

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2141626	(X3) Date Survey Completed 01/19/2023
Name of Provider or Supplier Pediatrics East, Inc - Arlington	Street Address, City, State 5580 Airline Rd, Arlington, TN	
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 observation of the laboratory, review of the manufacturer's operators manual, laboratory maintenance and temperature records, and interview with the technical consultant (TC), the laboratory failed to monitor and document the humidity in the area where the complete blood count (CBC) instrument was being used for patient testing in 2021, 2022, and 2023. The findings include: 1. Observation of the laboratory on 01.19.2023 at 9:35 am revealed a CELL-DYN Emerald CBC instrument (serial number 030717-007230) in use for performing patient testing. 2. Review of the manufacturer's operators manual, environmental specifications section, revealed the CELL-DYN Emerald instrument has a relative humidity of 80 % maximum at 89.6 degrees Fahrenheit (32 degrees Celsius). 3. Review of the laboratory's maintenance and temperature records revealed the laboratory did not monitor humidity in 2021, 2022, and 2023. 4. Interview with the TC on 01.19.2023 at 1:35 pm confirmed the laboratory did not monitor or document the humidity in the area where the CBC instrument was used for patient testing in 2021, 2022, and 2023.</p>