

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0710014	(X3) Date Survey Completed 02/20/2024
Name of Provider or Supplier Bmg Family Physicians Group Foundation, Inc	Street Address, City, State 7685 Winchester Rd, Suite 100, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, review of patient complete blood count (CBC) results and lack of documentation, and staff interview, the laboratory failed to follow its' own policy for protocol to follow when CBC results were flagged by the instrument for three of three patients with flagged CBC results reviewed from 01/29/24 from the nursing triage instrument (serial # 74900). The findings include: 1. Review of the laboratory procedure titled "Sysmex XS-Series Automated Hematology Analyzer" "Flagging Interpretation Guide" approved by the laboratory director on 10/10/23 revealed the following: WBC and differential results that are flagged with (*) should be allowed to sit for five minutes and then repeated. "If flags do not clear, specimen should be forwarded to reference lab." "Delta Check" "Means there is significant difference between this result and a previous result. Recollect. Allow to sit for 5 minutes. If Delta check does not clear, show the ordering provider before finalization." "Suspect PLT Clumps?" " Recollect sample if capillary sample. If flags do not clear, collect and run venous sample. 2. Review of patient CBC instrument printouts and final patient results from the nurse triage area revealed flagged patient results that were reported without following laboratory protocol as follows: Date 01/29/2024: CBC results for patient ID 1C11786870 with an action message of "Delta Check Failure. Check Sample." CBC results for patient ID 1C11692956 with WBC (White Blood Cell), WBC differential, platelet, and mean platelet volume (MPV) results that were flagged with (*) and a Platelet Message of "PLT Clumps?." Also noted was an action message of "Delta Check Failure. Check</p>

Sample." CBC results for patient ID 1C11620261 with an Action Message of "Delta Check Failure. Check Sample." There was no evidence that the samples were repeated, recollected, or sent to a reference laboratory before reporting. 4. During an interview on 02/20/24 at 2:00 pm, the laboratory liaison confirmed that three of three patients with flags that were performed and reported on 01/29/24 were not handled according to the laboratory's written protocol.

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 review of patient wet prep reports, patient wet prep worksheet, laboratory procedure for wet prep and staff interview, the laboratory procedure for wet prep failed to define criteria for determining what rare, few, moderate, several or many meant. The findings include: 1. Review of patient MRN 11608913 revealed reporting for genital wet prep on 02/06/24. The result for the White Blood Cell (WBC) was recorded as "Many." 2. Review of the wet prep worksheet revealed the following: WBC 5-10. 3. Review of the laboratory procedure for wet prep revealed elements for WBC, Yeast, Trichomonas, and Clue cells were to be reported as rare, few, moderate, several or many. The procedure did not define what rare, few, moderate, several or many meant. 4. During an interview on 02/20/24 at 2 pm, the laboratory liaison confirmed the laboratory procedure for wet prep failed to define the criteria for determining rare, few, moderate, several or many.

D5775

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, lack of documentation, and staff interview, the laboratory failed to compare results between the two instruments used for patient testing for complete blood count (CBC) in 2023. The findings include: 1. Observation of the laboratory on 02/20/24 at 9:15 am revealed two Sysmex XS 1000i CBC instruments used for patient testing, one in the main laboratory (serial # 74901) and one in the nurse triage area (serial #74900). 2. There was no documentation that results between the CBC instruments were compared twice in 2023. 3. The laboratory liaison confirmed during interview on 02/20/24 at 11:15 am, that the laboratory failed to compare results between the two CBC instruments twice a year in 2023.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on review of the laboratory procedure manual, final patient test report for wet prep, and staff interview, the final patient test report for wet prep failed to include the units of measure for one of one patients reviewed. The findings include: 1. Review of the laboratory procedure for wet prep revealed the laboratory reports what is seen on high power field. 2. Review of the final patient test report for patient MRN 11608913 revealed wet prep elements for white blood cell (WBC), Yeast, Trichomonas and Clue cells reported on 02/06/24. The final patient test report did not include units of measure. 3. Interview with the laboratory liaison on 02/20/24 at 2 pm confirmed the laboratory's final patient test report for wet prep did not include the units of measure for the patient reported on 02/06/24.