

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2115701	(X3) Date Survey Completed 08/01/2018
Name of Provider or Supplier New York Gastroenterology & Endoscopy Pc	Street Address, City, State 79-11 41st Avenue, A-108, Elmhurst, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the proficiency test verification records and an interview with the laboratory director, the laboratory failed to perform verification of accuracy for the interpretation of FISH image and Cytology slide interpretations. Findings Include: On August 1, 2018, at approximately 11:30 AM the laboratory director confirmed that the laboratory failed to perform twice annual verification for FISH images and Cytology slide interpretation from March 2017 through the date of this survey. Approximately 1400 patient specimens were tested and reported for FISH and the reading Cytology slides testing during this time.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory procedure manual and an interview with the laboratory director, the laboratory did not have a procedure for FISH image testing. Finding: It was confirmed with the laboratory director on August 1, 2018 at approximately 10:45 am, that the laboratory director failed to have a complete</p>

procedure for reading and diagnosing of FISH image to include what constitutes a negative and positive result.

D5433

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory procedure manual and an interview with the laboratory director, the laboratory failed to have a complete maintenance protocol or procedure for histopathology. Findings Include: On August 1, 2018, at approximately 11:00 AM, it was confirmed by the laboratory director that the laboratory failed to have a procedure available for service maintenance of the laboratory Microscope to include the interval between service performance.

D5475

CONTROL PROCEDURES

CFR(s): 493.1256(e)(3)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of quality control (QC) stain records for histopathology and an interview with the laboratory director, the laboratory failed to document the QC test results for special stains, cytology and FISH images. Findings Include: The laboratory director confirmed on August 1, 2018 at approximately 11:15 AM that the laboratory failed to perform and document the QC for special stains, cytology slides and the quality of the FISH images reading, from October 2017 through the date of this survey. Approximately 525 patient specimens were tested and reported for all readings of special stains, cytology slides and FISH images during that time.

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 a lack of cytology procedures and confirmed by the laboratory director in an interview on August 1, 2018 at approximately 10:45 am, 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 cytological examinations and reporting results. The procedure must include: 1. Cytology cases examined; 2. Specimens processed by specimen type; 3. Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation).

D5633

CYTOLOGY

CFR(s): 493.1274(d)(1)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening.

This STANDARD is not met as evidenced by:

Based on a lack of cytology procedures and confirmed in an interview by the laboratory director on August 1, 2018 at approximately 10:45 am, the laboratory failed to establish written policies and procedures to ensure that a maximum workload limit was set for the person who performed primary screening for non-gynecologic specimens.

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 a lack of cytology procedures and confirmed in an interview by the laboratory director on August 1, 2018 at approximately 10:45 am, the laboratory failed to establish and follow written policies and procedures to ensure that the workload limit for the individual who performs primary screening is reassessed at least every six months and adjusted when necessary.

D5639

CYTOLOGY

CFR(s): 493.1274(d)(2)(i)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the Following: (d)(2) The maximum number of slides examined by an individual in each 24-hour period does not exceed 100 slides (one patient specimen per slide; gynecologic, nongynecologic, or both) irrespective of the

site or laboratory. This limit represents an absolute maximum number of slides and must not be employed as an individual's performance target. In addition-- (d)(2)(i) The maximum number of 100 slides is examined in no less than an 8-hour workday;

This STANDARD is not met as evidenced by:
Based on a lack of cytology procedures and confirmed in an interview by the laboratory director on August 1, 2018 at approximately 10:45 am, the laboratory failed to have written policies and procedures to ensure that the maximum number of slides examined by an individual in 24-hours does not exceed 100 slides.

D5641

CYTOLOGY
CFR(s): 493.1274(d)(2)(ii)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(2)(ii) For the purposes of establishing workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined. The formula-- Number of hours examining slides X 100 / 8 is used to determine maximum slide volume to be examined;

This STANDARD is not met as evidenced by:
Based on a lack of cytology procedures and confirmed in an interview by the laboratory director on August 1, 2018 at approximately 11:00 am, the laboratory failed to have a policy and procedure for the individual who exam slides in less than an 8-hour workday.

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 a lack of cytology procedures and confirmed in an interview by the laboratory director on August 1, 2018 at approximately 11:00 am, 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.

D5655

CYTOLOGY
CFR(s): 493.1274(e)(4)

(e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: (e)(4) Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory.

This STANDARD is not met as evidenced by:

	<p>Based on a lack of cytology procedures and confirmed in an interview by the laboratory director on August 1, 2018 at approximately 11:00 am, the laboratory failed to establish a written policy and procedure to ensure that unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory.</p>
D6076	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on a surveyors review of the laboratory's records and interview with the laboratory director/technical supervisor, the laboratory director failed to fulfill his/her responsibilities and provide overall management of the laboratory and assure compliance with all CLIA regulations and standards. Refer to D6093, D6094</p>
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on a review of QC records and confirmed in an interview by the laboratory director on August 1, 2018 at approximately 11:00 am, the laboratory director failed to ensure that the QC program for histopathology was followed to assure the quality of laboratory services. Refer to D5475</p>
D6094	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of procedures and confirmed in an interview with the laboratory director on August 1, 2018 at approximately 11:00 am, the director failed to have procedures for: 1) microscope maintenance and schedule; 2) Twice annual verification; 2) FISH testing and; 3)Cytology testing. Refer to: D5401, D5217, D5629, D5433, D5637, D5639, D5641, D5647, and D5655</p>
D6130	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(2)(3)</p> <p>(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</p>

(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 a lack of cytology procedures and confirmed in an interview by the laboratory director on August 1, 2018 at approximately 11:00 am, the laboratory director failed to establish the workload limit for the individual who examines slides and reassess the workload at least every six months. Refer to: D5633, D5637, D5639, D5641, and D5647