

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D1059373	<b>(X3) Date Survey Completed</b>  07/12/2018
<b>Name of Provider or Supplier</b>  Pathologists Diagnostic Laboratory, Pa	<b>Street Address, City, State</b>  1800 South Hawthorne Road, Suite 100, Winston-Salem, NC	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5417</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interviews of the general supervisor (GS) and staff interview on 7/12/18, the laboratory failed to discard material that had exceeded the expiration date and was available for use. Finding: During tour of the laboratory at 3:00 p.m. the surveyor observed one bottle of 0.1% Gold Chloride, Lot No.: 160830101; and, Exp. Date: 08/30/20017 located on the door of refrigerator \$1. During interview with GS and staff at 3:00 p.m., it was confirmed that the solution was expired and immediately took possession of the solution for immediate disposal.</p>
<b>D6149</b>	<p><b>GENERAL SUPERVISOR RESPONSIBILITIES</b> CFR(s): 493.1463(b)(1)</p> <p>The director or technical supervisor may delegate to the general supervisor the responsibility for assuring that all remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications.</p> <p>This STANDARD is not met as evidenced by: Based on testing personnel Competency Assessment records review on 7/12/18 the laboratory director failed to delegate the responsibility and duty to the general</p>

superiors. The general supervisor had documented testing personnel competency assessments, but the director had not delegated in writing the responsibility and duty to the general supervisors.