

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0326926	(X3) Date Survey Completed 02/10/2022
Name of Provider or Supplier Elizabethtown Hematology Oncology	Street Address, City, State 1107 Woodland Drive Suite 105, Elizabethtown, KY	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and record review on 02/10/2022, the laboratory failed to monitor and document room temperature and humidity in the laboratory from 01/11/2020 through 02/09/2022. Findings include: 1. Room temperature readings were not recorded from 01/11/2020 through 02/09/2022. 2. Humidity readings were not recorded from 01/11/2020 through 02/09/2022. 2. Laboratory staff acknowledged in an interview at 9:45AM on 02/10/2022, that the laboratory failed to have a system in place to ensure room temperature and humidity were monitored and documented daily, using the manufacturer's recommended range for the Beckman Coulter Ac-T Diff Hematology analyzer.</p>
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p>

This STANDARD is not met as evidenced by:

Based on staff interview and record review on 02/10/2022, the laboratory failed to perform method comparison between the two (2) Beckman Coulter Ac-T Diff Hematology analyzers from 01/11/2022 through 02/09/2022. Finds Include: 1. Record review failed to show any documented method comparison between method one (1) and method two (2) of the Beckman Coulter Ac-T Diff Hematology analyzers from 01/11/2020 through 02/09/2022. 2. Interview with the staff on 02/10/2022 at 9:00AM revealed the laboratory did not have a system in place to ensure the two (2) Beckman Coulter Act-T Diff Hematology analyzers had method comparisons performed on a six (6) month interval between 01/11/2020 and 2/9/2022.