Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0705040	09/06/2024
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 was conducted from September 4th to 6th, 2024. FAMILY MEDICAL CENTRE clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(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 interview, the laboratory testing personnel failed to sign attestation for the Proficiency Testing (PT) Hematology in 2023 2nd and 3rd events, in 2024 1st and 2nd events, for 4 out of 6 events reviewed (3rd of 2022, 1st /2nd /3rd of 2023 and 1st /2nd of 2024). Findings included: 1-Review of the PT records 2024 American Association of Bioanalysts (AAB) revealed that the testing personnel (TP1) failed to sign attestation for the 1st and 2nd event in 2024. 2-Review of the PT events in 2023 of the AAB revealed that the TP1, failed to sign attestation for the 2nd event performed on 06/02/2023, and for 3rd event performed on 9/15/2023. 3-Review of the AAB General Program Instructions under the Reporting Results, Step 2 stated "Be sure to keep all attestations printed from your online reporting form. We do not require this for grading. The attestation statements must be signed for each analyte by the analyst performing the procedure and keep in your files for inspection purposes." 4-Interview on 09/04/2024 at 11:45 AM the laboratory medical assistant admitted to not having paper attestation since the attestation is done with electronic submission of results and the laboratory director's electronic signature. The laboratory did not provide electronic record of attestation for the analyst (TP1) performing the procedure.

D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform competency evaluations on 2 testing personnel who perform Complete Blood Count (CBC) in the specialty of Hematology for one out of two (2023 and 2024) years reviewed. Findings included: 1- Review of the CMS-209 form signed by laboratory director on 09/04 /2024 revealed the laboratory has two testing personnel (TP1 & TP2) 2-Review of competency records found no competency evaluation was performed on TP1 due in 7 /2024 and TP2 due in April 2024. 3-Interview on 09/04/2024 at 2:48 PM the laboratory medical assistant confirmed that there was no documented competency evaluation for each TP1 and TP2 in 2024.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to complete verification for Sysmex XN-330 Series Complete Blood Count (CBC) Hematology analyzer. Findings included: 1-Review of the laboratory's verification records for the Sysmex XN-330 Serial Number 15864, found that the laboratory had not completed correlation studies and reference range verification. 2-Review of the XN-Series XN-L Method Verification Manual #1251-12SS, Rev 2, Dec 2016 stated "It is the customer's responsibility to perform additional studies following the requirements of their accrediting agency." 3-Interview on 09/04/2024 at 2:48 PM the laboratory medical assistant confirmed that the laboratory did not perform the correlation studies and reference range verification