

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D2139249	(X3) Date Survey Completed 06/17/2019
Name of Provider or Supplier Scl Health Cancer Centers Of Colorado	Street Address, City, State 1601 Lowell Blvd, Denver, CO	
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
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 the lack of proficiency testing (PT) records and staff interview, the laboratory failed to enroll in an HHS-approved PT program for 2019 in the specialty of hematology for complete blood counts (CBCs) for which it seeks certification since testing began in March 2019. Findings include: a. The laboratory tests patient blood specimens for CBCs using the Sysmex XS 1000i hematology analyzer. b. No documentation existed to show that the laboratory had enrolled in an approved PT program for 2019 for CBC testing performed in the laboratory. c. On 6-17-19 at about 10:00 a.m., staff stated they were unaware that participating in a PT program was required for these analytes. d. On 6-17-19 at about 10:30 a.m., staff confirmed the laboratory hadn't enrolled in a PT program for CBC testing for 2019 as required by subpart I of the federal CLIA regulations.</p>