

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D1021143	(X3) Date Survey Completed 10/30/2023
Name of Provider or Supplier Anatomic Laboratory Of The Tri-State	Street Address, City, State 3700 Bellemeade Ave Ste 102, Evansville, IN	
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>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 observation, record review and interview, the laboratory failed to establish a maintenance protocol to ensure daily, weekly, monthly, and annual maintenance is performed on one of two microscopes (Eclipse e400 Serial # A39248) used for reading histology slides for six of nine (PT4-PT9) patients samples reviewed during 8 /10/22 through 10/23/23. Findings include: 1. On 10/30/23 at 1:22pm, upon request for maintenance logs for the microscope, Eclipse e400 Serial # A39248, SP-3 stated the sticker located on the microscope had a date of 7/2022. SP-3 provided an invoice that confirmed last date of service for the microscope was performed on 7/14/22, and that the maintenance was overdue. SP-3 was not able to provide further documentation including daily, weekly, or monthly logs to validate the microscope had maintenance after 7/14/22. 2. The microscope function check completed on 7/14 /2022, documented arrival aesthetics as "Dusty". 3. On 10/30/23 at 2:20pm, during a tour of the laboratory, the microscope, Eclipse e400 Serial # A39248 was located in the SP-1 (Laboratory Director) office. The microscope had dust particles on the ocular, stage, and field diaphragm. 4. Review of patient records indicated the following patients had slides read without documentation of maintenance for the microscope: a. PT4 test date 08/10/22 b. PT5 test date 12/29/22 c. PT6 test date 02/23 /23 d. PT7 test date 06/08/23 e. PT8 test date 08/15/23 5. Review of the Policy and</p>

Procedures (revised 6/10/23), signed by SP-3 (General Supervisor) and the SP-1 (Laboratory Director) on 5/28/04, specified under "Essential Functions", #2 Quality Control responsibilities includes, "equipment maintenance and documentation (daily, weekly, monthly, etc.) ... describes the general nature and level of work performed by the laboratory manager." The policy did not indicate what maintenance was required daily, weekly, monthly, or annually for the microscope. 6. The annual test volume for Histopathology is approximately 30,200.