

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D1047704	(X3) Date Survey Completed 05/07/2026
Name of Provider or Supplier Southern Cancer Center Pc	Street Address, City, State 29653 Anchor Cross Blvd, Daphne, AL	
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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation during the laboratory tour, a review of electronic history testing records and an interview with the Technical Supervisor (TS), the laboratory failed to ensure in-date Urine test strip was utilized for the patient Urinalysis Test. The surveyor noted 16 of the 100 test strips were left in the container. The findings include: 1. Direct observation of the Consult Diagnostics 10 SG Urine Reagent Strips revealed Lot URS4040066 was utilized for six days to perform patient Urinalysis testing after it had expired on 04-24-2026. 2. During an interview with the TS, the electronic history testing records revealed 17 patients were performed after 04-24-2026. 3. TS confirmed the above findings during the exit conference on 05-07-2026 at 10:30 AM.</p>
D2077	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(c)</p> <p>(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two</p>

proficiency testing events.

This STANDARD is not met as evidenced by:

Based on reviews of the API (American Proficiency Institute) Proficiency Testing (PT) records and an interview with the Technical Supervisor (TS), the laboratory failed to ensure PT results were submitted before the due date specified by API. This was noted for one of the three 2025 Immunology PT events. The findings include: 1. A review of the API PT records revealed a score of 0 percent due to "Failure to participate" on the 2025 Immunology Event. 2. TS confirmed the above findings during the exit conference on 05-07-2026 at 10:30 AM.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on reviews of the Sysmex XS-1000i Maintenance Log, the XS-1000i Hematology analyzer Quick Guide and an interview with the Technical Supervisor (TS), the laboratory failed to completely document the monthly or 1200 cycles maintenance as per manufacturer's requirements. The surveyor noted two of the 10 maintenances had no documentation from September 2024 through June 2025. The findings include: 1. A review of the 2024-2026 Sysmex XS-1000i Maintenance Logs revealed a place to document the 1200 cycles maintenance for the analyzer. 2. A further review of the Sysmex XS-1000i Maintenance Logs revealed the following months without documentation of the monthly maintenance. A) September 2024 B) June 2025 3. A review of the Sysmex XS-1000i analyzer Quick Guide revealed the manufacturer's maintenance requirement on page 24, "Monthly Rinse Sequence... Perform monthly or every 1200 samples (cycles)..." 4. TS confirmed the above findings during the exit conference on 05-07-2026 at 10:30 AM.