Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475262	02/29/2024
Name of Provider or Supplier	**Street Address, City, State**	
Haskell Regional Hospital, Inc	401 Nw H Street, Stigler, 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 02/29/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with testing person # 1, director of nursing, technical consultant, and operations manager during an exit conference performed at the conclusion of the survey.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant and testing person #1, the laboratory failed to take remedial action for unacceptable proficiency testing scores for one of six Chemistry Core events reviewed in 2022 and 2023. Findings include: (1) A review of Chemistry Core proficiency testing records for the first, second, and third events of 2022; and the first, second, and third events of 2023 event identified the following failures for one of six events reviewed: (a) First Event 2023 (i) pCO2 - The laboratory received a score of 60%. The results for samples IB-02 and IB-03 had failed. There was no documentation to prove that remedial action had been taken for the failures; (ii) pH - The laboratory received a score of 60%. The results for samples IB-02 and IB-03 had failed. There was no documentation to prove that remedial action had been taken for the failures; (iii) pO2 - The laboratory received a score of 20%. The results for samples IB-01, IB-02, IB-03, and IB-05 had failed. There was no documentation to prove that remedial action had been taken for

	the failures. (3) The records were reviewed with the technical consultant and testing person #1 who stated on 02/29/2024 at 11:00 am, there was no evidence that remedial action had been taken for the failures.
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 and testing person #1, the laboratory failed to review and evaluate proficiency testing results for one of six Chemistry Core proficiency testing events reviewed. Findings include: (1) A review of Chemistry Core Proficiency testing records for six events (First 2022, Second 2022, Third 2022, First 2023, Second 2023, and Third 2023) identified the following failure with no evidence that corrective action had been documented as performed: (a) First 2023 Event - The laboratory attained a score of 80% for TCO2 (i-STAT CHEM8+). (2) The records were reviewed with the technical consultant and testing person #1 who stated on 02/08/2024 at 03:15 pm, corrective action had not been taken and documented for the failure.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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 records, policies and procedures, and interview with the technical consultant and testing person #1, the laboratory failed to follow their written policy for implementing new lot numbers of control materials for six of 24 lot numbers used during the review period of 11/24/2022 through 02/22/2024. Findings include: (1) On 02/27/2024 at 10:50 am, testing person #1 stated the following: (a) The laboratory performed CBC (complete blood count) testing using the Sysmex XS-1000i analyzer; (b) Three levels of e-Check QC (quality control) materials were performed each eight hours of patient testing; (c) Laboratory established means and historic SD's (standard deviations) were used to determine acceptability of quality control results. (2) A review of the procedure manual titled, "General Quality Control" on page 5, under the section "11. Establishment of Ranges" stated the following: (a) "a. For new assays or a new method for an existing assay, the mean and SD for each control is established by running at least twenty (20) replicates over an appropriate period, usually approximately one (1) month, using assayed controls and manufacturer's insert ranges as a starting range"; (b) "Often on an established platform, the historical SD has been developed and is carried over from lot to lot. The twenty (20) replicate data is used to establish the mean." (3) A review of records for 24 control lot numbers used from 11/24/2022 through 02/22/2024 identified the laboratory did not follow their policy for six of 24 lot numbers as follows: (a) Lot #31300801, Lot #31300802, and Lot #31300803 used from 05/15/2023 through 07/31

	/2023 - The controls had been tested one time prior to putting into use; (b) Lot #32980801, Lot #32980802, and Lot #32980803 used from 11/03/2023 through 01/03 /2024 - The controls had been tested ten times prior to putting into use. (4) The findings were reviewed with the technical consultant and testing person #1 who stated on 02/28/2024 at 03:13 pm, the laboratory did not follow their written policy. 48517 I. Based on a review of written policies and procedures, and interview with the technical consultant, the laboratory failed to follow written procedures, that explained the current practices and procedures being performed in the laboratory for blood bank alarm checks. Findings include: (1) On 02/28/2024 at 11:00 am, the technical consultant stated the following: (a) The laboratory routinely maintained 1 unit of O negative and 1 unit of O positive packed red blood cells in the Helmer blood bank refrigerator. The units were available for emergency patient transfusions (packed red blood cells must be stored at 1-6 degrees Centigrade-C); (b) The laboratory was not staffed 24 hours a day, seven days a week, therefore, remote alarms were housed at the nurses station and emergency department, and the departments would be required to respond to an activated alarm when the laboratory was not staffed. (2) On 02/28 /2024, a review of the laboratory's written policy, titled, "Blood Storage and Temperature Monitoring" revealed the alarm checks were to be performed on a quarterly basis. In addition, the policy stated the following: (a) "The Blood Bank refrigerator has a continuous temperature monitor chart recorder"; (b) "Quarterly the temperature probe inside the refrigerator will be placed first in ice slurry. This should cause a low alarm"; (c) "There should be a noticeable decrease of temperature on the chart. Note that an alarm test was being conducted"; (d) "Record the time and individual who called from the nurses station or emergency department"; (e) "Next place the probe in warm water. This should activate the high alarm. Record the same information." (f) "Note the alarm test on the temperature chart". (3) A review of the alarm check records from March 2022, through the current date revealed the alarm checks that had been performed on 11/9/2022, 6/18/2023, 11/11/2023, and 2/17/2024 following was identified: (a) Alarm checks had not been performed quarterly. There was no documentation alarm checks had been performed: (i) Between 11/9/2022 and 6 /18/2023; (ii) Between 6/18/2023 and 11/11/2023. (b) For the alarm checks that had been performed, the following was identified: (i) There was no documentation of the temperatures that the low and high alarms sounded; (ii) There was no documentation that individuals from the nurses station and emergency department responded to the activated alarms. (4) The records were reviewed with the technical consultant who stated on 02/28/2024 at 11:00 am, the alarm checks had not been performed quarterly, the temperatures the low and high alarms had not been documented, and the responses to the remote alarms had not been documented.
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 observation and interview with the technical consultant and testing person #1, the laboratory failed to ensure expired supplies were not available for use. Findings include: BD VACUTAINER SST TUBES (1) Observation of the draw room on 02/27/2024 at 10:45 am, identified the following expired collection tubes were available for use: (a) Seven BD Vacutainer SST tubes, lot 3041219, expired 01/31

	/2024. (2) Interview with the technical consultant on 02/27/2024 at 10:50 am confirmed the collection tubes were available for use. E-CHECK HEMATOLOGY QUALITY CONTROL MATERIALS (1) On 02/27/2024 at 10:50 am, testing person #1 stated the following: (a) The laboratory performed CBC (complete blood count) testing using the Sysmex XS-1000i hematology analyzer; (b) Three levels of e-Check QC (quality control) materials were performed each day of patient testing, with each level (L1, L2, and L3) performed every 8 hours. (2) Observation of the laboratory refrigerator on 02/27/2024 at 10:50 am identified the following three levels of e-check hematology controls: (a) Level 1 - lot #40450801, Level 2 - lot #40450802, and Level 3 - lot #40450803 - The handwritten label on the bottles stated an open date of 02/16 /2024 and an open vial expiration date of 03/01/2024 (14 days). (3) Review of the manufacturer's package insert for the e-Check QC materials, under the heading "Storage and shelf life after first opening" stated, "Opened and recapped vials and vials whose caps have been pierced will retain stability for 7 days if stored at 2-8C."; (4) A review of patient records confirmed patient CBC results had been reported on 02 /24,25,26,27,28/2024 when the laboratory had used QC materials that had exceed their open vial expiration date to assess the acceptable performance of the analyzer:(5) The findings were reviewed with the technical consultant and testing person #1 who stated on 02/28/2024 at 04:35 PM, the QC materials had been used beyond the manufacturer's open vial expiration date as stated above.
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 the technical consultant and testing person #1, the laboratory failed to document function checks every six months as defined by the manufacturer for the iSTAT 1 analyzer during the review period of 05/01/2022 through 01/31/2024. Findings include: (1) On 02/28/2024 at 04:35 pm, the testing person stated the laboratory performed the following on the iSTAT 1 analyzer: (a) Glucose, Creatinine, BUN, Chloride, Potassium, Sodium, TCO2, and Ionized Calcium testing using the Chem 8+ cartridge; (b) pH, pCO2, pO2, and Lactic Acid testing using the CG4+ cartridge; (c) Troponin I testing using the cTnI cartridge. (2) A review of the i-STAT 1 Operator's manual stated in chapter 14-1 (quality control),"Ensure the thermal probe check is performed every 6 months on each handheld reader"; (3) Documentation of thermal probe checks during the review period of 05/01/2022 through 01/31/2024 could not be located; (4) The findings were reviewed with the technical consultant and testing person #1 who stated on 02/29/2024 at 10:14 am, the thermal probe checks had been performed every six months, but they had not been documented.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (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 technical consultant and testing person #1, the laboratory failed to perform calibration verification procedures at least once every six months for the i-STAT 1 test system during the review period of May 2022 through January 2024. Findings include: (1) On 02/28/2024 at 04:35 pm, the testing person stated the laboratory performed the following on the iSTAT 1 analyzer: (a) Glucose, Creatinine, BUN, Chloride, Potassium, Sodium, TCO2, and Ionized Calcium testing using the Chem 8+ cartridge; (b) pH, pCO2, pO2, and Lactic Acid testing using the CG4+ cartridge; (c) Troponin I testing using the cTnI cartridge. (2) A review of records from 05/01/2022 through 01/31/2024 identified no evidence the calibration verification procedures had been performed prior to 01/05/2024 for the Chem8+ and CG4+ test systems, and prior to 01/04/2024 for the cTnI test system; (3) The findings were reviewed with the technical consultant and testing person #1 who stated on 02/29/2024 at 10:08 am, the calibration verification procedures had not been performed every six months as stated above.
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. (c) The laboratory must document all test result comparison activities. 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 sodium, potassium, chloride, glucose, urea nitrogen, creatinine, and carbon dioxide testing performed using two test methods during the review period of March 2022 through the current date. Findings include: (1) On 02/28/2024 at 10:56 am, the laboratory manager stated the laboratory performed sodium, potassium, chloride, glucose, urea nitrogen, creatinine, and carbon dioxide testing using the Olympus AU analyzer as the primary method and the iSTAT

	analyzer and the chem8+ cartridge as the backup method; (2) On 02/28/2024 a review of records from March 2022 through the current date identified no records to prove the relationship between the different test methods had been evaluated between 08/17 /2022 and 08/27/2023; (3) The records were reviewed with the laboratory manager who stated on 02/28/2024 10:56 am, the relationship between the above test methods had not been evaluated between 08/17/2022 to 08/27/2023.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to ensure patient test reports included the address for the testing location and the interpretive data (normal patient reference ranges) for two of two patient downtime blood gas reports reviewed. Findings Include: (1) On 02/29/2024 at 10:00 am, the technical consultant stated blood gas testing was performed using the iStat analyzer using the CG4+ cartridge; (2) A review of two patient downtime reports (used during a computer downtime) with testing performed on 01/29/2024, identified the downtime reports did not include the laboratory address or reference ranges for blood gas analysis; (3) The report was reviewed with the technical consultant who stated on 02/29/2024 at 10:00 am, the laboratory address and normal reference ranges were not included on the patient reports.
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 02 /27/2024 at 10:50 am, testing person #1 stated the laboratory performed CBC (complete blood count) testing using the Sysmex XS-1000i analyzer; (2) On 02/28 /2024 two patient CBC reports were reviewed - the first report was for an adult female patient with the testing performed on 02/28/2024 at 12:41 pm; the second report was for an adult male patient with the testing performed on 02/28/2024 at 13:29 pm. Both reports included the same reference intervals for the following CBC parameters: (a) RBC (red blood cell) count - 4.17-5.37 (10^6/ L); (b) Hemoglobin - 14.0-18.0 g/dL; (c) Hematocrit - 39.2-48.9 %. (3) The reports were reviewed with the technical

	consultant and testing person #1 who stated on 02/28/2024 at 4:00 pm, the patient reports did not include gender specific reference ranges for RBC, Hemoglobin, and Hematocrit.