

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0710017	(X3) Date Survey Completed 01/05/2018
Name of Provider or Supplier Bmg Family Physicians Group Foundation, Inc	Street Address, City, State 8110 Cordova Road Suite 111, Cordova, 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 American Academy of Family Physicians (AAFP) proficiency testing attestation statements, the Centers for Medicare and Medicaid (CMS) Laboratory Personnel Report (CMS form 209) and interview with the laboratory liaison the laboratory failed to perform proficiency testing by personnel who routinely perform patient testing in 2016 and 2017. The findings include: 1. Review of the 2016-A, 2016-B, 2016-C, 2017-A, and 2017-B AAFP proficiency testing attestation statements revealed that proficiency testing for all events was performed by testing personnel number one. 2. Review of the CMS form 209 revealed eleven personnel who perform patient testing. 3. Interview with the laboratory liaison on January 5, 2018 at 11:00 am confirmed that other personnel perform patient testing and the laboratory failed to perform proficiency testing by the same personnel who routinely perform patient testing in 2016 and 2017.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for</p>

the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of validation data for the Sysmex XS-1000i complete blood count (CBC) instrument and interview with the laboratory liaison, the laboratory failed to verify the manufacturer's normal range in 2016. The findings include: 1. Review of the validation data performed on 5-25-2016 for two Sysmex XS-1000i instruments (serial #s 74907 and 74908) revealed no normal range study. 2. Interview with the laboratory liaison on January 5, 2018 at 1:15 pm confirmed the laboratory uses the Sysmex XS-1000i instruments for patient CBC testing, uses the manufacturer's normal values, and failed to verify the manufacturer's normal values in 2017.

D5775

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of laboratory records and interview with the laboratory liaison the laboratory failed to compare results between two complete blood count (CBC) instruments twice a year in 2016 and 2017. The findings include: 1. Observation of the laboratory on January 5, 2018 at 9:00 am revealed two Sysmex XS 1000i instruments in use for patient testing, one in the main laboratory and one in the nurse's laboratory area. 2. Review of available laboratory records revealed no studies were present for twice a year comparison between the two Sysmex XS 1000i CBC instruments. 3. Interview with the laboratory liaison on January 5, 2018 at 1:30 pm confirmed the laboratory uses two different Sysmex XS 1000i instruments for patient testing and failed to compare results between the two instruments twice a year in 2016 and 2017.

D6051

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

Based on review of testing personnel competency assessment forms and interview with the laboratory liaison, the technical consultant failed to include blind testing as part of competency assessment for eleven of eleven employees in 2016 and 2017. The findings include: 1. Review of the 2016 and 2017 testing personnel competency assessment forms revealed blind testing was not used as part of competency assessment for eleven of eleven employees. 2. Interview with the laboratory liaison on January 5, 2018 at 12:30 confirmed the competency assessment of employees does not include blind testing.