Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 37D0469490	**(X3) Date Survey Completed** 10/09/2020
Name of Provider or Supplier Carnegie Tri-County Municipal Hospital	**Street Address, City, State** 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 10/07,08/2020. The findings were reviewed with the technical consultant, laboratory manager, and testing person #2 at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager and technical consultant, the laboratory failed to ensure an analyzer and materials were stored as required by the manufacturer for 3 of 9 months. Findings include: (1) On 10/07/2020 at 10:30 am, the laboratory manager stated the following to surveyor #2: (a) CKMB, Troponin I, and D-Dimer testing were performed in the laboratory using the Alere Triage analyzer. (2) Surveyor #2 reviewed the manufacturer's test device environmental requirements for the analyzer: (a) The operator's manual for the analyzer on page 2 under "STORAGE AND HANDLING REQUIREMENTS" required a room temperature of 20-24 degrees Centigrade (C). (3) Surveyor #2 reviewed laboratory room temperature records for 9 months (January 2020 through September 2020) and identified that for 3 of 9 months the room temperatures were colder than the manufacturer's storage requirements as follows: (a) April 2020 - 3 of 30 days (i) 04/25/2020 - The room temperature had been

	documented at 18 degrees C; (ii) 04/26/2020- The room temperature had been documented at 18 degrees C; (iii) 04/30/2020 - The room temperature had been documented at 18 degrees C. (b) August 2020 - 2 of 31 days (i) 08/04/2020 - The room temperature had been documented at 19 degrees C; (ii) 08/19/2020 - The room temperature had been documented at 18 degrees C. (c) September 2020 - 6 of 30 days (i) 09/09/2020 - The room temperature had been documented at 18 degrees C; (ii) 09 /13/2020 - The room temperature had been documented at 19 degrees C; (iii) 09/14 /2020 - The room temperature had been documented at 19 degrees C; (iv) 09/19/2020 - The room temperature had been documented at 18 degrees C; (v) 09/24/2020 - The room temperature had been documented at 18 degrees C; (vi) 09/28/2020 - The room temperature had been documented at 18 degrees C. (4) Surveyor #2 reviewed the records with the laboratory manager and technical consultant. The laboratory manager and technical consultant stated on 10/08/2020 at 02:25 pm to surveyor #2 , the laboratory did not store the manufacturer's test device according to the manufacturer's requirements as indicated above.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager and technical consultant, the laboratory failed to ensure the demonstrated reportable ranges were utilized for 2 of 2 new analyzers. Findings include: (1) On 10/07/2020 at 10:30 am, the laboratory manager stated the following to surveyor #2: (a) The laboratory began using a replacement Alere Triage analyzer to perform CKMB, Troponin I, and D-Dimer testing on 02/05/2020; (b) The laboratory began using Beckman Coulter AcT Diff2 analyzer to perform CBC (Complete Blood Count) testing on 02/05/2019. (2) Surveyor #2 reviewed the performance specification records and identified the laboratory had demonstrated reportable ranges as follows: (a) Alere Triage (i) CKMB - 0.07 - 25.1 ng/ml; (ii) Troponin I - 1.7 - 55.7 ng/ml. (b) Beckman Coulter AcT Diff2 (i) Hemoglobin - 1.7 - 20.0 g/dL (ii) Platelets - 27.0 - 962.0 X 10^3/l (iii) Red Blood Cells - 0.6 - 6.85 X 10^6 /l (iv) White Blood Cells - 0.7 - 90.2 X 10^3/l (3) Surveyor #2 requested the reportable ranges that were being utilized by the laboratory. The laboratory manager provided surveyor #2 linearity ranges from the LIS (Laboratory Information System) and stated on 10/07/2020 at 02:45 pm the linearity ranges were the laboratory's reportable ranges: (a) Alere Triage (i) CKMB - 0.05 - 27.9 ng/ml; (ii) Troponin I - 1.0 - 80.0 ng/ml. (b) Beckman Coulter AcT Diff2 (i) Hemoglobin - 2.0 - 27.0 g/dL (ii) Platelets - 10.0 - 2327.0 X 10^3/l (iii) Red Blood Cells - 0.2 - 8.70 X 10^6 /l (iv) White Blood Cells - 0.5 - 122.0 X 10^3/ (4) The surveyor reviewed the findings with the laboratory manager and technical consultant. The laboratory manager and technical consultant stated on 10/07/2020 at 04:14 pm the laboratory was not using the reportable ranges that had been demonstrated by the laboratory.
D5441	CONTROL PROCEDURES

	CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (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 and technical consultant, the laboratory failed to have control procedures that would detect immediate errors that would occur due to test system failure, adverse environmental conditions, and operator performance three of three months for Acetaminophen and two of three months for Sodium testing. Findings include: (1) On 10/07/2020 at 10:00 am, the laboratory manager stated to surveyor #1 Acetaminophen and Sodium testing were performed on the Ortho Vitros 4600; (2) On 10/08/2020 at 11:00 am the laboratory manager stated the following to surveyor #1: (a) The laboratory began performing patient testing using the new analyzer in December 2019; (b) Three levels of Bio-Rad Liquid Assayed Multiqual QC (quality control) materials were performed each day of patient testing. (3) Surveyor #1 reviewed the package insert for the control materials which stated, "The mean values and corresponding +/-3SD ranges in the Assignment of Values Data Charts (available separately) were derived from replicate analyses and are specific for this lot of product. Data from Unity Interlaboratory Program are included in the determination of some ranges. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of product. It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides"; (4) Surveyor #1 then reviewed QC records for three lot numbers of control materials used from June through August 2020 (level 1 lot #45861, level 2 lot #45862, and level 3 lot #45863). The review showed the laboratory was using ranges wider than the package insert guideline ranges as follows: (a) Acetaminophen (i) Level 3 - The package insert range was 127-146. A range of 124-148 had been used to evaluate QC results. (b) Sodium (i) Level 1 - The package insert range was 110-122. A range of 106.1-124.1 had been used to evaluate QC results; (ii) Level 2 - The package insert range was 136-151. A range of 129.4-151.4 had been used to evaluate QC results; (iii) Level 3 - The package insert range was 154-171. A range of 148-172 had been used to evaluate QC results. (5) Surveyor #1 reviewed the records with the technical consultant who stated on 10/08/2021 at 12:30 pm ranges wider than the package insert guideline ranges, as indicated above, had been used to evaluate QC results.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (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 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 and technical consultant, the laboratory failed to perform quality control testing as required in the IQCP. Findings include: (1) On 10/07/2020 at 10:30 am, the laboratory manager stated to surveyor #2 that D-Dimer testing was performed in the laboratory using the Alere Triage analyzer; (2) Surveyor #2 reviewed records, and identified the laboratory had performed an IQCP (Individualized Quality Control Plan) for this test system, which had been reviewed and accepted by the laboratory director as effective beginning 05/10/2018. The IQCP quality control plan stated two levels of external quality control (QC) materials were to be performed with new lot numbers and every 30 days (this QC frequency was as stringent as the manufacturer's requirements); (3) Surveyor #2 reviewed records from January 2020 through the first day of the survey (10/07/2020). It was identified that the laboratory did not satisfy the IQCP as follows: (a) One level of QC had been performed on 05/03/2019. (4) On 10/08/2020, surveyor #2 reviewed the records with the laboratory manager an technical consultant. The laboratory manager and technical consultant stated on 10/08/2020 at 02:30 pm the laboratory did not performing two levels of QC, as stated in their IQCP.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager and technical consultant, the laboratory failed to ensure corrective actions were taken when quality control results failed to meet the laboratory's established criteria for acceptability for 1 of 6 months; Findings include: (1) On 10/07/2020 at 10:35 am, the laboratory manager stated to surveyor #2 Troponin I testing was performed in the laboratory using the Alere Triage analyzer; (2) On 10/08/2020 at 02:00 pm, the laboratory manager stated the following: (a) Two levels of Triage Cardiac Control materials were tested with each new lot number and monthly according to the laboratory's IQCP (Individualized Quality Control Plan); (b) The results for two levels of control materials must be acceptable in order to report patient results. (3) On 10/08/2020, surveyor #2 reviewed quality control records for testing performed from June 2019 through December 2019. For 1 of 6 months, 1 of the 2 QC values was beyond the limits of acceptability as follows: (a) Level 2 (Lot#03563) was tested on 12/28/2021. The result was 20.3 ng/mL (the 2 SD range was 10.4 - 19.4 ng/mL). (4) Surveyor #2 further reviewed the records. There was no evidence corrective action had been taken

	for the above QC failure, with an acceptable result obtained; (5) Surveyor #2 reviewed the records with the laboratory manager and technical consultant. Both stated on 10/08/2020 at 02:45 pm 1 level of QC was unacceptable, with no corrective action taken.