Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0858571	01/31/2023
Name of Provider or Supplier	**Street Address, City, State**	
Oncology Hematology Care Center Incorporate	501 Riverside Drive, Waycross, GA	

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	A proficiency testing desk review was completed on January 31, 2023. At the time of the review, the laboratory was not in compliance with the Clinical Laboratory Improvement Amendments of 1988, 42 CFR 493.1 through 42 CFR 493.1780. The following condition deficiencies were cited: D2016 - 42 CFR 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 CFR 493.1403 Condition: Moderate Complex Laboratory Director
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 review of the CMS CASPER 155 report and review of Medical Laboratory Evaluation (MLE) reports, the laboratory failed to maintain satisfactory proficiency

	testing (PT) participation for automated hematocrit (HCT) in 2021 event 2 and 2022 events 1 and 3, resulting in the non-initial unsuccessful participation for HCT. Refer to D 2130
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 review of the Centers for Medicare and Medicaid (CMS) CASPER 155 REPORT and review of the Medical Laboratory Evaluation (MLE) proficiency testing (PT) reports, the laboratory failed to maintain satisfactory participation in three testing events (2nd event of 2021 and 1st and 3rd events of 2022), resulting in the non-initial unsuccessful participation for automated hematocrit (HCT). Findings: 1. A review of Casper Reports 153 and 155 revealed the laboratory failed HCT on the following: 2021 Event 2 HCT Score 60% 2022 Event 1 HCT Score 40% 2022 Event 3 HCT Score 20% 2. A review of the laboratory's proficiency testing reports from Medical Laboratory Evaluation (MLE) confirmed the laboratory failed HCT with the aforementioned scores.
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 review of the Centers for Medicare and Medicaid (CMS) CASPER 155 report and review of Medical Laboratory Evaluation (MLE) reports, the laboratory director failed to provide overall management and direction for PT performance. The laboratory director failed to ensure PT samples were tested as required. 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 review of the CMS CASPER 155 report and the Medical Laboratory Evaluation (MLE) 2021 and 2022 Proficiency testing (PT) evaluation reports, the laboratory director failed to maintain compliance with successful PT for three events

	(2021 event 2 and 2022 events 1 & 3) for hematocrit (HCT) resulting in the non-initial unsuccessful participation for HCT. Refer to D 2130