

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D1064020	(X3) Date Survey Completed 02/06/2020
Name of Provider or Supplier Fertility Institute Of New Orleans, Apc	Street Address, City, State 8585 Picardy Ave, Ste 418, Baton Rouge, 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 at Fertility Institute of New Orleans-Baton Rouge, CLIA ID 19D1064020 on February 6, 2020. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>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 February 6, 2020 at 2:38 pm , General Supervisor 1 stated upon hire an initial and annual competency assessment are performed for testing personnel. General Supervisor 1 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 follow their written competency assessment policy for one (1) of two (2) testing personnel. 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. Review of the laboratory's CMS 209 (Laboratory Personnel Report) form revealed General Supervisor 1 and General Supervisor 2 also serve as the laboratory's testing personnel. 3. In interview on February 6, 2020,</p>

General Supervisor 1 stated General Supervisor 2 serves as the back-up testing personnel if she is off. 4. Review of personnel records for General Supervisor 2 revealed the laboratory did not have competency assessments for testing personnel duties for 2018 and 2019. 5. In further interview on February 6, 2020 at 2:10 pm, General Supervisor 1 stated the laboratory did not have documentation of competency assessments for General Supervisor 2 since 2017.

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. In interview on February 6, 2020 at 1:28 pm, General Supervisor 1 stated the laboratory added semen analysis in 2018. General Supervisor 1 further stated the laboratory previously performed Sperm Isolations. 2. Review of the laboratory's "Sperm Isolation Concentration Quality Control" policy (effective date: "7/19/2017"), provided to surveyor as the quality control policy for semen analysis, revealed the laboratory did not include the following: Quality Control to include, but not limited to: The establishing of means and ranges, how to establish ranges for quality control material and/or verification of quality control material; who is to monitor and how changes are to be made to the ranges of quality control material; and that the correct means and ranges are available to testing personnel. Also to include what quality control is required for each test and the acceptability criteria for each., corrective action for unacceptable results. 3. In further interview on February 6, 2020 at 4:35 pm, General Supervisor 1 confirmed the identified information was not included.

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

	<p>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;</p> <p>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 for assessing personnel competency were maintained. Refer to D5209 I and D5209 II.</p>
D6054	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory personnel records and interview with personnel, the Technical Consultant(s) failed to annually evaluate the competency for one (1) of two (2) testing personnel performing moderate complexity testing. Refer to D5209 II.</p>
D6103	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>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.</p> <p>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 for assessing personnel competency were maintained. Refer to D5209 I and D5209 II.</p>
D6106	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5403.</p>