

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2188836	(X3) Date Survey Completed 03/30/2022
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
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with laboratory director (LD); the laboratory failed to establish written policies and procedures for specimen handling, receiving, and referral, prior to receiving patient specimens for Oral Pathology affecting 14 of 14 patients' reported. Findings include: 1. The laboratory procedures manual was reviewed. 2. The laboratory received Oral Pathology specimens for slide interpretation. 3. The manual failed to include the following written policies and procedures: -Patient preparation. -Specimen collection. -Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. -Specimen storage and preservation. -Conditions for specimen transportation. -Specimen processing. -Specimen acceptability and rejection. -Specimen referral. 4. Further review of the manual showed the laboratory failed to include the step-by-step procedure detailing how patients' slides are to be received and documented from the tissue processing laboratory. 5. The laboratory director confirmed the above findings on 03/30/2022 at 11:15 AM.</p>
D5601	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <p>(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must</p>

be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on record review, lack of documentation, and interview, the laboratory failed to document all control procedures performed affecting for 14 of 14 patients tests.

Findings Include: 1. The laboratory's manual and patient log sheet were reviewed. 2. The procedures manual revealed the following: *The laboratory director (LD) performed Oral pathology slide interpretations only. *Patients' specimens were sent to SEMC Pathology (14D0982965) for tissue processing and pathology slide production. 3. The patient log sheet revealed the LD began reading Oral Pathology slides on 08/30/2021; 4. Interview on 03/30/2022 at 10:50 AM; LD stated the quality of the slides received from SEMC were assessed during the reading of patients. slides, however these evaluations were not documented. 5. The patient log revealed that 14 patients Oral Pathology slides have been read and reported since testing began in 08/30/2021. 6. The log and manual further showed that the laboratory failed to document the reactivity the Hematoxylin and eosin (H&E) stains and special stains, if applicable, for 14 of 14 reported patient cases. 7. The laboratory failed to document all tissue staining quality controls and failed to establish procedures which would ensure the tissue stain quality of all processed tissue are assessed and documented when received from SEMC laboratory, prior to reading patients' Oral Pathology slides. 8. The LD confirmed the above findings on March 30, 2022 at 11:00 AM.