Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2131795	03/03/2022
Name of Provider or Supplier	**Street Address, City, State**	
Healthcare Express	23150 I30 North, Bryant, AR	

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
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: Through observations made during a tour of the laboratory and interview with laboratory staff members it was determined that the laboratory had blood collection tubes and lipid control material available for use after they were past their date of expiration. Findings follow: A) During a tour of the laboratory on 3/3/22 at 11:30 AM one of one box of BRT Liquid Assay Lipid Control, lot number 2007036 expiration date 2022-01-31 was observed in the laboratory reagent freezer and five of five sodium citrate blood collection tubes lot number 0316282 expiration date 2021-08-31 were observed in a storage cabinet. B) In an interview on 3/3/22 at 11:30 AM the laboratory staff members, identified as numbers two and three on the CMS 209 form, confirmed that the items identified above had exceeded their dates of expiration and were available for use.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

	This STANDARD is not met as evidenced by: Through observations made during a tour of the laboratory, a review of the Sysmex XP-300 maintenance log for March 2021, July 2021, and November 2021, and interviews with laboratory staff, it was determined the laboratory failed to perform and document daily system checks for the Sysmex XP-300 on two days of testing in November 2021 and failed to document required weekly and monthly maintenance on two of the three months reviewed. Survey findings include: A) During a tour of the the laboratory on 3/3/22 at 08:45 a.m. the surveyor observed the Sysmex XP-300 instrument as the only hematology analyzer for all routine hematology testing. B) Review of Sysmex XP-300 maintenance log revealed system checks require daily documentation of the performance of system shutdown, verification of background checks, verification of vacuum pressure, and check of trap chamber, and weekly cleaning of RBC and WBC transducers, cleaning of the waste chamber and monthly cleaning of the SRV tray. C) Review of the Sysmex XP-300 maintenance log revealed that on 11/3/21and 11/24/21 (two of thirty days in November 2021) the laboratory failed to document any of the required Sysmex XP-300 Daily System Checks and patients had been tested on those days. D) Review of the Sysmex XP-300 maintenance log revealed that the laboratory failed to document weekly and monthly maintenance for July 2021 and November 2021, two of the three months reviewed. E) In an interview on 3/3/22 at 11:45 AM, the laboratory staff members, identified as numbers two and three on the CMS 209 form, confirmed that the required maintenance for the Sysmex XP-300 hematology analyzer was not documented on the occasions identified above.