

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D1084977	(X3) Date Survey Completed 06/28/2023
Name of Provider or Supplier Healthcare Express	Street Address, City, State 1509 W Loop 281, Longview, 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
D0000	An onsite survey conducted 06/28/2023 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory-provided test list, review of laboratory documents, and confirmed in interview the laboratory failed to have a written policy for one of one new test methods added, D-Dimer, since it was put into use in February 2023. The findings included: 1. Review of the laboratory-provided test list included the following new test on the Triage Meter that was put into use for patient testing in February 2023: D-Dimer 2. Review of laboratory policy did not include a policy for the D-Dimer testing on the Triage Meter. The surveyor queried for the new policy, and none was provided. 3. In an interview on 6/28/2023 at 10:40 hours, in the office, testing person (TP) 1 and the technical consultant (TC) confirmed that the laboratory did not have a written policy for D-Dimer testing on the Triage Meter.</p>
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different</p>

concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of laboratory quality control (QC) records, patient test results, and confirmed in interview, the laboratory failed to perform D-Dimer QC, every day of patient testing, for 82 of 85 patients tested from February to May on the Triage Meter. The findings include: 1. Review of laboratory quality control records had the following days where QC was performed for D-Dimer testing on the Triage Meter: 2/13/2023 3/9/2023 4/6/2023 5/8/2023 Surveyor queried for the individualized Quality Control Plan (IQCP) to support the reduction in QC frequency from every day of patient testing to once monthly and none was provided. 2. Review of patient test records included 82 patients with D-Dimer testing on days where QC had not been performed to include the following 20 patients: February 2023: 02/17/2023 - Patient ID: 02051992 02/17/2023 - Patient ID: 09271999 02/20/2023 - Patient ID: 031264 02/23/2023 - Patient ID: 91870 02/25/2023 - Patient ID: 06271954 March 2023: 03/13/2023 - Patient ID: 092397 03/13/2023 - Patient ID: 121852 03/21/2023 - Patient ID: 103047 03/22/2023 - Patient ID: 102340 03/23/2023 - Patient ID: 070749 April 2023: 04/07/2023 - Patient ID: 72442 04/19/2023 - Patient ID: 12040 04/21/2023 - Patient ID: 22762 04/21/2023 - Patient ID: 083067 04/24/2023 - Patient ID: 07181953 May 2023: 05/07/2023 - Patient ID: 05.15.35 05/10/2023 - Patient ID: 10.28.1936 05/18/2023 - Patient ID: 09.04.1966 05/30/2023 - Patient ID: 06.25.1947 05/31/2023 - Patient ID: 03171939 3. In an interview on 6/28/2023 at 09:44 hours, in the office, testing person (TP1) and the technical consultant (TC) confirmed that QC was not performed every day of patient D-Dimer testing on the Triage Meter.