

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D2055268	<b>(X3) Date Survey Completed</b>  11/19/2025
<b>Name of Provider or Supplier</b>  Immediate Care Foley	<b>Street Address, City, State</b>  1265 South Mckenzie Street, Foley, 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>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) Proficiency Testing (PT) records, and an interview with the General Supervisor (GS), the laboratory failed to implement a mechanism to verify the accuracy of the D-Dimer test, a non-regulated analyte. The surveyor noted unsatisfactory PT evaluations occurred in two of the three events in 2025. The findings include: 1. A review of the 2025 AAB-MLE PT records revealed failing D-Dimer scores of 40 percent for the following events: A) Chemistry M2 2025 Event B) Chemistry M3 2025 Event 2. The GS confirmed the above findings during the exit conference on 11-19-2025 at 4:30 PM.</p>
<b>D5429</b>	<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 Operator's manual, and an interview with the General Supervisor (GS), the laboratory failed to perform and document the semi-annual maintenance, as per manufacturer's instructions. There was no documentation the laboratory performed the required semi-annual maintenance the past 15 months since</p>

the analyzer installation on 08-16-2024. The findings include: 1. A review of the Hematology maintenance records revealed the Abbott Cell-Dyn Emerald analyzer had no documentation of the semi-annual maintenance from the date of installation, 08-16-2024 through date of the current survey, 11-19-2025. 2. A review of the Cell-Dyn Emerald Operator's manual revealed on page 9-13, "Section 9: Service and Maintenance ...Semi-Annual Maintenance - Lubricating the Pistons...". 3. The GS confirmed the above findings during the exit conference on 11-19-2025 at 4:30 PM.

**D5431**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(a)(2)

(a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following:

This STANDARD is not met as evidenced by:  
Based on reviews of the i-STAT maintenance logs, the ABBOTT i-STAT System Manual and an interview with the General Supervisor (GM), the laboratory failed to perform and document function checks required by the manufacturer every six months on the i-STAT analyzer from the previous survey on 05-24-2023 to the current survey on 11-19-2025. The findings include: 1. A review of the i-STAT maintenance logs revealed no documentation of the manufacturer's required function checks for the Thermal Probe every six months. 2. A review of the i-STAT System Manual on page 14-17 revealed the following: "...Thermal Probe Check: Check the thermal probes on the i-STAT 1 Analyzer as follows: ...4. Interpretation of the thermal probe check value: Acceptable: a value from -0.1 to +0.1, inclusive... Documentation of Results: ... use the form included in this section of the manual to record the results." 3. The laboratory was unable to provide documentation of the thermal probes checks during the survey. 4. During the exit conference on 11-19-2025 at 4:30 PM, the GM confirmed the above findings.