

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0966028	(X3) Date Survey Completed 11/02/2021
Name of Provider or Supplier Family Medical Centre	Street Address, City, State 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	A recertification survey conducted on 11/02/2021 found that the FAMILY MEDICAL CENTRE clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D2121	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of American Association of Bioanalysts (AAB) proficiency testing (PT) records and staff interview, the laboratory received an unsatisfactory score in the 1st event of 2020 for the White Blood Cell Differential (WBC DIFF) in the specialty of Hematology. Findings include: Review of AAB PT records revealed a score of 66 % for WBC DIFF in the 1st event of 2020. During an interview on 11/02/2021 at 2:25 PM, the testing personnel A confirmed the proficiency testing failure.</p>
D2122	<p>HEMATOLOGY CFR(s): 493.851(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of American Association of Bioanalysts (AAB) proficiency testing (PT) records and staff interview, the laboratory received an unsatisfactory score in the 1st event of 2021 for the specialty of Hematology. Findings include: Review of AAB PT records revealed a score of 26 % for White Blood Cell differential, 20% for Red</p>

	<p>Blood Cells, 20 % Hematocrit, 20% Hemoglobin, 20 % White Blood Cells, 20 % Platelets tests resulting in an overall score of 21 % in the 1st event of 2021. During an interview on 11/02/2021 at 2:30 PM, the testing personnel A confirmed the proficiency testing failure.</p>
<p>D2128</p>	<p>HEMATOLOGY CFR(s): 493.851(e)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document remedial action for unsatisfactory proficiency testing (PT) results for White Blood Cells Differential (WBC DIFF) analyte in 1st event of 2020 and for the Hematology specialty in 1st event of 2021. Findings include: - Refer to D2121 and D2122 -No documentation of the remedial and corrective actions found during the survey for the failing scores in PT. During an interview on 11/02/2021 at 2:45 PM, the testing personnel A confirmed that the laboratory had no documentation of the remedial actions for the failures of reference.</p>
<p>D3011</p>	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with Testing personnel A (TP A), the laboratory stored food in a refrigerator where reagents and patient blood specimen were stored for an undetermined amount of time. Findings include: During a tour of the laboratory on 11/02/2021 at 1:30 PM, the surveyor found that in the refrigerator the laboratory stored: medications (Trulicity, Ozempic, Engality), Vaccines (Measles, Mumps and Rubella combined, Human Papiloma Virus), reagent (Complete Blood Cells controls) , one tube with a blood sample and staff food (a 2-liter Coca Cola bottle in use, a 2-liter Cranberry Juice in use, a bottle of Cesar Salad dressing, a transparent food container with food, etc). In the freezer compartment of the refrigerator a unlabelled plastic bag with mini hotcakes was stored together with frozen transportation bags including one from Quest. Photographic evidence obtained. The food was discarded during the tour. -Review of the Safety Summary notice to All Staff revealed that it stated that " Use of laboratory Refrigerator only for the storage of reagents, controls, or specimens. No food, contaminated specimens or unsealed volatile materials should be stored in the refrigerator. During an interview on 11/01/2021 at 1:30 PM, the TP A confirmed that the laboratory had food stored with the reagents failed to follow the safety instructions.</p>

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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, user manual review and staff interview, the laboratory failed to document room temperature and humidity requirement to assure optimal operation of the Sysmex XP-300 analyzer in 2020 and 2021. The findings include: - During the laboratory tour on 11/02/2021 at 1:30 PM, the surveyor found no thermometer /humidity meter to measure room temperature and humidity. -The review of Sysmex XP-300 analyzer manual revealed a room temperature requirement range of 15-30 Centigrade and humidity range of 35 to 85 %. Temperature log record review revealed no records of room temperature and humidity in 2020 and 2021 During an interview on 11/02/2021 at 3:30 PM, the testing personnel A confirmed that there was no record of room temperature and humidity.

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, staff interview, the laboratory failed to label complete blood controls (CBC) currently on use with the open and new expiration date. Findings include: -Review of the EIGHTCHECK-3WP X-TRA Hematology control for Sysmex analyzers product insert revealed that, controls are stable after opening 14 days if stored at 2-8 Centigrade (C) . -During the laboratory tour on 11/02/2021 at 1: 35 PM, the surveyor observed that the laboratory had the 3 CBC 2 ml control bottles stored in one container, the 3 controls did not have the open date and the new expiration date and the bottle with the red cap that is the one for low abnormal, had no label at all. During an interview on 11/02/2021 at 2:30 PM, the Testing Personnel A, confirmed that controls in use were not label with the open date and new expiration date and that the low control had no label.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iv)

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)(4)(iv) Ensure that 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 interview with laboratory personnel, there was no documentation to indicate that the director ensured that corrective action was performed when Proficiency Testing (PT) results were unsatisfactory. The findings include: -Refer to D2128. During an interview on 11/02/2021 at 2:00 PM, with testing personnel A, she confirmed that there was no documentation that the laboratory director ensured a corrective action was performed for the PT failures of reference.