Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475409	02/28/2025
Name of Provider or Supplier	**Street Address, City, State**	
Pushmataha Hospital	510 E Main St, Antlers, 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 02/25,26,27,28/2025. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the chief executive officer, lab manager and testing person #2 during an exit conference performed at the conclusion of the survey.
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 laboratory manager, the laboratory failed to follow manufacturer's directions to ensure Accu-Chek Inform II glucose controls had not exceeded their room temperature expiration date for two of two bottles observed. Findings include: (1) On 02/25/2025 at 12:28 pm, the laboratory manager stated glucose testing was performed on the Accu-Chek Inform II Meter in the emergency department and on the nursing floor; (2) Observation of the emergency department on 02/25/2025 at 12:28 pm identified 2 bottles (Lot #23700524, expiration 11/03/2025) of quality control solutions stored at room temperature, without documentation of when they were put in use; (3) Review of the manufacturer's storage requirements showed the following: (a) "Write the discard date on the bottle label. The control solution is stable for 3 months after opening or until the expiration date on the bottle label, whichever comes first"; (4) Interview with the laboratory manager on 02/25/2025 at 12:28 pm confirmed the bottles had been opened without a method to monitor if they exceeded the manufacturer's modified expiration date.
D3021	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(1)

	Blood and blood products storage and distribution. If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product. This STANDARD is not met as evidenced by: Based on a review of records, observation, policies and procedures, and interview with the laboratory manager, the laboratory failed to ensure an adequate alarm system was in place for the blood bank refrigerator for four of four alarm checks performed from February 2023 through December 2024 and failed to ensure thermograph readings accurately reflected refrigerator temperatures. Findings include: Alarm Checks: (1) On 02/27/2025 at 02:30 pm, the laboratory manager stated the laboratory routinely maintained one unit of O negative and one unit of O positive packed red blood cells in the blood bank refrigerator. The units were available for emergency patient transfusions; (2) A review of the policy titled "Testing Refrigerator Alarm" required the alarm checks be performed on a quarterly basis and stated the following: (a) "Quarterly Refrigerator Low and High Temperature Sensor Activation Test: The recommended low temperature should not be any colder than 1.5 degrees Centigrade and the high temperature should not be any warmer than 5.5 degrees Centigrade". (3) A review of the alarm check records from January 2024 through December 2024 identified the high alarm checks sounded at temperatures beyond the acceptable limit for four of four alarm checks performed as follows: (a) 03/27/2024 - The documented high alarm temperature was 6.3 degrees C (Centigrade) (b) 06/12/2024 - The documented high alarm temperature was 6.7 degrees C (c) 09/11/2024 - The documented high alarm temperature was 6.5 degrees C (d) 12/11/2024 - The documented high alarm temperature was 6.3 degrees C (4) The findings were reviewed with the laboratory manager who stated on 02/27/2025 at 02:30 pm the documented temperatures for the high alarm checks above were not acceptable. Temperature Charts: (1) Observation of the laboratory on 02/25/2025 at 11:00 am identified the blood bank refrigerator thermograph charts displayed readings of 58-60 degrees Fahrenheit (14.4 - 15.6 degrees Celsius; (2) A review of the blood storage policy stated, "Blood is to be stored at 1-6 degrees C"; (3) A review of the thermograph charts from February 2023 through the current date identified that in December 2023, the laboratory had purchased Dickson thermograph charts with Fahrenheit graduations, instead of Celsius and were continuing to use them; (4) The findings were reviewed with the laboratory manager who stated on 02/25/2025 at 11: 00 am the thermograph charts did not reflect the correct temperatures.
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 procedures, and interview with the general supervisor, the laboratory failed to have a written policy to assess the competency of the general supervisor, based on the position responsibilities as listed in Subpart M, for one of one person. Findings include: (1) A review of the laboratory

	policy and procedure manual identified no evidence of a policy for assessing the competency of the general supervisor, including the frequency of the assessments; (2) A review of the Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed during the review period of February 2023 through the current date identified competencies, based on job responsibilities, had not been performed for one of one person listed as the general supervisor; (3) The findings were reviewed with the laboratory manager who stated on 02/25/2025 at 02: 00 pm, a policy had not been written and competencies had not been performed for the position as stated above.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) (d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on interview with the laboratory manager, the laboratory failed to provide written instructions to clients collecting and referring specimens for testing performed in the laboratory. Findings include: (1) On 02/25/2025 at 11:15 am, the laboratory manager stated the following testing were performed and specimens were transported to the laboratory from nursing homes and home health care agencies: (a) CBC (complete blood count) testing using the Sysmex XP-300 analyzer; (b) Routine Chemistry testing using the Siemens Dimension EXL 200 analyzer. (2) Interview with the laboratory manager on 02/25/2025 at 11:30 am confirmed the laboratory did not provide written instructions (i.e., client service manual) to the clients to explain the laboratory's specimen collection and transportation policies.
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 a review of records, observation, and interview with the laboratory manager, the laboratory failed to ensure two of two boxes of Triage total 5 quality control materials were stored as required by the manufacturer. Findings include: (1) On 02/25 /2025 at 11:45 am observation of the contents of the Summit laboratory freezer identified the following materials: (a) One box of Triage total 5 quality control materials, level one, lot # C4080AN (b) One box of Triage total 5 quality control materials, level two, lot # C4083AN (2) The storage requirement, as stated on the bottles for the materials was -20 degrees C (Celsius) or colder; (3) Observation of the freezer temperature logs for October 2024 and November 2024, identified the freezer

	was warmer than -20 degrees celsius for 20 of 61 days. (4) Interview with the laboratory manager on 02/25/2025 at 11:45 am confirmed the control materials were used to assess the acceptable performance of D-dimer testing and were not being stored as required by the manufacturer.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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 observation and interview with the technical consultant, the laboratory failed to ensure expired supplies were not available for use. Findings include: (1) Observation of the laboratory on 06/16/2024 at 02:17 pm, identified the following expired supplies that appeared to be available for use: (a) Four BD Vacutainer Buffered Na Citrate 0.19M, 3.2%, lot 3257665, expired 06/30/2024; (b) Two BD Vacutainer Buffered Na Citrate 0.19M, 3.2%, lot 4045010, expired 08/31/2024. (2) Interview with the technical consultant on 06/16/2024 at 02:20 pm confirmed the expired supplies were available for use.
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 centrifuge function check protocol that included the frequency of check and specified time and speed check. Findings include (1) On 02/25 /2025 at 11:22 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 McKesson Variable Speed Centrifuge MFR 642; (2) Although the speed and time function checks had been performed semiannually for the urine centrifuge, a function check protocol that defined the frequency of centrifuge speed and timer checks, specific time and speed to perform the centrifuge checks had not been included in the procedure; (3) The findings were reviewed with the laboratory manager who stated on 02/27/2025 at 11:00 am, the laboratory failed to include the frequency, and specific time and speed checks to be performed for the urine centrifuge in the protocol as stated above.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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 laboratory manager, the laboratory failed to perform calibration verification procedures at least once every six months for one of two test systems during the review period of June 2023 through the current date. Findings include: (1) On 02/25/2025 at 11:05 am, the laboratory manager stated the laboratory performed arterial blood gas (pH, pCO2, pO2) testing using the GEM Premier 3000 analyzer; (2) A review of calibration records from June 2023 through the current date identified no evidence calibration verification had been performed at least once every six months between 09/19/2023 and 06/11/2024; (3) The records were reviewed with the laboratory manager who stated on 02/27/2025 at 04:41 pm, calibration verification procedures had not been performed every six months as stated above.
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 QC (quality control) as stated in the IQCP (Individualized Quality Control Plan) for two of two test systems; failed to ensure the IQCP included all required components for one of two test systems; and failed to ensure data supported the QC frequency for one of two test systems during the review period of February 2024 through the current date. Findings include: QUAILITY CONTROL PERFORMANCE FOR D-DIMER (1) On 02/25/2025 at 11:05 am, the laboratory manager stated the following: (a) The laboratory performed D-Dimer testing using

	Biosite Triage Meter Pro analyzer; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system; (c) The laboratory performed two levels of QC (Quality Control) materials monthly according to the QCP (Quality Control Plan). (2) A review of QC records from April 2024 through the current date identified no documentation to prove QC had been performed between 08/26/2024 and 10/04/2024; (3) The records were reviewed with the laboratory manager who stated on 02/26/2025 at 03:45 pm, QC had not been performed as stated above. QUAILITY CONTROL PERFORMANCE FOR CLOSTRIDIUM DIFFICILE (1) On 02/25/2025 at 11:05 am, the laboratory manager stated the following: (a) The laboratory performed Clostridium difficile testing using Alere C.Diff Quik Chek Complete test kit on stool specimens; (b) An IQCP had been developed for the test system. (2) A review of the QCP for the test system identified external positive and negative QC materials were to be tested with every new box and every new lot of test kits; (3) A review of records from February 2024 through November 2024 identified no evidence external QC had been documented as performed; (4) The findings were reviewed with the laboratory manager who stated on 02/27/2025 at 03:37 pm, external QC performance was routinely documented on the test kit boxes which had been discarded and QC records were unavailable for review. REQUIRED COMPONENTS NOT INCLUDED FOR CLOSTRIDIUM DIFFICILE (1) A review of the IQCP document for Clostridium difficile (dated as approved on 08/11/2021) identified the following: (a) The Risk Assessment did not include the Test System component; (b) The QA (Quality Assessment) plan had not been included. (2) The findings were reviewed with the laboratory manager who stated on 02/27/2025 at 03:40 pm, the IQCP did not include all the required components. DATA DID NOT SUPPORT QC FREQUENCY FOR CLOSTRIDIUM DIFFICILE (1) A review of IQCP records for Clostridium difficile identified no evidence of data to support the QC frequency as stated in the QCP; (2) The findings were reviewed with the laboratory manager who stated on 02/27/2025 at 03:40 pm, there was no data available to support the QC frequency.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. 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 policies for monitoring the effectiveness of the QCP (Quality Control Plan) for one of two test systems. Findings include: (1) On 02/25/2025 at 11: 00 am, the laboratory manager stated the following: (a) The laboratory performed D-Dimer testing using Biosite Triage Meter Pro analyzer; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) A review of the IQCP (dated as approved on 08/11/2021) identified the QA (Quality Assessment) portion of the IQCP did not include a schedule for evaluating the QCP to ensure it continued to provide accurate and reliable results; (3) The findings were reviewed with the laboratory manager who stated on 02/26/2025 at 03:47 pm, the QA plan did not include an evaluation of the QCP to include the frequency of the reviews.