Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	37D0469490	06/30/2022
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
D0000	The recertification survey was performed on 06/28,29,30,2022. The laboratory was found out of compliance with the following CLIA Conditions of Participation: 493.1213; D5022: Toxicology 493.1441; D6076: Laboratory Director, High Complexity Testing 493.1487; D6168: Testing Personnel, High Complexity Testing The findings were reviewed with the chief clinical officer, chief executive officer, technical consultant, laboratory manager, testing person #3, testing person #6, and phlebotomist during an exit conference performed at the conclusion of the survey.
D5022	TOXICOLOGY CFR(s): 493.1213 If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of records, urine drug screen package insert and test kit box, FDA database, email correspondence with an FDA representative, and interview with the technical consultant and laboratory manager, the laboratory failed to ensure the requirements were met for the subspecialty of Toxicology for six of six months of patient testing. Findings include: (1) The laboratory failed to have written policy defining the method to verify the accuracy of the urine drug screen testing at least twice annually. Refer to D5401; (2) The laboratory failed to establish the performance specifications for the Accurate Urine DOA Rapid Test Dipcard test not cleared or approved by the FDA. Refer to D5423; (3) The laboratory failed to perform a negative and positive control material 20 of 22 days of patient urine drug screen testing. Refer to D5449.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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 a review of records, policies and procedures and interview with the laboratory manager, the laboratory failed to have written policy defining the method to verify the accuracy of the urine drug screen testing at least twice annually. Findings include: (1) On 06/29/2022 at 01:33 pm, the laboratory manager stated the Accurate Urine DOA Rapid Test Dipcard had been put into use for patient testing on 01/03/2022 (refer to D5423 for specific information pertaining to the test kit not being FDA approved and defaulting to a high complexity test system); (2) A review of urine drug screen records, policies and procedures, and proficiency testing for 2022 revealed the laboratory had not enrolled and participated in a proficiency testing program and there was no evidence a policy had been written to ensure a method to verify the accuracy of the testing at least twice annually; (3) The records were reviewed with the laboratory manager who stated on 06/29/2022 at 01:43 pm the laboratory did not have a method to verify the accuracy of urine drug screen testing at least twice annually because it was believed the test kit was categorized as waived; (4) Refer to D5423 for examples of patient testing.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of policies and procedures and interview with the laboratory manager, the laboratory failed to have a step by step procedure for one of five procedures reviewed. Findings include: (1) On 06/28/2022 at 11:30 am, the laboratory manager stated urine microscopic testing was performed in the laboratory; (2) On 06/29/2022, a review of the urine microscopic procedure titled, "Microscopic Urine Sediment Examination" revealed the procedure did not include the steps to prepare the

	urine sample for microscopic examination of the sediment (including the required volume of urine, required speed and time to centrifuge the urine, etc.); (3) The procedure was reviewed with the laboratory manager who stated on 06/29/2022 at 10:32 am, the procedure did not include the preparation of the urine specimen for microscopic analysis.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on a review of records, urine drug screen package insert and test kit box, FDA database, email correspondence with FDA representative, and interview with the technical consultant and laboratory manager, the laboratory failed to establish the performance specifications for the Accurate Urine DOA Rapid Test Dipcard test not cleared or approved by the FDA. Findings include: (1) On 06/28/2022 at 11:30 am, the laboratory manager stated urine drug screen testing was performed using the Accurate Urine DOA Rapid Test Dipcard test kit, as stated on the test kit box; (2) On 06/29/2022 a review of the urine drug screen package insert showed the name of the test as "CLIA Waived One Step Multi-Drug Screen Test Dip Card" which did not match the name on the test kit box; (3) A review of the FDA (Food and Drug Administration) test classification database did not include a classification for the test kit (if a test is not included on the FDA site, then it did not go through the FDA approval process, which defaults the classification of the test as high complexity). This was also confirmed during email correspondence with an FDA representative on 06/29/2022 at 01:12 pm; (4) Interview with the laboratory manager on 06/29/2022 at 01:33 pm confirmed the test kit had been put into use for patient testing on 01/03/2022; (5) A review of records for the test system revealed no evidence the performance specifications of accuracy, precision, analytical sensitivity, analytical specificity, reportable range, and reference intervals as applicable, had been established prior to putting the test into use for patient testing; (6) The findings were reviewed with the technical consultant and laboratory manager. Both stated on 06/29/2022 at 01:40 pm the laboratory did not establish the performance specifications prior to putting the test kit into use because it was believed the test kit was categorized as waived; (7) The following were examples of patient urine drug screen testing performed (number represents accession number): (a) Patient #2201030075 - Testing performed on 01/03/2022 (b) Patient #2201090021 - Testing performed on 01/09/2022 (c) Patient #2201150001 - Testing performed on 01/15/2022 (d) Patient #2201290015 - Testing performed on 01/30 2022 (e) Patient #2202090039 - Testing performed on 02/09/2022 (f) Patient #2202150057 - Testing performed on 02/15/2022 (g) Patient #2202200020 - Testing performed on 02/20/2022 (h) Patient #2202280020 - Testing performed on 02/28/2022 (i) Patient #2203220056 - Testing performed on 03

	/22/2022 (j) Patient #2203310034 - Testing performed on 03/31/2022 (k) Patient #2204050057 - Testing performed on 04/05/2022 (l) Patient #2201000027 - Testing performed on 04/10/2022 (m) Patient #2204200044 - Testing performed on 04/20 /2022 (n) Patient #2204250037 - Testing performed on 04/25/2022 (o) Patient #2205070005 - Testing performed on 05/07/2022 (p) Patient #2205160062 - Testing performed on 05/16/2022 (q) Patient #2205240036 - Testing performed on 05/24 /2022 (r) Patient #2205260052 - Testing performed on 05/26/2022 (s) Patient #2206130027 - Testing performed on 06/13/2022 (t) Patient #2206190009 - Testing performed on 06/19/2022 (u) Patient #2206210070 - Testing performed on 06/21 /2022 (v) Patient #2206280034 - Testing performed on 06/28/2022
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) 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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to perform a negative and positive control material 20 of 22 days of patient urine drug screen testing. Findings include: (1) On 06/29/2022 at 01:33 pm, the laboratory manager stated the Accurate Urine DOA Rapid Test Dipcard had been put into use for patient testing on 01/03/2022 (refer to D5423 for specific information pertaining to the test kit not being FDA approved and defaulting to a high complexity test system); (2) A review of QC (Quality Control) and patient testing records from January through June 2022 revealed negative and positive QC materials had not been performed each day of patient testing for 20 of 22 days of patient testing and there was no evidence an IQCP (Individualized Quality Control Program) had been developed; (3) The laboratory manager stated on 06/29/2022 at 01:35 pm negative and positive QC materials had not been performed each day of patient testing and an IQCP had not been developed because it was believed the test kit was categorized as waived; (4) The following were the days of patient testing reviewed when negative and positive QC materials had not been performed: (a) Patient #2201030075 - Testing performed on 01/03/2022 (b) Patient #2201090021 - Testing performed on 01/09 /2022 (c) Patient #2201150001 - Testing performed on 01/15/2022 (d) Patient #2201290015 - Testing performed on 01/30 2022 (e) Patient #2202090039 - Testing performed on 02/09/2022 (f) Patient #2202150057 - Testing performed on 02/15/2022 (g) Patient #2202200020 - Testing performed on 02/20/2022 (h) Patient #2203220056 - Testing performed on 03/22/2022 (i) Patient #2203310034 - Testing performed on 03 /31/2022 (j) Patient #2204050057 - Testing performed on 04/05/2022 (k) Patient #2201000027 - Testing performed on 04/10/2022 (l) Patient #2204200044 - Testing performed on 04/20/2022 (m) Patient #2204250037 - Testing performed on 04/25 /2022 (n) Patient #2205070005 - Testing performed on 05/07/2022 (o) Patient #2205160062 - Testing performed on 05/16/2022 (p) Patient #2205240036 - Testing performed on 05/24/2022 (q) Patient #2205260052 - Testing performed on 05/26 /2022 (r) Patient #2206130027 - Testing performed on 06/13/2022 (s) Patient #2206190009 - Testing performed on 06/19/2022 (t) Patient #2206210070 - Testing performed on 06/21/2022

D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, urine drug screen package insert and test kit box, FDA database, email correspondence with an FDA representative, and interview with the technical consultant and laboratory manager, the laboratory director failed to provide overall management and direction for a urine drug screen test for six of six months of testing. Findings include: (1) The laboratory director failed to ensure the Accurate Urine DOA Rapid Test Dipcard urine drug screen test provided quality results for patient care for six of six months of testing. Refer to D6085.
D6085	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3) The laboratory director must ensure that the test methodologies selected have the capability of providing the quality of results required for patient care. This STANDARD is not met as evidenced by: Based on a review of records, urine drug screen package insert and test kit box, FDA database, email correspondence with FDA representative, and interview with the technical consultant and laboratory manager, the laboratory director failed to ensure a urine drug screen test provided quality results for patient care for six of six months of patient testing. Findings include: (1) The laboratory director failed to ensure the FDA catergorization of the Accurate Urine DOA Rapid Test Dipcard prior to using for patient testing. Refer to D5401, D5423, and D5449.
D6168	TESTING PERSONNEL CFR(s): 493.1487 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. This CONDITION is not met as evidenced by: Based on a review of records and interview with the technical consultant and laboratory manager, the laboratory failed to ensure five of nine 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 urine drug screen testing met the qualification requirements. Refer to D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (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 have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (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; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
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 five of nine persons listed on the CMS-209. Findings include: (1) On 06/28/2022 at 11:30 am, the laboratory manager stated urine drug screen testing was performed using the Accurate Urine DOA Rapid Test Dipcard test kit (as stated on the test kit box); (2) On 06/29/2022 a review of the urine drug screen package insert showed the name of the test as "CLIA Waived One Step Multi-Drug Screen Test Dip Card" which did not match the name on the test kit box; (3) A review of the FDA (Food and Drug Administration) test classification database did not include a classification for the test kit (if a test is not included on the FDA site, then it did not go through the FDA approval process, which defaults the classification of the test as high complexity). This was also confirmed during email correspondence with an FDA representative on 06/29/2022 at 01:12 pm; (4) Interview with the laboratory manager on 06/29/2022 at 01:33 pm confirmed the test kit had been put into use for patient testing on 01/03/2022; (5) A review of the Laboratory Personnel Report (Form CMS-209) and education records for nine testing persons revealed that five of the nine persons (testing person #1, testing person #6, testing person #7, testing person #8, and testing person #9) did not meet the qualification requirements to perform high complexity testing; (6) The records were reviewed with the technical consultant and laboratory manager. Both stated on 06/29 /2022 at 01:50 pm, the five testing persons did not meet the qualification requirements to perform high complexity testing.