Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D1027412	09/30/2021
Name of Provider or Supplier	**Street Address, City, State**	
Gregory Shifrin Md Pc Ob Gyn	1766 East 12th Street, Basement, Brooklyn, NY	

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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on surveyor's review of the laboratory's Quality Assessment (QA) policy, QA review records for the calendar year 2020, 2021 and an interview with the general supervisor/testing person, the laboratory failed to follow their established QA policy for an ongoing mechanism to monitor, assess and correct problems identified in the general laboratory systems. FINDINGS: 1. The general supervisor/testing person confirmed on September 29, 2021 at approximately 3:15 PM, that the laboratory failed to follow their established QA policy for an ongoing mechanism to monitor, assess and correct problems identified in the general laboratory systems. 2. The laboratory's QA policy requires an annual review of all phases of laboratory's testing and take corrective action when problems are identified. a. The laboratory failed to identify the failure to record the address of the second location was recorded on the test requisition in use. b. The laboratory failed to identify the Quality Control failures for the test analyte's Follicle Stimulating Hormone (FSH), Luteinizing Hormone (LH), Beta Human Chronic Gonadotropin Hormone (b-Hcg) and Folate. Refer: D5305 and D5441.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting

	the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on surveyor's review of thirty randomly selected patient test requisitions and an interview with the general supervisor/testing person, the laboratory failed to ensure that the address of the second location was recorded on the test requisition in use. FINDINGS: The general supervisor/testing person confirmed on September 28, 2021 at approximately 2:30 PM, that the current test requisition in use did not record the second office location. The practice located at 1502 East 12th St. Brooklyn NY merged with the practice located at 1766 East 14th Brooklyn NY on March 30, 2021. a. Surveyor performed a random review of thirty test requisition from April 1, 2021 through September 28, 2021 and found that the reports did not have the address for the second office. Refer to D5291 and D6094
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review surveyor's review of the Cytology procedure manual, test requisition forms and interview with the pathologist and general supervisor, the laboratory failed to include a procedure for transportation of cytology specimen from the second location. FINDINGS: The pathologist confirmed on September 30, 2021, at approximately 12:30 PM that the current transpiration procedure did not define the method of transpiration for cytology specimen from the second location to the main lab. a. The office located at 1502 East 12th St. Brooklyn NY merged with this practice located at 1776 East 12th St. Brooklyn on March 30, 2021.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the

	laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: D5441 Based on a surveyor's review of the Quality Control (QC) reports and the manufacturer's control requirement for the Roche Cobas 411e endocrinology analyzer, QC records for the Roche Integra 400 chemistry analyzer and an interview with the general supervisor/ testing person, the laboratory failed to follow the laboratory's established QC procedure and manufacturer's requirements for the Roche Cobas 411e from 2/4/2020 through 2/29/20. FINDINGS: 1. The general supervisor/testing person confirmed on September 29, 2021, at approximately 3:30 PM, that the laboratory failed to perform the 3 levels of Bio-Rad lymphcheck controls for the test analyte's Follicle Stimulating Hormone (FSH), Luteinizing Hormone (LH), Beta Human Chronic Gonadotropin Hormone (b-Hcg) and Folate from 2/4/2020 through 2/29 /2020. 2. The laboratory failed to follow their established QC policy and perform 3 levels of control as required and the validated assay stating that 2 levels of control must be in range to perform patient testing. 3. The following controls were run for the test analyte's FSH, LH, b-Hcg and Folate. a. Level 1 control was run and reported for the following dates February 4,5,6,7,8,11,13,14,15,18,19,20,22,24,26,27,28 & 29, 2020 b. Level 2 and 3 control were run and reported on February 7 & 20, 2020; were level 3 control was out of range. 4. Approximately 239 patients were tested and reported for b-Hcg a. 35 patients were tested and reported for Folate b. 18 patients were tested and reported for each of the following analyte's FSH and LH 5. The laboratory's QC reports for the Integra 400 analyzer failed to reflect the true ranges provided by the manufacturer. resulting in falsely lower Standard Deviation (SD) & Coefficient of Variation (CV). a. The range on the printed QC reports were different from the manufacturer's required ranges. b. The onsite Information Technology (IT) technician is aware of the software issues with the Laboratory Information System (LIS) LABDAQ system. Refer to D5291 and D6094
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on surveyor's review of laboratory policies and procedures, QC and QA laboratory records and confirmed in an interview with the pathologist/laboratory director/technical supervisor, the laboratory director/technical supervisor failed to ensure that established QA programs were maintained to assure the quality of laboratory services and identify failures in quality as they occur. Refer to D5291, D5311, D5305 and D5441.