

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2168136	(X3) Date Survey Completed 03/07/2023
Name of Provider or Supplier Premier Plus Urgent Care	Street Address, City, State 2804 Sw 134th St, Oklahoma City, OK	
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
D0000	The recertification survey was performed on 03/07/2023. The laboratory was found in compliance with a standard-level deficiency cited. The findings were reviewed with the office manager at the conclusion of the survey.
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 a review of records, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to ensure the humidity was maintained as required by the manufacturer of the Sysmex pocH-100i analyzer for was stored as required by the manufacturer for two of 14 months. Findings include: (1) On 03/07 /2023 at 10:30 am, the office manager stated the laboratory performed CBC (Complete Blood Count) testing using the Sysmex pocH-100i analyzer; (2) A review of the manual "Sysmex pocH-100i Instructions for Use" in Section 1.2.2 titled, "Performance Characteristics-Specifications" stated, "Relative humidity 30-85%"; (3) A review of the laboratory humidity records from January 2022 through February 2023 identified the humidity readings were less than 30% for four of 14 months as follows: (a) January 2022 - 25 of 31 humidity readings were documented as less than 30% (days 02,03,04,06,07,10,11,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28,29,30,31); (b) February 2022 - five of 28 humidity readings was documented as less than 20% (days</p>

08,09,10,11,15). (4) The records were reviewed with the office manager who stated on 03/07/2023 at 11:50 am the laboratory humidity had not been maintained as required by the manufacturer as shown above.