

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2018441	(X3) Date Survey Completed 01/31/2018
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 findings were reviewed with the laboratory practice manager, business coordinator, and clinical consultant #1 at the conclusion of the survey.
D5601	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory practice manager and the laboratory business coordinator, the laboratory failed to document the reaction of the staining control slides. Findings include: (1) At the beginning of the survey, the laboratory practice manager and the laboratory business coordinator stated to the surveyor the laboratory performed the following testing: (a) Microscopic interpretations of slides made from frozen tissue specimens - The tissue specimens were sectioned and the tissue placed on slides, fixed, stained with H & E (Hematoxylin and Eosin), dried, coverslipped, and examined microscopically for diagnosis; (b) Microscopic interpretations of slides made from touch prep specimens - Slides of touch preps from sentinel lymph nodes were fixed, stained with Diff Quik, dried, coverslipped and examined microscopically for a rapid assessment. (2) The laboratory practice manager and the laboratory business coordinator also stated to the surveyor a QC (Quality Control) slide was included in each batch of patient slides being stained, to monitor the acceptability of the staining process. At the time of the microscopic examination, the condition of the stain was documented on the patient test log by the pathologist who examined the slides as "S" for satisfactory or "U" if</p>

unsatisfactory; (3) The surveyor then reviewed the patient testing log from 03/29/16 through 01/23/18. For 2 of the 21 patient specimens tested, there was no evidence the control slide had been observed and had stained appropriately: (a) Patient #11: Testing performed on 03/09/17 - Touch preps of 4 sentinel lymph nodes had been stained with Diff Quick. There was no indication on the log if the QC stain was satisfactory or unsatisfactory; (b) Patient #12: Testing performed on 03/16/17 - Touch preps of 4 sentinel lymph nodes had been stained with Diff Quick. There was no indication on the log if the QC stain was satisfactory or unsatisfactory. (4) The surveyor reviewed the records with the laboratory practice manager and the laboratory business coordinator, who agreed the pathologist performing the microscopic interpretation listed above had not documented the condition of the Diff Quick control slide. NOTE: D5601 was cited at the previous recertification survey performed on 02/05/16.

D5787

TEST RECORDS
CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the laboratory practice manager and the laboratory business coordinator, the laboratory failed to ensure permanent testing records were maintained. Findings include: (1) At the beginning of the survey, the laboratory business coordinator stated to the surveyor the laboratory performed microscopic interpretations of slides made from surgical tissue specimens. The tissue specimens were frozen and sectioned using the Leica CM 1800 cryostat. The tissue was placed on slides, fixed, stained with H & E (Hematoxylin and Eosin), dried, coverslipped, and examined microscopically for diagnosis; (2) During the survey, the surveyor reviewed records for the cryostat from 04/01/16 through 01/23/18. The surveyor identified during 2 of the 22 months reviewed, the cryostat temperature and the laboratory humidity had been documented in pencil: (a) November 2016: Days 2 through 30 (b) December 2016: Days 1 through 30 (3) The surveyor reviewed the findings with the laboratory practice manager and the laboratory business coordinator who verified the records listed above included documentation made in pencil; (4) The surveyor explained to the laboratory practice manager and the laboratory business coordinator the use of pencil does not ensure permanence of documentation. The laboratory practice manager and the laboratory business coordinator agreed the laboratory failed to maintain permanent laboratory records when documentation was recorded in pencil. NOTE: The Interpretive Guidelines at 493.1283(a) states, "Corrections of laboratory results include the corrected result, incorrect result (noted as such), the date of the correction, and the initials of the person making the correction. Laboratory records should not be documented in pencil and the use of whiteout is not acceptable for making corrections."