

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2007525	(X3) Date Survey Completed 01/16/2018
Name of Provider or Supplier Progressive Gastroenterology Llc	Street Address, City, State 3584 Jerome Avenue, 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
D5629	<p>CYTOLOGY CFR(s): 493.1274(c)(5)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of mucosal cytology procedures and confirmed by the laboratory director in an interview on January 16, 2018 at approximately 12:25 pm , the laboratory failed to established 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).</p>
D5633	<p>CYTOLOGY CFR(s): 493.1274(d)(1)</p> <p>(d) Workload limits. The laboratory must establish and follow written policies and</p>

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 mucosal cytology procedures and an interview with the laboratory director, the laboratory failed to have a written policy and procedure to ensure that a maximum workload limit was established. Findings Include: On January 16, 2018, at approximately 12:25 pm, the laboratory director confirmed that the laboratory failed to have a written procedure to establish the maximum workload limit for the person who performs the primary screening of 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 mucosal cytology procedures and an interview with the laboratory director, the laboratory failed to establish and follow written policies and procedures to ensure that the workload limit is reassessed every six months. Findings Include: On January 16, 2018, at approximately 12:25 pm, the laboratory director confirmed that the laboratory failed to have procedures to assess at least every six- months and adjust if necessary the work-load limit for the individual reading non-gynecologic slides.

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 mucosal cytology procedures and an interview with the laboratory director, the laboratory failed to have written policies and procedures for the maximum number of slides examined by an individual. Findings Include: On January 16, 2018, at approximately 12:25 pm, the laboratory director confirmed that the laboratory failed to have a procedure in place to ensure that the maximum number of slides an individual can examine within 24-hour period and not to 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 mucosal cytology procedures and confirmed by the laboratory director during the laboratory survey on January 16, 2018, at approximately 12:25 pm, 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 mucosal cytology procedures and confirmed by laboratory director on January 16, 2018, at approximately 12:25 pm, the laboratory failed to establish a written policy and procedure to ensure that workload limit records are established for those 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:
Based on a lack of mucosal cytology procedures and confirmed by the laboratory director in an interview on January 16, at approximately 12:25 pm, the laboratory failed to establish a written policy and procedure to ensure that unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory.