

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0882201	(X3) Date Survey Completed 05/23/2018
Name of Provider or Supplier Summit Medical Group	Street Address, City, State 15000 Midlantic Drive, Mount Laurel, 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, 2 and 3 of 2017 PT event with American Proficiency Institute at the time of survey. The TP # 1 listed on CMS form 209 confirmed on 5/23 /18 at 1:30 pm that PT records were not maintained.</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>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.</p>

	<p>This STANDARD is not met as evidenced by: Based on surveyor review of the Operator Manual and interview with the Testing Personnel (TP), the laboratory failed to follow calibration procedure for Urinalysis test performed on the Clinitek Advantus analyzer from August 2017 to the date of survey. The finding includes: 1. The calibration must be performed on each day of patient testing but the laboratory did not have any records to substantiate that calibration was done. 2. The TP # 1 listed on CMS form 209 confirmed on 5/23/18 at 2:00 pm that calibration procedure 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 # 1 listed on CMS form 209 confirmed on 5/23/18 at 1:45 pm that the PS were not performed.</p>
<p>D5463</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(7)(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-- Over time, rotate control material testing among all operators who perform the test. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor review of the Quality Control (QC) Records and interview with the Testing Personnel (TP), the laboratory failed to rotate control material testing among all TP who perform Urinalysis test from August 2017 to the date of survey. The TP #1 listed on the CMS form 209 confirmed on 5/23/18 at 1:35 pm that only one TP performed QC on each day of testing.</p>
<p>D5791</p>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(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.</p>

This STANDARD is not met as evidenced by:
 a) Based on surveyor review of Temperature Records (TR), observation of TR in closet and interview with the Testing Personnel (TP), the laboratory failed to records room temperature accurately from January 2017 to the date of survey. The findings include: 1. The room TR where urinalysis strips were stored did not include year and acceptable range of storage in 2017. 2. The room temperature from January 2018 to the date of survey was records on the refrigerator TR without year on it. 3. The TP # 1 listed on CMS form 209 confirmed on 5/23/18 at 2:00 pm that TR for room was not accurate. b) Based on the surveyor review of Quality Control (QC) records and interview with the 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 # 1 confirmed on 5/23/18 at 1:30 pm 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 # 1 listed on CMS form 209 confirmed on 5/23/18 at 1:30 pm that the correct name of the laboratory was not on 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 # 1 listed on CMS form 209 confirmed on 5/23/18 at 2:15 pm 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 # 1 listed on the CMS form 209 confirmed on 5/23/18 at 2:00 pm that a CA procedure was not established.

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 reviewed revealed that it was performed by the License Practice Nurse who had an Associate Degree. 2. The TP # 1 listed on CMS form 209 confirmed on 5/23/18 at 1:40 pm that the TC did not ensure that a qualified personnel performed CA.