

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2109323	(X3) Date Survey Completed 11/18/2020
Name of Provider or Supplier Naaman Clinic	Street Address, City, State 1722 Pine Street, Suite 400, Montgomery, 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 Linistat Linear Stainer, Microm HM520 and Leica CM1510s (cryostats) Operator's Manuals, a review of the Cryostat Maintenance Records, a review of the patient test logs, and an interview with the laboratory technician, the surveyor determined the laboratory failed to monitor and document room temperature and humidity each day of patient testing. This affected the survey review period from March 2018 to October 2020. The laboratory further failed to monitor and document the cryostat's temperature for December 2018. The findings include: 1. A review of Linistat Linear Stainer Operator's Manual Chapter 1 Table 1-8 stated "General environmental specification - Temperature (Operating Limits) +5 degrees Celsius to +40 degrees Celsius - Relative Humidity Max. 80% RH up to 31 degrees Celsius Decreasing linearly to 50% RH at 40 degrees Celsius." A review of Microm HM520 Operator's Manual stated "Operating conditions +5 degrees Celsius up to +35 degrees Celsius (at a max. relative humidity of 60%)." A review of Leica CM1510s Operator's Manual stated "Operating temperature range from +18 degrees Celsius to +35 degrees Celsius. All specifications related to temperature are based on an ambient temperature of +22 degrees Celsius and maximum air humidity of 60%." 2. A review of the Cryostat Maintenance records revealed the following missing documentation: a) The laboratory did not document the cryostat temperature [established -15 - (-)30 degree</p>

Celsius] for the month of December, 2018. The patient test log revealed 76 patients were tested in December, 2018. 3. During an interview on 11/18/2020 at 11:30 AM, the laboratory technician reviewed the maintenance record for the cryostats and confirmed no documented temperatures for December of 2018. At 11:50 AM, the laboratory technician confirmed the laboratory had not monitored room temperature and humidity from March 2018 to October 2020.