

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0702926	(X3) Date Survey Completed 01/10/2018
Name of Provider or Supplier South Carolina Oncology Associates Pa	Street Address, City, State 166 Stoneridge Drive, Columbia, 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
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: During an onsite recertification survey on 1/10/2018, based on direct observation, record review, and testing personnel interview, the laboratory failed to document twice a year comparison for PT/INR testing on the Abbott I-Stat and ACL coagulation analyzer for the year 2017. Findings include: 1. During the laboratory tour at 9:45 am, Abbott I-Stat meters were observed in the laboratory. Testing personnel stated that PT /INR was being performed on the I-Stat. 2. Review of the installation and validation records for the I-Stat revealed that PT/INR testing on the instrument began in January 2017. A test method comparison was performed in January 2017 as part of the instrument validation. 3. Testing personnel stated during an interview at 1:45 pm that primary PT/INR testing was being performed on the I-Stat, and that the ACL was being used for confirmation or back up. 4. During the exit interview at 3:30 pm, testing personnel confirmed that an instument comparison was not performed twice per year as required.</p>