

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0105783	(X3) Date Survey Completed 05/09/2023
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
D2123	<p>HEMATOLOGY CFR(s): 493.851(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on an office review of the CASPER reports 153, 155 and the performance summary form American Proficiency Institute (API). 2022 hematology event 1. The laboratory failed to participate in the third API aforementioned Proficiency Testing (PT) event of 2022 for Hematology tests.</p>
D3027	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(1)</p> <p>Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Semen Analysis (SA) Work rewords (WR), Final Repots (FR), Consent Forms (CF) and interview with the Office Manager (OM), the</p>

	<p>laboratory failed to retain CF on the date of survey. The finding includes; 1) Seven out of ten patients records for SA did not have CF. 2) The OM confirmed on 5/9/23 at 1:30 pm that the CF were not retained.</p>
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 Office Manager (OM), the laboratory failed to review and evaluate PT results obtained from the American Proficiency Institute (API) for Hematology/Coagulation 1st event 2023 and 3rd event of 2022. The findings include: 1. The laboratory did not evaluate "Not Graded" response from API for the following: a. Sperm Classification samples SCL-03,05, and 10 in event 1, 2023. b. Sperm Motility (%) sample MOT-01 in event 1, 2023. c. Sperm Progressive Motility (%) sample MOT-01 in event 1, 2023 d. Sperm Classification samples SCL-11,15, and 10 in event 3, 2022. 2. The OM confirmed on 5/9/23 at 1:30 pm that the laboratory failed to evaluate the above mentioned coded results.</p>
D5313	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b)</p> <p>The laboratory must document the date and time it receives a specimen.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Work Recorded and interview with the Office Manager (OM), the laboratory failed to ensure that the laboratory accurately recorded the date Semen Analysis (SA) specimens were received on the date of survey. The finding includes; 1) Ten out of ten WR did not have the date the specimen was received recorded. 2) The OM confirmed on 5/9/23 at 2:20 pm that the laboratory did not ensure that specimen date was recorded accurately.</p>
D5391	<p>PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Office Manager (OM), the laboratory failed to established a written procedure on how Semen Analysis Calculations performed by the Laboratory Information System (LIS) will be monitored from 6/29/21 to the date of survey. The OM confirmed on 5/9/23 at 2:00 PM that the laboratory did not have the procedure mentioned above.</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</p>

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 Cell-VU Manufacturers Package Insert (MPI), Semen Analysis (SA) Word Records (WR), Final Report (FR) and interview with the Office Manager (OM), the laboratory failed to follow MPI for control values on the date of survey. The findings include: 1) The Cell-VU MPI states "count all motile and non-motile sperm within 10 small boxes of this grid. Divide this number by 2". 2) SA WR done on 4/25/23 for 3390416 had no recorded value for "Motile Count" and "Non-Motile count", "total count" was 21 the FR had "Sperm Density" as 21. 3) SA WR done on 2/6/23 for 1672397 had no recorded value for "Motile Count" and "Non-Motile count" the FR had "Sperm density" as 60. 4) SA WR done on 4/24/23 for 3408715 had 25 for "Motile Count" no recorded value for "Non-Motile Count" and a "Total Count" as 25 the FR had "Sperm density as" 60. 5) SA WR done on 4/24/23 for 3466461 had 48 for "Motile Count" no recorded value for "Non-Motile Count" and a "Total Count" as 240 the FR had "Sperm density as" 48. 6) The OM confirmed on 5/9/23 at 2:00 pm the laboratory did not follow the MPI.

D5433

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on surveyor lack of Maintenance Records and interview with the Office Manager (OM), the laboratory failed to perform and document maintenance of Variseal Thermolyse Centrifuge from 6/29/21 to the date of survey. The OM confirmed on 5/9/23 at 1:15 PM the laboratory failed to perform and document maintenance on the centrifuge.

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 the lack of Quality Control Verification (QCV) records and interview with the Office Manager (OM), the laboratory failed to verify QC material before use for Semen Analyses from 6/29/21 to the date of survey. The OM confirmed 5/9/23 at 1:15 pm that QC material was not verified before putting in use.

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 surveyor review of the Procedure Manual and interview with Office Manager (OM) the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems from 6/29/21 to the date of survey. The findings include: 1. The laboratory failed to have a procedure to verify new lots of controls before they were put in use. 2. The OM confirmed on 95/9/23 at 1:45 pm that the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems.

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 Procedure Manual (PM), Electronic Medical Record (EMR), Work Records (WR) and interview with the Office Manager (OM), the Laboratory Director (LD) failed to ensure a Quality Assurance (QA) program was maintained to assure quality of laboratory services for Hematology tests provided from 6/29/21 to the date of the survey. The findings include: 1. The QA procedure did not include a review to ensure that Semen Analysis (SA) Consent Forms (CF) were accurately scanned into the patients Electronic Medical Record (EMR). a) Seven out of ten patient in the EMR that has SA performed did not have a SA CF. 2. There were no calculations for SA on ten out out ten WR. 3. There was no

evidence that SA calculations performed by the Laboratory Information System (LIS) were verified. 4. The OM confirmed on 5/9/23 at 1:45 pm that a QA program was not maintained.