| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 45D1083412 | 07/11/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Fe Family Clinic Llc | 8305 N La Homa Blvd, Suite B, Mission, 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** | Laboratories issued a certificate of compliance must meet the following conditions: (a) Notify HHS or its designee within 30 days of any change in-- (1) Ownership; (2) Name; (3) Location; (4) Director; or (5) Technical supervisor (laboratories performing high complexity only). (b) Notify HHS no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included on the laboratory's certificate of compliance, so that compliance with requirements can be determined. (c) Notify HHS no later than 6 months after any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of compliance. The laboratory failed to notify HHS or its designee within 30 days of its change in director. |
| **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 Medonic M-series hematology analyzer, review of patient test results, and staff interview, the laboratory failed to have documentation of a policy for resolving flags on CBC (complete blood count) results for 5 of 5 patient results that required follow up from April 1, 2022 to July 10, 2022. The findings were: 1. A review of the manufacturer's instructions for the Medonic M-series hematology analyzer (Art. no 1504283 December 2012) under the section titled "9.2 System Information Messages" revealed the manufacturer identified the following flags on CBC differential which required the laboratory to develop and follow its policy for the verification of the results: BD NM OM TM 2. A |

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| | sampling of patient test results from April 1, 2022 to July 10, 2022 identified the following patient results which were reported to the provider with flags on the differential portion of the results: Date Sequence ID Flag 04/27/2022 6572 SE, TM 04 /30/2022 6477 OM 05/04/2022 6629 OM 05/05/2022 6645 TM 07/06/2022 7179 OM 3. The laboratory was asked to provide documentation of a policy to resolve flags prior to their release to the healthcare provider. No documentation was provided. 5. An interview with the laboratory owner on July 11, 2022 at 1730 hours in the laboratory confirmed the findings. |
| **D5785** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(3)<br><br>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's room temperature records from January 2022 to July 2022 and staff interview, the laboratory failed to have documentation of performing corrective action when documented temperatures were not within the laboratory's defined acceptability ranges for 2 of 90 days randomly reviewed. The findings were: 1. Surveyor observation on July 11, 2022 at 16:30 hours found the room temperature of the laboratory was 79F according to the laboratory's thermometer located on the laboratory refrigerator. 2. A review of the laboratory's room temperature records from January 2022 to July 2022 found the laboratory's acceptable room temperature range was 73 - 77 F. 3. Further review of the temperature records from January 2022 to July 2022 identified the following days when the documented room temperature was outside the laboratory's defined acceptable range: 05/30/2022 79F 07/06/2022 79F 4. The laboratory was asked to provide documentation of performing corrective actions on the identified days. No documentation was provided. 5. An interview with the laboratory owner on July 11, 2022 at 17:30 hours in the laboratory confirmed the findings. Key: F - Fahrenheit |
| **D5803** | TEST REPORT<br>CFR(s): 493.1291(b)<br><br>Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of final patient results and confirmed in interview of facility personnel, the laboratory failed to ensure 10 of 10 randomly reviewed final patient results was available in the patient's medical record from April 2022 to July 2022 . The findings were: 1. Review of the following 10 of 10 patient final reports found patients results were not available in the patient's medical record: Sequence #: 6477 Date of Test: 04-18-2022 Test: Complete Blood Count (CBC) Sequence #: 6499 Date of Test: 04-19-2022 Test: Complete Blood Count (CBC) Sequence #: 6572 Date of Test: 04-27-2022 Test: Complete Blood Count (CBC) Sequence #: 6629 Date of Test: 05-04-2022 Test: Complete Blood Count (CBC) Sequence #: 6645 Date of Test: 05-05-2022 Test: Complete Blood Count (CBC) Sequence #: 6977 Date of Test: 06-10-2022 Test: Complete Blood Count (CBC) Sequence #: 7029 Date of Test: 06-16-2022 |

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| | Test: Complete Blood Count (CBC) Sequence #: 7104 Date of Test: 06-27-2022 Test: Complete Blood Count (CBC) Sequence #: 7179 Date of Test: 07-06-2022 Test: Complete Blood Count (CBC) Sequence #: 7193 Date of Test: 07-07-2022 Test: Complete Blood Count (CBC) 2. The findings were confirmed in interview with the primary testing person at 17:20 hours in the laboratory. She confirmed that they were behind with scanning and that patient results from at least April of 2022 are scanned into a file but not available on the patient chart at this time. |
| **D6053** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's testing personnel records and confirmed in interview of facility personnel, the technical consultant failed to perform competency assessments at least twice annually for 1 of 1 testing persons who required one. The findings were: 1. Review of personnel records for testing personnel #1 (as listed on Form CMS-209) revealed she had one competency assessment available for review within her first year of patient testing. 2. An interview with the laboratory owner on July 11, 2022 at 18:00 hours in the laboratory confirmed the findings. . Key: CMS - Centers for Medicare and Medicaid Services |
| **D6066** | TESTING PERSONNEL QUALIFICATIONS<br>CFR(s): 493.1423(b)(4)(ii)<br><br>Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's submitted CMS 209 form, review of the laboratory's personnel records, and staff interview, the failed to have documentation of training on the Medonic hematology analyzer prior to performing patient testing for 1 of 2 testing persons. The findings included: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 7/11/22) found the laboratory identified 2 testing personnel who performed moderate complexity testing. 2. A review of the laboratory's personnel records revealed that 1 of 2 testing personnel listed did not have documentation of training on the Medonic hematology analyzer prior to performing patient testing. 3. An interview with the laboratory owner on 07/11 /22 at 18:00 hours in the laboratory confirmed the findings. |