

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D1039708	(X3) Date Survey Completed 10/08/2019
Name of Provider or Supplier Farshad Shafizadeh Md Pc	Street Address, City, State 461 Park Avenue South, 5th Floor, Rm 503, 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
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 surveyor's review of the the laboratory's manual and confirmed at survey with the laboratory director/pathologist, the laboratory failed to establish the written policy for twice-yearly verification procedure to verify the accuracy of the FISH images, urine cytology and histology slides and retention for the following records: test requisition, histology/cytology test reports, and slides.</p>
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a surveyor's review of the laboratory procedure manual and an interview</p>

with the laboratory director/pathologist, the laboratory failed to establish a written policy to define the maintenance frequency for the microscope used for histopathology and cytology slides. FINDINGS: The laboratory director/pathologist confirmed on October 8, 2019 at approximately 10:30 AM, the surveyor's findings that the laboratory failed to establish a written policy to define the maintenance frequency for the microscope used for histopathology and cytology slides.