

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0130511	(X3) Date Survey Completed 04/11/2018
Name of Provider or Supplier Janusz Plawner Md	Street Address, City, State 205 East 78th Street, New York, 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 cytology procedures and confirmed by the laboratory director in an interview on April 11, 2018, at approximately 12:15 pm, 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).</p>
D5641	<p>CYTOLOGY CFR(s): 493.1274(d)(2)(ii)</p> <p>(d) Workload limits. The laboratory must establish and follow written policies and</p>

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-- $\text{Number of hours examining slides} \times 100 / 8$ 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 by the laboratory director during the laboratory survey on April 11, 2018, at approximately 12:15 pm, the laboratory failed to have a policy and procedure for the individual who exam slides in less than an 8-hour workday.