| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 45D1050414 | 02/15/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Healthcare Express Llp | 3515 Richmond Road, Texarkana, 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 |
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| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>. 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 six out of ten patients reviewed from December 2021 through February 2022. The findings include: 1. Review of the laboratory procedure "Resolving CBC Flags", section "WBC [white blood cell] Flags" and "PLT [platelet] Flags" stated: "WBC Flags: WL T1 T2 F1 F2 F3 WU 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. 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. Review of patient instrument printouts from December 2021 to February 2022 have the following six patients with either a WBC flag, PLT flag, or both, that wasn't resolved with repeat testing and reported to the provider. 12/16/2021 - Patient 111874: WBC - WL*, PLT - AG* 01/03/2022 - Patient 120764: PLT - AG* 01/19/2022 - Patient - 021976: PLT - AG* 02/01/2022 - Patient 08271944: WBC - T2 02/04/2022 - Patient 04251988: WBC - WL*, PLT - AG* 02/14/2022 - Patient - 112354: PLT - AG* 3. On 2/15/2022 at 09:45 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 2/15/2022 at 09:50 hours in the laboratory, the |

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| | laboratory operations person confirmed that the patient CBC results were reported without resolving the instrument flags prior to sending the sample to a reference laboratory. . |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>. Based on review of proficiency testing (PT) records and confirmed in interview, the laboratory failed to have performance verification to demonstrate accuracy, precision, and reportable range for one of one new Alere Triage meter put into use in 2021. The findings include: 1. Review of Chemistry PT records in 2021 document testing performed on the following Alere Triage meters as indicated by their serial number: Chemistry PT 1st Event: SN 33637 Chemistry PT 2nd Event: SN 88315 Chemistry PT 3rd Event: SN 88315 2. The laboratory operations person informed the surveyor on 2/15/2022 at 10:45 hours, that the laboratory received the new Alere Triage meter with the SN 88315 in February 2021, and that the laboratory began patient testing on 2/5/2021. 3. Surveyor queried for performance verification documentation on reportable range, precision, and accuracy, for the new Alere Triage meter, and none was provided. 4. In an interview on 2/15/2022 at 10:50 hours, in the conference room, the laboratory operations person confirmed that the laboratory did not have performance verification to demonstrate accuracy and precision for the new Alere Triage meter prior to its use in 2021. . |
| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(g)<br><br>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>. Based on review of the laboratory and patient test records, the Centers for Medicare and Medicaid Services (CMS) form 116, and confirmed in interview, the laboratory failed to re-evaluate the quality control plan (QCP) and/or Risk Assessment (RA) of the Alere Triage individualized quality control plan (IQCP) when changes in the test system occurred for two of two tests: CKMB and Troponin in 2021. The findings include: 1. Review of laboratory records from 2021 documents that the laboratory |

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| | received a new Triage meter (SN 88315) for patient testing in 02/2021. 2. Review of laboratory records from 2021 had no documentation of re-evaluation of the QCP and RA for CKMB and Troponin to reduce the frequency of quality control to every 30 days for the new triage meter. 3. Review of the CMS form 116, subsection VII. Non-Waived Testing lists an estimated annual volume for the subspecialty routine chemistry as 100. 4. In an interview on 2/15/2022 at 10:51 hours, in the conference room, the laboratory operations person confirmed that the laboratory did not perform a QC quality assessment, for their IQCP, for the new Alere Triage meter prior to its use in 2021. . |
| **D5781** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(1)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>. 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 eleven out of twenty random days reviewed from February through April 2021, and August 2021. 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 February 2021 through April 2021, and August 2021 has the following eleven out of twenty days of QC failures with no documented corrective action: February 2021: 2 Days 2/12/21 - Lot 03370710, Expiration (EXP) 3/10/2021 2/26/21 - Lot 03370710, EXP 3/10/2021 March 2021: 2 Days 3/04/21 - Lot 03370710, EXP 3/10/2021 3/23/21 - Lot 10550710, EXP 6/2/2021 April 2021: 3 Days 4/8/221 - Lot 10550710 Exp 6/2/2021 4/11/21 - Lot 10550710 Exp 6/2/2021 4/25/21 - Lot 10550712 Exp 6/2/2021 August 2021: 4 Days 9/09/21 - Lot 12230710 Exp 11/17/2021 9/13/21 - Lot 12230710 Exp 11/17/2021 9/23/21 - Lot 12230710 Exp 11/17/2021 9/25/21 - Lot 12230710 Exp 11/17/2021 3. In an interview on 2/15/2022 at 10:30 hours, in the conference room, the laboratory operations person confirmed that the laboratory did not document the corrective action for QC on those days. . |