

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D1086984	(X3) Date Survey Completed 01/08/2019
Name of Provider or Supplier Bbh Pcn Calera	Street Address, City, State 206 Highway 304, Calera, 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 API (American Proficiency Institute) proficiency testing evaluations and the CASPER reports (#153/#155), the surveyor determined the laboratory failed to successfully participate in proficiency testing for the WBC Differential (White Blood Cell Differential) for two of three consecutive testing events, Events #1 and #3 of 2018. These failures resulted in the laboratory's initial unsuccessful participation. The findings include: 1. The laboratory scored seventy-three percent (73 %) for the WBC Differential for Event #1 and #3 of 2018. 2. These failures of two of three consecutive testing events resulted in the laboratory's initial unsuccessful proficiency testing participation.</p>

D2130

HEMATOLOGY

CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on a review of API (American Proficiency Institute) proficiency testing evaluations and the CASPER reports (#153/#155), the surveyor determined the laboratory failed to satisfactorily perform in proficiency testing the WBC Differential (White Blood Cell Differential) for two of three consecutive testing events, Events #1 and #3 of 2018. These failures resulted in the laboratory's initial unsuccessful participation. The findings include: 1. The laboratory scored seventy-three percent (73 %) for the WBC Differential for Event #1 and #3 of 2018. 2. These failures of two of three consecutive testing events resulted in the laboratory's initial unsuccessful proficiency testing participation.