

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2029867	(X3) Date Survey Completed 02/10/2026
Name of Provider or Supplier Vaughn Family Care Llc	Street Address, City, State 9540 Wynlakes Place, Montgomery, 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 Testing Personnel 1 (TP1), the laboratory failed to document the semi-annual maintenance, as per manufacturer's instructions. This was noted for four of the four semi-annual maintenances required in 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. TP1 confirmed the above findings during the exit conference on 02-10-2026 at 1:19 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 Abbott Cell Dyn Hematology Quality Control (QC) records and interviews with Testing Personnel 1 (TP1), the laboratory failed to retain the monthly documentation of Levey Jennings (L-J) charts to monitor shifts and trends of test performance over time. The surveyor noted one of the three QC levels was missing the L-J charts in April 2025 and three of the three QC levels were missing the L-J charts for 6 of the 30 days in September 2025. The findings include: 1. A review of the Abbott Cell Dyn Emerald Hematology QC records revealed the High QC level was missing L-J charts in April 2025 2. A review of the L-J charts revealed all three levels of QC in the month of September 2025 were missing for the following days, September 1-5 and September 7. 3. During the exit conference on 02-10-2026 at 1:19 PM, TP1 confirmed the above findings.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--

This STANDARD is not met as evidenced by:

Based on a review of the personnel records and an interview with Testing Personnel 1 (TP1), the TC failed to ensure competency assessments for Testing Personnel (TP) performing moderate complexity testing included the six minimal CLIA regulatory requirements. The surveyor noted the semi-annual and annual competency assessments of two TP were missing six of the six CLIA requirements in 2024-2026. The findings include: 1. A review of the 2024-2026 personnel records revealed TP competency assessments for TP1 and TP2 in the Hematology specialty had no documentation of the six minimal CLIA regulatory requirements which are as follows: (1) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing, and testing. (2) Monitoring the recording and reporting of test results. (3) Review of intermediate test results of worksheets, quality control records, proficiency testing results, and preventive maintenance results. (4) Direct observation of performance of instrument maintenance and function checks. (5) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. (6) Assessment of problem-solving skills. 2. TP1 confirmed the above findings during the exit conference on 02-10-2026 at 1:19 PM.