

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0707377	<b>(X3) Date Survey Completed</b>  03/04/2026
<b>Name of Provider or Supplier</b>  Medhelp Lakeshore Pc	<b>Street Address, City, State</b>  1 W Lakeshore Drive 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 package inserts for Hematology Cell-Dyn 18 Plus Controls, Liquichek Immunoassay Plus Control, Cardiac and D-Dimer test devices, and an interview with the Technical Consultant (TC), the laboratory failed to document the corrective action when the refrigerator temperature was outside the manufacturer's specified range. The surveyor noted refrigerator temperatures were out of range for 4 of the 28 days in February 2025. The findings include: 1. A review of the temperature charts revealed the following refrigerator temperatures were recorded as follows with no corrective action documented when the temperature was outside manufacturer's acceptable limits for four days in February 2025. A) February 12, 2025, temperature was 1.6 degrees Celsius B) February 20, 2025, temperature was 1.6 degrees Celsius C) February 21, 2025, temperature was 1.8 degrees Celsius D) February 26, 2025, temperature was 0.4 degrees Celsius 2. A review of the package inserts for the temperature requirements for the materials stored in the refrigerator revealed the following manufacturer's established limits. a) Hematology Cell-Dyn 18 Plus Controls, Storage and Stability, "... capped and stored at 2-10 degrees Celsius." b) Liquichek Immunoassay Plus Control, Storage and Stability, "...opened and stored tightly capped at 2-8 degrees Celsius." c) Cardiac and D-Dimer test devices, Storage</p>

and Handling requirements, page 4 in the Triage Cardiac and D-Dimer Panel Product insert, "Store Test Devices in a refrigerator at 2-8 degrees Celsius." 3. The TC confirmed the above findings during the exit conference on 03-04-2026 at 1:21 PM.

**D5429**

**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 every six months' maintenance, as per manufacturer's instructions. The surveyor noted four of the four required maintenances from 2024-2025 had no evidence of documentation. 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 every six months' 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 03-04-2026 at 1:21 PM.

**D6045**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(7)

(b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

This STANDARD is not met as evidenced by:

Based on a review of personnel records, and an interview with the Technical Consultant (TC), TC failed to ensure training was performed and documented as per CLIA requirements for all Testing Personnel (TP). The surveyor noted two of the seven TP listed on the Form CMS-209 (Laboratory Personnel Report) were missing training documentations in the moderate complexity tests before patient testing. The findings include: 1. A review of the personnel records revealed no 2024 training documentation for TP6 and no 2025 training documentation for TP7 for the following moderate complexity testing. a) Abbott Emerald Cell Dyn analyzer for Complete Blood Count testing b) Quidel Ortho Triage Meter Pro analyzer for Cardiac Panel and D-Dimer testing c) Serum Human Chorionic Gonadotropin kit test 2. The TC confirmed the above findings during the exit conference on 03-04-2026 at 1:21 PM.