Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475339	05/15/2026
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 05/12/2026 through 05/15/2026. The laboratory was found out of compliance with the following CLIA Condition: 493.1403; D6000: Moderate Complexity Laboratory Director
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 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. This STANDARD is not met as evidenced by: Based on a review of records, observation, and interview with the technical consultant, the laboratory failed to follow manufacturer's directions to ensure one of one vial of Nova StatStrip glucose test strips had not exceeded their open vial expiration date. Findings include: (1) On 05/12/2026 at 12:28 pm, the technical consultant stated glucose testing was performed on the Nova Stat Meter in the emergency department and on the nursing floor; (2) Observation of the nurse's station on 05/12/2026 at 12:28 pm identified one open vial (Lot #0325024249, expiration 11 /20/2027) of Novastat test strips stored at room temperature, without documentation of when they were put in use; (3) A review of the manufacturer's storage requirements stated the following: (a) "Write the discard date on the bottle label. The test strips are stable for six months after opening or until the expiration date on the bottle label, whichever comes first". (4) Interview with the technical consultant on 05/12/2026 at 12:28 pm confirmed the vial had been opened without a method to monitor if they exceeded the manufacturer's modified expiration date.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235

	As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of records, written policies, and interview with the laboratory manager, the laboratory failed to establish written policies to assess the competencies of the technical consultant, technical supervisor, and general supervisor based on the position responsibilities as listed in Subpart M. Findings include: I. TECHNICAL CONSULTANT (1) On 05/12/2026, a review of policies identified no evidence of a policy for assessing the competency of the technical consultant based on the position responsibilities, including the frequency of the assessment; (2) Interview with the laboratory manager on 05/12/2026 at 03:00 pm confirmed a written policy for assessing the technical consultant competency based on the position responsibilities was not available for review as stated above. II. TECHNICAL SUPERVISOR (1) On 05/12/2026, a review of policies identified no evidence of a policy for assessing the competency of the technical supervisor based on the position responsibilities, including the frequency of the assessment; (2) Interview with the laboratory manager on 05/12/2026 at 03:00 pm confirmed a written policy for assessing the technical supervisor competency based on the position responsibilities was not available for review as stated above. III. GENERAL SUPERVISOR (1) On 05/12/2026, a review of policies identified no evidence of a policy for assessing the competency of the general supervisor based on the position responsibilities, including the frequency of the assessment; (2) A review of the Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed during the review period of May 2024 through the current date identified, although competencies, based on the position responsibilities, had been performed for one of one person listed as the general supervisor on 05/08/2026, the assessment policy was not available for review; (3) The findings were reviewed with the laboratory manager who stated on 05/12 /2026 at 03:00 pm, a written policy for assessing the general supervisor was not available, although competencies had been performed for the position as stated above.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to review and evaluate proficiency testing results for three of 11 testing events. Findings include: (1) On 05/12/2026 at 2:00 pm, A review of proficiency testing from the American Proficiency Institute (API) records and identified the following unsuccessful long-term performance: (a) Second 2024 Chemistry Miscellaneous Event (i) Urine Microalbumin - Unsuccessful participation (composite score of 0%); (b) First 2025 Chemistry Miscellaneous Event (i) Urine Microalbumin - Unsuccessful participation (composite score of 0%); (c) Third 2025 Chemistry Miscellaneous Event (i) Urine Microalbumin - Unsuccessful participation (composite score of 0%); (2) There was no documentation that the unsuccessful

	participation was identified and no documentation of corrective action; (3) The records were reviewed with the laboratory manager, who stated on 05/12/2026 at 2:00 pm that the unsuccessful events had not been addressed.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to have an ongoing mechanism for performing general laboratory systems quality assessment. Findings include: (1) It was determined the laboratory did not have a mechanism for performing quality assessment of general laboratory systems due to the following issue identified: (a) The laboratory failed to thoroughly review and evaluate proficiency testing results. Refer to D5211.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 the policy and procedure manual and interview with technical consultant #1, the laboratory failed to follow written procedures for Complete Blood Count (CBC) testing for one of one patient report. Findings include: (1) On 05/13 /2026 at 10:00 am, technical consultant #1 stated CBC testing was performed on the Sysmex XN-1000 hematology analyzer; (2) A review of the written procedure titled, "Preparation of Blood Smears" stated, "Count 100 leukocytes and differentiate the various types"; (3) A review of one patient record identified laboratory staff had not followed their written procedure as follows: (a) Patient reported on 05/12/2026 at 10: 57 am - 99 Leukocytes were counted, not 100 as the policy defines. (4) The findings weren reviewed with technical consultant #1 who stated on 05/13/2026 at 10:30 am the procedure had not been followed as indicated above.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of procedures and interview with the laboratory manager, the laboratory failed to ensure one of one procedure manual had been approved, signed,

	and dated by the current laboratory director. Findings include: (1) On 05/14/2026 at 10:00 am, the laboratory manager stated that platelet poor plasma was performed in the laboratory; (2) A review of the platelet poor plasma procedure identified no evidence the manual had been approved signed, and dated by the current laboratory director; (3) The manual was reviewed with the laboratory manager who stated on 05 /14/2026 at 10:00 am, the manual had not been signed and dated as approved by the current laboratory director.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 observation and interview with the materials manager, the laboratory failed to ensure two of two types of blood collection tubes were stored as required by the manufacturer in the central supply room. Findings include: (1) Observation of central supply on 05/12/2026 at 11:00 am, identified the following: (a) 800 Vacutainer 3 ml K2EDTAs tubes, lot 5317214, storage temperature requirement of 4-25 degrees (C) Centigrade; (b) 1300 Vacutainer Serum Separator (SST)5 mL tubes, 6047416, storage temperature requirement of 4-25 degrees C. (2) Interview with the materials manager on 05/13/2026 at 09:00 am confirmed the facility was not monitoring the temperature of the central supply room.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and interview with the laboratory manager, the laboratory failed to label one of one BD butterfly blood collection devices with the expiration date and lot number of the contents. Findings include: (1) On 05/15/2026 at 11:35 am, observation of the laboratory identified one unlabeled BD butterfly device on a phlebotomy tray: (a) The 23 gauge butterfly blood collection device had been removed from it's primary packaging and placed on the tray. (2) Interview with the laboratory manager on 05/15/2026 at 11:35 am, confirmed that the packaging had been discarded and they had no way to track the lot number or expiration date of the butterfly collection device.

D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) 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 and interview with the laboratory manager, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures on the Cepheid GeneXpert DX analyzer during the review period of April 2025 through April 2026. Findings include: (1) On 05/12 /2026 at 08:53 am, the laboratory manager stated Methicillin Resistant Staphylococcus Aureus (MRSA), Chlamydia Trachomatis (CG/NT), Neisseria Gonorrhoeae, SARS-CoV-2, Influenza A, Influenza B, and Respiratory Syncytial Virus (RSV) testing were performed using the Cepheid GeneXpert DX analyzer; (2) A review of the manufacturer's maintenance logs required the following: (a) Quarterly: (i) Clean plunger rod and cartridge bays; (ii) Clean instrument surfaces. (3) A review of maintenance logs from April 2025 through April 2026 identified maintenance had not been documented as performed for the following: (a) Quarterly: (i) Between 04/01/2025 and 04/30/2026. (4) The records were reviewed with the laboratory manager who stated on 05/14/2026 at 01:35 pm, maintenance procedures had not been documented as performed as stated above.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to have a written function check protocol to ensure the urine centrifuge was functioning properly during the review period of April 2024 through the current date. Findings include: (1) On 05/12/2026 at 09:55 am, the laboratory manager stated the laboratory performed urine microscopic testing and urine specimens were processed at a speed of 1500 rpm (revolutions per minute) for 5 minutes using the Horizon Model 642VES centrifuge; (2) Although the speed and time function checks had been performed every six months for the urine centrifuge, a function check protocol that defined the frequency of the speed and timer checks and limits of acceptability could not be located; (3) The findings were reviewed with the laboratory manager who confirmed on 05/13/2026 at 11:15 am, there was no written protocol that defined the centrifuge speed and timer function check.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) 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. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: 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 Quality Control (QC) as stated in the Individualized Quality Control Plan (IQCP) for the i-STAT 1 test system for one of four months reviewed. Findings include: (1) On 05/12/2026 at 10:30 am, the laboratory manager stated the following: (a) The laboratory performed sodium, potassium, chloride, ionized calcium, TCO2, BUN (blood urea nitrogen), creatinine, and glucose testing using the Chem8+ cartridge and the i-STAT 1 analyzer; (b) Three levels of QC materials were tested every 30 days according to the IQCP. (2) A review of QC records from January through April 2026 identified no documentation to prove QC had been performed as stated in the Quality Control Plan (QCP) between 02/03/2026 and 04/21/2026; (3) The records were reviewed with the laboratory manager who stated on 05/13/2026 at 03:00 pm, QC had not been performed as shown above.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; 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 positive and negative control materials for four of four days of patient serum pregnancy testing reviewed between January through April 2026. Findings include: (1) On 05/13/2026 at 10:50 am, the laboratory manager stated the laboratory performed Qualitative Human Chorionic Gonadotropin (HCG) pregnancy testing using the Cardinal Health hCG Combo Rapid test kits on serum samples; (2) A review of Quality Control (QC) and patient testing records for testing performed between January and April 2026 identified positive and negative QC materials had not been performed each day of patient testing for four of four days (the specific dates were 01/09/2026, 04/06/2026, 04/10/2026, and 04/25/2026); (3) The records were reviewed with the laboratory manager who stated on 05/13/2026 at 10: 52 am, QC materials had not been performed each day of patient testing.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented.

	This STANDARD is not met as evidenced by: Based on a review of records, and interview with the laboratory manager, the laboratory failed to ensure that blood products were stored under appropriate conditions for one of four alarm checks reviewed between January through December 2025. Findings include: (1) On 05/14/2026 at 12:50 pm, the laboratory manager stated Packed Red Blood Cells (PRBC) were stored in the blood bank refrigerator for patient transfusions; (2) A review of the Quarterly Maintenance record identified documentation of low and high refrigerator alarm checks with an acceptable range defined as 1.1 C to 5.9 C (Centigrade); (3) A review of the alarm check records from January through December 2025 identified the following: (a) On 04/18/2025 - The high temperature sounded at 6.3 degrees C. (4) The findings were reviewed with the laboratory manager, who stated on 05/14/2026 at 01:30 pm, the high alarm check had sounded at a temperature beyond the acceptable limits.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to have a system that twice a year evaluated and defined the relationship between test results for routine chemistry testing performed using two test methods during the review period of January 2025 through the current date. Findings include: (1) On 05/13/2026 at 02:00 pm, the laboratory manager stated the following: (a) The laboratory performed chemistry testing which included the analytes BUN, Chloride, CO2, Creatinine, Glucose, Potassium, and Sodium using the Ortho Vitros 5600 analyzer; (b) The laboratory performed chemistry testing which included the analytes BUN, Chloride, CO2, Creatinine, Glucose, Potassium, and Sodium using the iSTAT 1 analyzer (Serial Number 425693) and the Chem 8+ cartridge. (2) A review of records from January 2025 through the current date identified no evidence the relationship between the different test methods had been evaluated twice in 2025. It had not been evaluated as follows: (a) Prior to 07/15/2025; (b) Between 07/15/2025 and 01/19/2026. (3) The records were reviewed with the laboratory manager who stated on 05/13/2026 at 04:15 pm, the relationship between the above test methods had not been evaluated at least twice during 2025.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory director failed to provide overall management and direction during the

	review period of May 2024 through the current date. Findings include: (1) The laboratory director failed to ensure that personnel performing moderate complexity testing respiratory therapy personnel performing Blood Gas testing had the appropriate training for five of five persons. Refer to D6029.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory director failed to ensure that respiratory therapy personnel performing Blood Gas testing had the appropriate training for five of five persons during the review period of May 2024 through the current date. Findings include: (1) On 05/14 /2026 the laboratory manager stated Blood Gas (pH, pCO2, pO2) testing was performed using the iSTAT 1 analyzer and the CG4+ cartridge by respiratory therapy personnel; (2) A review of respiratory therapy personnel records identified the following for five of five testing persons: (a) Testing Person #8 - There was no documentation of intial training and/or competency assessment records; (b) Testing Person #9 - There was no documentation of initial training and/or competency assessment records; (c) Testing Person #10 - There was no documentation of initial training and/or competency assessment records; (d) Testing Person #11 - There was no documentation of initial training and/or competency assessment records; (e) Testing Person #12 - There was no documentation of initial training and/or competency assessment records. (2) The findings were reviewed with the laboratory manager who stated on 05/15/2026 at 10:15 am, documentation was not available.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the technical consultant failed to ensure personnel performing moderate complexity testing had been evaluated at least annually for four of five testing persons during the review period of May 2024 through the current date. Findings include: (1) On 05/12/2026, a review of personnel records for five persons performing moderate complexity testing from May 2024 through the current date identified no evidence an annual competency evaluation had been performed for four of five testing persons as follows: (a) Testing Person #2 - not performed prior to 07/22/2025; (b) Testing Person #3 - not performed prior to 07/22/2025; (c) Testing Person #4 - not performed prior to 07/22/2025; (d) Testing Person #5 - not performed prior to 07/22/2025. (2) The records were reviewed with the technical consultant who stated on 05/12/2026 at 03:08 pm, the annual evaluations had not been documented as performed as stated above.