

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2081323	(X3) Date Survey Completed 06/08/2021
Name of Provider or Supplier North Shore Pathology Service, Apmc	Street Address, City, State 2240 Gause Boulevard, E, Slidell, LA	
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
D0000	A Recertification survey was performed on June 8, 2021 at NorthShore Pathology Service, APMC, CLIA ID # 19D2081323. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</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 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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's microscope maintenance logs and interview with personnel, the laboratory failed to document the annual microscope maintenance per laboratory policy for one (1) of two (2) years reviewed. Findings: 1. Review of the laboratory's "Preventative Maintenance Schedule" log for the Nikon microscope revealed the following tasks: a) "Cleaning: Frequency: Day of use" b) "Covering: Frequency: After use and during storage" c) "Decontamination: Frequency: After sample contact" d) "Replace lamp: Frequency: As needed" e) "Service: Frequency: As needed" f) "Annual Inspection: Frequency: Once annually" 2. Further review of the laboratory's "Preventative Maintenance Schedule" logs for the Nikon microscope for 2019 and 2020 revealed the laboratory did not perform the annual inspection in 2019. 3. In interview on June 8, 2021 at 1:23 pm, the Laboratory Director stated the annual inspection was not done in 2019. She further stated after she got a contract with a pathology group the annual inspection for the microscope was performed in 2020.</p>

D6095

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(6)

The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.

This STANDARD is not met as evidenced by:

Based on review of maintenance logs and interview with personnel, the Laboratory Director failed to ensure required maintenance was performed to ensure acceptable levels of performance. Refer to D5433.