Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1100352	08/29/2025
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
D0000	An announced CLIA recertification survey was conducted at FAMILY MEDICAL CENTRE from 08/20/2025 to 08/29/2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have documentation of the rotation of testing Personnel (TP) performing Proficiency Testing (PT), for Hematology specialty for two out of two years reviewed. Findings included: 1-Review of FORM CMS-209 signed and dated by the Laboratory Director (LD) on 08/20/2025 revealed the laboratory had five TP listed (TP#1, TP#2, TP#3 TP#4, TP#5). 2-Review of American Association of Bioanalysts /Medical Laboratory Evaluation (AAB/MLE) PT records for 2024, (first (02/09/2024), second (04/08 /2025) and third (09/24/2024) event) and 2025 (first (02/19/2025) and second event (05/202/2025) in the specialty of Hematology, revealed that instrument prints out failed to have identification of the TP testing the PT samples. 3-During an interview on 08/20/2025 at 12:30 PM, with TP#1 she confirmed that the laboratory failed to identify the TP doing the PT and failed to have documentation of TP rotation in PT.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) 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. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have attestations signed by the testing Personnel (TP) and Laboratory Director (LD), for Hematology specialty for two out of two years reviewed. Findings included: 1-Review of American Association of Bioanalysts /Medical Laboratory Evaluation (AAB/MLE) PT "GENERAL INSTRUCTIONS in the "REPORTING RESULTS" section stated "be sure to keep the attestation statements printed from your online reporting form. The attestation must be signed for each analyte by the analyst performing the procedure and kept in your files for inspection purposes. In addition to the analyst signatures the director or the directors' designee must sign only once for each reporting form 2-PT records review for 2024, (first, second third event) and 2025 (first and second event) in the specialty of Hematology, revealed that the laboratory failed to have attestation signed by the TP and LD. 3-During an interview on 08/20 /2025 at 12:30 PM, with TP#1 she confirmed that the laboratory failed to have attestation signed for the events listed above by the LD and TP.
D2122	HEMATOLOGY CFR(s): 493.851(b) (b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory received an unsatisfactory score for 1 out of 5 events reviewed for Hematology specialty in 2024 and 2025. Findings included: Review of American Association of Bioanalysts / Medical Laboratory Evaluation (AAB-MLE) records for 2024 and 2025 revealed that the laboratory received a score of 44% for the Cell ID and 0% for White Blood Cell count in the second event of 2024 resulting in an overall score of 74 % for the Hematology specialty. During an interview on 08/20/2025 at 11:30 AM, the Lead Technician confirmed the proficiency testing failure.
D2128	HEMATOLOGY CFR(s): 493.851(e) (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 one unsatisfactory score for Hematology specialty in one out of five events reviewed. Findings included: -Review of American Association of

	Bioanalysts / Medical Laboratory Evaluation (AAB-MLE) records for 2024 and 2025, revealed that the laboratory had an unsatisfactory score for the Hematology specialty in the second event of 2024. -No documentation of corrective action found for this failure. During an interview on 08/20/2025 at 12:00 PM, the Lead Technician confirmed that the laboratory had no documentation of the remedial actions for the failure of reference.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) 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 analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory Quality Assessment (QA) failed to monitor the laboratory performance and implement corrective actions for two out of two years reviewed. Findings included: 1-Review of Monthly QA checklists revealed after August 2023 no Monthly QA checklists found. 2- The absence of QA documentation failed to identify and correct that the laboratory was not signing Proficiency Testing (PT) attestations. Refer to D2009. 3-The laboratory failed to have corrective actions for the failures in PT in the 1st and 2nd event of 2024. Refer to D2128. 4-The QA failed to identify and correct that there was no documentation fo the Quality Control review by the Technical Consultant/Laboratory Director. 4-There was no documentation of QA activity during the two years review (2024-2025). During an interview on 08/20/2025 at 12:45 PM, the lead technician confirmed that the QA failed to correct the deficiencies listed above.
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities. This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director (LD) failed to establish a policy to be onsite once every six months and document the onsite visits. Findings included: 1-Review of the laboratory's policies and procedures signed by the LD on 07/05/2025, revealed that there was no policy to reflect that the LD will be onsite at least once every six months or how an onsite visit would be documented. 2-During an Interview on 08/20/2025 at 12.46 PM, the Lead technician confirmed that there was no policy to monitor the LD visits to the laboratory.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) (e)(4)(iv) An approved corrective action plan is followed when any proficiency testing

	results are found to be unacceptable or unsatisfactory; This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director (LD) failed to ensure that when unsatisfactory and unsuccessful testing scores were received that a corrective action plan was written and followed by the laboratory personnel. Refer to D2128
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Director (LD), the LD failed to ensure the Quality Assessment (QA) corrected the laboratory deficiencies. Refer to D5791.
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b(8)(i) (b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; This STANDARD is not met as evidenced by: Based on record review and staff interview revealed that the Technical Consultant (TC) or a qualified designee failed to observe patient testing during competency evaluation for four out of five Testing Personnel (TP) for one out of two years reviewed. Findings included: 1-Review of FORM CMS 209 signed by the Laboratory Director on 08/20/2025, revealed the following: Laboratory Director (LD) was also Clinical Consultant and Technical Consultant for Hematology specialty and 5 TP (TP#1, TP#2, TP#3 TP#4 and TP#5). 2-Review of personnel records revealed that competency for TP#1 (Lead Medical Assistant (Lead MA)) was observed on 04/14 /2025 by another staff not listed in the 209, TP#2 competency overserved by TP#1 on 04/10/2025, TP#3 was observed on 04/18/2025 by TP#1 and TP#4 observed on 07/08 /2025 by TP#1. Lead MA did not qualify for a peer review in competence. 3-During an interview on 08/20/2025 at 12:50 PM, the Lead MA confirmed that the TC failed to observe patient testing observation during annual competency for TP#1, TP#2, TP#3 and TP#4.
D6050	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iv) (b)(8)(iv) Direct observation of performance of instrument maintenance and function checks; This STANDARD is not met as evidenced by:

	Based on record review and staff interview revealed that the Technical Consultant (TC) or a qualified designee failed to observe direct observation of performance of instrument and function check during competency evaluation for four out of five Testing Personnel (TP) for one out of two years reviewed. Findings included: 1-Review of FORM CMS 209 signed by the Laboratory Director on 08/20/2025, revealed the following: Laboratory Director (LD) was also Clinical Consultant and Technical Consultant for Hematology specialty and 5 TP (TP#1, TP#2, TP#3 TP#4 and TP#5). 2-Review of personnel records revealed that competency for TP#1 (Lead Medical Assistant (Lead MA)) was observed on 04/14/2025 by another staff not listed in the 209, TP#2 competency overserved by TP#1 on 04/10/2025, TP#3 was observed on 04/18/2025 by TP#1 and TP#4 observed on 07/08/2025 by TP#1. Lead MA did not qualify for a peer review in competence. 3-During an interview on 08/20/2025 at 12: 52 PM, the Lead MA confirmed that the TC failed to observe direct observation of performance of instrument and function check observation during annual competency for TP#1, TP#2, TP#3 and TP#4.