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| <b>Statement of Deficiencies</b>                                                                                           | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>39D0657854          | <b>(X3) Date Survey Completed</b><br><br>02/26/2025 |
| <b>Name of Provider or Supplier</b><br><br>Public Health Lab City Of Philadelphia                                          | <b>Street Address, City, State</b><br><br>1930 South Broad Street, Philadelphia, PA |                                                     |
| 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>(b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 review of laboratory temperature records, lack of documentation and interview with the Quality Officer, the laboratory failed to monitor and document temperatures to ensure proper storage of reagents and test system operating conditions were met for instrumentation used to perform hematology, chemistry, immunology and microbiology examinations for 242 of 852 days from 09/07/2022 to 12/31/2024. Findings include: 1. On the day of survey, 02/26/2025 at 1:31 pm, review of the laboratory's temperature logs revealed the laboratory failed to monitor and document the following temperatures for 242 of 852 days from 09/07/2022 to 12/31/2024: - refrigerator temperature (laboratory's acceptable range 2 to 8 degrees Celsius) - freezer temperature (laboratory's acceptable range -13 to -31 degrees Celsius) - room temperature (laboratory's acceptable range 15 to 30 degrees Celsius) 2. The hours of laboratory testing are Monday-Friday 07:00 am to 07:00 pm (CMS 116). The laboratory could not provide documentation of temperatures taken on days the laboratory was closed. 3. The Quality Officer confirmed the above findings on 02/26/25 at 1:40 pm.</p> |