

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D2056419	<b>(X3) Date Survey Completed</b>  03/05/2026
<b>Name of Provider or Supplier</b>  Medhelp Trussville	<b>Street Address, City, State</b>  5915 Chalkville Mountain Rd Suite 100, Birmingham, AL	
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>(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 reviews of the Temperature Charts, the Abbott Cell Dyn operator's manual, the patient history records and an interview with the Technical Consultant (TC), the laboratory failed to document the corrective action when the Room Temperature (RT) was outside the manufacturer's established limits. The surveyor noted the RT was out of range for 3 of the 31 days in January 2025 and 1 of the 30 days in November 2025. The findings include: 1. A review of the Temperature Charts and the Abbott Cell Dyn operator's manual revealed the following RT were recorded as follows with no corrective action documented when the temperatures were outside manufacturer's acceptable limits of 18-30 degrees Celsius for three days in 2025. A) January 2, 2025, temperature was 17.7 degrees Celsius B) January 12, 2025, temperature was 17.5 degrees Celsius C) November 11, 2025, temperature was 17.8 degrees Celsius 2. A review of the patient history records revealed a total of 78 patients were tested when the Rt was outside manufacturer's established limits. 3. The TC confirmed the above findings during the exit conference on 03-04-2026 at 1:21 PM.</p>
<b>D5429</b>	MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

(a)(1) 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 reviews of the Abbott Cell-Dyn Hematology maintenance records, the Abbott Cell-Dyn Emerald Quick Reference Guide, and an interview with the Technical Consultant (TC), the laboratory failed to document the semi-annual maintenance, as per manufacturer's instructions. This was noted for four of four semi-annual maintenances required in 2024-2025. The findings include: 1. A review of the Hematology maintenance records revealed the 2024 and 2025 Abbott Cell-Dyn Emerald maintenance logs had no documentation of the semi-annual maintenance. 2. A review of the Cell-Dyn Emerald Quick Reference Guide revealed on page 80 the following instructions, Semi-annual Maintenance - Lubricating the Pistons, "For optimal operation, ...be lubricated every six months ...". 3. The TC confirmed the above findings during the exit conference on 03-05-2026 at 2:26 PM.