

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0705040	(X3) Date Survey Completed 10/22/2018
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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with testing personnel (TP) # A, the laboratory failed to follow manufacturer's instructions of performing quality control for waived tests. There was no documented record of quality control for the following waived tests: Urispec 11 Way (Urine Reagent Strips) (URS), Immuno /hCG detector for human chorionic gonadotropin (hCG) in urine, Immuno/Strep A Detector for Streptococcus (Strep) A antigen for throat swabs, Alere afinion HbA1c for measuring hemoglobin A1c in whole blood test from 2016 to 2018. Findings include: Record review from 2016 to 10/22/2018 showed that the laboratory was not following manufacturer instructions of performing quality control for the following waived tests: - URS test, manufacturer instructions stated that user should do confirmation of performance of reagent strips by testing known positive and negative specimen or controls whenever a new bottle is opened, with each new lot. -Urine hCG test, as per manufacturer instructions it is recommended that a positive and negative control tested to verify a proper test performance with each new shipment or lot is received. - Strep A it is recommended that a positive and negative control be run once per kit as per manufacturer instruction. -Alere HbA1c controls to be run with each new shipment, new lot, at least every 30 days, when training new users or unexpected results is obtained. During an interview on 10/22/2018 at 12:00 pm, the TP#A, confirmed that the laboratory was not documenting quality control on the waived tests listed above for the period of reference.</p>
D2127	HEMATOLOGY

CFR(s): 493.851(d)

Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

This STANDARD is not met as evidenced by:

Based on record review of AAB (American Association of Bioanalysts) Hematology proficiency testing (PT) results and interview with Testing Personnel # A (TPA), the laboratory failed to submit PT results in the specified timeframe for 2nd event of 2018 for the specialty of Hematology resulting in a score of 0% for all hematology analytes. Findings include: Review of AAB Hematology PT records revealed that the laboratory failed to submit the results for the second event of 2018 on time resulting in a score of 0 % score for Hematology, Cell Identification or White Blood Differential, Red Blood Cell, Hematocrit, Hemoglobin, White Blood Cells and Platelets. During an interview on 10/22/2018 at 11:30 AM, the TP#A confirmed that the laboratory failed to submit on time the results for the 2nd event of 2018.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on record review and interview with Testing Personnel # A (TPA), the laboratory failed to verify the accuracy of Urine Microscopic Analysis at least twice annually from 2016 through October 22 2018. Findings include: Review of laboratory's proficiency testing records from 2016 to 2018 showed that the laboratory was not enrolled in proficiency testing for this test and had not done verification of accuracy by other method for Urine Microscopic Analysis at least twice annually since 2016 to October 22 2018. During an interview with the TP#A on 10/22/2018 at 11:30 a.m., the TP#A confirmed that the laboratory was not enrolled in proficiency testing for the above analyte and had not verified the accuracy of the test by another method during the period of reference.

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 review of quality assurance policy and laboratory records from 2016 to 2018 and interview with Testing Personnel (TP) # A revealed that the laboratory failed to document the quality assurance (QA) activity during the years 2016, 2017 and 2018. Findings include: Review of quality control records revealed that there was no

documentation of the QA activity during the years 2016 to 2018. During an interview on 10/22/2018 at 12:00 PM, with the TP#A, she confirmed that there were no records of QA activity for the years of reference.

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 review of user manual for Hematology analyzer Drew 3 and Sysmex XP 300, and interview with testing personnel (TP) # A, the laboratory failed to document room temperature and humidity requirement to assure optimal operation of the analyzer during 2016, 2017 and up to 10/22/2018. Findings include: -Review of the Drew 3 manual indicates that the operation temperature range is 18 to 32 C and humidity below 80 %. This was the equipment used from 2016 to 2017. -Review of XP300 manual indicates that the operation temperature range is of 15 to 30 C and humidity 35 to 85 %. This equipment is operating since 2018. -There was no log available for documenting the temperature and humidity of the laboratory room during the years of reference. During an interview on 10/18/2018 at 11:30 a.m., the TP # A confirmed that there was no documentation of room and humidity control check for the years of reference.

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 review of quality assurance policy and laboratory records from 2016 to 2018 and interview with testing person (TP) # A revealed that the laboratory director failed to document the quality assurance (QA) activity during the years 2016, 2017 and 2018. Findings include: Review of quality control records revealed that there was no documentation of the QA activity during the years 2016 to 2018. During an interview on 10/22/2018 at 12:00 PM, with the TP#A, she confirmed that there were no records of QA activity for the years of reference. Refer to 5293