Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2076088	10/30/2019
Name of Provider or Supplier	**Street Address, City, State**	
Reproductive Management Services Inc	7003 Nw 11th Place Suite, Gainesville, 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
D0000	At the time of the announced, onsite recertification survey, Advanced Reproductive Specialists of Gainesville was found to NOT be in compliance with the CLIA laboratory requirements of 42 CFR 493.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document annual competency assessment on one of one testing personnel for two of two years reviewed. Findings include: Review of the Quality Assurance Program policy showed "Employee competency testing must be performed and documented 6 months after the date of hire, 12 months after the date of hire and then annually thereafter". The laboratory was unable to provide documentation of competency assessment at time of survey. During an interview with the Testing person on 10/30/19 at 10:50 AM, it was confirmed that personnel competency had not been performed annually.
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 facility failed to ensure the accuracy

	of testing was verified twice annually for semen analysis testing for one of two events in 2017. Findings include: 1. The record review of the American Association of Bioanalysts (AAB) Proficiency Testing (PT) for 2017 showed the facility failed to participate in the 2nd event of 2017 for the following non regulated analytes: Sperm Count and Sperm Motility. An interview with the Testing Person was performed on 10 /30/19 at 10:40am. The Testing Person stated they were "not sure what happened to the proficiency testing kit" and confirmed that no verification of accuracy was done in its place.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on record review and staff interview, the facility failed to ensure that the temperature of the refrigerator and the heat block used for semen analysis was being monitored and documented for two of two years reviewed. Findings include: At the time of survey, the laboratory was unable to provide documentation showing the temperature of the refrigerator used to store the sperm wash media and the heat block used during semen analysis testing had been monitored in 2018 and 2019. The interview with the testing person on 10/30/19 at 10:52am confirmed temperatures were not documented.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observations and staff interview, the laboratory failed to ensure pH strips were not expired prior to patient testing since August 15, 2018. Findings Include: A tour of the laboratory on 10/30/19 at 11:20AM revealed a package of Hydrion pH strips (Lot #223515) which had an expiration date of 08/15/2018. During an interview on 10/30/19 at 11:21 AM, the Testing person confirmed the pH testing strips were expired.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291.

	This STANDARD is not met as evidenced by: Based on record review and staff interview, the facility failed to follow its written policy for monitoring the postanalytic practices of the laboratory for two of two years reviewed. Findings include: The review of the laboratory's Quality Assessment (QA) Program indicated "Five patient charts are randomly selected for review, check each order against the patient's medical record to ensure that all tests ordered were performed and resulted , and all tests performed and resulted had orders to correspond". The interview with the testing person on 10/30/19 at 11:15am confirmed the laboratory was not monitoring or assessing the postanalytic testing process as stated in the QA policy.