

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0264171	(X3) Date Survey Completed 07/20/2022
Name of Provider or Supplier Internal Medicine Associates	Street Address, City, State 330 Hospital Drive Building C Suite 200, Macon, GA	
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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) Recertification survey was completed on July 20, 2022. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on review of the daily temperature and relative humidity charts for November 2020, to April 2022, and staff interview the laboratory failed to properly document the humidity. Findings: 1. Review of the Daily Humidity logs for November 2020 through April 2021, and November 2021 thru April 2022 shows that the humidity was documented out of range the following number of days: November 2020, out of 34 entries the humidity was out of range 6 times December 2020, out of 36 entries the humidity was out of range 11 times January 2021, out of 31 entries the humidity was out of range 8 times February 2021, out of 30 entries the humidity was out of range 5 times March 2021, out of 30 entries the humidity was out of range 4 times April 2021, out of 44 entries the humidity was out of range 6 times May thru October 2021 all humidity entries were within the range November 2021, out of 38 entries the humidity was out of range 5 times December 2021, out of 42 entries the humidity was out of</p>

range 5 times January 2022, out of 41 entries the humidity was out of range 23 times February 2022, out of 39 entries the humidity was out of range 7 times March 2022, out of 46 entries the humidity was out of range 5 times April 2022, out of 42 entries the humidity was out of range 7 times Out of 18 months the humidity was out of range 92 times 2. Interview with the Laboratory Supervisor, on July 20, 2022, at approximately 3pm, in the laboratory office confirmed the aforementioned statements.

D6010

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(2)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed.

This STANDARD is not met as evidenced by:

Based on review of the daily temperature and relative humidity charts for November 2020, to April 2022, and staff interview the Laboratory Director failed to provide oversight when the humidity was out of range. Findings: 1. Review of the Daily Humidity logs for November 2020 through April 2021, and November 2021 thru April 2022 shows that the humidity was documented out of range the following number of days: November 2020, out of 34 entries the humidity was out of range 6 times December 2020, out of 36 entries the humidity was out of range 11 times January 2021, out of 31 entries the humidity was out of range 8 times February 2021, out of 30 entries the humidity was out of range 5 times March 2021, out of 30 entries the humidity was out of range 4 times April 2021, out of 44 entries the humidity was out of range 6 times May thru October 2021 all humidity entries were within the range November 2021, out of 38 entries the humidity was out of range 5 times December 2021, out of 42 entries the humidity was out of range 5 times January 2022, out of 41 entries the humidity was out of range 23 times February 2022, out of 39 entries the humidity was out of range 7 times March 2022, out of 46 entries the humidity was out of range 5 times April 2022, out of 42 entries the humidity was out of range 7 times Out of 18 months the humidity was out of range 92 times Review of the humidity charts for the dates above the charts had been reviewed, signed and marked as being acceptable. 2. Interview with the Laboratory Supervisor, on July 20, 2022, at approximately 3pm, in the laboratory office confirmed the aforementioned statements.