

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0977771	(X3) Date Survey Completed 02/12/2018
Name of Provider or Supplier Cancer Specialists Llc	Street Address, City, State 700 3rd Street Suite 302, Neptune Beach, 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
D2122	<p>HEMATOLOGY CFR(s): 493.851(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the facility failed to have a passing proficiency test score for the first testing event of 2016 for the speciality of Hematology. The findings include: The 2/12/18 record review of the American Proficiency Institute testing results for the first event of 2016 showed a score of 47% for White Blood Cell Differential, 60% Granulocytes, 40% Lymphocytes, and 40% Monocytes. The 2/12/18 interview with the laboratory manager at 1:00pm confirmed the laboratory had failed proficiency testing. .</p>
D5481	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with laboratory staff, the laboratory failed to have quality controls (QC) in acceptable range prior to reporting patient results for 1 of 31 days in August 2016. The findings include: Record review of the laboratory's QC records for August 2016 showed on 8/19/2016, the normal level control for the hematology test of Platelet was out of range at 258 (acceptable range was 174-244), the high level control for the hematology test of Platelet was 588 (acceptable range</p>

was 395-565). The laboratory failed to document corrective action and performed /reported testing. During interview on 2/12/18, the laboratory manager confirmed the QC was out of range for the two control levels on 8/19/2016 and verified that patient testing should not have been performed.