

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D1041401	<b>(X3) Date Survey Completed</b>  05/07/2025
<b>Name of Provider or Supplier</b>  William I Roth Md Pa	<b>Street Address, City, State</b>  10075 Jog Rd Ste 206, Boynton Beach, FL	
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>D0000</b>	An announced CLIA recertification survey was conducted at William I Roth MD PA on May, 7 2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
<b>D5435</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(b)(2)</p> <p>(b)(2)(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. (b)(2)(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 interview, review of the procedure manual and quality control documents, the laboratory failed to document maintenance and function checks for six days that Mohs surgical procedures were performed from March 2023 to May 2025. Findings: Review of the procedure titled, Maintenance of Equipment noted, "Daily maintenance is performed, recorded and kept at each location." Review of the procedure titled, Temperature / Thermometer Quality Control noted, "Temperatures must be monitored and recorded daily." Review of the procedure titled, H&amp;E Staining noted, "Maintenance of the stain line is recorded on an appropriate quality assurance log." The procedure also noted, "Each slide is examined by a doctor and the quality of cutting and staining are documented daily." Review of the Mohs Daily Quality Control Worksheet revealed the laboratory documented the Hematoxylin and Eosin H&amp;E stain control slide, microscope verification and maintenance, cryostat maintenance, cryostat temperature, room temperature, room humidity, and the initials of the technician and the doctor. Review of the Hematoxylin and Eosin Staining</p>

Maintenance Log revealed the laboratory documented if the reagents in the H&E stain were changed, rotated, filtered, added to, or okay to use. Review of the Mohs Daily Quality Control Worksheet and the Hematoxylin and Eosin Staining Maintenance Log showed no documentation recorded for the following dates: 01/17/2024, 06/04/2024, 06/05/2024, 11/07/2024, 11/20/24, and 12/17/2024. Review of the Mohs Session Log showed there was a Mohs surgical procedure performed on one patient on each of the following days: 01/17/2024, 06/04/2024, 06/05/2024, 11/07/2024, and 12/17/2024, and there were Mohs surgical procedures performed on two patients on 11/20/24. During an interview on 05/07/2025 at 12:45 PM, the Mohs Technician acknowledged the information was not recorded.