

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2125921	(X3) Date Survey Completed 03/05/2026
Name of Provider or Supplier Tchms - Ii Green Township	Street Address, City, State 5885 Harrison Ave, Cincinnati, OH	
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	An on-site validation survey was conducted on March 05, 2026 with the following standard level deficiencies cited.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 direct observation, manufacturer instructions, laboratory policies, temperature records, and interview with Technical Consultant (TC) #1, according to the Centers for Medicare and Medicaid (CMS) Form 209, the laboratory failed to define room temperature ranges consistent with manufacturer instructions of storage requirements for 1,000 of 1,000 Becton Dickinson (BD) Vacutainer tubes. Findings Included: 1) During a laboratory tour at 11:15AM, the following BD Vacutainer tubes were observed in the storage cabinets of the laboratory with manufacturer storage temperature requirements of 4 to 25 degrees Celsius: a. 400 K2E Purple Top Tubes, Lot Number 5260183 b. 300 SST Yellow Top Tubes, Lot Number 5324063 c. 100 Lithium Heparin Green Top Tubes, Lot Number 5197604 d. 200 Sodium Citrate Tubes, Lot Number 5225439 2) Review of the laboratory's policy and procedure manual '06-108 SYSMEX XN-430-CBCDMONC' revealed the following differing room temperature ranges defined: a. Page 2 - "EDTA blood samples should be analyzed within 24 hours when stored at room temperature (18-26 degrees Celsius)"</p>

b. Page 4 - "SULFOLYSER Storage. Allow the container to equilibrate to environmental temperature (15-35 degrees Celsius)" c. Page 5 - "Lysercell WDF Storage. Use at environmental temperature (15 to 35 degrees Celsius)" 3) Review of the laboratory's temperature logs revealed an acceptable room temperature range of 18 to 30 degrees Celsius. 4) In an interview at 11:20 AM, TC #1 confirmed the findings that the laboratory failed to define room temperature ranges in accordance with manufacturer's instructions.