Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2109688	(X3) Date Survey Completed 11/10/2021
Name of Provider or Supplier Florida Institute For Reproductive Medicine	**Street Address, City, State** 302 Norton Drive Suite 101, Tallahassee, 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	A recertification survey was conducted on November 11, 2021. Florida Institute for Reproductive Medicine clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
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 interview with Testing Personnel (TP) #A, the laboratory failed to perform annual competencies on TP #B for the years 2019, 2020, and 2021 reviewed. Findings included: Record review of personnel files revealed that no competencies had been performed on TP #B for 2019, 2020, or 2021. During interview with TP #A, it was confirmed that no competencies had been completed for TP #B.
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 with Testing Personnel (TP) #A, the laboratory

	failed to perform Quality Assurance activity for 2021. Findings included: Based on review of the laboratory's Quality Assurance Plan, it was revealed that there was no Quality Assurance activity documented for the year of 2021. During interview with TP #A, it was confirmed there had been no Quality Assurance activity for 2021.
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 review of microscope maintenance and interview with Testing Personnel (TP) #A, the laboratory failed to have the preventative maintenance performed on two microscopes in 2020 and 2021. Findings included: Based on review of microscope maintenance, it was revealed that the Accu-Scope EXC-350 series microscope was due for preventative maintenance in July of 2020 and the Olympus CX41 microscope was due for preventative maintenance in July of 2021. During interview with TP #A, it was confirmed that preventative maintenance had not been performed on the two microscopes.