

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  26D0437600	<b>(X3) Date Survey Completed</b>  06/02/2026
<b>Name of Provider or Supplier</b>  St Louis Cancer Care	<b>Street Address, City, State</b>  3440 Depaul Lane Ste 201, Bridgeton, MO	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2009</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) policy, PT records for 2024, 2025 and to date 2026, patient hematology results and interview with the laboratory personnel manager, the laboratory failed to provide attestation documentation for seven of seven PT testing events. Findings: 1. Review of "Proficiency Testing Policy Revised 3/29 /10" states "All attestation sheets will be signed and dated with the nurse or nurses who performed the test". 2. Review of PT records for 2024, 2025, and to date 2026 showed the laboratory could not provide attestation records for testing personnel to show routine integration of samples into the patient workload for the following proficiency testing events: 2024 American Association of Bioanalysts (AAB)-Medical Laboratory Evaluation (MLE) Hematology M1 Event 2024 AAB-MLE Hematology M2 Event 2024 AAB-MLE Hematology M3 Event 2025 AAB-MLE Hematology M1 Event 2025 AAB-MLE Hematology M2 Event 2025 AAB-MLE Hematology M3 Event 2026 AAB-MLE Hematology M1 Event 3. Review of patient hematology results showed the laboratory performs approximately 3,641 CBC's annually. 4. Interview with the laboratory personnel manager on June 2, 2026 at 1:30 PM confirmed the laboratory could not provide attestation records for seven PT testing events in 2024, 2025 and to date 2026.</p>
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) The laboratory must define criteria for those conditions that are essential for</p>

proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on review of Abacus 3CP User Manual, laboratory humidity records, and patient hematology results and interview with the laboratory personnel manager, the laboratory failed to ensure the humidity was maintained for 71 of 251 days. Findings:

1. Review of the Abacus 3CP User Manual states "Operate Abacus 3CP analyzer within a relative humidity range of 10-80%".
2. Review of the laboratory humidity records shows that the humidity in the laboratory where the Abacus 3CP is located was out of range for 71 of 251 days from January 2025 to December 2025.
3. Review of patient's hematology results showed the laboratory performs approximately 3,641 CBC's annually.
4. Interview with the laboratory personnel manager on June 2, 2026 at 1:00 PM confirmed the laboratory failed to ensure the humidity was maintained.