

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D1045198	<b>(X3) Date Survey Completed</b>  12/08/2022
<b>Name of Provider or Supplier</b>  Kids Choice Pediatrics, PLLC	<b>Street Address, City, State</b>  212 Phoenix Court Suite #1, Seymour, 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>
<b>D5413</b>	<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 review of ABX Micros 60 operator's manual, lack of documentation and interview with laboratory director, the laboratory failed to monitor the room temperature and humidity in the area where the complete blood count (CBC) instrument is located in 2020, 2021, and 2022. Findings included: 1. Review of the ABX Micros 60 operator's manual stated the following in the section titled "Operating Temperature/Humidity": "18 to 32 C (65 to 90 F)" "Maximum relative humidity, 80% for temperatures up to 31 C (88 F)" 2. There were no environmental records for monitoring of room temperature and humidity for surveyor review. 3. Phone interview with the laboratory director on 12.08.2022 at approximately 2:30 pm confirmed the laboratory failed to monitor the room temperature and humidity where the CBC instrument was located in 2020, 2021, and 2022.</p>