

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0305481	(X3) Date Survey Completed 02/12/2026
Name of Provider or Supplier Imc Diagnostic And Medical Clinic	Street Address, City, State 1700 Springhill Ave Suite 100, Mobile, 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
D2009	<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 College of American (CAP) Proficiency Testing (PT) records and an interview with the General Supervisor (GS), the laboratory failed to ensure the Laboratory Director (LD) or designee and the Testing Personnel (TP) had signed the attestation statements for 5 of the 83 PT events reviewed in 2024-2025. The findings include: 1. A review of the 2024-2025 CAP PT records revealed the LD or designee and TP failed to sign the attestation statements for the following PT events: a) Y-B 2024 Sex Hormones, no TP signature b) GH5-A 2025 Hemoglobin A1C, no TP signature c) CAR-A 2025 Cardiac Markers, no LD or designee signature d) BNP-B 2025 B-type Natriuretic Peptide, no LD or designee signature e) CRS-B 2025 Crystals, no LD or designee signature 2. The GS confirmed the above findings during Day 2 exit conference on 02-12-2025 at 11:15 AM.</p>
D5211	<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 College of American (CAP) Proficiency Testing (PT) records and an interview with the General Supervisor (GS), the laboratory failed to</p>

document review and evaluation of PT performance. This was noted for one of the three 2024 PT events reviewed. The findings include: 1. A review of the CAP PT records revealed no documentation of review on the returned evaluations by the Laboratory Director, or designee, for the K-C 2024 Ligand General event. 2. The GS confirmed the above findings during Day 2 exit conference on 02-12-2025 at 11:15 AM.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

(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.

This STANDARD is not met as evidenced by:

Based on reviews of the daily room Humidity logs, the Sysmex XN-9100 Instructions for Use (IFU) Manual and an interview with the General Supervisor (GS), the laboratory failed to document the corrective action when the Humidity was outside the manufacturer's specified range. The surveyor noted temperatures were out of range for 2 of the 31 days in January 2025 and 1 of the 28 days in February 2025. The findings include: 1. A review of the daily room Humidity logs revealed the following recorded humidity. A) January 21, 2025, humidity was 17.0 percent B) January 23, 2025, humidity was 18.5 percent C) February 21, 2025, humidity was 18.1 percent 2. A review of the Sysmex XN-9100 IFU manual revealed on Chapter 15 Technical Information, 15.1 Performance Specifications, "Operating environment, Relative Humidity: 20 to 85 percent". However, on the days when the humidity reading was below 20 percent, no corrective actions were documented. 3. The GS confirmed the above findings during Day 2 exit conference on 02-12-2025 at 11:15 AM.