Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2157376	10/23/2020
Name of Provider or Supplier	**Street Address, City, State**	
Healthcare Express-Edmond	2300 East 2nd St, Edmond, 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 initial survey was performed on 10/23/2020. The laboratory was found in compliance with a standard-level deficiency cited. The findings were reviewed with the technical consultant and director of laboratory operations at the conclusion of the survey.
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: Based on a review of records and interview with the technical consultant and director of laboratory operations, the laboratory failed to ensure the demonstrated reportable ranges were utilized for CKMB and Troponin I testing on the Triage Meter Pro; and failed to provide evidence the verification data had been evaluated prior to implementing the Sysmex XP-300 analyzer. Findings include: QUIDEL TRIAGE METER PRO (1) At the beginning of the survey, the director of laboratory operations stated to the surveyor the laboratory began using the Quidel Triage Meter Pro to perform CKMB and Troponin I testing on 10/15/2018; (2) The surveyor reviewed the performance specification records for the analyzer and identified the following: (a) CKMB - The laboratory had demonstrated a reportable range of 2.0-67.7 ng/ml; (b) Troponin I - The laboratory had demonstrated a reportable range of 0.09-28.1 ng/ml. (3) The surveyor then requested documentation to verify the reportable ranges that were being utilized by the laboratory for CKMB and Troponin I. The following was

	identified: (a) CKMB - The laboratory was using the manufacturer's reportable range of 1.0-80 ng/ml; (b) Troponin I - The laboratory was using the manufacturer's reportable range of 0.05-30 ng/ml. (4) The surveyor reviewed the findings with the technical consultant and director of laboratory operations. Both stated the laboratory was not using the reportable ranges that had been demonstrated by the laboratory. SYSMEX XP-300 ANALYZER (1) At the beginning of the survey, the technical consultant stated to the surveyor the laboratory began using the Sysmex XN-330 analyzer to perform CBC (Complete Blood Count) testing on 10/11/2018; (2) The surveyor reviewed the performance specification records for the test system. There was no evidence the data had been reviewed and evaluated by the laboratory until 11 /13/2018; (3) The surveyor reviewed the records with the technical consultant and director of laboratory operations. The director of laboratory operations stated the data had not been signed and dated as approved until 11/13/2018. (NOTE: The interpretive guidelines at 493.1253(b)(1) state, "The laboratory is responsible for verifying the performance specifications of each nonwaived unmodified FDA-cleared or approved test system that it introduces, prior to reporting patient test results." In addition, the interpretive guidelines state, "Prior to introducing a test for routine patient testing, the laboratory must review and evaluate the verification data.")