Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0660752	10/25/2022
Name of Provider or Supplier	**Street Address, City, State**	
Haskell Memorial Hospital	1 North Avenue N, Haskell, TX	

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	Laboratory representatives were present at the entrance conference. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas Health and Human Services Commission, Health Facility Compliance Arlington Group. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Southern Operations Branch-Dallas for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 review of laboratory policy, direct observation, and confirmed in staff interview, the laboratory failed to follow their own written policy for the Alere Triage D Dimer Test Device operating specifications for 2 of 2 months reviewed in 2022 (August 2022 and September 2022). Findings Included: 1. During a tour of the facility, the surveyor observed an Alere Triage Analyzer (SN: 85378) on the laboratory work bench. Further observation revealed 1 Alere D Dimer pouch

	containing 1 test device (Lot Number: T13206N Exp: 01/23/2022), stored in the laboratory cabinet at room temperature. 2. Review of laboratory policy, "Triage D Dimer Test" (Approved by Laboratory Director on 03/2022) revealed the following: " 13. Storage and Handling Requirements... 2. Once removed from refrigeration, the pouched Test Device is stable for 14 days at room temperature, but not beyond expiration date printed on pouch. 3. Before using refrigerated Test Device, allow individual foil pouches to reach operating temperature at 20-24 Celsius. This will take a minimum of 15 minutes..." 3. Review of laboratory environmental logs for August 2022 and September 2022, "Main Laboratory Temperature Log" revealed the following temperature range: 18-30 C The laboratory failed to follow their own written policy for the Alere Triage D Dimer Test Device operating specifications for 2 of 2 months reviewed in 2022 (August 2022 and September 2022). 4. During an interview on 10/25/2022 at 10:25 a.m., in the facility chapel, the laboratory director confirmed the above findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of laboratory's policy, quality control (QC) records, and staff interview, it was revealed the laboratory failed to have a written policy or procedure for how it will remediate all patients tested from the last acceptable quality control, after multiple QC failures resulting in instrument adjustments. Findings Included: 1. Review of laboratory policy and procedures revealed the laboratory failed to include patient remediation in the analyzer quality control (QC) troubleshooting steps, following instrument adjustments due to out of control QC. 2. Review of laboratory quality control records revealed the following days instrument adjustments were made following quality control issues: August 2022 a. Amylase; Performed on: 08/04/2022; QC Troubleshooting Step: Rerun using new QC material; New FLEX used No patient remediation from the last acceptable QC was documented. b. Blood Urea Nitrogen (BUN); Performed on: 08/07/2022; QC Troubleshooting Step: Rerun using new QC material; New FLEX used No patient remediation from the last acceptable QC was documented. c. Glucose; Performed on: 08/25/2022; QC Troubleshooting Step: Rerun using new QC material; New FLEX used No patient remediation from the last

	acceptable QC was documented. d. Aspartate Aminotransferase (AST); Performed on 08/28/2022; QC Troubleshooting Step: Rerun using new QC material; New FLEX used No patient remediation from the last acceptable QC was documented. September 2022 e. BUN; Performed on: 09/20/2022; QC Troubleshooting Step: Rerun using new QC material; New FLEX used No patient remediation from the last acceptable QC was documented. f. Total Bilirubin; Performed on: 09/24/2022; QC Troubleshooting Step: Rerun using new QC material; New FLEX used No patient remediation from the last acceptable QC was documented. g. Albumin; Performed on: 09/24/2022; QC Troubleshooting Step: Rerun using new QC material; New FLEX used No patient remediation from the last acceptable QC was documented. h. Sodium; Performed on: 09/26/2022; QC Troubleshooting Step: Rerun using new QC material; New FLEX used No patient remediation from the last acceptable QC was documented. The laboratory failed to have a written procedure for how it will remediate all patients tested from the last acceptable QC, after quality control failures, following instrument adjustments. 3. Review of patient final reports, revealed the following patients that failed to be evaluated from the last acceptable QC following instrument adjustments: a. Amylase; Performed on: 08/03/2022 Patient Identification (ID): 101128; 32680 b. BUN; Performed on: 08/06/2022 Patient ID: 102149; 102150; 102151; 23212; 102152;41244 c. Glucose; Performed on: 08/24/2022 Patient ID: 20057; 102238; 102236; 25272; 40984; 38092; 19591; 38170; 25326; 22950; 30470; 20095; 28089; 23212; 26622; 18638 d. AST; Performed on: 08/27/2022 Patient ID: 26187; 37934 e. BUN; Performed on: 09/19/2022 Patient ID: 31047; 24032; 26747; 21093; 29707; 41079; 102368; 23351 f. Albumin; Performed on: 09/23/2022 Patient ID: 32318; 38997; 21836; 32707; 21348; 31318; 100144; 102386; 102324; 25166; 25264; 43030 g. Total Bilirubin; Performed on: 09/23/2022 Patient ID: 32318; 38997; 21836; 32707; 21348; 31318; 100144; 102386; 102324; 25166; 25264; 43030 h. Sodium; Performed on: 09/27/2022 Patient ID: 40058; 30666; 23461; 32740; 31849; 25083; 30804; 21129; 40157; 30810; 39754; 30417; 39361; 102396; 26825; 42890; 39835; 33039; 36426; 22764; 35233 4. During an interview on 10/24/2022 at 2:15 p.m., in the laboratory, the laboratory director confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: I. Based on direct observation, review of Alere Triage D Dimer package insert, laboratory policy, environmental records, and confirmed in interview, the laboratory failed to ensure room temperature ranges were within manufacturer specifications for the Alere Triage D Dimer Test Device for 2 of 2 months reviewed in 2022 (August 2022 and September 2022). Findings Included: 1. During a tour of the facility, the surveyor observed an Alere Triage (SN: 85378) on the laboratory work bench. Further observation revealed 1 Alere D Dimer pouch containing 1 test device (Lot Number: T13206N Exp: 01/23/2023), stored in the laboratory cabinet at room temperature. 2. Review of Alere Triage D Dimer test device package insert (Published 2017) revealed

the following: "Storage and Handling Requirements: Before using refrigerated Test Device, allow individual foil pouches to reach operating temperature (20-24 C or 68-75 F). This will take a minimum of 15 minutes." 3. Review of laboratory policy, "Triage D Dimer Test" (Approved by Laboratory Director on 03/2022) revealed the following: " 13. Storage and Handling Requirements: 2. Once removed from refrigeration, the pouches Test Device is stable for 14 days at room temperature, but not beyond expiration date printed on pouch. 3. Before using refrigerated Test Device, allow individual foil pouches to reach operating temperature at 20-24 Celsius. This will take a minimum of 15 minutes." 4. Review of laboratory environmental logs for August 2022 and September 2022, "Main Laboratory Temperature Log" revealed the following temperature range: 18-30 C The laboratory failed to ensure room temperature ranges were within manufacturer specifications for the Alere Triage D Dimer Test Device for 2 of 2 months reviewed in 2022 (August 2022 and September 2022). 5. During an interview on 10/25/2022 at 10:25 a.m., in the facility chapel, the laboratory director confirmed the above findings. II. Based on direct observation, review of Alere Triage Total 5 Quality Control package insert, laboratory environmental records, and confirmed in interview, the laboratory failed to ensure room temperature ranges were within manufacturer specifications for the Alere Triage Total 5 Quality Control for 2 of 2 months reviewed in 2022 (August 2022 and September 2022). Findings Included: 1. During a tour of the facility, the surveyor observed an Alere Triage (SN: 85378) on the laboratory work bench. Further observation revealed 1 set of Alere Triage Total 5 quality controls (Lot:T13204N Expiration Date:01/18/2023) stored in the laboratory refrigerator. 2. Review of Alere Triage Total 5 quality control package insert revealed the following: "Sample Preparation: Remove only tubes to be used from the box and place on benchtop. Return remaining tubes to the freezer. Thaw at room temperature (19-25 C) for at least 30 minutes." 3. Review of laboratory environmental logs for August 2022 and September 2022, "Main Laboratory Temperature Log" revealed the following temperature range: 18-30 C The laboratory failed to ensure room temperature ranges were within manufacturer specifications for the Alere Triage Total 5 Quality Control for 2 of 2 months reviewed in 2022 (August 2022 and September 2022). 4. During an interview on 10/25/2022 at 10:25 a.m., in the facility chapel, the laboratory director confirmed the above findings. III. Based on direct observation, laboratory environmental records, patient records and confirmed in interview, the laboratory failed to ensure room temperature ranges were within manufacturer specifications for the Sediplast ESR (erythrocyte sedimentation rate) pipettes and tubes for 2 of 2 months reviewed in 2022 (August 2022 and September 2022). Findings Included: 1. During a tour of the facility, the surveyor observed 3 packages of Sediplast ESR pipettes and tubes in the main lab cabinet. Further observation revealed the following printed on the Sediplast container, "Disposable pipettes and test tubes with 0.2 ml Sodium Citrate and capped pink stoppers. Store in a cool dry location at 20-25 C." 2. Review of laboratory environmental logs for August 2022 and September 2022, "Main Laboratory Temperature Log" revealed the following temperature range: 18-30 C The laboratory failed to ensure room temperature ranges were within manufacturer specifications for the Sediplast ESR pipettes and tubes for 2 of 2 months reviewed in 2022 (August 2022 and September 2022). 3. During an interview on 10/25/2022 at 11: 05 a.m., in the facility chapel, the laboratory director confirmed the above findings. IV. Based on direct observation, laboratory environmental records, patient records and confirmed in interview, the laboratory failed to ensure room temperature ranges were within manufacturer specifications for the Greiner Bio-One Sodium Fluoride /Potassium Oxalate collection tubes for 2 of 2 months reviewed in 2022 (August 2022 and September 2022). Findings Included: 1. During a tour of the facility, the surveyor observed 2 packages of Greiner Bio-One Sodium Fluoride/Potassium Oxalate

	collection tubes in the phlebotomy/small lab area. Further observation revealed a temperature range of 4-25 C printed on the sodium fluoride/potassium oxalate collection tube packaging. 2. Review of laboratory environmental logs (August 2022 and September 2022) for the phlebotomy area revealed the following: "RT (Room Temperature): 15-30 C." The laboratory failed to ensure room temperature ranges were within manufacturer specifications for the Greiner Bio-One Sodium Fluoride /Potassium Oxalate Lactic Acid collection tubes for 2 of 2 months reviewed in 2022 (August 2022 and September 2022). 3. During an interview on 10/25/2022 at 11:05 a. m., in the facility chapel, the laboratory director confirmed the above findings. V. Based on direct observation, laboratory environmental records, patient records and confirmed in interview, the laboratory failed to ensure room temperature ranges were within manufacturer specifications for the BD Vacutainer K2 EDTA collection tubes for 2 of 2 months reviewed in 2022 (August 2022 and September 2022). Findings Included: 1. During a tour of the facility, the surveyor observed 2 packages of BD Vacutainer K2 EDTA collection tubes in the phlebotomy/small lab area. Further observation revealed a temperature range of 4-25 C printed on the collection tube packaging. 2. Review of laboratory environmental logs (August 2022 and September 2022) for the phlebotomy area revealed the following: "RT (Room Temperature): 15-30 C." The laboratory failed to ensure room temperature ranges were within manufacturer specifications for the BD Vacutainer K2 EDTA collection tubes for 2 of 2 months reviewed in 2022 (August 2022 and September 2022). 3. During an interview on 10/25/2022 at 11:05 a.m., in the facility chapel, the laboratory director confirmed the above findings.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation, manufacturer's instructions, and staff interview, the laboratory failed to ensure reagents stored in secondary containers were labeled with proper identification, concentration, and poured/expiration dates for 3 of 3 reagents in October 2022. Findings: 1. During a tour of the laboratory on 10/25/2022 at 11:30 am, the surveyor observed the following: 1 coplin jar labeled "STEP 1, SOL C, 5 DIPS" 1 coplin jar labeled "STEP 2, SOL A, 8 DIPS" 1 coplin jar labeled "STEP 3, SOL B, 3 DIPS" The laboratory failed to label the secondary container with the lot numbers, concentration, and poured/expiration dates. Without proper labeling, the reagent could not be linked to an original container and therefore the expiration dates could not be determined. 2. Review of EKI Differential Rapid Blood Stain Kit #2295 package insert revealed: "Storage and Stability: Store tightly closed at room temperature (15-30C). Do not use after the expiration date." 3. During the exit interview on 10/25/2022 at 12:30 pm, the Laboratory Director confirmed the laboratory failed to ensure reagents stored in secondary containers were labeled with proper identification, concentration, and poured/expiration dates.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)

	(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory policy, peripheral smear stain quality control (QC) records, patient reports, and confirmed in interview, the laboratory failed to document the intended reactivity of the Differential Rapid Blood Stain Kit for CBC (complete blood count) peripheral blood smears each day of use for 112 of 116 days from July to October 2022 (random review). The findings include: 1. Review of the laboratory policy titled "Peripheral Blood Smear and Staining" revealed: "5. QUALITY CONTROL 1. The solutions for staining must be checked prior to use. Prepare a smear using a random specimen and stain the slides using the solutions following the recommended procedure. 2. The QC check must be done: 1. When a new solution set is opened 2. Once a month after usage ..." 2. A random review of the laboratory's "Peripheral Smear Stain QC" logs from July to October 2022 did not include for each day of use, documentation of the intended reactivity for the stain set for CBC peripheral blood smears performed on the following days patients were tested and reported in 2022: July 2nd through 31st August 2nd through 30th September 1st through 29th October 1st through 25th 3. A random review of patient reports revealed no documentation of intended reactivity (QC) of the Differential Rapid Blood Stain Kit for CBC peripheral blood smears. The following is a random sampling of patients that were tested and reported when quality control was not documented: 07/05/2022 Specimen ID: 11221860035A 07/11/2022 Specimen ID: 11221920029A 07/12/2022 Specimen ID: 11221930021A 08/05/2022 Specimen ID: 11222170019B 08/11/2022 Specimen ID: 11222230068A 08/25/2022 Specimen IDs: 11222370034A, 11222370015B 09/04/2022 Specimen IDs: 11222470001C, 11222470015A 09/13/2022 Specimen ID: 11222560030B 09/16/2022 Specimen ID: 11222590002A 10/07/2022 Specimen IDs: 11222800033A, 11222790017A 10/16/2022 Specimen ID: 11222890025A 4. During an interview on 10/25/2022 at 9:30 a.m., Laboratory Director confirmed the above findings.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory policy, quality control (QC) documents, patient records, and confirmed in interview, the laboratory failed to evaluate all patient test results from the last acceptable QC, after quality control failures, following instrument adjustments for 4 of 4 QC failures reviewed in August 2022 and 4 of 4 QC failures

	reviewed in September 2022. Findings Included: 1. Review of laboratory policy and procedures revealed the laboratory failed to include patient remediation in the quality control (QC) troubleshooting steps, following instrument adjustments due to out of control QC. 2. Review of QC records revealed the following QC failures reviewed in August and September 2022: August 2022 a. Amylase; Performed on: 08/04/2022; QC Troubleshooting Step: Rerun using new QC material; New FLEX used No patient remediation from the last acceptable QC was documented. b. Blood Urea Nitrogen (BUN); Performed on: 08/07/2022; QC Troubleshooting Step: Rerun using new QC material; New FLEX used No patient remediation from the last acceptable QC was documented. c. Glucose; Performed on: 08/25/2022; QC Troubleshooting Step: Rerun using new QC material; New FLEX used No patient remediation from the last acceptable QC was documented. d. Aspartate Aminotransferase (AST); Performed on 08/28/2022; QC Troubleshooting Step: Rerun using new QC material; New FLEX used No patient remediation from the last acceptable QC was documented. September 2022 e. BUN; Performed on: 09/20/2022; QC Troubleshooting Step: Rerun using new QC material; New FLEX used No patient remediation from the last acceptable QC was documented. f. Total Bilirubin; Performed on: 09/24/2022; QC Troubleshooting Step: Rerun using new QC material; New FLEX used No patient remediation from the last acceptable QC was documented. g. Albumin; Performed on: 09/24/2022; QC Troubleshooting Step: Rerun using new QC material; New FLEX used No patient remediation from the last acceptable QC was documented. h. Sodium; Performed on: 09/26/2022; QC Troubleshooting Step: Rerun using new QC material; New FLEX used No patient remediation from the last acceptable QC was documented. The laboratory failed to evaluate all patient test results from the last acceptable QC, after quality control failures, following instrument adjustments for 4 of 4 QC failures reviewed in August 2022 and 4 of 4 QC failures reviewed in September 2022. 3. Review of patient final reports, revealed the following patients that failed to be evaluated from the last acceptable QC following instrument adjustments: a. Amylase; Performed on: 08/03/2022 Patient Identification (ID): 101128; 32680 b. BUN; Performed on: 08/06/2022 Patient ID: 102149; 102150; 102151; 23212; 102152; 41244 c. Glucose; Performed on: 08/24/2022 Patient ID: 20057; 102238; 102236; 25272; 40984; 38092; 19591; 38170; 25326; 22950; 30470; 20095; 28089; 23212; 26622; 18638 d. AST; Performed on: 08/27/2022 Patient ID: 26187; 37934 e. BUN; Performed on: 09/19/2022 Patient ID: 31047; 24032; 26747; 21093; 29707; 41079; 102368; 23351 f. Albumin; Performed on: 09/23/2022 Patient ID: 32318; 38997; 21836; 32707; 21348; 31318; 100144; 102386; 102324; 25166; 25264; 43030 g. Total Bilirubin; Performed on: 09/23/2022 Patient ID: 32318; 38997; 21836; 32707; 21348; 31318; 100144; 102386; 102324; 25166; 25264; 43030 h. Sodium; Performed on: 09 /27/2022 Patient ID: 40058; 30666; 23461; 32740; 31849; 25083; 30804; 21129; 40157; 30810; 39754; 30417; 39361; 102396; 26825; 42890; 39835; 33039; 36426; 22764; 35233 4. During an interview on 10/24/2022 at 2:15 p.m., in the laboratory, the laboratory director confirmed the above findings.