

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2063375	(X3) Date Survey Completed 05/23/2018
Name of Provider or Supplier Summit Medical Group DbA Summit Health	Street Address, City, State 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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>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 failed to maintain Urinalysis work records and attestation statement for 1-2018 PT event with American Proficiency Institute at the time of survey. The TP # 5 listed on CMS form 209 confirmed on 5/23/18 at 10:15 am that all PT records were not maintained.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p>

	<p>Based on surveyor review of the Competency Assessment (CA) records and interview with the Testing Personnel (TP), the laboratory failed to perform CA correctly on six out of six TP in 2017. The findings include: 1. The laboratory did not document what records were reviewed and how CA was assessed. 2. The TP # 5 listed on CMS form 209 confirmed on 5/23/18 at 11:00 am that CA was not performed correctly.</p>
<p>D5401</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Testing Personnel (TP), the laboartory did not follow their scanning policy from October 2017 to the date of survey. The finding includes: 1. The laboratory had a policy to scan patient results into the Eletronic Medical Records (EMR) but patient results were not scanned in EMR from October 2017. 2. The TP # 5 listed on CMS form 209 confirmed on 5/23/18 at 11:00 am that scanning policy was not followed.</p>
<p>D5421</p>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on lack of Performance Specifications (PS) records and interview with the Testing Personnel (TP), the laboratory failed to verify PS for Urinalysis tests performed on the Clinitek Advantus analyzer from August 2017 to the date of survey. The TP # 5 listed on CMS form 209 confirmed on 5/23/18 at 11:15 am that the PS were not performed.</p>
<p>D5469</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>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</p>

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 the Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to verify that the assayed QC materials were within the acceptable ranges before they were put into use for analytes performed on the Clinitek Advantus analyzer from August 2017 to the date of survey. The finding includes: 1. The laboratory changed lots every quarter. 2. The laboratory ran and reported around 400 patient samples a month. 3. The TP #5 listed on CMS form 209 confirmed on 5/23/18 at 11:00 am that the laboratory did not verify QC materials for Urinalysis analytes.

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 the surveyor review of Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to establish a written policy for new QC lot verification used for Urinalysis tests performed on the Clinitek Advantus analyzer from August 2017 to the date of the survey. The TP # 5 confirmed on 5/23/18 at 11:30 am the laboratory did not establish written policies for new QC lot verification.

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 have correct name of the laboratory where the Urinalysis tests were performed from August 2017 to the date of survey. The TP # 5 listed on CMS form 209 confirmed on 5/23/18 at 11:30 am that correct name of the laboratory was not on the FR.

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 have a procedure to verify manually entered results into electronic medical records for accuracy from August 2017 to the date of survey. The TP # 5 listed on CMS form 209 confirmed on 5/23/18 at 10:15 am that the laboratory did not have the procedure mention above.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual and interview with the Testing Personnel (TP), the Laboratory Director failed to establish a Competency Assessment (CA) procedure with the required elements from August 2017 to the date of the survey. The TP # 5 listed on the CMS form 209 confirmed on 5/23/18 at 11:00 am that a CA procedure was not established.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Personnel Files (PF) and interview with the Testing

Personnel (TP), the Laboratory Director (LD) did not specify in detail the duties and responsibilities of TP engaged in the performance of preanalytic, analytic and post analytic phases for Urinalysis tests from August 2017 to the date of survey. The TP # 5 listed on CMS form 209 confirmed on 5/23/18 at 11:15 am that the LD did not specify the duties and responsibilities of TP.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(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 the Personnel Files and interview with the Testing Personnel (TP), the Technical Consultant (TC) failed to ensure Competency Assessment (CA) was evaluated by a qualified individual in 2017. The finding includes: 1. CA on six out of six TP was performed by the License Practice Nurse who had an Associate Degree. 2. The TP # 5 listed on CMS form 209 confirmed on 5/23/18 at 10:40 am that the TC did not ensure that a qualified personnel performed CA.