| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 10D1100352 | 01/06/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Family Medical Centre | 3470 Nw 82 Ave Ste 118, Doral, FL | |

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** | An announced CLIA recertification survey was conducted at Family Medical Centre on 01/06/2022. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies: |
| **D5411** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with the Laboratory Manager the laboratory failed to follow manufacturer's instructions when the Sysmex XP300 Complete Blood Count (CBC) Hematology analyzer failed the background check on 09/15/2020. Findings Included: Review of the manual for the Sysmex XP300 CBC analyzer revealed that the background check limit for WBC (White Blood Cell) is 0.3 or less and if it does not fall below the acceptable levels during the background check then "Auto Rinse, Clean TD, Clean SRV, or Replenish reagent" and that "the next sample could be affected". On 09/15/2020 the WBC was 0.6 and rejected at 10:29 AM, 1:28 PM, and 1:29 PM. No corrective actions or maintenance was recorded. A Patient (#1) was ran and reported at 11:23 AM. Interview on 01/06/2022 at 3:00 PM the Laboratory Manager confirmed that there was no corrective actions or maintenance recorded and 1 Patient had been reported on that day. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b) |

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| | 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 observations, record review, and interview with the Laboratory Manager the laboratory failed to store the Complete Blood Count (CBC) quality control (QC) per the manufacturer's instruction for 2 (May 2021 and October 2020) out of 4 months (February 2020, September 2020, May 2021, and October 2020) reviewed. Findings Included: Review of policy and procedures signed by the Laboratory Director on 11/16 /2021 stated "All equipment is maintained according to manufacturer's specifications." Tour of the laboratory on 01/06/2022 at 10:00 AM revealed CBC quality control stored in the refrigerator. The manufacturer's instructions revealed that the QC must be stored 2-8 degrees Celsius (35.6-46.4 degrees Fahrenheit). Review of the refrigerator temperature log revealed an incorrect acceptable temperature range of 35-46 degrees Fahrenheit. Review of May 2021 temperatures revealed 20 out of 21 days the temperature recorded was less than 35 degrees Fahrenheit. October 2021 temperatures revealed 17 out of 21 days the temperature was less than 35 degrees Fahrenheit. Interview on 01/06/2022 at 12:00 PM the Laboratory Manager confirmed that the temperature range was not correct and that the temperatures were recorded out of the acceptable range with no corrective action. |
| **D5481** | CONTROL PROCEDURES<br>CFR(s): 493.1256(f)(g)<br><br>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview the Laboratory failed to have 3 levels of Hematology controls within acceptable ranges for 6 days (02/14/2020, 05/04/2021, 05 /07/2021, 05/10/21, 05/11/2021, and 05/12/2021) out of 4 months reviewed (February 2020, September 2020, May 2021, and October 2021). Findings Included: Review of the policy and procedure manual signed by the Laboratory Director on 11/16/2021 revealed that "3 levels of controls are run daily; all levels must be in acceptable ranges before the patient's sample can be done." The 3 levels include a Low, Normal, and High level. On 02/14/2020 there were no Hematology controls ran and 2 Patients were reported. On 05/04/2021, 05/07/2021, 05/10/21, 05/11/2021, and 05/12/2021 only the Low control was ran and 1 Patient was reported each day. Interview on 01/06/2022 at 4:00 PM the Laboratory Manager confirmed that the aforementioned Patients were reported without 3 levels of controls within acceptable range. |