

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2135612	(X3) Date Survey Completed 04/11/2025
Name of Provider or Supplier Delta Pathology Group, Llc At Touro Infirmiry	Street Address, City, State 1401 Foucher St, New Orleans, LA	
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	An Initial survey was performed at Delta Pathology Group, LLC at Touro Infirmiry, CLIA ID 19D2135612, on April 11, 2025. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5413	<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 observation by surveyor, review of manufacturers' storage requirements, and interview with personnel, the laboratory failed to monitor the room temperature of one (1) of one (1) slide storage rooms where laboratory supplies were stored. Findings: 1. Observation by surveyor during the laboratory tour on April 11, 2025 at 9:52 am revealed the following items stored in the slide storage room without temperature monitoring: a) EpreDia Cytoseal b) CytoLyt solution c) Sakura Tissue-Tek OCT compound d) Cancer Diagnostics Ink Aid e) BD Vacutainer Sodium heparin blood collection tubes f) BD Vacutainer K2EDTA blood collection tubes 2. Review of the manufacturers' storage requirements revealed the following: a) EpreDia Cytoseal storage requirement of 15-30 degrees Celsius b) CytoLyt solution storage requirement of 15-30 degrees Celsius c) Sakura Tissue Tek OCT compound storage requirement of 15-30 degrees Celsius d) Cancer Diagnostics Ink Aid storage requirement of 15-30</p>

degrees Celsius e) BD Vacutainer blood collection tubes 4-25 degrees Celsius 3. In interview on April 11, 2025 at 10:04 am, the Compliance personnel stated the laboratory has a thermometer in the room, but does not record the temperature.

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