

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2107181	(X3) Date Survey Completed 06/18/2018
Name of Provider or Supplier Urology Specialists Of The Carolinas, Pllc	Street Address, City, State 971 Broad Street, Augusta, GA	
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
D0000	An onsite survey was completed on June 18, 2018 to investigate complaint number GA00188960 . One of the allegations was substantiated. The following deficiencies were cited:
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT 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, review of maintenance records 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: Olympus BX-45 microscope: 02/2015 Nikon Eclipse 50i microscope: 06/12 /14 Drying oven: 10/2016 Shandon Cytospin 3: 10/16 Thermofisher Legend XTR centrifuge: 10/16 Paraffin dispenser: 10/16 Surgipath embedding station: 10/16 Water bath: 10/16 Leica RM2235 microtome: 11/16 2. Review of service records performed by Southeast Pathology Instrument service, Inc. revealed documents showing service was performed on the centrifuge, paraffin dispense, embedding center, waterbath, and warming oven on 10/14/16. Documents revealed service was performed on the microtome in 11/16. No other records for service were available. 3. 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</p>

as follows: Microscope(s) : annually by a qualified company 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: annually by a qualified company. Drying oven: annually by a qualified company. No annual maintenance requirement was given for the paraffin dispenser or embedding station. 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.