Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0710017	10/10/2019
Name of Provider or Supplier	**Street Address, City, State**	
Bmg Family Physicians Group Foundation, Inc	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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and interview with testing personnel number seven, the laboratory failed to test proficiency testing samples in the same manner as patient samples in 2018. The findings include: 1) Review of the laboratory's proficiency testing records for microscopy (wet prep, urine microscopy, Potassium Hydroxide (KOH) for 2018 event two revealed the following: Two sets of results for microscopy slide responses in different handwriting. 2) Interview with testing personnel number seven on October 10, 2019 at 1:00 p.m. confirmed the laboratory did not test proficiency testing samples the same as patient samples. The laboratory does not have patient tests for microscopy read by two people. Testing personnel number seven stated that the previous testing personnel had incorrect responses recorded. She stated that when she was sending the results to the PT program she read the slides and corrected them because she knew they were wrong.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)

	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. This STANDARD is not met as evidenced by: Based on review of patient number one test report, the laboratory's complete blood count (CBC) quality control (QC) records and maintenance records, and interview with the laboratory liaison, the laboratory failed to retain CBC quality control limits and background counts in 2018. The findings include: 1) Review of patient number one CBC test report revealed patient testing for CBC on 04.06.2018. 2) Review of the laboratory's QC and maintenance records for CBC for April 2018 revealed the following: QC lot number 8016 in use during April 2018 - no retention of the QC limits in use at the time of patient testing. No retention of the background count for date of patient testing. 3) Interview with the laboratory liaison on October 10, 2019 at 1:00 p.m. confirmed the laboratory failed to retain CBC QC limits for lot 8016 and instrument background count in 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 procedure manual, employee personnel records for 2018 and 2019 and interview with the laboratory liaison, the laboratory failed to have a procedure to include all six criteria for assessing personnel competency. The findings include: 1) Review of the laboratory procedure manual revealed the following six criteria were not included in the procedure and competency documentation: direct observation of routine patient test performance; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and assessment of problem solving skills. 2) Review of the 2018 and 2019 employee personnel records revealed the use of training documents for documenting competency. The training documents did not specify the methods used for assessment of competency. The training documents did not include all six criteria required for competency assessment. 3) Interview on October 10, 2019 at 1:00 p.m. with the laboratory liaison confirmed the testing personnel competency procedure /documentation did not include the six criteria for testing personnel competency assessment required by the Centers for Medicare and Medicaid Services (CMS).
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(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 and interview with the laboratory liaison, the laboratory director failed to ensure corrective action was performed for unacceptable proficiency testing scores in 2018. The findings include: 1) Review of the laboratory's proficiency testing records revealed the following: Performance evaluation report for 2018 event one for wet prep revealed a score of "Fail" for slide number CM-6. No corrective action was performed for the missed cell identification. Report was signed by both the laboratory liaison and laboratory director. 2) Interview with the laboratory liaison on October 10, 2019 at 1:00 p.m. confirmed the laboratory director failed to ensure corrective action was performed for unacceptable proficiency testing score for wet prep in 2018.
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 review of patient number eleven test report for complete blood count (CBC), testing personnel records, patient number eleven test report, and interview with the laboratory liaison, the laboratory director failed to ensure testing personnel number six had documented training prior to performing patient testing in 2019. The finding include: 1) Review of patient number test report revealed CBC reported by testing personnel number six on 09.17.19 2) Review of personnel records for testing personnel number six revealed no training documents were present for performing patient testing for CBC. 3) Interview with the laboratory liaison on October 10, 2019 at 1:00 p.m. confirmed testing personnel number six performs patient testing for CBC and no training records were present. The date of hire for testing personnel number six was 08.26.2019.
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on review of patient number three complete blood count (CBC) final report, the

	manufacturer's linearity range for the hematocrit analyte, and interview with the laboratory liaison, testing personnel number five failed to follow the laboratory procedure for reporting of patient test results. The findings include: 1) Review of patient number three final CBC test report revealed a reported hematocrit value of 64%. 2) Review of the Sysmex XS 1000i CBC instrument manufacturer operator's manual revealed a linearity range of 0.0 - 60% for the hematocrit analyte. 3) Interview with the laboratory liaison on October 10, 2019 at 1:15 p.m. confirmed the laboratory uses the manufacturer's linearity range for their reportable range. Testing personnel number five failed to ensure patient results were not reported outside the reportable range of the instrument.