

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0304677	(X3) Date Survey Completed 06/18/2025
Name of Provider or Supplier Tanner Medical Center East Alabama	Street Address, City, State 1032 Main Street South, Wedowee, 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
D2130	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Testing (API) proficiency testing (PT) records and an interview with the General Supervisor (GS), the laboratory failed to achieve satisfactory performance for Nucleated Red Blood Cells (nRBC) in two of three 2024 testing events. The findings include: 1. A review of the PT results revealed unsuccessful performance for nRBC's for two consecutive PT events, as follows: A) Year 2024 - 2nd Event: 50% B) Year 2024 - 3rd Event: 50% 2. During an interview on 6/17/2025 at 12:32 PM, the GS confirmed the above findings.</p>
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 a review of the Helmer Cell Washer maintenance records and an interview with the General Supervisor (GS), the Laboratory failed to perform and document monthly maintenance on the Helmer Cell Washer as per the manufacturer's requirements for 15 of 27 months in 2023 through 2025. The findings include: 1. A review of the Helmer Cell Washer records revealed no documentation of monthly</p>

maintenance for the following months: a) March through December 2023. b) January, September, and November 2024. c) April and May 2025. 2. During an interview on 6/18/2025, at 2:32 PM, the GS confirmed the above findings.

D5455

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(v)(g)

(d)(3)(v) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of the iSTAT Chem 8+ QC (Quality Control) records, iSTAT patient log and an interview with the General Supervisor (GS), the Laboratory failed to ensure testing personnel performed the iSTAT QC every 30 days as per the IQCP. The surveyor noted four out of sixteen months reviewed in 2023 through 2025 when QC was not performed as required by the IQCP. The findings include: 1. A review of the iSTAT QC records revealed the laboratory exceeded the 30-day requirements for the Chem 8+ cartridge for the following dates: a) 4/1/2025; 5 patients performed. b) 5/2/2024; 1 patient performed. c) 11/28/2023; 5 patients performed. d) 6/14/2023; 3 patients performed. 2. During an interview on 6/18/2025, at 12:38 PM, the GS confirmed the iSTAT QC is performed every 30 days or new lot.