

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2052850	(X3) Date Survey Completed 11/26/2024
Name of Provider or Supplier Pathology Group Of La-Cypress Pointe Surgical Hosp	Street Address, City, State 42570 S Airport Road, Hammond, 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	A Recertification survey was performed at Pathology Group of LA-Cypress Pointe Surgical Hospital, CLIA ID 19D2052850, on November 26, 2024. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, manufacturer's manual, maintenance records, and interview with personnel, the laboratory failed to perform the annual maintenance for the cryostat per the manufacturer's requirements in 2023. Findings: 1. In interview on November 26, 2024 at 1:05 pm, the Compliance Personnel stated the laboratory replaced their old Leica 1850 cryostat on November 14, 2024. 2. Review of the laboratory's "Cryostat Maintenance and Decontamination" policy under the "Annually" section revealed "Preventative maintenance as required by the manufacturer." 3. Review of the Leica 1850 Cryostat manual revealed "have the instrument inspected by a qualified service engineer authorized by us once a year." 4. Review of the laboratory's maintenance records revealed the laboratory did not have</p>

the annual preventative maintenance (PM) performed for the cryostat in 2023. 5. In interview on November 26, 2024 at 2:05 pm, the Compliance Personnel confirmed the laboratory did not have the 2023 annual PM for the cryostat performed.

D6095

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(6)

The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies, maintenance records, manufacturer's manual, and interview with personnel, the Laboratory Director failed to ensure maintenance procedures were followed to ensure acceptable levels of test performance. Refer to D5433.