

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2106017	(X3) Date Survey Completed 05/19/2020
Name of Provider or Supplier Brigs Center For Cancer Care	Street Address, City, State 1400 Dowell Springs Blvd Ste 220, Knoxville, 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: ===== Hematology: The laboratory failed to maintain satisfactory participation in two consecutive events for the red blood cell (RBC) analyte, resulting in the first unsuccessful proficiency testing (PT) occurrence for the RBC analyte. (Refer to D2130) =====</p>
D2130	<p>HEMATOLOGY CFR(s): 493.851(f)</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.

This STANDARD is not met as evidenced by:

===== Based on a desk review of the CMS CASPER Report 0155D and the laboratory's 2019/2020 Proficiency Testing (PT) performance summary records from the API Proficiency Testing program, the laboratory failed to maintain satisfactory performance for the RBC (Red Blood Cell) analyte in the 3rd event of 2019 and 1st event of 2020, resulting in the first unsuccessful PT occurrence. The findings include: 1. A review of the CMS 0155D report revealed the RBC analyte scores for the 3rd event of 2019 and the 1st event of 2020 were 40%. 2. A review of the laboratory's API Proficiency Testing records revealed the 2019 3rd event had unacceptable performance for RBC's resulting in a 40% score. 3. A review of the laboratory's API Proficiency Testing records revealed the 2020 1st event had unacceptable performance for RBC's resulting in a 40% score, resulting in the first unsuccessful PT occurrence.

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