

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2063463	(X3) Date Survey Completed 03/11/2026
Name of Provider or Supplier Southern Cancer Center Pc	Street Address, City, State 669 S Mckenzie Street, Suite 103, Foley, 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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on reviews of the Medica Easy RA Chemistry maintenance records, the Medica Easy RA operator's manual, and an interview with the Laboratory Director (LD), the laboratory failed to document the weekly and monthly maintenances, as per manufacturer's instructions. The surveyor noted 96 of the 96 weeks reviewed from 2024-2026 had no weekly precision test documented and 3 of the 12 months reviewed in 2025 had no monthly maintenance documented. The findings include: 1. A review of the Chemistry maintenance records revealed the 2025 Medica Easy RA maintenance logs were missing the following maintenances. A) Weekly Precision Test from March 2024 through February 2026 B) Monthly in February, March and November 2025 2. A review of the Medica Easy RA operator's manual revealed in Chapter 10, Performing Maintenance, page 10.22, the following instructions. a) "Weekly Testing, you must perform the Precision Test weekly...". b) "Monthly Cleaning, the following are the monthly cleaning...". 3. A further review of the Medica Easy RA operator's manual revealed on page B.1-B.3, the manufacturer's daily, weekly, and monthly logs ready for the lab to use when documenting the recommended analyzer maintenance requirements. 4. The LD confirmed the above findings during the exit conference on 03-11-2026 at 1:31 PM.</p>
D5481	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test</p>

results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on reviews of the 2024-2025 Hematology Quality Control (QC) records for the Sysmex XS-1000i analyzer, the patient electronic history records from the Orchard Harvest Laboratory information System (LIS), and interview with the laboratory Director (LD), the laboratory failed to ensure at least two levels of QC were performed and acceptable, prior to analyzing patient specimens and reporting of Complete Blood Count (CBC) results. The surveyor noted 71 of the 121 days reviewed from the last survey, 02-28-2024, through the current survey, 03-11-2026 were missing the QC documentation. The findings include: 1. A review of the Sysmex XS-1000i QC records revealed no documentation of the three levels of QC performed prior to patient for the following days. A) March 2024, 15 days B) October 2024, 20 days C) January 2025, 20 days D) February 2026, 16 days 2. A review of the Orchard Harvest LIS revealed 2,642 patients' CBC were performed and resulted during the 71 days without QC documentation. 3. The LD confirmed the above findings during the exit conference on 03-11-2026 at 1:31 PM.