

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0943328	(X3) Date Survey Completed 03/07/2018
Name of Provider or Supplier St Louis Cancer Care	Street Address, City, State 226 S Woods Mill Ste 45w, Chesterfield, MO	
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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of policies and interview with the lab supervisor the laboratory failed to follow policy and review 10 of 24 months of hematology quality control (QC) and one of six proficiency testing (PT) for 2016 and 2017. Findings: 1. Laboratory policy states "all MLE reports, proficiency testing, or any lab evaluation reports will be signed by" lab director or technical consultant "after reviewing and taking any corrective action necessary." 2. Review of PT showed the technical consultant did not review MLE #1 in 2017. 3. Review of hematology quality control showed the technical consultant did not review QC from March 2016 through December 2017. 4. Interview with the lab supervisor on March 7, 2018 at 12:30 PM confirmed the laboratory failed to follow policy and review all QC and PT.</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of hematology cell dyn maintenance procedure and interview with the lab supervisor the laboratory failed to perform preventive maintenance as recommended by the manufacturer. Findings: 1. Review of manufacturer maintenance for the cell dyn hematology analyzer states "cleaning the system with a bleach solution is performed monthly." Laboratory failed to bleach the cell dyn in November 2016 and August 2017. 2. Interview with the lab supervisor on March 7, 2018 at 12:30 PM confirmed the laboratory failed to perform bleach cleaning monthly as recommended by the manufacturer.