Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0705040	11/12/2020
Name of Provider or Supplier	**Street Address, City, State**	
Family Medical Centre	3410 W 84 St #110, Hialeah, 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
D0000	A recertification survey conducted on 11/12/2020 found that the Family Medical Centre clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following conditions were cited: -D2000 -D5200 -D5400 -D6000
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of Casper report 96 Clinical Laboratory Improvement Amendments (CLIA) Application and Survey Summary and interview with Testing Personnel (TP) A, the laboratory failed to enroll in a Proficiency Testing (PT) program approved by the Department of Health and Human Services (HHS) and Centers for Medicare and Medicaid Services (CMS) for the specialty of hematology for 1st and 2nd event of 2019. Findings include: Review of Casper report 96 pulled on 11/11/2020 revealed blanks for the 3 events of 2019 for the specialty of hematology. American Association of Bioanalysts (AAB) PT records review revealed that the laboratory failed to participate in PT for 1st and 2nd event of 2019. During an interview on 11/12/2020 at 9:30 a.m. TP A confirmed that the facility failed to enroll in PT for 2019 for the specialty of reference during 1st and 2nd event 2019.

D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of American Association of Bioanalysts (AAB) proficiency testing (PT) records and staff interview, the laboratory failed to score at least 80 % on Red Blood Cell (RBC), Hematocrit (HCT) and Hemoglobin (HGB) analytes for 1 (2nd event of 2020) out of 4 events for Hematology reviewed. Findings include: Review of AAB PT records revealed a score of 60 % for RBC, HCT and HGB in the 2nd event of 2020. During an interview on 11/12/2020 at 12:30 PM, the testing staff A confirmed the proficiency testing failure.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document remedial action for 3 out of 3 Hematology analyte unsatisfactory scores in 2nd event of 2020: Red Blood Cells (RBC), Hematocrit (HCT) and Hemoglobin (HGB) in proficiency testing (PT). Findings include: -Review of American Association of Bioanalysts (AAB) proficiency testing results in 2019 and 2020, showed that the laboratory had analyte unsatisfactory score for RBC, HCT and HGB of 60 % for the 2nd event of 2020. -No documentation of the remedial and corrective actions found during the survey. During an interview on 11/12/2020 at 2:00 PM, the testing staff A confirmed that the laboratory had no documentation of the remedial actions for the failures of reference.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.

	This CONDITION is not met as evidenced by: Based on record review and staff interview the laboratory failed to follow their Quality Assurance policy from 2019 to 2020. See D 5293
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to follow their Quality Assurance (QA) policy for 2 out of 2 years (2019 and 2020). This is a repeated deficiency. Findings include: -Review of QA policy stated that Proficiency Testing (PT) results are reviewed by the Laboratory Director. -The Laboratory failed to enroll in PT for 2019 and failed 3 analytes in 2nd event of 2020. -No documentation found in the QA records about the review of these PT failures. -Review of the QA checklist records found no QA review for 2019. During an interview on 11/12/2020 at 2:00 PM, with testing personnel A, she confirmed that the laboratory failed to follow the QA policy.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and staff interview the laboratory failed to document room temperature and humidity, see 5413. The laboratory failed to document the maintenance work log for Sysmex XP-300 as per manufacturer instructions, see 5429. The laboratory failed to document the calibration verification at least every 6 months, see D 5439.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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.

	This STANDARD is not met as evidenced by: Based on observation, user manual review and staff interview, the laboratory failed to document room temperature and humidity requirement to assure optimal operation of the Sysmex XP-300 analyzer in 2019 and 2020. This is a repeated deficiency. The findings include: -The manual review of Sysmex XP-300 analyzer revealed a room temperature requirement range of 15-30 C and humidity range of 35 to 85 %. During the laboratory tour on 11/12/2020 at 9:30 am, observation of laboratory indicated no thermometer/humidity meter to measure room temperature and humidity. Temperature log record review revealed no records of room temperature and humidity in 2019 and 2020 During an interview on 11/12/2020 at 9:30 a.m., the testing staff A confirmed that no record of room temperature and humidity were kept for 2019 and 2020.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on lack of records and staff interview, the laboratory failed to document the maintenance performed on the Sysmex XP-300 analyzer from 11/2018 to 11/2020. Findings include: Based on user manual for Sysmex XP-300 analyzer the laboratory has to perform daily, weekly, monthly and quarterly maintenance. The laboratory failed to have documentation of the required maintenance. During an interview on 11 /12/2020 at 2:00 pm, the testing personnel A confirmed that there was no documentation of the required maintenance.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent

	calibration verification. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document calibration verification procedures of the Sysmex XP-300 analyzer at least every 6 months from 7/25/2018 to 7/7/2019. Findings include: -Review of the Sysmex XP-300 calibration records revealed that the laboratory performed calibrations on 7/25 /2018, 7/17/2019, 12/12/19 and 7/7/2020. During an interview on 11/12/2020 at 2:00 p.m., the testing person A confirmed that there was no documentation to indicate the instrument calibration every 6 months in the period of 7/25/2018 to 7/17/2019.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on record review and staff interview, the Laboratory Director (LD) failed to ensure that the laboratory enrolled in an approved Proficiency Testing program during 2019 1st and 2nd event. See D 6015. The LD failed to ensure the laboratory follow the quality Assurance Policy. See 6021.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory director (LD) failed to ensure the laboratory enrolled in a proficiency testing program during 1st and 2nd event of 2019. Findings include: -Review of Casper report 96 Clinical Laboratory Improvement Amendments (CLIA) Application and Survey Summary pulled on 11/11 /2020 the laboratory failed to enroll in a Proficiency Testing (PT) program approved by the Department of Health and Human Services (HHS) and Centers for Medicare and Medicaid Services (CMS) for the specialty of hematology for 2019. -American Association of Bioanalysts (AAB) PT record review revealed that the laboratory failed to participate in PT for 1st and 2nd event of 2019. During an interview on 11/12 /2020 at 9:30 a.m, testing staff A confirmed that the LD failed to ensure that the laboratory enrolled in PT for 2019 for the specialty of reference.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)

	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and staff interview the Laboratory Director (LD) failed to ensure that the laboratory followed the Quality Assurance policy. This is a repeated deficiency. See D5293