

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0721437	(X3) Date Survey Completed 07/19/2023
Name of Provider or Supplier Summit Medical Group Pa	Street Address, City, State 150 Park Ave, Florham 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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Performance Specifications (PS) and interview with the General Supervisor (GS), the laboratory failed to have accurate Reference Intervals (RI) for Chemistry Tests performed on the I-Stat analyzer on the date of the survey. The findings include: 1. The RI for Chemistry tests in the PM did not match the PS established RI which include: a) Sodium had a RI of 136-145 mmol/L but had an established RI of 138-146 mmol/L b) Blood Urine Nitrogen (BUN) had a RI of 9.0-25 mg/dl but had an established RI of 8.0-26 mg/dl c) Chloride had an RI of 100-109 mmol/L but had an established RI of 98-109 mmol/L</p>

2. The GS confirmed on 7/19/23 at 11:50 am that the PM did not have accurate RI for Chemistry tests.