

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D2284152	<b>(X3) Date Survey Completed</b>  02/03/2025
<b>Name of Provider or Supplier</b>  Delta Pathology, Llc Slidell Memorial East	<b>Street Address, City, State</b>  100 Medical Center Dr, Slidell, LA	
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>	An Initial survey was performed at Delta Pathology, LLC Slidell Memorial East, CLIA ID 19D2284152, on February 3, 2025. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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's policies, temperature logs, and interview with personnel, the laboratory failed to define the acceptable range for the room temperature. Findings: 1. Review of the laboratory's "Temperature &amp; Environmental Monitoring" policy revealed "Acceptable ranges are to be clearly stated on each log sheet and results checked daily to ascertain if the reading is in range." 2. Review of the laboratory's "Frozen Section Room/Area Environmental Logs" revealed the laboratory had two (2) differing acceptable ranges for the room temperature. 3. Further review of the laboratory's "Frozen Section Room/Area Environmental Logs" revealed the following differing acceptable room temperature ranges: a) 20-25 degrees Celsius was the acceptable range for June 2024, October 2024, and November 2024 b) 18-35 degrees Celsius, was the acceptable range for July 2024, August 2024, September 2024, December 2024, and January 2025 4. In interview on February 3,</p>

2025 at 11:13 am, Compliance Personnel 1 confirmed the laboratory did not define the acceptable range for the room temperature. The Compliance Personnel 1 stated she was unsure why the room temperature's acceptable range varied.

**D5785**

**CORRECTIVE ACTIONS**

CFR(s): 493.1282(b)(3)

(b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies, temperature logs, test menu, and interview with personnel, the laboratory failed to perform corrective actions when the room temperature was not maintained within acceptable limits for three (3) of four (4) random test dates reviewed in 2024. Findings: 1. Review of the laboratory's test menu revealed the laboratory's annual test volume for Histopathology testing was four (4). 2. Review of the laboratory's "Temperature & Environmental Monitoring" policy revealed "Acceptable ranges are to be clearly stated on each log sheet and results checked daily to ascertain if the reading is in range. Any problems, deviations, or adjustments will be documented on the log sheets. The department supervisor or other designated personnel will review all temperature and environmental charts and instrument records on a monthly basis. Any discrepancies will be discussed with the recording personnel for resolution and will be documented." 3. Review of random selection of cases performed in 2024 revealed corrective actions were not performed for the following room temperatures that were outside of acceptable limits: a) June 5, 2024: documented room temperature of 18.0 degrees Celsius, maximum temperature 19.1 degrees Celsius, and minimum temperature 18.0 degrees Celsius (acceptable room temperature range listed as 20-35 degrees Celsius). For the month of June 2024 a total of thirty (30) days had recorded temperatures below 20 degrees Celsius without performance of corrective actions. b) October 18, 2024: documented room temperature of 16.9 degrees Celsius, maximum temperature 18.0 degrees Celsius, and minimum temperature 16.4 degrees Celsius (acceptable room temperature range listed as 20-35 degrees Celsius). For the month of October 2024 a total of thirty-one (31) days had recorded temperatures below 20 degrees Celsius without performance of corrective actions. c) October 24, 2024: documented room temperature of 18.8 degrees Celsius, maximum temperature 19.1 degrees Celsius, and minimum temperature 18.1 degrees Celsius (acceptable room temperature range listed as 20-35 degrees Celsius). 4. In interview on February 3, 2025 at 11:13 am, Compliance Personnel 1 confirmed corrective actions were not performed for unacceptable room temperatures for the identified dates.

**D6087**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(3)(iii)

(e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5413.

**D6096**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(7)

(e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified, and

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Refer to D5785.