

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0858286	<b>(X3) Date Survey Completed</b>  11/13/2018
<b>Name of Provider or Supplier</b>  University Of Florida Oral Pathology Laboratory	<b>Street Address, City, State</b>  1395 Center Dr Room D8-8, Gainesville, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A recertification survey was conducted on November 13, 2018. University of Florida Oral Pathology Laboratory had three deficiencies found at the the time of the visit.
<b>D3043</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(7)</p> <p>The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, it was determined that the laboratory did not retain and store the pathology slides for quality control stains for 2 out of 2 years documents reviewed. Findings included: Upon review of the reports and slides of pathology records, there were no slides found for quality control stains of patients for 2 out of 2 years documents reviewed from November 2016 through November 2018. Interview on 11/13/18 at 2:00 PM, testing person # B confirmed that the laboratory did not keep and store the slides for quality control stains performed in Oral Pathology.</p>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p>

This STANDARD is not met as evidenced by:  
Based on record review and interview with testing person # B, the laboratory failed to ensure that the histology technologists maintained competency based on performance of test procedures and reporting of tests accurately for 2 out of 2 years documents reviewed. Findings included: Based on review of the documents of histology technologists # D and # E, records revealed no competency evaluations for 2 years from November 2016 through November 2018. During interview on 11/13/18 at 11:00 AM , testing person # B confirmed that the laboratory was not aware of the CLIA criteria for competency and assessments were not performed on 2 out of 2 histology technologists.

**D5473**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on record review and staff interview, the laboratory failed to check special tissue stains for negative reactivity each time of use for 2 (2016-2018 ) out of 2 years documents reviewed in Oral Pathology. Findings included: Review of a sample of 2 years for patient stain test results and corresponding quality control results for the special stains showed that there was a positive control run with the stain and no negative control was run for all 2 out of 2 years patient stains performed from November 2016 through November 2018. The following special stains did not show a negative control run with the stain on the day that the patient slides were stained: Grocott-Gomori's Methenamine Silver (GMS), Periodic Acid Schiff (PAS), Acid-Fast Bacillus (AFB) and Trichrome. During an interview on 11/13/18 at 2:30 PM, testing person # B confirmed that the laboratory did not run a negative control with the stains and he was not aware that quality control for negative reactivity was required for the pathology stains along with the check for positive reactivity.