Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 10D0687267	**(X3) Date Survey Completed** 10/15/2021
Name of Provider or Supplier Florida Institute For Reproductive Medicine	**Street Address, City, State** 841 Prudential Dr Ste 260, Jacksonville, 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, Florida Institute For Reproductive Medicine was found to not be in compliance with the CLIA laboratory requirements of 42 CFR 493.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on record review and staff interview, the facility failed to ensure weekly maintenance was performed on the Beckman Coulter Access 2 analyzer for 3 of 3 months reviewed (December 2020, August 2021, September 2021). The findings include: The Access 2 Instructions for Use booklet states "In order to keep the Access 2 system running properly, perform weekly maintenance once every seven days. Note: If the system is not used to run assays every day, it is still important to perform weekly schedule to ensure that the system is ready when needed." The record review of the Access 2 Maintenance Log dated December 2020 showed weekly maintenance was performed on 12/7/20 and 12/14/20. The review of the August 2021 Maintenance Log showed weekly maintenance was performed on 8/10/21 and 8/24/21. The review of the September 2021 Maintenance Log showed weekly maintenance was performed on 9/9/21 and 9/29/21. The interview with Testing Person A on 10/15/21 at 10:00am confirmed weekly maintenance was not performed every seven days as per the Access 2 Instructions for Use.