

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2207494	(X3) Date Survey Completed 12/08/2022
Name of Provider or Supplier Diagnostic Pathology Services Llc	Street Address, City, State 16 Lilac Way, Skillman, 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
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 review of the Procedure Manual (PM), and interview with the Laboratory Director (LD), the laboratory failed to have a procedure for Biannual Assessment (BA) on the date of survey. The LD confirmed on 12/8/22 at 10:00 am that the laboratory did not have the aforementioned procedure.</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 surveyor review of the Procedure Manual (PM) and interview with the</p>

Laboratory Director (LD), the laboratory did not establish a maintenance protocol for the microscope on the date of survey. The LD confirmed at 10:00 am on 12/8/22 the laboratory did not have a maintenance protocol.