Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2050604	02/14/2022
Name of Provider or Supplier	**Street Address, City, State**	
Healthcare Express	106 South Oop 59, Atlanta, 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
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, instrument printouts, patient final results, and confirmed in interview, the laboratory failed to follow its policy for the processing of hematology CBC (complete blood count) instrument flags for five out of eight patients reviewed from October through December 2021. The findings include: 1. Review of the laboratory procedure "Resolving CBC Flags", section "PLT [platelet] Flags" stated: "PLT FLAGS: PL PU MP DW AG Remix the sample by gentle inversion and repeat. If the flags are still present, DO NOT REPORT RESULTS. Send the sample to the reference laboratory." 2. Random review of patient instrument printouts from October 2021 through December 2021 have the following five patients that had PLT AG flags that weren't resolved with repeat testing, and reported to the provider. 10/5/2021 - Patient ID: 021193 11/5/2021 - Patient ID: 102584 12/9/2021 - Patient ID 052686 12/27/2021 - Patient ID 041568 12/13/2021 - Patient ID 022755 3. On 2/14/2022 at 14:45 hours, surveyor queried for the patient's final reports and documentation that the CBC's were sent to a reference laboratory as described by the policy. The patient final reports listed two separate CBC results: one result set was from the laboratory, and the other result set was from the reference laboratory. 4. In an interview on 2/14/2022 at 14:50 hours in the laboratory, the laboratory operations person confirmed that the patient CBC results were reported to the provider without resolving the instrument flags prior to sending the sample to a reference laboratory. .
D5781	CORRECTIVE ACTIONS

	CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on review of laboratory policy, laboratory quality control (QC) records, and confirmed in interview, the laboratory failed to document corrective actions for QC on the Sysmex-XP300 hematology analyzer, for eight out of twenty random days reviewed from 2021 and 2022. The findings include: 1. Review of the policy titled "Laboratory Duties" section "E." stated: "Document any corrective actions needed for the temperatures, humidity and quality controls." 2. Review of random days in August 2021, December 2021, and January 2022, has the following eight out of twenty days of QC failures with no documented corrective action: August 2021: 3 Days 8/27/2021 - Lot 12230711, Expiration (Exp) 11/17/21 8/8/2021 - Lot 11390710, Exp 8/25/21 8 /19/2021 - Lot 11390710, Exp 8/25/21 December 2021: 2 days 12/28/21 - Lot 13070710, Exp 2/9/22 12/29/21 - Lot 13070710, Exp 2/9/22 January 2022: 3 days 1/3 /22 - Lot 13070712, Exp 2/9/22 1/7/22 - Lot 13070712, Exp 2/9/22 1/25/22 - Lot 13070712, Exp 2/9/22 3. In an interview on 2/14/2022 at 15:20 hours, in the breakroom, the laboratory operations person confirmed that the laboratory did not document the corrective action for QC on those days. .