

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2010995	(X3) Date Survey Completed 06/05/2025
Name of Provider or Supplier Bmg Family Physicians Group Foundation, Inc	Street Address, City, State 4625 Poplar Avenue, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory procedure manual, review of testing personnel records, and a lack of records, and staff interview, the laboratory failed to follow the policy for testing personnel competency assessment when it did not perform one of the three annual testing personnel competency assessments due in 2024 for performance of CBC w/Diff. The findings include: 1. A review of the laboratory's policy titled "PERSONNEL ASSESSMENT POLICY" revealed the following statement: "At the completion of 1 year working as testing personnel, each employee will have a yearly "Competency Assessment." 2. A review of testing personnel records revealed the following: Testing Person four was hired on 09/27/2023. There was no documented annual competency assessment record in 2024. 3. The laboratory liaison confirmed the survey findings during an interview on 06/05/2025 at 4:15 p.m.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on a review of the laboratory procedure manual, a review of the laboratory's Complete Blood Count with Automated White Blood Cell Differential (CBC w/Diff) College of American Pathologists (CAP) Proficiency Testing (PT) records, a review of the laboratory's quality assessment records, and staff interview, the laboratory failed to perform corrective action for missing signatures on the PT attestation statements from 2024 Event Two and 2024 Event Three (two of five events reviewed). The findings include: 1. A review of the laboratory policy titled "Proficiency Test Performance" revealed the use of a PT checklist to monitor proficiency testing events for completeness, including PT attestation signatures. 2. A review of the laboratory's CAP PT records revealed that the PT attestation statements were not signed by four of five testing personnel for the 2024 PT Event Two; five of five testing personnel did not sign the PT attestation statement for the 2024 PT Event Three (two of five PT events reviewed). There was no documentation that the PT checklist was used for either PT event. 3. A review of the laboratory's quality assessment records revealed that missing signatures were identified on quality reviews dated 05/28/24 and 12/05/24. No documented corrective action was taken for the use of the PT monitoring checklist. 4. The laboratory liaison confirmed the survey findings during an interview on 06/05/25 at 4:15 p.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 patient CBC w/Diff results, the laboratory procedure manual, and a staff interview, the laboratory failed to follow the policy for verifying flagged CBC w/Diff results for five of fourteen flagged patient CBCs selected for review from 2024 and 2025. The findings include: 1. A review of patient instrument printouts and results in the electronic medical record revealed the following flagged results with no documented corrective actions: Patient 1C11551532 was reported on 06/03/24 with WBC and differential results flagged with asterisks and a message of "Immature Gran?"; the PLT count and MPV parameters were flagged with asterisks and a message of "PLT clumps?". Patient 1C11870860 was reported on 12/09/24 with WBC differential parameters flagged with asterisks and a WBC message of "Atypical Lympho?". Patient 1C14105404 was reported on 12/09/24 with the WBC and Differential parameters flagged with asterisks; and a WBC message of "Immature Gran?"; the PLT count and MPV parameters were flagged with asterisks and a message of "PLT clumps?". Patient 1C12321408 was reported on 12/09/24, with the PLT count and MPV flagged with asterisks and a message of "PLT clumps?." Patient 1C14079046 was reported on 12/09/24 with WBC flagged with an asterisk with a WBC message of "WBC Abn Scattergram", "Immature Gran?", and "NRBC"; the differential results had dashes in place of numeric data. The PLT count and MPV were flagged with asterisks and a PLT message of 'PLT Clumps?'. 2. A review of the laboratory procedure titled "CBC performed on Sysmex XS-1000i, revealed the following statements: "Review the results in IPU to determine whether repeat analysis or collection is recommended. 1. Rerun the sample if flags are present. Always note 'verified by repeat testing' under comments. 2. 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." The action for "Suspect, Immature Gran?" included sending immature cells to a reference lab for confirmation. The action for "Suspect, Atypical Lymph" included that the results should be reviewed by the ordering provider to decide if the specimen should be sent to a reference lab for confirmation. The action for "Suspect, PLT Clumps?" included recollecting the sample if it was capillary, and if the flag did not clear, recollecting a venous sample and repeating the testing. 3. The laboratory liaison confirmed the survey findings during an interview on 06/05/25 at 4:15 p.m. Word Key: Gran=Granulocyte MPV=Mean Platelet Volume NRBC=Nucleated Red Blood Cell PLT=Platelet WBC=White Blood Cell