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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>31D0882201        | <b>(X3) Date Survey Completed</b><br><br>10/16/2019 |
| <b>Name of Provider or Supplier</b><br><br>Summit Medical Group  | <b>Street Address, City, State</b><br><br>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. |   |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>  |
|---------------------------|---|
| <b>D3037</b>              | <p><b>RETENTION REQUIREMENTS</b><br/>CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on surveyor review of Proficiency Testing (PT) records and interview with the Technical Consultant (TC), the laboratory failed to retain Urinalysis 2-18 PT event printouts performed with the American Institute of Proficiency. The finding includes:<br/>1. The laboratory did not retain urinalysis printout to substantiate reported values. 2. The TC confirmed on 10/16/19 at 10:30 am that PT printouts were not retained.</p>  |
| <b>D5209</b>              | <p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b><br/>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:<br/>Based on survey review of the Competency Assessment (CA) records and interview with the Technical Consultant (TC), the laboratory failed to follow its Competency Assessment (CA) procedures in 2019 assessment on 12 out of 12 Testing Personnel (TP). The findings include: 1. The laboratory failed to assess criteria # 5, assessment of test performance through testing Proficiency Samples or internal blind samples correctly. a. The TC used audit of EMR for criteria #5. b. The TC put proficiency testing for all 12 TP assessed where as only two events were performed and by same personnel. 2. The TC confirmed on 10/16/19 at 10:30 am the laboratory did not follow the CA procedure.</p> |

**D5421**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**

CFR(s): 493.1253(b)(1)

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.

This STANDARD is not met as evidenced by:

Based on lack of Performance Specifications (PS) records and interview with the Technical Consultant (TC), the laboratory failed to verify PS for Urinalysis tests performed on the Clinitek Advantus analyzer from 5/23/18 to the date of survey. The TC confirmed on 10/16/19 at 10:45 am that the PS were not performed. NOTE: 1. This deficiency was cited in the survey report dated 5/23/18. 2. The plan of correction stated it will be implemented by 9/8/18/

**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 and interview with the Technical Consultant (TC), the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment of Urinalysis testing performed on the Clinitek Advantus analyzer from 5/23/18 to the date of survey. The TC confirmed on 10/16/19 at 10:15 am that the assayed values of QC material were not verified before putting in use.

**D5787**

**TEST RECORDS**

CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel

who performed the test(s).

This STANDARD is not met as evidenced by:

Based on surveyor review of the Quality Control (QC) records, observation of the QC material and interview with the Technical Consultant (TC), the laboratory failed to record accurate information on the Clinitek Daily QA log from 5/23/18 to the date of survey. The findings include: 1. The laboratory recorded Urinalysis strip lot numbers instead of QC lot #s. 2. The laboratory did not keep any records of how many QC lots were received and expiration and in use date of QC material. 3. The TC confirmed on 10/16/19 at 10:45 am that the laboratory did not have accurate information on records.

**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 Test Report (TR) and interview with the Technical Consultant (TC), the laboratory failed to include the address of the laboratory where Urinalysis testing was performed from 5/23/18 to the date of survey. The TC confirmed on 10/16/19 at 11:00 am that the address of the laboratory was not on the TR.

**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 Personnel Files and interview with the Technical Consultant (TC), the Laboratory Director failed to have education documented for two of twelve Testing Personnel (TP) from 5/23/18 to the date of the survey. The TC confirmed on 10/16/19 at 10:40 am education records were not available for two TP.