

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  18D0945636	<b>(X3) Date Survey Completed</b>  05/13/2024
<b>Name of Provider or Supplier</b>  Commonwealth Cancer Center	<b>Street Address, City, State</b>  95 Bogle Office Park Drive, Somerset, KY	
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>D0000</b>	The following deficiencies are a result of a desk review of proficiency testing (PT) scores obtained from the national database and verified with the PT company. The facility was found to be out of compliance with the conditions of the Clinical Laboratory Improvement Amendments (CLIA) program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: D2016 - SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) D6000 - MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403
<b>D2016</b>	<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 PT desk review of the Certification and Survey Provider Enhanced</p>

	<p>Reporting (CASPER)-0155 and American Proficiency Institute (API) 2023 records (2nd and 3rd events) and 2024 records (1st Event), the laboratory failed to successfully participate in a PT program approved by United States Department of Health and Human Services (HHS), for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory failed to successfully participate in the specialty of Hematology for Cell Identification or White Blood Cell Differential (Cell I.D. or WBC Diff) (Refer to D2130).</p>
<b>D2131</b>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a PT desk review of the CASPER-0155 report and API 2023 records (3rd event) and 2024 records (1st event), the laboratory failed to achieve overall satisfactory performance (80% or greater) for 2 of 2 consecutive events in the specialty of Hematology. The findings include: 1. Review of the CASPER-0155 report revealed the following: Hematology 2023- 3rd Event Laboratory received an unsatisfactory score of 76% for Hematology. Hematology 2024- 1st Event Laboratory received an unsatisfactory score of 66% for Hematology. 2. A PT desk review from API 2023 and 2024 PT records confirmed the above findings.</p>
<b>D6000</b>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> 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 desk review of laboratory PT performance, it was revealed that the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6016.</p>
<b>D6016</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> 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 of PT results, it was revealed that the laboratory director failed to ensure the overall quality of the laboratory services provided. The laboratory</p>

director failed to ensure successful participation in an HHS approved PT program.  
Refer to D2130.