

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0666807	(X3) Date Survey Completed 09/26/2022
Name of Provider or Supplier Baptist Memorial Health Care	Street Address, City, State 7424 Hwy 64 Ste 111, 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
D0000	The following condition level deficiencies were cited: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director, Moderate Complexity
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: Based on a desk review of the Center for Medicare and Medicaid Services Casper Report 0155D (CMS 155), the laboratory's American Proficiency Institute (API) proficiency testing records, and staff interview, the laboratory failed to maintain</p>

	<p>satisfactory proficiency testing (PT) performance for the automated white blood cell differential (WBC Diff) for three out of five testing events, resulting in non-initial unsuccessful PT participation. (Refer to D2130)</p>
<p>D2130</p>	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on a desk review survey of the CMS 155, the laboratory's 2021 and 2022 API PT records, and phone interview with the laboratory liaison, the laboratory failed to maintain satisfactory performance in three out of five PT events for the WBC Diff analyte, resulting in non-initial unsuccessful PT participation. The findings include: 1. Review of the CMS 155 revealed the following unsatisfactory PT scores for the WBC Diff analyte: 2021 Event one: 36% 2021 Event three: 28% 2022 Event two: 60% 2. Review of the laboratory's API PT performance evaluation records revealed the following unsatisfactory scores for WBC Diff analyte: 2021 Event one: 36% 2021 Event three: 28% 2022 Event two: 60% 3. Phone interview with the laboratory liaison on September 26, 2022 at 4:40 pm confirmed the survey findings.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of the CMS 155 report, the laboratory's API PT records, and interview with the laboratory liaison, the laboratory director failed to ensure the laboratory performed PT in such a manner as to achieve and maintain satisfactory performance with successful PT for the WBC Diff analyte, resulting in non-initial unsuccessful PT participation. (Refer to D6016)</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <p>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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;</p> <p>This STANDARD is not met as evidenced by: Based on a desk review survey of the CMS 155 and the laboratory's 2021 and 2022 API PT evaluation records, staff interview, and laboratory communication, the laboratory director failed to ensure the laboratory performed PT in such a manner as</p>

to achieve and maintain satisfactory performance, resulting in unsatisfactory performance for three out of five PT events for the WBC Diff analyte, and non-initial unsuccessful PT participation. Refer to D2130.