Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0966028	09/24/2025
Name of Provider or Supplier	**Street Address, City, State**	
Family Medical Centre	17933 Nw 7th St Ste 102, Pembroke Pines, 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 09/05/2025 to 09/24/2025. The laboratory was not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D6063 CFR 493.1421 Condition: Laboratory Testing Personnel
D2014	TESTING OF PROFICIENCY TESTING SAMPLES (b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory failed to keep records of the testing of Proficiency Testing (PT) in the Specialty of Hematology for one (M1 2024) out of three events (M1, M2, M3) in 2024. Findings included: 1-Review of FORM CMS-209 Laboratory Personnel Report dated and signed by the Laboratory Director on 08/26/2025 listed six TP (TP#1, TP#2, TP#3, TP#4, TP#5 and TP#6). 2-Review of American Association of Bioanalysts /Medical Laboratory Evaluation (AAB/MLE) PT records for M1 2024 revealed that the laboratory did not maintain instrument testing records and kit instructions for the first event in 2024. 3- Review of American Association of Bioanalysts /Medical Laboratory Evaluation (AAB/MLE) PT records for M1 2024 revealed attestation was signed by laboratory director and analyst (TP1) on 02/20/2024. 4-During an interview on 09/05/2025 at 2:30 PM, TP#1 did not provide the instrument printed records for M1 2024. Records were requested via email on 09/09/2025 but not provided by the laboratory.

D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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, record review and staff interview, the laboratory failed to establish appropriate storage criteria at the appropriate temperature requirements to assure performance of the Hematology Sysmex XN controls as per manufacturer instructions for nine (9) out of 22 days in December 2023, 13 out of 23 days in April 2024, 16 out of 21 days in September 2024. Findings included: 1- During a tour of the laboratory on 09/05/2025 at approximately 10:30AM, observed in use vials XN-L1, L2, L3 and a box of the Sysmex XN-L Check containing six unopened new vials of controls with storage requirement of +2C to +8C (Celsius). Conversion to Fahrenheit (F) was 35.6 F to 46.4 F. 2- Review of the Monthly Thermometer Log for random months of December 2023, April 2024, and September 2024 stated at the bottom of the form " ...the acceptable temperature for the refrigerator ranges from 35 F to 46 F." 3 - Monthly Thermometer Log for random months of December 2023, April 2024, and September 2024 revealed that refrigerator temperature was not at 2 to 8C (35 F to 46 F) for the dates listed: 12/04/2023 recorded 30 degrees F, 12/07/2023 recorded 30 degrees F, 12/08/2023 recorded 30 degrees F, 12/11/2023 recorded 32 degrees F, 12 /13/2023 recorded 34 degrees F, 12/18/2023 recorded 34 degrees F, 12/19/2023 recorded 34 degrees F, 12/20/2023 recorded 32 degrees F, 12/21/2023 recorded 34 degrees F, 04/01/2024 recorded 34 degrees F, 04/05/2024 recorded 34 degrees F, 04 /09/2024 recorded 34 degrees F, 04/10/2024 recorded 34 degrees F, 04/11/2024 recorded 32 degrees F, 04/12/2024 recorded 34 degrees F, 04/15/2024 recorded 34 degrees F, 04/16/2024 recorded 32 degrees F, 04/18/2024 recorded 32 degrees F, 04 /19/2024 recorded 34 degrees F, 04/23/2024 recorded 34 degrees F, 04/25/2024 recorded 34 degrees F, 04/30/2024 recorded 34 degrees F, 09/03/2024 recorded 34 degrees F, 09/04/2024 recorded 34 degrees F, 09/06/2024 recorded 34 degrees F, 09 /09/2024 recorded 34 degrees F, 09/13/2024 recorded 34 degrees F, 09/16/2024 recorded 34 degrees F, 09/17/2024 recorded 32 degrees F, 09/19/2024 recorded 34 degrees F, 09/20/2024 recorded 34 degrees F, 09/21/2024 recorded 32 degrees F, 09 /23/2024 recorded 34 degrees F, 09/24/2024 recorded 34 degrees F, 09/26/2024 recorded 34 degrees F, 09/27/2024 recorded 34 degrees F, 09/28/2024 recorded 32 degrees F, 09/30/2024 recorded 32 degrees F 5- Interview on 09/05/2024 at 12:58 PM the TP1 confirmed that the refrigerator was out of range for storage of hematology controls.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations;

	This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to obtain at least two out of three levels of Hematology control on 02/08/2025 as required for the complete blood counter (CBC) Sysmex XN-330 quantitative analyzer. The laboratory tested and released results for two patients on February 08, 2025. Findings included: 1. Review of the quality control (QC) records for the three levels of QC during February of 2025 revealed that the monthly QC Charts for lot 43481401, 43481402, and 43481403 did not have runs recorded for 02/08/2025 out of 20 listed. 2. Review of the Quality Control Policies and Procedure stated, "Control are to be run daily before any patient testing are run." 3. Interview on 09/05/2024 at 12:25 PM the TP1 confirmed that the hematology controls were not run on 02/08/2025. 4. Email received on 09/24 /2025 at 8:57 AM from TP1 confirmed that two patients were tested and reported on Saturday 02/08/2025.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 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. This CONDITION is not met as evidenced by: Based on record review and staff interview, the Laboratory failed to verify the education of 1 out of 6 Testing Personnel performing the Hematology Complete Blood Count (CBC) test. See D6065
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to verify the education of one out of six testing personnel (TP). Findings included: 1-Review of FORM CMS-209 Laboratory Personnel Report dated and signed by the Laboratory Director on 08/26/2025 listed six TP (TP#1, TP#2, TP#3, TP#4, TP#5 and TP#6). 2-Review of employee files revealed that TP#4 had Competency evaluations in 05/23 /2024 and 06/16/2025 and there was no diploma submitted. 3-During an interview on

	09/05/2025 at 12:35 PM with TP#1, laboratory lead (TP#1) confirmed that the laboratory failed to have documentation to proof that the TP#4 fulfill the minimum education requirement.