

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D0701535	<b>(X3) Date Survey Completed</b>  10/03/2024
<b>Name of Provider or Supplier</b>  District Health Center 1	<b>Street Address, City, State</b>  1930 South Broad Street, 2nd Floor, Unit #30, 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>
<b>D3009</b>	<p><b>FACILITIES</b> CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on document review and interview with the Laboratory Director (LD), the LD failed to be present for a reasonable period of each working day in each laboratory for which he was director from 01/01/2017 to 10/03/2024 as required by Pennsylvania (PA) state regulations. Findings include: 1. The PA State regulation 5.22 (g) states: "A director shall be present for a reasonable period of each working day in each laboratory for which he is director." 2. Review of the Application for Approval to Direct more than Two Clinical Laboratories (Exception to 5.22) form, revealed the LD currently oversees 10 compliance laboratories (39D0701535) throughout multiple sites in the state of PA. 3. During an interview on 10/03/2024 at 12:20 pm, the LD confirmed he is on-site a few times annually.</p>
<b>D5413</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> 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>

This STANDARD is not met as evidenced by:  
Based on lack of documentation and interview with the Quality Officer (QO), the laboratory failed to monitor and document room temperature and humidity to ensure operating conditions were met for reliable test system operation and test result reporting of microscopic slide examinations performed in microbiology in 2022, 2023 and 2024. Findings include: 1. The Philadelphia Department of Public Health Laboratory Services Quality Plan policy states, "For all areas that have room temperature dependent reagents and supplies, daily room temperature monitoring is required." 2. Review of the Leica DM 750 microscope manufacturer's instructions revealed the technical specifications for ambient operating temperatures are 10-40 C and 20 -90% relative humidity. 3. On the day of the survey, 10/03/2024, the laboratory failed to provide documentation of the monitoring of room temperature and humidity to ensure operating conditions were met when Trichomonas (wet prep) and potassium hydroxide (KOH) microscopic examinations were performed in 2022, 2023 and 2024. 4. The QO confirmed the above findings on 10/03/2024 at 12:20 pm.