

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0675421	(X3) Date Survey Completed 04/05/2018
Name of Provider or Supplier Jay D Geller Md Pc	Street Address, City, State 310 Route 24 East, Chester, 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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Operations Manual, Maintenance Records (MR) and interview with the Testing Personnel (TP), the laboratory failed to perform and document maintenance as specified by the manufacturer on the Varistain Gemini Stainer, Tissue Tek and the Finesse Microtome used in Histotechnology Testing in the calendar years 2016 and 2017. The finding includes: 1. A review of the MR revealed annual maintenance was not performed on any instrument listed above. 2. The TP #2 listed on CMS form 209 confirmed on 4/5/18 at 10:05 am that annual maintenance as specified by the manufacturer was not performed. This was cited on the previous survey done on 3/10/16.</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>

This STANDARD is not met as evidenced by:

Based on surveyor review of Maintenance Records (MR) and interview with the Testing Personnel (TP), the laboratory failed to establish a maintenance protocol for the fume hoods used in Histology testing from 3/10/16 to the date of the survey. The finding includes: 1. A review of the Inspection and Maintenance record for the fume hoods revealed the laboratory did not establish an acceptable range for verification of fume hood face velocity. 2. The TP #1 listed on the CMS form 209 confirmed on 4/5 /18 at 10:45 am that the laboratory did not establish a maintenance protocol.