

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0318984	(X3) Date Survey Completed 08/22/2025
Name of Provider or Supplier Family Practice/After Hours Clinic,The	Street Address, City, State 110 Millsaps Drive, Hattiesburg, MS	
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	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's written Individualized Quality Control Plan (IQCP), review of quality control (QC) records, manufacturer's acceptable ranges, and patient test records for the Quidel Triage Meter Pro analyzer from 12/27/2024 through 8/22/2025, the laboratory failed to ensure two levels of external quality control were acceptable for Troponin I for three of the eight months reviewed, when a total of 27 patient Troponin I results were reported. Findings include: 1. Review of the laboratory's written IQCP for the Quidel Triage Meter Pro analyzer revealed the Quality Control Plan of the IQCP stated that external controls would be performed every 30 days, with a new lot or shipment of cartridges, or anytime patient results were questioned. 2. Review of QC printouts from the Quidel Triage Meter Pro analyzer, manufacturer's acceptable ranges, and patient Troponin I results from 12/27/2024 through 8/22/2025 revealed: (a) On 3/20/2025 and 4/3/2025 when external QC was performed, the Level 2 control results were outside the manufacturer's acceptable range for Troponin I. A total of 13 patient Troponin I results were reported from 3/20/25 through 5/1/2025. Acceptable QC results were obtained on 5/2/2025. (b) There were no external controls performed when the 30-day QC was due on 6/2/2025. The next external controls were performed and acceptable on 7/9/2025. A total of 9 patient Troponin I results were reported from 6/2/2025 through 7/8/2025. (c) On 8/6/2025 and 8/22/2025 when the external QC was performed, the Level 2 control results were</p>

outside the manufacturer's acceptable range for Troponin I. A total of 6 patient Troponin I results were reported from 8/9/2025, when the 30-day controls were due, through 8/22/2025.