Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0945636	(X3) Date Survey Completed 06/14/2024
Name of Provider or Supplier Commonwealth Cancer Center	**Street Address, City, State** 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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: Based on a proficiency testing desk review of the Certification and Survey Provider

	Enhanced Reporting (CASPER)-0155 and American Proficiency Institute (API) 2023 records (3rd event) and 2024 records (1st Event), the laboratory failed to successfully participate in a proficiency testing program. The laboratory failed to successfully participate in the specialty of Hematology for Red Blood Cell (RBC) for 2 of 2 testing events. (Refer to D2130).
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 proficiency testing desk review of the CASPER-0155 Individual Laboratory Report and API 2023 records (3rd event) and 2024 (1st event), the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte in 2 of 2 consecutive testing events in Hematology, subspecialty of RBC. The findings include: 1. Review of the CASPER -0155 report revealed the following: Hematology 2023- 3rd Event Laboratory received an unsatisfactory score of 60% for RBC. Hematology 2024- 1st Event Laboratory received an unsatisfactory score of 60% for RBC. 2. A proficiency testing desk review from API 2023 and 2024 proficiency testing records confirmed the above findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 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. This CONDITION is not met as evidenced by: Based on a desk review of laboratory proficiency testing performance, it was revealed that the laboratory director failed to provide overall management and direction of the laboratory services to ensure successful PT participation of RBC testing during 2 of 2 testing events. (Refer to D6016).
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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; This STANDARD is not met as evidenced by: Based on a desk review of proficiency testing results, it was revealed that the laboratory director failed to ensure the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation of RBC

	testing during 2 of 2 testing events in an HHS approved proficiency testing program. (Refer to D2130).