Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2150843	04/07/2021
Name of Provider or Supplier	**Street Address, City, State**	
Healthcare Express - Sherwood	1554 Country Club Rd, Sherwood, 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
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: Through observation and interview with laboratory staff it was determined that the laboratory failed to label the contents of one of one containers of hematology instrument cleaning fluid. findings follow: A) During a tour of the laboratory on 4/7 /21 at 11:00 AM a plastic container containing a liquid substance was observed on the counter adjacent to the Sysmex XP300 hematology analyzer labeled as only "4/7". B) When asked during an interview on 4/7/21 at 11:00 AM what the identity of the contents of the container was, the laboratory staff member, identified as number three on the CMS 209 form, said the container held cleaning fluid for the analyzer and the container "could have been labeled better".
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 observation and interview with laboratory staff it was determined that the

	laboratory had supplies available for use after they had exceeded their expiration date. Findings follow: A) During a tour of the laboratory on 4/7/21 at 11:00 AM a flat of 100 BD 4.5 ml. EDTA blood collection tubes, lot # 9280912 with an expiration date of 2021-02-28, was observed in a storage cabinet in which blood collection tubes were stored. B) In an interview on 4/7/21 at 11:00 AM the laboratory staff member, identified as number two on the CMS 209 form, confirmed that the blood collection tubes identified above had expired and were available for use.
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: Through review of the technical consultant's quality assurance reports for the years of 2019, 2020 and 2021, system performance verification documentation, lack of documentation and interview with laboratory staff it was determined that the laboratory failed to establish the precision of CKMB and troponin determinations performed on the Alere Triage MeterPro analyzer. Findings follow: A) Review of an undated technical consultant's quality assurance report reviewing records for October, November and December 2019 revealed under the heading "Sherwood" that "Triage instrument was replaced on 12/20. The old instrument was damaged in a power outage". B) Review of the performance verification documents for the Alere Triage chemstry instrument revealed one set of five level calibration material was performed for CK-MB and one set of five level calibration material was performed for Troponin and one set of two level control material was performed for each assay. This documentation did not have an adequate number of replicates to provide a statistically valid determination of system precision. C) Upon request, the laboratory was unable to provide data sufficient to determine test system precision for the Alere Triage MeterPro analyzer. D) In an interview on 4/7/21 at 11:15 AM laboratory staff members, identified as numbers two and three on the CMS 209 form, confirmed that there was no additional information to establish precision for the AlereTriage MeterPro analyzer.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

	This STANDARD is not met as evidenced by: . Through a review of verification studies for Alere Triage analyzer, lack of documentation, as well as interview with staff, it was determined the laboratory director failed to ensure that the verification procedures used were adequate to determine the precision, for the Alere Triage Cardiac analyzer as evidence by: D5421: The laboratory director failed to ensure verification procedures demonstrate the Alere Triage Cardiac analyzer could obtain precision, and established by the manufacturer and the director failed to sign the verification of the new instrument to indicate approval.