Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D0250660	06/25/2026
Name of Provider or Supplier	**Street Address, City, State**	
Roper Saint Francis Physicians Partners Laboratory	4450-A Leeds Place West, North Charleston, 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 on-site validation survey was completed on June 25, 2026 with the following standard level deficiencies cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form Centers for Medicare and Medicaid Services (CMS) 209, written policies and procedures, lack of Technical supervisor (TS) competency assessment records, and interview with Technical Supervisor (TS) #1, the laboratory failed to establish written policies and procedures to assess competency for supervisors for 2 of 2 years (2024 and 2025). Findings Included: 1) Review of the laboratory's Form CMS 209 revealed 2 TS's listed for the specialties of Diagnostic Immunology and Hematology. 2) Review of the laboratory's policies did not contain elements regarding performing competency on supervisors. 3) The laboratory was unable to provide competency assessment records for the two TSs listed, for their supervisory roles. 4) In an interview on 6/25/2026 at 9:45 AM, TS #1 confirmed the findings of no Technical supervisor competency recorded on file.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

	This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instructions, patient testing records, and interview with the Technical Supervisor (TS) #1, according to the Form Centers for Medicare and Medicaid Services (CMS) 209, the laboratory failed to follow manufacturer instructions to ensure Trichomonas Vaginalis (TV) specimens were not run on patients under the age of 18 for 43 of 1,811 TV specimens run on the Roche Cobas 6800 analyzer from January 1, 2026 to April 1, 2026 (Sampling). Findings Included: 1) During a laboratory tour on 6/25/2026 at 12:58 PM, one Roche Cobas 6800 analyzer (Serial Number 2474) was observed in use for the testing of TV. 2) Review of the Roche manufacturer instructions titled 'Cobas TV/MG Qualitative Nucleic Acid Test for Use on Cobas 6800/8800 Systems 08308535001-02EN Doc. Rev. 2.0 stated the following on page 25: "cobas TV/MG has not been evaluated in patients younger than 18 years of age" 3) Review of patient testing records from January 1, 2026 to April 1, 2026 (Sampling) revealed the following specimens run of patients under the age of 18 out of a total of 1,811 tested for TV: a. 17 years old (31 patient specimens); Specimen IDs: 26-050-004969, 26-027-005511, 26-061-005543, 26-070-004709 ... b. 16 years old (8 patient specimens); Specimen IDs: 26-012-005612, 26-006-005426, 26-070-005012, 26-006-005400 ... c. 15 years old (4 patient specimens); Specimen IDs: 26-041-003416, 26-072-004602, 26-061-005608, 26-084-002260. 4) In an interview on 6/25/2026 at 3:30 PM, TS#1 confirmed the laboratory did not follow manufacturer's instructions and ran patient tests for TV for the specimens above under the age of 18.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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. This STANDARD is not met as evidenced by: I. Based on direct observation, review of manufacturer's instructions, laboratory temperature records, and interview with Technical Supervisor (TS) #1, according to the Form Centers for Medicare and Medicaid Services (CMS) 209, the laboratory failed to define, monitor and document temperatures for 40 of 40 temperature dependent laboratory supplies and reagent solutions. Findings Included: 1) During a laboratory tour at 12:58 PM on June 25, 2026, the following reagents were found stored in the laboratory's supply storage rooms (Storage room and Room 120): a. 2 boxes of Greiner Bio Vacuette Quickshield Safety Tube Holders, Lot #B2505357, Manufacturer storage temperature requirements 4 to 25 degrees Celsius. b. 3 boxes of Thermo Scientific Stop Solutions, Lot #W5PN, Manufacturer storage temperature requirements 2 to 32 degrees Celsius. c. 24 boxes of Siemens Multistix Reagent Strips, Ref #2161, Lot #(10) 503054, Manufacturer storage temperature requirements 15 to 30 degrees Celsius. d. 1 pack of Cobas Sample Cups, Lot #25005175, Manufacturer storage temperature requirements 2 to 32 degrees Celsius. 2) Review of

	the laboratory's temperature records revealed no temperatures defined, monitored and documented for Room 120 and supply storage room, where the temperature-dependent supplies above were stored. 3) In an interview at 1:00PM on 6/25/2026, TS #1 confirmed the supply storage areas' temperatures were not defined, monitored and documented. II. Based direct observation, review of manufacturer's instructions, laboratory temperature records, and interview with Technical Supervisor (TS) #1, according to the Form Centers for Medicare and Medicaid Services (CMS) 209, the laboratory failed to define temperature ranges in accordance with manufacturer instructions for 23 of 23 Becton Dickinson (BD) Vacutainer Tubes. Findings Included: 1) During a laboratory tour at 3:22 PM on June 26, 2025, 23 BD Vacutainer serum separator tubes (SST) were observed stored in racks available for use in the phlebotomy area, with manufacturer storage temperature requirements of 4 to 25 degrees Celsius. 2) Review of the laboratory's temperature record titled 'Roper St. Francis Laboratory Temperature Record' revealed an acceptable room temperature range of 16 to 32 degrees Celsius. 3) In an interview at 3:25 PM on 6/25/2026, TS#1 confirmed the acceptable temperature range on the temperature log sheet was not in accordance with manufacturer's instructions. III. Based on review of laboratory policies and procedures, and interview with the Technical Supervisor (TS) #1, according to the Form Centers for Medicare and Medicaid Services (CMS) 209, the laboratory failed to define temperature ranges for Room Temperature (RT) and Frozen (FZ) within their policy for specimen collection and processing for 2 of 2 years (2024 and 2025). Findings Included: 1) Review of the laboratory's policy titled 'SCM 1023 List-090121R7 Roper St Francis Health Hospital Laboratory Services Specimen Collection and Lab Processing Guidelines' stated the following: "Key: RF = Refrigerated @ 2-8 degrees Celsius, RT= Room Temperature, FZ = Frozen ..." 2) In an interview at 3:30 PM on 6/25/2026, TS #1 confirmed room temperature and frozen ranges were not defined in the policy.