

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0300241	(X3) Date Survey Completed 09/20/2018
Name of Provider or Supplier Bbh P & Scn Forestdale	Street Address, City, State 1480 Forestdale Boulevard, Birmingham, AL	
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: Based on a review of the CMS Casper reports (#153, #155), a review of API (American Proficiency Institute) performance evaluations and an interview with the Technical Consultant (TC), the surveyor determined the laboratory failed to successfully participate in three consecutive testing events for RBC (Red Blood Cell Count, Hematology testing). These failures resulted in non-initial, unsuccessful proficiency testing participation for the laboratory. The findings include: 1. A review of the Casper reports #153/#155 revealed the laboratory failed to successfully participate in proficiency testing for RBC for three consecutive testing events, as noted below: a) The laboratory scored 20 % RBC for Event #3, 2017 b) The</p>

	<p>laboratory scored 20 % RBC for Event #1, 2018 c) The laboratory scored 60 % RBC for Event #2, 2018 2. A review of the API performance evaluations for the laboratory confirmed the 20 % RBC scores for Event #3, 2017 and Event #1, 2018, and the 60 % score for Event #2, 2018. 3. The TC left a voice mail message for the State Agency on 9/11/18 at 11:09 AM, inquiring about the failures. The surveyor returned the call on 9/14/18, and the TC confirmed the laboratory failed the RBC testing as described in the above paragraphs.</p>
D2130	<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 review of the CMS Casper reports (#153, #155), a review of API (American Proficiency Institute) performance evaluations and an interview with the Technical Consultant (TC), the surveyor determined the laboratory failed to achieve satisfactory performance of proficiency testing for three consecutive testing events for RBC (Red Blood Cell Count, Hematology testing). These failures resulted in non-initial, unsuccessful proficiency testing participation for the laboratory. The findings include: 1. Refer to D2016.</p>
D6000	<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 a review of the CMS Casper reports (#153, #155), a review of API (American Proficiency Institute) performance evaluations and an interview with the Technical Consultant (TC), the surveyor determined the Laboratory Director failed to ensure the analytical systems were maintained to assure acceptable analytical performance and quality of laboratory services. The laboratory failed RBC proficiency testing (Red Blood Cell Count, Hematology) for three consecutive testing events, resulting in non-initial, unsuccessful proficiency testing participation for the laboratory. The findings include: 1. A review of the Casper reports #153/#155 revealed the laboratory failed to successfully participate in proficiency testing for RBC for three consecutive testing events, as noted below: a) The laboratory scored 20 % RBC for Event #3, 2017 b) The laboratory scored 20 % RBC for Event #1, 2018 c) The laboratory scored 60 % RBC for Event #2, 2018 2. A review of the API performance evaluations for the laboratory confirmed the 20 % RBC scores for Event #3, 2017 and Event #1, 2018, and the 60 % score for Event #2, 2018. 3. The TC left a voice mail message for the State Agency on 9/11/18 at 11:09 AM, inquiring about the failures. The surveyor returned the call on 9/14/18, and the TC confirmed the laboratory failed the RBC testing as described in the above paragraphs.</p>
D6023	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6)</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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

This STANDARD is not met as evidenced by:

Based on a review of the CMS Casper reports (#153, #155), a review of API (American Proficiency Institute) performance evaluations and an interview with the Technical Consultant (TC), the surveyor determined the Laboratory Director failed to ensure the analytical systems were maintained to assure acceptable analytical performance and quality of laboratory services. The laboratory failed RBC proficiency testing (Red Blood Cell Count, Hematology) for three consecutive testing events, resulting in non-initial, unsuccessful proficiency testing participation for the laboratory. The findings include: 1. Refer to D6000. Patricia Watson, BS, MT (ASCP) Licensure and Certification Supervisor