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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>44D0310629             | <b>(X3) Date Survey Completed</b><br><br>10/19/2023 |
| <b>Name of Provider or Supplier</b><br><br>State Of Franklin Healthcare  | <b>Street Address, City, State</b><br><br>215 East Springbrook Drive, Johnson City, TN |   |
| 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>   |
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| <b>D5413</b>              | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br/>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:<br/>Based on direct observation, review of the laboratory's procedures and environmental logs, and interview with the laboratory supervisor, determined the laboratory failed to ensure refrigerated storage fluctuations did not exceed approved temperature ranges for 146 of 177 days from 01.01.2023 through 08.31.2023. The findings include: 1. Observation of the laboratory at 09:25 am on 10.19.2023 revealed an Alinity refrigerated storage unit (S#221240021) in use for storing patient samples. 2. Review of the laboratory's "Temperature Ranges" procedure stated, "Acceptable ranges are established as follows: Refrigerator: 2-8C ....If any temperature is out of range, a supervisor should be notified immediately and action taken to remediate the problem. If the problem cannot be corrected reagents or patient samples should be moved to a safe storage area until the problem is resolved. Document all actions taken to correct the problem and monitor the temperature closely to assure the proper temperature is maintained." 3. Review of the laboratory's environmental records from 01.01.2023 through 08.31.2023 revealed temperatures below the accepted minimum temperature of 2C for the following dates: 2023-01-03, 2023-01-04, 2023-01-05, 2023-01-06, 2023-01-09, 2023-01-10, 2023-01-11, 2023-01-12, 2023-01-13, 2023-01-16, 2023-01-17, 2023-01-18, 2023-01-19, 2023-01-20, 2023-01-23, 2023-01-24, 2023-01-25, 2023-01-26, 2023-01-27, 2023-01-30, 2023-01-31, 2023-02-01, 2023-02-02, 2023-02-03,</p> |

2023-02-06, 2023-02-07, 2023-02-08, 2023-02-09, 2023-02-10, 2023-02-13, 2023-02-14, 2023-02-17, 2023-02-20, 2023-02-22, 2023-02-23, 2023-02-24, 2023-02-27, 2023-02-28, 2023-03-01, 2023-03-02, 2023-03-06, 2023-03-07, 2023-03-08, 2023-03-09, 2023-03-10, 2023-03-13, 2023-03-14, 2023-03-15, 2023-03-16, 2023-03-21, 2023-03-22, 2023-03-23, 2023-03-24, 2023-03-27, 2023-03-28, 2023-03-29, 2023-03-30, 2023-04-03, 2023-04-04, 2023-04-05, 2023-04-06, 2023-04-07, 2023-04-10, 2023-04-11, 2023-04-12, 2023-04-13, 2023-04-17, 2023-04-18, 2023-04-19, 2023-04-20, 2023-04-21, 2023-04-25, 2023-04-26, 2023-04-28, 2023-05-01, 2023-05-05, 2023-05-09, 2023-05-10, 2023-05-11, 2023-05-15, 2023-05-16, 2023-05-17, 2023-05-18, 2023-05-22, 2023-05-23, 2023-05-24, 2023-05-25, 2023-05-30, 2023-05-31, 2023-06-05, 2023-06-07, 2023-06-08, 2023-06-09, 2023-06-12, 2023-06-13, 2023-06-14, 2023-06-15, 2023-06-16, 2023-06-19, 2023-06-20, 2023-06-21, 2023-06-22, 2023-06-23, 2023-06-26, 2023-06-28, 2023-06-29, 2023-06-30, 2023-07-03, 2023-07-04, 2023-07-05, 2023-07-06, 2023-07-07, 2023-07-10, 2023-07-11, 2023-07-12, 2023-07-13, 2023-07-14, 2023-07-17, 2023-07-18, 2023-07-19, 2023-07-20, 2023-07-21, 2023-07-24, 2023-07-25, 2023-07-26, 2023-07-27, 2023-07-28, 2023-07-31, 2023-08-01, 2023-08-02, 2023-08-03, 2023-08-04, 2023-08-09, 2023-08-10, 2023-08-11, 2023-08-16, 2023-08-17, 2023-08-18, 2023-08-21, 2023-08-22, 2023-08-23, 2023-08-24, 2023-08-28, 2023-08-29, 2023-08-30, 2023-08-31

4. Interview with the laboratory supervisor at 2:15 pm on 10.19.2023 confirmed the laboratory failed to ensure refrigerated storage fluctuations did not exceed approved temperature ranges for 146 of 177 days from 01.01.2023 through 08.31.2023. Word Key: C = degrees Celsius