Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0710014	07/07/2022
Name of Provider or Supplier	**Street Address, City, State**	
Bmg Family Physicians Group Foundation, Inc	7685 Winchester Rd, Suite 100, Memphis, 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 the laboratory's proficiency testing (PT) records and interview with the laboratory liaison, the laboratory director and testing personnel failed to sign five of six PT attestation statements in 2020, 2021, and 2022. The finding include: 1. Review of the laboratory's proficiency testing records revealed the following: Events not signed by testing personnel = 2020 Event B, 2021 Event B, 2021 Event C Events not signed by lab director = 2021 Event A, 2021 Event B, 2021 Event C, 2022 Event A 2. Interview with laboratory liaison on 07.07.2022 at 3:30 pm confirmed that four of six PT events were not signed by the lab director and three of six PT events were not signed by testing personnel. Five of six PT events reviewed for 2020, 2021 and 2022 were not signed by either the testing personnel and/or the laboratory director.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: The laboratory failed to have a written procedure for use of the Sysmex XS-1000i complete blood count instrument (Refer to D5401), failed to perform twice a year

	comparison between its' two complete blood instruments (Refer to D5775), failed to follow its' own quality assessment process/procedures (Refer to D5791) and failed to have an effective quality assessment process in place to prevent problems associated with quality control review and failure to perform twice a year comparisons between complete blood count instruments (Refer to D5793).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on observation of the laboratory, document request, and interview with the laboratory liaison, the laboratory failed to have a written and approved procedure for use of the Sysmex XS-1000i Complete Blood Count (CBC) instrument. The findings include: 1. Observation of the laboratory on 07.07.2022 at 8:30 am revealed two Sysmex XS-1000i CBC instruments in use for patient testing. 2. Document request made on 07.07.2022 at 11:30 am to the laboratory liaison revealed no written and approved procedure for use of the Sysmex XS-1000i was available. 3. Interview with the laboratory liaison on 07.07.2022 at 12:00 pm confirmed no written procedure manual for use of the Sysmex XS-1000i CBC instrument was available.
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 of complete blood count (CBC) results between their two Sysmex XS-1000i CBC instruments in 2020, 2021, and 2022. The findings include: 1. Observation of the laboratory on 07.07.2022 at 8:30 am revealed two Sysmex XS-1000i CBC instruments in use for patient testing (serial number 74901 in the main lab and serial number 74900 in the nurse triage area). 2. Review of laboratory records revealed no twice a year comparison between the instruments in 2020, 2021, and 2022. 3. Interview with the laboratory liaison on 07.07.2022 at 11:55 am confirmed the laboratory failed to compare results between CBC instruments twice a year in 2020, 2021, and 2022.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems

	identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure manual, review of complete blood count (CBC) quality control (QC) records, and interview with the laboratory liaison, the laboratory failed to follow the quality assessment process/procedure in 2020, 2021 and 2022 (12 of 39 lots reviewed for the laboratory instrument and 27 of 39 lots reviewed for the nurse triage instrument.) The findings include: 1. Observation of the laboratory on 07.07.2022 at 8:30 am revealed two Sysmex XS-1000i instruments in use for performing patient testing for CBC (Instrument serial #74901 in the lab area and instrument serial #74900 in the nurse triage area). 2. Review of the laboratory procedure titled "Quality Control" revealed that new QC lot targets are validated over 10 runs and must be reviewed and approved for acceptability by the lab director before use. The policy also states the lab director will review the entire QC packet for each lot to include the package insert for controls, range verification, raw data and levey jennings printouts as well as the peer review report from Sysmex. 3. Review of the laboratory's CBC quality control records revealed the following: Instrument serial number 74901 (Lab Instrument) Note: Level 1 (0804), Level 2 (0805), and Level 3 (0806) per parent lot Lot 0182-No records for validating QC targets, no cumulative data, no review of quality control. In use from 07.20.2020 to 09.18.2020 Lot 0238-No records for validating QC targets. In use on 09.03.2020 Lot 1208-No cumulative data printed, no review of QC data. In use from 08.23.2021 to 10.15.2021 Lot 1264-No records for validating QC targets, no cumulative data, no review of QC data. In use from 10.18.2021 to 12.10.2021. Lot 1320--No cumulative data, no review of QC data. In use from 12.13.2021 to 02.02.2022 Lot 2011--No review of QC data. In use from 01.26.2022 to 04.01.2022 Lot 2067--No review of QC data. In use from 03.23.2022 to 05.27.2022 Instrument serial number 74900 (Nurse Triage Area) Note: Level 1 (0804), Level 2 (0805), and Level 3 (0806) per parent lot Lot 0182--No record of target validation, no cumulative data, no review of QC. In use from 07.20.2020 to 09.18.2020 Lot 0238--No record of target validation. In use on 09.03.2020. Lot 0294--No review of QC data. In use from 11.06.2021 to 01.08.2021. Lot 0350--No cumulative QC data, No review of QC. In use from 12.30.2021 to 03.05.2021. Lot 1040--No cumulative QC data, no review of QC. In use from 03.02.2021 to 04.30.2021. Lot 1208-No cumulative QC data, no review of QC. In use from 08.23.2021 to 10.15.2021. Lot 1264--No cumulative QC data, no review of QC. In use from 10.18.2021 to 12.10.2021 Lot 1320--No cumulative QC data, no review of QC. In use from 12.13.2021 to 02.02.2022 Lot 2011--No lot validation records, no cumulative QC data, No review of QC. In use from 01.26.2022 to 04.01.2022 Lot 2067---No lot validation records, no review of QC. In use from 03.23.2022 to 05.27.2022. 4. Interview with the laboratory liaison on 07.07.2022 at 3:30 pm confirmed the laboratory failed to follow the quality assessment process/procedure for review of CBC QC target limits and QC cumulative data in 2020, 2021 and 2022 for 12 of 39 lots for the laboratory instrument and 27 of 39 lots for the nurse triage instrument.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems

	quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of laboratory complete blood count (CBC) quality control (QC) records, instrument to instrument comparison records, laboratory corrective action documentation, and interview with the laboratory liaison, the laboratory's quality assessment program was ineffective in preventing problems related to quality control/quality assessment activities in 2020, 2021, and 2022, and instrument to instrument comparisons. The findings include: 1. Observation of the laboratory on 07.07.2022 at 8:30 am revealed two Sysmex XS-1000i instruments in use for performing patient testing for CBC (Instrument serial #74901 in the lab area and instrument serial #74900 in the nurse triage area). 2. Review of the laboratory's QC records revealed no evidence of QC lot validation and/or QC review for 12 of 39 lots of CBC QC for the laboratory instrument and 27 of 39 lots for the nurse triage instrument. (Refer to D5791) 3. Review of laboratory records for comparison between the two Sysmex CBC instrument revealed evaluations/comparisons had not been completed twice a year in 2020, 2021, and 2022. (Refer to D5775) 4. Review of laboratory records revealed no evidence that corrective action was performed for the lack of documentation of QC lot validation, QC review, and instrument to instrument comparisons. 5. Interview with the laboratory liaison on 07.07.2022 at 3:30 pm confirmed the laboratory's quality assessment program was not effective in preventing problems related to the laboratory not following its' own procedure for CBC QC lot validation, CBC QC review, and instrument to instrument comparisons in 2020, 2021, and 2022.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(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 observation of the laboratory, review of the laboratory procedure manual, review of complete blood count (CBC) quality control (QC) records, and interview with the laboratory liaison, the laboratory director failed to ensure the laboratory's quality assessment process/procedure was maintained in 2020, 2021 and 2022 (12 of 39 lots reviewed for the laboratory instrument and 27 of 39 lots reviewed for the nurse triage instrument). Refer to D5791. The findings include: 1. Observation of the laboratory on 07.07.2022 at 8:30 am revealed the Sysmex XS-1000i in use for performing patient testing for CBC (Instrument serial #74901 in the lab area and instrument serial #74900 in the nurse triage area). 2. Review of the laboratory procedure titled "Quality Control" revealed that new QC lot targets are validated over 10 runs and must be reviewed and approved by the lab director before use. The policy also states the lab director will review the entire QC packet for each lot to include the package insert for controls, range verification, raw data and levey jennings printouts as well as the peer review report from Sysmex. 3. Review of the laboratory's CBC

	quality control records no documentation that this procedure was followed for 12 of 39 lots for the laboratory instrument and 27 of 39 lots for the nurse triage instrument. These lots were in use in 2020, 2021, and 2022. Refer to D5791. 4. Interview with the laboratory liaison on 07.07.2022 at 3:30 pm confirmed the lab director failed to ensure the laboratory's quality assessment program was maintained in 2020, 2021, and 2022.
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 review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) Form CMS-209, testing personnel records, interview with the laboratory liaison, and review of an email communication, the laboratory director failed to ensure three of seven new testing personnel (TP) had documentation of training and demonstration of accuracy, and one of seven new testing personnel failed to have documentation of highest level of education prior to performing patient testing for Complete Blood Count (CBC). The findings include: 1. Review of the Form CMS-209 revealed testing personnel numbers two, three and four listed as performing moderately complex patient testing. 2. Review of testing personnel records revealed the following: One of seven new testing personnel (testing personnel number four) did not have any records available to show the highest level of education. One of seven new testing personnel (testing personnel number four) did not have any records available on the date of the survey for training/competency. Review of the form titled Training/Competency Assessment revealed two of seven new testing personnel training and competency documentation had not been reviewed or approved by the lab director (testing persons number two and three). There was no evidence the laboratory director had participated in the training or competency assessment. 3. Interview with the laboratory liaison on 07.07.2022 at 10:30 am confirmed the laboratory director failed to ensure three of seven testing personnel had demonstrated accuracy for performance of CBCs; one of seven new testing personnel did not have evidence of the highest level of education. She further confirmed all three perform patient testing for CBC. 4. Review of an email communication received on 07.11.2022 revealed that TP #2 had performed twenty-three CBCs, TP #3 had performed thirteen CBCs, and TP#4 had performed eight CBCs.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all

	personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on observation of the laboratory, document request, and interview with the laboratory liaison, the laboratory director failed to ensure an approved procedure was available for the Sysmex XS-1000i complete blood count (CBC) instrument. The findings include: 1. Observation of the laboratory on 07.07.2022 at 8:30 am revealed two Sysmex XS-1000i CBC instruments in use for patient testing. 2. Document request made on 07.07.2022 at 11:30 am to the laboratory liaison revealed no written and approved procedure for use of the Sysmex XS-1000i was available.(Refer to D5401) 3. Interview with the laboratory liaison on 07.07.2022 at 12:00 pm confirmed no written procedure manual for use of the Sysmex XS-1000i CBC instrument was available. The laboratory director failed to ensure an approved procedure for the use of the Sysmex XS-1000i CBC instrument was available to testing personnel.