Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0315216	08/09/2018
Name of Provider or Supplier	**Street Address, City, State**	
Bmg Family Physicians Group Foundation, Inc	400 Market Blvd, Suite 101, Collierville, 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	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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 review of the Centers for Medicare and Medicaid Services form 209 (CMS 209), the laboratory's proficiency testing attestation statements from 2017 and 2018 and interview with the laboratory coordinator, the laboratory failed to rotate proficiency testing among personnnel who routinely perform patient testing in 2017 and 2018. The findings include: 1. Review of the CMS form 209 revealed seven persons listed as testing personnel. 2. Review of the laboratory's proficiency testing attestation statements from 2017 and 2018 revealed the signatures of testing personnel (TP) number one and one previous testing person as follows: 2017 event 1-TP #1-microscopic, Other-CBC; 2017 event 2-TP #1-all, 2017 event 3-TP #1-micro, Other-CBC; 2018 event 1-TP #1-micro, Other-CBC; 2018 event 2-TP #1-all. 3. Interview with the laboratory coordinator on August 9, 2018 at 11:00 am confirmed seven personnel perform patient testing and did not participate in proficiency testing in 2017 and 2018.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and interview with the

	laboratory coordinator, the laboratory failed to retain all proficiency testing records for at least 2 years in 2016, 2017, and 2018. The findings include: 1. Review of the laboratory's proficiency testing records revealed the following: 2016 event two-no instrument printouts, no attestation statements; 2016 event three-no instrument printouts, no attestation statements, no data submission reports; 2017 event two-no data submission report; 2018 event one-no data submission report; 2018 event two-no data submission report. 2. Interview with the laboratory coordinator on August 9, 2018 at 11:00 am confirmed the laboratory failed to retain all proficiency testing records for at least 2 year in 2016, 2017, and 2018.
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 review of the laboratory's testing personnel assessment policy and interview with the laboratory coordinator, the laboratory's policy for competency assessment of testing personnel failed to include the six required elements for competency assessment. The findings include: 1. Review of the laboratory's testing personnel assessment policy revealed that none of the six required elements for competency assessment were included in the policy. The six required elements include: Direct observation of patient testing, including patient preparation, if applicable, specimen handling, processing and testing; Monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventive maintenance records; Direct observation of performance of instrument maintenance and function checks; assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and assessment of problem solving skills. Competency assessment is the responsibility of the technical consultant. 2. Interview with the laboratory coordinator on August 9, 2018 at 12:00 pm confirmed the laboratory 's policy for testing personnel competency assessment failed to include the six required elements for competency assessment.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing evaluation reports and interview with the laboratory coordinator, the laboratory failed to evaluate non-graded scores for complete blood count (CBC) for 2016 event three, and urine microscopy, and wet prep for 2017 event two. The findings include: 1. Review of the laboratory's 2016 event three proficiency testing evaluation report for CBC revealed the following

	for all CBC parameters: "Not Graded-Changed Instrument/Module/Method"; score of Pass, with no documented review or corrective action for the non-graded scores. 2. Review of the laboratory's 2017 event two proficiency testing performance evaluation reports for urine microscopy and wet prep revealed the following: sample numbers CM-12, CM-13, and CM-15 scored as "Not Graded-Lack of Referee Consensus" with no evaluation of results to determine laboratory's accuracy. 3. Interview with the laboratory coordinator on August 9, 2018 at 11:00 am confirmed the laboratory failed to evaluate the accuracy of CBC for 2016 event three and urine microscopy and wet prep for 2017 event two.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure for potassium hydroxide (KOH) and interview with the laboratory coordinator, the laboratory's procedure for KOH failed to include protocol for reporting patient results. The findings include: 1. Review of the laboratory's procedure for KOH revealed no protocol for reporting patient results. 2. Interview with the laboratory liaison on August 9, 2018 at 11:40 am confirmed the laboratory's procedure for KOH failed to include protocol for reporting patient results.