Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D1012476	(X3) Date Survey Completed 04/03/2018
Name of Provider or Supplier Fertility Institute Of New Orleans, Apc	**Street Address, City, State** 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 conducted on April 3, 2018 at Fertility Institute of New Orleans-CLIA ID # 19D1012476. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard 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: Based on record review and interview with personnel, the laboratory failed to ensure written policies and procedures were established to assess competency for the laboratory's Technical Consultant. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not establish written policies and procedures for personnel competency assessment of the Technical Consultant. 2. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) revealed Personnel 2 as the Technical Consultant. 3. Review of personnel records revealed a competency assessment was not performed for the duties of Technical Consultant by the Laboratory Director for Personnel 2. 4. In interview on April 3, 2018 at 9:40 am, Personnel 2 confirmed a competency assessment related to duties as Technical Consultant was not performed.
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 for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Findings: 1. The laboratory failed to ensure written policies and procedures were established to assess competency for the laboratory's Technical Consultant. Refer to D5209. 2. The Technical Consultant failed to ensure the procedures to assess personnel competency were complete. Refer to D6046. 3. The Technical Consultant failed to ensure all testing personnel were assessed through testing previously analyzed specimens, internal blind samples or external proficiency samples. Refer to D6051.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to ensure the procedures to assess personnel competency were complete. Findings: 1. Review of personnel records revealed the laboratory utilized a "Competency Checklist;" however, this form did not include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. In interview on April 3, 2018 at 9:48 am, Personnel 2 stated he was aware the identified competency form used did not include at a minimum the six (6) procedures listed.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to ensure all testing personnel were assessed through testing previously analyzed specimens, internal blind samples or external proficiency samples. Findings: 1. Review of the laboratory's CMS 209 (Laboratory Personnel Report) form revealed the following testing personnel: Personnel 2 Personnel 3 Personnel 4 Personnel 5 2. Review of the laboratory's 2017 American Proficiency Institute (API) Proficiency Testing (PT) and personnel competency assessment records revealed the following personnel did not perform previously analyzed specimens, internal blind samples, or external proficiency samples testing: Personnel 3 Personnel 5 3. In interview on April 3, 2018 at 10:00 am, Personnel 2 stated he and Personnel 4 performed PT testing in 2017. Personnel 2 confirmed the identified testing personnel were not assessed through testing previously analyzed specimens, internal blind samples, or external proficiency samples.
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 policies and procedures were established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Findings: 1. The Technical Supervisor(s) failed to ensure the procedures to assess personnel competency were complete. Refer to D6121. 2. The Technical Supervisor(s) failed to ensure the procedures to assess personnel competency included assessment of test performance through testing previously analyzed specimens, internal blind samples, or external proficiency samples. Refer to D6125.
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(s) failed to ensure the procedures to assess personnel competency were complete. Findings: 1. Review of personnel records revealed the laboratory utilized a "Competency Checklist;" however, this form did not include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel

	performing laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. In interview on April 3, 2018 at 9:48 am, Personnel 2 stated he was aware the identified competency form used did not include at a minimum the six (6) procedures listed.
D6125	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Supervisor(s) failed to ensure the procedures to assess personnel competency included assessment of test performance through testing previously analyzed specimens, internal blind samples, or external proficiency samples. Findings: 1. Review of the laboratory's CMS 209 (Laboratory Personnel Report) form revealed the following testing personnel: Personnel 2 Personnel 3 Personnel 4 Personnel 5 2. Review of the laboratory's 2017 American Proficiency Institute (API) Proficiency Testing (PT) and personnel competency assessment records revealed the following personnel did not perform previously analyzed specimens, internal blind samples, or external proficiency samples testing: Personnel 3 Personnel 5 3. In interview on April 3, 2018 at 10:00 am, Personnel 2 stated he and Personnel 4 performed PT testing in 2017. Personnel 2 confirmed the identified testing personnel were not assessed through testing previously analyzed specimens, internal blind samples, or external proficiency samples.