

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2080594	<b>(X3) Date Survey Completed</b>  02/08/2018
<b>Name of Provider or Supplier</b>  Advanced Reproductive Specialists Llc	<b>Street Address, City, State</b>  2100 Aloma Ave Ste 100, Winter Park, FL	
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>D5200</b>	<p><b>GENERAL LABORATORY SYSTEMS</b> CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to have a written policy to access employee training and competency (D5209), failed to achieve satisfactory performance for Sperm Motility Forward Progress for 2017 (D5217), failed to establish and follow a written quality assessment policy (D5291), failed to establish and follow a written policy for proficiency testing (D5291), and failed to maintain complete proficiency testing records (D5291).</p>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have a written policy to access employee training and competency. Findings: Review of the laboratory procedure manual did not show a policy on training and evaluating the</p>

competency of employees. During an interview on 2/08/18 at 11:45 AM, the Medical Technologist stated the lab did not have a policy on training and competency.

**D5217**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**

CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to achieve satisfactory performance for Sperm Motility Forward Progress for 2017. Findings: The laboratory is enrolled in proficiency testing for semen analysis with the American Association of Bioanalysts (AAB) in Embryology, Andrology and Fetal. Review of the AAB proficiency testing records showed that the laboratory received a score of 50% for sperm motility forward progression for the 1st event of 2017, and failed to perform the proficiency testing for the 2nd event in 2017. Review of the laboratory's corrective action form titled "AAB Proficiency Testing Services Proficiency Testing Action Form" for the 2nd event in 2017 read, "The Embryology, Andrology and Fetal S2 2017 survey was received in my office while I was away at a conference. When I returned, I resumed my practice and I wasn't notified that I had received the material. Once I became aware of the survey, the deadline for submission had passed." During an interview on 2/08/18 at 9:50 AM, the Medical Technologist acknowledged they had an unsuccessful proficiency testing in the 1st event of 2017 for sperm motility forward progression, and that they did not perform proficiency for the second event in 2017.

**D5291**

**GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT**

CFR(s): 493.1239(a)

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 general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to establish and follow a written quality assessment policy, failed to establish and follow a written policy for proficiency testing, and failed to maintain complete proficiency testing records. Failure to maintain complete proficiency testing records is a repeat deficiency from the laboratory's recertification survey from 1/14/16. Findings: Review of the laboratory procedure manual did not show a written quality assessment policy. During an interview on 2/08/18 at 11:38 AM, the Medical Technologist stated the lab did not have a written quality assessment policy. She stated they just received a "Monthly Quality Assurance Checklist" but had not implemented the checklist yet. Review of the laboratory procedure manual did not show a policy on proficiency testing.. During an interview on 2/08/18 at 11:35 AM, the Medical Technologist stated they did not have a policy on proficiency testing for the laboratory. The laboratory is enrolled in proficiency testing for semen analysis with the American Association of Bioanalysts (AAB) in Embryology, Andrology and Fetal Record review of the laboratory proficiency records showed that laboratory failed to maintain the raw data for

proficiency testing for 2016 and 2017. This is a repeat deficiency from the recertification survey from 1/14/16. During an interview on 2/08/18 at 9:50 AM, the Medical Technologist confirmed they did not have the raw data for their proficiency testing for the laboratory.

**D5403**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratories procedure on collection of patient samples was incomplete. Findings: Record review of the laboratory's Assisted Reproductive Technology (ART) procurement procedure titled "Procurement of ART Specimens" revealed that the procedure failed to have instructions on labeling specimens collected by the patients. The procedure's effective date was 8/01/13, and the procedure was reviewed on 11/03/15, 10/28/16 and 10/20/17. The procedure instructs the technologist to give the patient instructions on how to collect the specimen. According to the procedure, the instructions, titled "Collection of Semen Specimen", are posted on the wall in the collection room. Examination of the "Collection of Semen Specimen" revealed that the collection instructions failed to include instructions on labeling the specimen. During an interview on 2/08/18 at 11:50 PM, the Medical Technologist stated the patients were verbally told how to label the specimen and that she did not realize there were no written instructions on labeling the semen specimens.