Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0969917	(X3) Date Survey Completed 09/02/2020
Name of Provider or Supplier Fertility Centers Of Illinois	**Street Address, City, State** 907 N Elm St, Hinsdale, IL	

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
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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 review of laboratory records; Laboratory Personnel Report (Form 209); laboratory procedures manual; personnel records, and interview with the technical supervisor, the technical supervisor failed to be responsible for ensuring that each individual performing tests received training and education appropriate for the type and complexity of laboratory services performed. Findings include: 1. Review of laboratory records from the previous survey performed in August of 2017 show that there were 2 testing personnel who performed all laboratory testing in 2017. 2. There were a total of 7 testing personnel listed on Form 209. 3. Six of 7 testing personnel listed on Form 209 were new testing personnel. 4. The laboratory's procedures manual has a section titled, "New Employee Orientation Checklist." It states, "1. This log is for documenting employee training in new tasks/assays. 2. Documentation is recorded for each task as it is completed." 5. Review of personnel records show that there was no documentation of training for 5 of 7 testing personnel. 6. On survey date 09/02/20 at 10:30 AM, the technical supervisor confirmed the surveyor's findings.
D6127	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory records; Laboratory Personnel Report (Form 209); laboratory procedures manual; personnel records, and interview with the technical supervisor, the technical supervisor failed to be responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. Findings include: 1. Review of laboratory records from the previous survey performed in August of 2017 show that there were 2 testing personnel who performed all laboratory testing in 2017. 2. There were a total of 7 testing personnel listed on Form 209. 3. Six of 7 testing personnel listed on Form 209 were new testing personnel. 4. The laboratory's procedures manual has a section titled, "EMPLOYEE COMPETENCY TESTING." It states, "During the first year of employment for an individual competency will be assessed every 6 months." 5. Review of personnel records show that there was no documentation to show the start date and 6-month competency assessment for 5 of 7 testing personnel listed on Form 209. 6. On survey date 09/02/20 at 10:30 AM, the technical supervisor confirmed the surveyor's findings.
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 review of Laboratory Personnel Report (Form 209); laboratory procedures manual; personnel records, and interview with the technical supervisor, the technical supervisor failed to be responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year Findings include: 1. There were a total of 7 testing personnel listed on Form 209. 2. The laboratory's procedures manual has a section titled, "EMPLOYEE COMPETENCY TESTING." It states, "All employees are to be evaluated at least once during the calendar year. During a calendar year, every testing employee will be graded for competency for all tests they perform." 3. Review of personnel records show that there was no documentation to show a competency assessment for 6 of 7 testing personnel listed on Form 209. 4. On survey date 09/02/20 at 10:30 AM, the technical supervisor confirmed the surveyor's findings.