Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475918	11/21/2024
Name of Provider or Supplier	**Street Address, City, State**	
Prague Regional Memorial Hospital	1322 Klabzuba Avenue, Prague, 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 11/18,19,21/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the chief executive officer, technical consultant, and laboratory manager during an exit conference performed at the conclusion of the survey.
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: Based on a review of records, nursing policy, and interview with the laboratory manager, the facility failed to ensure written policies were followed for preventing transfusion reactions for one of four units of packed red-blood cells transfused. Findings include: (1) On 11/18/2024 at 11:55 am, the laboratory manager stated blood transfusions were performed by nursing staff; (2) On 11/21/2024, a review of the hospital policy titled, "Blood Product Administration" stated: (a) "Vital signs are taken immediately prior to infusing the blood" (b) "Every 15 minutes for the first hour, then" (c) "Every 30 minutes during the remainder of the transfusion" (3) A review of transfusion records for four units transfused, identified the policy had not been followed for one of the four units as follows: (a) Unit #W091024207629 - The transfusion started on 06/23/2024 at 08:00 pm. Vital signs had not been taken as follows: (i) 30 Minute Vital Signs - Not taken between 09:30 pm and 11:28 pm. (4) The records were reviewed with the laboratory manager who stated on 11/21/2024 at 02:10 pm, the vital signs had not been documented according to policy.
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 technical consultant, the laboratory failed to review and evaluate proficiency testing results to identify biases for two of five Hematology proficiency testing events and to identify and address a failure for one of five Hematology proficiency testing events reviewed in 2023 and 2024. Findings include: BIASES (1) On 11/18/2024, a review of Hematology proficiency testing records for 2023 (first, second, and third events) and 2024 (first and second events) identified the following biases (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program) for two of five events: (a) First 2023 Event (i) MCH (Mean Corpuscular Hemoglobin) - five of five results exhibited a positive bias (aa) Sample DXH-01 - SDI of 2.7 (bb) Sample DXH-02 - SDI of 2.4 (cc) Sample DXH-03 - SDI of 2.1 (dd) Sample DXH-04 - SDI of 2.4 (ee) Sample DXH-05 0 SDI of 3.3 (b) Second 2024 Event (i) Hemoglobin - five of five results exhibited a positive bias (aa) Sample DXH-06 - SDI of 3.1 (bb) Sample DXH-07 - SDI of 3.9 (cc) Sample DXH-08 - SDI of 2.9 (dd) Sample DXH-09 - SDI of 3.2 (ee) Sample DXH-10 - SDI of 4.2 (2) There was no evidence in the records to prove the biases had been identified and addressed; (3) The records were reviewed with the technical consultant who stated on 11/18/2024 at 01:40 pm, the biases had not been addressed. FAILURE (1) During the review of Hematology proficiency testing records, the following failure was identified for one of five events: (a) Second 2024 Event (i) MCH - The laboratory received a score of 80%. The result for sample DXH-05 had failed. There was no documentation to prove that corrective action had been taken for the failure. (2) The records were reviewed with the technical consultant who stated on 11/18/2024 at 01:40 pm, corrective action had not been taken for the failure.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to evaluate the accuracy of testing when proficiency results had not been graded by the proficiency program for one of five Hematology events reviewed in 2023 and 2024. Findings include: (1) On 11/18/2024, a review of Hematology proficiency testing records for 2023 (first, second, and third events) and 2024 (first and second events) identified the following for one of five events: (a) Second 2024 Event (i) Vaginal Wet Preparation - One of one result (VA-02) stated, "See Data Summary" under "Expected Result". There was no evidence the laboratory reviewed the "Participant Summary Report" to evaluate their result. (2) The records were reviewed with the technical consultant who stated on 11/18/2024 at 01:40 pm, the

	laboratory had not evaluated the result that was not graded by the proficiency testing program.
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 technical consultant and laboratory manager, the laboratory failed to demonstrate the performance specifications for one of three new test methods introduced into the laboratory during the review period of January 2023 through the current date. Findings include: (1) On 11/18/2024 at 11:40 am, the laboratory manager stated the laboratory began using the Consult Diagnostics hCG Combo Tests Cassette test kit and serum samples on 08/15/2023; (2) A review of records for the test kit identified no evidence the performance specifications (accuracy, precision, etc, as applicable for the test system) had been demonstrated; (3) Interview with the technical consultant and laboratory manager on 11/19/2024 at 11:15 am confirmed the performance specifications, as applicable, had not been demonstrated prior to putting the test kit into use for patient testing.
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 laboratory manager, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures for two of three analyzers reviewed from July 2023 through October 2024. Findings include: BECKMAN COULTER DXH 520 ANALYZER (1) On 11/18/2024 at 11:45 am, the laboratory manager stated CBC (Complete Blood Count) testing was performed using the Beckman Coulter DXH 520 analyzer; (2) On 11/19/2024, a review of the manufacturer's maintenance log showed the following required monthly maintenance procedure: (a) Clean the WBC Bath Filter (3) A review of maintenance logs from July 2023 through October 2024 identified no documentation maintenance had been performed between 05/03/2024 and 08/11/2024; (4) The records were reviewed with the laboratory manager who stated on 11/19/2024 at 03:20 pm, the monthly maintenance had not been documented as performed as stated above. BECKMAN COULTER AU 480 ANALYZER (1) On 11/18/2024 at 12:00 pm, the laboratory manager stated the following testing were performed using the Beckman Coulter AU 480 analyzer: (a) Acetaminophen, Albumin, Alcohol, Alkaline Phosphatase, ALT

	(Alanine Aminotransferase), Ammonia, Amylase, AST, Aspartate Aminotransferase, BUN, Calcium, Chloride, Cholesterol, CO2, Creatinine, Digoxin, Dilantin, Direct Bilirubin, Glucose, HDL Cholesterol, Lactate, Lipase, Magnesium, Phosphorus, Potassium, Salicylate, Sodium, Total Bilirubin, Total Protein, Triglyceride, and Uric Acid. (2) On 1/21/2024, a review of the manufacturer's maintenance logs showed the following required maintenance procedures: (a) ISE Maintenance Schedule (i) Every Three Months (aa) Replace the Roller Tubes for MID Solution Dispense and Mixture Aspiration (bb) Replace the Pinch Valve Tubing (b) AU480 Maintenance Schedule (i) Quarterly (aa) Clean the Air filters (bb) Replace the Detergent Rolling Tube (3) A review of maintenance logs from July 2023 through October 2024 identified no documentation maintenance had been performed as follows: (a) Every Three Months - Not documented as performed between 08/02/2023 and 05/21/2024 (b) Quarterly - Not documented as performed during the review period (4) The records were reviewed with the laboratory manager who stated on 11/21/2024 at 01:40 pm, the maintenance procedures had not been documented as performed as stated above.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (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. (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, policies and procedures, and interview with the laboratory manager, the laboratory failed to follow their written protocol for ensuring the urine centrifuge timer was functioning properly for three of four function checks performed during the review period of January 2023 through the current date. Finding include: (1) On 11/18/2024 at 11:45 am, the laboratory manager stated the following: (a) Urine sediment examinations were performed; (b) The specimens were processed in the Ultra 8V centrifuge at a speed of 1700 rpm (revolutions per minute) for 5 minutes. (2) A review of the centrifuge function check policy titled, "Centrifuge Function Check Protocol" stated the following for timer checks: (a) "Centrifuge timer checks are performed bi-annually"; (b) "Acceptable Limits" (i) "Timer Check - +/-5.0 Seconds @ 5 minutes" (3) A review of centrifuge function check records during 2023 through the current date identified the timer checks did not meet the acceptable limits as defined by policy for three of four checks performed as follows: (a) 10/08/2023 - The result of the timer check was documented as "5:50" (five minutes 50 seconds); (b) 05/09/2024 - The result of the timer check was documented as "5:20" (five minutes 20 seconds); (c) 10/30/2024 - The result of the timer check was documented as "4:50" (four minutes 50 seconds). (4) The records were reviewed with the laboratory manager who stated on 11/19/2024 at 11:00 am, the laboratory had not followed their policy.