Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2259493	(X3) Date Survey Completed 01/25/2024
Name of Provider or Supplier Southern Illinois University Dental Associates	**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	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. 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 verification of the accuracy of oral pathology specimens as required per 493.1236 in 2023. Findings include: 1. Regulation 493.1236 requires accuracy verification "at least twice annually". Review of the laboratory's "Quality Assessment" policy stated, "Quality assurance/assessment will be performed once every year." 2. Upon review of the laboratory's quality assessment records, surveyors identified two patient cases that were reviewed by another pathologist but no assessments of accuracy for oral pathology testing were found for 2023. 3. An interview with the LD at 10:02 am confirmed the above findings.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) 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.

	This STANDARD is not met as evidenced by: 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. Upon a tour of the laboratory on 1/25 /2024 at 08:35 am, the surveyors identified a Leitz Laborlux D microscope (Serial Number: 512795/060560) 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 above-mentioned microscope. 3. A lack of documentation revealed no preventative maintenance was documented for the Leitz Laborlux D microscope used for oral pathology testing from the start of testing in November of 2022 through the survey date of 01/25/2024. 4. On survey date 1/25/2024, during the tour of the laboratory at 08:35 am, the surveyor findings were confirmed by the LD.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with the laboratory director (LD); the laboratory failed to document results of control materials before reporting patient test results as required per 493.1256 for one of one Periodic Acid-Schiff (PAS) stain performed. Findings include: 1. Review of laboratory records revealed one PAS stain was performed from start of testing in November 2022 to the time of the survey on 01/25/2024. Date of testing: Lab Accession Number: 10/10 /2023 SIUDA-119 2. Upon review of the laboratory's "Biopsy Policies and Procedures" document, under Number 8, it's stated, "Prior to reading the patient's Oral Pathology slides....The quality of the slides received from the SEMC lab is assessed, and the evaluation is documented in the Quality Control Sheet." 3. Based on lack of documentation, quality control was not documented for the PAS stain associated with the above-mentioned patient report (SIUDA-119). 4. An interview on 01/25/2024, at 09:30 am, with the LD, confirmed the above findings.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to include all the name and address of the laboratory that

	performed the grossing for six of six Oral Pathology test reports reviewed from start of testing in November 2022 to the time of the survey on 01/25/2024. Findings Include: 1. Review of the laboratory's "Biopsy Policies and Procedures" document revealed the processing procedures (including gross examination and staining) for Oral Pathology testing took place at a reference laboratory: "All specimens will be processed at the SEMC pathology laboratory." 2. Review of six of six patient test reports (Patient Accession: SIUDA22-01, SIUDA23-17, SIUDA23-57, SIUDA23-93, SIUDA23-119, and SIUDA23-172) for Oral Pathology testing found the laboratory failed to indicate the name and address of the laboratory location where the grossing of the specimens was performed. 3. On survey date 01/25/2024, at 09:17 am, the LD confirmed the above findings.