

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2018441	(X3) Date Survey Completed 01/10/2020
Name of Provider or Supplier Tulsa Medical Laboratory, Llc	Street Address, City, State 1323 West 6th Avenue, Stillwater, OK	
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	The recertification survey was performed on 01/10/2020. The findings were reviewed with the practice manager and business coordinator at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D3043	<p>RETENTION REQUIREMENTS 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 a review of patient histology slides and interview with the practice manager and business coordinator, the laboratory failed to ensure that patient histology slides were available for review during the survey for 8 of 40 patients. Findings include: (1) At the beginning of the survey, the practice manager stated: (a) The laboratory prepared frozen sections using the Leica CM1800 Cryostat. The slides were stained with H&E (Hematoxylin & Eosin), then reviewed microscopically by a pathologist; (b) The laboratory prepared cytological samples using the Touch Prep technique. The slides were stained with Diff Quik staining materials. (2) The surveyor requested patient histology slides for 40 patients with microscopic interpretations performed in 2018 and 2019. Slides could not be retrieved for 8 of 40 patients. The specific dates of service were 03/29/18, 04/03/18, 05/31/18, 06/19/18, 09/20/18, 11/02/18, 12/04/18, 06/25/19; (3) The surveyor asked the practice manager and business coordinator to explain why the 10 patient slides could not be retrieved. The practice manager and business coordinator stated the slides were stored off-site and were not available for the survey.</p>

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES

CFR(s): 493.1235

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.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory director, the laboratory failed to have a written competency policy for the clinical consultant based on the job responsibilities as listed in Subpart M. Findings include: (1) During the survey, the surveyor reviewed personnel records for competency assessments performed during 2018 and to date in 2019. There was no evidence competencies had been performed for the clinical consultant based on their job responsibilities; (2) The surveyor asked the practice manager if a written policy to evaluate the positions based on job responsibilities was available and if competencies had been performed during the review period. The practice manager stated a policy to evaluate the clinical consultant based on job responsibilities had not been written; and competencies had not been performed.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on an observation and interview with the practice manager and business coordinatory, the laboratory failed to ensure containers of staining materials had been labeled with lot numbers and expiration dates. Findings include: (1) At the beginning of the survey, the practice manager stated: (a) The laboratory prepared frozen sections using the Leica CM1800 Cryostat. The slides were stained with H&E (Hematoxylin & Eosin), then reviewed microscopically by a pathologist; (b) The laboratory prepared cytological samples using the Touch Prep technique. The slides were stained with Diff Quik staining materials (3 bottles - Fixative, Solution I, and Solution II). (2) Later during the survey, the surveyor observed the current staining materials with the practice manager and business coordinator. The following was identified: (a) The bottle containing the Hematoxylin stain and the bottle containing the Eosin stain were not labeled with the manufacturer's lot numbers and expiration dates; (b) The bottles containing the Diff Quik staining materials were not labeled with the manufacturer's lot numbers and expiration dates. (3) The surveyor explained to the practice manager and business coordinator that the bottles must be labeled with the lot numbers and expiration dates of the materials.