Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2163771	12/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
Priority Private Medical Care, Pc	255 Greenwich St 5th Fl Ste 505, New York, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of analyzer quality and control calibration records, standard operating procedures (SOPs), as well as interview with the Testing Personnel (TP), the laboratory failed to retain analyzer quality control and calibrator assay information sheets for minimum two years. FINDINGS: 1. There was no documentation of Sysmex pocH-100i analyzer quality control and calibrator assay information sheets for calendar year 2023. 2. The current, approved SOPs did not include instructions for retaining such analyzer records for minimum two years. 3. The TP confirmed the findings on December 3, 2024, at approximately 11:30 A.M.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or

	control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 review of the SOPs, lack of thermometer calibration records, as well as interview with the Technical Consultant (TC) and TP, the laboratory failed to draft and approve procedures for thermometer calibration. FINDINGS: 1. There was no calibration certificate documentation for thermometers utilized for laboratory room and refrigerator temperature monitoring where patient specimen processing and reagent storage occurred. It was noted that the respective room thermometer probe included a calibration tag indicating recalibration due June 2024. 2. The current, approved SOPs did not include instructions for thermometer calibration and calibration certificate retention. 3. The TC and TP confirmed the findings on December 3, 2024, at approximately 11:30 A.M.