

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D1091355	<b>(X3) Date Survey Completed</b>  01/16/2025
<b>Name of Provider or Supplier</b>  Immediate Care Of The South	<b>Street Address, City, State</b>  4270 Cottage Hill Road, Mobile, 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>D2009</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Medical Laboratory Evaluation (MLE) Proficiency Testing (PT) records and an interview with Testing Personnel 1 (TP1), the laboratory failed to ensure the Laboratory Director (or designee) signed the attestation statements for three of the six events reviewed from 2023-2025. The findings include: 1. A review of the MLE PT records revealed no signature by the Laboratory Director (or designee) on the attestation statements for the following events. A) 2024 MLE-1 Event B) 2024 MLE-2 Event C) 2024 MLE-3 Event 2. The RN/Administrator, Laboratory Supervisor and TP1 present during the exit conference on 01-16-2025 at 2:35 PM, confirmed the above findings.</p>
<b>D5211</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Medical Laboratory Evaluation (MLE) Proficiency Testing (PT) records and an interview with the Testing Personnel 1 (TP1), the laboratory failed to document the PT evaluation review for four of the six events reviewed from 2023-2024. The findings include: 1. A review of the MLE PT records revealed no</p>

documentation of the PT performance review from the Laboratory Director (or designee) for the following events. a) 2023 MLE-3 b) 2024 MLE-1 c) 2024 MLE-2 d) 2024 MLE-3 2. The RN/Administrator, Laboratory Supervisor and TP1 present during the exit conference on 01-16-2025 at 2:35 PM, confirmed the above findings.

**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 a review of Abbott i-STAT maintenance records, Abbott i-STAT manual, and an interview with Testing Personnel 1 (TP1), the laboratory failed to perform and/or document software updates and function checks required by the manufacturer on the i-STAT analyzer for 2023. The findings include: 1. A review of the i-STAT maintenance records revealed lack of documentation of the CLEW software updates, the external Electronic Simulator checks or the thermal probes checks during the survey. 2. A review of the Abbott manufacturer's instructions revealed the following: A) A review of the i-Stat Technical Bulletin revealed "...it is necessary to update standardization values .. to maintain long-term consistency of performance. ...New CLEW software--delivered twice a year ...re-establishes these standardization values ...". B) A review of the Abbott i-Stat System Manual revealed "...A quality check is performed on the thermal probes each time the external Electronic Simulator is used. ...Therefore [Abbott] recommends that the thermal probe check be verified ever six months". 3. During an interview on 01-16-2025 at approximately 12:47 PM, TP1 expressed she had always performed the CLEW updates and function checks, however she was unable to find the documentation for 2023. 4. The RN /Administrator, Laboratory Supervisor and TP1 present during the exit conferenc on 01-16-2025 at 2:35 PM, confirmed the above findings.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on a review of the personnel records and an interview with the Testing Personnel 1 (TP1), the Technical Consultant failed to ensure all Testing Personnel (TP) listed on the CMS-209 (Laboratory Personnel Report) who performed moderate complexity testing had semi-annual competency assessments. The surveyor noted four of the eight TP had no documentation of semi-annual competency assessment from 2023-2025. The findings include: 1. A review of the personnel records revealed four of the eight TP who performed moderate complexity Hematology testing did not have documentation of the semi-annual competency assessment. 2. The RN/Administrator,

Laboratory Supervisor and TP1 present during the exit conference on 01-16-2025 at 2: 35 PM, confirmed the above findings.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

(b)(9) Thereafter, evaluations must be performed at least annually

This STANDARD is not met as evidenced by:  
Based on a review of the personnel records and an interview with the Testing Personnel 1 (TP1), the Technical Consultant failed to ensure all Testing Personnel (TP) listed on the CMS-209 (Laboratory Personnel Report) who performed moderate complexity testing had annual competency assessments. The surveyor noted three of the eight TP had no documentation of annual competency assessment from 2023-2025. The findings include: 1. A review of the personnel records revealed three of the eight TP who performed moderate complexity Hematology testing did not have documentation of the annual competency assessment. 2. The RN/Administrator, Laboratory Supervisor and TP1 present during the exit conference on 01-16-2025 at 2: 35 PM, confirmed the above findings.