

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D0105783	<b>(X3) Date Survey Completed</b> 06/29/2021
<b>Name of Provider or Supplier</b> Summit Medical Group	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5401</b>	<p><b>PROCEDURE MANUAL</b> 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 Office Manager (OM), the laboratory failed to establish a procedure for Semen Analysis counts, morphology and motility from 8/30/18 to the date of survey. The OM confirmed on 6/29/21 at 1:30 pm that the laboratory did not establish the above procedures. Note: This is a repeat deficiency. It was previously cited on survey date 8/30/18.</p>
<b>D5543</b>	<p><b>HEMATOLOGY</b> 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 Office Manager (OM), the laboratory failed to test patient specimens in duplicate for the Semen Analysis Total Count test from 8/30/18 to the date of survey. The finding includes: 1. A review of six samples revealed that four out of six were not run</p>

in duplicate. 2. The OM confirmed on 6/29/21 at 1:15 pm that the laboratory did not test patient specimens in duplicate. Note: This is a repeat deficiency. It was previously cited on survey date 8/30/18