| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number<br>31D2067191 | (X3) Date Survey Completed<br>08/27/2019 |
|---|---|---|
| **Name of Provider or Supplier**<br>Diamond Institute For Infertility & Menopause | **Street Address, City, State**<br>16 Pocono Rd, Denville, 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 |
|---|---|
| **D5543** | HEMATOLOGY<br>CFR(s): 493.1269(a)(d)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on the lack of work records and interview with the General Supervisor (GS), the laboratory failed to document semen counts in duplicate from 8/27/17 to the date of survey. The GS confirmed on 8/27/19 at 10:45 am that the laboratory did not document patient semen counts in duplicate. |