Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D0918834	10/23/2023
Name of Provider or Supplier	**Street Address, City, State**	
South Carolina Oncology Associates, Pa	1105 North Lafayette Drive, Sumter, SC	

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 Recertification Survey was initiated on 10/23/2023 and concluded on 10/23/2023. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
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 Clinical Laboratory Quality Assurance Program, graded reports from American Proficiency Institute (API), CASPER Report 0096D (CLIA Application and Survey Summary), and laboratory manager interview, the laboratory

	failed to successfully participate in proficiency testing the specialty of chemistry, the analyte sodium (NA) for 2 out of 3 consecutive proficiency testing events reviewed in 2023 (2023, Events 1 and 2). Findings included: See D2087, D2096
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the Clinical Laboratory Quality Assurance Program, graded reports from American Proficiency Institute (API), CMS CASPER Report 0096D (CLIA Application and Survey Summary), and laboratory manager interview, the laboratory failed to successfully participate in proficiency testing the specialty of chemistry, the analyte sodium (NA) for 2 out of 3 consecutive proficiency testing events reviewed in 2023 (2023, Events 1 and 2). Findings included: 1. A review of the Clinical Laboratory Quality Assurance Program, revised July 2018, revealed the following: a. The regulations further stipulate that for each testing event, the laboratory must obtain acceptable results in 80% or more of the five challenges for each analyte tested, and must obtain overall acceptable results in at least 80% or more of all challenges for all analytes tested in a given specialty or subspecialty. Failure to achieve this degree of acceptability is designated unsatisfactory performance for that testing event (mailing) in the given specialty/subspecialty. If the laboratory performs unsatisfactorily in a given specialty or subspecialty in two consecutive testing events, or in two of three consecutive testing events, proposed regulation stipulates that the laboratory to undertake documented remedial action or suspend testing for the analyte (s) in question. 2. A review of graded reports from API revealed the following proficiency testing scores for the analyte NA for the laboratory: a. API Proficiency Testing Performance Evaluation 2023 Chemistry Core 1st Event, reviewed and signed by the Laboratory Director on 03/06/2023, revealed the Performance Summary for the analyte NA was 60%. b. API Proficiency Testing Performance Evaluation 2023 Chemistry Core 2nd Event, reviewed and signed by the Laboratory Director on 07/07 /2023, revealed the Performance Summary for the analyte NA was 40%. 3. A review of the CMS Casper Report 0096D revealed the proficiency testing score for the analyte NA for event 1 was 60%, and the proficiency testing score for event 2 was 40%. 4. During an interview on 10/23/2023 at 11:15 AM, the Laboratory Manager confirmed the test scores were unsatisfactory and that the laboratory failed to successfully participate for two consecutive events for the analyte sodium.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in 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 the Clinical Laboratory Quality Assurance Program, graded reports from American Proficiency Institute (API), CASPER Report 0096D (CLIA Application and Survey Summary), and laboratory manager interview, the laboratory

	failed to successfully participate in proficiency testing the specialty of chemistry, the analyte sodium (NA) for 2 out of 3 consecutive proficiency testing events reviewed in 2023 (2023, Events 1 and 2). Findings included: See D2087