Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0472664	12/05/2024
Name of Provider or Supplier	**Street Address, City, State**	
Fairview Regional Medical Center	523 E State Road, Fairview, 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 12/3,4,5/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the chief nursing officer, human resources director, and laboratory manager during an exit conference performed at the conclusion of the survey.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 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 Abbott Affinion hemoglobin A1C cartridges had not exceeded their room temperature expiration date for one of one cartridge type observed. Findings include: (1) On 12/03/2024 at 11:28 am, laboratory director stated hemoglobin A1C testing was performed on the Abbott Affinion analyzer; (2) Observation of the laboratory on 12/03/2024 at 11:30 am identified 12 hemoglobin A1C cartridges (Lot #10229258) stored at room temperature, without documentation of when they were removed from refrigeration; (3) Review of the manufacturer's storage requirements showed the following: (a) The cartridges were stable at 2-8 degrees C (Centigrade) until the expiration date listed on the box; (b) The cartridges were stable at room temperature (18-30 degrees C) for 90 days. (4) Interview with the laboratory manager on 12/03/2024 at 11:30 am confirmed the cartridges had been placed at room temperature without a method to monitor if they exceeded the manufacturer's room temperature expiration date.
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 two of seven units of packed red-blood cells transfused. Findings include: (1) On 12/5/2024 at 11:55 am, the laboratory manager stated blood transfusions were performed by nursing staff; (2) A review of the hospital policy titled, "Administration of Blood Products" stated: (a) "Vital signs are taken immediately prior to infusing the blood" (b) "Every 15 minutes twice, then" (c) "30 minutes then" (d) "Every hour for the remainder of the transfusion, then" (e) "On hour after infusion is complete." (3) A review of transfusion records for seven units transfused, identified the policy had not been followed for two of seven units as follows: (a) Unit #W091024143368 - The transfusion started on 07/24/2024 at 02:25 pm and ended at 04:52 pm. Vital signs had not been taken as follows; (i) One hour post-transfusion vital signs - Not taken between 04:50 pm and 07:01 pm. (b) Unit #W091024214384 - The transfusion started on 06/04/2024 at 12:21 pm and ended at 02:15 pm. Vital signs had not been taken as follows; (i) One hour post transfusion vital signs not taken. (4) The records were reviewed with the laboratory manager who stated on 12/05/2024 at 11:55 am, the vital signs had not been documented according to policy.
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 laboratory manager, 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/Coagulation events reviewed. Findings include: (1) On 12/04/2024 at 01:00 pm, he laboratory manager stated that prothrombin time testing was performed using the Hemochron Signature Elite analyzer; (2) A review of proficiency testing records for 2023 (first, second, and third event) and 2024 (first and second events) identified three of five results had not been graded by the proficiency testing program and the laboratory's reported result for one of the three results did not agree with the "Expected" result for the first 2024 event: (a)Sample HCP-03 was reported as 12.0 and the expected range was 12.6-17.6 (3) There was no evidence in the records proving corrective action had been taken for the unacceptable response; (4)The records were reviewed with the laboratory manager, who confirmed on 12/4/2024 at 1:00 pm, the laboratory had failed to evaluate the ungraded results.

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 laboratory manager, the laboratory failed to utilize the demonstrated reportable range for five of five analytes reviewed for the Ortho Vitros XT 3600 test system. Findings include: (1) On 12/04/2024 at 10:00 am, the laboratory manager stated the laboratory began using the Ortho Vitros XT 3600 analyzer to perform routine chemistry testing which included the analytes ALKP (Alkaline Phosphatase), ALTV (alanine aminotransferase), AMY (amylase), LIP (lipase), and TBIL (total bilirubin) on 04/17/2024; (2) A review of the performance specifications records identified the laboratory had demonstrated the following reportable ranges for five of five analytes reviewed: (a) ALKP - 13.9-1306.8 (b) ALTV - 11.9-741.8 (c) AMY - 38.7-887.6 (d) LIP - 26.5-2042.8 (e) TBIL - 0.99-18.7 (3) Interview with laboratory manager on 12/04/2024 at 10:00 am confirmed the laboratory was using the following manufacturer's reportable ranges instead of the reportable ranges that had been demonstrated by the laboratory: (a) ALKP - 20-1500 (b) ALTV - 4-750 (c) AMY - 30-1200 (d) LIP - 10-2000 (e) TBIL - 0.1-30