

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D2045945	(X3) Date Survey Completed 12/02/2022
Name of Provider or Supplier Omar A Ibrahimi Md,Phd, Llc	Street Address, City, State 2777 Summer St Ste 600, Stamford, CT	
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 record review and staff interview, the laboratory failed to provide evidence of monitoring and documenting humidity requirements and room temperature in the subspecialty of histopathology. Findings include: 1. Record review on 12/02/2022 of the 'Procedure Manual and Patient Quality Control Binder' for the year of 2022 revealed lack of documentation of humidity levels and room temperature. 2. Record review on 12/02/2022 of the 'Leica CM1850 Cryostat Instructions for Use V2.5 RevB - 09/2011' manual revealed the following site requirements: a. Air humidity must not exceed 60%. b. Room temperature maximum 35 degrees Celsius. 3. Staff interview on 12/02/2022 at 11:45 AM with the Laboratory Director (LD) and the Office Manager (OM) revealed the following: a. The LD was unaware of the requirement to monitor for and document room temperature and humidity results for proper function of the Cryostat. b. The OM further commented that building maintenance monitors the room temperature, but he/she was unaware how to access records. 4. The laboratory performs 600 MOHS surgeries annually in the subspecialty of histopathology.</p>