

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0990698	(X3) Date Survey Completed 03/20/2025
Name of Provider or Supplier Gina Sevigny Md Pa	Street Address, City, State 305 Clyde Morris Blvd Ste 150, Ormond Beach, FL	
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	At the time of the announced, onsite recertification survey, Gina Sevigny MD was found to be NOT in compliance with the CLIA laboratory requirements of 42 CFR 493.
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 record review and staff interview, the laboratory failed to document the room temperature and humidity of the laboratory for 3 of 66 days reviewed in February 2024, August 2024, and January 2025; and failed to ensure the cryostat temperature was documented for 3 of 66 days reviewed in February 2024, August 2024, and January 2025. Findings include: Review of the daily laboratory accession log showed patient testing was performed on 2/23/24 (12 patients), 8/9/24 (12 patients), and 1/10/25 (6 patients). Review of the laboratory document titled "Cryostat Temperature Log Leica 1510S" showed no documentation of the daily cryostat temperature on 2/23/24, 8/9/24, and 1/10/25. Review of the laboratory document titled "Laboratory Room Temperature and Humidity Log" showed the daily room temperature and humidity of the laboratory was not documented on 2/23/24, 8/9/24, and 1/10/25. The facility policy titled "Daily Routine" states "1. Check and log temperature on cryostat. 2. Check and log room temperature." During an interview on</p>

3/20/25 at 10:23am with the Laboratory Director, it was confirmed that the temperature of the cryostat, room temperature and humidity was not documented those three days.