

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0683439	<b>(X3) Date Survey Completed</b> 12/05/2022
<b>Name of Provider or Supplier</b> Surgical Pathologists Of Dallas	<b>Street Address, City, State</b> 1411 N Beckley Ave, Suite 174-Pav 3, Dallas, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	Laboratory representatives were present at the entrance conference. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas Health and Human Services Commission, Health Facility Compliance Arlington Group. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Southern Operations Branch-Dallas for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory policy, laboratory environmental logs, and confirmed in interview, the laboratory failed to monitor temperature for the Tissue TEK Embedding Center for 12 of 12 months in 2022. The findings include: 1. Review</p>

of the laboratory policy titled "Equipment Quality Control-Tissue Tek Embedding Center (SS6.8)" revealed: "EQUIPMENT QUALITY CONTROL-TISSUE TEK EMBEDDING CENTER 1. Record embedding center temperature on quality control log when used. Temperature range is 58-62 centigrade ..." 2. Review of the laboratory environmental logs from January to December 2022 revealed no log with documentation of temperature for the Tissue TEK Embedding Center. The surveyor asked for documentation of temperatures for the Tissue TEK Embedding Center for 2022. None was provided. 3. During an interview on 12/05/2022 at 10:30 a.m., the Laboratory Manager and Histotechnician confirmed the above findings.

**D5417**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(d)

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.

This STANDARD is not met as evidenced by:  
Based on direct observation and confirmed in interview, the laboratory failed to ensure 2 of 2 tissue marking dyes did not exceed their expiration date. The findings include: 1. During a tour of the laboratory on 12/05/2022 at 10:45 a.m., the surveyor observed the following expired tissue marking dyes in the IHC processing center: Red Tissue Marking Dye Lot# 109668; Expiration: 2022-11-30 Yellow Tissue Marking Dye Lot# 109671; Expiration: 2022-11-30 2. During an interview on 12/05/2022 at 11:00 a.m., the Laboratory Director, Laboratory Manager, Histotechnician, and IHC Histotechnologist confirmed the above findings. Key: IHC: Immunohistochemical

**D5781**

**CORRECTIVE ACTIONS**  
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory policy, laboratory environmental logs, and confirmed in interview, the laboratory failed to document corrective action for out-of-range temperatures on the Tissue TEK Embedding Center for 11 of 253 days in 2021. The findings include: 1. Review of the laboratory policy titled "Equipment Quality Control-Tissue Tek Embedding Center (SS6.8)" revealed: "EQUIPMENT QUALITY CONTROL-TISSUE TEK EMBEDDING CENTER 1. Record embedding center temperature on quality control log when used. Temperature range is 58-62 centigrade ..." 2. Review of laboratory environmental logs for the Tissue TEK Embedding Center from 2021 revealed the laboratory had an established acceptable temperature range of "58-62 C". 3. Further review of the laboratory environmental logs for the Tissue TEK

Embedding Center from January to December 2021 revealed the following documented temperatures that were not within the defined range of 58-62 degrees centigrade: "64" 10/14/2021; "64" 10/18/2021; "65" 10/19/2021; "65" 10/20/2021; "65" 10/21/2021; "65" 10/22/2021; "65" 10/25/2021; "65" 10/26/2021; "65" 10/27/2021; "65" 10/28/2021; "65" 10/29/2021; "65" There was no documentation of corrective action for the out-of-range temperatures for the above dates. 4. During an interview on 12/05/2022 at 10:30 a.m., the Laboratory Manager confirmed the above findings.