

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D0867580	<b>(X3) Date Survey Completed</b> 11/19/2024
<b>Name of Provider or Supplier</b> Grace U Chung, Md Pc	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5435</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(b)(2)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Office Manager (OM), the laboratory failed to provide a written procedure for calibrating or replacing the thermohygrometer used for room temperature and humidity in the laboratory when the calibration expires from 9/26/23 to 11/19/24. The findings include: 1. The laboratory could not provide a written procedure for the calibration or purchasing of a replacement for the thermohygrometer used for room temperature in the laboratory when it expires. 2. The OM confirmed on 11/19/24 at 1:15 pm that they could not provide a written procedure for performing calibration or purchasing a new thermohygrometer when the calibration expires.</p>
<b>D5601</b>	<p><b>HISTOPATHOLOGY</b> CFR(s): 493.1273(a)(f)</p> <p>(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</p>

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 the lack of Quality Control (QC) slides found during a random review of 10 patients from 1/5/24 to 10/11/24 and interview with the Office Manager (OM), the laboratory failed to provide QC slides for each day of Histopathology slide reading from 9/26/23 to 11/19/24. The finding includes: 1. The laboratory failed to provide QC slides for 7 out of 10 patient records and slides reviewed, the laboratory could not provide the QC slide for the following patients: a. M24-02 from 1/5/24 b. M24-132 from 5/10/24 c. M24-207 from 7/26/24 d. M24-217 from 8/2/24 e. M24-263 from 8/30/24 f. M24-269 from 9/13/24 g. M24-292 from 10/11/24 2. The laboratory read approximately 1,500 patients annually. 3. The OM confirmed on 11/19/24 at 1:45 pm that the QC slides could not be provided for the aforementioned patients.