| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 10D0687607 | 02/27/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Specialists In Reproductive Medicine & Surgery Pa | 12611 World Plaza Ln Bldg 53, Fort Myers, FL | |

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 |
|---|---|
| **D5407** | PROCEDURE MANUAL<br>CFR(s): 493.1251(d)<br><br>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with laboratory personnel, the current laboratory director had not signed the quality assurance manual. Findings include: Review of the Quality Assurance procedure manual on 02/27/18 revealed that it was signed by a previous director. The current director had not signed it initially or biennially. During an interview with the practice manager at 11:00 a.m. on 02/27/18, she confirmed that the procedure had not been signed by the current director. |
| **D5449** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(ii)(g)<br><br>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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with the laboratory personnel, the laboratory did not perform quality control for the the antisperm antibody assay each day of patient testing. Findings include: Review of the procedure manual and quality control records on 02/27/18, the laboratory performed a postivie and negative control for the antisperm antibody once per week. During an interview with the technologist at 10:45 |

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| | a.m. on 02/27/18, she said that the laboratory usually performed patient testing more than once a week and confirmed that they did not do quality control each day of patient testing. They had not written an Individualized Quality Control Plan (IQCP ) to justify performing quality control weekly. |