Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D1027412	01/25/2024
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on review of the current, approved standard operating procedures, and training records as well as interview with the General Supervisor (GS), it was determined that the Laboratory Director (LD) failed to perform and document GS competency evaluation. FINDINGS: 1. The GS was hired on September 30, 2023, and basic lab training was completed on October 1, 2023. 2. There was no documentation of GS competency evaluation. 3. The GS confirmed the findings on January 24, 2024, at 2: 00 P.M.
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 review of the current, approved Quality Assurance (QA) policy and interview with the GS, the laboratory failed to identify and address multiple test requisitions in use, expired reagent inventory, as well as GS competency evaluation. FINDINGS: 1. It was noted that LD QA review was performed and documented for

	2021, 2022, and 2023. It was also noted that QA review frequency was updated from semi-annual to annual. 2. The QA review failed to identify and address retention and use of expired cytostain and Hematoxylin reagents for patient specimen processing. 3. The GS confirmed the findings on January 24, 2024, at 2:00 P.M.
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 review of randomly selected patient test requisitions, month of December 2023 test requisitions and an interview with the general supervisor (GS), the laboratory failed to ensure that the address for the three locations was recorded on the test requisition four different test requisition in use. FINDINGS: Based on review of selected patient test requisitions and interview with the GS, the laboratory failed to document patient specimen collection site address on the test requisition. FINDINGS: 1. The four, current, approved laboratory test requisitions did not document which address the patient specimens were received from: 1502 East 14th Street, Brooklyn, New York; 100 Einstein Loop North Bronx, New York; and 3 East 69th Street, New York, New York. a. Seventy-three December 2023 test requisitions did not specify patient specimen collection and receipt locations: 1766 12th Street Brooklyn, New York; or East 69th Street New York, New York; or 100 Einstein Loop, Ground Floor, North Bronx, New York; or 1502 East 14th Street, Brooklyn, New York. 2. The GS confirmed the findings on January 25, 2024, at approximately 10:30 A.M. Refer to D5291 and D6094. THIS IS A RECITED DEFICIENCY FROM THE SURVEY CONDUCTED SEPTEMBER 30, 2021.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and interview with the GS, the laboratory failed to document the date and time patient specimens were received in the laboratory. FINDINGS: 1. Patients samples were collected from 1502 East 14th Street, Brooklyn, New York; 100 Einstein Loop, North Bronx, New York; and 3 East 69th Street, New York, New York; and subsequently transported to the main

	laboratory location at 1776 12th Street, Brooklyn, New York. 2. The GS confirmed on January 25, 2024, at approximately 10:30 A.M., that the current, approved laboratory procedure manual did not include written instructions for receipt and accessioning of patient samples collected from the three respective site locations. a. No documentation was available to determine the number of patient samples received from January 2, 2022, through the survey date. Refer to D5305.
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 on review of the PAP staining quality control log, direct observation, and interview with the LD, the laboratory failed to remove from inventory and dispose of expired reagents utilized for patient specimen processing. Findings: 1. According to the QC log, Hematoxylin stain Lot 104357 expired September 2022 and was utilized for patient specimen processing of: a. October 2022, 165 patient slides; November 2022, 116 patient slides; December 2022, 105 patient slides; January 2023, 123 patient slides; February 2023, 92 patient slides; March 2023, 138 patient slides; April 2023, 168 patient slides; May 2023, 102 patient slides. b. The LD confirmed the findings on January 23, 2024, at 1:00 P.M. 2. According to the QC log, Cytostain Lot 101581 expired November 2022 and was utilized for patient specimen processing of: a. December 2022, 105 patient slides; January 2023, 123 patient slides; February 2023, 92 patient slides; March 2023, 138 patient slides; April 2023, 168 patient slides; May 2023, 102 patient slides. b. The LD confirmed the findings on January 23, 2024, at 1:00 P.M. 3. According to the QC log as well as direct observation of the reagent container, Cytostain Lot 129845 expired August 2023 and was utilized for patient specimen processing of: a. September 2023, 148 patient slides; October 2023, 146 patient slides; November 2023, 110 patient slides; December 2023, 96 patient slides; January 2024, 39 patient slides. b. The LD confirmed the findings on January 23, 2024, at 1:00 P.M. 4. According to the QC log, Cytoseal Lot 105926 and Clarifier Lot 101692 both expired March 2023 and were utilized for patient specimen processing of: a. April 2023, 168 patient slides; May 2023, 102 patient slides. b. The LD confirmed the findings on January 23, 2024, at 1:00 P.M.
D5637	CYTOLOGY CFR(s): 493.1274(d)(1)(ii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary. This STANDARD is not met as evidenced by: Based on review of the current, approved Cytology procedure manual, 2022 and 2023 cytology workload records, as well as interview with the pathologist/technical supervisor, the laboratory failed to comply with current, approved policies and procedures ensuring that workload limits would be reassessed at least every six months and adjusted when necessary for the pathologist(s) who performed the

	cytology slide primary gynecologic screening. FINDINGS: 1.The pathologist /technical supervisor, confirmed on January 23, 2024, at approximately 1:00 P.M. that the laboratory failed to comply with current, approved policies and procedures for pathologist workload reassessment at least every 6 months and adjustment when necessary. Refer to D6130.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of the current, approved standard operating procedures, training records, as well as interview with the GS, the LD failed to perform and document GS competency evaluation and assure compliance with applicable GS regulations. Refer to D5209 and D6107.
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 QA review performed, the LD failed to identify and address multiple test requisitions in use, expired reagent inventory, as well as GS competency evaluation.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as 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 result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the current, approved policies and procedures, training records, as

	well as interview with the GS, the LD failed to draft and develop written GS responsibilities and duties. Refer to D5209.
D6130	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(2)(3) (c) In cytology, the technical supervisor or the individual qualified under 493.1449(k)(2)-- (c)(2) Must establish the workload limit for each individual examining slides and (c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary. This STANDARD is not met as evidenced by: Based on review of the Cytology procedure manual, 2022 and 2023 cytology workload records, as well as interview with the pathologist/technical supervisor, the pathologist, acting as the technical supervisor, failed to reassess workload limit for personnel who performed cytology slide primary gynecologic screening. Refer to D5637.