

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0966028	(X3) Date Survey Completed 10/23/2019
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 was conducted on October 23, 2019. Family Medical Centre clinical laboratory was found not in compliance with 42 CFR 493, requirements for clinical laboratories.
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to enroll in proficiency testing with an approved proficiency testing (PT) program for 2019 in the specialty of hematology. Findings: Review of PT record from American Association of Bioanalysts (AAB) showed that there was no proficiency testing performed in 2019. The laboratory performs testing on the following analytes: Erythrocytes Count (RBC), Hematocrit, Hemoglobin, Leukocyte Count (WBC), Platelet Count, and WBC Differential. During an interview on 10/23/19 at 9:56 AM, Testing Personnel A stated they were not enrolled in proficiency testing for 2019 and reinstated their enrollment about a week ago with AAB.</p>
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p>

The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to have all testing personnel rotate through the testing of proficiency testing (PT) samples for 2018 (1st, 2nd and 3rd event). Findings: Review of the American Association of Bioanalysts (AAB) PT computer generated attestation forms showed that Testing Personnel A performed all the PT for 2018 (1st, 2nd and 3rd event). Review of the CMS-209 form title "Laboratory Personnel Report (CLIA)" that was signed and dated by the Laboratory Director on 10/15/19 listed 5 testing personnel. Review of competency evaluations showed that 4 (A, B, C, E) out of 5 (A, B, C, D, E) testing personnel listed on the CMS-209 worked in the laboratory in 2018. During an interview on 10/23/19 at 10:01 AM, the Testing Personnel A stated that all of the proficiency testing for 2018 was performed by a Former Testing Personnel and that she failed to change the name of the Testing Personnel A to the name of the Former Testing Personnel in the computer.

D2009

TESTING OF PROFICIENCY TESTING SAMPLES
CFR(s): 493.801(b)(1)

The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory Testing Personnel and Laboratory Director failed to sign the attestation forms for proficiency testing (PT) for the 1st, 2nd and 3rd event in 2018 for the specialty of hematology. Review of the American Association of Bioanalysts (AAB) PT records showed that the laboratory failed to verify that PT samples were run in the same manner as patients by signing the attestation statement. Attestation statements for the 2018 hematology 1st, 2nd, and 3rd event were not signed by the Former Testing Personnel or the Laboratory Director. During an interview on 10/23/19 at 9:45 AM, the Testing Personnel A stated that all of the proficiency testing for 2018 was performed by the Former Testing Personnel, and that the Former Testing Personnel and the Laboratory Director had not signed the attestations.

D5200

GENERAL LABORATORY SYSTEMS
CFR(s): 493.1230

Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on record review and interview, the laboratory's quality assessment program failed to monitor and evaluate the overall quality of the general laboratory system and correct problems identified. Findings: Cross Reference D5209. Based on record review and interview, the laboratory failed to follow written policies and procedure to access testing personnel's competency. Cross Reference D5211. Based on record review and interview, the laboratory failed to document the review and evaluation of proficiency testing (PT) for the 3rd event in 2017, and the 1st, 2nd, and 3rd events in 2018 for the specialty of hematology.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory failed to follow written policies and procedures to access testing personnel's competency. Findings: The procedure titled "Quality Assurance Plan" states "Personnel are evaluated by the lab director semi-annually during the first year of employment and annually thereafter." 1. Review of the competency evaluations showed that documentation of initial training and evaluation for Testing Personnel D was not available for review. During an interview on 10/23/19 at 10:05 AM, the Testing Personnel D stated she started working the week of Thanksgiving in 2018. During an interview on 10/23/19 at 10:10 AM, the Testing Personnel A acknowledged that the initial training and evaluation was not done and that only one competency evaluation was performed on Testing Personnel A. 2. Review of the competency evaluation forms for 5 out of 5 (A, B, C, D, E) Testing Personnel showed that the competency evaluation were performed in 2018 and 2019 were signed by the Medical Assistant Supervisor. Review of the "State Operations Manual Appendix C - Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services" states a Technical Consultant can perform competency evaluations on testing personnel and that the Technical Consultant must have at least a Bachelor of Science degree. During an interview on 10/23/19 at 10:16 AM, the Testing Personnel A stated that Medical Assistant Supervisor performed the competency evaluations and that the Medical Assistant Supervisor did not have at least a Bachelor of Science degree.

D5211

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory failed to document the review and evaluation of proficiency testing (PT) for the 3rd event in 2017, and the 1st, 2nd, and 3rd events in 2018 for the specialty of hematology Findings: Review of the American Academy of Family Physicians (AAFP) PT showed that the laboratory director failed to sign proficiency testing evaluation forms for 3rd events in 2017. Review of the American Association of Bioanalysts (AAB) PT showed that the

	<p>laboratory director failed to sign proficiency testing evaluation forms for 1st, 2nd, and 3rd events in 2018. During an interview on 10/23/19 at 11:30 AM, the Manager acknowledged that the Laboratory Director did not sign the evaluation forms.</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 interview, the Laboratory Director failed to provide overall management and direction. Findings: Cross Reference D6015. Based on record review and interview, the Laboratory Director failed to ensure that the laboratory was enrolled in proficiency testing for 2019. Cross Reference D6016. Based on record review and interview, the Laboratory Director failed to ensure that proficiency testing was performed according to CLIA regulations. Cross Reference D6030. Based on record review and interview, the Laboratory Director failed to ensure the testing personnel were competent.</p>
<p>D6015</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)</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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure that the laboratory was enrolled in proficiency testing for 2019. Findings: Based on record review and interview, the laboratory failed to enroll in proficiency testing with an approved proficiency testing (PT) program for 2019 in the specialty of hematology. (See D2000).</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure that</p>

proficiency testing was performed according to CLIA regulations. Findings: Based on record review and interview, the laboratory failed to have all testing personnel rotate through the testing of proficiency testing (PT) samples for 2018 (1st, 2nd and 3rd event). (See D2007). Based on record review and interview, the laboratory Testing Personnel and Laboratory Director failed to sign the attestation forms for proficiency testing (PT) for the 1st, 2nd and 3rd event in 2018 for the specialty of hematology. (See D2009). Based on record review and interview, the laboratory failed to document the review and evaluation of proficiency testing (PT) for the 3rd event in 2017, and the 1st, 2nd, and 3rd events in 2018 for the specialty of hematology. (See D5211).

D6030

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:
Based on record review and interview, the Laboratory Director failed to ensure the testing personnel were competent. Findings: Based on record review and interview, the laboratory failed to follow written policies and procedure to assess testing personnel's competency. (See D5209).