

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0705040	(X3) Date Survey Completed 09/30/2022
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	A recertification survey conducted from 09/26/2022 to 09/30/2022 found the FAMILY MEDICAL CENTRE clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories. Cited the following Conditions: -D5400. Analytic Systems. -D6000. Moderate Complexity Laboratory Director.
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory did not meet the condition for analytic systems. Findings include: -Failed to perform Sysmex XP-300 Complete Blood Cell Analyzer instrument calibration verification at least every six months from 01/01/2021 to 09/30/2022. Refer to 5439. This is a repeated deficiency form the survey on 2020.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p>

(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 staff interview, refrigerator temperatures were outside the acceptable range for the Sysmex Hematology Controls storage for 103 out of 188 days in 2022. The findings include: -Review of temperature refrigerator log revealed an acceptable range of 35 to 46 Fahrenheit degrees. -Temperature log record review for 2022 from January to September revealed the following dates, the temperature were outside of the acceptable range: 01/03/2022, 01/04/2022, 01/07/2022, 01/10/2022, 01/11/2022, 01/12/2022, 01/18/2022, 01/25/2022, 01/28/2022, 02/14/2022, 02/15/2022, 02/16/2022, 02/18/2022, 02/22/2022, 02/23/2022, 02/24/2022, 02/25/2022, 02/28/2022, 03/02/2022, 03/03/2022, 03/08/2022, 03/10/2022, 03/11/2022, 03/14/2022, 03/15/2022, 03/16/2022, 03/18/2022, 04/04/2022, 04/05/2022, 04/06/2022, 04/11/2022, 04/12/2022, 04/13/2022, 04/20/2022, 04/22/2022, 04/25/2022, 04/26/2022, 04/27/2022, 05/02/2022, 05/04/2022, 05/05/2022, 05/06/2022, 05/09/2022, 05/10/2022, 05/11/2022, 05/12/2022, 05/16/2022, 05/19/2022, 05/26/2022, 05/30/2022, 06/07/2022, 06/08/2022, 06/13/2022, 06/20/2022, 06/21/2022, 06/22/2022, 06/23/2022, 06/24/2022, 06/28/2022, 06/29/2022, 07/01/2022, 07/05/2022, 07/06/2022, 07/07/2022, 07/08/2022, 07/12/2022, 07/13/2022, 07/15/2022, 07/19/2022, 07/21/2022, 07/22/2022, 07/26/2022, 07/28/2022, 08/01/2022, 08/02/2022, 08/04/2022, 08/08/2022, 08/09/2022, 08/12/2022, 08/15/2022, 08/16/2022, 08/17/2022, 08/18/2022, 08/22/2022, 08/23/2022, 08/24/2022, 08/25/2022, 08/29/2022, 08/30/2022, 08/31/2022, 09/06/2022, 09/07/2022, 09/08/2022, 09/09/2022, 09/12/2022, 09/15/2022, 09/16/2022, 09/19/2022, 09/20/2022, 09/21/2022, 09/22/2022, 09/23/2022 and 09/26/2022, During an interview on 09/26/2022 at 01:02 PM, the testing personnel A confirmed that the refrigerator temperatures were outside the acceptable range in the days listed above.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on observation and staff interview, the laboratory failed to label complete blood cells (CBC) controls currently in use with the open and new expiration dates. Findings include: - During the laboratory tour on 09/30/2022 at 10:00 AM, the surveyor observed that the laboratory had in use SYSMEX EIGHTCHECK- 3WP X-TRA CBC controls with Lot # 2193. The controls in use failed to have the opening date and the new expiration date. -Review of EIGHTCHECK- 3WP X-TRA controls insert revealed that opened controls are stable for 14 days if stored at 2-8 Degree Celsius. During an interview on 09/30/2022 at 10:35 AM, the Testing Personnel # A, confirmed that controls in use were not label as described above and she explained that they started using the current control vials on 09/20/2022.

D5431

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(2)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to repeat a rejected background check in the Sysmex complete blood analyzer (CBC) in seven (7) days out of two months reviewed (July and August of 2021). Findings include: -Review of Background checks for Sysmex XP-300 revealed that in the months of July and August of 2021, the laboratory had 7 seven days with background check rejected. The laboratory failed to repeat the background check in the days of reference. The days that the background check failed were: 07/27/2021, 08/12/2021, 08/16/2021, 08/17/2021, 08/18/2021, 08/19/2021 and 08/20/2021. -Review of patients tested revealed that on 08/12/2021, 08/16/2021 and 08/20/2021 the laboratory tested one patient each day and on 08/19/2021 the laboratory tested two patients. During an Interview on 09/26/2022 at 1:30 PM, TP A confirmed that the laboratory failed to repeat the background check for the days of reference.

D5439

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to document calibration verification procedures of the Sysmex XP-300 analyzer at least every 6 months from 01/01/2021 to 09/26/2022. This is a repeated deficiency from previous survey. Findings include: -Review of the Sysmex XP-300 calibration records revealed that the laboratory performed calibration verification on 12/30/2020 and 06/17/2022.

	<p>During an interview on 09/26/2022 at 1:05 p.m., Testing Person A confirmed that there was no documentation to indicate the laboratory performed instrument calibration verification every 6 months in the period of 01/01/2021 to 09/26/2022.</p>
<p>D5791</p>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(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. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the Quality Assessment (QA) failed to correct that the refrigerator temperature for complete blood controls (CBC) storage was in range for 103 days in 2022, failed to ensure the Sysmex XP-300 instrument was ready before patient testing in seven days in 2021 and failed to do the calibration to Sysmex XP-300 at least every six months since 2021. Findings include: -Review of the Monthly Quality Assurance Checklist records revealed no documentation of the QA activity since December 2020. -No documentation of corrective actions for refrigerator temperatures outside of the required range. Refer to D5413. -No corrective actions for Background check rejected and patients tested when the instrument was displaying "Not Ready". Refer to D5431. -Failed to correct that the laboratory performed calibration verification for the Sysmex XP-300 at least every six months. Refer to D5439. During an interview on 09/26/2022 at 01:07 PM, the Office Manager confirmed that the QA failed to correct the deficiencies listed above.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on record review and office manager interview, the Laboratory Director (LD) failed to effectively oversee the laboratory from 01/01/2021 to 09/30/2022. This is a repeated deficiency from the previous survey on 2020 Findings include: -The LD failed to ensure the laboratory performed calibration verification at least every 6 months. Refer to D6013 -The LD failed to ensure the Quality Assessment corrected deficiencies. Refer to D 6021</p>
<p>D6013</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</p> <p>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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance</p>

characteristics of the method;

This STANDARD is not met as evidenced by:

Based on record review and interview, the Laboratory Director failed to ensure the laboratory performed the calibration verification to the Sysmex XP 300 analyzer at least every six months from 01/01/2021 to 09/30/2022. Refer to D5439

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on record review and interview, the Laboratory Director (LD) failed to ensure the laboratory had an effective Quality Assessment. Findings include: -Refer to D5791.