Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2209975	09/24/2025
Name of Provider or Supplier	**Street Address, City, State**	
Priority Private Medical Care Pc	760 Montauk Hwy, Suite 2c, Water Mill, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of American Proficiency Testing (API) PT (Proficiency Testing) records as well as interview with the Technical Consultant (TC), the laboratory failed to document attestation to the routine integration of the samples into the patient workload using the laboratory's routine methods. FINDINGS: 1. There was no documentation of API testing personnel attestation for the following PT events: a. 2023 Routine Chemistry Third Event. b. 2023 Hematology Second and Third Events. c. 2023 Immunology Second Event. d. 2024 Routine Chemistry First and Third Events. e. 2024 Immunology Second and Third Events. f. 2025 Routine Chemistry Second and Third Events. g. 2025 Hematology Second and Third Events. 2. The TC confirmed the findings on September 24, 2025, at approximately 11:30 A.M.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) (a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of Standard Operating Procedures (SOPs), lack of API PT records, as well as interview with the TC, the laboratory failed to retain all PT records for at least two years. FINDINGS: 1. There was no documentation of performance and

	verification for API PT 2024 Immunology Third Event and 2025 Hematology Third Event. 2. The current, approved SOPs did not include instructions for performing such activity. 3. The TC confirmed the findings on September 24, 2025, at approximately 11:30 A.M.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on the review of SOPs, API PT performance review forms, as well as interview with the TC, the laboratory failed to review and evaluate the results obtained on PT performed. FINDINGS: 1. There was no documentation of Laboratory Director (LD) review and signature for the following APT PT performance review forms: a. 2023 Chemistry Second and Third Events. b. 2023 Hematology Second and Third Events. c. 2023 Immunology Second Event. d. 2024 Hematology Third Event. e. 2024 Immunology Third Event. f. 2025 Hematology Second Event. 2. The current, approved SOPs did not include instructions for performing such activity. 3. The TC confirmed the findings on September 24, 2025, at approximately 11:30 A.M.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of SOPs, API PT summary reports, lack of corrective action records, as well as interview with the TC, the laboratory failed to perform and document plan of correction for all unsatisfactory PT scores. FINDINGS: 1. There was no documentation of plan of correction performance for the following unsatisfactory API PT scores: a. Troponin I Test Analyte: 2023 Third Event = 60%. b. C-Reactive Protein Test Analyte: 2023 Second Event = 50%. 2. The current, approved SOPs did not include instructions for performing such activity. 3. The TC confirmed the findings on September 24, 2025, at approximately 11:30 A.M.
D5309	TEST REQUEST CFR(s): 493.1241(e) (e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately. This STANDARD is not met as evidenced by: Based on the review of SOPs as well as interview with the TC, the laboratory failed to have ongoing mechanism to ensure the accuracy of manual entries by personnel into the Laboratory Information System (LIS) to ensure the information was transcribed or entered accurately. FINDINGS: 1. The current, approved SOPs did not include instructions for validation of patient test results entered into the Athena Electronic

	Medical Records (EMR). 2. The TC confirmed the findings on September 24, 2025, at approximately 10:00 A.M.
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 the review of SOPs, external Quality Control (QC) hematology analyzer manufacturer's recommendations, as well as interview with the TC, the laboratory failed to comply with the hematology analyzer manufacturer's recommendations for patient testing. FINDINGS: 1. There was no documentation of Sysmex pocH-100i hematology analyzer three levels of external QC performance for December 13, 2023, and December 17, 2023. 2. This is contrary to instructions indicated in the current, approved SOPs and analyzer manufacturer's recommendations. 3. One patient test specimen was processed, analyzed, and results released for each of the respective days. 4. The TC confirmed the findings on September 24, 2025, at approximately 12: 00 P.M.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on the review of hematology analyzer calibration records, manufacturer's instructions, as well as interview with the TC, the laboratory failed to perform analyzer calibration as defined by the manufacturer. FINDINGS: 1. There was no documentation of Sysmex pocH-100i hematology analyzer six-month calibration performance for 2023 and 2024. 2. This is contrary to instructions indicated in the Sysmex pocH-100i hematology analyzer manufacturer's specifications. 3. It was noted that calibration was performed annually for both 2023 and 2024. 4. The TC confirmed the findings on September 24, 2025, at approximately 10:30 A.M.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on review of temperature records, SOPs, lack of corrective action records as well as interview with the TC, the laboratory failed to perform and document corrective action for test systems that did not meet the laboratory's established performance specifications. FINDINGS: 1. Documented freezer temperature deviated from the specified range of -20C - 30C for January 2024 through October 2024. 2. There was no documentation of corrective action performance for the respective out-of-range freezer temperatures. 3. This is contrary to instructions included in the current, approved SOPs. 4. The TC confirmed the findings on September 24, 2025, at approximately 11:00 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 Quality Assessment (QA) records, as well as interview with the TC, the Laboratory Director (LD) and TC failed to ensure compliance with established QC and QA programs to assure the quality of laboratory services provided and to identify failures in quality as they occur. FINDINGS: 1. There was no documentation of QA performance for calendar years 2023 and 2024. 2. This is contrary to instructions included in the current, approved SOPs. 3. The TC confirmed the findings on September 24, 2025, at approximately 12:00 P.M.