Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0710016	03/20/2025
Name of Provider or Supplier	**Street Address, City, State**	
Bmg Family Physicians Group Foundation, Inc	3091 Kirby Whitten Road, Bartlett, 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 March 20, 2025, the laboratory was NOT IN COMPLIANCE with the following conditions: 493.1250 Condition: Analytic systems. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) (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 direct observation, review of proficiency testing records, and staff interview, the laboratory failed to retain the 2023 Event Three Proficiency Testing (PT) records for Complete Blood Count with automated White Blood Cell differential (CBC w /Diff) (one of eight PT records from 2023, 2024, and 2025.) The findings include: 1. Laboratory observation on 03/20/25 at 9:15 a.m. revealed the Sysmex XS 1000i CBC w/Diff instrument used for patient testing. 2. A review of the laboratory's PT records revealed that the 2023 Event Three CBC w/Diff records were unavailable. 3. The laboratory liaison confirmed the survey findings during an interview on 03/20/25 at 11:30 a.m.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236.

	This STANDARD is not met as evidenced by: Based on a review of the laboratory's College of American Pathologists (CAP) Proficiency Testing (PT) records, lack of documentation, and staff interviews, the laboratory failed to provide documentation of testing personnel retraining and reassessment of competency after failed urine microscopy and wet prep proficiency testing in 2024. The findings include: 1. A review of the laboratory's proficiency testing records revealed the following: The urine microscopy results for 2024 Event One revealed an unacceptable response for USP-01. The expected response was Red Blood Cell cast, and the response provided by the laboratory was Erythrocyte. The vaginal wet prep results for 2024 event One revealed an unacceptable response for CMMP-26. The expected response was Epithelial Cell Present, the laboratory responded with Clue Cells Present. The urine microscopy results for 2024 Event Two revealed unacceptable responses for USP-05 and USP-06. The expected response for USP-05 was Fiber Fecal Contamination, and the response provided by the laboratory was Mucus Strand. The expected response for USP-06 was Bacteria, and the response provided by the laboratory was Waxy Cast. 2. The laboratory failed to provide documentation that the documented corrective actions had been reviewed with the testing personnel or that retraining of the testing personnel occurred. 3. The laboratory liaison confirmed the survey findings during interview on 03/20/25 at 4:00 p.m.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on direct observation, review of the laboratory procedure manual, patient test results, lack of documentation, and staff interviews, the laboratory failed to follow written procedures for labeling of CBC w/Diff controls and wet prep transport reagent (Refer to D5401 Citation One), failed to follow the procedure for performing urine microscopy (Refer to D5401 Citation Two), failed to follow the procedure for resolving flagged CBC w/Diff results (Refer to D5401 Citation Three), failed to have a procedure to resolve discrepant CBC w/Diff results before release (Refer to D5403) and failed to ensure the procedure used for performing urine microscopy was approved (Refer to D5407).
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:
CITATION ONE: Based on direct observation, review of the laboratory procedure manual, and staff interview, the laboratory failed to follow the policy for labeling CBC w/Diff controls (six of six observed) and labeling saline used for wet prep sample transport on the survey date (03/20/25). The findings include: 1. Laboratory observation on 03/20/25 at 9:15 a.m. revealed the following: The Sysmex XS 1000i used for performing patient testing for CBC w/Diff, and a microscope used for performing urine microscopy, potassium hydroxide (KOH) fungal detection, and vaginal wet prep testing. The CBC control vials, six of six observed for lot 5024, were not labeled with the corrected expiration date according to laboratory procedure. A clear liquid was noted in the nursing station area. The laboratory liaison stated during observation that the fluid was saline and was used to transport wet prep samples to the laboratory. The vials were not labeled with content or lot number. 2. A review of the procedure titled "Corrected Expiration Dates for Controls and Reagents" revealed the following: Sysmex e-CHECK XS control are stable 14 days after opening and "Record the opened date and the revised expiration date on each vial upon opening." "Any reagent or solution (including but not limited to Saline and KOH) used in lab or any other area involved in patient care that is stored outside its original manufacturer container must be labeled clearly with the name, Lot #, Opened or prepared date, and revised expiration date of 30 days if not otherwise specified by the manufacturer." 3. The laboratory liaison confirmed the survey findings during an interview on 03/20/25 at 4:00 p.m. CITATION TWO: Based on direct observation, review of the procedure manual, patient test results, and staff interviews, the laboratory failed to follow the procedure for processing urine for microscopic examination on the survey date (03/20 /25). The findings include: 1. Laboratory observation on 03/20/25 at 9:15 a.m. revealed a centrifuge and microscope used for processing and performing urine microscopy examination. During observation, testing person one was asked to describe the process for performing urine microscopy. She stated that she poured the urine into a tube and then spun it in the urine centrifuge. When asked how much urine she put into the tube, she pointed to the 1.5 mL line on the urine tube.The observed urine centrifuge was set to spin at 3200 RPM for 10 minutes. She stated she centrifuged the urine sample until the centrifuge cut off automatically and that she had always performed urine microscopics that way. 2. A review of the laboratory's procedure for urine microscopy examination revealed the following: "Centrifuge 10-12 ml of freshly voided urine at 2000 RPMs for a minimum of 5 minutes." 3. A patient urine microscopy results review revealed patient number 11060913 performed by testing person one on 02/26/24. 4. The laboratory liaison confirmed the survey findings during an interview on 03/20/25 at 4:00 p.m. Word Key mL=milliliter RPM=Revolutions per Minute CITATION THREE: Based on a review of the laboratory procedure manual, patient result review, lack of documentation, and staff interview, the laboratory failed to follow the policy for actions to take for flagged CBC w/Diff results in 2024 and 2025. 1. A review of the laboratory procedure titled "Sysmex XS-1000i" revealed the following statement under the section for "Reporting Abnormal Results to Physicians": "Rerun the sample if flags are present. Always note "verified by repeat testing" under comments. Recollect the sample by venipuncture if repeating the test does not clear the flags on a capillary sample. If the flags remain on a venous sample, ask the physician if they want to send the test out for analysis. Always note if physician says to send out for verification under comments." 2. A review of patient CBC w/Diff records revealed the following: Patient #12153743 (performed on 08/15/24): the instrument printouts had CBC results flagged with immature granulocyte and platelet clumps. There was no documentation that the physician had been consulted regarding the flagged results. Patient #10047469 (performed on 10/21/24): The instrument printout for the first run at 10:05 a.m. was

	flagged with possible blasts. The 2nd run performed at 10:08 a.m. was flagged with Atypical Lymphocyte. There was no documentation that the physician had been consulted regarding the flagged results. Patient #12126686 (performed on 01/20/25): the instrument printout had CBC results flagged with immature granulocyte and platelet clumps. There was no documentation that the CBC had been repeated to verify results, or that the physician had been consulted regarding the flagged results. Patient #12296632 (performed on 01/20/25): The instrument printout was flagged for Monocytosis and Atypical Lymphocyte. There was no documentation that the CBC had been repeated to verify results, or that the physician had been consulted regarding the flagged results. Patient #13004785 (performed on 02/17/25): The instrument printouts for both the original and repeat runs were flagged with Immature Granulocyte. There was no documentation that the physician had been consulted regarding the flagged results. 4. The laboratory liaison confirmed the survey findings during interview on 03/20/25 at 4 p.m. Word key: th/uL=thousand/microliter M /uL=Million/microliter g/dL=Grams/deciliter %=Percent
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 a review of patient CBC w/Diff results, review of the laboratory procedure manual, lack of procedure, and staff interview, the laboratory CBC w/Diff procedure failed to have steps to take to resolve discrepant CBC w/Diff results. 1. A review of patient 12071354 CBC w/Diff results reported on 01/20/25 revealed the following: The instrument printouts revealed testing performed at 3:12 p.m. with multiple flagged results. The sample was repeated at 3:15 p.m., and the results between the first and second runs were discrepant as follows: White Blood Cell (th/uL): 1st run 6.69, 2nd run 8.16 Red Blood Cell (M/uL: 1st run 4.78, 2nd run 5.46 Hemoglobin (g/dL): 1st run 13.0, 2nd run 14.7 Hematocrit (%): 1st run 41, 2nd run 47.7 Platelet count (th /uL): 1st run 44, 2nd run 153 The results from the second run were reported on the patient. Neither the instrument printouts nor the chart copy had any comments indicating how the discrepancy was resolved. 2. A review of the CBC w/Diff procedure revealed the procedure did not include instructions for testing personnel to

	follow if results between original and repeated results were discrepant. 3. The laboratory liaison confirmed the survey findings during interview on 03/20/25 at 4 p. m. Word key: th/uL=thousand/microliter M/uL=Million/microliter g/dL=Grams /deciliter %=Percent
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on laboratory observation, review of laboratory procedures, and staff interview, the laboratory director failed to approve, sign and date the urine microscopy procedure used by the laboratory. The findings include: 1. Laboratory observation on 03/20/25 at 9:15 a.m. revealed a centrifuge and microscope used for processing and performing urine microscopy examination. 2. A review of the laboratory procedure manual revealed the following: A procedure titled "Urinalysis" stated, "If a urine microscopic is required, pour off a portion of the specimen into a labeled container and send to the appropriate reference laboratory." A second procedure provided by the laboratory liaison titled "URINALYSIS CHEMISTRY ON CLINITEK" included instructions for performing a urine microscopic exam. The procedure had not been approved, signed and dated by the laboratory director. 3. The laboratory liaison stated during an interview on 03/20/25 at 4:00 p.m. that the laboratory did not use the procedure titled "Urinalysis", and confirmed that the procedure used by the laboratory was not approved, signed and dated by the laboratory director. This confirmed the survey findings.
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic 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 postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on a review of patient wet prep results, and staff interview, the laboratory failed to have an effective quality assessment process in place to resolve discrepancies in the final patient test reports for one of three vaginal wet prep results reviewed from 2024 and 2025. The findings include: 1. A review of the wet prep results for patient 12331414, performed on 07/02/24, revealed discrepancies between the worksheet and final patient test report as follows: Worksheet: Yeast-mod WBC-few B+-Mod Bv-Pos RBC-Few Final patient test report: Yeast-Many White Blood Cells-Many Trichomonas-None Clue Cells-Few 2. The laboratory liaison confirmed the survey findings during the interview on 03/20/25 at 4:00 p.m.
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 direct observation, procedure manual review, patient result review, PT record review, lack of documentation, and staff interview, the laboratory director failed ensure testing personnel were performing test methods as required (Refer to D6014), failed to ensure an effective quality assessment process was in place to identify and resolve discrepancies in reported patient results (Refer to D6020), failed to ensure competency was reassessed after unacceptable proficiency testing microscopy results (Refer to D6030) and failed to ensure approved procedures were in place for test performance (Refer to D6031).
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 direct observation, review of procedure manual, patient result review, and staff interview, the laboratory director failed to ensure testing personnel were performing test methods as required (Refer to D5401 Citation One, Citation Two, and Citation Three).
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of patient test reports and staff interview, the laboratory director failed to have an effective quality assessment process to identify and resolve discrepancies in reported patient results (Refer to D5893).
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 PT records, lack of documentation, and staff interview, the laboratory director failed to ensure the competency of testing personnel was reassessed when proficiency testing urine microscopy and wet prep results were unacceptable (Refer to D5291).
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on direct observation, review of procedure manual and staff interview, the laboratory director failed to ensure the procedure manual included approved procedures for performing urine microscopy examinations (Refer to D5407).
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 review of testing personnel competency assessment documents, quality assessment reviews, lack of documentation, and staff interview, the person performing testing personnel competency assessments and quality assessment reviews did not qualify (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 review of testing personnel competency assessment and quality assessment records, lack of documentation and staff interview, 2024 testing personnel competency assessments were performed by a previous employee who did not qualify to perform technical consultant duties, and 2025 quality assessment review were performed by a person that did not have documentation of education and experience to perform the reviews. The finding include: 1. A review of testing personnel competency assessment records revealed the following: The section at the bottom of the form titled "Competency Assessment Performed By:" revealed the name of an employee no longer employed at the laboratory. The testing personnel competency assessments performed by the former employee were the 2024 annual competency assessment for testing person one, testing person two, and testing person three, and the six-month competency assessment for testing person four. 2. A review of the Quality Assessment Review worksheet dated 03/03/25 revealed the review was performed by a Registered Nurse. 3. There was no documentation that qualified the previous employee to perform the task of testing personnel competency assessments or the Registered Nurse to perform the Quality Assessment reviews. 4. The laboratory liaison confirmed the survey findings during an interview on 03/20/25 at 4:00 p.m.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) (b)(6)(ii) Have documentation of laboratory training appropriate for the testing performed prior to analyzing patient specimens. Such training must ensure that the individual has- (b)(6)(ii)(A) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation, and storage of specimens; (b)(6)(ii)(B) The skills required for implementing all standard laboratory procedures; (b)(6)(ii)(C) The skills required for performing each test method and for proper instrument use; (b)(6)(ii)(D) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(6)(ii)(E) A working knowledge of reagent stability and storage; (b)(6)(ii)(F) The skills

	required to implement the quality control policies and procedures of the laboratory; (b)(6)(ii)(G) An awareness of the factors that influence test results; and (b)(6)(ii)(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a review of initial training documentation and staff interview, the laboratory's training documentation failed to include documentation to ensure the testing personnel could implement the laboratory's procedures, demonstrated a knowledge of reagent stability and storage, and awareness of factors that influence test results for two of two initial training documents reviewed from 2024. The findings include: 1. A review of initial training documents for testing persons five and eight for the performance of microscopic procedures (wet prep, KOH, and urine microscopy) revealed the training documentation did not include the elements of implementing all standard laboratory procedures, a working knowledge of reagent stability and storage, and an awareness of the factors that influence test results. 2. The laboratory liaison confirmed the survey findings during an interview on 03/20/25 at 4:00 p.m.