

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D1009754	(X3) Date Survey Completed 02/03/2026
Name of Provider or Supplier Medhelp Pelham	Street Address, City, State 3170 Pelham Parkway, Pelham, 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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>(a)(1) 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 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 from 2024-2025. The findings include: 1. A review of the Hematology maintenance records revealed the 2024-2025 Abbott Cell-Dyn Emerald maintenance logs had no documentation of the semi-annual maintenance. 2. A further review of the Cell-Dyn Emerald Quick Reference Guide revealed on page 80, 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 02-03-2026 at 1:07 PM.</p>
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system</p>

performance and environmental conditions, and variance in operator performance.

This STANDARD is not met as evidenced by:

Based on a review of the Hematology Abbott Cell-Dyn Emerald Quality Control (QC) records and an interview with the Technical Consultant (TC), the laboratory failed to provide documentation to monitor for shifts and trends of test performance over time. The surveyor noted one of the four months reviewed from 2024-2025 was missing at the time of the survey. The findings include: 1. A review of the Abbott Cell-Dyn Emerald QC records revealed only the daily QC data from the instrument were retained in December 2024. No evidence of Levey-Jennings (LJ) charts or peer group data was available for review at the time of the survey. 2. The TC confirmed the above findings during the exit conference on 02-03-2026 at 1:07 PM.