Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D1101314	11/15/2021
Name of Provider or Supplier	**Street Address, City, State**	
Endoscopy Place, Pc, The	2425 Eastchester Road, Bronx, 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
D5032	CYTOLOGY CFR(s): 493.1221 If the laboratory provides services in the subspecialty of Cytology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1274, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on surveyor's review of laboratory policies and procedures, laboratory records and confirmed in an interview with the pathologist/laboratory director, the laboratory failed to establish, reassess and document a workload limit for the pathologist the primary reader, acting as the technical supervisor. Refer to D5633, D5637, D5645 and D5647 The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results in the subspecialty of Cytology.
D5629	CYTOLOGY CFR(s): 493.1274(c)(5) (c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial

	lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms. This STANDARD is not met as evidenced by: Based on the lack of the annual statistical data for NON-GYN cytology for 2019, 2020 and interview with the pathologist/laboratory director, the laboratory failed to establish policies and procedures for a program to evaluate and compare the laboratory statistics annually to detect errors in the performance of non-cytological examinations and reporting results. FINDINGS: 1. The pathologist/laboratory director confirmed on November 15, 2021 at approximately 2:00 PM, that the laboratory failed to establish policies and procedures for a program designed to detect errors in the performance of non-cytological examinations and the reporting of results annually for the calendar years 2019 and 2020 a. the laboratory must include three primary data sets to detect any non-cytological performance errors: 1. Number of Cytology Cases, 2. Number of patient cases by specimen type, 3. Number of patient cases reported by diagnosis (including unsatisfactory for interpretation)" 2. The surveyor requested the data for 2019 and 2020, the laboratory failed to provide documentation of the laboratory's evaluation of three of three required non-gynecologic statistics.
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 surveyor's review of the laboratory's cytology procedure manual, daily slide tracking form and an interview with the laboratory director/pathologist, the laboratory director, acting as the technical supervisor, failed to establish workload limit procedures that include reassessment of the individual's workload every six months. Refer to D5645 FINDINGS: The pathologist confirmed on November 15, 2021 at 2: 00 PM, the surveyor's findings that the pathologist, acting as the technical supervisor, did not establish workload limit procedures that include reassessment of the individual's workload every six months.
D5645	CYTOLOGY CFR(s): 493.1274(d)(3) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory. This STANDARD is not met as evidenced by: Based on surveyor's review of the Cytology procedure manual and lack of workload records for the calendar years 2019, 2020 and 2021 through survey date and an interview the pathologist/laboratory director, the pathologist failed to follow the established workload procedure. FINDINGS: 1. The pathologist/laboratory director confirmed on November 15, 2021 at approximately 2:00 PM, the surveyor's findings

	that the pathologist, the primary reader, failed to follow the established workload procedure. a. The procedure states' " that the total number of slides examined by the primary reader during the 24- hour period is no more than 100 slides." b. The Cytology workload lists were not available for review at survey, therefore, the surveyor could not determine if the pathologist, as the primary reader, recorded the number of slides examined in a 24- hour period for the calendar years 2019, 2020 through 2021 survey date.
D5647	CYTOLOGY CFR(s): 493.1274(d)(4) (d) Workload limits.The laboratory must establish and follow written policies and procedures that ensure the following: (d)(4) Records are available to document the workload limit for each individual. This STANDARD is not met as evidenced by: Based on surveyor's review of Cytology policies and procedures, laboratory records and confirmed in a interview with the pathologist/laboratory director/technical supervisor, at the time of this survey, the laboratory failed to establish written policies and procedures to ensure that records are maintained and available to document the workload for the individual who performs primary screening of non-gynecologic cytology slides
D5659	CYTOLOGY CFR(s): 493.1274(e)(6) (e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(6) Corrected reports issued by the laboratory indicate the basis for correction. This STANDARD is not met as evidenced by: Based on surveyor's review of laboratory policies and procedures, laboratory records and interview with the pathologist/laboratory director, the laboratory failed to establish written policies and procedures to ensure that corrected reports indicated the basis for the correction on the report.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor's review of the Histology/Cytology laboratory policies and procedures and an interview with the pathologist/laboratory director, the laboratory director failed to provide overall management and fulfill the responsibility for the overall operation of the laboratory and failed to ensure compliance with applicable regulations. Refer to D6079

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 surveyor's review of laboratory policies and procedures, laboratory records and confirmed in an interview with the pathologist/laboratory director/technical supervisor, the laboratory director/technical supervisor failed to be responsible for the overall operation and administration of the laboratory, to include assuring compliance with the applicable regulations and ensuring that all the duties of the laboratory director were performed. Refer to D5629, D5637, D5645, D5659 and D5647