Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475339	04/01/2022
Name of Provider or Supplier	**Street Address, City, State**	
Wagoner Community Hospital	1200 W Cherokee, Wagoner, 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 03/30,31/2022 and 04/01/2022 The laboratory was found out of compliance with the following CLIA regulation: 493.1409; D6033: Technical Consultant The findings were reviewed with the director of laboratory services at the conclusion of the survey.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the director of laboratory services, the laboratory failed to follow the manufacturer's instructions for implementing coagulation reagents for one of two lot numbers. Findings include: (1) On 03/30/2022 at 10:30 am, the director of laboratory services stated: (a) The Sysmex CA-660 analyzer was used to perform PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing (the INR was calculated using the PT reference interval mean); (b) The following reagent lot numbers were put into use in 05/29/2021: (i) PT - Innovin reagent, lot #549770 (ii) PTT - Actin FSL reagent, lot #562663 (iii) Ci-Trol 1 control, lot #564821 (iv) Ci-Trol 3 control, lot #556537 (2) A review of the manufacturer's instructions contained in the "Lot Roll-Over Procedure" for implementing new reagents stated, "The following recommendations should be used as a guideline when converting to new lots of reagents for Hemostasis analyzers. These procedures should be followed each year before new lots of reagents are put into use on the existing Hemostasis system". In addition, the manufacturer required the following: (a) Section titled "Verification of Reference Range" (i) "20 Normal Individuals * 10 males; 10

	females * Medication History: no aspirin, no hormones, no herbal supplements * 20 is the minimum requirement for statistical validity"; (ii) "Assay samples on current and new lot number reagents simultaneously or within 10 minutes of each other. This data can be used in Section II"; (iii) "Calculate mean and 2 SD range"; (iv) "MNPT for INR calculation should be the geometric mean". (b) Section titled, "Method Correlation" (i) "40 samples: 20 normal, 20 abnormal"; (ii) "Normal samples (Section I) may be used for the Method Correlation and Verification of Reference Range"; (iii) "Abnormal samples should span the Reportable Range of assay"; (iv) "Assay samples on current and new lot number reagents simultaneously or within 1 our of each other"; (v) "Calculate Linear Regression statistics". (c) Section titled "Quality Control" (i) "Assay new lot number of QC material with the new lot of reagent in PTN and APTT protocols"; (ii) "Collect a minimum of 30 data points"; (iii) "Calculate the mean, 2 SD and 3 SD range". (3) A review of the records for the lot changes revealed the following: (a) PT - Innovin reagent, lot #549770 (i) Normal Range Study - Three of the 10 male participants were taking aspirin and two of the 10 female participants were taking aspirin (ii) Method Correlation - The records showed the laboratory had used 15 normal samples, instead of 20 as required by the manufacturer (b) PTT - Actin FSL reagent, lot #562663 (i) Normal Range Study -Three of the 10 male participants were taking aspirin and two of the 10 female participants were taking aspirin (ii) Method Correlation - The records showed the laboratory had used 15 normal samples, instead of 20 as required by the manufacturer. (c) Quality Control (QC) (i) Ci-Trol 1, lot #564821 - The records showed the laboratory had used 20 data points to establish QC ranges for PT and 20 data points to establish QC ranges for PTT instead of 30 data points as required by the manufacturer. (ii) Ci-Trol 3, lot #556537 - The records showed the laboratory had used 20 data points to establish QC ranges for PT and 20 data points to establish QC ranges for PTT instead of 30 data points as required by the manufacturer. (4) The findings were reviewed with the director of laboratory services who stated on 03/30/2022 at 12:15 pm, the manufacturer's instructions had not been followed for the reagent lot changes as specified 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, written procedures, and interview with the director of laboratory services, the laboratory failed to ensure the reportable ranges had been utilized for two of two new test methods. Findings include: DIESSE MINI-CUBE ANALYZER (1) On 03/30/2022 at 09:45 am, the director of laboratory services stated the laboratory began performing automated ESR (Erythrocyte Sedimentation Rate) testing using the Diesse Mini-Cube on 10/11/2021; (2) A review of the performance specification records for the new test system revealed the following: (a) The laboratory had demonstrated a reportable range of 0-80; (b) Documentation in the records showed the laboratory had approved using the manufacturer's reportable range

	of 0-140. (3) On 03/30/2022 at 02:00 pm, the findings were reviewed with the director of laboratory services who stated the laboratory was using the manufacturer's reportable range of 0-140 instead of the reportable range that had been demonstrated by the laboratory. G3+ AND ISTAT 1 ANALYZER (1) On 03/30/2022 at 09:50 am the director of laboratory services stated the laboratory began performing Blood Gas (pH, pCO2, pO2) testing using the G3+ cartridge and iSTAT 1 analyzer on 03/25 /2022; (2) On 03/31/2022, a review of the performance specification records for the new test system revealed the following reportable ranges had been demonstrated by the laboratory: (a) pH - 6.550-7.914 (b) CO2 - 18.8-100.2 mmHg (c) pO2 - 66-407 mm Hg (3) A review of the procedure titled, "iSTAT G3+" showed the following manufacturer's reportable ranges being used by the laboratory: (a) pH - 6.5-8.20 (b) CO2 - 5-130 mm Hg (c) pO2 - 5-800 mm Hg (4) On 03/31/2022 at 01:45 pm, the findings were reviewed with the director of laboratory services who stated the laboratory was using the manufacturer's reportable ranges instead of the reportable ranges that had been demonstrated by the laboratory. 39088 Based on a review of records, manufacturer's instructions, and interview with the director of laboratory services, the laboratory failed to ensure the reportable ranges had been utilized for two of two new test methods. Findings include: (1) On 03/30/2022 at 10:45 am, the director of laboratory services stated the laboratory began performing chemistry testing using the Vitros 5600 on 03/07/2021; (2) On 03/31/2022, a review of the performance specification records for the new test system revealed the following reportable ranges had been demonstrated by the laboratory: (a) Alkaline Phosphatase - 26 - 1473.5 U/L (b) Aspartate Aminotransferase - 16.3 - 793.2 U/L (c) Ammonia - 6 - 478.7 umol/L (d) B12 - 63.8 - 983 mcg (e) CKMB - 0.22 - 343 IU/L (f) Creatine Kinase - 37.9 - 1516.4 IU/L (g) Glucose - 30 - 589 mg/dL (h) Glycated Hemoglobin - 5.9 - 10.4% (i) Lipase 31.8 - 1886.3 U/L (j) Total Bilirubin - 0.93 - 18.3 mg/dL (k) Triglycerides - 34.6 - 520.8 mg/dL (3) A review of the manufacturer's reportable range showed the following manufacturer's reportable ranges being used by the laboratory: (a) Alkaline Phosphatase - 20 -1500 U/L (b) Aspartate Aminotransferase - 3 - 750 U/L (c) Ammonia - 9 - 500 umol/L (d) B12 - 159 - 1000 mcg (e) CKMB - 0.22 - 400 IU/L (f) Creatine Kinase - 20 -1600 IU/L (g) Glucose - 20 -625 mg/dL (h) Glycated Hemoglobin - 4 - 14% (i) Lipase 10 -2000 U/L (j) Total Bilirubin - 0.1 - 27 (k) Triglycerides - 10 - 525 mg/dL (4) On 03/31/2022 at 01:45 pm, the findings were reviewed with the director of laboratory services who stated the laboratory was using the manufacturer's reportable ranges instead of the reportable ranges that had been demonstrated by the laboratory.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or

	replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of records and interview with the director of laboratory services, the laboratory failed to perform calibration verification procedures at least once every 6 months for one of six analytes. Findings include: (1) On 03/30/2022 at 09:57 am, the director of laboratory services stated the laboratory began performing Vitamin B12 testing using the Ortho Vitros 5600 analyzer on 01/04/2021; (2) On 04/01/2022, a review of 2022 calibration records revealed the calibration procedures for Vitamin B12 had been performed with two levels of calibrators therefore, calibration verification procedures, using three or more levels of calibration materials that included a low, mid, and high value, were required every six months; (3) A review of analyzer records from January 2021 through March 2022 revealed that calibration verification had not been performed after 01/04/2021; (4) The records were reviewed with the director of laboratory services who stated on 04/01/2022 at 12:30 pm, calibration verification procedures had not been performed every six months.
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of written policies and interview with the director of laboratory services, the laboratory failed to ensure that written policies provided safety for individuals being transfused for 10 of 10 units of packed red blood cells. Findings include: (1) On 03/30/2022 at 11:10 am, the director of laboratory services stated: (a) The laboratory stored units of packed red blood cells in the blood bank refrigerator. The units were to be used for patient transfusions; (2) A review of the hospital policy titled, "Blood Product Administration" under the section titled, "ADMINISTRATION OF PACKED RED BLOOD CELLS, AUTOLOGOUS, AND DIRECTED DONOR BLOOD", stated: (a) "12. After initiation vital signs will be documented as follows:" (i) "a. Once within the first 15 minutes"; (ii) "b. Every hour until completion of infusion," (iii) "c. There will then need to be a vital sign 1 hour post transfusion. The vital signs will be recorded on the blood request form and in the nurse's notes. The unit number and time of transfusion will be recorded in the electronic record.". (3) A review of patient records for 10 units of PRBCs (Packed Red Blood Cells) that had

	been transfused between 10/07/2021 through 03/01/2022 for five patients, revealed the following: (a) Vitals on the blood request forms were documented as "BEFORE", "DURING" AND "AFTER" but did not include a time the three vitals were taken during infusion for 10 of 10 units; (i) Patient #1 - Transfused with one unit of PRBCs (unit #W091021346317) on 10/07/2021; Transfused with one unit of PRBCs (unit #W091021331639) on 10/07/2021; (ii) Patient #2 - Transfused with one unit of PRBCs (unit #W091021368295) on 11/18/2021; Transfused with one unit of PRBCs (unit #W091021389089) on 11/18/2021 (iii) Patient #3 - Transfused with one unit of PRBCs (unit #W0910214156008) on 12/04/2021; Transfused with one unit of PRBCs (unit #W091021448478) on 01/29/2022 (iv) Patient #4 - Transfused with one unit of PRBCs (unit #W091021404643) on 12/04/2021; Transfused with one unit of PRBCs (unit #W091022120171) on 03/01/2022; (v) Patient #5 - Transfused with one unit of PRBCs (unit #W0910214374440) on 01/29/2022; and Transfused with one unit of PRBCs (unit #W091021452778) on 012/29/2022. (4) The findings were reviewed with the director of laboratory services who stated on 04/01/2022 at 11:45 am the vitals had been taken but not documented and the written policy and procedure for blood administration had not been followed as indicated above.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) 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; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of

	laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on a review of records and interview with the director of laboratory services , the laboratory failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications for one of seven competency evaluations. Findings include: (1) On 03/30/2022, a review of records for seven persons performing moderate complexity testing in 2020 and 2021 revealed the following for one of seven testing persons: (a) Testing Person #5 - The 02/26/2021 evaluation and 07/02/2021 evaluation had been performed by the director of laboratory services (this person had earned an associate's degree in applied clinical laboratory science). (2) The findings were reviewed with the director of laboratory services who stated on 03/30/2022 at 01:45 pm, the evaluations had been performed by an individual who did not meet the qualifications of a technical consultant.