

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2177369	(X3) Date Survey Completed 08/26/2021
Name of Provider or Supplier Pierre J Mendoza Md	Street Address, City, State 9 Mule Road, Toms River, NJ	
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
D3027	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(1)</p> <p>Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the patient Test Requisitions (TR) and interview with the Office Manager (OM), the laboratory failed to retain TR for Cytology and Histopathology in the year 2020. The OM confirmed on 8/26/2021 at 10:00 am that the TR were not retained.</p>
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>

This STANDARD is not met as evidenced by:
Based on surveyor review of the Procedure Manual and interview with the Office Manager (OM), the laboratory failed to establish a written procedure which included number of cytology cases examined, specimens processed by type and patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation) from January 2020 to the date of the survey. The OM confirmed on 8/26/21 at 10:15 am the laboratory did not have the above procedure.

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 review of the Procedure Manual and interview with the Office Manager (OM), the laboratory failed to establish a procedure for maintaining records of the total number of slides reviewed in 24 hours from January 2020 to the date of the survey. The OM confirmed on 8/26/21 at 10:15 that the above mentioned procedure was not established.