

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0315382	(X3) Date Survey Completed 05/16/2019
Name of Provider or Supplier Baptist Memorial Medical Group Inc-Ucdc	Street Address, City, State 1412 East Reelfoot Ave, Union City, 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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: The laboratory failed to maintain satisfactory participation in three out of three proficiency testing events for automated white blood cell (WBC) differential, resulting the second unsuccessful PT occurrence for the automated WBC differential analyte. (Refer to D2130)</p>
D2130	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive</p>

events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on a desk review of the Centers for Medicare and Medicaid Services Casper Form 155 (CMS 155) and the laboratory's 2018 events two and three, and 2019 event one proficiency testing records, the laboratory failed to maintain satisfactory performance in three out three consecutive events for the white blood cell (WBC) differential, resulting in the second unsuccessful occurrence for the WBC differential. The findings include: 1) Review of the CMS 155 revealed the following unsatisfactory WBC differential scores: 2018 event two 53%, 2018 event three 13%, 2019 event one 60%. 2) Review of the laboratory 2018 event two evaluation report revealed unacceptable scores for WBC differential as follows: Granulocytes %-sample numbers HEM-06, Hem-07, Hem-10; Lymphocytes %-sample number HEM-06; Monocytes/Mids %- sample numbers HEM-06, HEM-07, HEM-10, resulting in an overall score for the WBC differential of 53%. 3) Review of the laboratory 2018 event three evaluation report revealed unacceptable scores for WBC differential as follows: Granulocytes %-sample numbers HEM-11, HEM-12, HEM-13, HEM-14, HEM-15; Lymphocytes %-sample numbers HEM-11, HEM-13, HEM-14; Monocytes/Mids %-sample numbers HEM-11, HEM-12, HEM-13, HEM-14, HEM-15, resulting in an overall score for the WBC differential of 13%. 4) Review of the laboratory 2019 event one evaluation report revealed unacceptable scores for WBC differential as follows: Granulocytes %-sample numbers HEM-03, HEM-05; Monocytes/Mids% HEM-01, HEM-03, HEM-04, HEM-05, resulting in an overall score for the WBC differential of 60% and the second unsuccessful PT occurrence. The laboratory director failed to ensure successful PT compliance.

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 maintain compliance with successful white blood cell (WBC) differential analyte proficiency testing (PT) for three consecutive events and failed to follow the approved allegation of compliance (AOC) for the WBC differential analyte, resulting in the second unsuccessful PT occurrence for the WBC differential analyte. (Refer to D6004)

D6004

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or

she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on a desk review of the Centers for Medicare and Medicaid Services Casper report 155 (CMS 155), the laboratory's 2018 event two, 2018 event three, and 2019 event one proficiency testing (PT) evaluation reports and the laboratory's Allegation of Compliance (AOC), the laboratory director failed to follow the approved January 25, 2019 AOC for the WBC differential analyte, resulting in the second unsuccessful PT occurrence for the WBC differential analyte. The findings include: 1) Review of the CMS 155 report and the laboratory's 2018 event two and three, and 2019 event one PT evaluation reports revealed the WBC differential scores as follows: 2018 event two = 53%, 2018 event three = 13%, 2019 event one = 60%. 2) Review of the laboratory's AOC date January 25, 2019, in reference to a previous failure to maintain compliance with successful PT, signed by the laboratory director on February 5, 2019 revealed the following statements: "To prevent these deficiencies from reoccurring the following will be done. TP will be trained to have a second person review results before final submission is done, to prevent clerical error. Training also of TP to monitor QC results for possible trending or shifts that might suggest need for calibration. TC will monitor this clinic bi-monthly to prevent this from reoccurring."