

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D2107230	<b>(X3) Date Survey Completed</b>  06/18/2018
<b>Name of Provider or Supplier</b>  Northwest Urology	<b>Street Address, City, State</b>  971 Broad Street Lab #5, Augusta, GA	
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>D0000</b>	An onsite survey was completed on June 18, 2018 to investigate complaint number GA00189960 . One of the allegations was substantiated. The following deficiencies were cited:
<b>D5791</b>	<p><b>ANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's written policy for instrument maintenance, observation by the surveyor, and staff interview, the laboratory failed to follow its written policy for performing instrument maintenance on equipment used in the subspecialties of histology and cytology. Findings include: 1. Observation by the surveyor of stickers attached to equipment indicating the date yearly maintenance was performed revealed the last date service was performed is as follows: Isotemp Drying oven: 10/2016 Thin Prep 2000 Cytoc : 04/22/2013 Thermo IEC Centra CL2 centrifuge: 10/16 Paraffin dispenser: 04/2015 Surgipath embedding station: 10/16 Tissue flotation bath : 10/16 Leica RM2235 microtome: 11/16 Thermolyne max mix plus vortexer; 3/11/15 2. Review of the laboratory's written policies titled "Preventive Maintenance - Procedure" , Document # CT-17 with an effective date of 8-7-15 and "Preventive Maintenance- Procedure", Document # HT-30 with an effective date of 6 /8/16 revealed maintenance is required as follows: Centrifuge: annually according to the manufacturer's recommended schedule and quarterly according to F-53 Centrifuge Calibration log. The F-53 log was not available and staff was not aware of its location. Microtome: annually by a qualified company. Waterbath/flotation bath: annually by a qualified company. Drying oven: annually by a qualified company. No annual</p>

maintenance requirement was given for the paraffin dispenser, embedding station, vortex mixer or Thin Prep 2000 Cytoc.. 4. Interview with the Molecular manager on June 18, 2018 at 12:35 pm in her office and with the POL Laboratory supervisor at 1 pm in the conference room confirmed the required yearly maintenance has not been performed.