

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0710017	(X3) Date Survey Completed 08/24/2023
Name of Provider or Supplier Bmg Family Physicians Group Foundation, Inc	Street Address, City, State 8110 Cordova Road Suite 111, Cordova, 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	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory proficiency testing (PT) records and staff interview, the laboratory director failed to sign the PT attestation statements for five of five events reviewed from 2022 and 2023. The findings include: 1. Review of the laboratory PT records revealed the laboratory director failed to sign the attestation statements for events 2023 Event one Provider Performed Microscopy, 2023 Event two Hematology, 2022 Events one, two, and three for Hematology and Provider Performed Microscopy (five of five events reviewed). 2. Interview on 08/24/2023 at 11:00 am with the laboratory liaison confirmed the laboratory director failed to sign the attestation statements for five of five events in 2022 and 2023.</p>
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's PT records and staff interview, the laboratory failed to retain the Sysmex XS 1000i complete blood count (CBC) instrument printouts for 2022 Hematology event one (one of five events reviewed) for a period of two years. The findings include: 1. Review of the laboratory's PT records for 2022 Event one Hematology revealed the CBC instrument printouts were not retained. 2. Interview on</p>

08/24/2023 at 11:00 am with the laboratory liaison confirmed the laboratory failed to retain the instrument print outs for 2022 Event one Hematology PT.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:
Based on review of the Department of Health and Human Services Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) for moderate and high complexity testing (Form CMS-209), laboratory policy, laboratory personnel records, and staff interview, the laboratory failed to follow their own policy for assessing testing personnel (TP) competency for CBC, potassium hydroxide (KOH), vaginal wet prep, and urine microscopic patient testing for 10 of 11 TP reviewed in 2022 and 2023, and failed to ensure the policy included requirements for demonstrated accuracy/competency prior to performing patient testing as required in Subpart M. The findings include: 1. Review of the Form CMS-209 revealed eleven TP that performed moderately complex patient testing. 2. Review of the laboratory policy titled "Personnel Assessment Policy" revealed competency assessment requirements for TP required six months after hire and annually thereafter that included the required six elements. The policy did not include a requirement for demonstration of accuracy/competency prior to patient testing. 3. Review of the laboratory personnel records revealed the following testing personnel with no documented competency assessments that included the required six elements. TP two and three: No documented initial competency prior to CBC, KOH, Wet prep, or Urine microscopic moderately complex patient testing in 2023. TP four: No documented annual competency that included the required six elements in 2022 and blind testing not included in 2023 for CBC patient testing. TP five, six, seven, 11: No documented initial competency prior to CBC patient testing in 2023. TP eight and nine: No documented initial, semi-annual, or annual competency for CBC patient testing in 2022 and 2023. TP 10: No initial or semi-annual competency for CBC patient testing in 2022 and 2023. 4. Interview on 08/24/2023 at 10:04 am with the laboratory liaison and office manager confirmed the laboratory failed to follow its' own policy for TP competency assessment and failed to have a competency assessment policy that was in compliance with the requirements in subpart M when it did not require demonstration of accuracy/competency prior to patient testing.

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:
I. Based on review of final patient test review, laboratory procedure, and staff interview, the laboratory failed to follow the procedure in use for reporting vaginal

wet prep examination patient results in 2022. The findings include 1. Review of one of two final patient test reports for wet prep revealed reporting of cholesterol crystals for patient 13693296 (resulted on 01/28/2022). 2. Review of the procedure titled "Wet Prep Exam for Vaginitis" revealed the following analytes to be reported: white blood cell, yeast, trichomonas, clue cells, bacteria, and sperm. 3. Interview on 08/24/2023 at 2:00 pm with the laboratory liaison confirmed the laboratory failed to follow its' own procedure for final patient test reporting for wet prep in 2022. II. Based on observation of two laboratory areas, lack of documentation, review of laboratory procedure, and staff interview, the laboratory failed to follow the procedure in use for instrument to instrument comparison of the two Sysmex XS 1000i hematology instruments used for CBC patient testing in 2021, 2022, and 2023. The findings include: 1. Observation of the laboratory on 08/24/2023 at 9:29 am revealed a Sysmex XS 1000i (Serial # 74908) in the main laboratory, with observation of a second Sysmex XS 1000i (Serial # 74907) 12:02 pm in the nursing triage area, in use for performing patient CBC testing. 2. There was no documentation of instrument to instrument comparison in 2021, 2022, or 2023. 3. Review of the laboratory policy titled "Proficiency Test Performance" revealed "For the offices with 2 Sysmex instruments you must run the CBC samples AFTER THE DATA SUBMISSION DEADLINE on the nurses' Sysmex." The instrument printouts are labeled with "Result Comparison" reviewed by the laboratory liaison and laboratory director, and filed in the proficiency test binder. Check lists are to be used to ensure all records are present, signed, and retained. 4. Interview on 08/24/2023 at 2:00 pm with the laboratory liaison confirmed the laboratory failed to follow its' own procedure for instrument to instrument comparison for the two Sysmex XS 1000i hematology instruments used for CBC patient testing in 2021, 2022, and 2023.

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 control package inserts, and staff interviews, the laboratory failed to label three of three CBC quality control (QC) vials with open date and expiration date on the date of the survey. The findings include: 1. Observation of the laboratory on 08/24/2023 at 9:40 am revealed QC vial lot numbers 32050804, 32050805, and 32050806 in use for performing QC on the Sysmex XS 1000i. The vials were not labeled with either open or corrected expiration dates. 2. Review of the Sysmex e-Check (XS) QC package insert revealed that the controls are stable for 14 days after opening. 3. Interview on 08/24/2023 at 9:43 am with the laboratory liaison, office manager, and testing personnel confirmed the laboratory failed to label QC vials with open dates and corrected expiration dates on the date of the survey.

D6015

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)

The laboratory director is responsible for the overall operation and administration of

the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory proficiency testing records, random patient test report review, and staff interview, the laboratory director failed to ensure the laboratory was enrolled in an HHS approved proficiency testing program for event one in 2023 for the complete blood count (CBC) regulated analytes to include white blood cell (WBC), red blood cell (RBC), platelet (PLT), hemoglobin (Hgb), hematocrit (Hct), and WBC differential (WBC Diff). The findings include: 1. Review of the laboratory PT records revealed there was no documentation of participation for 2023 event one for the regulated analytes WBC, RBC, PLT, Hgb, Hct, and WBC Diff. 2. Review of patient test reports revealed patient reporting for CBC on 02/09/2023 (patient 160505450). 3. Interview on 08/24/2023 at 11:00 am with the laboratory liaison confirmed the laboratory director failed to ensure the laboratory was enrolled in PT for 2023 event one for regulated CBC analytes with patient testing performed.