

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D1069700	<b>(X3) Date Survey Completed</b>  12/20/2019
<b>Name of Provider or Supplier</b>  Gulfcoast Oncology	<b>Street Address, City, State</b>  3535 Gates Blvd Ste 100, Port Arthur, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> 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 review of an Individual Laboratory Profile (CASPER Report 0155D) dated 12-06-2019, confirmed by proficiency testing (PT) results provided on 12-19-2019 by the American Association of Bioanalysts (AAB), the laboratory failed to successfully participate in an approved PT program for the specialty of hematology in 2019. Refer to D 2131. .</p>
<b>D2123</b>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(c)</p>

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:  
. Based on review of an Individual Laboratory Profile (CASPER Report 0155D) dated 12-06-2019, confirmed by proficiency testing (PT) results provided on 12-19-2019 by the American Association of Bioanalysts (AAB), the laboratory failed to participate in PT for the specialty of hematology in the second and third quarter testing events of 2019. Refer to D 2131. .

**D2131**

**HEMATOLOGY**  
CFR(s): 493.851(g)

Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:  
. Based on review of an Individual Laboratory Profile (CASPER Report 0155D) dated 12-06-2019, confirmed by proficiency testing (PT) results provided on 12-19-2019 by the American Association of Bioanalysts (AAB), the laboratory failed to achieve overall event scores of satisfactory performance for two consecutive testing events in 2019 in the specialty of hematology. Findings: 1. Review of the CASPER Report 0155D run date 12-06-2019 revealed the following scores for the second and third quarters of 2019: 0760 Hematology-2019 EVENT 2ND Q 3RD Q WBC DIFF 0 0 RBC 0 0 HCT 0 0 HGB 0 0 WBC 0 0 PLATELETS 0 0 OVERALL 0 0 2. The above scores were confirmed by the AAB in documents provided on request dated 12-19-2019. In both events results were marked "no data received," indicating that the laboratory had failed to provide PT results for grading. No indication of instrument or facility issues was included.