Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475339	03/01/2018
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 survey was performed from 02/26/18 - 03/01/18. The findings were reviewed with the laboratory director, technical consultant, general supervisor, and the chief executive officer at the conclusion of the survey.
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, manufacturers' instructions, and interview with the technical consultant and the general supervisor, the laboratory failed to ensure the manufacturers' required environmental specifications were met for the analyzers used for patient testing. Findings include: (1) On the first day of the survey, the technical consultant stated to the surveyor the laboratory performed moderate complexity testing, which included the following examples: (a) Coagulation testing - PT/INR (Prothrombin Time/International Normalized Ratio), APTT (Activated Partial Thromboplastin Time), and D-dimer using the Sysmex CA600 analyzer (b) CBC testing (i.e. WBC-White Blood Count, RBC-Red Blood Count, Hemoglobin, Hematocrit, Platelet Count, etc.) using the Sysmex XT-4000i analyzer (2) On the second day of the survey, the surveyor reviewed the manufacturer's instructions (operation manuals) for the analyzers listed above and identified the required humidity ranges: (a) Sysmex CA600: 30-80% (b) Sysmex XT-4000i: 30-85% (3) The surveyor then reviewed humidity records from 12 months (April, May, June,

	November, and December 2016; January, February, July, October, November, and December 2017; and January 2018) and identified the humidity was lower than the manufacturers' required range, as follows: (a) 2016: 1 of 5 months reviewed: (i) November: 6 of 30 days (aa) Day 20 - The humidity was 29.2% (bb) Day 21 - The humidity was 26.2% (cc) Day 22 - The humidity was 28.5% (dd) Day 24 - The humidity was 28.9% (ee) Day 29 - The humidity was 29.1% (ff) Day 30 - The humidity was 26.7% (b) 2017: 5 of 6 months reviewed: (i) January: 7 of 31 days (aa) Day 7 - The humidity was 25.6% (bb) Day 26 - The humidity was 26.5% (cc) Day 27 - The humidity was 26.8% (dd) Day 28 - The humidity was 25.6% (ee) Day 29 - The humidity was 25.8% (ff) Day 30 - The humidity was 27.3% (gg) Day 31 - The humidity was 26.6% (ii) February: 2 of 28 days (aa) Day 25 - The humidity was 26.3% (bb) Day 27 - The humidity was 22.8% (iii) March: 1 of 31 days (aa) Day 9 - The humidity was 29.4% (iv) October: 2 of 31 days (aa) Day 30 - The humidity was 26.8% (bb) Day 31 - The humidity was 26.3% (v) November: 10 of 30 days (aa) Day 11 - The humidity was 27.8% (bb) Day 19 - The humidity was 27.3 (cc) Day 20 - The humidity was 26.9% (dd) Day 22 - The humidity was 26.7% (ee) Day 23 - The humidity was 23.4% (ff) Day 24 - The humidity was 25.3% (gg) Day 25 - The humidity was 25.5% (hh) Day 26 - The humidity was 25.5% (ii) Day 27 - The humidity was 25.5% (jj) Day 28 - The humidity was 27.4% (4) The surveyor reviewed the findings with the technical consultant and the general supervisor, who stated to the surveyor the laboratory failed to ensure the manufacturers' humidity requirements had been met as listed above. NOTE: D5413 was cited on the previous recertification survey performed 03/02/16-03/04/16.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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 a review of records, manufacturer's instructions, and interview with the technical consultant and the general supervisor, the laboratory failed to ensure expired testing materials were not used. Findings include: (1) On the first day of the survey, the technical consultant stated to the surveyor, the laboratory performed patient Blood Bank testing, which included: (a) ABO/Rh typing (b) Antibody Screen testing (c) Compatibility testing (2) On the second day of the survey, the surveyor reviewed Blood Bank QC (Quality Control) and patient testing records from 04/01/16 through 02/22/18 and identified documentation showed expired testing materials had been used on days of patient testing: (a) Anti-D Reagent, Lot #DB30541, with the manufacturer's expiration date, 12/11/16 had been used to perform QC and patient testing on 12/12/16 and 12/13/16; (b) Ortho Coombs Control Cells, Lot #K398, with the manufacturer's expiration date, 02/21/17 had been used to perform QC and patient testing on 02/22/17; (c) Ortho Coombs Control Cells, Lot #K404, with the manufacturer's expiration date, 03/21/17 had been used to perform QC and patient testing on 03/22/17; (d) Blood bank Saline, Lot #817476, with the manufacturer's expiration date, 04/28/17 had been used to perform QC and patient testing on 05/03 /17; (e) Reagent Screening Cells 1 and Cells 2, Lot #S013, with the manufacturer's expiration date, 01/16/18 had been used to perform QC and patient testing on 01/22 /18. (3) The surveyor reviewed the records with the technical consultant and the general supervisor, who stated to the surveyor expired testing materials had been used

	as indicated above; (4) Examples of patient Crossmatch testing performed using the expired materials were: (a) Patient #1 - Testing performed on 12/12/16 and 12/13/16 (b) Patient #2 - Testing performed on 02/22/17 (c) Patient #3 - Testing performed on 03/22/17 (d) Patient #4 - Testing performed on 05/03/17 (e) Patient #5 - Testing performed on 01/22/18 NOTE: D5417 was cited on the previous recertification survey performed 03/02/16-03/04/16.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant and the general supervisor, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Findings include: (1) On the first day of the survey, the technical consultant stated to the surveyor the laboratory used the Sysmex CA-600 analyzer to perform PT/INR (Prothrombin Time /International Normalized Ratio), APTT (Activated Partial Thromboplastin Time), and D-dimer testing; (2) The surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs. The following was identified: (a) Weekly: Clean instrument interior/exterior (b) Yearly: Replace Rinse Filter (3) The surveyor then reviewed maintenance records for 15 months (June 2016 through January 2018). There was no documentation which proved the weekly and yearly maintenance had been performed: (a) Weekly: Had not been documented as having been performed: (i) Between 07/14/16 and 07/28/16 (ii) Between 08/03/16 and 08/14/16 (iii) Between 09/15/16 and 09/26/16 (iv) Between 11/30/16 and 12/20/16 (v) Between 12/28/16 and 01/08/17 (vi) Between 04/21/17 and 04/30/17 (vii) Between 05 /25/17 and 06/16/17 (b) Yearly: Had not been documented as having been performed: (i) Between 06/02/16 and 02/27/18 (4) The surveyor reviewed the records with the technical consultant and the general supervisor, who stated to the surveyor the laboratory failed to perform the manufacturer's required maintenance procedures as listed above.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant and the general supervisor, the laboratory failed to ensure function checks for cuvette temperatures on the Dimension EXL 200 chemistry analyzer were acceptable. Findings include: (1) On the first day of the survey, the technical consultant stated to the surveyor the laboratory performed patient chemistry (i.e., Albumin, Glucose, Potassium, TSH (Thyroid Stimulating Hormone), Digoxin,

	Uric Acid, etc.) testing using the Dimension EXL 200 analyzer; (2) On the fourth day of the survey, the surveyor reviewed the manufacturer's instructions for performing daily function checks on the analyzer. The instructions required the cuvette temperatures be read daily and documented. In addition, the manufacturer's acceptable cuvette temperature range was 36.8 to 37.2 degrees Centigrade (C); (3) The surveyor then reviewed the cuvette temperature records from 11 months (June, July, August, September, October, and December 2016; January, June, September, and December 2017; and January 2018). The surveyor identified the cuvette temperatures were unacceptable on 17 of the 184 days reviewed in 2016, as follows: (a) July - On 3 of 31 days, the temperatures were unacceptable: (i) 36.7 degrees: Days 15,27,29 (b) August - On 6 of 31 days, the temperatures were unacceptable: (i) 36.6 degrees: Days 6,7,20,28 (ii) 36.7 degrees: Days 21,27 (c) September - On 6 of 30 days, the temperatures were unacceptable: (i) 36.7 degrees: Days 17,18,23,27,28,30 (d) October - On 1 of 31 days, the temperature was unacceptable: (i) 36.7 degrees: Day 3 (e) December - On 1 of 31 days, the temperature was unacceptable: (i) 36.7 degrees: Day 9 (4) The records were reviewed with the technical consultant and the general supervisor, who stated to the surveyor the temperatures were not being maintained within the manufacturer's acceptable range. NOTE: D5431 was cited on the previous recertification survey performed 03/02/16-03/04/16.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on a review of records, manufacturers' instructions, and interview with the technical consultant and the general supervisor, the laboratory failed to take corrective action for unacceptable environmental conditions. Findings include: UNACCEPTABLE HUMIDITY (1) On the first day of the survey, the technical consultant stated to the surveyor the laboratory performed moderate complexity testing, which included the following examples: (a) Coagulation testing - PT/INR (Prothrombin Time/International Normalized Ratio), APTT (Activated Partial Thromboplastin Time), and D-dimer using the Sysmex CA600 analyzer (b) CBC testing (i.e. WBC-White Blood Count, RBC-Red Blood Count, Hemoglobin, Hematocrit, Platelet Count, etc.) using the Sysmex XT-4000i analyzer (2) On the second day of the survey, the surveyor reviewed the manufacturer's instructions (operation manuals) for the analyzers listed above and identified the required humidity ranges: (a) Sysmex CA600: 30-80% (b) Sysmex XT-4000i: 30-85% (3) The surveyor then reviewed humidity records from 12 months (April, May, June, November, and December 2016; January, February, July, October, November, and December 2017; and January 2018) and identified the humidity was lower than the manufacturers' required range, as follows: (a) 2016: 1 of 5 months reviewed: (i) November: 6 of 30 days (aa) Day 20 - The humidity was 29.2% (bb) Day 21 - The humidity was 26.2% (cc) Day 22 - The humidity was 28.5% (dd) Day 24 - The humidity was 28.9% (ee) Day 29 - The humidity was 29.1% (ff) Day 30 - The humidity was 26.7% (b) 2017: 5 of 6 months reviewed: (i) January: 7 of 31 days (aa) Day 7 - The humidity was 25.6% (bb) Day 26 - The humidity was 26.5% (cc) Day 27 - The humidity was 26.8% (dd) Day 28 - The humidity was 25.6% (ee) Day 29 - The humidity was 25.8% (ff) Day 30 - The humidity was 27.3% (gg) Day 31 - The

	humidity was 26.6% (ii) February: 2 of 28 days (aa) Day 25 - The humidity was 26.3% (bb) Day 27 - The humidity was 22.8% (iii) March: 1 of 31 days (aa) Day 9 - The humidity was 29.4% (iv) October: 2 of 31 days (aa) Day 30 - The humidity was 26.8% (bb) Day 31 - The humidity was 26.3% (v) November: 10 of 30 days (aa) Day 11 - The humidity was 27.8% (bb) Day 19 - The humidity was 27.3 (cc) Day 20 - The humidity was 26.9% (dd) Day 22 - The humidity was 26.7% (ee) Day 23 - The humidity was 23.4% (ff) Day 24 - The humidity was 25.3% (gg) Day 25 - The humidity was 25.5% (hh) Day 26 - The humidity was 25.5% (ii) Day 27 - The humidity was 25.5% (jj) Day 28 - The humidity was 27.4% (4) The surveyor reviewed the records again but could not find documentation the laboratory took corrective action (e.g. used a humidifier, etc.) for the unacceptable humidity readings; (5) The surveyor asked the technical consultant and the general supervisor, if the laboratory had documentation which showed for the dates listed above, the laboratory had taken corrective action for the unacceptable humidity. The technical consultant and the general supervisor stated to the surveyor that corrective action had not been taken for the unacceptable humidity levels. UNACCEPTABLE CUVETTE TEMPERATURE (1) On the first day of the survey, the technical consultant stated to the surveyor the laboratory performed patient chemistry (i.e., Albumin, Glucose, Potassium, TSH (Thyroid Stimulating Hormone), Digoxin, Uric Acid, etc.) testing using the Dimension EXL 200 analyzer; (2) On the fourth day of the survey, the surveyor reviewed the manufacturer's instructions for performing daily function checks on the analyzer. The instructions required the cuvette temperatures be read daily and documented. In addition, the manufacturer's acceptable cuvette temperature range was 36.8 to 37.2 degrees Centigrade (C); (3) The surveyor then reviewed the cuvette temperature records from 11 months (June, July, August, September, October, and December 2016; January, June, September, and December 2017; and January 2018). The surveyor identified the cuvette temperatures were unacceptable on 17 of the 184 days reviewed in 2016, as follows: (a) July - On 3 of 31 days, the temperatures were unacceptable: (i) 36.7 degrees: Days 15,27,29 (b) August - On 6 of 31 days, the temperatures were unacceptable: (i) 36.6 degrees: Days 6,7,20,28 (ii) 36.7 degrees: Days 21,27 (c) September - On 6 of 30 days, the temperatures were unacceptable: (i) 36.7 degrees: Days 17,18,23,27,28,30 (d) October - On 1 of 31 days, the temperature was unacceptable: (i) 36.7 degrees: Day 3 (e) December - On 1 of 31 days, the temperature was unacceptable: (i) 36.7 degrees: Day 9 (4) The surveyor reviewed the records again but could not find documentation which showed corrective action (i.e., checking the temperature at a later time, recalibration of cuvette temperature, etc.) had been taken for the unacceptable temperatures; (5) The surveyor asked the technical consultant and the general supervisor if corrective action had been taken for the unacceptable cuvette temperatures listed above. The technical consultant and the general supervisor stated to the surveyor corrective action had not been taken for the unacceptable cuvette temperatures.