Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0315216	10/25/2021
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory liaison, the laboratory director failed to sign proficiency testing attestation statements for five of eight proficiency testing events in 2019, 2020, and 2021. The findings include: 1. Review of the laboratory's proficiency testing attestation statements revealed the laboratory director did not sign proficiency testing attestation statements for five of eight proficiency testing events. Events not signed include 2019 events one, two, and three, 2020 event one, and 2021 event two. 2. Interview with the laboratory liaison on October 25, 2021 at 4 pm confirmed the laboratory director did not sign five of eight proficiency testing attestation statements in 2019, 2020, and 2021.
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 procedure manual, laboratory records and interview with the laboratory liaison, the laboratory failed to test proficiency testing samples the same number of times it would a patient sample for one of eight proficiency testing events in 2019. The findings include: 1. Review of the laboratory procedure titled

	"Alert Value Procedure" revealed that repeat Complete Blood Count (CBC) patient testing is performed based on defined alert criteria. 2. Review of laboratory proficiency testing records for 2019 event one revealed repeat testing of proficiency testing samples that did not meet the laboratory's criteria for an alert value. 3. Interview with the laboratory liaison on October 25, 2021 at 4 pm confirmed the laboratory tested proficiency testing samples more times than it would a patient with the same values for 2019 event one (two of five samples); one of eight survey events reviewed.
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 laboratory records and interview with the laboratory liaison, the laboratory failed to retain Complete Blood Count (CBC) quality control (QC) records in 2021 (one of nine lots reviewed). 1. Review of QC records for the Sysmex XS-1000i CBC instrument revealed no retention of Level 2 quality control data for Lot 03500805 to include daily QC performance as compared with expected ranges or daily quality control graphed on the Levy-Jennings plot. The lot was in use through 03 /05/2021. 2. Interview with the laboratory liaison on 10/25/21 at approximately 4 pm confirmed the laboratory failed to ensure retention of QC records for at least two years in 2021.
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, testing personnel records, and interview with the laboratory liaison, the laboratory failed to follow the competency assessment policy for three of six testing personnel in 2019 and 2020. The findings include: 1. Review of the laboratory's competency assessment policy revealed that competency would be performed to include all six required elements as defined in Subpart M of the Clinical Laboratory Improvement Amendments (CLIA) regulations. 2. Review of testing personnel competency assessments revealed that all six elements were not included for testing personnel numbers one, two and five in 2019 and 2020 (three of six testing personnel, six of thirteen competencies). 3. Interview with the laboratory liaison on 10/25/21 at approximately 4 pm confirmed the laboratory failed to follow the personnel competency assessment policy in 2019 and 2020.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other

	supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. 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 label controls with open date and corrected expiration date in 2021. The findings include: 1. Observation of the laboratory on 10/25/21 at approximately 9:45 am revealed quality control (QC) material for the Sysmex Complete Blood Count (CBC) instrument that were in use and not labeled with open date and corrected expiration date. 2. Review of the manufacturer QC package insert revealed that controls are stable for 14 days after opening. 3. Interview with the laboratory liaison on 10/25/21 at approximately 4 pm confirmed the laboratory failed to label controls with open date and corrected expiration date in 2021.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the laboratory records and interview with the laboratory liaison, the laboratory director failed to review eight of eight proficiency testing reports in 2019, 2020, and 2021. The findings include: 1. Review of the laboratory's proficiency testing records revealed the laboratory director had not reviewed eight of eight proficiency testing performance evaluation reports in 2019, 2020 and 2021. The events that were not reviewed include 2019 events one, two, and three; 2020 events one, two and three; 2021 events one and two. 2. Interview with the laboratory liaison on October 25, 2021 at 4:00 pm confirmed the laboratory director failed to review and evaluate proficiency testing results for eight of eight events in 2019, 2020, and 2021.