Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D1012476	03/11/2020
Name of Provider or Supplier	**Street Address, City, State**	
Fertility Institute Of New Orleans, Apc	4770 South I-10 Service Road Suite 201, Metairie, 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 performed on March 11, 2020 at Fertility Institute of New Orleans, CLIA ID # 19D1012476. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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: I. Based on record review and interview with personnel, the laboratory failed to have a complete competency assessment policy. Findings: 1. Review of the laboratory's "Laboratory Personnel Competency" policy revealed "Each new employee will be assessed initially and then annually on all procedures for which they will be responsible." 2. Further review of the "Laboratory Personnel Competency" policy revealed the laboratory's policy did not include a semi-annual assessment during the first year of hire. 3. In interview on March 11, 2020, the Technical Supervisor confirmed the laboratory did not include a semi-annual assessment during first year of hire in their policy. II. Based on record review and interview with personnel, the laboratory failed to ensure written policies and procedures to assess competency for one (1) of two (2) Technical Consultants reviewed were complete. Findings: 1. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) revealed two (2) Technical Consultants. 2. Review of personnel records for Technical Consultant 2 revealed a competency assessment was not performed for her duties as

	Technical Consultant. 3. In interview on March 11, 2020 at 3:25 pm, the Laboratory Director confirmed a competency assessment for Technical Consultant 2 was not performed.
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 with personnel, the laboratory failed to establish a complete policy and procedure manual. Findings: 1. Review of the laboratory's "Semen Analysis" procedure revealed the following was not included: a) Quality control, instructions to include, but not limited to: handling, step-by step performance, type of control, number and frequency, acceptability criteria, corrective action for unacceptable results 2. In interview on March 11, 2020, the Laboratory Director confirmed the semen analysis procedure did not include written instructions for quality control performance.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and interview with personnel, the laboratory failed to label reagents utilized for semen analysis with an expiration date and storage requirements. Findings: 1. Observation by surveyor during laboratory tour on March 11, 2020 revealed the following solutions without storage requirement, lot or expiration date information included: a) bottle labeled "EA 50" b) Hematoxylin 2. In interview on March 11, 2020, the Technical Supervisor stated the two bottles seen contained

	filtered EA solution. The Technical Supervisor confirmed the bottles did not include storage requirements, lot information, or expiration dates.
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to delegate, in writing, the responsibilities of Technical Consultant for one (1) of two (2) personnel reviewed. Findings: 1. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) revealed General Supervisor 2 also serves as a Technical Consultant. 2. Review of personnel records for General Supervisor 2 revealed the laboratory did not have documentation of the Laboratory Director delegating the tasks and responsibilities of Technical Consultant to her. 3. In interview on March 11, 2020, the Technical Supervisor confirmed the laboratory did not have documentation of Technical Consultant responsibilities delegated by the Laboratory Director for General Supervisor 2.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure Testing Personnel 3 had appropriate training documentation prior to patient testing. Findings: 1. Review of the laboratory's "Laboratory Personnel Competency" policy revealed "Each new employee will be assessed initially and then annually on all procedures for which they will be responsible." 2. In interview on March 11, 2020, the Technical Supervisor stated Testing Personnel 3 was hired in September 2018. 3. Review of personnel records for Testing Personnel 3 revealed the following: a) Chemistry: An initial training for the Advia Centaur CP performed December 11, 2018; however, no documentation of the Laboratory Director's approval/signature for patient testing. b) Urinalysis: No documentation of an initial training 4. In interview on March 11, 2020 at 3:14 pm, the Laboratory Director stated there was not an official

	paper signed off approving Testing Personnel 3 to test. The Laboratory Director stated at 3:20 pm, the laboratory did not have training documents for urinalysis testing for Testing Personnel 3.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were established and maintained for assessing personnel competency. Findings: 1. The laboratory failed to have a complete competency assessment policy. Refer to D5209 I. 2. The laboratory failed to ensure written policies and procedures to assess competency for one (1) of two (2) Technical Consultants reviewed were complete. Refer to D5209 II. 3. The Technical Consultants failed to ensure the evaluation and documentation of annual competency assessments were performed at the laboratory's location for one (1) of five (5) testing personnel reviewed. Refer to D6054 I. 4. The Technical Consultants failed to retain documentation of competency assessments annually for one (1) of five (5) testing personnel reviewed. Refer to D6054 II.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: I. Based on record review and interview with personnel, the Technical Consultants failed to ensure the evaluation and documentation of annual competency assessments were performed at the laboratory's location for one (1) of five (5) testing personnel reviewed. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed General Supervisor 2 also serves as Technical Consultant, and testing personnel. 2. Review of General Supervisor 2's personnel records revealed the competency assessments for 2018 and 2019 were performed at another Fertility Institute of New Orleans location, not the location specific to the CLIA identification number 19D1012476. 3. In interview on March 11, 2020 at 3:20 pm, the Laboratory Director confirmed the testing personnel competency assessments for General Supervisor 2 were not performed at the Fertility Institute of New Orleans location specific to the CLIA identification number. The Laboratory Director stated he thought

	since General Supervisor 2 worked at multiple locations for the Fertility Institute of New Orleans an assessment performed at another location could be used. II. Based on record review and interview with personnel, the Technical Consultants failed to retain documentation of competency assessments annually for one (1) of five (5) testing personnel reviewed. Findings: 1. In interview on March 11, 2020 at 3:25 pm, the Technical Supervisor stated the following two employees were no longer employed at the laboratory: Testing Personnel 4: no longer employed as of July 2018 Testing Personnel 5: no longer employed as of July 2019 2. Review of personnel records for Personnel 5 revealed the laboratory did not have documentation of annual competency assessment for 2018 or 2019. 3. Review of the laboratory's "Retention of Samples and Records" policy revealed personnel records are kept "indefinitely (those records are to be kept in Human Resources)." 4. In further interview on March 11, 2020 at 3:25 pm, the Technical Supervisor confirmed the laboratory did not have documentation of competency assessment performance for Testing Personnel 5.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. Refer to D5415.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure Testing Personnel 3 had appropriate training documentation prior to patient testing. Findings: 1. Review of the laboratory's "Laboratory Personnel Competency" policy revealed "Each new employee will be assessed initially and then annually on all procedures for which they will be responsible." 2. In interview on March 11, 2020, the Technical Supervisor stated Testing Personnel 3 was hired in September 2018. 3. Review of personnel records for Testing Personnel 3 revealed no documentation of an initial training or approval by Laboratory Director for Semen Analysis/Andrology testing. 4. In interview on March 11, 2020 at 3:14 pm, the Laboratory Director stated there was not an official paper signed off approving Testing Personnel 3 to test. The Laboratory Director stated at 3:20 pm, the laboratory did not have training documents for andrology testing for Testing Personnel 3.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)

	The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure complete policies and procedures were established for assessing personnel competency. Findings: 1. The laboratory failed to have a complete competency assessment policy. Refer to D5209 I. 2. The Laboratory Director failed to ensure Testing Personnel 3 had appropriate training documentation prior to patient testing. Refer to D6102. 3. The Technical Supervisor failed to ensure the evaluation and documentation of annual competency assessments were performed at the laboratory's location for one (1) of three (3) testing personnel. Refer to D6121. 4. The Technical Supervisor failed to retain documentation of competency assessments annually for one (1) of five (5) testing personnel reviewed. Refer to D6128.
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. Refer to D5403.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on observation and interview with personnel, the Technical Supervisor failed to provide technical and scientific oversight for the laboratory. Refer to D5415.
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Supervisor failed to ensure the evaluation and documentation of annual competency assessments were performed at the laboratory's location for one (1) of three (3) testing personnel. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed General Supervisor 2 also serves as testing personnel. 2. Review of General Supervisor 2's personnel records revealed the competency assessments were performed at another Fertility Institute of New Orleans location, not the location specific to the CLIA identification number 19D1012476 3. In interview on March 11, 2020 at 3:20 pm, the Laboratory Director confirmed the testing personnel competency assessments for General Supervisor 2 were not performed at the Fertility Institute of New Orleans location specific to the CLIA identification number. The Laboratory Director stated he thought since General Supervisor 2 worked at multiple locations for the Fertility Institute of New Orleans an assessment performed at another location could be used.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Supervisor failed to retain documentation of competency assessments annually for one (1) of five (5) testing personnel reviewed. Findings: 1. In interview on March 11, 2020 at 3:25 pm, the Technical Supervisor stated the following two (2) employees were no longer employed at the laboratory: Testing Personnel 4: no longer employed as of July 2018 Testing Personnel 5: no longer employed as of July 2019 2. Review of personnel records for Testing Personnel 5 revealed the laboratory did not have documentation of annual competency assessment for 2018 or 2019. 3. Review of the laboratory's "Retention of Samples and Records" policy revealed personnel records are kept "indefinitely (those records are to be kept in Human Resources)." 4. In further interview on March 11, 2020 at 3:25 pm, the Technical Supervisor confirmed the laboratory did not have documentation of competency assessment performance for Testing Personnel 5.