

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0705040	(X3) Date Survey Completed 07/24/2026
Name of Provider or Supplier Family Medical Centre	Street Address, City, State 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	An announced CLIA recertification survey was conducted at FAMILY MEDICAL CENTRE from July 23, 2026 to July 24, 2026. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D6000 493.1403 - Condition: Moderate Complexity Laboratory Director D6063 493.1421- Condition: Laboratory Testing Personnel
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on observation, records review, and staff interview, the laboratory failed to retain records for Quality Control (QC) from 6/19/2025 to 02/09/2026 and failed to retain records of Background testing for the Sysmex XN Hematology analyzer for random months December 2024, May 2025 and November 2025. Findings included: 1. During observation of QC files on the Sysmex XN-330 Hematology analyzer #15864 on 07/23/2026 at 1:55 PM, revealed that the BeyondCare Quality Monitor (BCQM) Peer Group report generator listed XN-L CHECK Lot 5066 with date range 03/12/2025 - 06/18/2025, Lot 6037 with date range 02/10/2026 - 05/20/2026. The laboratory did not provide the QC Peer group data sets covering date range 6/19/2025 to 02/09/2026. 2. During review of Patient reports for P-1 (12/12/2024), P-2 (05/28 /2025), and P-3 (11/12/2025), the surveyor requested background checks of the analyzer for the days of testing, the laboratory did not provide background check evidence for testing days during December 2024, May 2025 and November 2025. 3. During an interview on 07/23/2026 at 2:15 PM, the Office Supervisor (TP-E) confirmed that the laboratory had a service visit on 06/01/2026 because they were

	unable to extract QC data, and a call with Sysmex support on 06/04/2026 to address missing QC data, and TP-E also confirmed that the background check printouts were not kept by the laboratory. The laboratory contacted Sysmex during the survey 07/23/2026 to enable printing until issue of loss of analytical testing data is resolved.
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 document the Quality Assessment (QA) activities in the Hematology laboratory including corrective actions for one (June 2026) out of four months reviewed (December 2024, May and November 2025, June 2026). Findings included: 1- Review of the Monthly Quality Assurance Checklist June 2026, under Section "Our general laboratory system has been followed: revealed a check mark for "Storage requirements have been met. All temperature readings have been logged." 2- Review of the Monthly Refrigerator Thermometer Log revealed no entries for refrigerator temperature on 06/11/2026 and 06/12/2026. 3- Review of the Monthly Quality Assurance Checklist signed by the Laboratory Director on 06/30/2026 revealed that the laboratory did not follow instructions, at the bottom of the form, to answer "NO" and provide corrective action. 4- During an interview on 07/23/2026 at 3:15 PM, TP-E (MA Office Supervisor) confirmed that corrective action was not documented for the daily temperature readings not recorded on 06/11/2026, and 06/12/2026.
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 record review and interview, the laboratory failed to document the refrigerator temperature for two days (06/11 and 06/12) out of 21 days of testing in Hematology specialty during the month of June 2026. Finding included: 1. Review of the Medical Assistant (MA) Duties (HIALEAH) 2026 dated 6/8/2026 stated under "MA Opening" a.(first bullet) "Turn on CBC analyzer and run controls" b.(second bullet) "Record refrigerator temperature" 2- Review of the Monthly Refrigerator Thermometer Log revealed no documentation for temperature on 06/11/2026 and 06/12/2026. The laboratory did not provide the number of patients tested on 06/11/2026,

	and 06/12/2026. 3- Review of the XN-L CHECK control insert stated under Storage and shelf life after first opening "open vials and vials which have been sampled with cap piercing will retain stability for 15 days if stored at 2-8 C after being recapped." 4- During an interview on 07/23/2026 at 2:30 PM, TP-E (MA Office Supervisor) confirmed that daily temperature was not recorded on 06/11/2026 and 06/12/2026.
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 the review of the laboratory manual, review of quality control records, and staff interview, the laboratory failed to obtain two out of three acceptable levels of hematology controls on November 12th, 2025 (random patient selected), as required per the Complete Blood Count (CBC) quantitative analyzer Sysmex XN 330. The laboratory did not provide the number of samples tested and released on 11/12/2025. Finding included: 1- Review of the Sysmex XN 330 Code No. AF 812533 Basic Operations for the Hematology analyzer stated in Chapter 3 that three levels of QC material (XN-L CHECK Level 1, XN-L CHECK Level 2, and XN-L CHECK Level 3) should be ran prior to reporting Patient results.. In addition, Section 3.2.2. stated "XN-L CHECK is the quality control material used to monitor the performance of the XN-L analyzer. Quality control should be run according to licensing agency regulation." 2- Review of Quality Control (QC) records for three levels of QC during November 2025 revealed that the lab did not have QC for level 2 and level 3. The laboratory had QC tables XN-L Level 1 of CBC results and Levey Jennings for lot 523415403 but did not have QC tables XN-L Level 2 and XN-L Level 3. 3- During an interview on 07/23/2026 at 10:42 AM, the Office Supervisor (TP-E) confirmed that the laboratory did not have the QC tables for Level 2 and Level 3 during the month of November of 2025.
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 observation, record review, and staff interview, the Laboratory Director (LD) failed to fulfill the LD duties by failing to provide overall management and direction to ensure the laboratory adhered to the regulations at least from December 2024 through June 2026. (See D6004)
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on observation, record review and staff interview, the Laboratory Director failed to provide overall management and direction to ensure the laboratory adhered to the regulations at least from January 1, 2025 through June 2026. Finding included: 1. Based on lack of records, the Laboratory Director failed to establish a policy to document they were onsite every six months to include evidence of performing laboratory director's responsibilities from January 1, 2025 through June 08, 2026 (See D6005) 2. The Laboratory Director failed to ensure that the quality control and quality assessment policy was established and followed to identify failures and corrective actions in June 2026 (See D6020) 3. The Laboratory Director failed to ensure that Testing Personnel had the appropriate education and experience for one out of five testing personnel, and failed to ensure Testing Personnel received the appropriate training and demonstrated they could perform the test operations for moderate complexity testing in the specialty of Hematology for three out of five testing personnel in 2025. (See D6029) 4. On 07/24/2026 at 11:43 AM email response from the Practice Administrator stated that the Laboratory Director was not available for interview and that he was "gone again for another week."

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 observation and staff interview, the Laboratory Director (LD) failed to establish a policy to document onsite visits every six months to include evidence of performing laboratory director responsibilities from January 1, 2025 through June 08, 2026. Finding included: 1. Review of Duties of the Laboratory Director signed by the LD on 06/08/2026, revealed the onsite daily supervision and delegation effective date as 06/08/2026. 2. During an interview on 07/23/2026 at approximately 3:00 PM, the Office Supervisor (TP-E) confirmed that the laboratory did not have a policy for tracking when the LD was onsite. 3. On 07/24/2026 at 11:43 AM email response from the Practice Administrator stated that the Laboratory Director was not available for interview and that he was "gone again for another week."

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, the Laboratory Director (LD) failed to ensure that the quality control (QC) and the quality assessment (QA) programs was established and maintained to assure the quality of laboratory services provided and to identify failures in quality when the laboratory failed to keep QC files for all three levels in November of 2025 each day of testing, and also when the laboratory failed to document the refrigerator temperature for two days (06/11 and 06/12) out of 21 days of testing in Hematology specialty during the month of June 2026. Finding included: 1. Review of Quality Control (QC) records for three levels of QC during November 2025 revealed that the lab did not have QC for level 2 and level 3. The laboratory had QC tables XN-L Level 1 of CBC results and Levey Jennings for lot 52341403 but did not have QC tables XN-L Level 2 (52341402) and XN-L Level 3 (52341401). 2. Review of the Monthly Quality Assurance Checklist revealed the LD signed on 06/30/2026 but did not ensure that the laboratory followed instructions, at the bottom of the form, to answer "NO" and did not provide corrective action. 3. On 07/24/2026 at 11:43 AM email response from the Practice Administrator stated that the Laboratory Director was not available for interview and that the LD was "gone again for another week."

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

(e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the Laboratory Director (LD) failed to ensure that testing personnel had the appropriate education and experience for one out of five Testing Personnel (TP), and failed to ensure TP received the appropriate training and demonstrated they could perform the test operations for moderate complexity testing in the specialty of Hematology for three out of five TP in 2025. Finding included: 1. Review of "Duties of the Laboratory Director" signed by the LD on 06/08/2026, revealed the onsite daily supervision and delegation effective date as 06/08/2026. 2. Review of FORM CMS 209 signed by the Laboratory Director on 06/12/2026, revealed that the laboratory had five TP (TP-A, TP-B, TP-C, TP-D and TP-E). 3. Review of the proficiency testing records by the AMERICAN ASSOCIATION OF BIOANALYSTS (AAB) Medical Laboratory Evaluation (MLE) Proficiency Testing Reinstatement AAB-MLE #7216631 revealed that on 10/17/2025 the LD and TP-E signed the attestation for analyst performing the procedure for proficiency testing. 4. Review of the TP-E qualifications revealed a High School diploma from a foreign country without equivalency certification, and a Medical Assistant certificate expiration date 12-31-25 from a US institution. 5. During interview on 07/23/2026 at approximately 10:40 AM, the Office Supervisor (TP-E) confirmed that she did not possess a high school diploma or GED from an accredited US institution. 6. Review of personnel records initial competency evaluation signed by the Laboratory Director (TP-B 10/14/2025, 10/28/2025 TP-C) and six months competency signed by the

	laboratory director (4/1/2026 TP-B, 4/21/2026 TP-C) revealed that the LD did not assess competency with the Hematology analyzer XN-330, for patient testing and performance of instrument and function check. There were no records of that the Laboratory Director had performed competency evaluation for moderate complexity testing with the Hematology analyzer XN-330 for TP-E. 7. On 07/24/2026 at 11:43 AM email response from the Practice Administrator stated that the Laboratory Director was not available for interview and that he was "gone again for another week."
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, the Technical Consultant (TC) or a designee failed to do direct observation of patient testing during competency evaluation for three Testing Personnel (TP) out five TP in 2025. Findings included: 1- Review of FORM CMS 209 signed by the Laboratory Director on 06/12/2026, revealed the following: Laboratory Director (LD) was also Clinical Consultant (CC) and Technical Consultant (TC) for Hematology specialty. The laboratory had five Testing Personnel (TP-A, TP-B, TP-C, TP-D and TP-E). 2-Review of personnel records initial competency evaluation (TP-B 10/14/2025, 10/28/2025 TP-C) and six months competency (4/1/2026 TP-B, 4/21/2026 TP-C) in the Hematology specialty, revealed that the direct observation for patient testing on the Hematology Analyzer XN-330 was not performed. The laboratory did not have competency records of TP-E for moderate complexity testing. 3- During an interview on 07/23/2026 at 10:42 AM, the Office Supervisor (TP-E) confirmed that TC did not perform the patient testing observation during competency evaluations on 10/14/2025 TP-B, 10/28/2025 TP-C, 4/1/2026 TP-B, 4/21/2026 TP-C. TP-E also confirmed that the laboratory did not have a competency evaluation procedure and that she did not have a competency evaluation done since she was the Office Supervisor.
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, the Technical Consultant (TC) or a designee failed to do direct observation of performance of instrument and function check during competency evaluation for testing personnel (TP) for three out five TP in 2025. Findings included: 1- Review of FORM CMS 209 signed by the Laboratory Director on 06/12/2026, revealed the following: Laboratory Director (LD) was also Clinical Consultant (CC) and Technical Consultant (TC) for Hematology specialty. The laboratory had five testing personnel (TP-A, TP-B, TP-C, TP-D and TP-E). 2- Review of personnel records initial competency evaluation (TP-B 10/14/2025, 10/28/2025 TP-C) and six months competency (4/1/2026 TP-B, 4/21/2026 TP-C) in the Hematology specialty, revealed that the direct observation of performance of

	instrument and function check for the Hematology Analyzer XN-330 was not performed. The laboratory did not have competency records of TP-E for moderate complexity testing. 3- During an interview on 07/23/2026 at 10:42 AM, the office supervisor (TP-E) confirmed that TC did not perform the direct observation of performance of instrument and function check during competency evaluations on 10/14/2025 TP-B, 10/28/2025 TP-C, 4/1/2026 TP-B, 4/21/2026 TP-C. TP-E also confirmed that the laboratory did not have a competency evaluation procedure and that she did not have a competency evaluation done since she was the Office Supervisor.
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 review of personnel records and staff interview, the laboratory failed to verify the educational qualifications (High School degree) for one (TP-E) out of five testing personnel (TP-A, TP-B, TP-C, TP-D, TP-E). (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 the record review and staff interview, the laboratory failed to verify the education of one testing person (TP-E) out of five testing personnel (TP-A, TP-B, TP-C, TP-D, TP-E). Findings included: 1. Review of FORM CMS 209 signed by the Laboratory Director on 06/12/2026, revealed the following: Laboratory Director (LD) was also Clinical Consultant (CC) and Technical Consultant (TC) for Hematology specialty. The laboratory had five testing personnel (TP-A, TP-B, TP-C, TP-D and TP-E). 2. Review of the AMERICAN ASSOCIATION OF BIOANALYSTS (AAB) Medical Laboratory Evaluation (MLE) Proficiency Testing Reinstatement AAB-MLE #7216631 revealed that on 10/17/2025 the LD and TP-E signed the attestation for analyst performing the procedure for proficiency testing. 3. Review of the TP-E qualifications revealed a High School diploma from a foreign country without

equivalency certification, and a Medical Assistant certificate expiration date 12-31-25 from a US institution. 4. During interview on 07/23/2026 at approximately 10:40 AM, the Office Supervisor (TP-E) confirmed that she did not possess a high school diploma or GED from a US accredited institution.