

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2304226	(X3) Date Survey Completed 01/28/2026
Name of Provider or Supplier Bay Ridge Medical Group Pllc	Street Address, City, State 7404 5th Ave, Ste 1, Brooklyn, NY	
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
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 Standard Operating Procedures (SOP), personnel training records, competency evaluation documentation, as well as interview with the Laboratory Personnel (LP), the laboratory failed to establish and follow written policies and procedures to assess employee competency. FINDINGS: 1. The current, approved Bay Ridge Medical Group, PLLC SOPs did not include a written training, competency evaluation policy comprising of the following guidelines for Testing Personnel (TP): a. Direct observations of routine patient test performance, specimen preparation, processing, and testing. b. Monitoring the recording and reporting of test results. c. Review of intermediate test results or worksheets, quality control records, Proficiency Testing (PT) results, and preventive maintenance records. d. Direct observations of instrument maintenance performance and function checks. e. Assessment of patient test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples. f. Assessment of problem-solving skills. 2. There was no documentation of TP initial training, six-month, and annual competency evaluations. 3. The LP confirmed the findings on January 28, 2026, at 11:30 A.M.
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:

Based on review of SOPs, analyzer manufacturer's instructions, lack of temperature and humidity records, as well as interview with the TP, the laboratory failed to monitor and document temperature and humidity in the area where patient specimen testing and test kit storage occurred. FINDINGS: 1. There was no documentation of refrigerator, room temperature, and humidity in the area where patient specimen testing and test kit storage occurred. 2. The i-Stat manufacturer's instructions specified analyzer operating temperature range of 16-30C (61-86F). 3. There was no documentation of temperature monitoring for the refrigerator utilized for storage of i-Stat test cartridges. 4. The i-Stat manufacturer's instructions specified test kit storage temperature between 2-8C (35-46F). 5. Approximately nine patients were tested in 2025. 6. The current, approved Bay Ridge Medical Group, PLLC SOPs did not include instructions for monitoring and documenting refrigerator, room temperature and humidity in the area where patient specimen testing and test kit storage occurred. 7. The TP confirmed the findings on January 28, 2026, at 11:30 A.M.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

(b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on review of SOPs, analyzer manufacturer's instructions, lack of calibration verification records, as well as interview with TP, the laboratory failed to perform and document calibration verification procedures following the manufacturer's calibration verification instructions. FINDINGS: 1. There was no documentation of PT/INR, ACT, and Chem 8+ calibration verification. 2. This is contrary to instructions indicated in the current, approved Bay Ridge Medical Group, PLLC SOP and PT /INR, ACT, and Chem 8+ analyzer manufacturer's instructions which specify

	calibration verification performance twice a year. 3. Approximately nine patients were tested in 2025. 4. The TP confirmed the findings on January 28, 2026, at 11:30 A.M.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on review of SOPs, analyzer manufacturer's instructions, lack of test system control records, as well as interview with TP, the laboratory failed to perform and document control procedures using the number and frequency specified by the manufacturer. FINDINGS: 1. There was no documentation of PT/INR, ACT, and Chem 8+ Quality Control (QC) performance for each new lot or shipment. 2. This is contrary to instructions indicated in the current, approved Bay Ridge Medical Group, PLLC SOP and PT/INR, ACT, and Chem 8+ analyzer manufacturer's instructions which specify QC performance for each new lot or shipment. 3. Approximately nine patients were tested in 2025. 4. The TP confirmed the findings on January 28, 2026, at 11:30 A.M.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of SOPs, personnel training and competency records, lack of Quality Assurance (QA) policies, as well as interview with the TP, the LD failed to provide overall management and direction of the laboratory services. FINDINGS: The LD failed to: 1. Draft, approve QA policies for all phases of moderate complexity testing. Refer to D6020. 2. Perform and document TP training and competency evaluations. Refer to D5209. 3. The TP confirmed the findings on January 28, 2026, at 11:30 A.M.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:

Based on review of SOPs, lack of QA policies, as well as interview with the LP, the LD failed to ensure that the QC and QA programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. FINDINGS: 1. The current, approved Bay Ridge Medical Group, PLLC SOPs did not include QA policies for all phases of the general laboratory system. 2. The TP confirmed the findings on January 28, 2026, at 11:30 A.M.