

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2273821	(X3) Date Survey Completed 05/15/2023
Name of Provider or Supplier Bmg Family Physicians Group Foundation	Street Address, City, State 5150 Airline Rd Ste 300, Arlington, 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	The laboratory was found NOT to be in compliance with the following 42 CFR Part 493, Requirements for Laboratories for the specialties/subspecialties for which it was surveyed: 493.1250 Analytic systems 493.1409 Laboratories performing moderate complexity testing; technical consultant
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on observation of the laboratory, review of procedure manuals, validation records, lack of records, manufacturer package insert, patient test reports, and staff interviews the laboratory failed to have an approved procedure for use of the Sysmex XN430 CBC instrument that met the regulatory requirements (Refer to D5403), the laboratory director failed to approve the procedure for the Sysmex XN430 (Refer to D5407), the laboratory failed to monitor room temperature and humidity in the area where the Sysmex XN430 was being used for patient testing (Refer to 5413), failed to label controls with open date and corrected expiration date (Refer to D5415), failed to verify the normal ranges used for CBC performed on the Sysmex XN430 (Refer to D5421), failed to establish performance specifications for the urine microscopic, wet prep and potassium hydroxide (Refer to D5423), and failed to have quality assessment procedures for the Sysmex XN430 (Refer to D5791).</p>
D5403	PROCEDURE MANUAL

CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 observation of the laboratory, review of the procedure for the Sysmex XN430 complete blood count (CBC) instrument, an email communication and interview with the laboratory liaison, the laboratory procedure for the Sysmex XN430 failed to include policies/procedures for calibration verification, quality control, reference ranges and procedures to follow when flagged or abnormal results are obtained with a total of 415 patient CBC tests performed since patient testing began on 02/02/23. The findings include: 1. Observation of the laboratory on 05/15/23 at 11:15 am revealed the Sysmex XN430 on the counter in use for patient testing for complete blood count with automated white blood cell differential. 2. Review of the procedure titled XN-450/XN-430 Automated Hematology Analyzer CLSI procedure revealed the following: The procedure that was printed contained instructions for tests not performed in the laboratory, No clear calibration verification protocol. No clear quality control procedures/protocols. No reference range. No procedure for abnormal results. 3. Review of an email communication received 05/15/23 at 2:29 pm revealed the laboratory has performed 415 patient CBCs since patient testing began on 02/02/23. 4. Interview with the laboratory liaison on 05/15/23 at 5 pm confirmed the procedure for the Sysmex XN430 had not been completed with required procedure elements. She further confirmed the document was printed for use without completing sections of the procedure with laboratory protocol, and included tests not performed in the laboratory.

D5407

PROCEDURE MANUAL

CFR(s): 493.1251(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 observation of the laboratory, review of patient test reports, laboratory procedures and staff interview, the laboratory failed to ensure procedures for

Complete Blood Count (CBC), urine microscopy, and wet prep were approved by the laboratory prior to patient reporting which began on 02/02/23. The findings include: 1. Observation of the laboratory on 05/15/23 at 11:15 am revealed laboratory a Sysmex XN 430 instrument in use for performing patient testing for CBC and a microscope on the counter in use for performing urine microscopy and wet prep. 2. Review of patient test reports revealed patient reporting for CBC and urine microscopic began on 02/02/23 (patient medical record number (MRN) 14429237); patient reporting for wet prep was noted on 02/17/23 (patient MRN 12612886). 3. Review of the laboratory procedures revealed the following: The procedure for performance of CBC on the Sysmex XN 430 had not approved. The procedure for urine microscopic was dated 02/27/23 (after patient tests were reported). The procedure for wet prep was dated 02/27/23 (after patient tests were reported). 4. Interview with the laboratory liaison on 05/15/23 at 5:00 pm confirmed the laboratory began patient testing for CBC, urine microscopic, and wet prep prior to laboratory director approval of procedures.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, review of manufacturer operator's manual, lack of records and interview with the laboratory liaison, the laboratory failed to monitor room temperature and humidity in the area where the Sysmex XN430 instrument was in use for patient testing for CBC with automated white blood cell differential (CBC w/diff) from 02/02/23 (date patient testing began) until the date of the survey on 05/15/23. The findings include: 1. Observation of the laboratory on 05/15/23 at 11:15 am revealed the Sysmex XN430 CBC instrument on the counter in use for patient testing. No device for monitoring of room temperature or humidity was observed. 2. Review of the Sysmex XN430 manufacturer operator's manual revealed the following operating environmental conditions: Ambient temperature 15 - 35 C Relative humidity 20 to 85% 3. No records were available for monitoring of room temperature or humidity. 4. Review of patient test records revealed patient testing for CBC w/diff began on 02/02/23, patient MRN 14429237. 4. Interview with the laboratory liaison on 05/15/23 at 5 pm confirmed the laboratory did not monitor room temperature or humidity in the area where the Sysmex XN430 CBC instrument was in use from the time patient testing began on 02/02/23 until the date of the survey on 05/15/23.

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 the manufacturer control package insert, and staff interview, the laboratory failed to label three of three controls used for performing quality control on the Sysmex XN 430 with open date and corrected expiration date. The findings include: 1. Observation of the laboratory on 05/15/23 at 11:15 am revealed the Sysmex XN 430 CBC instrument (serial #11767) in use for patient testing. Also observed were three levels of Sysmex XN-L CBC controls (Lot 3041) that were not labeled with open date or corrected expiration date. 2. Review of the manufacturer control package insert revealed the controls are good for 15 days after opening. 3. Interview with the laboratory liaison on 05/15/23 at 5:00 pm confirmed the laboratory did not label CBC controls with open date or corrected expiration date for three of three control vials observed on the date of the survey.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 observation of the laboratory, review of validation records, email communication and staff interview, the laboratory failed to verify the normal ranges in use for the complete blood count and automated white blood cell differential (CBC w/diff) for the Sysmex XN430 in 2023, with 415 patient CBCs performed since testing began on 02/02/23. The findings include: 1. Observation of the laboratory on 05/15/23 at 11:15 am revealed the Sysmex XN430 CBC instrument in use for patient testing for CBC with automated WBC differential. 2. Review of validation records for the Sysmex XN430 revealed verification of the normal ranges in use had not been performed. 3. Review of an email communication received on 05/25/23 at 2:29 pm revealed the laboratory performed a total of 415 patient CBCs since testing began on 02/02/23. 3. Interview with the lab liaison on 05/15/23 at 5 pm confirmed the laboratory had not verified the normal ranges used for CBC w/diff with patient testing performed beginning on 02/02/23.

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv)

Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, document request, review of patient test results, email communication and interview with the laboratory liaison, the laboratory failed to validate the urine microscopy, wet prep and potassium hydroxide (KOH) before testing began on 02/02/2023 with two urine microscopies performed and nine wet preps performed since patient testing began on 02/02/23. The findings include: 1. Observation of the laboratory on 05/15/23 at 11:15 am revealed a microscope on the counter in use for performing patient testing for urine microscopy, wet prep and KOH. 2. Request made to the laboratory liaison for validation records for the urine microscopy, wet prep and KOH on 11/15/23 at 12:45 pm revealed no validations had been performed. 3. Review of patient test records revealed reporting for urine microscopy on 02/02/23 for patient medical record number (MRN) 14429237, and wet prep for patient MRN 12612866 for wet prep on 02/17/23. No patient KOH had been reported. 4. Review of an email communication received on 05/25/23 at 2:29 pm revealed the laboratory had performed two urine microscopies and nine wet preps since patient testing began on 02/02/23. 5. Interview with the laboratory liaison on 05/15/23 at 5 pm confirmed the laboratory performs testing for urine microscopy, wet prep, and offers testing for KOH, but had not validated any of the three tests.

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 review of patient test reports, the laboratory's procedure manuals, record request and staff interview, the laboratory failed to have a quality assessment plan in place for the Sysmex XN430 instrument since patient testing began on 02/02/23. The findings include: 1. Review of patient test records revealed patient testing for CBC w /Diff began on 02/02/23 (patient MRN 14429237). 2. Review of the procedure manual revealed no quality assessment plan for the Sysmex XN430 CBC instrument. 3. Request for review of CBC maintenance records and quality control revealed no documented reviews had been performed since the laboratory began patient testing on 02/02/23. 4. Interview with the laboratory liaison on 05/15/23 at 5 pm confirmed the laboratory did not have a quality assessment plan for review of records for the Sysmex XN430 CBC instrument from the time patient testing began on 02/02/23 to the date of the survey on 05/15/23.

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 personnel records, validation records, a lack of records and staff interview, the technical consultant failed to have the required laboratory training or experience for performing technical consultant duties (Refer to D6035), failed to review and approve validations for the Sysmex XN430 CBC instrument and failed to ensure validations for the urine microscopy, wet prep and KOH were performed (Refer to D6040).

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 possess qualifications that are equivalent to those required for such certification; 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 one year of laboratory training or experience, or both in non-waived 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) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

Based on review of testing personnel records, document request, and interview with the laboratory liaison, the lab director who was performing the technical consultant duties failed to have documentation of laboratory training or experience for the four moderately complex test systems in use by the laboratory (urinalysis, hematology, wet prep and KOH). The findings include: 1. Review of testing personnel records revealed the signature of the laboratory director on the form labeled as "TRAINING

/COMPETENCY ASSESSMENT" for four of five testing personnel performing patient testing. 2. Request on 05/15/23 at 1pm for evidence of laboratory training or experience for the person performing technical consultant duties revealed no documentation was available. 3. Interview with the laboratory liaison on 05/15/23 at 5 pm confirmed the laboratory director was performing technical consultant duties to include testing personnel training and competency, but did not have documentation of laboratory training or experience for any of the four moderately complex test systems performed by the laboratory.

D6040

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(2)

The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:

Based on review of test system verification studies, a lack of records, patient test reports, and interview with the laboratory liaison, the person functioning as the technical consultant failed to review or approve the Sysmex XN430 CBC w/Diff validation studies that were performed in January 2023 (Refer to D5421) and failed to ensure validations were performed for the urine microscopic, wet prep, and KOH (Refer to D5423). The findings include: 1. Review of the verification studies performed for the Sysmex XN430 CBC instrument revealed the studies had not been reviewed or approved. 2. There were no records for validation of the urine microscopic, wet prep and KOH. 3. Review of patient test reports revealed the first patient CBC w/Diff and urine microscopic was reported on 02/02/23, patient MRN 14429237; patient testing for wet prep was reported on 02/17/23, patient MRN 12612866. 4. Interview with the laboratory liaison on 02/02/23 at 5 pm confirmed the acting technical consultant did not review or approve the Sysmex XN430 validation studies and failed to ensure validations were performed for the urine microscopic, wet prep and KOH.