

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0648857	(X3) Date Survey Completed 05/16/2018
Name of Provider or Supplier Lsusd Oral Pathology Laboratory	Street Address, City, State 1100 Florida Avenue, Room 8314, New Orleans, LA	
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
D0000	A Certification Survey was conducted on May 16, 2018 at LSUSD Oral Pathology Laboratory-CLIA ID # 19D0648857. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard deficiencies were cited.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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> <p>This STANDARD is not met as evidenced by:</p> <p>I. Based on record review and interview with personnel, the laboratory failed to establish and follow written policies and procedures to assess competency for the Technical Supervisor and General Supervisor. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed Personnel 1 and Personnel 2 serve as the Technical and General Supervisors. 2. Review of the laboratory's policies and procedures revealed the laboratory did not have a policy for competency assessment of Technical Supervisor and General Supervisor. 3. Review of personnel records for Personnel 2 revealed competency assessments for the duties of Technical Supervisor and General Supervisor were not performed. 4. In interview on May 16, 2018 at 10:30 am, Personnel 2 stated competency assessments for her duties as Technical Supervisor and General Supervisor were not performed. Personnel 2 further stated the laboratory was unaware that a competency assessment was needed. II. Based on record review and interview with personnel, the laboratory failed to establish and follow written policies and procedures to assess competency for testing personnel. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing: a) Direct observations of routine patient test performance, including patient</p>

	<p>preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting of test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. In interview on May 16, 2018 at 10:30 am, Personnel 2 stated the laboratory was unaware that a competency assessment that included the six (6) procedures was needed.</p>
<p>D5401</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to establish complete policies and procedures. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not establish complete policies for the following: a) Record Retention requirements b) Twice a year verification for accuracy of Oral Pathology testing to include corrective action plan 2. In interview on May 16, 2018 at 10:30 am, Personnel 2 stated the laboratory did not have the identified policies. Personnel 2 further stated the laboratory was unaware that the identified policies were needed.</p>
<p>D6103</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D5209.</p>
<p>D6106</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p>

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D5401.