Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0103619	09/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
Summit Medical Group	1037 Route 46 East, Suite 201, 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
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 Nurse Manager (NM), the laboratory failed to ensure that Testing Personnel (TP) who performed Bacteriology Tests participated in the College of American Pathologists PT events in the calendar years 2017 and 2018. The finding includes: 1. A review of all PT event revealed that only one out of six TP performed PT events in 2017 and 2018. 2. The NM confirmed on 9/18/18 at 1:30 pm that PT events were not rotated between TP.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on surveyor observation of the Reagent Refrigerator (RR) and interview with the Nurse Manager (NM), the laboratory failed to establish safety procedures to ensure protection from biochemical hazards at the time of the survey. The finding

	includes: 1. Observation of agar plates and Bacitracin discs used for Bacteriology tests revealed juice was stored in the RR. 2. The NM confirmed on 9/18/18 at 1:10 pm that the laboratory did not establish safety procedures.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records and interview with the Nurse Manager (NM), the laboratory failed to perform and document CA accurately on six of six Testing Personnel (TP) in 2017 and 2018. The findings include: 1. The laboratory did not document what records were reviewed. 2. The CA was not assessed for monitoring the recording and reporting test results. 3. The laboratory did not use the procedures below but CA was assessed for them: a. Critical Values: handling and notification b. Properly documented & corrective action for QC outliers c. Follows preventative maintenance & documentation for instruments d. Demonstrates proper calibration procedure 4. The NM confirmed on 9/18/18 at 12:30 pm CA was not done accurately.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on surveyor review of the accession log, final report and interview with the Office Manger (OM) the laboratory failed to have a written or electronic test request from an authorized person from May 2018 to the date of the survey. The finding includes: 1. The laboratory had a result but no order from an authorized person for two of ten patients reviewed. 2. The OM confirmed on 9/18/18 at 1:10 pm there was no order for testing.
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: Based on surveyor review of the Manufacturers Instructions (MI), observation of streaked plates and interview with the Nurse Manager (NM), the laboratory failed to follow MI for plating throat culture specimens from 10/26/16 to the date of the survey. The finding includes: 1. The MI stated to inoculate plates according to

	standard microbiological procedures but the laboratory streaked two patients per plate. 2. The laboratory did not establish a standard microbiological procedure for plating throat cultures. 3. The NM confirmed on 9/18/18 at 1:20 pm that the laboratory did not follow the MI.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on surveyor review of Temperature Charts (TC), observation of the Refrigerator and interview with the Nurse Manager (NM), the laboratory failed to accurately monitor and document the temperature where Bacteriology media and reagents were stored at the time of the survey. The findings include: 1. There was no thermometer in the refrigerator at the time of the survey but the temperature was documented on the TC. 2. The NM was unable to locate the thermometer by the end of the survey. 3. The NM confirmed on 9/18/18 at 12:40 pm that the temperature wasn't monitored and documented accurately.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the surveyor review of Quality Control (QC) records and interview with the Nurse Manger (NM), the laboratory failed to check QC on each batch of Throat Culture (TC) media from 10/26/18 to the date of the survey. The findings include: 1. TC media was not checked for: a. Sterility b. Ability to support growth c. Ability to select or inhibit specific organisms 2. The NM confirmed on 9/18/18 at 2:10 pm that the laboratory did not perform QC.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on surveyor review of the Personnel Files and interview with the Office Manager (OM), the Laboratory Director failed to have education documented for one out of six Testing Personnel (TP) from 10/26/16 to the date of the survey. The OM confirmed on 9/18/18 at 1:30 pm that all TP did not have education records.