

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0867580	(X3) Date Survey Completed 09/26/2023
Name of Provider or Supplier Grace U Chung, Md Pc	Street Address, City, State 500 Grove St, Haddon Heights, NJ	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Biannual Assessment (BA) records and interview with Office Manager (OM), the laboratory failed to verify the accuracy and reliability of Mohs and Histopathology testing twice annually from 12/4/19 to the date of the survey. The findings include: 1. The BA for Mohs was not performed twice annually in 2021, 2022 and 2023. 2. The BA for Histopathology was not performed twice annually in 2021 and 2023. 3. The OM confirmed on 9/26/23 at 10:30 am that the laboratory did not perform BA twice annually for Mohs and Histopathology testing as stated above.</p>
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 surveyor review of the Lecia DME Microscope, Leica CM1510S Cryostat</p>

and Avantik QS12 Cryostat Instruction Manuals (IM's) and "Equipment Quality Control Form 18: Room and Temperature Log Sheet" and interview with the Office Manager (OM), the laboratory failed to document the room temperature and humidity per the IM's requirements in the laboratory from 12/4/19 to the date of the survey. The findings include: 1. The surveyor observed requirements for room temperature, 50-71F and humidity, 20-60%, per the IM's. 2. Room temperature, humidity and Cryostat temperature acceptable ranges were not provided. 3. Room humidity was not documented. 4. The OM confirmed on 9/26/23 at 11:00 am that acceptable ranges were not provided and humidity was not documented on the "Equipment Quality Control Form 18: Room and Temperature Log Sheet".

D5435

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Procedure Manual (PM) and thermometers and interview with the Office Manager (OM), the laboratory failed to provide a written procedure for and documentation of calibration for the thermometer used in the laboratory. The findings include: 1. The laboratory could not provide a written procedure for the calibration or purchasing of a replacement of the thermometer used for room temperature in the laboratory from 12/4/19 to the date of the survey. 2. The laboratory could not provide documentation of calibration for the thermometer used in the laboratory. 3. The OM confirmed on 9/26/23 at 11:15 am that they could not provide a written procedure for performing calibration or purchasing a new thermometer nor provide documentation of calibration.