

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0070377	(X3) Date Survey Completed 06/01/2026
Name of Provider or Supplier Acton Medical Associates, Pc	Street Address, City, State 321 Main Street, Acton, MA	
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 CLIA recertification survey was conducted for the Acton Medical Associates, PC laboratory on 06/01/2026 pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
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 surveyor review of instrument manuals and interview with the general supervisor #1 (GS1) conducted on 06/01/2026, the laboratory failed to monitor and document the laboratory's relative humidity daily from 08/01/2024 to present. The findings include: 1. Record review on 6/1/2026 of the following analyzer operating manuals revealed the following relative humidity requirements: a. Roche Diagnostics COBAS 6000 Analyzer (Operator's Manual Version 8.1, page A-117) ambient humidity during operation: (30-85%) b. Sysmex XN Series (XN-1000) Automated Analyzer (Chapter 15 Technical Information, Section 15.1) relative humidity (30-95%) c. Vitek 2 Laboratory Quick Guide, page 11, Table 5 Environmental Characteristics, Relative Humidity Operating: 20-80%. 2. Record review on 6/1/2026 of analyzer quality control records for the instruments listed above revealed no</p>

documentation for recording the humidity since August 1, 2024 to present. 3. The GS1 confirmed during an interview on 06/01/2026 at 1:45 PM that the laboratory did not document the daily relative humidity readings.