

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0677021	(X3) Date Survey Completed 01/25/2023
Name of Provider or Supplier Memphis Childrens Clinic	Street Address, City, State 7672 Airways, Southaven, MS	
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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on review of the maintenance log in the Sysmex XNL-330 User's Manual, lack of documentation from 4/15/2022 through 1/25/2023, and interview with the office manager at 12:00 p.m. on 1/25/2023, the laboratory failed to document as performed the manufacturer's required daily and weekly maintenance and reagent change information on the Sysmex XNL-330 hematology analyzer. Findings include: 1. The Sysmex XNL-330 manufacturer's requires the following maintenance be performed and documented: Daily Maintenance: a. Execute shutdown Daily QC: a. Quality Control b. Verify Background Count Weekly Maintenance: a. Run Cell Clean Auto Reagent Change: Cell Pack DCL, Lysercell WDF, Sulfolyser SLS, Fluorocell WDF 2. Interview with the Office Manager on 1/25/2023 at 12:00 p.m. confirmed maintenance was not documented as performed for the Sysmex XNL-330 hematology analyzer since instrument installation on 4/15/2022.</p>
D6049	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of laboratory testing records to include temperature logs from 6/1/2021 through 1/25/2023 and interview with the Office Manager at 12:00 p.m. on 1/25/2023, the following records had not been documented as reviewed by the technical consultant (TC): Findings Include: 1. The surveyor reviewed laboratory records to include temperature logs from 6/1/2021 through 1/25/2023. There was no documented review of the following records by the technical consultant: a. Temperature logs (room, humidity and refrigerators) from 6/1/2021 through 1/25/2023 2. Interview with the Office Manager 12:00 p.m. on 1/25/2023 confirmed there was no documented review of the temperature records by the TC.