

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2110836	(X3) Date Survey Completed 09/17/2026
Name of Provider or Supplier Naaman Clinic Llc	Street Address, City, State 6234 Tattersall Blvd, Birmingham, 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	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 humidity records for the embedding and processing rooms, the manufacturer's manual on environmental operating specifications, and an interview with the Office Manager (OM) and Testing Personnel (TP) #1, the laboratory failed to ensure that the humidity in the embedding and processing rooms were within the manufacturer's acceptable limits. Humidity was noted below acceptable ranges for the embedding room for 66 out of 133 days, and the processing room for 71 out of 133 days from 2024 to 2026. The findings include: 1. A review of the embedding and processing room humidity records revealed that humidity was below the manufacturer's acceptable parameters. The following months were affected: a. Embedding room: i. December 2024; 3 out of 10 days ii. January through April 2025; 23 out of 45 days iii. November through December 2025; 13 out of 22 days iv. January through April 2026; 27 out of 56 days b. Processing room: i. December 2024; 3 out of 10 days ii. January through April 2025; 26 out of 45 days iii. November through December 2025; 16 out of 22 days iv. January through April 2026; 26 out of 56 days 2. Reviews of the manufacturer's manuals revealed the following Humidity specifications: a. Tissue-Tek VIP 5 page 1.8, " Under Introduction, Operating Conditions, Relative Humidity: 30-85%". b. Tissue-Tek TEC 5 page 1.3, "Under

Specifications, ...Relative Humidity Range 30-85%". c. Tissue-Tek DRS 2000 page 1.7, "Under Specifications, Operating Conditions: Relative Humidity: 30-85%". 3. The OM and TP #1 confirmed the above findings during the exit interview on 9/17/26, at 12:30pm.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(7)(8)

(b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on a review of the Testing Personnel (TP) competency assessment records, and an interview with the Office Manager (OM) and TP #1, the Technical Supervisor (TS) failed to ensure the competency assessment of TP listed on the CMS 209 form (Laboratory Personnel Report) included the six minimal CLIA regulatory requirements for high complexity testing. The surveyor noted two of the two TP annual competency assessments in 2025 and 2026 were missing all regulatory requirements. The findings include: 1. A review of the laboratory's competency assessment form showed the following instructions: a. "Carefully evaluate employee's work performance in relation to the essential functions of the job". b. There is a comment section for the employee to write a self-evaluation. 2. A further review of the laboratory's assessment form revealed it was missing the following six minimal CLIA regulatory requirements: a. Direct observation of routine test performance. b. Monitoring test recording and reporting. c. Review of intermediate results, worksheets, QC, PT, and maintenance records. d. Direct observation of instrument maintenance and function checks. e. Assessment via previously analyzed specimens, blind samples, or PT. f. Assessment of problem-solving skills. 3. The OM and TP #1 confirmed the above findings during the exit interview on 9/17/26, at 12:30pm.