

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1044372	(X3) Date Survey Completed 05/22/2018
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
D6013	<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 characteristics of the method;</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the complete blood count (CBC) instrument records and interview with the laboratory director, the laboratory director failed to ensure the new CBC instrument verification of performance specifications were adequate for accuracy, precision and linearity, in 2017. The findings include: 1) Observation of the laboratory on May 22, 2018 at 9:15 a.m. revealed a new CBC instrument in use for patient testing, serial number BA43407. 2) Review of the CBC instrument records revealed installation of serial number BA43407 CBC instrument on December 8, 2017 and that no verification of performance specification records and no installation records were available. 3) Interview on May 22, 2018 at 11:30 a.m. with the laboratory director confirmed the new CBC instrument was installed December 8, 2017 and that the December 8, 2017 CBC instrument records were not available.</p>
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</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</p>

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 the monthly quality assurance (QA) records, the QA review and checklist procedure and interview with testing personnel number one, the laboratory director failed to ensure the monthly QA was maintained, in 2017 and 2018. The findings include: 1) Review of the 2017 monthly QA records revealed no monthly QA checklist performed for November, December 2017, and January 2018 to current date. 2) Review of the QA review and checklist procedure revealed, "The QA Checklist Form will be used to assess (1) Patient Test Management (2) Quality Control and Calibration Data and (3) Instrument Checks. This form should be completed monthly by reviewing 1-2 Patient Charts. 3) Interview on May 22, 2018 at 10:45 a.m. with testing personnel number one confirmed the November, December 2017, January, February, March and April 2018 QA checklist monthly reviews were not performed.