

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 26D0652268	<b>(X3) Date Survey Completed</b> 11/14/2023
<b>Name of Provider or Supplier</b> Northwest Medical Center	<b>Street Address, City, State</b> 705 N College St, Albany, MO	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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 procedures, review of d-dimer patient results, quality control (QC) records, and interview with the technical supervisor (TS) #2, the laboratory failed to follow the procedure for d-dimer controls for one of twenty-one patient results. Findings: 1. Review of the "D-Dimer ACL Elite-COAG" procedure states "Controls must be tested each time reagents are placed on instrument and patient testing is performed." 2. Review of twenty-one patient results from March 6, 2023 to date November 14, 2023 were performed. 3. Review of the of the quality control records showed on March 27, 2023 the d-dimer QC was not performed with each patient test performed. 4. Interview with TS #2 on November 14, 2023 at 12:00 PM confirmed the laboratory failed to follow procedure for running d-dimer controls.</p>
<b>D5445</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The</p>

laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the Abbott i-STAT 2022 and 2023 quality control (QC) records, review of individualized quality control plan (IQCP), and interview with technical supervisor (TS) #2, the laboratory failed to follow the IQCP for 3 of 22 months. Findings: 1. Review of QC from January 2022 to October 2023 showed no QC was performed for July 2022, September 2022 and March 2023 for EG7+, CG4, and Chem 8 cartridges. 2. Review of IQCP states, "complete QC on each new shipment of cartridges and once every month." 3. Interview with TS #2 on November 14, 2023 at 12:00 PM confirmed the laboratory failed to follow the IQCP for the Abbott i-STAT system.

**D6128**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on the review of employee annual performance evaluations and interview with the technical supervisor (TS) #2, the TS failed to perform annual performance evaluations for 1 of 5 testing personnel (TP). Findings: 1. Review of employees competencies showed the TS failed to perform the annual performance evaluation for TP #2 in 2022. 2. Interview with TS #2 on November 14, 2023 at 12:00 PM confirmed the TS failed to perform the annual performance evaluation for TP #2.