

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D1035201	(X3) Date Survey Completed 08/21/2025
Name of Provider or Supplier Northshore Center For Medical Aesthetics	Street Address, City, State 1535 Lake Cook Rd, Ste 401, Northbrook, IL	
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
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>(b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: D5433 - 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 establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. Based on surveyor review of laboratory policies and procedures, preventative maintenance records, direct observation and interview with laboratory representative; the laboratory failed to perform and document preventative maintenance for one of one microscopes used for histopathology interpretations in 2024 through the date of survey, 08/21/2025. Findings Include: 1. Review of the laboratory procedure manual revealed "Microscope Maintenance Plan", which stated, "2. The scope should be cleaned thoroughly once a year and documented on the equipment itself (a sticker stating the date of the cleaning and initial)". 2. Upon a tour of the laboratory on 08/21/2025, at 9:30 am, surveyors observed one Olympus CHK2-F3-100 microscope, serial number 6E15633, used for histopathology interpretations with maintenance sticker stating service last performed 05/22/2023 and next due 05/2024. 3. Review of preventative maintenance records found no documented maintenance for Olympus CHK2-F3-100 microscope used for histopathology interpretations in 2024 through date of survey 08/21/2025. 4. Interview with laboratory representative on date of survey, 08/21/2025, at</p>

11:15 am, confirmed the laboratory failed to perform and document preventative maintenance for one of one microscopes (Olympus CHK2-F3-100) used for histopathology interpretations in 2024 through the date of survey, 08/21/2025.