

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0652227	(X3) Date Survey Completed 08/22/2018
Name of Provider or Supplier Laboratory Of Oral Pathology	Street Address, City, State Umkc School Of Dentistry 3rd Fl Room 375, Kansas City, MO	
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
D5401	<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 the lack of a mycology procedure manual and interview with the laboratory director on August 22, 2018 at 09:30 AM confirmed, the laboratory failed to have a step by step procedure for fungal culture testing.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation of mycology (mycobiotic) media and interview with the laboratory director, the laboratory failed to ensure culture media in use did not exceed the manufacturer's expiration date. Findings: 1. Observation of mycobiotic media lot number 172862 revealed one box of media expired March 20, 2018 and available for use. 2. Observation of mycobiotic media lot number 229001 revealed 4 boxes of</p>

media expired July 5, 2018 and available for use. 3. Interview with the laboratory director on August 22, 2018 at 09:30 AM confirmed the media exceeded the manufacturer's expiration date and available for patient testing.

D5477

CONTROL PROCEDURES

CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on observation of mycology (mycobiotic) culture media in use, lack of documentation for 2017 and to date August 22, 2018 and interview with the laboratory director, the laboratory failed to check each batch of culture media for its ability to support growth and inhibit growth. Findings: 1. Observation of mycobiotic culture media showed lot number 172862 and lot number 229001 were in use for patient testing. 2. No documentation was available to show the laboratory checked each batch (lot numbers) of media for its ability to support growth and inhibit growth. 3. Interview with the laboratory director on August 22, 2018 at 09:30 AM confirmed, the laboratory failed to perform and document mycobiotic media control procedures before or concurrent with initial use.

D5601

HISTOPATHOLOGY

CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must 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 review of histopathology records and interview with the laboratory director on August 22, 2018 at 09:30 AM confirmed, the laboratory failed to document control procedures / stain quality acceptability with each patient slide or group of patient slides for 2017 and to date August 22, 2018.