

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0923800	(X3) Date Survey Completed 06/25/2025
Name of Provider or Supplier Microphase Clinical Laboratory	Street Address, City, State 1428 Weatherly Road, Suite 109, Huntsville, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the temperature records, the Hitachi Chemical AP 3600 Allergy analyzer, and an interview with the General Supervisor, the Laboratory failed to document room temperature and humidity for the Hitachi AP 3600 Allergy analyzer since the date of implementation on 8/24/2023 to the date of the current survey on 6/25/2025. 1. A review of the temperature records revealed the laboratory failed to document room temperature and humidity for the Hitachi AP 3600 Allergy analyzer since the date it was implemented on 8/24/2023. 2. A further review of the Hitachi AP 3600 Allergy user manual revealed, "Environmental requirements: Room Temperature (15-33 degrees Celsius) and Humidity (10-85%)." 3. During an interview on 6/25/2025, at 11:53 AM, the General Supervisor confirmed the above findings.</p>
D6054	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>(b)(9) Thereafter, evaluations must be performed at least annually</p>

This STANDARD is not met as evidenced by:
Based on a review of the personnel records and an interview with the General Supervisor, the Technical Consultant/ General Supervisor failed to evaluate annual competencies for Testing Personnel performing high and moderate complexity testing. This was noted for four out of four Testing Personnel previously qualified since the date of the last survey (4/27/2023) to the date of the current survey (6/25/2025). The findings include: 1. A review of the personnel records revealed no evidence of evaluation by the Technical Consultant/ General Supervisor for annual competency assessments of Testing Personnel #1-4. 2. During an interview on 6/25/2025, at 9:44 AM, the General Supervisor confirmed the above findings.