

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0105783	(X3) Date Survey Completed 08/30/2018
Name of Provider or Supplier Summit Medical Group	Street Address, City, State 225 Millburn Ave, Millburn, 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
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Practice Manager (PM), the laboratory failed to review and evaluate Sperm Morphology PT results obtained from the American Proficiency Institute (API) in the calendar year 2017 and 2018. The findings include: 1. There was no review or evaluation documented when the laboratory received "Not Graded" results with an exception code of 2 (no consensus) on samples: a. 1-2017 SCL: 01, 02, 04, 06 and 07 b. 3-2017 SCL: 12, 13, and 17 c. 3-2018 SCL: 01, 03 thru 06 d. 3-2018 SM-02 2. This was cited on the previous survey performed on 4/4/17. The Plan of Correction (POC) stated "Laboratory Director will review and evaluate PT events following each quarterly event period" effective 6/1/17. 3. The PM confirmed on 8/30/18 at 11:10 am that the laboratory did not follow the POC to review and evaluate PT results.</p>
D5401	<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 Practice</p>

	<p>Manager (PM), the laboratory failed to establish a procedure for Semen Analysis counts, morphology and motility from 4/4/17 to the date of survey. The PM confirmed on 8/30/18 at 11:40 am that the laboratory did not establish the above procedures.</p>
<p>D5413</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Incubator Temperature Log (ITL) and interview with the Practice Manager (PM), the laboratory failed to ensure that the temperature of the incubator where semen samples were incubated was documented on the actual date and time recorded on the ITL from August 1, 2018 to the date of the survey. The finding includes: 1. The review of the ITL revealed: a. At 9:45 am on the day of the survey the temperature had been documented in the time column at 10:30 am. b. Temperature was documented for 8/31/18. 2. The PM confirmed on 8/30/18 at 9:50 am that the incubator temperature was not accurately monitored and recorded.</p>
<p>D5445</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Practice Manager (PM), the laboratory failed to perform and document a control on each day of patient testing for semen morphology from 4/4/17 to the date of the survey\ . The PM confirmed on 8/30/18 at 12:10 pm that the laboratory did not perform QC each day of patient testing for semen morphology.</p>
<p>D5543</p>	<p>HEMATOLOGY CFR(s): 493.1269(a)(d)</p> <p>(a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section.</p>

	<p>This STANDARD is not met as evidenced by: Based on surveyor review of the Work Records, Procedure Manual and interview with the Practice Manager (PM), the laboratory failed to test patient specimens in duplicate for the Semen Analysis Total Count test from 4/4/17 to the date of survey. The PM confirmed on 8/30/18 at 10:45 am that the laboratory did not test patient specimens in duplicate.</p>
D5791	<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> <p>This STANDARD is not met as evidenced by: Based on the surveyor review of the Quality Control (QC) records and interview with the Practice Manager (PM), the laboratory failed to establish a written policy for new QC lot verification used for Semen Analysis tests from 4/4/17 to the date of the survey. The PM confirmed on 8/30/18 at 10:30 am the laboratory did not establish written policies for new QC lot verification.</p>
D5891	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Practice Manger (PM), the laboratory failed to have a procedure to verify manually entered results into Electronic Medical Records (EMR) from 4/4/17 to the date of the survey. The PM confirmed on 8/30/18 at 11:15 am that the laboratory did not have the procedure mentioned above. This was cited on the previous survey performed on 4/4/17. The Plan of Correction stated "A written procedure to verify manually entered results into the EMR are monitored for accuracy will be added to the procedure manual." To be completed by 6/1/17.</p>
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the</p>

Practice Manager (PM), the Laboratory Director failed to ensure that the laboratory maintained a QC program from January 2018 to the date of the survey. The findings include: 1. The Sperm Count QC note stated "Perform both sets of QC in duplicate. Average should be within 10%. If not repeat QC". 2. A review of documented QC data revealed QC average greater than 10% as follows: a. January - Hi QC - 1/12/18, 1/17/18, 1/22/18 - Low QC - 1/2/18 - 1/4/18, 1/8/18, 1/11/18, 1/12/18, 1/15/18 b. March - Low QC - 3/8/18 and 3/28/18 c. April - Low QC - 4/6/18 and 4/27/18 d. May - Low QC - 5/10/18, 5/11/18, 5/17/18, 5/18/18, 5/29/19 and 5/31/18 e. June - Low QC - 6/5/18, 6/7/18, 6/8/18, 6/12/18, 6/14/18, 6/18/18, 6/20/18, 6/22/18, 6/25/18 thru 6/29/18 f. July - Low and High QC - 7/26/18. g. August - Low and High QC 8/11/18 - 8/12/18, High QC - 8/17/18 - Low - QC 8/2/18 thru 8/5/18, 8/8/18, 8/15/18, 8/25/18, 8/26/18 3. There was no documented evidence QC listed above was repeated. 4. The PM confirmed on 8/30/18 at 10:30 am the laboratory did not ensure the QC program was maintained.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on surveyor review of the laboratory's Quality Assurance (QA) Plan and interview with the Practice Manager (PM), the laboratory failed to maintain the Quality Assessment (QA) plan from 4/4/17 to the date of the survey. The findings include: 1. The Laboratory Manual Section 9.2 QA plan stated on a monthly basis the Laboratory Director would review: a. The Facility b. Personnel c. Proficiency Testing d. Test Systems e. Patient Test Management 2. There was no documented evidence of review on any item listed above. 3. The PM confirmed on 8/30/18 at 10:55 am the QA plan was not maintained.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(12)

The laboratory director must 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 Records (PR) and interview with the Practice Manager (PM), The Laboratory Director failed to ensure that two of two Testing Personnel had appropriate education and training documented prior to patient testing from 4/4/17 to the date of survey. The PM confirmed on 8/30/18 at 10:20 am that education and training were not documented. This was cited on the previous survey performed on 4/4/17. The Plan of Correction stated the "Laboratory Director will ensure education documentation and applicable training records are in place or all TP". To be completed by 6/1/17