

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0251274	(X3) Date Survey Completed 06/10/2026
Name of Provider or Supplier Roper St Francis Physician Network	Street Address, City, State 306 Station 22 1/2 Street, Sullivans Island, SC	
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 announced onsite CLIA recertification survey was conducted on June 10, 2026, at the laboratory of Roper St. Francis Physician Network on Sullivan's Island by the South Carolina Department of Public Health (SC DPH) Bureau of Nursing Homes and Medical Services. The laboratory was found to be out of compliance with Medicare condition 42 CFR Part 493, CLIA requirements for laboratories. The following is a list of STANDARD LEVEL deficiencies cited as a result of the June 10, 2026 recertification survey.
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 direct observation and staff interview, the laboratory failed to document the received and opened date on reagents used in the laboratory. Findings included: 1. While on a tour of the laboratory on June 10, 2026 at 1:00pm with the technical consultant (TC), the surveyor observed 4 out of 4 Seimens Multistick urinalysis reagents with no received or open dates documented on them. 2. In an interview with the TC on June 10, 2026 at 1:00pm in the laboratory, the findings were confirmed.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p>

(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 staff interview, the laboratory failed to ensure that no expired equipment, instruments, reagents or materials were available for use. Findings included: 1. In a tour of the laboratory on June 10, 2026, at 1:00pm with the TC, the surveyor observed a Timer/Thermometer which had an expiration of 05/2026. 2. In an interview on June 10, 2026, at 1:00pm in the laboratory with the TC, the finding was confirmed.