Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D1099219	04/16/2019
Name of Provider or Supplier	**Street Address, City, State**	
Oregon Fertility Institute	9370 Sw Greenburg Rd Suite 412, Portland, OR	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based upon review of Proficency Testing (PT) records and interview with the Laboratory Director (LD), the laboratory failed to ensure the attestation forms for PT were signed by the LD and testing personnel. Findings include: 1. No completed and signed attestation forms by testing personnel and the LD could be produced during the survey 4/16/2019 for Event #3 (2017) or Events 1 & 2 (2018). 2. During an interview with the LD 4/16/2019 at approximately 1230, she confirmed that she was unaware of this CLIA requirement.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based upon inspection of the laboratory area during survey and discussion with staff,

	it was noted that reagents for testing patient samples were not being stored according to manufacturer's requirements. Findings include: 1. Two boxes of Vidas test packs were noted to be stored on top of one of two refrigerators (at Room Temperature or RT) in the lab area when the manufacturer requires storage at 2 - 8 degrees Celcius. Lot # 1006840100 Expires 9/25/2019. 2. Upon review of the refrigerator temperature logs for January 2 through April 16, 2019, it was noted that Refrigerator #1 had been out of the established range of 2 - 8 degrees Celcius nineteen days (19) out of seventy eight (78) days of clinic operation. The Laboratory Director (LD) confirmed there was no written documentation for corrective action during interview 4/16/2019 at approximately 1230. 3. Upon review of the refrigerator temperature logs for January 2 through April 16, 2019, it was noted that Refrigerator #2 had been out of the established range of 2 - 8 degrees Celcius four (4) days out of seventy eight (78) days of clinic operation. The Laboratory Director (LD) confirmed there was no written documentation for corrective action during interview 4/16/2019 at approximately 1230. 4. Bio-Rad controls were noted to be stored in Refrigerator #1. Staff confirmed during interview 4/16/2018 at approximately 1100 that the controls had been stored in the same refrigerator during the time period the refrigerator was out of temperature range (1 degree Celcius). The manufacturer clearly states a storage temperature range of 2 - 8 degrees Celcius.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based upon inspection of the reagent packs in use in refrigerator #2 and discussion with staff, it was noted that the lab was using expired test packs for Leutinizing Hormone (LH) assays. Findings include: 1. A partially used box of LH cassettes, lot # 106466490 expired 04/09/2019 were found to be available for patient testing. 2. Upon interview with staff during survey, she confirmed that these cassettes were still being used to test patient specimens at approximately 1130.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based upon a review of the Quality Control (QC) records and interview the Laboratory Director (LD), it was noted that Follicle Stimulating Hormone (FSH) controls had been out of control two (2) out of eight (8) days of use for the month of February 2018. Findings include: 1. On February 2, 2019, the QC value recorded was

	14.99 mUI/ml. The QC control range was noted to be 8.7mIU/ml - 12.10 mUI/ml. 2. On February 6, 2019, the QC value recorded was 14.05 mUI/ml. The QC control range was noted to be 8.7mIU/ml - 12.10 mUI/ml. 2. No written documentation of corrective action could be produced during survey 04/16/2019. 3. The LD confirmed via email on 04/17/2019 that she could not provide any written documentation of corrective action.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Upon review of records and discussion with the Laboratory Director (LD), it was revealed that the current list of approved testing personnel was not up to date. Findings include: 1. The list of testing personnel approved to perform moderate complexity testing had not been updated by the LD since 07/13/2011. 2. The LD confirmed she had not updated the list since this date.