

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D1099598	(X3) Date Survey Completed 02/05/2019
Name of Provider or Supplier Professional Diagnostics Inc	Street Address, City, State 1050 East South Temple, Salt Lake City, UT	
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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on the laboratory intranet and hardcopy version of the laboratory procedure manual review and confirmation by the laboratory director, the director failed to sign and date as approved 2 of 2 new laboratory procedures before they were placed into use, the laboratory procedures for histology test requisitions and for histology test reports. The laboratory performed approximately 40 tests per year for outpatient histology specimens. Findings include: 1. The laboratory procedures failed to include the director's signature, electronic or handwritten, for changes made to the requisition procedure on 12/13/2018 and report procedures on 10/22/2018. 2. In an interview with the director and staff on 02/05/2019 at approximately 1:00 P.M., the director and staff confirmed the procedures were updated and were missing the director's signature as documentation the changes were approved.</p>