

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D0863212	<b>(X3) Date Survey Completed</b>  11/19/2019
<b>Name of Provider or Supplier</b>  Institute Of Reproductive	<b>Street Address, City, State</b>  94 Old Short Hills Rd, Livingston, 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>D5543</b>	<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 laboratory records, Sperm Counting Chambers (SCC) and interview with the Technical Supervisor (TS) and Testing Personnel (TP), the laboratory failed to count patient samples in duplicate by not counting two hemocytometer chambers from 11/2/17 to the date of survey. The finding includes: 1. The TP stated at the time of the survey the laboratory performed duplicate counts on semen samples by counting another area of the grid in the same SCC. 2. The TS confirmed on 11/19/19 at 10:45 am that the laboratory did not count patient specimens in duplicate.</p>
<b>D5891</b>	<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 Final Report (FR) and interview with the Technical Supervisor (TS), the laboratory failed to identify problems on the FR from 11/2/17 to the date of the survey. The finding includes: 1. The "Result" column on the FR did not</p>

contain the test results but the results were located in a column with out a heading. 2. The TS confirmed on 11/19/19 at 11:30 am the laboratory did not identify problems on the FR.