Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2063375	11/17/2022
Name of Provider or Supplier	**Street Address, City, State**	
Summit Medical Group Dba Summit Health	1103 West Sherman Ave, Vineland, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to enroll in an approved PT program for Urine Chemistry tests in the calendar year 2022. The TP confirmed on 11/17/2022 at 10:40 am the laboratory was not enrolled in PT for Urine Chemistry tests.
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 the survey review of Quality Control (QC) records, Manufactures Package Directions (MPD) and interview with the Testing Personnel (TP) the laboratory failed to retain the assayed control values from the MPD for MAS UA Controls from 10/3

	/21 to the date of survey. The TP confirmed on 11/17/22 at 11:00 am that Assayed Control values from the MPD were not retained.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(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 surveyor review of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to retain work records for Urine Chemistry PT event in the calendar year 2021 performed with the American Proficiency Institute. The TP confirmed on 11/17/22 at 11:45 am that all PT work records were not retained.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor review of Manufactures Package Inserts, observation of the Quality Control material, and interview with the Testing Personnel (TP), the laboratory failed to put open and expiration dates on Urine chemistry control material run on the Clinitek Advantus Urine Chemistry Analyzer on the date of survey. The TP confirmed on 11/17/22 at 12:00 pm the laboratory failed to put open and expiration dates on the control material.
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 the lack of Quality Control Verification (QCV) records and interview with

	the Testing Personnel (TP), the laboratory failed to verify QC material before use for Urine Chemistry tests performed on the Clinitek Advantus Urine Chemistry Analyzer from 10/03/19 to the date of survey. The TP confirmed 1/17/22 at 11:15 am that QC material was not verified before putting in use.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyors observation of controls in use and interview with the Testin Personnel (TP), the laboratory failed to follow Manufacturers Specifications (MS) for controls at the time of the survey. The finding includes: 1. Controls in use did not have an open or expiration date documented as per MS. 2. The LD confirmed on 8/9/18 at 1:15 pm that MS were not followed.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with Testing Personnel (TP) the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems from 10/03/19 to the date of survey. The finding includes: 1. The laboratory failed to have a procedure to verify new lots of controls before they were put in use. 2. The TP confirmed on 11/17/22 at 10:45 am that the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

	This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR) Work Records (WR), Electronic Medical Record (EMR) and interview with the Testing Personnel (TP) the laboratory failed to ensure test results were reported accurately into the EMR on 11/17/2022. The finding includes: 1. A review of ten EMR entries revealed one patient had results as follows: a) Blood results of "Negative" on the WR but the FR had "Moderate+2". b) Protein results of "Trace" on the WR but the FR had "Negative". c) Ketones results of "Trace" on the WR by the FR had "Negative" 2. The TP confirmed on 11/17/22 at 11: 30 am that the laboratory did not ensure test results were accurately recorded in the EMR.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR) and interview with the Testing Personnel (TP) the laboratory failed to ensure that the FR included the address of the laboratory where testing was performed from 10/03/19 to the date of survey. The TP confirmed on 11/17/22 at 10:00 am that the FR did not have the address of the laboratory where testing was performed.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to establish a procedure for verifying manually entered results from 10/03/19 to the date of survey. The TP confirmed on 11 /17/22 at 10:30 am that the laboratory did not have the procedure mentioned above.
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 surveyor review of the Laboratory records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to provide overall management and direction to the laboratory from 10/25/22 to the date of survey. The findings include: 1. The LD failed to ensure that PT samples were tested . Cross refer D6016 2. The LD failed to ensure a Quality Control program was established and maintained. Cross refer D6020. 3. The LD failed to establish a QA plan. Cross refer D6021.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that PT samples were tested for Urine Chemistry (UC) tests in the calendar year 2022. The TP confirmed on 11/17/22 at 9:45 am that the LD did not ensure PT UC samples were tested.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the review of Quality Control (QC) records, Procedure manual (PM), Quality Control Manufactures package insert (MPI) and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that the QC program was maintained for laboratory services provided from 10/03/19 to the date of the survey. The TP confirmed on 8/18/22 at 11:30 am the LD did not ensure a QC plan was maintained. .
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory

	director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a lack of a Quality Assurance (QA) plan and interview with the Testing Personnel (TP), the Laboratory Director failed to establish a QA plan from 10/03/19 to the date of the survey. The TP confirmed on 11/17/22 at 11:00 am that a QA plan had not been established.