

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0941021	(X3) Date Survey Completed 02/22/2019
Name of Provider or Supplier Oral Pathology Services	Street Address, City, State 610 Professional Drive, Gaithersburg, MD	
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
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation and interview with the laboratory director (LD), the laboratory did not ensure that an eye wash station was located in the laboratory area where testing occurs. Findings: 1. During a tour of the laboratory at 10:15 AM, it was observed that there was no eye wash station available in the laboratory where laboratory testing is performed. 2. During an interview on 2/22/19 at 2:20 PM, the LD confirmed that the eye wash station was not located in the room where laboratory testing is performed.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in</p>

the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

II. Based on review of the laboratory's procedure manual and interview with the laboratory director, the laboratory's procedure manual did not include instructions for labeling the prepared histopathology slide before and after the staining process.

Findings: 1. Review of the histopathology slides showed that the slides prepared in-house were originally labeled with the accession number given by the laboratory.

Then a sticker was placed over the original accession number with a sticker that had the name of the laboratory, first initial of the patient and last name of the patient, and the original accession number. 2. Review of the procedure manual showed that there were no instructions for initially labeling the slide and then applying the sticker with the additional information. 3. During the survey on 02/22/2019 at 2:20 PM the laboratory director confirmed that the procedure manual did not include labeling instructions for the histopathology slides. 38127 I. Based on review of the procedure manual and interview with the laboratory director (LD), the laboratory failed to update quality assurance (QA) procedures to reflect the actual practice of the laboratory. Findings: 1. The procedure "Remedial Actions" states that "Exchange slides will be made every 6 months with Department of Oral & Maxillofacial Pathology, AFIP for quality assurance." The procedure was reviewed and signed by the LD on 12/20/12. During an interview at 11:25 AM, the LD stated that the laboratory had not sent slides to AFIP "in years" and that the laboratory did not follow that procedure. 2. Record review showed two other documents titled, "Addendum (QA and QC of Reporting System Proficiency)" (dated 2/3/17) and "MDODT Corrective Actions (Plan of Correction) CLIA Survey - June 15, 2017" which were written as part of the plan of correction from the previous laboratory survey on 2/2/17. At 11:25 AM the LD stated that the documents reflected the current practice of the laboratory, however the documents were not signed and dated by the LD to show that they were approved procedures. 2. During the survey on 02/22/19 at 2:20 PM the LD confirmed that the QA section of the procedures was not updated to reflect the current practice of the laboratory.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 2/2/2017 for not documenting the performance of routine preventative maintenance checks on laboratory equipment. The plan of correction stated that this would be corrected. Based on record review and interview with the laboratory director (LD), the laboratory did not document performance of routine preventative maintenance checks on laboratory equipment. Findings: 1. A review of "Tissue Tek III Console

System QC" maintenance records from February, 2017 to January, 2019 showed that the laboratory did not document that the air filter was vacuumed annually. 2. During an interview on 2/22/19 at 2:20 PM, the LD confirmed that preventative maintenance was not documented.

D6098

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(8)

The laboratory director must ensure that reports of test results include pertinent information required for interpretation.

This STANDARD is not met as evidenced by:
Based on review of the quality assurance (QA) procedure manual, split-sample peer review and interview with the laboratory director, the laboratory director did not ensure that the proficiency testing (PT) portion of the QA program was enforced. Findings: 1. The addendum to the "QA and quality control of reporting system proficiency" procedure states that the laboratory will check the accuracy of the testing personnel by sending "about 12 cases by year" out for peer review. 2. Review of the QA documentation showed that the peer review was performed and documented for "2017-2018" using specimens from 07/12/17 through 04/16/18. There was no QA documentation showing that a peer review had been performed since 04/16/18. 3. During the survey on 02/22/2019 at 2:20 PM the laboratory director confirmed that the peer review had not been performed since 04/16/18.