

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0315216	(X3) Date Survey Completed 07/21/2026
Name of Provider or Supplier Bmg Family Physicians Group Foundation, Inc	Street Address, City, State 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
D0000	During a recertification survey performed on July 21,2026, the laboratory was found out of compliance with the following conditions: D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; D6033 - 42 C.F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant;
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: A. Based on laboratory observation, a review of patient test records, testing personnel records, the laboratory's testing personnel policy, a staff interview, and electronic mail (email) communication, the laboratory's policy for testing personnel competency assessment was not in compliance with the requirements in Subpart M of the Clinical Laboratory Improvement Amendments (CLIA), as it did not require reassessment of competency when test methodology changed, resulting in 7 of 7 testing personnel without reassessment of competency for use of the new Sysmex XN-430 Complete Blood Count with Automated White Blood Cell Differential (CBC w/Diff) instrument, with approximately 540 patient reported since testing began on 06/16/26. The findings include: 1. Laboratory observation on 07/21/26 at 9:00 a.m. revealed the Sysmex XN-430 (serial number 22381) used to perform CBC w/Diff patient testing. The instrument was new since the last survey date. 2. A review of patient test records revealed that patient testing for CBC w/Diff on the new instrument model began on 06 /16/26, with patient medical record number 10159175. 3. A review of testing personnel records revealed that competency had not been reassessed for seven of seven testing personnel when the laboratory changed to the new CBC w/Diff

instrument model. 4. A review of the laboratory's testing personnel policy revealed that the policy did not require reassessment of competency when test methodology changes occurred. 5. The laboratory liaison confirmed the survey findings during an interview on 07/21/26 at 9:30 a.m. 6. A review of email communication received from the laboratory liaison on 07/28/26 at 3:05 p.m. revealed that approximately 540 patient CBCs w/Diff had been performed on the new instrument since patient testing began on 06/16/26. B. Based on a review of the laboratory procedure manual, a review of testing personnel (TP) competency assessment records, and staff interview, the laboratory failed to follow the policy for including all six competency assessment elements for 8 of 9 competency assessments reviewed from 2025 and 2026. The findings include: 1. A review of the laboratory's policy titled "PERSONNEL ASSESSMENT POLICY" revealed the following statement: "The following 6 procedures are required for assessment of competency for all testing personnel:" The policy listed the six elements required in Subpart M. 2. A review of testing personnel competency assessment documentation revealed the following: TP 2 did not have a documented review of worksheets, logs, quality control records, and maintenance records for the annual competency assessment completed on 09/18/25. TP 3 did not have a documented review of worksheets, logs, quality control records, and maintenance records for the annual competency assessment completed on 09/17/25. TP 4 did not have a documented review of worksheets, logs, quality control records, and maintenance records for the annual competency assessment completed in 2025. The competency assessment was not reviewed or signed by the laboratory director. The exact date the competency was completed was not recorded. TP 5 did not have a documented review of worksheets, logs, quality control records, and maintenance records for the annual competencies completed on 04/21/25 and on 04/08/26. TP 6 did not have a documented review of worksheets, logs, quality control records, and maintenance records for the six-month competency assessment completed on 03/03/26. TP 7 did not have a documented review of worksheets, logs, quality control records, and maintenance records, nor was there an assessment of test performance using blind samples, for the six-month competency assessment completed on 08/26/25 or the annual competency completed on 03/03/26. 3. The laboratory liaison confirmed the survey findings during an interview on 07/21/26 at 10:15 a.m.

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

(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 a review of the laboratory procedure manual, patient CBC w/Diff records, and a staff interview, the laboratory failed to follow the procedure for resolving CBC w/Diff results flagged by the instrument for four of six patients with flagged CBC w/Diff results in 2025 and 2026. The findings include: 1. A review of the laboratory procedure for the previous CBC w/Diff instrument (Sysmex XS-1000i) revealed the following: For the PLT Clumps Message: All capillary samples are to be checked for clots before they are run. Redraw specimen and repeat testing. For the WBC Abnormal Scattergram-"Confirm result by repeat testing. Recollect if Flags remain. Do not accept (verify) result." "Send to reference lab after notifying provider of results." For the Blasts flag: "Confirm result by repeat testing. Recollect if Flags

	remain. Do not accept (verify) result." "Send to reference lab after notifying provider of results." For the Immature granulocyte flag: "Verify result by repeat testing. Take result to provider for matching result to patient presentation. Follow provider instructions." 2. A review of patient CBC w/Diff test records from randomly selected dates revealed the following: On 03/07/25- Patient 12280919, the instrument printout showed a message of PLT Clumps?. The results were reported without any evidence of repeat analysis. Patient 10816748-the instrument printout showed a message of Blasts?. The results were reported without any evidence of repeat analysis. Patient 10745341-the instrument printout showed a message of WBC Abn Scattergram. The results were reported without any evidence of repeat analysis. On 10/08/25- Patient 12328078- the instrument printout showed a message of "Immature Gran?" The results were reported without any evidence of repeat analysis. 3. The laboratory liaison confirmed the survey findings during an interview on 07/21/26 at 1:00 p.m.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on laboratory observation, lack of documentation, a review of patient test records, a staff interview, and review of an electronic mail (email) communication, the laboratory failed to verify the patient normal / reference ranges used by the laboratory for Complete Blood Count with Automated White Blood Cell Differential (CBC w/Diff) testing using the Sysmex XN-430 instrument, with approximately 540 patients reported since testing began on 06/16/26. 1. Laboratory observation on 07/21/26 at 9:00 a.m. revealed that the Sysmex XN-430 (serial number 22381) was used to perform CBC w/Diff patient testing. The instrument was new since the last survey date. 2. A review of the instrument validation records revealed no documentation that a normal / reference range study had been performed to verify the ranges used by the laboratory. 3. A review of patient test records revealed that patient testing for CBC w/Diff began on 06/16/26 on the new instrument, with patient medical record number 10159175. 4. During an interview on 07/21/26 at 9:30 a.m., the laboratory liaison stated that the laboratory used corporate normal / reference ranges (separate for males and females) and had not conducted a study to verify those ranges on the new instrument. This confirmed the survey findings. 5. A review of email communication received from the laboratory liaison on 07/28/26 at 3:05 p.m. revealed that approximately 540 patient CBCs w/Diff had been performed since patient testing began on 06/16/26.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number

of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.

This STANDARD is not met as evidenced by:

Based on laboratory observation, a review of the laboratory's procedure for the Sysmex XN-430 instrument, quality control (QC) records, and a staff interview, the laboratory failed to ensure the manufacturer's QC package insert ranges were maintained in the instrument QC files for three of three lots reviewed since patient testing began. The findings include: 1. Laboratory observation on 07/21/26 at 9:00 a. m. revealed the Sysmex XN-430 (serial number 22381) used to perform CBC w/Diff patient testing. 2. A review of the laboratory's quality control procedure revealed that "As soon as the new QC lot is received, the new lot is analyzed in conjunction with the current QC. The BeyondCare quality Monitor program establishes the target and limit values for the new QC lot as soon as the first vial of each level gets analyzed." 3. A review of the laboratory's QC records for master lot 6122 (printed on 07/15/26) revealed the following: Lot numbers 61221401, 61221402, and 61221403 validation performed beginning 05/06/26; documented patient testing with the lots beginning 06/16/26. The QC data printed from the instrument showed QC ranges that differed from those on the manufacturer's package insert for all three levels, as follows for randomly selected analytes: 61221401 (Level One): RBC ($10^6/\mu\text{L}$) Package insert = 2.17 - 2.40 Laboratory range = 2.14 - 2.40 HCT % Package insert = 15.3 - 17.6 Laboratory range = 15.4 - 17.8 MCV (fL) Package insert = 67.7 - 76.4 Laboratory range = 69.4 - 76.8 Platelet ($10^3/\mu\text{L}$) Package insert = 36 - 86 Laboratory range = 34 - 84 WBC ($10^3/\mu\text{L}$) Package insert = 2.07 - 2.80 Laboratory range = 2.16 - 2.72 61221402 (Level Two) RBC ($10^6/\mu\text{L}$) Package insert = 4.13 - 4.47 Laboratory range = 4.08 - 4.50 HGB g/dL Package insert = 11.3 - 12.3 Laboratory range = 11.1 - 12.1 HCT % Package insert = 31.2 - 35.2 Laboratory range = 31.3 - 35.7 MCV (fL) Package insert = 72.6 - 81.8 Laboratory range = 74.5 - 81.9 Platelet ($10^3/\mu\text{L}$) Package insert = 182 - 256 Laboratory range = 173 - 251 WBC ($10^3/\mu\text{L}$) Package insert = 6.12 - 7.49 Laboratory range = 6.24 - 7.40 61221403 (Level Three) RBC ($10^6/\mu\text{L}$) Package insert = 5.05 - 5.48 Laboratory range = 5.00 - 5.52 HGB g/dL Package insert = 15.4 - 16.7 Laboratory range = 15.3 - 16.5 HCT % Package insert = 41 - 46.2 Laboratory range = 41.6 - 47.0 MCV (fL) Package insert = 77.8 - 87.8 Laboratory range = 80.3 - 87.9 Platelet ($10^3/\mu\text{L}$) Package insert = 463 - 590 Laboratory range = 452 - 574 WBC ($10^3/\mu\text{L}$) Package insert = 14.95 - 17.91 Laboratory range = 15.1 - 17.51 Word Key: HCT=Hematocrit HGB=Hemoglobin MCV=Mean Corpuscular Volume PLT=Platelet Count RBC=Red Blood Cell WBC=White Blood Cell $10^3/\mu\text{L}$ =thousand/microliter $10^6/\mu\text{L}$ =million/microliter g/dL=grams/deciliter %=percent fL=femtoliters 4. The laboratory liaison stated during an interview on 07/21/26 at approximately 1 p.m. that the ranges in the instrument are updated and changed automatically using data from the Sysmex Beyond Care System and are not controlled by the laboratory. This confirmed the survey findings.

D5803

TEST REPORT
CFR(s): 493.1291(b)

(b) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.

	This STANDARD is not met as evidenced by: Based on laboratory observation, a review of final patient test reports, a lack of documentation, a staff interview, and review of an electronic mail (email) communication, the laboratory failed to ensure the final patient test results in the electronic medical record for Immature Granulocyte % did not flag as increased when the value was within the laboratory's normal range. The laboratory began reporting the parameter on 06/16/26, with approximately 540 CBC patient tests reported since testing began. The findings include: 1. Laboratory observation on 07/21/26 at 9:00 a. m. revealed the Sysmex XN-430 (serial number 22381) used to perform CBC w/Diff patient testing. 2. A review of final patient test reports in the electronic medical record revealed the following: Patient medical record number 10159175, performed on 06/16/26 (first patient on instrument): Immature Granulocyte percent result of 0.1 was flagged as increased; the normal range was 0.0-1.0%. Patient medical record number 12330861, performed on 07/21/26 (most recent patient): Immature Granulocyte percent result of 0.3 was flagged as increased; the normal range was 0.0-1.0%. 3. There was no documentation that the laboratory had validated the electronic medical record results prior to patient testing that began on 06/16/26 with patient 10159175. 4. The laboratory liaison confirmed the survey findings during an interview on 07/21/26 at 1 p.m. 5. A review of email communication received from the laboratory liaison on 07/28/26 at 3:05 p.m. revealed that approximately 540 CBC patient tests had been performed since testing began on 06/16/26. Word Key: %=Percent
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on laboratory observation, a review of the Sysmex XN-430 CBC w/Diff validation records, a review of patient CBC w/Diff test records, a review of an electronic mail communication, lack of documentation, a review of the laboratory's testing personnel competency assessment policy, a review of testing personnel records, a review of current and previous CBC w/Diff procedures, review of QC records, and staff interviews, the laboratory director failed to perform onsite laboratory visits (Refer to D6005), failed to review and approve instrument validation records (Refer to D6013), failed to ensure testing personnel were performing patient testing according to established procedures (Refer to D6014), failed to review calibration records (Refer to D6023 A), failed to ensure QC acceptable ranges were maintained (Refer to D6023 B), failed to ensure competency assessments were conducted according to established policies and procedures and failed to ensure the current policy was in compliance with the regulations in Subpart M (Refer to D6030).
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the

	laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities. This STANDARD is not met as evidenced by: Based on laboratory observations, lack of documentation, and staff interviews, the laboratory director failed to conduct on-site laboratory visits at least every six months with four months between the minimum two on-site visits in 2025 and 2026. The findings include: 1. Laboratory observation on 07/21/26 at 9:00 a.m. revealed that the Sysmex XN-430 (serial number 22381) was used to perform CBC w/Diff. 2. On the survey date, there was no documentation showing that the laboratory director had conducted on-site laboratory visits in 2025 or 2026. 3. The laboratory liaison confirmed the survey findings during an interview on 07/21/26 at 11:25 a.m.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on laboratory observation, a review of the Sysmex XN-430 Complete Blood Count with Automated White Blood Cell Differential (CBC w/Diff) validation records, a review of patient test records, a staff interview, and a review of an electronic mail communication, the laboratory director failed to review and approve instrument validation studies for the Sysmex XN-430, with approximately 540 patients reported since testing began on 06/16/26. The findings include: 1. Laboratory observation on 07/21/26 at 9:00 a.m. revealed that the Sysmex XN-430 (serial number 22381) was used to perform CBC w/Diff patient testing. The instrument was new since the last survey date. 2. A review of the instrument validation records revealed that the accuracy, precision, and reportable range studies had not been reviewed or approved by the laboratory director. 3. A review of patient test records revealed that patient testing for CBC w/Diff began on 06/16/26 for the new instrument model, with patient medical record number 10159175. 4. The laboratory liaison confirmed the survey findings during an interview on 07/21/26 at 9:30 a.m. 5. A review of email communication received from the laboratory liaison on 07/28/26 at 3:05 p.m. revealed that approximately 540 patient CBCs w/Diff had been performed since patient testing began on 06/16/26.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results; This STANDARD is not met as evidenced by: Based on a review of the laboratory procedure manual, patient CBC w/Diff records, and a staff interview, the laboratory director failed to ensure testing personnel were performing patient testing according to established procedures. Refer to D5401.

D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: A. Based on a review of the previous CBC w/Diff instrument calibration records and a staff interview, the laboratory director failed to review three of three calibrations performed on the Sysmex XS-1000i instrument in 2025 and 2026. The findings include: 1. A review of the calibration records for the previous CBC w/Diff instrument (Sysmex XS-1000i, serial number 74777) revealed the calibrations had not been reviewed by the laboratory director. Calibration dates were 03/12/25, 08/12/25, and 02/05/26. 2. The laboratory liaison confirmed the survey findings during an interview on 07/21/26 at 1:00 p.m. B. Based on laboratory observation, a review of the laboratory procedure manual, a review of the CBC w/Diff quality control (QC) records from the first date of patient testing (06/16/26) for the new Sysmex XN-430 instrument, and interview with the laboratory liaison, the laboratory director failed to ensure the establishment and maintenance of acceptable levels for QC testing on the Sysmex XN-430 instrument from 06/16/26 to the survey date on 07/21/26. Refer to D5469.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on a review of the laboratory's testing personnel competency assessment policy, a review of testing personnel records, and staff interview, the laboratory director failed to ensure testing personnel competency procedures were in compliance with Subpart M (Refer to D5209 A), and failed to conduct competency assessments according to established policies and procedures for 8 of 9 competency assessments performed in 2025 and 2026 (Refer to D5209 B).
D6033	TECHNICAL CONSULTANT-MODERATE COMPLEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by:

Based on a review of testing personnel competency assessment records, lack of documentation, and staff interview, testing person three did not meet the educational requirements to perform technical consultant duties. Refer to D6035.

D6035

TECHNICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; AND (b)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

This STANDARD is not met as evidenced by:

Based on a review of testing personnel competency assessment records, lack of documentation, and staff interview, testing person three did not meet the educational requirements to perform the technical consultant duty of assessing testing personnel competency in 2025 and 2026. The findings include: 1. A review of testing personnel competency assessment records from 2025 and 2026 revealed the following: The

2025 annual competency assessment for testing person four did not include the name of the person who performed it. The 6-month competency assessment for testing person six (dated 03/03/26) revealed that "Competency assessment performed by: [testing person three]", and then signed by the laboratory director. The 6-month and annual competency assessments for testing person seven, completed on 08/26/25 and 03/03/26 respectively, revealed that "Competency assessment performed by: [testing person three]", and then signed by the laboratory director. 2. There was no documentation that qualified testing person three to perform the technical consultant duty of assessing testing personnel competency. 3. The laboratory liaison confirmed the survey findings during an interview on 07/21/26 at 9:30 a.m.