| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 10D1100352 | 12/17/2019 |
| **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** | A recertification survey conducted on 12-17-19 , found the Family Medical Centre clinical laboratory not in compliance with 42 CFR Part 493 , Requirements for Laboratories . The following Conditions were not met : D 2000 - Enrollment And Testing of Samples D 5200 -General Laboratory Systems D 6000-Laboratory Director D 6056- Clinical Consultant D 6063- Testing Personnel |
| **D2000** | ENROLLMENT AND TESTING OF SAMPLES<br>CFR(s): 493.801<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on record review and staff interview the laboratory failed to enroll in profociency testing (PT) for the speciality of Hematology for the year of 2019 and beginning 2020. Findings included : A review of the CMS Casper Report 0096 D showed that the laboratory had no results for the 1st , 2nd and 3rd events in 2019 . A review of American Association of Bioanalysts (AAB) proficiency testing record revealed no documentation or performance of PT for the specialty of Hematology for 3 (1st, 2nd and 3rd) out of 3 testing events in 2019. The list of testing for Hematology: White Blood Cell Differential, Red Blood Cell, Hematocrit, Hemoglobin, White Blood Cell and Platelets. There was no billing records or paperwork for 2020 |

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| | enrollment. During an interview on 12-17-19 at 12:00pm , testing person A confirmed no enrollement in AAB Hematology PT for the 1st , 2nd and 3rd events of 2019 and beginning 2020 . |
| **D2009** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview, the laboratory director failed to sign the attestations for 2 (2nd and 3rd) out of 3 proficiency testing (PT) events for the specialty of Hematology in 2018. Findings Included: A review of 2018 American Association of Bioanalysts proficiency testing record revealed that the laboratory director did not sign the attestation for second and third Hematology PT events for May and October 2019 . During an interview on 12-17-19 at 12:00 pm, testing personnel A confirmed that the laboratory director did not sign the attestations for 2nd and 3rd Heamtology PT events for 2018 . |
| **D3011** | FACILITIES<br>CFR(s): 493.1101(d)<br><br>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation and staff interview, the laboratory failed to provide an eyewash station to ensure the protection from chemical and biohazardous material for testing personnel. Findings Include: An observation of the laboratory revealed no eye wash station by the sink to ensure the safety of biochemical splatter. . During an interview on 12-17-19 at 12:00 pm, testing person A confirmed there was no eyewash station in the laboratory. |
| **D5200** | GENERAL LABORATORY SYSTEMS<br>CFR(s): 493.1230<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on record review and staff interview, the laboratory failed to monitor and evaluate the quality assessment. Findings : Cross Reference D5209. Based on record review and staff interview , the laboratory failed to provide six point competencies for |

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| | the following : Initial competencies for 2(B and C) out of 3 testing personnel (TP) , six month competency for 1 (C ) out of 3 testing personnel and annual competencies for clinical consultant (CC) , technical consultant (TC) and 1 (A) of 3 testing personnel . Cross Reference D5292. Based on record review and staff interview, the laboratory failed to monitor quality assessment for the year of 2018 and 2019 (10 out of 11). |
| **D5201** | CONFIDENTIALITY OF PATIENT INFORMATION<br>CFR(s): 493.1231<br><br>The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation and staff interview, the laboratory failed to protect patient information by placing visible patient demographics in a box next to the patient drawing station. Findings Include: An observation of the laboratory revealed a three shelf specimen cart next to a blood drawing station. On the second level shelf of the cart was a box filled with patient demographics visible to patients in the drawing station. The box contained names, birthdates, social security and testing information. During an interview on 12-17-19 at 12:00 pm, the testing person A confirmed that patient information in a box was visible on the second shelf of cart to patients in the drawing station. |
| **D5203** | SPECIMEN IDENTIFICATION AND INTEGRITY<br>CFR(s): 493.1232<br><br>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.<br><br>This STANDARD is not met as evidenced by:<br>Based record review and staff interview the laboratory failed to create and implement a policy for the labeling of patient specimen samples. Findings Include: A review of the 2019 Policy and Procedure Manual record revealed there was no specimen labeling and rejection policy to ensure specimen samples are identified through medical identification number or name and date of birth. During an interview on 12-17-19 at 12:00 pm, testing person A confirmed there was no policy for the labeling of patient specimen samples . |
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>A repeat deficiency from the 12/13/17 recertification survey : Based on record review |

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| | and staff interview , the laboratory failed to provide six point competencies for the following : Initial competencies for 2(#B and C) out of 3 testing personnel (TP) , six month competency for 1 (C ) out of 3 TP and annual competencies for clinical consultant (CC) , technical consultant (TC) and 1 (A) of 3 TP . Findings Include: A review of CMS 209 Laboratory personnel record revealed that employee A, B and C are TP , Employee E is a CC and Employee F is a TC. A review of laboratory personnel competency record revealed that initials for TP #B and TP #C were not preformed in 2019. The six-month competency for TP# C was not preformed. The annual competencies for TP#A, CC and TC was not preformed. During an interview on 12-17-19, the testing personnel A confirmed that the annual, 6-month, initial competencies had not been done for the following employees. |
| **D5291** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(a)<br><br>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview, the laboratory failed to follow their policy and monitor quality assessment (QA) for the year of 2018 and 2019 (10 out of 11). Findings Include: A review of the Quality Assessment Checklist record revealed that there was no QA checklist for 12 months in 2018. January through October 2019 there was no documentation for QA checklist. During an interview on 12-17-19 at 12:00pm, testing person A confirmed that the quality assurance checklist was not preformed monthly for the year of 2018 and 10 out of 11 months in 2019. |
| **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 observation , record review and staff interview , the laboratory failed to monitor room temperature and humidity for the Hematology Sysmex XP-300 machine through 2018 - 2019 . Findings Include : An observation on the laboratory revealed there was no thermometer recording temperature and humidity. A review of the Sysmex XP- Validation Record stated the machine was in use February 13, 2018 . A review of the Sysmex-XP Manual states the use of instrument in temperatures ranging between 15 C to 30 C and relative humidity between 30 and 85 percent . A review of the temperature log record showed that there was no humidity and temperature documented for the Sysmex XP -300 between February 2018- November 2019 . During an interview on 12-17-19 at 12:00pm , lead testing person A confirmed that |

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| | humidity and temperature was not documented for the Sysmex XP-300 February 2018-November 2019 . |
| **D6000** | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on record review and staff interview the laboratory director failed to provide documentation of medical degree and ensure enrollement of proficency testing . Findings : Cross Reference D6033 . Based on record review and staff interview , the laboratory director failed to provide proof of medical degree for qualification of the laboratory director (LD). Cross Reference D6015. Based on record review and staff interview , the Laboratory Director failed to ensure enrollment of Hematology proficiency testing (PT)for the year of 2019 and the beginning 2020 . |
| **D6003** | LABORATORY DIRECTOR QUALIFICATIONS<br>CFR(s): 493.1405 AND 493.1406<br><br>The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the Laboratory is located; and (b)(2)(ii) Have had laboratory training or experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; or (b)(2)(ii)(B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in 493.1407; or (b)(2)(ii)(C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and (b)(3)(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or (b)(3)(ii) Have had at least one year experience directing or supervising non-waived laboratory testing; (b)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; (b)(4)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and (b)(4)(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or (b)(5)(i) Have |

earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and (b)(5)(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing; (b)(6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under 493.1406; or (b)(7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which the laboratory is located. Laboratory director qualifications on or before February 28, 1992 The laboratory director must be qualified to manage and direct the laboratory personnel and test performance. (a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and (b) The laboratory director must: (b)(1) Be a physician certified in anatomical or clinical pathology (or both) by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (b)(2) Be a physician who: (b)(2)(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or (b)(2)(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or (b)(2)(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification; or (b)(2)(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for certification; (b)(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and (b)(4)(i) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties; or (b)(4)(ii) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, either: (b)(5)(i) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or (b)(5)(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or (b)(6) Qualify under State law to direct the laboratory in the State in which the laboratory is located. Note: The January 1, 1968 date for meeting the 12 months' laboratory direction requirement in paragraph (b)(5) of this section may be extended 1 year for each year of full-time laboratory experience obtained before January 1, 1958 required by State law for a laboratory director license. An exception to the July 1, 1971 qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975 and had been employed in a laboratory for at least 3 years of the 5 years preceding the

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| | date of submission of his qualifications.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview , the laboratory director failed to provide proof of medical degree for qualification of the Laboratory Director (LD). Findings Include: A review of the CMS 209 Laborotory Personnel record revelaled that employee F was a LD . A review of the Personnel Degreee record displayed that the Labortory directors medical degree was not there . During an interview on 12-17-19 at 12:00pm , the testing personnel and office manager (OM) confirmed that there was no medical degree in the office . OM stated that degree would be emailed by 12-20-19. |
| **D6015** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview , the Laboratory Director failed to ensure enrollment of Hematology proficiency testing (PT) for the year of 2019 and the beginning 2020 . Finding Include : Based on record review and staff interview the laboratory failed to enroll in profociency testing (PT) for the specilaity of Hematology for the year of 2019 and beginning 2020. (See D2000) |
| **D6032** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(14)<br><br>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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview , the laboratory director failed to provide job description policies for 4 out of 4 (Testing Personnel (TP) , Technical Consultant (TC), Clinical Consultant (CC) , Laboratory Director (LD) ). Findings Include : A review of the 2019 Procedure Manual record revealed missing job description policies for the TP,CC. TC and LD . During an interview on 12-17-19 at 12:00 pm, testing person A confirmed the job description policies were missing for the testing personnel , clinical consultant , technical consultant , and laboratory director . |

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| **D6056** | CLINICAL CONSULTANT<br>CFR(s): 493.1415<br><br>The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part.<br><br>This CONDITION is not met as evidenced by:<br>Based on record review and staff interview , the Clinical Consultant failed to provide proof of medical degree for qualification . Findings : Cross Reference D6057: Based on record review and staff interview , the Clinical Consultant failed to provide proof of medical degree for qualification of the Clinical Consultant (CC). |
| **D6057** | CLINICAL CONSULTANT QUALIFICATIONS<br>CFR(s): 493.1417<br><br>The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493. 1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview , the Clinical Consultant failed to provide proof of medical degree for qualification of the Clinical Consultant (CC). Findings Include: A review of the CMS 209 Laboratory Personnel record revealed that employee E was a Clinical Consultant. A review of the Personnel Degree record displayed that the Clinical Consultant medical degree was not there . During an interview on 12-17-19 at 12:00pm , the testing personnel and office manager (OM) confirmed that there was no medical degree for clinical consultant in the office. OM stated that degree would be emailed by 12-20-19. |
| **D6063** | LABORATORY TESTING PERSONNEL<br>CFR(s): 493.1421<br><br>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed.<br><br>This CONDITION is not met as evidenced by:<br>Based on record review and staff interview , 3 (A,B,C) out 3 testing personnnel failed to provide proof of high school dipolmas for qualification of postion . Findings : Cross Reference D6064. Based on record review and staff interview , 3 (A,B,C) out 3 testing personnel (TP) failed to provide proof of high school dipolmas for qualification of postion. |
| **D6064** | TESTING PERSONNEL QUALIFICATIONS<br>CFR(s): 493.1423(a) |

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| | Each individual performing moderte complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview, 3 (A,B,C) out 3 testing personnel (TP) failed to provide proof of high school diplomas for qualification of the testing person.<br>Findings Include: A review of the CMS 209 Laboratory Personnel record revealed that employee A, B and C are testing personnel. A review of the Personnel Degree record displayed that there was no high school diplomas for 3 (A,B,C) out of 3 TP. During an interview on 12-17-19 at 12:00pm , the testing personnel and office manager (OM) confirmed that there was no high school diplomas for TP #A , B and C . OM stated that diplomas would be emailed by 12-20-19. |