

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number</p> <p>11D2180727</p>	<p>(X3) Date Survey Completed</p> <p>07/31/2023</p>
<p>Name of Provider or Supplier</p> <p>Metroderm, Pc - Alpharetta</p>	<p>Street Address, City, State</p> <p>3155 North Point Parkway, Bldg E, Suite 100, Alpharetta, GA</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p>(X4) ID Prefix Tag</p>	<p>Summary Statement of Deficiencies</p>
<p>D0000</p>	<p>A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on August 24, 2023. 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:</p>
<p>D5413</p>	<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 document review and interview with the staff, it was determined the laboratory failed to document accurate Relative Humidity (RH) on each day of testing as required by the Cryostat manufacturer from 2021 to June 2023. Findings: 1. The review of maintenance records revealed that the laboratory failed to document Relative Humidity (RH) accurately on each day of testing using the Avantik QS 12 Cryostat as required. According to the instrument manufacturer, (RH) normal range is (0 - 60%), but (RH) was above 60% at least once each month from April 2021 to June 2023. 2. Monthly Quality Assurance (QA) review by the laboratory director did NOT initiate a corrective action. 3. An interview with the laboratory's lead at 12:05 PM on 07/31/2023 confirmed the laboratory failed to correct (RH) documentation above normal limit from April 2021 to June 2023.</p>

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on documents review and interview with the lab lead, the Lab Director(LD) failed to ensure that ALL Quality Assurance (QA) guidelines were followed to identify and fix problems in the laboratory in 2023 as required by Clinical Laboratory Improvement Amendments (CLIA). Finding: 1. Monthly QA document review revealed the Lab Director who is also the Technical Supervisor (TS), did NOT observe the Relative Humidity (RH) readings (0 - 60%) were above normal limits at once a month from April 2021 to June 2023. 2. An interview with the laboratory's lead in the review room on 07/31/2023 at approximately 12:15 PM, confirmed the Lab Director failed to ensure proper oversight of the laboratory from April 2021 to June 2023.