

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 26D2275848	<b>(X3) Date Survey Completed</b> 09/16/2025
<b>Name of Provider or Supplier</b> Jackson Road Medical Building	<b>Street Address, City, State</b> 516 Jackson Road, Boonville, 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>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following:</p> <p>This STANDARD is not met as evidenced by: Based on review of i-STAT chemistry quality control (QC), lack of quality control package inserts, and interview with the technical consultant (TC) #2, the laboratory failed to retain QC package inserts from January 2024 to date September 16, 2025. Findings: 1. Review of chemistry QC showed the laboratory used i-STAT chemistry QC for the analytes: sodium, potassium, chloride, total carbon dioxide, creatinine, glucose, ionized calcium, blood urea nitrogen (BUN), hematocrit, hemoglobin and troponin I 2. Lack of quality control package inserts showed the laboratory failed to retain QC package inserts from January 2024 to date September 16, 2025. 3. Interview with the TC #2 on September 16, 2025, at 2:30 PM, confirmed the laboratory failed to retain i-STAT chemistry QC package inserts.</p>
<b>D5413</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(b)</p> <p>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test</p>

reports.

This STANDARD is not met as evidenced by:

Based on review of the Abbott i-STAT 1 system manual, lack of humidity logs, and interview with the office manager, the laboratory failed to define criteria for humidity in the i-STAT testing area in 2024 and to date September 16, 2025. Findings: 1. Review of the Abbott i-STAT 1 system manual states, "Relative humidity 10-90% non-condensing". 2. Lack of humidity logs showed no documentation of humidity. 3. Interview with the office manager on September 16, 2025, at 3:00 PM confirmed the laboratory failed to define criteria for humidity in the i-STAT testing area.

**D5417**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(d)

(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observation of laboratory supplies during the laboratory tour, and interview with the technical consultant (TC) #2, the laboratory failed to ensure laboratory supplies were not used when they had exceeded their expiration date. Findings: 1. Observation of laboratory supplies during the laboratory tour on September 16, 2025, showed one Copan LQ Amies eSwab Lot # 119HB expiration 5/8/25 and one Eurotrol Hemotrol Level 2 quality control lot # 40666 expiration 8/31/25, still in use. 2. Interview with the TC #2 on September 16, 2025, at 3:30 PM confirmed the laboratory failed to ensure laboratory supplies were not used when they had exceeded their expiration date.

**D5807**

TEST REPORT  
CFR(s): 493.1291(d)

(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on review of i-STAT Chem 8+ normal values quick reference procedure, review of 1 of 1 patient reports, and interview with the technical consultant (TC) #2, the laboratory failed to ensure the reference intervals or normal values on the patient report matched the procedure. Findings: 1. Review of "i-STAT Chem 8+ normal values quick reference procedure" revealed: CTnI-Troponin Normal Range: 0-0.04 ng/mL 2. Review of the patient report revealed: POC Troponin I i-STAT reference range 0.00-0.08 ng/mL 3. Interview with the TC #2 on September 16, 2025 at 3:15 PM confirmed the normal values on the patient report did not match the procedure.

**D6054**

TECHNICAL CONSULTANT RESPONSIBILITIES  
CFR(s): 493.1413(b)(9)

(b)(9) Thereafter, evaluations must be performed at least annually

This STANDARD is not met as evidenced by:

Based on review of performance evaluations and interview with the technical consultant (TC) #2, the technical consultant (TC) failed to evaluate and document the annual performance evaluation for seven of seven testing personnel (TP) in 2024. Findings: 1. Review of performance evaluations showed no annual performance evaluation for TP #1, TP #2, TP #3, TP #4 TP #5, TP #7, TP #9 in 2024. 2. Interview with the TC #2 on September 16, 2025, at 3:00 PM confirmed the technical consultant failed to evaluate and document the annual performance evaluation for all testing personnel in 2024.