

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2110836	(X3) Date Survey Completed 01/12/2021
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	<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 a review of the Tissue-Tek TEC 5 Tissue Embedding Console System Operator's Manual, temperature records, and an interview with the Testing Personnel, the laboratory failed to monitor and document room temperature and humidity for the room in which the Embedding Console System is located for more than two and a half years since the previous survey on 5/15/2018. The findings include: 1. A review of Tissue-Tek TEC 5 Tissue Embedding Console System Operator's Manual stated on page 1.3 "Ambient Operating Temperature and Relative Humidity Range: Embedding Module 10 - 40 degrees Celsius 30% - 85% RH (noncondensing), Cryo Module 10 - 40 degrees Celsius 30% - 85% RH (noncondensing)". 2. A review of the temperature records (May 2018 to January 2021) revealed that the laboratory was documenting the room temperature and humidity in the room that housed the Processor and Stainer, but the Embedding Console System was located in a separate room where temperature and humidity was not documented. 3. During an interview conducted on 01/12/2021 at 1:15 PM, the Testing Personnel confirmed the above noted findings. .</p>
D6120	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8)</p>

(7) The technical supervisor is responsible for 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; (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 personnel records and interviews with the Testing Personnel and Practice Manager, the Technical Supervisor (who also serves as the Laboratory Director) failed to ensure initial training and competency evaluations were performed by qualified personnel. This was noted on one of one testing personnel records reviewed by the surveyor. The finding include: 1. A review of the personnel records revealed that Testing Personnel #1 was employed in May 2019, however there was no documentation of initial training. 2. A review of the personnel records revealed that Testing Personnel #1 had a six-month evaluation performed on 11/01/2019, and annual evaluations performed on 05/06/2020 and 09/10/2020. These evaluations were performed and signed by the Practice Manager. 3. During an interview conducted on 01/12/2021 at 11:15 AM, Testing Personnel #1 provided a training guide used for her initial training, however the previous employee had failed to document the training. 4. During an interview conducted on 01/12/2021 at 11:25 AM, the Practice Manager confirmed he had performed the competency evaluations for the Testing Personnel; the Practice Manager further confirmed did not have laboratory experience in the specialty of Histopathology, and did not have a degree in a Chemical, Physical or Biological Science. SURVEYOR ID #32258 Licensure and Certification Surveyor