

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1044372	(X3) Date Survey Completed 11/12/2019
Name of Provider or Supplier Family Medicine Group Pllc (The)	Street Address, City, State 2996 Kate Bond Road Suite #405, Bartlett, TN	
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <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</p> <p>This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), the laboratory's proficiency testing records, and interview with the laboratory director, the laboratory failed to rotate proficiency testing samples among personnel who perform patient testing for wet prep and complete blood count (CBC) in 2018 and 2019. The finding include: 1) Review of the form CMS-209 revealed three providers who perform wet prep microscopy and six personnel who perform CBCs. 2) Review of the laboratory proficiency testing records revealed the following: Provider number two performed four of five proficiency testing events for wet prep microscopy. CBCs proficiency testing was performed by testing personnel number two for events 2018 C, 2019 A, and 2019 C; and by testing personnel number four for event 2019 B. 3) Interview with the laboratory liaison on November 12, 2019 at 1:30 p.m. confirmed proficiency testing was not performed by all personnel who routinely perform patient testing in 2018 and 2019.</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
Based on review of the laboratory's proficiency testing records and interview with the laboratory liaison, the laboratory director and testing personnel failed to sign proficiency testing attestation statements in 2018 and 2019. The findings include: 1) Review of the laboratory's proficiency testing attestation statements revealed the following: The handwriting on the attestation statements for each event in 2018 and 2019 was the same for the lab director, provider who performed the microscopy, and the testing personnel for complete blood count (CBC). The name of the lab director that was written in on the attestation statements did not match the lab director signature on the Centers for Medicare and Medicaid (CMS) survey forms for four proficiency testing surveys (2018 event B, 2018 event C, 2019 event B, 2019 event C). No lab director signature was present for 2019 event A. No testing personnel signature for 2018 event B for CBC. 2) Interview with the laboratory liaison on November 12, 2019 at 1:30 p.m. confirmed the attestation statements did not include the actual signature of the laboratory director and testing personnel for five of five events in 2018 and 2019.

D2010

TESTING OF PROFICIENCY TESTING SAMPLES
CFR(s): 493.801(b)(2)

The laboratory must test samples the same number of times that it routinely tests patient samples.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's procedure manual, proficiency testing records, and interview with the laboratory liaison, the laboratory failed to test proficiency testing samples the same number of times it tests patient samples in 2019. The findings include: 1) Review of the laboratory's procedure manual revealed the laboratory is to repeat testing of patient complete blood count (CBC) if the result is flagged with an asterisk or an X, or if it is an alert value. 2) Review of the laboratory's proficiency testing records revealed repeat testing of proficiency testing samples that did not meet the laboratory's criteria for repeat testing of patient samples for 2019 event C, sample numbers 11 and 14. 3) Interview with the laboratory liaison on November 12, 2019 at 1:30 p.m. confirmed the laboratory failed to test proficiency testing samples in the same manner as patient samples for 2019 event C.

D2015

TESTING OF PROFICIENCY TESTING SAMPLES
CFR(s): 493.801(b)(5)(6)

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

	<p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and interview with the laboratory liaison, the laboratory failed to retain all proficiency testing records in 2019. The findings include: 1) Review of the laboratory's proficiency testing records revealed the following: No paper trail for provider responses to microscopy for 2019 event B. No identity of the person who performed the microscopy 2019 event A. 2) Interview with the laboratory liaison on November 12, 2019 at 1:30 p.m. confirmed the laboratory failed to retain all proficiency testing records in 2019.</p>
<p>D3031</p>	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records and interview with the laboratory liaison, the laboratory failed to retain quality control package insert for lot numbers 06880, 07880, 08880 in 2018. 1) Review of the laboratory's quality control records revealed lot numbers 06880, 07880, and 08880 in use on 12.21.2018. No package insert was present in the quality control records. 2) Interview with the laboratory liaison on November 12, 2019 at 1:30 p.m. confirmed the laboratory failed to retain quality control package inserts for two years in 2018.</p>
<p>D5805</p>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on review of patient test reports for complete blood count (CBC) and interview with the laboratory liaison, the final patient test reports did not include the laboratory address or units of measure for CBC. The findings include: 1) Review of patient numbers one, two, three, and four final report in the electronic medical record revealed no units of measure for any of the CBC parameters, and no facility address. 2) Interview with the laboratory liaison on November 12, 2019 at 1:30 p.m. confirmed the laboratory final patient test report did not include the facility address or units of measure for CBC parameters.</p>
<p>D6019</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)</p> <p>The laboratory director is responsible for the overall operation and administration of</p>

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 review of the laboratory's proficiency testing records, procedure manual, and interview with the laboratory liaison, the laboratory director failed to ensure corrective action was performed for unacceptable proficiency testing scores in 2019. 1) Review of the laboratory's proficiency testing records revealed the following: 2019 event B slide number CM-14 wet prep slide scored as 'Fail.'" No corrective action was performed. The report was signed by the lab director on 06.30.2019. 2) Review of the laboratory's procedure titled "QUALITY ASSURANCE PLAN" revealed that unacceptable proficiency testing scores will be evaluated to determine the cause of the failure. 3) Interview with the laboratory liaison on November 12, 2019 at 1:30 p.m. confirmed the laboratory director failed to ensure corrective action was performed for the unacceptable proficiency testing score for 2019 event B, slide CM-14.

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:

Citation number one Based on review of the laboratory quality assurance plan, quality assessment records, and interview with the laboratory liaison, the laboratory director failed to ensure the quality assessment plan was maintained in 2018 and 2019. The findings include: 1) Review of the laboratory quality assurance plan revealed that quality assessments would be performed monthly. 2) Review of the laboratory quality assessment records revealed no quality assessments documents were present for June through October 2018, January 2019, and March 2019 to October 2019. 3) Interview with the laboratory liaison on November 12, 2019 at 11:50 a.m. confirmed the laboratory director failed to ensure the quality assessment plan was maintained in 2018 and 2019. _____ Citation number two

Based on review of the laboratory's quality assurance plan, proficiency testing records, and interview with the laboratory liaison, the laboratory director failed to ensure proficiency testing records were reviewed in 2018. The findings include: 1) Review of the laboratory's quality assurance plan revealed that "We will evaluate the results of our proficiency testing with the laboratory director within one week of their return from the PT program." 2) Review of the laboratory's proficiency testing records revealed that no performance evaluation report was present for 2018 event B, and the performance evaluation report for 2018 event C had not been reviewed by the laboratory director. 3) Interview with the laboratory liaison on November 12, 2019 at 1:30 p.m. confirmed the laboratory director failed to ensure proficiency testing records were reviewed in 2018 for 2018 events B and C.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

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)(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 observation of the laboratory, review of the Center for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), testing personnel records and interview with the laboratory director, the laboratory director failed to ensure testing personnel number eight received training for performing patient testing for complete blood count (CBC) in 2018. The findings include: 1) Observation of the laboratory on November 12, 2019 at 8:15 a.m. revealed the Beckman Coulter AcT Diff 2 in use for patient testing for CBC. 2) Review of the form CMS-209 revealed the name of testing personnel number eight as a testing personnel for performing patient testing for CBC. 3) Review of testing personnel records revealed no documented training for testing personnel number eight for performing patient testing on the Beckman Coulter AcT Diff CBC instrument. 4) Interview with the laboratory director on November 12, 2019 at 1:30 p.m. confirmed that testing personnel number eight did not have documented training for performing patient testing for CBC on the Beckman Coulter AcT Diff 2 in 2018. Testing personnel number eight date of hire was in November 2018.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) Form CMS-209, testing personnel records, and interview with the laboratory liaison, the technical consultant failed to perform interim competency assessment for testing personnel number eight in 2019. The finding sinclude: 1) Review of the form CMS-209 revealed the following: The name of testing personnel number eight, new since the last survey date. The lab director functions as the technical consultant. 2) Review of testing personnel records revealed that no interim competency was performed for testing personnel number eight for the performance of complete blood count during the first year of patient testing. 3) Interview with the laboratory director on November 12, 2019 at 1:30 p.m. confirmed the technical consultant failed to perform interim competency assessment the first year of patient testing for testing personnel number eight.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), testing personnel records and interview with the laboratory liaison, the technical consultant failed to perform annual competency assessments for 7 of 7 testing personnel in 2018. The findings include: 1) Review of the CMS-209 form revealed 9 testing personnel who perform moderately complex testing. There were five established testing personnel who perform patient testing for complete blood count, two established providers who perform wet prep microscopy procedures. 2) Review of testing personnel records revealed the following: No annual competency assessments were performed in 2018 for 5 of 5 established personnel who perform complete blood counts. No annual competency assessments were performed in 2018 for 2 of 2 established personnel who perform provider microscopy. 3) Interview with the laboratory liaison on November 12, 2019 at 10:30 a.m. confirmed the technical consultant failed to perform competency assessments for 7 of 7 established testing personnel who perform moderately complex testing in 2018.