Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2150939	04/13/2021
Name of Provider or Supplier	**Street Address, City, State**	
Healthcare Express	5220 Se Loop 286, Paris, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. 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 Dallas Regional Office (RO) 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.
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: I. Based on a review of the laboratory's verification records, a review of the laboratory's reference ranges for analytes tested on the Alere Triage meter, and staff interview, it was revealed the laboratory failed to have documentation of verifying its patient normal ranges for 2 of 2 analytes tested on the Alere Triage meter. Findings include: 1. A review of the laboratory's verification records for the Alere Triage meter

	(Serial number 81886) revealed verification studies were approved by the laboratory director on August 10, 2018. 2. The laboratory was asked to provide documentation of verifying the following patient normal ranges for the 2 analytes tested on the Alere Triage meter. No documentation was provided. CKMB (creatine kinase myocardial band) Normal range: 0.0 - 4.3 ng/mL TNI (Troponin) Normal range: 0.00 - 0.40 ng /mL 3. An interview with the technical consultant (as indicated on the CMS 209 form) on 4/13/21 at 10:15 a.m. in the break room, after review of the records, confirmed the above findings. II. Based on a review of the laboratory's verification records, a review of the laboratory's reference ranges for analytes tested on the Sysmex XP-300 hematology analyzer, and staff interview, it was revealed the laboratory failed to have documentation of verifying its patient normal ranges for 18 of 18 analytes tested on the Sysmex XP-300 hematology analyzer. Findings include: 1. A review of the laboratory's verification records for the Sysmex XP-300 hematology analyer (Serial number B4807) revealed verification studies were performed on August 7, 2018. 2. The laboratory was asked to provide documentation of verifying the following patient normal ranges for the 18 analytes tested on the Sysmex XP-300 hematology analyzer. No documentation was provided. WBC male: 5.0 - 10 k/mL WBC female: 4.5 - 10.0 k /mL RBC male: 4.50 - 5.50 M/mcL RBC female: 4.00 - 5.00 M/mcL HGB male: 14.0 - 17.4 g/dL HGB female: 12.0 - 16.0 g/dL HCT male: 42 - 52 % HCT female: 36 - 48 % MCV male and female: 84 - 96 fL MCH male and female: 28 - 34 fL RDW male and female: 11.5 - 14.5 pg PLT male and female: 140,000 - 400,000 mcL Neutrophils: 50 - 62 % Lymphocytes: 25 - 40 % Monocytes: 3 - 7 % Eosinophils: 0 - 3 % Basophils: 0 - 1 % Bands: 3 - 6 % 3. An interview with the technical consultant (as indicated on the CMS 209 form) on 4/13/21 at 10:15 a.m. in the break room, after review of the records, confirmed the above findings. Key: WBC - white blood cell RBC - red blood cell HGB - hemoglobin HCT - hematocrit MCV - mean corpuscular volume MCH - mean corpuscular hemoglobin RDW- red cell distribution width PLT - platelet
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, a review of the laboratory's quality control records for the Alere Triage meter from August 2018 to March 2021, and staff interview, it was revealed that the laboratory failed to have a method in place to monitor quality control values over time to detect shifts and trends for 2 of 2 analytes tested on the Alere Triage meter. Findings include: 1. A review of the laboratory's policy titled 'Alere Triage Cardiac Panel (CK-MB and Troponin I)' revealed the following: "External Controls - Good laboratory practice suggests that external controls should be tested with each new lot or shipment or every 30 days. - Assayed

	controls, Alere Total 5 Control 1 and Alere Total 5 Control 2, are used in this laboratory." 2. A review of the quality control records from August 2018 to March 2021 revealed the laboratory failed to have a method in place for monitoring and evaluating quality control results over time for the following 2 analytes tested on the Alere Triage meter: CK-MB (creatine kinase myocardial band) TNI (troponin) 3. An interview with the technical consultant (as indicated on the CMS 209 form) on 4/13 /21 at 10:50 a.m. in the break room revealed the laboratory only assessed quality control values each day and did not monitor or evaluate values over time for shifts or trends. This confirmed the above findings.
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 a patient test report for CBC (complete blood count) testing and staff interview, it was revealed the laboratory failed to provide normal ranges for 8 of 17 analytes included in the CBC test. Findings include: 1. A review of a patient test report (Patient's date of birth: 01/04/1981, resulted 04/30/2020) revealed the laboratory failed to provide normal ranges for the following 8 analytes included in the CBC test: MCHC MXD% LYM# MXD# NEUT# RDW-SD RDW-CV MPV 2. An interview with the technical consultant (as indicated on the CMS 209 form) on 4/13 /21 at 11:15 a.m. in the break room, after review of the patient test report, confirmed the above findings. Key: MCHC = Mean Corpuscular Hemoglobin Concentration MXD% = Mixed Percent (Monocyte, Eosinophil, Basophil) LYM# = Absolute Lymphocytes MXD# = Absolute Mixed (Monocyte, Eosinophil, Basophil) NEUT# = Absolute Neutrophils RDW-SD = Red Cell Distribution Width- SD RDW-CV = Red Cell Distribution Width- CV MPV = Mean Platelet Volume
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 a review of the laboratory policies, a review of the laboratory's records, and staff interview, it was revealed that the laboratory's quality assessment procedures failed to monitor, assess, and correct problems in the laboratory for the postanalytic phase of testing. Findings were: 1. Review of the laboratory's policy titled 'Quality Assurance Policy and Procedures' revealed the following: "Postanalytic - Test reports will be review periodically to ensure that the correct normal ranges are used and that interpretive information is correct." 2. Review of the laboratory's records revealed the laboratory's quality assessment procedures failed to detect and correct problems in the post analytical systems by not providing normal patient ranges for 8 of 17 analytes for

	CBC (complete blood count) testing. Refer to D5807. 3. An interview with the technical consultant (as indicated on the CMS 209 form) on 4/13/21 at 11:15 a.m. in the break room confirmed the above findings.