

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2047966	(X3) Date Survey Completed 07/19/2018
Name of Provider or Supplier Daniel A Lindenberg Md Pa	Street Address, City, State 16244 S Military Trl Ste 170, Delray Beach, FL	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory did not verify accuracy of histopathology and cytology slide reading twice annually. Findings include: Review of proficiency testing records for the past two years on 07/19/2018 revealed that the laboratory verified the accuracy of slide reading through peer review once in 2017. During an interview with the histotechnologist at 10:45 a.m. on 07/19/2018, she confirmed that there was one proficiency test missing for 2017.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT 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 interview with laboratory personnel, the only hematoxylin solutions in the flammable cabinet were expired. Findings include: During a tour of the laboratory at 10:25 a.m. on 07/19/2018, the surveyor observed that Weigerts Hematoxylin solution A, lot #346756 that expired on 07/10/2018 and Weigerts Hematoxylin solution B, lot #347315 that expired on 07/16/2018. During an interview with the histotechnologist at 10:45 a.m. on 07/19/2018, the histotechnologist confirmed that they had expired.</p>

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

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.

This STANDARD is not met as evidenced by:

Based on record review and interview with laboratory personnel, there was no documentation to indicate that any maintenance was performed on the microscope used to read histopathology and cytology slides. Findings include: Review of quality control and maintenance records on 07/19/2018 revealed that there was no documentation of microscope maintenance. During an interview with the histotechnologist at 11:00 a.m. on 07/19/2018, she said that the microscope had been serviced by an outside company, but there was no documentation available to show that it was done.