Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475262	03/20/2026
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 03/17,18,19,20/2026. The laboratory was found out of compliance with the following CLIA Conditions: 493.1215; D5024: Hematology 493.1210; D5016: Routine Chemistry 493.1403; D6000: Laboratory Director; Moderate Complexity Testing
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 technical consultant, the facility failed to ensure written policies were followed for preventing transfusion reactions for one of six units of packed red-blood cells transfused. Findings include: (1) On 03/18/2026 at 10:00 am, the technical consultant stated blood transfusions were performed by nursing staff; (2) A review of the hospital policy titled, "Administering Blood or Blood Products" stated: (a) "Vital signs must be taken and documented on the transfusion administration record just prior to administering blood or blood products, then"; (b) "after first fifteen minutes of transfusion": (c) "hourly until transfusion is complete"; (d) "and then upon completion of the transfusion"; (e) "One hour post infusion"; (f) "Each unit of blood must be completely infused within four (4) hours of removing from the blood bank refrigerator". (3) A review of transfusion records for six units transfused, identified the policy had not been followed for one of six units as follows: (a) Unit #W091026116010 - The unit was issued on 02/14/2026 at 09:01 pm and was stopped

	on 02/15/2026 at 01:30 am; (i) The unit was infused in 4 hours and 29 minutes. (4) The records were reviewed with the technical consultant who stated on 03/18/2026 at 10:00 am, the unit had not been given according to policy.
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION 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 ensure the requirements were met for the subspecialty of Routine Chemistry for High Sensitivity Troponin I testing during the review period of 11/25/2025 through the current date. Findings include: (1) The laboratory failed to have a written procedure for one of two new test systems introduced into the laboratory. Refer to D5401; (2) The laboratory failed to perform two levels of QC (quality control) materials for 54 of 58 days of patient High Sensitivity Troponin I testing. Refer to D5447.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION 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 ensure the requirements were met for the specialty of Hematology for CBC testing during the review period of September 2024 through the current date. Findings include: (1) The laboratory failed to demonstrate a the performance specifications for one of two new test methods introduced into the laboratory in 2024. Refer to D5421.
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 for three of five Chemistry proficiency testing events reviewed in 2024 and 2025. Findings include: I. BIASES (1) On 03/17/2026, a review of Chemistry proficiency testing records for 2024 (second, and third events) and 2025 (first, second, and third event) identified the following biases (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program) for three of five events: (a) 2024 -

	Chemistry Core 2nd Event (i) Aspartate Aminotransferase (AST) - five of five results exhibited a positive bias (aa) Sample CH-06 - SDI of 4.5 (bb) Sample CH-07 - SDI of 4.8 (cc) Sample CH-08 - SDI of 2.7 (dd) Sample CH-09 - SDI of 3.6 (ee) Sample CH-10 - SDI of 4.7 (ii) Alanine Aminotransferase (ALT) - five of five results exhibited a positive bias (aa) Sample CH-06 - SDI of 6.7 (bb) Sample CH-07 - SDI of 6.0 (cc) Sample CH-08 - SDI of 1.3 (dd) Sample CH-09 - SDI of 6.6 (ee) Sample CH-10 - SDI of 5.3 (b) 2024 - Chemistry Core 3rd Event (i) Aspartate Aminotransferase (AST) - five of five results exhibited a positive bias (aa) Sample CH-11 - SDI of 5.0 (bb) Sample CH-12 - SDI of 4.3 (cc) Sample CH-13 - SDI of 4.8 (dd) Sample CH-14 - SDI of 4.5 (ee) Sample CH-15- SDI of 5.0 (ii) Alanine Aminotransferase (ALT) - five of five results exhibited a positive bias (aa) Sample CH-11 - SDI of 6.6 (bb) Sample CH-12 - SDI of 6.5 (cc) Sample CH-13 - SDI of 6.3 (dd) Sample CH-14 - SDI of 7.2 (ee) Sample CH-15- SDI of 6.9 (c) 2025 - Chemistry Core 1st Event (i) Aspartate Aminotransferase (AST) - five of five results exhibited a positive bias (aa) Sample CH-01 - SDI of 2.7 (bb) Sample CH-02 - SDI of 2.9 (cc) Sample CH-03 - SDI of 3.2 (dd) Sample CH-04 - SDI of 2.3 (ee) Sample CH-05 - SDI of 3.6 (ii) Alanine Aminotransferase (ALT) - five of five results exhibited a positive bias (aa) Sample CH-01 - SDI of 6.2 (bb) Sample CH-02 - SDI of 6.5 (cc) Sample CH-03 - SDI of 7.2 (dd) Sample CH-04 - SDI of 3.2 (ee) Sample CH-05 - SDI of 7.2 (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 03/17/2026 at 11: 40 am, the biases had not been identified and addressed.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 policies and procedures and interview with the technical consultant and testing person #1, the laboratory failed to have a written procedure for one of two new test systems introduced into the laboratory. Findings include: (1) On 03/17/2026 at 02:23 pm, the technical consultant and testing person #1 stated the following: (a) The laboratory began performing High Sensitivity Troponin I testing using the iSTAT1 analyzer and hs-TnI cartridge on 11/25/2025. (2) A review of the laboratory's written procedure manual identified that there was no procedure available for the High Sensitivity Troponin I testing; (3) Interview with the technical consultant and testing person #1 on 03/19/2026 at 10:30 am confirmed that the laboratory did not have a written policy and procedure for High Sensitivity Troponin I testing.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 testing person #1, the laboratory failed to demonstrate the performance specifications for one of two new test methods introduced into the laboratory in 2024. Findings include: (1) On 03/17/2026 at 02:15 pm, the technical consultant and testing person #1 stated the laboratory began performing CBC (Complete Blood Count) testing using the Sysmex XN 1000 analyzer on 09/03/2024; (2) On 03/19/2026, a review of records identified no evidence the performance specifications had been demonstrated prior to putting the analyzer into use for patient testing; (3) Interview with the technical consultant and testing person #1 on 03/19/2026 at 02:25 pm confirmed there was no documentation to substantiate the performance specifications had been demonstrated prior to beginning patient testing; (4) The following were examples of patient testing performed: (a) Patient # 10023658 - testing performed on 09/04/2024 (b) Patient # 10023681- testing performed on 09/05/2024 (c) Patient #10023792 - testing performed on 09/13/2024 (d) Patient # 10023817 - testing performed on 09/16/2024 (e) Patient # 10023722 - testing performed on 09/22/2024 (f) Patient # 10024041 - testing performed on 10/01/2024 (g) Patient # 10024093 - testing performed on 10/06 /2024 (h) Patient # 10024150 - testing performed on 10/09/2024 (i) Patient # 10024226 - testing performed on 10/15/2024 (j) Patient # 10024341 - testing performed on 10/23/2024 (k) Patient # 10024491 - testing performed on 11/04/2024 (l) Patient # 10024587 - testing performed on 11/11/2024 (m) Patient # 10024654 - testing performed on 11/17/2024 (n) Patient # 10024663 - testing performed on 11/18 /2024 (o) Patient # 10024707 - testing performed on 11/20/2024 (p) Patient # 10024627 - testing performed on 12/09/2024 (q) Patient # 10024923 - testing performed on 12/10/2024 (r) Patient # 10025013 - testing performed on 12/18/2024 (s) Patient # 10025026 - testing performed on 12/19/2024 (t) Patient # 10025037 - testing performed on 12/20/2024 (u) Patient # 10025053 - testing performed on 01/09 /2025 (v) Patient # 10025312 - testing performed on 01/14/2025 (w) Patient # 10025390 - testing performed on 01/19/2025 (x) Patient # 10025412 - testing performed on 01/21/2025 (y) Patient # 10025723 - testing performed on 02/12/2025 (z) Patient # 10025748 - testing performed on 02/14/2025 (aa) Patient # 10025841 - testing performed on 02/21/2025 (bb) Patient # 10025862 - testing performed on 02/23 /2025 (cc) Patient # 10025936 - testing performed on 02/28/2025 (dd) Patient # 10026113 - testing performed on 03/13/2025 (ee) Patient # 10026149 - testing performed on 03/16/2025 (ff) Patient # 10026238 - testing performed on 03/23/2025 (gg) Patient # 10026311 - testing performed on 03/27/2025 (hh) Patient # 10026373 - testing performed on 03/31/2025 (ii) Patient # 10026403 - testing performed on 04/02 /2025 (jj) Patient # 10026442 - testing performed on 04/06/2025 (kk) Patient # 10026462 - testing performed on 04/08/2025 (ll) Patient # 10026464 - testing performed on 04/08/2025 (mm) Patient # 10026485 - testing performed on 04/10 /2025
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) 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 maintenance checklist, and interview with the technical consultant, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures during the review period of July 2024 through the current date. Findings include: (1) On 03/20/2026 at 11:15 am, the technical consultant stated Protime and Activated Partial Prothrombin Time testing were performed using the Sysmex CA-600 series analyzer; (2) A review of the the manufacturer's CA-600 maintenance checklist required the following maintenance procedure: (a) Yearly - "Replace Rinse Filter". (3) A review of maintenance logs from July 2024 through the current date identified the yearly maintenance had not been documented as performed between 07/01/2024 and 03/20 /2026; (4) The findings were reviewed with the technical consultant who stated on 03 /20/2026 at 11:15 am the laboratory was unable to provide documentation of maintenance performed 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 technical consultant and testing person #1, the laboratory failed to perform QC (quality control) as stated in the IQCP (Individualized Quality Control Plan) for D-dimer testing during the review period of April 2024 through December 2025. Findings include: (1) On 03/17/2026 at 02:20 pm, the technical consultant and testing person #1 stated the following: (a) The laboratory performed D-Dimer testing using Biosite Triage Meter Pro analyzer; (b) An IQCP had been developed for the test system; (c) The laboratory performed two levels of QC materials every thirty days according to the IQCP. (2) A review of QC records from April 2024 through December 2025 identified no documentation to prove QC had been performed between 02/21/2025 and 04/21/2025; (3) The records were reviewed with the technical consultant and testing person #1 who stated on 03/18 /2026 at 03:00 pm, QC had not been performed as stated above.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations; 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 two levels of QC (quality control) materials for 53 of 58 days of patient High Sensitivity Troponin I testing and failed to

perform two levels of QC materials for one of seven days of patient Chem 8+ testing. HIGH SENSITIVITY TROPONIN I CARTRIDGE (1) On 03/17/2026 at 02:23 pm, the technical consultant and testing person #1 stated the following: (a) The laboratory began performing High Sensitivity Troponin I testing using the iSTAT1 analyzer and hs-TnI cartridge on 11/25/2025; (b) The laboratory performed QC (Qualtiy Control) materials monthly and with each new lot and new box of cartridges. (2) On 03/18 /2026, a review of records for patient testing performed during 11/25/2025 through the current date identified at least two levels of QC materials had not been performed each day of patient testing; (3) The records were reviewed with the technical consultant who stated on 03/19/2026 at 10:20 am, two levels of QC materials had not been performed each day of patient testing. (4) The following were examples of patient High Sensitivity Troponin I testing: (a) Patient # 10029310 - testing performed on 11/25/2025 (b) Patient # 10029335 - testing performed on 11/27/2025 (c) Patient # 10029402 - testing performed on 12/03/2025 (d) Patient # 10029408 - testing performed on 12/04/2025 (e) Patient # 10029409 - testing performed on 12/04/2025 (f) Patient # 10029453 - testing performed on 12/08/2025 (g) Patient # 10029477 - testing performed on 12/09/2025 (h) Patient # 10029492 - testing performed on 12/11 /2025 (i) Patient # 10029513 - testing performed on 12/12/2025 (j) Patient # 10029514 - testing performed on 12/13/2025 (k) Patient # 10029544 - testing performed on 12/15/2025 (l) Patient # 10029557 - testing performed on 12/16/2025 (m) Patient # 10029558 - testing performed on 12/17/2025 (n) Patient # 10029585 - testing performed on 12/19/2025 (o) Patient # 10029602 - testing performed on 12/20 /2025 (p) Patient # 10029607 - testing performed on 12/22/2025 (q) Patient # 10029625 - testing performed on 12/23/2025 (r) Patient # 10029641 - testing performed on 12/25/2025 (s) Patient # 10029665 - testing performed on 12/27/2025 (t) Patient # 10029702 - testing performed on 12/31/2025 (u) Patient # 10029718 - testing performed on 01/02/2026 (v) Patient # 10029747 - testing performed on 01/03 /2026 (w) Patient # 10029752 - testing performed on 01/04/2026 (x) Patient # 10029770 - testing performed on 01/06/2026 (y) Patient # 10029795 - testing performed on 01/07/2026 (z) Patient # 10029835 - testing performed on 01/10/2026 (aa) Patient # 10029861 - testing performed on 01/13/2026 (bb) Patient # 10029885 - testing performed on 01/16/2026 (cc) Patient # 10029898 - testing performed on 01/18 /2026 (dd) Patient # 10029913 - testing performed on 01/20/2026 (ee) Patient # 10029933 - testing performed on 01/21/2026 (ff) Patient # 10029947 - testing performed on 01/22/2026 (gg) Patient # 10029966 - testing performed on 01/24/2026 (hh) Patient # 10029983 - testing performed on 01/27/2026 (ii) Patient # 10030011 - testing performed on 01/29/2026 (jj) Patient # 10030026 - testing performed on 01/31 /2026 (kk) Patient # 10030039 - testing performed on 02/01/2026 (ll) Patient # 10030056 - testing performed on 02/02/2026 (mm) Patient # 10030059 - testing performed on 02/03/2026 (nn) Patient # 10030093 - testing performed on 02/05/2026 (oo) Patient # 10030129 - testing performed on 02/08/2026 (pp) Patient # 10030170 - testing performed on 02/12/2026 (qq) Patient # 10030207 - testing performed on 02/14 /2026 (rr) Patient # 10030213 - testing performed on 02/15/2026 (ss) Patient # 10030244 - testing performed on 02/17/2026 (tt) Patient # 10030272 - testing performed on 02/19/2026 (uu) Patient # 10030289 - testing performed on 02/21/2026 (vv) Patient # 10030290 - testing performed on 02/21/2026 (ww) Patient # 10030297 - testing performed on 02/22/2026 (xx) Patient # 10030362 - testing performed on 02/28 /2026 (yy) Patient # 10030381 - testing performed on 03/02/2026 (zz) Patient # 10030442 - testing performed on 03/05/2026 (aaa) Patient # 10030459 - testing performed on 03/07/2026 (bbb) Patient # 10030502 - testing performed on 03/10/2026 (ccc) Patient # 10030532 - testing performed on 03/13/2026 (ddd) Patient # 10030547 - testing performed on 03/14/2026 (eee) Patient # 10030583 - testing performed on 03 /17/2026 (fff) Patient # 10030594 - testing performed on 03/18/2026 II. CHEM 8+

	CARTRIDGE (1) On 03/17/2026 at 02:15 pm, the technical consultant and testing person #1 stated the following: (a) The laboratory performed Sodium, Potassium, Chloride, Ionized Calcium, Glucose, BUN (Blood Urea Nitrogen), Creatinine, Anion Gap, and Total Carbon Dioxide testing using iSTAT 1 analyzer serial number 408446 and the Chem 8+ cartridge; (b) Two levels of QC (Quality Control) materials (Level 1 and Level 3) were tested on each day of patient testing. (2) A review of QC records from January through February of 2026 identified two levels of QC materials had not been performed for one of seven days of patient testing as follows: (a) Patient #10030248 - testing performed on 02/18/2026 at 00:16am. (3) The records were reviewed with the technical consultant and testing person #1 who stated on 03/19 /2026 at 09:00 am, QC materials had not been performed each day of patient testing as stated above.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the the technical consultant and testing person #1, the laboratory director failed to provide overall management and direction during the review period of September 2024 through the current date. Findings include: (1) The laboratory director failed to ensure verification procedures for new test systems were adequate to determine the performance characteristics for one of two new test systems introduced into the laboratory. Refer to D6013; (2) The laboratory director failed to ensure quality control programs were maintained to ensure the quality of laboratory services. Refer to D6020; (3) The laboratory director failed to ensure an approved procedure manual was available and followed by all personnel responsible for the testing process. Refer to D6031.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and 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 director failed to ensure verification procedures for new test systems were adequate to determine the performance characteristics for one of two new test systems introduced into the laboratory. Findings include: (1) The laboratory director failed to ensure the performance specifications had been demonstrated for one of two new test methods introduced into the laboratory in 2024. Refer to D5421.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established

	and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; 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 director failed to ensure quality control program was maintained to ensure the quality of laboratory services during the review period of November 2025 through the current date. Findings include: (1) The laboratory director failed to ensure the laboratory performed two levels of QC (quality control) materials for 53 of 58 days of patient High Sensitivity Troponin I testing. Refer to D5447.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and 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 director failed to ensure an approved procedure manual was available and followed by all personnel responsible for the testing process one of two new test systems. Findings Include: (1) The laboratory director failed to ensure the laboratory have a written procedure for one of two new test systems introduced into the laboratory. Refer to D5401.