Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2063375	10/03/2019
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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Office Manager (OM), the laboratory failed to ensure that Testing Personnel (TP) who performed Urinalysis Tests participated in the American Proficiency Institute PT events in the calendar years 2018 and 2019. The finding includes: 1. A review of all PT event revealed that two out of five TP performed PT events in 2018 and 2019. 2. The OM confirmed on 10/3/19 at 1:30 pm that PT events were not rotated between TP.
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 observation of the Quality Control (QC) material in use and interview with the Office Manager (OM) the laboratory failed to label the control material used for Urinalysis testing with an open and new expiration date after

	opening at the time of survey. The findings include: 1) There was no open and expiration date written on the QC material. 2) The OM confirmed on 10/3/19 at 111: 00 am controls were not labeled.
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, Manufacture's Package Insert (MPI) and interview with the Office Manager (OM), the laboratory failed to document QC verification for Urinalisys testing performed on the Clinitek Advantis analyzer from August 2017 on the date of survey. The finding includes: 1. The work records for QC verification did not differentiate between old and new lot numbers being tested. 4. The OM confirmed on 10/3/2019 at 12:00 pm that QC verification was not properly documented before putting new QC in use.
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 Office Manager (OM), the laboratory failed to have the address of the laboratory where the Urinalysis tests were performed from August 2017 to the date of survey. The OM confirmed on 10/3/19 at 11:30 am the address of the laboratory was not on the FR.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Office Manager (OM), the Laboratory Director failed to ensure that all PT results received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action for Urinalysis testing performed with the American Proficiency Institute (API) in event 1 and 2-2019. The OM confirmed on 10/3/19 at 10:30 am that the API PT results were not reviewed.