

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2150937	<b>(X3) Date Survey Completed</b> 06/28/2023
<b>Name of Provider or Supplier</b> Healthcare Express-Mt Pleasant	<b>Street Address, City, State</b> 1004 S Jefferson, Mt Pleasant, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An onsite survey conducted 06/28/2023 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
<b>D5401</b>	<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 March 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 March 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 14:25 hours, in the breakroom, testing person (TP) 1 and the technical consultant (TC) confirmed that the laboratory did not have a written policy for D-Dimer testing.</p>
<b>D5447</b>	<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:

I. 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 five of five patients reviewed from March to May 2023 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: 3/1/2023 4/3/2023 5/2/2023 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 had the following five patients with D-Dimer testing on days where QC had not been performed: March 2023: 1 patient 3/27/2023 - one patient (see patient crosswalk) April 2023: 1 patient 4/10/2023 - one patient (see patient crosswalk) May 2023: 3 patients 5/5/2023 - one patient (see patient crosswalk) 5/9/2023 - one patient (see patient crosswalk) 5/23/2023 - one patient (see patient crosswalk) 3. In an interview on 6/28/2023 at 14:23 hours, in the break room, testing person (TP1) and the technical consultant (TC) confirmed that QC had not been performed every day of patient D-Dimer testing on the Triage Meter. II. Based on a review of laboratory quality control (QC) records, patient test results, and confirmed in an interview, the laboratory failed to perform hematology QC every day of patient testing for three of four days where hematology QC had not been performed on the Sysmex XP-300 hematology analyzer during a record review from October 2022 to May 2023. The findings included: 1. Review of the Sysmex XP-300 QC records, and patient test records, had the following three days where QC was not performed, and patients were tested: October 2022: 10/1/2022 - No documented Sysmex XP-300 QC Patient 092653, tested on 10/1/2022 December 2022: 12/14/2022 - No documented Sysmex XP-300 QC Patient 072488, tested on 12/14/2022 Patient 04011964, tested on 12/14/2022 Patient 111589, tested on 12/14/2022 January 2023: 1/26/2023 - No documented Sysmex XP-300 QC Patient 080267, tested on 1/26/2023 2. In an interview on 6/28/2023 at 15:35, in the breakroom, testing person (TP1) and the technical consultant (TC) confirmed that patients had been tested on the Sysmex XP-300 hematology analyzer on days where QC had not been performed.