Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2262329	05/14/2024
Name of Provider or Supplier	**Street Address, City, State**	
Ivf-Pgt Lab Tinley Park	16345 S Harlem Ave, Tinley Park, 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
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 review of laboratory's policy and procedure manual, lack of documentation, and interview with laboratory representative; the laboratory's procedure failed to include reference intervals (normal values) for five of five endocrinology analytes tested, as required by 493.1251. Findings Include: 1. Review of the laboratory policy and procedure manual identified the following five analytes being performed on the TOSOH AIA 630 instrument: a. Follicle Stimulating Hormone (FSH) b. Luteinizing Hormone (LH) c. Estradiol (E2) d. Progesterone e. Human Chorionic Gonadotropin (HCG) 2. Review of the laboratory policy and procedure manual for endocrinology

	testing identified the policy "Automated Immunoassays Using TOSOH AIA 360", which failed to outline the reference intervals (normal values) for five of five endocrinology analytes performed. 3. During survey date 05/14/2024, at 12:42 pm, the laboratory representative confirmed the above findings.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the laboratory representative; the laboratory failed to include the address of the laboratory that performed the endocrinology testing for six of six patient test reports reviewed. Findings Include: 1. Review of six of six endocrinology patients test reports found the laboratory failed to indicate the address of the performing laboratory on the final reports. Patient Accession #: Date of Testing: 33380294 03/28/2024 33364694 04/05 /2024 33371920 04/08/2024 33355446 04/08/2024 33364865 04/16/2024 33363417 05/08/2024 2. On survey date 05/14/2024, at 01:19 pm, the laboratory representative confirmed the above findings.