Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2057960	12/12/2025
Name of Provider or Supplier	**Street Address, City, State**	
Physicians Quality Care	15463 S First St, Milan, TN	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on laboratory observation, review of the laboratory's procedure manual, calibration verification records, and staff interview, the laboratory failed to perform calibration verification every six months as required by procedure for analytes performed on the Alere Triage instrument in 2025 (one of four were not performed when due). The findings include: 1. Laboratory observation on December 12, 2025, at 9:00 a.m. revealed an Alere Triage instrument used to perform Creatine Kinase-MB, Troponin, Myoglobin, and D-dimer analytes. 2. A review of the laboratory's procedure manual revealed the laboratory would verify calibration for the Alere Triage meter every six months. 3. A review of calibration verification documentation revealed that the laboratory failed to perform calibration verifications every six months, as outlined in the laboratory's Quality Assurance Plan. The calibration verification due on October 15, 2025 was not performed until November 12, 2025. 4. The findings were confirmed by the laboratory liaison on December 12, 2025, at 11: 45 a.m.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems

	quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of the laboratory's Quality Control Plan, daily temperature logs, Quality Assurance Plan, quality assessment documentation, and staff interviews, the laboratory's quality assessment process was not effective in identifying and correcting problems on dates when room temperatures were outside the laboratory's stated acceptable range with no corrective action performed. The findings include: 1. A review of the laboratory's "Quality Control Plan" indicated that temperature checks will be recorded daily and "if any are out of acceptable range, corrective action must be documented." 2. A review of daily temperature logs revealed twenty-nine occasions of room temperature readings outside of the stated acceptable range with no corrective action documented between October 2024 and October 2025. In 2024: October 17, November 12, November 13, December 2, December 3, December 4, December 26, December 30, December 31. In 2025: January 9, January 11, January 13, January 14, January 15, February 16, February 21, February 22, February 23, February 24, , February 25, February 26, March 2, April 8, October 10, October 11,, October 12, October 20, October 30, October 31. 3. A review of the procedure titled "Quality Assurance Plan" states that the "plan will evaluate the effectiveness of our policies and procedures, identify problems and make corrections and assure accurate, reliable and prompt performance of testing and reporting results.""Each phase must be addressed, Pre-Analytical, Analytical, and Post-Analytical." "Quality Assurance Review Form - to be filled out each month for each analysis being reviewed." 4. A review of bi-monthly quality assessment documentation revealed that the out-of-range temperatures were not identified, and no corrective action was taken. 5. The laboratory liaison confirmed the findings on December 12, 2025, at 1:58 p.m.