

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0862657	(X3) Date Survey Completed 02/17/2022
Name of Provider or Supplier Doctors Premier Care	Street Address, City, State 199 Hempstead Turnpike, West Hempstead, NY	
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 the review of the temperature log, the laboratory failed to document and define room temperature range for BD Vacutainer tubes and Siemens Urine Multisticks stored in the laboratory. Finding: 1. The laboratory failed to document room temperature log according to manufacturer's requirement. a. BD Vacutainer tubes manufacture requirement of room temperature is 4-25C. b. Siemens Urine Multistix manufacture requirement of room temperature is 15-30C. 2. The testing person confirmed on 2/17/2022 approximately at 10am the laboratory failed to document the room temperature.</p>
D6024	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established</p>

performance specifications are identified,

This STANDARD is not met as evidenced by:

Based on lack of room temperature log, it was determined that the laboratory director failed to identify the failure to establish a room temperature range and take remedial action, as defined in their quality assessment policy. It was confirmed on an interview with testing person on 2/17/2022 approximately at 10:00am. Refer 5413