

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2275483	(X3) Date Survey Completed 11/16/2023
Name of Provider or Supplier Med 360 Urgent Care Northport Llc	Street Address, City, State 3250 Mcfarland Blvd, Northport, AL	
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 a review of the temperature records, QuantStudio user manual, Sysmex XP 300 technical support, and an interview with the Technical Supervisor, the Laboratory failed to ensure room temperature for the Sysmex XP 300 Hematology analyzer and QuantStudio PCR analyzers was documented. This was noted for three of three months. The findings include: 1. A review of the temperature records for the Sysmex XP 300 Hematology analyzer and QuantStudio PCR analyzers revealed the room temperature was not documented from August through November 16, 2023. 2. A further review of the Sysmex XP 300 and QuantStudio user manual revealed the QuantStudio Enviromental Requirements Table 2, "Operating Conditions Temperature: 15-30 degrees Celcius." 3. A call to Sysmex Technical Support confirmed the optimal temperature for the Sysmex XP 300 analyzer is 15-30 degrees Celcius. 4. During an interview on November 16, 2023, at 1:00 PM, the Technical Supervisor confirmed the above findings.</p>
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</p>

must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on a review of the Hematology maintenance records, the Sysmex XP 300 user manual, and an interview with the Technical Supervisor, the Laboratory failed to document daily, weekly, and monthly maintenance on the Sysmex XP 300 Hematology analyzer as per the manufacturer's requirements for three of three months in 2023. The findings include: 1. A review of the Sysmex XP 300 Hematology analyzer records revealed no documentation of the daily, weekly, and monthly maintenance from August through November 16, 2023. 2. A further review of the Sysmex XP 300 user manual revealed: a) Page 8, "ShutdownDaily Maintenance Procedure" b) Page 9, "Weekly Maintenance- Clean the SRV tray" c) Page 10, "Monthly Maintenance- Clean Waste Chamber (Rinse Sequence)" 2. During an interview on November 16, 2023, at 12:30 PM, the Technical Supervisor confirmed the above findings.