

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D1057101	(X3) Date Survey Completed 02/28/2018
Name of Provider or Supplier Annapath, Inc	Street Address, City, State 4801 Tesla Dr Suite H J K L & M, Bowie, MD	
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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with the histologist, the laboratory did not update the immunohistochemistry (IHC) quality control (QC) procedure to reflect the change in the way QC is performed for patient testing. Finding: 1. The laboratory did not document the antigen retrieval steam bath temperature nor the pH of the buffer solution used to perform the patient test on the IHC analyzer. 2. The histologist stated that the manufacturer now have prediluted materials for testing and there is no mixing of reagents that require the antigen retrieval steam bath temperature and the pH of the buffer solution to be documented. 3. The histologist confirmed that the IHC QC procedure was not updated to reflect the change in the way QC is performed.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p>

This STANDARD is not met as evidenced by:
Based on review of the written procedure manual and interview with the histologist, the laboratory did not document the temperature of the over flow refrigerator purchased during the year 2017. Findings: 1. The laboratory installed a new refrigerator at the end of the year 2017. 2. The histologist stated that the refrigerator was needed for over flow laboratory material. Observation of the refrigerator at 11:00 AM showed immunohistochemical reagents used for performing patient testing stored in the refrigerator. 3. The laboratory did not document the refrigerator temperature once it was put into place to store test reagents and supplies. 4. The histologist confirmed that temperatures were not documented on the over flow refrigerator.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

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.

This STANDARD is not met as evidenced by:
Based on review of the written procedure manual, laboratory stain material log, and interview with the histologist, the laboratory did not ensure that staining material needed to prepare patient slides for review did not exceed the intended expiration date. Findings: 1. The laboratory stain material log did not show the lot numbers and expiration dates of the material needed to prepare patient slides for review. 2. The histologist stated that when stain reagents are opened laboratory personnel pays attention to the expiration date, but the lot and expiration date of the material is not documented anywhere in the laboratory in the event of a recall or problem and when empty containers are discarded. 3. The histologist confirmed that stain material lot numbers and expiration dates were not documented.