

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2188836	(X3) Date Survey Completed 07/03/2025
Name of Provider or Supplier Southern Illinois Univ - School Of Dental Med	Street Address, City, State 2800 College Ave, Alton, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, laboratory records, and interview with the laboratory director (LD); the laboratory failed to perform bi-annual method accuracy verification of oral pathology specimens in 2024 through date of survey 07/03/2025. Findings include: 1. Review of the laboratory's "Quality Assessment" policy/protocol stated, "For quality assurance and assessment purposes, one to two slides will be sent to another board certified oral pathologist annually for review". Regulation 493.1236 requires accuracy verification at least twice annually. 2. Review of laboratory records found no bi-annual method accuracy verification for oral pathology testing in 2024 through the date of survey 07/03/2025. 3. On survey date 07/03/2025, at 09:43 am interview with the LD confirmed the laboratory failed to complete bi-annual method accuracy comparisons in 2024 or 2025 for oral pathology testing.</p>
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:</p>

Based on direct observation, review of the laboratory's records, lack of documentation, and interview with the laboratory director (LD); the laboratory failed to define and document performance of microscope preventative maintenance (PM) as required per 493.1254. Findings include: 1. During the tour of the laboratory on 07/03/2025 at 10:30 am, the surveyor identified an Olympus BX 46 microscope (Serial Number: 0D47332) used for oral pathology testing. 2. Review of the laboratory procedure manual, entitled "Biopsy Policies and Procedures", failed to outline the PM methods for the laboratories microscope. 3. A lack of documentation revealed no preventative maintenance had been completed for the Olympus BX 46 microscope used for oral pathology testing from the start of testing in September of 2021 through the survey date of 07/03/2025. 4. On survey date 07/03/2025, at 10:30 am, interview with the LD confirmed the laboratory failed to have preventative maintenance records for the Olympus BX 46 microscope (Serial Number: 0D47332).