

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1093354	(X3) Date Survey Completed 12/02/2021
Name of Provider or Supplier Healthcare Express	Street Address, City, State 4701 W 7th St, 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
D3033	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i)</p> <p>In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, and confirmed in interview of laboratory personnel, the laboratory failed to retain the original EQC documents used to complete its Individualized Quality Control Plan (IQCP) for cardiac markers Troponin and CK-MB. The findings included: 1. Review of the laboratory's IQCP for Troponin and CK-MB found the laboratory did not retain the original Equivalent Quality Control (EQC) records used to develop its IQCP that it performed to reduce the frequency of external quality control testing to each new lot, each new box, and every 30 days of patient testing. 2. The laboratory was asked to provide documentation of retaining the original EQC documents used to perform the IQCP for Troponin and CK-MB. No documentation was provided. 3. An interview with the office manager and technical consultant on December 2, 2021 at 11:00 hours in the Marketing Office confirmed the findings. The office manager confirmed the records could not be located.</p>
D5785	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.</p>

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's policies, a review of the the laboratory's environmental records from October, November, and December 2020 and January and February 2021, and staff interview, the laboratory failed to perform corrective action when the laboratory's humidity readings were outside of its acceptable range for 24 of 151 days reviewed. The findings included: 1. A review of the laboratory's Quality Assurance policy stated under 'Humidity' states the following: "Humidity must be checked every morning and documented. If the humidity is less than 30%: Turn humidifier on and recheck humidity in one hour. If humidity is above 30%, Record corrected humidity level on the daily temperature log. If humidity is NOT above 30%, Continue to run humidifier until it is greater than 30%. Humidity MUST be above 30% and less than 80%. Record rechecks on the daily temperature log." 2. A random review of the laboratory's Temperature records from October 2020 to February 2021 found the following dates where humidity was documented outside of the laboratory's established acceptable range of 30 % to 80%: October 29, 2020 28% October 30, 2020 29% October 31, 2020 29% November 2, 2020 28% November 3, 2020 29% November 16, 2020 28% November 17, 2020 28% November 18, 2020 26% November 19, 2020 27% November 23, 2020 23% November 30, 2020 25% December 2, 2020 26% December 4, 2020 29% December 5, 2020 25% December 8, 2020 26% December 9, 2020 27% December 10, 2020 27% December 15, 2020 28% December 16, 2020 29% December 17, 2020 22% December 18, 2020 24% December 21, 2020 28% December 22, 2020 28% December 24, 2020 25% 3. The laboratory was asked to provide documentation of performing corrective action when humidity was documented outside of the laboratory's acceptable range. No documentation was provided. 4. An interview with the technical consultant (as indicated on the CMS 209 form, signed by the laboratory director on 11/14/19) on 11 /19/19 at 9:40 a.m. in the break room, after review of the records, confirmed the above findings.