

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D2109325	<b>(X3) Date Survey Completed</b>  10/27/2020
<b>Name of Provider or Supplier</b>  Naaman Clinic	<b>Street Address, City, State</b>  100 Concourse Parkway Suite 240, Hoover, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5411</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on a review of procedures/reagent package inserts, an observation by the surveyor during the walk through of laboratory areas, and an interview with the Practice Manager, the laboratory failed to store reagent at the appropriate temperature, according to the manufacturer's instructions. The findings include: 1. A review of ImmunoDNA Washer 20X package insert stated "Storage Store at 20 - 25 degrees C". 2. During the walk through of the laboratory, the surveyor observed the ImmunoDNA Washer 20X being stored in the refrigerator, outside of the temperature range indicated in the manufacturer's instructions. 3. During the exit interview, conducted on 10/27/2020 at 1:06 PM, the Practice Manager confirmed that the refrigerator usually stays between 7-8 degrees C.</p>
<b>D5413</b>	<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>

This STANDARD is not met as evidenced by:  
Based on a review of the Leica CM 1850 and Leica CM 1510s Operator's Manuals, a review of procedures/reagent package inserts, an interview with the histotech, and an observation by the surveyor during the walk through of laboratory areas, the laboratory failed to monitor and document room temperature and humidity for the Mohs laboratory and Immunostain laboratory. The findings include: 1. A review of Leica CM 1850 Operator's Manual stated "Operating temperature range (ambient temperature): 18 degrees C to 40 degrees C. All specifications related to temperature are valid only up to an ambient temperature of 22 degrees C and an air humidity lower than 60%!" A review of Leica CM 1510s Operator's Manual stated "Operating temperature range from +18 degrees C to +35 degrees C. All specifications related to temperature are based on an ambient temperature of +22 degrees C and maximum air humidity of 60%!" 2. A review of ImmunoDNA Washer 20X package insert stated "Storage Store at 20 - 25 degrees C". 3. During an interview conducted on 10/27/2020 at 1:06 PM, the histotech confirmed that the laboratory had not monitored room temperature and humidity. 4. During walk through of the Immunostain lab it was observed by the surveyor that there was one bottle of the ImmunoDNA Washer stored in the area, where room temperature was not monitored.

**D5601**

**HISTOPATHOLOGY**  
CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:  
Based on a review of a patient report and interviews with the histotech and the Laboratory Director, the laboratory failed to document the reactivity of the controls for the immunostains. This was noted on one of one chart reviews. The findings include: 1. During an interview on 10/27/2020 at 11:45 AM, while explaining the Immunostain procedure, the Laboratory Director stated the positive and negative controls were included with each patient slide. 2. A review of a patient report revealed that controls were documented by stating appropriately reactive controls were performed (valid). The reactivity of the controls was not documented, only that appropriate controls were performed. 3. During an interview conducted on 10/27/2020 at 12:28 PM. the histotech stated the necessary controls for Immunostains were documented in the patients' report.