

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0697769	(X3) Date Survey Completed 10/07/2019
Name of Provider or Supplier Cancer Specialists Llc	Street Address, City, State 2 Shircliff Way Mary Virginia Terry Cancer Center, Jacksonville, FL	
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	At the time of the announced, onsite recertification survey, Cancer Specialists Llc was found to not be in compliance with the CLIA laboratory requirements of 42 CFR 493.
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory was not enrolled in proficiency testing (PT) for the first event in 2019 for the specialty of Hematology. Findings include: Review of PT records showed that the laboratory had failed to enroll in proficiency testing for the first event in 2019. Testing performed under this specialty includes: White Blood Cell Count, Red Blood Cell Count, Hemoglobin, Hematocrit, Platelet count, WBC Differential, and Manual WBC Differential. The interview with the Laboratory Supervisor on 10/7/19 at 11:30am confirmed the laboratory had not been enrolled in proficiency testing for the first testing event of 2019.</p>
D2123	HEMATOLOGY CFR(s): 493.851(c)

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 record review and interview, the laboratory failed to participate in proficiency testing (PT) for the third testing event in 2018 for the specialty of Hematology . Finding include: Review of the American Association of Bioanalysts (AAB) records for 2018 Hematology 3rd Event showed the laboratory received a score of 0% for all analytes to be tested. The Laboratory Manager confirmed during the interview on 10/7/19 at 11:30AM that the laboratory had mailed the results to the proficiency testing company but the results were never received resulting in the 0% score.

D6015

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)

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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:
Based on review of AAB proficiency testing records and staff interview, the Laboratory Director failed to recognize that the laboratory was not enrolled in proficiency testing (PT) for the first testing event of 2019. Findings Include: Review of PT records showed that the laboratory had failed to enroll in proficiency testing for the first event in 2019. Testing performed under this specialty includes: White Blood Cell Count, Red Blood Cell Count, Hemoglobin, Hematocrit, Platelet count, WBC Differential, and Manual WBC Differential. The interview with the Laboratory Supervisor on 10/7/19 at 11:30am confirmed the laboratory had not been enrolled in proficiency testing for the first testing event of 2019.