

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0710016	(X3) Date Survey Completed 06/05/2018
Name of Provider or Supplier Bmg Family Physicians Group Foundation, Inc	Street Address, City, State 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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing attestation statements and interview with the operations manager, the laboratory failed to ensure attestation statements were signed by testing personnel and laboratory director in 2016, 2017, and 2018. The findings include: 1. Review of the laboratory's proficiency testing attestation statements revealed no signature of testing personnel for 2016 events one, two and three; 2017 events one, two and three; 2018 event one; no signature of the laboratory director for 2016 events one, two, and three, and 2017 events one and two. 2. Interview with the operations manager on June 5, 2018 at 2:30 pm confirmed the laboratory recorded the names of personnel responsible for the proficiency events but failed to obtain signatures of testing personnel and laboratory director on the proficiency testing attestation statements in 2016, 2017, and 2018.</p>
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p>

Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

This STANDARD is not met as evidenced by:
Based on review of available laboratory records documenting quality assessment activities, review of the laboratory's quality assessment policy and interview with the operations manager the laboratory failed to retain quality assessment records for the complete blood count (CBC) laboratory for at least two years in 2016, 2017, and 2018. The findings include: 1. Review of available quality assessment records for the CBC laboratory revealed that no records were present for the last 2 years documenting laboratory director review of quality control for the CBC laboratory. 2. Review of the laboratory's policy titled "Quality Assurance Review" revealed the following statement "reviews are performed at least quarterly." Records for these reviews could not be located for 2016 quarters three and four, 2017 quarters one and two, and 2018 quarter one. 3. Interview with the operations manager on June 5, 2018 at 5:00 pm revealed the following: Quality control is printed off at regular intervals and is review by the laboratory director for acceptability, shifts and trends; however, those records cannot be located. The operations manager confirmed the laboratory failed to retain records documenting laboratory director review of quality control and quality assessment review documents for at least two years in 2016, 2017, and 2018.

D5417

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

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, review of the Sysmex complete blood count (CBC) quality control package insert, and interview with the operations manager, the laboratory failed to ensure controls were labeled with open date and corrected expiration date in 2018. 1. Observation of the laboratory on June 5, 2018 at 12:15 pm revealed Sysmex CBC controls in the refrigerator in use for quality control testing that were not labeled with open date or corrected expiration date. 2. Review of the Sysmex CBC quality control package insert revealed that opened vials are stable for 14 days. 3. Interview with the operations manager on June 5, 2018 at 12:30 pm confirmed the laboratory failed to label controls with open date and corrected expiration date in 2018.

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:
The laboratory director failed to ensure the quality control program was maintained

(refer to D6020) and failed to ensure the quality assessment program was maintained (refer to D6021) resulting in immediate jeopardy.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of the Sysmex XS-1000i operator's quick users guide, the document titled "Sysmex Evidence-Based Control Limits", the available complete blood count (CBC) instrument quality control (QC) records, the lack of laboratory director review of records, and interview with the operations manager, the laboratory director failed to ensure the quality control program was maintained in 2016, 2017, and 2018 resulting in immediate jeopardy. The findings include: 1. Observation of the laboratory on June 5, 2018 at 12:15 pm revealed the Sysmex XS-1000i CBC instrument in use for patient testing. 2. Review of the Sysmex quick users guide revealed the following for "new lot registration": For empty QC files the appropriate control level must be selected, the lot number manually entered and the "limit range %" for each parameter entered. The information input must be verified. When reusing QC files, the old QC data is deleted, the lot number entered, and the limit range % must be verified for each parameter. 3. Review of the Sysmex quick users guide obtained from Siemens technical assistance center on June 7, 2018 at 5:13 pm revealed the following for establishing target values: "analyze each new control level once and compare to the assay sheet." "Analyze New Lot control at least 10 times before Auto Setting Targets." "Minimum of 5 days, 2 points per day." After auto setting the target "Verify that the values returned as your analyzer's target values fall within range for each parameter on the Assay Sheet." 4. Review of the Sysmex document titled "Sysmex Evidence-Based Control Limits" obtained from Siemens technical assistance center on June 7, 2018 at 5:13 pm revealed the following limit range % values for the red blood cell (RBC), hemoglobin (HGB), hematocrit (HCT), platelet (PLT) and white blood cell (WBC) analytes for the Sysmex XS 1000i instrument: Level 1 Level 2 Level 3 RBC 5.0 4.0 4.0 HGB 6.0 4.3 4.2 HCT 6.0 5.1 5.0 PLT 23.0 12.0 9.7 WBC 11.4 7.8 7.8 5. Review of the laboratory's available quality control records and instrument quality control settings for the Sysmex XS-1000i revealed the following: Lot #s 62990804, 62990805, 62990806 Extremely wide QC limits. No documents available documenting verification of target and limit range % values. Review of the laboratory's report documenting peer comparison printed at the time of the survey revealed approximate in use dates from 11.21.2016 to 01.13.2017. Lot #s 80160804, 80160805, 80160806 Instrument QC setting for limit range % = 100% for RBC, HGB, HCT, PLT, WBC. No documents available documenting verification of target and limit range % value. Review of the laboratory's cumulative QC data reprinted from the instrument at the time of survey revealed in use dates from approximately 02.12.2018 to 04.06.2018. Lot # 80720804, expiration date 06.03.2018 Instrument QC setting for limit range % = 100% for RBC, HGB, HCT, PLT, WBC. No documents available documenting verification of target and limit range % values. Review of the laboratory's cumulative QC data reprinted from

the instrument at the time of survey revealed in use dates from approximately 04.09.2018 to 06.01.2018. 6. No records were available for the past two years to include: laboratory director review of quality control; documentation of verification of QC target compared to manufacturer's package insert; documentation of verification of QC limit range % compared to manufacturer's stated limit range % values; clear dates the QC lots were placed in use for patient testing. 7. Interview with the operations manager on June 5, 2018 at 9:00 pm revealed the following: The laboratory uses evidence based limits as recommended by the manufacturer, but was unsure what the correct limit range % value was suppose to be for each parameter. No document could be located that provided the manufacturer's correct limit range % value. The QC files used for maintaining the above lot numbers had incorrect limit range % values assigned. The laboratory director reviews the quality control cumulative data and statistics on a regular basis and the QC range in use is included on this report. The laboratory reports approximately 30 patient CBCs per day and a total of approximately 3400 patients could be affected by the period these lot numbers were in use. The operations manager confirmed the laboratory director failed to ensure the quality control program was maintained in 2016, 2017, and 2018.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on review the policy titled "Quality Assurance Reviews," the document used for recording quality assessment reviews, and interview with the operations manager, the laboratory director failed to ensure the quality assessment program was maintained in 2016, 2017, and 2018 resulting in immediate jeopardy. The findings include: 1. Review of the policy titled "Quality Assurance Review" revealed the following statement: "These reviews are done at least quarterly." 2. Review of the documents used for recording quality assessment revealed the following: No quality assessment documents were available for the third and fourth quarter of 2016, the first and second quarter of 2017, and the first quarter in 2018. The quality assessments dated Aug 2017 and Dec 2017 were not signed by the laboratory director. 3. Interview with the operations manager on June 5, 2018 at 6:30 pm confirmed no quality assessment documents were available for third and fourth quarter of 2016, the first and second quarter of 2017, and the first quarter in 2018; there was no lab director signature on the reviews dated Aug 2017 and Dec 2017 and the laboratory director failed to ensure the quality assessment program was maintained in 2016, 2017, and 2018.