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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 05D1082600 | (X3) Date Survey Completed 01/31/2019 |
| Name of Provider or Supplier Pacific Reproductive Center | Street Address, City, State 10 Post Ste 100, Irvine, CA | |
| 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 |
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| D5481 | <p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on the review of several patient sampling (which included: test orders, test report, quality control records), the laboratory failed to record the Makler counting chamber controls results when performing a patient semen count. Findings included: a. On January 10, 2019, the laboratory performed a semen chamber count on patient #011019-358). b. For the above patient testing, the laboratory also ran two levels of quality control materials (#170103181, expiry 3/19; and #170103351, expiry 3/19) on that day. c. The laboratory was unable to produce records of the above quality control testing results. d. The Technical Supervisor affirmed (January 31, 2019, 9:10 A.M.) that the quality control testing for the above was performed, but confirmed the documentation could not be presented.</p> |