Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0943328	07/09/2026
Name of Provider or Supplier	**Street Address, City, State**	
St Louis Cancer Care	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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the performance verification procedures for the Diatron Abacus 3 CP analyzer and patient results and interview with the laboratory personnel manager, the laboratory failed to verify performance specifications prior to reporting patient test results. Findings: 1. Review of the performance verification procedures for the Diatron Abacus 3 CP analyzer showed the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the analytes: white blood cell (WBC), red blood cell (RBC), hemoglobin, hematocrit (HCT), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), red blood cell distribution width (RDW), platelets, mean platelet volume (MPV), percent granulocytes, percent lymphocytes, percent monocytes, absolute granulocytes, absolute lymphocytes, and absolute monocytes prior to the beginning of patient testing in June 2024. 2. The laboratory performs approximately 5,805 hematology patient tests annually. 3. Interview with the laboratory personnel manager on July 8, 2026 at 11:30 AM confirmed the laboratory failed to verify performance specifications prior to reporting patient test results.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on review of verification procedures and patient reports and interview with the laboratory personnel manager, the laboratory director (LD) failed to ensure that verification procedures for the Diatron Abacus 3 CP analyzer were adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method prior to patient testing. Findings: 1. Review of the Diatron Abacus 3 CP analyzer verification procedures showed no documentation to show verification procedures for the Diatron Abacus 3 CP analyzer were adequate, reviewed and approved by the laboratory director for accuracy, precision, reportable range of test results, and verification that the manufacturer's reference intervals (normal values) were appropriate for the laboratory's patient population for the analytes: white blood cell (WBC), red blood cell (RBC), hemoglobin, hematocrit (HCT), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), red blood cell distribution width (RDW), platelets, mean platelet volume (MPV), percent granulocytes, percent lymphocytes, percent monocytes, absolute granulocytes, absolute lymphocytes, and absolute monocytes prior to the beginning of patient testing in June 2024. 2. The laboratory performs approximately 5,805 hematology patient tests annually. 3. Interview with the laboratory personnel manager on July 8, 2026 at 11:30 AM confirmed the LD failed to ensure that verification procedures for the Diatron Abacus 3 CP analyzer were adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method prior to patient testing.