

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2046671	(X3) Date Survey Completed 05/24/2022
Name of Provider or Supplier Healthcare Express	Street Address, City, State 711 East End Blvd South, Marshall, 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 05/24/2022 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories. .
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: . Based on a review of proficiency testing records, the Centers for Medicare and Medicaid Services (CMS) 209, and confirmed in interview, the laboratory failed to rotate proficiency testing samples through testing persons for nine of fourteen proficiency testing events reviewed from 2020 to 2022 The findings include: 1. Review of the CMS209 personnel list has four testing persons available for testing in 2020 and five testing persons available for testing in 2021 for the specialty of chemistry and hematology. 2. Review of the American Proficiency Institute (API) testing records from 2020 and 2022 has the following nine of fourteen events performed exclusively by testing personnel 2. 2020: Hematology Event 1: TP2 Chemistry Event 2: TP2 Hematology Event 2: TP2 Chemistry Event 3: TP2 Hematology Event 3: TP2 2021: Chemistry Event 1: TP2 Hematology Event 1: TP2 Chemistry Event 2: TP2 Hematology Event 2: TP2 3. In an interview on 5/24/2022 at 11:00 hours, in the office, testing personnel 1, as designated by the CMS209, confirmed that the laboratory was not rotating proficiency testing through the testing persons. .</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p>

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

. Based on review of laboratory policy, laboratory individualized quality control plan (IQCP), Centers for Medicare and Medicaid Services (CMS) form 116, and confirmed in interview, the laboratory failed to have a QC policy to include criteria to determine acceptable control results for two of two tests performed on the Quidel Triage Meter for creatine kinase-MB (CKMB) and troponin I (TNI). The findings include: 1. Review of the laboratory procedure titled "Alere Triage Cardiac Panel (CK-MB and Troponin I) section C. "External Controls" did not include the criteria to determine control acceptability. 2. Review of the laboratory IQCP for titled "Alere Triage Cardiac Panel Quality Control Plan" section "Test Systems", subsection 1. "External Controls" did not include the criteria to determine control acceptability. 3. Review of the CMS116, section VIII "Non-Waived Testing" had the annual test volume for the specialty of "Routine Chemistry" at 50. 4. In an interview 5/24/2022 at 11:45 hours, in the office, the technical consultant confirmed that the laboratory policy failed to include criteria for acceptability for CKMB and TNI on the Quidel Triage Meter. .