Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0459459	05/17/2018
Name of Provider or Supplier	**Street Address, City, State**	
Fertility Institute Of New Orleans	800 North Causeway Boulevard, Suite 2c, Mandeville, LA	

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 Certification Survey was conducted on May 17, 2018 at Fertility Institute of New Orleans-CLIA ID # 19D0459459. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard deficiencies were cited.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to establish complete policies and procedures. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not establish a complete policy for the following: a) Control procedure for Semen Analysis (Accubeads) to include number and frequency 2. In interview on May 17, 2018 at 12:00 pm, Personnel 2 stated for semen analysis the laboratory performs quality control in duplicate prior to patient testing. Personnel 2 confirmed the laboratory's policy did not include the number and frequency of control material utilized for semen analysis.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to have the policy and procedure manual, approved, signed, and dated by the current Laboratory Director. Finding: 1. In interview on May 17, 2018 at 9:05 am, Personnel 2 stated the laboratory had a new Laboratory Director as of April 2018. 2. Review of the laboratory's Policy and Procedure Manual revealed the manual was not approved and signed by the current Laboratory Director. 3. In interview on May 17, 2018 at 10:08 am, Personnel 2 stated the new Laboratory Director did not sign the policy and procedure manual.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to establish and verify performance specification for accuracy, precision, reportable and reference ranges, analytical sensitivity, and specificity for microscopic semen analysis testing. Findings: 1. Observation by surveyor during laboratory tour on May 17, 2018 revealed the laboratory performs microscopic semen analysis. 2. In interview on May 17, 2018 at 9:05 am, Personnel 2 stated the laboratory added microscopic semen and post vasectomy analysis since their previous inspection. 3. Review of laboratory records revealed the laboratory did not have documentation of performance specification studies for microscopic semen analysis. 4. In interview on May 17, 2018 at 10:25 am, Personnel 2 stated the laboratory began performing microscopic quantitative semen analysis including post vasectomy semen analysis on November 1, 2017. Personnel 2 further stated no performance specification studies had been performed for semen analysis testing. Personnel 2 stated she was unaware it was needed. 5. Review of the laboratory's Task 1 and 3 form revealed the laboratory performs three hundred (300) microscopic semen and one hundred (100)microscopic post vasectomy analysis annually.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to perform microscope preventative maintenance per laboratory policy. Findings: 1. Review of the laboratory's microscope maintenance records revealed "semi-annual PM of microscope." 2. Further review of the laboratory's 2017 microscope maintenance records revealed the laboratory performed semi-annual preventative maintenance on the following date: April 10,2017 3. In interview on May 17, 2018 at 12:21 pm, Personnel 2 stated preventative maintenance for the microscope is performed semi-annually by an outside vendor. Personnel 2 confirmed preventative maintenance was not performed semi-annually in 2017.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to establish pertinent performance characteristics for microscopic semen analysis. Refer to D5423.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure documentation of maintenance procedures as required. Refer to D5433.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Findings: 1. The laboratory failed to establish complete policies and procedures. Refer to D5401. 2. The laboratory failed to have the policy and procedure manual, approved, signed, and dated by the current Laboratory Director. Refer to D5407.