| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 37D0469490 | 04/24/2026 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Carnegie Tri-County Municipal Hospital | 102 N Broadway, Carnegie, OK | |

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 |
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| **D0000** | The recertification survey was performed on 04/21, 22, 23, 24/2026. The laboratory was found out of compliance with the following CLIA Condition: 493.1487; D6168: Testing Personnel, High Complexity Testing |
| **D1001** | CERTIFICATE OF WAIVER TESTS<br>CFR(s): 493.15(e)<br><br>493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, review of manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to ensure test materials were not used beyond the open vial stability. Findings include: (1) On 04/21/2026 at 11:40 am, the laboratory manager stated the laboratory performed Glucose testing using the Stat Strip analyzers in ER (Emergency Room) #1 and in the Med Room; (2) Observation of ER #1 on 04/21/2026 at 11:43 am identified one vial of Stat Strip Express Glucose Test Strips, Lot 0325199249 which had not been dated with an opened date and modified expiration date; (3) A review of the manufacturer's storage and stability instructions for the test strips on the insert required once the test strips are opened, the test strips are stable for 30 days when stored at 2 - 8 degrees C (Centigrade); (3) Interview with the laboratory manager on 04/21/2026 at 12:55 pm confirmed the vial of test strips had not been dated with the modified expiration date. |
| **D3003** | FACILITIES<br>CFR(s): 493.1101(a)(2)<br><br>(a)(2) Contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized. |

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| | This STANDARD is not met as evidenced by:<br>Based on observation, and interview with the laboratory manager, the laboratory failed to ensure five of five bottles of Thermo Scientific Trutol glucose tolerance beverages were stored to minimize contamination. Findings include: (1) On 04/21 /2026 at 11:52 am observation of the contents of the laboratory refrigerator identified the following materials: (a) Patient blood specimens for storage; (b) Two bottles of Thermo Scientific Trutol 50 glucose tolerance beverages for patient consumption; (c) Two bottles of Thermo Scientific Trutol 75 glucose tolerance beverages for patient consumption; (d) One bottle of Thermo Scientific Trutol 100 glucose tolerance beverage for patient consumption. (2) Interview with the laboratory manager 04/21 /2026 at 12:55 pm confirmed the laboratory failed to minimize contamination by storing patient beverages for consumption with biohazard materials. |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records and interview with the technical consultant and laboratory manager, the laboratory failed to utilize the demonstrated reportable ranges for two of five analytes reviewed for the QuidelOrtho Vitros 4600 test system. Findings include: (1) On 04/21/2026 at 11:59 am, the technical consultant and laboratory manager stated the laboratory began using the QuidelOrtho Vitros 4600 analyzer to perform routine chemistry testing which included the analytes AMY (Amylase) and MG (Magnesium) in October 2025; (2) A review of the performance specification records identified the laboratory had demonstrated the following reportable ranges for two of five analytes reviewed: (a) AMY - 34.9-1038.2 U/L; (b) MG - 0.56-9.42 mg/dL. (3) Interview with the technical consultant and laboratory manager on 04/23/2026 at 11:08 am confirmed the laboratory was using the following manufacturer's reportable ranges instead of the reportable ranges that had been demonstrated by the laboratory: (a) AMY - 30.0-1200.0 U/L; (b) MG - 0.20-10.0 mg /dL. |
| **D6168** | TESTING PERSONNEL<br>CFR(s): 493.1487<br><br>The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of records and interview with the technical consultant and laboratory |

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| | manager, the laboratory failed to ensure three of seven testing persons met the qualification requirements to perform high complexity testing. Findings include: (1) The laboratory failed to ensure that each person performing high complexity testing met the qualification. Refer to D6171. |
| **D6171** | TESTING PERSONNEL QUALIFICATIONS<br>CFR(s): 493.1489(b)<br><br>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records and interview with the technical consultant and laboratory manager, the laboratory failed to ensure that each person performing high complexity testing met the qualification requirements for three of seven persons listed on the CMS-209. Findings include: (1) On 04/21/2026 at 11:30 am, the technical consultant and laboratory manager stated the laboratory performed CMP (Comprehensive Metabolic Panel), Lipids, CK (Creatine Kinase), Lactic Acid, Lipase, Amylase, Magnesium, Phosphorous, Uric Acid, Acetaminophen, Salicylates, Ethanol, Ammonia, Prealbumin, and Vancomycin testing using the QuidelOrtho Vitros 4600 analyzer; (2) A review of the FDA (Food and Drug Administration) database did not |

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| | include a categorization for the QuidelOrtho Vitros 4600 analyzer, which defaults the test system to high complexity. This was also confirmed during email correspondence with an FDA representative on 04/23/2026 at 12:58 pm; (3) Interview with the technical consultant and laboratory manager on 04/23/2026 at 01:33 pm confirmed the test analyzer had been put into use for patient testing on 10/16/2025; (4) A review of the Laboratory Personnel Report (Form CMS-209) and education records for seven testing persons revealed that three of seven persons (testing person #3, testing person #5, and testing person #7) did not meet the qualification requirements to perform high complexity testing; (5) The records were reviewed with the technical consultant and laboratory manager. Both stated on 04/23/2026 at 01:50 pm, the three testing persons did not meet the qualification requirements to perform high complexity testing. |