Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0472309	08/15/2024
Name of Provider or Supplier	**Street Address, City, State**	
Harmon Memorial Hospital	400 East Chestnut, Hollis, 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 08/13,14,15/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director, laboratory manager, laboratory supervisor, and testing person #2 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 testing person #2 and the director of nursing, the facility failed to ensure written policies were followed for preventing transfusion reactions for one of three patients transfused. Findings include: (1) On 08/13/2024 at 11:50 am, testing person #2 stated Crossmatch Testing, which consisted of ABO/Rh, Antibody Screen, and Compatibility testing, was performed using the Ortho ID MTS gel system; (2) On 08/14/2024, a review of the hospital policy titled, "Blood and Blood Component Transfusion" defined vitals as temperature, blood pressure, pulse and respirations and stated: (a) "Vital signs after initiation of the transfusion (every 15 minutes times 2 with each unit of blood)." (3) A review of transfusion records for three patients identified the policy had not been followed for one patient as follows: (a) Patient transfused on 04/02/2024, Unit #W091024192077 - The documented vitals taken at 02:37 am and 02:51 am did not include the temperature readings. (4) The records were reviewed with the director of nursing who stated on 08/15/2024 at 01:00 pm, the temperature readings for the two sets of vitals had not been documented.

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 policy, and interview with testing person #3, the laboratory failed to have a written policy that included assessing the competency of the general supervisors, based on the position responsibilities as listed in Subpart M, for three of three persons. Findings include: (1) On 08/13/2024, a review of written policies identified no evidence of a policy for assessing the competency of the general supervisors; (2) A review of the Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed during the review period of January 2023 through the current date identified competencies, based on job responsibilities, had not been performed for two of two persons listed as general supervisor. (3) The findings were reviewed with testing person #3 who stated on 08/13 /2024 at 2:00 pm, there was no policy for assessment of the general supervisors and competencies had not been performed.
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 testing person #2, the laboratory failed to review and evaluate proficiency testing results for two of nine proficiency testing events reviewed in 2023 and 2024. Findings include: BIASES (1) On 08/13 /2024, a review of Chemistry 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 one of five events: (a) First 2024 Chemistry Core Event (i) Creatinine - three of five results exhibited a positive bias (aa) Sample CH-02 - SDI of 3.5 (bb) Sample CH-03 - SDI of 2.7 (cc) Sample CH-04- SDI of 2.2 (ii) Valproic Acid - five of five results exhibited a negative bias (aa) Sample CH-01 - SDI of -2.8 (bb) Sample CH-02 - SDI of -3.9 (cc) Sample CH-03- SDI of -3.6 (dd) Sample CH-04 - SDI of -3.3 (this resulted in a failure, see below) (ee) Sample CH-05 - SDI of -2.7 (2) There was no evidence in the records to prove the biases had been identified and addressed; (3) The records were reviewed with testing person #2 who stated on 08/14 /2024 at 10:00 am, the biases had not been addressed. FAILURES (1) On 08/13/2024, a review of Chemistry proficiency testing records for 2023 (first, second, and third events) and 2024 (first and second events); and Hematology proficiency testing records for 2023 (first, second, and third events) and 2024 (first event) identified the following failures for two of nine events: (a) Third 2023 Hematology Event (i) Basophil % - The laboratory received a score of 0%. The results for samples XE-11, XE-12, XE-13, XE-14, and XE-15 had failed. There was no documentation to prove that corrective action had been taken for the failures; (ii) Eosinophil % - The laboratory received a score of 0%. The results for samples XE-11, XE-12, XE-13, XE-

	14, and XE-15 had failed. There was no documentation to prove that corrective action had been taken for the failures; (iii) Lymphocyte % - The laboratory received a score of 0%. The results for samples XE-11, XE-12, XE-13, XE-14, and XE-15 had failed. There was no documentation to prove that corrective action had been taken for the failures; (iv) Monocyte % - The laboratory received a score of 0%. The results for samples XE-11, XE-12, XE-13, XE-14, and XE-15 had failed. There was no documentation to prove that corrective action had been taken for the failures; (v) Neutrophil % - The laboratory received a score of 0%. The results for samples XE-11, XE-12, XE-13, XE-14, and XE-15 had failed. There was no documentation to prove that corrective action had been taken for the failures. (b) First 2024 Chemistry Core Event (i) Creatinine - The laboratory received as score of 80%. The results for sample CH-04 had failed. There was no documentation to prove that corrective action had been taken for the failure. (2) The records were reviewed with testing person #2 who stated on 08/14/2024 at 10:00 am, there was no evidence that corrective actions had been taken for the failures.
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 testing person #2, the laboratory failed to evaluate the accuracy of testing when proficiency testing results had not been graded by the proficiency program for one of five Chemistry Core proficiency testing events reviewed in 2023 and 2024. Findings include: (1) On 08/13/2024, a review of Chemistry 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) First 2023 Chemistry Core Event (i) Pro BNP (B-type natriuretic peptide) - Two of five results had not been graded by the proficiency testing program and stated, "See Data Summary" under "Expected Result". There was no evidence the laboratory reviewed the "Participant Summary Report" to evaluate their results. (2) The records were reviewed with testing person #2 who stated on 08/14/2024 at 10:00 am, the laboratory had not evaluated the results that were not graded by the proficiency testing program.
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, observation, and interview with testing person #2, the laboratory failed to ensure Accu-Sed Plus controls had not exceeded their room temperature expiration date for two of two controls observed, and failed to ensure expired supplies were not available for use. Findings include: ACCU-SED BI-LEVEL

	CONTROLS (1) On 08/13/2024 at 11:45 am, testing person #2 stated ESR (erythrocyte sedimentation rate) testing was performed using the Vital Diagnostics eXcyte M automated analyzer; (2) Observation of the laboratory on 08/13/2024 at 11: 45 am identified two vials of Accu-Sed Plus Bi-Level controls stored at room temperature, without documentation of when the vials were opened; (3) Review of the manufacturer's storage requirements identified the following: (a) Open vials were stable for 31 days when stored at 18-30 Centigrade protected from light. (4) Interview with testing person #2 on 08/13/2024 at 3:57 pm confirmed the controls had been placed at room temperature without an open date to monitor if they exceeded the manufacturer's room temperature expiration date. BLOOD COLLECTION TUBES (1) Observation of the draw room on 08/15/2024 at 11:40 am, identified the following expired supplies that appeared to be available for use: (a) 15 BD Microtainer MAP K2E (1.0 mg) blood collection tubes, lot #2347360 with an expiration date of 06/30 /2024; (b) Two BD Vacutainer Trace Element K2EDTA 10.8 mg blood collection tubes, lot #2321419 with an expiration date of 11/30/2023; (c) Eight BD Vacutainer Buff. Na Citrate 0.109 M, 3.2% blood collection tubes, lot #3289129 with an expiration date of 07/31/2024. (2) Interview with testing person #2 on 08/15/2024 at 11:42 am confirmed the collection tubes had exceeded their expiration dates and were available for use.
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 testing person #2, the laboratory failed to utilize the demonstrated reportable range for five of five anaalyes reviewed for the Ortho Vitros 5600 test system. Findings include: (1) On 08/14/2024 at 10:00 am, testing person #2 stated the laboratory began using the Ortho Vitros 5600 analyzer to perform routine chemistry testing which included the analytes ALKP (Alkaline Phosphatase), Folate, TSH (Thyroid Stimulating Hormone), NTBNP (B-type Natriuretic Peptide), and BUN (Urea) on 09/01/2023; (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 - 17.5-1236 (b) Folate - 0.0-17.65 (c) BUN - 4.5-112.25 (d) NTBNP - 0.0-26700 (e) TSH - 0.0-92.55 (3) Interview with testing person #2 on 08/14/2024 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) Folate - 0.0-22 (c) BUN - 2-120.00 (d) NTBNP - 0.0-33000 (e) TSH - 0.015-100.00
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 testing person #2, the laboratory failed to perform function checks as defined by the manufacturer for the MTS dispenser. Findings include: (1) On 08/15/2024 at 03:20 am, testing person #2 stated the following: (a) The MTS 0.5 milliliter (ml) dispenser was used to dispense MTS Diluent 2 Plus to make cell suspensions for ABO/Rh typing; (b) The dispenser was put into use on 06/21/2024. (2) A review of the manufacturer's instructions for the Ortho MTS Dispenser stated, "A calibration should be done as part of a routine laboratory quality control schedule and after each repair. Dispense 10 times into a clean, dry 10.0 mL graduated cylinder and record volume"; (3) A review of written procedures identified no evidence of a policy, to include defining the frequency, for performing the dispenser checks; (4) A review of records from June 2024 through the current date identified no evidence the dispenser calibration checks had been performed prior to putting into use and to date; (5) The findings were reviewed with testing person #2 who stated on 08/15/2024 at 11:20 am, the laboratory did not have a policy for performing the calibration checks to include the frequency of the checks; and the dispenser volume calibration checks had not been performed to date.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) 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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #2, the laboratory failed to perform QC (quality control) as stated in the IQCP (Individualized Quality Control Plan) for the C. DIFF QUIK CHEK COMPLETE test system for one of 12 months reviewed. Findings include: (1) On 08/13/2024 at 11:45 am, testing person #2 stated the following: (a) The laboratory performed Clostridium difficile testing using the C. DIFF QUIK CHEK test system; (b) Positive and negative QC (quality control) materials for the toxin and antigen were tested monthly according to the IQCP. (2) A review of QC records from July 2023 through July 2024 identified no documentation to prove QC had been performed monthly between 12/01/2023 and 02/01/2024; (3) The records were reviewed with testing person #2 who stated on 08/15/2024 at 10:59 am, QC had not been performed as stated above.
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. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the laboratory manager and testing person #2, the laboratory failed to ensure that blood products were stored under appropriate conditions for five of nine alarm checks reviewed in 2023 and to date in 2024. Findings include: (1) On 08/13/2024 at 11:45 am, the laboratory manager and testing person #2 stated units of packed red blood cells were stored in the blood bank refrigerator for patient transfusions; (2) A review of the procedure titled, "Testing Refrigerator Alarms" stated. "the high temperature of activation should be no higher than 6C, activation below 6C is acceptable"; (3) A review of high alarm check records from 02/28/2023 through 07/08/2024 identified the following: (a) 06/20/2023 - The documented temperature the alarm sounded was 6.2C; (b) 09/05/2023 - The documented temperature the alarm sounded was 6.1C; (c) 01/05/2024 - The documented temperature the alarm sounded was 6.1C; (d) 06/29 /2024 - The documented temperature the alarm sounded was 6.1C; (e) 07/08/2024 - The documented temperature the alarm sounded was 6.1C. (3) The findings were reviewed with testing person #2 who stated on 08/15/2024 at 11:59 am, the high alarm had sounded at temperatures that were not acceptable.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #1, the laboratory failed to ensure reference intervals were determined as appropriate for the laboratory's patient population for two of two patient reports reviewed. Findings include: (1) On 08 /14/2024 at 10:50 am, testing person #2 stated the laboratory performed CBC (complete blood count) testing using the Sysmex XN-550 analyzer; (2) On 08/14 /2024 two patient CBC reports were reviewed - the first report was for an adult female patient with the testing performed on 07/02/2024 at 9:41 am; the second report was for an adult male patient with the testing performed on 08/08/2024 at 10:33 am. Both reports included the same reference intervals for the following CBC parameters: (a) RBC (red blood cell) count - 4.0-5.2 (10^6/uL); (b) Hemoglobin - 12.0-15.0 g/dL; (c) Hematocrit - 37.0-47.0 %. (d) WBC (white blood cell count - 4.5-11.9 (10^3/uL) (e) PLT (platelets) - 130-400 (10^3/uL) (3) The reports were reviewed testing person #2 who stated on 08/14/2024 at 10:50 am, the patient reports did not include gender specific reference ranges for RBC, Hemoglobin, Hematocrit, WBC, and PLT.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, patient reports, observation and interview with testing person #2, the laboratory failed to identify, monitor, assess, and correct problems in the postanalytic phases of chemistry testing. Findings include: (1) On 8/14/2024 at 1:00 pm testing person #2 stated that the lab performed chemistry testing on the Vitros 5600 test system to include BUN (urea) and CREA(Creatinine testing). The results were transmitted to a laboratory information system (LIS) which reported the results and included a calculated BUN:CREA ratio; (2) A review of the policy HMH CHEM 004a stated, "BUN/CREA ratio = BUN divided by CREA with a LIS Mnemonic of BUN/Crea ratio"; (3) A review of patient reports printed from the LIS revealed the following: (a) On 6/13/2024 patient # HM0000196983 had a BUN of 10 and a CREA of 0.9 with a reported BUN/Crea ratio of 11.6. A calculation check revealed a BUN/Crea ratio of 11.11; (b) On 7/22/2024 patient # HM0000201430 had a BUN of 10 and a CREA of 0.8 with a reported BUN/Crea ratio of 13.3. A calculation check revealed a BUN/Crea ratio of 13.0; (c) On 7/23/2024 patient # HM0000201553 had a BUN of 14 and a CREA of 0.8 with a reported BUN/Crea ratio of 16.8. A calculation check revealed a BUN/Crea ratio of 17.5; (d) On 8/8/2024 patient # HM0000202851 had a BUN of 11.0 and a CREA of 1.3 with a reported BUN /Crea ratio of 8.0. A calculation check revealed a BUN/Crea ratio of 8.46. (4) On 08 /14/2024 at 1:00 pm, testing person #2 confirmed the laboratory failed to identify and correct problems identified in the postanalytic phases of testing for the BUN/Crea ratio.