

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D1021472	(X3) Date Survey Completed 09/03/2026
Name of Provider or Supplier Select Specialty Hospital-	Street Address, City, State 96 Parkway, Rochelle Park, NJ	
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 September 03, 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 (CMS) 209, written policies and procedures, lack of competency assessment documentation, and interview with the Technical Consultant (TC), the laboratory failed to follow written policies and procedures assessing competency assessments for 1 of 1 TC. Findings Included: 1) Review of the laboratory's submitted Form CMS 209 revealed one individual delegated the consultant position of TC since 2024. 2) Review of the laboratory's written policy titled 'SSH-NENJ Job Description and Qualifications; Non-Waived Testing Laboratory Services, Policy Number LS-07' stated the following on page 1 of 10: "Procedure: Laboratory personnel will be fully qualified by education, training, and experience according to the minimum levels established by CMS ...Documentation verifying the credentials, education, and training for all laboratory personnel shall be maintained in the personnel files.." Page 4 of 10: "Technical Consultant ... 1. Prior to delegating responsibility as a Technical Consultant, the following information will be reviewed ... a. Education b. Proof of training or experience ... If the individual's education, training, and experience satisfies one of the above, the Laboratory Director shall document a written and signed delegation of authority to the individual to serve as the laboratory's Technical Consultant ..." 3) Review of the laboratory's written policy titled 'SSH-NENJ Competency Verification for Non-Waived Laboratory Personnel, Policy Number LS-

04' stated the following on page 3 of 4: "2. Competency Assessment for the Technical Consultant: The Laboratory Director shall conduct a formal competency review of any individual serving as the Laboratory's Technical Consultant to evaluate the individual's competency to perform all required responsibilities of the Technical Consultant, as outlined under 42 CFR 493.1413. For avoidance of doubt, this competency assessment is solely related to the Technical Consultant's fulfillment of responsibilities related to the Technical Consultant role and shall not authorize the Technical Consultant to act as Testing Personnel absent a separate competency assessment performed in accordance with the requirements outlined ... The Laboratory Director shall complete the Technical Consultant Competency Assessment at the following intervals: (i) within thirty (30) days of the Laboratory Director's delegation of authority to the individual to serve as Technical Consultant ..." 4) Review of the laboratory's competency records revealed no competency assessment for the TC in 2024 or 2025. 5) In an interview on 9/3/2026 at 9:48 AM, the TC confirmed the findings above and her delegation as TC in 2024, but no competency assessment completed until 2026.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
Based on direct observation, review of the laboratory's written policies and procedures, and interview with the Technical Consultant (TC), the laboratory failed to include instructions on corrective actions to take when control results fail to meet the laboratory's criteria for acceptability for 1 of 1 Radiometer ABL 90 Flex analyzer. Findings Included: 1) During a tour of the laboratory on 9/3/2026 at 10:54 AM, one Radiometer ABL 90 Flex Analyzer (Serial Number 092R0708N012) was observed in use. 2) Review of the laboratory's written policy titled 'SSH-NENJ Quality Control Plan (ABL), Policy Number LS-05 (ABL)' did not include corrective actions to take when control results failed to meet the laboratory's acceptability criteria. 3) In an interview on 9/3/2026 at 11:00AM, the TC confirmed the finding that the written policy failed to include instructions on corrective actions when control results failed.

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:

Based on direct observation, review of manufacturer's instructions, laboratory's written policies and procedures, temperature records, and interview with the Technical Consultant (TC), the laboratory failed to define temperatures in accordance with manufacturer's instructions for 5 of 5 reagents. Findings Included: 1) During a laboratory tour on 9/3/2026 at 10:54 AM, the following reagents and supplies were observed stored in the cabinets of the testing area: a. 2 Radiometer ABL90 Flex Solution Pack -SP90s, Lot Number BP-18, Manufacturer storage temperature requirements 2 to 25 degrees Celsius. b. 1 Radiometer ABL Qualicheck L1, Lot Number R0235, Manufacturer storage temperature requirements 2 to 25 degrees Celsius. c. 1 Radiometer ABL Qualicheck L2, Lot Number R0248, Manufacturer storage temperature requirements 2 to 25 degrees Celsius. d. 1 Radiometer ABL Qualicheck L3, Lot Number R0254, Manufacturer storage temperature requirements 2 to 25 degrees Celsius. 2) Review of the laboratory's written policies and procedures titled 'SSH-NENJ Temperature and Humidity Monitoring (ABL), Policy Number LS-09 (ABL)' stated the following on page 1 of 2: "Solution Pack storage, Ambient temperature between 2 and 25 degrees Celsius ...Analysis of samples will be performed only when ambient temperature is between 15 and 32 degrees Celsius". 3) Review of the laboratory's temperature logs revealed an acceptable room temperature range of 15 to 32 degrees Celsius, exceeding the upper threshold requirement of 25 degrees for the Radiometer ABL supplies and reagents. 4) In an interview on 9/3/2026 at 11:00AM, the TC confirmed the findings the laboratory's acceptable temperature range was not defined in accordance with manufacturer instructions of reagents and supplies stored.