. Review of the manufacturer's instructions located on package labeling stated storage temperature as "4 - 25 degrees Celsius." 2. Surveyor observation on June 11, 2019 at 09:15 hours in the Procedure Room revealed the following items available for use: BBL Culture swabs Lot 182096693 Expiration 2020-02-29 1 open box of 50 a. Review of the manufacturer's instructions located on package labeling stated storage temperature as "5 - 25 degrees Celsius." 3. The findings were confirmed in interview with the technical consultant on June 11, 2019. |
| **D5441** | CONTROL PROCEDURES<br>CFR(s): 493.1256(a)(b)(c)(g)<br><br>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's quality control records for the Sysmex XP-300 and confirmed in interview of facility personnel, the laboratory failed to ensure daily quality control testing detected immediate errors. The findings were: 1. Review of Sysmex XP-300 quality control records from December 2018 to June 2019 revealed that testing personnel failed to ensure quality control materials were run under appropriate instrument files. In the following instances the quality control reagents were ran under patient profiles. January 4, 2019 Normal Control No documentation of manual check that quality control was acceptable February 4, 2019 Normal Control |

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| | No documentation of manual check that quality control was acceptable February 5, 2019 Low Control No documentation of manual check that quality control was acceptable May 3, 2019 Low Control No documentation of manual check that quality control was acceptable May 23, 2019 Low Control No documentation of manual check that quality control was acceptable June 16, 2019 Low Control No documentation of manual check that quality control was acceptable 2. Since the laboratory ran quality control (QC) reagents as patients, the laboratory would need to manually check the runs against value assignment sheets to ensure the accuracy of the control to detect immediate errors There was no documentation on the printout or elsewhere that would ensure that the manual check was performed. 3. The findings were confirmed in interview with the primary testing person on July 11, 2019 at 11:00 hours when she revealed that when the QC is performed under the wrong file, she manually evalutes the QC against the assigned values but does document the manual review. |
| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's Individualized Quality Control Plan (IQCP), review of manufacturer's instructions, review of patient results, and confirmed in interview of facility personnel, the laboratory's IQCP failed to support its reduction in frequency to every 30 days. The findings were: 1. Review of the laboratory's IQCP revealed that the facility performed a study to reduce quality control frequency to every new lot, new shipment and every 30 days for the Quidel Solana Strep A test. 2. Review of the study revealed that on the 13th day of the study the negative control failed, and there was no evidence that the control was repeated. The laboratory failed to evaluate its IQCP based on performing quality control every 12 days. 3. Review of the Solana Strep A manufacturer's instructions (PIM301002EN00) stated, "Quality Control:...External control tests should be performed thereafter in accordance with appropriate federal, state and local guidelines. The Solana GAS Assay should not be used in patient testing if the external controls do not produce the correct results." 4. According to the CMS-116, approved by the laboratory director on July 11, 2019 the laboratory has an annual test volume of of 100. 5. Interview with the primary testing person and technical consultant on July 11, 2019 at 12:20 hours in the office confirmed the findings. They were unaware of the failure. |
| **D5805** | TEST REPORT<br>CFR(s): 493.1291(c)<br><br>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where |

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| | the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor observation, review of patient results, and confirmed in interview of laboratory personnel, the laboratory failed to ensure at least two unique patient identifiers were available on patient final reports. The findings were: 1. Surveyor observation on June 11, 2019 revealed the primary testing person attempt to access patient final reports in the facility's electronic medical records system. She was unsuccessful and stated, "We have been having trouble since yesterday." She went on to say that patient results were being given to providers on paper. She agreed it was "Downtime." 2. Review of patient records from June 10, 2019 revealed the following 1 of 3 patient results was finalizes with the patient's date of birth only. Sample ID: 05-09-2014 Run time: 17:12 When asked how one would know whose result this was, she revealed that she would have to go to the Patient Master Log to match up the date of birth. 3. Further review of patient reports from May and June 2019 revealed the following 10 of 10 patient records that were resulted with only the patient's date of birth. Sample ID: 07-17-1999 Date: 05-02-2019 Sample ID: 10-29-2017 Date: 05-03-2019 Sample ID: 10-29-2018 Date: 05-03-2019 Sample ID: 11-20-2009 Date: 05-03-2019 Sample ID: 12072010 Date: 05-05-2019 Sample ID: 05-30-2018 Date: 05-06-2019 Sample ID: 12-13-2016 Date: 05-06-2019 Sample ID: 11-12-2013 Date: 05-06-2019 Sample ID: 07-21-2018 Date: 05-07-2019 Sample ID: 07-21-2019 Date: 05-07-2019 4. The findings were confirmed in interview with the primary testing person on July 11, 2019 at 11:00 hours in the office. She agreed that the results had only one patient identifier and that without being able to access the electronic record there was no way to prove that the results had more than one patient identifier. |