Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0957525	09/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Summit Medical Group	1255 Broad St, Clifton, 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
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 surveyor review of laboratory records and interview with the General Supervisor (GS), the laboratory failed to maintain the patient raw data print-outs from the Cobas integra 400 used for chemistry testing. The findings include 1. The raw data print-outs containing results and data alarm flags were not maintained. 2. The GS confirmed on 9/13/23 at 11:00 am that raw data print-outs containing results and data alarm flags were not maintained
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: A) Based on surveyor review of the Procedure Manual (PM) and interview with the General Supervisor (GS), the laboratory failed to have a complete Quality Assessment procedure from 10/12/22 to the date of survey. The findings include: 1. The PM under QA procedures did not provide the calculation that verified estimated Glomerular Filtration Rate (eGFR) as accurate. 2. The GS confirmed on 9/12/23 at 12:30 pm that

	the laboratory failed to have the aforementioned procedure. B) Based on surveyor review of the PM, Quality Control Assay Sheet (QCAS), Cobas Integra 400 analyzer and interview with the GS, the laboratory failed to follow their policy for "Establishing a Working Mean an 2SD Range:" from 10/12/22 to the date of survey. The findings include: 1. The PM stated under "Establishing a Working Mean an 2SD Range:" "2. Collect a minimum of twenty data points for each level of control material.". "6. Calculate acceptable limits for the control" 2. Bio-Rad Liquid Assayed Multiqual Lot #45930 QCAS stated as follows. a) Level 1 Chloride 74.60-83.20 mmol /L b) Level 1 Carbon Dioxide 11.80-20.20 mmol/L c) Level 1 Lipase 16.60-28-60 16.60-124.0 U/L 3. Control values in the Cobas Itergra 400 analyzer was as follows. a) Level 1 Chloride 74.60-83.20 mmol/L b) Level 1 Carbon Dioxide 11.80-20.20 mmol/L c) Level 1 Lipase 16.60-28-60 16.60-124.0 U/L 4. The laboratory did not use the control values calculated as per the PM 5. The GS confirmed on 9/13/23 at 12:30 pm that the laboratory failed to follow the aforementioned procedures.
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: A) Based on surveyor review of the "Hematology Procedure Manual Sysmex XN-2000" Procedure Manual (PM), Sysmex XN-2000 validation book (VB) and "Sysmex XN Series (XN-1000) Instructions for Use" (IFU) and interview with the Technical Supervisor #2 (TS #2) provided on the survey CMS-209, the laboratory failed to have all applicable procedures in the PM and VB for Hematology tests performed on the Sysmex XN-2000 used for complete blood counts (CBC) with automated differential and Retic counts in the oncology laboratory from 10/12/22 to the date of the survey. The findings include. 1. The laboratory failed to provide the established Platelet (PLT) reportable range in the PM and VB. 2. The TS #2 confirmed on 9/12/23 at 11:30 am that the laboratory PLT reportable range in the PM and VB was incorrect as they used the manufacturer's PLT reportable range instead of the stricter PLT reportable range achieved by the laboratory. 48354 B) Based on surveyor review of the Procedure Manual (PM) and interview with the Laboratory Director (LD), the laboratory failed to have a written procedure for the criteria required for performing Urine Microscopy tests from 10/12/22 to the date of survey. The LD confirmed on 9/12/23 at 12:00 pm

	the laboratory failed to have the criteria required for performing urine microscopy tests.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: A) Based on surveyor observation of the Liquicheck Cardiac Markers Plus Control LT quality control (QC) for the Cobas e411 Analyzer Manufacturers Package Insert (MPI) and Control Values (CV) in the Cobas e411 analyzer interview with the General Supervisor (GS), the laboratory failed to follow MPI for control values on the date of survey. The findings include: 1. MPI for level 1 Liquicheck Cardiac Markers Plus Control LT QC Lot 67690 had a CV of 28.9 - 98.5 ng/L for Troponin. 2. CV for Troponin level 1 QC in the Cobas e411 Analyzer was 28.9 - 99 ng/L 3. The GS confirmed on 9/13/23 at 11:30 am the MPI was not followed. 48354 B) Based on surveyor review of the Procedure Manual, BeyondCare Quality Monitor (BCQM) Insight Report and interview with Laboratory Director (LD) the laboratory failed to follow the Manufacturers Instructions for the BCQM Insight Report for the XN-550 analyzer from 10/12/22 to the date of survey . The findings include: 1. The BCQM Insight report states "if your Coefficient of Variation (CV) is 1.5 times greater than the group CV, your result is presented in bold and an investigation is warranted." 2. The IQCR report for Lot 2322, Period 1, from 11/22/22 to 12/23/22, for XN-550 analyzer, SN 24155 had the following analytes CV presented in bold: a. Red Blood Cell (RBC) Level 1 b. Hemoglobin (HGB) Level 1 c. Hematocrit)HCT) Level 1 d. White Blood Cell-D (WBC-D) Level 1 e. Neutrophil % (Neut) Level 1 f. Lymphocyte % (Lymph) Level 1 3. There was no documented evidence an investigation was warranted for the above mentioned analytes CV. 4. The LD confirmed on 9/13/23 at 11:00 am the laboratory failed to follow the manufacturers instructions for the BCQM Insight Report.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: A) Based on surveyor review of Performance Specification (PS) records and interview with the Technical Supervisor #2 (TS #2) on the survey CMS-209, the laboratory failed to ensure that all PS records were adequate for all analytes run on the Sysmex XN-2000 analyzer in the oncology laboratory from 10/12/22 to the date of the survey.

	The findings include: 1. The established reportable range for Platelet (PLT) was not placed into use through the laboratory information system (LIS) to ensure that PLT results beyond the established PLT reportable range would not be reported. 2. The TS #2 confirmed on 9/12/23 at 12:00 pm that the laboratory used the manufacturer's PLT reportable range in the LIS instead of their stricter established PLT reportable range. 48354 B) Based on surveyor review of PS records and interview with the TS #2 as listed on the CMS-209 form, the laboratory failed to ensure that all PS records were adequate for all analytes performed on the Sysmex XN-550 analyzer from 10/12/22 to the date of the survey. The findings include: 1. The laboratory failed to implement the strictest established reportable ranges for the following analytes: a. White Blood Cell (WBC) b. Red Blood Cell (RBC) c. Hemoglobin (HGB) 2. The TS #2 confirmed on 9 /12/23 at 12:20 pm laboratory failed to ensure that all PS records were adequate for all analytes performed on the Sysmex XN-550 analyzer.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) 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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC) records and interview with the General Supervisor (GS), the laboratory failed to verify commercial QC material with each new lot and/or shipment of QC used for Chemistry tests performed on iStat analyzer on the date of survey. The finding includes: 1. There was no documented evidence that QC was verified before being put into use. 2. The GS confirmed on 9/12 /23 at 12:20 pm that the QC material was not verified before putting in use.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on surveyor review of the Patient Work Records (PWR), and Operators Manual (OM) and interview with the General Supervisor (GS) the laboratory failed to follow Corrective Action (CA) procedures for flagged PWR on the date of survey. The findings include 1. Ten out to ten PWR had analyzes there were flagged "q". 2. The OM stated for "q" flags "Recommended action: 1. Repeat the quality control

	measurement in order to obtain an unflagged control result." 3. The GS confirmed on 9 /12/23 at 12:00 pm that the laboratory failed to follow the CA procedures.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on surveyor review of Performance Specifications (PS), Manufactures package insert (MPI) and interview with the General Supervisor (GS) the technical supervisor (TS) failed to identify training needs and education appropriate for the type and complexity of the laboratory services performed from 10/12/22 to the date of survey. The findings includes 1. The GS could not provide the State Agency (SA) with linearity values onboard the Cobas Integra 400 and e411 analyzers. 2. The GS confirmed on 9/13/23 at 1:30 the the GS could not provide the SA linearity values onboard the aforementioned analyzers.